Pharmaceutical patent policy in developing countries: learning from the Canadian experience[1]

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Introduction

It is often believed that Canada is in a delicate position for adopting a strongly different patent policy from the United States (US). It is true that the Canadian economy is still greatly, although decreasingly, dependent on its southern neighbor. The Canadian government intentionally strengthened these economic and industrial ties by signing a bilateral free trade agreement with the US (FTA) in 1987, followed by the *North American Free Trade Agreement* (NAFTA) in 1992. In 2008, 78 per cent of Canadian exports were destined for the US market and 58 per cent of foreign direct investment stock in Canada was owned by American investors (Canada 2009). Few other countries, including in Latin American, are as dependant on the US economy and therefore vulnerable to US trade pressures regarding their pharmaceutical patent policy.

Nevertheless, Canada did not hesitate to depart from the US model to design a unique patent policy for pharmaceutical products. The history of the Canadian pharmaceutical patent policy, although increasingly imprinted by US influences, reveals a Canadian philosophy for justice in access to health care services. One could even argue that universal access to health services is a symbol of the Canadian identity and a source of national pride, enabling Canadians to distinguish themselves from Americans. 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. Few other nations, if any, treat health care policy as a key component of their national identity.

This continuous concern to provide access to pharmaceutical products, combined with a heavy dependence on the US economy, contribute to the uniqueness of the Canadian patent policy. On the one hand, Canada has always accepted the patentability of pharmaceutical processes and accepts the patentability of pharmaceutical products since 1987. On the other hand, Canadian lawmakers demonstrated a strong sense of legal creativity by continuously conceiving new limitations and exceptions for these pharmaceutical patents.

The Canadian experience could be of interest to large developing countries with significant generic manufacturing capacities, foreign investment in the pharmaceutical sector, modest private investment in drug discovery, numerous international IP obligations and constant pressure from the US[4].

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[4] In 2008, the pharmaceutical sector employed 28.697 persons, accounting for 1.5% of total employment in manufacturing. That year, R&D expenditures in Canada were $1.3 bilion. It is worth noting that 74.6% of this sum was for applied research. The Canadian market for drugs is quite small. In 2008, it accounted for 3.8% of total major-market sales, a share comparable to that of Italy. (PMPRB 2008 report)

These countries should find in this study a sign that, even in presence of international trade agreements, there is room to make medicines more accessible.

Each of the six following sections presents distinctive features of the Canadian patent policy, following a roughly chronological order. [5] To begin, we provide an overview of the history of compulsory licenses in Canada. [6] 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 patented drug prices. Following this analysis, we highlight the 'early working' and 'stockpiling' exceptions introduced to limit the negative impact of restricted compulsory licenses on the access to medicines. In the fifth section, we draw attention to the Canadian *Patented Medicines (Notice of Compliance) Regulations* (NOC Regulations). These regulations, sometimes associated to an 'automatic injunction tool' available to the pharmaceutical industry, were 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.. This chapter ends as it started, with a review of the Canadian compulsory licenses 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. Although this chapter has a clear legal perspective on the issue of access to medicines, one of its main conclusion is that outcomes depend more on politics, especially international politics, than international law.

A special regime of compulsory licenses

Past and present Canadian policies regarding compulsory licenses are often provided as an example to follow. Jerome Reichman and Catherine Hasenzahl from Duke University suggest that Canada's historical use of compulsory licenses could inspire policy makers in developing countries (Reichman and Hasenzahl 2002). However new international rules forced the Canadian policy to undergo radical changes in the early 1990s and would make policy transfer to WTO member difficult.

During most of the twentieth century, Canada had few international obligations with respect to compulsory licensing. The only restriction prescribed by the *Paris Convention* (article 5A) was a minimum period of time before a compulsory license could be applied for. Since no international treaty prohibited discrimination in the field of technology, Canada could develop an aggressive policy for compulsory licenses 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 'license of right' for manufacturing purposes. To obtain a compulsory license, it was not

[5] For the purpose of the paper, the «Canadian patent policy », not only includes direct pharmaceutical patent policies but also the data protection policy in Canada. When adopted, this last policy has been presented as closely linked to patents rights for the pharmaceutical industry.

[6] Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner. The principal requirement for the issue of a compulsory license is that attempts to obtain a license under reasonable commercial terms must have failed over a reasonable period of time. Specific situations in which compulsory licenses may be issued are set out in the legislation of each patent system and vary between systems.

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 (Orlhac 1990).

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, p. 81-82). In consequence, until 1969, only 49 applications were submitted, of which 22 were granted (Canada 1985, p. 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 1966).

This reform occurred in 1969 when the Canadian Parliament amended its *Patent Act*. According to the amendment, 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 license unless he saw 'good reasons' not to, with the result that most license 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 (Reichamn and Hasenzahl 2002, p. 38). The generic industry significantly increased its market share and drug prices decreased substantially. For example, according to the report of the Eastman Commission of Inquiry on the Pharmaceutical Industry (Eastman Report), Canadians saved more than 210 millions dollars in 1983 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, p. 62-63).

Despite these positive results, Canada was under diplomatic pressure to move away from its policy. At the end of the 1980s, while the FTA was under negotiation, the Reagan Administration used the access to the large American market to pressure the Canadian government (French 1987, p. 341-342; Harrison 2000). 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. It extended patent protection to pharmaceutical products themselves, as opposed to merely protecting processes by which these products were made. As a result, a generic producer could not anymore circumvent the patent protection by finding a way to manufacture the medicine by a different process. In addition, Section 46 of Bill C-22 provided that generic producers could not obtain a compulsory license on a pharmaceutical product until a deferral period of exclusivity had elapsed. Patent covering a new process of manufacturing a known drug were excluded from this period of exclusivity. But it was only a modest exclusion since a compulsory license with immediate effect was effective on process patent if, and only if, the drug itself was not protected by another patent.

On the other hand, Bill C-22 included two discriminatory measures that were heavily condemned by the US government. First, the deferral period varied with whether the generic drugs would be imported or locally manufactured. It could be reduced from ten to seven 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 US and transnational corporations.

Not surprisingly, 'the Canadian reform of 1987 became emblematic of the type of regime the United States 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, p. 2-3; Robert 2000, p. 298). The US 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 US 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.

The *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPswas adopted in April 1994, 16 months after NAFTA. This new multilateral agreement duplicated NAFTA's rule on non-discrimination with the consequence that, legally speaking, no other WTO member could duplicate Canada's former regime of compulsory licenses. In reality however compliance with the non-discrimination rule depends more on WTO politics than on WTO law. Indeed, several countries do not fully comply with a rigid interpretation of the non-discrimination rule. One could even argue that the US itself maintains several discriminatory measures, advantaging for example PCT applications writing English, oral disclosure made in the US territory, or undisclosed invention made in the US (see Section 102(a)(e) and (g) of the United States Code title 35). But few of the discriminatory measures found in several WTO members are challenged under the dispute settlement body. Formal complains must be raised by a government rather than a private entity and therefore are subjected to strategic considerations and political transactions. A good illustration is the Brazilian measure favoring compulsory licenses on imported rather than locally produced pharmaceutical drugs (Brazil Law *n° 9279*, art. 68). When the US argue that this measure was contrary to the WTO rule of non-discrimination, the Brazilian government immediately responded that the US law is equally discriminatory (Brazil 2001a). Soon after, the American and the Brazilian delegations at the WTO announced that they reached a mutual understanding and the dispute was never submitted to a WTO panel (Brazil 2001b). This is only one illustration that domestic patent law depends greatly on international politics, arguably more than on international law. But as the next section establishes, foreign political pressures, even coming from powerful actors, do not fatally prevail over domestic priorities.

The uniqueness of the Canadian drug price regulations

What particularly distinguishes the drug price control scheme in Canada from those of other countries is the federal government's direct price control regulation. This regulation is supplementary to provincial indirect price regulations and exclusive to patented drugs (Paris and Docteur 2006).

Theoretically, drug price regulations in Canada is part of the provincial constitutional's jurisdiction. Provincial drug price regulations only apply for public drug coverage. Although there are no incentives to do so, private insurers may thus 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, p. 20-21). However in order to provide the brand-name industry with an incentive to invest in R&D, Quebec has implemented a '15-years rule'. This rule allows the reimbursement of a brand-name drug for 15 years after it is marketed in Quebec even if a generic drug is already available on the market. This policy is highly criticized by the generic industry and it is not clear whether it effectively helps the province to attract R&D investments (Bahan 2005). 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. Considering the foregoing, the provincial drug price control schemes are generally qualified as 'indirect' since they do not directly impose a price on drugs but provide an incentive to the industry to provide its products at a price that will allow them to be reimbursed by the different provincial insurance plans.

As previously mentioned, in Canada, in addition to being regulated at the provincial level, patented drug prices are controlled by a federal, independent and quasi-judicial board, the PMPRB. This board 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 licenses would have had on drug prices, that is, 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 UK and the US. 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, Spain or Greece, when determining what brand-name drug (patented or not, in this case) can be listed on drug formularies. According to the *Patent Act* (sections 79ss), patented drug prices cannot, in any case, exceed changes in the *Consumer Price Index*.

In contrast with some 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, the board 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 board was created, the price of patented drugs was 23 per cent higher than the international median price. After 1987, patented drug prices were reduced considerably and have become, on average, below the international median price (Paris and Docteur 2006, p.15). According to the PMPRB's 2008 Annual Report however, Canadian prices for patented drugs that year were below those of the US but relatively close to those of the UK, Germany, Sweden and Switzerland.

Although the PMPRB's creation in 1987 was relatively 'accepted' by the pharmaceutical industry, this industry now imposes a constant pressure on the Canadian government to eliminate the review board. This pressure has particularly emerged due to the US consumers' growing interest in cheap Canadian drugs, which can be up to 40 per cent less expensive than in the US. 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 US (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.

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 both the PMPRB and limited compulsory licenses. 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 2008 Annual Report, we note that after 1987, R&D investments have increased (although they seem to be now decreasing). We may wonder however if these investments would have been higher without the existence of the PMPRB. In any case, considering the fact that most developing countries already have a low investment rate in R&D from the brand-name industry, it might be pertinent for them to consider the benefits attached the implementation of a price control scheme if their goal is to circumvent the negative impact of the TRIPs on drug prices and access. The Canadian experience certainly demonstrates that this goal is realist and viable.

Exceptions to rights conferred

When the special regime for compulsory license 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 (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 US 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 two or three 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 'early working' and 'stockpiling' exceptions were, predictably, heavily criticized by innovative pharmaceutical companies (United States 2001). Nevertheless, they did not succeed in convincing the US government to bring the matter under the WTO dispute settlement mechanism. Drug pricing 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 US 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, 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. For greater clarity, the US government provided its most recent free trade agreements that the 'Bolar exception' is a legitimate but voluntary exception to patent law (Morin 2007, p. 433). Despite the panel decision and the US clarification, several developing countries do not provide an exception to patent rights to support an application for marketing approval of a pharmaceutical product (Thorpe 2002).

The panel found however that the 'stockpiling' exception did 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.' (WTO 2000, 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 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.' (WTO 2000, para 7.37).

Canada did not refer the dispute to the Appellate Body, complied with the panel report and amended its *Patent Act*. Canada probably felt that it had little political support and legitimacy to bring the 'stockpiling' exception to the Appellate Body since, contrary to the 'Bolar exception', it was one of the few developed country to provide such a generous exception. However, 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 NOC Regulations, initially adopted to limit the effect of the 'early working' and 'stockpiling' exceptions.

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. These regulations are essentially based on the US linkage regulations' model. They are, from time to time, referred to as 'linkage regulations' because they require the Minister of Health (Minister) to take into consideration the registered patents before issuing a notice of compliance (NOC) to a generic drug company. These regulations exclusively apply when this company files an abbreviated new drug submission (ANDS). [7] By filing an ANDS a generic drug company can only demonstrate the bioequivalence of its product with the brand-name drug to prove its safety and efficacy. The company is thus exempted from undertaking the complete clinical trial process normally required to prove the safety and efficacy of a new drug.

According to the NOC Regulations, when a brand-name company submits a NOC application, it can join a list of patents to be registered on a patent register administered by the Minister. When a generic company files its ANDS it must inform the 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 file a notice of allegation alleging that the registered patents have expired, are invalid or will not be infringed by the NOC's delivery to the generic company.

Once the brand-name drug company is notified, it can request the Tribunal to issue an order prohibiting the Minister from delivering a NOC until after the expiration of the registered patents. The simple deposit of this request by the brand-name company triggers a 24-month stay before the NOC can be issued to the generic drug company except if, during that time, the patent expires or the Tribunal issues its order. Because the Tribunal is only competent to assess the validity of the patent registration, and not the validity of the patent *per se* (Merck Frosst Canada Inc v Canada, 1994), it is possible, following this order, that a generic company markets its product and infringe an existing and valid patent according to the *Patent Act*. *Vice versa*, an order from the Tribunal may refrain a generic

[7] This prohibition does not apply if the generic company has filed a complete NDS. In such case, the Minister would thus not be tied up by the existence of patents applying to the brand name product (Bristol-Myers Squibb Co. v. Canada, 2005).

company from marketing its product, the patent being well registered but, in fact, invalid according to the *Patent Act'* criteria for patentability. The likelihood of such contradictory judgments provides high incentives for pharmaceutical companies to occupy the judicial system in Canada (Janssen-Ortho inc. v. Novopharm, 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 interesting for the brand-name companies, considering the fact 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 Cyanamid v. Ethicon, 1975). 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 also happened in the US, some pharmaceutical companies 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[8] Also, due to the lack of clarity in their writing, the NOC Regulations have triggered different judicial interpretations that did not always fit with their original purpose. Considering the forgoing, in October 2006, the government introduced important clarifications to the regulations.

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 (2003)). 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 2003; 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. 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. 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 a 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.

[8]These practices artificially extended their patent protection (*evergreening* practices). In 2002, the Commission on the Future of Health Care in Canada (Canada 2002) reported persisting concerns about still existing *evergreening* practices from the pharmaceutical industry.

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 regulations is the Minister granted with the power to withdraw a patent from the registry if it is qualified as invalid by a Court. Consequently, this forces generic companies to file a notice of allegation for a drug, although the patent registered for it has previously been judged to be invalid.

Until recently, linkages regulations only existed in the US and in Canada. This situation has changed however over the last few years, particularly since some other countries, such as Morocco, Jordan and Chili, have entered into bilateral agreements with the US.[9] Upon the terms of these agreements, these countries must make sure that a generic drug is not marketed if a patent still exists on the brand-name drug to be copied (Sanjuan 2006). This requirement is certainly open to modulations. Before nationally modeling and implementing linkage regulations, or even before contemplating their introduction, developing countries should certainly consider the *evergreening* practices that have occurred both in Canada and in US following their implementation. Also, a critical assessment of the positive impact of the last amendments adopted in Canada to reduce such practices would certainly be appropriated.

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 1 October 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 three years. For 'Old Act patents', filed before 1 October, 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' (section 1709(12)). The US took advantage of this flexibility and adopted the 20-year standard only in 1995, to comply with the TRIPs. 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.

[9] However, we underline that some countries, such as Mexico in 2003, may have implemented linkages regulations without having any obligations to conform with bilateral, regional or international agreements.

The Canadian term of protection came under the international spotlight in 1999 when the US filed a complaint with the WTO dispute settlement mechanism. The US claimed that the term of protection available for the 'Old Act patent' did not comply with Article 33 of the TRIPs, 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 1 October 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 US applicants, would expire sooner than would be the case if Canada had provided a term of 20 years from filing (WTO 2000, para 6.60). Despite these impressive numbers, the real issue under this dispute was related to some 30 commercially significant drugs (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 2000, para 80-101). They concluded that the term of protection for 'Old Act patents' is inconsistent with Article 33 of the TRIPs. 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, the effective patent term could be shorter than it would have been prior to the 1989 amendment (Canada 2001, p. 16). To avoid this problem, the US 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 effective term 17 years from the granting of the application, even though the US has formally converted to a standard of 20 years from the application's filing.

The case *Canada – Term of Patent Protection* made it clear however that WTO members do not have an obligation to ensure a effective term of protection and therefore do not have to offer extension in case of administrative delay. Developing countries are free to not adjust the term of a patent to compensate for delay that could occur in granting the patent or the drugs' marketing approval. In that respect, the Canadian legislation could serve a reassurance to developing countries that at least some OECD countries consider that patent term extensions are neither a legal obligation under TRIPs nor a wise policy for ensuring access to patented medicines. As the next section shows, Canada is less a model to follow in respect of data protection.

Data protection

Data protection in Canada was intended to implement Canada's NAFTA (sec.1711(5)(6)) and TRIPs (art. 39(3)) obligations, which require signatories to provide a 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. The main objective of this measure is to protect the investments made by a brand-name company by ensuring a minimal period of market exclusivity. This market exclusivity must however be distinguished from the one resulting from patent rights. The result of such protection is to prevent generic drug companies from obtaining an ANDS'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 (these data demonstrate 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 as ineffective due to the Federal Court's interpretation of the protection given in *Bayer Inc. v. Canada (Attorney General)*. Precisely, it has been held by this court that the protection was not triggered if the generic drug company could 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 eight-year data protection with the possibility for generic companies to file an ANDS two years before the expiration of the protection. In the case of pediatric drugs, the protection is prolonged for six 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 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 eight-year data protection, when NAFTA requires a minimum of five years (and it is still unclear whether the previous existing five-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 US and in European countries. The former offers a five-year data protection to its industry, while the latter offers ten years. It would have been interesting to compare cost-benefit analyses demonstrating the positive impact of an eight-year data protection, versus five years, on R&D investments in Canada. If these analyses exist, the government has not published them.

Fortunately, in Canada, the negative impact of data protection in term of access to medicines is still fairly limited, but nonetheless present (Pugatch 2006, p. 120). In practice, the protection 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. In the former case, data protection might however eventually represent a problem due to the emergence of out-of-patent biologic drugs, for which companies now increasingly rely on trade secrets.

It must be stressed that no minimum protection time for clinical data is required by the TRIPs. The TRIPs' requirement for data protection is actually particularly vaguely defined. To the risk of being listed on the 301 Watch-list and until this requirement is defined by the WTO Dispute Settlement Body, developing countries should take advantage of the TRIPs' flexibility (ICTSD, 2005).

The original data protection that existed in Canada before the 2006 amendments could actually represent a source of inspiration for them.

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 establish to implement a WTO decision.

The WTO decision that Canada implemented was adopted on 30 August 2003, on the eve of the Cancun Ministerial Conference. Although the TRIPs 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 30 August 2003 decision 'waived' under specific conditions, this restriction on exports to countries that cannot manufacture the pharmaceuticals themselves.

On 26 September 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 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 license 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 licenses 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 license 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 while ignoring the WHO approval process

presumably more appropriate for drugs needed in developing countries. These features are the most significant aspects that do not typically appear in legislations of other WTO members who implemented the 30 August 2003 Decision, including Norway, India, Korea, China and the European Union.

Canada is not only the first country to have announced its intention to implement the 30 August 2003 Decision, but also the first to effectively use its legislation. On 20 September 2007, the Federal Commissioner of Patents granted a compulsory license to Apotex to produce and export 260 000 packs of TriAvir, an HIV/AIDS combination therapy, to Rwanda. To date, no other WTO member has ever issued a compulsory license for export. The WTO has not even receive other notification from exporting or importing country of their intention to use the so-called 'paragraph 6 system'.

The fact that Canada's Access to Medicines Regime was used only once in five years raised some criticisms, 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 Canadian Parliament. Two private bills were introduced in 2009 to facilitate the issuing of compulsory license by simplifying the conditions and requirements. 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*.

Conclusions

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 PMPRB; 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.

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) leaves 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 per cent 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 US (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 mainly to comply with international trade treaties. Giving these similarities, it is surprising that

Canada do not actively cooperate with Brazil, Argentina, India and other countries to influence the global patent regime.

Canada's cooperation with developing countries have focused in the unilateral design a mechanism for the export of generic drugs under compulsory. The Canadian government should consider however exporting its expertise in health and patent policy in addition of exporting generic drugs. Canada has developed a unique legal environment for pharmaceutical products that reflects its social values, economic priorities and industrial ambitions. Unfortunately, several developing countries lack the necessary expertise for exercising the same legal and policy creativity. They simply transplant in their domestic legal system strategies developed for the most advanced economies, missing opportunities to increase their access to cheap drugs of good quality. Canada can and should provide advice on the regulatory environment necessary to ensure quality production of drugs, price control and access to generics.

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