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Revised Intellectual Property Enforcement Guidelines clarify the Competition Bureau's approach in IP matters

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The Competition Bureau (Bureau) released revised *Intellectual Property Enforcement Guidelines* (2016 IPEGs) on March 31, 2016, after engaging in a lengthy consultation period based on a draft released in June 2015 (2015 Draft). In releasing the 2016 IPEGs, the Bureau stated that it is "making it a priority to provide increased clarity on how it deals with competition issues involving intellectual property. To support innovation and ensure that guidance keeps pace with developments, it has committed to review the IPEGs annually and will revise them as needed in light of experience, changing circumstances and decisions of the Competition Tribunal and the courts." As evidence of the importance and broad implications of these issues, the Bureau received a significant volume of comments from various domestic and international stakeholders, including the Canadian Bar Association, the American Bar Association, U.S. Federal Trade Commissioners, economists, Google, Microsoft, Apple, Ericsson and other private companies.

The 2016 IPEGs go well beyond simply clarifying the Bureau's overall conceptual approach to the interface between the *Competition Act* (Act) and intellectual property (IP) matters. Rather, they provide welcome substantial and practical guidance to the legal and business communities on the Bureau's approach to this interface in the context of dynamic IP matters, including patent settlement agreements, product switching, patent assertion entities (PAEs), and collaborative standard setting and standard essential patents (SEPs). In summary:

- **Patent Settlement Agreements** – Antitrust scrutiny of patent litigation settlement agreements has been a high profile and controversial topic among competition law enforcers in the United States and Europe for years. The Bureau had been notably silent on the issue until the fall of 2014 when it released a white paper devoted to the topic. The white paper unleashed significant criticism primarily because of its lack of clarity about when the Bureau would pursue criminal enforcement action in respect of such settlements and about the factors the Bureau would examine in determining whether a settlement involving a payment from the brand to the generic raised a significant competition law concern under the civil provisions of the Act. It also created controversy as it called for the introduction of a notification regime for all patent settlements similar to that in the United States. The 2016 IPEGs effectively deal with these key issues by
  - clarifying that settlements will be reviewed under the criminal provisions of the Act in only three specific circumstances and, outside of these narrow circumstances, settlements will typically be reviewed under the civil competitor agreement provisions of section 90.1 of the Act

  - providing detailed guidance on the factors the Bureau will consider when determining whether the payment from the brand to the generic has the effect of delaying generic entry and is likely to result in a substantial lessening or prevention of competition
  - eliminating the suggestion of a notification regime for patent settlement agreements
- **Product Switching** – The 2016 IPEGs confirm that while an IP owner's use or non-use of the IP is usually the mere exercise of an IP right (and therefore not subject to the general provisions of the Act), in certain circumstances such as product switching the non-use of IP may constitute something more than "mere exercise" and could raise competition concerns.
- **PAEs** – The 2016 IPEGs acknowledge the ongoing debate regarding the establishment and conduct of PAEs and note that as developments occur in this rapidly evolving area the Bureau will continue to further refine its enforcement approach. Hypothetical examples address patent assignments for the sole purpose of enforcement as well as misleading advertising and deceptive marketing in the context of a PAE asserting its patents against alleged infringers.
- **Collaborative Standard Setting and SEPs** – Here, as in its discussion on PAEs, the Bureau explicitly signals that its thinking about the interface of IP and antitrust in this dynamic area may evolve such that it "may revisit certain aspects of the guidance in this subsection in the future in light of experience, changing circumstances and court decisions." With this caveat, the 2016 IPEGs
  - confirm that joint conduct involving participants in standard development organizations (SDOs) that is clearly for the purpose of setting an industry standard would be reviewed under the civil agreement between competitor provisions of section 90.1 and not the criminal conspiracy provisions of section 45
  - resolve the confusion in the 2015 Draft about SEPs and differentiating patents by clarifying that SEPs are part of the standards developed through formal SDOs and eliminating any suggestion that SEPs include proprietary differentiating patents, including those that others have labelled as commercially essential or "de facto" standards
  - confirm that alleged anti-competitive conduct by a SEP holder will be reviewed under the abuse of dominance provision rather than being treated only as a contractual dispute between the parties
  - discuss in practical terms the potential for anti-competitive conduct by a SEP holder seeking to improperly leverage its SEPs (e.g., patent hold up, patent ambush, reneging on a license commitment or seeking an injunction against willing licensees after making a licensing commitment) and the Bureau's framework for analyzing such conduct under the abuse of dominance provision of section 79 of the Act

This Update provides further information regarding the review process that culminated in the 2016 IPEGs as well as a more detailed discussion of each of the topics outlined above.

SECTIONS

A. Background

The Bureau first articulated its views on the interface between competition law and IP in the guidelines released in 2000 (2000 IPEGs). The 2000 IPEGs set out the Bureau's overall conceptual approach as being "based on the premise that the *Competition Act* generally applies to conduct involving IP as it applies to conduct involving other forms of property." The foundation of the Bureau's approach was that the circumstances in which the Bureau may apply the Act to conduct involving IP fall into two broad categories: those involving something more than the mere exercise of the IP right, and those involving the mere exercise of the IP right and nothing else. The 2000 IPEGs explained that the Bureau will use the general provisions of the Act to address the former circumstances and section 32 to address the latter. (Section 32 of the Act is a unique and rarely used provision which provides for a special remedy that, upon application by the Attorney General, endows the Federal Court with powers to prevent the use of IP rights to unduly restrain trade or lessen competition.)

Subsequent to the release of the 2000 IPEGs, there were significant international developments in the treatment of IP and IP rights by competition laws and enforcement agencies. For example, pharmaceutical patent settlements received extensive attention from the U.S. Federal Trade Commission (FTC) for years and were the subject of a landmark decision of the U.S. Supreme Court in 2013 (for further information regarding this decision refer to our Update). International enforcement agencies and courts also scrutinized the application of competition law to the conduct of PAEs and activities related to SEPs. In Canada, the Bureau commenced an inquiry in 2012 into alleged anti-competitive conduct involving product switching in the pharmaceutical sector (the inquiry was discontinued in 2014).

In October 2013, the Bureau announced that revisions to the 2000 IPEGs would occur in a two-stage process. In our view, the first stage was comprised of the September 2014 release of revised IPEGs (2014 IPEGs) and the white paper entitled *Patent Litigation Settlement Agreements: A Canadian Perspective* (White Paper). The second stage was comprised of the release of the 2015 Draft.

With one exception, the 2014 IPEGs principally reflected amendments to the Act since the publication of the 2000 IPEGs. The exception related to the Bureau's decision to limit its interpretation of the meaning of a "mere exercise" of an IP right, to which only the rarely used section 32 of the Act applies. Until 2014, the Bureau had considered the "mere exercise" of an IP right to be an IP owner's *use or non-use* of the IP. In 2014 the Bureau indicated that it no longer viewed an IP owner's non-use of IP as the "mere exercise" of an IP right. Therefore allegations relating to an IP owner's non-use of IP would be open to examination under the general provisions of the Act rather than only the special remedy available under section 32. For further details regarding the 2014 IPEGs, refer to our Update.

The White Paper was intended to "provide some background on Canada's regulatory system governing generic entry, its competition legislation, and the Bureau's preliminary views as to

how the Canadian competition law could apply to settlements," suggesting that the Bureau may continue to refine its views. The White Paper created some uncertainty as to when the Bureau may investigate patent litigation settlement agreements pursuant to the criminal conspiracy provisions of the Act. Given the significant stakes associated with IP settlements and the increasing frequency with which costly follow-on class action proceedings are initiated even where the Bureau does not pursue the matter, the lack of clarity on this important issue was disappointing. The White Paper also created controversy as it called for the introduction of a notification regime for all patent settlements similar to the U.S. requirement to notify the FTC of all pharmaceutical patent litigation settlement agreements. For further details regarding the White Paper, refer to our Update.

The 2015 Draft addressed in much more detail than ever before recent developments related to competition policy and IP law, demonstrating that the Bureau was grappling with these issues and recognized that substantive changes to its guidance were required. The 2015 Draft set out the Bureau's enforcement position in respect of a range of topical IP-related practices and issues including patent settlement agreements, product switching, PAEs, and collaborative standard setting and SEPs. As noted above, there was a lengthy and broad consultation process in respect of the 2015 Draft and the Bureau also benefitted from the fact that antitrust enforcers in other jurisdictions such as Europe, China and Korea were undertaking similar consultations.

Significantly, the 2016 IPEGs adopt the same overall conceptual approach to the interface between competition law and IP as was set out in the 2000 IPEGs. The highlights of the 2016 IPEGs are set out below.

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B. Settlements of proceedings under the Patented Medicines Notice of Compliance regulations

In the 2016 IPEGs, the Bureau has effectively responded to the criticisms of the White Paper, provided significantly more clarity on its enforcement approach and eliminated any suggestion of a notification regime for patent settlements.

The Bureau explicitly recognizes the benefits of settlements between brand and generic pharmaceutical companies of proceedings under the Patented Medicines Notice of Compliance (PMNOC) regulations – both to the parties themselves and to society at large – with the caveat that "litigation settlements may pose competition risks if the agreement of the parties goes beyond what is reasonably necessary to reach a settlement, for example including a payment to delay generic competition."

Importantly, in setting the context for this detailed discussion of the analytical framework the Bureau applies in reviewing such settlements and the factors it will consider, the Bureau underscores that there are significant differences in countries' regulatory regimes which "may have implications for both the incentives of parties to reach settlements and the terms of settlements that may occur in Canada." The Bureau highlights the features of Canada's PMNOC regime which distinguish it from the U.S. regime and are relevant in considering both the incentives of generics to challenge patents and the terms of PMNOC proceedings settlements, namely: the absence of an exclusivity period for the first generic filer; the ability of generics to claim damages against the patentee pursuant to section 8 of the PMNOC regulations; the risk for brands and generics of dual litigation (e.g., after having succeeded in defending a prohibition proceeding brought under the PMNOC regulations, a generic faces the possibility of an infringement action by the brand firm, if the generic launches prior to patent expiry; similarly, a brand whose prohibition application was successful still faces the

possibility of proceedings for impeachment of its patent); and the significant restrictions on the prices brands and generics may charge for their products in order to be listed on provincial formularies.

The Bureau's enforcement approach to settlements may be summarized as follows:

1. Entry-split settlement: No competition law risk

If a settlement does not involve the brand providing any consideration to the generic other than allowing the generic to enter the market on or before patent expiry (an "entry-split" settlement), the Bureau will not review the settlement under the Act.

2. "Sham" settlements and settlements extending exclusionary term or scope of brand patent: Analyzed under criminal conspiracy provisions of section 45

The Bureau will only review a settlement under the criminal provisions of section 45 if: (a) the settlement extends beyond the exclusionary potential of the patent by delaying generic entry past the date of patent expiry; (b) the settlement extends beyond the exclusionary potential of the patent by restricting competition for products unrelated to the product subject to the PMNOC proceeding; or (c) the settlement is a "sham" such that it is being entered into even though the parties recognize that the patent is invalid and/or not infringed.

With regard to (c), the 2016 IPEGs indicate that the Bureau will find that a settlement is a sham if the Bureau has reason to believe that both parties recognized that the patent was not valid and/or not infringed. In short, it describes a circumstance where "the PMNOC regulations and the settlement are used as a disguise for an otherwise naked conspiracy." In such a case, the Bureau would investigate whether the parties reached an agreement in violation of section 45. If the Bureau believed there was such an agreement, it would likely refer the matter to the Director of Public Prosecutions (DPP). Where the matter is referred but the DPP elects not to pursue prosecution, the Bureau may choose to re-evaluate whether the settlement should be subject to a remedy under the reviewable matters provisions of the Act.

3. Entry-split settlement with a payment from brand to generic and not a sham: Analyzed under civil reviewable practice provision of section 90.1

The Bureau indicates that a settlement involving the brand providing compensation to the generic, in addition to allowing the generic market entry, *could* create competitive harm:

Because the brand firm would typically make more profit by keeping the generic out of the market than the brand firm and the generic firm would receive in total by competing in the market (because generics are typically sold at a much lower price than branded drugs, with the difference being savings that would accrue to drug buyers), the parties have an aligned incentive to cede the market to the brand firm and split the profits from preventing competition. The competition concern with the settlement is that the payment obtained by the generic firm may arise from the sharing of the brand firm's (now guaranteed) supra-competitive profits. Drug buyers may be impacted by this type of settlement through higher prices, and patients may experience delayed access to affordable medicines.

Since a settlement involves more than one party the Bureau would generally review a settlement as an agreement between competitors pursuant to section 90.1 of the Act and apply its analytical framework as set out in the Bureau's *Competitor Collaboration Guidelines*. (The 2016 IPEGs note that given that settlement practices are dynamic and continue to evolve, circumstances may arise where the Bureau elects to review a settlement with a payment under the abuse of dominance provisions of section 79 if the requisite elements are present.)
In determining whether a settlement will likely result in a substantial prevention or lessening

of competition, the Bureau will apply the "but for" test. In particular, the Bureau will determine whether "but for" the settlement the generic would have entered earlier than the entry date specified in the settlement by examining whether the magnitude of the payment was likely to have had the effect of delaying the generic's entry and whether earlier entry by the generic would have lowered prices paid by drug buyers.

In regard to the payment, the Bureau indicates that the form of the payment (e.g., monetary transfer or compensation for services) does not change the Bureau's fundamental analysis as to whether its effect was to delay generic entry and that it would consider factors such as: the fair market value of any goods or services provided by the generic; the magnitude of the brand's section 8 damages exposure under the PMNOC regulations; and the brand's expected remaining litigation costs absent settlement. Expected remaining litigation costs absent settlement may include the expected costs of a subsequent patent infringement action and impeachment counterclaim, and potential adverse cost awards at the prohibition application stage and in an infringement/impeachment proceeding. The Bureau would also consider other justifications, including efficiencies that could be realized through the settlement and would not be obtained in the absence of the settlement.

In regard to the question of whether earlier entry by the generic would have lowered prices, the Bureau indicates that it would consider: the likely price difference that would have prevailed between the price of the brand and the generic; whether other prospective generic suppliers had delivered or were likely to deliver NOAs and, if so, when they would likely enter the market; and if there were other generics who had delivered NOAs and were involved in PMNOC litigation with the brand, whether the brand was in the process of negotiating settlements with those generic suppliers and, if so, what terms and conditions were being considered.

If the Bureau determined that the payment was so large that it likely delayed entry, that the competitive effects from the generic's delay were significant, and that timely entry from other generics was not likely to occur on a scale and magnitude to sufficiently constrain the ability of the brand and generic to exercise market power in the relevant market, it would conclude that the settlement substantially prevented or lessened competition within the meaning of section 90.1. In the absence of satisfying the efficiency exception, in such circumstances, the Bureau may seek a remedy from the Tribunal to prohibit any person from doing anything under the settlement or requiring any person (with the consent of that person and the Bureau) to take any other action.

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C. Product Switching

The 2014 IPEGs indicated that the Bureau no longer viewed an IP owner's non-use of IP as the "mere exercise" of an IP right, with the result that allegations relating to an IP owner's non-use of IP would be open to examination under the general provisions of the Act rather than only section 32.

The rationale behind the 2014 IPEGs' removal of the non-use of IP from the definition of "mere exercise" appeared to be that the Bureau did not want to be constrained from challenging product switching as a potential anti-competitive act under the abuse of dominance provision in section 79 of the Act. (So long as the definition of "mere exercise" included the non-use of IP, the withdrawal of a patented product from the market could be characterized as a "mere exercise" of an IP right and therefore outside the scope of the general enforcement provisions of the Act.)

Significantly, the 2016 IPEGs further refine the Bureau's approach as to what constitutes a "mere exercise" of an IP right, stating that "the Bureau defines the mere exercise of an IP right as the exercise of the owner's right to unilaterally exclude others from using the IP. The Bureau views an IP owner's use or non-use of the IP also as being the mere exercise of an IP right." However, a corresponding footnote goes on to state that "as noted in Example 9A, there may be limited circumstances where non-use of an IP right may be seen as something more than the 'mere exercise' of an IP right, and therefore could potentially raise issues under the general provisions of the Act." Accordingly, the Bureau has to some extent returned to the original definition set out in the 2000 IPEGs, with the caveat that in "limited circumstances" the non-use of an IP right could nonetheless raise concerns under the Act.

Example 9A broadly reflects the publicly-stated facts from the Bureau's 2012 investigation into Alcon Canada Inc.[1] In that example, a branded pharmaceutical company withdraws from the market an older product for which the patent is close to expiry and instead sells a newer similar product which is patent protected. At the same time, a generic substitute for the older product is poised to enter the market as soon as its patent expires. The competition provided by generic entry may be hindered by the withdrawal of the older product (upon which the generic product is formulated and could therefore be a substitute for) and the introduction of a newer similar product which has patent protection. The Bureau advises that the brand's conduct, referred to as a "hard switch," would likely be reviewed under the abuse of dominance provision in section 79 of the Act if the Bureau was of the view that the conduct could be for the purpose of excluding or impeding generic entry. Example 9A sets out in detail the steps the Bureau would take to determine whether, in its view, the conduct constitutes an abuse of dominance.

This is in contrast to Example 9B, where the brand does not withdraw its product from the market but only stops promoting the drug to physicians. The Bureau advises that this conduct, referred to as a "soft switch," would not likely raise concerns under the Act provided that it did not anti-competitively undermine the prescription base of the brand's older product (for example, by making false or misleading statements about the product).

It is noteworthy that both examples provided in the 2016 IPEGs relate to activity within the pharmaceutical sector. It is unclear whether the Bureau would consider investigating alleged product switching outside of the pharmaceutical sector, or whether its concerns are limited only to this highly regulated industry.

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D. Patent Assertion Entities

The 2016 IPEGs refer to the ongoing debate regarding the establishment and conduct of PAEs. Some view PAEs' activities as potentially resulting in higher settlements because PAEs face different incentives than the original patent holders and are not open to infringement counterclaims. In comparison, others view PAEs as beneficial for innovation because they assist innovators in maximizing their returns on R&D investment which in turn facilitates further R&D. The 2016 IPEGs also note that there is a concern that PAEs may use false and misleading claims to extract licensing fees from smaller businesses who want to avoid a possible patent infringement lawsuit.

Example 10 notes that companies who acquire patents for the sole purpose of asserting them against firms allegedly infringing the patented technologies must, like all businesses in Canada, abide by the misleading advertising and deceptive marketing practices provisions of the Act which prohibit the making of a representation to the public that is false or misleading in a material respect, where the representation is made to promote a product or business.

The Act contains both civil reviewable and criminal misleading advertising and deceptive marketing practices provisions, with a potential violation of the criminal provision occurring when the misrepresentation is made knowingly or recklessly. Accordingly, PAEs should take care to ensure notices sent to alleged patent infringers do not include representations that are false or misleading in a material respect.

In response to comments received during the consultation period, Example 11 addresses the assignment of patents for the sole purpose of enforcement. The Bureau notes that while the assignment of a patent is something more than the mere exercise of an IP right, in general "IP holders arranging their affairs so as to more effectively enforce their IP rights do not raise issues under the Act."

The Bureau acknowledges that competition law enforcement relating to PAEs is rapidly evolving and, as developments occur, the Bureau will continue to further refine its enforcement approach.

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E. Collaborative standard setting and standard essential patents

The 2016 IPEGs recognize that collaborative standard-setting activity through SDOs plays a valuable and pro-competitive role in promoting innovation and interoperability, increasing consumer choice and efficiency, and lowering production costs and barriers to entry. However, the 2016 IPEGs also recognize and discuss in practical terms the potential for anti-competitive conduct by a SEP holder seeking to improperly leverage its SEPs (e.g., patent hold up, patent ambush, reneging on a license commitment or seeking an injunction against willing licensees after making a licensing commitment). Commitments by holders of the SEPs related to the collaboratively-developed standard to make them available on fair, reasonable and non-discriminatory (FRAND) terms are intended to offset the anti-competitive effects of SDO standard-setting while preserving the pro-competitive effects of such standard-setting.

As a threshold matter, the 2016 IPEGs resolve the confusion in the 2015 Draft about SEPs and differentiating patents. The 2016 IPEGs clarify that SEPs are part of the standards developed through formal SDOs and eliminate any suggestion that SEPs include proprietary differentiating patents, including those that others have labelled as commercially essential or "de facto" standards. This reflects the fact that while a differentiating patent may achieve market power, it does so in competition with available substitutes and such market power is legally and legitimately acquired and not the result of an agreement among competitors. On the other hand, SEPs achieve their market power through the collaborative standard-setting agreements involving competitors that, as a practical matter, eliminate substitutes, and implementers become "locked in" to the standard. The context surrounding jointly-developed standards does not provide a rationale for imposing antitrust-based limits on the ordinary assertion and enforcement of patents relating to differentiating proprietary patents.

The Bureau's guidance on the competition law implications of the patent holder's conduct in connection with its FRAND-encumbered SEPs include the following highlights:

- Joint conduct involving SDO participants clearly for the purpose of setting an industry standard would be reviewed under the civil agreement between competitors provisions of section 90.1 and not the criminal conspiracy provisions of section 45.
- Consistent with the guidance and jurisprudence in other jurisdictions, the Bureau rejected arguments that alleged anti-competitive conduct by a holder of FRAND-encumbered SEPs

should be treated only as a contract dispute between the parties. The 2016 IPEGs indicate that alleged anti-competitive conduct by the SEP holder will be reviewed under the abuse of dominance provisions of section 79. However, the Bureau recognizes "that conduct that may result in patent hold-up could be addressed as a matter of contract law and will consider this possibility when exercising its enforcement discretion in a given case. In some situations, the competitive effects caused by the conduct may not be able to be sufficiently addressed by means other than competition law remedies."

- In determining whether the holder engaged in the alleged anti-competitive act is dominant, the Bureau will examine the patentee's position in markets that include the standardized technology or markets that include products that implement the standard. Importantly, the Bureau will consider "not only a patentee's pre-existing market power (i.e., any market power held by the patentee before the conduct), but also market power derived from the conduct." In determining whether the anti-competitive act resulted in or is likely to result in a substantial lessening or prevention of competition, the Bureau will apply the "but for" test to examine whether the patentee's conduct created, preserved or enhanced its market power in a market that uses the standardized technology:

Central to this examination, the Bureau would look to identify any alternative technologies that the SDO could have turned to at the time the standard was being chosen. The Bureau would also look to identify any alternative technical standards or technologies that firms could turn to as a substitute for the SDO standard after it was chosen. If such alternatives exist, the Bureau would seek evidence on the magnitude of the switching costs that firms would face to switch to these alternatives. If alternative technologies would likely have been chosen as the SDO standard but for the patentee's conduct and if alternatives to the SDO standard did not exist, or if switching costs were prohibitively high, the Bureau would likely conclude that the patentee increased its market power in the market that includes the standardized technology.

The Bureau would also look to determine whether competition would be harmed in markets for products that implement the SDO standard. This analysis would determine whether consumers of standard-compliant products would likely pay higher prices due to manufacturers of these products facing increased costs of accessing the standard. The Bureau would seek evidence as to the effect that royalties had on standard-compliant product prices and the options that consumers could turn to if faced with an increase in these prices.

- The Bureau makes it clear that in examining the alleged anti-competitive acts (e.g., patent hold-up, patent ambush, reneging on a licensing commitment or use of injunctions), "the Bureau is not a price regulator and will leave the determination of royalty rates to negotiations between parties or the courts. Absent a clear breach of a licensing commitment (e.g., demanding a royalty exceeding an *ex ante* commitment), it will not take enforcement action against a patentee solely based on the magnitude of the royalty that it charges." The Bureau goes on to state that it while it "will not regulate the specific terms and conditions that a standard essential patentee may impose when seeking to license its patents," such terms and conditions may be reviewed if they have the potential to cause competitive harm.
- The 2016 IPEGs devote considerable discussion to the potential anti-competitive use of injunctions by FRAND-encumbered SEP owners, a topic which has been the subject of

litigation in other jurisdictions. The Bureau indicates that a FRAND commitment is not a commitment to license on a royalty-free basis and that firms are "entitled to seek royalties to recover the value of their investment." The Bureau indicates that circumstances where it may conclude that the seeking of an injunction is appropriate include: "(i) when a prospective licensee refuses to pay a royalty that is determined to be FRAND by a court or arbitrator; (ii) when a prospective licensee refuses to engage in licensing negotiations; (iii) when a prospective licensee constructively refuses to negotiate (for example, by insisting on terms clearly outside the bounds of what could be considered to be FRAND terms); or (iv) when a prospective licensee has no ability to pay damages (for example, a firm that is in bankruptcy)."

This is one area of the 2016 IPEGs where the Bureau explicitly forewarns that it "may revisit certain aspects of the guidance in this subsection in the future in light of experience, changing circumstances and court decisions."

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F. Conclusion

The 2016 IPEGs dispel much of the uncertainty that was created by the 2014 IPEGs and the White Paper. Moreover, the 2016 IPEGs provide a fair amount of practical and detailed guidance on the Bureau's enforcement approach to current IP issues.

For further information regarding this Update or the IPEGs, contact a member of the firm's Competition and Foreign Investment Group.

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[1] The Bureau's investigation involved whether Alcon had intentionally disrupted the supply of a drug – the patent for which was about to expire – as part of a strategy to switch patients to a second generation formulation of the drug and hinder meaningful competition from generic drug companies. The investigation was ultimately discontinued in 2014 after Alcon voluntarily resumed supply of the drug into the Canadian market, as the competitive dynamic appeared to have been restored in the market and the temporary conversion strategy did not appear to have delayed generic entry.