Canada’s Updated Draft Intellectual Property Enforcement Guidelines and the Pharmaceutical Industry (Anita Banicevic and Mark Katz)

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I. INTRODUCTION

In June 2015, Canada’s Competition Bureau released its updated draft of the Intellectual Property Enforcement Guidelines (“Draft IPEGs”) for public review and consultation. The Draft IPEGs are intended to reflect the 2009 amendments to the Competition Act (the “Act”), including the changes to the criminal conspiracy provisions and the introduction of a new civil competitor collaboration provision. The Draft IPEGs are also designed to ensure consistency with other Bureau guidelines that have been released since the 2009 amendments (such as the Bureau’s Competitor Collaboration Guidelines).

The other principal objective of the Draft IPEGs is to set out the Bureau’s initial enforcement positions regarding several issues involving the nexus between competition law and intellectual property law that have attracted considerable attention recently. These include two topics that are of particular interest to the pharmaceutical industry: patent litigation settlement agreements and “product switching.”

The Bureau has addressed both of these issues in recent speeches, workshops, and a white paper but the Draft IPEGs are its first attempt to formulate enforcement principles in a systematic fashion. In this article, we describe and discuss the Bureau’s views as reflected in the Draft IPEGs as well as the practical implications for the pharmaceutical industry in Canada.

II. PATENT SETTLEMENT AGREEMENTS

In Canada, patent settlement agreements typically arise as a result of a generic’s challenge to an innovator’s patent under the Patented Medicines (Notice of Compliance) Regulations (“PMNOC Regulations”). Pursuant to the PMNOC Regulations, a generic may apply for a Notice of Compliance or “NOC” and serve a Notice of Allegation on the innovator either challenging the innovator’s patent or taking the position that the generic will not infringe the patent. If ultimately the innovator is not successful in defending its patent under the PMNOC process, Section 8 of the PMNOC Regulations provides that the innovator will be liable to the generic entrant for any losses it sustained during the period it was excluded from the market.

The possibility that an innovator could be required to pay monetary damages to a generic entrant is a significant difference from the U.S. regulatory scheme and may inform the rationale for an innovator to enter into a settlement agreement as well as the rationale for including a monetary payment as part of such a settlement.

Although patent settlement agreements have been a hot topic in other jurisdictions, the Bureau has not had occasion yet to deal with the issue from an enforcement perspective. That said, the Bureau signaled its interest in patent settlements by hosting a workshop in November 2013 that focused on the potential competition law implications of certain strategies and practices employed by pharmaceutical firms, including patent settlement agreements (also known more pejoratively as “pay-for-delay” settlements). The workshop attracted approximately 100 participants from both Canada and abroad, including representatives from the Bureau, Health Canada, the U.S. Federal Trade Commission, the pharmaceutical sector, the legal community, and academia. Following its November 2013 workshop, the Bureau issued a White Paper on Patent Settlements in September 2014 (the “White Paper”).

In what was regarded as a controversial and aggressive position, the White Paper indicated that the Bureau would consider using the Act’s criminal conspiracy offense (section 45) to pursue patent settlements where the generic agreed not to enter the market before a certain date and there was compensation (i.e., a “payment”) from the brand to the generic (e.g., cash, a promise not to launch an authorized generic, or provision of services). The White Paper stated that factors the Bureau would consider in this regard include, in general terms: the type and value of consideration flowing from the brand to the generic for an agreed upon generic entry date, the amount of time until generic entry, and any other available evidence.

The Draft IPEGs take a significantly less aggressive approach to patent settlement agreements than the Bureau’s White Paper. While the Bureau continues to reserve the right to apply section 45 to patent settlement agreements in certain limited circumstances, the Draft IPEGs clearly state that the application of section 45 would occur “only where the intent of the payment was to fix prices, allocate markets or restrict output.” As a result, the draft IPEGs reflect a significant (and helpful) departure from the previously suggested approach of applying the criminal conspiracy provisions to such settlements in a potentially broad manner. This position is also more consistent with the enforcement approach in other jurisdictions such as the United States.

The Draft IPEGs also provide the following additional guidance regarding the application of the Act to patent settlement agreements:
• An entry-split settlement pursuant to which the generic firm enters the market prior to patent expiry will not pose an issue under the Act;
• Not every settlement that involves a payment (whether in monetary form or via the provision of services) will be actionable under the Act. Instead, the Bureau would likely conclude that settlement does not raise issues under the Act if the payment represents a reasonable estimate of: (i) the fair market value of any goods or services provided by the generic firm, (ii) the magnitude of the brand company’s section 8 damages exposure under the PMNOC regulations, and (iii) the brand company’s expected litigation costs absent settlement;
• The Bureau would likely view any settlement that involves an agreement to enter the market after patent expiry as contravening the criminal conspiracy provisions found in section 45 of the Act; and
• The Bureau would view any settlement that is accompanied by direct evidence of market allocation (e.g., documentary evidence that the parties recognized that the patent was not valid) as actionable under section 45 of the Act.

The Bureau has provided helpful guidance by recognizing that entry split settlements, as well as payments that represent a reasonable assessment of the damages and costs associated with a successful challenge, should not pose issues under the Act. That said, the fact that the Bureau continues to reserve the right to apply the criminal provisions to this area remains troubling and likely to draw adverse comments. However, from a practical perspective, such challenges are likely to be extremely rare given the limited fact scenarios where the criminal provisions could apply as well as the legal burden associated with bringing a successful prosecution.

III. PRODUCT SWITCHING

Product switching“ (also sometimes referred to as “product hopping”) was another topic explored by the Bureau at its November 2013 workshop on competition issues affecting the pharmaceutical industry. “Product switching” refers to a strategy whereby an innovator or branded pharmaceutical firm, when faced with the prospect of generic entry, obtains one or more additional patents for variations on the same general medicinal compound while the drug is still covered by one or more pre-existing patents.

Critics of this strategy contend that the additional patents are sometimes for very minor reformulations—such as the switching from a capsule to a tablet—which are of little therapeutic benefit, but which allow the branded firm to extend its exclusivity over the therapeutic compound. In contrast, proponents argue that firms are under no obligation to promote old products or refrain from promoting new products to the benefit of competitors, and that the new patents protect reformulations that provide real therapeutic benefits.

In 2012, the Bureau commenced an inquiry into “product-switching” by Alcon Canada Inc. (“Alcon”), a branded or innovator pharmaceutical firm. The matter involved allegations that Alcon had, among other acts, intentionally disrupted the supply of its prescription anti-allergy drug Patanol as part of a conversion strategy meant to forcibly switch patients to a reformulated version of the drug and discourage or delay the entry of a generic version. The Bureau investigated the conduct under the abuse of dominance section of the Act (section 79). The investigation was ultimately discontinued as Alcon resumed the supply of Patanol and generics were able to enter and capture a significant share of the market.

Under Canadian legislation and jurisprudence, it is widely accepted that the “mere exercise of an IP right and nothing else” will not constitute anticompetitive conduct under the abuse of dominance provisions of the Act. In the prior version of the IPEGs, the Bureau stated that it “views an IP owner’s use or non-use of the IP … as being the mere exercise of an IP right” (emphasis added). In the Draft IPEGs, this phrase has been changed to: “[t]he Bureau views an IP owner’s use of the IP… as being the mere exercise of an IP right.”

The removal of the words “or non-use” is a more aggressive position that is likely related to the Bureau’s interest in pursuing life-cycle management/”product hopping” under the Act. That is, the Bureau appears to be reserving the right to argue that the “non-use” of a patent right could in and of itself be considered anticompetitive conduct under the Act. Whether the Bureau’s proposed approach would hold up in a contested case before the courts remains to be seen, particularly in light of the existing Canadian jurisprudence. However, it is a clear signal of the direction that the Bureau intends to pursue.

To further illustrate its intentions in the “product-hopping” area, the Bureau has also included an example in the Draft IPEGs involving a “hard switch” (the removal of branded product “A” from the market prior to a pending expiry in patent protection) and subsequent introduction of a new branded product “B” (that treats the same affliction). In example #9 of the Draft IPEGs, the Bureau takes the position that such a “hard switch” could potentially give rise to concerns under the Act’s abuse of dominance provisions. Relevant factors include (i) an assessment of whether the branded company is in fact dominant in a relevant market (or whether there are sufficient alternatives/substitutes), (ii) whether the product withdrawal is accompanied by any valid business justification and (iii) whether the branded company’s conduct has caused a substantial lessening or prevention of competition. With respect to the latter consideration, the Bureau states that it would “likely examine the difference between the price of Product B and the price at which generic A would have been expected to have been sold if it had not been delayed or foreclosed,” and whether Product A’s withdrawal would limit “physician/patent choice for prescription drugs.”

In light of the existing jurisprudence, the outcome of any product-hopping case in Canada is likely to turn at least in part on a court’s evaluation of whether a unilateral decision to remove a patented product can in and of itself be considered to be anticompetitive. That judgment, in turn, could depend significantly on whether the innovator offers a clear and cogent business justification for the “product switching.”

IV. CONCLUSION

The consultation period for the Draft IPEGs ended on August 10. Although not all of the comments have been made public yet, the Draft IPEGs attracted an unusual degree of attention, including from the American Bar Association’s Section of Antitrust Law as well as from former FTC Commissioner Joshua Wright and Justice Douglas Ginsburg of the Court of Appeals for the D.C. Circuit.

It is not clear yet when the Bureau will issue its final version of the IPEGs and its final views on patent settlements and product switching. When it does, however, pharmaceutical companies operating in Canada will undoubtedly have much to consider when designing future strategies.

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