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ARTICLE

Questionable Policy: New Canadian IP Enforcement Guidelines Miss The Mark On Pharma

On March 31, 2016, the Canadian Competition Bureau released a long-awaited substantive update of its 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. The newly published updated IPEGs (the "New IPEGs") set out the Bureau's enforcement approach in respect of the settlement of patent litigation proceedings in the pharmaceutical industry, so-called "product switching" strategies by innovator pharmaceutical companies, the activities of patent assertion entities ("PAEs") (i.e., companies whose business model is asserting patents although they do not manufacture or sell products or services related to such patents), and conduct involving standard essential patents ("SEPs") (i.e., a patent that claims an invention that must be used in order to conform to a standard adopted by a standard setting or development organization ("SDO")).

Pharmaceutical Patent Litigation Settlements

As reflected in the New IPEGs, the Bureau's enforcement approach to patent litigation settlements may be summarized as follows:

1. There are two antitrust safe harbours. The first is for entry-split settlements, defined as "a settlement [that] does not involve the [innovator] firm providing any consideration to the generic firm other than allowing the generic to enter the market on or before patent expiry". The second is for settlements providing for entry by the generic firm on or before patent expiry plus a payment within the reasonable estimate of the sum of (a) the fair market value of any goods or services provided by the generic firm to the innovator manufacturer, (b) the magnitude of the innovator company's section 8 damages exposure under the *Patented Medicines Notice of Compliance* ("PMNOC") regulations — the Canadian equivalent of the US Hatch-Waxman Act — and (c) the innovator company's expected remaining litigation costs absent settlement.
2. Settlements involving compensation (a "payment") to a generic firm may attract scrutiny under the *Competition Act* (the "Act"). Civil review under the civil agreements provision in section 90.1 is the default. Subject to the second safe harbour noted above, settlements including a payment to the generic firm pursuant to which the generic firm enters the market on or before patent expiry may be reviewed under section 90.1 of the Act, or "possibly" under the abuse of dominant position provision in section 79. The Bureau's concern here is with payments from innovators to generic firms that could have the effect of delaying generic entry and competition ; and
3. The scope for criminal review is restricted. The Bureau will not review a settlement under the criminal conspiracy provision in section 45 of the Act unless (a) the settlement extends beyond the exclusionary potential of the patent by (i) delaying generic entry past the date of patent expiry or (ii) restricting competition for products unrelated to the patent subject to the PMNOC proceeding, or (b) the settlement is a "sham". A "sham" is defined as a settlement "where the parties recognize that the patent is invalid and/or not infringed and use a purported settlement of the PMNOC proceedings to engage in conduct contrary to [the criminal conspiracy provision in] Section 45 as opposed to addressing patent-protected rights. That is, the PMNOC regulations and the settlement are used as a disguise for an otherwise naked conspiracy".

"Product switching"

With respect to so-called "product switching" strategies by innovator companies, the New IPEGs draw a distinction between "hard switches" (i.e., withdrawing from the market an older, less effective product for which the underlying patent(s) will soon expire in order to switch demand to a new or improved product which enjoys on-going patent

protection), on the one hand, and "soft switches" (i.e., where the innovator firm continues to sell the older product but stops promoting it to physicians), on the other hand.

The new guidelines indicate that "hard switches" will likely be examined by the Bureau under the abuse of dominance provision in section 79 of the Act. According to the Bureau, if the conduct of the innovator company "could be for the purpose of forcing the replacement of sales of [the older product] with those of [a new product] to exclude or impede" entry of the generic version of the older product, the Bureau would view the withdrawal of the older product as falling outside the statutory exception in section 79(5) of the Act which immunizes from review under section 79 any "act engaged in pursuant only to the exercise of any right" under a federal IP statute, including the *Patent Act*. As for "soft switches", the New IPEGs state these will not "likely" raise an issue under the Act, provided that the innovator firm does "anti-competitively undermine the prescription base" of the older product through, for example, the making of false or misleading statements regarding that product.

Conduct involving PAEs

The New IPEGs address conduct involving PAEs with respect to the "representations made in the context of asserting patents" and the "assignment of patents for enforcement".

The new guidelines set out the Bureau's position that the use by PAEs of false or misleading claims (e.g., that many other businesses have already paid the significant licensing fee demanded by a PAE, when in fact they have not, or that the PAE intends to commence litigation if the fee is not paid immediately, when in fact it has no such intention) as a means of extracting licensing fees from small- and medium-sized businesses will attract scrutiny under the misleading advertising provisions of the Act. Those provisions include a general criminal prohibition against false or misleading representations (section 52) and a general civil prohibition against deceptive marketing practices (section 74.01). These prohibitions are substantially similar, except that liability under the criminal prohibition also requires proof that the representation was made "knowingly or recklessly." Both require a representation — made to the public — to promote a product, service, or business interest that is false or misleading in a material respect.[1] Notably, the New IPEGs emphasize that "in most instances of misleading advertising", civil, as opposed to criminal, enforcement will be pursued by the Bureau.

With respect to the assignment of patents for enforcement, the New IPEGs confirm that while the assignment of a patent is potentially subject to review under the Act, "in general, IP holders arranging their affairs so as to more effectively enforce their IP rights [including by assigning those rights to a firm specializing in the enforcement of IP rights] does not raise issues under the Act".

Conduct involving SEPs

The New IPEGs indicate that the activities of SDOs raise competition risks (including potential criminal prosecution under the criminal conspiracy provision in section 45 of the Act) insofar as the conduct of SDO participants involves, among other things, the foreclosure of innovative technologies, the restriction of access to a standard or the facilitation of an agreement prohibited under section 45.

With respect to so-called "patent ambush", the New IPEGs indicates that a failure to disclose patents essential to a standard coupled with subsequent infringement litigation in respect of the previously undisclosed patents against those implementing the standard could attract antitrust liability under the abuse of dominance provision in section 79 of the Act. So too could breaches by an SEP owner of a voluntary commitment to license on fair, reasonable and non-discriminatory ("FRAND") terms. Notably, the New IPEGs indicate that where private litigation has been commenced in respect of the SEP owner's reneging on its FRAND commitment, the Bureau may forbear from taking enforcement action.

On the question of whether competition law imposes any limits on the right of owners of FRAND-encumbered SEPs to seek injunctive relief when their patents are allegedly infringed by implementers, the New IPEGs state the Bureau's position that it may be appropriate for the SEP owner who has made a licensing commitment to seek injunctive relief "in certain circumstances," including "(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)." The New IPEGs indicate that outside of these (and other unidentified) circumstances, the Bureau would likely review the seeking of injunctive relief by the holder of a FRAND-encumbered SEP as a potential abuse of dominance under section 79.

Comment

While the enforcement policy set out in the New IPEGs regarding SEPs, SDOs and PAEs is generally unobjectionable, the Bureau's intended approach to patent litigation settlements and "product switching" miss the mark in several important respects, including the following.

First, criminal review of patent litigation settlement agreements is clearly inappropriate. The criminal conspiracy provision in section 45 of the Act was never intended to be used to prosecute parties to settlements of contested, costly and highly-complex patent litigation. Further, the Bureau's intended use of section 45, even in the limited circumstances contemplated in the New IPEGs, constitutes an unjustified divergence from the approaches in both the US and the EU, where settlements of complex contested patent litigation is subject to civil antitrust review only. The divergence created by the new Canadian IP guidelines cannot be explained or justified with reference to any legal, regulatory or other differences between Canada and the US or the EU.

Second, notwithstanding that section 79 is by its express terms concerned with acts that have as their purpose an intended negative effect on a competitor that is predatory, exclusionary or disciplinary (that have had, are having or are likely to have the effect of substantially lessening or preventing competition in a market) and therefore cannot properly be applied to consensual settlements of patent litigation proceedings, the Bureau has refused requests from various stakeholders to remove from the New IPEGs reference to the possibility that patent ligation settlements could be challenged under the abuse of dominance provision in section 79 of the Act. Compounding the problem, the New IPEGs contain no meaningful guidance as to the circumstances in which the Bureau might proceed under section 79. Given the dramatically different consequences of a review under the civil agreements provision in section 90.1 versus the abuse provision in section 79 (i.e., prohibition order only vs. multi-million dollar fines), the Bureau's failure to provide the requested guidance is unfortunate.

With respect to so-called "product switching", the Bureau's position that "hard switches" are reviewable under the abuse of dominance provision in section 79 because "BRAND's conduct [in withdrawing the older product before the generic version was able to enter the market and take advantage of provincial automatic substitution laws] could be for the purpose of excluding entry by GENERIC" is inconsistent with, among other things, the *Patent Act*, the IPEGs as they existed before April 2014 and the relevant Canadian case law.

In this last regard, for example, the Competition Tribunal confirmed almost 20 years ago in *Director of Investigation and Research v Tele-Direct (Publications) Inc and Tele-Direct (Services) Inc*,[2] that an alleged exclusionary effect or exclusionary intent on the part of an IP owner is insufficient to transform the mere exercise of statutory rights under the IP statutes into something more, thereby depriving the IP owner of the protection of section 79(5). In its decision in *Tele-Direct*, the Tribunal rejected the Director's argument that "subsection 79(5) does not preclude a finding that 'abuses' of intellectual property rights are anti-competitive acts", and his position that Tele-Direct's alleged "exclusionary intent in respect of their trademarks" and practice of selective licensing constituted an abuse of its trademark rights reviewable under section 79 of the Act. In explaining this conclusion, the Tribunal stated (in relevant part):

"... in the Tribunal's view, something more than the mere exercise of statutory rights, even if exclusionary in effect, must be present before there can be a finding of misuse of a trademark. Subsections 79(5) explicitly recognizes this.

The respondents' refusal to license their trademark falls squarely within their prerogative. Inherent in the very nature of the right to license a trademark is the right for the owner of the trademark to determine whether or not, and to whom, to grant a licence; selectivity in licensing is fundamental to the rationale behind protecting trademarks...

While the evidence suggests that Tele-Direct is motivated, at least in part, by competition in its decision to refuse to license its trademarks, that fact is that the *Trade-marks Act* allows trademarks owners to decide to whom they will license their trademarks. The respondents' motivation for their decision to refuse to license a competitor becomes irrelevant as the *Trade-marks Act* does not prescribe any limit to the exercise of that right.

...

... Although the respondents may have been zealous in protecting their trademarks, both in refusing to license and in threatening litigation for infringement, the irrefutable fact is that the respondents have been, through the provisions of the *Trade-marks Act*, accorded the right to refuse to license their trademarks, even selectively. The exercise of this right is protected from being an anti-competitive act by subsection 79(5) of the Act".[3]

In the same way, product switching and other product innovation or improvement strategies (even if allegedly exclusionary in effect or intent) constitute the legitimate exercise of an innovator company's rights as a patent holder under the *Patent Act*, through the valid use (in obtaining a patent for an innovation or improvement, and using that invention in a new or improved product)[4] and non-use (in, among other things, discontinuing the supply of an older product) of IP, and therefore falls squarely within the statutory exception in section 79(5) of the Act. The *Patent Act* provides a comprehensive regulatory framework for determining whether a product improvement is sufficient for patent protection. Section 32 of the *Patent Act* expressly provides that a person who has invented an improvement on any patented invention may obtain a patent for the improvement. To qualify for patent protection, an improvement must be new and useful, and must be an invention in its own right (not an obvious equivalent of the original invention). With respect to the non-use of IP, subject to section 65 of the *Patent Act* (abuse of rights under patents), the rights conferred by a patent include a right of non-use; there is no obligation under the Canadian patent system for a patentee to use or work an invention.

Parliament could have sought to restrict or regulate the exercise of IP rights in connection with the introduction of new or improved patented medicines, but perhaps understanding the adverse effects this could have had on innovation and competition, it did not. A great deal of pharmaceutical R&D is incremental and incremental innovation has been the key to many major advances in the treatment and prevention of disease. Product switching encourages incremental innovation and the early introduction of improved products. The Bureau's enforcement approach in respect of "hard switches" therefore risks chilling investments in innovation and undermining vigorous, welfare-enhancing competition. As a matter of competition law policy, the proposition underlying the Bureau approach to "hard switches", namely that Canadian competition law should impose a legal obligation on innovator drug manufacturers, enforced through potential multi-million dollar fines, to continue selling an old product in order to facilitate entry by generics by the most efficient means available, is startling, to say the least.

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[1] The consequences of contravening the Act's civil deceptive marketing practices provisions can be severe. Among other things, the Act provides for the imposition of an administrative monetary penalty of up to $10 million for a first offence, and a penalty of up to $15 million for each subsequent contravention of the Act. Violations of the Act's criminal misleading advertising provisions can attract serious consequences, including fines in the discretion of the court and/or up to 14 years imprisonment.

[2] (1997), 73 CPR (3d) 1 (Comp Trib).

[3] *Tele-Direct*, *supra* at 29, 31-33.

[4] After patenting the original medication, an innovator company may obtain new patents for improvements or innovations on the original medicine, such as new dosages, strengths, formulations, delivery methods or new uses for the drug. For example, patients may find improved dosing — such as once a day dosing instead of multiple times a day dosing — more convenient and doctors may prefer it for improved patient compliance (as patients are more likely to take the proper dose of the drug). Similarly, improvements in a drug's formulation or delivery method, such as a drug for schizophrenia that dissolves in the patient's mouth, rather than having to be swallowed, or one that has a stable colour over time, in contrast to an older version of the same drug that did not have a consistent colour over time and was unsettling to the patient, may be preferable from both the patient's and his or her doctor's perspective.

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