TROLLS, HOPPING, AMBUSH AND HOLD-UP: EMERGING INTERNATIONAL APPROACHES TO THE INTERSECTION OF COMPETITION AND PATENT LAW REGIMES

Selected Excerpts

George Addy
gaddy@dwpv.com

Erika Douglas
edouglas@dwpv.com

May 2014
Author's Note: The following report was produced with the financial support of Industry Canada, which is gratefully acknowledged. The views expressed in this study are those of the authors only, and do not necessarily reflect those of Industry Canada or the Government of Canada. The report has been modified for republication.
The following is an excerpt only of the full report. A PDF of the full report is available here.

I. AUTHORS' NOTE ........................................................................................................... 1

II. EXECUTIVE SUMMARY .............................................................................................. 2
   a. General Conclusions ............................................................................................ 3
   b. Conclusions Regarding Standard-Setting/FRAND Licensing: Active Enforcement and Recent Guidance from the EU and U.S.: All Quiet in Other Jurisdictions .................. 6
   c. Conclusions Regarding Reverse Payment Settlements: Clear Agency Opposition, Emerging Judicial Interpretations ................................................................. 9
   d. Conclusions Regarding Patent Assertion Entity Conduct: The U.S. Experience and Awareness on the International Horizon ............................................................. 11
   e. Conclusions Regarding Product Hopping: A Multitude of Cases and A Theoretical Conundrum ............................................................................................................... 12

III. RECOMMENDATIONS ................................................................................................ 13
   a. General Recommendations .................................................................................. 13
   b. Recommendations Regarding Standard-Setting/FRAND Licensing ...................... 15
   c. Recommendations Regarding Reverse Payment Settlements .............................. 16
   d. Recommendations Regarding Patent Assertion Entity Conduct ......................... 17
   e. Recommendations Regarding Product Hopping ................................................... 17
I. Authors' Note

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. 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.
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 can 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 standard-essential patents (referred to as "SEPs"). 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.

a. **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: a product hopping case in the U.K. (OFT Decision No CA98/02/2011 *Abuse of a Dominant Position by Reckitt Benckiser*), a product hopping case in the EU (Case T-321/05 *AstraZeneca v. Commission*), a Supreme Court of the U.S. reverse payment settlement case (*FTC v. Actavis, Inc.* 133 S.Ct. 2223 (2013), "*Actavis*") and a European Commission Directorate-General for Competition ("EC", the European-Union level competition authority) reverse payment settlement case (Case COMP/39.226 *Lundbeck* (June 19, 2013), "*Lundbeck*"). 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 Canadian Competition Bureau's (the "Bureau") 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 Competition Act, RSC 1985 c C-34 (the "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. 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. 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 and Consumer Act 2010 ("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 ("MOU") 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 U.S. Federal Trade Commission ("FTC", one of the U.S. agencies tasked with competition law enforcement), Department of Justice ("DOJ") (together with the FTC, the "Agencies") and the Patent and Trademark Office ("PTO"). As early as the 2003 FTC report entitled To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy, 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 Productivity Commission Compulsory Licensing of Patents Inquiry Report No.61 (March 2013) ("Compulsory Licensing Report"). 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's Intellectual Property Enforcement Guidelines ("IPEGs"), the main guidance on the interface between competition policy and IP rights, date to 2000. After the first draft of this report, the Bureau issued an initial, revised IPEGs draft 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 formal Antitrust Guidelines for the Licensing of Intellectual Property date to 1995, there is more recent guidance available from the 2007 report, Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition, 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 guidelines in 2011 on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements (the "Horizontal Agreement Guidelines"), 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 Guidelines On The Application Of Article 81 Of The EC Treaty To Technology Transfer Agreements ("Technology Transfer Guidelines").

The risk of a lack of Canadian 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 Federal Trade Commission 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 pursuing actions in the areas of concern discussed in this report.

b. Conclusions Regarding Standard-Setting/FRAND Licensing: 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 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 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. 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 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 (*Study on the Interplay Between Standards and Intellectual Property Rights Final Report (2011)*). 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 2013 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 Agreement 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.
c. Conclusions Regarding Reverse Payment Settlements: Clear Agency Opposition, Emerging Judicial Interpretations

- **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 Office of Fair Trading (now referred to as the Competition and Markets Authority) 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. also 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 Canadian abbreviated approval regimes for generic drugs 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 Patented Medicines (Notice of Compliance) 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 necessarily "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).

d. Conclusions Regarding Patent Assertion Entity Conduct: The U.S. Experience and Awareness on the International Horizon

- **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. A 2011 U.K. Intellectual Property Office report entitled *Digital Opportunity: A Review of Intellectual Property and Growth* 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.

e. Conclusions Regarding Product Hopping: A Multitude of Cases and A Theoretical Conundrum

- There is active, recent enforcement by the European, Australian and U.K. competition agencies 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 U.K. 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.

### III. Recommendations

#### a. 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 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.

- 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.

b. 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. A 2006 report to the Bureau entitled The Interface Between Competition Law and Intellectual Property Law: Present Concerns and Future Challenges Facing Industry Canada, recommended developing guidance on when competition concerns could arise from standard-setting activities. 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.

c. 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.

d. **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.

e. **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.*
Toronto
155 Wellington Street West
Toronto, ON  M5V 3J7
TEL 416.863.0900

Montréal
1501 McGill College Avenue
26th Floor
Montréal QC  H3A 3N9
TEL 514.841.6400

New York
900 Third Avenue
24th Floor
New York, NY  USA  10022
TEL 212.588.5500