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Revised Canadian Intellectual Property Enforcement Guidelines Worth a Closer Look

On March 13, 2019, the Canadian Competition Bureau issued revised Intellectual Property Enforcement Guidelines (the IPEGs). The IPEGs, first issued in September 2000, describe the Bureau's approach to the interface between competition law and intellectual property rights, and its enforcement approach to conduct involving the exercise of IP rights, including in respect of pharmaceutical patent litigation settlements and so-called "product switching" strategies by innovator pharmaceutical companies.

The revisions are the product of what the Bureau has indicated will be its final yearly review of the IPEGs. When it first made substantive updates to the IPEGs in March of 20161, the Bureau had promised to review the IPEGs annually going forward. In the revised IPEGs, however, the Bureau gives the more modest undertaking to review the guidelines "as needed".

As the Bureau stated in November 2018 when it published a draft version of the revised IPEGs for public consultation, "[t]he updates are modest and will not substantially change the Bureau's approach in enforcing the *Competition Act* with respect to matters involving intellectual property". That being said, certain of those updates are worthy of note and attention by life sciences companies and firms in other patent-intensive industries.

First, the Bureau has added a reference to the Competition Tribunal's *Toronto Real Estate Board* (TREB) decision and to the Federal Court of Appeal's (FCA) decision2dismissing TREB's appeal,[3] as further authority for its enforcement position that conduct representing the "mere exercise of an IP right" is not cause for concern under the general provisions of the *Competition Act*(*e.g.*, criminal conspiracy under section 45, abuse of dominance under section 79 and agreements between competitors that prevent or lessen competition substantially under section 90.1). Conduct involving "something more" than the mere exercise of an IP right, however, may be reviewed under those provisions.

In the TREB case, the Competition Tribunal rejected TREB's claim that it held copyright in respect of its multiple listing service (MLS) database and that certain restrictions imposed by it on the use and dissemination of MLS data were therefore protected from review under the abuse of dominance provision by the statutory exception in section 79(5) of the *Competition Act*. [4] The Tribunal found that TREB had not established copyright in the database, but concluded that the impugned restrictions conferred advantages on TREB and certain of its members "beyond those derived from the*Copyright Act*" [5] and were therefore something more than the mere exercise of an IP right. While the Tribunal's decision is consistent with the dichotomy between the mere exercise of an IP right and "something more", as traditionally understood and applied, the point of note and potential concern here is the Bureau's statement in the revised IPEGs that the FCA "also noted that Parliament intended to insulate intellectual property rights from allegations of anti-competitive conduct where the IP right is the sole purpose of exercise or use".[6] In other words, the Bureau appears to interpret the FCA as holding that an alleged exclusionary or otherwise anti-competitive intent on the part of an IP owner is sufficient to transform the mere exercise of a statutory right under one of the federal IP statutes into "something more", thereby depriving the IP owner of the protection of the exception in section 79(5). Although the Bureau's position in this regard was already reflected (at least impliedly) elsewhere in the IPEGs,[7] the Bureau's express statement regarding its interpretation of the TREB appeal decision suggests a hardening of its position on this issue.

Second, the Bureau has added a statement in the footnote to the heading to hypothetical Example 9A — which deals with a so-called "hard" product switching strategy by an innovator pharmaceutical manufacturer — that "[b]rand-name manufacturers withholding Canadian Reference Products to delay generic entry may also be conduct that poses competition concerns".[8] In this regard, the revised footnote now also refers to the Bureau's inquiry relating to the policies or practices of certain innovator companies, which were alleged to restrict generic manufacturers' access to samples of the innovators' products contrary to the abuse of dominance provision in section 79 of the*Competition Act*. Although that inquiry was discontinued in 2018 with no finding of abuse, the position statement issued by the Bureau following that inquiry included the following warning to pharmaceutical industry participants: "the [alleged] practices within the pharmaceutical industry that gave rise to [the] investigation are of concern to the Bureau, and may warrant further enforcement or advocacy action in the future".[9] Recent statements by the newly appointment Commissioner of Competition, Matthew Boswell, also confirm that the Bureau is specifically targeting the pharmaceutical industry.[10]

Third, in light of the amendments to the*Patented Medicines (Notice of Compliance) Regulations*(the PMNOC Regulations) that replaced summary determinations with full actions, the Bureau has removed "dual litigation" from its description of the "significant differences in the regulatory regimes governing pharmaceuticals in Canada relative to

other jurisdictions [which] may have implications for the both the incentives of parties to reach settlements and the terms of settlements that may occur in Canada".[11] While litigation under the PMNOC Regulations is now considered final and results in an in rem determination of patent validity and infringement, obviating the need for a second patent infringement or impeachment action by the unsuccessful party in respect of the patents at issue in a PMNOC proceeding, innovator and generic firms in Canada can still be subject to a form of dual litigation. Unlike in the United States, patents not listed on the Patent Register [12] cannot be joined to a PMNOC proceeding. As a result, an innovator firm is free to launch litigation in relation to these unlisted patents at any time. This includes once the PMNOC proceeding has concluded and after the patents on the Patent Register have expired. This significant difference is not expressly accounted for in the revised IPEGs.

Finally, the Bureau has further qualified its longstanding position "that, in general, IP holders arranging their affairs so as to more effectively enforce their IP rights do not raise issues under the [*Competition Act*]".[13] In footnote 58, the Bureau has added the following statement which will be of interest to owners of standard essential patents: "A transfer of IP could also create a competition issue if it is made by an owner of a standard essential patent for the purpose of avoiding a licensing commitment". As discussed in Life Signs 2019, the *Patent Act* was recently amended to include a reference to standard essential patents, however, further clarity is still needed by way of regulation to understand how these provisions will be applied.

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[1] See BLG Publication "Questionable Policy: New Canadian IP Enforcement Guidelines Miss The Mark On Pharma"

[2] See Toronto Real Estate Board v. Commissioner of Competition, 2017 FCA 236 (CanLII), [2018] 3 FCR 563

[3] See *The Commissioner of Competition v. The Toronto Real Estate Board*, 2016 Comp Trib 7 [TREB CT], aff'd 2017 FCA 236 [TREB FCA].

[4] That exception states that "an act engaged in pursuant only to the exercise of any right or enjoyment of any interest derived under [a federal intellectual property statute, including the *Copyright Act*and the *Patent Act*] is not an anti-competitive act".

[5] TREB CT,*supra*at para 757.

[6] See para 41 of the revised IPEGs. [emphasis added] See also TREB FCA, supra at para 180.

[7] See the Bureau's discussion and analysis of a "hard" product switching strategy in hypothetical Example 9A at paras 131-38 of the revised IPEGs ["If the Bureau was of the view that BRAND's conduct could be for the purpose of forcing the replacement of sales of Product A with those of Product B to exclude or impede entry by GENERIC and Generic A, the Bureau would not view the withdrawal of Product A by BRAND as a mere exercise of its patent right and thereby conduct exempt under subsection 79(5)"]. This was language was added to the IPEGs in the March 2016 update. See our critique of this change in our bulletin, "Questionable Policy: New Canadian IP Enforcement Guidelines Miss the Mark on Pharma," April 5, 2016.

[8] See footnote 55 of the revised IPEGs.

[9] See "Competition Bureau Statement Regarding Its Investigation into Alleged Practices of Celgene, Pfizer, Sanofi" available athttps://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/04407.html.

[10] See, e.g., "Julius Melnitzer, "New Competition Bureau commissioner targets telecom, pharma and infrastructure industry", Financial Post (23 May 2019): available athttps://business.financialpost.com/legal-post/new-competition-bureau-commissioner-targets-telecom-pharma-and-infrastructure-industry.

[11] Para 160 of the revised IPEGs.

[12] The listing rules are extremely strict, such that relevant and enforceable patents may not be and, in certain cases, cannot be listed on the Patent Register. For example, the timing restrictions are extremely strict and it is not uncommon for a patent listing deadline to be missed if it is not filed timely or if the patent was filed at the 'wrong' time (*e.g.*, the only time a compound Act patent can be listed is with a new drug submission). Further, process patents as a class are ineligible for listing on the Patent Register. It is often the case that such a patent will describe and claim a method of making the medicinal ingredient that is the only economically viable method for that molecule to be made.

[13] See para 156 of the revised IPEGs.

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