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**COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS**

**Contribution from Canada**

-- Session III --

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## COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

-- Canada --

### 1. Introduction

1. Canada's Competition Bureau (the "Bureau") is pleased to provide this submission to the OECD Competition Committee roundtable on "Competition Issues in the Distribution of Pharmaceuticals". The Bureau, as an independent law enforcement agency, ensures that Canadian businesses and consumers prosper in a competitive and innovative marketplace. Headed by the Commissioner of Competition, the Bureau is responsible not only for the administration and enforcement of the *Competition Act* (the "Act") and certain other statutes, but also for advocating for greater reliance on market forces to deliver the benefits of competition to Canadians.

2. Health care markets are of critical importance to the welfare of Canadians and represent a significant share of the country's economy (11.6% of 2012 GDP).<sup>1</sup> Pharmaceuticals are an important high-growth component of health care costs, with total Canadian pharmaceutical sales doubling from 2001 levels to \$22.3 billion in 2011.<sup>2</sup> Accordingly, the pharmaceuticals sector remains an area of interest for the Bureau's enforcement and advocacy work. The Bureau has especially focused on the role of generic drugs in fostering greater competition in Canadian health care markets. Generics play an important role in keeping down health care costs by providing competition for brand drugs.<sup>3</sup>

3. Canada is characterized by markets for generic pharmaceutical products that are highly concentrated. According to a study conducted by the Patented Medicine Prices Review Board ("PMPRB"), in 2007, the two leading suppliers in a typical generic market accounted for 84.5 percent of sales, while the top four suppliers accounted for 96.7 percent.<sup>4</sup> Canadians appear to pay higher prices for generic drugs when compared with other jurisdictions. A 2006 study on non-patented drugs by the PMPRB found that average international prices for generic drugs in ten developed countries were 15 to 77 percent lower than average Canadian prices,<sup>5</sup> a result in line with the Bureau's own study on the generic drug sector.<sup>6</sup>

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<sup>1</sup> Canadian Institute for Health Information, Canada's health care spending growth slows, available: [http://www.cihi.ca/CIHI-ext-portal/internet/EN/document/spending+and+health+workforce/spending/release\\_30oct12](http://www.cihi.ca/CIHI-ext-portal/internet/EN/document/spending+and+health+workforce/spending/release_30oct12)

<sup>2</sup> Industry Canada, Pharmaceutical Industry Profile, available: [http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h\\_hn01703.html](http://www.ic.gc.ca/eic/site/lsg-pdsv.nsf/eng/h_hn01703.html).

<sup>3</sup> By "brand drugs", we are referring to patented prescription drugs that are marketed and sold under a trademarked brand name. Similarly, this submission refers to the manufacturers of these patented drugs as "brand manufacturers."

<sup>4</sup> Patented Medicine Prices Review Board, "Generic Drugs in Canada: Market Structure – Trends and Impacts, December 2010, ("PMPRB Study") at page 12.

<sup>5</sup> Patented Medicine Prices Review Board, "PMPRB Non-Patented Prescription Drug Prices Reporting: Canadian and Foreign Price Trends" (2006), quoted by SECOR Consulting on behalf of the Health Council of Canada, "Generic Drug Pricing and Access in Canada: What are the implications?" (June 2010), available: [http://www.secorgroup.com/files/pdf/ARTICLES/generics\\_June182010\\_rpt.pdf](http://www.secorgroup.com/files/pdf/ARTICLES/generics_June182010_rpt.pdf)

However, the PMPRB's study found that there does not seem to be a simple relationship between high market concentration and the relative cost of a generic drug in Canada, concluding that complex factors were at play.

## 2. Overview of the Canadian pharmaceutical sector

4. Pharmaceuticals in Canada are governed by a complex regulatory regime. This regime introduces several factors that a competition analysis must take into account when examining conduct in this industry. A brief summary of the relevant legislation is provided below.

### 2.1 *Bringing pharmaceuticals to market*

5. There are two federal statutes governing pharmaceutical products in Canada. The *Food and Drugs Act*<sup>7</sup> enables the Minister of Health to regulate the safety, efficiency, and quality of drugs, while the *Patent Act*<sup>8</sup> sets out private intellectual property rights and obligations for the owners and licensees of brand drugs.

6. The *Food and Drug Regulations*<sup>9</sup> require all new drugs to successfully pass a review conducted by Health Canada to assess their safety, efficacy, and quality. If all the requirements are met, Health Canada will issue a Notice of Compliance ("NOC") for the drug. If a manufacturer wishes to begin selling a generic drug in the Canadian market and the brand name version of that drug has already received its NOC, then the *Food and Drug Regulations* allow the generic manufacturer to file an Abbreviated New Drug Submission ("ANDS") in order to get regulatory approval. Instead of duplicating the same battery of tests and evidence that the brand was required to provide for approval, a generic manufacturer filing an ANDS need only show that the generic drug is bio-equivalent to the brand drug.

7. The *Patented Medicine Notice of Compliance ("PM(NOC)") Regulations*<sup>10</sup> provide a link between the *Patent Act* and the review process under the *Food and Drugs Act*. The purpose of the PM(NOC) Regulations is to balance protection for the investments of brand manufacturers, while also ensuring that Canadians receive timely access to lower cost generic medicines.

8. Under the PM(NOC) Regulations, a generic manufacturer may apply to Health Canada for its NOC and begin selling its generic version of a brand drug before the date of patent expiry. To do this, the generic manufacturer must serve the brand manufacturer with a Notice of Allegation (NOA) stating that the generic drug will not infringe the brand manufacturer's patent rights, or that the brand's patent is invalid.

9. In response, the brand manufacturer may elect to commence proceedings contesting the generic manufacturer's claim of non-infringement or invalidity. If the brand manufacturer does launch such proceedings, it is automatically granted a 24 month stay from the court prohibiting the Minister of Health from issuing an NOC to the generic manufacturer. The generic may only be granted an NOC after the 24 month stay expires or once the litigation is resolved in its favour, whichever is earlier.

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<sup>6</sup> Competition Bureau, "Generic Drug Sector Study" ("Generic Drug Study"), (2007), available: <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/02495.html#C2>.

<sup>7</sup> R.S.C., 1985, c. F-27.

<sup>8</sup> R.S.C., 1985, c. P-4.

<sup>9</sup> C.R.C., c. 870.

<sup>10</sup> SOR/93-133.

10. If the brand manufacturer is successful in contesting the generic's NOA, then the NOC for the generic cannot be issued until the final patent expires. If the generic manufacturer is successful, the NOC can be issued as soon as Health Canada has finished its review for safety and efficiency, allowing the generic to enter the market.

11. Once a drug receives a NOC from the Minister of Health, it can be sold anywhere in Canada. In practice, a manufacturer will need to establish distribution channels and arrange to have its drug listed on public and private formularies if it hopes to capture significant sales in the market. These aspects of the market are described in more detail below.

## **2.2 *Distribution of pharmaceuticals in Canada.***

12. Most prescription drugs in Canada are distributed to retail pharmacies through wholesalers known as independent pharmacy distributors ("IPDs"). These companies are generally third parties that acquire brand drugs and generic drugs from a variety of manufacturers to distribute to their pharmacy clients. They may also stock over-the-counter medicines, health and beauty aids, and confectionary items.<sup>11</sup> IPDs are popular with retailers because of the convenience they provide through one-stop shopping. Canadian IPDs do not generally appear to enter into or maintain restrictive supply agreements with drug manufacturers, although they may make use of "most favoured nation" ("MFN") clauses to ensure that they are getting the best possible price for the drugs they carry.

13. Prescription drugs may also be distributed to the retail pharmacy level by self-distributing pharmacy chains or through direct supply by manufacturers. Direct shipments to pharmacies and hospitals are infrequent in Canada, accounting for as little as 9.2% of drug distribution to retail.<sup>12</sup>

14. Retail pharmacies are the main retail point of sale for prescription drugs in Canada. There were more than 7,900 retail pharmacies in 2006, purchasing more than \$15.74 billion worth of prescription drugs.<sup>13</sup>

15. Pharmacies play a pivotal role in competition among prescription drugs in Canada. After a physician has prescribed a drug, pharmacists have a broad scope under provincial and professional laws and policies to substitute among interchangeable brand and generic drug products when filling prescriptions. As pharmacies have an interest in stocking only a small number of products to minimize their costs, competition is fierce among drug manufacturers to secure contracts to have their products stocked. As discussed further below, this competition, however, has not necessarily benefited insurers or consumers who pay out-of-pocket.

16. The choice of which drug to stock may have complicating factors. Provincial drug plans may require pharmacies to substitute the lowest-priced drug available, typically a generic.<sup>14</sup> In addition, generic companies have traditionally offered significant rebates to pharmacies on their generic drug products as an added financial incentive to substitute generics for brand products. The province of Ontario banned these rebates in 2006 in the hopes that generic drug prices would fall, but manufacturers circumvented the ban

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<sup>11</sup> Generic Drug Study at page 22.

<sup>12</sup> Canadian Association for Pharmacy Distribution Management, "CAPDM Industry Trends Report: Focus on Retail Pharmacy" (2006), available: <http://capdm.ca/members/pdf/Retail%20Pharmacy%20Trends%20Report%20dec06.pdf>, at page 2.

<sup>13</sup> Generic Drug Study at page 25.

<sup>14</sup> Exceptions are generally provided if the physician specifies in the prescription that the brand drug must be issued, or if the patient specifically requests the brand drug and is willing to pay the difference in cost.

through the use of professional allowance fees. In 2010, Ontario banned these allowances, and also introduced regulation to prevent pharmacies from selling “private label” generic drugs from their own manufacturers.

17. Hospitals are also an important source of retail sales. Prescription drugs used in Canadian hospitals are usually paid for from public funds, and provided to patients in the course of treatment. The type of pharmaceutical products used in hospitals can differ significantly from what is sold in pharmacies, e.g., drugs that are administered by injection rather than orally, and this may be reflected in manufacturers’ share of sales to hospitals.<sup>15</sup>

18. While hospitals may negotiate their supplies of drugs directly with manufacturers, they more often rely on other organizations for this purpose. Group purchasing organizations (“GPOs”) are stand alone operations whose shares are held by hospitals and other health care organizations and are established to provide centralized procurement to capture volume discounts for their members. Hospitals may also rely on Regional Health Authorities (“RHAs”) to negotiate their supply needs. RHAs are entities that were established by most provincial governments in the 1980s and 1990s to amalgamate health services within a given region.<sup>16</sup> Hospitals may also retain the services of IDPs.

### 2.3 *Reimbursement of drugs*

19. Once a manufacturer has obtained an NOC for a drug, it may sell its drug anywhere in Canada. However, as mentioned above, a drug must be listed on formularies before it can be reimbursed under public and private drug programs.

20. An estimated 98 percent of the Canadian public is covered by some sort of drug insurance plan. Public plans, at both the provincial and federal level, cover roughly one third of the insured population, with private insurance plans covering the remaining. However, public plans cover a disproportionately large amount of prescription drug sales due to their coverage of high-use individuals (e.g., senior citizens). As such, provincial governments have significant influence on the pharmaceutical sector by choosing which drugs, brand and generic, will be included on the provincial formulary.<sup>17</sup> Private sector drug plans and out-of-pocket cash payments tend to be based on the prices listed on provincial drug formularies.

21. Drug insurance plans, both public and private, use deductibles and co-payments as a means to keep down overall drug plan costs, and to discourage over-use of prescription drugs.

22. The PMPRB is a federal regulatory agency responsible for reviewing the prices of patented brand name drug products to ensure that they are not excessive, establishing price ceilings to this effect. However, the actual price paid for patented drugs on an insurer’s formulary is negotiated between the insurer and the brand manufacturer, and can differ from the PMPRB’s ceiling.

23. Generic drug prices are also regulated by provinces, and tend to be a fixed proportion of the price of the brand name drug. There has been considerable legislative activity in Canada surrounding price caps for generic drugs on provincial formularies. For example, in April 2010, the Ontario government amended

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<sup>15</sup> Generic Drug Sector Study, page 32.

<sup>16</sup> Generic Drug Sector Study, pages 33-34.

<sup>17</sup> SECOR Consulting on behalf of the Health Council of Canada, “Generic Drug Pricing and Access in Canada: What are the implications?” (June 2010), available: [http://www.secorgroup.com/files/pdf/ARTICLES/generics\\_June182010\\_rpt.pdf](http://www.secorgroup.com/files/pdf/ARTICLES/generics_June182010_rpt.pdf).

its regulations so that under the Ontario Drug Benefit Plan, generic drugs can be sold for no more than 25% of the equivalent brand drug.

24. In instances where the equivalent brand drug is not listed on a formulary, a generic may still qualify for listing. In these circumstances, pricing will be determined either through negotiation or pursuant to a regulatory formula. Generic drugs in these circumstances are generally higher priced than they would be otherwise.

25. Observation of Canadian markets<sup>18</sup> suggests that there is limited competition in the pricing of generic drugs on provincial formularies. Generic drug prices listed on formularies have tended towards the maximum amount allowed by regulation. The PMPRB study noted that Canadian markets do not appear to enjoy the significant price reductions that one would expect from generic manufacturers competing to get their drugs listed on the formulary, even in markets with significant numbers of competing generics.<sup>19</sup>

### **3. Conduct in the pharmaceutical industry that may be subject to Bureau review**

26. The unique and complex regulatory framework that governs the pharmaceutical industry has created challenges for competition law enforcement by the Bureau. Nevertheless, as there are no specific laws relating to competition in the pharmaceutical sector, the Bureau has applied, and continues to apply, the general provisions of the Act, which are described below, to potentially anti-competitive conduct as it arises in these markets. Examples of conduct specific to the pharmaceutical industry, as well as a brief description of the provisions of the Act that may apply to the conduct, follows.

#### **3.1 Relevant provisions of the Competition Act**

27. The following provisions of the Act have been considered by the Bureau when considering various forms of conduct that has been observed in the pharmaceutical sector. The list provided below does not preclude the Bureau from considering other provisions of the Act should the particular circumstances of the case justify it.

- The criminal provisions of the Act, which include:
  - Section 45, the conspiracy provision of the Act, prohibits agreements or arrangements between competitors to fix prices, allocate markets or customers, or limit production or supply.<sup>20</sup> Conspiracies are a criminal offense that may involve both fines and prison terms.
  - Section 47, the bid-rigging provision of the Act, which prohibits agreements or arrangements between competitors making a bid, where the agreement or arrangement is not made known to the person calling for the bid.
- The restrictive practices provisions of the Act, which include:
  - Section 75, the refusal to deal provision of the Act, which deals with situations where a supplier refuses to provide its product to a customer on the usual trade terms;

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<sup>18</sup> See e.g. the Generic Drug Sector Study and the PMPRB study.

<sup>19</sup> PMPRB study at page 12.

<sup>20</sup> For greater information concerning which agreements between competitors are likely to be enforced on a criminal standard by the Bureau, please consult the Bureau's "Competitor Collaboration Guidelines", (2009), available: [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](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).

- Section 76, the price maintenance provision of the Act, prevents a company from influencing a price upwards in a market, or discouraging a price decrease, by means of a threat, promise, or agreement. It also prohibits suppliers from discriminating against a customer due to that customer’s low pricing policy;
  - Section 77, which deals with exclusive dealing, market restrictions, and tying practices; and
  - Section 79, the abuse of dominance provision, which seeks to prevent firms that are dominant in a market from engaging in anti-competitive acts that create, maintain or entrench their market power. Paragraph 79(5) contains an exception for firms that are engaged in the “mere exercise” of an IP right. In practice, section 79 is frequently applied by the Bureau in cases that could also justify the application of section 75 or section 77.
- Section 90.1 of the Act, a civil provision that prohibits agreements or arrangements between competitors that do not merit treatment as conspiracies, but which nonetheless harm competition in a market; and
  - Section 92, which allows the Bureau to review proposed and consummated<sup>21</sup> mergers to determine whether they will likely result in a substantial lessening or prevention of competition.

### 3.2 *Pay-for-delay settlements*

28. “Pay-for-delay” settlements, also known in the industry as “reverse payments”, describe a type of settlement agreement that may arise in litigation between a brand manufacturer and a generic manufacturer pursuant to an NOA under the PM(NOC) Regulations. In these settlements, the brand manufacturer provides a payment to the generic manufacturer in exchange for the generic delaying its entry into the market. Unlike the United States, there is no requirement in Canada for the parties to provide prior notification of these transactions.

29. For the brand manufacturer, such a settlement removes the threat that the generic drug will enter the market well before the expiry of the brand’s patent. This provides the brand manufacturer with a greater period of time during which it may reap the higher profits without facing competition from a generic. For the generic manufacturer, the settlement involves a considerable cash payment, or increasingly, valuable consideration in the form of IP licenses, co-promotion or co-development agreements, or an agreement from the brand manufacturer that it will not launch an authorized generic. In effect, the consumer surplus that would have resulted from early entry by the generic drug (and the accompanying lower prices) is instead split between the brand manufacturer and the generic manufacturer.

30. The Bureau has reviewed some NOA-related litigation settlements in the course of its issuance of advisory opinions<sup>22</sup> to pharmaceutical firms. Depending on the facts of the case, section 45 or section 90.1 are the provisions of the Act most likely to apply to this conduct..

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<sup>21</sup> Section 97 of the Act provides that *no application may be made under section 92 in respect of a merger more than one year after the merger has been substantially completed.*

<sup>22</sup> At its discretion, the Bureau may, on request from any person, provide a written advisory opinion on the applicability of one or more provisions of the Act to a proposed practice or conduct.

### **3.3 *Product-switching strategies***

31. Brand manufacturers may use a variety of life-cycle management strategies to try to extend their market power with respect to particular therapeutic treatments. These may include, but are not limited to, introducing new innovative drugs or product-hopping or switching strategies.

32. “Product-hopping” or “product-switching” describes situations where a brand manufacturer responds to the threat of patent expiry and/or entry by a generic drug by introducing a patented reformulation of its original patented brand drug. The reformulation involves minor changes (such as a change in dosage method or product strength) that are of little therapeutic benefit, but differentiate the product just enough so that a generic version of the original drug would not be considered equivalent to the reformulated drug for purposes of automatic substitution at the pharmacy level.

33. Product-hopping or product-switching strategies also involve the brand manufacturer taking steps to switch physicians and patients from the original drug to the patented reformulated drug in advance of the generic’s entry, through such steps as terminating supply of the original drug, buying up and destroying stock of the original drug, and, in combination with other anti-competitive conduct, using targeted advertising campaigns to convince physicians (who are not price-sensitive) to prescribe the reformulated drug. If the brand firm manages to switch enough patients to the new formulation, then it may have eliminated the market for the generic, thus blocking its entry.

34. Depending on the facts of the case, section 79 is the provision most likely to apply to product-switching conduct, as it involves anti-competitive acts by a single dominant company designed to exclude competitors and to create, maintain, or enhance its market power. In the Bureau’s view, such conduct in certain circumstances may go beyond the “mere exercise” of an IP right and thus cannot be shielded pursuant to the exception contained in paragraph 79(5) of the Act.

### **3.4 *Authorized generic drugs***

35. An authorized generic is a version of a brand drug that is manufactured and sold as a generic drug by the brand manufacturer, or by a licensee. They are distinguished from independent generics, which are generic drugs manufactured by firms other than the brand manufacturer that compete directly with the brand drug. Authorized generics are generally introduced shortly before, or concurrent with, entry by independent generics.

36. From a theoretical perspective, authorized generics have an ambiguous effect on drug prices. On the one hand, they are competitors in the marketplace and could be expected to lower prices. On the other hand, authorized generics (or the threat of an authorized generic) may deter entry by independent generics, reducing competition.

37. Generic drug markets are generally characterized by a critical first-mover advantage – the first generic to enter the market is most likely to gain significant market share by getting itself listed on provincial formularies (which also affords it a higher regulatory price cap than succeeding generics) and successfully negotiating stocking agreements with pharmacies. Since authorized generics generally have an advantage in terms of manufacturing and distribution systems, as well as in the regulatory approval process, they may enter the market before the independent generic and capture all these benefits, discouraging entry by the independent generic.

38. Empirical evidence as to the actual effect of authorized generics in the Canadian market is mixed. In a paper by Professor Paul Grootendorst of the University of Toronto, it was found that although average prices decreased by 12% when an authorized generic entered the market, there was anecdotal evidence that

the threat or actual entry by an authorized generic discouraged independent generics from entering the market.<sup>23</sup>

39. The introduction of an authorized generic drug into a drug market facing entry by generic competitors may be analyzed by the Bureau in the context of other potentially anti-competitive conduct, such as pay-for-delay settlements and brand switching strategies.

### **3.5 Other potentially anti-competitive conduct**

40. Given the concentrated nature of the Canadian pharmaceutical industry, many practices engaged in by firms in this sector may trigger investigations and enforcement action by the Bureau. The Bureau has reviewed several mergers in the sector, both horizontal (which could potentially include mergers between manufacturers, wholesalers, and retailers) and vertical (particularly between wholesalers and retailers).

41. Firms in the pharmaceutical market may also engage in a wide variety of unilateral conduct. The Bureau may investigate such acts as exclusive dealing, tying of drug product offerings, and the use of MFN clauses by wholesalers and retailers under the restrictive practices of the Act.

42. The Bureau has also been called upon to review joint ventures between market participants in the pharmaceutical sectors. Such arrangements are subject to review under section 90.1 or, when the possibility of allocating prices or markets arises, under section 45 of the Act.

## **4. Bureau activity in the pharmaceutical sector**

43. Bureau activity in the pharmaceutical sector can be broadly categorized into two sections, 1) non-enforcement work in the form of advocacy initiatives and guidance documents, and 2) and enforcement cases.

### **4.1 Non-Enforcement work and Industry Guidance**

#### *4.1.1 Workshop on Antitrust Issues in the Pharmaceutical Sector*

44. On November 13, 2013, the Bureau held a workshop on the pharmaceutical sector. This workshop was intended to signal to the industry that competition issues in the health care sector are of interest to the Bureau, and to signal to international antitrust authorities the desire to discuss and address the competition issues in the industry for convergence purposes. The workshop participants benefited from hearing the experiences of representatives from both the US and the EU.

45. The workshop featured a number of panels on developments in the pharmaceutical sector, including international trends in pharmaceuticals and antitrust, pay-for-delay settlements, and life-cycle management strategies.

#### *4.1.2 The Intellectual Property Enforcement Guidelines (September 2000)*

46. With the goals of offering transparency and predictability to firms operating in technologically complex industries, the Bureau released its *Intellectual Property Enforcement Guidelines* (“IPEGs”) in

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<sup>23</sup> See Boyer, Trebilcock and Vaver, *Competition Policy and Intellectual Property* (Toronto: Irwin Law 2008), Ch.3, Grootenorst, “Effects of “Authorized Generics” on Canadian Drug Prices”, and Hollis, “Commentary on “Effects of “Authorized Generics” on Canadian Drug Prices””.

September 2000.<sup>24</sup> The IPEGs were intended to set out the approach used by the Competition Bureau when considering the interface between IP rights and competition law. In the guidelines, the Bureau confirmed that in its view, the mere exercise of an IP right does not constitute an anti-competitive act, e.g., a unilateral refusal to license a particular IP, and nothing more. Where a firm is engaged in something more, such as selective licensing of its IP rights in an effort to exclude competitors in other markets, the provisions of the Act may apply. In very limited circumstances, a mere exercise could contravene section 32 of the Act, but there is no jurisprudence concerning this provision.

47. As the IPEGs are now 13 years old, they do not reflect either the amendments to the Act made in 2009, or developments that have occurred in the pharmaceutical sector. This was among the concerns that led the Bureau to hold its workshop on the pharmaceutical sector on November 13, 2013. As described above, the workshop was a collaborative exercise with various stakeholders from the industry, including representatives from brand manufacturers, generic manufacturers, academics, and government agencies. The Bureau intends to use the information gathered through this workshop to help guide its planned update of the IPEGs.

#### 4.1.3 *The Canadian Generic Drug Sector Study (October 2007)*<sup>25</sup>

48. As this study will be the focus of a separate discussion as part of this OECD Roundtable, we have abbreviated its discussion below.

49. Following the publication of studies showing that prices for generic drugs were relatively higher in Canada compared to other jurisdictions, the Bureau conducted a study into the generic drug sector to examine the market and identify areas where changes in the market framework could secure greater benefits through competition.

50. The Bureau's study resulted in several key findings, including:

- Generic drugs in Canada are supplied through a unique and complex framework;
- Generic manufacturing has become more competitive in recent years, with strong competition in the supply of many drugs;
- In most Canadian provinces, an important way in which manufacturers compete to have their product stocked by pharmacies is by offering them rebates off invoice prices.
- Competition by generic manufacturers through low prices in the form of rebates is not reflected in prices paid by insurance plans, or out-of-pocket.
- Plans incorporate various policies, such as maximum generic prices and MFN clauses, to reduce their generic drug costs. However, these policies provide limited incentive for manufacturers to compete by offering competitive generic prices to the plans.

51. In November 2008, the Bureau published a follow-up backgrounder to the study, "Benefiting from Generic Drug Competition in Canada: The Way Forward."<sup>26</sup> This backgrounder developed recommendations for private and public drug plans based on the Generic Drug Study.

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<sup>24</sup> Competition Bureau, "Intellectual Property Enforcement Guidelines", available: <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng/01286.html>.

<sup>25</sup> Generic Drug Sector Study, *supra* note 6.

- Private plans were recommended to: 1) develop preferred pharmacy networks as a means of achieving savings; 2) promote greater use of mail-order pharmacies; and 3) provide patients with incentives to seek lower prices.
- Public plans received a wider range of recommendations, including: 1) using measures to obtain true generic drug prices such as through competitive tendering; 2) separate reimbursement of pharmacy services to remove the need for subsidies in the form of rebates for generic drugs; 3) removing restrictions on competition between pharmacies; and 4) improving inter-provincial coordination.

52. At the time of, and subsequent to, the Generic Drug Study, provincial governments were examining and making important amendments to their regulatory frameworks for pharmaceuticals. The study, as well as the follow-up background, played an important role in the regulatory climate at that time.

#### 4.1.4 *Study on Self-Regulated Professions*

53. In December 2007, the Bureau released a study on *Self-Regulated Professions: Balancing Competition and Regulation*. The study was aimed at developing a discussion on competition issues and general principles pertaining to the interface between regulation and the competitive supply of professional services. In addition, the study examined the regulation of five self-regulating professions, including pharmacists, with the objective of identifying measures that may be unnecessarily restricting the benefits of competition for Canadians.

54. The study made several recommendations that the Bureau felt would improve competition in the pharmacy profession, including reducing admission requirements for foreign-trained pharmacists, reducing barriers to mobility between provinces, removing unnecessary restrictions on advertising, and a review of restrictions on business structures used in the profession. The Bureau has subsequently noted improvements in many areas of regulation within these professions, although some areas could still benefit from increased competition.<sup>27</sup>

## 4.2 **Enforcement work**

55. The Bureau has a long history of enforcement work in the pharmaceutical industry. The cases discussed below are representative of some of the cases that the Bureau has taken in this area, starting with the most recent.

### 4.2.1 *Alcon Canada*

56. In 2012, the Bureau commenced an investigation to determine whether Alcon was engaged in a practice of anti-competitive acts relating to product-switching contrary to section 79 of the Act. In particular, the Bureau was concerned 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.

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<sup>26</sup> Available: [http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/GenDrugStudy-Report-081125-fin-e.pdf/\\$FILE/GenDrugStudy-Report-081125-fin-e.pdf](http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/vwapj/GenDrugStudy-Report-081125-fin-e.pdf/$FILE/GenDrugStudy-Report-081125-fin-e.pdf).

<sup>27</sup> Competition Bureau, “Self-Regulated Professions – Post-Study Assessment” (2010), available: <http://www.competitionbureau.gc.ca/eic/site/cb-bc.nsf/eng%20/03407.html>.

57. Alcon received permission from Health Canada in 1997 to market Patanol, a prescription ophthalmic solution used to treat allergic conjunctivitis. The patent for the active pharmaceutical ingredient, olopatadine hydrochloride, would expire on November 21, 2012, while a further patent would expire on May 3, 2016.

58. Apotex Inc., Canada's largest generic pharmaceutical company, sought Health Canada's approval to market its generic version of Patanol in February 2010. Pursuant to the PM(NOC) Regulations, Apotex served an NOA on Alcon. Alcon responded by contesting Apotex's NOA, which triggered a 24-month stay on Health Canada approval of Apotex's generic drug. As it had challenged only one of Alcon's two patents, Apotex was prepared to await the expiry of the medicinal ingredient patent on November 21, 2012, before obtaining its NOC from Health Canada. Alcon's application to the Federal Court contesting Apotex's allegations was heard in early 2012. Following the hearing of the patent challenge between Alcon and Apotex, and while the decision from the Federal Court was on reserve, Alcon withdrew its challenge to Apotex's patent claims. On November 22, 2012, the day after the patent expired on the medicinal ingredient, Health Canada issued Apotex its NOC for its generic version of Patanol. However, due to various circumstances, Apotex's product only entered the market in July 2013.

59. In January 2011, Alcon received an NOC from Health Canada for Pataday, essentially a reformulated higher concentration version of Patanol, and entered the Canadian market in April 2011. Pataday is under patent protection until 2022.

60. Alcon continued to supply the Canadian market with Patanol until July 2012. During the time period where both Patanol and Pataday were simultaneously on the market, Pataday sales remained marginal compared to those of Patanol. Accordingly, in July 2012, approximately five months before the earliest possible date of entry of a generic version of Patanol, Alcon chose to discontinue the supply of Patanol in Canada and advised the market that Patanol would be on "backorder" for the foreseeable future. With the supply disruption, physicians no longer had the option of prescribing Patanol and many began prescribing Pataday. Sales of Pataday largely replaced the sales of Patanol.

61. The Bureau was concerned that Alcon's behaviour would prevent the entry of a generic version of Patanol and result in patients paying a high price for Pataday until 2022 rather than having the option of paying a lower priced generic for Patanol. This investigation is still ongoing as of this writing.

#### 4.2.2 *Novartis/Alcon*

62. On August 9, 2010, the Bureau approved Novartis AG's acquisition of control of Alcon, Inc., subject to certain divestitures. The Bureau concluded that the proposed transaction was likely to result in a substantial lessening of competition in Canada for the supply of certain ophthalmic products, including contact lens cleaners and disinfectants, injectable miotics, and ocular conjunctivitis drugs. Certain assets and associated licenses for these products were required to be divested to third party purchasers.

#### 4.2.3 *Teva/ratiopharm*

63. On July 30, 2010, the Bureau approved a merger between two generic drug manufacturers, Teva Pharmaceutical Industries Ltd. ("Teva") and the Merckle Group (carrying on business as ratiopharm). The Bureau concluded however that the merger would likely lead to a substantial lessening of competition in the supply of certain drugs commonly used for the relief of moderate to severe pain, acetaminophen oxycodone tablets and morphine sulphate sustained-released tablets. Accordingly, the Bureau required the parties to divest certain assets and associated licenses relating to the sale and supply of certain dosage forms of these products in Canada.

#### 4.2.4 *Pfizer/Wyeth*

64. On October 14, 2009, the Bureau announced that it had approved a merger between Pfizer and Wyeth on the condition that, among other things, the companies divest a significant number of animal health products to resolve competition concerns. In addition, Pfizer was required to amend the terms of its existing arrangement with Paladin Laboratories, a Canadian speciality drug company, governing the distribution, marketing, and sale of the drug Estring to ensure continued competition in the supply of human hormone replacement therapy products.

### **5. Conclusion**

65. Pharmaceutical markets are complex and subject to a variety of overlapping regulatory frameworks. Change and innovation is rapid and continuous, forcing competition agencies to frequently update their market information and their understanding of current trends in the market. In the last few years, competition authorities, including the Bureau, have taken notice of business tactics adopted by pharmaceutical companies to protect their innovations such as settlements delaying generic market entry and product switching strategies.

66. The pharmaceutical sector remains of great interest to the Bureau, both in terms of enforcement work and advocacy efforts. The Bureau will continue to enforce the general competition laws of Canada as this sector continues to develop.