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Canada's Updated Intellectual Property Enforcement Guidelines

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I. INTRODUCTION

On March 31, 2016, the Competition Bureau Canada (the "Bureau") released an updated and expanded version of its Intellectual Property Enforcement Guidelines (the "Guidelines").[2] The release was the culmination of a long process that involved two rounds of public consultations, many discussions with stakeholders and consideration of past Bureau enforcement experience, Canadian case law, and guidance documents released in other jurisdictions.[3]

The Guidelines were initially released in September 2000. Since that time, there were a number of developments that occurred which motivated the Bureau to undertake a revision. These include:

- Amendments to Canada's *Competition Act* (the "Act");[4]
- Bureau enforcement experience;[5]
- Release of new Bureau guidance documents and revisions to others;[6] and
- The introduction of new types of business conduct involving IP.

In regard to new business conduct involving IP, the Guidelines include a discussion of the Bureau's enforcement approach to: (i) patent litigation settlement agreements, (ii) product-switching in the pharmaceutical industry, (iii) conduct involving patent assertion entities, and (iv) conduct associated with collective standard setting. Each of these areas is discussed in turn below.

II. PATENT-LITIGATION SETTLEMENT AGREEMENTS

The issue that created the most discussion in the process leading to the release of the Guidelines was the Bureau's enforcement approach to patent litigation settlement agreements ("settlements"). In September 2014, the Bureau released a white paper to explain its initial thoughts on how settlements may be reviewed under the Act.[7] The comments the Bureau received in connection

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[2] Available at: http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/04031.html.

[3] The Bureau's first public consultation took place from April 2 to June 2, 2014, and the second from June 9 to August 10, 2015.

[4] The Government of Canada introduced significant amendments to the Act in January 2009, which were designed to modernize the Act and to align it more closely with the competition laws of Canada's major trading partners. The amendments, relating to reform of the conspiracy provisions and new provisions on competitor collaborations were particularly relevant for the Guidelines. The Act is available at: http://laws-lois.justice.gc.ca/eng/acts/c-34/.

[5] A significant Bureau enforcement matter relating to the intersection of competition and IP law involved the conduct of product switching in the pharmaceutical industry. The Bureau published a position statement regarding this investigation: http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03686.html.

[6] The Bureau released *Competitor Collaboration Guidelines* in 2009 (available at: http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03177.html), updated its *Merger Enforcement Guidelines* in 2011 (available at: http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03420.html) and updated its *Abuse of Dominance Provisions Enforcement Guidelines* in 2012 (available at: http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03497.html). The Bureau undertook to revise the Guidelines to ensure they were consistent with these and other guidance documents.

[7] The white paper was titled *Patent Litigation Settlement Agreements: A Canadian Perspective* and is available at: http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03816.html.

with this document, as well as those received from its public consultations, were very helpful in shaping its current views on this issue.

In short, the Bureau's enforcement approach is outlined with respect to three general categories of settlements. First, if a settlement does not involve the brand firm providing any consideration to the generic firm other than allowing the generic firm to enter the market on or before patent expiry, the Bureau would not review the settlement under the Act. In this circumstance, the Bureau would view the agreed entry date as reflecting a compromise between the parties based on each party's underlying expectation of succeeding in the litigation. The greater the likelihood that the patent is valid and infringed, the later in the patent term generic entry would be expected. Furthermore, settlements when the only consideration provided by the brand firm is early generic entry are marked by opposing incentives, with brand firms seeking later entry and generic firms seeking earlier entry. If there is no other consideration flowing from the brand firm to the generic firm, there would be no reason to believe that the terms of the settlement were for anything other than a compromise on the patent merits.

A second category involves settlements when the brand firm provides compensation to the generic firm in addition to allowing generic market entry on or before patent expiry (*i.e.,* the brand firm makes a payment to the generic firm). In this case, the Bureau may review the settlement under the civil competitor collaboration provision (section 90.1), or possibly the abuse of dominance provision of the Act (section 79). The concern in this circumstance is that the payment may serve as compensation to the generic firm in return for delaying its entry into the market. In determining if a payment likely had the effect of delaying a generic firm's entry, the Bureau would consider factors such as: (i) the fair market value of any goods or services provided by the generic firm; (ii) the magnitude of the brand firm's section 8 damages exposure under Canada's Patented Medicines Notice of Compliance ("PMNOC") regulations;[8] and (iii) the brand firm's expected remaining litigation costs absent settlement. If a payment was in a reasonable estimate of these factors based on information known at the time the settlement was reached, the Bureau would conclude that the settlement does not raise issues under the Act. The Bureau would also consider other justifications and evidence proffered by the parties.

The third category of settlements identified in the Guidelines is those that reach beyond the exclusionary potential of the patent or are a sham. Examples of settlements that go beyond the exclusionary potential of the patent would be those that restrict generic firms' entry beyond the end of the patent term or those that fix prices, allocate markets or restrict supply of products not at issue in the litigation. A settlement that is a "sham" would be a circumstance when the parties recognize that the patent is invalid or not infringed and use a purported settlement of the litigation to reach a naked agreement to fix prices, allocate markets or restrict supply. For settlements in this third category, the Bureau would review the settlement under the Act's criminal conspiracy provision (section 45).

[8] The PMNOC regulations govern the process of allowing generic entry prior to the expiry of the brand firm's patents. Generic firms in Canada who are engaged in litigation under the PMNOC regulations have a contingent claim to damages against the patentee pursuant to section 8 of the PMNOC regulations. The PMNOC regulations are available at: http://laws-lois.justice.gc.ca/eng/regulations/sor-93-133/FullText.html.

III. PRODUCT-SWITCHING IN THE PHARMACEUTICAL INDUSTRY

The Guidelines discuss two types of cases involving product-switching in the pharmaceutical industry. The first is a "hard switch," when a brand firm withdraws a product whose patent protection is close to expiry and faces imminent generic competition from the market to forcibly switch patients to another of its products that still has an extensive period of patent protection. The second case is a "soft-switch," when the brand firm does not withdraw its product from the market but rather stops its marketing activities to promote the drug.

In the case of a hard switch, the Bureau will review the conduct under the abuse of dominance provision of the Act (section 79). Under this provision, the Bureau would seek to determine whether the brand firm was dominant in a relevant market that included the product that it withdrew from the market and if so, whether the conduct constituted a practice of anti-competitive acts. As part of this analysis, the Bureau would examine the likely effect of the brand firm's product withdrawal on the ability of the generic firm to enter and compete in the relevant market. The Bureau would also examine whether the purpose of the product withdrawal was to delay or foreclose the supply of the generic or whether there was a legitimate business justification for the conduct. For example, if the brand firm removed its product from the market because it was not profitable, that may be viewed as a legitimate business justification. As a final part of its analysis, the Bureau would examine whether the product withdrawal had caused a substantial lessening or prevention of competition. One factor in this analysis would be to identify the difference between the price of the generic and the price of the brand's product to which patients were forcibly switched.

Secondly, in regard to the soft switch, the Guidelines make it clear that this type of conduct would not raise an issue under the Act provided that the brand firm did not anti-competitively undermine the prescription base of its product that was approaching patent expiry (*e.g.,* make false or misleading statements about the product to discourage physicians from prescribing it).

IV. CONDUCT INVOLVING PATENT-ASSERTION ENTITIES

The Guidelines discuss two types of business conduct involving patent-assertion entities ("PAEs"). The first case involves a PAE making potential false or misleading claims in notices that it sends to businesses that it believes may have infringed its patents. The second instance involves an operating company outsourcing the assertion of its patent portfolio to a PAE.

In the first case, the Guidelines make it clear that, like other businesses in Canada, PAEs must abide by the misleading advertising and deceptive marketing practices provisions of the Act. In particular, the Act prohibits making a representation to the public that is false and misleading in a material respect, when the representation is made to promote a product or business interest (paragraph 74.01(1)(a)).

In determining whether representations that are made are false or misleading, the Bureau would consider both the general impression created by the representations, as well as their literal meaning. For example, if a PAE claimed that other businesses had agreed to pay its licensing fee and it intended to commence legal proceedings if its licensing demands were not met, the Bureau would investigate the veracity of these claims. If either claim was not true, then this would raise concerns

that the representations were false and misleading. Furthermore, if the Bureau concluded that the representations would affect the likelihood of the recipients taking some significant action in response to the claims, up to and including acceding to the demand, then the representations would also be considered material.

In the case of an operating company outsourcing the assertion of its patent portfolio to a PAE, the Bureau is of the view that, in general, IP holders arranging their affairs so as to more effectively enforce their IP rights do not raise an issue under the Act. This may include engaging the services of firms that specialize in the enforcement of IP rights.[9]

V. CONDUCT ASSOCIATED WITH COLLABORATIVE STANDARD SETTING

The final topic that the Guidelines address is that of collaborative standard setting and the conduct of standard essential patent owners. The Guidelines recognize that the development of standards through formal Standards Development Organizations ("SDOs") can provide many pro-competitive benefits, such as lowering production costs, increasing efficiency and consumer choice, reducing barriers to entry, and fostering interoperability and innovation. However, the Guidelines also recognize that standard development can pose competition concerns, such as reducing price and/or non-price competition, foreclosing innovative technologies and restricting firms' ability to compete by denying access to the standard or providing access on discriminatory terms.

In terms of enforcement approach, the Guidelines note that if there was a circumstance when the Bureau was to review joint conduct involving SDO participants, if the Bureau determined that the arrangement was for the purpose of setting an industry standard and there was no evidence that it was for the purpose of facilitating a naked agreement to fix prices, allocate markets or restrict supply, the Bureau review would proceed according to its approach outlined in its *Competitor Collaboration Guidelines*[10] under the Act's civil competitor collaboration provision (section 90.1). Importantly, the Guidelines recognize that SDOs may encourage participants to make *ex ante* licensing commitments before a standard is determined and that SDO participants may rely on such commitments to facilitate bilateral licensing negotiations necessary for the successful adoption of the standard and to provide assurances to firms who wish to use the standard that they will be able to obtain access to the necessary patented technologies. The Guidelines also recognize that before a standard is chosen, SDOs may facilitate negotiations between participants who are potential licensees of the standard and IP owners of rival technologies. Such negotiations provide SDO participants important information that allows them to choose a standard based not only on technical merit, but also on the cost of accessing the IP needed to implement the standard.

The Guidelines recognize that there is the potential for patent "hold-up" in the context of standard setting. The Guidelines outline three cases:

- An owner of a patented technology participating in a standardization process, in violation of SDO rules, fails to disclose its patent to an SDO and then later asserts that patent when

[9] A competition issue could arise however, if a transfer of IP results in the combination of IP rights covering substitutable technologies within a single entity allowing that entity to enhance its market power.

[10] *Supra* note 6.

access to its patented technology is required by firms that wish to implement the standard;

- An owner of a patented technology makes an *ex ante* licensing commitment, such as an explicit maximum royalty rate, and then later, once its technology has been adopted into the standard, abandons that commitment by charging a royalty higher than the maximum royalty it promised to charge; and

- A patentee makes a licensing commitment before its technology is adopted in a standard and then later seeks injunction orders against firms that are willing to license the technology on terms and conditions meeting the commitment.

In all three cases, the Bureau would review the conduct under the abuse of dominance provision (section 79) of the Act. The Bureau's competitive concern would be that the conduct could enhance the patentee's market power beyond what was inherent in its patents. Such conduct may increase the cost of accessing the standard for firms that wish to develop products that incorporate the standard and thereby reduce their incentive to innovate or otherwise produce products that use the standard. The patentee's conduct may result in foreclosure of companies making standard-compliant products. There is also concern that the increased cost of access will result in increased prices to consumers of standard-compliant products or that the conduct excludes alternative technologies that would have been considered for the standard. Finally, the Bureau would have concerns that the conduct may weaken incentives for firms to participate in procompetitive standard-setting activity generally.

VI. CONCLUSION

The Guidelines represent a significant and important update for the Bureau in terms of articulating its enforcement approach to business conduct involving IP that has become increasingly important over the past decade. These issues include patent litigation settlement agreements, product-switching in the pharmaceutical industry, conduct involving PAEs, and conduct associated with collective standard setting. Given the complexity of the issues and ongoing developments in the intersection of competition and IP law, the Bureau has committed to annually review its Guidelines and to make further updates as needed in light of experience, changing circumstances and decisions of Canada's Competition Tribunal and courts.