Pharmaceutical Antitrust Issues in Canada: An Update

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Recent actions and statements from the Competition Bureau confirm that it has set its sights on the pharmaceutical industry and is preparing for increased intervention and enforcement in this sector.

In recent speeches, Canada's Commissioner of Competition has repeatedly emphasized the importance of the health and pharmaceutical industry to Canada's economy and pinpointed this sector as one where the Competition Bureau would like to focus its advocacy and enforcement efforts.[2] Consistent with this stated interest in increasing its enforcement and advocacy efforts, in early November 2013, the Bureau hosted a workshop to discuss antitrust issues in the Canadian pharmaceutical sector (the "Pharma Workshop"), a move that the Commissioner has explained "signaled to the pharmaceutical industry that competition issues in the health care sector are a current priority."[3]

As a follow-up to the Pharma Workshop and following calls for the Competition Bureau to provide its views regarding patent litigation settlement agreements in the pharmaceutical sector, the Bureau recently released a "white paper" that discusses the Bureau's "preliminary views as to how the Canadian competition law could apply" to such settlement agreements.[4] As discussed in greater detail below, the Bureau's white paper stakes out a relatively aggressive enforcement position including the ability for the Bureau to pursue such agreements (under certain circumstances) under the *per se* criminal conspiracy provisions of the *Competition Act* (the "Act").[5]

Provided below is an overview of the most recent antitrust developments in Canada and

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[2] *See* Press Release, Competition Bureau, *Remarks by John Pecman, Interim Commissioner of Competition* (Feb. 7, 2013), http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03529.html.

[3] *See* Press Release, Competition Bureau, *Competition Law in a Global and Innovative Economy – A Canadian Perspective* (Nov. 21, 2013), http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03631.html.

[4] *See* Competition Bureau, *Patent Litigation Settlement Agreements: A Canadian Perspective* (Sept. 23, 2014), http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03816.html.

[5] R.S.C. 1985, c. C-34.

possible implications for the Canadian pharmaceutical sector.

Patent Settlement Agreements in Canada

The European Commission and the Federal Trade Commission have both expended significant enforcement resources to address what are believed to be the negative antitrust implications of patent settlements or "pay for delay agreements" and life cycle management strategies in the pharmaceutical sector. Not surprisingly, it is these same issues that the Canadian Competition Bureau has also been grappling with. However, certain unique aspects of the Canadian antitrust legislation and regulatory process for pharmaceuticals means that the application of the antitrust legislation to this sector must be viewed from an angle that is specific to Canada.

With respect to patent settlement agreements, in Canada, such settlements 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. Once served with a Notice of Allegation, the innovator may, within 45 days, commence a proceeding in Federal Court for an order prohibiting the Minister from issuing a NOC to the generic until the expiration of the relevant patent or patents. The Minister is precluded from issuing an NOC to the generic pending a disposition of the proceeding (in favor of the generic challenger) or the expiration of 24 months after commencement of the proceeding, whichever is earlier.

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 have to pay monetary damages to a generic entrant is a significant difference from the U.S. regulatory scheme (unless the U.S. generic supplier is in a position to enter at risk and the patent holder gets a TRO/PI to keep the generic off the market in exchange for committing to a bond payment should the patent prove to be invalid or not infringed) and may inform the rationale for an innovator to enter into a settlement agreement as well as the rationale for a monetary payment as part of such settlement.

It is also noteworthy that the PMNOC process does not entirely dispose of the issue of the validity of the innovator's patent. In fact, a generic could be successful at the PMNOC phase, launch its generic product and then find itself being sued by the innovator for infringement of the patent. In addition, unlike in the U.S. there is no exclusivity period that is granted to the generic. Even without this exclusivity period, it is widely recognized that there are significant benefits to being the first generic to launch in Canada. Despite the lack of exclusivity and high-stakes involved with bringing a challenge, the Federal Court docket shows that the PMNOC challenge process is alive and well in Canada.

Another important difference is the possibility that the Canadian Competition Bureau may attempt to pursue such settlement agreements under Section 45 of the Act, the *per se* criminal provisions that apply to agreements between competitors with respect to pricing or supply of a product. Section 45 of the Act prohibits any agreement between competitors to "allocate

sales, territories, customers or markets for the production or supply of the product" or any agreement "to fix, maintain, control, prevent, lessen or eliminate the production or supply of the product."

In its recently released white paper, the Bureau has staked out its preliminary enforcement position and in doing so has stated that it may pursue such settlements under the Act's criminal *per se* conspiracy provisions under certain circumstances. The key elements of the white paper are as follows:

- The Bureau is "likely" to pursue such settlements under Section 45 where: (1) the agreement is beyond the scope of the patent (e.g., fixes a date of generic entry that is beyond the term of the patent); or (2) if the Bureau finds evidence to suggest that the settlement is merely a vehicle for a "naked restraint" on competition or was motivated by factors beyond the issues associated with the litigation.[6]

- The criminal provisions "could apply" to settlements that result in the delay of generic entry. Settlements that "cause delay" may have terms where the generic agrees not to enter the market before a certain date and there is compensation from the brand to the generic. Such compensation may, according to the Bureau, take a variety of forms including a cash payment, a promise not to launch an authorized generic, or provision of services.

- If the Bureau believes that the requisite elements of Section 45 have been made out, the Bureau will then consider whether the "ancillary restraints [defense]" or any other defenses are made out.[7] The ancillary restraints defence is available when: (i) the agreement is "ancillary to a broader or separate agreement"; (ii) the agreement is "directly related to and reasonably necessary for giving effect to the objective of that broader or separate agreement"; and (iii) that broader agreement does not itself contravene the conspiracy provisions.

- If the Commissioner elects to examine the settlement agreement under the civil provisions found in Part VIII of the Act, the Commissioner is "most likely" to proceed under Section 90.1 (which prohibits agreements between competitors that result in a substantial lessening of competition) but may also consider the application of the abuse of dominance provisions (which require a dominant position, a practice of anti-competitive acts and that the acts have resulted in a substantial lessening of competition) under certain circumstances. The key difference between the abuse of dominance provisions (found in Section 79) and Section 90.1 is the availability of administrative monetary penalties.

- In his accompanying speech to launch the white paper, the Commissioner also noted the absence of a notification system for reverse payment settlements in Canada and stated that he "intends to advocate for better information on patent settlements and the need to explore approaches that could be adapted to Canada's regulatory framework."[8] This statement foreshadows

[6] *Id*. at 9.

[7] *Id*. at 10.

[8] *See* Press Release, Competition Bureau, *Remarks By John Pecman, Commissioner of Competition* (Sept. 23,

> the possibility that the Competition Bureau will be seeking to implement a new notification system for settlement agreements in the pharmaceutical sector.

The possibility that the Competition Bureau could seek to challenge settlement agreements that go beyond the scope of the patent and/or where the settlement is motivated by other factors is perhaps not surprising. What is, however, surprising is that the Bureau has taken the position that it "could" pursue criminal liability if the generic's entry is delayed and where there is some form of compensation paid to the generic. Presumably, the Bureau is pointing to a delay that is not "beyond the scope of the patent" but something less. No doubt this area will be one that will be important for advisors to understand and debate as the Bureau moves to finalize its guidance.

Another point that is also somewhat surprising is the Bureau's treatment of the U.S. Supreme Court's decision in *Federal Trade Commission v. Actavis*[9] and, in particular, the U.S. Supreme Court's determination that a *per se* treatment is not appropriate for such settlements. While the white paper does make reference to certain aspects of the Supreme Court's decision, it does not directly address this important difference. Commissioner Pecman, in his accompanying speech averted to this difference in approach by stating that while the Bureau "appreciates" the *Actavis* decision, it has decided to take a "decidedly different view" in Canada.[10]

Whatever the Bureau's stated enforcement approach, the practical reality is that, unless the patent settlement agreement is all but a sham (for instance - where the settlement agreement is used as cover for a blatant market-sharing agreement between competitors), any attempt by the Bureau to challenge a settlement agreement under the criminal conspiracy provisions would be met with a number of challenges. As an initial hurdle, Section 45 applies only to agreements between competitors.[11] One would expect that the Bureau would almost certainly be met with arguments that the generic and innovator are not "competitors" or "potential competitors" until and unless the Bureau can demonstrate that the generic would have been successful in entering the relevant market. Furthermore, in most cases, it is likely that the rationale for any patent settlement is likely to settle existing litigation and avoid the expense and uncertainty of a litigated challenge to the innovator's patent and the possibility of having to pay damages under Section 8. Such a rationale would arguably allow settling parties to rely on the ancillary restraints defence.

Given the difficulties and vociferous defenses that will no doubt arise if a criminal challenge were to be initiated, it may be more likely that the Competition Bureau would review any patent settlement agreement under either the civil abuse of dominance provisions or Section 90.1, a civil provision that prohibits agreements between competitors where the agreement is likely to prevent or lessen competition substantially in a market. Under both the abuse of dominance provisions or Section 90.1, it is only the Commissioner who can challenge an agreement before the Competition Tribunal. Under Section 90.1, if the Commissioner is

2014), http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03817.html.

[9] 570 U.S. 756 (2013).

[10] *Id.*

[11] Section 45(8) defines "competitor" to include "a person who it is reasonable to believe would be likely to compete with respect to a product in the absence of a conspiracy, agreement or arrangement to do anything referred to in paragraphs 1(a) to (c)."

ultimately successful in his challenge, the Competition Tribunal is empowered to issue an order prohibiting any person from doing anything under the agreement or requiring any person (on consent of that person and the Commissioner) to take any other action. Under the civil abuse of dominance provisions, if the Commissioner is successful in demonstrating that the agreement is an anti-competitive act that has resulted in a substantial lessening of competition, the Tribunal can also order administrative monetary penalties of up to $10 million for an initial contravention.

Product Hopping

The Bureau has also recently shown a keen interest with respect to life-cycle management strategies or "product hopping" in the pharma sector. In May, the Bureau reported that it had terminated an investigation of Alcon with on allegations of "product hopping" with respect to its Pataday and Patanol eye drop products.[12] In particular, the investigation concerned allegations that Alcon had discontinued its branded Patanol product at a time when it would soon be facing generic competition (due to patent expiry) and attempted to drive demand to its new and improved Pataday product. As the Competition Bureau explained in its press release:

> In July 2012, Alcon implemented a strategy that could have limited or prevented future competition from generic versions of Patanol, a prescription drug used to treat allergic conjunctivitis. Among other things, the Bureau's investigation found that Alcon's strategy involved suspending the supply of Patanol from the Canadian market to switch prescriptions from Patanol to another product, in most cases Pataday, a second generation formulation[13] with twice the concentration of the medicinal ingredient and protected under patent until 2022.[14]

In its decision to terminate the investigation, the Bureau pointed to the fact that Alcon had voluntarily agreed to re-introduce the Patanol product to the Canadian market and that this decision, combined with the resulting competition from generics, had remedied the competitive dynamics and alleviated the Bureau's concerns.

Although the Bureau's concerns in this particular case may have been addressed, Bureau officials have publicly stated that they remain interested in bringing a case involving product hopping. In fact, the Bureau's press release regarding the Alcon investigation states:

> [L]ife-cycle management strategies that are designed to impede competition from generic drug companies, such as product switching strategies, may cause significant harm to competition. Strategies that include supply disruptions for the purpose of forcibly switching demand, including terminating,

[12] *See* Press Release, Competition Bureau, *Competition Bureau Statement Regarding the Inquiry into Alleged Anti-Competitive Conduct by Alcon Canada Inc.* (Mar. 19, 2014), http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03686.html.

[13] *Id.*

[14] *Id.*

> repurchasing or recalling market supply or any other attempt to frustrate supply of a product under patent challenge by potential generic drug competitors, are likely to raise concerns of an abuse of dominance.

While these statements clearly signal the Bureau's intent to review certain life-cycle management strategies under the abuse of dominance provisions, it remains to be seen whether the Bureau will be able to show that all of the requisite elements (market power, anticompetitive act, and substantial lessening or prevention of competition) have been met. In fact, and as discussed in further detail below, a key determinant will be whether the Bureau is able to demonstrate that the non-use or limited use of an IP right constitutes an "anticompetitive act" for the purposes of the abuse of dominance provisions.

The Bureau's Update to the IPEGs

In April 2014, the Bureau released a draft update version of the Intellectual Property Enforcement Guidelines or "IPEGs" for comment.[15] Based on comments from the Bureau, it was understood that the first update would simply reflect the legislative changes to the Act that have taken place since the IPEGs were last issued in 2000.[16] The Bureau also asked for input as to areas that it should address in any second, more substantive update to the IPEGs, and commentators have, not surprisingly, asked the Bureau to weigh in and provide guidance on its proposed approach to such settlements in the second phase. An updated draft of the IPEGs (reflecting input received in this first phase) was issued in September.[17] Based on the updated IPEGs, it appears that the Bureau is continuing to reserve the right to pursue certain types of patent pooling arrangements (and as noted above, certain patent settlements) under the criminal conspiracy provisions of the Act.

While the current version of the updated IPEGs (after the first phase of consultations) is not significantly different from the prior version, there are, however, two aspects of the draft IPEGs that may be of interest to the pharma sector. The first aspect that may be of interest relates to a subtle change made to the language of the IPEGs with respect to what types of actions the Bureau will consider the "mere exercise of an IP right." In particular, 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 Competition Act. In the prior version of the IPEGs, the Bureau took the following position: "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." (emphasis added) In the revised IPEGs, the

[15] *See* Press Release, Competition Bureau, *Draft update of Intellectual Property Enforcement Guidelines*, http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03689.html (last visited Oct. 1, 2014).

[16] *See* Press Release, Competition Bureau, *Competition Bureau Seeks Input on the Updated Intellectual Property Enforcement Guidelines* (Apr. 2, 2014), http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03715.html.

[17] *See* Press Release, Competition Bureau, *Competition Bureau Releases Updated Intellectual Property Enforcement Guidelines* (Sept 18, 2014), http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03814.html

second sentence has been changed to: "The Bureau views an IP owner's use of the IP also as being the mere exercise of an IP right." The removal of the words "or non-use," from the IPEGs is likely related to the Bureau's interest in pursuing life-cycle management/product hopping (as discussed above). While it remains to be seen whether the Bureau's stated approach would hold up in a contested case before the courts, it is a clear signal to pharma companies as to the direction that the Bureau appears poised to take.

The second aspect that may be of interest relates to a new hypothetical relating to product-hopping. Specifically, in Hypothetical #9, the Bureau discusses its analysis and approach to evaluating when 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) could give rise to antitrust concerns. In its analysis under this hypothetical, the Bureau states that it would be likely to evaluate such conduct under the abuse of dominance provisions. As part of its analysis, the Bureau would evaluate whether, among other things, the branded company is, in fact, dominant in the relevant market. The analysis of dominance would include whether other drugs are sufficiently close substitutes to be considered in the relevant market by looking at evidence of patient/physician switching behavior when product "A" was withdrawn. The Bureau would also consider whether the brand had any compelling business justification as to the introduction of the new product. In evaluating any business justification offered by the branded company, the Bureau would consult with physicians to see whether they viewed product "B" as offering any substantive medical benefits over product "A." If no substantive medical benefits are believed to be available, then the Bureau would "doubt any argument advanced that Product B is superior to Product A." While the substantive analysis included in the hypothetical is not surprising (particularly in light of the Alcon case described above), the inclusion of the hypothetical is yet another signal that the Bureau is very interested in pursuing a "product hopping" case under the abuse of dominance provisions.

Conclusion

While Canada's Competition Bureau has, to date, been less active in the pharmaceutical sector than its foreign antitrust counterparts, recent signals suggest that the Bureau could be poised to take action soon. Even if the Bureau's professed interest in the sector does not result in enforcement action, at a minimum, companies should expect to see more guidance, debate and discussion of the Bureau's intended enforcement approach in the coming months.