

Canadian Pharmaceutical Patent Policy: International constraints and domestic priorities¹

Mélanie Bourassa-Forcier and Jean-Frédéric Morin²

Chapter 5 of *A New Intellectual Property Paradigm*, edited by Y. Gendreau, Edward Elgar, 2008, pp. 81-103.

1. Introduction

This chapter addresses the Canadian pharmaceutical patent policy and underscores the aspects of this policy that demonstrate CND's continuing effort to promote pharmaceutical R&D and consumer access to new medicines.

In order to ensure that our study has worldwide appeal, we have adopted a comparative approach towards Canadian patent policy and policies of other countries. It is often believed that Canada is in a delicate position for adopting a strongly different patent policy from United States ("U.S."). It is true that the Canadian economy is greatly dependent on its southern neighbor. In 2005, 84% of Canadian exports were destined for the U.S. market and 64% of foreign direct investment stock in Canada was owned by American investors (Office of the Chief Economist of Foreign Affairs and International Trade Canada, 2006). Additionally, the Canadian government intentionally strengthened these economic and industrial ties by signing a free trade agreement in 1988, followed by the North American Free Trade Agreement (NAFTA) in 1992.

Nevertheless, our study reveals that during the last century Canada did not hesitate to depart from the U.S. model to design a unique patent policy for pharmaceuticals products. While the U.S. patent policy mostly reflects libertarian values, the history of the Canadian patent policy, although increasingly imprinted by U.S. influences, reveals a Canadian philosophy for justice in access to health care services. One could even argue that universal access to health services is an integral component of the Canadian identity and a source of national pride. In 2004, Tommy Douglas, a politician known as Canada's father of Medicare, was named the Greatest Canadian of all time in a nationwide contest casting over 1.2 million votes.

Although the federal government consistently took into account the objective of providing fair access to pharmaceutical products in its patent policy, the *Constitution Act* of 1867, s.92(7), provides the provinces and territories with the exclusive power to deliver health care services. While the federal government has jurisdiction over patents and the initial approval of prescription drugs, it is the provincial governments that pay for drugs dispensed in facilities providing hospital care and administer public drug insurances (Anis, 2000, p.523). Interestingly enough, a province can use its purchasing power and capacity to pay higher prices as policy tools, in combination with fiscal policies, to attract pharmaceutical investments. The end result is a sharp

¹ The authors want to thank Rhonda Grintuch for her assistance and the anonymous reviewer for his/her helpful comments.

² Both authors are affiliated with the Centre for Intellectual Property Policy at McGill University. Jean-frederic.morin@mcgill.ca; Melanie.bourassaforcier@mcgill.ca

asymmetry in the geographical distribution of the pharmaceutical industry. While most generic companies, including Apotex, the largest Canadian-owned pharmaceutical company, are headquartered in the province of Ontario, many transnational innovative companies established their Canadian operations in the province of Quebec.

This continuous concern to provide access to pharmaceutical products, and the capacity to create incentives for investments in R&D by other means, contribute to the uniqueness of the Canadian patent policy. In many ways, this Canadian experience could be of interest to large developing countries with significant generic manufacturing capacities, foreign investment in the pharmaceutical sector, and numerous international IP obligations. These countries should nevertheless find in this study a sign that, even in presence of international trade agreements, there is always room to make medicines more accessible.

Each of the six following sections presents past or present distinctive features of the Canadian patent policy, following a roughly chronological order. To begin, we provide an overview of the history of compulsory license rights in Canada. For a length of time, compulsory licenses were considered an essential tool for containing drug expenditures in Canada. In the third section, we describe the uniqueness of the Canadian price regulations scheme and focus on the role of the Patented Medicine Prices Review Board (PMPRB), a federal organization created to control drug prices. Following this analysis, we highlight the “early working” and “stockpiling” exceptions introduced to limit the negative impact of restricted compulsory license rights on the access to medicines. In the fifth section, we draw attention to the Canadian *Notice of Compliance Regulations*. These regulations, sometimes qualified as “automatic injunction tools” available to the pharmaceutical industry, were, in turn, created in response to the early working and stockpiling exceptions in an effort to keep the balance of the Canadian patent policy. The sixth section of this chapter provides a review of the history of the different patent terms that have existed in Canada. In contrast to its American and European counterparts, Canada has not provided the industry with a patent term restoration to compensate delays in drugs’ approval. However, as explained in the following section, the Canadian government has recently granted the industry an 8-year clinical data protection. This chapter ends like it started, with a review of the Canadian compulsory licences policy. While the earlier regime was abandoned to comply with NAFTA requirements, the federal government amended its patent law in 2004, following a WTO decision authorizing compulsory licensing to provide countries with insufficient manufacturing capacities.

2. A special regime of compulsory licences

Past and present Canadian policies regarding compulsory licences are often provided as an example to (or not to) follow. Jerome Reichman and Catherine Hasenzahl from Duke University suggest that Canada’s historical use of compulsory licences could inspire policy makers in developing countries (Reichman and Hasenzahl, 2002). From another perspective, Harvey Bale, of the International Federation of Pharmaceutical Manufacturers Association, used the Canadian example to demonstrate that the abandonment of a generous compulsory licensing system could foster local investment in R&D (Presentation at the Conference on the International Patent System, Geneva 2002). Although it is difficult to establish which policies are best for developing countries, it is undisputable that the Canadian legal history of compulsory licensing is unique,

having undergone radical changes in the early 1990s, announcing broader shifts at the international level.

During most of the twentieth century, Canada had few international obligations with respect to compulsory licensing. The only restriction prescribed by the Paris Convention was a minimum period of time before a compulsory licence could be applied for (art. 5A). Since no international treaty prohibited discrimination in the field of technology, Canada could develop an aggressive policy for compulsory licences on pharmaceutical products. The initial conceptualization of this policy dates back to 1923 when the Parliament adopted a bill, modeled on British patent law, to keep the price of medicines reasonably low and encourage the domestic generic drug industry. Under the regime of the *Patent Act*, any person with an interest in exploiting a patent on foods and medicines was virtually entitled to a “licence of right” for manufacturing purposes. To obtain a compulsory licence, it was not necessary to demonstrate any abuses of the patentee's rights, failures to work locally, or anticompetitive practices. The only requirement was to manufacture the chemical ingredients in Canada (Orlac, 1990, p.3). This single requirement was, in fact, a major impediment and contributed to the modest results of the regime. Since the Canadian market was relatively small, the generic producers had neither the capacity nor the willingness to manufacture the chemical ingredients in Canada (McFetridge, 1998, pp.81-82) In consequence, until 1969, only 49 applications were submitted, of which 22 were granted (Canada, 1985, pp.14-15). Some innovative companies even took advantage of their favorable position and prices of patented medicines became significantly higher in Canada than in other industrialized countries. This failure of the Canadian regime became a major public crisis in the 1960s when Canadian provinces were nationalizing their medical services and beginning to pay for pharmaceuticals. A Royal Commission established by the government and a special Parliamentary committee investigated the issue and concluded that the regime needed to be reformed (Canada, 1963; Canada, 1964; Canada, 1966).

This reform occurred in 1969 when the Canadian Parliament amended its *Patent Act*. According to the amendment (Act to Amend the *Patent Act*, the *Trade Marks Act* and the *Food and Drug Act*, S.C. 1968-69, c.49; art. 41(4)), any person could apply for a compulsory license to import medicines or bulk active ingredients produced with patented processes. The Commissioner of Patents was required to grant the licence unless he saw “good reasons” not to, with the result that most licence applications filed and not abandoned were granted.

The reform had immediate consequences. In the two decades following the enactment of these provisions, 1030 applications were filed and 613 licenses were granted (Reichman and Hasenzahl, 2002, p.38). The generic industry significantly increased its market share and drug prices decreased substantially. According to the report of the Eastman Commission of Inquiry on the Pharmaceutical Industry, Canadians saved more than 210 millions dollars per year as a result of the 1969 amendment (Canada, 1985, p. xvii). More surprisingly, investments in R&D in the pharmaceutical sector did not experience major fluctuations (Canada, 1985, pp. 62, 63, 230).

Despite these positive results, Canada was under diplomatic pressure to move away from its policy. At the end of the 1980s, while a bilateral free trade agreement with United States was under negotiation, the Reagan Administration used the access to the large American market to pressure the Canadian government (French, 1987, pp.341-342; Gherson, 1985, p.1; Harrison, 2001.). It also threatened the Canadian government with trade sanctions by adding the Canadian

compulsory licensing regime for pharmaceutical products to the Special 301 Watch List. Consequently, Bill C-22, amending the Canadian *Patent Act*, was introduced and adopted in 1987. The Bill provided that generic producers could not obtain a compulsory licence until a deferral period of exclusivity had elapsed. On the other hand, it included two discriminatory measures that were heavily condemned by the U.S. government. First, the deferral period varied with whether the generic drugs would be imported or locally manufactured. It could be reduced from 10 to 7 years if production occurred in Canada. Second, the amendment excluded patented pharmaceutical products invented or developed in Canada from the application under the compulsory licenses regime. This “Made-in-Canada” policy was obviously adopted to encourage local investment more than to alleviate criticism from the United States and transnational corporations.

Not surprisingly, “the Canadian reform of 1987 became emblematic of the type of regime the United State Trade Representative would challenge in the course of regional and international trade negotiations” (Reichman and Hasenzahl, 2002, p. 42). Pressure on the Canadian government reached an unprecedented level during the negotiation of NAFTA (Lexchin, 2001, pp. 2-3; Maryse, 2000, p.298). The U.S. government especially condemned the less favorable treatment given by the Canadian regime to pharmaceutical products, inventions made outside Canada and imported generics. Accordingly, Canada traded a privileged access to U.S. market against a reinforced protection of its intellectual property rights, including a provision that made patents “available and patent rights enjoyable without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced.” (NAFTA, art 1703). This provision forced Canada to abolish its special regime of compulsory licensing for patented medicines, which it did in 1993, through the adoption of the Bill C-91.

NAFTA’s rule on non-discrimination was duplicated in the TRIPs Agreement (Art. 27(1)) with the consequence that no other WTO member could follow the Canadian experience on compulsory licensing. Nevertheless, another specificity of the Canadian system, the Patented Medicine Prices Review Board (PMPRB), created by the Bill C-22 in 1987 to compensate for the effect of the new restrictions on compulsory licenses through price control, is not prohibited by multilateral treaties and can serve as an alternative model for countries wishing to maintain low drug prices.

3. The uniqueness of the Canadian drug price regulations

As mentioned in an OCDE report (Paris and Docteur, 2006), all OCDE countries use some form of price control regulations in order to contain drug expenditures. What distinguishes Canada from other countries is the federal government’s direct price control, which is suppletive to provincial price regulations and exclusive to patented drugs.

Drug price regulations in Canada were originally part of the provincial jurisdiction. Provincial drug price regulations, however, only apply for public drug coverage. Therefore, private insurers could theoretically decide not to follow the different provincial pricing schemes. Each province has a distinct drug coverage policy. Some provinces, such as Quebec, offer comprehensive public drug coverage while others only offer catastrophic drug insurance (Paris and Docteur, 2006). Each province determines the criteria for reimbursing (or not) a new drug

under the public coverage. For example, British Columbia has created a reference-pricing scheme. In this scheme, drugs with the same therapeutic effects are clustered into different groups. A drug will be fully reimbursed by the province if its price is equal to, or below, the reference price. This reference price is, in British Columbia, that of the most cost-effective drug within each group (a reference price could also be an average price of the lowest price for a drug within a group). Other provinces, such as Ontario or Quebec, have decided not to follow the British Columbia model and have preferred to limit their policy to the reimbursement of generic drugs, once marketed (Paris and Docteur, 2006, pp. 20-21). To this end, Quebec has created the “15-year rule” as part of its effort to attract R&D investments from the brand-name industry. According to this rule, brand-name drugs can be reimbursed for 15 years after they are marketed in Quebec even if generic drugs are available. This rule is highly criticized by the generic industry and it is not clear whether it effectively helps the province to attract R&D investments (Bahan, D *et al.*, 1995). Finally, most provinces use positive drug reimbursement lists and have established a “lowest price” policy. According to this policy, a province will not reimburse a drug if its price is not the lowest among all Canadian provinces.

The provincial drug pricing schemes can be compared to the different pricing schemes existing in countries with public drug coverage, such as the PBS pricing scheme in Australia (Harvey, 2001) or the reference pricing scheme in Germany (Danzon and Ketcham, 2003). These schemes could be referred to as “indirect pricing schemes” since they do not directly regulate the pharmaceutical industry but provide a strong incentive for reducing the price of its drug.

In Canada, in addition to be regulated at the provincial level, patented drug prices are also controlled by a federal, independent and quasi-judicial body, the Patented Medicines Price Review Board (PMPRB). The PMPRB was created by the 1987’s amendments to the *Patent Act*, concomitantly to the introduction of limited rights to compulsory licenses. Its creation was a clear attempt to limit the negative impact that restrictive compulsory license rights would have had on drug prices, i.e. by limiting generic entry (Paris and Docteur, 2006, p.12).

The PMPRB’s mandate is to protect Canadian consumers from excessive prices for patented drugs prior to or after their marketing. When determining whether a drug is being sold or has been sold at an excessive price, the PMPRB takes different factors into consideration. Only off-factory prices are considered (as opposed to retail prices). In the presence of a breakthrough drug, particular attention is given to the median price for this drug in seven comparable countries: France, Germany, Italy, Sweden, Switzerland, the United Kingdom and the United States. If the drug contains a small improvement to already existing drugs, the Board will first compare its price with one of the drugs in the same therapeutic class. This price comparison system is, in fact, very similar to those used in other countries, such as in France or Spain, when determining what brand-name drug (patented or not, in this case) can be listed on drug formularies. In Canada, patented drug prices cannot, in any case, exceed changes in the Consumer Price Index.

In contrast with other countries, where a drug is not reimbursed if its price exceeds a ceiling price, a Canadian patented drug cannot be marketed if its price is not first approved by the PMPRB. If, once marketed, a drug price becomes excessive in the opinion of the PMPRB, it may either direct the patentee to reduce the price of the drug or any of its marketed drugs in Canada,

or order the patentee to compensate the government for the excess in profits having resulted from the sale of the high-priced drug.

It is generally acknowledged that the creation of the PMPRB has been effective in controlling and keeping the price of Canadian patented drugs low. In 1987, before the organization was created, the price of patented drugs was 23% higher than the international median price. After 1987, patented drug prices were reduced considerably and have become, over the last few years, on average, below the international median price (Paris and Docteur, 2006, p.15). According to the PMPRB's 2005 Annual Report, Canadian prices for patented drugs that year were below those of the United States, the United Kingdom, Germany and Switzerland but greater than in Italy, France and Sweden.

Although the PMPRB's creation in 1987 was accepted by the pharmaceutical industry, we note a growing pressure from the American Pharmaceutical Association (PhRMA) on the Canadian government to eliminate the review board. This growing pressure has emerged following the U.S. consumers' growing interest in cheap Canadian drugs, which can be up to 40% less expensive than in the U.S. In fact, some Canadian provinces, particularly Manitoba, are now recognized for the success of Internet Pharmacies whose main business is cross-border-trade of drugs between Canada and the U.S. (Skinner, 2006, p.9). Even though the pharmaceutical industry has deployed lobbyists in Canada to urge the government to free-up drug prices, the government keeps sending the signal that the PMPRB will survive. However, due to the industry threat that the exportation of drugs may limit the supply in Canada, it is likely that a law will soon be adopted in Canada to prevent such exportation.

Considering the pharmaceutical industry's general dissatisfaction with restrictive marketing rights, it has occasionally been pointed out that, although effective on controlling drug prices, the PMPRB might have chilled R&D investments in Canada. This argument lacks empirical data due to the difficulty in isolating the specific impact of the 1987 amendments to the *Patent Act* which introduced at the same time (1) the PMPRB and (2) limited compulsory licensing rights. This last amendment was precisely aimed at promoting R&D in Canada. Considering the dichotomist effects these amendments might have had on R&D, we are confronted with uncertainty as to the impact one or the other has had on R&D. From the PMPRB's 2005 Annual Report, we note that after 1987, R&D investments have increased. However, we may wonder if these investments would have been higher without the existence of the PMPRB.

3. Exceptions to rights conferred

When the special regime's compulsory licensing on medicines was completely abolished in 1993 to comply with the NAFTA and TRIPS requirements, the Canadian government sought to maintain the equilibrium of its patent system and ensure access to low-cost drugs. The need to find another policy tool to address cost control in the health care system was especially crucial as the expenditures on therapeutic drugs had dramatically risen between 1975 and 1993 (Health Canada, 1996). With this objective in mind, the Canadian Parliament introduced two new exceptions to rights conferred by a patent.

The first exception authorized the production, use and sale of a patented invention for the purpose of seeking regulatory approval in Canada or any other country (sometimes referred to as the “early working exception.”) This exception is similar to what is known in the U.S. as the Bolar exception, introduced in 1984 by the *Hatch-Waxman Act*. Since the regulatory approval process needed to demonstrate that a generic drug is equivalent to the brand-name drug takes about 2-3 years, this measure could significantly accelerate the market entry of generic drugs. The second exception, called the stockpiling exception, was a unique Canadian measure, having had no equivalent in European or American law. It allowed generic producers who use the regulatory approval exception to manufacture and store, during the last six months of the patent term, the drugs intended for sale. With these exceptions, generic producers were able to market and sell their products the day after the patent expired.

The regulatory approval and the stockpiling exceptions were, predictably, heavily criticized by innovative pharmaceutical companies (USTR, 2001). Nevertheless, they did not succeed in convincing the U.S. government to bring the matter under the WTO dispute settlement mechanism. Drug price was a sensitive issue in American politics and the government did not want to put its own Bolar exception at risk (Matthews, 2002, p.101). Therefore, European and U.S. companies, through their European branches, turned to the European Commission, which requested the establishment of a WTO panel in 1998.

Canada acknowledged that its exceptions conflicted with the patent rights granted in accordance with article 28 of the TRIPs Agreement, but it claimed that they were exceptions authorized by article 30 of the Agreement. Consequently, the main task of the Panel was to determine if the two exceptions fulfilled the triple-test of article 30. Inspired by article 9(2) of the Berne Convention, this provision authorizes exceptions to rights conferred as long as they are limited, do not unreasonably conflict with the normal exploitation of the patent, and do not unreasonably prejudice the legitimate interests of the patent owner.

In its report issued in March 2000, the panel concluded that the exception for regulatory approval could be covered by article 30. It does not need to be compensated by an extension of the patent term in proportion with the duration of delays caused by the regulatory approval process, as the U.S. did with the *Hatch-Waxman Act*. However, the panel found that the stockpiling exception does not fulfill the triple test. It failed to be limited, as evidenced by the first requirement for authorized exceptions: “With no limitations at all upon the quantity of production, the stockpiling exception removes that protection [on making and using] entirely during the last six months of the patent term, without regard to what other, subsequent, consequences it might have.” (WT/DS114/R, para 7.34). The panel dismissed Canada’s argument that the curtailment was limited because it preserved the exclusive right to sell, it could only be used by those having utilized the regulatory approval exception, and it only applied for six months. It agreed with the European Community (EC) that “six months was a commercially significant period of time, especially since there were no limits at all on the volume of production allowed, or the market destination of such production.”(WT/DS114/R, para 7.37).

Canada did not refer the dispute to the Appellate Body, complied with the Panel report, and amended its *Patent Act*. Since the stockpiling exception was introduced to compensate for the abandonment of its compulsory licensing regime for drugs, with its abrogation, Canada once again faced the prospect of a unbalanced patent system. This was even more the case if one

considers the parallel maintenance of the *Patented Medicines (Notice of Compliance) Regulations (NOC Regulations)*, initially adopted to limit the effect of the regulatory approval and the stockpiling exceptions.

4. Notice of compliance (NOC) regulations

The *NOC Regulations* were adopted in 1993 in order to limit the likelihood of patent infringements by generic companies facilitated by the newly introduced early working and stockpiling exceptions (“Regulatory Impact Analysis Statement”, 2006, p.1611). The *NOC Regulations* are, from time to time, referred to as linkage regulations because they now require the Minister of Health (“Minister”) to take into consideration the existing registered patents before issuing a Notice of Compliance (NOC) to a generic drug company after it has filed an Abbreviated New Drug Submission (ANDS). By filing an ANDS a generic drug company can only demonstrate the bioequivalence of its product with the brand-name drug. The company is thus exempted from undertaking the complete clinical trial process required to prove the safety and efficacy of a new drug.

Until recently, linkage regulations only existed in the United States and Canada. This situation has now changed since different countries have entered into bilateral agreements with the U.S., where the U.S. has made linkage regulations a component of these agreements. In consequence, Australia and different co-contracting developing countries have recently introduced linkage regulations into their national laws (Sanjuan, 2006).

According to the Regulations, when a brand-name company submits a NOC application or a supplement to its NOC application, it can join a list of patents to be registered on the patent registry. When a generic company files an ANDS it must inform the Health Minister of the existing registered patents, if any, pertaining to the brand-name drug to be copied. When the brand-name drug is still under patent, the generic company must either state that it is willing to wait until the patent expires before a NOC is issued for the generic drug or allege (“Notice of Allegation”) that the registered patent has expired, is invalid or will not be infringed by the NOC’s delivery.

Once the brand-name drug company is informed of this allegation, it can ask the Court for an order prohibiting the Minister from issuing a Notice of Compliance until after the expiration of the patent that is the subject of the Notice of Allegation. This prohibition would however not apply if the generic company has filed a NOC instead than an ANDS. In such case, the Minister would thus not be tied-up by the existence of patents applying to the brand-name product (*Biolyse Pharma Corporation v. Bristol-Myers Squibb Company et al*, 2005).

The simple deposit of this request by the brand-name company triggers a 24-month delay before an NOC can be issued to the generic drug company except if, during that time, the patent expires or the Court renders its order. We underline here that, in this order, the Court is not allowed to assess the validity of patent(s) as it would do in patent infringement proceedings (*Merck Frosst Canada Inc. v. Canada (Minister of National Health & Welfare*, 1994). Consequently, it is possible that, following this order, a generic company be allowed to market its product and, afterward, be judged by another court to infringe an existing patent or, *vice versa*, a generic company could be prevented from marketing its product by this order but another court

could conclude that the existing patents are invalid. The likelihood of such contradictory judgments provides high incentives for pharmaceutical companies to occupy the judicial system in Canada (*Janssen-Ortho inc. v. Novopharm limited*, 2006).

Because the brand-name company's request to prevent the Minister from issuing a NOC to the generic company triggers a 24-month stay, its effect can be compared to the one of an automatic interlocutory injunction. This makes the Canadian patent policy particularly favorable to brand-name companies, considering that it is generally acknowledged that interlocutory injunctions are rarely granted to pharmaceutical companies in Canada. Effectively, in contrast to European courts, Canadian courts do not generally consider a loss of profit to be a criterion for granting an interlocutory injunction (*American Cyanimid v. Ethicon*, 1975; *Centre Ice Ltd. v. National Hockey League*, 1994). Nevertheless, during this suspension period, the Minister will examine the generic company's ANDS. This factor is crucial because it allows the generic company to obtain an NOC as soon as the 24-month delay elapse.

Since their creation, the regulations have been highly criticized due to the existence of important pitfalls leading to evergreening practices by brand-name drug companies. Rapidly, as in also happened in the US, the industry developed different strategies for registering additional patents for marketed drugs or abused of the opposition process to prevent generic companies from obtaining an NOC approval. With this regard, the case *Ferring Inc. v. Canada* (2002) provides a good illustration of the tactics used by the brand-name industry to extend its monopoly. In this case, Ferring tried extend its monopoly by filing, on a strategic date, a supplement to its NOC for a change in the name of its product. This strategy was used to file, at the same time, a new patent list in order to remediate to the company's fault to file on time an additional patent to its product. Fortunately, this practice has been rejected by the Federal Court of Appeal which stated:

Against this background, it is apparent that the only conclusion that can be drawn is that, as in BMS, the change in trade name was part of a strategy designed to overcome the time limitation within which a first person must file its patent list under section 4 of the *Patent Regulations*. As was pointed out in BMS, this strategy, if sanctioned by the Court, would render the time requirements embodied in section 4 meaningless.

In order to rebalance the Canadian patent policy, the government was thus forced to amend its regulations several times after their initial implementation. The first amendments were a response to the 1997 Report of the House of Commons Committee on Industry which recommended a regulatory reform to prevent abuses by the brand-name industry. After their introduction in 1998, the proportion of court orders prohibiting the Minister of Health from issuing an NOC to a generic company fell from 26% to 9% (Valiquet p. 10). Among others, one of these amendments aimed at shortening the suspension period, which was at that time 30 months, to 24 months (*Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, Canada Gazette II*, vol. 132, No. 7, 1998, p. 1051). In 2002, the Commission on the Future of Health Care in Canada (Romanow Report) reported persisting concerns about still existing evergreening practices from the pharmaceutical industry. Also, due to the lack of clarity of the NOC Regulations, Canada was faced to different judicial interpretations of the regulations (Federal Trade Commission, 2002, p.i). In 2003, after the U.S. proposed a modification to its own

regulations, the House of Commons Standing Committee on Industry, Science and Technology entered into another reviewing process of the NOC regulations. It was in October 2006, both after a long negotiating process with industry stakeholders and the submission of proposals for modifications in 2004 that the government finally introduced important clarifications to the regulations (*Regulations Amending the Patented Medicines*, 2006).

In particular, it is now clear that to be listed on the patent registry, the patent list submitted by the patentee must be linked to the drug subject to the NOC application. Previously, it was unclear whether a company could submit a new list of patents when it filed a supplementary drug application for cosmetic changes to the drug, name change, or changes in manufacturing facilities (*Ferring Inc. v. Canada*, 2002; *Hoffmann-La Roche Ltd. v. Canada*, 2005). Some companies benefited from this lack of clarity to continuously file new patents and thus, prevented generic drug companies from obtaining a NOC (*Ferring Inc. v. Canada*, 2002; *Hoffmann-La Roche Ltd. v. Canada*, 2005). The new amendments also limit the type of patents that can be included in the registry. Since 2006, the patent must relate to: 1) a claim for the approved medicinal ingredient, 2) a claim for the approved formulation containing that medicinal ingredient, 3) a claim for the approved dosage form, or (4) a claim for an approved use of the medicinal ingredient (sect. 4). The delay for registering new patents on the registry is also limited to 30 days after the patent is issued if the patent application was submitted to the patent office before the NOC application (sect. 4(6)). This time limit was introduced in order to prevent brand-name companies, who had forgotten to register the patents attached to their drug at the time they had filed their NOC, from adding these patents to the registry. Finally, to limit the number of Notice of Allegation's requirement for generic companies, the amendments provide that the register will be "frozen" from the time a generic drug company files an NOC application. Consequently, this modification impedes brand-name companies from submitting new patents after the generic company's NOC application to force it to constantly send new Notices of Allegation (sect. 5(4)).

By clarifying the NOC Regulations, it is the Canadian government's hope that they will finally reach their objective of creating a balance between the promotion of R&D in the pharmaceutical industry, through a strong IP protection, and access to generic and affordable drugs. Only the future can tell whether or not this will occur. For now, it can be noted that discrepancies still exist within the regulations. In particular, nowhere in the regulation is the Minister granted the power to withdraw a patent from the registry if it is qualified as invalid by the Court. Consequently, this forces generic companies to file a Notice of Allegation for the drug, although the patent registered for it has been judged as invalid in a previous opposition process.

If the future reveals the Canadian government's failure to reach its objective, it would probably be the time to consider different avenues for balancing the Canadian patent policy. Considering the U.S. trade pressures on countries for implementing linkage regulations, it would, however, be surprising that Canada would abrogate its NOC Regulations. However, different options could be offered. For example, Canada could follow the U.S. example where brand-name companies only benefit from a single 30-month waiting period for each new drug subject of a new drug application *Federal Food, Drug, and Cosmetic Act*, 21 USCS § 355 (2005), (j) (5) (B) (iii)). The 24-month delay in Canada could be shortened to the average generic approval time in Canada, which is about 17 months (Health Canada, 2004, p. 31). On the contrary, the future could theoretically reveal abuses by generic companies. This last aspect is seldom mentioned in

discussions of linkage regulations. It must not be forgotten that these regulations aim at limiting patent infringements. If they accomplish their role without strengthening the brand-name industry's monopoly they should be considered a good tool to free up the judicial system.

5 Term of protection

Members of the Paris Union are free to determine the term of protection. In the 1980s, the duration varied extensively from one country to another, and sometimes between fields of technology, ranging from 3 to 20 years and calculated either from the filing date of the application or the date of the grant. Canada and its southern neighbour had offered a protection of 17 years, calculated from the grant of the patent in any field of technology. But the Canadian legislation was amended twice to modify this term of protection.

The first and most important amendment entered into force in 1989. It moved to a term of protection of 20 years from the filing date for patents filed after October 1st 1989. In other words, these "New Act patents" could benefit from a longer effective term of protection if the period between the filing and the granting was less than 3 years. For "Old Act patents," filed before October 1st, the term remained unchanged.

Contrary to most legislative amendments to the Canadian *Patent Act*, this change in term of protection was not externally dictated. Even NAFTA, signed in 1992, left some flexibility to its signatories by providing that the term of protection should be "at least 20 years from the date of filing or 17 years from the date of grant." (art. 1709(12)) The U.S. took advantage of this flexibility and adopted the 20-year standard only in 1995, to comply with the TRIPS agreement. In fact, the 1989 change in the term of protection was adopted, together with the first-to-file principle, early publication of applications, and deferred examination, to simplify administrative procedures and increase the predictability of the patent system.

Canadian term of protection came under international spotlights in 1999 when the U.S. filed a complaint with the WTO dispute settlement mechanism. The U.S. claimed that the term of protection available for the "Old Act patent" did not comply with Article 33 of the TRIPs Agreement, which requires that "the term of protection available shall not end before the expiration of a period of twenty years counted from the filing date." It argued that Canada should protect patents filed before October 1st 1989 for a duration of 20 years from the filing date or 17 years from the grant date, whichever is longer. It estimated that over 66,000 "Old Act patents," including 33,000 from U.S. applicants, would expire sooner than would be the case if Canada had provided a term of 20 years from filing. (WT/DS170/R, para 6.60) Despite these impressive numbers, the real issue under this dispute was related to some 30 commercially significant drugs (Industry Canada, 2001).

Canada's main argument was that an "effective" term of protection of 17 years is equivalent to a nominal term of 20 years and, therefore, consistent in substance with Article 33. Canada made this assertion based on the fact that the administrative procedures between the filing date and the issuance date could exceed three years, making a term of 20 years "available" to patent holders. The Panel and Appellate Body dismissed Canada's arguments, stating that the notion of an "effective" term of protection was not supported by Article 33, and that making a term of protection "available" is a matter of legal right and certainty (WTO Appellate Body

Report, 2000). They concluded that the term of protection for “Old Act patents” is inconsistent with Article 33 of the TRIPs Agreement. In 2001, Canada complied with the Appellate Body’s recommendations and amended its *Patent Act* to entitle “Old Act patents” to the longer term of 17 years from the date of the grant or 20 years from the date of filing.

Since the time-period between the filing date and the granting date is sometimes longer than three years, especially in Canada, the effective patent term could be shorter than it would have been prior to the 1989 amendment (Canadian Biotechnology Advisory Committee, 2001, p.16). To avoid this problem, the U.S. adopted the *Patent Term Guarantee Act* in 1999 and extended the term of protection in the event that issuance was delayed due to a secrecy order, interference, or successful appellate review. This measure has the effect of ensuring a term 17 years from the granting of the application, even though the U.S. has formally converted to a standard of 20 years from the application’s filing. Although Canada did not follow this model and does not compensate any delays in examination, it followed and even surpassed the U.S. model on data protection.

6 Data protection

Data protection in Canada was intended to implement Canada’s NAFTA obligations, which require signatories to provide a minimum of a 5-year protection against the unfair commercial use of undisclosed tests or other data submitted by a pharmaceutical company in order to obtain a new drug submission (NDS) approval (art. 1711 (5) and (6)). The main objective of this protection is to grant a protection to the company of the investments made in the development of the product by allowing a period of market exclusivity. This market exclusivity must be distinguished from the one resulting from patent rights. The result of such protection is to prevent generic drug companies from obtaining an abbreviated new drug’s approval until the period of protection expires. The underlying reasoning is that, to prove the bioequivalence of its product with the brand-name one, a generic company must refer to the data submitted by the brand-name company in its NDS (this data demonstrates the safety and efficacy of the new drug). Therefore, until the data protection expires, this comparison is impossible.

Before 2006, Canada granted a 5-year data protection to brand-name companies from the date of their first NOC. This protection was, however, considered ineffective due to the interpretation given to the protection in *Bayer Inc. v. Canada (Attorney General)*. In this case, it was held that the protection is not triggered if the generic drug company can demonstrate the bioequivalence of its product without requiring the Minister to consult the data submitted by the brand-name company. Since this situation was common, the protection was seldom applied.

At the end of 2006, following pressures from the pharmaceutical industry and allegations that Canada was not following its international obligations (PhRMA, 2003) the government modified its regulations and introduced an 8-year data protection with the possibility for generic companies to file an ANDS two years before the expiration of the protection.³ In the case of pediatric drugs, the protection is prolonged for 6 months. The possibility for a generic drug company to file an ANDS two years before the protection ends reflects the Canadian government’s effort to facilitate generic entry. During these two years, it is possible for the

³ Regulations Amending the Food and Drug Regulations (Data Protection,) Canada Gazette, Part I, June 17, 2006.

Minister to review the ANDS application, thus, making possible the marketing of the generic drug immediately after the data protection expires.

The Canadian data protection model is somewhat peculiar. It is difficult to trace the impetus of the choice to grant an 8-year data protection, when NAFTA requires a minimum of 5 years (and it is still unclear whether the previous existing 5-year data protection in Canada, as applied by the *Bayer* decision, effectively contradicted NAFTA). Actually, the Canadian data protection seems to result from somewhat of an average of the data protection periods existing in the U.S. and in European countries. The former offers a 5-year data protection to its industry, while the latter offers 10 years.⁴ It would have been interesting to compare cost-benefit analyses demonstrating the positive impact of an 8-year data protection, versus 5 years, on R&D investments in Canada. If these analyses exist, the government has not published them.

Fortunately, the impact of data protection in term of access to medicines is still fairly limited. The protection only grants a period of market exclusivity for non-patented drugs or for drugs for which the patent expires before the end of the 8-year data protection. However, in the former case, data protection might soon represent a problem due to the emergence of out-of-patent biologic drugs, for which companies now decide to rely on trade secrets.

7. Canada's Access to Medicines Regime

This chapter begins and ends with an analysis of two different Canadian regimes for compulsory licensing in the pharmaceutical sector. As mentioned earlier, the first regime was intended to improve access to medicines for Canadians and was abolished in 1993 in order to comply with Canada's international obligations. In contrast, the second regime that is described in this section is intended to improve access in developing countries and was established to implement a WTO decision.

The WTO decision that Canada implemented was adopted on August 30th 2003, on the eve of the Cancun Ministerial Conference. Although the TRIPs Agreement allows WTO members to issue compulsory licenses, countries with insufficient manufacturing capacities in the pharmaceutical sector cannot make effective use of them. WTO members also face difficulties importing pharmaceutical products manufactured under compulsory licenses because article 31(f) of TRIPs provides that they must be "authorized predominantly for the supply of the domestic market of the Member authorizing such use." The August 2003 decision "waived," under specific conditions, this restriction on exports to countries that cannot manufacture the pharmaceuticals themselves.

On September 26th 2003, the Canadian government was the first WTO member to announce its intention to implement the 2003 WTO decision. This announcement was partly the result of pressure from the Canadian Generic Pharmaceutical Association and Canadian activists, including Stephen Lewis, the UN Special ambassador for HIV/AIDs. It was above all the result of a few individual leaders inside the Jean Chrétien government which, in the last months of its 10-year reign, wanted to leave a positive legacy, including assistance for African countries. The

⁴ Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. §355 (1994)) and Supplementary certificate, EEC Directive 1786/92.

government promptly drafted a bill, sought advice from the industry and selected NGOs, and made sure that the Bill C-9, oddly named the *Jean Chrétien Pledge to Africa*, would be enacted prior to the 2004 general elections.

The Canadian government had little flexibility in the drafting of its bill since it was bound by the numerous conditions already negotiated in the 2003 WTO decision. Nevertheless, the Canadian legislation clarified some ambiguities and included additional restrictions (Elliott, 2006; Rimmer, 2005). With the objective of improving access to medicines in developing countries, the royalty rate is linked to the ranking of the importing country on the UNDP Development Index; the requisite negotiations over a possible voluntary licence between the generic producer and the patent holder are limited to 30 days; the regime is open to least-developed countries and other developing countries that are not WTO members; and NGOs authorized by the government of the importing country are considered eligible purchasers. On the other hand, to maintain the integrity of its patent system, pharmaceutical products that can be manufactured and exported under this regime are restricted to a specific list; the term of compulsory licences is limited to a 2-year cap with the possibility of one easily obtained renewal; and patent holders may apply for a court order terminating a compulsory licence or ordering a higher royalty on the grounds that a generic company's contract with a purchaser is commercial in nature. Another controversial provision of the Canadian legislation is the requirement that a drug manufactured solely for export undergo a Canadian regulatory approval process. These features are the most significant aspects that do not typically appear in legislations of other WTO members who implemented the August 2003 Decision, including Norway, India, Korea, China, and the European Union.

Although legislations implementing the August 2003 decision are slightly different, none of them were used at the time of writing this chapter. This lack of effectiveness brought Canada's Access to Medicines Regime from initial warm reactions to criticism, especially from the NGO community. Among the explanations frequently mentioned for its ineffectiveness are the procedural burdens that dissuade generic producers, the lack of capacity and information in potential importing countries, and the competition from other exporting countries, including India and China. These issues and potential amendments are currently under discussion by the government and the Canadian Parliament, since the law is under review. Although Canada's Access to Medicines Regime is one of the last innovations of the Canadian patent system, it may well be the target of the next amendment to the *Patent Act*.

8 Conclusions

To conclude, the Canadian patent policy history is rich with examples demonstrating the Canadian government's efforts in promoting the equilibrium between R&D investments and consumers' access to medicines. Limits to compulsory licenses rights, NOC Regulations and data protection are all different components of the Canadian patent policy aimed at promoting the interest of the pharmaceutical industry with, as justification, positive effects on R&D investments. On the other hand, other components of the policy, such as the PMPRM; the Canadian refusal for adopting a patent term restoration; the possibility for a generic company to file an ANDS two years before the end of the data protection; and the early working exception all exist to promote access to medicines in Canada.

Our study, being law oriented, does not provide empirical data for assessing the effectiveness of each of the Canadian patent policy aspects in reaching the Canadian government's equilibrium goal. However, the fact that R&D in Canada is increasingly focused on clinical trials, combined with the relatively small size of the Canadian market (Paris and Docteur, 2006), leave us questioning whether the patent policy could ever, in practice, represent an effective tool for promoting R&D. However, it certainly contributed to promote access to pharmaceutical drugs. Canadian prices for patented medicines consistently decreased from 1987 to 1994, when prices stabilized up to 10% below the median in seven comparative countries (Paris and Docteur, 2006, p.15). Simultaneously, the generic industry flourished and increased the export of its products to the U.S. (Paris and Docteur, 2006, p.69).

Given the priorities of the Canadian society for access to pharmaceutical product, the modest amount of investment in pharmaceutical R&D, and the trading perspectives for generic industry, it appears that Canada shares significant characteristics with large developing countries. Like most of them, the Canadian government had a defensive approach at the WTO and strengthened its patent system to comply with international trade treaties.

Nevertheless, some new characteristics of the Canadian regime are puzzling. In that respect, we recommend the undertaking of an in-depth economic analysis of the usefulness of the NOC regulations and of the 8-year data protection, particularly in the context where the government is not compelled by any agreements to have these regulations as part of its patent policy. In addition, considering the new emergence of biomedicines, where it is recognized that the "product is the process," we are worried that the PMPRB's role might become limited in the next few years. These products, often out-of-patents, would not be subject to PMPRB and thus, would represent a real threat to consumers' access to affordable medicines. As for the success of the Canadian policy in making generic drugs accessible to developing countries, our doubts are now certitudes. A parliamentary review is currently investigating the reasons behind this failure, which might well lie in the 2003 WTO decision itself.

References

Legislation

Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended 21 U.S.C. §355 (1994))

Patent Act, R.S. 1985, c. P-4

Patented Medicines (Notice of Compliance) Regulations , SOR/93-133

Regulations Amending the Food and Drug Regulations (Data Protection,) *Canada Gazette*, Part I, June 17, 2006.

Regulations Amending the Patented Medicines (Notice of Compliance) Regulations”, *Canada Gazette*, Part I, June 17, 2006.

Regulations Amending the Patented Medicines (Notice of Compliance) Regulations, *Canada Gazette II*, vol. 132, No. 7, 1998, p. 1051.

Regulatory Impact Analysis Statement (2006), *Canada Gazette Part I*, (June 17).

Supplementary Certificate, EEC Directive 1786/92

Cases

American Cyanimid v. Ethicon, A.C. 396 (1975).

Bayer Inc. v. Canada (Attorney General), 1 C.F. 553 (1999).

Biolysse Pharma Corporation v. Bristol-Myers Squibb Company et al, [2005 SCC 26](#)

Centre Ice Ltd. v. National Hockey League, 53 C.P.R. (3d) 34 (C.A.F.) (1994).

Ferring Inc. v. Canada (Attorney General), FCA 274 (2003).

Hoffmann-La Roche Ltd. v. Canada (Minister of Health), FCA 140 (2005).

Janssen-Ortho inc. v. Novopharm limited (2006 FC 1234)

Merck Frosst Canada Inc. v. Canada (Minister of National Health & Welfare), (1994) 55 C.P.R. (3d) 302 (F.C.A.)

WTO Appellate Body Report (2000), ‘Canada – Term of Patent Protection’, (18 September), 80-101.

Articles

- Anis, Aslam H. (2000), 'Pharmaceutical Policies in Canada: Another Example of Federal-Provincial Discord', *Canadian Medical Association Journal*, **162** (4), 523-526
- Bahan, David, Valérie Caverivière, Bernard Decaluwé, Christian Arnault Emini and André Lemelin (2005), 'Les Impacts Économiques de la "Règle des 15 Ans" appliquée au Remboursement des Médicaments Innovateurs au Québec', *Travaux de Recherche*, [2005]-022
- Bale, Dr. Harvey E., Jr. 'The Impact of the Patent System on Research Investment for Developing Countries'
<http://www.wipo.int/patent/agenda/en/meetings/2002/presentations/bale.pdf>
- Danzon, Patricia, and Jonathan D. Ketcham (2003), 'Reference Pricing of Pharmaceuticals for Medicare: Evidence from Germany, The Netherlands and New Zealand',
<http://www.nber.org/papers/w10007>
- Elliott, Richard (2006), "Pledge and Pitfalls: Canada's Legislation on Compulsory Licensing of Pharmaceuticals of Export", *International Journal of Intellectual Property Management*, **1** (1) 94-112
- French (1987), "Patent Law Reform in Canada" *Canadian Intellectual Property Rev.*, **4**, 337
- Gherson, Giles (1985), 'Free Trade Flash Points: Lumber, Drugs, Publishing are Prickly Issues', *Fin. Post*, (21 December), section, p.1
- Gorecki, P.K. (1981), *Regulating the Price of Prescription Drugs in Canada: Compulsory Licensing, Product Selection, and Government Reimbursement Programmes*, Technical Report No.8, Ottawa: Economic Council of Canada.
- Harrison, Christopher Scott (2000-01), 'Protection of Pharmaceuticals as Foreign Policy: The Canada-U.S. Trade Agreement and Bill C-22 versus the North American Free Trade Agreement and Bill C-91', *North Carolina Journal of International Law and Commercial Regulation*, **26**, 457-528
- Harvey, Ken (2001), 'The Pharmaceutical Benefits Scheme: History, current status and post-election prognosis', *The Drawing Board: An Australian Review of Public Affairs*, (2 November).<http://www.australianreview.net/digest/2001/11/harvey.html>
- Lexchin, Joel (2001), 'Globalization, Trade Deals and Drugs: Heads, the Industry Wins; Tails, Canada Loses', *Canadian Centre for Policy Alternatives, Briefing Paper Series: Trade and Investment*, (November), **2** (8), 1-14
- Maryse, Robert (2000), *Negotiating NAFTA: Explaining the Outcome in Culture, Textiles, Autos, and Pharmaceuticals*, Toronto: University of Toronto Press

Matthews, Duncan (2002), *Globalising Intellectual Property Rights: The TRIPs Agreement*, New York: Routledge

McFetridge, Donald G. (1998), 'Intellectual Property, Technology, Diffusion, and Growth in the Canadian Economy', in Robert D. Anderson and Nancy T. Gallini (eds), *Competition Policy and Intellectual Property Rights in the Knowledge-Based Economy*, Calgary: University of Calgary Press, pp. 65-110

Paris, Valerie and Elizabeth Docteur (2006), 'Pharmaceutical Pricing and Reimbursement Policies in Canada', *OECD Health Working Papers*, (December 22), **24**,
<http://www.oecd.org/dataoecd/21/40/37868186.pdf>

Reichman, Jerome H. and Catherine Hasenzahl (2002), 'Non-voluntary Licensing of Patented Inventions: The Canadian Experience',
http://www.iprsonline.org/unctadictsd/docs/reichman_hasenzahl_Canada.pdf

Rimmer, Matthew (2005), "The Jean Chrétien Pledge to Africa Act: Patent Law and Humanitarian Aid", *Expert Opinion on Therapeutic Patents*, **15** (7), pp. 889-909.

Sanjuan, Judit Rius (2006) 'Patent-Registration Linkage',
<http://www.cptech.org/publications/CPTechDPNo2Linkage.pdf>

Skinner, Brett J. (2006), *Price Controls, Patents and Cross-Border Internet Pharmacies, Risks to Canada's Drug Supply and International Trading Relations*, The Fraser Institute: Critical Issues Bulletin

Valiquet, Dominique The *Patented Medicines (Notice of Compliance) Regulations*, Law and Government Division, 4 May 2006

Reports

Canada, Department of Justice, Restrictive Trade and Practices Commission (1963), *Report Concerning the Manufacture, Distribution and Sale of Drugs*, Ottawa: Queen's Printer

Canada, House of Commons, Special Committee on Drug Costs and Prices (1966), *Report of the Standing Committee on Drug Costs and Prices*, Ottawa: Queen's Printer

Canada, Minister of Supply and Services, Commission of Inquiry on the Pharmaceutical Industry (1985), *The Report of the Commission of Inquiry on the Pharmaceutical Industry*, Ottawa: Queen's Printer

Canada, Royal Commission on Health Services (1964), *Report of the Royal Commission on Health Services*, Ottawa: Queen's Printer

Canadian Biotechnology Advisory Committee (2001), 'Biotechnological Intellectual Property and the Patenting of Higher Life Forms', Consultation Document,
[http://cbac-cccb.ca/epic/site/cbac-cccb.nsf/vwapj/Consultation_IP_e.pdf/\\$FILE/Consultation_IP_e.pdf](http://cbac-cccb.ca/epic/site/cbac-cccb.nsf/vwapj/Consultation_IP_e.pdf/$FILE/Consultation_IP_e.pdf)

Federal Trade Commission (2002), *Generic Drug Entry Prior to Patent Expiration: An FTC Study*, (July), Washington: Federal Trade Commission,
<http://www.ftc.gov/os/2002/07/genericdrugstudy.pdf>

Health Canada, Policy and Consultation Branch. *National health expenditures in Canada, 1975-1994*. Ottawa: Supply and Services Canada, 1996

Health Canada, *Annual Drug Submission Performance Report – Part I, Therapeutic Products Directorate (TPD)*, 2004, p. 31.

Industry Canada (2001), ‘Government Tables Amendments to Bring Patent Act Into Conformity with WTO Agreement’,
<http://www.ic.gc.ca/cmb/welcomeic.nsf/ffc979db07de58e6852564e400603639/85256779007b82f4852569f9006a56c7!OpenDocument>

Office of the Chief Economist of Foreign Affairs and International Trade Canada (2006), ‘Seventh Annual Report on Canada’s State of Trade’ (June) Canada: Minister of Public Works and Government Services. http://www.international.gc.ca/eet/trade/sot_2006/sot-2006-en.asp#aiv1

PhRMA, *Special 301 Submission*, 2003
international.phrma.org/content/download/916/5369/file/PhRMA%20Special%20301%20Submission%202007.pdf

United States Trade Representative (2001), *Special 301 Report*.