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I. INTRODUCTION

Health care is a very important sector within the Canadian economy. A recent report estimates total health care spending at CDN $211.2 billion in 2013 which represents 11.2 percent of the Canadian economy or approximately CDN $5,988 per capita.[2] Pharmaceuticals comprise the second largest component of total health care spending, estimated to be 16.3 percent of such spending in 2013 (CDN $34.5 billion).[3] A significant percentage of pharmaceutical spending is for prescription drugs (84.6 percent in 2011) and, unlike spending on hospitals and physicians, most pharmaceutical spending is from the private sector.[4] Private sector spending includes spending by both private health insurance plans, estimated at 59.6 percent in 2011, and households who pay out-of-pocket, estimated at 40.4 percent.[5]

Among Canadian prescription drugs in 2013, generics were estimated to have a 66 percent share of retail prescriptions but only 23.5 percent of total prescription drug expenditures.[6] These figures reflect the dramatic savings that consumers who pay out-of-pocket and drug plan providers experience from the availability of generic prescription drugs.

Given the importance of pharmaceuticals to Canada's health care sector and the role that generic drugs have played in limiting pharmaceutical spending, the Canadian Competition Bureau ("Bureau") has focused its advocacy and enforcement efforts in this sector on continuing to ensure that competition from generic drugs is not delayed or foreclosed through anticompetitive conduct. This article discusses two topics related to this effort. First, it discusses a recent Bureau enforcement investigation relating to a product life-cycle management strategy

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[2] Canadian Institute for Health Information, *National Health Expenditure Trends, 1975 to 2013*, at xiii. *Available at* https://secure.cihi.ca/free_products/NHEXTrendsReport_EN.pdf.

[3] Hospitals are the largest component and are estimated at CDN $62.6 billion in 2013 (29.6 percent of total health care spending). Spending on physicians is the third largest component at CDN $31.4 billion (14.8 percent). *Ibid.,* at xiii.

[4] In 2011, 57 percent of total expenditure on prescribed drugs was from the private sector while 43 percent was from the public sector. *Id*., at 29.

[5] *Id*., at 31.

[6] Canadian Generic Pharmaceutical Association, *available at* http://www.canadiangenerics.ca/en/advocacy/docs/CanadianMarketShare2013.pdf.

commonly known in competition circles as "product hopping" or "product switching." Second, this article provides some preliminary thoughts as to how Canadian competition law could apply to patent litigation settlements ("Settlements") in the pharmaceutical industry. To set the stage for what follows, a brief overview of Canada's competition statute is provided in the following section.

II. CANADIAN COMPETITION LEGISLATION

Canada's legislation to prohibit anticompetitive practices is the federal *Competition Act* ("Act").[7] Its principal provisions include those governing: (i) criminal conspiracies, (ii) civil collaborations or agreements among competitors, (iii) abuses of dominance, (iv) mergers, and (v) deceptive marketing practices.

The criminal conspiracy provision of the Act (section 45) prohibits agreements or arrangements between competitors to fix prices, allocate markets or customers, or limit production or supply.[8] Conspiracies are a criminal offense that may involve both fines and prison terms imposed by the courts.

Part VIII of the Act deals with conduct that is not anticompetitive in all circumstances, and, as such, constitutes reviewable matters by the Competition Tribunal ("Tribunal") under civil law. It includes the abuse of dominance provision (section 79) and the civil competitor collaborations provision (section 90.1). The abuse of dominance provision seeks to prevent dominant firms from engaging in anticompetitive acts that cause a substantial prevention or lessening of competition ("SPLC"). The civil competitor collaborations provision prohibits agreements or arrangements between competitors that do not merit treatment as criminal conspiracies, but which nonetheless substantially prevent or lessen competition in a market.

More information on sections 45, 79, and 90.1 will be provided below in the context of discussing the potential application of the Act to Settlements.

III. LIFE CYCLE MANAGEMENT STRATEGIES: "PRODUCT SWITCHING"

Life-cycle management strategies in the pharmaceutical industry are not inherently anticompetitive. In pro-competitive circumstances, such strategies may bring significant advancements in health care for the benefit of consumers, as well as drug companies. However, life-cycle management strategies that are designed to impede competition from generic drug companies, such as product switching strategies, may cause significant harm to competition.

In November 2012, the Bureau initiated an inquiry to examine whether Alcon Canada Inc. ("Alcon"), a branded pharmaceutical firm, was dominant in a relevant market and, if so, whether it had, among other things, intentionally disrupted the supply of its prescription ocular anti-allergy drug, Patanol, as part of a strategy to switch patients to a second generation formulation of the drug and hinder meaningful competition from generic companies. This

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

[8] To provide guidance concerning which agreements between competitors are likely to be enforced on a criminal standard, the Bureau has issued *Competitor Collaboration Guidelines* (2009), *available at* http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/Competitor-Collaboration-Guidelines-e-2009-12-22.pdf/$FILE/Competitor-Collaboration-Guidelines-e-2009-12-22.pdf.

strategy is widely known as "product switching" or "product hopping" in the antitrust literature.[9] The Bureau's inquiry sought to determine whether Alcon's conduct excluded generic drug companies from the relevant market, contrary to the abuse of dominance provision of the Act.

By way of background, Alcon began supplying Patanol in Canada in February 1998. Alcon's patent for the medicinal ingredient of Patanol, olopatadine hydrochloride, expired on November 21, 2012. Alcon also had a formulation patent with respect to Patanol that would expire on May 3, 2016.

In February 2010, Apotex Inc., Canada's largest generic pharmaceutical company, had sought Health Canada's approval to market a generic version of Patanol. Pursuant to Canada's regulations governing generic entry prior to patent expiry, Apotex provided Alcon with notice that it was challenging Alcon's formulation patent but that it would wait until the expiry of Alcon's patent on the medicinal ingredient olopatadine hydrochloride before entering the market. Alcon responded by triggering an automatic 24-month stay that prevented Health Canada from providing regulatory approval to Apotex until Apotex's patent challenge could be resolved by the Federal Court. Ultimately, the Federal Court litigation involving Apotex's challenge was discontinued by Alcon in April 2012. Meanwhile, in April 2011, Alcon had begun selling Pataday in Canada. Pataday is an olopatadine formulation for once-a-day dosing and is under patent protection until 2022.[10]

While Patanol and Pataday were simultaneously on the market, Pataday sales were increasing but remained low compared to those of Patanol. In July 2012, Alcon suspended the supply of Patanol in Canada and advised the market that Patanol would be on "back order" for the foreseeable future. With that supply disruption, physicians no longer had the option of prescribing Patanol and many began prescribing Pataday. Sales of Pataday replaced the vast majority of sales of Patanol.

Following commencement of the Bureau's inquiry in November 2012, Alcon resumed supply of Patanol to the Canadian market in January 2013. By May 2013, Patanol sales were comparable with sales prior to the supply disruption. Subsequently, competitors entered the market with generic versions of Patanol and the Bureau's inquiry was discontinued.[11]

IV. PATENT LITIGATION SETTLEMENTS: A CANADIAN APPROACH

Given the importance of pharmaceuticals to Canada's health care sector, the Bureau has an interest in preventing Settlements between brand name and generic pharmaceutical manufacturers that delay generic entry. The Bureau's general approach to assessing collaborations among competitors, which includes Settlements that may delay generic entry, is reflected in the Bureau's *Competitor Collaborations Guidelines*.[12] Where the Bureau has determined that a Settlement could raise issues under either criminal or civil provisions of the

[9] *See* Jessie Cheng, *An Antitrust Analysis of Product Hopping in the Pharmaceutical Industry,* 108 COLUMBIA L. REV. (2008) and Michael A. Carrier, *A Real-World Analysis of Pharmaceutical Settlements: The Missing Dimension of Product Hopping*, 62 FLORIDA L. REV. (2010).

[10] Patanol requires twice-a-day dosing.

[11] The Bureau published a position statement on the case that is *available at* http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03686.html.

[12] *Supra* note 8.

Act, it will then determine whether the criminal conspiracy provision in section 45, the civil competitor collaboration provision in section 90.1, or the abuse of dominance provision in section 79 is applicable. The decision to pursue a matter under either the criminal or civil provisions will depend on the facts and evidence of each case. Accordingly, in the event an inquiry is commenced under section 10 of the Act, the Bureau may pursue a dual-track inquiry under criminal and civil provisions (i.e., sections 45, 90.1, and 79) until a decision is made on the appropriate section to be applied.[13]

If a Settlement is between competitors and includes conduct with respect to markets or products that are not the focus of the patent litigation, or the conduct is beyond the scope of the patent—such as fixing a generic entry date beyond the term of the patent—the Bureau would likely pursue the Settlement under the section 45 criminal provision if the conduct is of a type prohibited under section 45. Similarly, if the Bureau finds direct or circumstantial evidence that indicates that a Settlement is a vehicle for a "naked restraint" on competition that is not implemented in furtherance of a legitimate collaboration, or was motivated by factors beyond the issues associated with the litigation, the Bureau would also likely pursue the Settlement under section 45.

For Settlements where neither of these two conditions is met, the Bureau will use its enforcement discretion to decide whether to pursue the matter under section 45 or one of the relevant civil provisions under Part VIII of the Act. Considerations that may inform the Bureau in the exercise of its enforcement discretion 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.

A. Section 45 of the Competition Act

Where business conduct satisfies the constituent elements of the criminal section 45, it may be investigated under section 45. In the Bureau's view, section 45 of the Act could apply to Settlements that have terms where there is compensation (i.e., a "payment") from the brand to the generic and the generic agrees not to enter the market before a certain date. This payment could take a variety of forms (e.g., cash, a promise not to launch an authorized generic, or provision of services, to name a few).

Where the constituent elements of an offense under section 45 are satisfied, the Bureau will consider whether the ancillary restraints defense under subsection 45(4), or another defense set out in section 45, may apply.[14]

Where the Bureau determines that there is sufficient evidence to establish that an agreement satisfies the ancillary restraints defense, it will not refer the matter to the Director of Public Prosecutions (the "DPP") with a recommendation to commence a prosecution under

[13] The Bureau's bulletin on *Communication during Inquiries* summarizes more generally when and how the Bureau generally communicates with parties whose conduct is being inquired into pursuant to section 10 of the Act. *Available at* http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03747.html.

[14] As described more generally in the Bureau's *Competitor Collaboration Guidelines*, agreements that are directly related to, and reasonably necessary for giving effect to, a broader agreement may be subject to an ancillary restraints defense.

section 45, but it may instead seek a remedy from the Competition Tribunal in respect of the agreement under section 90.1 where the Settlement is likely to prevent or lessen competition substantially.

As is the case in general, parties may approach the Bureau at any time to resolve a criminal matter prior to referral to the DPP for prosecution. The Bureau's Immunity and Leniency Programs provide a clear framework for cooperation and the provision of information by cooperating parties during investigations related to the criminal provisions of the Act.[15] However, the DPP has the sole authority to engage in plea and sentencing discussions with counsel for an accused.

While the Bureau may, where appropriate, initially elect to evaluate a Settlement under the criminal section 45, it may subsequently decide that circumstances warrant pursuing a remedy from the Competition Tribunal under the civil provisions of the Act at any time prior to referral of the matter to the DPP for prosecution. In cases where the matter is referred, but the DPP elects not to pursue prosecution, the Bureau may choose to re-evaluate whether the Settlement should be subject to a remedy under the civil provisions of the Act. At no time, however, will the Bureau use the threat of criminal prosecution to induce a Settlement in cases proceeding by way of the civil track.

B. Part VIII of the Competition Act: Civil Reviewable Practices

Where the Bureau, in exercising its enforcement discretion, elects to pursue a matter under Part VIII of the Act, it is most likely to examine a Settlement agreement under section 90.1, but may also consider an examination under section 79 under certain circumstances.[16] In general, agreements between competitors that may be examined under section 79 include, but are not limited to situations where (i) the parties are dominant, or jointly dominant, and (ii) the agreement results in or facilitates conduct that has a negative effect on a competitor that is exclusionary, predatory, or disciplinary, such that it has had, is having, or is likely to have the effect of preventing or lessening competition substantially in a market.[17] Both sections 79 and 90.1 require the Bureau to establish that the agreement at issue has, or is likely to have, the effect of causing an SPLC.

The Tribunal has adopted a "but for" test to assess whether an SPLC was caused by a given anticompetitive practice.[18] If, but for the Settlement, the parties would have been likely to compete, thereby disciplining the exercise of market power to lead to lower cost alternatives for consumers, the Settlement may be found to be causing an SPLC. This analysis may include an examination of the expected date of generic entry but for the Settlement and the agreed entry

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[15] For more information, please consult the Bureau's bulletins *Immunity Program under the Competition Act* (*available at* http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03248.html) and the *Leniency Program* (*available at* http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/03288.html), as well as their respective FAQs.

[16] There are limits to initiating more than one proceeding arising from the same or substantially the same facts. *See* section 79(7) and section 90.1(10) of the Act.

[17] *Supra* note 8, at 2.

[18] This test was first accepted by the Federal Court of Appeal in *Canada (Commissioner of Competition) v. Canada Pipe Co. 2006 FCA 233.*

date, and the difference between the prices that would have been expected to prevail in each case. Importantly, the alternative "but for" the Settlement is not necessarily the fully litigated outcome. It is possible that the parties may have reached an alternative Settlement with less restrictive terms.

One approach to help determine whether a Settlement has created an SPLC is to consider whether the value transfer to the generic is in excess of what the patentee could have been expected to pay in the event it had lost the litigation. The rationale behind this approach is that any payment exceeding this amount would likely be for the purposes of delaying generic entry. In Canada, this threshold could include the patentee's expected litigation costs and, perhaps, the patentee's potential liability for damages under Canada's regulatory regime governing generic entry before patent expiry.[19] All else being equal, the greater the value transfer from the brand to the generic, the greater the likelihood of an SPLC.

Where the constituent elements of sections 79 or 90.1 are met, the Bureau will then consider possible business justifications (under section 79) or economic efficiencies (under section 90.1). When assessing business justifications or efficiencies, the Bureau will consider a number of factors, including (i) the credibility of the claims, (ii) the link to the Settlement, (iii) the likelihood of the benefits being achieved, and (iv) whether the benefits would or could not be obtained but for the Settlement.

Where the business justifications or economic efficiencies provided by the parties are not valid, or do not offset any negative effects on competition, the Bureau may seek a remedy from the Tribunal to prohibit the Settlement or the anticompetitive terms of the Settlement. The Bureau may also seek an administrative monetary penalty from the parties to the Settlement.[20] In addition, the Tribunal is also empowered to make an order directing any or all persons against whom an order is sought to take such actions as are reasonable to overcome the effects of the practice of anticompetitive acts in that market.

Under section 90.1, the Tribunal may make an order prohibiting any person from doing anything under the Settlement, or requiring any person (with the consent of that person and the Bureau) to take any other action.

V. CONCLUSION

Given the importance of pharmaceuticals to Canada's health care sector, and the role that generic entry plays in fostering the benefits of competition, one of the Bureau's enforcement concerns is to prevent anticompetitive conduct in the pharmaceutical industry. In this regard, the Bureau has taken a fervent interest in life-cycle management strategies, such as "product-hopping," as well as Settlements between brand and generic drug manufacturers that may delay generic entry.

[19] Canada's *Patented Medicine Notice of Compliance Regulations* governs generics that seek to sell their product before patent expiry. Under section 8 of these regulations, the brand is liable for the generic's losses from being kept off the market until issues such as patent validity and infringement can be addressed by the Courts.

[20] Subsection 79(3.1) of the Act specifies that if the Tribunal makes an order against a person under section 79, it may also order them to pay an administrative monetary penalty in an amount not exceeding CDN$10 million and, for each subsequent order, an amount not exceeding CDN$15 million.