DAVIES

Trolls, Hopping, Ambush and Hold-Up

Emerging International Approaches to the Intersection of Competition and Patent Law Regimes

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I. INTRODUCTION: THE INEVITABILITY OF PATENT LAW AND COMPETITION LAW CHALLENGES

The issues canvassed in this report reflect a perfect storm that has been brewing for several decades. Monumental shifts in the role and predominance of intellectual property, combined with the rise of competition law and policy have made the topics in this report virtually inevitable and only likely to grow in relevance. The challenge is charting the course for Canadian policy and enforcement with respect to the intersection of competition law and patent law.

Over the past two decades, the role of intellectual property ("IP") has fundamentally shifted; innovation, protected by IP, is increasingly a competitive battleground. Years ago, patents were considered a technical, specialized concern for a few lawyers and agencies. Now, patents play a central role in firm strategies and national innovation policies. Consider that in 1978, the asset distribution of corporations on the S&P 500 was 95% tangible assets and 5% intangible assets, such as patents. By 2010, this had nearly inverted to 20% tangible and 80% intangible assets.[1] The new importance of IP is reflected in the worldwide surge in patent filings; between 1995 and 2012, the number of patent applications worldwide more than doubled. Canada is no exception; the number of patents examined in Canada almost quadrupled from 1992 to 2012.[2] Many jurisdictions have also strengthened patent rights, reinforcing the exclusive rights conferred to patent holders and expanding their coverage.[3] During this same period, new regulatory regimes were introduced with significant implications for patent holders, like the generic drug regulation scheme under the Hatch-Waxman Act in the U.S. and the Canadian equivalent, the Patented Medicines (Notice of Compliance) Regulations.

In parallel to this changing role of patents, there has also been a worldwide proliferation in the adoption and enforcement of competition law. Consider that the International Competition Network was founded by a mere 15 competition agencies in 2001;[4] there are now over 120 competition law enforcement agencies worldwide.[5] Agencies and courts around the globe are actively engaging in competition law enforcement and this heightened enforcement is expected to continue unabated.[6]

Both competition law and patent law have also become increasingly global propositions. Over the past two decades, extensive international co-operation between competition agencies has

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1 Francis Gurry, Director of WIPO, "Re-Thinking the Role of Intellectual Property" (Speech delivered at Melbourne Law School, The University of Melbourne, 22 August 2013) online: <http://www.wipo.int/export/sites/www/about-wipo/en/dgo/speeches/pdf/dg_speech_melbourne_2013.pdf>.

2 Total patents examined: 7,326 in 1992, up to 29,191 in 2012, Canadian Intellectual Property Office, *Annual Report* [Various] (Ottawa: Industry Canada, 1994/95 – 2011/2012), online (2009-2012).

3 Catalina Martinez & Dominique Guellec, "Overview of Recent Changes and Comparison of Patent Regimes in the United States, Japan and Europe", *Patents, Innovation and Economic Performance: OECD Conference Proceedings* (OECD Publishing, 2004) at 295.

4 The ICN's Vision For Its Second Decade, 10th Annual Conference of the ICN (The Hague, Netherlands; 17-20 May, 2011)

5 Christine A. Varney, Assistant Attorney General, "International Cooperation: Preparing for the Future Antitrust Division U.S. Department of Justice" (Remarks as Prepared for the Fourth Annual Georgetown Global Antitrust Enforcement Symposium, Washington, D.C., 21 September 2010)

6 Robert E. Block et al, Worldwide: Global Competition Outlook: 2014 (23 January, 2014) online: <http://www.mondaq.com/unitedstates/x/288056/Antitrust+Competition/Global+Competition+Outlook+2014> .

grown to be the norm.[7] There is a clear emphasis on international convergence in enforcement efforts and outcomes;[8] bilateral trade and co-operation agreements often expressly contemplate coordination between antitrust agencies. The Canadian Competition Bureau has frequently emphasized the importance of such inter-jurisdictional collaboration as a key strategic aspect of its enforcement capacity. On the patent law side, the implementation of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* signalled a new era in the internationalization of intellectual property law. Consistency between trading partners in the treatment of patent rights has become the subject of major recent international agreements for Canada, such as the Comprehensive Economic and Trade Agreement recently reached with the European Union.

These trends in competition and patent law and policy have been accompanied by a shift in thinking about the interface between the two regimes. The goals of competition law and intellectual property law used to be perceived as incompatible; patent law's grant of exclusivity was seen as creating monopolies that were in tension with competition law's attack on monopoly power. In the past several decades, thinking on the interface between the regimes has become more nuanced. The common refrain from competition enforcement agencies and the courts is now that intellectual property law and competition law share the same fundamental goals of enhancing consumer welfare and promoting innovation.

But this oft-repeated reconciliation of patent law and competition law is generalized, and it belies the significant complexity of the analysis ultimately required to reconcile the two regimes. Reaching the "right" balance to promote innovation across the two regimes is a difficult proposition, on which bright minds, including most recently the Supreme Court of the U.S., have differed. Many crossover issues at the forefront of patent and competition law occur in industries with fast technological change and/or key economic and social importance, which exacerbate the challenges for policy makers and enforcers. As the length of this report reflects, there is a significant amount of – sometimes divergent – thinking in this space.

This report provides an in-depth global survey of four current issues at the interface of competition and patent law and policy: reverse payment settlements, standard-setting/fair, reasonable and non-discriminatory ("FRAND") licencing commitments, patent assertion entity conduct and product hopping. The approaches of several key jurisdictions – the United States, the European Union ("EU"), the United Kingdom and Australia – are explained and compared to that of Canada.

As is often the case in competition law, the U.S. and EU are clear thought leaders, with extensive agency analytical and enforcement activities, literature and some legislative activity on these issues. The U.K. has generally followed the EU approach, and recently entered the fray with its first reverse payment settlement case. Australia, although it has little agency enforcement activity, has undertaken significant recent analysis of broader related issues in the patent and competition law space and recently commenced a product hopping case. There has been relatively little public debate or analysis in Canada on these issues. We found it challenging to assess the Canadian approach because of a combined lack of empirical information on the relevance of these issues to Canada and comparative dearth of literature, cases or agency guidance in Canada. However, there are early indications this may be

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7 *Ibid.*

8 Rachel Brandenburger, Special Advisor, International Antitrust Division U.S. Department of Justice, "Transatlantic Antitrust: Past And Present" (Remarks Prepared for St. Gallen International Competition Law Forum, St. Gallen, Switzerland; 21 May 2010).

changing; the Bureau recently began expanding its analytical perspective through a workshop on the pharmaceutical industry, issued initial revisions to its guidance on IP and commenced (although has since discontinued) an inquiry into potentially anti-competitive product hopping.

For the purposes of this report, we looked at current issues through a competition law and policy lens. As the Canadian government forays into consideration of patent law reforms, with the goal of balancing promotion of innovation and fostering of competition, competition law and policy are important, interrelated considerations.[9] Reform to litigation rules is another key aspect of addressing some of the current issues discussed here. However, the breadth and complexity of potential patent reforms and litigation reforms being considered in the jurisdictions discussed could easily form the basis of separate, extensive studies and are outside the terms of reference of this report (although we refer to such reforms where they appear to have direct implications for competition law and policy).

While related reforms may be appropriate for competition, patent and litigation systems, we do not believe they need to proceed in tandem. Reform of patent law in particular can take a considerable amount of time, whereas competition law solutions may be faster to put in place, and have faster effects.[10] We do not see the patent and competition law solutions as mutually exclusive, but generally think that competition law and policy may offer a more expeditious means of controlling unacceptable commercial behaviour and of addressing legacy issues (such as over-issuance of weak patents, as seen in the U.S.).

Finally, this report focuses largely on cases brought by competition enforcement agencies rather than private parties. Since the report is intended to inform Canadian public policy, we felt that this focus was appropriate.

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9 See e.g. Intellectual Property Regime In Canada, *Report of the Standing Committee on Industry, Science and Technology* (March 2013) 41st Parliament, First Session ("IP policy exists as one policy that supports innovation amongst a suite of other policies. For example, competition policy is also very important to ensuring an innovative and productive economy.").

10 European Union, European Commission, *Assessment Of Potential Anticompetitive Conduct in the Field of Intellectual Property Rights and Assessment of the Interplay Between Competition Policy and IPR Protection*, (November 2011) prepared by Pierre Regibeau and Katharine Rockett at 16 [Competition Policy and IPR Protection]. This report was an input into the process of public consultation by the EU on the revision of rules for the assessment of licensing agreements for the transfer of technology under EU competition law.

II. EXECUTIVE SUMMARY

Internationally and in Canada, the past two decades have seen skyrocketing value and importance of patents, as well as the rise of competition law and enforcement. This combination is raising inevitable and pressing questions on how to reconcile the areas of competition and patent law and policy in a manner that maximizes innovation and consumer benefits. In charting a course through this complex and novel area, Canada cam draw on the experience of other major jurisdictions, some of which have been considering these issues for some time. In this report, we consider the emerging approaches to the reconciliation of patent law and competition law in the U.S., European Union ("EU"), United Kingdom ("U.K.") and Australia, and how those approaches might inform Canadian law and policy on the topic.

In particular, we canvass four specific types of conduct capturing the current attention of antitrust authorities in these jurisdictions, each of which involves potentially anti-competitive conduct as well as patent rights. In short, the competition concerns in each of the four areas are as follows:

- **Standard-setting and fair, reasonable and non-discriminatory ("FRAND") royalty commitments** – Industry standard-setting is widely acknowledged as promoting competition and innovation to the benefit of consumers. Many industry standards incorporate patented technology; a current example is the hundreds of standards incorporated into a smartphone, each of which can involve many patents. The setting of standards by its nature involves competitor collaboration, and therefore a (somewhat older) concern exists over collusive conduct that might occur between competitors engaging in the standard-setting process. Once a standard has been set, there is potential for the standard to confer market power. This has led to more recent concerns over (i) anti-competitive foreclosure preventing effective access to the standard and (ii) the potential for patent hold-up, where the threat of an injunction prohibiting the sale of products incorporating the standard results in higher royalties than would have been secured in the absence of the market power conferred by the standard, and/or breaches of commitments by the patent holder to license at FRAND royalty rates.

- **Reverse payment settlements** – In the course of seeking approval for generic versions of drugs, the patents held by branded companies may be the subject of judicial proceedings. To resolve such litigation, the branded and generic companies may enter into a settlement agreement whereby the generic company agrees to delay the introduction of a generic version of patented drug, in exchange for certain types of consideration from the branded company (which often may include a financial payment). Such agreements are often referred to by competition authorities as "pay for delay" or "reverse payment settlements" and have raised allegations from competition authorities of higher health-care costs as a result of delayed generic drug entry.

- **Patent assertion entity ("PAE") conduct** – Patent assertion entities, often referred to as "patent trolls" by their critics, are firms that engage in the business of acquisition and assertion of patents against parties who are alleged to be using the patented technology. PAEs are renowned for their voluminous and sometimes questionable demands for payment of royalties on their patents and related patent infringement litigation. Commentators, particularly in the U.S., have questioned whether PAEs by asserting their patents in this fashion, adversely affect innovation and thus competition.

– **Product hopping** – "Product hopping" refers to conduct by branded manufacturers introducing new variations of a patented drug shortly before the patent protection on the older version of the drug expires, accompanied by a withdrawal of the older drug that is facing imminent generic competition. From a competition policy perspective, there is concern that removal of the old, branded drug from the market could make it more difficult for the generic drug to enter the market.

An overview of our broader, general conclusions, as well as our findings in each of these topic areas is provided below.

1. General Findings

Overall, there is a perceptible increase in international competition law enforcement efforts with respect to conduct involving patent rights. The EU and the U.S. have been particularly active and are advanced in their consideration of complex issues in this space. Even smaller jurisdictions such as the U.K. are grappling with the issues addressed here. Their experience appears to be a valuable source of guidance and insight on approach for jurisdictions like Canada.

Canada and Australia have seen a comparative lack of competition agency guidance, enforcement and cases related to issues at the intersection of the competition and patent law regimes. There are encouraging but very recent initial indications that this may be changing; both Canadian and Australian competition authorities have turned their attention to product hopping, and the Canadian Competition Bureau ("Bureau") is looking at broader engagement in the form of new guidance and workshops. It is not clear whether the difference in engagement to date on these issues is due to differences in the Canadian factual situation that make enforcement inappropriate, differences in Canadian law, the Bureau's perceived lack of jurisdiction to act on issues at the intersection of patent and competition law, or other factors. Many of the recommendations we make in this report are aimed at determining the cause of this difference.

Across the four topic areas in multiple jurisdictions, we saw common themes in their efforts to reconcile competition and patent law and policy. One theme was strengthening cross-agency collaboration between intellectual property agencies and competition enforcement agencies. This overlapped with a trend of extensive agency knowledge-building through cross-agency and public engagement, in the form of reports and workshops on specific subjects involving patent and competition law and policy. Inter-agency collaboration and institutional knowledge building are common in the jurisdictions which are more advanced in charting a course through issues at the intersection of competition law and patent law. We suspect this approach is necessary, because the issues are often highly complex, technical and interdependent, with public importance spanning across agencies, such as public health spending or accessibility of standards.

We believe the foundation for addressing the issues in this report from a Canadian perspective is building similarly close ties between the Canadian Intellectual Property Office and the Bureau, emphasizing strategic collaboration within Industry Canada and developing the knowledge base of the agencies. Such cross-silo collaboration is necessary to strike the right balance between patent and competition protection in government policies; striking this balance will promote innovation and maximize economic returns for Canadians.

The other pillar to successfully reconciling patent and competition law in Canada is having the right legislative framework. Our impression is the Canadian *Competition Act* (the "*Act*") and related guidance stand out as dated in some respects on their approach to reconciling patent and competition law, and may even be dampening enforcement.

Canada has two unique provisions on intellectual property in its competition legislation. Section 79(5) of the *Act* prevents the application of the abuse of dominance provisions to conduct involving only the exercise of IP rights or interests. The other jurisdictions studied have no equivalent legislative exception, and have applied their respective abuse of dominance prohibitions to address conduct such as repudiation of standard-setting commitments, reverse payment settlements and product hopping. We recommend considering a repeal of the limit on abuse of dominance under Section 79(5) of the Act, or at least an assessment of its continued relevance. Further, we recommend considering whether its interpretation in the "mere exercise" approach in the Canadian *Intellectual Property Enforcement Guidelines* ("IPEGs") is dampening the application of competition law to anti-competitive conduct involving patent rights.

Another uniquely Canadian competition law provision is found in Section 32 of the *Act*, which provides the Attorney General with the power to seek special remedies where an intellectual property right has been used to prevent or lessen competition unduly. At a minimum, we think it would be useful to assess why Section 32 is almost never applied, and to update Section 32 to align it with the 2009 overhaul of the Act. Even further, we think it is worthwhile to consider a shift of jurisdiction under Section 32 away from the Attorney General to the Commissioner of Competition.

The Canadian competition law framework could also be enhanced by expanding avenues other than public enforcement, such as increasing the role for private actions. Although we do not address private actions extensively in this report, we note the U.S. has seen several product hopping cases proceed privately, and standard-setting/FRAND licensing competition law issues have been raised in very extensive private litigation in the U.S. and EU.

2. Specific Topic Area Findings

(a) Standard Setting and FRAND Licensing Commitments: Active Enforcement and Recent Guidance from the EU and U.S., All Quiet in Other Jurisdictions

In the jurisdictions studied, the pro-competitive benefits of standard-setting are widely acknowledged by competition authorities as being economically and socially significant. The promotion of competition in the standard-setting space is considered important to realize those significant benefits.

Recent enforcement action by the U.S. Federal Trade Commission ("FTC", one of the U.S. agencies tasked with competition law enforcement) and the European Commission Directorate-General for Competition ("EC", the European-Union level competition authority), over standard-setting conduct is rooted in concern about anti-competitive patent hold-up, either in the context of hold-up arising from deception in standard-setting (patent "ambush") or through the abrogation of licensing commitments (including seeking injunctions with respect to standard essential patents in certain circumstances). The U.K. approach to standard-setting and FRAND licensing commitments, based on a recent report, appears similar to that of the U.S. and EU. The U.K. competition authority does not have any current cases underway.

In the 2007 – 2009 timeframe, the U.S. FTC and the EC saw decisions in parallel cases to sanction patent ambush by the high-tech company Rambus relating to standard-setting. Although the legal provisions under which the cases were brought differed, the underlying theoretical concerns about harm from patent hold-up were largely the same. The EC was successful in obtaining voluntary commitments in its case against Rambus. Although the FTC's Rambus case was overturned by a U.S. court, the approach to causation in the court decision has been criticized. The common concern over patent ambush shared by the EU and U.S. also appears relevant to Canada at a theoretical level.

The issue of patent ambush is an older one, but is rooted in similar concerns over patent hold-up as the current cases on injunctive relief for standard essential patents ("SEPs") subject to FRAND licensing commitments. The U.S. FTC has reached two consent agreements in cases where it challenged the seeking of injunctions for FRAND-encumbered SEPs, while the EC has two ongoing cases on the subject. The FTC has pursued such conduct under unfair competition prohibitions, while the EC has pursued it as an abuse of dominance. Despite differences in the legal provisions applied in the cases, the FTC and DOJ (together, the "Agencies") as well as the EC have taken a similar position that the use of injunctive relief in cases involving standard-essential patents subject to FRAND licensing commitments may disrupt competition and should be limited to certain circumstances. There is a shared concern that the threat of an injunction may distort licensing negotiations unduly in the SEP-holder's favour, by forcing potential licensees into onerous licensing terms such as higher royalties than would otherwise have been agreed to, or forced cross-licenses. We see no reason why such concerns would not apply equally to Canada, to the extent similar conduct is occurring here.

In contrast to the other jurisdictions studied, Australia has seen a low level of concern over standard-setting/FRAND licensing obligations from competition authorities and policy makers. The 2013 Australian Compulsory Licensing Report found standard-setting concerns were, as a factual matter, unlikely to be relevant to Australia which is a "taker" rather than a setter of standards. Competition and patent legislation were thought to be unlikely to be called upon often in Australia to resolve SEP disputes. Existing provisions in Australian competition legislation were thought to be sufficient to protect against misuse of market power involving a failure to comply with FRAND commitments.

Although Canada may be in a similar factual situation to Australia, further research on the relevance to Canada of standard-setting would be helpful to confirm this. There are distinctions in Canadian competition legislation, such as Section 79(5), that may also make the Australian conclusions inapplicable. The Australian perspective may also be over simplified. Complex, recent private litigation is raising issues over standard-setting and FRAND in Australia, showing that even jurisdictions which do not drive standard-setting can be impacted domestically by FRAND disputes.

In several of the jurisdictions studied, literature suggests standard-setting organizations ("SSOs", the industry groups which drive standard-setting processes), should play a key role in controlling anti-competitive conduct in standard-setting. SSO policies are considered important in ensuring competition is preserved in the setting of standards and in restraining the exercise of market power after the standard is adopted. Some commentators go as far as arguing that disputes over the availability of injunctions for FRAND-encumbered SEPs are merely contractual in nature, and therefore competition authorities should not become involved. This disregards the potential for anti-competitive harm to consumers and competitors not under the auspices of the SSO or the relevant agreement on FRAND royalties. As a matter of competition policy it appears appropriate for competition authorities to continue to engage in oversight of

issues related to standard-setting and patents in conjunction with encouraging pro-competitive SSO policies. Both the U.S. and EU agencies have indicated in recent merger approvals involving SEPs that they will continue to watch this space and ongoing enforcement efforts are likely.

The EC recently provided formal agency guidance on standard-setting enforcement issues in competition law, and the U.S. has provided guidance through cases and speeches. The formal guidance arose from EC's experience in investigating cases, the key lesson from which was the difficulty of attempting to untangle complex standard-setting issues after standards have been locked-in. The EC approach is thus aimed at providing much more detailed guidance up front, in an effort to reduce later issues. The benefits to providing more detailed guidance are also thought to include: promoting standard-setting and associated benefits, discouraging the abuse of standard-setting processes and encouraging SSOs to play an active role in imposing policies that reduce such abuse.

In Canada guidance is limited and there are no major cases addressing when conduct involving standard-setting and patents could violate Canadian competition law. Several of the benefits of providing guidance outlined above appear applicable to Canada. Conversely, a lack of guidance could deter standard-setting or reduce beneficial self-regulation by SSOs, based on perceived competition law risk. A Canadian case challenging the use of injunctions for FRAND-encumbered SEPs would likely be closer to the approach taken in EC cases than the U.S. cases, although differences in the law of abuse of dominance between Canada and the EU may make it more challenging for Canadian authorities to bring a case.

Even in jurisdictions where guidance has been provided, key open issues include (i) what constitutes a FRAND rate; (ii) who is considered a "willing" licensee; and (iii) the appropriate limiting factors in competition enforcement to ensure patent rights are not impinged. The FTC has faced criticism for a perceived failure to define meaningful limiting principles to govern the use of its *FTC Act* Section 5 authority to address such conduct. Critics emphasize that to avoid impinging on patent rights, such cases should include sufficient evidence that rights to seek injunctions were waived in the standard-setting process. The resolution of currently ongoing EU cases may provide a better indication of international consensus on when injunctions should be permissible for SEPs that are subject to FRAND commitments. Indications are there may be basic similarities in the EC resolution and the commitments reached in the most recent U.S. case. Any such consensus would be helpful in guiding Canada's approach.

An empirical study on the extent to which private standard-setting involving patents is occurring in Canada and whether anti-competitive concerns exist over related licensing conduct here could clarify whether Canadian competition authorities (and courts) should be concerned over standard-setting issues within Canada. One possibility is that international competition law enforcement efforts may be sufficient to address impacts within Canada. If empirical evidence suggests potential anti-competitive effects in Canada, we recommend that more detailed guidance be provided by the Bureau on when conduct related to standard-setting, and the violation of licensing commitments made therein, might violate Canadian competition laws.

(b) Reverse Payment Settlements: Clear Agency Opposition, Emerging Judicial Interpretations

Several of the jurisdictions studied situate the reverse payment settlement debate in the context of public health spending, and the essential role generic drugs play in reducing costs while still ensuring widespread access. Studies in the U.S. and the EU and statements from the U.K.

competition authorities have indicated that reverse payment settlements delaying generic entry reduce the competitive pressure from generic companies on branded companies, potentially leading to higher health-care costs. The cost savings to consumers and the government from a ban on the reverse payment settlements which delay entry of generic drugs has been estimated by the FTC at billions of dollars.

For some time, competition regulatory agencies in the U.S., EU and U.K. have taken the clear position that certain reverse payment settlements have anti-competitive effects and violate competition laws. Since the early 2000's, the FTC has argued reverse payment settlements are prohibited by U.S. antitrust law because they restrict competition and increase drug prices. Both the U.S. and EC have been monitoring reverse payment settlements through mandatory reporting for several years. This has led to challenges of certain settlements by authorities and may have the effect of discouraging anti-competitive settlements over time.

Overall, 2013 could be labelled the year of reverse payment settlement cases in international antitrust. The U.S. Agencies' position condemning reverse payment settlements was tested in a Supreme Court of the U.S. decision (*Actavis*). The EC also released its first decision in 2013 on reverse payment settlements (*Lundbeck*) and that agency interpretation may soon be tested in court under the ongoing appeal of the EC's decision. Finally, also in 2013, the U.K. competition agency brought a case challenging reverse payment settlements.

The legality of reverse payment settlements has not been addressed in Australian competition law jurisprudence or competition agency guidance. However, a 2013 Australian report from the patent-law perspective shares concerns with other major jurisdictions over the ability of generic pharmaceuticals to enter the market, and whether the Australian system for pharmaceutical patents is effectively balancing the objectives of securing timely access to competitively priced pharmaceuticals and fostering innovation.

The Supreme Court of the U.S. and the EC have applied differing analytical standards to their assessment of reverse payment settlements. In *Lundbeck*, the EC ruled reverse payment settlements violate prohibitions on anticompetitive agreements by object, meaning anti-competitive effects are presumed. Although the U.S. Agencies argued for a similar *per se* illegality approach to reverse payment settlements, the *Actavis* decision rejected this position and instead established a rule of reason approach to assessing reverse payment settlements in the U.S. The pending U.K. competition authority reverse payment settlement case is likely to follow the EU approach, although the agency is also considering whether the settlements violate prohibitions on anti-competitive agreements (in addition to constituting an abuse of dominance). The Supreme Court of the U.S. position appears to provide more scope for permitting reverse payment settlements than the stricter prohibitions taken to date by the EC.

Although the outcome in *Actavis* was not the standard of analysis for which the FTC advocated, the decision cast a role for antitrust that was stronger than the "scope of patent" approach adopted by multiple lower courts in the U.S. The scope of patent view was that reverse payment settlements involving the transfer of value do not infringe antitrust laws if they are within the exclusionary scope of the patent in dispute. The scope of patent approach largely removed such agreements from antitrust scrutiny. Instead, the rule of reason approach in the *Actavis* decision allows for antitrust scrutiny of reverse payment settlements, and this outcome reflects the significant role that persistent and principled agency enforcement can play in rebalancing the patent/competition law regimes.

There remain several open questions on reverse payment settlements U.S. and EU, such as the amount of permissible settlements, to what extent the validity of the patent should be considered in competition litigation and the permissibility of arrangements that involve non-cash payments. The remanded *Actavis* dispute and several other ongoing U.S. cases, as well as the *Lundbeck* appeal, should provide more clarity on these issues in coming years. Continued enforcement by agencies is expected in both the U.S. and the EU, and is also likely in the U.K.

The U.S. and EU have provided recent agency guidance on their approach to reverse payment settlements through reports, speeches and in the EC, formal guidance. Cases and monitoring of reverse payment settlements also help to clarify the agencies' positions. In contrast, the Canadian IPEGs do not address reverse payment settlements and there has been no informal guidance or cases in Canada on the subject. The last in-depth Canadian consideration appears to have been around 2007, when the Bureau released a study concluding that there was strong competition in the supply of generic drugs in Canada (with a follow-up study in 2008).

It is unclear whether reverse payment settlements are occurring in Canada to any significant extent because of a lack of tracking, by government or otherwise. The debate around reverse payment settlements in Canada, although not extensive, tends to focus on distinctions in the regulatory regimes for generic drug approval between the U.S. and Canada that may alter (i) incentives and (ii) legitimate justifications for engaging in reverse payment settlements here. If reverse payment settlements are occurring that may have anti-competitive effects in Canada, such settlements should not be immune from competition law scrutiny, despite regulatory differences between the U.S. and Canada. The basic reasoning adopted by the majority in *Actavis* appears applicable to Canada; simply because the effects of a reverse payment settlement might fall within the exclusionary scope of a patent does not mean a settlement should necessarily be "immunized" from all competition law scrutiny.

Canadian commentary suggests it would be difficult to establish a violation of Section 45 (criminal conspiracies provisions) of the *Act* arising from reverse payment settlements. The more likely section for a challenge of a reverse payment settlement, if it were to be brought in Canada, appears to be Section 90.1 of the *Act* (anti-competitive agreements between competitors). Although thought to be less likely, such conduct could also be considered under the Canadian abuse of dominance provisions (Section 79). The current "mere exercise" approach in Canada's IPEGs and Section 79(5) of the *Act* shares commonalities with the scope of patent analysis rejected by the majority of the U.S. Supreme Court in Actavis (although strongly supported by the dissent).

Given the minimal consideration of reverse payment settlements specific to the Canadian context, and the potential competitive significance, it is important to gather empirical information on the extent to which settlements are occurring here. As in other jurisdictions studied, reduced competition in the pharmaceutical industry in Canada could have implications for Canadian government health-care spending. Given our public health system, lower health-care costs are equally, if not more, important to the government of Canada than to jurisdictions such as the U.S. where competition authorities have long been questioning the effects of reverse payment settlements. If there are concerns over anti-competitive settlements, a system of Bureau monitoring could be an important means of signalling concern and of identifying any settlements meriting challenge.

If reverse payment settlements are occurring that negatively affect competition in Canada, it becomes all the more essential that the Bureau provide guidance on its position in Canadian competition law. First, the IPEG's current approach may make enforcement action with respect

to reverse payment settlements unlikely and may also mean a Canadian court would be unlikely to find such settlements violate the Act. Second, if arguments over distinctions in the Canadian pharmaceutical regulatory context affect the analysis of reverse payment settlements, clarifying such distinctions could help to avoid unnecessary chilling of legitimate settlements. The global climate of active enforcement against reverse payment settlements, including the strong stance against such payments taken by U.S. competition authorities, might otherwise be assumed to apply within Canada.

(c) Patent Assertion Entity Conduct: The U.S. Experience and Awareness on the International Horizon

International approaches to PAE conduct are not well established in comparison to the other topic areas canvassed in this report. Other jurisdictions have paid little attention to PAEs, since none have seen litigation by PAEs reach the levels in the U.S.

Despite this, competition authorities in each of the U.S., EU and U.K. have all acknowledged the potential issue of patent hold-up, which underlies antitrust concerns about both patent assertion entities and standard-setting/FRAND licensing. Exploitation of the potential for patent hold-up, as with standard-setting/FRAND issues, is at the core of the PAE litigation strategy. Other jurisdictions are not blind to the potential PAE concern; the EC is watching this space very carefully and has acknowledged the potential for PAE conduct in Europe, which commentators argue will be heightened by pending implementation of a unified patent court. In the U.K., an empirical study found some PAE litigation is occurring. The potential for problematic PAE hold-up has been acknowledged, along with an awareness that conduct by PAEs in other jurisdictions could be imposing costs on European companies. Patent assertion entities have not been addressed in Australian cases or literature, but there is some anecdotal evidence of recent potential PAE litigation in the Australian Federal Court.

In the U.S., studies suggest there has been a rapid rise in the number of patent infringement lawsuits brought by PAEs over a short period of time. By some estimates, such litigation now forms the majority of patent infringement lawsuits in the U.S. Litigation by PAEs has also been the subject of several studies that suggest it has distinguishing characteristics from patent infringement litigation brought by non-PAEs.

Estimates of costs imposed by PAE conduct in the U.S. are high, and include both costs related to litigation and costs of non-public demands made by PAEs. The latest literature, as well as commentary from the FTC, reflect two emerging trends in PAE activity that heighten potential antitrust law and policy concerns: (i) privateering, where operating companies employ PAEs as “hired guns” to target their competitors and (ii) targeting of small businesses by PAEs with false infringements claims.

The extensive PAE litigation in the U.S. is being targeted by legislative reforms, although none have yet passed the Senate. The key themes in the proposed U.S. legislation and reforms are (i) a shift to a loser-pays system for patent infringement litigation, (ii) increased transparency in patent ownership and litigation, and (iii) end-user protection. Another approach to controlling PAE conduct has been consumer-protection type legislation and enforcement against PAEs at a state level.

The legislative reforms reflect the U.S. perspective that PAE activity is just one piece of a broader issue; flaws in the patent litigation and granting systems are fueling the PAE-imposed costs. Although the FTC and the DOJ have focused significant attention on understanding

patent assertion entities, including a public workshop and a pending formal study, the Agencies have yet to take any antitrust enforcement action. The shift to a loser-pays system in U.S. patent infringement litigation, either through legislation or more gradually through judicial precedent, seems most likely to significantly impact the financial risk imbalances that drive PAE litigation. To date, the U.S. courts have played an important role in controlling PAE hold-up potential by limiting the availability of injunctions, although this has led to forum-shopping within the U.S.

The impact of PAE conduct on Canada has not been studied to any extent; the dearth of empirical information leaves little on which to base Canada-specific enforcement policies or advocacy efforts. This is in contrast to the wide array of public and private studies/reports on PAE conduct in the U.S. and some consideration in other jurisdictions.

Canada may be directly impacted by PAE litigation here, and/or indirectly impacted by PAE litigation in the U.S. Recent infringement claims in the Canadian Federal Court illustrate that Canada is not immune to PAE litigation. However, fee-shifting in patent infringement litigation, which Canada has, is considered by some to temper PAE litigation.

Given market integration between the U.S. and Canada, it seems probably that conduct of PAEs in the U.S. is having at least some effect here. In theory, the effects might include harms similar to those identified in the U.S., such as potential innovation chill, unmerited litigation and settlement costs, excessive payments in response to demand letters, technology withdrawn from the market where infringement is alleged and more indirect business costs. An assessment of the impacts, if any, of PAE conduct on the Canadian economy and competition in Canada, including licensing demands which do not reach the stage of litigation, would help to frame the Canadian debate and gauge the appropriate level of concern and action in Canada to address PAEs.

(d) Product Hopping: A Multitude of Cases and a Theoretical Conundrum

In all of the jurisdictions studied, there have been recent competition agency cases or investigations into product hopping, or agency intervention in private cases. The EC has brought a successful major case involving product hopping (*AstraZeneca*, in 2010), as has the competition authority in the U.K. (*Reckitt Benckiser*, in 2011). The FTC has filed briefs in private litigation on product hopping but has not brought a contested case of its own. The U.S. courts' position remains somewhat unsettled as there have only been preliminary rulings. Australian competition authorities brought their first product hopping case in February 2014. Finally, the Bureau has been investigating its first potential product hopping case since November 2012, an encouraging foray into the issues raised by the intersection of patent law and competition law. The Bureau recently announced that the inquiry had been discontinued, because the branded drug company had recommenced supply of the older drug and there had been subsequent competing generic drug entry, restoring competition to the relevant market.

The reasoning in imposing product hopping liability under competition laws varies across jurisdictions. The FTC has taken the view that product hopping may violate U.S. antitrust laws where it involves branded companies forcing consumers to switch to the new product formulation by withdrawing the older formulation from the market, and the consumer harm created by lost generic competition outweighs the benefits of the product reformulation. A preliminary ruling in a private U.S. product hopping case agreed with this approach. In *AstraZeneca*, the European Union General Court focused instead on the regulatory action of the branded company in withdrawing market authorizations, ancillary to the introduction of the new

drug formulation. Although the U.K. competition authority's major product hopping case also involved a regulatory authorization withdrawal, liability was not expressly based on this, and appears to have been driven by the intent to hinder generic competition reflected in internal company documents (an approach that has been the subject of criticism). Although at the early stages, the Australian product hopping allegations appear to hinge on a variation where the "hop" is to an authorized generic of the branded company, and there is no apparent withdrawal of the older branded product from the market. The U.S. approach appears to impose wider liability for product hopping, challenging conduct even in the absence of any specific regulatory gaming to block generic competition with the prior drug formulation.

At the root of product hopping cases is the difficult theoretical question of when and how innovation in the form of new products should be policed by antitrust. Literature suggests the European Union General Court's approach in *AstraZeneca* of focusing on regulatory gaming may avoid the challenge of distinguishing between legitimate and predatory innovation. Making such a distinction is inherent in the U.S. "weighing of benefits" approach. It is argued the EU court's approach reduces the risk of false positives in enforcement that could chill pharmaceutical product innovation.

In the Bureau's recent inquiry into a potential product hopping case, which has since been discontinued, the generic company appeared to remain free to continue to compete with its generic version of the older drug. In fact, there was subsequent entry by competing generic drug companies after the branded company recommenced supply of the older formulation of the drug. The potential case did not hinge on any regulatory withdrawal, meaning if it had proceeded, the Tribunal could have faced a U.S.-style challenge of adjudicating how much innovation is "enough" not be considered a predatory attempt to block generic competition.

The Bureau provided a position statement on the case, indicating that product life-cycle management strategies for pharmaceuticals are not inherently anti-competitive, but are likely to raise concerns over abuse of dominance where such strategies are designed to impede competition, such as product hopping strategies. The statement is largely consistent with the FTC's view, and is helpful because it sets out for branded pharmaceutical companies the general types of conduct that could form the basis of future Bureau cases on product hopping.

We did not find any major recent empirical studies in any jurisdiction measuring the competitive effects of product hopping, but the extent of agency enforcement makes clear that concerns exist over the competitive effects of product hopping on generic competition. Further research into the effect on generic competition arising from product hopping in Canada (or occurring elsewhere with impacts in Canada) would be helpful in this regard.

III. DESCRIPTION OF OBJECTIVES AND ISSUE SELECTION

The objective of this report is to identify and discuss key issues where patent rights are being exercised in potentially anti-competitive ways in both the Canadian and international context. We provide a basic overview of competition law and agency guidance relevant to patent issues, and then examine four major current areas of attention: reverse payment settlements, standard-setting/FRAND licensing commitments, patent assertion entities and product hopping. In the first segment of the report addressing the U.S., we have included background sections on the fundamentals required to understand each of these four main topics. Finally, we include a discussion of the outstanding questions at the forefront of the competition law approach to conduct involving patents and suggestions for further research.

The report looks at the behaviours of patent rights holders that are being considered and, in some cases addressed, by competition authorities and courts in the U.S., the EU, the U.K. Australia and Canada. It is not intended to set out the entirety of the basics, or history of potentially relevant cases or literature related to the interaction of competition law and patent law; it is intended to be a detailed survey of emerging enforcement and legal approaches. Where possible, we draw conclusions and make recommendations applicable to Canada; however, we note international approaches in this area are fast-evolving and often unsettled.

The topics were selected based on the existence of recent or ongoing agency enforcement or cases in multiple international jurisdictions, particularly the U.S. and EU. We took this as a proxy for likely relevance to Canada, given the prevalence of international convergence in competition law and the heavy influence of the U.S. and EU on Canadian trade, law and policy. The issues selected also reflect areas of intense current debate and relevancy among competition law agencies and practitioners.

There are other issues which have been addressed in the past in this area of legal/policy analysis, but which are not the subject of current cases, such as patent pools. There are still other issues which we consider to relate predominantly to patent law phenomena and considerations, such as patent thickets. The extensive menu of possible topics, if anything, reflects the message of this report that there is ever-increasing need to understand the intersection of competition and patent law and policy.

The report is intended to be current to December 31, 2013, although wherever possible for Canada we have also endeavoured to provide commentary current to the delivery of the final report. There are ongoing developments in all areas covered by the report.

IV. GENERAL OVERVIEW OF THE INTERSECTION OF PATENT AND COMPETITION LAW REGIMES

1. Theoretical Basics on the Intersection of Competition and Patent Law and Policy

We do not propose to provide an in-depth discussion of the basic theoretical intersection of these areas of the law, which has been subject to other extensive commentary. We set out some of the basic background here to situate the reader, but assume for the remainder of the report a basic level of familiarity in order to dedicate the report to more novel and advanced considerations.

Historically, the goals of competition law and patent law were thought to be in conflict.[11] Patent law fundamentally functions by granting patent rights to exclude others from making, using or selling a patented invention. Competition law was historically seen as directed at eliminating the effects of monopolies and the promotion of competitive markets. The goals of patent law and competition law were thus seen as being in tension, with one directed at the granting and the other at the limitation of monopolies.

A more nuanced understanding of the legal regimes of competition law and patent law has since emerged. Both regimes are now generally considered complementary instruments of government policy, each promoting innovation and enhancing consumer welfare. Competition law and policy strive to maintain competitive markets, prohibiting unreasonable restraints on trade that could act as barriers to new innovation. Robust and effective competition in turn drives competitors to improve existing products or introduce new products to maintain their market share. Patent law and policy aim to foster long-term dynamic efficiency through incentives to invest and innovate over time. This statutorily-granted patent monopoly is intended to promote innovation by allowing innovators to recoup investments in research and development and by enabling other innovators to build on the patent owner's technology, which must be disclosed in exchange for the patent protection.

The challenge is in striking the delicate balance between exclusivity granted by patent law, and competition. Competition law enforcement may limit the use of patent rights where such use is anti-competitive, for example by imposing unreasonable conditions on the transfer and licensing of patent rights. To optimize the promotion of innovation and consumer welfare, competition law and patent law need to be aligned in both design and enforcement. The legitimate practicing of patents must be accommodated by competition law; condemning legitimate, efficient uses of patent rights would undermine the incentives to innovate created by the patent system. Conversely, the improper use of patents has the potential to chill innovation, reduce competition and raise prices through unnecessary litigation and licensing. The Supreme Court of Canada explained that at the root of IP law "lies a concern to avoid overextending monopoly rights on the products themselves and impeding competition."[12] As explained in the introduction to this

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11 See the discussion on IP and competition law interface history in Calvin S. Goldman, Q.C. and John D. Bodrug, *Competition Law of Canada* (Huntington, New York, USA: Juris Publishing, 2010) at §12.02, quoting a 1946 report of the Commissioner of Competition under the precursor to the Act, which indicated "participants in cartels often make use of patent rights to divide the markets of the world by national territories and to establish within a national territory a comprehensive system of marketing control" [Goldman & Bodrug]. We discuss here competition law and patent law, but similar considerations apply to the intersection of competition law and other types of intellectual property law.

12 *Kirkbi AG v. Ritvik Holdings*, [2005] 3 S.C.R. 302 at para 52.

report, rising prominence of both patent and competition law means the optimal balance of these regimes is increasingly coming into question.

The modern approach to reconciliation of IP and competition law in all of the jurisdictions discussed here begins from the basic premise that IP is subject to competition law as are other types of property. Competition law may thus apply to the anti-competitive exercise of IP rights, as it does to other types of property, where required to maintain competitive markets. However, the delineation of patent and other IP rights can be inherently more challenging than for other types of property; the nature of intellectual property means many individuals may possess IP rights simultaneously, and the boundaries of the IP itself can be more challenging to delineate than with physical property.[13] This contributes to challenging questions over where to draw the line between anti-competitive and legitimate uses of patent rights.

2. Legislation and Enforcement Basics at the Intersection of Competition Law and Patent Law

(a) Canada

(i) Applicability of Competition Law to Conduct Involving Patents

Canada's competition law is largely contained in the federal *Act*, which is a statute of general application. The *Act* contains both criminal offences and reviewable practices.

Conduct involving patent rights, like conduct involving other forms of property, is potentially subject to the general provisions of the Canadian *Act*. The general sections most likely to be relevant to the conduct discussed in this report are the criminal conspiracy provision (Section 45), the civil provision addressing agreements between competitors (Section 90.1), and abuse of dominant position (Section 79). Other potentially relevant provisions include the price maintenance provisions (Section 76), exclusive dealing/tied selling/market restrictions (Section 77), refusal to deal (Section 75) and the merger review provision (Section 92).[14] Where a general provision is likely to be relevant to certain conduct, we address the provision in greater detail below.[15] In addition to these general provisions, there is also Section 32 of the *Act*, which provides specifically for special remedies where an intellectual property right has been used to prevent or lessen competition unduly, discussed further below. **Appendix A** provides a brief overview of each of these provisions.

The Commissioner of Competition brings most of the cases that occur under these provisions. Private applications are only permitted in connection with price maintenance (Section 76, which is unlikely to be relevant to conduct discussed in this report), exclusive dealing/tied selling/market restrictions and refusals to deal. However, Section 36 of the *Act* permits private civil actions by any person who has suffered loss or damages as a result of conduct that is

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13 Canada, Competition Bureau, *Intellectual Property Enforcement Guidelines* (September 2000) at 9, online: <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng%20/01286.html> [IPEGs].

14 For example, major recent pharmaceutical mergers in which the Bureau required divestitures include Novartis/Alcon (August 9, 2010) and Teva/Ratiopharm (July 30, 2010).

15 For a general discussion of the provisions of the *Act*, see James Musgrove, *Fundamentals of Canadian Competition Law*, 2nd Edition (Carswell: 2010).

contrary to any of the *Act*'s criminal provisions, to recover damages from the person or persons who engaged in that conduct.[16]

There are two sections of the *Act* that specifically refer to intellectual property rights: Section 32 and Section 79(5). In contrast to the general provisions discussed above, Section 32 of the *Act* provides for special remedies, essentially where an intellectual property right has been used to prevent or lessen competition in the production, manufacture, trade, purchase, barter, sale, transportation or supply of an article or commodity, or to unreasonably enhance the price thereof.[17]

Section 32 of the *Act* authorizes the Federal Court, exclusively on application by the Attorney General to issue remedial orders if it finds that a company has used the exclusive rights and privileges conferred by a patent, trade-mark, copyright or registered integrated circuit topography to restrain trade or lessen competition "unduly". Pursuant to Section 32, the remedial orders issued may:

- declare any agreement or license relating to the anti-competitive use void;
- restrain any person from carrying out any or all of the terms of the agreement or license;
- order compulsory licensing of the intellectual property right (except in the case of trade-marks);
- expunge or amend a trade-mark; or
- direct that other things be done to prevent anti-competitive use of the intellectual property right.

Section 32 was introduced in 1910, in the precursor legislation to the current *Act*. At one point, amendments to Canadian competition legislation repealed the equivalent provision to the current Section 32, based on the perception that the existing remedies under the *Patent Act* were sufficient. In 1946, the provision was reinstated after a report of the Commissioner of Competition found that the *Patent Act* inadequately addressed anti-competitive abuses of patents.

Section 32 is unusual because the Commissioner of Competition does not have the power to initiate an application. The power is held instead by the Attorney General, although the recommendation of the Commissioner of Competition that an application be brought would likely be persuasive. Despite the provision's long-standing existence, re-introduction into the *Act*, and

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16 Section 36 also permits a private action based on the failure to comply with a Tribunal or court order under the *Act*.

17 RSC 1985, c C-34. The section also refers to limiting unduly facilities for transport, production, manufacturing, supplying, storing or dealing in any article or commodity that may be a subject of trade or commerce, restraining or injuring unduly, trade or commerce in relation to any such article or commodity, and to preventing, limiting or lessening unduly, the manufacture or production of any such article or commodity or unreasonably enhancing the price thereof.

recognition in the *Intellectual Property Enforcement Guidelines* ("IPEGs") (discussed below), no contested case has ever been brought to trial addressing Section 32.[18]

Section 32 itself is outdated on its face in comparison to the rest of the *Act*. The standard of "unduly" lessening competition persists only in Section 32 of the *Act*, having been replaced with the standard of "substantial" lessening in 2009 amendments to several other provisions of the *Act*. The conduct prohibited under Section 32 where IP rights are used also employs language that is not seen elsewhere in the *Act*, making it unclear what conduct is actually being targeted by the provision.[19] Subsection 32(3) also contains a limiting clause requiring that Section 32 orders not be "at variance with any treaty, convention, arrangement or engagement with any other country" related to IP and to which Canada is a party. Although the intent of this provision seems reasonable – ensuring Canada complies with international IP obligations – it is broad and leaves unclear what limitations are being imposed on Section 32 remedies in practice. It may function simply to completely discourage any proceedings under Section 32.

The second provision specifically referring to intellectual property under the *Act* is Section 79(5), which provides an exemption from the abuse of dominance provisions in the *Act* (Sections 78 and 79). Section 79(5) specifies that where an act is engaged in pursuant "only" to the exercise of any right or enjoyment of any interest derived under Canadian intellectual property statutes, including under the *Patent Act*, it is not an anti-competitive act. For example, in a case involving trade-marks, the Competition Tribunal relied on Section 79(5) to conclude that the rights holder's decision to refuse to license its trade-marks was a legitimate exercise of its rights under the *Trade-marks Act* and thus not an abuse of dominance.[20]

The use of the word "only" in Section 79(5) is thought to highlight "the distinction between uses and abuses of intellectual property rights".[21] Section 79(5) limits the application of the abuse of dominance provisions, but the scope of the exception has not been clearly delineated or been the subject of any cases involving patents. Where conduct goes beyond the intellectual property

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18 Section 32 was briefly considered in *Re Genentech Canada Inc*. The case comments that Parliament's overall scheme to deter abuse of patents and to provide relief to the public where abuse occurs "involves regulatory powers applied outside the enforcement of patent rights by the civil courts. Provisions addressing abuse of patent are also found in sections 65 to 71 of the *Patent Act* and sections 31 and 32 of the *Competition Act*. These measures establish remedial jurisdiction with respect to past abuses of patent rights". The case involved an attempt to circumvent an excessive pricing proceeding initiated by the Canada Patent Medicine Prices Review Board. The patent holder dedicated its patents to the public use, then disputed the jurisdiction of the Board in the proceeding on the basis of the dedication. The Board held that its jurisdiction could not be evaded through a retrospective public dedication of the patent, reasoning that if such an evasion were possible, it would also follow that section 32 of the *Act* could be evaded by a dedication of a patent to the public. This would run contrary to the intent and objectives of Parliament. 44 CPR (3d) 316 (Cad. Patented Medicine Prices Review Board); stay granted (1992), (sub nom *Genentech Inc. v Canada (Patented Medicine Prices Review Bd)*) 44 CPR (3d) 335 (Fed. T.D.); Section 32 was also raised in a claim regarding tied selling but the case ended in a settlement agreement; See also on Section 32 the mention of *R v Union Carbide Canada Limited*, Exchequer Court of Canada, Court No. B-1979, Information filed October 12, 1967, Minutes of Settlement filed December 12, 1969 as referred to in Richard Corley et al, "The Interface Between Competition Law and Intellectual Property Law", Report of Canadian Competition Bureau (March 2006) at 33 online: <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/02285.html> [2006 IP and Competition Report].

19 See *supra* note 17. For example, Section 32 prohibits the use of IP rights to "prevent, limit or lessen, unduly, the manufacture or production of any such article or commodity or unreasonably enhance the price thereof".

20 *Canada (Director of Investigation and Research) v Tele-Direct (Publications) Inc.*, 73 CPR (3d) at 7 [*Tele-Direct*]. See also *Director of Investigation and Research v Warner Music Canada Ltd* (1997), 78 CPR (3d) 321 involving an alleged refusal to deal related to copyright [*Warner Music*].

21 Goldman & Bodrug, *supra* note 11 at 9-129.

right granted, an abuse of dominance could still be found. We also note there are no equivalent exceptions in any other provisions in the *Act*, meaning all other provisions apply fully to conduct involving intellectual property.[22]

Cases involving patent law and competition law in Canada have been relatively few and far between. The leading case on the intersection of these areas of law is *Eli Lilly and Co v Apotex Inc* in which the Federal Court of Appeal held that "the assignment of a patent may, as a matter of law, unduly lessen competition".[23] The Competition Bureau was an intervener in this case, and argued that simply because the *Patent Act* permits patents to be assigned does not mean it immunizes the transfer from the scrutiny of competition law. The Federal Court agreed that the *Patent Act* assignment provisions did not preclude Section 45 of the *Act* (criminal conspiracy provisions) from applying "when the assignment increases the assignee's market power in excess of that inherent in the patent rights assigned".[24] This interpretation was considered by the Court to be consistent with the IPEGs, in that it enables the *Act* to apply to conduct by intellectual property holders but does not challenge the mere exercise of an intellectual property right.[25] The Federal Court of Appeal referred to Section 32 as evidence that "Parliament did not intend to exclude the exercise of patent rights from the reach of the *Competition Act* altogether".[26]

(ii) Relevant Agencies and Adjudicative Bodies

The federal *Competition Act* (the "*Act*") is administered by the Competition Bureau (the "Bureau"), an independent law enforcement agency that is part of Industry Canada. The head of the Bureau is the Commissioner of Competition, who has statutory responsibility for administering and enforcing the *Act.* Much of the guidance on the intersection of competition law and intellectual property law, discussed below, is issued by the Bureau.

As detailed above, the *Act* contains both criminal offences and reviewable practices. The Bureau staff routinely investigate potential competition law violations and the *Act* empowers, and in some circumstances requires, the Commissioner to commence an inquiry where he or she believes on reasonable grounds that there has been a contravention of the criminal or reviewable practices provisions of the *Act*.

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22 *Ibid* at para 26. The Court in *Eli Lilly and Co v Apotex Inc*, (2005) 44 CPR (4th) 1 (FCA) noted in particular that section 45 does not contain any exemption analogous to section 79(5) that would limit the application of the *Act* to conduct involving intellectual property rights.

23 *Eli Lilly*, *ibid* at para 14. In this case, Eli Lilly and Co. ("Eli Lilly") filed a statement of claim alleging that Apotex Inc. ("Apotex") had infringed several of its patents, including four patents that had previously been assigned to it by Shionogi and Company Limited ("Shionogi"). In its statement of defence and counterclaim, Apotex alleged, among other claims, that the assignment of the Shionogi patents to Eli Lilly violated section 45 of the *Act*, and counterclaimed for damages. On a motion for summary judgment, the Federal Court concluded that Apotex's pleadings did not disclose a cause of action under section 45 on the basis that a precedent case, *Molnlycke*, precluded a cause of action under the *Act* in respect of "the simple assignment of patent rights". Based on this reasoning, the Federal Court held there was no cause of action in Apotex's counterclaim and granted summary judgment in favour of Eli Lilly and Shionogi. The FCA reversed the decision and distinguished *Molnlycke*, reasoning that, where there is evidence of something more than the mere exercise of patent rights that may affect competition in the relevant market, *Molnlycke* does not purport to completely preclude application of the *Act*.

24 *Ibid* at para 21.

25 *Ibid* at para 33.

26 *Ibid* at para 28.

In Canada, initiation and prosecution of criminal offences is carried out by the competition law section of the Public Prosecution Service of Canada ("PPSC") on behalf of the Attorney General, usually on referral of the cases by the Bureau after a Bureau investigation. The Department of Justice provides legal services to the Commissioner on matters for which the PPSC is not responsible.

Criminal matters are heard in the courts of criminal jurisdiction as set out in the *Criminal Code* of Canada. For reviewable matters under the *Act*, the Canadian Competition Tribunal, an independent adjudicative body, generally has jurisdiction, although for some reviewable practices the Commissioner of Competition may bring an application before the civil courts. Appeals from the Competition Tribunal are to the Federal Court of Appeal.

The *Patent Act*, the Canadian federal patent legislation, is administered by the Canadian Intellectual Property Office ("CIPO"). CIPO is a Special Operating Agency associated with Industry Canada and also responsible for administering most other intellectual property rights in Canada. Much of Canadian patent law is also determined by the Federal Court of Canada and the Federal Court of Appeal.

(iii) Agency Guidance on Applicability of Competition Law to Conduct Involving Patents

(I) The IPEGs

The major guidance document on the enforcement of the *Act* where IP rights are involved is the Bureau's Intellectual Property Enforcement Guidelines ("IPEGs") issued in 2000.[27] The IPEGs are currently under review, and stage one consultation draft was very recently issued; a second, more in depth update is also anticipated.

The 2000 IPEGs followed on the heels of two decisions regarding the Bureau's ability to seek compulsory licensing of intellectual property, both outside of the patent context.[28] The IPEGs reflect the input of an expert panel and consultative meetings held by the Bureau across Canada.[29]

The IPEGs also took into account the U.S. Antitrust Guidelines for Licensing of Intellectual Property and the approach taken in the EU at the time.[30] However, the Bureau rejected certain concepts that the U.S. adopted in its IP guidance, such as licensing safe harbours and innovation markets. The Bureau has not established any explicit safe harbours for licensing agreements. It also expressly declined to adopt a definition of markets based on research and development or innovation efforts ("innovation markets"), instead focusing on defining the market based on the more traditional concept of goods that include the technology.[31]

As in the other jurisdictions discussed here, the IPEGs begin from the basic position that IP laws and competition laws are complementary instruments of government policy, both of which

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27 IPEGs, *supra* note 13.

28 *Warner Music*, *supra* note 20; *Tele-Direct*, *supra* note 20.

29 2006 IP and Competition Report, *supra* note 18 at 8.

30 *Ibid*.

31 *Ibid*, s 5.1 ("The Bureau does not define markets based on research and development activity or innovation efforts alone.").

promote an efficient economy.[32] The enforcement approach is premised on the *Act* applying to conduct involving IP as it does to conduct involving other forms of property.[33]

The Bureau then delineates two broad categories where the *Act* may be applied to anti-competitive conduct involving intellectual property rights: conduct that is something more than the "mere exercise" of the intellectual property right, and conduct involving the mere exercise of the intellectual property right and nothing else. This "mere exercise" approach is based on the Competition Tribunal decisions in *Tele-Direct* and *Warner*, which (as described above) held that mere refusal to license trademark and copyright, respectively, did not comprise an anti-competitive act under the abuse of dominance provisions.[34] The Bureau considers this approach consistent with Section 79(5) of the abuse of dominance provisions in the *Act*, which provides that an act engaged in only pursuant to the exercise of an IP right or enjoyment of an interest derived under Canadian IP legislation is not an anti-competitive act.

The Bureau defines the mere exercise of an intellectual property right as the exercise of the owner's right to unilaterally exclude others from using the intellectual property. The Bureau views an owner's use or non-use of its intellectual property also as being the mere exercise of an intellectual property right.[35] In the very recently issued draft for consultation on updating the IPEGs, the main substantive change was to remove "non-use" of a patent from conduct considered to constitute "mere exercise", meaning non-use could be considered to raise concerns under the general provisions of the *Act.* Given that no specific examples are provided of when non-use of an IP right might fall within the *Act* the precise implications are not clear. Commentary suggests it is difficult to envision a scenario where mere non-use (such as a refusal to license) of IP and nothing more would violate the general provisions of the Act. Commentary also speculates that this change might have been in anticipation of the Bureau's product hopping case, which has since been discontinued.

According to the IPEGs, the Bureau will apply the "general" provisions of the *Act*, meaning those other than Section 32 (as described above), to address conduct involving more than the mere exercise of intellectual property rights. Both the criminal and reviewable matters provisions of the *Act* may apply to arrangements involving IP.[36] However, the Bureau's starting position is evidently cautious, in the interest of maintaining IP rights:[37]

> The unilateral exercise of the IP right to exclude does not violate the general provisions of the *Competition Act* no matter to what degree competition is affected. To hold otherwise could effectively nullify IP rights, impair or remove the economic, cultural, social and educational benefits created by them and be

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32 IPEGs, *supra* note 13 at 1.

33 *Ibid*.

34 *Warner Music*, *supra* note 20; *Tele-Direct*, *supra* note 20. ("The Tribunal is in agreement with the Director that there may be instances where a trade-mark may be misused. However in the Tribunal's view, something more than the mere exercise of statutory rights, even if exclusionary in effect, must be present before there can be a finding of misuse of a trade-mark."). The mere exercise approach was also reflected in the *Eli Lilly* decision, *supra* note 22.

35 IPEGs, *supra* note 13 at 4.2.1.

36 *Ibid* at 4.

37 *Ibid* at 7. This section remains unchanged in the draft IPEGs issued April 2, 2014.

inconsistent with the Bureau's underlying view that IP and competition law are generally complementary.

The Bureau specifies that it will apply the general provisions of the *Act* when intellectual property rights form the basis of arrangements between independent entities, whether in the form of a transfer, licensing arrangement or agreement to use or enforce intellectual property rights, and when the alleged competitive harm stems from such an arrangement and not just from the mere exercise of the intellectual property right and nothing else. The Bureau considers this approach may limit to whom and how the IP owner may license, transfer or sell the IP, without challenging the fundamental right of the IP holder to do so. The IPEGs also provide generally that where a company "uses IP protection to engage in conduct that creates, enhances or maintains market power", the Bureau may intervene. Specific instances considered to be more than the mere exercise of IP rights if there is also market power, are described:

- where the joint conduct of two or more firms lessens or prevents competition, the competitive harm "clearly" flows from something more than the mere exercise;

- the transfer of IP rights that lessens or prevents competition, for example where a product covered by an IP right is tied to another product that is not covered, or when a firm extends its market power beyond the term of its patent via an exclusive contract; and

- if a firm systematically purchases a controlling collection of IP rights and refuses to license the rights to others, lessening or preventing competition.

The analytical framework applied to assess whether such conduct violates the *Act* is described as the same as the framework the Bureau uses to determine the presence of anti-competitive effects arising from the exercise of rights to other forms of property.[38]

Where conduct involves the "mere exercise" of IP rights, the Bureau may seek to have the Attorney General bring an application for the special remedies under Section 32 to the Federal Court. As explained above, Section 32 of the *Act* essentially provides for special remedies where an intellectual property right has been used to prevent or lessen competition unduly. The Attorney General may then commence proceedings, and it seems he or she would be likely to do so on the recommendation of the Bureau. There is no public record of such a request ever having been made by the Bureau.

The Bureau sets out its analytical approach to Section 32 in the IPEGs. First, it would determine if the mere refusal has adversely affected competition to a degree that would be considered substantial in a relevant market that is "different or significantly larger" than the subject matter of the IP or the products or services which result directly from the exercise of the IP. The Bureau considers this would only occur where the IP holder is dominant and the IP is an essential input or resource for firms participating in the relevant market, in that refusing access prevents competition. Second, the Bureau would have to establish that invoking a Section 32 remedy would not adversely alter the incentives to invest in research and development in the economy.

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[38] This framework is described in the IPEGs, *ibid*, as identifying the transaction or conduct; defining the relevant market(s); determining if the firm(s) under scrutiny possess market power by examining the level of concentration and entry conditions in the relevant market(s), as well as other factors; determining if the transaction or conduct would unduly or substantially lessen or prevent competition in the relevant market(s); and, considering, when appropriate, any relevant efficiency rationales.

The second step is considered by the Bureau to be satisfied if the refusal to license the IP is stifling further innovation.

The Bureau indicates only in "very rare" circumstances would the factors required to apply Section 32 be satisfied, and that it "expects such enforcement action would be required only in certain narrowly defined circumstances."[39] The Bureau provides as an example where such factors might be satisfied the situation of a network industry where access to industry standards is required to compete (see further discussion, below). Another example of conduct that might violate Section 32 is an "illegitimate extension of an IP right", such as a patent holder claiming its patents cover products not within the scope of its patents.[40]

This narrowed approach to Section 32 set out in the IPEGs does not appear to be based on any case or other discernible authority. It is possible that the Bureau may be fettering its own authority more than is statutorily required by establishing such a high hurdle to Section 32 enforcement and setting out the expectation that enforcement would be very rare.

Although the IPEGs endeavor to add colour to the "mere exercise" approach, we find the distinction between mere exercise and more than mere exercise to be fairly opaque. The fact that current Canadian guidance is opaque may be attributable to the Bureau having to make some sense of the language of Section 79(5). By establishing a standard that is difficult to parse in practical terms, the IPEGs provide little help to industry or their counsel in determining when conduct involving intellectual property rights crosses the line into anti-competitive conduct. This question is admittedly complex and challenging. We acknowledge that jurisdictions like the EU and the U.S., which provide more specific guidance either through actual guidelines or via enforcement and advocacy efforts, may face more complex issues in the area of IP and competition law that necessitates more in-depth guidance. For example, the relevant agreements may be struck in the U.S. and EU, and differences in their legal systems may give rise to unique issues. However, there is a clear trend toward greater enforcement efforts worldwide in the overlap space of patent and competition law, and Canada is, like other countries, seeing a rising economic importance of patents. As such, providing practical and clear guidance in Canada in this area is increasingly important. The currently issued guidance is also now over 13 years old, predating many of the novel competition and patent law issues canvassed in this report.

Subsequent to the initial draft of this report, the Bureau issued a draft initial update to the IPEGs. The update consists largely of housekeeping changes targeted at updating the guidance to reflect changes to the *Act* since the last IPEGs were issued. The main substantive change was to remove "non-use" of a patent from conduct considered to constitute "mere exercise", as discussed above. The topics in this report are not covered in the revised draft IPEGs. We understand that the current draft is the first stage only, and that the Bureau anticipates a second stage of changes with more substantive updates to the guidance. We would encourage the Bureau's second, substantive update to the IPEGs in order to provide guidance on pressing topics such as those covered herein.

(II) Other Guidance and Reports

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39 IPEGs, *supra* note 13.

40 *Ibid* at 10.

Although not specific to intellectual property, the Bureau's *Competitor Collaboration Guidelines* (2009) could also be relevant in assessing any conduct involving competitor collaboration and intellectual property rights.[41] For example, the Bureau also addresses industry standard-setting briefly in the *Competitor Collaboration Guidelines*, which indicate that an agreement among competitors to implement a new industry standard is not considered "alone" to be an agreement to fix or increase prices. The *Competitor Collaboration Guidelines* acknowledge such agreements might be protected by the ancillary restraints defence.[42]

Similarly, although not specific to intellectual property, the Bureau's *Enforcement Guidelines on the Abuse of Dominance Provisions (Sections 78 and 79 of the Competition Act)* ("Abuse of Dominance Guidelines") could be relevant where an alleged abuse involves intellectual property.[43] For example, when assessing market power the Abuse of Dominance Guidelines indicate that "evidence of a rapid pace of technological change and the prospect of firms being able to "innovate around" or "leapfrog" an apparently entrenched position of an incumbent firm could be an important consideration, along with change and innovation".[44] Such considerations could, for example, be relevant in high-tech industries where disputes like those involving standard-setting tend to occur.

Finally, although also not specific to intellectual property, the Bureau's *Merger Enforcement Guidelines* could be relevant to the extent questions over patent and competition law reconciliation arise in the merger context. In assessing whether there is a merger, a significant interest is considered to be held in the whole or part of a business where the person holding the interests has the ability to materially influence the economic behaviour of the target, including the licensing of IP rights. The Bureau will then look at any impact on innovation, as a dimension of competition, when evaluating the competitive effects of a merger.[45] For example, the Bureau recognizes pressure exerted by innovation on competitors "may be such that a material price increase is unlikely to be sustainable, especially when technology or a merger reduces barriers to entry or stimulates or accelerates the change or innovation in question".[46] The Bureau's assessment of the anti-competitive effects of a merger will include consideration of whether one of the merging parties "has recently acquired intellectual property rights or other inputs" that enhance its ability to compete or will do so soon.[47]

The Bureau released a Report in 2006 on the interface between competition law and intellectual property ("2006 IP and Competition Report"). It identified several issues as likely future challenges in the area of patent law and competition law: patent pooling, patent ambush in

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41 Canada, Competition Bureau, *Competitor Collaboration Guidelines* (December 2009) online: <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/Competitor-Collaboration-Guidelines-e-2009-12-22.pdf/$FILE/Competitor-Collaboration-Guidelines-e-2009-12-22.pdf> [*Competitor Collaboration Guildelines*].

42 *Ibid*.

43 Canada, Competition Bureau, Enforcement Guidelines on the Abuse of Dominance Provisions (Sections 78 and 79 of the Competition Act) (September 2012) online: <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03497.html>.

44 *Ibid,* at 9.

45 Canada, Competition Bureau, Merger Enforcement Guidelines (October 2011), online:< http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/cb-meg-2011-e.pdf/$FILE/cb-meg-2011-e.pdf> at para 2.2.

46 *Ibid,* at para 6.8.

47 *Ibid,* at para 6.5.

standard-setting, product hopping (the term was used to refer to using multiple patents to delay market entry), authorized generics and extraterritoriality of U.S. patent law. The Report recommended empirical studies be pursued with regard to patent pooling and product hopping. The Report also recommended developing guidance on standard-setting, and when related conduct may be considered a violation of the *Act*. The recommendations do not appear to have been pursued, with the possible exception of studying product hopping, at least publicly.

(iv) Patent Law and Trends in Patent Issuance Litigation

(I) *Patent Act* Provisions Relevant to Competition Law

Sections 65 and 66 of the *Patent Act* provide for an application for relief in certain situations where a patent is being abused.[48] The remedies available where an abuse is found include compulsory licensing or revocation of the patent, as set out in Section 66 of the *Patent Act*. Our understanding based on initial research only is that these *Patent Act* provisions have rarely been applied, and the few cases have involved compulsory licensing of pharmaceuticals.[49] In practice, they may have minimal significance to addressing the issues in this report.

(II) Trends in Patent Issuance and Litigation

Both patents granted and patent examinations in Canada have grown since the early 1990s. The number of patents examined almost quadrupled from 1992 to 2012.[50] Although much less than the rise in patents examined, the number of patents granted also jumped significantly, by almost 30% in the same period.[51] Computer-related patents have remained roughly constant as a proportion of patents examined.[52] The number of business method patents issued and applied for dropped sharply in 2010, the most recent year for which we found data available.[53]

The number of patent litigation suits in the Canadian Federal Court was relatively consistent from 2009 to 2012, with approximately 50-60 suits. However, it rose dramatically in 2013, with 101 actions for patent infringement in 2013. Much of the 2013 increase is attributable to the 27 actions launched by a single company, Dovden Investments Ltd., which has been characterized by some as a PAE.

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48 See also section 19 of the *Patent Act* which provides for compulsory licensing of a patent for use by the Government of Canada or of a provincial government on application only by that government.

49 See for example *Torpharm Inc v Merck & Co*, (2000) 9 CPR (4th) 520 (Canada Patent Appeal Board and Patents Commissioner); 2006 IP and Competition Report, *supra* note 18 at 31-32 suggests that this decision created the possibility that competition law and principles could be considered in determining if there has been an abuse under the *Patent Act*, for example the anti-competitive acts listed under the abuse of dominance in section 78 of the Act. For a brief history of the compulsory licensing provisions in the *Patent Act*, see 2006 IP and Competition Report, *supra* note 18 at 31-32.

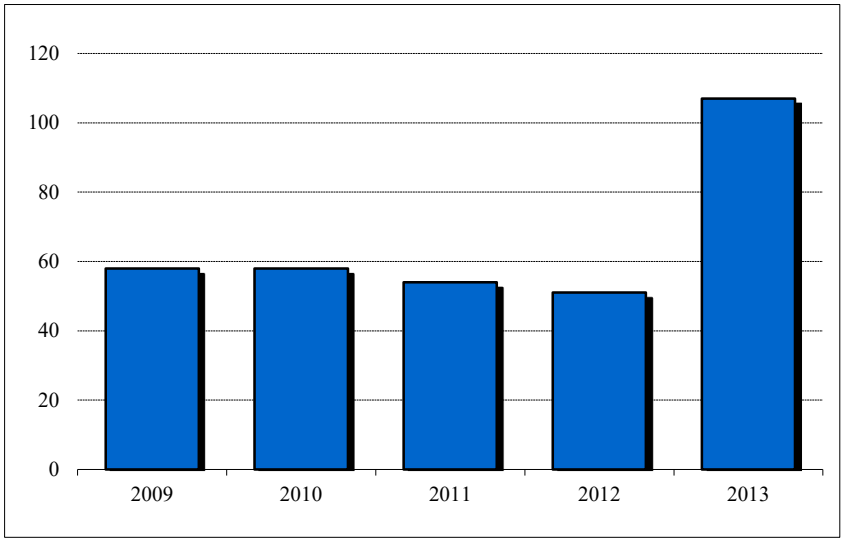
50 Total patents examined: 7,326 in 1992, up to 29,191 in 2012; Canadian Intellectual Property Office, *Annual Report* [Various] (Ottawa: Industry Canada, 1994/95 – 2011/2012), online: (2009-2012).

51 *Ibid.* Total patents granted: 16,248 in 1992, up to 20,927 in 2012.

52 *Ibid.*

53 Norton Rose, "Business Method Patents Report" (May 2012) at 14, online <http://www.nortonrosefulbright.com/files/business-method-patents-pdf-246mb-72865.pdf>.

Figure 1 – Number of Patent Infringement and Impeachment Cases Commenced in Federal Court, Canada[54]



(b) United States

(i) Applicability of Competition Law to Conduct Involving Patents

U.S. competition laws apply generally to conduct involving intellectual property, including patents. The main legislation applied by the DOJ and FTC are the *Sherman Act* (prohibitions on monopolies), the *Clayton Act* (prohibiting corporate acquisitions that substantially lessen competition) and the *Federal Trade Commission Act* ("*FTC Act*", prohibiting unfair methods of competition and unfair or deceptive acts or practices).[55] There are no exceptions specific to intellectual property law provided in these statutes. The securing, assertion and licensing of intellectual property rights, as well as transactions involving intellectual property rights, may all be the subject of antitrust scrutiny.[56]

The main provisions likely to be applied in the context of the issues discussed in this report are Section 1 of the *Sherman Act* (prohibiting conspiracies in restraint of trade), Section 2 of the *Sherman Act* (prohibiting unilateral monopolization or attempted monopolization and monopolization by combination or conspiracy), Sections 3 and 7 of the *Clayton Act* (concerning the conditional sale of goods and mergers that may have the effect of substantially lessening competition, or tending to create a monopoly) and Section 5 of the *FTC Act* (prohibiting unfair methods of competition and unfair acts and practices). Each of these provisions is discussed in more detail below where relevant to a particular form of conduct.

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54 Federal Court Statistics and IPPractice.ca, online: <http://www.ippractice.ca/litigation-statistics/>.

55 The U.S. also has state-level antitrust laws, which have no equivalent in Canada.

56 American Bar Association, *ABA Section of Antitrust Law, The Federal Antitrust Guidelines for the Licensing of Intellectual Property: Origins and Applications*, 3d ed (United States: ABA Publishing, 2010) [ABA Federal Antitrust Guidelines].

(I) Common Law Doctrine of Patent Misuse

The common law doctrine of patent misuse is raised by some literature regarding the reconciliation of patent law with the promotion of competition.[57] The doctrine of patent misuse, in short, prevents a patent owner from "extend[ing] the monopoly of his patent to derive a benefit not attributable to the use of the patent's teachings".[58] The main inquiry is whether the patentee has "impermissibly broadened the scope of the patent grant with anti-competitive effect" by imposing conditions that derive their force from the patent.[59] The doctrine is regarded as a defence to claims of infringement, rather than an originating claim.[60]

The doctrine originated in cases involving tying allegations around the early 1990's, but it has also been raised regarding refusals to deal, grant-back clauses, territorial and price restrictions and other related conduct.[61] After a series of cases that took a fairly broad approach to the doctrine of patent misuse, it was statutorily limited by the introduction of Section 271(d) of the U.S. *Patent Act*.[62] This section essentially excludes certain conduct from constituting patent misuse, by providing that no patent owner otherwise entitled to relief for infringement may be denied relief on the basis of certain enumerated conduct.[63] It imports competition law concepts by requiring that, for trying to constitute patent misuse, the patent owner must have market power in the relevant market for the patent or patented product on which the license or sale is conditioned. It also provides that a mere refusal to license is not patent misuse.

In practice, U.S. Federal Courts have applied the common law doctrine of patent misuse narrowly and rarely find claims of patent misuse valid. The Federal Circuit's 2010 *Princo Corp v International Trade Commission* decision set a high standard to demonstrate patent misuse in patent pooling arrangements.[64] However, two dissenting judges disagreed with this narrow interpretation of the doctrine of patent misuse, arguing that past U.S. Supreme Court cases and legislation support a "vigorous misuse defense".[65] One article argues that by permitting conduct that was admittedly anti-competitive and yet not controlled by patent law, the *Princo* decision

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57 For a recent and in-depth discussion of the patent misuse doctrine, see Daryl Lim, *Patent Misuse And Antitrust Law Empirical, Doctrinal and Policy Perspectives* (Edward Elgar Publishing; 2013).

58 *Zenith Radio Corp v Hazeltine Research, Inc*, 395 US 100 (1969) at 136.

59 *CR Bard v M3 Sys*, 157 F (3d) 1340 at 1372 (Fed Cir 1998).

60 *Ibid.*

61 Hedvig Schmidt, *Competition Law, Innovation and Antitrust: Analysis of Tying and Technological Integration* (Edward Elgar Publishing; 2009) at 166.

62 *Ibid* at 168.

63 U.S. *Patent Act*, Ch 28 s. 271 (d) provides that no patent owner otherwise entitled to relief for infringement or contributory infringement of a patent shall be denied relief or deemed guilty of misuse or illegal extension of the patent right by reason of his having done one or more of the following: (1) derived revenue from acts which if performed by another without his consent would constitute contributory infringement of the patent; (2) licensed or authorized another to perform acts which if performed without his consent would constitute contributory infringement of the patent; (3) sought to enforce his patent rights against infringement or contributory infringement; (4) refused to license or use any rights to the patent; or (5) conditioned the license of any rights to the patent or the sale of the patented product on the acquisition of a license to rights in another patent or purchase of a separate product, unless, in view of the circumstances, the patent owner has market power in the relevant market for the patent or patented product on which the license or sale is conditioned.

64 16 F (3d) 1318 (Fed Cir 2010). Since Princo, Barnes & Noble asserted the patent misuse defence in ongoing patent infringement litigation brought by Microsoft, which ultimately settled.

65 *Ibid* at 1342.

heightened the importance of antitrust action in situations of anti-competitive patent use.[66] Another author argues the patent misuse doctrine offers a useful means of addressing misconduct in the standard-setting context.[67]

(ii) Relevant Agencies

The U.S. agencies most involved in the issues at the intersection of competition law and patent law are the Federal Trade Commission ("FTC"), the Antitrust Division of the Department of Justice ("DOJ") and the Patent and Trademark Office ("PTO"). Both the FTC and DOJ enforce federal U.S. antitrust law, but only the DOJ has jurisdiction over criminal antitrust violations (*Sherman Act*) and over certain industries.[68] However, violations of the *Sherman Act* are also considered to violate the *FTC Act*; therefore the FTC may bring cases under the *FTC Act* against the same type of conduct that violates the *Sherman Act*. The *FTC Act* also covers other practices that harm competition but may not be prohibited by the *Sherman Act*. In addition to initiating enforcement actions, the FTC also adjudicates challenges under certain sections of the *FTC Act*.

The U.S. also has an Office of the U.S. Intellectual Property Enforcement Coordinator, whose mandate is to work with all relevant federal agencies, law enforcement organizations, foreign governments, private companies, public interest groups, and others to develop and implement the best strategies for U.S. intellectual property enforcement. The Enforcement Co-ordinator has issued two Joint Strategic Plans for Intellectual Property Enforcement, one in 2010 and one in 2013, setting out broad priorities regarding intellectual property enforcement, such as ensuring efficiency and coordination in enforcement efforts.[69]

Antitrust agency action by the FTC and DOJ has played a central role in addressing the intersection of patent and competition law in the U.S. The active and flexible role of antitrust enforcers has been seen as reducing any perceived need to amend antitrust legislation in response to technological and economic change. For example, the U.S. Antitrust Modernization Commission reviewed U.S. antitrust law in 2007 to ensure its effectiveness in light of competition in the twenty-first century increasingly involving innovation, intellectual property, technological change, and global trade. It concluded there was no need to revise antitrust laws to apply different rules to industries in which innovation, intellectual property, and technological change are central features.[70] Instead, the Commission emphasized the important role of antitrust enforcers and sound economic analysis in regulating competition in industries in which innovation, intellectual property, and technological change are central features.

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66 Scott Sher, Jonathan Lutinski & Bradley Tennis, "The Role of Antitrust in Evaluating the Competitive Impact of Patent Pooling Arrangements" (2012) 13 Sedona Conference Journal 111 at 129.

67 Daryl Lim, "Misconduct in Standard Setting: The Case for Patent Misuse" (2011) 51 IDEA: The Journal of Law and Technology 557 at 557 [Misconduct in Standard Setting].

68 The DOJ investigates and, if required, prosecutes; this is in contrast to Canada where there is a separate agency that prosecutes criminal offences.

69 See Office of the U.S. Intellectual Property Enforcement Coordinator website, online: <http://www.whitehouse.gov/omb/intellectualproperty>.

70 United States, Antitrust Modernization Commission, *Antitrust Modernization Commission Report and Recommendations* (2007), Introduction and Recommendations online: <http://govinfo.library.unt.edu/amc/report_recommendation/toc.htm>.

Aside from agency enforcement, there are also some private rights to bring suits to enforce the antitrust laws. Many antitrust suits in the U.S. are brought by businesses and individuals seeking damages for violations of the *Sherman* or *Clayton Act*.

(iii) Agency Guidance on Applicability of Competition Law to Conduct Involving Patents

The FTC has identified advocacy at the intersection between IP rights and antitrust law as an "important priority" for the past several years. As a policy matter, the FTC is "interested in seeing that the patent system serves its important role in driving innovation and that the system is not manipulated in a manner that is harmful to competition or innovation".[71]

The FTC and DOJ (the "Agencies") issued *Antitrust Guidelines for the Licensing of Intellectual Property* in 1995 (the "US IP Guidelines") setting out their approach to the intersection between intellectual property and competition law. In announcing the development of the US IP Guidelines, emphasis was placed on the importance of preserving competition in innovation, and on "the anti-competitive potential of restrictive practices at or beyond the borders of the clearly conveyed statutory rights".[72] The Guidelines have not been revised since 1995.[73] The US IP Guidelines are similar to, and formed the basis for, the Canadian IPEGs first issued in 2000.

The US IP Guidelines are based on three general principles.[74] First, for the purposes of antitrust analysis, intellectual property is essentially considered comparable to other forms of property. The Agencies apply the same general antitrust principles to conduct involving intellectual property that they apply to conduct involving any other form of property, although the Guidelines recognize that intellectual property has several important characteristics that distinguish it from some other forms of property.[75] This approach reflects the modern perspective that intellectual property and competition are complementary instruments of economic policy that "share the common purpose of promoting innovation and enhancing consumer welfare",[76] which is also seen in U.S. jurisprudence.[77] The older view was that the two regimes conflicted and intellectual property was an exception to competition law, to be construed narrowly.[78] Second, intellectual

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71 Renata Hesse, Deputy Assistant Attorney General, Antitrust Division, U.S. Department of Justice "The Art of Persuasion: Competition Advocacy at the Intersection of Antitrust and Intellectual Property" (Speech delivered at Seattle, Washington 8 November 2013) online: <http://www.justice.gov/atr/public/speeches/301596.pdf> [The Art of Persuasion].

72 Anne K. Bingaman, Assistant Attorney General, Antitrust Division, U.S. Department of Justice, "Antitrust and Innovation in High Technology Society" (Remarks delivered at Commemoration of the Antitrust Division's 60th Anniversary, Washington D.C., 10 January 1994) online: <http://www.justice.gov/atr/public/speeches/0108.htm>.

73 United States, The Federal Trade Commission & The Department of Justice, *Antitrust Guidelines for the Licensing of Intellectual Property*, (United States: Department of Justice, 1995) online: <http://www.justice.gov/atr/public/guidelines/0558.htm> [1995 U.S. IP Guidelines].

74 *Ibid*, s 2.0.

75 *Ibid,* s 2.1.

76 *Ibid,* s 1.0.

77 Courts have similarly described intellectual property law and competition law as "complementary, as both are aimed at encouraging innovation, industry and competition". *Atari Games v Nintendo of America, Inc*, 897 F (2d) 1572 (Fed Cir 1990); ABA Federal Antitrust Guidelines, *supra* note 56 at 20.

78 See e.g. *Sears, Roebuck & Co v Stiffel Co*, 376 US 225 at 230 (1964).

property rights are not presumed to create market power. Even where monopoly power is conferred by a patent, that alone does not create an antitrust violation.[79] Conversely, though, the limited monopolies granted to patent owners do not exempt them from the application of antitrust laws.[80] And third, intellectual property licensing is generally considered pro-competitive because it enables the combination of complementary factors of production.[81]

The US IP Guidelines set out the general principles under which the Agencies will evaluate IP licensing arrangements, and then provide specific detail on the application of the general principles in the areas of horizontal restraints, resale price maintenance, tying arrangements, exclusive dealing, cross-licensing and pooling arrangements, grant-backs and the acquisition of intellectual property rights.

Unlike the Canadian Competition Bureau IPEGs, the US IP Guidelines set out a safe harbour defining permitted licensing arrangements. Licensing is generally considered to promote innovation and enhance competition. Absent extraordinary circumstances, the Agencies will not challenge a restraint in an intellectual property licensing arrangement if (i) the restraint is not facially anti-competitive and (ii) the licensor and its licensees collectively account for no more than 20% of each relevant market significantly affected by the restraint.[82] The safety zone is intended to provide intellectual property owners with certainty in competition law scrutiny of their licensing arrangements.[83] Arrangements falling outside the safe harbour will not necessarily be anti-competitive, but may be considered more closely.

The US IP Guidelines indicate a licensing arrangement may affect price or output in three types of markets: a market for existing goods and services; a technology market consisting of intellectual property that is licensed and its close substitutes; and an innovation market. Innovation markets consist of the research and development directed at particular new or improved goods or processes, and the close substitutes for that research and development. The Agencies will assess the impact of licensing arrangements on such markets as appropriate.

The significance of innovation markets to the U.S. analysis is unclear: some commentators argue that research and development is merely an input into other goods and services rather than a separate market, while others characterize innovation markets as superior analytical

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79 United States, Federal Trade Commission, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy*, (United States: Federal Trade Commission, 2003) at 2-3, online: <http://www.ftc.gov/sites/default/files/documents/reports/promote-innovation-proper-balance-competition-and-patent-law-and-policy/innovationrpt.pdf> [To Promote Innovation]; 1995 U.S. IP Guidelines, *supra* note 73.

80 *Standard Oil Co (Indiana) v United States*, 283 US 163 at 174 (1931) ("[T]he limited monopolies granted to patent owners do not exempt them from the prohibitions of the Sherman Act").

81 United States, Federal Trade Commission & The U.S. Department of Justice, *Antitrust Enforcement And Intellectual Property Rights: Promoting Innovation And Competition*, (United States: Federal Trade Commission, 2007), online: <http://www.ftc.gov/reports/antitrust-enforcement-intellectual-property-rights-promoting-innovation-competition-report> [2007 IP Report]; 1995 U.S. IP Guidelines, *supra* note 73.

82 1995 U.S. IP Guidelines, *supra* note 73, s 4.3. If an examination of the effects on competition among technologies or in research development is required, and if market share data are unavailable or do not accurately represent competitive significance, different safety zone criteria will apply as set out in the 1995 U.S. IP Guidelines.

83 *Ibid*.

tools in assessing innovation effects.[84] The concept of innovation markets in the US IP Guidelines was rejected in the Canadian IPEGs.

Many of the DOJ cases in the area of IP and competition law in the past have focused on whether a mere refusal by a patent holder to license IP can constitute an antitrust violation. Courts have split on the issue.[85] The position of the Agencies is now similar to that of Canada on refusals to license, with the Agencies stating that "liability for mere refusals to license will not play a meaningful part in the interface between patent rights and antitrust protections."[86] Arguably the concept of "mere refusal" is simply another means of introducing the enforcement flexibility needed to scrutinize potentially anti-competitive IP-related conduct.

The issuance of the US IP Guidelines is thought to have preceded a sharp increase in the proportion of merger enforcement actions where innovation effects were an issue.[87] There are also merger-specific guidelines that generally apply to transfers of intellectual property rights.[88] The U.S. 2010 Horizontal Merger Guidelines placed a new emphasis on the potential for mergers to reduce innovation,[89] which has been a key recent consideration in addressing transactions in high-tech markets that involve patents. A recent example of this is the DOJ's consideration of CPTN Holdings LLC's acquisition of patents from Novell Inc.[90] The Agencies acknowledge that innovative, high-tech markets may have unique features, such as a fast pace of technological change and network effects, which can have a significant influence on merger and other antitrust analysis.[91] For instance, the rapid evolution of technology in high-tech

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84 Richard J. Gilbert, "Competition And Innovation" (2007) Competition Policy Center, Institute for Business and Economic Research, UC Berkeley, Working Paper Series at 5 & 7, online: <http://elsa.berkeley.edu/users/gilbert/wp/competition_and_innovation.pdf> [Competition and Innovation]; ABA Federal Antitrust Guidelines, *supra* note 56.

85 ABA, Federal Antitrust Guidelines, *supra* note 56 at 15 citing *Image Technical Services v Eastman Kodak Co,* holding Kodak liable for refusing to sell its patented products to an independent, competitor service provider and *In re Independent Service Organizations Antitrust Litigation,* where a ruling was made in favour of Xerox regarding a similar refusal to deal.

86 2007 IP Report, *supra* note 81 at 23-24. This is in contrast to the much more restrictive approach of the DOJ toward limiting IP licensing that prevailed in the 1960's (exemplified by the treatment of certain licensing practices referred to as the "nine no-no's" as *per se* illegal) which was softened throughout the late 1970's and early 1980's to a rule of reason approach. See the history of the U.S. approach to licensing, described in ABA Federal Antitrust Guidelines, *supra* note 56 at 8 and onward; Section of Antitrust Law, *Antitrust Law Developments (Seventh)* (United States: American Bar Association, 2012) at 1047.

87 Competition and Innovation, *supra* note 84 at 5.

88 United States, Federal Trade Commission & Department of Justice, *Horizontal Merger Guidelines* (2010) online: <www.ftc.gov/sites/default/files/attachments/merger.../100819hmg.pdf>.

89 *Ibid,* section 6.4 Innovation and Product Variety.

90 CPTN is a holding company owned by Microsoft Inc., Oracle Corp., Apple Inc. and EMC Corp. CPTN planned to acquire the patents and, in a second transaction, distribute them to its owners. The DOJ found "as originally proposed, the deal would jeopardize the ability of open source software, such as Linux, to continue to innovate and compete" in the development and distribution of operating systems and other product. The purchase agreements were revised and the transaction was permitted, but the DOJ warned "it will continue investigating the distribution of the Novell patents to the CPTN owners". United States, Department of Justice, Press Release "CPTN Holdings LLC and Novell Inc. Change Deal In Order To Address Department of Justice's Open Source Concerns" (20 April 2011) online: <http://www.justice.gov/atr/public/press_releases/2011/270086.htm>.

91 Renata Hesse, Deputy Assistant Attorney General, Antitrust Division, U.S. Department of Justice " At the Intersection of Antitrust & High-Tech: Opportunities for Constructive Engagement" (Speech delivered at the Conference on Competition and IP Policy in High-Technology Industries, Stratford, California 22 January 2014) online: <http://www.justice.gov/atr/public/speeches/303152.pdf>.

markets can result in quickly shifting market shares, making market dominance merely temporary.[92] Features such as strong network effects can act as a barrier to new entry and have played important roles in U.S. agency analysis of mergers.[93]

(iv) Agency Reports and Inquiries

The Agencies have issued three significant and fairly recent reports on the interaction of patent law, competition and innovation, with accompanying hearings and workshops.[94]

A 2003 FTC report, based on extensive public hearings, considered how to promote innovation by finding the proper balance of competition and patent law and policy.[95] It concluded that "in some ways the patent system is out of balance with competition policy" and focused on proposals for legislative and regulatory changes to improve patent quality. The 2003 report also emphasized ways to increase communication between the FTC and the PTO, including filing of *amicus* briefs in patent cases that affect competition and creating a liaison panel between the FTC, DOJ and PTO to exchange policy views.

Although arising from the same hearings as the 2003 report, the antitrust portion of the report was not issued until 2007. The 2007 Report, from both the FTC and DOJ, was intended to express the Agencies' position on the application of competition law to a range of activities involving IP.[96] It discusses issues such as refusals to license patents, collaborative standard-setting, patent pooling, intellectual property licensing, the tying and bundling of intellectual property rights, and methods of extending market power conferred by a patent beyond the patent's expiration. It focuses on incorporating consideration of the benefits of patent rights into antitrust analysis. An overview of the 2007 Report's conclusions on these topics is set out in **Appendix B**.

In 2011, the Agencies issued their most recent report, titled *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* ("2011 Report"). The 2011 Report was based on workshops held jointly by the FTC, DOJ and PTO in May 2010, addressing the intersection of competition policy and patent policy. These workshops included panels specifically addressing standard-setting involving patents, consideration of the patent

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92 *Ibid*, referring to *US v Microsoft*, 253 F.3d 35, 49 (D.C Cir. 2001) [*Microsoft*] ("[r]apid technological change leads to markets in which firms compete through innovation for temporary market dominance, from which they may be displaced by the next wave of product enhancements.").

93 See e.g. *Memorandum Opinion* at 132-33*, United States v Bazaarvoice,* No. 13-cv-00133 (ND Cal 8 January 2014) ("[T]he Court finds that syndication, switching costs, intellectual property/know how, and reputation are formidable barriers to new firms entering the market for R&R platforms and to existing R&R providers expanding their operations to replace the competition previously provided by PowerReviews.")

94 To Promote Innovation, *supra* note 79; 2007 IP Report, *supra* note 81; United States, Federal Trade Commission, *The Evolving IP Marketplace: Aligning Patent Notice And Remedies With Competition*, (United States: Federal Trade Commission, 2011) online: <http://www.ftc.gov/reports/evolving-ip-marketplace-aligning-patent-notice-remedies-competition> [Evolving IP Marketplace]. The DOJ participated in the 2007 report issuance.

95 To Promote Innovation, *ibid*. This report was based on Competition and IP Law and Policy in the Knowledge-Based Economy Hearings (2 February 2002) online: <http://www.ftc.gov/news-events/events-calendar/2002/02/competition-ip-law-policy-knowledge-based-economy-hearings>.

96 See United States, Federal Trade Commission, Press Release, "Federal Trade Commission and Department of Justice Issue Report on Antitrust and Intellectual Property" (17 April 2007) online: <http://www.ftc.gov/news-events/press-releases/2007/04/federal-trade-commission-and-department-justice-issue-report>.

application backlog and discussion regarding the availability of permanent injunctions in patent infringement cases.[97] The 2011 Report also reflected independent research by the FTC and eight days of hearings held by the FTC in December 2008.[98]

The 2011 Report emphasizes the ability of antitrust and patent laws to strike a balance that promotes innovation is greatly impacted by (i) patent notice (how well a patent informs the public of what technology is protected) and (ii) appropriateness of patent remedies. It explains that the patent notice function is essential, because poor notice tends to disrupt the patent-antitrust balance by making it difficult for potential competitors to determine a clear path for follow-on innovation, deterring later competition. Poor patent notice can also distort competition by forcing firms to design products and make investments with incomplete knowledge of the cost and availability of different technologies. As a result, poor patent notice is more likely to lead to unnecessary litigation, with the cost of litigation reflected in higher consumer prices.[99] Conversely, clear notice of what a patent covers promotes innovation by encouraging collaboration, technology transfer, and design-around. The appropriateness of patent remedies was also considered a key issue. Patent damages that under-compensate patentees for infringement can deter innovation overall, but overcompensation may lead to higher prices and encourage speculation in patent rights, which is considered to deter innovation.[100]

The 2011 Report observed certain strategies by patent holders that raised the risk of distorting competition and deterring innovation. The risk of such deterrence was particularly high for activity driven by poor patent notice and by remedies that did not align the compensation received by patent holders with the economic value of their patented inventions in cases of infringement.[101] The 2011 Report made recommendations in two general areas, first for the improvement of patent notice at the PTO and second, for U.S. courts to better ground in economic principles both the calculation of damages and the analysis related to injunctions.[102] The recommendations of the 2011 Report are outlined in **Appendix B.**

The FTC has also used its formal investigative powers under Section 6(b) of the *FTC Act* to consider issues related to authorized generic drugs (2011 report),[103] generic drug entry before

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97 United States, Patent and Trademark Office, *Summary of Commentary at the Intersection of Competition Policy and Patent Policy Symposium* (26 May 2010), online: <http://www.uspto.gov/ip/global/patents/ir_pat_workshop.jsp>.

98 United States, Federal Trade Commission, Press Release, "Federal Trade Commission, Department of Justice, and U.S. Patent and Trademark Office to Hold Workshop on Promoting Innovation" (10 May 2010) online at:<http://www.ftc.gov/news-events/press-releases/2010/05/federal-trade-commission-department-justice-and-us-patent-and> The hearing focused on the intersection of patent policy and competition policy and its implications for promoting innovation. The sessions addressed several topics: how challenges posed by the patent backlog affect the competitive strategies of patent applicants and innovators; the impact of the U.S. Supreme Court's 2006 opinion in *eBay Inc v MercExchange LLC*, 547 US 388 (2006) [*eBay*] on permanent injunctions for patent infringement in district courts and the U.S. International Trade Commission; and the role of patents in connection with industry standards/the impact such standards have on competition.

99 Evolving IP Marketplace, *supra* note 94 at 134 – 135. Questions have been raised as to whether poor notice may be deliberately used to enable greater scope for infringement claims and whether the blame in such situations rests with patent authorities.

100 *Ibid* at 141.

101 *Ibid*.

102 *Ibid.*

103 United States, Federal Trade Commission, *Authorized Generic Drugs – Short-Term Effects and Long-Term Impact* (United States: Federal Trade Commission, 2011) online: <http://www.ftc.gov/reports/authorized-

patent expiry (2002 report)[104] and the currently ongoing study of patent assertion entities that is discussed further below. Section 6(b) of the *FTC Act* empowers the agency to legally require responses to questions posed and enables the FTC to conduct wide-ranging economic studies that do not necessarily have a specific law enforcement purpose.[105] Similar authority does not exist in the *Act*.

We believe the history of workshops and reports by the FTC in conjunction with the DOJ and PTO is significant in that (i) it points to a willingness of the antirust agencies to engage in a hands-on approach to setting patent policy where there are impacts on competition policy and (ii) it evidences inter-agency co-operation across the silos of the patent and the antitrust agencies. Such inter-agency co-operation, along with formal studies like those undertaken by the FTC, serve to build deep institutional knowledge and understanding that is essential for public agencies tasked with addressing the highly complex issues at the intersection of patent and competition law.

(c) Europe

(i) Applicability of Competition Law to Conduct Involving Patents

There is general agreement between the EU and the U.S. on the fundamental objectives of antitrust law and policy being to ensure consumer welfare in terms of price, quality, innovation and choice. Both jurisdictions emphasize analysis based on economic effects.

The basic EC position is that both intellectual property rights and competition are necessary to promote innovation and competition, with intellectual property rights targeting dynamic competition and competition imposing pressure on companies to innovate.[106] However, the fact that intellectual property laws grant exclusive rights "does not imply that intellectual property rights are immune from competition law intervention."[107] Both Articles 101 and 102 of the *Treaty on the Functioning of the European Union* ("TFEU") may apply to conduct involving intellectual property rights, and each is discussed in more detail below.

At a broader level, the EC, like the Bureau, has emphasized a focus on the digital economy and its potential to impact many other economic sectors. In 2010, Europe launched a Digital Agenda setting out the EU's strategy to help digital technologies, including the internet, to deliver sustainable economic growth. The digital economy is seen as an essential element of Europe's future economic success and a key area of promoting competition.[108] The EC has taken up this

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generic-drugs-short-term-effects-long-term-impact-report-federal-trade-commission> [Authorized Generic Drugs 2011 Report].

104 United States, Federal Trade Commission, *Generic Drug Entry Prior to Patent Expiration: An FTC Study* (United States: Federal Trade Commission, 2002) online: <http://www.ftc.gov/reports/generic-drug-entry-prior-patent-expiration-ftc-study> [Generic Drug Entry].

105 See United States, Federal Trade Commission, *A Brief Overview of the Federal Trade Commission's Investigative and Law Enforcement Authority Revised*, (United States: Federal Trade Commission 2008) online: <http://www.ftc.gov/about-ftc/what-we-do/enforcement-authority>.

106 European Union, European Commission, "Guidelines On The Application Of Article 81 Of The EC Treaty To Technology Transfer Agreements" 2004/C 101/02 (27 April 2004) at 3 & 4 [Technology Transfer Guidelines].

107 *Ibid* at 2.

108 Joaquín Almunia, Vice President of the European Commission, "Competition in the Online World" (Speech delivered at LSE Public Lecture, London, U.K., 11 November 2013) online: <http://europa.eu/rapid/press-release_SPEECH-13-905_en.htm?locale=en> [Competition in the Online World].

theme in its enforcement priorities.[109] Given the importance of patents to certain aspects of the digital economy this prioritization seems to set the stage for ongoing enforcement at the intersection of patent and competition law in Europe.

(I) Article 102 Applicability to Conduct Involving Patents

Article 102 of TFEU prohibits a dominant undertaking from engaging in conduct that constitutes an abuse of a dominant position with no objective justification. Similar to the U.S., Canada and the U.K., EU cases indicate mere possession and enforcement of an intellectual property right does not, in principal, violate Article 102.[110] However, cases have also established that under certain circumstances the acquisition of an intellectual property right or its enforcement could, in itself, constitute an abuse.[111]

A series of significant cases from 1988 onward specifically addressed whether a refusal to license intellectual property could amount to an abuse of dominance in violation of Article 102. Cases established that a refusal to license does not constitute an abuse except in "exceptional circumstances", which require the following:[112] (i) the product or service for which the license is being refused must be indispensable for carrying on business in a secondary market, (ii) the refusal prevents the emergence of a new product for which there is potential consumer demand (including the imposition of restrictions on technical development), (iii) the refusal is likely to exclude any effective competition in the secondary market, and (iv) there is no objective justification for the refusal.[113]

The EC has issued guidelines on the application of Article 102 that refers to the seminal cases establishing this test, and confirms a refusal to license IP rights could constitute a refusal to supply in exceptional circumstances.[114] The guidelines then explain the exceptional circumstances test as it applies to any refusal to deal (not specifically to intellectual property) do not otherwise refer to intellectual property.

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109 *Ibid.*

110 *Parke, Davis & Co v Probel, Reese, Beintema-Interpharm and Centrapharm* (24/67) [1968] CMLR 47; More recently see Case COMP/A. 37.507/F3 *AstraZeneca* at 741 (appealed on other grounds).

111 Case T-51/89- *Tetra Pak Rausing SA v Commission of the European Communities*, , at paras 23-24 and Case T-111/96- *ITT Promedia NV v Commission of the European Communities*, paragraph 139.

112 Case CT69/89, *Radio Telefis Eireann (RTE) v Commission* [1991] ECRII485, Case T70/ 89, *British Broadcasting Corporation and BBC Enterprises Ltd (BBC) v Commission* [1991] ECRII535, and Case T76/89, *Independent Television Publications Ltd (ITP) v Commission* [1991] ECR II575, and further confirmed in Joined Cases C241/ 91 P and C242/91 P. *Radio Telefis Eireann and Independent Television Publications Ltd (RTE & ITP) v Commission* [1995] ECR I743; Case C418/01, *IMS Health GmbH & Co OHG v NDC Health GmbH & Co KG* [2004] ECR I 539; Case T201/04, *Microsoft Corp v Commission* [2007] ECR 113601 [*Microsoft I*].

113 See *Microsoft I*, although all of the cases in the prior footnote contributed to the establishment of this test. Ariel Ezrachi & Mariateresa Maggiolino, "European Competition Law, Compulsory Licensing, and Innovation" (2012) 8(3) Journal of Competition Law & Economics 595 at 601 [Ezrachi & Maggiolino].

114 European Union, European Commission, "Communication from the Commission — Guidance on the Commission's Enforcement Priorities In Applying Article 82 Of The EC Treaty To Abusive Exclusionary Conduct By Dominant Undertakings (Text with EEA relevance)" (2009/C 45/02) at 18, online: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:045:0007:0020:EN:PDF> [Guidance on Article 102].

The test is rooted in the essential facilities doctrine, which has been applied to compel competitors to grant access to essential physical facilities in certain circumstances.[115] The distinction from the traditional essential facilities analysis is the "new product" requirement: a compulsory license is not available when the refusal merely prevents rivals from commercially exploiting the protected product in competition with the IP holder. It requires a higher threshold of losses in terms of efficiency and preventing or delaying the development of *other* goods or services.[116] This modification from the essential facilities doctrine has been characterized as an effort to reconcile IP and competition law. Commentators have characterized the exceptional circumstances test as difficult to apply in practice and it is seen as hinging on a case-by-case analysis.[117]

The EU General court has confirmed outright "misuse" of the regulatory framework for patents leading to delayed generic drug entry is a violation of Article 102. The first case brought by the EC finding an abuse of a dominant market position in the pharmaceutical sector against AstraZeneca, confirmed by the EU General Court in 2010, involved such conduct, including the provision of misleading information to patent offices and misuse of rules and procedures regulating generic entry.[118] This case is discussed further in the EU product hopping section, below. The exercise of a patent has also contributed to a finding of product tying by a dominant undertaking in older cases.[119]

Although generally similar, there are aspects of the EU abuse of dominance action that differ from U.S. and Canadian law. Exploitative practices – such as unfair or excessive pricing – are covered by Article 102 of the EU Treaty but not by Section 2 of the *Sherman Act* or the Canadian *Act*. In Canada, there is also a distinct requirement that in order to constitute an abuse of dominance, the alleged anti-competitive act must have "an intended negative effect on a competitor that is predatory, exclusionary or disciplinary."[120] Perhaps most significantly, in the EU dominant undertakings are also considered to be subject to a "special responsibility"[121] not to constrain competition in the market, a concept not recognized in U.S. or Canadian competition law.

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115 See e.g. Case C-7/97 *Bronner v Mediaprint* (November 26, 1998).

116 *Ibid*; Mauro Squitieri, "Refusals To License Under European Union Competition Law After Microsoft" (2012) 11 Journal of International Business & Law 65 at 83 [Refusals to License After Microsoft]. See also *Oscar Bronner*.

117 Elena Cortes *et al*, "IP and Antitrust: Squaring the Circle: The EU's quest for Balance Between Antitrust and Intellectual Property" (2014) Global Competition Review, online: <http://globalcompetitionreview.com/reviews/53/sections/177/chapters/2063/ip-antitrust/>.

118 Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission*, Judgment of the General Court (Sixth Chamber, extended composition) (1 July 2010) [*AstraZeneca*] (the case was unsuccessfully appealed by AstraZeneca to the EU Court of Justice (case C457/10 P)).

119 Case T-30/89 *Hilti v Commission* (1991). Hilti was a dominant undertaking that manufactured one patent-protected product (nail guns with required cartridge strips) and also non-patented nails. Hilti made sales of cartridge strips conditional on the purchase of a certain number of nails and frustrated patent license applications from other parties who wanted to product cartridge strips. The exercise of the patent *combined* with the tying of the nails, and the refusal to license the patent were found to foreclose competitors from the nail market. Summary from Colston & Galloway, "Modern Intellectual Property Law" (3rd ed) (Routledge, 2010) at 103 (accessed on Google books).

120 *Canada (Commissioner of Competition) v Canada Pipe Co*, 2006 FCA 233 at para 77.

121 Case 322/81 *Nederlandsche Banden-Industrie Michelin NV v Commission* (1983).

(II) Commentary on Perceived Article 102 Expansion

Several recent articles observe a widening of the application of Article 102 to conduct involving intellectual property, both through cases and guidance.[122] Cases on the exceptional circumstances test, particularly *Microsoft I*, have gradually expanded its application, effectively widening the scope of conduct involving intellectual property to which Article 102 applies.[123] In *Microsoft I*, the most recent of the major cases on the test, the court expanded the "new product" requirement to include not only original, new products but also technical development, allowing the test to be satisfied if the conduct merely prevents the introduction of competing products with different and improved technological features.[124] *Microsoft I* is also thought to have widened the notion of what constitutes indispensability and lowered the threshold for "elimination" of competition.[125] Cases establishing or widening the test have involved types of intellectual property licenses other than patents.[126] Recent enforcement action in the area of standard-essential patents, discussed below, may suggest a similar approach to the application of Article 102 to patents as has been applied to other types of intellectual property.

In its 2009 guidelines on the application of Article 102, the EC adopts a version of the exceptional circumstances test that one author argues expands its application beyond that in the jurisprudence.[127] The author argues the test in the Guidelines is based on consumer harm arising from the refusal. He concludes the emphasis on consumer harm as the benchmark for agency intervention, although it may increase uncertainty over specific applicability of Article 102 to refusals to license, could also act as a useful limiting principle by leading to competition enforcement only where there is consumer harm and not merely an exclusion of competitors.[128]

While observing the optimal balance is difficult to determine[129] Ezrachi and Maggiolino question whether the increasingly expansive approach to Article 102 compulsory licensing might impact innovation incentives for IP. The authors present two major views on the issue. First, that enforcement in innovation-driven sectors may be less likely to be chilled by a few selective compulsory licensing cases, especially since key refusal to license cases in the EU have tended to involve unique facts (like *Microsoft I*).[130] In IT-heavy industries, intellectual property may not

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122 Refusals to License After Microsoft, *supra* note 116; Ezrachi & Maggiolino, *supra* note 113; EC Policy on Licensing SEPs, *supra* note 306.

123 In particular, the *Microsoft I* case is thought to have widened the conduct that will be considered to fall within the exceptional circumstances test. See discussion in Ezrachi & Maggiolino, *supra* note 113; Refusals To License After Microsoft, *supra* note 116.

124 Refusals To License After Microsoft, *ibid* at 83.

125 European Competition Law, *supra* note 113 at 602-603.

126 Mark Furse, *Competition Law of the EC and the UK* (6th ed) (New York: Oxford University Press, 2008) at 446 [Competition Law of the EC and the UK].

127 *Ibid.* The Guidelines on Article 102 specify that the EC will consider refusals to license an enforcement priority where (i) the refusal relates to a product or service that is objectively necessary to be able to compete effectively on a downstream market, (ii) the refusal is likely to lead to the elimination of effective competition in the downstream market, and (iii) the refusal is likely to lead to consumer harm. at 18-19. Furse argues this modifies the test established in the case law which specifies that prevention of innovation is the harm; the Guidance leaves open the potential for other types of harm to be recognized. Guidance on Article 102, *supra* note 114.

128 *Ibid.*

129 Ezrachi & Maggiolino, *supra* note 113 at 610.

130 *Ibid*.

be the most important appropriation mechanism, because other factors such as lead time, secrecy and first mover advantage act as innovation incentives.[131] Dominant companies remain subject to these market-based factors which impose pressure to continually innovate.[132] The other view is that the mere perception of "over enforcement" chills innovation, regardless of the actual number of challenges or cases. To the extent the EC indicates an appetite for enforcement, and particularly to the extent that such *ex-post* enforcement is unpredictable, the authors suggest it may ultimately chill innovation. Ezrachi & Maggiolino point to the lack of compulsory licensing cases under Article 102 involving patents as a potential reason why encroachment into IP rights by competition enforcement had not chilled innovation as of their 2012 article.[133] This argument may be less applicable in light of recent EC enforcement in the area of SEPs. Clarifying the analytical framework applicable to issues involving IP and competition law, and providing certainty as to when enforcement will occur, can reduce the impacts on innovation arising from such unpredictability.

(ii) Article 101 Applicability to Conduct Involving Patents

Article 101 of TFEU prohibits agreements and concerted practices which may affect trade and prevent or restrict competition. The European Court of Justice has distinguished between the grant or existence of intellectual property rights and the use of those rights, finding that an IP owner could be prevented from exercising its intellectual property rights to the extent necessary to give effect to the TFEU prohibitions on anti-competitive agreements.[134]

The *Guidelines on the Applicability of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Co-Operation Agreements* (2011) ("Horizontal Guidelines") set out the principles for the EC's assessment of agreements between undertakings and concerted practices under Article 101. [135] Most relevant to the intersection of patent law and competition law is the detailed guidance on standardization agreements, discussed in the EU section on standard-setting and FRAND licensing commitments below. The Horizontal Guidelines also address research and development agreements. The research and development agreement section emphasizes that R&D co-operation may affect not only competition in existing markets, but also competition in innovation and new product markets, and that the effects on competition in innovation may be important. Where credible R&D efforts to develop competing products can be identified, this will be taken into account by the EC in its assessment of competition.

The EU has enacted a Technology Transfer Block Exemption Regulation ("TTBER") which provides block exemptions from the application of Article 101(1) to certain IP licensing

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131 Inge Graef, "Tailoring the Essential Facilities Doctrine to the IT Sector: Compulsory Licensing of Intellectual Property Rights After *Microsoft*" (2011) 7 Cambridge Student Law Review 1 at 13.

132 *Ibid*.

133 Ezrachi & Maggiolino, *supra* note 111.

134 See e.g. Joined Cases 56/64 and 58/64, *Établissements Consten S.à.R.L.* and *Grundig-Verkaufs-GmbH* [1966] ECR 429.

135 European Union, European Commission, "Guidelines on the Applicability of Article 101 of the Treaty on the Functioning of the European Union to Horizontal Co-Operation Agreements (Text with EEA Relevance)" (2011/C 11/01) at 11 online: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52011XC0114(04):EN:NOT> [Horizontal Guidelines]. Such licensing agreements may also be caught by Article 102, but this is addressed by the separate EC guidance on this topic.

agreements (referred to as "technology transfer agreements").[136] The regulation is intended to reconcile the need for adequate protection of IP rights while promoting competition in the application of Article 101(1). It is "designed to give incentives to innovation but also to prevent that these agreements are misused to partition markets or foreclose new technologies".[137]

The degree of market power of the parties to a technology agreement is considered likely to determine whether efficiency-enhancing and pro-competitive effects will outweigh any anti-competitive effects due to restrictions contained in their agreement. On this basis, the TTBER establishes certain market share thresholds above which the block exemption does not apply. If the parties to the agreement are below the market share thresholds, and none of the hardcore restrictions of competition listed in TTBER are included in the agreement, the agreement is exempted from the application of Article 101(1).[138] The current TTBER expires in April 2014 and two public consultations have already been held with respect to proposed replacement regulations.[139]

The EC's *Guidelines On The Application Of Article 81 Of The EC Treaty To Technology Transfer Agreements* ("Technology Transfer Guidelines") elaborate on the applicability of TTBER, and also address in-depth the type of licensing agreements that might have significant anti-competitive effects and thus be caught by Article 101.[140] The starting position of the Technology Transfer Guidelines is that licensing is pro-competitive, because it generally results in technology dissemination and promotes innovation. The great majority of license agreements are considered compatible with Article 101.[141] However, grant-back and non-challenge clauses are not included in the block exemption (i.e. they are subject to Article 101); the stated purpose of exclusion from the exemption is that such may reduce incentives to innovate.

To accompany the ongoing process of revising TTBER, the EC has also proposed updates to the Technology Transfer Guidelines (which were last issued in 2004). In addition to the changes

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136 Regulation 772/2004, which expires April 30, 2014. The precursor regulation to Regulation 772/2004 was criticized for its overly "rigid approach" and in 2000, the EC published an Evaluation Report on the Transfer of Technology Block Exemption Regulation No. 240/96, which led to reforms by way of introducing 772/2004. Competition Law of the EC and the UK, *supra* note 123 at 442. Art 101(3) provides that the EU can grant exemptions where certain criteria are met, both for agreements with individual merit or through the application of a block exemption. Other block exemptions potentially relevant to this discussion include those for vertical agreements (Regulation No 330/2010/EU), R&D cooperation (Regulation No 1217/2010/EU), and specialization agreements (Regulation 1218/2010/EU). The approach to granting exemptions is through administrative action, unlike in Canada and the U.S. where exemptions have been based on laws or court decisions.

137 Joaquín Almunia, Vice President of the European Commission "Intellectual Property and Competition Policy" (Speech delivered at IP Summit 2013, Paris; December 9, 2013) online: <http://europa.eu/rapid/press-release_SPEECH-13-1042_en.htm> [December 2013 Almunia Speech].

138 The TTBER also lists certain "excluded restrictions", that remain subject to individual assessment and are not exempted from art 101(1), although the rest of the agreement containing such restrictions may still fall within the block exemption.

139 See European Union, European Commission, "Draft Proposal for a Revised Block Exemption for Technology Transfer Agreements and for Revised Guidelines" <http://ec.europa.eu/competition/consultations/2013_technology_transfer/index_en.html>, describing the key changes to the TTBER.

140 European Union, European Commission, *Technology Transfer Guidelines*, (2004/C 101/02). The Technology Transfer Guidelines define technology transfer agreements as those concerning the licensing of technology where the licensor permits the license to exploit the licensed technology for the production of goods or services, as defined in Article 1(1)(b) of the TTBER.

141 *Ibid*.

driven by the new TTBER, the draft of the new guidelines includes additional guidance on reverse payment settlement agreements (discussed below) and technology pools. The changes with respect to technology pools, including patent pools,[142] provide that a central factor in assessing whether such pools are pro-competitive is whether complementary technology (and not competing technology) is included in the pool.[143] The revised guidelines are expected in 2014.

(iii) Agency Guidance on Applicability of Competition Law to Conduct Involving Patents

The EC has been signalling an increased level of concern over the use of patents for potentially anti-competitive purposes.[144] The EC Vice President in charge of competition and policy (the head of the EC) said recently he thinks "that companies should spend their time innovating and competing on the merits of the products they offer – not misusing their intellectual property rights to hold up competitors to the detriment of innovation and consumer choice."[145] In clearing the Google/Motorola merger in February 2012, he indicated further that "the Commission will continue to keep a close eye on the behaviour of all market players in the sector, particularly the increasingly strategic use of patents."[146]

The EC head of Competition reiterated in recent speeches the fundamental position that patent law and competition law systems are complementary instruments in the pursuit of innovation.[147] He characterizes enforcement at the intersection of competition law and intellectual property as "a very challenging spot", requiring careful selection of cases for enforcement.[148] Despite this challenge, he reiterates a willingness to enforce in the intellectual property space where necessary, and that "IP is not immune from competition law scrutiny".[149] As discussed below, there have been a number of recent investigations, settlements and cases in the competition and patent law space that clearly signal willingness on the part of the EC to take action.

The major formal competition law agency guidance relevant to the relationship between patent law and competition law in the EU are, as discussed above, the Technology Transfer Guidelines the Horizontal Guidelines on Article 101 and, although less specific in guidance on intellectual

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142 Patent pools are cooperative arrangements that allow the owners of several patents, all of which are necessary for the development of a product, to license their rights as a bundle, see Commonwealth of Australia, Australian Law Reform Commission, Genes and Ingenuity Report: Gene Patenting And Human Health (June 2004) online: <http://www.alrc.gov.au/publications/report-99> [Genes and Ingenuity Report].

143 Memorandum of the European Commission, "Antitrust: Commission Consults On Proposal For Revised Competition Regime For Technology Transfer Agreements – Frequently Asked Questions" (20 February 2013) online: <http://europa.eu/rapid/press-release_MEMO-13-120_en.htm> [EC Memo on Proposed Revised Technology Transfer Guidelines].

144 See e.g. European Union, European Commission, Press Release, "Commission sends Statement of Objections to Motorola Mobility on Potential Misuse Of Mobile Phone Standard-Essential Patents" (6 May 2013), quoting Joaquìn Almunia online: <http://europa.eu/rapid/press-release_IP-13-406_en.htm>.

145 *Ibid*.

146 European Union, European Commission, Press Release, "Mergers: Commission Approves Acquisition of Motorola Mobility By Google" (13 February 2012) online: <http://europa.eu/rapid/press-release_IP-12-129_en.htm>.

147 December 2013 Almunia Speech, *supra* note 137.

148 *Ibid.*

149 *Ibid.*

property, the guidelines on Article 102. In an EC report issued in 2011, the manner in which these guidelines treat the intersection between the two legal regimes was characterized as "consistent with both current legal doctrine and the current state of economic analysis".[150]

One author characterizes the EC as facing fewer limitations than U.S. antitrust agencies on the use of law enforcement powers to address claims of exclusion involving intellectual property. This is in part because of the willingness of the courts in the EU to support a stricter enforcement approach, in contrast to the prevailing judicial interpretations of the U.S. *Sherman*, *Clayton* and *FTC Acts*.[151] As examples, in *Microsoft I* and another seminal case against Intel, the EU obtained "more substantial" remedies than U.S. authorities in parallel cases.[152] The EU may also obtain settlements in parallel cases more often than the U.S. with respect to issues of patent and competition law. One relatively recent example is the parallel cases against Rambus, where the FTC finding was overturned in court, but the EC obtained remedies.

One distinction in the EU enforcement agenda is the unique concerns arising from the tension between national protection and the goal of a common market. This has led to a number of cases in the context of IP and competition. We have not addressed these cases here because the concerns they raise are often unique to the European context.

(iv) Agency Reports

A recent report, commissioned by the EC, attempted to provide economic analysis on emerging issues of intellectual property rights contracting and competition policy,[153] as well as for licensing arrangements in the context of merger control remedies. The authors consider three levels at which competition law and patent law intersect: (i) the patent holder's own use of the patent and licensing agreements (considered to be an older concern subject to standard abuse of dominance analysis), (ii) the behaviour of patent applicants and patent holders within IP regulatory regimes and (iii) the regulation of mergers involving IP rights.

The authors observed that the second type of intersection, involving regulatory regimes, was likely to become "increasingly important".[154] Conduct which follows the letter of the IP regulations could, in their opinion, still have implications that merit antitrust scrutiny. However, the authors found the scarcity of relevant empirical work on this type of intersection constrained their study.[155] The authors indicated that although theoretical work was available, there was "currently insufficient case law [in the EU] to usefully apply economic analysis".[156] This is in

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150 Competition Policy and IPR Protection, *supra* note 10 at 3, although the authors specifically address cross-licensing, patent pools, grant-backs and mergers control as areas where more recent economic analysis could add to the debate on appropriate approaches to regulation at the intersection of patent and competition law.

151 William E. Kovacic, "From Microsoft to Google: Intellectual Property, High Technology and the Reorientation of US Competition Policy and Practice" (2013) 23 Fordham Intellectual Property Media & Entertainment Law Journal 645 at 652 [From Microsoft to Google].

152 *Ibid*.

153 Competition Policy and IPR Protection, *supra* note 10. The main non-merger topics addressed were patent thickets, cross-licensing, patent pools, grant-backs and pass-through protection for infringement in licensing arrangements.

154 *Ibid* at 1.

155 *Ibid*.

156 *Ibid* at 10.

contrast to the first type of intersection, involving "traditional" patent and competition law considerations, which the authors found was the subject of more extensive scrutiny by competition authorities.[157]

Regarding mergers, the authors suggest transactions that cause a less symmetric distribution of intellectual property should be scrutinized carefully by competition authorities, even where they involve complementary intellectual property rights.[158] Such mergers may decrease the merged entities' incentives to settle infringement issues with third parties.[159] However, there may also be benefits arising from consolidation of rights into the hands of fewer parties, which can reduce the issues otherwise faced in negotiation where patent thickets are involved.[160] The authors also raise the challenge of designing effective merger remedies in the context of IP rights.[161]

(v) Recent Patent Law Reforms in the EU

Europe is in the process of adopting a unitary patent system among EU member states. Under the existing system, there are both national patents and so-called "European patents". European patents are granted centrally but have to be validated in each member-state to obtain effective EU-wide protection, even though a single patent application is possible.[162] The new unitary or "community" patents filed with the European Patent Office will be valid in all participating European countries, providing uniform protection on a "one-stop shop" basis. The unitary patents system has been strongly supported by many stakeholders, particularly in the pharmaceutical sector, as a means of improving efficiency of filing and parallel court cases in different member states that sometimes have inconsistent outcomes under the current system.[163]

A new unified patent court will also be established to resolve disputes related to the validity and infringement of unitary patents. An agreement on the unified patent court framework was signed in February 2013 and is now being ratified in various countries. Some stakeholders have expressed concern that the draft proposed rules of procedures could create opportunities for abuse of the system by patent holders, as discussed further below.[164]

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157 *Ibid*.

158 *Ibid* at 7.

159 *Ibid*.

160 *Ibid*.

161 *Ibid*.

162 European Patent Office, Unitary Patent Summary (last updated March 10, 2014), online: <http://www.epo.org/law-practice/unitary/unitary-patent.html> and European Commission, The Patent Reform: Patent Protection And The Unified Patent Court, online: <http://ec.europa.eu/internal_market/indprop/patent/index_en.htm>.

163 European Union, European Commission, *Pharmaceutical Sector Inquiry Final Report*, (8 July 2009) at 367, online: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf> and European Union, European Commission, *Communication From The Commission: Executive Summary of the Pharmaceutical Sector Inquiry Report*, (2009) at 20 online: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf> [Pharma Report Executive Summary].

164 Letter from Stakeholders including Apple Inc., BlackBerry Limited, Google Inc. and Microsoft Corporation to Member States of the European Union, Members of the European Parliament, European Commission and Preparatory Committee, Unified Patent Court (26 September 2013) online: <https://docs.google.com/file/d/0BwxyRPFduTN2NkpoN29UVm11OWc/edit> [Letter from Stakeholders].

Like Australia and the U.S., Europe has also seen a push to raise the quality of patents granted and the speed of the agency procedures related to patents.[165]

(d) U.K.

(i) Applicability of Competition Law to Conduct Involving Patents

Competition law applicable in the U.K. largely overlaps with that discussed for the European Union, above. U.K. courts are statutorily required to decide questions arising under the *Competition Act 1998* ("*U.K. Competition Act*") in a manner consistent with European Community law in respect of competition.[166] U.K. courts are also statutorily directed to treat European Court decisions as precedent.[167] Anti-competitive behaviour which may affect trade within the U.K. is prohibited by Chapters I and II of the *U.K. Competition Act* and the *Enterprise Act 2002*; where the effect extends beyond the U.K. to other EU-member states, it is addressed by Articles 101 and 102 of TFEU.

The *U.K. Competition Act* specifies the enforcement procedures and substantive civil prohibitions for anti-competitive agreements and abuse of dominance, and mirrors the EU-level approach in the TFEU. The *Enterprise Act 2002* addresses the institutional framework for competition enforcement and includes the substantive provisions for merger review, market investigations and a *per se* cartel offence. The market investigation regime authorizes the Competition Commission ("CC"), on a reference from the Office of Fair Trading or the Secretary of State, to assess whether competition in a market is effective. It provides for a focus on the functioning of the market as a whole, rather than on a single aspect or the conduct of particular firms within it.

Chapter I of the *U.K. Competition Act* prohibits agreements or concerted practices that have the object or effect of preventing, restricting or distorting competition in the U.K. and which may affect trade in the U.K. Chapter I is the U.K. counterpart of the EU-level Article 101 (which covers equivalent agreements or concerted practices that may affect trade between EU Member States), see discussion in the EU section, above. The *U.K. Competition Act* also creates parallel exemptions to the EU block exemptions, excluding from the Chapter I provisions any agreement that would be exempt under the EU-level, if the agreement in question had an effect on trade between Member States.[168] Agreements or concerted practices involving patents and with the requisite object or effect on competition would be generally subject to the Chapter I prohibitions.

In Chapter II, the *U.K. Competition Act* prohibits the abuse of a dominant position that may affect trade in the U.K. The U.K. approach to abuse of dominant position (which mirrors the EU

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165 Pharma Report Executive Summary, *supra* note 163 at 21.

166 *Competition Act 1998* (UK), c 41, Section 60(1) directs that U.K. courts should ensure that questions "in relation to competition within the United Kingdom are dealt with in a manner which is consistent with the treatment of corresponding questions arising in Community law in relation to competition within the Community."

167 *Ibid*, Section 60(2) directs U.K. courts to determine questions of competition law "with a view to securing that there is no inconsistency between … the principles laid down by the Treaty and the European Court, and any relevant decision of that Court, as applicable at that time in determining any corresponding question arising in Community law."

168 See *Ibid,* Section 10, which in effect makes applicable certain block exemptions. Pursuant to Section 10(5), the OFT may impose conditions on a parallel exemption or vary or cancel it where granted by the European Commission.

prohibition under section 102 of the TFEU) is broadly comparable to that under Canadian law, both requiring a demonstration that a firm (or multiple dominant firms jointly) has abused its market power within a given market. Unlike the abuse of dominance under Canadian law, the U.K. dominance provisions do not require a negative impact on competitors; any conduct by a dominant firm that lessens competition or injures consumers without an objective justification is caught, including "exploitative pricing" by dominant entities.[169] Although no specific provisions in the Chapter II address intellectual property, the general provisions would apply. There are no special exemptions for intellectual property in the *U.K. Competition Act*.

Under the *Enterprise Act 2002*, issues related to intellectual property may also arise in the merger context or under the "market investigation provisions". Remedies in merger transactions have, in at least one fairly recent U.K. case, required the transfer of intellectual property.[170] In the context of market investigation, there may be consideration of whether intellectual property constitutes a barrier to entry or the imposition of remedies involving intellectual property where an adverse effect on competition in a market is found to result from intellectual property rights.[171] No market investigations pursuant to the *Enterprise Act 2002* have concerned patent rights specifically. Earlier market investigations by the CC's predecessor, the Monopolies and Mergers Commission implied that intellectual property rights may constitute barriers to entry, noting that withholding of technical information in order to inhibit an independent supplier from manufacturing complementary products could be the subject of a market investigation.[172]

(ii) Relevant Agencies and Adjudicative Bodies

Presently, enforcement responsibilities for UK competition laws are bifurcated between the Office of Fair Trading ("OFT") and the CC; however, these will fuse into a single agency, the Competition and Markets Authority, as of April 1, 2014. The OFT is mandated to enforce the civil prohibitions of the *Competition Act 1998* and corresponding provisions of the TFEU, as well as the criminal cartel provisions of the *Enterprise Act 2002* while the CC oversees merger reviews (upon a reference from the OFT) and market investigations. The Competition Appeal Tribunal is a specialized tribunal that hears appeals of the decisions made by the OFT and CC under applicable statutory provisions.

In the U.K., the government body tasked with granting IP rights, including patent rights, is the U.K. Intellectual Property Office, an Executive Agency of the Department for Business Innovation and Skills. IP disputes may be heard through the specialized England and Wales Intellectual Property Enterprise Court (for lower value cases) or the High Court (for more complex or valuable claims).

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169 Alastair Chapman & Simon Peart "Dominance 2014: United Kingdom" in Thomas Janssens & Thomas Wessely, *Dominance 2014* (London: Law Business Research, 2014) 256 at 258-259.

170 *Ibid* at 79. See discussion of 2009 Nufarm Limited / AH Marks Holdings Limited merger in United Kingdom, Competition Commission, *Understanding Past Merger Remedies: Report On Case Study Research* (Updated September 2012).

171 *Enterprise Act 2002* (UK), ch 40, pt 4.

172 United Kingdom, Monopolies and Mergers Commission, *Postal Franking Machines: A Report On The Supply, Maintenance And Repair Of Postal Franking Machines In The United Kingdom*, Cmnd 9747 (London: Her Majesty's Stationery Office, 1986) at para 9.71.

(iii) Agency Guidance on Applicability of Competition Law to Conduct Involving Patents

As with the other jurisdictions canvassed in this report, the OFT characterizes competition law and IP law as having complementary goals.[173] The OFT describes itself as not having made any infringement decisions in which the "key issue" was the exercise or non-exercise of intellectual property rights. However, the OFT has acted in recent circumstances in which patents or expired patents were relevant, [174] including the 2010 *Reckitt Benckiser* decision and the 2013 issuance of a statement of objections against several pharmaceutical companies in respect of alleged reverse payment settlements, both discussed in more detail below. The OFT has recently signalled a clear willingness to take enforcement action in this space, saying it:[175]

> can and will take enforcement action under anti-trust law against the anti-competitive exercise of intellectual property rights where it considers it appropriate to do so. The OFT will not be passive if intellectual property rights are being deployed in an anti-competitive manner that stifles or blocks innovation, either through anti-competitive agreements or through unilateral conduct.

In particular, the OFT has indicated Chapter II of the *U.K. Competition Act* may still be applicable where a firm's market power arises from its intellectual property rights.[176]

Draft OFT guidelines on IP licencing were published in November 2001, but no final guidelines were ever issued.[177] The draft guidelines are no longer available on the OFT website, and so would no longer appear to provide relevant guidance.

The OFT has several more general guidelines with relevance to conduct involving IP. In its guidelines on assessing market power, the OFT identifies that intellectual property rights can constitute barriers to entry but may also act as incentives stimulating competition. Even where an intellectual property right constitutes a barrier to entry, the OFT does not view competition as automatically reduced, noting the short-term barrier created by an intellectual property right may be surmounted by a competitor through longer-run innovation.[178] The OFT views the rate of innovation in a given market as a critical factor in assessing barriers to entry; provided there are no barriers to entry into innovative activity itself, high rates of innovation may overcome barriers to entry relatively quickly.[179]

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173 Clive Maxwell, "The Competition and IP Interface: Setting the Scene" (Speech, United Kingdom, 7 May 2013) at 2, online: <http://www.oft.gov.uk/news-and-updates/speeches/2013/05-13> [Competition and IP Interface].

174 *Ibid*.

175 *Ibid*.

176 United Kingdom, Office of Fair Trading, *Decision of the Director General of Fair Trading Bskyb Investigation: Alleged Infringement Of The Chapter II Prohibition* (17 December 2002), No CA98/20/2002, Case CP 01916-00 at paras 331-340, online: <http://www.oft.gov.uk/shared_oft/ca98_public_register/decisions/bskybfinal1.pdf>.

177 Richard Whish and David Bailey, *Competition Law*, (Oxford University Press, 2012) at 806 (accessed on Google Books).

178 United Kingdom, Office of Fair Trading, *Assessment Of Market Power* (December 2004), OFT 415 at para 5.15, online: <http://www.oft.gov.uk/shared_oft/business_leaflets/ca98_guidelines/oft415.pdf>.

179 *Ibid* at para 5.36.

In its guidelines on abuse of dominance, the OFT emphasizes that ownership of an intellectual property right does not necessarily mean the holder has a dominant position.[180] As with non-IP abuse of dominance cases, whether ownership of the intellectual property right results in market dominance is considered to depend on the extent of substitutes for the given product, process or work.[181]

The OFT has also issued guidelines on the application of Article 101 of TFEU and Chapter 1 of the *U.K. Competition Act* which include an explanation of the block exemption in TTBER (discussed in the EU section of this report) applicable to technology transfer agreements (which may relate to the assignment or use of IP rights). Generally, in assessing the applicability of the TTBER exception for technology transfer agreements, the U.K. will consider the EC's applicable guidance.

At a broader strategic level, the OFT identifies as a priority in its 2013-2014 plan taking enforcement action in rapidly evolving, high-innovation markets where there is risk to consumers.[182] In particular, the OFT emphasizes the important role of regulation of mergers in high-innovation or intellectual property-heavy markets. In analyzing such markets, the OFT emphasizes considering market positions in "a more strategic sense", taking into account factors such as pace of innovation, rather than just traditional indicators such as turnover or current market share. The OFT sees its role as more important in these transactions; such cases may not trigger EU-level review, because high-tech companies often have low or non-existent turnover, and the U.K. regime applies more broadly (for example, to situations involving minority shareholdings).[183]

(iv) Other Policy Developments of Note

(I) Reports on Intellectual Property and Competition

The U.K. Prime Minister recently commissioned a review and report to assess whether the U.K. intellectual property framework supports growth and innovation.[184] The report, entitled *Digital Opportunity: A Review of Intellectual Property and Growth* (the "U.K. IP Report"), was issued in May 2011. It concluded the U.K.'s intellectual property framework was falling behind what was needed to create economic incentives for growth. The report emphasized the growing and crucial importance of innovation, and thus of intellectual property as a tool for economic growth in the U.K. Throughout, the report emphasizes that evidence should drive policy decisions in the intellectual property area. Although much of the content in the U.K. IP Report focuses on copyright or patent law-specific reforms, it includes some commentary relevant to competition policies which we discuss here.

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180 United Kingdom, Office of Fair Trading, *Abuse Of A Dominant Position* (December 2004), OFT 402 at para 4.22, online: <http://www.oft.gov.uk/shared_oft/business_leaflets/ca98_guidelines/oft402.pdf>, citing *Radio Telefis Eireann v Commission (Magill)* [1995] ECR I-743 at para 46.

181 *Ibid*.

182 Competition and IP Interface, *supra* note 173 at 6; and United Kingdom, Office of Fair Trading, *Annual Plan 2013–14*, (March 2013) OFT 1462 at 18, online: <http://www.oft.gov.uk/shared_oft/about_oft/annual-plan13-14/OFT1462.pdf>.

183 Competition and IP Interface, *ibid* at 4.

184 Ian Hargreaves, *Digital Opportunity: A Review of Intellectual Property and Growth* (May 2011), online: Intellectual Property Office < http://www.ipo.gov.uk/ipreview-finalreport.pdf > [U.K. IP Report].

The U.K. IP Report emphasizes that strong growth in patenting is creating "patent thickets which obstruct entry to some markets and impede innovation, particularly in industries covered by computer program and business method patents."[185] The U.K. IP Report attributes the growth in patenting to changes in the innovation process, but also to growth in computer technology patents. It finds that the resulting patent thickets encourage strategic or defensive patenting behaviour, especially where there is fragmentation of intellectual property rights into the hands of multiple owners.[186] Such strategic behavior includes firms building portfolios of patents for defensive rather than innovative purposes, to create a "store of bargaining chips in cross licensing negotiations" or a defensive shield to avoid patent litigation.[187] The U.K. IP Report found such behavior intensifies thickets, raises transaction costs, and reduces the market value of private sector firms.[188] The report also discusses patent hold-up, as addressed in more detail in the section on standard setting and FRAND licensing commitment and on PAEs, below.[189]

The U.K. IP Report found evidence that patenting supports innovation to a lesser extent in the areas of computer technology and telecommunications, where inventions are largely sequential, building cumulatively on previous invention and innovation.[190] As an example in telecommunications, consider the need in the case of smartphones to backward integrate new devices to account for lagging network upgrades. In such industries, there may be higher welfare and more innovation arising from lesser patent protection because such protection can lead to patent thickets and uncertainty over the boundaries of patents.

The U.K. IP Report explains that patents are thought to encourage innovation to a greater extent in non-sequential innovation fields where up-front costs are high. In non-sequential innovation areas, such as pharmaceuticals, a patent generally corresponds to a single product and knowledge is less likely to be cumulative. The disparate impact of patents on incentives between industries with sequential versus non-sequential innovation was characterized as a "serious concern" in light of anticipated growth in digital technology across the U.K. economy.[191] This suggests the oft-repeated refrain that patents create incentives for innovation that may have subtler emerging interpretations, where the argument patents protect innovation has more force in some industries than in others.

In its official response to the U.K. IP Review, the U.K. government undertook to: (i) resist extensions of patents into areas such as computer programs and business methods, absent clear evidence of a benefit to innovation and growth; (ii) reduce patent backlogs; and (iii) investigate the scale and prevalence of issues with "patent thickets", particularly with respect to

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185 *Ibid* at 58. The U.K. IP Report recommends against extending patent coverage into non-technical computer programs and business methods, and further investigation into the use of patent fees to discourage lower value patents that contribute to such patent thickets. To this end, the U.K. IP Report urges authorities to press the case for withholding patents on non-technical computer programs and business methods in the harmonization of the European patent regimes.

186 *Ibid* at para 6.14.

187 *Ibid*.

188 *Ibid*.

189 *Ibid* at para 6.29.

190 See also Bronwyn Hall, et al, "A Study of Patent Thickets: Final report prepared for the U.K. Intellectual Property Office" (30 July 2013), online: <http://www.ipo.gov.uk/ipresearch-thickets.pdf > [A Study of Patent Thickets].

191 U.K. IP Report, *supra* note 184 at para 6.19.

whether these hinder entry by small and medium businesses into technology sectors.[192] Since the U.K. IP Report, the U.K. government has publicly tracked initiatives to implement the recommendations in the review.[193]

The promised subsequent investigation into patent thickets, commissioned by the U.K. Intellectual Property Office, issued a report in 2013 examining whether thickets formed a barrier to entry and how patent thickets affected small and medium-sized enterprises (the "Patent Thicket Report").[194] Patent thickets are understood to be a dense web of overlapping intellectual property rights held by multiple parties that a company must "hack its way through in order to actually commercialize new technology".[195] The Patent Thicket Report suggests such thickets are driven mainly by an increase in the number of patent filings, and increased technological complexity and interdependence.[196] Although the Patent Thicket Report is clearly patent reform focused, we discuss the conclusions relevant to competition policy briefly here.

The Patent Thicket Report concludes, based on a literature review, that evidence overwhelmingly indicates patent thickets are arising in specific technology areas. The literature indicates there are few reasons to believe that thickets are associated with higher social welfare, and many authors indicate that thickets are "creating important welfare losses".[197] The Patent Thicket Report also conducted an empirical study of the impact of thickets, and found the density of a patent thicket (at the European Patent Office level) was associated with reduced entry of U.K. firms into the given technology area.[198] A follow-up study by the same authors who produced the Patent Thicket Report concludes that the effect of reduced entry was "particularly pronounced" in the areas of electronics and telecommunication, and that the effect was greater on small companies in comparison to large companies.[199] The Patent Thicket Report finds that, although patent thickets constitute a barrier to entry, this does not necessarily mean that reducing the barrier would lead to improved innovation or competition; instead it simply suggests that the current patent system may not be working as well as it should be.[200]

The U.K. approach of framing its discussion of patent and competition as being an issue of patent thickets is somewhat unique.[201] Although this leads to the consideration of issues similar to those addressed in other jurisdictions, such as standard-setting, patent pools, cross-licensing and PAEs, each is framed by the U.K. IP Report within the context of its relation to patent thickets. We suggest that patent thickets are generally understood to be a phenomenon

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192 United Kingdom, HM Government, *The Government Response to the Hargreaves Review of Intellectual Property and Growth* (3 August 2011) at 9, online: <http://www.ipo.gov.uk/types/hargreaves.htm>.

193 United Kingdom, Intellectual Property Office, *Implementing The Hargreaves Review* (last updated March 2014), online: <http://www.ipo.gov.uk/types/hargreaves.htm>.

194 A Study of Patent Thickets, *supra* note 190.

195 *Ibid*, quoting Shapiro.

196 *Ibid* at 59.

197 *Ibid*.

198 *Ibid* at 60, measuring entry as a firm's decision to patent for the first time in a given technology area.

199 Bronwyn Hall, et al, "Technology Entry in the Presence of Patent Thickets" (2013) UC Berkeley Papers, online: <http://128.32.105.3/users/bhhall/papers/HHvGR13_patent_thickets.pdf> at 2 [Technology Entry in the Presence of Patent Thickets].

200 *Ibid.*

201 See discussion centred on patent thickets in U.K. IP Report, *supra* note 184; A Study of Patent Thickets, *supra* note 190; and Technology Entry in the Presence of Patent Thickets, *supra* note 199.

coinciding with behaviour raising issues at the intersection of patent law and competition law, but that patent thickets are not necessarily a separate problem in and of themselves to be addressed by competition law.

(II) Inter-Agency Co-operation

The OFT has emphasized the need to reach out to intellectual property policy makers to inform competition enforcement.[202] Most recently, the OFT signed a Memorandum of Understanding in July 2012 with the U.K. Intellectual Property Office, which is included in **Appendix C**.[203] Although relatively straightforward in its content, the MOU is significant in that it publicly formalizes the relationship between the agencies and acts as acknowledgement that the interface between IP and competition law is increasingly relevant and complex. The MOU sets out the roles of each agency at a high level, and provides for general co-operation including at a policy level and in regular engagement. It further provides that the U.K. Intellectual Property Office may refer to the OFT any concerns it has in respect of competition or consumer protection issues that arise from or relate to IP rights, and allows the U.K. Intellectual Property Office to share information with the OFT within the bounds of any legal constraints. It is unclear why the MOU contemplates only a one-way flow of issue referrals.

(v) *Patents Act* Provisions Relevant to Competition Law

If the CC, following a market investigation, finds an anti-competitive practice or conduct against the public interest, the Minister in charge of the CC may apply under the UK *Patents Act* to the Comptroller General of Patents for certain remedies.[204] If the Comptroller agrees with the assessment that the conduct is against the public interest, he or she can cancel or modify any conditions of patent licenses and grant compulsory licenses. The *Patents Act* also provides for the Comptroller to grant compulsory licenses after three years from the date of a grant of a patent where satisfied of various conditions set out in Section 48 are met.[205] In practice, few applications are received annually and the granting of compulsory licenses is rare, with none issued in the last decade.[206]

(I) Review of the Groundless Threats Provision

The U.K. *Patents Act 1977* provides remedies for "groundless threats of infringement proceedings", including declaratory relief, injunctions and damages.[207] The provision applies where there has been no infringement of a patent or where the right allegedly infringed is

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202 Competition and IP Interface, *supra* note 173 at 5.

203 United Kingdom, Intellectual Property Office and Office of Fair Trading, *Memorandum of Understanding Between the Intellectual Property Office and the Office of Fair Trading* (31 July 2012), online: <http://www.ipo.gov.uk/types/hargreaves.htm>.

204 *Patents Act 1977* (UK), ch 37, s 51 [*UK Patents Act*].

205 *Ibid*, s 48.

206 World Intellectual Property Organization, *Survey on Compulsory Licenses Granted by WIPO Member States To Address Anti-Competitive Uses Of Intellectual Property Rights*, (4 October 2011) at 13, online: <http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_4_rev_study_inf_5.pdf>. A notable decision refusing such a licence was issued in: *Swansea Imports Limited v Carver Technology Limited* (2004), O/170/04, online: <http://www.ipo.gov.uk/p-challenge-decision-results-bl?BL_Number=O/170/04>.

207 *UK Patents Act*, *supra* note 204, s 70.

invalid.[208] The provision places the onus on the claimant for relief to demonstrate the lack of infringement or a patent's invalidity. Even if a patent is invalid, the party asserting the patent may establish a good faith belief in its validity as a defence.[209]

Liability is imposed for threats made against "secondary" infringers, which are often retailers or customers who are less likely to be in a position to determine they are infringing.[210] The purpose behind the provisions is "to obviate the possibility of the patentee seeking to coerce the customers of a competitor not to purchase the competitors goods".[211] Threats made by rights holders against "primary" infringers that are the trade source, such as a manufacturer or importer, are not caught by the groundless threats provision.[212] Legal advisors who make threats on their client's behalf may also be liable.

Following calls for the elimination of the groundless threats provision, the provision was reformed in 2004 to narrow the scope of applicability.[213] Against this backdrop, the U.K. Law Commission is currently undertaking an examination of the legal framework for groundless threats. An interim report has been issued with a final report expected in Spring 2014. The interim report identifies 39 relevant judgments involving the groundless threats provision over the prior 15 years.[214]

The Law Commission's interim report characterizes the goal of the groundless threats provision as preventing a patent rights holder from shutting down the network of supply, without the risk and cost of proceedings to justify their infringement claim. The fear of litigation costs and availability of alternative suppliers (including the rights holder) "act as powerful incentives" for downstream retailers and distributors to abandon a product and stock another, based on threatened infringement.[215] This appears to be a very real concern, as relatively recent cases under the groundless threats provision involved a buyer of the allegedly infringing product who stopped buying it in response to the threat, [216] and an intermediary who delisted the allegedly

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208 Law Commission, *Patents, Trademarks and Design Rights: Groundless Threats: A Consultation Paper*, Consultation Paper No 212 at para 2.4 [Interim Groundless Threats Report].

209 In the wake of several cases where a plaintiff was unable to establish the requisite malicious intent to obtain a remedy for threats of patent infringement litigation that deprived of customers, legislation was introduced in 1883 as section 32 of the *Patents, Designs and Trade Marks Act 1883*, 46 & 47 Vict, c 57, to provide a cause of action for an injunction or damages as a result of the threat if the asserted right was invalid. The party threatening litigation may avoid liability by showing that the patent was valid (or, following 2004 amendments, to show a good faith belief in validity) or that alleged act would constitute an infringement.

210 Interim Groundless Threats Report, *supra* note 208 at para 13.

211 *Ibid* at para 7.6.

212 *Ibid*. The interim report notes the distinction between primary and secondary infringers can be fuzzy in practice.

213 *Ibid* at 29. Changes included reformulating the distinction between primary and secondary infringement, and excluding groundless threats where a rights holder is thought to have a valid reason to make the threat.

214 *Ibid* at 10.2, para 10.3. These figures do not capture instances when litigation is settled before final judgement. A recent example involving the groundless threats provision is the litigation between Apple and Samsung, where Samsung alleged Apply had made groundless threats through a series of cases, pronouncements by Apple spokespeople and correspondence. However, the court found the conduct did not violate the groundless threats provision. See *Samsung Electronics (UK) Ltd, Samsung Electronics Co Ltd v Apple Inc* [2012] EWHC 889, [2013] FSR.

215 *Ibid*, Interim Groundless Threats Report, *supra* note 208 at 30.

216 *Zeno Corporation v BSM-Bionic Solutions* [2009] EWHC 1829 (Pat).

infringing product from its sales site in response to threats.[217] The interim report specifically notes the proliferation of intellectual property rights in recent years, and the rise of phenomena such as patent thickets, has greatly increased the "fear factor" arising from threats of infringement, by increasing the risk of violating another's intellectual property and increasing the likely complexity of litigation that results.[218] In particular, the report emphasizes that the current "good faith" defence (i.e., the defendant did not know or reasonably suspect that the patent was invalid) provides too much protection for the party making the threat and encourages settlement in respect of an ultimately invalid patent.[219]

Thus, although the report does not refer specifically to patent hold-up, it recognizes similar underlying concerns to those fueling the debate over patent assertion entities in the U.S. and standard-setting/FRAND issues in the U.S. and EU.

The interim report from the Law Commission suggests the threats provision should be retained, but with some modifications.[220] In drawing comparisons to other jurisdictions, the interim report notes most European jurisdictions deal with groundless threats under common law of unfair competition. The consultation on groundless threats is ongoing.

(e) Australia

(i) Applicability of Competition Law to Conduct Involving Patents

Part IV of the *Competition and Consumer Act 2010* ("*Australian Competition Act*") proscribes a range of restrictive trade practices that are considered anti-competitive, including contracts, arrangements or understandings which have the purpose or effect of substantially lessening competition, or contain "exclusionary provisions"'; exclusive dealing and resale price maintenance; the misuse of market power; and anti-competitive mergers or acquisitions. [221] Some conduct is prohibited entirely on the presumption that it has anti-competitive effects (referred to as the *per se* provisions), and other conduct is prohibited only where it has the purpose or effect of substantially lessening competition in a market. We canvass briefly the main provisions likely to apply to the conduct involving intellectual property discussed herein.

Section 46 of the *Australian Competition Act* prohibits a corporation with a substantial degree of market power from taking advantage of its market power for the purpose of eliminating or substantially damaging a competitor, preventing or deterring a person from entering a market, or engaging in competitive conduct in that or any other market. The basic elements of Section 46 require that a firm have a substantial degree of market power, that the firm "take advantage" of that market power and that there be an anti-competitive purpose for the conduct. The provision is roughly equivalent to the Canadian prohibition on abuse of dominance.

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217 *Quads 4 Kids v Thomas Campbell* [2006] EWHC 2482 (Ch).

218 Interim Groundless Threats Report, *supra* note 208 at 6.

219 *Ibid* at 128-29.

220 *Ibid* at 143. The proposed changes include eliminating liability for legal advisors, changes related to the equivalent provisions in the trade mark and design rights legislation and considering the creation of a new tort of making false or misleading allegations similar to that in Canada.

221 *Competition and Consumer Act 2010* (Austl), Act No. 51 of 1974 as amended [*Australian Competition Act*], On January 1, 2011 the consumer law of the commonwealth and the states and territories in Australia was consolidated into this Act, which replaced the *Trade Practices Act 1974*.

Prohibitions on multilateral conduct may also apply in the IP context. Section 45 of the *Australian Competition Act* prohibits the making or giving effect to an exclusionary provision in a contract, arrangement or understanding, with no required impact on competition. Section 45 also prohibits provisions in a contract, arrangement or understanding which have the purpose, effect or likelihood of substantially lessening competition.

The Australian Competition and Consumer Commission ("ACCC") is tasked with enforcement of the *Australian Competition Act*. Criminal prosecutions are brought by the Commonwealth Director of Public Prosecutions, generally on the recommendation of the ACCC. Appeals of ACCC decisions are heard by the Australian Competition Tribunal.

The election of Australia's coalition federal government in September 2013 means a comprehensive and in-depth review of Australia's competition laws is forthcoming.[222] The review is intended to further the coalition's policy of improving competition rules so competitive forces drive productivity growth. Most relevant to the discussion here, the review will look at whether the competition laws and enforcement "adequately address competition issues in emerging markets and across new technologies, particularly e-commerce environments, to promote entrepreneurship and innovation."[223]

(I) Special Exemptions for Patent Licenses and Assignments from Competition Law

Part IV of the *Australian Competition Act* applies to conduct involving patents, but contains a special exemption. Section 51(3) exempts from the application of Part IV the imposition of conditions on licenses and assignments of patents, to the extent they "relate to the subject matter of the patent". The exemption does not apply to the misuse of market power (Section 46, discussed above) or the resale price maintenance provisions, which would therefore continue to apply in full to conduct involving patents. There is no precise equivalent in the EU or U.S. competition legislation.[224]

The exception in Section 51(3) has existed since its enactment in 1974 of the *Trade Practices Act*, the precursor to the *Australian Competition Act*. The rationale for the exemption was described in a recent government report as "unclear",[225] but it is speculated that the section was enacted to avoid a "perceived clash" between the monopoly interests of IP owners and competition law.[226] As early as 1999, a report characterized this original objective as "no longer

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222 As of December, 2013, draft terms of reference for the review had been struck, see Australian Competition Law, online: <http://www.australiancompetitionlaw.org/reports/2014rootbranch.html>. The extensive review will look at both substantive law and effectiveness if enforcement. Australia undertook prior reviews of its competition laws in 1993 (the *Hilmer Review*, a major independent inquiry) and in 2001 (the *Dawson Review*, which was more limited in scope). Dr. Martyn Taylor, "Australian Competition Regulation: What Should We Expect For The 2013/14 Financial Year?" (July 2013) online: <http://www.nortonrosefulbright.com/au/knowledge/publications/100861/australian-competition-regulation-what-should-we-expect-for-the-201314-financial-year#section3>.

223 *Ibid.*

224 Commonwealth of Australia, Productivity Commission 2013, *Compulsory Licensing of Patents, Inquiry Report No 61*, (March 2013) at 143 online: <http://www.pc.gov.au/__data/assets/pdf_file/0018/122661/patents.pdf> [Compulsory Licensing Report].

225 *Ibid* at 15.

226 *Ibid*; See also Robertson Wright SC & Julia Baird SC, "Competition and Intellectual Property: The Intersection of Competition and Intellectual Property Law and the New Economy" 2008 CCLJ Lexis 6 at 18 which describes Section 51(3) as being founded on the assumption that an exemption for IP rights was

relevant" in light of the modern understanding that IP rights are merely property rights and the goods and services produced using IP rights compete in the marketplace with other goods and services.[227]

The Section 51(3) exemption has been the subject of considerable controversy and numerous recommendations for its amendment or repeal.[228] In a 2000 report, the Intellectual Property Competition Review Committee ("IPCRC") concluded that the exemption was inappropriate since its scope was uncertain, leaving open the possibility that almost all agreements touching on intellectual property could be exempted. The IPCRC was also of the opinion there was no clear policy reason for the exemption. It recommended rebalancing the needs of the IP system and goals of competition policy by replacing Section 51(3) with a new provision indicating there is no contravention of Part IV of the *Australian Competition Act* by reason of conditions in a license related to intellectual property, as long as those conditions do not result or are not likely to result in a substantial lessening of competition.[229] The Australian Government signalled an intention to adopt this lessening of competition test for *per se* prohibitions in the *Australian Competition Act* only, but such an amendment was never implemented.[230]

The ACCC has also been critical of the exemption in Section 51(3). In submissions regarding the Compulsory Licensing Report, the ACCC emphasized that, at least with respect to copyright, the exception could potentially exclude "significant anticompetitive conduct" from the application of the *Australian Competition Act*. The ACCC pointed to the U.S. as an example where IP rights are subject to the same competition laws as other property rights, and indicated this has not resulted in any apparent erosion of IP rights.[231] The 2013 Compulsory Licensing Report agreed with the ACCC, indicating "[g]enerally, to the extent that there are competition issues warranting government intervention, it is desirable to treat them similarly across the different sources of market power. The alternative approach of customising competition law for

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required because of a conflict between promoting competition and the existence and exploitation of IP rights, a conflict that the author suggests does not in fact exist [Competition and Intellectual Property].

227 Commonwealth of Australia, National Competition Council, *Review of Sections 51(2) and 51(3) of the Trade Practices Act 1974*, *Final Report* (1999) [Review of Sections 51(2) and 51(3)].

228 Mark J. Davison, Ann L. Monotti & Leanne Wiseman, "Australian Intellectual Property Law" (Melbourne: Cambridge University, 2008) at 608 [Davison et al.]. Prior recommendations that amounted to the repeal of the section include Commonwealth of Australia, Intellectual Property and Competition Review Committee, *Review of IP Legislation Under the Competition Principals Agreement, Final Report* (2000) and the Report of the Intellectual Property and Competition Review Committee, *Review of Intellectual Property Legislation Under the Competition Principles Agreement,* (September 2000) at 212; Section 51(3) was also considered in the National Competition Council, Review of Sections 51(2) and 51(3)*, ibid*; Amendments were also recommended the Genes and Ingenuity Report, *supra* note 142; Competition and Intellectual Property, *supra* note 226 at 30; The ACCC's submission to the ALRC in its ongoing review of copyright and the digital economy also recommended the IP rights be fully subject to the competition provisions in the *Act* by repealing section 51(3) of the *Act* (which also currently provides an exemption for certain copyright licence conditions form certain competition provisions), see the Commonwealth of Australia, Australian Competition and Consumer Commission, *Annual Report 2012-2013* (2013) at 166, online: <http://www.accc.gov.au/publications/accc-aer-annual-report/accc-aer-annual-report-2012-13>.

229 Commonwealth of Australia, Intellectual Property and Competition Review Committee, *Review of IP Legislation Under the Competition Principals Agreement*, *Final Report* (2000), as referred to in the Compulsory Licensing Report at 140.

230 Compulsory Licensing Report, *supra* note 224 at 141.

231 *Ibid* at 143.

different sources of market power could generate economic distortions, by inefficiently encouraging some types of behaviour over others."[232]

The Compulsory Licensing Report also reflects some evidence from market participants that without Section 51(3), their transaction costs for licensing would rise and their likelihood of taking on the risk of licensing would decline. However, the report ultimately found it unclear whether the current benefit of Section 51(3) in this respect was significant. The Compulsory Licensing Report concludes there was no "convincing evidence" presented to rebut that principle of general applicability of competition law in the context of access to patents.[233]

Leaving aside policy arguments, Section 51(3) has also been criticized on the more practical basis that its scope of application is unclear, because it exempts conditions in patent licenses and assignments from Part IV to the extent they "relate to" the subject matter of an intellectual property right, a concept that lacks clarity.[234] The text of the provision also seems unnecessarily complex, which may well contribute to the lack of clarity in its application.

(ii) Agency and Jurisprudential Guidance

The ACCC, the equivalent of the Canadian Competition Bureau, appears to have paid relatively little attention to intellectual property as it relates to competition law. Instead, the rough equivalent to CIPO, called IP Australia, appears to have much of the responsibility for the regulation of competition with respect to IP and has considered some issues similar to those discussed for other jurisdictions herein.

The ACCC takes the position that IP rights should be treated the same as other property.[235] Although the ACCC indicated in its 2003-2004 annual report that it was preparing draft intellectual property guidelines that would clarify the application of Section 51(3), no guidelines were ever released.[236] Other calls have been made for guidelines on Section 51(3).[237] Most recently, the Compulsory Licensing Report indicated there is a "strong case" for clarifying the application of Part IV of the *Act* (not just Section 51(3)) in relation to IP licensing through the issuance of guidelines by the ACCC.[238] It notes the issuance of guidelines on the application of

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232 *Ibid* at 142.

233 *Ibid* at 144.

234 See further discussion in Genes and Ingenuity Report, *supra* note 142 at 24.53 & 24.54. Only one reported case has mentioned Section 51(3). In considering the term "relates to" the court indicated that the exemption would not apply where a license term seeks to obtain advantage collateral to the subject matter of the invention. It also acknowledged that a patentee is "entitled to impose conditions" when granting a license or assignment in order to protect their legal monopoly. *Transfield Pty Ltd v Arlo International Limited* (1980) 30 ALR 201.

235 *Ibid*; Compulsory Licensing Report, *supra* note 224 at 142, referring to ACCC submissions. Most recently, in the copyright context, the ACCC submitted in its comments on the ALRC Review, *Copyright and the Digital Economy* (2012) that IP rights should be treated the same as other property rights and Section 51(3) should be repealed.

236 Compulsory Licensing Report*, ibid.*

237 *Ibid* at 139.

238 Genes and Ingenuity Report, *supra* note 142 similarly recommended that the *Trade Practices Act* should be amended to clarify the relationship between Part IV of the *Act* and intellectual property rights, and that the ACCC issue guidelines to provide further clarification on when the licensing or assignment of intellectual property might be exempted under s 51(3) or might breach Part IV and when conduct that would otherwise breach Part IV might be authorised under Part VII of the *Trade Practices Act*. Recommendation 24-1 and 24-2. The government "noted" the recommendation in its response but only committed to issuing guidelines

competition to IP issued by the EU in 2004, U.S. in 1995 and the Canadian Competition Bureau in 2000. Given the lack of Australian IP guidelines, we address some of the key principles from basic older case law in this section.

As in other jurisdictions, the ownership of intellectual property does not in itself mean the owner has the substantial degree of market power required for prohibitions such as misuse of market power (Section 46) to apply.[239] However, it is possible that a single patent may confer a significant degree of market power if it is extremely inventive, of great commercial value and it is not possible to easily patent "around" it; such patents are considered rare.[240] Even where there is no significant degree of market power, if the intention of the party was to substantially lessen competition, that may be sufficient to contravene the exclusive dealing provisions and refusal to supply provisions.

A firm's purpose under Section 46 is subjective, but may be inferred objectively based on the circumstances.[241] The ACCC has indicated that in the absence of a "smoking gun", it would be particularly difficult to prove that a firm has acted with the necessary purpose where intellectual property is involved.[242] In an old background paper, the precursor agency to the ACCC indicated a firm is most likely to misuse its market power in relation to an intellectual property right where it seeks to obtain an advantage greater than that conferred by the relevant statute, or seeks to extend the monopoly conferred into markets other than those protected by the statutory grant.[243]

The ACCC generally follows the U.S. approach to patent pools and cross-licensing arrangements, operating on the basis that such arrangements could be either pro-competitive or anti-competitive in certain circumstances.[244]

Australia has another agency which has engaged in work relevant to the patent/competition law interface. The Australian Productivity Commission plays an independent advisory role akin to a law reform commission.[245] It is a research and advisory body that focuses on strategic means of achieving a more productive economy through better policy, including on economic, social and environmental issues. It tends to adopt an economic cost-benefit framework for analyzing

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if Section 51(3) was amended. Commonwealth of Australia, *Australian Government Response to Senate Community Affairs References Committee Gene Patents Report* (November 2011) online: <http://www.google.ca/url?sa=t&rct=j&q=&esrc=s&frm=1&source=web&cd=1&ved=0CCYQFjAA&url=http://www.ipaustralia.gov.au/pdfs/Australian-Government-response-senate-committee-gene-patents-report.doc&ei=PszhUquODOalsQSw54HABA&usg=AFQjCNGDjpkoErE3iVVou6qwafDGufywuQ&bvm=bv.59930103,d.cWc at 34>.

239 *Re: Broderbund, Software Inc and Dataflow Computer Services Pty Limited v Computermate Products (Australia) Pty Limited; Raymond Firth; Broderbund Software Inc and Dataflow Computer Services Pty Limited* No G492 of 1990 Fed No 711 Trade Practices (299) 14 ATPR 41-155 (1991) 22 IPR 215.

240 *Murex Diagnostics Australia Pty Ltd v Chiron Corporation* (1995) 55 FCR 194, 196.

241 *Australian Competition Act*, *supra* note 221, s 46(7).

242 Genes and Ingenuity Report, *supra* note 142 at 559.

243 Commonwealth of Australia, Trade Practices Commission, *Misuse of Market Power: Section 46 of the Trade Practices Act 1974I,* (1990) Background Paper at 35.

244 Michael Blakeney, "Intellectual Property Rights and Food Security" (Australia: CABI, 2009) (accessed on Google Books).

245 Lyria Bennett Moses, "Agents of Change: How the Law 'Copes' with Technological Change" (2011) 20 Griffith Law Review 763 at 779 [Moses].

government policy and is thought to have had an important role in assessing regulation and ensuring it remains effective over time in light of the impact of technological change.[246] Given its mandate, and the recent Productivity Commission examination of compulsory licensing in Australian law (discussed below), it appears to be a helpful institution in charting the reconciliation of patent law and competition law.

(iii) *Patents Act* Provisions Relevant to Competition Law

Like the U.K., Australia has in its *Patents Act* a groundless threats provision to address unjustified threats of patent infringement proceeding.[247] The Australian provision does not distinguish between primary and secondary infringers, and legal advisors are immune from liability.[248] There is also a compulsory licensing regime under the Australian *Patents Act*, addressed in more detail in the Australian Standard-Setting and FRAND Licensing section, below.

Effective as of April 15, 2013, Australia introduced its most significant overhaul of intellectual property laws and practice in twenty years.[249] The reform is the culmination of several consultation papers aimed at improving the fit and function of the Australian patent system as a vehicle to support innovation, including the balance between patent and competition.[250] Australia's standards for patentability were considered lower than its major trading partners, particularly the lower standards for inventiveness and the lesser disclosure of details of inventions. This raised concern that such standards might be supressing competition and discouraging competition,[251] upsetting the balance between patent and competition, by allowing over-patenting in Australia and reducing follow-on innovation and the concomitant consumer benefits.[252] We did not find any major commentary in Australia addressing the impact of the recent reforms on competition law.

Australia also recently completed a consultation on recommendations to introduce an "objects clause" to assist in interpretation of its *Patents Act*.[253] The clause is intended to identify the underlying purpose of the legislation. The proposed clause refers to intellectual property rights

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246 *Ibid*, generally.

247 *Patents Act 1990 (Cth),* s 128. Also of potential relevance to competition generally are *Patents Act* sections 144, 146, 133-136.

248 *Ibid*, ss 117 & 132.

249 *Intellectual Property Laws Amendment (Raising the Bar) Act 2012* introduced changes to the following: *Australia Patents Act*; *Patents Regulations 1991*; *Trade Marks Act 1995*; *Trade Marks Regulations 1995*; *Designs Act 2003*; *Designs Regulations 2004*; *Plant Breeder's Rights Act 1994*; *Copyright Act 1968*.

250 This includes a paper in 2007 on the incorporation of patent and trade mark attorneys, in 2008 on penalties and additional damages, several reports in 2009 on exemptions to patent infringement, getting the balance right, resolving divisional applications, opposition proceedings for trademark and for patent and on a stronger and more efficient IP rights system.

251 Commonwealth of Australia, Exposure Draft, *Intellectual Property Laws Amendment (Raising the Bar) Bill 2011*, Schedule 1 at 7 [Exposure Draft]. These concerns were also recognised in the 2008 review of the national innovation system "Venturous Australia" and the Government's response to this review: Powering Ideas: the innovation agenda for the 21st century.

252 *Ibid*; See also Commonwealth of Australia, *IP Australia, Getting the Balance Right: Toward a Stronger and More Efficient IP Rights System* (2009) at 4, online: <http://www.ipaustralia.gov.au/ip-professional-portal/consultation-papers-ip-reforms/>.

253 This was a response to three reports on gene patents and patentable subject matter. See <http://www.ipaustralia.gov.au/about-us/public-consultations/objects-clause/>.

protection and enforcement as promoting technological innovation and includes reference "to a balance of rights and obligations".[254] It is thought that an objects clause would "clarify the interaction between the patent system and competition policy".[255] As of December 30, 2013, the consultation had not finalized its report.

(I) Trends in Patent Issuance

In terms of standard patent filings, Australia has not seen any major uptick in recent years.[256] There was a surge in patent examination requests recently, however– more than double the prior year – as people attempted to avoid the uncertainty of the new patent regime discussed above. In Australia, 90% of patent applications are from non-residents, of which U.S. residents lead by far.[257]

Australian innovation patents, on the other hand, have seen a fairly significant increase in applications, from around 2008 (1,297 applications) to 2012 (1,856 applications), with most of the increase coming from non-resident filings.[258] The Australian innovation patent system has seen rising levels of foreign applicants overall, from around 17% in 2001 to almost 40% of innovation patents filed in 2011.[259] IP transactions (royalties and licensing) have remained relatively steady as a percentage of current accounts for the past decade, meaning IP transactions in Australia have not followed the global trend of rising volume.[260] Overall Australia is a net importer of IP.[261] Much like Canada, reports in Australia have identified a considerable lag in innovation-related investment.[262]

(I) Innovation Patents

Australian patent law provides for the issuance of innovation patents. None of the other jurisdictions considered in this report have an innovation patent system. The innovation patent system in Australia is intended to protect incremental or low level inventions that do not meet

254 Commonwealth of Australia, IP Australia, *Patentable Subject Matter: Consultation on an Objects Clause and an Exclusion from Patentability* (July 2013) online: <http://www.ipaustralia.gov.au/about-us/public-consultations/objects-clause/>. The objects clause also refers to mutual advantage of producers and users, in a manner conducive to social and economic welfare.

255 *Ibid* at 5.

256 Commonwealth of Australia, IP Australia, Australian Intellectual Property Report 2013, (2013), online <http://www.ipaustralia.gov.au/about-us/corporate/reports/australian-ip-report-2013> indicates that in 2012, just over 26,300 patent applications were filed, compared to about 21,500 in 2003 [Australian IP Report].

257 *Ibid* at 8, indicating US residents filed over 11,300 patents in 2012.

258 *Ibid* at 10.

259 *Ibid* at 16. Apple is far and away the largest holder of Australian innovation patents that are certified with 98 innovation patents as of 2012. *Ibid* at 20.

260 *Ibid* at 22.

261 *Ibid* at 23; Australia spent $8.3 billion on technology imports in 2011, but only earned $4.9 billion exporting IP and technology.

262 Commonwealth of Australia, Department of Industry, Innovation, Science, Research and Tertiary Education, *Australian Innovation System Report 2012* (September 2012), online: <http://www.innovation.gov.au/science/policy/AustralianInnovationSystemReport/AISR2012/index.html> noted the "considerable gap between Australia and other OECD countries" in this regard.

the inventive threshold required for standard patent protection and are not covered by design legislation.

As mentioned above, there has been a dramatic upswing in the number of innovation patents issued in Australia in recent years, mainly in pharmaceutical, IT and electronics industries. There is concern that innovation patents are not being used to protect actual research and development investment but rather as tactical tools to supress competition and evergreen standard patents.[263] There is also concern that innovation patents are being granted for improvements that lack sufficient levels of innovation to merit protection, but that despite this, after an innovation patent is granted the remedies available are the same as standard patents.[264]

In 2011, the Advisory Council on Intellectual Property ("ACIP") began a review (which is still ongoing) of the innovation patent system.[265] It is considering several issues regarding the innovation patent system, the main issues relevant to this report being: (i) whether the inventiveness threshold is appropriate, particularly given that the relief available for infringement of a certified innovation patent is the same as for a standard patent,[266] (ii) whether the innovation patent system is actually stimulating innovation in small and medium size enterprises as it was intended to do, (iii) whether the innovation system creates uncertainty that stifles competition because the holder has a potential right, not an enforceable right (until certification) and (iv) perceived abuses of the innovation patent system.

Survey respondents and those participating in roundtables with ACIP generally saw the innovation patent system as useful in promoting innovation, but ACIP found no evidence supporting or contradicting the idea that innovation patents in fact contribute to innovation.[267] The perception among commentators to ACIP was also that the level of innovation required for such patents was currently too low, and the remedies and protection available too high, to the point of being anti-competitive.[268] ACIP found evidence that the system is being 'strategically' used by a small proportion of large companies for the following: evergreening,[269] creating patent

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263 Charles Davies, "Should Innovations Be More Inventive? A Call For Public Comment" Memorandum of King & Wood Mallesons (10 October 2012) online: <http://www.lexology.com/library/detail.aspx?g=fdfbabbb-0f2f-431c-bed7-2e230c0c62e7> [Should Innovations be More Inventive].

264 *Ibid*.

265 The ACIP advises the Australian Minister for Innovation, Industry, Science and Research, as well as IP Australia (the agency equivalent to Canada's CIPO) on intellectual property matters and the strategic administration of IP Australia. See ACIP website, online: <http://www.acip.gov.au/about-acip/>. In February 2011, the then-Minister for Innovation, Industry, Science and Research requested that ACIP investigate the effectiveness of the innovation patent system in stimulating innovation by Australian small to medium business enterprises.

266 Although there is no in-depth examination before an innovation patent is issued, if an innovation patent holder wishes to enforce their rights, the patent must then undergo substantive examination and be certified. The patent carries no enforceable rights until certification, which is seen as increasing uncertainty within the patent system. Commonwealth of Australia, Advisory Council on Intellectual Property*, Review Of The Innovation Patent System Options Paper* (August 2013) online: <http://www.acip.gov.au/pdfs/Options_Paper_Innovation_Patent_Review.pdf> at 13 [Innovation Patents Options Paper].

267 *Ibid* at 27.

268 *Ibid*.

269 *Ibid* at 23. Evergreening in this context was considered to mean filing an innovation patent application around when the standard patent is about to expire, which opponents to the practice claim allows the patent to be extended for another 8 years (the term of an innovation patent) for virtually the same invention.

thickets around standard patents (using multiple innovation patents for variants of the invention),[270] or to bolster standard patents during infringement proceedings.[271]

A final report on the innovation patent issue was anticipated from ACIP at the end of 2013, but has yet to be issued.[272] Overall, although anecdotally well regarded by businesses, the evidence of benefits to innovation arising for the innovation patent system in Australia is inconclusive even after 12 years in operation. Recent trends suggest foreign companies may be increasingly the beneficiaries, and there is some suggestion of abuse or gaming of the system. Although some have recommended Canada adopt an innovation patent system,[273] it would be important to take into account the Australian experience in assessing whether such an approach is likely to benefit innovation within Canada.

V. BACKGROUND ON CURRENT TOPICS AT THE INTERSECTION OF PATENT AND COMPETITION LAW REGIMES: THE COMPETITION PERSPECTIVE

This section provides a brief overview of the competition law concerns in the four areas of intersection with patent law addressed in this report: standard setting, reverse payment settlements, patent assertion entities and product hopping. It is intended to frame the basic understanding of the competition and innovation concerns raised in each area, before later sections proceed to an in-depth discussions of the treatment of the four issues in each jurisdiction.

1. Standard-Setting and FRAND Licensing Commitment Concerns in Competition Law

The acknowledged benefits of industry standards are extensive, including making products less costly to produce, increasing innovation, efficiency and consumer choice and promoting public health and safety.[274] As the complexity of products such as mobile devices and computers skyrockets, standardization is playing an increasingly important role and has been called “one of

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270 *Ibid* at 30. Apple’s use of the innovation patent system in recent years was cited by stakeholders as an example of such a thicket strategy.

271 *Ibid*. Essentially the party alleging infringement can obtain innovation patents, drafted to capture the alleged infringement based on details that become available during the case, in an effort to patch up the weaknesses in the standard patent.

272 *Ibid*. As of December 31, 2013. A paper outlining reform options was released in August 2013, framing the three options for addressing innovation patents simply as “no change” (essentially waiting to see the impact of the 2013 IP law reforms and if they are sufficient), abolishing the innovation system, or reforming it to address issues of tactical abuse and over-protection. The ACIP initially opened its review up for stakeholder comment, but found that small to medium businesses did not engage to the extent expected in the process. In light of this, a research survey was commissioned instead to try and assess whether the innovation patent system is effective in stimulating innovation by SMEs, Commonwealth of Australia, IP Australia, *The Economic Value Of The Australian Innovation Patent: The Australian Innovation Patent Survey* (24 March 2013) online: <http://www.acip.gov.au/pdfs/Economic_Value_of_the_Innovation_Patent_-_Final_Report_-_Verve_Economics_-_24_Mar_2013.pdf>.

273 Sumaiya Sharmeen, “Should Canada Adopt an ‘Innovation Patent System’ to Promote Small to Medium Enterprises?” (11 December 2013) online: <http://www.iposgoode.ca/2013/12/should-canada-adopt-an-innovation-patent-system-to-promote-small-to-medium-enterprises/>.

274 *Ibid.* U.S. Congress and the Executive Branch have recognized the benefits of voluntary consensus standards. See, e.g., *National Technology Transfer and Advancement Act of 1995*, Pub. L. No. 104-113 § 12(d), 110 Stat. 775, 783 (1996), 15 U.S.C. § 272 note (2006)).

the engines driving the modern economy".[275] From a competition perspective, the establishment of standards plays an important role in promoting competition by promoting innovation and by facilitating interoperability, which lowers switching costs between products using the same standard.

Standards are often set by standard-setting organizations ("SSOs") composed of industry participants who work together to reach a consensus on the standard to be adopted.[276] Standards may also simply arise from *de facto* industry or public adoption. Where standards are set by SSOs, those organizations generally have choices among competing technologies and choose one to become the standard.[277] The technology adopted as the standard may be encumbered by patents, meaning implementers of the standard must obtain a license from the patent holders whose patents are essential to the standard.

Not all standards necessarily involve patents, but many standards have one or more patents that read on the standard. A patent is generally considered "standard-essential" when it is declared or incorporated by an SSO into an industry standard. Standard-essential patents ("SEPs") must be licensed in order to implement the standardized technology or risk infringing intellectual property rights.[278] Such patents are often the subject of commitments to an SSO by the patent holder to license on fair, reasonable and non-discriminatory ("FRAND") terms;[279] these commitments are aimed at avoiding the exploitation of monopoly power arising from the SSO participant's coordinated decision on the adoption of a standard.[280]

Potential anti-competitive harms related to standard-setting have generally fallen into categories of (i) the (somewhat older) concern that collusive conduct might occur between competitors engaging in the standard-setting process, and, (ii) after a standard is established and results in market power, concerns over (a) anti-competitive foreclosure preventing effective access to the standard and (b) the potential for patent hold-up, which is a concept explained in more detail in the section on PAEs, below.

2. Reverse Payment Settlement Concerns

In the pharmaceutical industry there is a division between the branded or "originator" companies who research, develop and patent new drugs and their generic competition, who launch generic versions of the drugs developed by branded companies.[281] When a generic company wishes to

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275 2007 IP Report, *supra* note 81.

276 The discussion here is focused on private standard-setting. Standard setting by government may raise other unique considerations.

277 George Cary et al, "The Case for Antitrust Law to Police the Patent Holdup Problem in Standard Setting" (2011) 77 Antitrust Law Journal 913 at 914 [Antitrust Law to Police the Holdup Problem].

278 Maureen K. Ohlhausen , Commissioner, Federal Trade Commission, "A Pragmatist's Approach to Navigating the Intersection of IP and Antitrust" (Speech delivered at the Standards and Patents Conference, London, United Kingdom, 4 December 2013) online: <http://www.ftc.gov/sites/default/files/documents/public_statements/pragmatists-approach-navigating-intersection-ip-antitrust/131204ukantitrust.pdf> [A Pragmatist's Approach].

279 Reference is also made to "RAND" terms, where the commitment to licence does not refer to "fairness". For simplicity we refer in this report to FRAND only.

280 Antitrust Law to Police the Holdup Problem, *supra* note 277 at 919.

281 The term "innovator" companies is also used, since branded companies are usually the creators of new drugs.

introduce a generic version of a drug, it may wait until the patent expires, challenge the patent of branded companies (which may occur in the context of regulatory approval for the generic drug entry), or simply proceed with "at risk" market entry and leave it to the branded company to bring a patent infringement lawsuit.

In situations where the branded company initiates legal proceedings, a practice has arisen wherein the two companies reach a settlement of such litigation providing for (i) the alleged infringer not to produce the patented drug until the patent expires, and (ii) the branded company to transfer consideration to the alleged infringer. Such "reverse payment settlements" are labelled "reverse" because the agreement involves the patent holder paying the alleged infringer, rather than the more common situation in infringement litigation where the alleged infringer makes the settlement payment.[282] The settlements are also referred to as "pay-for-delay" agreements because they are seen as the generic agreeing to delay entry and drop its infringement suit, in exchange for value transfer from the branded company. In the absence of such a settlement, the court may have issued a decision that the patent was invalid or not infringed.

The concern is that reverse payment settlements are being used by branded companies to prevent competition in exchange for a share of monopoly profits paid to the generic company. Competition authorities have indicated reverse payment settlements may lead to higher prices for pharmaceuticals by delaying generic entry, contributing to increased health-care costs. The question is whether some or all reverse payment settlements constitute an abuse of dominance or illegal agreement in competition law. From the patent law perspective, there is concern over recognition of the valid rights of a patent holder to prevent infringement, and arguments that there is a genuine, pro-competitive interest in ending time and cost-consuming litigation through a reverse payment settlement.

3. Patent Assertion Entities and The Hold-up Problem

Patent assertion entities, often referred to as "patent trolls" by their critics, are firms that engage in the business of acquisition and assertion of patents against parties who are already using the patented technology.[283] PAEs are neither creators nor consumers of the technology underlying the patent; they generally do not conduct research or practice their acquired patents.[284] PAEs tend to rely heavily on actual or threatened litigation to extract patent licensing royalties or settlements.[285] The polar opposite of a PAE, for the purposes of the discussion here, is a "typical" firm which engages in research, obtains the related patents and applies the patented

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282 The term "pay-for-delay" is often used to describe such settlements as well, since they may involve the generic delaying their entry into the market.

283 Although U.S. literature on PAEs debates their proper definition extensively, for the purposes of this paper we adopt this recent FTC definition. Evolving IP Marketplace, *supra* note 94. A distinction is often made in empirical studies between PAEs and non-practicing entities ("NPEs"), a broader category encompassing all organizations that do not practice their patents (including PAEs but also institutions such as universities). Where relevant, we endeavor to refer to NPEs rather than the narrower category of PAEs.

284 Raymond Millien & Ron Laurie, "Meet the Middlemen" (2008) Intellectual Asset Management 53 at 53, in reference to all intellectual property intermediaries, rather than just PAEs.

285 By way of example, a firm sometimes labelled as a PAE is the private equity-backed Digitude Innovations. The company's mission statement is to build its patent portfolio (which has estimated at least 550 patents) through the purchase of patents, then licensing of the patents to industry-leading technology companies, "offering patent owners a new and innovative way to monetize their intellectual property assets" See Digitude Innovations <http://www.digitudeinnovations.com/news.html>.

technology to produce a product or service (or some combination of these activities); their business includes turning inventions into useful innovations.[286]

Particularly in the U.S., some estimates indicate PAE patent infringement litigation has skyrocketed in recent years. This reflects PAEs' focus on *ex post* patent licensing, meaning licensing after the firm accused of infringement has invested in creating, developing or commercializing the technology. This type of licensing is thought to distort competition and deter innovation, because it imposes unexpected costs and increases uncertainty for firms who are seeking to develop technology.[287] In contrast, most *ex ante* licensing of patent technology, occurring before the buyer has obtained the technology through its own development or other means, is thought to advance innovation and increase competition. The notion of turning inventions into useful innovations is the foundation underpinning the social bargain allowing for patent monopoly and exclusion rights. PAE conduct raises questions on how to approach licensing and related litigation which may *not* be contributing to innovation as the patent system is intended to do, and may also be deterring competition.

The concept of licensing *ex post* as opposed to *ex ante* relates to the concept of economic hold-up at the core of the PAE litigation strategy. A similar concept of hold-up is also the basis for the standard-setting concerns discussed above, although we explain here in the context of PAEs. Licensing of technology after it has been incorporated into a product is an important means of asserting patent rights. However, it also raises the spectre of hold-up, wherein the threat of an injunction (or other costs) leads an alleged infringer to pay higher royalties than could have been obtained in a competitive market. Injunctions, a legal remedy that may be available to PAEs who allege infringement of a patent, are significant and powerful because they can completely prevent the sale of the product or use of a key feature that contains an allegedly infringing component. The reality is that once a firm has proceeded with the development and commercialization of new technology, it is in a poor negotiating position when responding to demands from PAEs for licensing fees. A firm approached after it is using the technology is likely to pay up in order to avoid the risk of an injunction, or other costs arising from litigation,[288] infringement liability or switching to a non-infringing technology. Once a firm has integrated a patented technology into its product, knowingly or not, the threat that a PAE may obtain an injunction barring sales of the product can thus enable the PAE to extract royalties greater than the economic value contributed to the patented invention.[289] The more patents that read on a given product, the less the contribution of any single patent to the overall market value of the product, [290] and the more likely hold-up could occur.

PAEs are particularly well-suited to engage in hold-up because, unlike traditional firms, PAEs lack an underlying business and therefore need not be concerned that counter-claims will

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286 John Johnson et al, "Don't Feed the Trolls?" (2007) 52(3) Les Nouvelles 487, online: <http://www.nera.com/extImage/PUB_DontFeedTheTrolls.pdf>.

287 Evolving IP Marketplace, *supra* note 94 at 3.

288 The American Intellectual Property Law Association estimates that where less than $1 million is at risk per patent, the costs of litigation may be $916,000, on average, to the final resolution. Where over $25 million is at risk, the cost averages an estimated $3.53 million through the end of discovery and $6.18 million in total. United States, American Intellectual Property Association Law Practice Management Committee, *Annual Economic Survey*, (United States: 2011).

289 Royalty Stacking, *supra* note 309.

290 Dr. Robert Harris, "Patent Assertion Entities & Privateers: Economic Harms to Innovation and Competition" (2013) forthcoming Antitrust Bulletin Symposium Spring 2014 at 6, online: <http://works.bepress.com/cgi/viewcontent.cgi?article=1004&context=robert_g_harris>.

threaten their operations or product revenue.[291] Where litigation is engaged in by producing companies with comparable patent stockpiles, each company tends to face symmetrical risk to their respective businesses.[292] Where patent infringement is brought between producing entities, a counter-claim of infringement would be common. Producing companies thus face a situation of mutually assured destruction from litigation, which is thought to drive cross-licensing and settlements, or merely ignoring of infringement between producing entities. In contrast, the PAE business model means no underlying business and thus little risk of counter-attack. Literature suggests that PAEs may also face much lower litigation costs than producing companies, arising from lower discovery costs,[293] the repetitive nature of PAEs revenue model (which enables leveraging of infringement filings and demand letters and experience from prior cases),[294] and the inherently minimal evidence required to assert patent infringement.[295] These factors create an asymmetry of litigation risk between the PAE and its target.

Because hold-up potential is related to the ease of availability of injunctions, the cost of litigation as well as the quality of patents that are relied on, the PAE debate is multi-faceted. We discuss the competition law perspective, but reform to litigation rules, infringement remedies and patent issuance are all part of the debate on PAEs.

4. Product Hopping Concerns

Another concern at the intersection of patent and competition policy is “product hopping” or “product switching”. Product hopping is sometimes categorized under the broader label of “life-cycle management strategies”, which refers to an array of practices used to maximize the value of pharmaceutical patents. Product hopping involves branded manufacturers introducing new variations of patented drugs shortly before the patent protection on the older version of the drug expires, while withdrawing from the market the older drug facing imminent generic competition. The FTC describes product hopping as “introducing new patented products with minor or no substantive improvements in the hopes of preventing substitution to lower-priced generics.”[296]

The branded manufacturers may use various strategies to steer physicians or pharmacies toward the new drug variation, for example indicating the older drug is back-ordered or giving

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291 Jason Williams, Mark V. Campagna & Olivia E. Marbutt, “Strategies For Combating Patent Trolls” (2010) 17 Journal of Intellectual Property Law 367 at 368, explaining the lopsided risk in PAE litigation and litigation strategies to counteract patent trolls.

292 See discussion in Colleen V. Chien, “From Arms Race to Marketplace: The Complex Patent Ecosystem and Its Implications for the Patent System” (2010) 62 Hastings Law Journal 297 at 311-312.

293 Since producing companies by definition have an underlying business, there is generally an asymmetric exposure to discovery burdens on such businesses in comparison to that faced by PAEs asserting patents against them. PAEs have few documents that could be the subject of discovery since they have no substantive operations outside of litigation. The defendants in patent litigation are thus thought to face comparatively onerous potential discovery and production. Mark A. Lemley & Douglas A. Melamed, “Missing the Forest for the Trolls” (2013) 113 Columbia Law Review 2117 at 2162 [Missing the Forest for the Trolls].

294 Colleen Chien & Michael Guo, “Does the US Patent System Need a Patent Small Claims Proceeding?” (2013) Santa Clara University Legal Studies Working Paper No. 10-13, online: <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2249896> [Patent Small Claims].

295 United States, Executive Office of the President, *Patent Assertion and U.S. Innovation Report* (United States: 2013) at 6 [Patent Assertion Report].

296 J. Thomas Rosch, Commissioner, Federal Trade Commission, “The Antitrust/Intellectual Property Interface: Thoughts on How To Best Wade Through the Thicket in the Pharmaceutical Context” (Speech delivered at the World Generic Medicine Congress, Washington, D.C., 17 November 2010) [How to Best Wade Through the Thicket].

discounts on purchases of the new drug. Since generic drugs tend to rely on substitution rules that allow pharmacies to swap the generic for the branded drug,[297] the competition concern is that removal of the old, branded drug from the market could make it more difficult for the generic drug to enter that market. In response, patent holders argue they are not under any obligation to continue to offer an older patented drug, and that the product being hopped to offers sufficient benefits to justify the switch.

VI. UNITED STATES

1. Standard Setting and FRAND Licensing Commitments

The U.S. Agencies have acknowledged standard-setting is often "economically beneficial" and pro-competitive; they consider standard-setting generally to increase efficiency and consumer well-being, bringing about lower prices and more product choice in the short run and increased innovation in the long run.[298] However, the Agencies have also acknowledged concerns that standard-setting activities and effects can be competitively harmful in certain situations. Standard-setting inherently involves competitor collaboration in the SSO context and can result in a successful standard that confers substantial market power. Once the standard is established and becomes widely adopted, switching costs can be high.[299] The development of alternative technologies may become less likely and it may be nearly impossible in practice to shift to another technology as the standard.[300]

Addressing anti-competitive conduct in the standard-setting context has been a priority for the Agencies since at least the late 1990's.[301] The potential anti-competitive harms related to standard-setting can be summarized in several general categories:[302] (i) the (somewhat older) concern that collusive conduct might occur between competitors engaging in the standard-setting process, and, (ii) after a standard is established and results in market power, concerns over (a) anti-competitive foreclosure preventing effective access to the standard and (b) the potential for patent hold-up.

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297 Generics tend to keep prices lower by not spending significantly to market their products, riding on the coattails of marketing efforts already engaged in for the equivalent branded drug and relying on regulation that allows substitution of the generic for the branded drug, see Sean Royall, Ashley E. Johnson & Jason C. McKenney, "Antitrust Scrutiny of Pharmaceutical 'Product Hopping" (2013) Antitrust 71 at 71, online: <http://www.gibsondunn.com/publications/Documents/RoyallAntitrustScrutinyABA.pdf> [Antitrust Scrutiny of Pharmaceutical Product Hopping].

298 The Art of Persuasion, *supra* note 71 at 2; A Pragmatist's Approach, *supra* note *supra* note 278.

299 Misconduct in Standard Setting, *supra* note 67.

300 *Ibid.*

301 J. Thomas Rosch, "Section 2 and Standard Setting: Rambus, N-Data & The Role of Causation" (Speech delivered at LSI 4th Antitrust Conference on Standard Setting & Patent Pools, Arlington, VA, 2 October 2008) online: <http://www.ftc.gov/sites/default/files/documents/public_statements/section-2-and-standard-setting-rambus-n-data-role-causation/081002section2rambusndata.pdf> [Rosch Speech: Section 2 and Standard Setting]. Points to the *In re Dell Computer Corp*, 121 FTC 616 (20 May 1996) (complaint and consent order) [*Dell*], *In re Union Oil Co of California*, No 9305 (FTC 25 November 2003) [*Unocal*], *Rambus Inc v Federal Trade Commission*, 522 F (3d) 456 (DC Cir 2008) [*Rambus*], and *In re Negotiated Data Solutions, LLC* (FTC 23 September 2008) [*N-Data*].

302 See generally Stanley M. Besen & Robert J. Levinson, "Introduction: The Use and Abuse of Voluntary Standard-Setting Processes in a Post-Rambus World: Law, Economics, and Competition Policy" (2012) 57 The Antitrust Bulletin 1 at 11 onward [Use and Abuse of Voluntary Standard-Setting].

We focus the discussion here on the patent hold-up issues such as patent ambush and breach of FRAND commitments, in particular the latter, which has received much of the enforcement attention in recent years. The concern over collusive conduct in the setting of a standard is an older issue. It is less likely to be related to patents than to more traditional competition questions over anti-competitive agreements between competitors. Direct foreclosure of access to a standard has also been addressed mainly in older cases,[303] although we note more recent reports that the DOJ is investigating a standard-setting agency that attempted to foreclose competition for a high-definition video standard by creating legal uncertainty as to whether the users of a competing standard would be exposed to claims of patent infringement by members of another standard.[304] As well, in a recent private case that settled, Avery Dennison alleged that the owners of intellectual property related to one standard collectively withheld property from those wishing to practice a competing standard.[305] Deception in standard-setting (patent ambush) or breach of FRAND commitments, which might lead to supra-competitive royalty rates but not necessarily outright foreclosure, present the most recent and perhaps complex questions in reconciling competition law and patent law.

We also focus the discussion here on developments that signal potential policy directions, such as enforcement agency cases and commentary, steering away from the private litigation in this space where the tide shifts almost daily. As mentioned above, in both the U.S. and the EU there has been extensive private litigation between virtually every large technology company regarding alleged contractual violations of commitments made to license SEPs at reasonable rates (dubbed the “smartphone wars”).[306]

(a) The Concern over Patent Hold-up

A key concept underlying the FTC and DOJ concern about standard-setting in recent years is the threat of patent “hold-up”. Patent hold-up occurs where the holder of a patent reading on a standard using the threat of litigation, injunctions or similar instruments to obtain supra-competitive royalties after the standard is implemented, higher than the royalties obtainable before the patent was included in the standard (or to force cross-licenses that would not have been granted in the absence of the standard).[307]

In such circumstances, the DOJ has expressed concern that the inclusion of the patents in the standard means the holder of the patent essential to the standard may gain market power beyond what its patent originally conferred.[308] The patent holder could conceivably employ that market power to capture economic value arising from the standardization, by threatening or enjoining a competitor, and demanding licensing fees that exceed the reasonable rates for the

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303 *American Society of Mechanical Engineers v Hydrolevel Corp*, 456 US 556 (1982); *Allied Tube & Conduit Corp v Indian Head, Inc*, 486 US 492 (1988).

304 Use and Abuse of Voluntary Standard-Setting, *supra* note 302.

305 *Avery Dennison Corp v 3M Co*, N. 2:10-cv-07931 (CD Cal filed 21 October 2010).

306 One author estimates patent disputes between Apple and Samsung alone have generated over 50 lawsuits in various jurisdictions: Damien Geradin, “The European Commission Policy Towards the Licensing of Standard-Essential Patents: Where Do We Stand?” (2013) 9(4) Journal of Competition Law & Economics 1125 [EC Policy on Licensing SEPs].

307 A Pragmatist’s Approach, *supra* note 278.

308 *Ibid*; The Art of Persuasion, *supra* note 71 at 3; Antitrust Law to Police the Holdup Problem, *supra* note 277 at 915.

technology.[309] It is often critical for those introducing smartphones and like devices incorporating new technology to build in backward interoperability with older technology. This potentially allows holders of patents garnering the earlier standard to "hold-up" entry and growth of newer competing technology. Such a threat of hold-up may also have additional negative feedback effects, if the threat of hold-up makes standard setting organization members reluctant to participate in standard-setting or to adopt standards, reducing the benefits of standard-setting overall.[310]

U.S. literature and commentators disagree on the significance of the hold-up concern in the context of standard-setting.[311] Slightly older literature disputes the magnitude of the hold-up problem, and questions whether there is empirical evidence that hold-up is "common enough and costly enough in actuality to warrant policy changes".[312] More recently, multiple authors point to a lack of "real-world evidence" or empirical studies indicating the frequency or extent to which the use of patented technologies in standards has led to hold-up or impeded the development of effective standards.[313] FTC Commissioner Maureen Ohlhausen has emphasized the need to analyze specific facts surrounding possible hold-up, to take into account factors in the market that could mitigate the likelihood of hold-up actually occurring.[314] Other authors argue that patent hold-up is an issue, and that it reduces dynamic efficiency without providing offsetting benefits.[315] Simcoe argues the high litigation rates for patents declared essential to SSOs, although not necessarily indicative of widespread hold-up, are a strong indication that the market for SEPs is not functioning well.[316] We suggest that even if the extent of hold-up is unclear, action by antitrust authorities in the U.S. and EU suggest that hold-up after standards have been set is a legitimate concern.

Hold-up cases in the U.S. (and the EU) can be conceptualized as involving two basic categories of concern: (i) concern over unilateral conduct during the standard-setting process, and (ii)

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309 See one of the seminal papers on hold-up, Mark A. Lemley & Carl Shapiro, "Patent Holdup and Royalty Stacking" (2007) 85 Texas Law Review 1992 [Royalty Stacking].

310 The Art of Persuasion, *supra* note 71 at 4.

311 Use and Abuse of Voluntary Standard-Setting, *supra* note 302; Antitrust Law to Police the Holdup Problem, *supra* note 277 at 921.

312 Damien Geradin, Anne Layne-Farrar & Jorge Padilla, "The Complements Problem Within Standard Setting: Assessing The Evidence on Royalty Stacking" (2008) 14 Boston University Journal of Science & Technology Law 144 [The Complements Problem]; J. Gregory Sidak, "Holdup, Royalty Stacking, and the Presumption of Injunctive Relief for Patent Infringement: A Reply to Lemley and Shapiro" (2008) 92 Minnesota Law Review 714.

313 Richard S. Taffet & Hill B. Wellford, "Questioning the FTCs Incremental Value Test and Claims of Widespread Hold-up in Technology Standards" (2012) 57 The Antitrust Bulletin 161; Roger C. Brooks, "Patent 'Hold-up', Standards-Setting Organizations and the FTC's Campaign Against Innovators" (2011) 39 AIPLA Quarterly Journal 435 [Campaign Against Innovators]; EC Policy on Licensing SEPs, *supra* note 306 at 1128.

314 A Pragmatist's Approach, *supra* note 278. Examples of such factors may include the reputational and business costs to a patent holder who engages in hold-up or cross-licensing agreements that protect against hold-up.

315 Daniel Culley, Malik Dhanani & Maurits Dolmans, "Learning from Rambus – How to Tame Those Troublesome Trolls" (2012) 57 The Antitrust Bulletin 117 [Learning from Rambus].

316 Timothy S. Simcoe, "Private and Public Approaches to Patent Hold-up in Industry Standard Setting" (2012) 57 The Antitrust Bulletin 59 [Private and Public Approaches].

concern over conduct after the standard has been adopted.[317] Cases in the first category in the U.S. have involved deceptive conduct that distorts the outcome of the standard-setting process with anti-competitive effects (referred to as standards "ambush").[318] Cases in the second category in the U.S. have involved the abrogation of licensing commitments made with respect to standard-essential patents, regardless of whether deception is involved.[319] Both categories of cases are discussed below, but the second category has been the focus of the most recent attention. In particular, a "hot topic" has been whether injunctions should be available to the holders of standard-essential patents subject to FRAND licensing commitments.

(b) Deception in Standard-Setting

Deception or "ambush" in standard-setting has been a concern of the Agencies for several years. The theory of harm is that deceptive conduct by a participant in the standard-setting process could lead to the participant's proprietary technology being incorporated into the standard in preference over other technology, enabling the participant to engage in hold-up after the adoption of the standard.[320]

(i) Key Cases

A leading case in this area is the private action of *Broadcom Corp v Qualcomm Inc* ("*Broadcom*"). The Third Circuit found that a patent holder's intentionally false promise to license standard-essential patents on FRAND terms, coupled with the SSO's reliance on FRAND commitments in selecting the patented technology over other available options, could constitute a claim under Section 2 of the *Sherman Act*.[321] Qualcomm allegedly made intentional, false promises to license on FRAND terms if its patents were included in the standard, and steered the SSO toward incorporating Qualcomm's patents instead of alternatives.

The Court acknowledged that failing to disclose relevant rights to the SSO could lead to patent hold-up.[322] It concluded that in a consensus-oriented private standard-setting environment, the following constitutes actionable anti-competitive conduct: (i) a patent holder's intentionally false promise to license essential proprietary technology on FRAND terms, (ii) coupled with an SSO's reliance on that promise when including the technology in a standard and (iii) the subsequent

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317 Separate Statement of Commissioner J. Thomas Rosch Regarding Google's Standard Essential Patent Enforcement Practices In the Matter of Google Inc., FTC File No. 121-0120 (3 January 2013) [Statement of Rosch in Google] ("False FRAND commitment not only may cripple competition for inclusion in the standard (so-called "ex ante competition"); it may also cripple competition among those using the standard (so-called "ex post" competition). See *Broadcom Corp v Qualcom, Inc*, 501 F (3d) 297 (3d Cir 2007).").

318 See Use and Abuse of Voluntary Standard Setting, *supra* note 304 at 4; Decision and Order, *Dell*, *supra* note 301; *Rambus*, *supra* note 301; See also statement of the Federal Trade Commission, *Unocal, supra* note 301.

319 Use and Abuse of Voluntary Standard Setting, *supra* note 304 at 8; See e.g. *N-Data*, *supra* note 301.

320 Rosch Speech: Section 2 and Standard Setting, *supra* note 301.

321 501 F (3d) 297 (3d Cir 2007) at 314. The lower court had dismissed Broadcom's claims. In separate litigation, the U.S. Federal Court of Appeals found that due to Qualcomm's strategy of concealing its patents from the SSO, Qualcomm had impliedly waived its right to enforce two of its patents against users of the standard. 1245 48 F.3d 1004, 1019-22 (Fed. Cir. 2008).

322 *Ibid.* A failure to disclose may mean the "the patent holder is in a position to "hold up" industry participants from implementing the standard. Industry participants who have invested significant resources developing products and technologies that conform to the standard will find it prohibitively expensive to abandon their investment and switch to another standard" at 310.

breach of that promise. Such deception "harms the competitive process by obscuring the costs of including proprietary technology in a standard and increasing the likelihood that patent rights will confer monopoly power on the patent holder."[323]

The leading case on standard-setting ambush brought by the FTC, and one of the few litigated outcomes, is *In the Matter of Rambus Incorporated*.[324] Rambus, a high-tech company, participated in a standard-setting process for dynamic random access memory (DRAM) computer technology. The FTC argued Rambus intentionally failed to disclose its patents reading on the selected standard, in violation of the SSO's disclosure rules. Only after the industry-wide standard was adopted and users were locked in did Rambus disclose its patents and proceed to seek "excessive" licensing fees. The FTC argued that through its course of deceptive conduct, Rambus was able to contribute to its acquisition of monopoly power by distorting the standard-setting organization's technology choices, and then engage in an anti-competitive "hold up" of the relevant industry.[325]

The essential question in the FTC's Rambus case was whether the company had unlawfully obtained its monopoly in the technology market at issue, which was the alleged violation of U.S. antitrust law. The FTC issued an opinion finding Rambus had engaged in deceptive conduct that violated Section 5 of the *FTC Act*, which in turn was also an unlawful monopolization of the markets for the standardized technology in violation of Section 2 of the *Sherman Act*.[326] The FTC imposed caps on the licensing fees Rambus could charge for licenses related to the disputed technology.[327]

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323 *Ibid*. The case was subsequently transferred to two other state courts and the federal antitrust claims were never adjudicated.

324 *Rambus, supra* note 301; United States, Federal Trade Commission, *In the Matter of Rambus Incorporated* (Matter #110017) (Case Summary 2009) online: <http://www.ftc.gov/enforcement/cases-and-proceedings/cases/2009/05/matter-rambus-incorporated> [Rambus Case Summary]. A private monopolization claim was also brought in this matter, and failed on the jury finding that SSO participants did not have the expectation that members would disclose relevant information, see *Rambus Inc v Hynix Semiconductor Inc*, 2007 US Dist Lexis 47530 (ND Cal 2007). See also the older case Unocal, *supra* note note 301 in which the FTC argued Union Oil had misrepresented to a standard-setting body that research was in the public domain, while pursuing a patent that would permit it charge substantial royalties if Union Oil's research results were included in the standard. Unocal allegedly failed to disclose relevant pending patent applications while participating in standard-setting process before the California Air Resources Board related to clean-burning gasoline, and later asserted its patents. The FTC argued this was a violation of section 5 of the *FTC Act*. The case settled with Union Oil agreeing not enforce the disputed patents.

325 Rambus Case Summary, *ibid*.

326 *In the Matter of Rambus Inc*, FTC Docket No. 9302 (August 2, 2006) at 59-65 and 154-59 (opinion). The FTC's decision followed an initial dismissal of all charges against Rambus by an administrative law judge, who found Rambus' conduct did not amount to deception or violate any duties (such as a duty of good faith disclosure), and finding there was insufficient evidence that there were viable alternatives to Rambus' technology before the standard setting organization.

327 The FTC barred Rambus from making misrepresentations or omissions to standard-setting organizations, required Rambus to license its technology related to the standard and set limits to the royalty rates it could collect, and requiring Rambus to employ an FTC-approved compliance officer to ensure it disclosed relevant patent information to any standard-setting organizations in which it participates in future. See *In the Matter of Rambus Inc*., Final Order (February 5, 2007). The filings in the FTC Rambus decision including regarding the remedy are available at FTC, *In the Matter of Rambus Inc.*, online: <http://www.ftc.gov/enforcement/cases-proceedings/011-0017/rambus-inc-matter>.

The FTC opinion was overturned on appeal in the D.C. Circuit in *Rambus Inc v Federal Trade Commission* ("*Rambus*").[328] The Circuit Court found the FTC had failed to prove that, absent Rambus's alleged deception, an alternative technology would have been selected as the standard. The non-disclosure of patents by Rambus was considered "an insufficient basis for liability" without proof that, but for the deception that had occurred, the SSO would have selected a different technology for inclusion in the standard.[329] The case distinguished *Broadcom* based on the lack of proof that Rambus's behaviour was the *cause* of the SSO's choice of preferred technology for the standard adopted.[330] Without such a finding, the Circuit Court presumed Rambus had lawfully obtained its monopoly; its deceptive conduct leading merely to higher prices was not considered a Section 2 *Sherman Act* violation. Despite this finding, the Court acknowledged the problem of lock-in to a certain technology arising from standardization and its impact on competition after a standard is adopted. The Court left open the possibility that deceptive conduct during the standardization process may violate Section 2 of the *Sherman Act* if it enables the patent holder to unlawfully acquire market power.[331]

(ii) Overview of Commentary

Commentators are critical of the approach to causation adopted by the Court in *Rambus*, arguing it is extremely difficult to prove that different technology would have been adopted but for the impugned conduct, because of uncertainty over hypothetical results of SSO processes and whether the marketplace would have adopted an alternative standard after it was defined by the SSO.[332] An FTC Commissioner involved in the case claimed "the D.C. Circuit got it wrong in *Rambus*" by applying a causation standard inconsistent with the same court's *U.S. v Microsoft ("Microsoft")* decision, where liability was imposed for acts that "reasonably appeared capable" of making a significant contribution to monopoly.[333] The Commissioner argued since it would be reasonable to find that Rambus's conduct may have caused it to acquire or maintain its monopoly power, the defendant should bear the burden of disproving their conduct was the cause of the harm.[334]

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328 *Rambus*, *supra* note 301.

329 *Ibid* at 464 and 467. The Court also found the SSO's rules on disclosure were unclear, and so may not have obliged Rambus to disclose its patents. The D.C. Circuit remanded to the FTC, which, after the Supreme Court of the U.S. denied the FTC's Petition for Writ of Certiorari. The FTC then formally dismissed the complaint against Rambus.

330 *Ibid* at 466.

331 *Ibid* relying on *NYNEX Corp v Discon, Inc*, 525 US 128 (1998) [*NYNEX*] as holding that deceptive conduct by a monopolist designed to exploit its monopoly power might be tortious, but does not constitute monopolization or attempted monopolization in violation of Section 2.; See also *Verizon Communications Inc v Law Offices of Curtis V Trinko, LLP*, 540 US 398 at 407 (2004) ("The opportunity to charge monopoly prices—at least for a short period—is what attracts 'business acumen' in the first place; it induces risk taking that produces innovation and economic growth.")

332 Joseph Farrell et al., "Standard Setting, Patents, and Hold-Up" (2007) 74 Antitrust Law Journal 603 at 653; Misconduct in Standard Setting, *supra* note 67 at 574; Rosch Speech: Section 2 and Standard Setting, *supra* note 301.

333 Rosch Speech*, ibid*; Ankur Kapoor, "What Is the Standard of Causation of Monopoly?" (2009) 23 Antitrust 38 at 38 & 39.

334 Rosch Speech*, ibid*, Commissioner Rosch draws an analogy to Microsoft, where the D.C. Circuit refused to require the government plaintiff "to reconstruct the hypothetical marketplace absent a defendant's anticompetitive conduct." Instead, it was willing to "infer causation" if exclusionary conduct "reasonably appear[s] capable of making a significant contribution to creating or maintaining monopoly power." *Microsoft*, *supra* note 92 at 305. Commissioner Rosch explains that the monopoly maintenance claim in Microsoft

Some authors criticize *Rambus* for its failure to consider alternate outcomes that would have resulted in Rambus failing to obtain the market power it achieved through its deceptive non-disclosure. For instance, the SSO could have chosen a different proprietary technology that was subject to a FRAND commitment, or delayed adopting a standard, or not adopted a standard at all.[335] They argue the *Rambus* decision failed to distinguish between the conduct of a lawful monopolist and a monopoly achieved via deception.[336]

The challenges the FTC faced in the *Rambus* case have been held up as an example of courts "typically giv[ing] broad deference when patents are involved" to avoid the risk of a clash between patent and competition law.[337] In the EU, Rambus's conduct was the subject of commitments strictly limiting the royalty rates the company could charge, suggesting the concern over the impact on competition was legitimate (see further discussion in the EU Standard Setting and FRAND Licensing Commitments section, below).[338]

Rambus and other cases the FTC has brought with respect to abuse in the standard-setting process have tended to involve allegations of the illegal acquisition of monopoly power through deception.[339] This leaves open the question of whether an antitrust violation could be established where a party that was already in a monopoly position, and then chose to employ deception in a standard-setting process to maintain its monopoly.

(c) Abrogation of Licensing Commitments Made for Patents Related to Standards

The FTC has brought recent cases involving commitments to license on FRAND terms that are made in the course of standard-setting and later reneged upon. Unlike earlier cases such as *Rambus*, the theory of harm is not dependent on deceptive conduct in the standard-setting process. The *N-Data* case involved a direct repudiation of commitments made to license at certain rates. More recent cases have considered whether the seeking and enforcement of injunctions for FRAND-encumbered SEPs is a violation of such commitments and of antitrust law.

(i) Direct Repudiation of Commitments

The FTC brought a complaint against N-Data regarding the repudiation of royalty commitments made by an earlier owner of the patents. The FTC alleged the SSO had relied on the

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rested on the theory that Microsoft sought to destroy Netscape and Java because they posed a potential threat to its operating system monopoly. The threat was nascent, and the theory that Netscape and Java would mature into a competitive alternative to Windows was fairly speculative.

335 Antitrust Law to Police the Holdup Problem, *supra* note 277 at 922; Thomas F. Cotter, "Patent Holdup, Patent Remedies, and Antitrust Responses" (2009) 34 Journal of Corporation Law 1151.

336 Antitrust Law to Police the Holdup Problem, *ibid* at 922. The D.C. Circuit relied on the *NYNEX* decision, which it is argued was misplaced because that case involved a lawfully-obtained monopoly, while the FTC found Rambus's acquisition of monopoly power was unlawful.

337 Misconduct in Standard Setting, *supra* note 67 at 575.

338 Case COMP/38.636 *Rambus* (9 December 2009) online: <http://ec.europa.eu/competition/antitrust/cases/dec_docs/38636/38636_1203_1.pdf>. No royalties could be charged for the technology at issue and the case, and royalty rates for subsequent versions were limited to rates lower than Rambus had demanded for its original technologies; Use and Abuse of Voluntary Standard-Setting, *supra* note 304 at 7.

339 See also *Dell* and *Unocal*, *supra* note 301.

commitments made by the patent owner in establishing the standard.[340] The technology was included in a standard in part due to the owner's offer to license its technology for a one-time, limited royalty. After the standard had been widely adopted, such that there were no commercially viable alternative technologies, the related patents were sold to another party. The second patent holder sought to change the terms of the licensing commitment, to increase the prices charged to companies that had implemented the standard, through conduct that involved demands and threatened legal action.[341] N-Data then became the subsequent owner of the patents, at which point the FTC raised its concerns.[342] The FTC claimed the threated or actual anti-competitive effects of the conduct included increased royalties and prices for products implementing the standard and reduced incentives to (i) produce those products, (ii) participate in standard-setting and (iii) rely on standards established by SSOs more generally.[343]

The majority of the FTC found the conduct to be an unfair method of competition and an unfair act or practice in violation of Section 5 of the *FTC Act*. A settlement was reached under which N-Data agreed to honour the licensing commitments made by the predecessor owner and any commitments that N-Data might make to SSOs in future.[344] A dissenting FTC Commissioner opinion characterized the N-Data case as a material departure from the prior line of SSO cases brought by the FTC, which were grounded in deceptive conduct in the standard-setting context that led to, or was likely to lead to, anti-competitive effects.[345]

An open question is whether deception in the standard-setting process, in the manner alleged in *Rambus*, is necessary for Section 2 of the *Sherman Act* to apply. Commentators argue that the FTC's pursuit of N-Data under Section 5 of the *FTC Act* rather than Section 2 of the *Sherman Act* suggests conduct not involving deception might fall outside of the purview of Section 2, on the basis that the monopoly appears to have been legally acquired.[346] From a competition policy standpoint, the DOJ suggests it is illogical to limit antitrust liability to instances of intentional deception. The competitive process is impacted where a party reneges on a commitment to license on FRAND terms, regardless of whether there is intentional deception, particularly if alternative technology would have been adopted in the absence of the FRAND commitments.[347] As one DOJ speaker notes, "competition and consumers appear to suffer either way".[348] The DOJ position is that it is continuing to explore whether Section 2 of the *Sherman Act* extends to situations not involving deception,[349] while the FTC seems to take the approach of instead pursuing conduct under Section 5 of the *FTC Act* where no deception is involved.

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340 See Rosch Speech: Section 2 and Standard Setting, *supra* note 301.

341 *N-Data*, *supra* note 301, Complaint of the FTC at para 31.

342 N-Data was not the party who had made the commitments nor the interim owner who had first reneged upon such commitments.

343 *N-Data*, *supra* note 301 Complaint of the FTC at para 37.

344 *N-Data*, *ibid*.

345 Dissenting Statement of Chairman Majoras, *In the Matter of Negotiated Data Solutions LLC*, File No. 0510094 (23 January 2008).

346 Antitrust Law to Police the Holdup Problem, *supra* note 277 at 942-43.

347 Renata B. Hesse, "IP, Antitrust and Looking Back on the Last Four Years" (Speech delivered at the Global Competition Review 2nd Annual Antitrust Law Leaders Forum, Miami, Florida, 8 February 2013) online: <http://www.justice.gov/atr/public/speeches/292573.pdf> [Speech by Renata Hesse: Looking Back].

348 *Ibid*.

349 *Ibid*.

(ii) Availability of Injunctions for FRAND-Encumbered SEPs

The most recent issue for the FTC and DOJ in abrogation of standard-setting commitments has been whether the seeking and enforcement of injunctions for FRAND-encumbered SEPs is a violation of such commitments and of antitrust law.

As mentioned above, in both the U.S. and the EU there has been extensive private litigation between virtually every large technology company regarding alleged contractual violations of commitments made to license SEPs at reasonable rates. In some cases, this leads to parties seeking and obtaining injunctions. Injunctions in patent infringement proceedings generally lead to the entire product being barred from the applicable jurisdiction, even if the allegedly infringing technology is only a minor component of the overall product. This means the threat of an injunction can lead to patent hold-up, as discussed above. The risk of hold-up and higher than justified royalty rates has raised questions for competition agencies about whether seeking or enforcing an injunction constitutes a violation of FRAND licensing commitments.

(I) Agency Position on Availability of Injunctions for FRAND-Encumbered SEPs

The DOJ has observed that, particularly in products such as smartphones that read on multiple standards, industry participants have begun to question the value of any one infringed patent to the end device.[350] They argue that the value of most small pieces of technology inside a smartphone, for example, is minimal. This raises the issue of whether the holders of the FRAND-encumbered SEP are obtaining unreasonably high royalties in comparison to the value of the patent to the smartphone, by leveraging the potential for the entire phone to be excluded from the market through an injunction or exclusion order, unless that SEP is licensed.[351] The concern of the Agencies is over a specific form of hold-up arising from the threat of injunctions. The potential harm to competition, consumers and innovation arising from injunction hold-up is explained by the FTC as follows:[352]

> By threatening to exclude standard-compliant products from the marketplace, a SEP holder can demand and realize royalty payments that reflect the investments firms make to develop and implement the standard, rather than the economic value of the

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350 *Ibid*.

351 *Ibid*.

352 Statement of the Federal Trade Commission, *In the Matter of Robert Bosch GmbH* (24 April 2013) at 2, online: <http://www.ftc.gov/enforcement/cases-and-proceedings/cases/2013/04/bosch-robert-bosch-gmbh> [FTC Statement Bosch]. The FTC also explained their position in a comment with the FTC Third Party United States Federal Trade Commission's Statement on the Public Interest filed on 6 June 2012 in *In re Certain Wireless Communication Devices, Portable Music & Data Processing Devices, Computers and Components Thereof, Inv*, ITC Investigation No 337-TA-745, online: <www.ftc.gov/os/2012/06/1206ftcwirelesscom.pdf> and in *In re Certain Gaming and Entertainment\ Consoles, Related Software, and Components Thereof, Inv*, No 337-TA-752, online: <http://www.ftc.gov/os/2012/06/1206ftcgamingconsole.pdf> ("High switching costs combined with the threat of an exclusion order could allow a patentee to obtain unreasonable licensing terms despite its RAND commitment, not because its invention is valuable, but because implementers are locked in to practicing the standard. The resulting imbalance between the value of patented technology and the rewards for innovation may be especially acute where the exclusion order is based on a patent covering a small component of a complex multicomponent product. In these ways, the threat of an exclusion order may allow the holder of a RAND encumbered SEP to realize royalty rates that reflect patent hold-up, rather than the value of the patent relative to alternatives, which could raise prices to consumers while undermining the standard-setting process.")

technology itself. This can harm incentives to develop standard-compliant products. The threat of an injunction can also lead to excessive royalties that can be passed along to consumers in the form of higher prices.

An analogous issue is whether the United States International Trade Commission ("ITC") should grant exclusion orders where FRAND-encumbered SEPs are allegedly infringed. ITC exclusion orders are like injunctions, in that their effect is to bar technology from the market by preventing the import and sale of allegedly infringing products in the U.S. In a Joint Policy Statement, the DOJ and U.S. PTO indicated that where a FRAND commitment has been made, the use of exclusion orders at the ITC to remedy infringement of FRAND-encumbered SEPs may cause competitive harm by facilitating patent hold-up and therefore, except in limited circumstances, "may be inconsistent with the public interest".[353] The limited circumstances where such exclusion may be appropriate include when a potential licensee (i) cannot afford a FRAND license, (ii) is not subject to the jurisdiction of a U.S. court that can award damages, (iii) refuses to pay a FRAND-determined royalty or (i) expressly or constructively refuses to negotiate a FRAND license. On this basis, the DOJ/PTO opinion is that injunctions and similar orders for the use of FRAND patents should be "rare".[354]

The Agencies' position is based on the logic that by agreeing to FRAND terms, a patent holder is voluntarily relinquishing the right to seek injunctions against willing licensees and acknowledging that, in most cases, monetary damages are sufficient to remedy infringement.[355] U.S. courts have taken a similar position in private cases,[356] which the FTC points to as "increasing judicial recognition" of the tension between committing to license on FRAND terms and seeking injunctive relief.[357] The commitment to license on FRAND terms suggests no irreparable harm can arise from the use of a FRAND-encumbered SEP and therefore limits on injunctions are seen as appropriate.[358]

The concern over the use of injunctive relief for FRAND-encumbered patents appears to be shared by the U.S. government, at least with respect to exclusion orders from the ITC. In a rare move, the U.S. Trade Representative reversed an ITC exclusion order that barred the

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353 United States, Department of Justice and Patent and Trademark Office, *Policy Statement On Remedies For Standards-Essential Patents Subject To Voluntary F/RAND Commitments* (8 January 2013). The policy statement was focused on the approach of the ITC, but based on the reference to injunctions, seems to apply more broadly.

354 The Art of Persuasion, *supra* note 71 at 6.

355 FTC Statement Bosch, *supra* note 352 at 2.

356 *Microsoft Corp v Motorola, Inc*, 696 F (3d) 872 at 885 (9th Cir 2012) ("Implicit in such a sweeping promise is, at least arguably, a guarantee that the patent-holder will not take steps to keep would-be users from using the patented material, such as seeking an injunction, but will instead proffer licenses consistent with the commitment made.") This was the first U.S. case to find the failure to license on FRAND terms was a breach of the duty of good faith and fair dealing in contract law.; *Apple, Inc v Motorola, Inc*, No. 1:11-cv-08540, 2012 US Dis Lexis 89960, at 45 (ND Ill 22 June, 2012), Posner, J., sitting by designation ("I don't see how, given FRAND, I would be justified in enjoining Apple from infringing the '898 [patent] unless Apple refuses to pay a royalty that meets the FRAND requirement. By committing to license its patents on FRAND terms, Motorola committed to license the '898 to anyone willing to pay a FRAND royalty and thus implicitly acknowledged that a royalty is adequate compensation for a license to use that patent. How could it do otherwise?")

357 FTC Statement Bosch, *supra* note 352 at 2.

358 Fiona M. Scott-Morton, Deputy Assistant Attorney General For Economic Analysis, "The Role of Standards in the Current Patent Wars" (Speech delivered at Charles River Associates Annual Brussels Conference: Economic Developments in European Competition Policy, Brussels, Belgium, 5 December 2012) online: <http://www.justice.gov/atr/public/speeches/289708.pdf> [The Role of Standards].

importation of certain Apple products into the U.S.[359] The exclusion order arose from a claim by Samsung that Apple had infringed a Samsung SEP subject to FRAND licensing commitments. In a letter explaining the decision to reverse the ITC, the U.S. Trade Representative referred extensively to the DOJ/PTO Joint Policy statement on remedies in FRAND cases, indicating he shared the concerns over potential patent hold-up.[360]

Seminal U.S. court decisions such as *eBay* have taken a similar track, holding that FRAND/SEP holders should not automatically be awarded injunctive relief as a remedy. Instead, the plaintiff bears the burden of demonstrating that monetary damages are inadequate to compensate for the infringement.[361]

(II) Recent Investigations and Cases on Availability of Injunctions for FRAND-Encumbered SEPs

At the FTC, concerns over the use of injunctions for FRAND-encumbered patents have been addressed through Section 5 of the *FTC Act*.[362] There have been two FTC decisions to date on liability under Section 5 of the *FTC Act* for breaching FRAND commitments where a party has sought injunctions in order to resolve a SEP/FRAND licensing dispute.[363] Both have been resolved through consent orders, which means that there is no judicial precedent establishing when a SEP owner's licensing practices will violate Section 5.

The first FTC challenge of an SEP owner's use of injunctions was in the merger context, involving Robert Bosch GmbH ("Bosch").[364] Despite having made commitments to license SEPs on FRAND terms, one of the merging parties was seeking injunctive relief against competing manufacturers in an alleged infringement of SEPs. The FTC found that the licensees were willing to license on reasonable terms,[365] and argued that reneging on the commitment to grant such a license constituted unfair competition in violation of Section 5. A consent agreement was finalized in April 2013 that required Bosch to abandon its claims for injunctive relief related to the key standard-essential patents.[366]

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359 Letter from Ambassador Michael B.G. Froman, U.S. Trade Representative, To Irving A. Williamson, Chairman, U.S. ITC Re: Disapproval of the U.S. International Trade Commission's Determination *In the Matter of Certain Electronic Devices, Including Wireless Communication Devices, Portable Music and Data Processing Devices and Tablet Computers* (ITC Investigation No. 337-TA-794) (3 August 2013).

360 *Ibid.*

361 *eBay*, *supra* note 98.

362 Rosch Speech: Section 2 and Standard Setting, *supra* note 301.

363 *In the Matter of Robert Bosch GmbH*, Docket No C-4377 (FTC 23 April 2013) [*Bosch*]; *In the Matter of Motorola Mobility LLC and Google Inc*, Docket No C-4410 (FTC 23 July 2013) [*Motorola*]; The FTC case against Rambus, discussed above, initially included a charge under Section 5 of the *FTC Act* but this argument was dropped. See *Rambus*, *supra* note 301 at 19.

364 *Bosch, ibid*. Interestingly, the case involved patents reading on industry standards for compliance with environmental relations in the repair of MVACs, rather than high tech patents, which are a more common area of concern and discussion.

365 *Ibid* at 19.

366 United States, Federal Trade Commission, Press Release, "FTC Approves Final Order Settling Competition Charges Against Robert Bosch GmbH; FTC Staff Files Comment With Illinois Legislature Regarding Pain Management Services" (24 April 2013), online: <http://www.ftc.gov/news-events/press-releases/2013/04/ftc-approves-final-order-settling-competition-charges-against>. Other remedies unrelated to the SEPs were also required in the transaction.

In its second challenge related to injunctions and SEPs, the FTC alleged that Motorola Mobility ("Motorola") had reneged on FRAND licensing commitments made to several standard-setting bodies to license its standard-essential patents relating to smartphones, tablet computers, and video game systems by seeking injunctions against allegedly willing licensees of those SEPs.[367] The FTC argued this conduct tended to impair competition in violation of Section 5 of the *FTC Act*. The FTC dismissed concerns that prohibiting injunctions could, in itself, harm competition by reducing incentives to innovate and to participate in standard setting, concluding the breach of a FRAND commitment posed a greater risk of harm to competitive processes and consumers.[368]

The Motorola challenge by the FTC came on the heels of the DOJ's significant investigation into three major patent acquisition transactions that included some SEPs subject to FRAND commitments.[369] The DOJ considered Google's acquisition of Motorola Mobility and the acquisitions of certain patents by Apple, Microsoft and RIM. The DOJ expressed concern that acquiring parties might have the incentive or ability to exploit ambiguities in commitments to license standard-essential patents on FRAND terms, in order to hold-up rivals and reduce competition. The DOJ took a careful look at the implications of the transactions on access of competitors to standard-essential patents and concluded that the acquisition would not significantly change existing market dynamics. The DOJ concluded that with respect to RIM and Microsoft's acquisition of Nortel patents, the companies' "low market shares in mobile platforms would likely make a strategy to harm rivals either through injunctions or supra-competitive royalties based on the acquired Nortel SEPs unprofitable".[370] The DOJ accepted from the merging parties commitments not to seek injunctions in disputes involving standard-essential patents, but considered the commitments only lessened, and did not eliminate, the DOJ's concerns over "potential inappropriate use of SEPs [standard essential patents] to disrupt competition".[371] The DOJ emphasized that it would "continue to monitor the use of SEPs in the wireless device industry", in particular with regard to smartphones and tablet computers.[372]

To resolve concerns over Motorola's conduct in seeking injunctive relief as a remedy for infringement of SEPs subject to FRAND-commitment, the FTC entered into a consent agreement with Google, which owned Motorola at the time. The settlement is more complex than the prohibition on injunctive relief imposed in *Bosch*,[373] and it sets out a multi-step process that Motorola is required to undertake before seeking injunctive relief with respect to its standard-essential patents.[374] The FTC characterized the settlement agreement as allowing the negotiation of licensing terms in the absence of an injunction threat, while preserving Motorola's

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367 *Motorola*, *supra* note 363.

368 *Ibid*, Letter from Donald S. Clark (23 July 2013) responding to commentator submissions on the proposed consent agreement [FTC Letter to Motorola Commentators].

369 United States, Department of Justice, Press Release, "Statement of the Department of Justice's Antitrust Division on Its Decision to Close Its Investigations of Google Inc.'s Acquisition of Motorola Mobility Holdings Inc. and the Acquisitions of Certain Patents by Apple Inc., Microsoft Corp. and Research in Motion Ltd." (13 February 2012) online: <http://www.justice.gov/opa/pr/2012/February/12-at-210.html> [Google/Motorola Transaction Approval].

370 *Ibid.*

371 *Ibid.*

372 *Ibid*.

373 A Pragmatist's Approach, *supra* note 278.

374 Ultimately, the Order allows Google to seek injunctive relief if a party "has stated in writing or in sworn testimony that it will not license the FRAND Patent on any terms".

right to recourse where an implementer of the technology delays or refuses to engage in the licensing process or refuses to accept a license. The agreement contains a "defensive use" exception that allows Motorola to respond by seeking injunctive relief for SEP infringement when Motorola faces a threat of injunction based on its own alleged infringement of a SEP. Motorola also committed not to obtain or enforce injunctions or exclusion orders in pending litigation.[375] The FTC has suggested the order reached with Motorola could be considered a template for the resolution of SEP licensing disputes across many industries, although the agency also indicated that the agreement was tailored to the circumstances in some respects such as the defensive-use exception.[376]

The dissenting opinions in *Bosch* and *Motorola* are critical of a perceived failure by the FTC to define meaningful limiting principles that govern the use of its Section 5 authority.[377] The dissent in *Bosch* also argued the FTC should strive for transparency and predictability, meaning it should fully articulate the conduct covered by Section 5 before taking enforcement action.[378] The dissent argued that without a clearly articulated position on the scope of Section 5, the FTC also runs the risk of a serious failure if the case goes to litigation and/or legislative backlash, which have historically occurred where the FTC has taken an expansive view of Section 5.[379]

The FTC confirmed that in appropriate cases it will continue to challenge the seeking of injunctions for FRAND-encumbered patents under Section 5 rather than the *Sherman Act* because this avoids the possibility of treble damages raised by the *Sherman Act* (in contrast, there is no private right of action under Section 5.[380]

(III) Commentary on Availability of Injunctions for FRAND-Encumbered SEPs

Echoing the dissent in *Bosch* and *Motorola*, commentators argue there is considerable uncertainty as to whether a Section 5 *FTC Act* violation could be established in court based on the conduct the FTC addressed via settlements in these two cases.[381] This is in part because the law on the application of Section 5 is not well-developed, even outside the standard-setting context.[382] Market participants may have insufficient guidance about what circumstances involving FRAND commitments will attract FTC attention. Proposed limiting principals for Section 5 claims have included the presence of monopoly power,[383] harm to competition and,

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375 Statement of the FTC, *In the Matter of Google Inc*, FTC File No 121-0120 (3 January 2013) [Google FTC Statement].

376 FTC Letter to Motorola Commentators, *supra* note 368.

377 *Bosch, supra* note 363, Statement Of Commissioner Maureen K. Ohlhausen (24 April 2013) at 2 [Olhausen Statement Bosch]; *Motorola, supra* note 363, and Dissenting Statement Of Commissioner Maureen K. Ohlhausen , FTC File No 121-0120 (3 January 2013) at 2 [Dissenting Olhausen Statement in Motorola].

378 Olhausen Statement Bosch, *supra* note 377. See also A Pragmatist's Approach, *supra* note 278 at 14. Clarity is thought to be required regarding the meaning of "unfair methods of competition" under section 5, the section's relationship to the *Sherman Act* and *Clayton Act* and how the FTC plans to use its enforcement discretion.

379 Olhausen Statement Bosch, *ibid* at 3.

380 FTC Statement Bosch, *supra* note 352 at 2.

381 Misconduct in Standard Setting, *supra* note 67 at 575; Urska Petrovcic, "Patent Hold-Up and The Limits Of Competition Law: A Trans-Atlantic Perspective" (2013) 50 Common Market Law Review 1363 at 1377.

382 Misconduct in Standard Setting, *ibid* at 575.

383 Statement of Rosch in Google, *supra* note 317.

with respect to FRAND licensing issues, requiring the conduct to occur in the context of standard-setting.[384] The FTC has indicated it believes action to prevent the use of injunctions against willing licensees where FRAND licensing commitments have been made is "well within" its Section 5 authority based on prior Supreme Court cases that confirm Section 5 extends to conduct beyond that covered by the *Sherman Act*.[385]

In questioning the FTC's approach in cases such as *Bosch* and *Motorola*, FTC Commissioner Maureen Ohlhausen raised the question of whether limiting the availability of injunctions or requiring the granting of royalty free licenses provides insufficient recognition of intellectual property rights.[386] She emphasizes the need for sufficient evidence that such rights were waived in the participation in the standard-setting process.[387] Without such evidence, she argues the U.S. may be sending a message to the market and to foreign jurisdictions that the value of patent rights may be on the decline in the U.S.[388] The concern is that the value and integrity of patent rights is being eroded through actions such as limiting the availability of injunctive relief in cases where there is no clear finding of a FRAND commitment that addresses availability of such relief.[389]

U.S. commentators observe that the agency action to date leaves open several questions regarding antitrust enforcement for violation of FRAND commitments. One key, open question is what constitutes a "fair and reasonable" royalty, which can be ambiguous. Another is the question of who constitutes a "willing licensee" in the eyes of courts and enforcers. It also remains unclear what exactly constitutes a clear commitment not to seek an injunction. Both the issue of whether the licensee was willing and whether a commitment was made became the subject of disagreement among the FTC Commissioners in *Motorola*,[390] and such determinations may prove fact-specific. These open questions are key considerations in determining whether injunctive relief may be sought without breaching FRAND commitments.

Another open question is whether competition enforcement could extend to commitments that are made outside of the SSO context, relied upon in adoption of *de facto* standards and then violated. A patent licensing commitment may be made publicly, outside of an SSO, with the same result that the commitment drives adoption of a standard technology in reliance upon the stated licensing commitments.[391] Commitments not governed by SSOs would seem to raise similar theoretical potential for consumer harm where there is a commitment, industry lock-in and a subsequent breach of the commitment. There may even be the potential for greater harm,

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384 Google FTC Statement, *supra* note 375.

385 FTC Statement Bosch, *supra* note 380 at 3.

386 A Pragmatist's Approach, *supra* note 278.

387 *Ibid.*

388 *Ibid*.

389 *Ibid*. Commissioner Ohlhausen indicated she believed Judge Posner was correct in his assessment of this issue in *Apple v Motorola*.

390 Dissenting Ohlhausen Statement in Motorola, *supra* note 377.

391 Commentators have given the example of Microsoft's public RAND commitment to license its ActiveSync technology, which became the industry standard. Since then, Microsoft has allegedly failed to honour the commitments, bundling ActiveSync with other patents for licensing and obtaining ITC exclusion orders regarding use of ActiveSync by competitors. See D. Daniel Sokol, Antitrust & Competition Policy Blog, Non-SSO Patent Commitments and Pledges symposium: David Balto comments, online: <http://lawprofessors.typepad.com/antitrustprof_blog/2013/10/non-sso-patent-commitments-and-pledges-symposium-david-balto-comments.html>.

since there is no SSO to constrain and deter opportunistic conduct of the holders of standard-essential patents through checks, balances and oversight in the adoption of the standard.[392] The DOJ has acknowledged that harm "comparable" to the deterred innovation and raised prices that can arise from SEP hold-up "may also arise in situations outside of the SSO context where a patent holder's prior actions, such as open source commitments, lead others to make complementary investments"[393] However, a DOJ representative has also argued that the hold-up power of SEPs is unique because it arises from a collective decision by competitors in the standards context, in contrast to a single innovation deployed unilaterally by its owner.[394] To date, the occurrence of such conduct within the standard-setting context has been suggested as a limiting principle in enforcement;[395] the collective action in the standards context may be the additional factor that justifies intervention by competition law in what would otherwise be a unilateral exercise of a patent right. It is unclear to what extent and when it would be appropriate for antitrust enforcers to address such conduct where standards are reached in the absence of an SSO.

(d) Resolving Standard-Setting and Competition Concerns

The literature and comments from antitrust authorities generally discuss three means of addressing issues of patent hold-up in the standard-setting context: (i) through governance by SSOs, (ii) through antitrust agency guidance, and (iii) through agency intervention such as in the cases discussed above.[396]

SSOs often adopt intellectual property policies that can play an important role in reducing the potential for members to engage in hold-up and accelerate the implementation of the standardized technology while enabling licensing on competitive terms and conditions.[397] Such policies can mitigate hold-up potential by promoting or requiring disclosure of patent holdings relevant to standards being considered and by requiring commitments to license standard-essential patents on FRAND terms, including specifying when members are permitted to seek injunctions.[398]

SSOs have faced criticism for vagueness in defining FRAND commitments. This includes uncertainty over what is considered to be a "FRAND" rate and when it is permissible to seek

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392 *Ibid*.

393 Google/Motorola Transaction Approval, *supra* note 369.

394 The Role of Standards, *supra* note 358.

395 Google FTC Statement, *supra* note 375.

396 For the purposes of this discussion we leave aside patent-law based solutions to issues in the context of standard-setting. For example, one article identifies the patent misuse doctrine as a potential solution, although this has since been greatly narrowed by the courts. Misconduct in Standard Setting, *supra* note 67. Another paper considers the applicability of equitable estoppel in patent law as a preferable means of addressing patent hold-up. Bruce H. Kobayashi & Joshua D. Wright, "Federalism, Substantive Pre-emption, and Limits on Antitrust: An Application to Patent Holdup" (2009) 5 Journal of Competition Law & Economics 469 at 471. Antitrust Law to Police the Holdup Problem, *supra* note 277 suggests at 938 the estoppel doctrine is insufficient to remedy standard-setting concerns because it generally requires direct communication between the patentee and the infringer and proof of substantial reliance in taking an action, which may be difficult to prove in the standard-setting context.

397 Antitrust Law to Police the Holdup Problem, *supra* note 277 at 915.

398 See discussion of SSO intellectual property policies in Michael A. Lindsay, "Safeguarding the Standard: Standards Organizations, Patent Hold-Up And Other Forms Of Capture" (2012) 57 The Antitrust Bulletin 17.

injunctions.[399] The SSO will often merely set out a framework for licensing, with the specific FRAND terms agreed to in bilateral agreements.[400] Vagueness in the boundaries of FRAND commitments is thought to have contributed to the extensive private litigation between several large technology companies in the Federal Courts and at the ITC.[401]

Authors and key agency representatives from the U.S. and EU have emphasized the significant role SSO rules can play in protecting against hold-up.[402] Some argue SSO policies, and collaboration on such policies with antitrust authorities, are a less expensive, less adversarial and less time consuming means of addressing hold-up issues in the SSO context in comparison to litigation by antitrust authorities.[403] The DOJ has engaged in advocacy for several years, working in conjunction with the EC, in an effort to have SSOs make their IP policies more pro-competitive.[404] The DOJ has suggested SSOs consider the following to reduce the risks of patent hold up, including:[405]

- Establishing procedures that seek to identify, in advance, proposed technology that requires licensing of patents not subject to FRAND commitments and consciously determine whether that technology should be included in the standard. Early disclosure of patents reading on a standard can help inform the evaluation of which standard should be adopted and provide more time to negotiate terms and conditions of potential licenses if the technology is adopted;[406]

- Making FRAND commitments clear;

- Making sure FRAND encumbrances are conveyed to subsequent owners of patents (e.g. addressing the issues raised in *N-Data*);

- Permitting cash-only licensing options, and prohibiting mandatory cross-licensing. The concern here is that it can be challenging to determine whether the value of complex cross-

399 The Role of Standards, *supra* note 358; A Pragmatist's Approach, *supra* note 298; Private and Public Approaches, *supra* note 316.

400 Misconduct in Standard Setting, *supra* note 67.

401 *Motorola*, *supra* note 363; *In the Matter of Certain Electronic Devices, Including Wireless Communication Devices, Portable Music and Data Processing Devices and Tablet Computers* (ITC Investigation No. 337-TA-794) finding Apple Inc. violated patents held by Samsung Electronics Co., Ltd. There is also litigation before the Southern District of Florida between Motorola Mobility and Intellectual Ventures in which FRAND commitments have been raised as a defence. *Intellectual Ventures v Motorola Mobility* (Southern District of Florida, case No 13-cv-61538).

402 Kai-Uwe Kühn, Fiona Scott Morton & Howard Shelanski, "Standard Setting Organizations Can Help Solve the Standard Essential Patents Licensing Problem" (2013) Special Issue CPI Antitrust Chronicle 1; Campaign Against Innovators, *supra* note 313 at Section V.

403 The Art Of Persuasion, *supra* note 71 at 5.

404 *Ibid* at 6. See for example Renata Hesse, Deputy Assistant Attorney General, Antitrust Division, U.S. Department of Justice, "Six 'Small' Proposals for SSOs Before Lunch" (Speech delivered at the ITU-T Patent Roundtable, Geneva, Switzerland, 10 October 2012) online: <http://www.justice.gov/atr/public/speeches/287855.pdf>. The American Bar Association is also working, through its Science and Technology and IP sections, to create a best-practices guide for alternative dispute resolution of FRAND disputes.

405 The Role of Standards, *supra* note 358; Renata Hesse, *ibid.*

406 See e.g. United States, American National Standards Institute (ANSI), "Guidelines for Implementation of the ANSI Patent Policy III.A" (Feb 2007) online: <http://standards.ieee.org/about/sasb/audcom/ansi_patent.pdf>.

licenses, where such licenses are required in exchange for a license to a SEP, are actually equivalent to a FRAND rate;

- Requiring certain processes be followed to resolve FRAND disputes, or requiring certain commitments in order to limit injunctive actions for FRAND-encumbered SEP infringement claims made against willing licensees. The DOJ suggests that injunctions be permitted only where the standards implementer is unwilling to have a neutral third-party determine the appropriate FRAND terms or is unwilling to accept the FRAND terms approved by such a third-party;

- Creating guidelines for what rates are considered to be FRAND, or providing for arbitration provisions to determine FRAND rates; and

- Attempting to determine which patents are truly essential to the standard among those patent owners claim are essential. The DOJ notes there has been a surge in patents being declared standard-essential, and also recent litigation where the standards-compliant product did not in fact infringe a supposed SEP.

Some commentators argue SSO policies are the best solution to antitrust concerns over standard-setting, because disputes related to FRAND are largely a contractual matter.[407] Since SSO members and users of the technology knew or should have known about the potential for hold-up, but participated anyway, some claim it is not up to public agency intervention to rescue the parties involved. In her dissent in *Bosch*, Commissioner Ohlhausen characterizes the conduct by Bosch as "garden variety breach-of-contract" that should be addressed by the relevant SSOs or by the affected parties through contract or patent claims.[408] Another FTC Commissioner argues antitrust laws are not well-suited to govern what are essentially contractual disputes over SEP commitments.[409] Others claim policing SSOs with competition law will undermine incentives for SSO participation, reducing the benefits of standard-setting,[410] although this argument has been criticized for its lack of supporting empirical evidence.[411]

Some commentators argue informal constraints on SSO participants, such as a desire to promote downstream implementation of their technology and repeat involvement in standard-setting, act to restrain participants from charging unreasonable royalty rates.[412] Other authors suggest SSO members have incentives that diverge from the public interest,[413] making it less likely that SSOs will form self-regulatory policies which promote competition. For example, each SSO member would likely choose to maximize its own ability to hold-up other organizations not

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407 Herbert J. Hovenkamp, "Standards Ownership and Competition Policy" (2007) 48 Boston College Law Review 87 referring to this argument at 106.

408 Olhausen Statement Bosch, *supra* note 377.

409 Joshua D. Wright, FTC Commissioner, "SSOs, FRAND, and Antitrust: Lessons from the Economics of Incomplete Contracts The Commercial Function of Patents in Today's Innovation Economy" (Speech delivered at George Mason University School of Law, Arlington, VA, 12 September 2013), online: <http://www.ftc.gov/public-statements/2013/09/ssos-frand-and-antitrust-lessons-economics-incomplete-contracts>.

410 David J. Teece & Edward F. Sherry, "Standards Setting and Antitrust" (2003) 87 Minnesota Law Review 1913 at 1986.

411 Antitrust Law to Police the Holdup Problem, *supra* note 277 at 923.

412 *Ibid*, referring to such arguments.

413 Learning from Rambus, *supra* note 315.

participating in the SSO, even if only for the purposes of extracting a cross-license from those organizations.[414] Hoffman and Simons explain that an SSO might adopt rules that expose it to hold-up, if such rules resulted in more participation in standard development and faster adoption of standards incorporating superior technologies.[415] Cary concludes that informal constraints offer no guarantee that hold-up will be prevented and so do not eliminate the potential need for antitrust enforcement.[416]

The FTC and some literature acknowledge a public interest in achieving the benefits of standard-setting activity that justifies, and even necessitates, the role of antitrust authorities in the regulation of such activity.[417] The harm suffered by foreclosing competitive alternatives is borne by consumers and other competitors, not solely by the contracting parties.[418] Culley points out that non-SSO members who are not subject to SSO oversight could be the parties engaging in hold-up; no amount of clarity in the SSO policies applicable to members can control such behaviour.[419] Further, to the extent that commitments made outside of the auspices of an SSO for *de facto* standards raise competition concern, as discussed above, there would be no SSO policies that could mitigate such competition concerns. SSO regulation is thus not likely sufficient on its own to prevent harm and, as such, antitrust intervention may be appropriate.[420]

(e) Conclusion on Standard-Setting and Competition Concerns in the U.S.

The recent enforcement action by the FTC over standard-setting conduct is rooted in concern over patent hold-up, either in the context of standard-setting "ambush" or through the abrogation of licensing commitments (including seeking injunctions with respect to standard essential patents in certain circumstances).

The FTC was not successful in establishing an antitrust violation in *Rambus,* where it argued deception in the standard-setting process led to the unlawful acquisition of a monopoly. However, the court decision overturning the FTC in this case has been criticized and the same conduct resulted in remedies being imposed in a parallel case in the EU. There is a question as to whether intentional deception in standard-setting is required for action under the *Sherman Act* rather than the *FTC Act* (which has been relied on in cases to date). The DOJ argues

414 *Ibid*.

415 D. Bruce Hoffman & Joseph J. Simons, "Known Unknowns: Uncertainty and Its Implications for Antitrust Policy and Enforcement in the Standard-Setting Context" (2012) 57 The Antitrust Bulletin 89.

416 Antitrust Law to Police the Holdup Problem, *supra* note 277 at 923.

417 *Ibid* at 3.

418 Misconduct in Standard Setting, *supra* note 67 at 572. The example is provided where firms, unable to relay on the FRAND commitments of others, are less likely to participate in standard-setting, leading to less interoperability of technology. Consumers may then find themselves paying for multiple, non-interoperable platforms or paying higher prices for products that work with the platform they chose to adopt. Antitrust Law to Police the Holdup Problem, *supra* note 277 at 941.

419 Learning from Rambus, *supra* note 315 at 136. The authors provide the example of Rambus, which withdrew from the relevant SSO and later asserted new patents against manufacturers and customers in ITC proceedings.

420 Speech by Renata Hesse: Looking Back, *supra* note 347 ("Competition advocacy [to SSOs] can, however, only go so far. To stop owners of FRAND-encumbered SEPs from harming consumers through arguably anti-competitive behavior, agencies and private parties may need to resort to judicial remedies."); *Bosch*, *supra* note 363.

competition and consumer harm may arise where standard-setting commitments are not upheld, regardless of whether there is intentional deception.

The Agencies' position is that the use of injunctive relief in cases involving standard-essential patents subject to FRAND licensing commitments may disrupt competition and should be limited to certain circumstances. The FTC has reached consent agreements in two cases where it challenged the seeking of injunctions for FRAND-encumbered SEPs, but there have been no U.S. court rulings in FTC cases. The FTC has faced criticism for a perceived failure to define meaningful limiting principles to govern the use of its *FTC Act* Section 5 authority to address such conduct. Critics emphasize that, to avoid impinging on patent rights, such cases should include sufficient evidence that rights to an injunction were waived in the standard-setting process.

Open questions remain as to what constitutes a FRAND royalty, and who is considered a "willing" licensee. There is also a question as to whether it would be appropriate for antitrust enforcers to take similar action where there is a breach of commitments related to *de facto* standards that arise outside of the SSO context.

SSO policies are considered to play a significant role in mitigating the potential for members to engage in patent hold-up. Antitrust authorities in the U.S. are engaging in advocacy efforts that include specific suggestions on how SSOs can improve the pro-competitiveness of their policies.

There are arguments that SSO self-regulation is not a complete solution to competition concerns in the context of standard-setting involving patents. The interests of SSO members individually and collectively do not necessarily coincide with the public interest. Although SSO disputes may be contractual in nature, anti-competitive harm may occur to consumers and competitors that are not parties to the agreement. Further, SSO policies are insufficient to address concerns over conduct by non-SSO members, or where standards are adopted in the absence of an SSO. As a matter of competition policy, it thus remains appropriate for antitrust authorities to engage in oversight of issues related to standard-setting and patents in conjunction with encouraging pro-competitive SSO policies.

2. Reverse Payment Settlements

In the U.S., both private plaintiffs and federal enforcement agencies have challenged reverse payment settlements as horizontal agreements to allocate markets and block entry of generic competition.[421] It is not surprising that reverse payments have merited antitrust attention, given the significance of generic competition in the U.S. (and other jurisdictions).[422] By one estimate,

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421 ABA Federal Antitrust Guidelines, *supra* note 56. See for example the recent agreement by Bayer to settle a private class action over reverse payments, with the continuing action against the generic defendants. Plaintiffs' Notice of Motion and Motion for Preliminary Approval of Class Settlement with Bayer Defendants, Cipro Cases I and II (Cal Sup Court 11 July 2013).

422 The FTC has also recently used the merger context to promote competition between generic drugs (although reverse payments were not involved in the case). In the acquisition by drug firm Teva of rival firm Cephalon, the FTC required the divestiture of certain generic drugs, including the generic Fentanyl product, which was the subject of a fine in an EU reverse payment settlement case. The FTC also required Teva to enter into a supply agreement that would allow a competing firm to sell a generic version of Cephalon's wakefulness drug Provigil in 2012. See *In the Matter of Teva Pharmaceutical Industries Ltd, and Cephalon, Inc* (2 July 2012), FTC, online: <http://www.ftc.gov/enforcement/cases-and-proceedings/cases/2012/07/matter-teva-pharmaceutical-industries-ltd-and>.

about 80% of prescriptions written annually in the U.S. were filled by generic drugs in 2011, with generic prices being on average 75% lower than branded drugs.[423]

In the U.S. context, reverse payment settlements refer to a sub-category of settlements of litigation related to paragraph IV certification in an abbreviated new drug application under the *Hatch-Waxman Act* regime ("*Hatch-Waxman*"). *Hatch-Waxman* creates an abbreviated process that permits generic drugs to "piggyback" on the findings of safety and effectiveness for the branded drug, in order to obtain marketing approval from the U.S. Food and Drug Administration for the generic version of the drug. Without getting into the detail of the complex regulatory scheme, essentially a generic company files an application for approval of generic market entry with the FDA that certifies certain grounds to enable entry (such as patent expiry, or under the contentious paragraph IV, certification that the patent is invalid or that will not be infringed by the proposed generic entry).[424] The branded company is notified of the application, and then has a certain period within which to commence a patent infringement action against the generic company. Once such an action is commenced, there is a stay during which the generic application will not be approved, unless during that stay a court determines the patent is invalid or not infringed. Litigation related to paragraph IV certification under *Hatch-Waxman* has been on the rise in recent years.[425]

(a) FTC Position on Reverse Payment Settlements

Since the early 2000's the FTC has taken the position that reverse payment settlements are prohibited by U.S. antitrust law because they restrict competition and increase drug prices, leading to higher health-care costs.[426] An FTC study in 2010 estimated that a ban on reverse payment settlements involving payments to a generic in exchange for delayed entry would result in approximately $3.5 billion in annual savings to American consumers.[427] The Congressional Budget Office estimated the U.S. Federal Government savings alone would be $900 million

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423 Julie Brill, Commissioner at the Federal Trade Commission, "Antitrust and Innovation: Rebalancing the Scale" (Speech Delivered to the International Bar Association, 14 September 2013) online: <http://www.ftc.gov/sites/default/files/documents/public_statements/antitrust-and-innovation-rebalancing-scale/130914iba_0.pdf> referring to a study by IMS Institute for Healthcare Informatics, The Use of Medicines in the United States: Review of 2011 (April 2012) for the 80% figure (no source for the 75% figure is cited in Commissioner Brill's speech) [FTC Commissioner Brill Innovation Speech].

424 For a more in-depth discussion of the U.S. and Canadian generic drug regulatory approval processes, see Ron Dimock & Geoff Mowatt, "Reverse Payment Settlements in Pharmaceutical Litigation: What Are They and do They Occur in Canada?" (2009) [Reverse Payment Settlements in Canada].

425 PWC Study, *supra* note 532 at 27 estimates that between 1995-2000 there were 17 such cases, and between 2007-2012 the number rose to 77 cases.

426 Ute Zinsmeister & Maria Held, "Pay-for-Delay or Reverse Payment Settlements – A War of Roses Between Competition and Patent Law in Europe and in the United States? European Commission Fines Lundbeck and Other Pharma Companies for Delaying Market Entry of Generic Medicines" (2013) 34 European Competition Law Review 621 at 623 [A War of Roses]; See for example FTC statement to US Congress that "pay for delay settlements should be prohibited under the antitrust laws", FTC, "Prepared Statement of the FTC to the Committee on the Judiciary of the US House of Representatives Subcommittee on Courts and Competition Policy on Anticompetitive Pay-for-Delay Settlements in the Pharmaceutical Industry: Why Consumers and the Federal Government are Paying Too Much for Prescription Drugs" (3 June 2009); Generic Drug Entry, *supra* note 104 at 25.

427 United States, Federal Trade Commission, *Pay-for-Delay: How Drug Company Pay-Offs Cost Consumers Billions*, (United States: Federal Trade Commission, 2010) at 2, online: <http://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf> [FTC Pay for Delay Study].

during 2010-2015 period and $2.7 billion during 2010-2020 period from eliminating reverse payment settlements.[428]

The FTC view is that reverse payment settlements can mean significant additional earnings for branded companies, if the branded company effectively extends their monopoly in the market where the generic might otherwise have entered.[429] The 2010 FTC study found reverse payment settlements involving compensation from the branded company to the generic restricted entry an average of 17 months longer than settlement agreements without payments.[430]

The FTC argues that, although branded companies and generic firms benefit from reverse payment settlements, "consumers lose the possibility of earlier generic entry".[431] The FTC is concerned consumers and public health agencies lose the benefits of generic competition (i.e., lower prices) prior to patent expiration that would otherwise arise from (i) litigation where the generic prevailed in the infringement suit, (ii) settlements without payments for delay and (iii) "at risk" entry by generics, where the generic proceeds to enter the market before a favourable infringement ruling is reached.[432] The FTC is concerned over settlement agreements where consideration flows to the generic in exchange for delayed entry. Settlement agreements involving an earlier market entry date for the generic (before the patent expires) but that do not involve a reverse payment appear to be permitted.[433] **Appendix D** contains a brief summary of the reverse payment settlement cases engaged in by the FTC and their status.

Several pieces of proposed U.S. legislation have been introduced to prohibit reverse payment settlements, but none have been enacted.[434] Opponents argued an outright ban on reverse payment settlements would stifle innovation, while making both branded and generic drugs

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428 United States, Congressional Budget Office, S. 369, the *Preserve Access to Affordable Generics Act*, As Reported by the Senate Judiciary Committee on October 15, 2009, (United States, 2010), online: <http://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/115xx/doc11582/s369_updated_table.pdf>.

429 As one CEO of a branded company noted regarding a settlement that was later subject to an FTC challenge, the settlement brought "[s]ix more years of patent protection. That's $4 billion in sales that no one expected." *FTC v Cephalon, Inc*, No 08-cv-2141 (ED Pa), complaint filed 13 February 2008, online <http://www2.ftc.gov/os/caselist/0610182/080213complaint.pdf>.

430 FTC Pay for Delay Study, *supra* note 427.

431 FTC, "Prepared Statement of the FTC to the Committee on the Judiciary of the US House of Representatives Subcommittee on Courts and Competition Policy on Anticompetitive Settlements in the Pharmaceutical Industry: Benefits of a Legislative Solution" (17 January 2007).

432 Markus Meier, "FTC Briefing on Pharmaceutical Pay-for-Delay Settlements" (Remarks delivered at Competition Bureau Workshop on Antitrust Issues in the Pharmaceutical Sector, Ottawa, 13 November 2013) at 9 [Briefing on Pharmaceutical Pay-for-Delay Settlements].

433 *Federal Trade Commission v Actavis, Inc*, 133 S Ct 2223 (2013) at 19, where the U.S. Supreme Court indicated that parties were permitted to settle their lawsuits in such a manner permitting generic entry [*Actavis*].

434 *Actavis, supra* note 433 (dissent) at 9, pointing out that at least 11 bills related to reverse payment settlements have been introduced in the Senate or House since 2006, without any being passed. See e.g. *HR 1432, 110th Cong* (2007); *HR 3200, 11th Cong* §2563 (a)(1)(A)(2009). The latter proposed legislation prohibiting the generic filer of an abbreviated new drug application under the *Hatch-Waxman* regime from receiving "anything of value", placing the burden on the parties to justify any settlement. It would also have empowered the FTC to create regulations exempting certain agreements where it was determined the agreements would enhance competition.

more expensive.[435] U.S. associations representing generic drug companies and IP owners argue antitrust laws and FTC power are sufficient to challenge any anti-competitive reverse payment settlements, while leaving room for other types of settlements that enable earlier generic entry.[436] Legislators ultimately responded to the FTC's concern over reverse payment settlements by passing legislation that requires settlements of patent disputes between branded companies and generics to be filed with the FTC and DOJ for antitrust review.[437] The filing process allows the Agencies to consider the universe of settlements and challenge any they believe are anti-competitive reverse payment settlements.

The Agencies report a declining trend in settlements potentially involving pay-for-delay each year from fiscal year 2006 (50% of all settlements) through to 2011 (18% of all settlements).[438] However, the 2012 report on the agreements filed saw an uptick to nearly 30% of all settlements categorized as potentially involving pay-for-delay, a significant increase from the 2011 reporting period.[439] The uptick has been attributed by some to the focus of U.S. courts on the scope of patent test, discussed below, which shielded many such agreements from antitrust scrutiny.[440] Despite the change, the vast majority of patent settlements in 2012 (greater than 70%) continued to be resolved without compensation being paid to the generic company. The overall number of reported settlements has also climbed year over year since fiscal year 2005, with the exception of 2011-2012, when it declined slightly.[441]

Critics of the FTC's position argue that where there is a true dispute about the validity or the infringement of the patent between the parties, there may be a genuine, pro-competitive interest in ending time and cost-consuming litigation through a reverse payment settlement.[442] There may be a quantifiable public benefit from settlements overall; a recent industry-commissioned study found that settlements of litigation that led to generic pharmaceutical launches before patent expiry resulted in savings to consumers of $25.5 billion from 2005-2012, with a projected

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435 Donald Zuhn, "Bill Prohibiting Reverse Payments Voted out of Committee" (25 July 2011) online: Patent Docs: Biotech & Pharma Patent Law & News Blog <http://www.patentdocs.org/2011/07/bill-prohibiting-reverse-payments-voted-out-of-committee.html> quoting the Intellectual Property Owners Association, referring to similar arguments by the Generic Pharmaceutical Association.

436 *Ibid.*

437 The *Hatch-Waxman Act* was amended by the *Medicare Prescription Drug Improvements and Modernization Act of 2003*, Pub L N 108-173, §§1111-1118, 117 Stat 2066, 2461-2464 (codified as amended at 21 USC §355(j)) to require settlements of Paragraph IV *Hatch-Waxman Act* litigation to be filed.

438 Briefing on Pharmaceutical Pay-for-Delay Settlements, *supra* note 432 at 11, reflecting a decline year over year in potential pay for delay settlements, from 50% of all settlements in fiscal year 2006 to 18% in 2011. This disregards the number of reverse payment settlements in the first two years of tracking: in 2004 (0%) and 2005 (27%).

439 The reporting period is the fiscal year of the FTC, from October 1- September 30. United States, Federal Trade Commission, *Agreements Filed with the Federal Trade Commission under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003: Overview of Agreements Filed in FY 2012 A Report by the Bureau of Competition*, (United States: Federal Trade Commission, 2013) (reporting 40 potential pay-for-delay agreements filed in 2011, with 140 settlements filed overall) [2012 FTC Patent Litigation Settlement Report].

440 FTC Commissioner Brill Innovation Speech, *supra* note 423.

441 2012 FTC Patent Litigation Settlement Report, *supra* note 439.

442 A War of Roses, *supra* note 426 at 624.

additional $61.7 billion in future savings.[443] About one third of the total savings flowed to the Federal Government. However, this figure combines both reverse payment settlements and settlements not involving payments to the generic, and so it is not comparable to the FTC estimate of cost savings from eliminating reverse payment settlements.

The rising number of settlements reached year-over-year, and the decline in settlements involving reverse payments, suggests settlements are continuing to be reached but that FTC tracking and enforcement action (or some other factor) is reducing the number of potentially troublesome settlements. It is not clear from the FTC data if there is any chilling effect occurring on total settlements reached overall (i.e. that a higher number of settlements might have been reached in the absence of tracking and enforcement efforts).

Finally, critics argue that the FTC position is inconsistent with patent law, which assumes a patent is valid until it is proven otherwise or withdrawn by the patentee.[444]

(b) U.S. Jurisprudence Before *Actavis*

Until the recent *Actavis* decision by the U.S. Supreme Court, lower U.S. courts were split on their view of reverse payment settlements.

One perspective was that reverse payment settlements involving the transfer of value do not infringe antitrust laws if they are within the exclusionary scope of the patent in dispute.[445] Although antitrust laws typically prohibit agreements where one competitor pays the other not to enter the market, the scope of patent approach considered the reverse-settlement context "atypical" because the patent involved conferred a lawful right to exclude others from the market.[446] Courts taking the scope of patent approach also tended to emphasize the legal interest in promoting settlement of litigation.[447] This "scope of patent" test essentially removed from antitrust scrutiny reverse payment settlements;[448] it amounted to a rule of *per se* legality for reverse payment settlements and largely ignored the anti-competitive potential of such agreements advanced by the FTC and private plaintiffs.

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443 Generic Pharmaceutical Association, *Impact of Patent Settlements on Drug Costs; Summary of Findings*, (IMS Institute for Healthcare Informatics, 2013), online: <http://www.gphaonline.org/media/cms/GPhA_IMPACT_OF_PATENT_SETTLEMENTS_7-8.FINAL.pdf>.

444 A War of Roses, *supra* note 426 at 624.

445 This approach assumes the patent was not procured by way of fraud on the U.S. PTO or that the infringement lawsuit was objectively baseless. This approach was adopted by the Eleventh Circuit in the cases *Valley Drug Co v Geneva Pharmaceuticals, Inc*, 344 F (3d) 1294 (11th Cir 2003); *Schering-Plough Corp v FTC*, 402 F (3d) 1056 (11th Cir 2005) [*Schering Plough*]; and *FTC v Watson Pharmaceuticals, Inc*, 677 F (3d) 1298 (11th Cir 2012) [*Watson Pharmaceuticals*], appealed in *Actavis*, *supra* note 433. The Second Circuit and Federal Circuit also took this approach, see *In re Tamoxifen* (2d Cir 2006) and *In re Ciprofloxacin* (Fed. Cir 2008 & 2d Cir 2010). See summary in Michael Clancy, Damien Geradin & Andrew Lazerow, "Reverse-Payment Patent Settlements in the Pharmaceutical Industry: An Analysis of US Antitrust Law and EU Competition Law" Forthcoming Antitrust Law Bulletin at 4-7, online: <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2345851> [Gerardin & Lazerow]. See also the case of *In re Cardizem Antitrust Litigation*, 332 F (3d) 896 (6th Cir 2003) which considered a reverse payment *per se* illegal.

446 *Watson* Pharmaceuticals, *supra* note 445 at 1307 (cert. granted).

447 A War of Roses, *supra* note 426 at 624.

448 James O'Connell, "The Elephant Remains", 28 Antitrust 1, Editor's Note at 5 [The Elephant Remains]; A War of Roses, *supra* note 426 at 624; FTC Commissioner Brill Innovation Speech, *supra* note 423.

The pendulum swung the opposite way when, in 2012, a Third Circuit decision rejected the scope of patent test and instead ruled that, although reverse payment settlements are not prohibited, they are a presumptively an unlawful restraint of trade.[449] The presumption of unlawfulness could be rebutted by showing the payment (i) was for a purpose other than delayed entry of the generic and (ii) offered some pro-competitive benefit. Under the Third Circuit approach, the parties to the settlement bear the burden of proving the compensation was not paid in exchange for delayed entry.[450] This approach does not require an investigation into the strength of a patent, instead adopting the FTC perspective that "absent proof of other offsetting consideration, it is logical to conclude that the *quid pro quo* for the payment was an agreement by the generic to defer entry beyond the date that represents an otherwise reasonable litigation compromise."[451]

Leading up to the *Actavis* decision, U.S. courts were thus widely divergent in their basic analytical standard for assessing reverse payment settlements.

(c) The U.S. Supreme Court *Actavis* Decision

The Supreme Court of the U.S. ("Supreme Court") addressed the legal standard applicable to reverse payment settlements in its much-anticipated June 2013 *Actavis* decision.[452]

Actavis- The Facts in Brief

Actavis, Inc. and Paddock Laboratories, both generic companies, applied for abbreviated new drug applications under *Hatch-Waxman* for the drug AndroGel. The drug was under a patent held by the respondent Solvay Pharmaceuticals, a branded drug company. Solvay initiated paragraph IV *Hatch-Waxman* litigation against the two generic companies. The litigation ended in settlements that involved Solvay making large payments – up to an estimated U.S.$30 million per year annually for several years– to each of the two generic companies. The generics agreed not to bring their drugs to market until a later point in time, albeit before the branded drug patent expired.[453] The generics also agreed to promote the branded drug and characterized the payment as being in exchange for such services, although the FTC contended the services had little value.[454] The FTC alleged the conduct violated Section 5 of the *FTC Act*. Both at the district court level and the Eleventh Circuit, the courts ruled there was no antitrust violation found under the scope of patent approach to the analysis. The FTC sought *certiorari* from the Supreme Court to determine the appropriate analytical standard to be applied to reverse payment settlements.

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449 *In Re K-Dur Antitrust Litigation* 686 F (3d) 197 at 218 (3rd Cir 2012) [*Re K-Dur*]. Adding to the legal uncertainty, the case involved a private antitrust claim regarding the same settlement agreements that the Eleventh Circuit had already rule were permissible in *Schering-Plough*.

450 *Ibid*.

451 *Ibid*, quoting the FTC *In Re Schering-Plough Corp,* Final Order, 136 FTC 956 (2003).

452 *Actavis, supra* note 433.

453 *Ibid* at 2231-2232

454 *Ibid* at 2232.

The Supreme Court rejected the "scope of patent" approach adopted in lower courts. It characterized whether a particular restraint is beyond the "limits of the patent monopoly" as a conclusion, rather than a starting point.[455] The Supreme Court reasoned that a patent holder's conduct should not be considered *per se* lawful where there is a factual question as to whether the patent might be invalid. The Supreme Court observed that *Hatch-Waxman* litigation puts such patent validity at issue, and an invalidated patent does *not* grant the holder any right to exclude.[456] Reverse payment settlements should thus not be assessed solely by reference to patent law, because even settlements within the scope of the relevant patent could potentially violate antitrust laws. The Court explained "it would be incongruous to determine antitrust legality by measuring the settlements anti-competitive effects solely against patent law policy, rather than by measuring them against pro-competitive antitrust policies as well".[457]

The Supreme Court also rejected the FTC's preferred approach of presumptive unlawfulness where a large reverse payment is made. This approach would place the burden on the defendant to prove the reverse payment is justified, and is the approach taken in the EU (discussed below). Given the complexities raised by reverse payment settlements and the necessary fact-specific analysis, the Court found the FTC should continue to bear the burden of proving the anti-competitive effects in each case.[458] It confirmed that antitrust questions in reverse payment settlement cases should be assessed by considering "traditional" antitrust factors, such as likely anti-competitive effects, redeeming characteristics, market power and any offsetting legal considerations such as patents.[459] In particular, considerations set out by the Court for assessing the anti-competitive effects included the size of the payment, its scale relative to future litigation costs, whether the payment is independent from other services provided by the recipient of the payment, the presence (or absence) of justification for the payment other than impacting competition and the influence of the specific industry on the anti-competitive consequences.[460]

With both of the lower court approaches rejected, the Supreme Court concluded that reverse payment settlements may potentially violate antitrust laws, and should be judged under the rule of reason.[461] The Supreme Court acknowledged there is "reason for concern" that reverse payment settlements might have significant adverse effects on competition.[462] Although the Supreme Court acknowledged the public policy interest in encouraging settlement of litigation, it found this interest was outweighed by five key considerations justifying the application of antitrust scrutiny to reverse payment settlements.[463]

– First, reverse payment settlements have the potential for genuine, adverse effects on competition, because they remove the most likely competitor.[464] Where such payments are

455 *Ibid* at 2236.

456 *Ibid*.

457 *Ibid* at 2234-2235.

458 *Ibid* at 2249.

459 *Ibid*.

460 *Ibid* at 2248.

461 *Ibid* at 2228.

462 *Ibid* at 2234.

463 *Ibid* at 2239.

464 *Ibid*; See also Joshua D. Wright, Commissioner, Federal Trade Commission, "FTC v. Actavis and the Future of Reverse Payment Cases" (Speech delivered at Concurrences Journal Annual Dinner New York, New

in exchange for staying out of a market, they have the potential to keep prices at the level set by the patent holder; the returns from keeping the price high are then essentially divided between the generic and the branded company, to the disadvantage of consumers.

- Second, the anti-competitive consequences arising from reverse payment settlements will not, in all cases, be justified by legitimate, "traditional" settlement considerations, such as avoiding litigations costs, or paying fair value for services from the generic. The payments may instead provide strong evidence that a patent holder seeks to induce the generic to share in its monopoly profits that would otherwise be lost due to competition.[465]

- Third, the patent holder is likely in the position to bring about potential harms in actual practice – otherwise the patent holder would be unlikely to pay large sums to induce others to stay out of the market.[466] The Court took note of studies raised by the FTC indicating reverse payment agreements are associated with the presence of higher than competitive profits, a strong indicator of market power.[467]

- Fourth, the Supreme Court found that it is not normally necessary to litigate patent validity within the antitrust suit. As such, it may not be as administratively complex as advocates of the scope of patent test argue to administer antitrust claims related to reverse payment settlements. The Court indicated that the reasonableness of a settlement and thus whether it raised competition concerns could normally be determined "without litigating the validity of the patent".[468] Unexplained, large, reverse payments could provide a "workable surrogate" for the weakness of the patent.[469]

- Finally, in response to concerns over promoting settlement, the Supreme Court noted that prohibiting large, unjustified reverse payment settlements does not eliminate the potential for settlement of the litigation altogether.[470] It leaves open the potential for settlements that do not include such payments, for example, settlements where the generic agrees to settle in exchange for the ability to enter the market before the patent expires.[471]

The Supreme Court also took into consideration the statutory policy behind the U.S. *Hatch-Waxman* regime. The goal of *Hatch-Waxman* is most often described as balancing the promotion of branded innovation incentives with the encouragement of generic competition.[472] The Supreme Court observed the regime has a "general procompetitive thrust" which is intended to facilitate generic entry by enabling a patent's validity to be challenged and by

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York; 26 September 2013) online: <http://www.ftc.gov/sites/default/files/documents/public_statements/ftc-v.actavis-future-reverse-payment-cases/130926actavis_0.pdf> [Future of Reverse Payment Cases].

465 *Actavis, ibid* at 2243.

466 *Ibid* at 2246.

467 *Ibid*.

468 *Ibid* at 2236-37.

469 *Ibid* at 2236.

470 *Ibid* at 2237

471 *Ibid* at 2247.

472 *Watson Pharmaceuticals*, *supra* note 445, Brief of *Amicus Curiae* Representative Henry Waxman, at 12 (internal citations omitted); FTC Commissioner Brill Innovation Speech, *supra* note 423: *Hatch-Waxman* also offers "patent extensions" for branded companies.

requiring settlements to be reported to U.S. federal antitrust regulators.[473] The Supreme Court indicated the scope of patent test is inconsistent with this pro-competitive object of the *Hatch-Waxman* regime.[474]

The three dissenting judges in *Actavis* argued strongly in favour of the scope of patent test. Their position is that "a patent *cannot possibly* impose unlawful anticompetitive harm if the patent holder is acting within the scope of the patent and therefore permitted to do precisely what the antitrust suit claims is unlawful".[475] Unlike the majority's reconciliation of patent and antitrust approaches, the dissent's view has been described as a "nearly irreconcilable tension between patent and antitrust that leads it to conclude that if the agreement is within the [patent] scope, patent law must win".[476]

The dissent argued the defendant patent holder will necessarily want to raise the validity of his patent in defence of the reverse payment settlement, within the context of the antitrust suit. Therefore, it is necessary to determine the patent validity in order to answer the antitrust question, unless the majority is denying such a validity defence exists. Such a denial would "defeat the point of the patent", being the conferral of a lawful monopoly. The dissent concludes the correct approach should be "to ask whether the settlement gives [the defendant] monopoly power beyond what the patent already gave it",[477] applying competition law scrutiny to such settlements within the scope of the patent only where the patent is fraudulently obtained or the settlement is a mere sham.[478]

The dissent argues the majority approach could discourage generics from ever choosing to challenge the patents covering the branded pharmaceutical. Eliminating the prospect of settlements (or limiting them to an early entry date) reduces the generic's expected value going into litigation, decreasing incentives to bring litigation.[479] The dissent also argues if litigation is brought, the majority approach will discourage patent litigation settlement.[480] The dissent felt parties would have no incentive to settle the patent litigation where, as part of the defence of the antitrust suit, the same issue of patent validity would have to be litigated again (which the dissent argued would be necessary).[481] The dissent characterized this as particularly unfortunate, in light of the fact that patent litigation is very complex and costly.[482]

Finally, the dissent took issue with the majority's characterization of the statutory policy behind *Hatch-Waxman* as being overly generalized. It argues if such a pro-competitive policy were intended to be the determinative approach in reconciling patent and antitrust, U.S. Congress

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473 And, as the Supreme Court noted, U.S. legislators made statements condemning reverse payment settlements at the time the *Hatch-Waxman Act* was introduced, with Senator Hatch saying it is "very clear" the regime is "not designed to allow deals between brand and generic companies to delay competition". *Actavis*, *supra* note 433 at 2242.

474 *Ibid* at 2228.

475 *Ibid* (Roberts C. J., dissenting, italics in original) at 2244.

476 Future of Reverse Payment Cases, *supra* note 464.

477 *Ibid* at 1.

478 *Actavis*, *supra* note 433 (dissent) at 2247.

479 *Ibid*.

480 *Ibid* at 2243.

481 *Ibid*.

482 *Ibid*.

could have enacted legislation prohibiting reverse payments – which it has declined to do on several occasions.[483]

(i) After *Actavis*: Open Issues

Actavis left open several issues that have been the subject of comment. First, *Actavis* has been called "relatively light on guidance" as to how the rule of reason should be applied in practice by lower courts to assess reverse payment settlements.[484] The case was remanded and explicitly leaves it to the lower courts to determine how to apply the rule of reason antitrust analysis in practice. Difficult issues may include market definition, what evidence on economic effects might be accepted and how efficiencies should be assessed.[485]

Perhaps most pressing in the eyes of critics of *Actavis*, it was left open when and to what extent the validity of the patent might need to be considered by lower courts as part of the defence of the branded company to the antitrust suit. Those advocating for the scope of patent test express concern that the antitrust court will have to evaluate the merits of the underlying patent dispute in order to determine whether the settlement was anti-competitive. The idea is that if the parties had litigated the dispute to resolution without settlement, and the patent holder had prevailed, the patent holder could lawfully have excluded all infringing products. In other words, whether the settlement was unlawfully exclusionary is seen as dependent on the outcome of the patent dispute.[486] One article argues the decision in *Actavis* means arguments on patent validity are no longer a feasible defence,[487] but an FTC Commissioner has indicated the strength of the patent is an argument available to the defendant to justify the size of the payment.[488]

This leads to the second open question of what would be considered a payment that is sufficiently "large" and "unexplained" to indicate an anti-competitive purpose.[489] The Supreme Court focused on the size of the reverse payment as potentially indicative of its anti-competitive purpose without setting specific parameters. The Court suggested one relevant inquiry would be a comparison of the size of the payment to the sum of expected litigation costs plus the value of any services provided by the generic. More detailed economic models in support of the *Actavis* reasoning suggest the same basic approach.[490]

Finally, it is unclear whether non-cash settlements that delay entry should be subject to the *Actavis* analysis.[491] Although the literature generally refers to reverse "payments", often more subtle forms of consideration are arranged between branded and generic companies, particularly given the antitrust attention to reverse payment settlements in recent years. In *Actavis*, for example, the branded pharmaceutical company arranged for the generics to receive

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483 *Ibid* at 2235, pointing out that at least 11 bills related to reverse payments had been introduced in the Senate or House since 2006, without any being successfully passed.

484 Amanda P. Reeves, "Muddying the Settlement Waters: Open Questions and Unintended Consequences Following *FTC v. Actavis*" 28:1 Antitrust Fall 2013 9 [Muddying Settlement Waters].

485 Future of Reverse Payment Cases, *supra* note 464.

486 The Elephant Remains, *supra* note 448 at 6.

487 Aaron Edlin, et al, "Activating Actavis" 28:1 Antitrust Fall 2013 16 at 19 [Activating Actavis].

488 Future of Reverse Payment Cases, *supra* note 464.

489 The Elephant Remains, *supra* note 448 at 7.

490 Activating Actavis, *supra* note 487 at 22.

491 The Elephant Remains, *supra* note 448 at 8.

large payments for "co-promotion" of the drug. The FTC argued the payments for co-promotion were merely disguised compensation in exchange for the generic's agreement to remain out of the market.

A lower court case decided after *Actavis* has since held that the *Actavis* analysis did not apply to a non-cash reverse payment settlement, dismissing the claims.[492] The FTC disagrees, and in separate litigation, submitted an *amicus* brief arguing a settlement involving a commitment by the branded company not to introduce its own competing "authorized generic" version of a drug when the first generic enters the market should be subject to the same analysis as in *Actavis.*[493] Such authorized generics have been studied in depth by the FTC, see the shaded below. Commitments not to introduce an authorized generic were involved in nearly half of the agreements filed with the FTC in 2012 that were identified as potentially involving problematic reverse payment settlements.[494] Regardless of whether the payment is cash or some other form, the FTC argues there is still a cost to consumers from reduced competition. The defendants in the authorized generic case argue *Actavis* does not apply to their agreement, which did not involve a cash payment.[495]

The FTC Study on Authorized Generic Drugs: Short-Term Effects and Long-Term Impact

The FTC conducted a study of authorized generic drugs, with a report, *Authorized Generic Drugs – Short-Term Effects and Long-Term Impacts* ("Authorized Generic Drugs Report"), issued in 2011. The Authorized Generic Drugs Report found agreements not to launch authorized generics were being used to compensate would-be generic competitors for delaying their entry into the market, and delays arising from such agreements could be "significant".[496] It found the introduction of an authorized generic can reduce both retail and wholesale drug prices, but this was particularly true in the 180-day exclusivity period granted to the generic (which Canada does not have). It also found generic challenges to branded drug patents remained robust, despite concern that over the longer term, by lowering expected profits for generic competitors, the introduction of an authorized generic could affect a generic drug company's decision to challenge patents on branded drug products with low sales.

(ii) After *Actavis*: Enforcement and Policy Implications

Given the open questions explained above, *Actavis* has been criticized as increasing uncertainty for parties contemplating reverse payment settlements.[497] One author claims that, rather than resolving the key issues, *Actavis* is "simply the start of the next phase of disputes,

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492 *Louisiana Wholesale Drug Co Inc v SmithKline Beecham Corp*, No. 2:12-cv-00995 (DNJ).

493 *In re Effexor XR Antitrust Litigation*, FTC *Amicus* Brief (D NJ, 14 August 2013), online: <http://www.ftc.gov/news-events/press-releases/2013/08/ftc-submits-proposed-amicus-brief-concerning-%E2%80%9Cno-authorized>. The plaintiffs in the Effexor XR case have challenged a patent settlement agreement between drug manufacturers Wyeth and Teva Pharmaceuticals, alleging that Teva agreed to delay introduction of its generic version of Wyeth's blockbuster antidepressant drug Effexor XR, and Wyeth agreed not to market an authorized generic version of Effexor XR for a period of time.

494 2012 FTC Patent Litigation Settlement Report, *supra* note 439.

495 *In re Effexor XR Antitrust Litigation*, *supra* note 493.

496 See Authorized Generic Drugs 2011 Report, *supra* note 103.

497 Dennis Crouch, "Supreme Court Adds Antitrust Consideration to Patent Settlements" (2013) Patently-O Blog, online: <http://www.patentlyo.com/patent/2013/06/supreme-court-adds-antitrust-consideration-to-patent-settlements.html>.

trials, FTC investigations and industry uncertainty".[498] The FTC is proceeding with the remanded litigation against Actavis, which may provide greater clarity on the exact U.S. approach to reverse payments. Some predict that as a result of *Actavis*, parties may face higher litigation costs as courts endeavor to assess the pro-competitive justifications of such agreements.[499]

However, Reeves posits that this lack of guidance from the Supreme Court is of little practical significance, because the general principles in everyday practice remain the same post-*Actavis.*[500] Because parties in the U.S. are already required to report reverse payment settlements to antitrust authorities, substantial payments not reasonably tied to anything of value have long been likely to result in FTC or DOJ investigation, and so in practice were largely avoided even before *Actavis*.[501] Settlements that defer generic entry but do not include value transfer continue to be considered likely lawful.[502] To the extent that *Actavis* impacts U.S. settlements, our opinion is that it seems likely to impact those settlements only in the "grey zone" between clearly lawful and clearly anti-competitive settlements. Given the significant apparent implications of reverse payment settlements for health-care costs, the public benefit of faster generic entry may outweigh concerns over the costs of inappropriately "chilling" this category of legitimate settlements.

Although their preferred approach was rejected, the FTC characterized *Actavis* as a victory for consumers and the FTC because it overturned the scope of patent test, which was perceived as protecting pay-for-delay settlements from antitrust action.[503] The FTC has made it clear that it will continue to pay close attention to pay-for-delay settlements and pursue those it believes are problematic.[504] The FTC is continuing to pursue a case against Cephalon that was stayed pending the *Actavis* decision,[505] as well as the remanded *Actavis* case. There are also approximately 13 ongoing private litigation cases related to reverse payment settlement that the FTC plans to monitor and file *amicus* briefs in, as appropriate.[506] How the FTC applies its discretion in subsequent cases is considered significant in determining whether the incentives for legitimate settlement are reduced; in other words, whether the fears of the *Actavis* dissent become a reality.

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498 The Elephant Remains, *supra* note 448 at 8.

499 Gerardin & Lazerow, *supra* note 445 at 8.

500 Muddying Settlement Waters, *supra* note 484.

501 *Ibid* at 9.

502 *Ibid*.

503 United States, Federal Trade Commission, "Prepared Statement of the FTC to the Committee on the Judiciary of the US Senate, Subcommittee on Antitrust, Competition Policy and Consumer Rights on Pay-for-delay Deals: Limiting Competition and Costing Consumers" 113th Cong 3 (23 July 2013).

504 *Ibid*; The Director of Competition at the FTC called challenging anti-competitive reverse payment settlements a "top priority", Harry Phillips, "Cephalon Pay-for-Delay Case Not Pointless says FTC" (2013) Global Competition Review, online: <http://globalcompetitionreview.com/features/article/34606/cephalon-pay-for-delay-case-not-pointless-says-ftc/>.

505 *Federal Trade Commission v Cephalon, Inc* (08-cv-2141-RBS). Cephalon is arguing that since generic versions of an alternative drug have now entered the market, the FTC case is moot. The FTC is also seeking to add Teva to the case.

506 FTC Briefing on Pharmaceutical Pay-for-Delay Settlements, *supra* note 432 at 12.

The FTC characterizes its role in the pay-for-delay debate as essential in rebalancing the "scale between innovation, patent policy and competition".[507] The FTC did not win a quick victory, and for some time the scope of patent approach made it seem the agency had lost the war. The FTC's persistent challenges over the long-term, pushing for what the FTC felt was the public interest in stemming reverse payment settlements, resulted in an approach that could restrict reverse payment much more significantly than if the scope of patent test had remained the law. Thus agency action can play a significant role in rebalancing the patent/competition regimes in the public interest. As FTC Commissioner Brill explains: "patents play an important role in fueling the innovation engine. But they are not iron clad property rights beyond the reach of antitrust. The public has a keen interest in competition, and it's our job – the job of antitrust agencies – to ensure that they get it. In other words, we must step up and seek to rebalance the scale."[508]

At a broader level, the *Actavis* decision has been called "a landmark moment in the evolution of antitrust/intellectual property interface" because of the Supreme Court's recognition of the potential for patent holder liability under antitrust laws even where conduct may be within the scope of its (presumptively valid) patent.[509] In an article critical of the *Actavis* dissent, a leading antitrust commentator explains the dissent's statement that a "patent carves out an exception to the applicability of antitrust laws" may be over-simplifying.[510] There is a high degree of federal regulatory supervision over the patent granting process, suggesting an exception from competition law for pre-patent issuance conduct is quite appropriate; but *after* a patent is issued, the patent is largely an unregulated asset "capable of both efficient and harmful use, just as any other business property".[511] He characterizes the majority as deferring to patent practices challenged under the *Sherman Act* where that practice is expressly authorized by the *Patent Act*, or is there by fair implication. But when this is not the case, he argues the *Actavis* decision means antitrust should be given greater rein.[512]

The Supreme Court's broad pronouncements on the relationship between patent and antitrust law may signal a shift toward greater antitrust focus in analysis, with resulting implications beyond the *Hatch-Waxman Act* litigation to other cases involving arguments that a patent shields from antitrust liability, such as product hopping cases (discussed below).[513] Given the recency of the decision, it is not yet clear how far-reaching the implications of *Actavis* will be in the broader patent/antitrust context. One author predicts at the very least, the Agencies and private plaintiffs will embrace the decision in future antitrust challenges involving intellectual

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507 FTC Commissioner Brill Innovation Speech, *supra* note 423.

508 *Ibid*.

509 Muddying the Settlement Waters, *supra* note 484.

510 Herbert Hovenkamp, "Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision" (28 November 2013) Minnesota Journal of Law, Science & Technology, Forthcoming U Iowa Legal Studies Research Paper No. 13-35, online: <http://ssrn.com/abstract=2286255> [Anti-competitive Patent Settlements].

511 *Ibid* at 28.

512 *Ibid* at 29.

513 Muddying the Settlement Waters, *supra* note 484 at 14; Mark Botti & Jessica Hoke, Squire Sanders LLP, "Redefining the Border Between Intellectual Property and Antitrust: Implications of FTC v. Actavis" (2013) online: <http://about.bloomberglaw.com/practitioner-contributions/redefining-the-border-between-intellectual-property-and-antitrust/>; Anti-competitive Patent Settlements, *supra* note 510 ("The Actavis decision thus invites the courts to consider the permissible scope of anti-competitive patent licensing, including restraints that settle disputes and those resulting from ordinary business transactions.").

property.[514] Private cases continue to be brought and remanded cases are beginning to consider the application of *Actavis*.[515]

(d) Conclusion on Reverse Payment Settlements in the U.S.

In the U.S., generic drugs are a significant source of price competition for branded drugs. The cost savings to consumers and the government from a ban on reverse payment settlements that delay entry of generic drugs has been estimated by the FTC at billions of dollars. Since the early 2000's, the FTC has taken the position that reverse payment settlements are prohibited by U.S. antitrust law because they restrict competition and increase drug prices. The FTC has been active in enforcement efforts to challenge anti-competitive reverse payment settlements.

The U.S. requires all settlements of patent disputes between branded companies and generic companies (including reverse payment settlements) be filed with antitrust Agencies for review. This enables tracking of settlements and the identification of any anti-competitive settlements the Agencies wish to challenge. Although U.S. settlements have grown in overall number, the percentage of settlements involving reverse payments has declined since 2006, with the exception of 2012.

In a major 2013 case, *Actavis*, the U.S. Supreme Court established that reverse payment settlements will be evaluated under the rule of reason. Before this case, there was a split between lower level U.S. courts on the proper analytical standard. Some took a "scope of patent" approach that protected reverse payment settlements from most antitrust scrutiny, and others took the approach that reverse payment settlements were presumptively unlawful.

There remain open questions on the application of the rule of reason standard after the U.S. Supreme Court *Actavis* ruling. The major questions relate to the application of the rule of reason in practice, and include (i) to what extent the validity of the patent should be considered in antitrust litigation, (ii) how to assess whether payments are sufficiently large and unexplained so as to indicate an anti-competitive purpose and (iii) whether non-cash settlements should be subject to the reasoning in *Actavis*. The remanded *Actavis* dispute and several other ongoing cases should provide more clarity on these issues. FTC comments confirm there will be continued scrutiny in the U.S. of reverse payment settlements going forward. It appears there should be no expectation that either the branded pharmaceutical companies or the generics are acting in the best interests of the public, making continued agency oversight appropriate.

The outcome of *Actavis* reflects the significant role that persistent and principled agency enforcement can play in rebalancing the patent/competition regimes. The FTC's belief that reverse payment settlements harmed the public overall led the agency to bring and persist with several challenges in this area. Although the outcome in *Actavis* was not the standard of

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514 Muddying the Settlement Waters, *supra* note 484 at 15.

515 See e.g. the new cases *NECA-IBEW Welfare Trust Fund v Teva Pharmaceuticals USA Inc*, No. 2:14-cv-00329 (ED Pa); *International Union of Painters and Allied Trades, District Council 21 v Teva Pharmaceuticals USA Inc,* No. 14-cv-00050 (D Minn.) *and American Sales Co LLC v Boehringer Ingelheim Pharma GMBH & Co KG,* No. 14-cv- 00003 (D Conn.) and the remanded case *Louisiana Wholesale Drug Co Inc v SmithKline Beecham Corp*, No. 2:12-cv-00995 (DNJ).

analysis for which the FTC advocated, the decision cast a role for antitrust that was stronger than the scope of patent approach adopted by many lower courts.

Some commentators argue the broad pronouncements in *Actavis* on the relationship between patent and antitrust law may signal a shift toward greater analytical focus on antitrust. This shift may have implications for other conduct where it is argued patents act as a shield from antitrust scrutiny. The recency of *Actavis* makes it too soon to assess any broader implications or shift toward antitrust intervention. What is clear, however, is that the U.S. Supreme Court has done away with the notion that patent law and patent holders operate in isolation from antitrust law. Conduct involving such rights is not immune from attack; just as there are public interest considerations in granting patents, there a public interest in how such intellectual property rights are used or misused.

3. Patent Assertion Entity Conduct

To date, the debate surrounding the application of competition law to patent assertion entities has occurred almost exclusively in the U.S. There has been a surge of literature on PAEs in the past several years, almost all of which considers U.S. law and policy, even when written in other jurisdictions. The U.S. perspective seems to be that the PTO, antitrust agencies, legislative reform and the courts all have a role to play in addressing PAE conduct.

Although the debate centres on PAEs, we believe that PAEs are a symptom of other systemic issues, rather than the problem themselves. For example, FTC Commissioner Ohlhausen has expressed doubt over whether PAEs are the "cause" of the recent surge in U.S. patent infringement litigation pointing instead to broader problems with the U.S. patent system.[516] A recent study by the GAO, a non-partisan congressional watchdog, indicated the key factors contributing to the rise in patent infringement lawsuits by both PAEs and non-PAEs include the prevalence of unclear property rights (such as broad software-related patents), the potential for large monetary awards from the courts even where the patent's contribution to the product is small and the overall recognition from companies that patents are a more valuable asset than once assumed.[517] We focus here on the competition perspective regarding PAEs, but note there are extensive discussions outside the terms of reference of this report on the role of patent law and general litigation reforms in controlling PAE issues.

(a) Emerging Evidence on PAE Conduct

PAEs are characterized by some as helpful and by others as harmful. The most common argument raised in defense is that PAEs are useful market intermediaries,[518] facilitating the monetization of patents. In theory, by bringing liquidity to patent markets as intermediaries, PAEs could enable small patent holders to sell and protect their patented technology, while also

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516 A Pragmatist's Approach, *supra* note 278, noting the GAO found about 89 percent of patent infringement lawsuits involved software-related patents in the 2007-2011 period and most of the suits brought by PAEs involved software-related patents.

517 See United States, Government Accountability Office, *Intellectual Property: Assessing Factors That Affect Patent Infringement Litigation Could Help Improve Patent Quality*, (GAO-13-465, 2013) online: <http://www.gao.gov/products/GAO-13-465> [GAO Report].

518 Robert P. Merges, "The Trouble with Trolls: Innovation, Rent-Seeking and Patent Reform" (2009) 24:4 Berkeley Law Journal 1583 at 1599; N. Myhrvold, "The Big Idea: Funding Eureka!" (2010) Harvard Business Review at para 7, online: <http://hbr.org/2010/03/the-big-idea-funding-eureka/ar/1> (available in part without a subscription).

enabling technology users to find relevant patents in the sea of other patents.[519] PAEs would act as a "market mechanism for the forgotten inventor whose innovations are in use every day but who remains uncompensated".[520]

However, recent studies suggest inventors are not the parties benefitting from PAE activity. A 2011 empirical study found that only 2% or less of the value reaped by PAE litigation is transferred back to inventors.[521] Recent research also indicates PAEs *target* small companies extensively with demand letters and litigation, raising the possibility that the benefits of any PAE market-making benefit may not, overall, outweigh the costs of settlement or higher royalty rates for smaller businesses.[522]

In the absence of significant rewards flowing back to inventors, the brokerage roll of PAEs could still, in theory, enable the transfer of technology to those with the capacity to commercialize it or further innovate to the benefit of the public. We find this argument relatively weak, in that it assumes the patent lands in the hands of someone who will apply the technology underlying the patent in some manner. This does not appear to be true in the case of PAEs, who tend to focus on licensing and litigation of patents that have already been used in a commercial product, instead of helping to produce something new.[523] By providing a market for high-tech patents which does not require the related technology to be sufficiently developed to demonstrate commercial viability (with such development being desirable to a "traditional" patent buyer), in conjunction with a failure to transform acquired rights into sold products, may mean PAEs are simply fueling a "patent bubble."[524] Although the FTC and scholars in the field suggest benefits from PAEs may exist, such benefits appear to be less likely to be realized than the costs imposed by PAEs (discussed below).[525]

By some estimates, there has been a rapid rise in the number of PAE patent infringement lawsuits in the U.S. over a short period of time.[526] Of the parties filing the highest number of patent infringement suits in the U.S. in 2012, one study finds the top ten were PAEs.[527] By some

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519 Patent Assertion Report, *supra* note 295 at 3.

520 The AIA 500 Expanded, *supra* note 526 at 20, referring more broadly to "mass aggregators", which include entities like universities that are not true PAEs; see also Sannu K. Shrestha, "Trolls or Market-Makers? An Empirical Analysis of Nonpracticing Entities" (2010) Columbia Law Review 110 at 114.

521 James Bessen, Michael Meurer & Jennifer Ford, "The Private and Social Costs of Patent Trolls" (2011) Boston University School of Law, Law and Economics Research Paper 11-45 at 20, online: <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1930272> found 2% or less of the defendant losses in NPE litigation were transferred to independent inventors [Social Costs of Trolls].

522 Patent Small Claims, *supra* note 294 at 6.

523 Brian J. Love, "An Empirical Study of Patent Litigation Timing: Could a Patent Term Reduction Decimate Trolls Without Harming Innovators?" (2013) 161 University of Pennsylvania Law Review 1309.

524 Alan Devlin, "Improving Patent Notice And Remedies: A Critique Of The FTC's 2011 Report" (2012) 18 Mich. Telecomm. Tech. L. Rev. 539 at 546.

525 Brian T. Yeh, Congressional Research Service, *An Overview of the Patent Trolls Debate* (United States: Congressional Research Service 7-5700, 2013) (characterizing the asserted benefits of PAE activity less likely to be realized than the costs, and tending to be more long-term, abstract, and indirect, and thus more difficult to estimate).

526 Robin Feldman, Thomas Ewing & Sara Jeruss, "The AIA 500 Expanded: The Effects of Patent Monetization Entities" (2013) UC Hastings Research Paper No 45 at 83 online: <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2247195> at 82 [The AIA 500 Expanded].

527 *Ibid*.

estimates, PAE litigation now forms the majority of patent infringement law suits in the U.S.[528] However, one of the most extensive studies of patent litigation by public authorities, conducted by the U.S. Government Accountability Office ("GAO")[529] found that operating companies brought an estimated 68% of all patent infringement lawsuits from 2007 to 2011, with no statistically significant increase in the litigation brought by PAEs in this period.[530] We note that a later private study, based on an updated and much larger data set encompassing that used by the GAO, found 58.7% of patent infringement lawsuits in 2012 were filed by PAEs (referred to as "monetizers"), up from only 24.6% in 2007.[531] This suggests that the surge in PAE litigation has been accurately characterized in recent years, despite the GAO findings. Even if estimates differ, it is clear that PAE litigation was what first attracted the attention of industry, antitrust regulators and legislators.

Litigation by PAEs has been the subject of several studies which suggests it may have distinguishing characteristics from other patent infringement litigation. Despite the extensive amounts of litigation being brought by PAEs, one study found that only 16% of identified U.S. patent infringement court *decisions* in 2012 involved PAEs, implying much of the PAE litigation is settling before a decision is reached.[532] Multiple studies also suggest PAEs are less successful than practicing companies in their litigation, which may imply PAE cases have less merit. One study found that PAEs were much less successful at the summary judgement stage, succeeding in only about 2% of decisions (compared to 10% success rate for all patent infringement litigation).[533] The same study suggests the overall success rate in final judgements may not be as poor, but is still lower for producing entities, with success in approximately 24% of decided cases brought by PAEs and 35% of decided cases brought by practicing entities

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528 *Ibid* at 47. This is the most comprehensive study of PAE litigation we have seen. Considering 13,000 cases, researchers at Duke University found that suits by patent "monetizers" (PAEs) and similar entities rose from about 25% in 2007 to nearly 59% of all patent infringement suits in 2012. This data includes confirmed NPEs (who describe their main source of revenue as patent litigation or licensing or which are subsidiaries of known NPEs) and suspected NPEs based on public evidence and individuals/trusts, whose behaviour was found to be similar to NPEs; see also the prior study indicating a similar trend Sara Jeruss, Robin Feldman & Joshua Walker, "The America Invents Act 500: Effects of Patent Monetization Entities on US Litigation" (2012) 11 Duke Law & Technology Review 357 at 377 [Effects of Patent Monetization Entities]. The data used in the 2012 study was a subset of that provided to the Government Accountability Office. The *America Invents Act* directed the GAO study the costs, economic impact and benefits of litigation brought by non-practicing entities or patent assertion entities. *157 Cong Rec* s. 5441 (daily ed. 8 September 2011) (Statement of Senator Patrick Leahy) [Leahy Statement]. We refer here to the more extensive private studies, but note that the GAO found only about one fifth of all litigation from 2000 to 2010 was brought by NPEs.

529 GAO Report, *supra* note 517 at 17.

530 The AIA 500 Expanded, *supra* note 526 at 39.

531 *Ibid* at 47. The AIA 500 Expanded study looked at 13,000 cases dating up to 2012 while the GAO study examined a representative sample of 500 lawsuits from 2007-2011. The authors of the AIA 500 Expanded study also looked at the GAO data and found the GAO had chosen to excluded trusts or individuals (even some that were widely characterized as PAEs) and instead include only PAEs organized as corporations or partnerships. This led to a lower percentage of litigation being attributed to PAEs. See Effects of Patent Monetization Entities, *supra* note 528.

532 Price Waterhouse Coopers, "2013 Patent Litigation Study: Big Cases Make Headlines, While Patent Cases Proliferate" (2013) at 3 [PWC Study]. This study refers to the broader category of "non-practicing entities", which includes universities and non-profits. However, universities and non-profits comprised only 5% of the entities involved in the litigation considered so statistics may be comparable to those of PAE alone, at 27.

533 *Ibid*. The study defined a success to include instances where a liability and damages/permanent injunction decision was made in favor of the patent holder.

from 1995–2012.[534] Where a case is litigated to trial on the merits, another study estimated the loss rate as much higher for non-practicing entities, at 92% of cases brought with respect to the most-litigated patents in the 2000-2009 time period.[535]

Empirical research has suggested PAEs destroyed over $500 billion in wealth between 1990-2010.[536]A follow-up study estimates that defendants and licensees incurred direct costs of $29 billion in the U.S. in 2011 alone as a result of PAE activity.[537] This includes the cost of outside legal services, license fees, and other direct costs incurred in response to NPE litigation risk (including settlement costs); it does not include indirect costs such as business disruption.[538] There is also emerging literature suggesting that litigation costs from PAEs are merely the tip of the iceberg for the costs imposed.[539] Estimates of the number of demands made by PAEs for every suit actually filed range from 25 (from a sell-side patent broker) to over 300 (from Cisco).[540]

Literature, as well as commentary from the FTC, reflect two emerging trends in PAE activity that would appear to heighten antitrust law and policy concern: (i) the targeting of small businesses and (ii) privateering.

The head of the FTC and a recent Executive Office of the President report both acknowledge indications that PAEs are targeting small businesses with false claims, made to induce the payment of illegitimate licensing fees.[541] PAEs have reportedly sent hundreds of small businesses letters alleging patent infringement based on the businesses' use of document

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534 *Ibid* at 35. But note also the study found median damage awards were higher for PAEs than for practicing entities.

535 John. R. Allison, Mark A. Lemley & Joshua Walker, "Patent Quality and Settlement Among Repeat Patent Litigants" (2011) 99 Georgetown Law Journal 677 at 694.

536 Social Costs of Trolls, *supra* note 521 at 3. The authors measured the market capitalization loss of defendants in PAE litigation, with adjustments to take into account market trends and other random factors affecting an individual share price. The work considers only a sample of U.S. publicly traded firms and so does not account for losses on a worldwide scale or losses to private firms.

537 James Bessen & Michael J. Meurer, "The Direct Costs from NPE Disputes" (2012) Boston University School of Law and Economics Research Paper No. 12-34, online: <http://www.bu.edu/law/faculty/scholarship/workingpapers/documents/BessenJ_MeurerM062512rev062812.pdf> see also criticism of this study's methodology suggesting the estimate is an outer limit and indicating it may adopt an overly-broad definition of which entities are PAEs, in David L. Schwartz and Jay P. Kesan, "Analyzing the Role of Non-Practicing Entities in the Patent System" Illinois Public Law and Legal Theory Research Paper No. 13-01, online: < http://ssrn.com/abstract=2117421>; Jon Leibowitz, Chairman, Federal Trade Commission, "Opening Remarks at Patent Assertion Entity Workshop" (10 December 2012) at 3, online: <http://www.ftc.gov/speeches/leibowitz/121210paeworkshop.pdf>.

538 Bessen & Meurer, *ibid* at 3. The study is based on a survey, augmented by information from a database of non-practicing entity litigation, and information derived from financial disclosures by publicly traded non-practicing entities.

539 Effects of Patent Monetization Entities, *supra* note 528 at 374-75, referring also to Tom Ewing & Robin Feldman, "The Giants Among Us" (2012) Stanford Technology Law Review 1 at 14 [Giants Among Us].

540 Colleen V. Chien, "Patent Assertion Entities" (Presentation at the FTC DOJ Workshop on Patent Assertion Entitles, 10 December 2012) [Chien PAE Workshop]. The estimate of over 300 is from *Cisco et al v Innovation*, Case No. 1:11-cv-09308.

541 Edith Ramirez, "Competition Law & Patent Assertion Entities: What Antitrust Enforcers Can Do" (Speech delivered at the Computer & Communications Industry Association and American Antitrust Institute Program, Washington, DC, 20 June 2013) [Competition Law & PAEs]; Patent Assertion Report, *supra* note 519.

scanners.[542] The letters demanded a "good faith payment" of $900-$1,200 U.S. per employee and allegedly targeted small business and non-profits unlikely to be familiar with patent law.[543] Some letters falsely claim that most other comparable businesses had already agreed to a license.[544]

This reflects the expansion by PAEs to beyond large IT companies; retailers (including online retailers), financial service providers and even hotels and coffee shops are becoming fair game for demand letters.[545] Emerging literature also suggests that this PAE activity has a significant impact on small companies. One author suggests start-up companies are particularly impacted by PAE activity.[546] In another paper, the same author estimates that companies making $10 million or less annually comprise 55% of the unique defendants named in PAE cases.[547] This appears to be supported by recent empirical research that found demands by PAEs are often made to start-ups and almost 60% of the start-up companies reported such patent demands had a significant impact on a company, including distracting management, expending resources or altering business plans.[548]

Such PAE "spray and pray" campaigns targeting small businesses appear unscrupulous and are raising consumer protection concerns. Concern over targeting of end-users has been voiced several times in U.S. Congressional hearings regarding abusive patent litigation.[549] The targeting of small businesses has prompted several states to take direct action against PAE conduct under consumer protection laws, although such efforts are considered to be potentially

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542 *Ibid* at 7.

543 *Ibid*; Memorandum from Ranking Member Henry A. Waxman to Democratic Members of the Subcommittee on Oversight and Investigations, "Hearing on The Impact of Patent Assertion Entities on Innovation and the Economy," Subcommittee on Oversight and Investigations (14 November 2013) online: <http://democrats.energycommerce.house.gov/index.php?q=hearing/hearing-on-the-impact-of-patent-assertion-entities-on-innovation-and-the-economy-subcommitte> noting "growing concern" that PAEs are "targeting a range of small businesses and non-profits".

544 United States, New York Attorney General, Press Release, "A.G. Schneiderman Announces Groundbreaking Settlement With Abusive 'Patent Troll'" (14 January 2014) online: <http://www.ag.ny.gov/press-release/ag-schneiderman-announces-groundbreaking-settlement-abusive-%E2%80%9Cpatent-troll%E2%80%9D> [AG Press Release].

545 Competition Law & PAEs, *supra* note 541.

546 Colleen V. Chien, "Patent Assertion and Startup Innovation" (2013) New America Foundation, Open Technology Institute, online: <newamerica.net/sites/newamerica.net/files/policydocs/Patent%20Assertion%20and%20Startup%20Innovation_updated.pdf>.

547 Colleen Chien, "Start-ups and Patent Trolls" (2012) Legal Studies Research Papers Series No 09-12, online: <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2146251&download=yes> at 2 [Start-ups and Patent Trolls].

548 Robin Feldman, "Patent Demands & Startup Companies: The View from the Venture Capital Community" (2013) University of California Hastings College of the Law, online: <papers.ssrn.com/sol3/papers.cfm?abstract_id=2346338> [Patent Demands & Startup Companies]. The study involved a survey of 200 venture capitalists and their portfolio companies. It was found that roughly one in three start-up companies reported receiving patent demands, the majority of which were from PAEs.

549 See e.g. United States, House of Representatives, Subcommittee on Oversight and Investigations Committee, Preliminary Transcript, "The Impact Of Patent Assertion Entities On Innovation And The Economy" (14 November 2013) at 7, online: <http://democrats.energycommerce.house.gov/index.php?q=hearing/hearing-on-the-impact-of-patent-assertion-entities-on-innovation-and-the-economy-subcommitte>.

pre-empted by Federal patent law.[550] Chairwoman Ramirez has indicated the FTC is "committed to protecting small businesses from deceptive PAE practices using its Section 5 authority under the *FTC Act*."[551]

A second emerging area of PAE conduct is "privateering", which involves the assertion of patent rights by a PAE acting as a "clandestine surrogate" for competitors of the operating company behind the privateer PAE.[552] The conduct generally involves an operating company transferring patents to a privateer PAE for assertion against that operating companies' competitors. FTC Chairwoman Edith Ramirez noted privateering deals often align the incentives of the PAEs with the goals of the operating companies from which they acquired patents.[553] Incentives may be provided for aggressive assertion, such as ongoing payments from the operating company to the privateer PAE based on a percentage of licensing revenues successfully obtained by the PAE.[554] The transfers may include an eventual reversion of patents back to the original operating company if the PAEs performance does not meet licensing revenue targets.

Transferring patents to a privateer PAE has implications for hold-up; it enables operating companies to avoid the threat of counter-suits while still receiving a royalty stream on their patents via the PAE. The underlying purpose of the activity, at least from the perspective of companies being targeted by privateers, is to use the privateer PAE to attack the producing companies' competitors,[555] without risk to the operating company of the counter-suits that would arise if the operating company brought the litigation itself. The issue has also been raised as to whether the transfer to a PAE may enable evasion of commitments by the original owner to license the patent portfolio at certain rates, because the transfer splits that portfolio into the hands of different parties who made no such commitments.[556]

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550 *Ibid* at 5-6, discussing action by the state Attorney Generals in Vermont, Nebraska and Minnesota, as well as legislation introduced in Vermont. See also the settlement reached between a PAE and the New York Attorney General, AG Press Release, *supra* note 544.

551 Competition Law & PAEs, *supra* note 541.

552 For an in-depth exploration of privateering, see Tom Ewing, "Indirect Exploitation of Intellectual Property Rights by Corporations and Investors" (2012) 4 Hastings Science & Technology Law Journal 1.

553 Competition Law & PAEs, *supra* note 541; Comments of Google, BlackBerry, EarthLink and Red Hat to the Federal Trade Commission and U.S. Department of Justice on Patent Assertion Entities (5 April 2013), at 3, online: <http://www.justice.gov/atr/public/workshops/pae/comments/paew-0049.pdf>. [Google et al. Comments to FTC].

554 A recent example is the sale on September 1, 2011 of 2,000 Nokia wireless technology patents to MOSAID (now Conversant Intellectual Property Management) for about $20 million in exchange for the agreement that MOSAID will pursue licensing and patent monetization against third parties. MOSAID agreed to fund the acquisition "through royalties from future licensing and enforcement revenues" and to "monetize the Assigned Patents" and pay Microsoft and Nokia two-thirds of the gross royalties. If minimum performance thresholds are not met by MOSAID, the patents reportedly revert to Nokia and Microsoft. MOSAID Technologies Incorporated, Press Release, "MOSAID Acquires 1,200 Nokia Standards-Essential Wireless Patents and 800 Wireless Implementation Patents" (September 1, 2011) online: <http://www.mosaid.com/corporate/news-events/releases-2011/110901.php>; Dennis Crouch, "Microsoft and Nokia Sue Apple for Patent Infringement (via a Holding Company)", Patently-O Blog, online: <http://patentlyo.com/patent/2012/03/microsoft-and-nokia-sue-apple-for-patent-infringement-through-a-holding-company.html>.

555 Christian Helmers & Luke McDonagh, "Trolls at the High Court?" (2012) LSE Legal Studies Working Paper No. 13/2012 at 6 online: <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2154958&download=yes> [Trolls at the High Court].

556 For example, the SEPs previously held by Nokia and sold to MOSAID were subject to a 2% royalty cap imposed on the portfolio of SEPs, regardless of how many SEPs were required by a licensee to implement

Concerns over the anti-competitive design and effect of privateering may be increasingly a reality. The Rockstar Consortium US LP ("Rockstar"), a Canadian PAE backed by Microsoft, Apple, BlackBerry and other large technology companies that compete with Google, holds a large number of patents that were obtained from Nokia. In October 2013, Rockstar commenced patent infringement litigation in the U.S. against Google and several of its mobile device manufacturers.[557]

(b) Evolving Competition Agency Perception of PAE Conduct?

Overall, the view from governmental agencies seems to be shifting increasingly toward a conclusion that PAEs are having a negative impact on consumers and innovation. A report from the Executive Office of the President in June 2013 concluded "[a] review of the evidence suggests that on balance, such patent assertion entities (PAEs) (also known as "patent trolls") have had a negative impact on innovation and economic growth."[558] In a March 2011 report, the FTC was relatively tentative, characterizing the societal benefits of PAEs as "uncertain" and considered whether PAEs threatened to "distort competition in technology markets, raise prices and decrease incentives to innovate".[559] As of mid-2013 this seems to have shifted, with FTC Chairwoman Edith Ramirez describing the FTC's view of the benefits of PAEs as skeptical, given the relatively limited evidence in support of PAE's positive impacts on innovation.[560] Chairwoman Ramirez indicated "PAEs are evolving in ways that raise red flags for competition and consumers. These entities are driving the increase in patent litigation and targeting firms in a growing slice of the economy… The costs to consumers from PAE activity appear increasingly tangible and direct."[561] She then canvassed potential antitrust concerns over privateering and the targeting of small businesses described above, as well as the assembly of a patent portfolio through acquisitions of substitute patents (no further explanation was provided on how this final concern relates specifically to PAEs). The FTC head concluded "[w]e have a role to play in advancing a greater understanding of the impact of PAE activity and using our enforcement authority where appropriate to curb anticompetitive and deceptive conduct".[562]

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the wireless standard the patents apply to. The division of the portfolio of SEPs between MOSAID and Nokia raises questions as to whether the 2% royalty cap obligation still applies. Mark S. Popofsky & Michael D. Laufert, "Patent Assertion Entities and Antitrust: Operating Company Patent Transfers" (2013) The Antitrust Source at 9, online: <http://www.ropesgray.com/~/media/Files/articles/2013/04/Antitrust-Attacks-on-Patent-Assertion-Entities.pdf>; Google et al. Comments to FTC, *supra* note 553 at 3.

557 See e.g. the case against Google, *Rockstar Consortium US LP v Google Inc* (ED Texas case 2:2013cv00893, filed 31 October 2013) alleging infringement of a number of U.S. patents used in mobile devices; Joe Mullin, "Patent War Goes Nuclear: Microsoft, Apple-owned "Rockstar" Sues Google: Rockstar paid $4.5 billion for Nortel Patents and has Launched a Major Attack" Ars Tecnica (31 October 2013) online: <http://arstechnica.com/tech-policy/2013/10/patent-war-goes-nuclear-microsoft-apple-owned-rockstar-sues-google/>.

558 Patent Assertion Report, *supra* note 295.

559 Evolving IP Marketplace, *supra* note 94.

560 Competition Law & PAEs, *supra* note 541; Sara Forden, " FTC Chief Ramirez Calls on Agency to Probe Patent Trolls" (2013) Bloomberg News, online: <http://www.bloomberg.com/news/2013-06-20/ftc-chief-ramirez-calls-on-agency-to-probe-patent-trolls.html> referring to a webcast by FTC Chief Edith Ramirez.

561 Competition Law & PAEs, *supra* note 541.

562 *Ibid*.

The FTC and DOJ have focused significant attention on understanding patent assertion entities, but have yet to take any enforcement action.[563] Most recently, the FTC commenced a study of PAEs under Section 6(b) of the *FTC Act*. The intent is to analyze the cost and benefits of PAEs in response to a perceived lack of information, particularly about any benefits of PAEs. Information gathered under such an inquiry seems likely to be useful for both enforcement and policy-making. The FTC's proposal for the study, including specific questions, are included in **Appendix E** and might be helpful in guiding Canada's approach to assessing PAE conduct.

The FTC has hinted that its enforcement approach would likely focus on misleading and deceptive demand letters sent out by PAEs. The FTC has indicated it will apply a fact specific, market power analysis in any action against PAEs, looking for evidence of harm to competition and consumers. Literature suggests a Section 5 *FTC Act* case might be the most likely, on the basis that PAE behavior constitutes an unfair method of competition.[564] Although there is no precise framework for Section 5 *FTC Act* actions, Carrier suggests that some PAEs may have market power in technology markets, that their licensing is likely to cause consumer harm in the form of higher prices/reduced innovation and is unlikely to give rise to efficiencies.[565] In such a case, the PAE would have the opportunity to demonstrate allegedly pro-competitive effects, such as benefit to inventors.

The message from the FTC has also been that PAE activity is just one piece of a broader issue, and that flaws in the patent granting and litigation systems are likely fueling much of the PAE-imposed costs.[566] Protecting competition and consumers from such harms requires effort from various corners of government. The PTO has, for example, begun a rulemaking process to require patent applicants and owners to regularly update patent ownership information and the DOJ has participated in this process.[567]

(c) Responses to PAE Conduct

(i) Legislative Responses

563 The FTC has held two joint workshops related to PAEs, with reports issued in March 2011 (Evolving IP Marketplace, *supra* note 94)and December 2012. The latter was a joint public workshop with the DOJ on PAE behavior, the economics of IP licensing, industry experiences with PAE behavior, economic and legal theories and empirical work concerning PAE activity, and the potential efficiencies and harms to innovation and competition that this activity may generate. The discussion included industry participants, academics, economists, lawyers, and other interested parties.

564 Although there is no precise framework for Section 5 FTC actions, Michael A. Carrier, "Patent Assertion Entities: Six Actions the Antitrust Agencies Can Take" (2013) CPI Antitrust Chronicle 2 at 11.

565 *Ibid*.

566 Competition Law & PAEs, *supra* note 541 at 10.

567 Teresa Stanek Rea, Acting Director U.S. Patent & Trademark Office, "USPTO and the Obama Administration Taking Action to Improve Incentives for Future Innovation via High Tech Patents" (Speech delivered at the Director's Forum: A Blog From USPTO'S Leadership, 17 June 2013); Speech by Renata Hesse: Looking Back, *supra* note 347 at 14. The DOJ submitted comments in the PTO roundtable on proposed regulations requiring better recording of the real party-in-interest behind a patent, and submitted comments with the FTC supporting the PTO's efforts and proposed regulations.

The U.S. has seen a multitude of recently proposed legislative reforms aimed at curbing PAE behavior. There have also been several congressional hearings on abusive patent litigation and related topics.[568]

The *America Invents Act* ("AIA"), passed in September 2011, was the first such legislation to be enacted. It introduced broad changes to the U.S. patent system, some of which were directed at fighting PAE conduct.[569] The key changes related to PAE conduct were (i) modification of the rules on joinder to require infringement to arise from the same occurrence or transaction and to involve common questions of fact (whereas the previous rule required only commonality on deciding the scope of the patent, even if infringement acts were not related)[570] and (ii) the introduction of new review proceedings to challenge and invalidate patents.[571] The hope was that the joinder changes would make litigation more expensive and difficult for PAEs, who before the changes were able to sweep unrelated defendants into a single suit. Preliminary estimates appear to indicate the new joinder provisions may have reduced the number of defendants in lawsuits brought by PAEs, from 3,018 in 2011 to 1,788 in 2012.[572] Unfortunately, this still leaves the number of defendants much higher than just a few years before the amendments.[573]

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568 United States, House Judiciary Committee, Subcommittee on Courts, Intellectual Property and the Internet, *Abusive Patent Litigation: The Impact on American Innovation & Jobs, and Potential Solutions* (14 March 2013) online: <http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=100399>; United States, House Judiciary Committee. Subcommittee on Courts, Intellectual Property and the Internet, *Abusive Patent Litigation: The Issues Impacting American Competitiveness and Job Creation at the International Trade Commission and Beyond* (16 April 2013) online: <http://docs.house.gov/Committee/Calendar/ByEvent.aspx?EventID=100672>; United States, House Committee on Small Business, *Patent Reform implementation and New Challenges for Small Businesses* (15 May 2013) online: <http://smallbusiness.house.gov/calendar/eventsingle.aspx?EventID=326571>; United States, Senate Commerce, Subcommittee on Consumer Protection, Product Safety, and Insurance, *Demand Letters and Consumer Protection: Examining Deceptive Practices by Patent Assertion Entities* (7 November 2013); United States, House Energy and Commerce Committee, Subcommittee on Oversight and Investigations, *The Impact of Patent Assertion Entities on Innovation and the Economy* (14 November 2013) online: <http://energycommerce.house.gov/hearing/impact-patent-assertion-entities-innovation-and-economy>.

569 The AIA also introduced wide-ranging and fundamental changes to the patent system which were not specifically related to PAEs. This included moving the U.S. from a first-to-invent to a first-to-file basis for patent grants (a regime which came into effect in 2013), changing the post-grant review and inter-parties review processes, expanding the prior commercial use defense and narrowing the availability of tax strategy patents. Legislative proposals for patent reform have long been percolating in the U.S., see e.g. *Patent Quality Assistance Act of 2004*, HR 5299, 108th Cong (2004) and the *Patent Reform Act of 2005*, HR 2795, 109th Cong (2005) and the similar *Patent Reform Act of 2007*, S 1145, 110th Cong (2007) (followed by another similar bill introduced in the 111th session of Congress) addressed reforms relevant to the PAE conduct problem.

570 Memorandum of Cleary Gottlieb Steen & Hamilton LLP, "Congress Makes Substantial Changes to Patent Law with the America Invents Act" (21 September 2011) at 1, online: <http://www.cgsh.com/files/News/20615f42-6ce1-42e1-b9ace8eeaac81c5a/PresentationNewsAttachment/0d904677-cb57-4aa0-aa81-ea5574b8d5cd/CGSH%20Alert%20-%20Invents%20Act.pdf>.

571 This includes (i) a specific procedure for challenging business method patents on any statutory ground, at any time, by a party that is sued for infringement of the business method patent (including the availability of a stay for the infringement action) and (ii) new post-grant review proceedings that enable anyone other than the patent owner to challenge the validity of a newly granted or reissued patent on broad statutory grounds within nine months of the patent grant.

572 Chien PAE Workshop, *supra* note 540 at 12.

573 The AIA 500 Expanded, *supra* note 526 at 7, (pointing out that the number of defendants sued by PAEs is much higher now than in 2007 and 2008, despite the AIA reforms). The drop may suggest the AIA was

U.S. President Barrack Obama acknowledged the *America Invents Act* did not go far enough in fighting PAEs.[574] For example, the AIA provisions restricting joinder do not apply to cases before the ITC, which has risen in popularity as a venue for PAE cases. On June 4, 2013, the White House announced five executive actions[575] and seven legislative recommendations related to patent issuance and litigation. The legislative recommendations include:

- Requiring disclosure of the "real party-in-interest" in demand letters, infringement suits and PTO reviews. PAEs are thought to use shell companies to bring litigation and identification of the party in control of a patent or related litigation may make it easier for the target of the litigation to assess whether it should settle;
- Permitting more discretion to courts to award fees to prevailing parties;
- Expansion of a PTO program to include computer enabled patents and to permit a wider range of challenges before the patent trial and appeals board. The program as it was introduced by the AIA enables the review of business method patents to be initiated by parties who are being sued based on such patents;
- Improving legal liability protection for off-the-shelf use of technology by consumers and businesses;
- Changing the ITC standard for obtaining an injunction to better align it with *eBay*;
- Using demand letter transparency to help curb abusive suits. This includes creating incentives for public filing of demand letters in a way that makes them accessible and searchable; and
- Ensuring the ITC has adequate flexibility in hiring qualified Administrative Law Judges.

The U.S. has since seen these recommendations reflected in several subsequent bills directed at PAEs, many of which focus on modifications to the litigation system. Each piece of proposed legislation takes a slightly different approach; the current bills are summarized briefly in **Appendix F**. The leading proposal is the *Innovation Act*, which was quickly passed by the House in December 2013.[576] The Senate must now pass companion legislation, after which the *Innovation Act* will go to the President for approval. Such approval is considered likely to be

successful in reducing the amount of litigation by PAEs, but some authors suggest it is too early to definitively conclude the AIA changes are responsible. *Ibid* at 59.

574 U.S. President Barrack Obama, February 14, 2013 as quoted in Patent Assertion Report, *supra* note 295 at 2 ("[O]ur efforts at patent reform only went about halfway to where we need to go and what we need to do is pull together additional stakeholders and see if we can build some additional consensus on smarter patent laws").

575 The Executive Actions, which require the PRO to engage in rulemaking processes for implementation, included identification of the "real party-in-interest" in proceedings before the PRO and in patent applications; tightening functional claiming by training patent examiners (considered to be a software patent issue, functional claiming allows patent to apply to many possible approaches to a problem rather than to a specific solution, leading to overly broad patents); empowering downstream users through education and outreach; expanding dedicated outreach and study on PAEs and strengthening the enforcement process for ITC exclusion orders

576 HR 3309.

granted given the public support from the President for the reforms. The *Innovation Act* is also thought to be generally supported by technology companies.[577]

The Innovation Act in Brief

The *Innovation Act* "aims to correct the current asymmetries surrounding abusive patent litigation",[578] principally by heightening the pleading standards for patent infringement complaints to require more detail, and by modifying the fee-shifting provisions in U.S. law to award costs to the winning party in patent infringement litigation "unless the court finds that the position of the non-prevailing party or parties was substantially justified or that special circumstances make an award unjust."[579] The *Innovation Act* also aims to protect end users of technology by empowering a court to stay a patent case against end consumers of a product or process, in favor of a case against the manufacturer of that product or process. Finally, the *Innovation Act* would require disclosure of the ultimate parent of the entity filing infringement litigation. It is expected such disclosure would be useful in enabling counterclaims, risk assessment and collection efforts by the targets of patent infringement litigation.[580]

Despite studies demonstrating that small businesses are increasingly targeted by PAE threats, critics of the *Innovation Act* are concerned it may discourage patent owners with limited resources, such as small businesses, from enforcing their patent rights.[581] They have also raised the specter of potentially unintended consequences arising from broad legislation targeting patent litigation, given Congress's relative lack of expertise in patent infringement litigation.[582] Finally, they question whether the proposal might violate the U.S. Constitutional grant of exclusive rights to patent holders.[583] It is unclear whether concerns over the *Innovation Act* are well-founded and it appears at this stage the legislation is likely to move ahead.

The overall themes in the proposed U.S. legislation and reforms focus on (i) a shift to a loser-pays system for patent infringement litigation, (ii) increased transparency in patent ownership and litigation and (iii) protection of end-users of technology from patent infringement claims.[584]

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577 Mark Klapow & Vincent Galluzzo, Memorandum of Crowell & Moring LLP, "Legislation Targeting So-Called 'Patent Trolls' Continues To Gather Steam" (13 November 2013) online: <http://www.crowell.com/NewsEvents/AlertsNewsletters/all/Legislation-Targeting-So-Called-Patent-Trolls-Continues-To-Gather-Steam> [Crowell & Moring Memo].

578 United States, House of Representatives, *H.R. ___, Patent Discussion Draft*, (May 2013) online: <http://judiciary.house.gov/_files/news/2013/052013%20-%20Patent%20Discussion%20Draft%201%20pager.pdf>.

579 Crowell & Moring Memo, *supra* note 577.

580 *Ibid*.

581 Representative Dana Rohrabacher (R-Calif.) said that the bill sends a "clear message to little inventors: give thanks for your intellectual property rights, because you may not have them by this time next year."; Representative John Conyers (D-Mich.), the House Judiciary Committee's top-ranking Democrat, and Representative Melvin Watt (D-N.C.) issued a joint statement against the bill and sought to delay the vote for further debate without success.

582 Crowell & Moring Memo, *supra* note 577, referring to comments of Former Federal Circuit Chief Judge Paul Michel.

583 *Ibid*.

584 ITC reforms are another key aspect of the U.S. reforms, but we leave aside this discussion on the basis that Canada has no equivalent adjudicative body.

The proposed changes moving toward a loser-pays system for patent infringement litigation would bring the U.S. model into closer alignment with that of Canada and the EU, where litigation costs are typically borne, at least in part, by the losing side. The existence of a loser-pays system in the EU has been credited with the minimal PAE activity there (see discussion below in the EU section on Patent Assertion Entities). The shift to loser-pays is designed to neutralize the significant financial risk advantage of PAE-initiated litigation. PAEs may be less likely to bring litigation where there is a risk of a cost award against them. If companies have been settling rather than fighting PAEs because litigation costs are high, they may be less likely to settle given the potential to recover some or all litigation costs.

Some argue cost shifting is not a full solution to the PAE conduct problem, because a loser-pays system still requires the defendant to engage in the litigation to the point of proving the patent is invalid or not infringed, diverting their business resources.[585] It requires a trial and a judgement. It would also require the winner to successfully collect costs from the PAE, which is often a shell company specifically structured to avoid the risk of losses in litigation.[586] Further, some PAEs establish litigation-specific entities to avoid exposure beyond the named plaintiff. Reforms to litigation processes could deter suits from being brought, but will have a less direct impact on cases where litigation is being threatened but not filed.[587]

The U.S. reforms that focus on transparency in patent ownership and litigation are a response to certain characteristics identified in PAE conduct. As a White House Report explains, the PAE business model may involve hiding the company's identity in litigation through numerous shell companies[588] and requiring those who settle litigation to sign non-disclosure agreements (although this also occurs in other patent infringement litigation as well). Overall, this can make it difficult for defendants to form common defensive strategies and to identify a company's history of bringing litigation. Some suggest PAEs benefit from concealing their patent holdings as well, because it supports their deferral of licensing discussions until the technology is integrated into a product and it helps avoid demands that an effective portfolio license be granted (increasing the potential for multiple assertion opportunities).[589] Measures such as those proposed by the White House thus focus on increasing transparency, such as requiring disclosure of the "real party-in-interest" in demand letters and litigation, and creating incentives for public disclosure of demand letters by recipients. Recording the party-in-interest is expected to contribute to efficiency and certainty in IP licensing, by enabling potential licensees to better assess the likelihood, merits and cost of licensing or the need to develop alternative, non-infringing technology.[590] Such measures may also facilitate defence coordination and tracking of trends in PAE demands.[591]

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585 Startups and Patent Trolls, *supra* note 547 at 1.

586 *Ibid.*

587 *Ibid* at 3.

588 Patent Assertion Report, *supra* note 295 at 4. For example, the company Intellectual Ventures, which some characterize as a PAE and others as merely a mass patent aggregator is organized in a complex structure of over 1,200 subsidiaries. The AIA 500 Expanded *supra* note 526 at 4.

589 Missing the Forest for the Trolls, *supra* note 293.

590 Startups and Patent Trolls, *supra* note 548.

591 Some call for even further measures such as the public disclosure of demand letters, Electronic Frontier Foundation "Legislative Solutions for Patent Reform", online: <https://www.eff.org/issues/legislative-solutions-patent-reform> [Legislative Solutions].

Criticism has been levied at some legislative proposals for focusing on "who is doing the asserting" by trying to define PAEs, rather than looking at the type of conduct or at reform of weak patents.[592] Some have raised concerns that universities and other entities considered to be legitimate intermediaries could be caught up in the net of reforms targeted at PAEs (although data suggests this concern is only hypothetical).[593] We agree that it is the conduct rather than the specific type of companies which reforms should target. The fast evolution of PAE conduct could mean legislation hinging on a definition of the type of entity, rather than the conduct at issue, will be difficult to draft in a manner that is effective against harmful patent related litigation conduct over the long term. We note that the *Innovation Act* reforms moving ahead in the U.S. are not based on the litigant identity and would apply to all patent infringement litigation.

Finally, some commentators support changes in the legislative proposals, but note "the underlying issue of broad software patents" is not addressed.[594] Consideration should be given to dealing with overly broad and poorly drafted patents (the "bad patent" issue). "Bad patents" that have already been issued may drive PAE litigation for some time into the future. This patent-issuance aspect of the reforms beyond the scope of this report.

(ii) Judicial Responses

Courts were the first to take action against PAE conduct in the U.S. The U.S. Supreme Court's decision in *eBay v MercExchange, LLC* in 2006 reversed two decades of law on infringement remedies by replacing the automatic issuance of a permanent injunction in patent infringement cases with a more flexible equitable test for the granting of an injunction.[595] In *eBay*, the concurring justices recognized that "an industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees".[596] They concluded that the issuance of an injunction may not serve the public interest where the injunction is being used as a "bargaining tool to charge exorbitant fees…when the patented invention is but a small component of the product."[597] The decision empowered U.S. courts to deny injunctions to PAEs and the subsequent drop in injunctions being issued by U.S. district courts has been dramatic.[598]

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592 Missing the Forest for the Trolls, *supra* note 293 at 72 referring to the proposed *SHIELD Act.*

593 The GAO study confirmed for example, that universities account for only about 0.2% of the parties bringing patent infringement litigation, based on first-named plaintiffs who filed lawsuits in a sample of 500 lawsuits filed between 2007 and 2011; Effects of Patent Monetization Entities, *supra* note 528 at 382; Similarly low statistics were confirmed in a subsequent study including data from 2012. The AIA 500 Expanded, *supra* note 526 at 52. The discretion of the judiciary in applying the law is another means through which universities and other legitimate intermediaries could be excluded from reforms intended to catch opportunistic PAE conduct.

594 Legislative Solutions, *supra* note 591.

595 The party seeking an injunction must now demonstrate "(1) that it has suffered an irreparable injury; (2) that remedies available at law, such as monetary damages, are inadequate to compensate for that injury; (3) that, considering the balance of hardships between the plaintiff and defendant, a remedy in equity is warranted; and (4) that the public interest would not be disserved by a permanent injunction." Edward H. Rice & Marina N. Saito, "After Ebay: Can The ITC Offer Better Remedies Than District Courts?" (2008) 19 Intellectual Property Litigation 2, online: <http://www.loeb.com/afterebaycantheitcofferbetterremediesthandistrictcourts/>.

596 *eBay*, *supra* note 98, concurring opinion at 396.

597 *Ibid* at 396-397.

598 Colleen Chien & Mark Lemley, "Patent Holdup, The ITC and the Public Interest" (2012-2013) 98 Cornell Law Review 1 at 9-10 [Patent Holdup] (finding an overall 20% drop in the granting of requests for injunctions by

Competition considerations are important when district courts consider granting injunctions post-*eBay*. When assessing the irreparable injury and the adequacy of the remedy at law, courts have looked at whether the infringement threatens the market share of the plaintiff, its reputation or its business model and have tended to deny injunctions where these harms are absent.[599] And, since PAEs are rarely active in the markets where they are asserting their patents, these considerations often mitigate against granting an injunction to PAEs.

Faced with less sympathetic courts since the *eBay* decision, PAEs have flocked to the alternative U.S. venue of the ITC. The ITC can grant an exclusion order, which provides relief similar to an injunction,[600] and some consider it to provide an "end-run around *eBay*." [601] The ITC is an administrative agency that awards exclusion orders based on statutory provisions,[602] so the equitable test for injunctive relief established in *eBay* does not apply.[603] The ITC is not empowered to award monetary damages, making exclusion orders the likely remedial option.[604] This forum shopping by PAEs, along with the ITC's popularity for standard-setting/FRAND disputes has led to proposed reforms and agency positions that favour limiting the availability of exclusion orders as relief.[605]

Another fairly recent Federal Circuit Court of Appeals case recognized and admonished trolling activity.[606] The Court affirmed a lower court finding that the plaintiff, Eon-Net LP ("Eon-Net"), had brought patent infringement litigation that was objectively baseless and in bad faith. Eon-Net's case had the "indicia of extortion" because it was part of Eon-Net and related companies' pattern of "filing nearly identical infringement complaints against a plethora of diverse defendants, where Eon-Net followed each filing with a demand for a quick settlement at a price far lower than the cost to defend the litigation".[607] Eon-Net and its related companies had filed

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district courts before and in the 2006-2011 period post-*eBa*y, and more specifically that over 90% of contested injunctions sought by PAEs post-*eBa*y were denied). See e.g. *z4 Techs, Inc v Microsoft Corp*, 434 F Supp (2d) 437 (ED Tex 2006) where a monetary award was found sufficient; Royalty Stacking, *supra* note 309 at 2036.

599 Patent Holdup, *supra* note 598 at 12.

600 The ITC saw 56 intellectual property investigations in the first 9 months of 2011, with a record 69 in the entire year. The proportion of NPE-initiated ITC cases also grew from 7% in 2006 to 25% of all ITC cases in 2011. *Ibid* at 3, referring to the Statistical Information of the US international Trade Commission Section 337.

601 *Ibid* at 19.

602 19 USC §1337, s 337 provides for the issuance of a special exclusion order remedy which blocks infringing imports.

603 Patent Holdup, *supra* note 598 at 1. The ITC expressly declined to follow *eBay*.

604 19 USC §1337 (2006).

605 See discussion above regarding U.S. Standard Setting/FRAND; In June 2013, the ITC announced a pilot program introducing procedural changes aimed at combatting PAEs by requiring proof earlier in the process that a company conducts economic activity within the U.S. in connection with at least one claim of an asserted patent (called the "domestic industry" requirement). Ted C. Koshiol, "New ITC Program Takes Aim at Patent Trolls" Memorandum of Fredrikson & Byron PA (1 July 2013) online: <http://www.fredlaw.com/news__media/2013/07/01/441/new_itc_program_takes_aim_at_patent_trolls>.

606 *Eon-Net LP v Flagstar Bancorp* 653 F (3d) 1314 (2011) at 22, appeal from *Eon-Net LP v Flagstar Bancorp*, No 2:05-CV-2129, Judgment (ECF No 200) (WD Wash 21 June 2010) [*Eon-Net*].

607 *Ibid.*

over 100 suits, following each with an offer to settle. [608] The court acknowledged that the cost of litigating even to the point of claim construction was so high (in this case, $600,000 for the defendant) that it was apparent why most of the companies accused of infringement by Eon-Net had agreed to settle.[609]

The U.S. Supreme Court will hear another five patent cases this term alone, considered to be "an extraordinary number".[610] Industry commentators have called the cases a "rare opportunity to rein in abusive litigation" by PAEs.[611] The cases do not specifically address PAE conduct, but they consider patent law issues that are likely to have implications for PAEs' business models. As with the legislative reforms discussed above, a key issue will be fee-shifting in two of the cases, which will address the test for determining when fees should be awarded to the winning party under the U.S. *Patent Act*, which provides such fees are awarded only in "exceptional" cases. An *amicus* brief argues "a real threat of fee shifting would take away PAE's biggest bargaining chip"; it advocates to replace the current test for fee-shifting with an approach that "takes account of the business models and motivations of the parties", among other factors.[612] A third case will address the patent eligibility of computer-related inventions, a fourth will consider liability for induced infringement when a customer performs the final step of the claimed patent method, and the final case will look at the standard for determining when claims are too vaguely drafted or ambiguous.[613]

(iii) Market Responses

Market-based responses to PAEs have also emerged in the U.S., such as defensive patent aggregation, where third party companies purchase and protect patents on their client's behalf.[614] Acquiring a patent stockpile prevents the patents from falling into the hands of PAEs and also makes the patents available for cross-licensing to settle or deter infringement claims. Ewing & Feldman explain that although producing companies still incur costs in such defensive measures, using mass aggregators to buy patents may be cheaper than buying off PAEs, and less of a distraction and aggravation for company executives than PAE litigation.[615] In another market-based response, public interest groups have launched the website "Trolling Effects", a searchable public database on which PAE demand letters are posted.[616] The theory, as with some of the proposed U.S. legal reforms, is that of making PAE demands public, it may facilitate

608 RIM indicated in 2011 it was involved in two patent infringement suits in U.S. District Courts with a similarly named and perhaps related company, EON Corporation IP Holdings LLC. RIM 2011 Annual Report at 37-38 online: <http://www.rim.com/investors/documents/pdf/annual/2011rim_ar.pdf>.

609 *Eon-Net*, *supra* note 606. The court affirmed the lower court award of almost $500,000 in attorney fees and costs, plus $140,000 in sanctions for litigating without a proper purpose.

610 See summary in Scott Graham, "Tech Companies Press Patent Wish List at Supreme Court" The Recorder, (24 January 2014) [Graham] The article also refers to a sixth patent case in which the Court has already issued a decision this term (*Medtronic Inc v Mirowski Family Ventures*, Slip Opinion, 22 January 2014).

611 *Ibid*.

612 Brief of Apple Inc. as *Amicus Curiae* in Support of Neither Party, *Octane Fitness, LLC v Icon Health* & *Fitness Inc* and *Fitness and Highmark Inc v Alcare Health Management Systems, Inc* (U.S. Supreme Court Cases 12-1163 and 12-1184).

613 Graham, *supra* note 610.

614 FTC Pay for Delay Study, *supra* note 427.

615 Giants Among Us, *supra* note 539 at 22.

616 See the Trolling Effects site at https://trollingeffects.org/ and discussion in Legislative Solutions, *supra* note 591.

coordination defence strategies and the identification of patterns in demand behavior which could impact the decision to settle litigation.

(d) Conclusions on PAEs in the U.S.

The debate surrounding the application of competition law to patent assertion entities has occurred almost exclusively in the U.S. Commentary and study of the topic from a U.S. perspective is extensive.

Studies suggest there has been a rapid rise in the number of PAE patent infringement lawsuits in the U.S. over a short period of time. By some estimates, such litigation now forms the majority of patent infringement law suits in the U.S. Litigation by PAEs has also been the subject of several studies that suggest it may have unique characteristics from patent infringement litigation brought by non-PAEs. Exploitation of the potential for patent hold-up, as with standard-setting/FRAND issues, is at the core of the PAE litigation strategy.

In the literature, PAEs are characterized by some as helpful and by others as harmful. Most of the commentary falls in the latter category. Estimates of costs imposed by PAE conduct in the U.S. are high. There is emerging literature suggesting that litigation costs are merely the tip of the iceberg, because many more non-public demands are likely being made by PAEs for each suit that ultimately reaches the courts. The latest literature, as well as commentary from the FTC, reflect two emerging trends in PAE activity that heightens potential antitrust law and policy concern: (i) privateering and (ii) the targeting of small businesses by PAEs.

The U.S. perspective is that the U.S. Patent and Trademark Office, the antitrust Agencies, legislative reform and the courts all have a role to play in addressing PAE conduct. PAE activity is seen as just one piece of a broader issue; flaws in the patent litigation and granting systems are fueling the PAE-imposed costs.

The FTC and the DOJ have focused significant attention on understanding patent assertion entities, including a public workshop and a pending formal study, but have yet to take any enforcement action. Information gathered from these activities will likely prove useful in informing enforcement and policy-making and in resolving questions about potential benefits from PAEs. Overall, the view from governmental agencies may be shifting toward a conclusion that some PAE conduct has a negative impact on consumers and innovation.

The U.S. has seen a multitude of recently proposed legislative reforms aimed directly or indirectly at curbing PAE behavior, although no legislation has yet been passed by the U.S. Senate. The key themes in the proposed U.S. legislation and reforms focus on (i) a shift to a loser-pays system for patent infringement litigation (ii) increased transparency in patent ownership and litigation and (iii) end-user protection. The leading reform proposals in the U.S. are not based on the litigant identity, and would apply to all patent infringement litigation.

The shift to a loser-pays system in U.S. patent infringement litigation, either through legislation or more gradually through judicial precedent, seems most likely to significantly impact the financial risk imbalances that drive PAE litigation. Some argue cost shifting is not a full solution to the PAE problem, though, because a loser-pays system still requires the defendant to engage in litigation to the point of proving the patent is invalid and to collect costs in practice from the PAE. The U.S. Supreme Court will hear several patent cases this term which, although not addressing competition law, may have significant implications for PAEs with respect to fee shifting under the U.S. *Patent Act.*

The U.S. courts have played an important role in controlling PAE hold-up potential by limiting the availability of injunctions, although this has led to forum-shopping within the U.S. Where PAE litigation is considered objectively baseless and in bad faith, it has also been dismissed in a U.S. case. Finally, market responses have emerged in the U.S. to help operating companies address PAE conduct.

4. Product Hopping

(a) U.S. Product Hopping Cases

Since at least 2006, the FTC has expressed concern that product hopping can harm competition in some circumstances by delaying or complicating generic drug entry.[617] No contested case on product hopping brought by the FTC has been decided. However, the FTC reached a consent agreement in 2006 in a product hopping case,[618] and more recently made its position clear in an *amicus* brief in a private case.

In November 2012, the FTC filed an *amicus* brief in *Mylan Pharmaceuticals, Inc v Warner Chilcott Public Limited Co,*(“*Warner Chilcott”*)[619] arguing the agency’s position that product hopping can constitute exclusionary conduct in contravention of Section 2 of the *Sherman Act*.[620] The product withdrawal at issue in *Warner Chilcott* involved discontinuing sales of the prior version, asking major customers to return inventory and otherwise making the prior version less available.[621]

As the FTC explains, when physicians stop writing prescriptions for the older drug, this eliminates the possibility of substitution at the pharmacy counter of the old drug and thus eliminates “meaningful generic competition.”[622] If the new formulation offers some marginal benefit, the question is whether the benefit is sufficient to make up for the foregone cost savings arising from lesser use of generics.[623] The theory of harm thus appears to hinge on skepticism over whether the new drug, which may involve a dosage or formula change, offers an improved

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617 Antitrust Scrutiny of Pharmaceutical Product Hopping, *supra* note 297 at 75, discussing comments by various FTC Commissioners flagging the issue of product hopping; *Mylan Pharmaceuticals, Inc, v Warner Chilcott Public Limited Company*, No 12-3824 (ED Pa, 21 November 2012), Brief of the Federal Trade Commission as *Amicus Curiae*, online: <http://www.ftc.gov/policy/advocacy/amicus-briefs/2012/11/mylan-pharmaceuticals-inc-et-al-v-warner-chilcott-public> [FTC Brief Warner Chilcott].

618 The FTC was also involved in a product hopping case in 2006, in the context of a pending reverse payment settlement case. The FTC sought a preliminary injunction against Warner Chilcott to require it to continue to offer a tablet formulation of a birth control product, at the same time as a new chewable formulation of the drug was launched. The FTC argued withdrawing the tablet formulation would have “essentially destroyed” the market for the generic version of the tablet formulation because it meant generic substitution would be unavailable. The case settled on terms requiring the original formulation to continue to be offered and requiring that Warner Chilcott not destroy or buy back product inventory of the older formulation for a certain period. United States, Federal Trade Commission, Press Release, “Consumers Win as FTC Action Results in Generic Ovcon Launch” (23 October 2006) online: <http://www.ftc.gov/news-events/press-releases/2006/10/consumers-win-ftc-action-results-generic-ovcon-launch>.

619 FTC Brief Warner Chilcott, *supra* note 617.

620 The private complainant in the case also alleges *Sherman Act* Section 1 violations arising from the conduct.

621 FTC Brief Warner Chilcott, *supra* note 617 at 14.

622 *Ibid*.

623 Lauren Battaglia, Pierre Larouche and Matteo Negrinotti, “Does Europe Have an Innovation Policy? The case of EU economic law”. GRASP Working Paper January 11, 2011 (Previously published in the CEPR Discussion Paper Series No.848) at 15 [Battaglia and Larouche].

therapeutic benefit over the older drug formulation.[624] Skepticism from the FTC over the innovative value of the new product formulations in *Warner Chilcott* is clear; the FTC calls the switch an effort to "game" the drug regulatory regime, with patent holders making product changes with little or no benefit in order to delay competition.[625] The FTC warns that an approach holding the product changes to be *per se* lawful, as advocated by *Warner Chilcott*, "would entitle brand pharmaceutical companies, as a matter of law, to manipulate the FDA regulatory process and undermine state and federal laws that encourage generic competition."[626]

There have also been three private U.S. cases litigated to the point of a decision on product hopping, although all involved interim motions to dismiss rather than substantive adjudication on the merits.[627] The central issue in two of these cases, *Abbott Laboratories v Teva Pharmaceuticals* and *Walgreen Co v AstraZeneca Pharmaceuticals* was whether there was an elimination of consumer choice arising from the branded company's withdrawal of its older product formulation.[628] Did the new product gain acceptance in the market through the free choice of consumers who switched, or through "coercion" because the older product was withdrawn from the market? The preliminary indication is that where coercion is responsible for the switch, such conduct is potentially anti-competitive.[629] The mere introduction of a new drug and discontinuance of marketing support for the old drug (without withdrawing it from the market) was not considered to be sufficient for an antitrust cause of action, because it actually led to greater consumer choice.[630]

Once a potentially anti-competitive withdrawal is shown, *Teva* suggests the relevant antitrust inquiry is whether the consumer harm created by lost generic competition outweighed the pro-competitive benefit of the product reformulation.[631] The harm alleged would have to be weighed against any benefits to the new formulation argued by the defendants. Where the product reformulation benefits are very incremental and the detriment to generic substitution is significant, exclusionary conduct violating antitrust law may be established. The FTC advocates for the same approach in its *amicus* brief in *Warner Chilcott*.

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624 *Ibid*. For example in the generic pharmaceutical company Teva alleged that Abbott had "responded to the threat of generic entry . . . by changing the formulation of TriCor [a branded drug], not to improve the product, but simply to prevent generic formulations from becoming AB-rated for substitution with TriCor." *Abbott Laboratories v Teva Pharmaceuticals USA*, 432 F Supp (2d) 408 (2006) [*Teva*].

625 *Ibid* at 9 quoting Herbert Hovenkamp & Christina Bohannan, "IP and Antitrust: Reformation and Harm" (2010) 51 Boston College Law Review 905.

626 *Ibid* at 14.

627 *Teva, supra* note 624*; Walgreen Co v AstraZeneca Pharmaceuticals*, 534 F Supp (2d) 146 (2008) [*AstraZeneca*]*; Mylan Pharmaceuticals, Inc, v Warner Chilcott Public Limited Company*, No 12-3824 (ED Pa, 21 November 2012) [*Warner Chilcott*]. For more detail on these cases, see Antitrust Scrutiny of Pharmaceutical Product Hopping, *supra* note 297.

628 *Teva*, *ibid; AstraZeneca*, *ibid*.

629 *Ibid*. The third U.S. product hopping private case provided little guidance on the proper approach; it merely found that although the product hopping claim was novel, the claim could not be dismissed at the pleadings stage without further inquiry. *Warner Chilcott*, *supra* note 627.

630 *AstraZeneca*, *supra* note 627.

631 *Teva, supra* note 624.

(b) The Challenge of Addressing Predatory Innovation

The theory of product hopping appears to be based on the idea of predatory innovation. The concept of predatory innovation is that not all innovation is competitively desirable, because some innovations "both harm rivals and fail to benefit consumers". Essentially, where product development or product design is intended to impede competition, entrench a dominant firm's position in the market or artificially change the structure of the market to make it more difficult for new entrants, but it does not improve the product in a material way or offer corresponding consumer benefits, such "innovation" may be unlawful under U.S. antitrust law.[632]

There is a divide between U.S. courts over the analytical framework to be applied in assessing whether innovation in product design is exclusionary or predatory in violation of U.S. antitrust laws. The *Microsoft*[633] judgement sets out a rule of reason approach, while *Allied Orthopedic v Tyco*[634] ("*Allied Orthopedic*") and other cases take a *per se* legality approach to product improvement.

Microsoft starts from the premise that courts should be "very skeptical about claims that competition has been harmed by a dominant firm's product design changes," particularly in technology markets where products change rapidly; it recognizes that the courts should not deter innovation in a market with rapidly changing products.[635] However *Microsoft* rejects a *per se* lawfulness approach to monopolist's product improvements and instead set out a framework under which the plaintiff must demonstrate that the challenged conduct had an anti-competitive effect, after which the defendant may rebut with evidence of a pro-competitive justification for its conduct. If a pro-competitive justification is established, the court then weighs the pro-competitive benefits against the anti-competitive effect.[636] The court in *Microsoft* ended its own analysis after the second step when no pro-competitive justification was proven.[637]

In contrast, *Allied Orthopedic* adopts a *per se* legality approach to product redesign, explaining that "[t]here is no room in the analysis for balancing the benefits or worth of a product improvement against its anti-competitive effects." It concludes that where a monopolist's design changes are shown to be some improvement, that design change is "necessarily tolerated by the antitrust laws" unless there is some other abuse or leverage involved, because to hold otherwise "would be contrary to the very purpose of the antitrust laws, which is, after all, to foster and ensure competition on the merits."[638] Weighing the benefits of an improved product

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632 *See*, Jacobson & Holman, "Predatory Innovation: An Analysis of Allied Orthopedic v. Tyco in the Context of Section 2 Jurisprudence", 23 Loyola Consumer Law Review 1; See also *In the Matter of Intel Corporation*, Decision and Order, FTC Docket No. 9341 (29 October 2010) (modifying a proposed order of 4 August 2010 to reflect the public comment period) prohibiting Intel from engaging in "predatory design".

633 *Supra* note 92.

634 See, 592 F 3d 991 (9th Circ. 2010). Neither *Microsoft* nor *Allied Orthopedic* involved product hopping allegations, but the cases are relevant to the debate in product hopping cases over the applicable legal standard.

635 *Microsoft, supra* note 92 finding however that "[j]udicial deference to product innovation . . . does not mean that a monopolist's product design decisions are per se lawful."

636 See also *Teva*, *supra* note 624, which refused to dismiss a complaint about drug product changes and indicated a Microsoft-type test would be applied.

637 Microsoft was held liable based on this stage of the analysis, since failed to show that its product integration "serve[d] a purpose other than protecting its operating system monopoly."

638 *Ibid* at 1000, and quoting *Foremost Pro Color, Inc v Eastman Kodak Co*, 703 F 2d 534 at 545 (9th Circ 1983).

design against the resulting injuries to competitors is considered by *Allied Orthopedic* to be "not just unwise" but also "unadministrable" because adjudicators are unable to "calculate the 'right' amount of innovation, which would maximize social gains and minimize competitive injury."[639] Unless the monopolist also engaged in "coercive conduct," the court left "the ultimate worth of a genuine product improvement" to be "judged only by the market itself."[640] What exactly was meant by coercion has not been clearly determined.[641] One author points out that even this *Allied Orthopedic* approach requires some initial assessment of whether there is a genuine product improvement at the outset of the analysis, but essentially allows that a modest consumer benefit would suffice to protect the conduct from antitrust scrutiny.[642]

Allied Orthopedic is closer to the approach in the older U.S. case *Berkey Photo Inc v Eastman Kodak Co* ("*Berkey Photo*"), which held that the successful introduction of a new or improved product, even if that introduction reduces competition, does not violate antitrust law, unless there was some form of coercion that occurred.[643] The underlying theory is that, as long as free consumer choice is preserved, there is no need to intervene to control the monopolist's actions. Where old products are removed by the branded company, the court in *Teva* declined to apply the *Berkey Photo* approach, on the basis that consumers were deprived of choice.[644]

The FTC seized on this argument in its *amicus* brief in *Warner Chilcott*. It describes the problematic conduct as being when customers do not choose the reformulated product based on its merits and instead "the brand forces the switch by removing the product from the market and preventing consumers from weighing the relative merits of competing products".[645] The absence of consumer choice is characterized by the FTC as the essential difference between product switching in the pharmaceutical industry, and product switching in other contexts (like *Berkey Photo*) where the courts have expressed caution over questioning the innovation value of new products, on the premise that the switch merely reflects consumer choice. Where consumer choice is lacking, the FTC argues less judicial deference to product innovation is appropriate.

Overall, the FTC argues the *Microsoft* approach should apply in analyzing product hopping, as reflected in the "weighing" approach of *Teva* described above.[646] Branded pharmaceutical companies advocate for the *Berkey Photo* approach. The challenge is that "[a]ny judicial rule for condemning possibly anticompetitive innovation under the antitrust laws must be formulated so

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639 *Ibid*.

640 *Ibid.*.

641 Antitrust Scrutiny of Pharmaceutical Product Hopping, *supra* note 297 at 72.

642 Donald M. Falk and Joseph W. Goodman, "Innovation in the Balance? Courts and Agencies Take Another Look at Product Innovation and the Competition Laws" (June 28, 2010) online: <http://www.martindale.com/antitrust-trade-regulation-law/article_Mayer-Brown-LLP_1065118.htm>.

643 603 F (2d) 263 at 287 (2nd Cir 1979) ("a monopolist is permitted, and indeed encouraged…to compete aggressively on the merits, [and] any success that it may achieve through the process of invention and innovation is clearly tolerated by the antitrust laws.) [*Berkey Photo*].

644 *Teva, supra* note 624.

645 FTC Brief Warner Chilcott, *supra* note 617.

646 *Ibid*.

as not to discourage the great majority of innovation that are competitive."[647] Assessing how much innovation is "enough" is particularly difficult in product hopping cases, where it is important to preserve branded companies' incentives to innovate by introducing newer versions of drugs.

(c) Commentary on Product Hopping in the U.S.

The focus of private cases to date on consumer choice has been criticized by one author as a "red herring".[648] In a slightly older article, it is argued that (i) there is no real consumer choice at issue since physicians, not consumers, act as gatekeepers in drug choice and (ii) generic manufacturers remain free to enter the market with their equivalent of the new drug variation. The author proposes that merely introducing a new drug and discontinuing sales of an old drug is not an antitrust violation.[649] Instead, he suggests antitrust enforcement should narrow its focus to product hopping where there is specific regulatory gaming that blocks generic substitution at the level of pharmacies.[650] For example, in *Abbott Laboratories v Teva Pharmaceuticals*, affirmative steps were taken by the branded company to change codes in the database used by pharmacies such that the old branded formulation was marked obsolete, preventing generic substitution.[651] This approach of focusing on a regulatory block may enable antitrust scrutiny but reduce the need to "police innovation", which, as discussed below, can prove very challenging.[652]

Branded companies argue that allowing antitrust liability for product hopping amounts to the imposition of a duty on the branded company to continue to market old products, in order to enable generic competitors to benefit from substitution. No such duty exists in competition law and the branded companies characterize this "free-riding" as "the antithesis of competition".[653] Branded companies argue if generic companies cannot compete successfully, it may reflect their lack of advertising spending and perhaps a problem with their business model more so than anti-competitive conduct.[654] Although valid arguments, it seems nevertheless that one can question the intent of non-therapeutic changes to successful products on the eve of potential generic entry.

One author warns that the *Hatch-Waxman* regime is already intended to be an inherently balanced regulatory scheme; he argues antitrust agency and court intervention in product hopping should be cautious not to upset the careful balance struck between innovation

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647 *In the Matter of Google Inc, FTC File No. 111-0163,* Concurring and Dissenting Statement of Commissioner J. Thomas Rosch Regarding Google's Search Practices (3 January 2013) at 6, quoting Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law (2012) at para 775 c.

648 Jessie Cheng, "Antitrust Analysis Of Product Hopping" (2008) 108 Colum. L. Rev. 1471 at 1498. We note that some of the literature canvassed here is slightly older overall.

649 *Ibid.*

650 *Ibid.*

651 *Ibid* at 1511. The author argues "[b]y taking affirmative steps to prevent such generic substitution from taking place, Abbott and Fournier subverted the legislative policy judgment that DPS [drug substitution] laws embody".

652 *Ibid* at 1515.

653 Memorandum of Law in Support of Defendant Warner Chilcott's Motion to Dismiss, *Mylan Pharmaceuticals, Inc v Warner Chilcott Public Limited Co* (1 October 2012).

654 *Ibid*.

incentives and promotion of generic entry.[655] The impact of greater enforcement may be to chill pharmaceutical innovation, even if such innovations are regarded by some as being modest.[656]

This limited role for antitrust in product hopping is rejected by Dogan and Lemley. They argue the mere existence of the regulatory scheme for approval of generic pharmaceuticals does not mean behavior related to that scheme is sanctioned by the U.S. Food and Drug Administration, or that the behaviour is protected from antitrust scrutiny when it has anti-competitive effects.[657] To the extent that product hopping is exclusionary behavior that harms consumers, the authors support antitrust intervention. Another author suggests that the *Actavis* decision on reverse payment settlements may alter how courts and the Agencies address product hopping, to the extent *Actavis* leans toward antitrust liability applying even in the presence of patent rights.[658]

Finally, Carrier argues that by considering reverse payment settlements and product hopping separately, the analysis may miss additional anti-competitive harm where the conduct occurs in conjunction.[659] He argues that a reverse payment settlement which prevents patent challenges for a period of time—even if less than the duration of the patent—gives the branded firm time during which it can comfortably switch the market to the new product. By the date of generic entry, the market may already have been switched to the new product, making product substitution of the old product (and generic competition) unlikely.

(d) Conclusions on Product Hopping in the U.S.

U.S. antitrust jurisprudence on product hopping is in its early stages and fairly unsettled. The FTC has taken the view that product hopping may violate U.S. antitrust laws where it involves branded companies forcing consumers to switch to the new product formulation by withdrawing the older formulation from the market, in which case the consumer harm created by lost generic competition should be weighed against the pro-competitive benefit of the product reformulation. In cases to date, which involve only preliminary rulings in private litigation, potential antitrust liability has required an elimination of consumer choice arising from the branded company's withdrawal of its older product formulation. The next analytical step in such product hopping cases would be to weigh the benefits of innovation against competitive harms. This raises broader, complex questions of when and how innovation in the form of new products should be policed by antitrust.

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655 Antitrust Scrutiny of Pharmaceutical Product Hopping, *supra* note 297 at 76.

656 *Ibid*.

657 Stacey L. Dogan and Mark A. Lemley, "Antitrust Law and Regulatory Gaming" (2009), 87 Texas Law Review 685, accessed online: http://ssrn.com/abstract=1287221 ("If a pharmaceutical company designs its products for the sole purpose of dragging out a regulatory process for years and thereby forestalling competition, it has engaged in exclusionary behavior that harms consumers. The fact that it has done so by taking advantage of a loophole in the regulatory scheme does not mean that the FDA has blessed this anticompetitive behavior or that antitrust law must get out of the way to avoid interference in the regulatory scheme.") at 42 [Dogan and Lemley].

658 Muddying Settlement Waters, *supra* note 484 at 15.

659 Michael A. Carrier, "A Real-World Analysis Of Pharmaceutical Settlements: The Missing Dimension Of Product Hopping" (2010) 62 Florida Law Review 1009.

VII. EUROPE

1. Standard Setting and FRAND Licensing Commitments

The EU, like the U.S., has acknowledged the potential economic advantages of standard-setting and the need to regulate competition in standard-setting to ensure such economic benefits are realized. EU policy documents seem to place an even greater emphasis on the "stronger role" for standardization as a contributor to the competitiveness of Europe in the global economy.[660] Active standardization, including the setting, updating and the uptake of standards by end users has been emphasized as an important enabler of innovation in the EU.[661] Interoperability and standards were identified as a pillar of the Digital Agenda for Europe, launched in 2010.[662] The Digital Agenda includes plans to "promote appropriate rules for essential intellectual property rights and licensing conditions in standard-setting,"[663] and acknowledges that standard-setting can result in effects on competition by potentially restricting price competition and limiting or controlling production, markets, innovation or technical development.

The importance of standard-setting to the EU economy means the EC has paid considerable attention to achieving the benefits of standardization. Broadly speaking, competition policy in the EU, by facilitating both competition in the establishment (and updating) of standards and effective access to standards after they have been set, is thought to enable the economic benefits of standardization to be realized. As discussed further below, the EC issued revised Horizontal Guidelines in 2011 with extensive guidance on standard-setting and competition policy and the EC has brought several recent cases in the area. The EC also engaged in an extensive study assessing the interplay between standards, competition policy and intellectual property right protection with a report issued in 2011 titled *Study on the Interplay Between Standards and Intellectual Property Rights (IPRs) Final Report* (the "2011 EC Report on IP").[664] The 2011 report was intended to provide a sound factual basis for policy development in the area,[665] and was based on a literature survey, analysis of intellectual property right databases, stakeholder interviews around the world, an international survey of SSOs and standards-implementing companies and the review of many SSO's IP policies.

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660 Communication From The Commission To The Council, The European Parliament And The European Economic And Social Committee, "Towards An Increased Contribution From Standardisation To Innovation In Europe" (11 March 2008, COM(2008) 133 final) [Towards An Increased Contribution From Standardisation To Innovation In Europe]; The EU also has broad regulations and guidelines applicable to European standardization organizations outside of the intellectual property and competition law context. Regulation (EU) No 1025/2012 of the European Parliament and of the Council on European standardization imposes obligations on European standardization organisations (CEN, CENELEC and ETSI) and national standardization bodies for transparency of standardization processes and for stakeholder participation in European and national standardization activities. These are part of a broader standardization framework that includes guidelines on cooperation with European standards organizations, see <http://ec.europa.eu/enterprise/policies/european-standards/standardisation-policy/general-framework/index_en.htm>. The emphasis of this framework is on transparency and stakeholder participation, which should at a general level also contribute to competition in standard-setting.

661 *Ibid*.

662 European Commission, Digital Agenda For Europe (2010), online:<http://ec.europa.eu/digital-agenda/> [EU Digital Agenda].

663 *Ibid*, Pillar II: Interoperability and Standards, Action 22.

664 European Union, European Commission, *Study on the Interplay Between Standards and Intellectual Property Rights (IPRs) Final Report* (April 2011) prepared by Knut Blind et al [Standards and IP Rights].

665 *Ibid*.

The 2011 EC Report on IP found that most standards include only a few patents, while a small number of other standards include large numbers of patents for each standard. Most of the patents in standards related to telecommunications and consumer electronics products with some in transport, logistics, energy and health industries.[666] The report also found most of the companies owning IPRs related to standards were from the U.S., Japan and Europe.[667] At a broader competition policy level, the 2011 EC Report on IP suggested that the globalization of stakeholders and the convergence of technologies "call for a global perspective on the interplay between IPRs and standardization". The report notes briefly that patents in standards can lead to the risk for patent hold-up, patent ambush and trolling, and royalty stacking. Where standardization includes intellectual property rights, the EC supports the general policy view that "standards should be open for access and implementation by everyone, with intellectual property rights relevant to the standard being taken into consideration in the standardization process, aiming to establish a balance between the interests of the users of standards and the rights of owners of intellectual property."[668]

The EC has organized three conferences in conjunction with the European Patent Office on topics related to standard-setting and patents.[669] The conferences were intended to inform the strategies of the agencies for improving competitiveness and innovation with respect to standardization, and also to increase the transparency and predictability of treatment at the interface between standardization and the patent system.

As in the U.S., the agency concerns over standard-setting in the EU can be summarized in general categories that include (i) the older concern that collusive conduct might occur between competitors engaging in the standard-setting process, and, (ii) after a standard is established and results in market power, concerns over (a) anti-competitive foreclosure preventing effective access to the standard, (b) the potential for patent hold-up via deception in standard setting (patent ambush) or breach of FRAND commitments.[670] The EU also points to concern over foreclosure of alternative technology arising from the standard-setting process, potentially creating a barrier to entry of other technologies.[671]

We focus on the most recent subject of concern, the potential for patent hold-up and discuss enforcement action with regard to deception in standard setting and the abrogation of licensing commitments below. None of the EC cases have been contested to the point of a court decision, so there is no judicial precedent on when licensing activity or patent enforcement related to SEPs will violate EU competition law.

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666 *Ibid* at 12.

667 *Ibid* at 11.

668 Towards An Increased Contribution From Standardisation To Innovation In Europe, *supra* note 660.

669 ICT Standards And Patents: The Public Authorities And International Perspective: How To Increase Transparency And Predictability (24 November 2011); Transparency and Predictability of Licensing in ICT through Patent Pools (18 April 2012); Implementing FRAND Standards In Open Source: Business As Usual Or Mission Impossible (22 November 2012). Links to the documentation related to these conferences are available here: <https://ec.europa.eu/digital-agenda/en/pillar-ii-interoperability-standards/action-22-promote-standard-setting-rules>.

670 See discussion in The Digital Agenda, *supra* note 662 Pillar II: Interoperability and Standards, Action 22.

671 *Ibid*. "While a standard is being developed, alternative technologies can compete for inclusion in the standard. Once one technology has been chosen and the standard has been set, competing technologies and companies may face a barrier to entry and may potentially be excluded from the market."

(a) Deception in Standard Setting

Like the U.S., the EC brought a case against Rambus alleging patent ambush. The EC's preliminary view was that Rambus had abused its dominant position by claiming unreasonable royalties for the licensing of certain patents that read on standards.

The EC alleged Rambus had intentionally failed to disclose the patents it held and later claimed those patents read on the standard which had been adopted. [672] The EC considered this a breach of the relevant SSO's policy, and also of a duty of good faith in the context of standard-setting. In the absence of such deception, the EC was of the view that Rambus would not have been able to obtain the royalty rates it claimed. The EC considered such conduct to undermine industry confidence in the standard-setting process, to the detriment of consumers. The SSO was U.S.-based, but the conduct was considered to have an effect in the EU. It is not illegal in the EU to obtain market power through unlawful means, so the alleged violation of Article 102 by Rambus centred on the company charging unreasonable royalties for its patents *after* it had obtained market power, in contrast to the unlawful acquisition of monopoly power that formed the central allegation in the U.S. *Rambus* case.[673]

The EU case was resolved by Rambus committing to a worldwide maximum percentage on its royalty rates for products compliant with the standards for five years, including specified later generations of the technology.[674] The commitments indicate that the obligations are not impacted by the sale of patents to a third party.[675]

The key message from the EC in resolving the *Rambus* case was that standard-setting "should take place in a non-discriminatory, open and transparent way to ensure competition on the merits and to allow consumers to benefit from technical development and innovation".[676] This approach is now reflected in the recently issued EC Horizontal Guidelines.

(b) Abrogation of Licensing Commitments Made for Patents Related to Standards

There have been a large number of private cases regarding licensing disputes over SEPs in national EU courts, and several are ongoing.[677] Parties to some of these disputes have also

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672 European Union, European Commission, Press Release, "Antitrust: Commission Accepts Commitments From Rambus Lowering Memory Chip Royalty Rates" (9 December 2009) online: <http://europa.eu/rapid/press-release_IP-09-1897_en.htm> [Rambus Press Release]. The rates imposed for later generations of the technology were actually considered "substantially lower" than the rates for the technology at issue. In the EC, a "commitment decision" is based on Article 9 of Regulation 1/2003 on the implementation of the EU's antitrust rules. It does not amount to a finding on an infringement, but it legally binds Rambus to the commitments it offered and ends the Commission's investigation. If Rambus were to break its commitments, the Commission could impose a fine of up to 10 percent of its annual turnover, without having to find an infringement of the antitrust rules.

673 EC Policy on Licensing SEPs, *supra* note 306 at 1131.

674 Rambus Press Release, *supra* note 672.

675 *Ibid*.

676 *Ibid*.

677 See e.g. Christof Swaak, "The European Commission Market Tests Commitments Offered By Samsung Regarding The Enforcement Of Its UMTS Standard Essential Patents" Memorandum of Stibbe (1 November 2013) online: <http://www.lexology.com/library/detail.aspx?g=0dda4d92-1779-4aa6-9c1c-cf3a594afcf4> regarding Huawei and ZTE litigation in Germany.

filed competition complaints, which have led to several investigations and statements of objection from the EC in recent years where conduct involves the abrogation of SEP licensing commitments, as discussed below.[678] None of the EC enforcement actions have yet resulted in a contested case.

(i) Direct Repudiation of Commitments

Slightly older cases in the EU mirror the concerns in cases brought in the U.S., although sometimes with different outcomes. The EC's investigation into Qualcomm, prompted by industry complaints, considered whether FRAND commitments had been breached by Qualcomm in its licensing terms for patents that were essential to standards for mobile phones (such as WCDMA, part of the 3G standard) in Europe.[679] The EC reportedly spent significant resources on the investigation into whether Qualcomm's licensing terms violated its FRAND commitments, but ultimately all complainants withdrew their complaints and the investigation was closed at the end of 2009. The challenge for the EC was reportedly to prove the rates were not just high, but that the rates actually reached the level of being exploitative under Article 102(a) of TFEU.[680] The negotiation of the terms at arm's length between sophisticated parties may have made this more difficult to establish. Benchmarks proposed to assess whether the rates were fair and reasonable were considered theoretically unsound, or raised complex implementation issues. [681] An EC press release on the closing of the investigation acknowledged the assessment of technology pricing in standard-setting "may be very complex, and any antitrust enforcer has to be careful about overturning commercial agreements".[682]

The EC also investigated IPCom over alleged FRAND breaches. As in the U.S. *N-Data* case, the issue was the continuation of FRAND commitments when patents were sold. When it acquired patents, IPCom was not willing to take over the commitments of the original patent owner, Bosch, to grant irrevocable FRAND licenses on patents reading on standards for mobile phones. Bosch had been part of the standard-setting processes and had committed to the SSO to grant such licensing on its SEPs. After discussions with the EC, IPCom reversed its position and announced publicly it would take over Bosch's previous commitment. No formal commitments were made to the EC and the case was closed in 2009.

The IPCom investigation highlighted the fragility of FRAND licensing commitments and the need to ensure that the commitment travels with the patent rights in transactions. In its press release on the conclusion of the investigation, the EC noted "unrestricted access to the underlying proprietary technology on FRAND terms for all third parties safeguards the pro-competitive

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678 There was also a major standard-setting case decided around the time of Qualcom and IPCom that did not involve patents, Case 39416 Ship Classification, Commission Decision of 14/10/2009 relating to a proceeding under Article 81 of the EC Treaty and Article 53 of the EEA Agreement.

679 See European Union, European Commission, Press Release, "Commission Closes Formal Proceedings Against Qualcomm" (24 November 2009) online: <http://europa.eu/rapid/press-release_MEMO-09-516_en.htm> [Commission Closes Formal Proceedings Against Qualcomm].

680 EC Policy on Licensing SEPs, *supra* note 306 at 1133.

681 *Ibid*.

682 Commission Closes Formal Proceedings Against Qualcomm, *supra* note 679.

economic effects of standard-setting. Such effects could be eliminated if, as a result of a transfer of patents essential to a standard, the FRAND commitment would no longer apply."[683]

(ii) Availability of Injunctions for FRAND-Encumbered SEPs

A major recent issue addressed by the EC is whether seeking injunctions with respect to FRAND-encumbered SEPs constitutes an abuse of dominance in violation of Article 102. The EC acknowledges recourse to injunctive relief is generally a legitimate remedy for patent infringement. However, the EC position is similar to the U.S. agencies, in that it considers seeking and enforcing an injunction for FRAND-encumbered SEPs may, in some circumstances, constitute an abuse of dominant position. Those circumstances are considered to exist where a SEP holder has committed to license the patents on FRAND terms and the company against which an injunction is sought has shown to be willing to enter into a FRAND license.[684] The EC has indicated "patent holders should not seek injunctions based on SEPs against companies that are willing to enter a license on FRAND terms."[685]

The underlying EC concern is similar to that of the U.S. The threat of an injunction may distort licensing negotiations unduly in the SEP-holder's favour, by forcing potential licensees into onerous licensing terms such as higher royalties than would otherwise have been agreed to, or forced cross-licenses.[686] To the extent that injunctions are actually enforced, prohibiting the allegedly infringing product from being sold, this may have a direct negative effect on consumers in the form of less product choice and less innovation.[687]

This concern over hold-up raised by injunctions was considered by the EC its approval of the Google acquisition of Motorola Mobility. Third parties to the transaction raised concerns about the merged entity seeking or enforcing injunctions against "good faith" competitors in order to impose more onerous licensing terms for SEPs, in particular, in respect of forcing cross-licenses. The EC decision acknowledges the potential hold-up threat of injunctions, which may "significantly impede effective competition by, for example, forcing the potential licensee into agreeing to potentially onerous licensing terms which it would otherwise not have agreed to" and "hav[ing] a direct negative effect on consumers if products are excluded from the market".[688]

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683 See European Union, European Commission, Press Release, "Antitrust: Commission Welcomes Ipcom's Public FRAND Declaration" (10 December 2009) online: <http://europa.eu/rapid/press-release_MEMO-09-549_en.htm>.

684 European Union, European Commission, Press Release, "Antitrust: Commission Sends Statement Of Objections To Motorola Mobility On Potential Misuse Of Mobile Phone Standard-Essential Patents-Questions And Answers" (6 May 2013) online: <http://europa.eu/rapid/press-release_MEMO-13-403_en.htm> [EC Press Release on Motorola SEPs].

685 December 2013 Almunia Speech, *supra* note 137.

686 European Union, European Commission, Press Release, "Antitrust: Commission sends Statement of Objections to Samsung On Potential Misuse Of Mobile Phone Standard-Essential Patents" (12 December 2012), online: <http://europa.eu/rapid/press-release_IP-12-1448_en.htm> [EC Press Release On Samsung SEPs].

687 "[H]old-ups of this kind can ultimately lead to less consumer choice with regard to interoperable products and less innovation." *Ibid*.

688 Commission Decision, European Commission, Case No COMP/M.6381 - *Google/Motorola Mobility* (13 February 2013) [*Google/Motorola*] at 22.

The EC concluded, however, that there were limited incentives for Google to seek anti-competitive royalties, or to use injunctions or threats of injunctions against good-faith prospective licensees in order to force cross-licenses that would not otherwise have been accepted.[689] The rationale for the transaction was to achieve a "patent balance" in the mobile device industry, given that Google had a much smaller patent portfolio prior to the transaction, and it wanted to preserve the ability of Android OEMs to compete free from litigation threats. In other words, there was no indication that the patents were being acquired in order to engage in hold-up to obtain high royalties or to force cross-licenses, and the main motivation was to defend against becoming a target for such conduct.

The risk of countersuits against Google Android OEMs was also thought to constrain Google's incentives to seek an injunction against large competitors such as Apple or Microsoft. Google would have to consider the large, complex and non-transparent patent portfolios of Apple or Microsoft (raising the spectre of cross-claims), the cost of litigation, the likelihood of success of cross-claims and ability to design around any alleged infringements in cross-claims. The EC also took into account that Google had assumed Motorola's FRAND commitments in a public letter to SSOs, which included maximum royalties and a commitment to engage in good faith negotiations with potential licensees. Finally, the EC also found its Horizontal Guidelines (which specify when injunctions were considered permissible) and the prospect of an investigation based on Article 102 TFEU likely constrained any incentive to impede competition through forced cross-licensing. Similarly to the U.S. Agencies, in approving Google's acquisition of Motorola, the head of the EC expressed a commitment to "keep a close eye" on the behavior of companies in this sector, "particularly the increasingly strategic use of patents".[690]

True to this warning, as of December 2013, the EC had brought two formal allegations of abuse of a dominant position where injunctions were sought in member states for FRAND-encumbered SEPs.[691] In the first, against Motorola, the EC's preliminary view is that Motorola's recourse to injunctions for FRAND-encumbered SEPs may have "distorted" the negotiation process with potential licensee Apple, with potentially harmful impacts on consumer choice and innovation.[692] The EC considers Apple to be a willing licensee. The concerns are similar to those expressed in the U.S. with respect to which Google/Motorola reached a consent order, although the EC indicated the commitments made in the U.S. applied only to the future seeking/enforcement of injunctions, while the EC was concerned with conduct predating the U.S. order.[693] The head of

689 *Ibid* at 24 onward.

690 *Supra* note 146.

691 EC Press Release on Motorola SEPs, *supra* note 684; EC Press Release On Samsung SEPs, *supra* note 686. Statements of Objection have been issued in both cases, which is a formal step in EC investigations before a final decision is made.

692 Apple and Microsoft had both filed complaints with the EC regarding the enforcement of Motorola's SEPs. On 17 February 2012, Motorola received a letter from the EC notifying it that the Commission has received a complaint against Motorola by Apple regarding the enforcement of Motorola's SEPs allegedly in breach of Motorola's FRAND commitments. Reuters Canada, "Motorola Mobility says Apple files EU patent complaint" (18 February 2012) online: <http://ca.reuters.com/article/technologyNews/idCATRE81H0BB20120218>. On February 22, 2012, Microsoft filed a similar complaint with the European Commission against Motorola and Google alleging that Motorola is refusing to make its SEPs available to Microsoft on FRAND terms. Microsoft Blog, Microsoft on the Issues, "Google: Please Don't Kill Video on the Web" (22 February 2012), online: <http://blogs.technet.com/b/microsoft_on_the_issues/archive/2012/02/22/google-please-don-t-kill-video-on-the-web.aspx)>.

693 EC Press Release on Motorola SEPs, *supra* note 684.

the EC recently indicated that Motorola would be receiving a prohibition decision with respect to the conduct,[694] but it had not been issued as of writing.

The second ongoing EC investigation involves similar allegations against Samsung, which allegedly abused a dominant position in seeking injunctions against Apple for FRAND-encumbered SEPs for mobile phones.[695] Samsung has offered commitments to the EC to resolve the concerns, including a commitment not to seek injunctive relief in Europe regarding all SEPs that read on technologies implemented in smartphones and tablets against any company which agrees to and complies with a particular licensing framework.[696] Samsung would, however, be permitted to seek an injunction defensively in response to a party first seeking an injunction against Samsung, provided certain conditions are met.[697] The commitments are in the process of market testing.[698] Samsung recently announced plans to withdraw applications for injunctions that seek to block the sales of Apple products in Europe, but this does not seem to have ended the EC's investigation.

One author suggests the EC is keen to set a precedent for the principles applicable to licensing of SEPs under EU competition with one or both of these ongoing cases; the EC was not able to do this in its in earlier cases involving Qualcomm and IPCom.[699] The head of the EC has indicated that the Samsung and Motorola decisions will clarify the EC's approach to standard essential patent commitments and that decisions are expected soon.[700] He also indicated there are other similar cases "in the pipeline".[701]

(c) Resolving Standard-Setting and Competition Concerns

As in the U.S., the EU dialogue on resolving competition concerns in the standard-setting context considers mainly the role of SSOs and antitrust agency guidance or enforcement. The EU has made a clear effort to provide in-depth agency guidance.

(i) EC Horizontal Guidelines

In January 2011, the EC adopted new Horizontal Guidelines that include an updated chapter on when standard-setting agreements are likely to violate Article 101 prohibitions on horizontal co-

694 Gaspard Sebag, "Motorola Mobility Faces EU Curbs in Patent Clash With Apple" Bloomberg (7 February 2014) online: <http://www.bloomberg.com/news/2014-02-07/motorola-mobility-faces-eu-curbs-in-patent-clash-with-apple.html>.

695 EC Press Release On Samsung SEPs, *supra* note 686.

696 *Ibid*. The licensing framework consists of: (i) a negotiation period of up to 12 months and (ii) a third-party determination of FRAND terms by either a court or arbitrator, as agreed by the parties.

697 Samsung is first required to (i) grant a license for its own mobile SEPs on FRAND terms and (ii) take a license on FRAND terms for the mobile SEPs of the company alleging an infringement by Samsung.

698 Competition in the Online World, *supra* note 108. Samsung has offered to, among other things, abstain from seeking injunctions for mobile phone SEPS in the European Economic Area for 5 years, against companies that agree to a particular licensing framework.

699 EC Policy on Licensing SEPs, *supra* note 306 at 1133.

700 Stephanie Bodoni and Gaspard Sebag, "Samsung, Motorola Mobility Antitrust Rulings Close, EU Says" Bloomberg (13 September 2013) online: http://www.bloomberg.com/news/2013-09-13/samsung-<motorola-patent-abuse-rulings-close-eu-s-almunia-says.html>.

701 *Ibid.*

operation agreements.[702] The revised Horizontal Guidelines provide much more extensive information on standard-setting competition regulation, and take a stricter stance against permissible standard-setting activities that incorporate intellectual property rights. The 2011 Horizontal Guidelines have been described as striking a "good balance" between the interests of licensors and licensees.[703]

Although the prior Guidelines had a chapter on standard-setting, they were perceived as out of date. The EC had several cases (discussed above) that did not result in any judicial precedent to guide conduct, and so there was a perceived need for formal guidance to be issued. The uncontested cases the EC brought with respect to standard-setting conduct also provided the EC with greater knowledge on enforcement approaches, which the 2011 Horizontal Guidelines reflect.[704]

The EC experience in investigating the standard-setting complaints was that once a standard is widely adopted, appropriate competition regulation raises extremely complex legal and technical issues.[705] Emanuelson points to the EC's investigations into Qualcomm and IPCom as examples of the complexity and expense that arose in attempting to assess whether FRAND commitments constituted a competition law violation. One of the most important goals of the revision to the Horizontal Guidelines was thus to "frontload" competition law enforcement with respect to standard-setting. By emphasizing and encouraging competition and transparency in the standard-setting process, including through the conduct of SSOs, the hope was to reduce the risk of competition issues arising from hold-up after a standard is locked-in and adopted.[706] Given that there are two major standard-setting investigations related to intellectual property against Motorola and Samsung, the effectiveness of this approach is not yet clear.

The Horizontal Guidelines explain at length the EC's analytical approach to standardization agreements, and provide several illustrative examples.[707] Although the discussion is not specific to standardization agreements involving patents, it applies to such agreements and the guidance is very relevant to current issues faced in the patent context.

The starting position of the Horizontal Guidelines is that standardization agreements "usually produce significant positive economic effects" such as encouraging the development of new and improved products, improving supply conditions, ensuring interoperability, all of which generally increase competition and lowering output and sales costs.[708] Standards that establish interoperability often encourage competition on the merits between the technologies of different companies, may reduce lock-in to one particular supplier, and may facilitate innovation by

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702 Horizontal Guidelines, *supra* note 135.

703 EC Policy on Licensing SEPs, *supra* note 306 at 1137.

704 Anna Emanuelson, "Standardisation Agreements in the Context of the New Horizontal Guidelines" (2012) 2 European Commission Law Review 69 at 69 [Emanuelson].

705 *Ibid* at 71.

706 *Ibid* at 71.

707 Horizontal Guidelines, *supra* note 135 at 55-72. For the purposes of the Horizontal Guidelines, "standardization agreements" is defined as agreements that "have as their primary objective the definition of technical or quality requirements with which current or future products, production processes, services or methods may comply", at 55.

708 *Ibid* at 57.

allowing companies to build on top of agree-upon solutions.[709] However, in certain circumstances standard-setting can impair competition, by restricting price competition, by foreclosing innovative technologies and by excluding or discriminating against certain companies (for example, by granting access only on discriminatory terms), preventing effective access to the standard.[710]

The Horizontal Guidelines specifically acknowledge the potential issue of anti-competitive hold-up, where a standard is a barrier to entry and companies holding patent rights essential to implement the standard refuse to license the necessary rights, in order to extract rents in the form of excessive royalties.[711] However, there is no presumption that simply because a party holds an intellectual property right essential to a standard that they have market power, and this is assessed on a case-by-case basis.[712]

The Horizontal Guidelines provide for the impacts of standardization agreements to be assessed in several potential markets: the product market to which the standard relates, the relevant technology market (if the rights to IP are marketed separately from the products to which they relate) and the market for standard-setting itself where different standard-setting bodies or agreements exist.[713]

The Horizontal Guidelines go on to set out a "safe harbour", within which standard-setting agreements are not normally considered restrictive of competition. The safe harbours in the Horizontal Guidelines are intended to provide SSOs with some legal certainty that agreements reached in standard-setting will not violate EU competition law,[714] and by doing so, avoid any unnecessary chill on standard-setting from perceived competition risks. Where there is no market power, a standard-setting agreement is not considered capable of restricting competition. But a standard-setting organization is unlikely to know at the outset whether their standard will be adopted by the market and ultimately give rise to market power. The safe harbour principles provide some assurance that standardization processes and agreements which comply with the principles are unlikely to raise competition issues, even if market power is ultimately conferred by the standard. Standard-setting agreements will not normally restrict competition in violation of Article 101 where the following principles are adhered to:

– There should be unrestricted participation in the standard-setting process which allows all competitors to participate in the development of the standard and to effectively impact which standard is adopted.[715] This would include objective procedures for allocating voting rights and, if relevant, the use of objective criteria to select the technology that is included in the standard;[716]

709 *Ibid* at 64.

710 *Ibid* at 57.

711 *Ibid* at 58.

712 *Ibid* at 58.

713 *Ibid* at 5. See criticism of the concept of innovation markets in the U.S. section on Agency Guidance, above. The market for testing and certification is also identified in the Horizontal Guidelines as potentially being affected by standardization agreements.

714 Emanuelson, *supra* note 704 at 72.

715 Horizontal Guidelines, *supra* note 135 at 59.

716 *Ibid*.

- The standard-setting process is transparent, which is interpreted to mean the SSO must have procedures that enable stakeholders (including those who are not members of the SSO) to inform themselves in a timely manner about upcoming, ongoing and finalized standard-setting efforts;[717]

- There is no obligation imposed on participants to comply with the standard.[718] Participants are free to use/develop other standards or products that do not comply with the standards adopted; and

- Effective access to the standard is provided, which requires the SSO to have intellectual property rights policies which:

  - Require good faith disclosure of all intellectual property rights that read on the standard being developed. This disclosure is considered important to enable the industry to make an informed decision on which standard is adopted and to assist in effective access to the standard.[719] "Reasonable endeavors" to identify IP rights reading on a standard are required (unless the standard will be royalty-free, in which case disclosure is not a concern); and

  - Require participants whose intellectual property rights are included in the standard to provide an irrevocable commitment in writing to license the right on FRAND terms, prior to adoption to the standard. To avoid a form of compulsory licensing, the policy should also allow patent holders to exclude specified technology at an early stage in the standard-setting process, so they are not obligated to commit to licensing it later in the process. The rights holders must also agree to ensure that companies to which the intellectual property rights are transferred are bound by their FRAND commitments. As indicated above, the theory is that such commitments will prevent rights holders from blocking the implementation of the standard by refusing to license or charging discriminatory royalties.[720]

Agreements outside the safe harbour in the Horizontal Guidelines do not necessarily violate competition law, but would be subject to an effects-based assessment if market power is held.[721] This assessment largely mirrors the criteria above used to define the safe harbour.[722] Finally, the efficiencies of the standardization agreement will be weighed against any anti-competitive effects. The efficiencies assessment requires that restrictions be the minimum

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717 *Ibid* at 60; See also Emanuelson, *supra* note 704 at 73.

718 Horizontal Guidelines, *supra* note 135 at 59.

719 *Ibid*; See also Emanuelson, *supra* note 704 at 73. However, in an example, the Horizontal Guidelines also note that where all possible standards being considered are covered by intellectual property rights, the disclosure of such rights will not likely have a positive impact on which technology is selected (since the standard chosen will be covered by intellectual rights, regardless of which technology is selected); disclosure may just raise costs for participants or delay adoption and so is not required. Horizontal Guidelines, *supra* note 135 at 67.

720 *Ibid* at 60. See also discussion of the EC's IPCom investigation, above.

721 *Ibid* at 61.

722 *Ibid* at 61-62. The focus of the analysis is on whether parties remain free to develop alternative standards, participation in the standard-setting process, any discrimination against participants or potential participants, effectiveness of access to the standard, market shares based on the standard and the model for intellectual property rights disclosure in the process.

necessary to achieve such efficiency gains,[723] and also require that such gains be passed on to consumers to an extent that outweighs the restrictive competition effect. [724] As the Horizontal Guidelines state at the outset of the standardization discussion, such efficiencies could be significant.

Where the most restrictive licensing terms have been disclosed in advance in the standard-setting agreement, such agreements are considered not to restrict competition in principle. The parties who adopt the standards are considered to be fully informed as to the likely cost and technical adoption options for the intellectual property right before it is adopted.[725] It has been suggested that SSOs require a declaration of the most restrictive licensing terms, even including the maximum royalty rates before adoption of a standard.[726] Doing so can enable competition for the standard both on technology and on price before it is adopted.[727] This emphasizes the theme throughout the Horizontal Guidelines, which is that informed and open decision making in the standard-setting process are important to protect the competitive benefits of standard-setting.

The Horizontal Guidelines attempt to define a test for assessing if licensing rates are FRAND, stating the determination of whether fees are unfair or unreasonable should be based on whether the fees bear a reasonable relationship to the value of the intellectual property right.[728] The Horizontal Guidelines dismiss a cost-based approach as not useful (i.e. assessing costs attributable to the development of a patent).[729] Instead, the Horizontal Guidelines suggest reasonableness and fairness could be assessed by several means: (i) comparing the licensing fees charged before the industry adopted the standard to those charged after the industry was locked into the standard, (ii) through an independent expert who assesses the centrality and essentiality of the intellectual property right to the standard, or (iii) by comparing the rates charged for the same IPR in other comparable standards.[730] The list is not intended to be exhaustive.

(ii) The Role of SSOs

Like the U.S., the EU has pointed to the role of SSOs in ensuring competition is preserved in the standard-setting context, as discussed in detail in the Horizontal Guidelines (see above. In the *Rambus* case, the EC made clear "[s]tandards bodies have a responsibility to design clear rules that ensure the standard-setting process takes place in a non-discriminatory, open and

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723 *Ibid* at 65.

724 *Ibid* at 66.

725 *Ibid* at 62-63.

726 European Union, European Commission, *White Paper, Modernising ICT Standardisation in the EU - The Way Forward* (3 July 2009) COM(2009) 324 final, online: <http://ec.europa.eu/enterprise/newsroom/cf/itemdetail.cfm?item_id=3263> [EC White Paper].

727 *Ibid*.

728 Horizontal Guidelines, *supra* note 135 at 61. This approach is based on an older EU case, Case 27/76, *United Brands v Commission*, 1978 ECR 207.

729 Horizontal Guidelines, *supra* note 135 at 61.

730 *Ibid* at 62.

transparent way and hence reduce the risk of competition problems, such as patent ambushes".[731]

The 2011 EC Report on IP concludes that legal uncertainty over the transfer of IPRs subject to FRAND licensing commitment is "becoming increasingly problematic", calling for this to be addressed by SSOs.[732] It notes an empirical study that found standard-essential patents are often disclosed after rather than before the release of standards.[733] The 2011 EC Report on IP encouraged competition policy guidelines to provide "safe harbours" for the setting of SSO intellectual property rights, a recommendation which was adopted. It also recommended that policies and guidance from the EC encourage SSOs to strive for:[734]

- clear and binding intellectual property rights policies including irrevocable and worldwide licensing commitments;
- legal certainty in case of the transfer of essential patents to third parties;
- reasonable incentives for good faith intellectual property rights inquiries and disclosure;
- transparent, complete and accessible intellectual property rights databases; and
- co-operation with patent offices in identifying prior art.

The increased role envisioned for SSOs in controlling anti-competitive conduct raises the question as to how to balance the concern that the conduct of participants in an SSO could itself be a horizontal agreement among competitors that violates Article 101(1).[735] For example, declaring precise royalties rates before their technology is incorporated into a standard could be seen as an agreement among competitors. Some commentators consider it unclear how the new SSO obligations the EC seems to be recognizing will be reconciled with existing EC guidelines limiting such collaboration between competitors.[736] The EC has expressed the view that it would not normally find *ex ante* agreements on royalties to give rise to competition concerns,[737] and the new Horizontal Guidelines appear helpful in delineating permitted conduct (see discussion above).

(iii) Open Issues Regarding Standard-Setting Concerns in the EU

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731 Rambus Press Release, *supra* note 672.

732 Standards and IP Rights, *supra* note 664.

733 *Ibid* at 24 referring to Anne Layne-Farrar, "Is Ex-ante the Norm? An Empirical Look at IPR Disclosure Timing Within Standard Setting" (Presentation delivered at Lausanne for EURAS, 2 July 2010) online: <http://www.euras.org/uploads/2010presentations/Layne-Farrar.pdf>.

734 *Ibid* at 13; Several similar suggestions were made in the EC White Paper, *supra* note 726.

735 United Kingdom, Intellectual Property Office, *Supporting Document AA: Patent Thickets, Licensing and Standards*, (2011) Independent Review of IP and Growth at 12 [U.K. Patent Thickets Summary], supporting U.K. IP Report, *supra* note 184.

736 Memorandum of Steptoe & Johnson LLP, Yves Botteman & Agapi Patsa, "EU Competition Briefing - Good Faith Disclosure and FRAND Commitment in the Context of Standardisation Agreements in the EU" (May 2011) points out that the EU Guidelines on information exchange provide ""if companies compete with regard to R&D it is the technology data that may be the most strategic for competition".

737 Standards and IP Rights, *supra* note 664.

Critics of the revised Horizontal Guidelines view the hold-up concern forming the basis for the Guidelines as purely theoretical, claiming there are no known instances where hold-up has prevented the successful adoption of a technical standard including intellectual property rights.[738] Similar arguments to those made in the U.S. have been raised, that market-based factors impacting SSOs and their participants are likely to constrain the risks of any hold-up such that there is limited role for competition law. For example, there is an argument that standards development often involves repeat participation, meaning intellectual property holders are unlikely to abuse market power because it might impact the inclusion of their technology in a later standard. It is argued further that intellectual property owners in the standards context are also likely to be intellectual property licensees, and so any abusive conduct may come back to haunt the party who is trying to obtain a license for another firm's standard-essential patents.[739]

Some are critical of the EC's involvement in the recent Samsung and Motorola investigations, characterizing the disputes as part of a broader commercial war between large and sophisticated parties which the EC is ill-advised to involve itself in.[740] However, the arguments canvassed in the U.S. standard-setting and FRAND licensing commitments section, above, on why there is a role for antitrust enforcement also appear to apply in the EU. Standard setting hold-up may involve private agreements, but it can have public impacts. Further, the 2011 EC Report on IP observed the potential for patent holders who are not members of an SSO to hold-up those wishing to access the standard. These non-members are not bound by any FRAND policy of the SSO.[741] SSO efforts alone may therefore not be sufficient, leaving room for a continued role for antitrust enforcement to ensure the many public benefits of standardization are realized.

A key open issue in the EU, as in the U.S., remains the assessment of what constitutes a "fair and reasonable" royalty. Even after the issuance of the Horizontal Guidelines touching on the question, the EC and European Patent Office indicated there is legal uncertainty and considerable ambiguity around what is defined as "fair and reasonable" in intellectual property rights policies of SSOs.[742] The 2011 EC Report on IP heard stakeholder comments indicating the meaning of what constitutes "FRAND" and "essential" can be unclear and that there is uncertainty over the transferability of FRAND commitments. The EC reportedly had difficulty in assessing whether royalties were fair and reasonable in its Qualcomm investigation.[743]

Although there are several economic approaches proposed for determining what is fair and reasonable in the Horizontal Guidelines, the interpretation of these terms is ultimately left to the courts.[744] In the two ongoing investigations on the use of injunctions for SEPs subject to FRAND

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738 Richard Taffet, "The Impact of the Draft EC Horizontal Guidelines on Intellectual Property Rights and Innovation" (2010) 1 CPI Antitrust Journal 1, online: <http://www.bingham.com/Publications/Files/2010/10/The-Impact-of-the-Draft-EC-Horizontal-Guidelines-on-Intellectual-Property-Rights-and-Innovation>, commenting on a draft version of the now-enacted Horizontal Guidelines.

739 *Ibid*.

740 EC Policy on Licensing SEPs, *supra* note 306 at 1140, pointing to the extensive litigation already engaged in by Samsung and Apple, and indicating Apple is one of Samsung's main components suppliers.

741 Standards and IP Rights, *supra* note 664

742 See e.g. European Union, European Commission Workshop Report, "Implementing FRAND standards in Open Source: Business as usual or mission impossible?" (22 November 2012) at 4. [EC Workshop Report].

743 EC Policy on Licensing SEPs, *supra* note 306 at 1133.

744 *Ibid* at 61.

commitments (as discussed above), the EC has not indicated what it considers a reasonable royalty rate and indicates it considers "national courts and arbitrators" well equipped to determine this. This is seen as a clear message from the EC that it does not want to become a "rate-setting authority" and does not consider itself to have the technical expertise to assume that role.[745] The Manheim District Court in Germany is currently conducting one of the first trials related to FRAND rate-setting.[746]

Another key open issue is what is considered to be a "willing licensee". The determination of whether a licensee is "willing" is central to whether the seeking or enforcement of an injunction against a potential licensee regarding FRAND-encumbered SEPs may raise competition concerns.[747] The EC preliminary position is that the acceptance of binding third party determination for the terms of a FRAND license (after bilateral negotiations fail to reach a conclusion) is a clear indication that a potential licensee is willing to enter into a FRAND license.[748] The EC does not consider a challenge by a potential licensee to the validity, essentiality or infringement of the SEP to make it "unwilling" if the party otherwise agrees to be bound by the determination of FRAND terms by a third party. A potential licensee who is "passive and unresponsive" to request for licensing negotiations or who employs "clear delaying tactics" is not considered willing.[749] In its recent consideration of Motorola's SEP licensing, the EC found Apple's willingness to enter into a FRAND license manifested itself in particular by its acceptance to be bound by a German court's determination of a FRAND royalty rate.[750] One author suggests the more relevant consideration is the negotiation history between the SEP holder and the potential licensee, including whether it evidences reasonableness, timeliness and any unwillingness to pay or adhere to decisions of neutral third parties.[751]

(d) Conclusion On Standard-Setting and Competition Concerns in the EU

The EU shares similar concerns to the U.S. over potential patent hold-up in the standard-setting context arising from patent ambush or repudiation of licensing commitments related to technology in standards. The EC, like the U.S. competition authorities, brought a case against Rambus based on allegations of patent ambush. However the EU case focused on an alleged abuse of dominance, rather than the US approach claiming unlawful acquisition of monopoly power. The EU case was resolved with voluntary commitments from Rambus limiting worldwide royalty rates.

There have been several EU investigations and statements of objections from the EC into conduct involving the abrogation of licensing commitments made regarding SEPs. The EC investigated Qualcomm extensively, but the case proved very complex and the investigation was ultimately closed without any remedy. The EC also investigated IPCom, but the case was closed after an informal commitment by IPCom to take over the commitments made by the prior

745 EC Policy on Licensing SEPs, *supra* note 306 at 1133.

746 December 2013 Almunia Speech *supra* note 137.

747 EC in its Google/Motorola clearance decision uses the term "good faith" potential licensee, which seems to be discussed as generally equivalent to (or at least inclusive of) a willing licensee, *supra* note 688 ; See also EC Policy on Licensing SEPs, *supra* note 306 at 1139.

748 EC Press Release on Motorola SEPs, *supra* note 684.

749 *Ibid*.

750 *Ibid*.

751 EC Policy on Licensing SEPs, *supra* note 306 at 1139.

owner of the patent. As in the U.S., the cases highlight the complexity of establishing a violation of FRAND commitments, and the concern of agencies that FRAND commitments travel with the patents to bind subsequent owners. None of the EC cases have been contested to the point of a court decision, so there is no judicial precedent on whether or when the abrogation of licensing commitments made regarding SEPs may violate EU competition law.

The EC has acknowledged concern that the threat of an injunction may distort licensing negotiations unduly in the SEP-holder's favour, by forcing potential licensees into onerous licensing terms such as higher royalties than would otherwise have been agreed to, or by requiring cross-licenses. The EC indicated in recent merger approvals involving SEPs that it will continue to monitor this space. As of December 2013, the EC had two ongoing cases in which statements of objection had been issued alleging abuse of a dominant position involving seeking injunctions in member states for FRAND-encumbered SEPs. The resolution of the EU cases may provide clearer principles on the application of EU competition law to licensing commitments involving SEPs. The emerging solutions for one of the cases appears similar to the U.S. It involves commitments not to seek injunctive relief for SEPs as long as a certain licensing framework is complied with, but permits injunctions to be sought defensively.

In 2011, the EC issued detailed guidance on its approach to competition regulation as it relates standard-setting, as part of its updated Horizontal Guidelines. Rather than untangling complex standard-setting issues after the fact, which has proven challenging in EC cases previously undertaken, the Horizontal Guidelines attempt to "frontload" competition law enforcement by providing detailed guidance which emphasizes and encourages competition and transparency in the standard-setting process to reduce the risk of competition issues arising from hold-up after a standard is established and locked-in.

The EC has emphasized the important role SSO policies can play in ensuring competition is preserved in the standard-setting context. As in the U.S., critics argue that disputes over the availability of injunctions for FRAND-encumbered SEPs are contractual disputes in which the EC should not become involved. However, arguments made in the U.S. in favour of continued antitrust agency oversight of standard-setting issues appear to apply in the EU.

2. Reverse Payment Settlements

As in the U.S., the potential for anti-competitive harm arising from reverse payments has been a major focus of EC authorities for several years. In 2011, the head of the EC referred to the pharmaceutical sector as "a priority in terms of enforcement of competition rules given its importance for consumers and for governments' finances," and noted "[p]harmaceutical companies are already rewarded for their innovation efforts by the patents they are granted. Paying a competitor to stay out of the market is a restriction of competition that the Commission will not tolerate."[752]

The EC theory of harm is similar to that in the U.S.: where a branded company eliminates or delays cheaper generic competition through significant payments (or other benefits) to a generic company for discontinuing or delaying the launch of generic medicine that challenges the branded company's patent, this is thought to lead to consumer harm by reducing the

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752 European Union, European Commission, Press Release, "Antitrust: Commission Opens Proceedings Against Johnson & Johnson And Novartis" (21 October 2011) online: <http://europa.eu/rapid/press-release_IP-11-1228_en.htm> [EC Press Release Regarding Johnson & Johnson].

competitive pressure exercised by potential generic market entry, essentially in exchange for the sharing of the branded company's monopoly rents.[753]

(a) Forthcoming Guidance on Reverse Payment Settlements Involving Licenses

The draft revised Technology Transfer Guidelines include a new section reflecting the EC's concern over reverse payment settlements. The proposed section indicates that reverse payment settlements involving a license may run counter to Article 101 TFEU, particularly where a licensee agrees, in exchange for a value transfer from the licensor, to more restrictive terms than the licensee would have accepted solely on the strength of the licensor's technology.[754] Further, clauses in reverse payment settlements not to challenge the patent in future are considered problematic, if the patent holder knows or should have known the patent does not meet criteria for granting of a patent.[755]

(b) The EC Pharmaceutical Sector Inquiry and Report

The concern of the EC over reverse payment settlements dates to at least 2008, when it launched a sector inquiry into pharmaceuticals focusing on the competitive relationship between branded and generic companies.[756] The inquiry was prompted by indications that competition in Europe's pharmaceuticals markets might not be functioning well: fewer new medicines were being brought to market, and the entry of generic medicines appeared to be delayed in some cases.[757] The inquiry investigated the cause of such trends and was intended to provide a strong factual basis for any enforcement action.[758]

The broader policy context prompting the sector inquiry was control of public health costs. Comments from the EC emphasize the potential harm to patients and national health systems, already facing budgetary restraints, which could arise from reverse payment settlements.[759] Generics are thought to play an important role in limiting public health-care expenditures while still providing widespread access to medicines. The EU Pharmaceutical Report, which resulted from the sector inquiry, estimated that savings from the availability of generic medicines in the EU averaged almost 20% after one year of generic entry and about 25% after two years.[760] It also estimated that savings could have been 20% higher if entry had taken place immediately following the loss of branded exclusivity.[761] Ensuring that generics can enter the market without

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753 European Union, European Commission, Press Release, "Antitrust: Commission Enforcement Action In Pharmaceutical Sector Following Sector Inquiry" (30 July 2012) online: <http://europa.eu/rapid/press-release_MEMO-12-593_en.htm> [EC Press Release Enforcement Action Following Pharmaceutical Sector Inquiry].

754 EC Memo on Proposed Revised Technology Transfer Guidelines, *supra* note 143.

755 *Ibid*.

756 Pharma Report Executive Summary, *supra* note 163.

757 *Ibid*.

758 *Ibid* at 3.

759 A War of Roses, *supra* note 426 at 621 & 622.

760 Pharma Report Executive Summary, *supra* note 163 at 9.

761 *Ibid.*

undue delay and compete effectively is thus considered important in maximizing the benefit of generics to public health budgets in the EU and its member states.[762]

The EU Pharmaceutical Report found that branded companies were using a variety of means to extend the commercial life of their drugs, and that this behavior likely contributed to delays in generic entry.[763] The branded company conduct included patent filing strategies aimed at extending the breadth and duration of patent protection,[764] patent-related exchanges and litigation,[765] the use of patent oppositions and appeals,[766] settlements and other agreements (considered as a practice separately from "litigation"), as well as life cycle strategies for second-generation branded products[767] and other strategies.[768]

One such "other" strategy included the branded company intervening in the market authorization process (and/or applications to pricing and reimbursement bodies) for generics on the basis the products were less safe, effective or of inferior quality, or violated patent rights.[769] Both branded companies and generic companies require marketing authorization and often price/reimbursement status before they can be put on the market in member states. EU legislation provides that marketing authorisation bodies are not to consider potential violation of patent rights (despite the fact such arguments were made).[770] The EU Pharmaceutical Report found branded companies were successful in only 2% of reported litigation on market authorizations. In the sample studied, marketing authorisations were granted on average four months later in cases in where such an intervention took place.[771]

With respect to litigation practices, the EU Pharmaceutical Report acknowledges enforcement of patent rights in courts is a legitimate and fundamental right. However, litigation was also found to be a means of creating competition obstacles for generic companies (particularly smaller ones). In some instances, branded companies used litigation less on its merits than as a signal to deter generic entrants.[772]

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762 See e.g. European Commission, Communication From The Commission To The European Parliament, The Council, The European Economic And Social Committee And The Committee Of The Regions, "Safe, Innovative and Accessible Medicines: a Renewed Vision of the Pharmaceutical Sector" (10 December 2008) COM (2008) 666 at 7, online: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2008:0666:FIN:en:PDF>.

763 Pharma Report Executive Summary, *supra* note 163 at 9.

764 For example, filing numerous patent applications for similar drugs to form patent thickets and filing divisional patent applications, which split the initial patent application and extend the examination period by the patent office (although the European Patent Office took measures to limit time periods for divisional patent filing in March 2009).

765 For example, the report found that originator companies invoked mainly primary patents before litigation and mainly secondary patents during litigation.

766 Oppositions and appeals to generic entry were found to be more common in the pharmaceuticals sector, and, due to their length of over two years on average, limited generic companies' ability to determine the patent position in a timely manner.

767 Pharma Report Executive Summary, *supra* note 163.

768 *Ibid* at 13.

769 *Ibid* at 14.

770 *Ibid.*

771 *Ibid*.

772 *Ibid* at 11.

Regarding settlement agreements, the EU Pharmaceutical Report found that there were a large number of settlement agreements between branded companies and generics, most of which were reached in litigation. The sector inquiry reviewed over 200 such agreements that had been reached between 2000 and 2008. Approximately half of the settlements restricted the generic's ability to market its medicine. A significant proportion (about 22%) also included a value transfer from the branded to the generic, either a direct payment (found in over 20 agreements), a license, a distribution agreement or other side deal.[773] The EU Pharmaceutical Report notes reverse payment settlements involving a direct payments have attracted antitrust scrutiny in the U.S.[774]

The EU Pharmaceutical Report concluded that competitive pressure from generic producers was not as strong as expected, particularly after the primary patent of the branded medicine expires.[775] Reverse payment settlements were considered to potentially contribute to this by transferring value to the generic company, reducing generic companies' incentives to compete or to challenge the patent.[776] Settlement agreements that limit generic entry and include a value transfer from a branded company to one or more generic companies (i.e. reverse payment settlements) were thus considered to be potentially anti-competitive, particularly where the motive of the agreement was to share monopoly profits.[777]

Overall, the use of reverse payment settlements, along with the many other branded company practices identified in the EU Pharmaceutical Report, were thought to increase the likelihood of delay of generic entry and to lead to "significant legal uncertainty" for generic competitors that was detrimental to their market entry.[778] However, the EU Pharmaceutical Report does not conclude that such practices are necessarily contrary to competition law; the Report aimed only to provide the factual basis for any future enforcement action. The EU Pharmaceutical Report concluded certain conduct would remain under scrutiny and at risk for enforcement action, particularly where innovation is blocked, including reverse payment settlements, intervention in generic regulatory approval processes to delay entry, defensive patenting strategies that focus on excluding competitors without pursuing innovative efforts and the refusal to grant licenses on unused patents.[779] The Report recommended that, to reduce the risk that reverse payment settlements "concluded at the expense of consumers", settlements with the potential to harm consumers continue to be monitored.[780]

(c) Monitoring of Reverse Payment Settlements

Following the U.S. lead and the recommendations in the EU Pharmaceutical Report, since mid-2008 the EU has been monitoring patent settlements agreements between branded and generic

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773 *Ibid* at 13.

774 *Ibid*.

775 "Primary patents" is a term referring to the first patents for a medicine. Further patents, for such aspects as different dosage forms, the production process or for particular pharmaceutical formulations are referred to by the industry as "secondary patents" *Ibid* at 5; EC Press Release Enforcement Action Following Pharmaceutical Sector Inquiry, *supra* note 753.

776 *Ibid*.

777 Pharma Report Executive Summary, *supra* note 163 at 20.

778 *Ibid* at 15.

779 *Ibid* at 19.

780 *Ibid* at 21.

companies.[781] The agreements examined include commercial agreements to settle questions of patent infringement or patent validity, that conclude in the context of patent "disputes", opposition procedures or litigation where there is no final adjudication. The monitoring is intended to help the EC better understand the use of patent litigation settlement agreements, and to identify any settlements that delay generic market entry in violation of competition law. [782] Annual reports are issued on the settlements tracked each year, and settlements are categorized as follows:

		Limitation on generic entry	
		No	Yes
Value transfer from the originator company to the generic company	No	Category A	Category B.I.
	Yes		**Category B.II.**

Source: European Commission, 4th Patent Settlement Monitoring Exercise

The settlements considered most likely to raise competition concerns are those in Category B.II, settlements which involve limitations on generic entry and value transfer from the branded company.[783] The most recent Monitoring Report, covering the period from January to December 2012 (the "2012 Monitoring Report", issued December 9, 2013) explains the value transferred from the branded company to the generic can take many forms, from cash payments, disguised asset deals, side deals for distribution, commitments from the branded company not to assert the patent or granting a license to the generic company enabling it to enter the market.[784]

The 2012 Monitoring Report found that this category of concerning settlements had dropped from 21% of all settlements in the first year of monitoring down to only 7%.[785] Despite this, the total number of settlements increased substantially over the years, including in 2012, which the EC interprets as an indication that its enforcement in this area has not chilled settlements (although this assumes an even higher number of settlements would not have been reached in

781 See European Commission, Sector Inquiry and Follow-Up online: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/> for copies of the various monitoring reports.

782 European Union, European Commission, *4th Report on the Monitoring of Patent Settlements*, covering period from January – December 2012 (published 9 December 2013) available at: <http://europa.eu/rapid/press-release_IP-13-1228_en.htm> [2012 Monitoring Report].

783 *Ibid* at para 4. The 2012 Monitoring Report also notes two other types of agreements that are likely to violate EU competition law, but does not address them in detail: (i) agreements reaching beyond the exclusionary zone of the patent (in beyond its geographic scope, its period of protection or its exclusionary scope) and (ii) agreements related to a patent which the patent holder knows does not meet the patentability criteria (for example, where a patent was granted following the provision of incorrect, misleading or incomplete information).

784 *Ibid* at para 17.

785 EC Press Release Enforcement Action Following Pharmaceutical Sector Inquiry, *supra* note 753.

the absence of such enforcement).[786] The 2012 Monitoring Report reiterates that the EC needs to continue to pay attention to the problematic types of settlements.[787]

(d) The *Lundbeck* Decision

The EC heeded the calls for continued action and, in June 2013, imposed its first fine with respect to reverse payment settlements.[788] The agreements at issue between branded company Lundbeck and several generic companies were found to violate Article 101 of TFEU by object.[789] Restrictions by object are restrictions on competition that have such a high potential for negative effects on competition that it is unnecessary to demonstrate any actual market effects, an approach akin to *per se* illegality in the U.S. The EC imposed a fine of approximately EUR 93.8 million on Lundbeck and fines totaling approximately EUR 52.2 million on four of the generics.

Lundbeck- The Facts in Brief

The Danish pharmaceutical company Lundbeck manufactured Citalopram, a branded antidepressant medication. Lundbeck held both the patent for the drug molecule and separate manufacturing process patents related to the drug. As of the 2002 expiry of the molecule patent, several generic versions of the drug were poised for entry. Lundbeck then brought patent infringement suits related to the manufacturing process patents it held, which had a longer term than the molecule patents.[790] The suits ended with agreements between Lundbeck and the generics which involved "substantial" value transfers from Lundbeck to the generics and an agreement by the generics not to enter the market with their versions of Citalopram. The value transfers included direct payments from Lundbeck to the generic competitors and also occurred in other forms, such as the purchase of generic Citalopram stock for destruction or guaranteed profits in a distribution agreement.

The EC's conclusion was based on the finding that (i) Lundbeck and the generics with which it struck reverse payment settlements were potential competitors at the time the settlement agreements were reached, (ii) Lundbeck provided significant value to the generics through the agreements, and (iii) there was a link between the value transfer and the generic's agreement

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786 European Union, European Commission, Press Release, "Commission Welcomes Continued Low Level Of Potentially Problematic Patent Settlements In EU Pharma Sector" (9 December 2013) online: <http://europa.eu/rapid/press-release_IP-13-1228_en.htm>.

787 *Ibid*; 2012 Monitoring Report, *supra* note 782 at 16. There are also several national European competition authorities that have taken action in the area of reverse payment settlements, see e.g. The French Competition Authority, "Sanofi –Aventis in the amount of Euro40.6 million with regard to delay of the generic version of Plavix" (14 May 2013); The Italian Competition Authority investigation against Hoffmann-La Roche, Novartis and Genentech with respect to the Lucentis drug (decision expected at the beginning of 2014); Office of Fair Trading, Press Release, "OFT Issues Decision In Reckitt Benckiser Case 53/11" (13 April 2011), online: <http://www.oft.gov.uk/news-and-updates/press/2011/53-11> (discussed in U.K. section below).

788 Case COMP/39.226 Lundbeck (19 June 2013) [*Lundbeck*]. Although the decision has yet to be issued, the initial statement of objections is available online: <http://europa.eu/rapid/press-release_MEMO-12-593_en.htm>.

789 European Union, European Commission, Press Release, "Antitrust: Commission Fines Lundbeck And Other Pharma Companies For Delaying Market Entry Of Generic Medicines" (19 June 2013) online: <http://europa.eu/rapid/press-release_IP-13-563_en.htm> [EC Press Release on *Lundbeck*].

790 *Ibid.*

not to enter the market for a certain period.[791] Lundbeck allegedly paid large lump sums, purchased products from the generic companies for the sole purpose of destroying these, and offered guaranteed profits to the generics through a distribution agreement.[792]

Because the decision itself has not yet been issued, the details on the reasoning of the EC have not yet been revealed.[793] However, the overall message is evident; in a press release on the case, the EC head said "[i]t is unacceptable that a company pays off its competitors to stay out of its market and delay the entry of cheaper medicines. Agreements of this type directly harm patients and national health systems, which are already under tight budgetary constraints. The Commission will not tolerate such anticompetitive practices".[794]

The state of EU competition law on reverse payment settlements remains in flux because the *Lundbeck* decision has been appealed by the generic companies and Lundbeck to the EU General Court. Although the appeals are on several grounds, the main issue is whether the EC erred in concluding the reverse payment settlements restricted competition in the market beyond the scope of Lundbeck's patent rights, and whether the agreements should be presumed not to violate Article 101 if within those rights.[795] Lundbeck's appeal claims the EC lacked sufficient reasoning for its dismissal of the scope of patent test as the relevant standard for competition law assessment of reverse payment agreements under Article 101.[796] These arguments suggest the scope of patent approach to analysis, now rejected by the U.S. Supreme Court in *Actavis*, is still being debated in the EC. The second main issue on appeal is whether the EC erred in law by holding that reverse payment settlements may constitute a restriction of competition by object under Article 101. Lundbeck also claims the efficiencies arising from the agreements were not properly considered by the EC under Article 101(3).

(i) Commentary on *Lundbeck*

Compared to the U.S. approach in *Actavis,* several articles indicate the EU has left much less leeway for entry into reverse payment settlements.[797] Authors Batchelor and Carlin are critical of the *Lundbeck* approach of considering all reverse payment settlements to restrict competition by object. The EC position is essentially to permit only the narrow category of settlements that do not include any benefit in exchange for generic delay or exclusion.[798] Given that such

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791 *Ibid*.

792 *Ibid*.

793 The decision had not yet been released as of May 24, 2014.

794 EC Press Release on *Lundbeck*, *supra* note 789.

795 Gerardin & Lazerow, *supra* note 445 at 14; See e.g. the summary of the appeal of Lundbeck, Action brought on 30 August 2013 – H. Lundbeck and Lundbeck v Commission (Case T-472/13) available online: http://curia.europa.eu (alleging the EC " failed to consider all the circumstances surrounding the agreements and erroneously concluded that their intended scope went beyond the scope of Lundbeck's patent rights")

796 *Ibid*.

797 *Ibid* at 17; Bill Batchelor & Fiona Carlin, "Turducken on the Menu: Initial Reflections on the Implications of the European Commission's Lundbeck Decision" (2013) Baker McKenzie at 2 online: <http://www.bakermckenzie.com/files/Publication/c3cdd58f-41b5-47c4-b1da-04a34ac8a327/Presentation/PublicationAttachment/7442ae01-97b8-4688-ab03-05930cb1bd39/AR_Europe_EuropeanCommissionsLundbec_Jun13.pdf> [Initial Reflections on Lundbeck].

798 Gerardin & Lazerow *supra* note 445 at 17. The head of the EC has indicated "paying competitors to stay out of the market at the expense of European citizens has nothing to do with the legitimate protection of

agreements are likely rare, this is similar to the presumption of illegality the FTC proposed in *Actavis*, and which was rejected by the U.S. Supreme Court. [799] The EU "by object" approach means the burden is on the defendant to rebut the presumption of illegality and prove the competitive benefits outweigh the harm (although the EC would still have to assess the facts and circumstances of each agreement).[800]

Further, the authors characterize the EC approach as inconsistent with the EC's Technology Transfer Guidelines, under which parties to a settlement agreement are not considered competitors where there is a genuine dispute and their technologies are in a one-way or two-way blocking position. A blocking position exists when technology cannot be exploited without infringing upon another technology; for example, where an improvement on a patented technology cannot be exploited without obtaining a patent for the basic technology that was improved upon.[801] Lundbeck still had process patents that were in force at the time of the reverse payment settlement (even though the patent over the drug itself had expired) and thus in theory could have blocked generic production by enforcing the process patents. Batchelor and Carlin predict the Technology Transfer Guidelines will have to be revised in response to *Lundbeck*.[802]

Batchelor and Carlin argue the correct approach to analyzing reverse payments is that of the dissent in *Actavis,* under which the court must consider the validity of Lundbeck's continuing process patents in order to determine if legitimate settlement interests were at play in reaching the reverse payment settlement.[803] In Europe, litigation may be brought in several jurisdictions, adding to the complexity, expense and uncertainty regarding the outcome – particularly where outcomes in different jurisdictions may have an impact on each other.[804] The interest in ending such litigation, and the potential for multi-jurisdictional impacts arising from a settlement may make the legitimate interest in settlement stronger in the EU than in the U.S. The authors emphasize that settlements may be efficiency-enhancing where there are *bona fide* grounds for the related dispute, such as because there is a valid patent, and therefore patent law should be the predominant consideration for the adjudication of such disputes rather than antitrust.

Although some authors believe the EC is taking a stricter approach to the illegality of reverse payment settlements, Zinsmeister and Held point out that, without the actual decision in *Lundbeck*, the similarity between the U.S. and EU approaches cannot be precisely determined.[805] It is not yet known whether and to what extent the EC considered arguments rebutting any presumption of illegality of the reverse payment settlement (i.e. rebutting the

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intellectual property; it is an illegal practice and the Commission will fight against it." EC Press Release on *Lundbeck*, *supra* note 789.

799 Gerardin & Lazerow*, ibid* at 17.

800 Initial Reflections on Lundbeck, *supra* note 797 at 2. See similarly Chillin' Competition, "Reverse Payments (Pay For Delay Settlements) In EU And US Antitrust Law (Part I)" online: <http://chillingcompetition.com/2013/07/02/reverse-payments-pay-for-delay-settlements-in-eu-and-us-antitrust-law/>.

801 Technology Transfer Guidelines, *supra* note 106 at 7.

802 Initial Reflections on Lundbeck, *supra* note 797 at 1.

803 *Ibid* at 2.

804 *Ibid*; A War of Roses, *supra* note 426 at 622 similarly emphasize that patent disputes in Europe can be particularly costly and time-consuming, with uncertain outcomes across jurisdictions. One judgement against the originator company can have echo effects on the commercial value of the drug in other jurisdictions.

805 *Ibid* at 626.

finding that the agreement was anti-competitive by "object"). The law remains unsettled because the *Lundbeck* decision has been appealed by all defendants, plus there are two other pending reverse payment settlement cases which the EC has committed to hear by the end of 2014.[806] Further, the authors point out that even for agreements considered to be anti-competitive by object, the EC must consider each agreement to determine its content, the objective and the economic and legal context of which it forms a part.[807]

The open issues after *Lundbeck* are similar to those raised in the U.S. after *Actavis*. Commentators question the amount of permissible settlements; are only payments that are disproportionate to the actual value of settlement prohibited?[808] How will proportionality be determined? It also remains unclear whether and to what extent the EC will consider patent-related issues within the competition case, such as the strength of the patent (whether it is likely valid) in assessing reverse payment settlements.

As in the U.S., another open issue is the permissibility of arrangements that do not involve the payment of money and instead transfer more subtle or complex value, such as cross-licenses or distribution agreements.[809] Given the subsequent EC fine imposed on Novartis/Johnson & Johnson for conduct that included a "co-promotion agreement" (see below) the EC appears to be applying the same prohibition to cash and non-cash arrangements. The approach may be even clearer after the other pending EC Teva/Cephalon case is resolved, which included several side deals in the settlement agreement.

(ii) EC Cases After *Lundbeck*

In December 2013, the EC announced the imposition of its second set of fines for a reverse payment settlement, this time between Johnson & Johnson and Novartis ("*Johnson & Johnson*"). This concluded a year-long investigation by the EC arrangements between the companies.[810] The EC found that under the pretext of a "co-promotion" agreement, Novartis agreed not to launch a generic version of its product Fentanyl, a pain killer, which it was on the verge of launching in The Netherlands. In exchange for monthly payments from Johnson & Johnson under the agreement, the EC found that Novartis did very little or nothing to promote the Johnson & Johnson drug. The agreement was terminated when another company entered the market with a fentanyl product. The EC found the result was that "artificially" high prices for the drug were borne by patients and the national health system for a period of seventeen months. The announcement of the decision emphasized the strain on public health budgets and the key role of generics in ensuring affordable access to health care.[811]

The EC distinguished the *Johnson & Johnson* case from *Lundbeck* because there were no patents remaining in force at the time of the *Johnson & Johnson* agreement. The absence of patent- related complexities may make the *Johnson & Johnson* case simpler to pursue in competition law. However, the underlying logic and illegality are characterized as the same by

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806 A War of Roses, *supra* note 426 at 629; See discussion of Servier and Cephalon cases below.

807 *Ibid* at 627.

808 *Ibid*.

809 *Ibid*.

810 EC Press Release Regarding Johnson & Johnson, *supra* note 752.

811 European Union, European Commission, Press Release, "Antitrust: Commission Fines Johnson & Johnson And Novartis € 16 Million For Delaying Market Entry Of Generic Pain-Killer Fentanyl" (10 December 2013) online: <http://europa.eu/rapid/press-release_IP-13-1233_en.htm>.

the EC in both cases: a company paying its potential competitor to delay the entry on the market of the generic version of a drug.

The EC has two other public ongoing cases,[812] both involving reverse payment settlements that were reviewed as part of the EC's 2008 sector inquiry. Only five days after the *Lundbeck* case was announced, the EC issued a statement of objections to French pharmaceutical company Servier containing similar allegations.[813] The EC took the preliminary view that patent infringement settlement arrangements entered into by Servier and several generics regarding Perindopril, a cardio-vascular medicine, were aimed at delaying or preventing market entry of generics in violation of competition law. The EC is also alleging that, in a separate practice, Servier acquired scarce competing technologies needed to produce the drug. In the second case, the EC is investigating patent litigation settlements between generic company Teva and Cephalon regarding the drug Moldafinil, used for sleeping disorders.[814] Although the companies are based in Israel and the U.S., respectively, and the settlements were in regard to disputes in the U.K. and U.S., the agreement included a commitment by Teva not to sell generic Moldafinil in the European Economic Area. The FTC is also pursuing a case against Cephalon with respect to the reverse payment settlements and seeks to add Teva.[815]

(e) Conclusion on Reverse Payment Settlements in the EU

As in the U.S., the potential for anti-competitive harm arising from reverse payments has been a major focus of the EC for several years. The EU, like the U.S., has emphasized the role generic drugs play in reducing public health-care expenditures while still ensuring widespread access. The 2009 EU Pharmaceutical Report found competitive pressure from generic companies was not as strong as expected, and that, along with several other practices, reverse payment settlements may be a contributing factor. It recommended monitoring of patent infringement litigation settlements that have the potential to harm consumers. The EC has been engaged in such monitoring since mid-2008. The total number of settlements has increased during the years in which settlements have been monitored. The EC considers settlement agreements that limit generic entry and include a value transfer from a branded company to one or more generic companies to be the most likely type of settlement to raise competition concerns. From the first monitoring report to the most recent (in 2012), this category of settlements dropped by two-thirds. The EC theory of harm is similar to that in the U.S.; where generic entity is delayed or eliminated as a result of the settlement of patent challenges, there may be consumer harm arising from reduced competitive pressure exercised by potential general market entry.

The EC imposed its first fine for a reverse payment settlement in June 2013. It found that agreements reached between branded company Lundbeck and several generic companies

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812 See case 39686 Cephalon - C.21.2 - *Manufacture of pharmaceutical preparations* and 39612 Perindopril (Servier)- C.21.2 - *Manufacture of pharmaceutical preparations*, documents available at: <http://ec.europa.eu/competition/elojade/isef/index.cfm>.

813 European Union, European Commission, Press Release, "Commission Sends Statement Of Objections On Perindopril To Servier And Others" (30 July 2012) online: <http://europa.eu/rapid/press-release_IP-12-835_en.htm?locale=en>.

814 The parties settled patent infringement disputes in the U.K. and U.S. in 2005 that included commitments by Teva Pharmaceutical Industries Ltd. not to sell its generic version of the drug in the European Economic Area until 2012, and which included several side deals. See European Union, European Commission, Press Release, "Antitrust: Commission Opens Investigation Against Pharmaceutical Companies Cephalon And Teva" (28 April 2011) online: <http://europa.eu/rapid/press-release_IP-11-511_en.htm?locale=en>.

815 *Federal Trade Commission v Cephalon Inc*, (08-cv-2141-RBS).

violated Article 101 of TFEU by object. The EC's approach presumes illegality, a stricter approach to prohibitions on reverse payment settlements than the rule of reason analysis adopted in the U.S. *Actavis* decision. The precise contours of the EC approach are not yet clear, because the *Lundbeck* decision had not been issued as of writing, and it is under appeal.

The EC imposed a second fine in December 2013 for a reverse payment settlement, although unlike in *Lundbeck*, no patent was in effect at the time of the agreement. The EC approach to addressing reverse payment settlements under competition law is likely to be refined further in two pending cases. Whether that approach will be sanctioned by the European General Court will be determined in appeal of the *Lundbeck* decision, although this will likely take several years. In particular, differences from the U.S. approach may be addressed by the appeal, which challenges the EC's dismissal of the "scope of patent" test and the conclusion that the disputed settlement agreements restricted competition in the market beyond the scope of Lundbeck's patent rights. This echoes questions in the U.S. *Actavis* case, which rejected the scope of patent approach to antitrust analysis of reverse payment settlements.

Commentators argue *Lundbeck* has left much less leeway for entry into reverse payment settlements in the EC because it adopts a by-object prohibition, despite arguments that legitimate reasons for settlement may be even more compelling in the European context than in the U.S. *Lundbeck* (although the decision has not yet been issued) is also thought to leave open similar questions to those raised after *Actavis*. Such issues include the amount of permissible settlements, the extent to which the validity of the patent should be considered in competition litigation and the permissibility of arrangements that involve non-cash payments (although the EC appears to be applying the same approach to both cash and other arrangements, given the circumstances in which it imposed its second fine).

3. Patent Assertion Entity Conduct

To date, EU literature and enforcement agencies appear to have paid minimal attention to patent assertion entities. Many characterize PAEs as an American phenomenon.[816] Authors, as well as the U.K. IP Report (discussed further below), indicate that there is very limited empirical evidence on the activities of PAEs in Europe.[817] The lack of evidence has left it unclear as to whether PAEs are posing similar challenges in the EU as in the U.S., which has in itself given rise to concern in Europe over the potential negative impact on innovation rates from PAE activities.[818]

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816 Nuno Pires de Carvalho, Director of Intellectual Property and Competition Policy Division, World Intellectual Property Organization "Public Comments at FTC Patent Assertion Entity Workshop" (Speech delivered at the FTC Patent Assertion Entity Activities Workshop, 2013) at 2 ("PAEs-enforcers are a problem, if they can be deemed so, in the United States only…[O]utside the United States to buy and hold patents with the mere purpose of enforcing them is not a financially wise decision.") online: <http://www.justice.gov/atr/public/workshops/pae/comments/paew-0007.pdf>; Gail Edmondson, "European Patent Office Enters New Era: Managing the EU Unitary Patent" (2013) Science Business ("'I think patent trolls are linked to…injunction powers in the US legal system…If we find a good balance between the interest of the patent holders and the interest of third parties – which is the basis of the European system – I am convinced we will have balanced and appropriate decisions.", quoting Benoît Battistelli, European Patent Office President) online: <http://www.sciencebusiness.net/news/76068/European-Patent-Office-enters-new-era-managing-the-EU-Unitary-Patent>.

817 Trolls at the High Court, *supra* note 555; U.K. IP Report, *supra* note 735 at 15.

818 U.K. IP Report, *supra* note 184 at 8.

There does seem to be a sense, however, that Europe is not necessarily immune to PAE conduct. The head of the EC acknowledged recently that, although PAEs have been less active in European litigation than in the US, "this could change in the future…. rest assured that we are watching this space very carefully".[819] The U.K. IP Report notes that patent funds financed by private equity have acquired patent portfolios consisting of several thousand European patents, and therefore a patent system favouring patent assertion entities in the EU "would immediately constitute a problem" (the Report does not elaborate on this further).[820] The same report speculates that even "troll activities" in the United States "may be costing European firms large amounts of money."[821]

The EC had the opportunity to consider privateering concerns in the merger context with respect to Microsoft's acquisition of Nokia's mobile device business.[822] The concern from industry commentators was that because Nokia would retain its patent portfolio in the transaction while transferring the rest of its business to Microsoft, it would essentially be turned into a PAE who could act with impunity to cross-claims. However, the EC indicated that since the seller Nokia was retaining its patent portfolio, any claims that the transaction would lead to anti-competitive conduct by Nokia were outside of the scope of the merger review.[823] Despite this, the EC cautioned if Nokia "were to take illegal advantage of its patents in the future" the agency would take action.[824]

The EC has received at least two private complaints over PAE concerns, both in 2012. Huawei claimed the conduct of a PAE in forcing it to conclude a "discriminatory, unfair and exploitative license" violated commitments made to a standard-setting organization and also violated Article 102 of TFEU.[825] The complaint converges at the issues of standard-setting and PAE. There have been no recent public updates as to the status of this complaint. Also in 2012, the EC received a complaint from Google that Nokia and Microsoft were engaging in collusive privateering conduct, by transferring patents to PAEs in order to evade royalty commitments on their patent portfolios, and to target the competing Google Android operating system with litigation brought by the PAEs.[826] By engaging the PAE to bring the litigation instead of bringing it directly, Nokia and Microsoft avoided the risk of counter-claims from Google. The concerns expressed in the complaint appear to be increasingly a reality in the U.S., where litigation has been brought by Rockstar Consortium US LP against Google and its Android manufacturers, as discussed in the U.S. section on PAEs above.

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819 December 2013 Almunia Speech, *supra* note 137.

820 U.K. IP Report, *supra* note 184.

821 *Ibid*.

822 The concept of privateering is explained in more detail in the U.S. section, Background on PAEs.

823 December 2013 Almunia Speech, *supra* note 137.

824 *Ibid.*

825 Huawei, Press Release, "Huawei Files Complaint against InterDigital for Patent Abuse" (24 May 2012) online: <http://pr.huawei.com/en/news/hw-134791-anti-trustcomplainteuropeancommissioninterdigitalp.htm>, alleging the "terms and scope" of the license sought by InterDigital, an alleged PAE, for its SEPs related to the 3G mobile standard constituted abusive conduct [Huawei Press Release].

826 Brian Womack & Susan Decker, "Google Files Complaint in Europe Against Microsoft, Nokia" (1 June 2012) online: <http://www.bloomberg.com/news/2012-05-31/google-files-complaint-in-europe-against-microsoft-correct-.html>.

(a) Commentary on PAEs in the EU

Several authors argue the lack of noticeable PAE litigation in the EU is attributable to differences in the European patent and litigation system compared to the U.S.[827] The key differences pointed out by the literature seem to be fewer software and business method patents in the EU, the EU loser-pays rule in patent ligation and the lower hold-up potential arising from multi-jurisdictional patent infringement litigation in the EU. Each of these three major considerations are discussed further below. Authors also point variously to a lower cost of defending, smaller damage awards, and different cultural attitudes[828] in Europe as the reasons for the lack of PAEs.

First, software patents and business method patents are understood to be more difficult to obtain in the EU than in the U.S., making them less prevalent and often not as strong once issued.[829] Authors argue that the problem of 'over-broad' patents with 'fuzzy' boundaries is therefore less noticeable in Europe than it is in the U.S.[830] Such patents are considered common fodder for PAEs. However, a recent empirical study in the U.K. (discussed further in the U.K. section on PAEs in this report) found little support for this argument in empirical evidence, which showed when PAEs bring litigation in the U.K., they overwhelmingly assert software patents. It is thus does not appear to be a shortage of such patents in Europe that guards against PAE conduct.[831]

Second, the EU has a "loser-pays" fee rule in patent litigation, rather than the American system in which each party generally bears its own costs of litigation.[832] This changes the risk equation for PAEs.[833] The same empirical U.K. study mentioned above concluded that the burden of paying the opposing party's legal fees was the most likely reason for the absence of PAEs in Europe, and that in contrast, many of the other arguments on why there are no PAEs in Europe did not hold up to scrutiny.[834] Considering that the currently proposed U.S. legislative reforms often include cost shifting in PAE litigation, it seems likely fee-shifting is a significant factor in deterring PAE litigation.

Third, the EU has no single court in which patent litigation can be brought; patent rights must be enforced in each national court. This substantially increases the cost and complexity of litigation

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827 Trolls at the High Court, *supra* note 555 at 4; Anna Mayergotz, "Lessons from Europe on How to Tame U.S. Patent Trolls" (2009) 42 Cornell International Law Journal 241 (generally) [Lessons From Europe].

828 See the excellent overview of literature on such arguments in Christian Helmers, Luke McDonagh and Brian J. Love, "Is There A Patent Troll Problem in the U.K.?" (2014) 24 Fordham Intellectual Property, Media & Entertainment Law Journal forthcoming at 4, online: <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2331543> [Patent Troll Problem in the U.K.].

829 The Convention on the Grant of European Patents (European Patent Convention) of October 5, 1973, 1065 UNTS 255, Art. 52(2); Trolls at the High Court, *supra* note 555 at 8; Robert C. Bird, Subhash Chander Jain, eds., "The Global Challenge of Intellectual Property Rights", (Edward Elgar Publishing: 2008) at 20-21.

830 Trolls at the High Court, *supra* note 555; Lessons From Europe, *supra* note 827 at 257.

831 Patent Troll Problem in the U.K., *supra* note 828 at 1.

832 Colleen V. Chien, "Reforming Software Patents" (2012) 50 Houston Law Review 323 at 375 (reporting fee-shifting in U.S. patent cases is quite rare; between 2005 and 2011, fees were awarded in just 56 of the approximately 3000 total patent infringement suits).

833 Lessons From Europe, *supra* note 827 at 266. Recent changes introduced by the *Leahy-Smith America Invents Act* bring the U.S. patent system into closer alignment with that of the European Union.

834 Patent Troll Problem in the U.K., *supra* note 828.

in the EU, in comparison to a single-jurisdiction battle PAEs would face in the U.S. The potential reward in a European national court case may be, at most, an injunction blocking sales in the specific EU member state.[835] This higher cost/lesser reward dichotomy may translate into reduced hold-up potential in Europe than in the U.S. which explains the lower levels of PAEs in the EU.

There is concern that the introduction of the unified patent court in the EU will eliminate this third perceived protection against PAEs. The U.K. Parliament indicated proposals for the Unified Patent Court "create a system that could be a playground for patent trolls, while legitimate investment in patent protection and enforcement in the EU could decline".[836] Several major high-tech companies issued a joint public letter explaining that the proposed rules of procedure for the new Unified Patent Court may "creat[e] significant opportunities for abuse".[837] Their concerns are essentially that the proposed procedural rules for the new court would facilitate PAE hold-up. The new court would be empowered to issue injunctions that, because they bar sales of allegedly infringing products across most of Europe, have greatly increased hold-up potential.[838] The proposed bifurcation rules for the new court would allow splitting of the consideration of whether a patent is invalid and whether it has been infringed, which could allow plaintiffs to quickly obtain an infringement ruling and a related injunction. Stakeholders argue the increased hold-up potential arising from the significant injunctive power could confer the ability to force excessive settlements, and ultimately undermine innovation in Europe. They note "PAEs have already begun to set up shop in several European countries, drawn by the potential for siphoning more revenue from European companies."[839] The solution called for is stronger guidance in the rules for the unified patent court judiciary, including on when to issue stays of infringement actions and when injunctions are appropriate.[840]

A separate and important consideration is whether PAE conduct would likely violate European competition laws, and we found no significant commentary in this regard. Under Article 102, a leading case indicates bringing of vexatious litigation may constitute an abuse only in exceptional circumstances (see discussion of the exceptional circumstances standard in the EU section above on Article 102 applicability to conduct involving patents). Such exceptional circumstances have been found to occur only when the lawsuit is manifestly unfounded, in the sense that it cannot reasonably be considered to be an attempt to assert the rights of the plaintiff, and that it only serves to harass the opposing party.[841] The court emphasized the importance of the right to bring ligation as fundamental.[842] There may also be challenging questions as to whether PAEs are dominant in a relevant market, although based on recent

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835 Trolls at the High Court, *supra* note 555 at 9.

836 U.K. House of Commons, Report of European Scrutiny Committee, *The Unified Patent Court: help or hindrance? Sixty–fifth Report of Session 2010–12* (3 May 2012) commenting on the proposed unified patent court as of May 2012.

837 Letter from Stakeholders, *supra* note 164; See also FOSS Patents, "Comments On The Ongoing Patent Troll Debate In The U.S. -- And Don't Forget About Europe" (5 May 2013) online: <http://www.fosspatents.com/2013/05/comments-on-ongoing-patent-troll-debate.html>.

838 *Ibid*.

839 *Ibid*.

840 *Ibid.*

841 *Promedia*, *supra* note 111.

842 *Ibid* at para 60 ("As access to the Court is a fundamental right and a general principle ensuring the rule of law, it is only in wholly exceptional circumstances that the fact that legal proceedings are brought is capable of constituting an abuse of a[..]dominant position...").

standard-setting enforcement by the EC, dominance would be more likely to be found where the PAE conduct involves standard-essential patents. Rather than just a pattern of high levels of litigation brought by PAEs, emerging PAE conduct such as privateering, which has been the subject of complaints to the EC, seems more likely to form the basis for any case either under Article 102, or Article 101 (as an agreement affecting competition).

(b) Conclusion on PAEs in the EU

PAE litigation is not considered a current problem in the EU and is generally thought of as a uniquely American phenomenon. The European Commissioner for Competition recently noted this could change; and indicated this space is being watched by competition enforcers. The EC has received multiple complaints from private parties over PAE conduct and has heard arguments on PAEs in the merger context, but has yet to pursue any enforcement action. There is some evidence of at least low levels of PAE litigation occurring in the U.K. and an awareness that conduct by PAEs in other jurisdictions could be imposing costs on European companies.

Literature to date argues in theory that the absence of PAEs in the EU is due mainly to (i) fewer software and business method patents in the EU, (ii) the EU loser-pays rule in patent ligation and (iii) the lower hold-up potential arising from the multi-jurisdictional nature of patent infringement litigation in EU member states. An empirical study in the U.K. suggests the first factor does not play a significant role in limiting PAEs in practice, but that the second factor may be significant (with the caveat that the study involved a relatively small number of PAE cases). There is concern from industry commentators that the introduction of the unified patent court in the EU could erode the third perceived protection, creating opportunities for growth of PAE litigation in Europe. There was no significant commentary on whether PAE conduct would likely violate European competition laws. We did not find any studies estimating the cost of PAE conduct arising from litigation or otherwise in the EU.

4. Product Hopping

The EC has also expressed concern over product hopping and has a significant recent case on the subject. The 2009 EU Pharmaceutical Report discusses the prevalence of brand firms pursuing “second generation medicines” shortly before the loss of exclusivity for a patented drug.[843] The Report estimates that 40% of the drugs surveyed had second-generation products, and that the second generation launches took place, on average, one year and five months before the loss of exclusivity for the first generation product. Patents relating to second generation products were sometimes criticized as “weak” as they only show a “marginal (if any) improvement or additional benefit to the patients.”[844] The Report also describes marketing efforts undertaken “with the aim of switching a substantial number of the patients to the new medicine prior to market entry of a generic version of the first generation product.”[845]

(a) The AstraZeneca Case

The concern over product hopping also seems to pre-date the EU Pharmaceutical Report. In 2006, the EC began a product hopping case against AstraZeneca. The case concluded with a July 2010 decision in which the EU General Court upheld the EC’s finding against AstraZeneca

843 Pharma Report Executive Summary*, supra* note 163

844 *Ibid*.

845 *Ibid*.

for abuse of dominance.[846] The case involved AstraZeneca hopping its Losec product, through the introduction of new tablet formulation and by requesting a withdrawal of market authorizations for the prior tablet formulation in three European countries. The patent protection on Losec's active ingredient was on the verge of expiry when this conduct occurred.[847] Under the EU system at the time, once the branded company requested the withdrawal of the branded market authorization, the equivalent generic was prevented from being introduced. Two generic companies complained about the conduct to the EC.

The EC framed the abuse as being (i) the request by AstraZeneca for deregistration of the drug marketing authorizations, in combination with (ii) the withdrawal of the original formula from the market and (iii) the launch of a reformulated version, effectively blocking or delaying entry by generic producers and parallel importers and harming competition. In its decision upholding the EC's finding of abuse, the EU General Court emphasized that the "central feature" of the abuse was AstraZeneca's deregistration of the old branded product authorizations,[848] because this created a barrier to generic entry (and parallel imports from other EU countries). The mere introduction of a new product and removal of the old product from the market would thus not necessarily have constituted an abuse.

AstraZeneca argued it had no obligation to assist competitors by maintaining market authorizations to enable generic entry.[849] It also argued it was within its rights as a holder of the market authorization for the original formula to withdraw that authorization. The General Court rejected this argument on the basis that "compliance or non-compliance with other legal rules" related to market authorizations was not determinative of whether Article 102 (then Article 82) applied.

AstraZeneca also argued the new product was an objective improvement over the prior formulation, making the change pro-competitive and not merely exclusionary. (Although AstraZeneca admitted that the purpose of the new formula being introduced was, at least in part, to minimize the downward pressure on the price of Losec that would result from the entry of generic versions, it maintained this was not sufficient to constitute an abuse.) The General Court found the emphasis on the improvement in the new product was not relevant, because it was not the transition of sales from one formulation to another that formed the basis for creating a barrier to generic entry; it was the withdrawal of the market authorizations, on which the generic depended. The Court concluded it is not an abuse for a firm to deploy a strategy "whose object…is to minimise erosion of its sales and to enable it to deal with competition from generic products" as long as that strategy involves competition on the merits. However, dominant companies cannot "use regulatory procedures solely in such a way as to prevent or make more difficult the entry of competitors on the market" without objective justification or a defence related to competition on the merits.[850]

Another form of abuse alleged was that AstraZeneca had made misleading representations to patent agents and applications to patent offices in order to obtain supplementary extensions to

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846 *AstraZeneca*, *supra* note 118.

847 See e.g. summary of the *AstraZeneca* case in Lauren E. Battaglia, "Drug Reformulation Regulatory Gaming in Pharmaceuticals: Enforcement & Innovation Implications" (2011) 7 European Competition Journal 379 [Drug Reformulation Regulatory Gaming].

848 *Ibid* at para 807.

849 *AstraZeneca*, *supra* note 118.

850 *Ibid.*

its patent protection.[851] The EC rejected arguments that challenging the extension certificate for the patent would be an attack on the existence of the intellectual property right, on the rationale that the intellectual property right would not have been granted without the misrepresentations made by AstraZeneca in order to obtain that right.

There have been no major cases on product hopping in the EU since *AstraZeneca*. Older cases have found that a dominant company's policy of continually registering patents for minor alterations to its products, even though it had the effect of extending the initial period of protection, was not an abuse even if it was done with the intent to eliminate competition.[852] However, if the strategy was pursued along with other policies that led to a restriction of competition, it was considered potential that it could violate Article 102.[853]

(b) Commentary on *AstraZeneca*

One author explains that *AstraZeneca* signalled a major shift for the EC, to a more active approach to enforcement in pharmaceuticals and that shift was driven, at least in part, by innovation concerns.[854] The EC Commissioner at the time indicated bringing the *AstraZeneca* case intended to promote inter-brand competition "in innovation for patented medicines between the pharmaceutical producers…and to encourage inter-brand competition from generic substitutes after patent expiry" to increase price competition.[855] The EC's comments in the case also reflected a view that the threat of generic entry acts as a driving force in *prompting* branded companies to innovate,[856] in contrast to the view that innovation incentives of branded companies might be reduced by imposing a near-obligation to facilitate generic entry.

Both the U.S. and EU cases on product hopping raise the challenging question of assessing when innovation, even if marginal, can be considered anti-competitive. As one author explains, the notion that enforcement will ultimately benefit consumers through promoting innovation relies on the assumption that competition enforcers and courts are able to accurately distinguish between follow-on drugs that are pro-competitive and "those that are merely used merely [*sic*] as a mechanism by which to inhibit generic competition"[857] In the complex regulatory environment for pharmaceuticals this can prove particularly challenging.

Multiple articles argue that in comparison to the U.S. approach, the EU theory of harm minimizes the potential for negative impacts on incentives for legitimate, pro-competitive incremental innovation.[858] The two primary U.S. cases involve a theory of harm based on the removal of the old version of the product from the market, while the EU case involves a theory

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851 *Ibid*, para 143 onward.

852 Commission Decision, Case - 92/163/EEC *Tetra Pack II* OJ [1992] L72/1, [1992] 4 CMLR 551.

853 *Ibid*.

854 Drug Reformulation Regulatory Gaming, *supra* note 847 at 13 ("the Commission is intent on taking a more active approach in using competition law enforcement as a tool to stimulate innovation in pharmaceuticals.").

855 Commissioner Neelie Kroes' reply to Oral Question put by the honourable Member of the European Parliament Mr von Boguslaw Sonik, (H-0459/06), as quoted in Nadia De Souza, "Competition in Pharmaceuticals: the challenges ahead post AstraZeneca" (Spring 2007), 1 Competition Policy Newsletter 39 at 41.

856 Drug Reformulation Regulatory Gaming, *supra* note 847 at para 646.

857 Battaglia and Larouche, *supra* note 623 at 15.

858 *Ibid*; Drug Reformulation Regulatory Gaming, *supra* note 847.

of harm based solely on a regulatory action ancillary to the introduction of a product reformulation.[859] The U.S. approach may necessitate a more complex balancing analysis to determine whether the pro-competitive benefits of any particular innovation outweigh its anti-competitive effects in the market.[860] The EU approach to the theory of harm rests on "regulatory gaming", which one author explains as "private behavior that harnesses procompetitive or neutral regulations and uses them for exclusionary purposes."[861]

The EU approach requires only an evaluation of the effects on competition arising from a specific regulatory action, which is thought to make a false positive less likely than where the courts must parse the value of a particular incremental innovation. Battaglia et al. explain two ways in which the EU approach is likely to reduce false positives.[862] First, in the EU approach, the anti-competitive harm is more severe and the boundary clearer than in the U.S. approach. In *AstraZeneca* the conduct led to a prevention (or at least significant delay) of the generic entry for the *old* drug, while in the U.S. case, the generic version of the old drug remained free to enter the market. The U.S. situation merely meant there was no generic version available for the *new* formulation of the drug. Some of the U.S. cases have thus been described as involving a change in available consumer choice, but no actual elimination of choice (as in the EU) due to delayed entry.[863] Second, the evidence required to assess the conduct under the EU approach is thought to be more readily available and easier to objectively assess; the sort of business justifications likely to be advanced by the defence under the U.S. approach are harder to parse for legitimacy.[864] Because the EC approach arguably has this evidentiary advantage, and also avoids trying to weigh the value of a specific innovation against the elimination of consumer choice, the authors argue it reduces the likelihood of false positives, relative to the U.S. approach.

(c) Conclusion on Product Hopping in The EU

The 2009 EU Pharmaceutical Report discusses the prevalence of branded firms pursuing product hopping strategies shortly before the loss of exclusivity for a patented drug.

In a significant 2010 decision, *AstraZeneca*, the EU General Court found AstraZeneca had abused its dominance by requesting a withdrawal of market authorizations for an older formulation of a drug where the withdrawal blocked or delayed entry of a generic version of the older drug and thus harmed competition. Commentators consider *AstraZeneca* to signal a broader shift for the EC to a more active approach to enforcement in the pharmaceutical industry that was driven, at least in part, by innovation concerns.

The EU General Court took a different approach to its theory of harm in *AstraZeneca* than has been seen to date in the U.S. The two primary U.S. cases advance a theory of harm based on the actual removal of the old version of the product from the market by the branded company, while the EU case focused on the regulatory action of withdrawing market authorizations,

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859 Battaglia and Larouche, *ibid* at 15.

860 See discussion in *Microsoft*, *supra* note 92 of the weighing of anti-competitive harm and pro-competitive benefits, which occurs if the plaintiff offers a pro-competitive justification for its conduct.

861 Dogan and Lemley, *supra* note 657.

862 Battaglia and Larouche, *supra* note 623 at 19.

863 Guy V. Amoresano, "Branded Drug Reformulation: The Next Brand vs. Generic Antitrust Battleground" (2007) 62 Food & Drug Law Journal 249 at 254.

864 Battaglia and Larouche, *supra* note 623 at 21.

ancillary to the introduction of a drug reformulation. Although a new drug formulation had been introduced by AstraZeneca at the same time the older formulation was withdrawn, the EU General Court made clear this was not the central factor in finding liability in *AstraZeneca.*

Commentators argue the EU reliance on regulatory gaming as the basis for liability is more likely to promote innovation overall. They suggest the U.S. approach necessitates a determination of whether a particular incremental innovation to a drug formulation is pro-competitive, which can be extremely difficult to assess in the complex regulatory environment governing pharmaceuticals.

VIII. U.K.

1. Standard-Setting and FRAND Licensing Commitments

The U.K. approach to standards involving patents is similar to that of the U.S. and EU, for example, the U.K. IP Report describes similar considerations to these other jurisdictions. The U.K. IP Report acknowledges the benefits of standard-setting, but also that standards may create or reinforce market power as a result of patents being included in the standard or through patent ambush.[865]The report observes that problems of patent hold-up and royalty stacking can be severe in the case of standard-setting, because redesign can be very costly or commercially infeasible.[866]

The U.K. IP Report observes that SSOs encourage *ex ante* disclosure of patents (before the standard is established) and FRAND commitments, but that the meaning of FRAND can be unclear.[867]The report refers to EU cases where there have been difficulties in enforcing FRAND obligations after patents are transferred,[868] and to literature suggesting issues of ambiguity in FRAND commitments are best dealt with by SSOs.[869] However, industry comments reflected in the U.K. IP Report suggest standards-setting systems generally work well, and do not favour policy intervention. One commentator noted SSOs generally develop their rules in line with "competition law and guidelines from competition authorities [presumably referring to EC-level guidance], but that when there are issues the U.K. courts were respected venues for resolving standards and FRAND related litigation".[870]

Despite the general satisfaction with the U.K. system, comments from RIM (now BlackBerry) predicted an uptick in disputes related to SEPs and competition law, due to weak rules of SSOs and opportunistic behaviour by participants in standards development and purchasers of standard-essential patents.[871] Interestingly, the U.K. IP Report notes a dramatic increase in the number of patents declared as standard-essential to standards setting organizations.[872]

The U.K. IP Report canvasses three measures to mitigate the hold-up problem in the context of standards, but does not recommend any particular changes in the U.K. First, it considers stays

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865 U.K. Patent Thickets Summary, *supra* note 735 at 2, 6.

866 *Ibid*. As an example, the report estimates based on industry comments that the value of licensing the standards for a mobile phone can amount to 15-20% of the value of the handset for each interface standard, with multiple standards required for each phone.

867 *Ibid.*

868 *Ibid* giving the example of *Nokia GmbH v Ipcom GmbH & Co KG*, [2009] EWHC 3482, regarding patents acquired from Bosch.

869 *Ibid* at 12.

870 *Ibid* at 10 (Nokia comments).

871 *Ibid* (RIM comments).

872 *Ibid.* at 7, noting the increase in declarations to standards setting organizations during the 15 years to 2005, citing Timothy S. Simcoe, "Explaining the Increase in Intellectual Property Disclosure" S. Bolin, ed. *The Standards Edge,* Vol. 3. Chelsea, MI: The Bolin Group, 153–162 (8 December 2005), online: <http://sws1.bu.edu/tsimcoe/documents/published/SSO_IPR_Disclosures.pdf>. More recent data indicates that this accelerating pace of declarations has continued to at least 2011. Rudi Bekkers, Christian Catalini, Arianna Martinelli & Timothy Simcoe, "Intellectual Property Disclosure in Standards Development" (Paper prepared for the NBER conference on Standards, Patents & Innovation, Tucson, Arizona, 20-21 January 2012) at Figure 3.1, online: <http://home.ieis.tue.nl/rbekkers/Bekkers_et_al_(2012)_NBER_conf.pdf>.

of injunctions for infringement in order to enable the defendant to introduce a non-infringing version of its product.[873] Because a non-infringing design around may not always be available or evident, it is acknowledged this may not be a full solution. There are also concerns over sufficiently recognizing the rights of patent holders to obtain injunctions.[874] Second, the report considers eliminating the availability of injunctive relief for patents essential to a standard or only allowing injunctive relief where the defendant is refusing to pay FRAND licensing fees.[875] Third, the report considers encouraging or requiring SSOs to adopt a definition of FRAND terms, and to tie those terms to the marginal benefit contributed by the patented technology to the product. The report notes the marginal benefit could be assessed relative to the best available alternative at the time of standard-setting.[876] The second and third considerations are being encouraged by competition agencies in the U.S. and the EU. Aside from the U.K. IP Report, there appears to be little consideration in the patent and competition law context of U.K.-specific standard-setting issues.

(a) Conclusion on Standard Setting and FRAND Licensing in the U.K.

The U.K. approach to standard-setting and FRAND licensing commitments is similar to that of the U.S. and EU. The U.K. IP Report provides the most recent consideration of standard-setting and related licensing issues from a U.K. perspective. The U.K. IP Report acknowledges the benefits of standard-setting, but also that standards may create or reinforce market power as a result of patents being included in the standard or through patent ambush. The U.K. IP Report canvasses three measures to mitigate the hold-up problem in the context of standards: stays of injunctions for infringement, limiting the availability of injunctive relief for patents essential to a standard and encouraging SSO self-regulation. The report does not make any particular recommendations for policy changes in the U.K. Aside from the U.K. IP Report, there appears to be little consideration in the patent and competition law context of U.K.-specific standard-setting issues.

2. Reverse Payment Settlements

The U.K.'s Office of Fair Trading has taken recent action where it considered reverse payment settlements to have inhibited the entry of generic competitors. In April 2013, the OFT issued a statement of objections against GlaxoSmithKline ("GSK") and several generic competitors in relation to patent litigation settlements struck in the early 2000s regarding the antidepressant drug Paroxetine. GSK made "substantial" payments to the generic companies that the OFT views as being in exchange for a commitment to delay their plans to supply a generic version of Paroxetine in the U.K.[877]

The OFT's statement of objections is not public, but a press release indicates the OFT is considering whether there was an infringement of prohibitions on agreements that have the object or effect of preventing, restricting or distorting competition in the U.K. (Chapter 1, and the

873 *Ibid* at 18.

874 *Ibid*.

875 *Ibid*. This approach was supported by Qualcomm in its submissions regarding the U.K. IP Report.

876 *Ibid* at 18-19.

877 United Kingdom, Office of Fair Trading, Press Release, "OFT Issues Statement Of Objections To Certain Pharmaceutical Companies" (19 April 2013), online: <http://www.oft.gov.uk/news-and-updates/press/2013/36-13#.UsC_ImSichM>. The OFT alleges GSK concluded agreements which infringed competition law with each of Alpharma Limited, Generics (UK) Limited and Norton Healthcare Limited.

equivalent to Article 101 at the EU level). It is also considering whether the conduct amounts to an abuse of dominance (Chapter II, equivalent to Article 102 at the EU level).

The OFT identifies an underlying concern over public health costs and ensuring strong price competition from the introduction of generic medicines. It notes delayed generic entry could deny the National Health Service in the U.K. "significant cost savings".[878] The outcome of the case is expected in the fall of 2014 and may provide more guidance on the legality of reverse payments in the U.K. For now, it is clear there is a concern from the OFT's perspective.[879] The EC's decision in *Lundbeck*, discussed above, will likely be persuasive in the OFT's assessment.[880]

Reverse payment settlements have been the subject of private actions in the U.K. as well. A recent example is the case brought by the Secretary of State for Health for England in parallel to the EC's case against Servier. The claim alleges violations of Articles 101 and 102 of TFEU and Section 18 of the *U.K. Competition Act* by Servier, arising from its strategy to delay generic entry through patenting tactics, threatened infringement proceedings and reverse payment settlements.[881] More generally, this reflects the availability of private actions for abuse of a dominant position being both permitted (unlike in Canada) and used in the U.K.

Our research did not uncover any significant literature, other cases brought by public authorities or empirical studies on reverse payment settlements that raised issues related to the U.K. (and not otherwise addressed in the discussion herein regarding Europe).

(a) Conclusion on Reverse Payment Settlements in the U.K.

Like other jurisdictions, the U.K. has expressed concern over ensuring timely generic entry as a means of ensuring strong price competition and controlling public health costs. The OFT recently commenced action against companies who reached reverse payment settlements alleged to have inhibited the entry of generic competitors. The OFT is considering both whether the settlements violate prohibitions on anti-competitive agreements and whether the conduct amounts to an abuse of dominance. The approach of the OFT is likely to be the same as that of the EC in Lundbeck.

3. Patent Assertion Entity Conduct

No major U.K. legislation, cases brought by competition agencies or enforcement actions involving PAEs were identified in our research. However, a government report addressing the related issue of patent hold-up, as well as a large private empirical study on PAEs in the U.K., are both addressed below.

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878 *Ibid*.

879 A Statement of Objections from the OFT gives notice of a proposed infringement decision under the *U.K. Competition Act* and/or the TFEU to the parties involved. The parties then have the opportunity to make written and oral representations in response to the case set out by the OFT. Such representations will be considered by the OFT before any final decision is made.

880 See the direction in Section 60 of the *Competition Act 1998* for U.K. courts to maintain consistency with EU competition law.

881 See discussion in Competition Litigation 2014, Jonathan Tickner and Emma Ruane, Chapter 3: "Anti-Competitive Camouflage: Pay-for-delay Agreements" (International Comparative Legal Guides to Competition Litigation; 2014).

(a) Government Report Addressing Hold-up and PAEs in the U.K.

The U.K. IP Report, issued in May 2011, presents similar arguments relating to patent hold-up as those articulated in the U.S.[882] In doing so, it comments to some extent on PAEs.

The U.K. IP Report acknowledges the potential issue of patent hold-up where the ability of a patent holder to obtain an injunction or high amounts of damages, "while traditionally fundamental to the property right associated with patents," also places the patent holder in a strong position in negotiations or disputes where the technology is allegedly being used.[883] It observes the targets of injunction threats will often be "young, small businesses" in high technology areas that tend to hold fewer patents than more established enterprises. The U.K. IP Report goes on to indicate hold-up "may be more problematic" when a non-practicing entity (such as a PAE) is involved, since the firm attempting to license will not be able to use cross-licensing as a bargaining chip. The U.K. IP Report acknowledges that problematic non-practicing entity behavior is more likely to arise as the quality of patent examination decreases.

The U.K. IP Report notes that courts generally refuse to consider the costs of inventing around a patent as a basis for damages. It speculates that a regime for patent infringement damages which considers the costs of inventing around a patent would dissuade PAE litigation in many cases by reducing the potential damage award. The approach would be to assess damages based on the marginal value added to a product by the patent in dispute and consider the infringer's costs in the counterfactual where the infringer used the next-best substitute for the infringed patent.[884]

The U.K. IP Report also considers there may be potential benefits from PAEs, in enabling smaller enterprises to obtain returns from their innovations by assisting in the enforcement of their patent rights.[885] It raises as a topic for further research whether PAEs play a role in ensuring salvage value for the patents of failing firms.[886]

The U.K. IP Report concludes more generally that standard-setting, patent pools and cross-licensing can offer market-based means of navigating around or alleviating the issues raised by patent thickets, because all involve a community of patent holders coming together and agreeing on the use of each other's patents. However, hold-up and PAEs mean such market-based solutions are not "a complete answer to the growing problem of [patent] thickets".[887] The resulting risk of this incomplete solution is that firms may under-use new knowledge, because too many patent owners can block each other's positions within a thicket.[888] Small and medium

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882 The U.K. IP Report, *supra* note 184, takes the somewhat unique perspective on framing these issues in that patent thickets are the true issue, as discussed above. The report then goes on to discuss the role of standard-setting, patent pools, cross-licensing and PAEs as they relate to patent thickets.

883 *Ibid* at para 6.29; and U.K. Patent Thickets Summary, *supra* note 735 at 14.

884 U.K. Patent Thickets Summary, *ibid* at 14.

885 *Ibid* at 15-16.

886 *Ibid* at 16.

887 *Ibid*.

888 U.K. IP Report, *supra* note 184 at para 6.30.

sized enterprises may also find the costs and terms of participation in market-based solutions to be prohibitive.[889]

The interim report relies largely on academic literature and industry comments; it does not include empirical data analysis on the issue of PAEs for the purposes of the report. The U.K. IP Report also does not adopt any determinative policy position for the U.K. on addressing PAEs.

(b) Literature on PAEs in the U.K.

In comparison to the U.S., literature addressing PAEs in the U.K. is relatively scarce.[890] However, we found two fairly extensive empirical studies of patent litigation by non-practicing entities in the U.K.: one analyzing patent infringement litigation by non-practicing entities (including PAEs) from 2000-2008 and the second, from some of the same authors, updated to reflect data through 2010.[891]

The more recent of the two studies, by Helmers, McDonagh & Love, reviewed approximately 300 patent suits involving non-practicing entities in the U.K.[892] The authors found that non-practicing entities were responsible for a relatively small percentage of the suits filed (11%, including PAEs, which accounted for 8% of this total), but accounted for consistent share of U.K. litigation and were "hardly a uniquely American phenomenon as some policymakers have suggested".[893] It was also found that PAEs are highly unsuccessful overall in their patent litigation on both sides of the Atlantic, when compared to producing companies.[894] The study does not consider whether the rate of non-practicing entity litigation has risen noticeably in recent years.

Helmers, McDonagh & Love found other similarities in PAE litigation between the U.K. and that in the U.S., including that non-practicing entity suits in the U.K. relate almost exclusively to the assertion of high-tech patents, particularly information communications technology patents.[895] Other authors have argued the reason for the lack of PAE litigation in the U.K. is an absence of weak or fuzzy patents issued (as discussed further in the Europe section, above),[896] but the focus on high-tech patents in the U.K. suggests there is no shortage of patents available for use by PAEs there.

The study suggests more broadly that several of the common explanations for Europe's relative scarcity of PAE activity may not in fact hold true, as discussed further in the EU section above. The authors argue further that, within the EU, the U.K. is the most similar jurisdiction to the U.S. due to its larger damage awards, higher costs of defence, more onerous discovery requirements

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889 *Ibid* at para 6.28.

890 Trolls at the High Court, *supra* note 555 at 3.

891 *Ibid*; Patent Troll Problem in the U.K., *supra* note 828.

892 *Ibid*.

893 *Ibid* at 30. Trolls at the High Court, *supra* note 555 at 20, found in their earlier study that PAEs represented less than 6% of all patent cases.

894 *Ibid*. The authors found only one of the suits litigated to judgment in which the PAE was even partially victorious, with one of four patents found to have been infringed.

895 *Ibid* at 16, also found the patents involved in PAE cases in the U.K. were "overwhelmingly concentrated" in the information communications technology sector.

896 Patent Troll Problem in the U.K., *supra* note 828 canvassing such arguments of other authors at 26.

and substantive similarities to U.S. patent law.[897] The explanations offered by the literature for Europe's lack of PAEs may therefore apply with less force within the U.K.[898]

Although the authors caution against drawing overly broad conclusions based on the small number of PAE suits within the study data set, they suggest the key factor in deterring PAE litigation in the U.K. (and Europe generally) is fee-shifting.[899] The conclusion is based on findings that PAE suits in the U.K. were less likely to end in a settlement[900] and very rarely end in victory for the PAEs, such that a fee award is fairly likely to occur under the U.K. system for the alleged infringer.[901] The comparatively high cost of patent infringement litigation in the U.K. contributes to the amount the PAE risks having to pay if it loses the case.[902] The earlier study by Helmers & McDonagh also concluded that there was a high likelihood of the PAEs' patent being declared invalid by the U.K. courts. Helmers, McDonagh & Love found few repeat PAE litigants, suggesting PAEs might be trying their hand at litigation in the U.K., losing, paying large fee awards and never risking further litigation.[903] The authors conclude that U.S. reforms focused on shifting fees in infringement litigation are thus likely to deter PAE litigation.[904]

Overall, the studies provide empirical evidence that PAEs are operating in the U.K., but also that, at least as of 2010, the litigation is not anywhere near the extent of that seen in the U.S. Although in-depth and helpful, we note the studies would not capture any very recent uptick in PAE conduct, which grew rapidly in the intervening period of 2011-2014 in the U.S. The existence of at least some PAE litigation seems to be supported by a recent case against ZTE Corporation in the U.K.[905] The study did not address indirect costs that may be imposed within the U.K. from litigation elsewhere, or costs potentially arising from threats that do not result in litigation (which may be less common in the U.K., given the groundless threats provision discussed above and the other distinctions in the U.K. system discussed here).

(c) Conclusion on PAEs in U.K.

The 2011 U.K. IP Report acknowledges the potential issue of patent hold-up and indicates hold-up "may be more problematic" when a non-practicing entity (such as a PAE) is involved. It considers patent quality, patent infringement damages and market-based solutions to the issues raised by PAEs, but does not make any recommendations specific to PAE conduct or on the role of competition law in controlling such conduct.

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897 *Ibid* at 23.

898 *Ibid*.

899 *Ibid*. The article estimates it is unlikely the PAE would pay around U.S.$375,000 as a result of a lost case.

900 *Ibid* at 20. The settlement rate in the U.K. was around 51% (although this may be higher than the actual rate since some of the settled cases were related) while in the U.S. approximately 75% of the comparable cases settled.

901 Trolls at the High Court, *supra* note 555 at 4.

902 *Ibid*.

903 Patent Troll Problem in the U.K., *supra* note 828 at 27.

904 *Ibid.*

905 Mark Summerfield, "Courts Play Host To NPE Global Licensing Strategies", Watermark Patent & Trade Marks Attorneys (13 November 2013) (originally published in IAM Magazine) reporting litigation brought in the U.K., Germany, France and Australia by a company characterized as a PAE [Summerfield].

An empirical study of patent litigation in the U.K. considered data on patent litigation involving non-practicing entities in the U.K. from 2000 to 2010. It found PAEs brought a small part of the overall non-practicing entity litigation, but that PAE litigation was in fact occurring within the U.K. The characteristics of such PAE litigation were found to be similar in several respects to PAE litigation in the U.S. The study also suggests that several of the common explanations for Europe's relative scarcity of PAE activity may not hold true, as discussed further in the EU summary above. The study did not address indirect costs that may be imposed within the U.K. from PAE litigation elsewhere, or costs potentially arising from threats that do not result in litigation.

The U.K. is currently studying a provision under its *Patents Act* that prohibits groundless threats of patent infringement. The draft report recognizes similar concerns to those fueling the debate over patent assertion entities in the U.S. and standard-setting/FRAND issues in the U.S. and EU, such as the risk that an ill-founded threat of patent infringement litigation could unjustifiably shut down the supply or sale of products.

4. Product Hopping

One of the most significant recent enforcement actions involving competition law and patents in the U.K. focused on allegations of product hopping. In April 2011, the OFT issued a decision against branded drug company Reckitt Benckiser for abusing its dominant position ("*Reckitt Benckiser*").[906] The decision gave rise to several private actions for damages, including by U.K. health authorities.[907]

***Reckitt Benckiser*- The Facts in Brief**

Following the expiry of its patent on its original heartburn product, but before the generic equivalent had been added to the database of prescription drugs available through the U.K.'s National Health Service, Reckitt Benckiser withdrew its original product from that prescription database.

Where a branded medicine's patent has expired and a generic name has been assigned to it, U.K. doctors can use a prescribing software/database to search for the branded version, find the relevant generic name and then provide patients with an "open" prescription that refers to its generic name. Once a branded medicine's patent expires and a generic version is available, there is a similar system to Canada under which the generic can be substituted for the branded drug by pharmacists. Pharmacies receiving the open prescriptions can choose whether to dispense the relevant branded or equivalent generic medicines. This substitution option is thought to enable strong price competition between drug suppliers resulting in significant savings to the U.K. National Health Service. Reckitt Benckiser's withdrawal of the older drug formulation from the database meant there would be no generic drug that would appear if a doctor searched for the branded name.

906 United Kingdom, Office of Fair Trading, Press Release, "Reckitt Benckiser - Investigation Into The Abuse Of A Dominant Position" online: <http://www.oft.gov.uk/OFTwork/competition-act-and-cartels/ca98/decisions/reckitt-benckiser#.UsC9gGSichM>. The company was found to have contravened the U.K. Chapter II Prohibition and article 102 TFEU.

907 *Ibid*. The fine was reduced from £12 million to reflect Reckitt Benckiser's admission and decision to co-operate as part of an early resolution agreement with the OFT.

The OFT found that Reckitt Benckiser had withdrawn and de-listed its original heartburn product from the market (and prescription database) with the intention of limiting pharmacy choice and hindering competition from suppliers of generic versions of the medicine.[908] The OFT press release on the decision focuses specifically on the withdrawal of the old product from the prescription database. The OFT rejected Reckitt Benckiser's argument that its withdrawal was part of "normal lifecycle management" for its products, explaining as follows:[909]

> While there is no accepted definition of a 'normal lifecycle management strategy' in the pharmaceutical sector, the OFT considers that in this context a 'normal lifecycle management strategy' would involve a pharmaceutical manufacturer choosing to replace an existing product with one that incorporates innovations that are valued by clinicians and patients alike, such that it can make commercial sense (irrespective of any gains from hindering the development of full generic competition) to withdraw the original product for which there may then be no (or only limited) residual demand.

In its lengthy decision, the OFT focuses on whether the rationale of Reckitt Benckiser was to hinder competition. It finds the drug withdrawal would have been irrational in the absence of the benefits that Reckitt expected to derive from hindering full generic competition. Internal documents of the company revealed that, were it not for the prospect of using the withdrawal to pre-empt competition, the withdrawal was expected to be loss-making and thus not a commercially rational strategy.[910]

Although the OFT quotes *AstraZeneca* extensively, authors suggest the OFT expanded the conduct constituting an abuse beyond that found in *AstraZeneca*. The court in *AstraZeneca* clearly stated that there was no reason to reproach the company for launching new product or withdrawing the old one, since that did not give rise to barriers to entry. The OFT appears to have merged the analysis of the de-listing and the withdrawal of the product/introduction of a new product. Norlander and Harrison argue that "the OFT's decision in Reckitt Benckiser gets very close to classifying as an abuse conduct which consisted in [sic] the simple withdrawal of an older, less effective version of a product."[911] These authors also contend that the focus on intent, which the OFT found was reflected in the company's internal documents, may also be

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908 *Ibid*; Competition and IP Interface, *supra* note 173.

909 *Abuse Of A Dominant Position By Reckitt Benckiser Healthcare (UK) Limited And Reckitt Benckiser Group Plc*, OFT Decision No. CA98/02/2011, Case CE/8931/08 (12 April 2011) at para 6.58, online: <http://www.oft.gov.uk/OFTwork/competition-act-and-cartels/ca98/decisions/reckitt-benckiser#.Us-C_2SichM>.

910 *Ibid*.

911 Kristina Nordlander & Patrick Harrison, "Abuse of Regulatory Procedures in the Pharmaceutical Sector – Developments Since the General Court's Judgment in *AstraZenecal*," (2012) CPI Antitrust Chronicle at 5. A U.K. OFT submission at a 2009 OECD roundtable (predating *Reckitt Benckiser*) on generic pharmaceuticals also suggests an approach focused on parsing innovation, stressing the anti-competitive potential of conduct "whereby a branded pharmaceutical company might seek to introduce new patented pharmaceutical products that provide no real benefits but are designed to forestall generic competition." OECD, Directorate for Financial and Enterprise Affairs, "Roundtable on Generic Pharmaceuticals" DAF/COMP(2009)39 (published 5 October 2010) at 10, online: <http://www.oecd.org/competition/abuse/46138891.pdf>. at 125, 134-135.

contrary to previous European Court of Justice jurisprudence under which abuse is to be assessed objectively, and intent is only of secondary importance.[912]

Other commentators have observed that *Reckitt Benckiser* may have limited effect, since the result appeared to be highly driven by the company's internal documents. Much of the evidence cited by the OFT related to internal company documents that outlined the "strategic rationale" for the withdrawal, which (as discussed above) the OFT found to be delaying generic entry as long as possible. Some authors argue product switches may still be justifiable as long as there is evidence that the decision is commercially reasonable and the intent is not to restrict competition.[913]

(a) Conclusion on Product Hopping in the U.K.

In April 2011, the OFT found an abuse of dominance based on product hopping. The conduct involved a branded company's withdrawal from the market and de-listing of its original product from a national prescription database, with the intention of limiting pharmacy choice and hindering competition generic suppliers. The decision gave rise to several private actions for damages, including by U.K. health authorities.

Commentators suggest the OFT decision expands potential liability for product hopping beyond that of the leading EU-level case *AstraZeneca*, because the OFT did not distinguish between liability based on the withdrawal of an older product from the market versus liability based on the delisting of that product on the public prescription database. The conduct at issue involved some regulatory "gaming" in the withdrawal from the prescription database; the OFT could have based liability on this alone, but it did not. Ultimately, the intent of hindering generic competition, reflected in internal company documents, appears to have driven the OFT decision. Commentators suggest this may limit the decision's applicability more generally. Product switches may thus still be justifiable in the U.K. as long as there is evidence that the decision is commercially reasonable and the intent is not to restrict competition. Like the U.S. approach, the U.K. approach may require the OFT to parse the sufficiency of innovation, since harmful intent in the OFT case was found in part because of the perceived lack of true innovation.

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912 *Ibid*.

913 Maria Isabel Manley & Maria Georgiou, "Reckitt Benckiser: The Sour Aftertaste Of A Settlement With The OFT In The UK" Memorandum of Bristows (October 2011), online: <http://www.bristows.co.uk/articles/reckitt-benckiser-the-sour-aftertaste-of-a-settlement-with-the-oft-in-the-uk>.

IX. AUSTRALIA

1. Note on Literature Review

Australian literature on the topics of the intersection of patent and competition is very limited in comparison to literature in jurisdictions such as the U.S. and EU and even the U.K. literature we reviewed echoed that of the U.S. and often referred to U.S. guidance on intellectual property, and as such we have not repeated the discussion here.[914] Papers presenting unique Australian considerations were rare. In an effort to identify consideration of the issues in Australia, we researched papers dating to earlier periods than in other jurisdictions and included some general commentary from online law firm publications.

One recent but more general Australian article steps back to consider how countries should attempt to facilitate law's response to technological change, as the pace of such change accelerates.[915] Overall, the article concludes that, although the lag of law behind technological development tends to be considered problematic, the goal should not be to race ahead by trying to anticipate technology, but instead to design mechanisms that promote goals that are desirable regardless of the exact technological development, such as promotion of innovation.[916] The author identifies two main challenges common to all existing institutions that manage legal change with regard to technology.[917] The most significant problem is that each organization tends to exist in a silo, focusing on their particular task or discipline. The author recommends collaborative, interdisciplinary efforts across law and technological borders as the key to better understanding and change. The other issue is the tendency for one-off momentous reform, rather than ongoing monitoring and adjustment. On this point, the author notes a growing focus on "real time" reform consultation[918] and more frequent review.[919] A related suggestion is also made that better "horizon scanning" – attention to emerging technologies and early management of technological risks – would enable the bodies responsible to have earlier understanding of the facts underlying the potential need for legal change.[920]

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914 For example see Daniel Gervais, "Challenges in Intellectual Property Governance: Providing the Right Incentives in the Quest for Global Innovation" (2012) 4(2) Trade Law & Development 385 at 394.

915 Moses, *supra* note 245.

916 *Ibid* at 788.

917 Such as the UK's Red Tape Challenge, which involves open, ongoing online consultation with the public on topics of proposed regulatory reform, see Moses, *supra* note 245 at 781-82.

918 *Ibid*.

919 *Ibid* at 780. For example, Australia has implemented a required review of regulations every 5 years to ensure the regulations remain fit and account for new technological circumstances. The author points to similar initiatives in Europe, called the "Better Regulation" initiative, as also having the potential to facilitate law's response to technological change.

920 *Ibid* at 777. The example of the U.K. Parliamentary Office of Science and Technology is given, which provides short, factual briefing notes on arising technologies to keep members of parliament informed. Europe also has EU and national level "technology assessment" bodies that operate to warn policy makers early on of the evolving scientific facts on which policy can be based.

2. Standard-Setting and FRAND Licensing Commitments

(a) The Compulsory Licensing Report

One of the few considerations of standard-setting/FRAND issues in Australia arose in the context of the recent Australian Government Productivity Commission review of the country's compulsory licensing system ("Compulsory Licensing Report").[921] The Productivity Commission acts as an independent research and advisory body that focuses on strategic means of achieving a more productive economy through better policy, including on economic, social and environmental issues.[922] The following explains the Australian compulsory licensing regime at a high level, addresses the context for the review and then explains the review's consideration of standard-setting/FRAND issues and more general legal reforms.

(i) The Australian Compulsory Licensing Framework

There are two means through which a compulsory license may be issued for a patent in Australian law. First, courts may issue a compulsory license under the *Australian Competition Act* where there is a violation of Section 46(1) (misuse of market power).[923] In the late 1990s the ACCC settled two alleged Section 46 contraventions with an order for a compulsory license, but neither involved patents.[924] Australian courts "are often hesitant to interfere with the incentive schemes provided by the patent monopoly by requiring compulsory licenses to patented technologies" under Section 46(1).[925]

Compulsory licensing may also be granted pursuant to the Australian *Patents Act* in certain circumstances.[926] The *Patents Act* provides that where a patentee does not exploit a patented invention for a period of three years from the date of grant, a third party may apply to the Federal Court for a compulsory license to work the invention under certain circumstances.[927] For a compulsory license to be granted, it must be shown that one of two tests is met. The first option is to show that the patentee has engaged in unlawful anti-competitive conduct in violation of the *Australian Competition Act* in connection with the patent. The second option is to show the following conditions are satisfied:

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921 Senate Committee and an Australian Law Reform Commission report on gene patents also recommended a review of the operation of the compulsory licensing provisions. There was also concern that patents over genetic technologies, or a perceived lack of licenses to use such patents in Australia unreasonably restricts or delays patient access to medical advice based on the latest diagnostic tests. Mark Dreyfus Parliamentary Secretary for Climate Change and Energy Efficiency and David Bradbury, Press Release, "Minister for Competition Policy & Consumer Affairs, Balancing Access to Technology and Innovation" (29 July 2012).

922 See the Productivity Commission website online: <http://www.pc.gov.au/about-us>.

923 Pursuant to Section 87 of the *Australian Competition Act* which provides wide jurisdiction to make such order or orders as the Court thinks appropriate.

924 See e.g. *ASX Operations Pty Ltd v Pont Data Australia Pty Ltd* (1990) 27 FCR 260, ASX Operations was found to have violated Section 46 and ordered to supply copyrighted information to a competitor on the terms that prevailed before the contravention.

925 Standardization and Patent Ambush, *supra* note 958 at 288.

926 *Patents Act 1990* (Austl), Section 133(2)(b) [*Australia Patents Act*].

927 *Ibid*, Section 133.

- the third party has attempted for a reasonable period, without success, to obtain a license from the patentee on reasonable terms and conditions;
- the reasonable requirements of the public have not been met;[928] and
- the patentee has provided no satisfactory reason for failing to exploit the invention.

The first option, referred to as the "competition test", was introduced in 2006 in response to a review of intellectual property legislation.[929] No applications have been made under this test since its introduction. In fact, applications for compulsory licenses have been made only three times under the *Patents Act* since the introduction of the overall provision in 1903, and none have been granted.[930] It has been suggested that Section 46 of the *Australian Competition Act* would be the most likely to be relied upon as having been violated in a case relying on the competition test.[931] Past reviews of Australia's patent system have questioned how the violation of competition law might be assessed under the compulsory licensing provisions.[932]

(ii) Review of the Compulsory Licensing Regime

Prompted in part by the lack of use of the compulsory licensing provisions, the Compulsory Licensing Report considered whether the current compulsory licensing provisions could be invoked efficiently and effectively, recommended measures to improve the provisions and considered whether any alternative mechanism would better balance the incentive to innovate with access to technology.

Based on stakeholder input, the Compulsory Licensing Report found there were three likely reasons as to why compulsory licensing went relatively un-used.[933] First, because the compulsory licensing provisions are an effective deterrent against refusals to license, they promote licensing and so applications for compulsory licenses are rarely necessary. Second, the provisions act as a safeguard that is only needed in exceptional circumstances. And third, the provisions are rarely used because of the substantial costs and length of time associated with obtaining such a license through an application to the Australia Federal Court. The Report found there was no clear alternative to a Federal Court application that was likely to be less costly while still maintaining the quality of outcomes and scope for appeal.[934]

(iii) Consideration of Standard-Setting/FRAND Licensing in the Compulsory Licensing Report

The Compulsory Licensing Report indicates that where a patent owner is abusing its market power in the form of a failure to comply with FRAND commitments for standard-essential

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928 Section 135 also sets out when the reasonable requirements of the public have not been met.

929 Commonwealth of Australia, Attorney General's Department, *Government Response To The Advisory Council On Intellectual Property Recommendations* (2000) online: <http://arts.gov.au/resources-publications/publications/government-response-advisory-council-intellectual-property-recom>.

930 Compulsory Licensing Report, *supra* note 224 at 3.

931 *Ibid* at 131. Section 46 has been used to obtain access to copyrighted competitor information.

932 *Ibid.* at 3. Past reports have also taken issue with the other branch of the test, and the lack of clarity of the "reasonable requirements of the public" criteria.

933 *Ibid* at 12.

934 *Ibid* at 13.

patents, such anti-competitive behavior "could conceivably be addressed by granting a compulsory license".[935] The Report contemplates whether explicit provisions relating to standards or FRAND commitments are needed under competition law to protect against FRAND licensing abuse in Australia. It concludes no such provisions are required, because of Section 46 of the *Australian Competition Act* and the availability of compulsory licensing provisions in the *Patents Act* (after the proposed reforms to streamline these statutes, discussed below) provide sufficiently broad protection against any such misuse of market power.

The Compulsory Licensing Report also considered stakeholder comments calling for the use of compulsory licensing for SEPs of social importance, such as patents essential to communications network.[936] It concludes such industry-specific measures are not necessary, because the general *Australian Competition Act* provisions and the public interest ground for compulsory licensing in the *Patents Act* were sufficient to address any concerns over enhanced market power arising from standards in areas of public interest. Further, it emphasizes the *Patents Act* is drafted to be technology neutral and altering the legal status of patents in specific industries may have unintended consequences.[937]

The Compulsory Licensing Report indicates that the "controversy" over standard-essential patents may be overstated.[938] It refers to recent comments from the International Telecommunications Union ("ITU", an SSO) that emphasized recent litigation in the area of FRAND is not representative of widespread problems with the concept of FRAND commitments, which it characterized as "rooted in exaggeration".[939] The ITU considered FRAND-based licensing practices to function as-intended and emphasized such practices have enabled hundreds of successful licensing arrangements and "spectacular innovation and growth in the mobile communications industry".[940]

The Compulsory Licensing Report concludes that current legislation is unlikely to be called upon often in Australia to resolve SEP disputes, because there are few industries associated with SEPs operating in Australia.[941] It refers to an EU survey that found 91% of SEPs were owned by companies from the U.S., EU or Japan.[942] Australian standards organizations tend to adopt standards set abroad by global or regional standard-setting organizations.[943]

(iv) Other Recommendations of the Compulsory Licensing Report

The Compulsory Licensing Report recommends that when a patent is used to engage in unlawful anti-competitive conduct, a compulsory license should be available only under the *Australian Competition Act*. It suggests that the provision allowing for compulsory licensing

935 *Ibid* at 12.

936 *Ibid* at 103.

937 *Ibid*.

938 *Ibid* at 104-105.

939 *Ibid* at 105.

940 *Ibid*.

941 *Ibid* at 105.

942 *Ibid*.

943 *Ibid*. The main Australian standards government regulatory body, Standards Australia, notes most influential and large SSOs operate at a global or regional level (often organized by industry) and describes its policy "bas[ing] Australian Standards on International Standards to the maximum extent feasible".

under the *Patents Act* based on a violation of to the *Australian Competition Act* (i.e. the competition test branch) should be repealed.[944] The Report found there was unnecessary overlap between the compulsory licensing provisions in the *Australian Competition Act* and those in the *Patents Act* with respect to anti-competitive behaviour, and inconsistencies across the legislation in aspects such as the range of remedies (exclusive vs. non-exclusive licenses), timing of when an application can be made, who can seek a compulsory license, court jurisdiction and whether or not there were limits on the court-imposed payment for the license.[945]

Although the Compulsory Licensing Report also considers the alternative of amending the *Patents Act* to trump the competition legislation, it concludes that merely moving the competition test branch compulsory license provision exclusively into the *Australian Competition Act* is the best option. This approach leaves "the responsibility for remedying anticompetitive behaviour relating to patent access with the regime that is specifically designed for the task."[946] The competition legislation was thought to be the preferable statute because it provides broader and lower-cost access to applicants and a broader range of remedies. The move to the competition legislation is also expected to make the compulsory licensing regime more certain and effective. The Report also notes the deterrent power of merely vesting antitrust courts with the power to issue compulsory licenses.[947]

The Compulsory Licensing Report observes that Section 46 of the *Australian Competition Act* (in conjunction with the existing compulsory licensing remedy) would not cover all circumstances in which a compulsory license could promote public welfare.[948] Section 46 requires an anti-competitive purpose in addition to the exercise of market power by the patent holder. The current test would not apply to situations where the patentee exercises market power without a goal of damaging a competitor or preventing or deterring competition, regardless of whether the granting of a compulsory license is in the public interest (the example of price gouging is given).[949] Section 46 thus operates as an incomplete "access regime" where compulsory licenses may be desirable. To address these additional situations, the Report recommends that a version of the *Patents Act* "reasonable requirements of the public" section be retained, but that it be improved, clarified and based instead on a test referring to the "public interest".[950]

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944 A possible means of inserting this into the *Australian Competition Act* suggested by the Compulsory Licensing Report is to add it to the remedies the court is empowered to issue when there is a violation of Part IV of the *Act* (s 87(2)).

945 See Compulsory Licensing Report, *supra* note 224 at 134 for a more in-depth discussion of the difference between the compulsory licensing regimes under statutes.

946 *Ibid*.

947 *Patents, Innovation and Competition in Australia* (1984) as quoted by the Compulsory Licensing Report, *supra* note 224 at 136-137. The Compulsory Licensing Report, *ibid.* notes the U.S. courts' power to order compulsory licenses to redress antitrust breaches is effective because "[i]ts existence and the possibility that it will be exercised also operate as important influences upon patentees to grant licences for the purposes of avoiding or settling antitrust litigation. In our opinion, the vesting of similar power in the relevant Australian court would be likely to assist in curbing unjustifiable, anticompetitive, patent-related conduct".

948 *Ibid* at 145.

949 *Ibid*.

950 *Ibid*.

Finally, the Compulsory Licensing Report recommended clarifying the interaction of the compulsory licensing provisions in the *Patents Act* with international treaty obligations. Section 136 of the *Patents Act* is a general provision requiring that a compulsory licensing order be consistent with international treaties. On a literal reading, the Report found Section 136 prevents a court from making an order inconsistent with an international treaty even when the treaty has not yet been incorporated into Australian legislation. In Australia, legislation is necessary to render international obligations enforceable in the courts, so Section 136 leaves the court in a position where they are supposed to enforce international obligations that are not domestic law.[951] The Compulsory Licensing Report recommended the approach of directly incorporating any relevant treaty obligations into the *Patents Act* compulsory licensing provisions.[952] Specifically incorporating the international obligations would remove ambiguity as to whether compulsory license issuance would be inconsistent with international agreements. The Report indicated another advantage to specifically incorporating the terms is that they would be "translated" into standard legislative language and more thoroughly scrutinized by the Australian Parliament. Australia has implemented other treaty obligations in this manner.[953] The downside of an increased cost of implementation is also acknowledged in the Report (including as treaty obligations change from time to time) but is thought to be outweighed by the certainty considerations.[954] Other portions of the *Patents Act* have been amended in the past to give effect to international treaties.[955]

(b) Other Consideration of Standard-Setting/FRAND Licensing

Our research found no cases brought by competition enforcement agencies or other guidance from competition agencies in the relevant period in Australia. As in many other jurisdictions, Australia has seen significant private litigation related to alleged patent infringement. In particular, there is a major ongoing dispute between Samsung Electronics Co. and Apple Inc. in which Apple claims Samsung breached FRAND obligations. The litigation involves mainly patent-related cases and is exceedingly complex.[956] With respect to competition law, Apple is arguing that by commencing proceedings for injunctive relief and making a non-FRAND licensing offer, Samsung misused market power in breach of Australian competition law.[957] This

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951 Compulsory Licensing Report, *supra* note 224 at 158.

952 *Ibid* at 16. Section 136 indicates simply that "An order must not be made under section 133 [the compulsory licensing section] or 134 that is inconsistent with a treaty between the Commonwealth and a foreign country." The international obligations were considered in the Compulsory Licensing Report to include the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights 1994, the Paris Convention for the Protection of Industrial Property 1883 and the Australia-United States Free Trade Agreement.

953 Compulsory Licensing Report, *supra* note 224 at 16.

954 *Ibid*.

955 *Ibid* at 159.

956 Joe Schneider, "Samsung Loses New Evidence Bid In Australia Apple Dispute", The Sydney Morning Herald (15 November 2013). online: <http://www.smh.com.au/it-pro/business-it/samsung-loses-new-evidence-bid-in-australia-apple-dispute-20131115-hv3fm.html>.

957 The proceedings began with claims that Samsung had infringed Apple patents. Samsung brought a countersuit of infringement of SEPs by Apple, which led to Apple claiming FRAND obligations had been breached. Private patent infringement litigation (without antitrust claims) was also brought in this case in several other jurisdictions including the U.K., Netherlands, France, Italy and Germany. There are several proceedings, but the FRAND and competition issues are being addressed in the case *Samsung Electronics Co Ltd & Anor v Apple Inc & Anor* (Federal Court of Australia, NSD315/2013), online: <https://www.comcourts.gov.au/file/Federal/P/NSD315/2013/actions>. The trial is scheduled to finish in April 2014 and the most recent decision related to permitting further evidence on the ongoing negotiation efforts by Apple to reach a royalty (*Samsung Electronics Co Limited v Apple Inc* [2013] FCA 1142). The overall

promises to be the leading case on FRAND issues in Australia in patent law, and will hopefully provide guidance on the competition law approach as well. The filings in this case have not been made public by the court and the decisions to date are interim only.

The literature addressing standard-setting/FRAND issues in Australia from a competition law perspective in the relevant period is limited. One of the few papers to address standard-setting/FRAND issues in Australian literature concludes that Section 46 of the *Australian Competition Act* is unlikely to be violated by either patent ambush or a refusal to license/licensing discrimination for FRAND-encumbered SEPs unless the refusal involves leveraging or exclusive dealing.[958] This seems somewhat inconsistent with the conclusion in the Compulsory Licensing Report that existing provisions in the *Australian Competition Act* provide sufficient protection against FRAND licensing abuse.

Using the U.S. *Rambus* case as an example, the authors conclude conduct involving non-disclosure of a patent by an entity before the patent is incorporated into a standard occurs prior to the point where that entity has market power, which makes it challenging to establish a violation under Section 46(1) of the *Australian Competition Act*. Section 46(1), unlike Section 2 of the *Sherman Act*, does not prohibit attempts to gain monopoly power, it only regulates conduct after monopoly power is held.[959]

Even if the firm extracts monopoly prices after acquiring monopoly power (through the inclusion of their patents in a standard), this conduct may not be sufficient to violate Section 46. Section 46(1) requires "taking advantage" of market power; the authors conclude that exploiting market power to charge maximum prices is not likely to constitute "taking advantage" without some additional form of exclusionary conduct.[960] The authors suggest more appropriate means of restraining such conduct might include Section 52 of the *Australian Competition Act* which could prohibit misleading and deceptive conduct where the patent holder remained silent in the face of a reasonable expectation of disclosure of patent interest, or the doctrine of estoppel.[961] Neither theory is explained further.

The authors also argue that a refusal to license or discriminatory licensing by a SEP holder would only give rise to a violation of the *Australian Competition Act* where the refusal involves leveraging of market power or exclusion of competitors.[962] Australia has established jurisprudence that Section 46 can be used as a *de facto* essential facilities doctrine to compel the owner of an essential facility to grant access, but the cases have involved physical infrastructure rather than intellectual property. One such case held in *obiter* that a refusal to license intellectual property rights could give rise to liability under Section 46(1) of the *Australian*

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proceedings, which have been ongoing since July 2011, are so complex that a second judge has been appointed to hear it, for the first time in Australian history. See an overview of the multiple proceedings Mark Summerfield, Patentology Blog, "What's Up Down Under With Apple and Samsung?", online: <http://blog.patentology.com.au/2013/11/whats-up-down-under-with-apple-and.html>.

958 See e.g. Kylie Pappalardo & Nicolas Suzor, "Standardisation and Patent Ambush: Potential Liability Under Australian Competition Law" (2011) 18 Competition & Consumer Law Journal 267 [Standardization and Patent Ambush].

959 *See Compulsory Licensing Report*, *supra* note 224 at 275.

960 Standardization and Patent Ambush, *supra* note 958 at 282.

961 *Ibid* at 8.

962 *Ibid*.

Competition Act.[963] A patent holder would have to use its monopoly power in one market (such as the market for technology the patent applies to) to influence another market (downstream markets for products or services requiring the standard) in order to contravene Section 46(1) of the *Australian Competition Act*. There must also be a causal connection between the refusal to license and the substantial market power (referred to as "taking advantage" of market power). Again, the authors suggest something more than merely charging high license fees would be required to satisfy this test. The example of a potential violation given is the *Broadcom* dispute in the U.S., where Qualcomm leveraged an existing monopoly over patents technology to gain an advantage in licensing other technology.[964]

As in some literature in the U.S. and EU, the authors argue that private contractual arrangements between SSOs and their participants are the best means of controlling abuse of standard-setting processes.[965] However, there is a perceived risk under Australian law that SSO policies would themselves violate the cartel provisions of the competition law, for example as an arrangement or understanding among competitors on the price to be charged for licensed technologies or assurance on the maximum price.[966] The result is that competition laws in Australia may be deterring conduct by SSOs which would otherwise play an important role in maintaining the competitiveness of standard-setting. The authors conclude that in order to promote competition in standard-setting, it is important for the ACCC to make clear that SSO policies regulating aspects of standard-setting licenses and promoting competition are permitted,[967] as the EU and U.S. have already done through guidance and speeches.

(c) Conclusion on Standard-Setting/FRAND Licensing in Australia

The level of concern over standard-setting/FRAND obligations from competition authorities and policy makers appears to be low in Australia. However, there is significant ongoing private patent litigation that will provide some guidance on whether seeking injunctions for FRAND-encumbered SEPs is a violation of the market abuse prohibitions in the *Australian Competition Act*.

The recent in-depth Australian Compulsory Licensing Report concluded that any concerns over abuse of standard-setting were adequately addressed by existing Australian competition law. The Compulsory Licensing Report found current competition and patent legislation was unlikely to be called upon often in Australia to resolve SEP disputes, because there are few industries associated with SEPs operating in Australia and Australian standards organizations tended to adopt standards set by global or regional SSOs.

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963 *NT Power Generation v Power & Water Authority* (2004) 219 CLR 90; 210 ALR 312; [2004] HCA 48; BC200406480 at [85].

964 Standardization and Patent Ambush, *supra* note 958 at 17. As the authors describe it, Qualcomm was discriminating among licensees of the essential (WCDMA) technology by charging higher fees to those who did not use Qualcomm's other (UMTS) chipsets, was demanding royalties on parts of UMTS chipsets for which Qualcomm did not own patents and was demanding that UMTS licensees grant back to Qualcomm licences for their own proprietary technologies on terms favourable to Qualcomm.

965 *Ibid*.

966 The authors argue the exception for IP licensing in Section 51(3) would not apply to such conduct because the agreement occurs before the licensing.

967 Standardization and Patent Ambush, *supra* note 958 at 290. The author points out that SSO members could also apply to the ACCC for an authorization of their agreement as provided by Section 88 of the *Australian Competition Act*.

The Compulsory Licensing Report made several other recommendations that were not specifically related to standard-setting/FRAND. It recommended that when a patent is used to engage in unlawful anti-competitive conduct, a compulsory license should be available under the *Australian Competition Act*, rather than under both the competition legislation and the patent legislation, as is currently the situation. This approach leaves the responsibility for remedying anti-competitive behaviour relating to patent access with the regime specifically designed for the task. The Compulsory Licensing Report also recommended a provision for compulsory licensing be retained in the *Patents Act* to allow conduct that does not violate competition laws to be addressed where doing so is in the public interest. Finally, the report recommended clarifying the interaction of the compulsory licensing provisions with international treaty obligations that are incorporated by reference into the *Patents Act*.

Although Australian literature is limited, one paper argues that the abuse of dominance provision in the *Australian Competition Act* is unlikely to be violated by either patent ambush or by a refusal to license/licensing discrimination for FRAND-encumbered SEPs, unless the refusal involves leveraging or exclusive dealing. It emphasizes the role of SSOs in controlling the abuse of standard-setting processes. To encourage regulation of anti-competitive conduct by SSOs, it recommends that agency guidance be provided to clarify permissible SSO conduct and to allay concerns that SSO regulation might in itself violate cartel provisions in the *Australian Competition Act*.

3. Reverse Payment Settlements

(a) Consideration by Courts and the Competition Agency

The legality of reverse payment settlements has not been addressed in Australian competition law jurisprudence or by competition agency guidance. Two reasons have been suggested for this: (i) there is no reporting requirement for reverse payments in Australia and so they have not been the subject of regulatory agency focus and (ii) Australian courts are more willing than the U.S. or EU courts to grant interlocutory injunctions in patent infringement cases, which place branded companies in a stronger position from the outset, making them less likely to settle.[968]

Australia has a regime for abbreviated generic drug approvals.[969] There is no automatic stay or exclusivity period. Although there is a damages provision comparable to that in Canada which enables recovery where an injunction improperly delays market entry of a generic, a recent IP Australia report on pharmaceutical patents (discussed further below) indicates it is not aware of any actions being pursued under that provision.[970]

We did not find any empirical studies of the predominance or the effect of reverse payment settlements in Australia. The closest Australian authorities appear to have come to considering the reverse payment issue is an IP Australia (patent agency) review of pharmaceutical patents,

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968 Lisa Huett, "Reverse Payment Settlements - Are Pay-For-Delay Agreements Anti-Competitive Or Is It The Free Market In Operation?" (20 April 2011) online: <http://www.mallesons.com/publications/marketAlerts/2011/Competition_Quarterly_Q1_2011/Pages/Reverse_payment_settlements_are_pay_for_delay_agreements_anti_competitive_or_is_it_the_free_market_in_operation.aspx> [Anti-Competitive or Free Market].

969 Commonwealth of Australia, IP Australia, *Pharmaceutical Patents Review* (May 2013) online: <http://www.ipaustralia.gov.au/about-us/ip-legislation-changes/review-pharmaceutical-patents/> [Pharma Patents Review Report].

970 *Ibid* at 171.

initiated in October 2012. Similar to the 2008 European Commission sector inquiry, the IP Australia review was initiated in response to concern over the ability of generic pharmaceuticals to enter the market and whether the system for pharmaceutical patents is effectively balancing the objectives of securing timely access to competitively priced pharmaceuticals, fostering innovation and supporting employment in research and industry. The report panel was instructed consider, among many other topics, (i) issues that impact competition in the pharmaceutical industry, for example, the ability of generic medicines to enter the market (ii) issues around fostering innovation and bringing new pharmaceuticals to market, (iii) whether there was evidence that the patent system was being used to extend pharmaceutical monopolies at the expense of new market entrants and (iv) patent-specific issues such as the effect of patent terms on innovation.[971]

A draft report was issued in April 2013 and the final in May 2013 (the "IP Australia Pharmaceutical Patents Report").[972] The IP Australia Pharmaceutical Patents Report's recommendations focus on patent law rather than competition law, but it leans toward enabling generic manufacturers to bring products to market more easily, which would help to foster competition in Australian pharmaceutical markets.[973] The IP Australia Pharmaceutical Patents Report found that generic pharmaceuticals are an important element of the pharmaceutical industry. The prospect of competition from generic medicines was found to encourage further innovation by branded companies to maintain their market position.[974]

The IP Australia Pharmaceutical Patents Report suggests there are low incentives for generic manufacturers in Australia to challenge patents, because Australia is a small market, there is no exclusivity period for the first generic (as in the U.S.), and once the patent is successfully challenged, the market is open to every generic who wishes to compete – not just the generic who bore the cost of the legal challenge.[975] As the Report frames the issue, the challenging generic bears the costs of the infringement litigation which may result in the finding the patent is invalid (i.e. of correcting the IP Australia decision to issue the patent). Despite this, the challenging generic is not the sole recipient of the reward of market access, and public health coffers are likely to internalize most of the benefits of a successful challenge. The Report argues that in Australia, as compared to other jurisdictions, there may be an even stronger argument for providing incentives for generic challenges because the inherent market returns available to a generic manufacturer following a successful patent challenge are substantially less than in the U.S.[976] The Report thus recommends greater incentives for competitors to challenge potentially

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971 Commonwealth of Australia, IP Australia, *Summary: Review of Pharmaceutical Patents in Australia* (15 October 2012) online: <http://www.ipaustralia.gov.au/about-us/ip-legislation-changes/review-pharmaceutical-patents/>; Michael Caine, "Australian Government Announces A Pharmaceutical Patent Review" Memorandum of Davies Collision Cave Intellectual Property (29 October 2012), online: <http://www.davies.com.au/pub/detail/656/australian-government-announces-a-pharmaceutical-patent-review> quoting Secretary for Industry and Innovation, Mark Dreyfus, on concerns leading to the report.

972 Pharma Patents Review Report, *supra* note 969.

973 Sue Rutledge & Denis Tuffery, "Summary of the Australian Pharmaceuticals Patents Review" Memorandum of AJ Park (17 April 2013) online: <http://www.lexology.com/library/detail.aspx?g=6896171d-54d0-4688-a244-2f173b434dd9>. The recommendations include reducing the length of patent term extensions, introducing patent linkage, making manufacture for export a non-infringing act, permitting the government to claim for losses incurred where a patent covering a listed medicine is found invalid, and rejecting the idea of lengthening the term of data protection.

974 Pharma Patents Review Report, *supra* note 969.

975 *Ibid* at 134.

976 *Ibid*. The comparison to the U.S. is made in the draft report at 157.

invalid patents,[977] and refers to the incentive offered by the U.S. exclusivity period. Reverse payment settlements are not expressly addressed in the Report.

(b) Commentary on Reverse Payment Settlements

Articles suggest variously that reverse payment settlements would likely violate the prohibitions on anti-competitive agreements (Section 45)[978], and possibly the misuse of market power provisions (Section 46) of the *Australian Competition Act*. One author also mentions the potential to violate the cartel provisions as an agreement with the purpose of restricting output (Division 1 of Part IV), but does not address this in-depth.[979]

In an article predating the major decisions on reverse payments in the U.S. and EU, Huett and Walsh explain it is possible that reverse payment settlements could violate Section 46 of the *Australian Competition Act*,[980] which is similar to Canada's abuse of dominance prohibition. The challenging aspect would be to distinguish between whether the branded company is merely exercising its proprietary rights or if it is taking advantage of its market power derived from its patent, the latter of which is required to establish a Section 46 violation. The author suggests comparing whether the terms of the reverse payment are inconsistent with terms that a patent owner without market power could have obtained in an otherwise competitive market. However, this would seem to involve a challenging hypothetical analysis.

The authors suggest reverse payment settlements would also likely violate the Section 45 prohibition on making or giving effect to an exclusionary provision in a contract, arrangement or understanding, which does not require any anti-competitive effect.[981] The difficult issue is that there must be an anti-competitive purpose to the conduct in order to violate Section 45. Courts might infer the settlement had the purpose of restricting supply of a drug, but the authors argue this raises the question of whether Australian courts would consider protection of a patent monopoly to be the predominant, legitimate purpose.[982]

A Section 45 action would also raise the issue of whether the exception for licenses and assignments of patents under the *Australian Competition Act* (Section 51(3)) applies. The exception applies to conditions of license or assignment granted by patent owner/applicant that "relate to" the patent invention. As discussed above, the scope of this exception is considered unclear. The lone older case assessing this provision explains that it operates "by excepting things authorized by the Patents Act" and does not apply to "conditions which seek to gain advantage collateral to the patent".[983] This suggest an approach similar to the scope of patent analysis that was recently rejected by the Supreme Court of the U.S. in *Actavis*. The authors focus instead on the "licensing or assignment" of patents as the basic requisite for the Section 51(3) exception to apply, concluding payments to compensate a generic for lost sales are not covered by the exception and so would likely violate the *Australian Competition Act*. They suggest alternative settlement arrangements that involve granting a license to the generic to sell

977 *Ibid* at Recommendation 7.1 and see also Draft Recommendation 8.1.

978 *Ibid*, s 45 (anti-competitive agreements) and Division 1 of Part IV (prohibiting cartels).

979 Anti-Competitive or Free Market, *supra* note 968.

980 Lisa Huett and James Walsh, "Splitting the Pharmaceutical Pie", (2007) 167 Managing Intell. Prop. 41.

981 *Ibid*.

982 *Ibid.*

983 *Transfield Pty Ltd v Arlo International* (1980) 30 ALR 201.

the product before the expiry of the patent might increase the likelihood of the exception applying and thus of reverse payment settlements being permitted under Section 45.

(c) Conclusion on Reverse Payment Settlements in Australia

The legality of reverse payment settlements has not been addressed in Australian competition law jurisprudence, or by competition agency guidance. We did not find any empirical studies of the predominance or the effect of reverse payment settlements in Australia. Commentators suggest variously that such settlements may not be occurring because of differences in incentives to settle, or they may simply not be coming to the attention of the Australian competition agency.

Despite the lack of competition law attention to reverse payment settlements in Australia, there are shared concerns with other major jurisdictions over the ability of generic pharmaceuticals to enter the market, and whether the system for pharmaceutical patents is effectively balancing the objectives of securing timely access to competitively priced pharmaceuticals and fostering innovation. These concerns led to a significant review of pharmaceutical patent-related issues and a resulting draft report in April 2013 and final in May 2013, which focuses on recommendations from a patent law perspective. It suggests current incentives for generic manufacturers in Australia to challenge patents are low. It indicates that since the inherent market rewards are lesser in Australia, greater incentives for competitors to challenge potentially invalid patents may be required.

Commentators suggest in older articles that reverse payment settlements may violate Australia's prohibition on misuse of market power or prohibitions on anti-competitive agreements, although each would present different challenges. The analysis predates recent major decisions in the U.S. and EU that would likely be influential in the Australian analytical approach.

4. Patent Assertion Entity Conduct

Patent assertion entities are not addressed in Australian cases or literature to any great extent. As of November 2013, however, some PAE litigation related to mobile communications systems had been identified in the Australian Federal Court.[984] Cases have been brought in the United Kingdom, Germany and France involving the same PAE and target.[985] The PAE arrangement appears to be of the "privateering" variety – the patents were previously owned by Nokia and Nokia will reportedly receive a 35% share of all licensing income after the initial purchase price is recouped by the PAE. One article suggests the strategic reason for bringing the litigation in Australia (along with other jurisdictions) is not to obtain an injunction or damages in Australia, but rather to prompt a global licensing agreement with the target of the litigation.

Although there is little written in Australia regarding PAEs, we note that the Australian *Patents Act* contains a unique provision that addresses the primary conduct of such entities. Section 128 of the *Patents Act* enables a person to obtain relief from the prescribed court (or any other

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984 Summerfield, *supra* note 905 reporting that Vringo Infrastructure Inc., which some characterize as a PAE, has commenced litigation in Australia (as well as in the) against Chinese telecommunications equipment manufacturer ZTE Corporation.

985 *Ibid*.

having jurisdiction) from unjustified threats of patent infringement proceedings.[986] Relief available includes a declaration that the threats are unjustifiable, an injunction against the continuance of the threats and recovery of any damages resulting from the threats. The right of application is available regardless of whether the person who made the threats is entitled to (or interested in) the patent or patent application. The standard for assessing whether a threat was made is that a reasonable person would understand that the person making the threat intends to bring infringement proceedings.[987] The person who made the threats bears the burden of proving that it was justified.[988] They may do so by, for example, showing that the acts in question infringed or would infringe a claim that the applicant has not shown to be invalid.

In a recent case involving Section 128, the Australian Federal Court of Appeal held that the threats were unjustified because the patents were invalid. The threatening party was also the subject of an injunction issued against it preventing threats of infringement and was ordered to pay costs. The use of Section 128 therefore hinges on considerations of patent validity or invalidity (not surprising given it appears in the *Patents Act*), without any consideration of the impact on competition of the unjustified threats. The increased risk of such threats would appear to increase the likelihood that a party will be careful in its assessment of the validity of its patent and the alleged infringement. We understand from informal discussions with those experienced in Australian patent litigation proceedings that Section 128 is often merely included in the context of infringement proceedings, with little particular consequence or importance to the infringement case.

(a) Conclusion on Patent Assertion Entities in Australia

Patent assertion entities have not been addressed in Australian cases or literature, but there is some anecdotal evidence of recent PAE litigation in the Australian Federal Court.

Like the U.K., the Australian *Patents Act* contains a provision that enables a person to obtain relief from the court from unjustified threats of patent infringement proceedings, including an injunction against the continuance of the threats and recovery of any damages resulting from the threats. The provision is rooted in patent law and does not take into account any impact on competition arising from unjustified threats.

5. Product Hopping

In February 2014, ACCC announced its first-ever product hopping case, against Pfizer Australia.[989] Pfizer offered to sell an "authorized generic" of its own patented drug (Lipitor) for significant discounts and the payment of rebates previously accrued if pharmacies acquired a minimum of 12 months' supply of the authorized generic. This alleged conduct occurred in early

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986 Or see Section. 129, 59 for a similar provision regarding innovation patents. Threats made with respect to an innovation patent application that has not been determined, or with respect to an uncertified innovation patent are always unjustifiable.

987 However lawyers are not liable for unjustified threats made in their professional capacity on behalf of a client. *HVE Electric Ltd v Cufflin Holdings Ltd,* [1964] RPC 149 at 158.

988 Davison et al., *supra* note 228.

989 Commonwealth of Australia, Australian Competition and Consumer Commission, Press Release, "ACCC Takes Action Against Pfizer Australia for Alleged Anti-Competitive Conduct" (13 February 2014) online: http://www.accc.gov.au/media-release/accc-takes-action-against-pfizer-australia-for-alleged-anti-competitive-conduct. The filings in the case before the Australian Federal Court were not publicly available at the time of writing (Case NSD146/2014 in New South Wales registry).

2012, with the loss of patent protection on the branded Lipitor looming as of May 2012. The ACCC alleges the offers were made prior to the patent expiry, when other suppliers of generic medicines were prevented from making competing offers to supply a generic version of the drug to pharmacies. The allegations thus appear to hinge on a variation of product hopping, where the "hop" is to an authorized generic and there is no apparent withdrawal of the older branded product from the market. The recency of the case and lack of details to date make it too early for comparison to product hopping cases in other jurisdictions.

The ACCC alleges that Pfizer's conduct constitutes anti-competitive conduct under the misuse of market power and exclusive dealing provisions of the *Australian Competition Act*. The head of the ACCC commented that "[t]his case also raises an important public interest issue regarding the conduct of a patent holder nearing the expiry of that patent and what constitutes permissible competitive conduct".[990] The Australian Minister for Small Business commented on the Pfizer case, drawing a connection to the ongoing review of Australian competition law and its consideration of whether the misuse of market power provision is failing to "liv[e] up to the expectations that the law makers had at the time of its introduction".[991]

The IP Australia Pharmaceutical Patents Report also discusses product hopping (referred to as "prescription switching" in the report), which commentators to the report identified as one of the most common and concerning "evergreening" strategies used to extend both the breadth and duration of patent rights. [992] Like other jurisdictions, the Report acknowledges the key concern over such strategies is that they delay the entry of generic drugs to the market, with potentially significant public health costs.[993]

The Report observes that follow-on (secondary) patents generally cover variations of the original active ingredient, and may cover new formulations, derivatives, delivery systems, methods of use and methods of production.[994] It explains that since follow-on patents have a later expiry date than the original patent, these patents may extend the duration of the patent protection awarded to a single pharmaceutical product. Multiple overlapping patents can contribute to a "patent thicket", which "can be effective in obstructing the entry of competitors into the market by reducing and rendering uncertain the space in which they may operate."[995]

The Report characterized views on such practices as "polarised".[996] Some commentators in the review thought branded companies were gaming the patent system to prolong patent protection and delay market entry of generic drugs, increasing costs to public health agencies. Others characterized the behaviour as legitimate maintenance of a patent portfolio, an essential element of the business strategy of any company operating within the IP system.

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990 *Ibid.*

991 The Honorable Bruce Billson, MP, Minister for Small Business, "Government to Keep a Close Eye on Misuse of Market Power Case" (13 February 2014) online: <http://bfb.ministers.treasury.gov.au/media-release/004-2014/>.

992 Pharma Patents Review Report, *supra* note 969..

993 *Ibid*.

994 *Ibid*.

995 *Ibid*.

996 *Ibid* at 178.

The IP Australia Pharmaceutical Patents Report concludes that conduct such as product hopping by branded pharmaceutical companies is to be expected in the high-risk, high-return pharmaceuticals industry. [997] The conduct is legitimately "within the confines of the various legal and regulatory systems in place in Australia (and indeed, the international community)", explaining that "[i]t is inefficiencies within these systems that permit the behaviours … rather than addressing behaviours of the companies working within this system, it would be more effective to address the inefficiencies within the system that permit these behaviours."[998] Patentability standards and other patent law considerations are identified as essential to controlling any undesirable but currently permitted behaviour.[999] Competition law is not referenced, but this may have been outside of the mandate of the patent-law focused report.

Although commentary on product hopping in the Australian context was very limited, one author suggests product hopping could constitute a misuse of market power under Section 46 of the *Australian Competition Act*.[1000] The challenge would be proving that the product hopping was a use of market power, and engaged in for the purpose of deterring competitors.[1001]

(a) Conclusion on Product Hopping in Australia

Product hopping has only very recently become the subject of a case in Australia. A recent report from the patent-law perspective acknowledges the behavior and suggests that patent regulatory change should be used to address any inefficiencies that may arise from product hopping. Commentary on product hopping in the Australian context was limited but suggests product hopping could conceivably constitute a misuse of market power.

997 *Ibid* at 140.

998 *Ibid*.

999 *Ibid*.

1000 Louise Beange, "In The Blue Corner… FTC Comes Out Swinging On Product-Switching" (24 January 2013) online: <http://www.incompetition.com.au/2013/01/in-the-blue-corner-ftc-comes-out-swinging-on-product-switching/>.

1001 *Ibid.*

X. CANADA

1. Standard-Setting and FRAND Licensing Commitments

Canada has not seen any recent competition cases, enforcement or guidance addressing standard-setting and patents or FRAND licensing commitments.

Guidance on standard-setting issues from the Bureau is limited. The IPEGs identify, as an example of where Section 32 might apply, the situation of a network industry where intellectual property rights and network externalities create *de facto* industry standards.[1002] The Bureau considers that the combination of intellectual property protection and substantial positive effects associated with the size of the network could create or entrench substantial market dominance. Access to the standard technology covered by intellectual property would be required in order for competition to occur. The Bureau would also require that the refusal to license be "stifling further innovation and not simply preventing the replication of existing products" before it would recommend that the Attorney General bring an application for a special remedy to the Federal Court. The Bureau also addresses industry standard-setting briefly in the *Competitor Collaboration Guidelines*, which indicate that an agreement among competitors to implement a new industry standard is not considered "alone" to be an agreement to fix or increase prices. The guidelines acknowledge such agreements might be protected by the ancillary restraints defence.[1003]

The 2006 IP and Competition Report recommended developing the guidance on when competition concerns could arise from standard-setting activities.[1004] This recommendation does not appear to have been pursued.

(a) Conclusion on Standard-Setting/FRAND Licensing in Canada

Canada has limited guidance and no major cases that assess issues related to standard-setting and patents or that address the breach of FRAND licensing commitments. It is unclear how significant the standard-setting concerns addressed in other jurisdictions are within Canada.

It is possible that standard-setting and related licensing are largely occurring outside of Canada and/or international enforcement efforts are sufficient to address potential impacts within Canada, and further that Canadian competition legislation is sufficient to address domestic concerns. This has essentially been the Australian position. The Australian Compulsory Licensing Report concluded that factual differences in the Australian position with respect to standard-setting largely eliminated competition law concerns, and that existing *Australian Competition Act* misuse of market power and *Patents Act* provisions were sufficient to protect against misuse of market power involving a failure to comply with FRAND commitments for standard-essential patents. At least one significant patent law dispute is now raising questions over whether the breach of FRAND commitments constitutes a violation of Australian competition law prohibitions on abuse of market power, casting doubt on the Australian position that such disputes have little relevance to the jurisdiction.

1002 IPEGs, *supra* note 13 at 9.

1003 *Competitor Collaboration Guidelines*, *supra* note 41 at 10.

1004 2006 IP and Competition Report, *supra* note 18 at 15.

Further, the conclusions on sufficiency of competition legislation in Australia may not be entirely applicable in Canada. Although Canadian competition law prohibits abuse of dominance in a manner similar to the *Australian Competition Act*, the abuse of dominance provision in the Canadian *Act* exempts conduct engaged in "only" pursuant to intellectual property statutes, while the Australian provision has no equivalent exception. In fact, the Australian position is nearly the reverse; the abuse of dominance equivalent provision in Australia is specifically not included in an exemption that otherwise shelters some licensing and assignments of patents from competition law scrutiny.

An empirical study on the extent to which private standard-setting involving intellectual property is occurring in Canada and whether anti-competitive concerns exist over related licensing conduct in Canada could clarify whether Canadian competition authorities (and courts) should be concerned over standard-setting issues.

Canada also has limited agency guidance on the competition law approach to standard-setting and related licensing. The benefits to providing guidance that are discussed in other jurisdictions include: promoting standard-setting and associated benefits, discouraging the abuse of standard-setting processes, encouraging SSOs to play an active role in imposing policies that reduce such abuse and reducing complex standard-setting competition issues that arise after standard adoption. In particular, the EC experienced challenges in attempting to address, after standards had been widely adopted, complex questions of whether conduct in standard-setting violated competition laws. This led to the EC approach of providing much more detailed guidance up front, in an effort to reduce later difficult-to-address issues. Similar benefits may also apply here, although some benefits depend on whether standard-setting is occurring in Canada.

The Canadian competition law approach to an abuse of standard-setting processes or reneging on FRAND licensing commitments would likely be closer to that of the EC than the U.S., because the provisions under which U.S. enforcers have pursued cases have no exact equivalents in Canada. *Rambus* and other cases U.S. antitrust enforcers have brought with respect to abuse in the standard-setting process have tended to involve allegations of the illegal acquisition of monopoly power through deception. The mere acquisition of a monopoly is not a competition law violation in Canada. The FTC has pursued FRAND-encumbered SEPs injunction cases as unfair methods of competition in violation of Section 5 of the FTC Act; there is no direct equivalent in Canada to this provision. The EC framed its case involving Rambus as an alleged violation of Article 102, based on the company charging unreasonable royalties for its patents after it had obtained market power. Similarly, the EC has framed its ongoing cases over the seeking of injunctions in member states for FRAND-encumbered SEPs as abuses of dominance. The legal approach in Canada would thus likely be closer to that of the EC, although differences in the law of abuse of dominance between Canada and the EU, such as the existence of Section 79(5) in the *Act*, would likely make the case more challenging for authorities to bring in Canada.

Notwithstanding differences in the legal approach, the underlying concern from both EU and U.S. competition authorities over potential harm arising from patent hold-up would appear to apply equally to Canada, to the extent similar conduct is occurring here.

2. Reverse Payment Settlements

As in other jurisdictions, the pharmaceutical industry is very significant to Canada; approximately $33 billion in 2012 health expenditures in Canada were on pharmaceuticals, and

the industry employed about 27,000 people in 2012.[1005] As the Bureau recently observed, "generic drugs make an important contribution to controlling rising drug costs by offering lower priced therapeutically equivalent alternatives".[1006] Impacts on competition in the pharmaceutical industry in Canada could thus have serious impacts on Canadian government health spending.

Like the regulatory regime set out in *Hatch-Waxman* in the U.S. (explained further in the U.S. section on reverse payment settlements, above), Canada has established an abbreviated application system for generic drugs in the *Patented Medicines (Notice of Compliance) Regulations*, (the "*Regulations*")[1007] under the *Patent Act*. The Canadian regime under the *Regulations* was modelled on *Hatch-Waxman*, and so at a high level the two are similar. [1008] Both involve a generic company filing an application for approval of market entry with regulatory authorities based on certain grounds (such as patent expiry, the patent being invalid, or the patent not being infringed by the proposed generic entry). The branded company is notified, and then has a certain period within which to commence a patent infringement action against the generic (in the U.S.) or to apply for judicial review to prohibit the issuance of the generic approval (in Canada, referred to as a Notice of Complaince or "NOC" proceeding). Once such an action is commenced in the U.S., there is a stay of a certain period during which the generic application will not be approved, unless during that stay a court determines the patent is invalid or not infringed. There is a similar stay period in Canada that prevents the Minister of Health from issuing its approval of the generic market entry until the court detemines that the allegations in the application for generic approval (invalidity and/or non-infringement) are justified, or the related patents expire. If the branded company wins the NOC proceeding, the Minister of Health is prohibited from issuing the approval to the generic applicant until the patent expires. If the generic manufacturer wins the proceeding, then, provided that the generic's drug submission has otherwise been approved by the Minister, an approval will be issued permitting the generic to enter the market.

We did not find any empirical studies on the extent to which branded and generic pharmaceutical companies are engaging in reverse payment settlements, either within or otherwise affecting Canada. One author calculates at a more general level that between 1998-2008, of 447 Federal Court NOC proceedings commenced (usually by branded companies) to block the issuance of a patented medicine Notice of Compliance (usually to a generic company), 219 or 49% were discontinued, meaning the proceedings were voluntarily ended by

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1005 Canada, Industry Canada Life Sciences Industries, Pharmaceutical Industry Profile, (2012) online: <https://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html#trade>.

1006 Canada, Competition Bureau, Position Statement, Competition Bureau Statement Regarding the Inquiry into Alleged Anti-Competitive Conduct by Alcon Canada Inc. (May 13, 2014) online at: http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03686.html [Alcon Position Statement].

1007 SOR/93-133. The *Regulations* replaced Canada's prior compulsory licensing system where the innovators were compelled to issue manufacturing licenses to generic manufacturers in Canada. The change was in response to compatibility concerns of the compulsory license regime given then-new TRIPs and NAFTA obligations. *Apotex Inc v Abbott Laboratories Ltd*, 2013 ONSC 356 [*Apotex*].

1008 For a more in-depth discussion of the U.S. and Canadian processes, see Ron Dimock & Geoff Mowatt, "Reverse Payment Settlements in Pharmaceutical Litigation: What Are They and Do They Occur in Canada?" (2009) [Reverse Payment Settlements in Canada].

the applicant.[1009] This does not, however, give any indication of whether a case necessarily ended in a settlement, or if the terms of any settlement might raise competition concerns.

(a) Consideration by Canadian Courts and the Bureau

There have been no competition law cases and there is no specific guidance from the Bureau addressing the permissability of reverse payment settlements in Canadian competition law.

Although not specific to reverse payment settlements, the Bureau has conducted two studies on the Canadian generic drug sector.[1010] The first, in 2007, was prompted by other studies that found prescription generic drugs were more expensive in Canada than in other countries.[1011] The 2007 study was based on public information, data from research firms and voluntary information provided by the industry. The study acknowledged the central importance of pharmaceuticals as the second highest source of health-care costs in Canada.[1012] It concluded there was strong competition in the supply of generic drugs in Canada, with the end of patent protection leading to the entry of multiple generic competitors within a short period of time.[1013] However, the study also found that the lower prices on pharmaceutical drugs achieved as a result of generic entry were not being passed on to end payers, being mainly public or private health plans. [1014] The report suggested that the design of public drug plans in Canada provided little incentives for pharmacists and manufacturers to compete to meet the needs of drug plans through lower prices.[1015] A follow-up report by the Bureau in 2008 suggested specific ways in which public and private drug plan providers could obtain the benefits of competitive generic drug prices.[1016]

The Bureau also recently held a workshop on competition issues in the pharmaceutical sector that included sessions on reverse payment settlements.[1017] Speakers and participants included international and Canadian lawyers and government agency representatives. Holding such events can be an important means of building institutional knowledge on the complex issues raised by competition and patent law regimes, in this case in the pharmaceutical context. The workshop was invitation-only and the materials were not made public.

1009 Joel Lexchin, “Canada’s Patented Medicine Notice of Compliance Regulations: Balancing the Scales or Tipping Them?” BMC Health Serv Res 2011 11:64 (24 March 2011) online: <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3073891/>.

1010 Canada, Competition Bureau, *Canadian Generic Drug Sector Study* (October 2007) online: <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng%20/02495.html> [Generic Drug Sector Study]; Canada, Competition Bureau, *Benefiting from the Generic Drug Competition in Canada: The Way Forward* (2008) online: <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/GenDrugStudy-Report-081125-fin-e.pdf/$FILE/GenDrugStudy-Report-081125-fin-e.pdf> [Benefiting from the Generic Drug Competition in Canada].

1011 Generic Drug Sector Study, *ibid* at 3.

1012 *Ibid*.

1013 *Ibid*.

1014 *Ibid*.

1015 *Ibid*.

1016 Benefitting from the Generic Drug Competition in Canada, *supra* note 1010.

1017 Agenda, Competition Bureau Workshop on Antitrust Issues in the Pharmaceutical Sector (Ottawa, November 13, 2013), as provided to the authors. Other sessions addressed international perspectives on antitrust in pharmaceuticals and life-cycle management strategies.

Although reverse payment settlements were not involved, in 2004 the Bureau conducted an inquiry into conduct that involved alleged misuse of Canada's *Regulations* by brand name pharmaceutical companies. In response to a complaint from a public employee union and health-care advocates, the Bureau looked at the practice of adding follow-on patents to the patent list for a given medicine after the generic company had filed for approval in relation to the first patent. Under the *Regulations* at the time, multiple stays of generic approvals could be obtained for each patent, with the effect of delaying entry of generic drugs beyond the patent protection period of the first-filed patent. The conduct was referred to by the Bureau as "evergreening", although this term tends to be used broadly for any conduct involving perceived patent extension.

The Bureau concluded the *Act* was not the appropriate means for resolving what amounted to "a patent dispute between two firms",[1018] given the ability to challenge the conduct under the *Regulations*, or in the courts. However, in a signal to policy makers, the Bureau indicated "[f]rom a competition policy perspective in particular, the Government may wish to review the current rules to ensure that an appropriate balance is maintained between protecting intellectual property rights and facilitating a competitive supply of pharmaceutical products for Canadian consumers".[1019] The Bureau noted there was no mechanism for compensating consumers affected by delays in the introduction of generic drugs "thereby creating a possible incentive for brand-name pharmaceutical companies to strategically use the NOC Regulations to improperly delay generic drug entry".[1020]

The specific concern over multiple stays under the *Regulations* was addressed by amendments to the *Regulation*s in 2006 which prevented multiple stays for patents filed after the generic's initial application for approval. This followed similar amendments in 2003 to *Hatch-Waxman* in response to similar concerns raised by the FTC over the effect on competition of multiple stays.[1021]

(b) Literature

Recent literature on reverse payment settlements in Canada is limited and tends to focus on differences between the U.S. and Canadian abbreviated regulatory processes through which generic versions of drugs can obtain regulatory approval for market entry.[1022] Several articles argue differences between the U.S. regime and the Canadian *Regulations* have a significant impact on the incentives to engage in reverse payments in Canada,[1023] with a focus on four main areas of difference.

1018 This was despite the six-resident complaint having come from the National Union of Public and General Employees and other public interest organizations. Competition Bureau, Press Release, Competition Bureau Responds to Complaint Over Alleged Misuse of Canada's Drug Patent Rules (27 February 2004).

1019 *Ibid*.

1020 Canada, Competition Bureau, Press Release, "Competition Bureau Responds to Complaint Over Alleged Misuse of Canada's Drug Patent Rules" (27 February 2004) [Bureau Press Release on Misuse of *Regulations*].

1021 Generic Drug Entry, *supra* note 104.

1022 And older articles such as Edward Hore, "Patently Absurd: Evergreening Of Pharmaceutical Patent Protection Under The Patented Medicines" (Notice of Compliance) Regulations of Canada's *Patent Act* online: <www.canadiangenerics.ca/en/news/docs/patently_absurd_04.pdf> focus on conduct under the *Regulations* that, in some cases, is no longer possible due to amendments to the *Regulations*.

1023 *Ibid* at 15.

First, *Hatch-Waxman* grants exclusivity to the first generic to challenge the branded drug patent, for a 180 day period after its application is approved (or an agreement is reached with the patent owner). This exclusivity period was intended to increase the incentives for generic research and development and to increase the speed of entry of generics into the market. The Canadian regime does not offer an exclusivity period.[1024]

Second, upon the application by the generic for approval, the U.S. regime allows an infringement action on the merits. The Canadian regime allows only for an application to prohibit the Minister of Health from issuing approval for the specific generic applicant and judicial review of whether the allegations that form the basis of the generic's application for approval are justified or not. This means a generic could still be sued for patent infringement by the branded company after it obtains regulatory approval to enter the Canadian market. In some cases, infringement has later been found, even where the generic was granted regulatory approval.[1025] Canadian generic launches are thus labelled as "at risk" where it is uncertain if a subsequent infringement action will occur. It also means that the Canadian court ruling does not govern subsequent generic applicants. In the U.S., the entire validity of the patent is at issue in the *Hatch-Waxman* regulatory proceeding. If the proceeding is lost by the branded company (i.e. its patent is invalidated) all generics are then theoretically able to enter the market, not just the generic involved in the proceeding.

Third, the length of the stay in the U.S. on regulatory approval of the generic where a branded company alleges infringement is six months longer than the period of the stay where an application for judicial review is commenced in Canada. The Canadian stay is 24 months in length.

Finally, the difference that garners the most attention is Section 8 of the Canadian *Regulations*, which provide for damages for delayed market entry where an application to prohibit Ministerial approval of a drug is withdrawn, discontinued or dismissed by the court (or reversed on appeal). Section 8 enables generic drug manufacturers to recover damages from the branded company for the period of time from which the approval for the generic would have been issued by the Minister of Health (had the branded company not challenged the generic company's application for regulatory approval) up until the date of one of these outcomes. It provides a remedy to drug manufacturers who are precluded from accessing the marketplace to sell their (usually generic) products on a timely basis, owing to their inability to obtain regulatory approval due to operation of the mandatory two year stay. Essentially, the provision is intended to create a disincentive to improper use of the *Regulations* by branded companies.[1026] There is no equivalent provision under the U.S. system.

The cumulative effect of these differences is thought by some commentators to create a much greater incentive in the U.S. for the branded manufacturer to reach a settlement with the first generic. There are "higher stakes" such as invalidation of the patent and the 180 day exclusivity period at play in the U.S. compared to Canada. If the branded company reaches a reverse payment settlement in a case it would otherwise have lost, it can "buy" an additional 180 days of exclusivity from the generic company. The absence of the exclusivity period and potential

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1024 *Ibid* at 1.

1025 Tim Gilbert, "A Litigator's Guide to Drug Patent Settlements in Canada" (13 November 2013) [Litigator's Guide to Drug Patent Settlements].

1026 *Ibid*.

invalidation of the patent in the Canadian context may mean there are lesser incentives compelling branded companies to settle litigation in Canada.

Dimock and Mowatt argue the differences discussed above create a greater incentive to settle in the U.S., but that there remain incentives in Canada for reverse payment settlements.[1027] For example, the Federal Court of Appeal has ruled that branded companies will not be permitted to defend against allegations under the *Regulations* by subsequent generics companies after the same allegation made by an earlier generic company is found to be justified.[1028] This means where a branded company is unsuccessful in fending off the first generic's invalidity allegation, subsequent proceedings brought by other generics alleging the same grounds will also be dismissed, leading to the likely entry of several generics in the market. The branded company would then be left having to bring separate infringement actions against each generic to defend its patent.[1029]

(i) Commentary on the Relevance of *Actavis* to Canada

More recent commentary, although also limited, considers the applicability of the reasoning in the U.S. Supreme Court *Actavis* decision to the Canadian context.

One article questions whether supra-competitive profits earned by branded companies during the term of an invalid patent (which *Actavis* noted could have potentially adverse effects on competition) are even a concern in Canada where drugs are subject to pricing restrictions under the Canadian patented medicines regulatory scheme and provincial government formularies.[1030]

The absence of an exclusivity period may also mean a lower value of settlement might be expected to be reached here, even leaving aside factors such as the smaller Canadian market. The recent *Actavis* decision pegged the value of the 180 day exclusivity period at potentially several hundred million dollars, although this would vary with the drug involved. The U.S. Supreme Court's analysis of the size of settlement as a proxy for the patent's weakness and indicative of potential antitrust harm might still apply in Canada, but the magnitude of permissible settlements (an issue that has yet to be determined post-*Actavis*) would have to take into account the lack of exclusivity period in Canada.

Another author considers the availability of Section 8 damages to be a key feature in the inapplicability of *Actavis* in the Canadian context.[1031] The U.S. Supreme Court in *Actavis* reasoned that reverse payment settlements are concerning from a competition perspective in part because the defendant generic receives a payment despite having no claim for damages (in contrast to more traditional settlements where avoiding damages may be a legitimate justification for settling). In contrast, the Canadian system provides for damages under Section 8 of the *Regulations*, such that the branded company risks liability to the generic for losses

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1027 Reverse Payment Settlements in Canada, *supra* note 1008 at 16.

1028 *Ibid* at 16, referring to *Sanofi-Aventis Canada Inc v Novopharm Ltd*, 2007 FCA 163 at para 50.

1029 *Ibid*.

1030 Navin Joneja, David Rosner, & Joshua Krane, "Canadian Perspectives on Competition Law and Reverse Payments Following FTC v. Actavis" (2013) CPI Antitrust Chronicle September 2 at 5 [Joneja et al].

1031 William Vanveen, "Competition Issues in the Pharmaceutical Industry" (Remarks given at the Canadian Competition Bureau Workshop on Antitrust Issues in the Pharmaceutical Sector, 3 October 2013) at 11 [Competition in the Pharma Industry].

caused as a result of delay in regulatory approval.[1032] The risk of such damages may mean there is a greater legitimate incentive to settle, based on "traditional" settlement rationale of avoiding damages in the Canadian context.[1033] Reverse payment settlements in Canada may just reflect anticipated Section 8 damages, rather than being a proxy for the branded company's perception of its patent strength as suggested in *Actavis*.

Although the availability of Section 8 damages in the Canadian context may mean there are more compelling justification for settlement, the availability of such damages does not mean the broader logic in *Actavis* on when reverse payment settlements are potentially anti-competitive is inapplicable to Canada. Economic models in support of the *Actavis* reasoning suggest that whenever the reverse payment settlement exceeds the patent holder's prospective litigation costs plus the value to the patent holder of any other goods and services provided by the allegedly infringing firm, the settlement likely diminishes the expected period of competition and harms consumers.[1034] The same logic seems generally applicable to Canada in parsing which reverse payment settlements might be of concern, but prospective costs would include potential Section 8 damages. The availability of damages may change the incentives and justifications for settlements in Canada, but it does not eliminate the potential for anti-competitive payments to occur. The arguments regarding Section 8 damages also assume only the regulatory process within Canada is relevant; agreements struck outside of Canada could theoretically also lead to delayed introduction of generic drugs within Canada.

Whether and how a reverse payment settlement is likely to be successfully challenged in Canadian competition law is a separate issue. Multiple articles suggest it would be difficult to establish a violation of Section 45 (criminal conspiracy) of the *Act* arising from reverse payments,[1035] and this may be even more so given the *Actavis* decision. Section 45 establishes a *per se* illegality approach analogous to that rejected by *Actavis*. Multiple authors also suggest that unless the reverse payment settlement delays entry beyond the period of the patent, it would be unlikely to be pursued by the Bureau under Section 45 because it is not more than a "mere exercise" of patent rights.[1036] Private litigants could seek to challenge reverse payment settlements pursuant to Section 36, but this would most likely also require establishing a violation of Section 45 and so would face similar challenges.

Vanveen suggests reverse payment settlements could conceivably be subject to Section 79 (abuse of dominance) allegations.[1037] He notes that a Section 79 case may be challenging in light of Section 79(5) limiting the application of the provision to conduct involving only the exercise of IP rights.[1038] It may also be difficult to show the anti-competitive acts were directed at a competitor of the dominant firm with the intended negative effect required by judicial

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1032 Litigator's Guide to Drug Patent Settlements, *supra* note 1025 characterizes the precise scope of damages available as not yet determined. See *Apotex v Sanofi-Aventis*, 2012 FC 553.

1033 Competition in the Pharma Industry, *supra* note 1031.

1034 Activating Actavis, *supra* note 487 at 22.

1035 Reverse Payment Settlements in Canada, *supra* note 1008 at 17; Competition in the Pharma Industry, *supra* note *1031* at 15; Joneja et al., *supra* note 1030.

1036 Competition in the Pharma Industry, *supra* note *1031*; Michelle Lally, Christopher Naudie and Vincent M. de Grandpré, "U.S. Supreme Court holds that "reverse payment" patent litigation settlements are not immune from antitrust review" (June 18, 2013, self-published) [Lally et al.].

1037 Competition in the Pharma Industry, *supra* note *1031*.

1038 *Ibid*.

precedent under Section 79, given that the conduct involves an agreement which benefits the potential competitors who are party to it.[1039]

Another possibility would be challenging reverse payment settlements under Section 32, but given this section has almost never been used (and the IPEG position that its use would be rare) commentators suggest this approach would be unlikely in practice.[1040]

If a case were to proceed under the *Act*, commentators suggest the most likely provision to apply would be the Section 90.1, the civil prohibition on agreements between competitors or potential competitors that are likely to substantially lessen or prevent competition.[1041] This provision applies a standard substantially similar to the rule of reason approach adopted in *Actavis*. A Section 90.1 case would likely consider the situation "but for" the agreement, and whether, in the absence of the agreement, the relevant market would be substantially more competitive. The key challenge in such a case would be whether and how to address the possibility that the patent would have been invalidated (or found not to have been infringed) as a result of the litigation that was settled.

It is not clear what role the presumption of patent validity would play in a Section 90.1 case. The majority in *Actavis* suggests fully litigating the patent within the antitrust case is not necessary or desirable; instead "the size of the unexplained reverse payment can provide a workable surrogate for a patent's weakness."[1042] How the lower U.S. courts address this issue in practice may be informative in determining the Canadian approach.

The current approach of the IPEGs, under which the general provisions of the *Act* apply only to conduct that is more than the "mere exercise" of an IP right, is comparable to the dissent's scope of patent approach in *Actavis*, depending on what is considered contained within the definition of mere exercise. In this regard, we agree with the U.S. Supreme Court statement that "to refer simply to what the holder of a valid patent could do does not by itself answer the antitrust question".[1043] The U.S. Supreme Court emphasized determining antitrust legality by measuring settlement effects not solely against patent law policy (as the scope of patent test advocates) but against antitrust policy as well. It confirms that both patent and antitrust policy are relevant to determine the scope of a patent monopoly and any potential antitrust immunity.[1044] We suggest that at a broad level, the *Actavis* decision supports a stronger role for competition analysis even when patents are involved, as they are for reverse payment settlements. Whether a particular restraint is beyond the "limits of the patent monopoly" is a conclusion that arises from traditional antitrust analysis, not a starting point that precludes such analysis.[1045] The "mere exercise" interpretation of the *Act*'s provisions is considered by some to make it unlikely that a Canadian court would find reverse payments violate the *Act*. At the least, it certainly seems to reduce the likelihood of enforcement action.

1039 *Canada Pipe*, *supra* note 120.

1040 Lally et al., *supra* note 1036.

1041 Competition in the Pharma Industry, *supra* note *1031* at 15; Joneja et al., *supra* note 1030.

1042 *Actavis*, *supra* note 433 at 19.

1043 *Ibid* at 2.

1044 *Ibid* at 9.

1045 *Ibid* at 10.

(c) Conclusion on Reverse Payment Settlements in Canada

There have been no competition law cases and there is no specific guidance from the Bureau addressing the permissibility of reverse payment settlements in Canadian competition law. We were not able to find any empirical studies on the extent to which branded and generic pharmaceutical companies are engaging in reverse payment settlements, either within or affecting Canada. The lack of data on the extent of reverse payment settlements in Canada reflects a gap that should be addressed.

In 2007, the Bureau released a study concluding that there was strong competition in the supply of generic drugs in Canada. However, the study found that lower prices on pharmaceutical drugs achieved as a result of generic entry were not being passed on to end payers, being mainly public or private health plans. More recently, the Bureau held a workshop on competition issues in the pharmaceutical sector that included a session on reverse payment settlements. The workshop was invitation-only and the materials were not made public. Holding such events and engaging in studies like that done in 2007 are an important means of building agency knowledge on the complex issues raised by reverse payment settlements. If participation was opened more widely and if the materials were made publicly available after, such sessions could also play an important role in prompting public dialogue and analysis on related issues, which is scarce in Canada.

Several articles argue differences between the U.S. regime and the Canadian *Regulations* have a significant impact on the incentives to engage in reverse payments in Canada. Despite these differences, other commentators argue there remain incentives in Canada for reverse payment settlements. Articles also argue differences between the Canadian and U.S. regimes mean the reasoning in *Actavis* is not entirely transferrable to the Canadian context. The absence of an exclusivity period may mean a lower value of settlement might be expected to be reached here, even leaving aside factors such as the smaller Canadian market. Price restrictions on drugs and the interest in avoiding damages pursuant to Section 8 of the *Regulations* may mean there are stronger legitimate justifications for engaging in settlements in Canada.

However, the basic reasoning in *Actavis* still appears applicable in the Canadian context: simply because the effects of a reverse payment settlement might fall within the exclusionary scope of a patent should not “immunize” that settlement from all competition law scrutiny. Basic economic models in support of the *Actavis* reasoning suggest that whenever the reverse payment settlement exceeds the patent holder’s prospective litigation costs plus the value to the patent holder of any other goods and services provided by the allegedly infringing firm, the settlement likely diminishes the expected period of competition and harms consumers. The same logic appears generally applicable to Canada in parsing which reverse payment settlements might be of competitive concern, but prospective costs would have to take into account potential Section 8 damages.

Multiple articles suggest it would be difficult to establish a violation of Section 45 (criminal conspiracies provisions) of the *Act* arising from reverse payment settlements. The most likely section for a challenge of a reverse payment settlement, if one were to be brought in Canada, appears to be Section 90.1 (anti-competitive agreements between competitors) of the *Act*.

The current approach of the IPEGs, under which the general provisions of the *Act* apply only to conduct that is more than the “mere exercise” of an IP right, is similar to the scope of patent approach rejected by the majority (although emphatically adopted by the dissent) in *Actavis*. The IPEGs approach may make enforcement action with respect to reverse payment

settlements unlikely and may also mean a Canadian court would be unlikely to find such settlements violate the *Act*.

As in other jurisdictions, reduced competition in the pharmaceutical industry in Canada could have serious implications for Canadian government health-care spending. Lower health-care costs are equally, if not more, important to the government of Canada than to the U.S., given our public health system. If reverse payment settlements may, in some cases, be delaying generic entry in Canada in a manner that is anti-competitive, adopting an approach in the IPEGs that shields such payments from competition scrutiny could result in un-addressed harms to competition and the public.

3. Patent Assertion Entity Conduct

(a) Litigation Cost-Shifting Changes the Risk Equation for PAEs

Canada has not faced a surge in litigation by PAEs comparable to that of the U.S. The subject of PAEs has been characterized as non-urgent in recent comments before the Standing Committee on Industry, Science and Technology.[1046] The absence of PAEs in other jurisdictions has been attributed to fee-shifting regimes, where the losing party pays at least a portion of the winning party's costs. This is thought to deter PAEs from bringing litigation, because, unlike in the U.S. where each party pays their own costs, the patent assertion entity risks having to pay the opposing party's costs as well. This argument may also have merit in Canada, but we did not find it was assessed to any extent in Canadian literature.

This argument may, however, also require closer scrutiny in the specific Canadian context. First, full reimbursement of the opposing parties' actual legal fees is rarely awarded in Canada. Partial indemnity is much more common. Past provincial Law Reform Commission reports have estimated between 30%-50% of litigation costs are recovered across Canada as a whole, while another study suggested between 66% and 75% of costs were recovered in Canadian Federal Courts, although we note these studies are somewhat older.[1047] In contrast, cost awards in the U.K. and Australia during the same period were thought to be somewhat higher, more commonly around 70-80%.[1048] If there are discrepancies in the cost awards between Canada and other jurisdictions, the Canadian system could still present a more desirable opportunity for patent assertion entity litigation than other legal systems where the costs awards are closer to actual costs incurred and thus present a greater potential downside risk for PAEs in bringing litigation. Second, it may be challenging to collect cost awards from PAEs. Literature suggests PAEs are set up in their structure and holdings to be "judgement proof". Finally, considering litigation costs alone, although potentially quite significant for the PAE risk equation in Canadian litigation, also does not account for some of the other possible costs addressed below.

1046 Intellectual Property Regime In Canada, Report of the Standing Committee on Industry, Science and Technology (March 2013) 41st Parliament, First Session, comments of Norman Siebrasse at 2. B.II.ii.

1047 Law Reform Commission of Saskatchewan, "Awards of Costs and Access to Justice", Research Paper (July 2011) at 7, referring to a study by the Alberta Law Reform Institute in 2005 and to Stephen Clarke, eds. Mary V. Capisio, *Awards of Attorney Fees by Federal Courts, Federal Agencies and Selected Foreign Findings, Canada*, (New York: Nova Publishers, 2002).

1048 *Ibid.*

(b) Recent Patent Assertion Entity Litigation in Canada

Recently, litigation by a company characterized as a patent assertion entity[1049] has been launched in the Canadian Federal Court. Dovden Investments has launched 42 lawsuits in the Canadian Federal Court, including 32 in the last year alone.[1050] None of the claims have yet proceeded to trial. Most of the claims have been terminated on consent, which may mean defendant companies are settling. Settlements are generally private, so the extent to which such settlements are occurring in Canada and their value is unclear.

An August 2013 statement of claim filed against Dovden in Federal Court by the Canadian Urban Transit Association ("CUTA"), a representative of various transit agencies, observes that its members and their suppliers are typically approached by Dovden by way of a demand letter, asserting infringement of Dovden's patents and seeking payment of a license fee. CUTA describes the amounts demanded as "a small fraction of the cost of the litigation that would be necessary to definitively resolve the issue pursuant to the processes set out in the *Patent Act*. The pursuit of a legitimate claim for infringement is never the goal."[1051] CUTA seeks to invalidate Dovden's four patents in relation to vehicular tracking and notification based on non-patentable subject matter, prior art and a lack of utility at the time of filing.[1052] The matter appeared to be ongoing as of late 2013.[1053]

(c) Potential PAE Effects in Canada - Beyond Canadian Litigation?

The absence of extensive patent litigation in Canadian courts by PAEs does not, in our opinion, prove that Canada is immune to the effects of PAEs because (i) Canadian companies have long been targets of PAE nuisance litigation in the U.S.[1054] (ii) demand letters and other threats by PAEs against Canadian companies are not public[1055] and (iii) costs flowing from settlements in

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1049 Joe Castaldo, "Patent Trolls Invade Canada" (15 July 2013), online: <http://www.canadianbusiness.com/companies-and-industries/patent-trolls-invade-canada/>.

1050 Canada, Federal Court and Federal Court of Appeal Proceedings Query, as of 20 November 2013 online: <http://cas-ncr-nter03.cas-satj.gc.ca/IndexingQueries/infp_queries_e.php?stype=party&select_court=All>. In one case, the Canadian Urban Transit Association has chosen to fight back, challenging the validity of Dowden's patents.

1051 *Canadian Urban Transit Association v Dovden Investments Ltd* (3 December 2013), Ottawa T-1337-13 (FC), Statement of Claim at para 21.

1052 IPPractice.ca, "Dovden Investments Impeachment Action", online: <http://www.ippractice.ca/2013/08/dovden-investments-impeachment-action/>.

1053 *Canadian Urban Transit Association v Dovden Investments Ltd* (22 November 2013), Ottawa T-1337-13 (FC). Dovden recently filed a motion for the statement of claim to be struck out as frivolous and vexatious, with a hearing scheduled for March 2014; see: *Canadian Urban Transit Association v Dovden Investments Ltd* (3 December 2013), Ottawa T-1337-13 (FC).

1054 In some cases this even involves a Canadian-based PAE asserting against a Canadian company in another jurisdiction. See Globe and Mail, "Wi-LAN, BlackBerry end Patent Fights" (9 October 2013) describing litigation brought by Ottawa-based Wi-Lan in Florida against BlackBerry with respect to a patent allegedly reading on Bluetooth technology.

1055 The settlements reached in response to demand letters, which may include disproportionately high royalties, are also generally private. Dovden, for example, recently demanded $10,000 in licensing fees from an individual who developed a free application that used GPS data from a public transit company to advise riders of the schedule for bus arrivals. The application developer estimated his revenues from advertising within the free application were around $200 per month, tiny in comparison to the royalty demand. The demanded amount was disclosed by the target in this case, but in most situations it remains private. David

the U.S. likely would also impact Canadian businesses and consumers indirectly. The potential impact may be more significant for Canada than the other jurisdictions in this report, given our close trading partnership with the U.S. and the clear magnitude of PAE conduct occurring there.

Patent Freedom reports that BlackBerry (RIM) was thirteenth on the list of companies most pursued by PAEs, based on a total of 87 lawsuits brought against it in the U.S. by non-practicing entities in the period from 2009 to June 30, 2013.[1056] This targeting of innovation leaders suggests the impact on innovation from PAE litigation may be quite high; companies such as BlackBerry lead in Canadian research and development, but their resources are being spent battling PAEs rather than on productive pursuits. If, as seen in the U.S., PAEs are also targeting end-users of technology such as retailers in Canada, this may be resulting in unjustified royalty payments by Canadian companies or the withdrawal by the target of the allegedly infringing technology.[1057]

It seems likely that Canadian companies targeted by PAEs would suffer harm similar to that identified in the U.S. (discussed above), including potential innovation chill, litigation and settlement costs, payments in response to demand letters and the withdrawal of technology from the market where infringement is alleged. However, harm such as non-public demand letter payments and innovation impacts may be particularly difficult to measure.

Even where Canadian companies are not involved in litigation, we know that Canada's closest trading partner, the U.S., has high levels of PAE litigation and threats. Canadian consumers may, in turn, be paying more for goods imported from the U.S. if disproportionate royalties are being successfully imposed by PAEs through either litigation or settlement, the royalties are "locked in" to the cost of the imported products sold in Canada.

Canada is also home to a number of companies that have been characterized as PAEs, including MOSAID (now Conversant Intellectual Property Management), Wi-Lan and Rockstar Consortium. Such companies have regularly been asserting their patents in U.S. litigation, frequently in Texas, which is considered to be a PAE-friendly jurisdiction.[1058] It is not clear how the presence of such entities within Canada affects the impact of PAEs here.

(d) Lack of Public Study/Literature on PAE Effects In Canada

We found little relevant literature on PAEs from a Canadian perspective. One of the few Canadian articles on PAEs takes a patent law perspective, considering the role of business

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Reevely, "He Took on a Patent Troll - and Won" (17 September 2013) online: <http://www.ottawacitizen.com/technology/took+patent+troll/8921261/story.html>.

1056 See Patent Freedom, Most Pursued Companies, online: <https://www.patentfreedom.com/about-npes/pursued/>.

1057 Competition Law & PAEs, *supra* 541.

1058 Joe Mullin, "Canadian 'Patent Troll' Wi-Lan Loses East Texas Trial" (16 July 2013) describing the recent loss of Wi-Lan infringement litigation in the East District of Texas. The defendant, HTC, commented that "HTC believes that Wi-Lan has exaggerated the scope of its patent in order to extract unwarranted licensing royalties from entities who have been focused on bringing innovation forward in their own products… and the jury confirmed that belief." See also for example MOSAID litigation, MOSAID, Press Release, "Core Wireless Launches Patent Litigation Against Apple" (29 February 2012); MOSAID, Press Release, "MOSAID Sues HTC and Sony Ericsson on Newly Acquired Cellular Handset Patents" (7 July 2011); MOSAID, Press Release, "MOSAID Files Complaint Against Cisco at International Trade Commission (ITC)" (18 May 2011); MOSAID, Press Release, "MOSAID Files Wireless Patent Infringement Litigation" (17 March 2011).

method patents in the PAE problem in the U.S.[1059] It argues the current litigation behaviour involving business method patents (which has been connected to PAEs) is merely a reflection of problems in the patent system more generally. Canadian legal reform to exclude business methods from patentability is identified as a viable option to address such behavior. However, the author suggests instead that application of a discretionary approach by Canadian courts to the issuance of permanent injunctions where PAEs are involved (similar to the U.S. *eBay* case) is a faster and more flexible means of reducing undesirable behaviour involving business method patents, largely because it does not require legislative reforms.[1060] (Such injunctive relief is already discretionary in law, so the suggestion is referring to its application in practice.)

Another article by the authors of this report surveys U.S. literature on PAEs.[1061] It observes that although Canada has not to date become "home" to many patent trolls as the venue of choice for litigation, it would be wrong for Canadians to ignore the problem because Canadian technology companies have been the targets of PAE litigation and U.S. litigation may have costs for Canada.[1062]

U.S. antitrust agencies, Canada's closest counterparts, have engaged in extensive study of the effects of PAEs and are continuing to do so. There is also extensive literature on PAEs and related topics in the U.S. An assessment of the Canadian impact on PAEs, including input from stakeholders, could be very beneficial in informing Canadian policy on the subject, and potentially even more broadly on the patent and competition law intersection. As it stands, the scope and impact of PAEs is much less understood here. The debate in Canada has yet to begin in earnest.

There are practical difficulties in assessing the extent of PAE activity in Canada (as elsewhere). PAEs are known to bring litigation under various shell corporations which may make it difficult to determine the extent of cases truly being brought by PAEs.[1063] There is no requirment that the ultimate party-in-interest be indicated. Further, there is no reporting of demand letters publicly in Canada.

(e) Conclusion on PAEs in Canada

Canadian courts have not faced a surge in litigation by PAEs comparable to that seen in the U.S. One PAE has launched significant numbers of lawsuits in the Canadian Federal Court recently, but there is no reporting of a broader uptick in PAE litigation in Canada. Canadian literature on issues surrounding PAEs is limited. One article suggests that limiting injunction availability in infringement litigation is the best theoretical approach to discouraging PAE conduct.

1059 Siebrasse, Norman, "Patent Trolls and Business Method Patents" (2013), 54 Canadian Business Law Journal 38; See also Berryman, Jeff, Comment on Norman Siebrasse, "Business Method Patents and Patent Trolls" (2013) Canadian Business Law Journal 54 at 58.

1060 *Ibid* at 56. See similar comments from the same author Intellectual Property Regime In Canada, Report of the Standing Committee on Industry, Science and Technology (March 2013) 41st Parliament, First Session, at 2. B.iii

1061 George Addy and Erika Douglas, "Mind the Gap; Economic Costs and Innovation Perils in the Space Between Patent and Competition Law" (June 2012), available online: <www.dwpv.com>.

1062 *Ibid.*

1063 Patent Assertion Report, *supra* note 519 at 4.

The lack of apparent PAE litigation in Canada may be attributable to fee shifting in patent infringement litigation. Literature in other jurisdictions indicates fee-shifting is a significant factor in the lack of PAE litigation and U.S. legislative reforms focused on introducing fee-shifting support this conclusion. The strength of this argument may vary somewhat across jurisdictions where cost awards differ, and also on whether fee awards can be collected from PAEs in practice.

Perhaps more concerning than litigation in Canadian courts are the potential impacts on Canadian business and consumers from PAE conduct in the U.S. In theory, this might include harms similar to those identified in the U.S., such as potential innovation chill, unmerited litigation and settlement costs, excessive payments in response to demand letters, technology withdrawn from the market where infringement is alleged or more indirect business costs. There has been no theoretical or empirical assessment of the potential impact of PAE conduct in Canada, in contrast to the extensive study in the U.S. by agencies and commentators. An assessment of the Canadian impact on PAEs could be very beneficial in informing Canadian policy on the subject, including whether there are benefits or harms to Canada from PAE conduct and the reforms required, in the competition policy context or otherwise.

4. Product Hopping

In November 2012, the Bureau commenced an inquiry into whether product hopping may constitute an abuse of dominance under the *Act*. The Bureau announced on May 13, 2014 that as of March 19, 2014, the inquiry had been discontinued. The Bureau also issued a position statement on the inquiry. Given that there have been no other product hopping cases under the *Act*, we discuss the inquiry here as the best available guidance on the Bureau's position. Had the Alcon case gone forward, it would likely have been a rare example of the Commissioner adopting an argument of "more than mere exercise" of patent rights.

Alcon- The Facts in Brief

Alcon Canada Inc. has two prescription eye-drop products for the treatment of allergic conjunctivitis sold in Canada. One, Patanol, is nearing the end of its patent protection. The patent for the active pharmaceutical ingredient in Patanol expired on November 21, 2012, while a further patent for the formulation will expire on May 3, 2016. The other product, Pataday, is newer, and at the beginning of its patent protection in Canada, which runs until 2022.

Apotex applied for Health Canada approval to market a generic version of Patanol in February 2010. Alcon challenged the issuance of the approval in Federal Court, but settled the litigation on the basis that Apotex would not enter the Canadian market until separate litigation between Alcon and Apotex was resolved.

Alcon commenced Pataday sales in April 2011, making both Pataday and Patanol available in Canada at the time. The Bureau reports that during the time both formulations were available, sales of the new drug were increasing but remained low in comparison to the prior formulation. Apotex Inc. received approval to market a generic version of Patanol, one day after the 2012 patent expired. Several months before the generic version of Patanol was expected to be introduced in the market, Alcon began informing its customers that Patanol was on backorder and that health-care professionals should recommend patients switch to the newer product Pataday instead.

The Bureau began an inquiry into Alcon's conduct in November 2012. By January 2013, Alcon had voluntarily resumed supply of Patanol in Canada. Subsequently, generic competitors entered the market with generic versions of Patanol, and the Bureau reports the generic version has captured significant market share.

The Bureau investigated whether Alcon abused its dominant position in the supply of prescription drugs for the treatment of allergic conjunctivitis by withdrawing the supply of Patanol in advance of the imminent entry of a generic substitute. It argued in initial filings that Alcon purposefully disrupted the supply of the older drug so that doctors would become habituated to prescribing Alcon's newer product, instead of the older product that would soon be subject to generic substitution. The Commissioner's theory was that the switch would exclude effective generic competition for prescription drugs for the treatment of allergic conjunctivitis, because it would eliminate prescriptions for Patanol, which pharmacists would be legally entitled or required under many health insurance plans to fill by dispensing Apotex's generic substitute.[1064] The Bureau claimed sales of Pataday largely replaced the sales of the older drug. The Commissioner obtained a court order for the production of records and written responses from Alcon, on the basis that it had reason to believe this conduct constituted an abuse of dominance under the Act.

Alcon argued unsuccessfully against the issuance of the order, claiming that its decision to cease marketing the older drug was not an anti-competitive act constituting an abuse of dominance.[1065] It argued the newer product was an innovation, and that Alcon was entitled to make the business decision to promote it. Alcon noted its decision to cease marketing the older drug did not prevent Apotex from marketing its generic version of the older drug in competition with the newer branded drug. It argued further, if there was an abuse, the inquiry was premature or the issues had been resolved because Alcon had since agreed to recommence supplying Patanol (although it had not yet done so at the time of the hearing on the order). The decision to issue the production order was not an endorsement by the court of the Commissioner's theory of the case, and was simply intended to enable the investigation.[1066]

The Bureau completed its inquiry by March 19, 2014. The Bureau concluded that because Alcon had voluntarily resumed supplying Patanol in Canada, and there had been subsequent entry by competing generic drug companies, competition had been restored and the Bureau's concerns were resolved. The Bureau indicated that the "temporary conversion strategy" by Alcon did not ultimately delay generic entry. [1067]

Helpfully, the Bureau indicated in a position statement on the inquiry that it views product life-cycle management strategies as not inherently anti-competitive, noting they may bring significant advancements in health care to the benefit of consumers and drug companies.

1064 *Commissioner of Competition v Alcon Canada Inc*, Federal Court of Canada, Court File No T-2223-12, Affidavit of Mark McLachlan (December 13, 2012).

1065 *Ibid*, Transcript of Hearing Before The Honourable Justice Bédard (December 18, 2012). Alcon also unsuccessfully challenged the issuance of the Section 11 order on procedural grounds.

1066 Alcon was able to raise its substantive argument at such an early stage of the Commissioner's investigation because it is a condition to obtaining a production order under Section 11 of the *Act* that the Commissioner has reason to believe that grounds exist for the making of an order, in this case, under the abuse of dominance provisions in Section 79 of the *Act*.

1067 Alcon Position Statement *supra* note 1006.

However, it does on to say those strategies designed to impede generic drug competition, such as product switching, may also cause significant harm to competition. Specifically, the Bureau indicates that strategies including "supply disruptions for the purpose of forcibly switching demand, including terminating, repurchasing or recalling market supply or any other attempt to frustrate supply of a product under patent challenge by potential generic drug competitors, are likely to raise concerns of an abuse of dominance."[1068]

Like the FTC, the Bureau focuses in on consumer choice to explain product switching harm. The Bureau indicates that to establish their product in the market, generic drugs generally depend on substitution for existing brand name drugs by pharmacists. When supply of the original formulation is discontinued by the branded company, it is eliminated as an option for consumers and makes it likely physicians will prescribe the new formulation of the branded company. As a result, the "demand for the new product is therefore not based on the merits of the brand name drug company's innovation, but rather on the reduction of consumer and physician choice."[1069] The Bureau indicates this can have "significant effects" on the ability of the generic version of the older drug to enter the market and compete, and that generics may forgo launch of their version of the older formulation.[1070]

Had the Alcon case proceeded, it would likely have raised similar questions to those in the U.S. over what constitutes predatory innovation (see the U.S. section on product hopping, above). There does not appear to have been any withdrawal of market approval for the older drug, like that which blocked generic competition with the older branded drug in the EU case *AstraZeneca*. As Alcon points out, Apotex remained free to compete on the basis of its generic version of the older drug. Both Patanol and Apotex's generic version of Patanol were listed on the Ontario formulary, making them eligible for public health coverage. Guidance on the application of the *Act* suggests technological improvements resulting in innovative new products or improvements in product quality or service are credibly pro-competitive.[1071] The approach of weighing innovation against a loss of consumer choice may also raise difficult issues on how to address branded companies' arguments that they are under no duty to continue to offer old products.

Apotex also brought a private competition claim in October 2012 against Alcon with respect to the conduct, seeking damages for conspiracy, anti-competitive conduct and unjust enrichment.[1072] No private action is possible under the abuse of dominance provisions, which the Bureau chose to frame its inquiry.

1068 *Ibid.*

1069 *Ibid.*

1070 *Ibid.*

1071 When the *Act* was introduced in 1985, an accompanying Guide from the Minister of Consumer and Corporate Affairs provided the example of "improvements in technology or production processes that result in innovative new products or improvements in product quality or service" as business justifications for conduct that have "a credible efficiency or procompetitive rationale". *Guide to Amendments* (Ottawa: Supply and Services Canada, 1985) at 21. This is reflected in the current Abuse of Dominance Guidelines *supra* note 43 at 11.

1072 See Ontario CV-12-465558 and CV-12-9890-00CL.

(a) Conclusion on Product Hopping in Canada

The Bureau's inquiry into Alcon is important because it evidences the Commissioner's apparent willingness to consider conduct which, although it involves complex issues related to patent, may also implicate competition law. This is in contrast to a historically restrained approach to any issues at the intersection of patent and competition law.

The Bureau's concern over product hopping is generally consistent with the enforcement action taken by the EC in *AstraZeneca* and the position taken by the U.S. FTC as *amicus curiae* in private litigation.[1073] The Bureau provided a position statement on the Alcon investigation indicating that product life-cycle management strategies for pharmaceuticals are not inherently anti-competitive, but are likely to raise concerns over abuse of dominance where such strategies are designed to impede competition, such as product switching strategies. Even though the case did not proceed, the issuance of the position statement is a helpful in that it provides branded pharmaceutical companies with some advance notice of the general types of conduct that could form the basis of future Bureau cases on product hopping, and such guidance has been lacking in Canada to date.

The Bureau's specific theory of harm, as indicated in its position statement on Alcon, is similar to that of the FTC. It is based on the elimination of choice driving demand for the new product, rather than demand being driven by the merits of the brand name drug company's innovation. Withdrawal of supply of the older drug and habituating of physicians to prescribe the new drug is thought to eliminate choice and reduce the likelihood of generic entry or of effective generic competition.

The conduct investigated by the Bureau does not appear to have involved any withdrawal of market approval analogous to the acts blocking generic competition with the older branded drug in the EU case *AstraZeneca*. As Alcon pointed out, Apotex remained free to compete on the basis of its generic version of the older drug. As with the FTC position, the Bureau may thus be taking a broader approach to prohibited product hopping conduct, by challenging conduct even where there is no regulatory action that blocks generic entry.

Had the case proceeded, it may have raised questions similar to the U.S. product hopping cases on what constitutes predatory innovation. The Tribunal could have faced a U.S.-style dilemma requiring adjudication of the difficult question of how much innovation is "enough" not be considered a predatory attempt to block generic competition, while trying to avoid a false positive that chills legitimate innovation by branded pharmaceutical companies. The case also could have raised challenging issues over how to address branded companies' arguments that they are under no duty to continue to offer old products.

The parallel private action with respect to the same conduct in Alcon was not brought under the abuse of dominance provisions selected by the Bureau to advance its inquiry. This raises the question of whether a private action under the *Act* for abuse of dominance would assist in addressing product hopping conduct. The U.S. cases on product hopping have been predominantly private actions and the U.K. has also seen private actions advanced by public health authorities (although the U.K. also had a significant case brought by competition authorities, as did the EU). Private actions based on abuse of dominance are permitted in the U.K. and at the EU level.

1073 FTC Brief Warner Chilcott, *supra* note 617.

XI. CONCLUSIONS

1. General Conclusions

– ***Overall, there are increasing international competition law enforcement efforts regarding conduct that involves patent rights and competition law.*** Enforcement agencies in most of the jurisdictions studied have been engaged in recent investigations and cases at the forefront of competition law and patent rights. Recently decided court and agency-level cases include *Reckitt Benckiser* (U.K., product hopping), *AstraZeneca* (EU, product hopping), *Actavis* (U.S., reverse payment settlements) and *Lundbeck* (EU, reverse payment settlements). There are several other ongoing cases in the U.S., U.K. and EU in the areas of standard-setting/FRAND licensing commitments and reverse payment settlements. In one of the most significant recent cases, *Actavis*, the Supreme Court of the U.S. recognized the potential for patent holder liability under antitrust laws even where conduct may be within the scope of a presumptively valid patent. The U.S. Supreme Court's broad pronouncements on the relationship between patent and antitrust law may signal a shift toward greater analytical focus on antitrust, with resulting implications beyond reverse payment settlement cases to other cases involving conduct where it is argued patents are shielded from antitrust liability. Given the recency of the decision, it is not yet clear how far-reaching the implications of *Actavis* will be in the broader patent/antitrust context.

  Canada and Australia have seen a comparative lack of competition law enforcement, although Canada has investigated allegations of product hopping, and after the first draft of our report, Australia commenced its first product hopping case. It is not clear whether this lack of activity is due to factual differences in the Canadian situation that make enforcement inappropriate, differences in Canadian law, the Bureau's perceived lack of jurisdiction to act on issues at the intersection of patent and competition law regimes or other factors. Many of the recommendations we make in this report are aimed at determining the cause of this difference.

– ***The approach of the Canadian Act (and related guidance) to the patent and competition law interface is dated in some respects, and may be dampening enforcement. Canada has a unique provision in Section 79(5) of the Act protecting against the application of abuse of dominance provisions to conduct involving only the exercise of IP rights or interests.*** The other jurisdictions studied have no equivalent legislative exception, and have applied their respective abuse of dominance prohibitions to address conduct such as repudiation of standard-setting commitments, reverse payment settlements and product hopping. Even in Australia, where there has been comparatively little enforcement on the issues canvassed in this report, there have been repeated recommendations for amendment or repeal of a special exclusion that shields some conduct involving intellectual property from the application of the *Australian Competition Act* (Section 51(3)). The rationale for this exclusion of IP rights from portions of the *Australian Competition Act* has been characterized as no longer relevant in light of evolved views on the compatibility of competition and patent law regimes. This Australian exclusion already does not apply to the equivalent of Canada's abuse of dominance provisions.

– ***Strong cross-agency co-operation is essential to address issues at the intersection of competition law and patent law.*** Interaction across competition and patent silos, in the form of workshops, conferences and reports, as well as pursuant to formal memoranda of understanding is evident in several of the jurisdictions we studied. The U.K. recently saw the signing of an MOU between its competition and intellectual property agencies. The EC has

organized three conferences in conjunction with the European Patent Office on topics related to standard-setting and patents, intended to inform the strategies of the agencies for improving competitiveness and innovation with respect to standardization. In the U.S., there is an emphasis on cross-agency collaboration across the FTC, DOJ and PTO. As early as the 2003 Report on IP, issued by the FTC, there was an emphasis on steps to increase communication between the FTC and the PTO, including filing of *amicus* briefs in patent cases that affect competition and as well as creating a liaison panel between the FTC, DOJ and PTO to exchange policy views. The DOJ, FTC and PTO have also held several inter-agency workshops related to topics in patent and competition law, most recently with the DOJ and FTC on PAEs in December 2012. There is also a separate agency in the U.S., the U.S. Intellectual Property Enforcement Coordinator, which coordinates intellectual property enforcement across relevant agencies at a strategic level. In Australia, a separate government agency, the Productivity Commission, acts as an independent research and advisory body focusing on strategic means to achieve a more productive economy through better policy, including on economic, social and environmental issues. The Productivity Commission has considered issues relevant to the intersection of patent and competition law in-depth, such as its recent study of Australia's compulsory licensing regimes.

– ***Extensive agency knowledge-building activities are occurring in several jurisdictions. At least in the U.S., such knowledge-building involves public engagement.*** Several of the jurisdictions studied have issued multiple in-depth reports on issues at the intersection of the patent (or IP more generally) and competition law regimes. The EU (in 2008) and Australia (in May 2013) have produced reports that consider the pharmaceutical industry, including how to secure timely generic entry to foster competition, and considering whether conduct involving patents may be creating barriers to entry. Australia has also engaged in recent more general studies relevant to the issues canvassed in this report (see, e.g., the Compulsory Licensing Report (2013)). The FTC has issued several in-depth reports on issues related to patent law, competition law and innovation, some in conjunction with other agencies. The reports are often based on workshops in which public participation is possible. The materials and transcripts from the workshops are made publicly available by the FTC. The last such reports from the Bureau or other Canadian agencies of which we are aware were the 2007-2008 generic drug studies.

  For the agencies, such studies and workshops serve to build important institutional capacity and understanding of these highly complex issues. For the public, the analysis and commentary of the experts involved in such events is valuable to build understanding and to facilitate academic literature and dialogue (of which there is comparatively little in Canada) on complex issues at the intersection of competition law and patent law.

– ***Several jurisdictions have issued revised guidance, including in the form of reports or public policy statements, on specific issues at the intersection of competition and patent law.*** Clarifying the analytical framework, and providing certainty as to when enforcement will occur, can reduce any potential chill on innovation arising from unpredictability in enforcement. Given the enforcement surge at the juncture of patent and competition law occurring with our close trading partners like the U.S. and EU, concern and uncertainty over enforcement may be heightened within Canada. Guidance may be particularly valuable to the extent there are Canada-specific factors which alter the enforcement concern level or analytical approach by the Bureau, relative to our trading partners.

Canada may be falling behind in the guidance it provides to businesses on issues at the intersection of intellectual property law and competition law. The Bureau IPEGs date to 2000. After the first draft of this report, the Bureau issued initial, revised IPEGs for consultation. The changes were predominantly housekeeping edits to reflect 2009 amendments to the *Act* and other Bureau guidance. The draft does not provide substantive guidance on the topics canvassed in this report. We understand a second phase update with more substantive changes is being contemplated by the Bureau. We applaud the Bureau's recently issued position statement on its discontinued inquiry into whether product hopping conduct by Alcon constituted an abuse of dominance under the *Act*. It provides a general sense of the Bureau's view on product life-cycle management strategies and when harm may be caused by product hopping strategies. However, product hopping is the only area studied in this report where the Bureau is known to have considered enforcement action or issued updated guidance.

In contrast, in the U.S., although the IP Guidelines date to 1995, there is more recent guidance available from the 2007 Report on Antitrust and Intellectual Property, which outlined the Agencies' enforcement positions. Further, the U.S. DOJ and PTO recently issued a Joint Policy Statement on the use of exclusion orders to remedy infringement of FRAND-encumbered SEPs. The position of the Agencies on many of the issues at the intersection of competition law and patent law is also evident from their speeches and enforcement activities. Similarly, the EC issued new Horizontal Guidelines in 2011, which elaborated greatly on the EC approach to standard-setting conduct. The EC is also in the process of issuing guidance on patent pools and reverse payment settlement agreements in its updated Technology Transfer Guidelines.

The risk of a lack of guidance is that Canadian businesses or those considering doing business here may not engage in economically beneficial conduct because of a misperception that it breaches competition laws, especially where complex considerations related to patent law are raised. Despite the comparatively greater level of guidance it has provided, the FTC still faces criticism for its application of Section 5 of the *FTC Act* in the absence of clear guidance/limiting principles on what constitutes a violation and when enforcement will be pursued. Without more detailed up-front guidance on the Bureau's position, it may face similar criticism for pursing actions in the areas of concern discussed in this report.

2. Conclusions Regarding Standard-Setting/FRAND Licensing

- ***In the jurisdictions studied, the pro-competitive benefits of standard-setting are widely acknowledged by competition authorities as economically and socially significant.***

- ***Competition authorities in the U.S. and EU have expressed concern over the potential for anti-competitive conduct in standard-setting. Attention has focused on the potential for hold-up arising from deception in standard-setting (patent ambush), and, more recently, from the breach of FRAND licensing commitments.***

- ***Both the U.S. and EU pursued cases to sanction patent ambush relating to standards.*** In the 2007–2009 timeframe, the U.S. FTC and the EC saw decisions in parallel cases to sanction patent ambush by the high-tech company Rambus. Although the legal provisions under which the cases were brought differed, the underlying theoretical concerns about harm from patent hold-up were largely the same. The EC was successful in obtaining

commitments in its case against Rambus. Although the FTC's *Rambus* case was overturned by a U.S. court, the approach to causation in the court's decision has been criticized. The Canadian competition law approach to patent ambush would likely be closer to that of the EC, although differences in the law of abuse of dominance between Canada and the EU might make the case more challenging for authorities to bring in Canada. The issue of patent ambush is an older one, but is rooted in similar concerns over patent hold-up as the current cases on injunctive relief for SEPs subject to FRAND licensing commitments. The common concern over patent ambush shared by the EU and U.S. at a theoretical level also appears relevant to Canada.

- ***Both the U.S. and EU are taking enforcement action to limit the use of injunctive remedies where patent infringement involves standard-essential patents subject to FRAND commitments.*** The U.S. antitrust authorities have pursued such conduct under unfair competition prohibitions, while the EC has pursued it as an abuse of dominance. The U.S. authorities faced some criticism for failing to define meaningful limiting principles to govern the use of FTC authority in these cases. As with patent ambush, the Canadian approach to any challenge of the use of injunctions for FRAND-encumbered SEPs would likely be closer to that of the EC. Despite differences in the legal provisions applied in the cases, the underlying theoretical concerns expressed by U.S. and EU agencies are quite similar, and focus on harm arising from patent hold-up in the standard-setting context. There is a shared concern that the threat of an injunction may distort licensing negotiations unduly in the SEP-holder's favour, by forcing potential licensees into onerous licensing terms, such as higher royalties than would otherwise have been agreed to or forced cross-licenses. We see no reason why such concerns would not apply equally to Canada, to the extent similar conduct is occurring here.

- ***The resolution of currently ongoing EC cases may provide more indication of international consensus on when injunctions should be permissible for SEPs that are subject to FRAND commitments.*** The proposed commitments in one of the EC cases appear generally similar to the commitments reached in a U.S. case; both involve commitments not to seek injunctive relief for SEPs as long as a certain licensing framework is complied with, but permit injunctions to be sought defensively.

- ***Key open issues regarding standard-setting and FRAND licensing commitments in the U.S. and EU include:***

  - ***What constitutes a FRAND licensing rate;***

  - ***Who is considered a "willing" licensee; and***

  - ***The appropriate limiting factors in enforcement to ensure patent rights are not impinged, including whether competition enforcement could extend to commitments that are made outside of the SSO context regarding de facto standards.***

- ***Continued enforcement is likely with regard to SEPs subject to FRAND commitments and appears appropriate since SSO self-regulation is not a complete solution to potential anti-competitive harm.*** Both the U.S. and EU have indicated in recent merger approvals involving SEPs that they will continue to watch this space. Although SSOs play an important role in achieving the benefits of competition in standard-setting, there are

arguments that SSOs are not a full solution to the concerns raised and therefore a continued role for competition authorities in regulation is appropriate.

– ***There is divergence in apparent competition law concern over standard-setting between the jurisdictions studied.*** The EU conducted a recent empirical study of the interplay between standards, competition policy and intellectual property rights protection, which was intended to provide a sound factual basis for policy development in the area. Both the U.S. and EU are taking enforcement action with respect to the use of injunctions where FRAND-encumbered SEPs are involved. In contrast, the recent Australian Compulsory Licensing Report found standard-setting concerns were unlikely to be relevant to Australia, and that competition and patent legislation were unlikely to be called upon often in Australia to resolve SEP disputes. Further, the *Australian Competition Act* misuse of market power provisions (in conjunction with certain *Patents Act* provisions) were found to be sufficient to protect against misuse of market power involving a failure to comply with FRAND licensing commitments. The report reasoned that there are few industries associated with SEPs operating in Australia, and Australian standards organizations tended to adopt standards set by global or regional SSOs.

  Canada may be in a similar factual situation as Australia; further research in Canada on the relevance of standard-setting here would be helpful to confirm this. We agree that competition authorities in jurisdictions which do not drive standard-setting would likely have fewer concerns over policing the standard-setting process (e.g., collusion in standard-setting) within their jurisdiction. However, in considering issues of hold-up after standards have been set, we find the Australian perspective may be too restrictive, as suggested by the recent private litigation raising issues over standard-setting and FRAND licensing in Australia. The Australian perspective fails to consider any impact of FRAND licensing disputes where agreements or standards are struck internationally, but competition is impacted domestically, for example through reduced access to standardized technology because of a failure to fulfill FRAND licensing commitments. A refusal to license on FRAND terms, or higher licensing fees, could translate into higher prices for Australian (or Canadian) consumers even if standards are being set elsewhere. Further, to the extent the *Australian Competition Act* was found sufficient to address abuses after standards adoption, we note that the same conclusion may not apply here because Canada's competition legislation contains an exception to abuse of dominance with no equivalent in the Australian legislation.

– ***The EU and the U.S. have provided guidance on issues involving standard-setting and competition.*** The revised Horizontal Guidelines issued by the EC in 2011 provide extensive guidance on standard-setting activities as it relates to competition policy. The U.S. Agencies have provided guidance on their enforcement approach to standard-setting issues through cases, a policy statement and speeches from leadership. The perceived risk that SSO conduct could violate competition law may chill pro-competitive forms of SSO self-regulation; providing detailed guidance can help to avoid this. The complexity of addressing competition concerns over hold-up after a standard is locked-in (which the EC has experienced in its cases) makes providing detailed guidance a preferable approach that "frontloads" competition law enforcement to reduce later, difficult issues.

3. Conclusions Regarding Reverse Payment Settlements

– ***Competition regulatory agencies in the U.S., EU and U.K. have taken the clear position that some types of reverse payment settlements have anti-competitive effects and violate competition laws. The U.S. has significant Supreme Court***

guidance on the legality of reverse payment settlements, but in the other jurisdictions studied there is no decided court case testing competition agencies' positions on reverse payment settlements. The analytical standard applied to assess reverse payment settlements varies between the Supreme Court of the U.S. and the EC. The EC position is that reverse payment settlements violate prohibitions on anticompetitive agreements by object, meaning anti-competitive effects are presumed. The release of the full decision in EC's first decided case on reverse payment settlements (*Lundbeck*) and the rulings in several other pending reverse payment cases will make the precise arguments of the EC clearer. Whether this position will be blessed by European courts is unknown, because the *Lundbeck* case is currently under appeal. The U.K.'s OFT has a pending reverse payment settlement case, and is likely to follow the EU approach.

The U.S. Agencies have argued for a *per se* illegality approach to reverse payment settlements, similar to that adopted by the EC. However, a recent Supreme Court of the U.S. decision (*Actavis*) rejected this position and instead established a rule of reason approach to assessing reverse payment settlements. The U.S. position appears to provide more scope for permitting reverse payment settlements than the approach taken to date by the EC.

Although the outcome in *Actavis* was not the standard of analysis for which the Agencies advocated, the decision cast a role for antitrust that was stronger than the "scope of patent" approach adopted by multiple lower courts in the U.S. The scope of patent view was that reverse payment settlements involving the transfer of value do not infringe antitrust laws if they are within the exclusionary scope of the patent in dispute. The scope of patent approach largely removed such agreements from antitrust scrutiny. Even though the FTC's analytical standard was rejected, *Actavis* is significant for the FTC because it confirms reverse payment settlements are not immune from antitrust scrutiny. The outcome in Actavis also reflects the significant role that persistent and principled agency enforcement can play in balancing the patent/competition law regimes.

There remain several open questions in both the U.S. and EU with respect to reverse payment settlements, such as the amount of permissible reverse payment settlements, to what extent the validity of the related patent should be considered in any competition-related assessment of the settlement agreement and the permissibility of arrangements that involve non-cash payments. Although these nuances are still being settled, the regulatory agency positions have long been established and, along with the *Actavis* and *Lundbeck* decisions, provide some guidance for parties considering such settlements.

– ***Both the U.S. and EC monitor reverse payment settlements through mandatory reporting and this may have the effect of discouraging anti-competitive settlements.*** The EC has put significant effort into assessing and tracking settlements of patent infringement between generic and branded pharmaceutical companies, including reverse payment settlements. This includes the EC's 2008 pharmaceutical sector inquiry (which led to three enforcement cases) and subsequent annual monitoring reports where settlements are reviewed. The EC is of the opinion such reviews reduce the number of anti-competitive agreements. The U.S. requires all settlements of patent disputes between branded companies and generics, including reverse payment settlements, to be filed with antitrust agencies for review.

Both the U.S. and EU have generally seen a declining trend in reverse payment settlements as a percentage of all settlements during the period of monitoring (although the U.S. saw instances of such agreements rise in 2012). Monitoring serves as a means of signalling

competition agency concern over the potential anti-competitive impacts of reverse payment settlements. It also enables competition authorities to review agreements and to challenge any agreements that are considered anti-competitive.

- ***It is unclear whether reverse payment settlements are occurring in Canada to any significant extent because of a lack of tracking, either by government or otherwise. Differences in the regulatory regimes for generic drug approval between the U.S. and Canada may mean there are distinctions in both (i) incentives and (ii) legitimate justifications for engaging in reverse payment settlements.*** Several articles argue differences between the U.S. and the Canadian *Regulations* have a significant impact on the incentives to engage in reverse payments in Canada. Price restrictions on drugs in Canada and the availability damages under Section 8 of the *Regulations* may reduce concerns over such conduct being anti-competitive. Despite differences in the Canada/U.S. regulatory context, economic models in support of the *Actavis* reasoning used to identify anti-competitive reverse payment settlements still appear generally applicable in the Canadian context.

- ***If reverse payment settlements are occurring that may have anti-competitive effects in Canada, such settlements should not be immune from competition law scrutiny, despite regulatory differences between the U.S. and Canada.*** The basic reasoning adopted by the majority in Actavis remains applicable to Canada: simply because the effects of a reverse payment settlement might fall within the exclusionary scope of a patent should not "immunize" that settlement from all competition law scrutiny. As *Actavis* explains, "to refer simply to what the holder of a valid patent could do does not by itself answer the antitrust question". Whether a particular restraint is beyond the "limits of the patent monopoly" is a conclusion that arises from traditional antitrust analysis, not a starting point that should preclude such analysis.

  Canadian commentary suggests it would be difficult to establish a violation of Section 45 (criminal conspiracies provisions) of the *Act* arising from reverse payment settlements. The more likely section for a challenge of a reverse payment settlement, if it were to be brought in Canada, appears to be Section 90.1 of the *Act* (anti-competitive agreements between competitors). Although thought to be less likely, such conduct could also be considered under the Canadian abuse of dominance provisions (Section 79). The current "mere exercise" approach in Canada's IPEGs and Section 79(5) of the *Act* shares commonalities with the scope of patent analysis rejected by the majority of the U.S. Supreme Court in *Actavis* (although strongly supported by the dissent).

- ***The potential for hold-up by patent holders is an acknowledged concern in the context of PAE litigation, as it is with respect to standard-setting/FRAND licensing commitment violations.*** The U.S., EU and U.K. authorities have all acknowledged the potential issue of patent hold-up, which underlies antitrust concerns about both patent assertion entities and standard-setting/FRAND licensing.

- ***The issues raised by PAE litigation appear to be extensive in the U.S. and are being targeted by legislative reforms, although none have yet passed the Senate.*** The U.S. has several pending pieces of litigation aimed at curbing PAE conduct. There is also some activity from a consumer-protection perspective in both legislation and law enforcement at a state level.

- ***There is emerging U.S. literature on two PAE trends which could increase levels of competition law and policy concern: (i) targeting of small businesses by PAEs and (ii) privateering.*** In the U.S., the head of the FTC and a recent Executive Office of the President report have both observed that PAEs are targeting small businesses with false claims of infringement. State-level action has generally focused on this type of PAE conduct. The U.K. IP Report somewhat similarly found the targets of injunction threats are often "young, small businesses" in high technology areas that tend to hold fewer patents than more established enterprises. If PAEs are targeting small businesses, which are widely acknowledged as being essential to innovation, this heightens the concern that PAEs are harming innovation. A second emerging area of PAE conduct is "privateering", which involves the assertion of patent rights by PAEs acting as surrogates for competitors of the operating company backing the privateer PAE. The EC has received complaints from private parties over privateering and the head of the FTC has acknowledged the potential for privateering to raise competition concerns.

- ***U.S. antitrust agency opinion may be leaning toward enforcement against PAE conduct and the ongoing study of PAEs is likely to be helpful in determining whether action will be taken.*** The U.S. Agencies have now held a workshop on PAEs and the FTC is conducting a formal study on the topic. PAE demand letters targeting end users of technology have been acknowledged in FTC comments as a potential area for antitrust concern, as has privateering. Some commentary suggests potential U.S. enforcement action against PAE conduct is forthcoming, but none has yet occurred.

- ***Other jurisdictions have paid little attention to PAEs, since none have seen litigation by PAEs reach levels seen in the U.S. Despite this, the EC has acknowledged the potential for PAE conduct in Europe (which may be exacerbated by pending implementation of a unified patent court) and the U.K. has at least one private empirical study indicating some PAE litigation is occurring in the U.K.***

- ***The impact of PAE conduct on Canada has not been studied publicly to any extent. Given market integration between the U.S. and Canada, it seems likely the conduct of PAEs in the U.S. has an effect in Canada.*** As mentioned above, the FTC is conducting a formal study of PAEs. Private U.S. studies have looked more broadly at whether the loss from litigation by PAEs exceeds the decline in value of companies targeted by PAEs, and found it has not, implying an overall net social loss arising from PAEs. Private empirical studies in the U.K. have looked at litigation behaviour of PAEs. Fee-shifting in litigation is thought to temper PAE litigation, so one might expect that the presence of such a regime in Canada may be tempering PAE conduct here. However, (i) at least one entity considered to be a PAE has begun to bring large numbers of infringement claims in the Canadian Federal Court, showing Canada is not immune to PAE litigation and (ii) there may still be indirect impacts on Canada from demand letters and litigation by PAEs that occurs in the U.S. Due to the lack of study in Canada of PAEs, there is almost no empirical foundation upon which to base Canada-specific enforcement policies or advocacy efforts.

4. Conclusions Regarding Product Hopping

- ***There is active, recent enforcement by the EC, ACCC and U.K. OFT to sanction product hopping, while the U.S. FTC has expressed its concern over the conduct in private litigation.*** The EC has brought a successful major case involving product hopping (AstraZeneca), as has the OFT in the U.K. (Reckitt Benckiser). The FTC has filed briefs in private litigation on product hopping but has not brought its own case. Australian competition

enforcers very recently brought their first product hopping case. We did not find any major recent empirical studies in any jurisdiction measuring the competitive effects of product hopping, but the extent of agency enforcement makes clear that concerns exist over the competitive effects of product hopping on generic competition.

- ***The Bureau has investigated its first potential product hopping case, which concluded with the subject of the investigation taking voluntary action that resolved competition concerns.*** The inquiry was an encouraging foray into the issues raised by the intersection of patent and competition law regimes, and the resulting Bureau position statement provides some helpful guidance to pharmaceutical companies.

- ***Although product hopping is clearly a common area of concern for competition authorities, theories of liability for product hopping vary across jurisdictions.*** The two primary U.S. product hopping cases hinge on the elimination of choice through efforts by the branded company to remove the old version of the product from the market. The major EU case focuses instead on the regulatory action by the branded company of withdrawing market authorizations, ancillary to the introduction of a drug reformulation. Although the OFT's major product hopping case involved regulatory authorization withdrawal, liability was not expressly based on this. Instead, it appears to have been driven by the intent to hinder generic competition reflected in internal company documents (an approach that has been the subject of criticism). Although at the early stages, the Australian product hopping allegations appear to hinge on a variation where the "hop" is to an authorized generic of the branded company, and there is no apparent withdrawal of the older branded product from the market. The Bureau's recent position statement on its discontinued Alcon inquiry reflects a theory of liability similar to that taken in the U.S.

- ***Literature suggests the major challenge in product hopping cases is distinguishing between legitimate innovation and predatory innovation.*** Literature suggests the European General Court's approach to the theory of harm in the *AstraZeneca* product hopping case may avoid the challenge of distinguishing between legitimate and predatory innovation. This could, in turn, reduce the risk of false positives in enforcement that chill pharmaceutical innovation. It is not clear whether the European courts might also find anti-competitive effects where no regulatory gaming has occurred. The U.S. and apparent Canadian approach leave room for wider potential liability for product hopping, in the absence of any specific regulatory gaming to block generic competition with the prior drug formulation. Unlike *AstraZeneca* and *Reckitt Benckiser*, it appears that in the Bureau's recent inquiry into product hopping, the generic company remained free (at least in theory) to continue to compete with its generic version of the older drug. This approach could require the Bureau and Canada's courts to parse a challenging, U.S.-style analysis to determine how much innovation is "enough" not be considered a predatory attempt to block generic competition.

XII. RECOMMENDATIONS

1. General Recommendations

- ***We recommend considering a repeal of the limit on abuse of dominance under Section 79(5) of the Act, or at least an assessment of its relevance. Further, we recommend considering whether its interpretation as the "mere exercise" approach in the IPEGs is inappropriately limiting (or has been inaccurately interpreted as limiting) the application of competition law to anti-competitive conduct involving patent rights.***

- ***We recommend with respect to Section 32 of the Act:***

  - ***Assessing why Section 32 of the Act has almost never been used in Canada.*** In the history of Section 32, no contested case has ever been brought. Australian inquiries, such as the recent Compulsory Licensing Report, look at "dormant" sections of Australian legislation to assess whether it is functioning properly;

  - ***Considering an update to Section 32 to align it with the 2009 revisions to several other major sections of the Act.*** We suggest at a minimum that section 32 is out of date in comparison to the remainder of the *Act* and that updating it could facilitate enforcement. We recommend revising Section 32 to refer to concepts understood under the *Act*, to the extent possible, eliminating outdated language such as reference to "unduly" lessening competition; and

  - ***Considering a shift of jurisdiction to act under Section 32 to the Commissioner of Competition. We recommend that the Commissioner of Competition, rather than the Attorney General, be responsible for enforcement of Section 32.*** From a competition law perspective, it is not clear that there is a compelling reason for the Attorney General to hold the current jurisdiction under Section 32.

- ***We recommend studying the possibility of additional amendments to facilitate competition law enforcement in Canada with respect to conduct involving patent rights, such as an increased role for private actions.*** Private actions play a comparatively limited role in Canadian competition law. In particular, Canada does not currently allow private actions for abuse of dominance. An example of the relevance to the issues here is the Bureau's discontinued inquiry into product hopping; the Bureau chose to frame its allegations under abuse of dominance, but a private action regarding the same conduct did not (and could not under Canadian competition law). The U.S. has seen several product hopping cases proceed privately. Standard-setting/FRAND licensing competition law issues have been raised in very extensive private litigation in the U.S. and EU, although the litigation often focuses on patent law claims.

  We acknowledge that other jurisdictions are not currently proposing amendments to their competition legislation to address the issues canvassed here. Although reverse payment settlement tracking was implemented legislatively in the U.S., and the U.S. is contemplating legislative changes to address PAEs, in neither case do the proposals involve changes to the antitrust legislation. The difference may be that in the U.S. and in the EU, competition agencies, courts and private litigants have actively taken up the task of applying existing laws or providing guidance to address issues at the forefront of competition and patent law regimes to a much greater extent than in Canada. The enforcement and private litigation in

such other jurisdictions may be providing the flexibility to address the conduct, without resorting to antitrust legislative change.

- ***We recommend building closer ties between the CIPO and the Bureau, and consideration of statutorily-mandated consultation on enforcement initiatives that implicate both agencies.*** A first step in this regard would be reaching an MOU between the agencies. This is consistent with the current Bureau emphasis on collaboration, as exemplified by its recent MOU with the Canadian Radio-television Telecommunications Commission. A second useful initiative would be further joint public workshops (for example, the recent pharmaceutical sector workshop held by the Bureau), conferences and the issuance of joint reports on challenges at the interface of both regimes. Dialogue between the agencies tasked with the two areas of regulation may be one of the most valuable tools in achieving lasting and effective reconciliation. *Note: Subsequent to the initial draft of this report, on April 2, 2014, we understand the Bureau and CIPO have reached an MOU providing for closer co-operation between the two agencies, a positive first step to closer collaboration.*

- ***We recommend that agencies within Industry Canada, including CIPO and the Bureau, collaborate at a strategic level to ensure on an ongoing basis that appropriate government policies and initiatives balance competition and innovation objectives to deliver the best economic return for Canadians.*** Issues at the intersection of this space are likely to grow; ongoing consideration at a strategic level is essential to finding the right balance between competition and intellectual property law regimes to promote innovation. While the Bureau and CIPO play a key role in achieving the right balance, the issues require a horizontal approach across many facets of government operations, programs and policies.

- ***We recommend increasing Bureau knowledge building (on its own and in collaboration with other constituents) and expanding public participation and availability of material on patent/competition issues arising from agency activities in Canada.*** We understand there are budgetary and size differences between Canadian agencies and those in jurisdictions like the U.S. and EU, but nevertheless, we recommend that the Bureau engage in more of the institutional knowledge building seen in other jurisdictions, to inform its approach to issues within Canada. We applaud, for example, the Bureau's initiative in holding recent sector days and the recent pharmaceutical workshop.

  Encouraging theoretical thinking and writing may be particularly valuable in Canada, because our enforcement approaches are often deeply influenced by the U.S., even though there could be important factual or legal distinctions from the U.S. We recommend that the related presentations or other publications, and if possible, transcripts, of Canadian agency events analysing competition law and patent law issues be made available to the public. If this is not feasible, we recommend that a final report summarizing the discussion be made public. For the same reasons, we also recommend that the Bureau consider opening attendance to the public for workshops on competition and patent law issues.

  Subsequent to the initial draft of this report, on April 29, 2014, the Bureau published highlights of its pharmaceutical workshop, which we see as a positive development. Given the fast pace of discussion on topics such as those canvassed here, we would encourage posting of materials more rapidly after future events, as there was a five-month gap between the workshop and the posting of the related material.

– ***We recommend the issuance of updated Bureau guidance on competition law enforcement as it relates to intellectual property.*** Subsequent to the initial draft of this report, on April 2, 2014, the Bureau released its first revision of its intellectual property guidelines. The initial draft reflects mainly "housekeeping" changes to reflect amendments to the *Act* and does not provide guidance on the issues canvassed here. We understand the Bureau expects to provide a subsequent, substantively updated version of the guidance at a later point in time, and we greatly encourage the issuance of updated guidance that includes coverage of substantive topics like those discussed herein. We recommend such guidelines specifically address issues related to standard-setting/FRAND, reverse payment settlements, patent assertion entities and product hopping as discussed herein (unless empirical studies indicate a lack of relevance of any of these issues to Canada). In this regard, the Bureau's issuance of a position statement in the recently discontinued inquiry into product hopping is a positive step. Improving the breadth, depth and clarity of Bureau guidelines on intellectual property enforcement would promote marketplace certainty and build the foundation for success in the application of the *Act* to patent-related conduct, should the Bureau choose to pursue such cases.

2. Recommendations Regarding Standard-Setting/FRAND Licensing

– ***We recommend an empirical study on the extent to which private standard-setting and subsequent licensing involving IP reading on such standards is occurring in Canada and whether anti-competitive concerns may exist over such conduct in Canada.*** Based on reports from jurisdictions like Australia, it is possible that standard-setting and related licensing is largely occurring outside of Canada. International enforcement efforts may also be sufficient to address competition impacts within Canada arising from the setting of such standards and/or the exercise of market power arising as a result of standards. An empirical study would help to determine to what extent Canadian competition authorities (and courts) should be concerned over standard-setting as it relates to competition within Canada.

– ***If empirical study suggests standard-setting activities and related licensing may have anti-competitive effects in Canada, we recommend that more detailed guidance be provided by the Bureau on when conduct related to standard-setting and the violation of licensing commitments made therein might violate competition laws.*** The Canadian 2006 IP and Competition Report recommended developing guidance on when competition concerns could arise from standard-setting activities.[1074] This recommendation does not appear to have been pursued. A lack of guidance may result in the loss of public benefit due to avoidance of standard-setting or the reduction of beneficial self-regulation by SSOs, based on perceived competition law risk. The benefits to providing more detailed guidance discussed in comparator jurisdictions include: promoting standard-setting and associated benefits, discouraging the abuse of standard-setting processes, encouraging SSOs to play an active role in imposing policies that reduce such abuse and reducing complex competition law enforcement issues arising after standards adoption. Such benefits may also apply in Canada, although this would depend in part on whether standard-setting is occurring here.

1074 2006 IP and Competition Report, *supra* note 18 at 15.

3. Recommendations Regarding Reverse Payment Settlements

- ***We recommend conducting empirical research on the extent to which settlements of infringement litigation between generic and branded pharmaceutical companies occur within Canada (or occur elsewhere and impact Canada), and whether such settlements involve delayed generic competition in Canada in exchange for payment from the branded company.*** Is generic competition in Canada being negatively impacted by reverse payment settlements? Do reverse payment settlements outside of Canada impact competition in Canada? The EU has taken action against companies which, although located in and engaging in litigation outside of Europe, have reached agreements impacting Europe. Concern over anti-competitive harm arising from reverse payments does not require that agreements be struck within the jurisdiction and enforcement efforts should take this into account. The underlying question is whether the Bureau's 2007 finding that there is strong competition in the supply of generic drugs in Canada still holds true.

- ***If potentially anti-competitive reverse payment settlements are occurring in Canada (or occurring elsewhere and impacting Canada), we recommend implementing a system of filing of patent litigation settlement agreements and/or monitoring of such agreements in Canada by competition authorities.*** Such filing allows the tracking of trends in the terms and numbers of such settlements, and may influence the percentage of settlements that raise competition law concerns. Tracking would also allow Canadian competition authorities to review and challenge any reverse payment settlements that raise competition law concerns.

- ***We recommend the Bureau issue guidance on its position with respect to reverse payment settlements in Canadian competition law.*** The EC's draft revisions to its Technology Transfer Guidelines propose a new section with guidance on the EC's concern over reverse payment settlements. The U.S. effectively has recent guidance in the form of major decided court cases on reverse payment settlements. The Canadian IPEGs do not address reverse payment settlements. In developing Bureau guidance, and in assessing whether reverse payment settlements in the Canadian context are anti-competitive, relevant distinctions from the U.S. in the regulatory regime should be taken into account.

4. Recommendations Regarding Patent Assertion Entity Conduct

- ***We recommend that Canada conduct at least a preliminary assessment of the impacts, if any, of PAE conduct on the Canadian economy and competition in Canada.*** A litigation study would be helpful. Another important part of the assessment would be measuring broader economic impacts through consultation with industry members (including PAEs and producing companies). We see the latter aspect as important in assessing the ultimate impacts of PAEs, given that there are indications in literature that the economic costs of PAE activity may be greater than the costs from cases that reach the litigation stage.

5. Recommendations Regarding Product Hopping

- ***We recommend further research into the effect on generic competition arising from product hopping in Canada (or occurring elsewhere with impacts in Canada).***

– ***If the Bureau proceeds with a product hopping case, we recommend careful consideration of the cases and commentary in the U.S. and EU, including the challenges in distinguishing predatory innovation.***

XIII. FOLLOW-UP RESEARCH RECOMMENDATIONS

This report does not contemplate the role of international legal obligations of Canada in this debate, which could be a significant factor in shaping any reforms and may require further investigation.

Further, this report addresses to only a limited extent the role of patent law and patent litigation reforms in controlling anti-competitive conduct at the intersection of the patent and competition law regimes. As discussed in the objectives of this report, both patent law and general patent litigation reforms could play a significant role in Canada's approach to the issues discussed in this report and we recommend each be considered further.

Another potential topic for additional research is the implications for competition law and policy of the building and holding of patent portfolios. Although the topic is touched on in this report, it could be considered in further depth from the perspective of both merger analysis and potentially abuse of dominance.

Several follow-up research recommendations are also addressed in the Recommendations section, above.

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XV. GLOSSARY

"**ACCC**" – Australian Competition and Consumer Commission

"**ACIP**" – Australian Advisory Council on Intellectual Property

"*Act*" – Canadian *Competition Act*

"**Agencies**" – FTC and DOJ

"**AIA**" – *America Invents Act*

"**Bureau**" – Canadian Competition Bureau

"**CC**" – United Kingdom Competition Commission

"**CIPO**" – Canadian Intellectual Property Office

"**Commissioner**" – Commissioner of Competition, Canadian Competition Bureau

"**DOJ**" – United States Antitrust Division of the Department of Justice

"**EC**" – European Commission Directorate-General for Competition

"**FRAND**" – Fair, Reasonable and Non-Discriminatory

"**FTC**" – United States Federal Trade Commission

"***FTC Act***" – United States *Federal Trade Commission Act*

"**GAO**" – United States Government Accountability Office

"**IP**" – Intellectual Property

"**IPCRC**" – Australian Intellectual Property Competition Review Committee

"**IPEGs**" – Canadian Competition Bureau Intellectual Property Enforcement Guidelines

"**IPO**" – United Kingdom Intellectual Property Office

"**ITC**" – United States International Trade Commission

"**ITU**" – International Telecommunications Union

"**OFT**" – United Kingdom Office of Fair Trading

"**PAE**" – Patent Assertion Entity

"**PTO**" – United States Patent and Trademark Office

"***Regulations***" – Canadian *Patented Medicines (Notice of Compliance) Regulations*

"**SEP**" – Standard-essential patent

"**SSO**" – Standard setting organization

"**TFEU**"–Treaty on the Functioning of the European Union

"**Tribunal**"– Canadian Competition Tribunal

"**TTBER**" – European Union Technology Transfer Block Exemption Regulation

XVI. APPENDICES

APPENDIX A
OVERVIEW OF KEY CANADIAN COMPETITION ACT PROVISIONS

Section 32

Section 32 of the *Act* provides for special remedies where an intellectual property right has been used to prevent or lessen competition unduly. Specifically, it provides that an order may be made where use has been made of the exclusive rights and privileges conferred by a patent, trade-mark, copyright or registered integrated circuit topography so as to:

- limit unduly the facilities for transporting, producing, manufacturing, supplying, storing or dealing in any article or commodity that may be a subject of trade or commerce;
- restrain or injure, unduly, trade or commerce in relation to any such article or commodity;
- prevent, limit or lessen, unduly, the manufacture or production of any such article or commodity or unreasonably enhance the price thereof; or
- prevent or lessen, unduly, competition in the production, manufacture, purchase, barter, sale, transportation or supply of any such article or commodity.

Section 32 of the *Act* authorizes the Federal Court, exclusively on application by the Attorney General to issue remedial orders if it finds that a company has made such a use of IP. Pursuant to Section 32, the remedial orders issued may:

- declare any agreement or license relating to the anti-competitive use void;
- restrain any person from carrying out any or all of the terms of the agreement or license;
- order compulsory licensing of the intellectual property right (except in the case of trade-marks);
- expunge or amend a trade-mark; or
- direct that other things be done to prevent anti-competitive use of the intellectual property right.

Section 32 specifies that no order may be made under this section that is at variance with any treaty convention, arrangement or engagement with any other country respecting patent, trade-mark, copyright or registered integrated circuit topography.

Section 36

Section 36 of the Act permits any person who has suffered loss or damages as a result of (i) conduct that is contrary to any of the Act's criminal provisions (such as Section 45, explained below), or (ii) the failure to comply with a Tribunal or court order under the Act, to commence a civil action to recover damages from the person or persons who engaged in that conduct.

Section 45

Section 45 of the Act makes it a *per se* criminal offence for competitors (or potential competitors) to enter into agreements to: (i) fix, maintain, increase or control the price for the supply of a product (price-fixing agreements); (ii) allocate sales, territories, customers or markets for the production or supply of a product (market allocation/division agreements); or (iii) fix, maintain, control, prevent, lessen or eliminate the production or supply of a product (supply restriction agreements).

Section 90.1

Section 90.1 is a civil provision that applies to agreements between competitors (or potential competitors) that are not caught by the per se offences but that have the effect, or are likely to have the effect, of lessening or preventing competition substantially. Section 90.1 is intended to apply to agreements between competitors that may have an anti-competitive effect but that do not involve the "naked restraints" targeted by the Act's criminal conspiracy offences in section 45.

Section 78 and 79

The Commissioner of Competition may apply to the Tribunal for relief against "abuses of dominance", and the Tribunal may grant the Commissioner's application pursuant to Section 79 if it finds that:

- a person (or persons) substantially or completely controls a type of business throughout Canada or any part of Canada;
- such person or persons are engaging in or have engaged in a practice of anti-competitive acts (defined non-exhaustively under section 18); and
- the practice has had, is having or will likely have the effect of preventing or lessening competition substantially.

Private applications to the Tribunal are not permitted and private civil actions are not possible for contravention of the abuse of dominance provisions of the *Act*.

Section 78 sets out certain anti-competitive acts, but is not considered exhaustive.

Section 75

Section 75 of the Act provides that a supplier may be prohibited from refusing to deal with a customer where:

- the refusal to deal has a "substantial effect" on the business of the customer or precludes the customer from carrying on business;
- the customer is not able to obtain adequate supplies of the product anywhere in the market on usual trade terms because of insufficient competition among suppliers of the product in the market;
- the customer is willing and able to meet the usual trade terms of the suppliers;
- the product is in ample supply; and

– the refusal to deal is having or is likely to have an "adverse effect on competition in a market".

Should these elements be satisfied, the Tribunal may order the supplier to accept the party as a customer on usual trade terms.

Section 76

The price maintenance provisions of the Act may apply where a supplier, by agreement, threat promise or any like means, directly or indirectly influences upward (or discourages the reduction of) the price at which the supplier's customer, or any other person (e.g., a retailer) to whom the product comes for resale, supplies or offers to supply or advertises a product within Canada.

The provisions may also apply where a supplier refuses to supply or otherwise discriminates against any person because of the low pricing policy of that person. Further, the provisions may be engaged where a person (e.g., a retailer) has, by an agreement, threat, promise or like means, induced a supplier, as a condition of doing business, to refuse to supply another person (e.g., a competing retailer) because of the low pricing policy of that other person.

The Tribunal may issue an order prohibiting the conduct, if the challenged conduct had or is having (or is likely to have) an adverse effect on competition in a market.

Section 77

The Tribunal may grant relief where it finds that a "major supplier of a product in a market" has engaged in the following types of conduct that have the effect of lessening competition substantially:

– Exclusive dealing: This occurs when a purchaser is required as a condition of sale, or is induced by favourable terms, to deal only or primarily in particular products (or to refrain from dealing in a specified class or kind of products).

– Tied selling: This occurs when a purchaser is required as a condition of sale of a product, or is induced by favourable terms, to purchase another product or to refrain from using or distributing another product.

– Market restriction: This occurs when a supplier, as a condition of sale, imposes restrictions on the market in which its customer may deal, or when a supplier exacts a penalty if its customer supplies any product outside of a specified market. Market restrictions impose limitations on geographic territories or on categories of customers.

Section 92

The provision provides that where on application by the Commissioner of Competition the Tribunal finds that a merger or proposed merger prevents or lessens (or is likely to prevent or lessen) competition substantially the Tribunal may prohibit the parties from proceeding with the merger or impose various other remedies.

APPENDIX B
FTC 2007 AND 2011 REPORTS ON INTELLECTUAL PROPERTY AND COMPETITION LAW TOPICS

The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition (2011)

The FTC recommendations in its report *The Evolving IP Marketplace: Aligning Patent Notice and Remedies with Competition* (2011) include:

1. Improving policies relevant to the patent notice function:

   > making patent claims more definite and improving the utility of descriptions in patents for delineating their boundaries;

   > enhancing the patent examination record as a source for interpreting claim scope; and

   > more fully incorporating consideration of third parties' ability to predict the potential breadth of evolving claims into the administrative and judicial review of the written descriptions of patent applications.

2. Grounding damages calculations and injunction analysis in economic principles that recognize competition among patented technologies by:

   > capping reasonable royalty damages at the amount a willing licensee would pay, which may be determined by the value of the invention over alternative technologies;

   > increasing the role of district courts in excluding unreliable expert testimony on damages from trial; and

   > incorporating concerns into the injunction analysis about the leverage that an injunction may give a patentee to obtain royalties exceeding the economic value of an invention.

Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition (2007)

The FTC and DOJ set out the following conclusions on enforcement policy in their report *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition* (2007):[1075]

> Antitrust liability for mere unilateral, unconditional refusals to license patents will not play a meaningful part in the interface between patent rights and antitrust protections. Antitrust liability for refusals to license competitors would compel firms to reach out and affirmatively assist their rivals, a result that is in tension with the antitrust laws.

> Conditional refusals to license that cause competitive harm are subject to antitrust scrutiny.

[1075] See the summary online at http://www.ftc.gov/news-events/press-releases/2007/04/federal-trade-commission-and-department-justice-issue-report and the full report available at http://www.ftc.gov/policy/reports

- Joint negotiation of licensing terms by standard-setting organization participants before the standard is set can be pro-competitive. Such negotiations are unlikely to constitute a *per se* antitrust violation. The agencies will usually apply a rule of reason analysis when evaluating these joint activities.

- The agencies evaluate the competitive effects of cross-licenses and patent pools under the rule of reason framework articulated in the 1995 Antitrust-IP Guidelines.

- Combining complementary patents within a pool is generally pro-competitive. A combination of complementary intellectual property rights, especially those that block the use of a particular technology or standard, can be an efficient and pro-competitive way to disseminate those rights to would-be users of the technology or standard. Including substitute patents in a pool does not make the pool presumptively anti-competitive–competitive effects will be ascertained on a case-by-case basis.

- The agencies apply a rule of reason analysis to assess intellectual property licensing agreements, including non-assertion clauses, grantbacks, and reach-through royalty agreements.

- The 1995 Antitrust-IP Guidelines will continue to guide the agencies' analysis of intellectual property tying and bundling. The agencies consider both the anti-competitive effects and the efficiencies attributable to a tie, and would be likely to challenge a tying arrangement if: (1) the seller has market power in the tying product, (2) the arrangement has an adverse effect on competition in the relevant market for the tied product, and (3) efficiency justifications for the arrangement do not outweigh the anti-competitive effects. If a package license constitutes tying, the agencies will evaluate it under the same principles they use to analyze other tying arrangements.

- The agencies consider both the anti-competitive effects and the efficiencies attributable to a tie or bundle involving intellectual property.

- The starting point for evaluating practices that extend beyond a patent's expiration is an analysis of whether the patent in question confers market power. If so, these practices will be evaluated under the agencies' traditional rule of reason framework, unless the agencies find a particular practice to be a sham cover for naked price fixing or market allocation.

- Collecting royalties beyond a patent's statutory term can be efficient. Although there are limitations on a patent owner's ability to collect royalties beyond a patent's statutory term, see *Brulotte v. Thys Co.*, 379 U.S. 29 (1964), that practice may permit licensees to pay lower royalty rates over a longer period of time which can reduce the deadweight loss associated with a patent monopoly and allow the patent holder to recover the full value of the patent, thereby preserving innovation incentives.

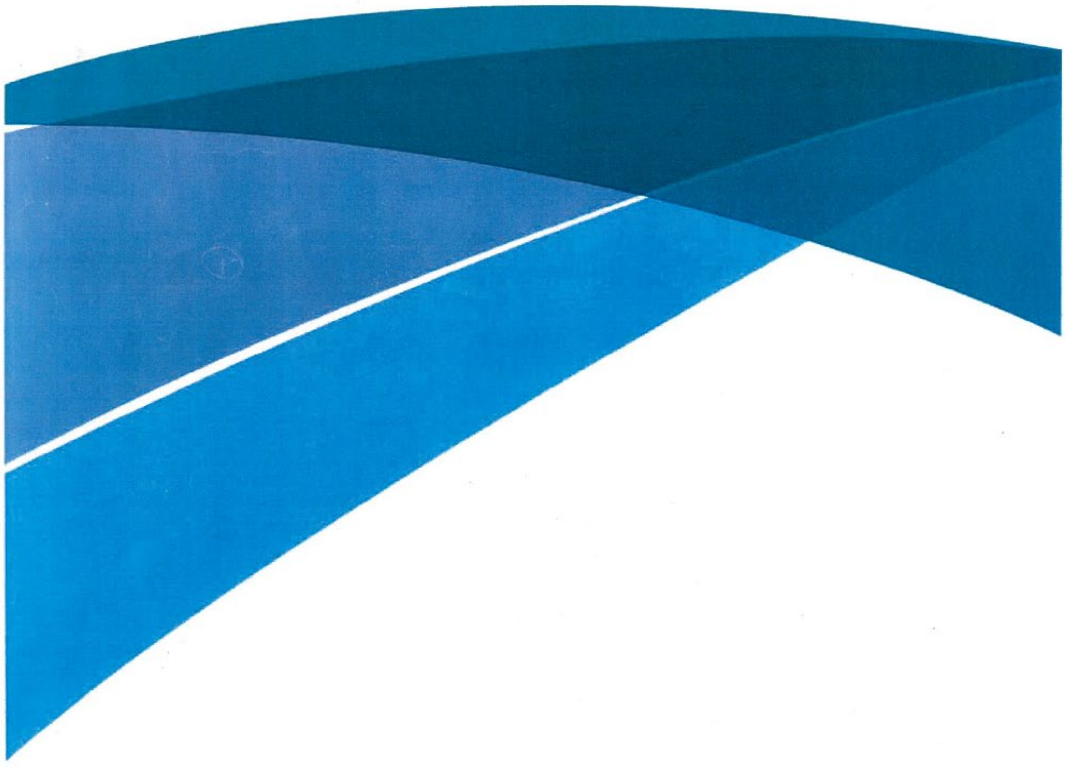
APPENDIX C
MEMORANDUM OF UNDERSTANDING BETWEEN THE U.K. INTELLECTUAL PROPERTY OFFICE AND THE OFFICE OF FAIR TRADING

INTELLECTUAL PROPERTY OFFICE

OFFICE OF FAIR TRADING

Memorandum of Understanding between the Intellectual Property Office and the Office of Fair Trading

July 2012



Intellectual Property Office is an operating name of the Patent Office

Memorandum of Understanding between the Intellectual Property Office (IPO), and the Office of Fair Trading (OFT)

Introduction

1. This Memorandum of Understanding (MoU) establishes a framework for cooperation and constructive communication between the Office of Fair Trading (OFT) and the Intellectual Property Office (IPO).

2. It is not intended that this MoU be legally binding.

3. The OFT and IPO have entered into this MOU as they are cognisant that properly functioning, competitive markets have a vital role to play in stimulating economic growth and in encouraging innovation in goods and services. In fulfilling this objective, Intellectual property (IP) and competition law have complementary roles.

Role of the OFT

4. The OFT's mission is to make markets work well for consumers. It has a range of tools at its disposal to address market failures and make markets work well for consumers. In many cases, the OFT uses a combination of tools to address failures in a holistic way. It also works in partnership with other organisations which have complementary powers or influence in relation to markets.

5. The OFT has a dual competition and consumer mandate and it has a broad remit. Most of its work consists of:
   - analysing markets;
   - enforcing consumer and competition law;
   - undertaking advocacy; and
   - working with partners to deliver education programmes to businesses and consumers.

6. The OFT's legal powers are conferred on it by several pieces of legislation including the Enterprise Act 2002 (EA02) and the Competition Act 1998 (CA98). In particular, the OFT has powers to investigate businesses suspected of infringing the prohibitions in the Competition Act 1998 and Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU) (formerly Articles 81 and 82 of the Treaty establishing the European Community (EC Treaty)), against anti-competitive agreements (such as cartels) and abuse of a dominant market position.

Role of the IPO

7. The IPO (whose current legal title is The Patent Office) is an Executive Agency of the Department for Business, Innovation and Skills. Its purpose is to promote innovation by providing a clear, accessible and widely understood IP system, which enables the economy and society to benefit from knowledge and ideas. The IPO's core activities are as follows:
   - the granting of patents and registering of trade marks and designs;
   - advising Ministers on the development and implementation of UK and international IP policy;
   - raising awareness of the use of IP as a tool for enhancing innovation and improving businesses' access to effective IP advice from the public and the private sectors; and
   - raising awareness of IP crime and coordinating efforts to build capacity in enforcement agencies.

General co-operation

8. The IPO and the OFT will endeavour to share knowledge, expertise and best practice in relation to any matters of mutual interest, and will consider secondments of staff. The IPO and the OFT may permit such secondments to the extent that they are appropriate, consistent with priorities and resources allow.

9. Within the bounds of any legal constraints on the sharing of information and as appropriate, this may include sharing of information on specific complaints, policy proposals or developments, including in respect of the following:
   - OFT enforcement activity.
   - OFT market studies.
   - Development of policy and regulation having an impact on IP and competition.
   - Advocacy – including raising awareness of IP and competition issues among stakeholders in both fields.

10. Where appropriate and feasible, and within the bounds of any legal constraints, IPO and OFT may also provide each other with technical, and/or policy assistance on projects that touch on matters of mutual interest.

Regular engagement

11. OFT and IPO officials will meet regularly, at least quarterly, to discuss matters of mutual interest and the operation of this MoU. In between those meetings, developments of mutual significance will be shared as quickly as possible. Where appropriate, and to the extent permitted by any relevant legal constraints, the IPO or OFT will afford officials from the other party observer status at relevant meetings.

Referral of competition concerns

12. The IPO may refer to the OFT any concerns it has in respect of competition and/or consumer protection issues that arise from, or relate to, IP rights. The IPO shall, within the bounds of any legal constraints on the sharing of information, provide the OFT with all information at its disposal that is relevant to the concerns it has referred. The OFT will give due consideration to the referral and will respond to the IPO stating what action, if any, the OFT proposes to take in respect of the concerns referred. Decisions on any action that might be taken by the OFT will, along with any other relevant considerations, be informed by the Prioritisation Principles currently applied by the OFT.

Review of the MoU

13. The MoU will be reviewed as appropriate. Any changes will be subject to the agreement of both parties.

Signed by ..... Date 31 July 2012.

Rosa Wilkinson, Director of Innovation, Intellectual Property Office

Signed by ..... Date 26/7/12

Jackie Holland, Senior Director, Office of Fair Trading

APPENDIX D
FTC REVERSE PAYMENT SETTLEMENT CASES

Case Name	Result
Abbott/Geneva (Hytrin/terazosin)	Consent order (2000)
Hoechst/Andrx (Cardizem)	Administrative litigation & consent order (2001)
American Home Products (K-Dur)	Administrative litigation & consent order (2002)
Bristol-Myers Squibb (BuSpar)	Consent order (2003)
Schering/Upsher-Smith (K-Dur)	Administrative litigation,11th Circuit appeal, Supreme Court denied cert (2006)
FTC v. Cephalon (Provigil)	Currently in E.D. Pa. (2008)
FTC v. Actavis (AndroGel)	Supreme Court decision (2013) on analytical standard, remanded

APPENDIX E
FTC PROPOSED QUESTIONS FOR PATENT ASSERTION ENTITIES

FEDERAL TRADE COMMISSION

Agency Information Collection Activities;

Proposed Collection; Comment Request

AGENCY: Federal Trade Commission (FTC).

ACTION: Notice and request for public comment.

SUMMARY: The FTC is soliciting public comments on proposed information requests to Patent Assertion Entities ("PAEs") and other entities asserting patents in the wireless communications sector, including manufacturers and other non-practicing entities and organizations engaged in licensing. For purposes of this notice, PAEs are firms with a business model based primarily on purchasing patents and then attempting to generate revenue by asserting the intellectual property against persons who are already practicing the patented technology.[1]

These comments will be considered before the FTC submits a request for Office of Management and Budget (OMB) review of the compulsory process orders described in this notice under the Paperwork Reduction Act (PRA). The compulsory process orders will seek information from those firms concerning, among other things, patent acquisition, litigation, and licensing practices.

DATES: Comments must be received on or before **[insert date 60 days from the date of publication in the FEDERAL REGISTER]**.

ADDRESSES: Interested parties may file a comment online or on paper, by following the instructions in the Request for Comment part of the **SUPPLEMENTARY INFORMATION** section below. Write "PAE Reports: Paperwork Comment; Project No. P131203" on your comment, and file your comment online at https://ftcpublic.commentworks.com/ftc/paestudypra,by following the instructions on the web-based form. If you prefer to file your comment on paper, mail or deliver your comment to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex J), 600 Pennsylvania Avenue, NW, Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be addressed to William F. Adkinson, Jr., Attorney Advisor, Office of Policy Planning, Federal Trade Commission, 600 Pennsylvania Avenue, NW, Washington DC, 20580; (202) 326-2096; paestudy@ftc.gov.

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[1] The Commission distinguishes PAEs from other non-practicing entities or NPEs that primarily seek to develop and transfer technology, such as universities, research entities and design firms. FED. TRADE COMM'N, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION, 8 n.5 (2011), *available at* http://www.ftc.gov/os/2011/03/110307patentreport.pdf.

SUPPLEMENTARY INFORMATION: On December 10, 2012, the FTC and the Antitrust Division of the United States Department of Justice (DOJ) jointly sponsored a workshop to explore the impact of PAE activity on innovation and competition.[2] The FTC and DOJ also received public comments in conjunction with the workshop. While workshop panelists and commenters identified potential harms and efficiencies of PAE activity, they noted a lack of empirical data in this area, and recommended that the Federal Trade Commission use its authority under Section 6(b) of the Federal Trade Commission Act, 15 U.S.C. § 46(b), to collect information on PAE acquisition, litigation, and licensing practices. Senator Amy Klobuchar and Representative Daniel Lipinski likewise have called on the Commission to conduct a Section 6(b) study of PAE activity.[3] Responding to these requests, and recognizing its own role in competition policy and advocacy, the Commission proposes a Section 6(b) study that will provide a better understanding of PAE activity and its costs and benefits.

I. Description of the Collection of Information and Proposed Use

The proposed study will add significantly to the existing literature and evidence on PAE behavior. Earlier studies have focused primarily on publicly available litigation data and concluded that PAE litigation activity is on the rise. The Commission, however, has unique Congressional authority to collect nonpublic information, such as licensing agreements, patent acquisition information, and cost and revenue data, which will provide a more complete picture of PAE activity.

Because the Commission believes a broader study will enhance the quality of the policy debate surrounding PAE activity, it proposes information requests directed to the following questions:

- How do PAEs organize their corporate legal structure, including parent and subsidiary entities? (Request B)
- What types of patents do PAEs hold, and how do they organize their holdings? (Request C & D)
- How do PAEs acquire patents, and how do they compensate prior patent owners? (Request E)
- How do PAEs engage in assertion activity (i.e. demand, litigation, and licensing behavior)? (Request F)
- What does assertion activity cost PAEs? (Request G); and
- What do PAEs earn through assertion activity? (Request H)

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[2] *See* Patent Assertion Entity Activities Workshop, Fed. Trade Comm'n, http://www.ftc.gov/opp/workshops/pae/.

[3] Letter from Senator Amy Klobuchar to The Honorable Edith Ramirez, Chairwoman, The Honorable Julie Brill, Commissioner, The Honorable Maureen K. Ohlhausen, Commissioner, and The Honorable Joshua D. Wright, Commissioner (June 24, 2013), and Letter from Representative Daniel Lipinski to The Honorable Edith Ramirez, Chairwoman (June 25, 2013).

The FTC proposes to send these information requests to approximately 25 PAEs (PAE Firms). To understand how PAE behavior compares with patent assertion activity by other patent owners, the FTC also proposes sending information requests to approximately 15 other entities asserting patents in the wireless communications sector, including manufacturing firms (Manufacturing Firms), and other non-practicing entities and organizations engaged in licensing (Other Firms).

Definitions

The following definitions apply to Information Requests A-H:

"**Acquire**" and "**Acquisition**" mean to purchase or obtain all legal rights to a Patent from another Person.

"**Assert**," "**Assertion**," and "**Asserted**" mean: (i) any attempt to license any Patent, in whole or in part, including any communication relating to licensing of the Patent, (ii) any communication relating to alleged infringement of the Patent by the recipient of the communication, (iii) any Demand that a Person obtain a license, or (iv) any civil action threatened or filed (by the Firm or other Person) relating to any Patent.

"**Class**," "**Subclass**," and "**Art Unit**" have the meanings defined by the United States Patent and Trademark Office (USPTO).

"**Firm**" means the Person or entity served with the information requests described in this notice and also includes all domestic and foreign parents, predecessors, divisions, subsidiaries, affiliates, partnerships and joint ventures, directors, officers, employees, agents, representatives, and all other persons acting or purporting to act on its behalf, regardless of how it is legally organized and established.

"**Demand**" means any communication, whether by letter or otherwise, to any Person, Relating to any effort to Assert Patent(s) held by the Firm since January 1, 2008. Demand does not include complaints or pleadings filed with a United States District Court or the United States International Trade Commission.

"**Economic Interest**" means rights or claims to current or future revenues derived from a Patent, whether as lump sum payments, royalty streams, or access to other Patents as part of a cross-licensing agreement.

"**Litigation**" means any civil action arising from a complaint filed in a United States District Court or with the United States International Trade Commission.

"**Maintenance Fee(s)**" has the meaning defined by the USPTO.

"**Patent**" means a United States patent or United States patent application as defined by 35 U.S.C. §§101, *et seq*.

"**Patent Portfolio**" means a collection of patents held by a single entity, including all of the patents held by the entity and any sub-groups into which the entity organizes its patents.

"**Person**" means any natural person, corporation, association, Firm, partnership, joint venture, trust, estate, agency, department, bureau, governmental, judicial, or legal entity, however organized or established.

"**Relating to**" means, in whole or in part, addressing, analyzing, concerning, constituting, containing, commenting, in connection with, dealing with, discussing, describing, identifying, reflecting, stating, or summarizing.

"**Standard-Setting Organization**" or "**SSO**" means any organization, group, joint venture or consortia that develops standards for the design, performance or other characteristics of products or technologies.

Information Requests

The FTC will have PAE Firms and Other Firms respond to Information Requests A-H. The FTC will have Manufacturing Firms respond to Information Requests A-B and E-H. The instructions will specify the Information Requests to which the Firm is required to respond.

A. Identification of Report Author: Identify by full name, title, business address, telephone number, and official capacity the Person(s) who prepared or supervised the preparation of the Firm's response to the Information Requests and specify the steps taken by the Firm to respond to the Information Requests.

B. Company Information:

1. State the Firm's complete legal name and all other names under which it has done business, its corporate mailing address, all addresses from which it does or has done business, and the dates and states of its incorporation.
2. Describe the Firm's business or corporate structure, and state the names of all parents, subsidiaries (whether wholly or partially owned), divisions (whether incorporated or not), affiliates, branches, joint ventures, franchises, operations under assumed names, websites, or entities over which the Firm exercises supervision or control, or any other Person(s) or entities with a contractual or other legal right to a share of revenues, profits, or other Economic Interest tied to profitability or financial performance of the Firm. For each such entity, describe the relationship with the Firm, including the percentage of ownership, control, or other legal entitlement to a share of revenues, profits or financial performance between the Firm and the entity. When responding to Requests A-H, provide all information for the Firm and all related entities identified in response to this request.
3. Identify each Person or entity having an ownership interest in the Firm, or other legal entitlement to share in the financial performance of the Firm, as well as their individual ownership or financial performance stakes, and, if relevant, their positions and responsibilities within the Company.

C. Patent Information:

1. Identify each Patent held by the Firm since January 1, 2008, and specify:
    a. the Patent number;
    b. the date the Patent was acquired;
    c. the Patent title;

d. the Patent's Class, Subclass, and Art Unit;

e. the Patent's filing date;

f. the Patent's issuance date;

g. the Patent's expiration date;

h. the maintenance status of the Patent, including whether the Patent has expired for failure to pay Maintenance Fees;

i. whether the Firm is engaged in pre-grant prosecution for any identified Patent application;

j. whether the Firm has abandoned any identified Patent application;

k. whether the Firm is engaged in post-grant prosecution for any identified Patent, and describe the nature of the post-grant prosecution;

l. whether the Firm has engaged in any research and development activities Relating to the Patent, and specify the nature and estimated cost of this research and development activity;

m. whether any Person(s), other than the Firm, holds any legal rights to the Patent. As part of your response:

   (1) identify the Person(s) who holds any legal rights to the Patent;

   (2) describe the nature of the legal rights held;

   (3) submit all documents(s) Relating to the legal rights held;

n. whether any Person, other than the Firm, has an Economic Interest in the Patent, and:

   (1) identify the Person(s) who hold an Economic Interest in the Patent;

   (2) describe the nature of the Economic Interest held by the Person(s);

   (3) submit all documents Relating to this Economic Interest;

o. whether the Patent (or any claims therein) is subject to a licensing commitment made to a Standard-Setting Organization and specify:

   (1) all Standard-Setting Organizations to which a licensing commitment has been made;

   (2) all standards to which such a licensing commitment applies;

   (3) the Person(s) who made the licensing commitment;

   (4) the date(s) on which the licensing commitment was made;

   (5) all encumbrances, including, but not limited to, all commitments to license the Patent or any of its claims on reasonable and non-discriminatory (RAND), fair, reasonable, and non-discriminatory (FRAND), or royalty-free (RF) terms;

p. whether the Firm has included the Patent in any Demand;

q. whether the Firm has Litigated the Patent; and

r. whether the Firm has licensed the Patent to any Person(s).

2. Provide the assignment and Assertion history for each Patent held by the Firm since January 1, 2008. As part of your response, specify:

a. all Person(s) to whom the Patent was assigned before the Firm Acquired the Patent and the date(s) of assignment;

b. all Person(s) to whom the Patent was licensed before the Firm Acquired the Patent and the date(s) and term(s) of license;

c. whether the Patent was Asserted before the Firm Acquired the Patent, and list the Person(s) who Asserted the Patent, the Person(s) against whom the Patent was Asserted and identify whether the Assertion resulted in Litigation(s) or license(s):

(1) if the Assertion identified in C.2.c resulted in Litigation, provide all information requested in Request F.2;

(2) if the Assertion identified in C.2.c resulted in a license agreement, provide all information requested in F.3;

(3) state whether the Assertion identified in C.2.c involved a technology transfer provision, and provide all technology transfer agreements Relating to this response.

3. Submit all documents Relating to any communication since January 1, 2008 between the Firm and any investor or potential investor, financial or otherwise, Relating to any Patent(s) held by the Firm since January 1, 2008.

D. Patent Portfolio Information:

1. Describe all Patent Portfolios held by the Firm since January 1, 2008; and specify:

a. how the Firm organizes the Patent Portfolio(s);

b. the numbers of the Patents included in the Patent Portfolio(s); and

c. the Firm's valuation of the Patent Portfolio(s) and the date of the valuation.

2. Submit all documents Relating to the Firm's reasons or business strategy for organizing the Patent(s) into Portfolio(s), including but not limited to, market analyses, financial analyses, business plans, statements to investors and potential investors, and disclosures required by the Securities and Exchange Commission or any other Person.

E. Patent Acquisition and Transfer Information:

1. For each Patent Acquired by the Firm since January 1, 2008, state whether the Firm Acquired the Patent individually or as part of a Patent Portfolio, and provide the following information:

    a. for all Patents that the Firm Acquired individually, identify the Patent, and specify:

        (1) the Person(s) from whom the Firm Acquired the Patent and state whether that Person(s) was the original inventor;

        (2) the date on which the Firm Acquired the Patent;

        (3) whether the Patent was Acquired in bankruptcy;

        (4) the financial terms of the Firm's Acquisition of the Patent. As part of your response, specify:

            (a) whether the Firm paid a lump sum, the amount of the lump sum; the Person(s) to whom the lump sum was paid, and the date the payment was made;

            (b) whether the Firm paid, or is paying, an ongoing payment, and specify:

                i. how the ongoing payment is calculated;

                ii. the total amount of the ongoing payment paid as of the date of this Request;

                iii. the amount of each individual payment paid as of the date of this Request, the Person(s) to whom each payment was made, and the date of each payment;

                iv. the total amount of the ongoing payment expected to be paid in the future, and all Person(s) expected to receive future payments;

            (c) whether another Person(s) contributed financially to the purchase of the Patent(s), and if so, identify the Person(s) and percentage share of ownership or other legal entitlement to the licensing or other revenue derived from such Patent(s).

    b. for all Patents that the Firm Acquired as part of a Patent Portfolio, specify:

        (1) all Patents included in the Patent Portfolio;

        (2) the Person(s) from whom the Firm Acquired the Patent Portfolio;

        (3) the date on which the Firm Acquired the Patent Portfolio;

        (4) the circumstances in which the Firm Acquired the Patent Portfolio, including, but not limited to, whether the Patent Portfolio was

Acquired in bankruptcy, or whether it was acquired from the original inventor;

(5) the financial terms of the Firm's Acquisition of the Patent Portfolio; As part of your response, specify:

(a) whether the Firm paid a lump sum, the amount of the lump sum; the Person(s) to whom the lump sum was paid, and the date the payment was made;

(b) whether the Firm paid, or is paying, an ongoing payment, and specify:

i. how the ongoing payment is calculated;

ii. the total amount of the ongoing payment paid as of the date of this Request;

iii. the amount of each individual payment paid as of the date of this Request; the Person(s) to whom each payment was made; and the date of each payment;

iv. the total amount of the ongoing payment expected to be paid in the future; and all Person(s) expected to receive future payments; and

(c) whether another Person(s) contributed financially to the purchase of the Patent Portfolio, and if so, identify the Person(s) and percentage share of ownership or other legal entitlement to the licensing or other revenue derived from such Patent(s).

2. Identify each Patent the Firm has sold or transferred since January 1, 2008. As part of your response, specify:

a. the Person(s) who Acquired the Patent;

b. the date(s) on which the Person(s) Acquired the Patent;

c. the financial terms of the Person(s)' Acquisition of the Patent. As part of your response, specify:

(1) whether the Person(s) paid a lump sum, the amount of the lump sum, the Person(s) to whom the lump sum was paid, and the date the payment was made;

(2) whether the Person(s) paid, or is paying, an ongoing payment, and specify:

(a) how the ongoing payment is calculated;

(b) the total amount of the ongoing payment paid as of the date of this Request;

(c) the amount of each individual payment paid as of the date of this Request, the Person(s) to whom each payment was made; and the date of each payment;

(d) the total amount of the ongoing payment expected to be paid in the future, and all Person(s) expected to receive future payments, and

(3) whether another Person(s) contributed financially to the purchase of the Patent(s), and if so, identify the Person(s) and percentage share of ownership or other legal entitlement to the licensing or other revenue derived from such Patent(s).

3. Identify any Patent not identified in response to E.1 or E.2 for which, since January 1, 2008, the Firm has had standing to sue and submit a copy of the license agreement that grants the Firm standing to sue.

4. Submit the Patent purchase or Acquisition agreement for all Acquisitions identified in response to Request E.1.

5. Submit all documents Relating to the Firm's Acquisitions identified in response to Request E.1, including but not limited to, market analyses, financial analyses, business plans, statements to investors and potential investors, and disclosures required by the Securities and Exchange Commission or any other Person.

6. Submit all documents Relating to the Firm's sales and transfers identified in response to Request E.2, including but not limited to, market analyses, financial analyses, business plans statements to investors and potential investors, and disclosures required by the Securities and Exchange Commission or any other Person.

F. Patent Assertion Information:

1. Demand Information:

a. identify all Demands sent by, or on behalf of the Firm since January 1, 2008 and specify:

(a) all Person(s) to which the Demand was sent;

(b) the Patent(s) Relating to the Demand;

(c) the total time spent and costs incurred by the Firm, or any Person working on behalf of the Firm, for any research Relating to the Demand, including but not limited to any attempt to compare the allegedly infringing product(s) or process(es) with the Asserted Patent claims;

(d) any Litigation initiated by the Firm Relating to the Demand, and the outcome of any such Litigation;

(e) any license agreement Relating to the Demand;

(f) any revenue obtained by the Firm Relating to each Demand, separately listed for each year since January 1, 2008, and for each Patent Portfolio held by the Firm.

b. for each year since January 1, 2008, identify the Firm's total expenses Relating to all Demands identified in response to Request F.1;

c. for each year since January 1, 2008, identify the Firm's total revenue Relating to all Demands identified in response to Request F.1;

d. submit a copy of each Demand identified in response to Request F.1, and all documents reflecting communications Relating the Demand;

e. submit all documents that reflect business strategy or financial research Relating to the Demand(s) identified in response to Request 6.A; and

f. submit all license or settlement agreements Relating to the Demand.

2. Litigation Information:

a. identify all Litigation(s) pending since January 1, 2008 to which the Firm is a party involving any Patent(s) held by the Firm since January 1, 2008. As part of your response, specify:

(1) whether the Firm is a plaintiff or defendant in the Litigation;

(2) the Patent(s) and claim(s) Asserted;

(3) the court, date filed, docket number, parties, current or final status (including dates);

(4) the remedies sought in the Litigation, including, but not limited to damages, enhanced damages, injunctive relief, or an exclusion order;

(5) whether the Patent was found infringed, invalid, or unenforceable and whether an injunction or an exclusion order issued;

(6) whether past damages were awarded, and the amount of any such award;

(7) whether future damages were awarded, and all projected revenue expected by the Firm as a result of the award for future damages, by year, together with the method for calculating future damages (e.g. as a fraction of revenue or a fee per unit sold);

(8) if the Litigation resulted in a settlement agreement, provide a copy of that agreement and specify:

(a) the stage of Litigation at which settlement was reached, e.g. before an order on a motion to dismiss, before an order on a motion for summary judgment;

(b) whether the Court issued an order construing any claim(s) of the Patent(s) Asserted before settlement was reached;

(c) the terms of the settlement agreement, and if the settlement included a license or cross-license, all licensing information requested in Request F.3;

(9) for each year since January 1, 2008, the costs the Firm incurred for the Litigation;

b. for each Litigation identified in Response to Request F.2, submit all orders Relating to disposition of any dispositive motions;

c. state whether the Firm has any contingency fee agreement(s) Relating to any Litigation(s) identified in response to Request F.2; and specify:

(1) the Person(s) with whom the Firm shares the contingency fee agreement(s);

(2) how the contingency fee is calculated;

(3) for each year since January 1, 2008, the amount paid pursuant to the contingency fee arrangement; and

(4) submit a copy of the contingency fee agreement(s).

3. License Information:

a. identify all license agreements the Firm entered into with any other Person(s) since January 1, 2008 Relating to any Patent(s) held by the Firm since January 1, 2008. As part of your response, specify:

(1) the Patent(s) licensed;

(2) the date and length of the license agreement;

(3) the licensor(s) and licensee(s);

(4) whether the license agreement Relates to any Litigation. As part of your response:

(a) identify the Litigation to which the license agreement Relates;

(b) for license agreements Relating to any Litigation, state when settlement was reached and when the license agreement was executed, e.g. after an order on a dispositive motion, on the eve of trial;

(c) state whether the Court issued an order construing any claim(s) of the Patent(s) Asserted before the license agreement was executed;

(5) all revenue obtained by the Firm Relating to each license agreement, separately listed for each year since January 1, 2008, and for each Patent Portfolio held by the Firm; and specify:

(a) the effective royalty rate, and the base to which it is to be applied;

(b) state whether this revenue was shared with any Person;

(c) identify the Person and the revenue shared;

(d) submit the revenue sharing agreement(s);

(6) all projected revenue expected by the Firm as a result of the license agreement, by year, and the method for calculating the projected revenue, e.g. as a fraction of revenue or a fee per unit sold;

(7) whether the license agreement includes any cross-license, and submit a copy of the cross-license;

(8) whether the Firm conducted a valuation of the cross-license, and submit all documents Relating to the valuation; and

(9) whether the license agreement includes any provisions for technology transfer from the Firm to the licensee(s).

4. For each license agreement identified in Response to Request F.3, submit a copy of the agreement and all documents Relating to the agreement, including but not limited to, documents reflecting communications Relating to the license, documents summarizing sales made by the licensee, and documents reflecting arrangements to share revenue generated by the license.

5. Submit all documents Relating to the Firm's rationale for all Assertions identified in response to Request F, including but not limited to, market analyses, financial analyses, business plans, statements to investors and potential investors, and disclosures required by the Securities and Exchange Commission or any other Person.

6. Submit all documents Relating to the Firm's projected gross revenue or return-on-investment for all Assertions identified in response to Request F, including, but not limited to, market analyses, financial analyses, business plans, statements to investors and potential investors, and disclosures required by the Securities and Exchange Commission or any other Person.

G. Aggregate Cost Information:

1. For each year since January 1, 2008, identify:

   a. the total cost to and amount paid by the Firm Relating to all Acquisitions identified in response to Request E.1. State whether the Firm shares any fraction of this cost with any Person(s), and if the answer is yes, specify:

      (1) the Person(s) with whom costs are shared;

      (2) how this amount is calculated;

      (3) the total cost shared to date;

      (4) any cost expected to be shared in the future;

   b. the total cost to and amount paid by the Firm Relating to all Assertions identified in response to Request F, and specify:

(1) the total cost to and amount paid by the Firm Relating to all Demands identified in response to Request F.1. State whether the Firm shares any fraction of this cost with any Person(s), and if the answer is yes, specify:

(a) the Person(s) with whom costs are shared;

(b) how this amount is calculated;

(c) the total cost shared to date;

(d) any cost expected to be shared in the future;

(2) the total cost to and amount paid by the Firm Relating to all Litigations identified in response to Request F.2. State whether the Firm shares any fraction of this cost with any Person(s), and if the answer is yes, specify:

(a) the Person(s) with whom costs are shared;

(b) how this amount is calculated;

(c) the total cost shared to date;

(d) any cost expected to be shared in the future;

(3) the total cost to and amount paid by the Firm Relating to all License Agreements identified in response to Request F.3. State whether the Firm shares any fraction of this cost with any Person(s), and if the answer is yes, specify:

(a) the Person(s) with whom costs are shared;

(b) how this amount is calculated;

(c) the total cost shared to date; and

(d) any cost expected to be shared in the future.

2. Submit all documents Relating to all costs and payments identified in response to Request G.

H. Aggregate Revenue Information:

1. For each year since January 1, 2008, identify:

a. the total revenue received by the Firm Relating to all transfers identified in response to Request E.2. State whether the Firm shares any fraction of this revenue with any Person(s), and if the answer is yes, specify:

(1) the Person(s) with whom revenue is shared;

(2) how this amount is calculated;

(3) the total revenue shared to date;

(4) any revenue expected to be shared in the future;

b. the total revenue received by the Firm Relating to all Assertions identified in response to Request F, and specify:

(1) the total revenue received by the Firm Relating to all Demands identified in response to Request F.1. State whether the Firm shares any fraction of this revenue with any Person(s), and if the answer is yes, specify:

(a) the Person(s) with whom revenue is shared;

(b) how this amount is calculated;

(c) the total revenue shared to date;

(d) any revenue expected to be shared in the future;

(2) the total revenue received by the Firm Relating to all Litigations identified in response to Request F.2. State whether the Firm shares any fraction of this revenue with any Person(s), and if the answer is yes, specify:

(a) the Person(s) with whom revenue is shared;

(b) how this amount is calculated;

(c) the total revenue shared to date;

(d) any revenue expected to be shared in the future;

(3) the total revenue received by the Firm Relating to all License Agreements identified in response to Request F.3. State whether the Firm shares any fraction of this revenue with any Person(s), and if the answer is yes, specify:

(a) the Person(s) with whom revenue is shared;

(b) how this amount is calculated;

(c) the total revenue shared to date;

(d) any revenue expected to be shared in the future;

(4) any revenue not identified above, shared with any Person(s) and specify:

(a) the Person(s) with whom revenue is shared;

(b) how this amount is calculated;

(c) the total revenue shared to date; and

(d) any revenue expected to be shared in the future.

2. Submit all documents Relating to all revenue identified in response to Request 8.

It should be noted that pending this information collection, the destruction, mutilation, alteration, or falsification of documentary evidence within the possession or control of a person, partnership or corporation subject to the FTC Act is subject to criminal prosecution. 15 U.S.C. § 50, *see also* 18 U.S.C. § 1505.

II. Estimated Burden Hours

Staff will ask respondents to answer several written questions and to provide documents related to the answers provided. Because the responses will necessarily vary depending on the respondent, we have provided a range of estimated response times from 90 to 400 hours. The total estimated burden of answering the questions and producing documents per respondent is based on the following:

Organize document and information retrieval: 15 – 50 hours

Identify requested information: 15 – 150 hours

Retrieve responsive information: 20 – 80 hours

Copy requested information: 20 – 40 hours

Prepare response: 20 – 80 hours

Thus the cumulative hours burden to produce documents and prepare the response sought will be between 3,600 (90 hours x 40 companies) to 16,000 (400 hours x 40 companies).

III. Estimated Cost Burden

It is not possible to calculate with precision labor costs associated with answering the questions and producing the documents requested, as each will entail various levels of management and/or support staff among many different companies. Individuals among some or all of those labor categories may be involved in the information collection process. Nonetheless, we have assumed that mid-management level personnel will handle most (estimate: 90%) of the tasks involved in gathering and producing the responsive information and we have applied a mean hourly wage of $52.20[4] for their labor. We also have applied a mean hourly wage of $16.54 for the labor of clerical employees[5] who will prepare the responsive materials for copying or electronic production. Thus the labor costs per company should range between $3,984.80 [(81 hours x $52.20/hour) + (9 hours x 16.54/hour) to $19,097 [(360 hours x $52.20/hour) + (40 hours x $16.54/hour)].

Staff anticipates that the capital or other non-labor costs associated with the information requests will be minimal. Although the information requests may require the respondent to store copies of the requested information provided to the Commission, industry members should already have in place the means to store information of the volume requested. Respondents may need to purchase minimal office supplies to respond to the request. Staff estimates that each respondent will spend $500 for such costs regarding the information request, for a total additional non-labor cost burden of $20,000 ($500 x 40 companies).

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[4] Bureau of Labor Statistics, May 2012 National Occupational Employment and Wage Estimates for the United States, Management Occupations: http://www.bls.gov/oes/current/oes_nat.htm.

[5] *Id.* (Office and Administrative Support Occupations).

IV. Request for Comment

Under the PRA, 44 U.S.C. 3501-3521, federal agencies must obtain approval from OMB for each collection of information they conduct or sponsor. "Collection of information" means agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. 44 U.S.C. 3502(3); 5 CFR 1320.3(c). As required by Section 3506(c)(2) of the PRA, 44 U.S.C. 3506, the FTC is providing this opportunity for public comment before requesting that OMB approve the study. Specifically, the FTC invites comments on: (1) whether the proposed collection of information is necessary for the proper performance of the functions of the FTC, including whether the information will have practical utility; (2) the accuracy of the FTC's estimate of the burden of the proposed collection of information; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of collecting information. The FTC encourages recipients of prior compulsory process orders to offer suggestions on how the burden of the proposed collection may be reduced. All comments should be filed as prescribed below, and must be received on or before **[insert date 60 days from the date of publication in the FEDERAL REGISTER]**.

You can file a comment online or on paper. For the Commission to consider your comment, we must receive it on or before **[insert date 60 days from the date of publication in the FEDERAL REGISTER]**. Write "PAE Reports: Paperwork Comment; Project No. P131203" on your comment. Your comment – including your name and your state – will be placed on the public record of this proceeding, including, to the extent practicable, on the public Commission Website, at http://www.ftc.gov/os/publiccomments.shtm. As a matter of discretion, the Commission tries to remove individuals' home contact information from comments before placing them on the Commission Website.

Because your comment will be made public, you are solely responsible for making sure that your comment does not include any sensitive personal information, like anyone's Social Security number, date of birth, driver's license number or other state identification number or foreign country equivalent, passport number, financial account number, or credit or debit card number. You are also solely responsible for making sure that your comment does not include any sensitive health information, like medical records or other individually identifiable health information. In addition, do not include any "[t]rade secret or any commercial or financial information which is obtained from any person and which is privileged or confidential," as provided in Section 6(f) of the FTC Act, 15 U.S.C. § 46(f), and FTC Rule 4.10(a)(2), 16 CFR 4.10(a)(2). In particular, do not include competitively sensitive information such as costs, sales statistics, inventories, formulas, patterns, devices, manufacturing processes, or customer names.

If you want the Commission to give your comment confidential treatment, you must file it in paper form, with a request for confidential treatment, and you have to follow the procedure explained in FTC Rule 4.9(c), 16 CFR 4.9(c).[6] Your comment will be kept confidential only if the FTC General Counsel grants your request in accordance with the law and the public interest.

[6] In particular, the written request for confidential treatment that accompanies the comment must include the factual and legal basis for the request, and must identify the specific portions of the comment to be withheld from the public record. *See* FTC Rule 4.9(c), 16 CFR 4.9(c).

Postal mail addressed to the Commission is subject to delay due to heightened security screening. As a result, we encourage you to submit your comments online. To make sure that the Commission considers your online comment, you must file it at https://ftcpublic.commentworks.com/ftc/paestudypra, by following the instructions on the web-based form. If this Notice appears at http://www.regulations.gov/#!home, you also may file a comment through that website.

If you file your comment on paper, write "PAE Reports: Paperwork Comment; Project No. P131203" on your comment and on the envelope, and mail or deliver it to the following address: Federal Trade Commission, Office of the Secretary, Room H-113 (Annex J), 600 Pennsylvania Avenue, NW, Washington, DC 20580. If possible, submit your paper comment to the Commission by courier or overnight service.

Visit the Commission Website at http://www.ftc.gov to read this Notice and the news release describing it. The FTC Act and other laws that the Commission administers permit the collection of public comments to consider and use in this proceeding as appropriate. The Commission will consider all timely and responsive public comments that it receives on or before **[insert date 60 days from the date of publication in the FEDERAL REGISTER]**. You can find more information, including routine uses permitted by the Privacy Act, in the Commission's privacy policy, at http://www.ftc.gov/ftc/privacy.htm.

By direction of the Commission.

Donald S. Clark,
Secretary.

APPENDIX F
SUMMARY OF U.S. LEGISLATIVE PROPOSALS TO COMBAT PAES

Bills introduced to address perceived abuses in patent litigation (113th Congress)[1076] and state legislation

Bill	Main Focus of the Bill	Summary of Bill and Major Commentary	Status
Federal Bills			
H.R. 845, "Saving High-Tech Innovators from Egregious Legal Disputes" (SHIELD) Act of 2013 (Rep. Defazio, D-OR-4)	**Fee shifting**	• Moves to amend federal patent law, with respect to the remedies available in actions involving validity or infringement of a patent. If the moving party is successful, the Court shall award the recovery of full costs to any prevailing party asserting invalidity or non-infringement, including reasonable attorney's fees, unless the court finds that exceptional circumstances make an award unjust. • This legislation targets PAEs in their pocket book by awarding full costs to the prevailing party in patent infringement litigation, unless the other party meets certain criteria that mean it is likely *not* a PAE. • The criteria are (i) that the party is the inventor, joint inventor or the original assignee of the patent; (ii) the party can provide evidence of substantial investment made by the party in the exploitation of the patent through production or sale of an item covered by the patent; or (iii) the party is an institution of higher education or is a technology transfer organization whose primary purpose is to facilitate commercialization of technology developed by such institutions. • It requires that PAEs post a bond to the court in order to enable full cost recovery by the prevailing party. • Critics claim that non-trolls are likely to be swept up in the SHIELD bond regime, because it bases the requirement to pay on certain characteristics of the party bringing the suit. The characteristics defining a PAE in the proposed bill do not include bringing a pattern of frivolous litigation, which is arguably the main distinguishing characteristic of PAEs from practicing companies.	Introduced: 2/27/2013

[1076] *Patent Public Advisory Committee Meeting*, *Legislative Update*, Dana Robert Colarulli, Director, Office of Governmental Affairs, November 21, 2013.

Bill	Main Focus of the Bill	Summary of Bill and Major Commentary	Status
H.R. 2024, "End Anonymous Patents Act" (Rep. Deutch, D-FL-21)	**Patent Owner Disclosure / Real Party in Interest**	• Requires all patentees to record ownership information at the U.S. PTO, including the identity of the patent owner and any real parties in interest. Recording of ownership is currently voluntary. • Ownership information is required when a party is issued a patent, upon payment of maintenance fees and when a patent, patent application, or interest is sold, granted, or conveyed.	Introduced 05/16/2013
H.R. 2236, "Promoting Start-up Innovation Act" (Rep. Chabot, R-OH-1)	**Raising the limits for Micro-entities**	• Amends federal patent law to modify the definition of "micro entity" (certain small entities eligible for reduced patent fees) to require applicants to certify that they: ◦ Have not been named as an inventor on more than seven (currently four) previously filed patent applications, subject to applicable exceptions for applications filed in another country, provisional applications, or international applications under the Patent Cooperation Treaty; and ◦ Did not have gross income exceeding five times (currently three times) the median household income in the preceding calendar year and have not transferred ownership interest in the application to an entity with gross income exceeding such limit.	Introduced 06/04/2013
H.R. 2639, "Patent Litigation and Innovation Act" (Rep. Jefferies, D-NY-1)	**Heighten Pleading Standards, Joinder, Stays, Discovery, Rule 11 sanctions**	• Heightens requirements in the court pleadings for a party alleging infringement in a civil action arising under any Act of Congress relating to patents. • Sets forth procedures with respect to the joinder of parties, stays of action against secondary parties and stays of discovery until the court has ruled on any motions to dismiss or transfer venue. • Directs the court, upon final adjudication, to include in the record specific findings on the compliance by each party and attorney with Federal Rules of Civil Procedure addressing proper representations to the court, including findings that motions and pleadings were not presented to harass, delay, or increase litigation costs and that claims were non-frivolous and based on evidentiary support.	Introduced 7/10/2013

Bill	Main Focus of the Bill	Summary of Bill and Major Commentary	Status
H.R. 3309, "Innovation Act" (Rep. Goodlatte, R-VA-6) – introduced: 10/23/2013	**Various Litigation-Related and Other Provisions**	Among other changes, the bill proposes the following: • Patent infringement claims must include in court pleadings, unless the information is not reasonably accessible, specified details concerning: ◦ Each claim of each patent allegedly infringed, including each accused process, machine; ◦ Manufacture, or composition of matter alleged to infringe the claim; ◦ For each claim of indirect infringement, the acts of the alleged indirect infringer that contribute to, or are inducing, a direct infringement; ◦ The principal business, if any, of the party alleging infringement; ◦ The authority of the party alleging infringement to assert each patent and the grounds for the court's jurisdiction; ◦ Each complaint filed that asserts any of the same patents; and ◦ Whether a standard-setting body has specifically declared such patent to be essential, potentially essential, or having potential to become essential to that body, as well as whether the United States or a foreign government has imposed any specific licensing requirements. • Requires courts to award prevailing parties reasonable fees and other expenses incurred in connection with such actions unless the position and conduct of the non-prevailing party was reasonably justified in law and fact, or special circumstances make an award unjust. • Directs courts, upon a motion of a party, to require another party to certify whether it will be able to pay any award of such fees and expenses in the event that such an award is made against such other party. • Allows the court, if a non-prevailing party is unable to pay such a fee award made against it, to make a party that has been joined to the action with respect to such party liable for the unsatisfied portion of such award. • Allows joinder by the defendant of an interested party where the other party has no substantial interest in the subject matter at issue other than asserting the patent claim in litigation, with certain exceptions.	Passed in the House 12/5/2013

Bill	Main Focus of the Bill	Summary of Bill and Major Commentary	Status
		• Requires the court to deny a joinder motion if the interested party, after receiving such notice, renounces any ownership, right, or direct financial interest in the patents at issue. • Directs the Judicial Conference of the United States to develop discovery rules and procedures, to be implemented by U.S. districts courts and the U.S. Court of Federal Claims. • Requires plaintiffs, upon filing an initial complaint, to disclose to the PTO, the court, and each adverse party the identity of: ◦ The assignee; ◦ Any entity with a right to sublicense or enforce the patent; ◦ Any entity that the plaintiff knows to have a specified financial interest in the patent or the plaintiff, and ◦ The ultimate parent entity of any such identified assignee or entity. • Directs plaintiffs, or subsequent owners of the patent, to provide the PTO with updates regarding such information after the initial identification. • Requires courts to grant a motion to stay an action against a customer accused of infringing a patent based on a product or process under specified conditions when: ◦ The manufacturer is a party to the action or to a separate action involving the same patent related to the same product or process; and ◦ The customer agrees to be bound by any issues in common with, and finally decided as to, such manufacturer in the action to which the manufacturer is a party. • Exempts from pleading, disclosure, and lift of stay requirements patent actions that include certain claims relating to abbreviated new drug applications for generic drugs under the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act. • Requires the PTO Director to develop educational resources for small businesses to address patent infringement concerns. Requires education and awareness on abusive patent litigation practices to be provided through	

Bill	Main Focus of the Bill	Summary of Bill and Major Commentary	Status
		existing PTO small business patent outreach programs along with the Small Business Administration and the Minority Business Development Agency. • Directs the PTO to notify the public on its website when a patent case is brought in federal court, including by providing patent ownership information with respect to each patent at issue in a manner that is searchable by patent number, art area, and entity. • Requires the PTO to study and report to Congress with recommendations regarding: ◦ Secondary market patent transactions, including transparency, accountability, licensing, and other oversight requirements; ◦ Patents owned by the U.S. government, including an examination of how such patents are licensed and sold, whether restrictions should be placed on patents acquired from the U.S. government, and whether agencies owning such patents maintain adequate records and a point of contact responsible for managing such portfolios; ◦ The prevalence of patent demand letters (indicating that the recipient or anyone affiliated with the recipient is or may be infringing the patent) sent in bad faith and the extent to which such practices may, through fraudulent or deceptive practices, impose a negative impact on the marketplace; and ◦ The economic impact of this Act on individuals and small businesses owned by women, veterans, and minorities. • Requires reports from the GAO concerning: ◦ Technologies available to improve PTO patent examination and patent quality, including an examination of best practices at foreign patent offices, procedures to prevent double patenting through applicant filings in multiple art areas, and prior art databases and search software; and ◦ Business method patents, including the volume and nature of litigation involving such patents and an examination of the quality of such patents asserted in suits alleging infringement. Directs the Administrative Office of the United States Courts to study and report to Congress with	

Bill	Main Focus of the Bill	Summary of Bill and Major Commentary	Status
		recommendations regarding the potential development of a pilot program for patent small claims procedures in certain judicial districts. • Amends the *Leahy-Smith America Invents Act* (AIA) to: ◦ Limit the grounds for invalidity of a patent claim that a post-grant review petitioner is prohibited, by estoppel, from asserting in subsequent civil actions (or certain U.S. International Trade Commission proceedings) to only those grounds that the petitioner actually raised during post-grant review (currently, the petitioner is estopped from asserting claims that the petitioner raised or could have raised during such review); ◦ Require claims of patent in post-grant and *inter partes* review proceedings to be construed in the same manner as a court would construe such claims in a civil action to invalidate the patent, including by interpreting the claim in accordance with its ordinary and customary meaning, as well as the prosecution history pertaining to the patent (currently, the PTO construes claims by considering the broadest reasonable interpretation); ◦ Codify judicial doctrine relating to the consideration of prior art in cases of double patenting for the purpose of determining the non-obviousness of a second patent's claimed invention, thereby specifying that such doctrine continues to apply under the AIA's first-inventor-to-file patent system; ◦ Revise the transitional covered business method patent review program to expand the scope of prior art that may serve as the basis of a challenge and permit the PTO to waive filing fees; and ◦ Exclude any time consumed by an applicant's request for continued examination from the calculation of a patent term adjustment that is based on the PTO failing to issue a patent within three years.	
H.R. 3349, "Innovation Protection Act" (Rep. Conyers, D-MI-13)	**PTO Funding**	• Establishes in the Treasury the United States Patent and Trademark Office Public Enterprise Fund (Public Enterprise Fund) to be used as a revolving fund by the Director of the U.S. Patent and Trademark Office (PTO) without fiscal year limitation.	Introduced 10/28/2013

Bill	Main Focus of the Bill	Summary of Bill and Major Commentary	Status
S.866, "Patent Quality Improvement Act of 2013" (Sen. Schumer, D-NY)	**Expanding PTO's Transitional Proceeding for Covered Business Method Patents**	• Amends Section 18 of the *Leahy-Smith America Invents Act* (AIA) to remove the eight-year sunset provision with respect to the transitional post-grant review program available to review the validity of covered business method patents, thereby making the program permanent. • Expands the term "covered business method patent" to include a patent that claims a method or corresponding apparatus for performing data processing or other operations used in the practice, administration, or management of any enterprise, product, or service, except technological inventions. (The current law limits the program to financial products or services.)	Introduced 05/06/2013
S. 1013, "Patent Abuse Reduction Act of 2013" (Sen. Cornyn, R-TX)	**Litigation-Related Provisions including Discovery, Joinder**	• Creates a loser pays system for all patent infringement lawsuits. It is broader than the SHIELD Act, above, which would shift costs only where the losing party is a PAE. • Directs a party alleging infringement in a civil action arising under any Act of Congress relating to patents to provide more detail in the court pleadings regarding each patent infringed and for what product, apparatus or product. • Requires a description of the direct infringement, the alleged infringer and the alleged acts of infringement. • Sets forth procedures with respect to the joinder of parties and discovery of evidence. • Directs each party to be responsible for the costs of producing core documentary evidence within the possession, custody, or control of that party.	Introduced 05/22/2013
S. 1612, "Patent Litigation Integrity Act" (Sen. Hatch, R-UT)	**Fee Shifting**	• Requires courts to award a prevailing party reasonable fees and other expenses, including attorney fees, incurred in connection with a civil action in which any party asserts a claim for relief arising under any Act of Congress relating to patents, unless the court finds that the position and conduct of the non-prevailing party were substantially justified or that special circumstances make an award unjust. • Authorizes courts, in response to a motion, to order the party alleging infringement to post a bond sufficient to ensure payment of such fees and expenses of the accused infringer.	Introduced 10/30/2013

Bill	Main Focus of the Bill	Summary of Bill and Major Commentary	Status
S.1720, "Patent Transparency and Improvements Act of 2013" (Sen. Leahy, D-VT)	**Various Litigation-Related Provisions and "Bad Faith" Demand Letters**	This is the Senate's companion legislation to the *Innovation Act*. Among other changes, the bill: • Directs a court to require a patentee who has filed a civil action for patent infringement to disclose to the court and to all adverse parties any persons, associations, corporations (including parent corporations), or other entities known by the patentee to have: ◦ a financial interest in the subject matter in controversy or in a party to the proceeding, or ◦ any other interest that could be substantially affected by the outcome of the proceeding. • Requires any assignment of all substantial rights in an issued patent that results in a change to the ultimate parent entity to be recorded in the PTO within three months of the assignment. • Prohibits a party asserting infringement from recovering increased damages or attorney's fees with respect to infringing activities taking place during any period of noncompliance in which the ultimate parent entity of an assignee has not been disclosed to the PTO. • Requires courts, if such an assignment has not been disclosed, to award a prevailing accused infringer its reasonable legal fees and expenses incurred in discovering any previously undisclosed ultimate parent entities. • Directs courts to grant a motion to stay an action against a customer accused of infringing a patent based on a product or process under specified conditions. • Requires the FTC to: ◦ exercise enforcement authority with respect to bad-faith demand letters and ◦ treat such letters as unfair or deceptive acts or practices. • Directs the PTO to notify the public on its website when a patent case is brought in federal court.	Introduced 11/18/2013
State Legislation			

Bill	Main Focus of the Bill	Summary of Bill and Major Commentary	Status
H. 299, *Bad Faith Assertions of Patent Infringement Act*	**Bad Faith Patent Assertions**	• Requires a bond to be paid in certain cases of "bad faith" assertions of patents. • The law identifies several factors for the court to consider in determining whether an infringement allegation is made in "bad faith", including (i) a lack of specificity in the demand letter and/or a failure to provide such information within a reasonable time upon request, (ii) a pattern of filing the same or similar claims of infringement that also lacked specific or which were found to be meritless, (iii) a failure to conduct sufficient analysis comparing the claims in the patents to the allegedly infringing product or service and (iv) unreasonable demands with regard to royalty amounts or the time periods for response or payment. • Conversely, the opposite factors are listed as supporting that an assertion is not being made in bad faith. • To that list is also added two further factors indicative of good faith: (i) the person alleging infringement has made a "substantial investment in the use of the patent or in the production or sale of a product or item covered by the patent" and/or (ii) the person is the original inventor, joint inventor or assignee, an institution of higher education. • The target of the assertion also has a right to file for equitable relief, damages, costs and fees, and exemplary damages of three times the total damage, cost and fee award. • The legislation does not require that an actual court filing be made, as reflected in the factors that establish bad faith, which include conduct involving demand letters. • The stated purpose in the legislation is to protect Vermont businesses from abusive and bad fair assertions of patent infringement, while respecting legitimate patent enforcement actions. It acknowledges that attracting small and medium sized IT and knowledge-based companies is an important aspect of Vermont's efforts to build a knowledge-based economy.	Codified at Vermont Statutes, Title 9, Chapter 120, §§ 4195-99

Bill	Main Focus of the Bill	Summary of Bill and Major Commentary	Status
		• Despite the acknowledgment that Vermont is pre-empted from passing any law that conflicts with federal patent law in the legislation, critics suggest it may be struck down on the basis that it pre-empts federal patent law.[1077]	

[1077] Adam R. Steinert, *New Vermont Law May Create Liability for Alleging Patent Infringement* (June 2013) available at: https://www.fredlaw.com/articles/ip/inte_1306_ars.html.

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