MEDICINES AND PATENTED MEDICINES: THE STATE OF THE LAW IN CANADA

by
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A. Introduction

Major changes have marked the evolution through time of the Canadian Law in respect of patents for medecines. We ought to visualize these changes by taking a brief look at some of its recent historical highlights.

Secondly, we will examine the state of law in Canada regarding patented medecines, by emphacizing one of its major topic: the new Canadian compulsory licensing provision.

Thirdly, it is generally known that the Canadian Patent Act confers to the patentee the right to the benefit of a patent and includes the right for the patentee to prevent any act involving the use of what is claimed in the patent without his prior authorization. The patent also gives the patentee the right to work his invention on a commercial scale. However, does the Canadian law admits as an exception to the scope of the patent right, the experimental use as a defence to a claim of patent infringment. We will

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Patent Agent, Thierry Orlhac is on of the senior partners in the patent and trademark agency firm ROBIC, g.p. to which the lawfirm LEGER ROBIC RICHARD,g.p. is associated. This material was designed as a summary presentation of some issues encountered in the Canadian pharmaceutical patented medecine; it was designed to be incorporated in a September 1992 special issue of the Managing Intellectual Property Review dealing with the pharmaceutical Industry. This material was meant for discussion and does not conclusively state the opinion of the author or the members of his firm on the subject matter nor does it provide an exhaustive review thereof. Publication 169.

examine this question and try to answer it in the light of the Canadian Patent Act and related Canadian court`s decisions.

B. Historical highlights

a) Since 1923, the Canadian Patent Act has always included compulsory licensing provisions specific to patents for inventions regarding food or medecine. The applicant does not have to wait for a patentee to abuse his rights under the patent nor wait for a grace period to obtain a compulsory licence under a patent for food or medecine.

Up until 1969, the grant of compulsory licences was limited to the manufacture of patented medecine in Canada. This means that no compulsory licence granted allowed the importation of medecines into Canada. These provisions drove the innovative pharmaceutical manufacturers in a position of force. They used this position to generate uge profits out of their medecines by selling them at prohibitive prices. This became apparent when these prices were compared to those of the same products sold by the same companies in other contries.

This abuse of their exclusive rights under their patents rendered the innovative companies suspect, so they became the subjet of many public enquiries, in the sixties. At the time, Canada was very interested in these enquiries, because it was achieving the nationalization of medical services, and was beginning to pay for them.

As a result, 1969 saw the compulsory licencing provisions being completely revised to permit the grant of compulsory licences for importation into Canada. That is why the former Canadian compulsory licencing provisions were generally well known to the public. These modifications of the Patent Act aimed at the reduction of the abuse done by the innovative companies and were an attemp to reduce the retail price of drugs by increasing the competition on the Canadian level between innovative and generic drug manufacturers.

The Patent Act made it practically sure that any interested person who requested it (mainly manufacturers of generic drugs) be granted a compulsory licence from innovative pharmaceutical companies in respect of their patents. Accordingly, many licences were applied for and granted. The licences conferred the licensees the right to manufacture or import into Canada medecines in return for which the licensees were required to pay an amount of royalty to the patentee of the drug.(Section 41, as it read prior to the amendments to the Patents Act R.C. 1985, c.33 (3rd supp.)). However, the royalty fees payable to the patentees were so low, that they did not provide a

sufficient reward for the investments made by innovative drug manufacturers in respect of the research and development leading to the new drugs.

As a result, these provisions encouraged the growth of the generic industry in Canada, but they were also the cause of a drop in the investments related to development and research in the Canadian pharmaceutical industry, because nearly all the compulsory licences granted were licences to import medecines into Canada, and some innovative drug manufacturers moved abroad.

Two main features made the Canadian compulsory licensing provisions different:

Since 1969, most, if not all of the compulsory licence applications applied for and not abandoned, have been granted, whatever the arguments submitted by the patentee; and

The amount of royalty granted to the patentee has always been fixed at a very low percentage of the net selling price (4%) of the drug, whatever the arguments of the patentee might have been.

The Canadian courts nerver reversed the decision of the Commissioner of Patents on such grounds.

In addition, these provisions of the Canadian Patent Act when attacked on a constitutional level were declared to be constitutional and in accord with the Canadian Charter of Rights.

b) Another feature of the former Patent Act, in relation to patents for medecines, qualifies as an anachronism for its history goes back to the British Patent Act of 1919. Its goal at the time was to relieve the British chemical industry from the German domination in this field. These provisions provided that inventions relating to substances prepared or produced by chemical processes and intended for food or medecine could not be claimed per se, but could only be claimed in a product-by-process form (Section 41(1), as it read prior to the amendments to the Patent Act R.C. 1985, c.33 (3rd supp.)).

By reason of the Canadian pharmaceutical lobbying, and because of the influence of the international opinion, these provisions were abrogated by the actual Canadian Patent Act. As a result, inventions relating to substances prepared or produced by chemical processes are patentable per se in Canada, since November 1987 (Section 14, R.C. 1985, c. 33 (3rd supp.)).

However, the actual Patent Act introduced new provisions in November 1987. According to these provisions, inventions relating to naturally occuring

substances prepared or produced by microbiological processes and intended for food or medecine could not be claimed per se, but could only be claimed in a product-by-process form (Section 14, R.C. 1985, c.33 (3rd supp.)). These provisions ceased to have effect 4 years later, on November 19, 1991. We never understood the very reason of the existence of these provisions. Perhaps they intended to provide temporary protection to the newly developing industry of manufacturers of generic drugs.

Since November 1991, inventions relating to naturally occuring substances, prepared or produced by microbiological processes and intended for food or medecine, are patentable per se in Canada.

C. The Canadian compulsory licencing provisions

With the reform of the Patent Act of 1969 and its numerous drawbacks in respect of its compulsory licensing provisions which were considered unfair to innovative drug manufacturers, Canada began to be perceived as an inhospitable land for pharmaceutical investment. This led the legislator to amend the Patent Act, in November 1987.

1. Compulsory licensing

The 1969 compulsory licensing provisions were replaced by a somewhat less permissive system. This system provides temporary protection to patentees and aims at increasing the research and development of the pharmaceutical industry in Canada, so drugs might become available at a reasonable price to Canadian consumers.

Pertaining to the new compulsory licensing system, a distinction must be made between Canadian pharmaceutical inventions and those which are not.

a) Canadian pharmaceutical inventions

In order to increase the development and research in the pharmaceutical industry in Canada, the new Act gives a very special status to patentees of drugs invented and developed in Canada. Accordingly, when the patentee satisfies the Commissioner that the medecine has been invented and developed in Canada, the Commissioner shall not grant a compulsory licence for the importation of the drug, during the lifespan of the patent (s. 39.16(1), 39.16 (2) of the Patent Act). However, a compulsory licence for the manufacturing of the drug in Canada can be requested by any interested

person after 7 years from the date the notice of compliance (authorization given by Health and Welfare Canada to a drug manufacturer so he can distribute his product in Canada if the said product met the various requirements regarding safety and efficacy) was accorded, if it appears at the time of the application that the patentee is not making the medecine in Canada for the purposes of completely or substancially supplying the Canadian market for that medecine (s.39.16(4) of the Patent Act).

b) Non Canadian pharmaceutical inventions

In respect of medecine which were not invented and developed in Canada, the period of protection available to patentees varies in respect of the following factors:

-the licence is applied for manufacture or importation;
-the date the patent was granted; and
-the date of issue of the notice of compliance

i.Licence applied for manufacture in Canada

A compulsory licence for the manufacture medecines in Canada is available 7 years after the date of issue of the first notice of compliance to the patentee, provided that this notice was issued after June 27, 1986 (s.39.14(1) of the Patent Act).

ii.Licence applied for importation into Canada

With respect to the compulsory licences applied for the importation of patented medecine into Canada, a compulsory licence may be granted:

- 7 years after the date of issue of the first notice of compliance, if this notice was issued before June 27, 1986 and a licence has been granted, but no notice of compliance has been issued to the licensee in respect of the medecine, or alternatively, the licensee has obtained a notice of compliance in respect of the medecine, but no licence has been granted to the person (s.39.11(2)a of the Patent Act).

- 8 years after the date of issue of the first notice of compliance, if this notice was issued before June 27, 1986 and that neither a compulsory licence was granted, nor another notice of compliance issued in respect of the medecine, at that date.

- 10 years after the date of issue of the first notice of compliance, if this date follows June 27, 1986 (s.39.11(2)c of the Patent Act).

These foregoing periods of protection accorded to patentees of medecine which were either invented and developed in Canada or elsewhere, are subject to modifications by the Patented Medecine Prices Review Board (39.16(7)d and s.39.15(3)d of the Patent Act) in cases where, in the opinion of the Board, a medecine is being sold in Canada at an excessive price or if a patentee violated certain provisions of the Patent Act.

At this time, it is worth mentioning that these period of exclusivity do not apply to a licence after the date of expiration of the first patent granted in Canada in respect of that medecine (s.39.11(3)). This also stands for a subsequent invention that is a process for the preparation or production of substantially the same medecine (s.39.13 of the Patent Act). Moreover, the Patent Act does not affect any compulsory licence pertaining to a medecine granted before June 27, 1986 and for which a notice of compliance has been issued to the licensee (s.39.11(4) of the Patent Act.).

2. The Patented Medecine Prices Review Board

The Patent Act created the Patented Medecine Prices Review Board (the "Board") so it could review the prices charged for patented medecines in Canada (s.39.18 to s.39.24 of the Patent Act). The idea of controlling the prices of patented medecines is not surprising nor new since the controversial amendments of 1969 were introduced to deal with such excessive pricing by innovative drug manufacturers and health services are nationalized in Canada.

The prime function of the Board is to make sure that Canadians do not pay excessive prices for patented medecines. The second task of the Board is to provide the Minister of Health with an annual report giving: the summary of pricing trends and the trends in the development and research in the pharmaceutical industry and the names of patentees subjected to enquiries in cases of excessive pricing (s.39.24 to 39.25 of the Patent Act).

In order for the Board to obtain these informations, the Patent Act imposes on patentees obligations as to provide specific informations and reports to the Board. These informations will differ substantially upon wheter they relate to the primary or the secondary task of the Board.

3. The Prices Review Process and the Powers of the Board

a) When a patentee increases the price of a drug sold in Canada by a percentage superior to that of the percentage increase in the Consumer Price Index as published by Statistics Canada, the Board may request the patentee to justify that increase. If the patentee fails to provide the Board with such information or if the Board still considers that the medecine is being sold at an excessive price, after consideration of the following list of factors:

- the prices at which the patentee sold the medecine during the preceding 5 years;
- the prices of other medecines belonging to the same therapeutic class sold sold during the preceding 5 years;
- the prices at which the medecine and other medecines belonging to the same therapeutic class have been sold in other countries durind the preceding 5 years; and if the Board is still undecided on wheter or not the medecine is being sold at an excessive price, it is entitled to consider the Canadian portion of the costs of making and marketing the medecine, and other factors deemed relevant (s.39.15(6 to 8) of the Patent Act)

the Board may, by order, revoque the time periods for exemption from the compulsory licensing (s.39.15(3)) in respect of either or both the patent pertaining to the medecine for which there was excessive pricing or any other patent of the patentee for an invention that pertains to other medecines (s.39.15(3)d). As an alternative, if the Board does not deem it necessary to revoque the period of exclusivity, it may order that the price of the medecine sold, be reduced to an acceptable level. If the patentee does not comply with such an order, he is punished by a furhter order to reduce the price of the medecine or by the revocation of the period of exclusivity from compulsory licensing.

In respect of patentees of medecines invented and developed in Canada, the foregoing penalties may be invoqued by the Board, for the same reasons, as stated above. Therefore, the patentees of Canadian pharmaceutical inventions might loose their special status (s.39.16(7)d) or alternatively, by order of the Board, be forced to reduce the price of the medecine.

4.Sales and Expense Information

The information task of the board pertaining to pricing trends in the pharmaceutical industry and costs of research and development relating to patented medecine in Canada requires from the patentees of medecine that they provide the Board every six months with:

-the price at which the medecine is being sold in Canada , or elsewhere and

-the costs of making and marketing the medecine (s.39.15(1) and s.39.16(5) of the Patent Act).

Each patentee must also provide the Board every year with:

-the name of any licensee of the patentee in Canada;
-the revenu, wheter direct or indirect, from sales of medecine in Canada; and
-the expenditures made by the patentee in Canada towards the cost of research and development relating to medecine.

If patentees fail to provide such information, as required by the Board, the Board may apply the same penalties as for excessive pricing except, of course, for the reduction of price (see part 3. The Prices review Process and the Powers of the Board).

D. Experimental use as a defence to a claim of patent infringment

According to the Patent Act (Section 42, R.S. 1985, c.P-4), a patent grants to the patentee the exclusive right, privilege and liberty of making, constructing, and using the invention and selling it to others to be used. In accordance with these exclusive rights, a person who violates a patent is liable to the patentee and to all persons claiming under the patentee for all damages sustained by the patentee or by any such person (Section 55(1)a R.S. 1985 c. P-4).

These statutory provisions define the positive rights conferred to the patentee upon grant of a patent. However, there is no statutory exclusion which further defines such rights conferred to the patentee nor any specific exception with respect to the experimental use.

Nevertheless, this last specific question was addressed, on a statutory basis, in the Working Paper on Patent Law Revision of 1976 (p. 203). Its purpose was to exposed for public criticism, proposals for reform of the law respecting patents. The working group considered the proposed law in respect of adding to it a series of exclusions in order to make clear what are the rights accorded to the patentees. Some of these specific provisions (Section 24) were devised to restrict the rights of patentees to the commercial exploitation of inventions. Section 24(1)b, further specified that the right to carry out experiments utilizing an invention is mutually exclusive to the right of the patentee to exploit his invention on a commercial base. The Working paper specified that the rights conferred by a patent to a patentee shall not extend to:

> "24(1)c the administration of a medecine or its preparation in individual cases for such use".

These specific provisions were not considered in the reform of the law regarding patents.

On the other side, if we examine the Canadian court`s decisions, the situation is rather uncertain. There are few Canadian cases.

The Supreme Court of Canada decided in Micro Chemicals Ltd. v. Smith Kline & French Inter-American Corp. (1971), 2 C.P.R.(2d) 193, S.C. that a bona fide experimental use of an invention does not constitute infringment. The Court followed the reasoning of Jessel M.R. in Frearson v. Loe (1878) 9 Ch.D. 48 at pp. 66-67:

> "He said he did this merely by way of experiment, and no doubt if a man makes merely by way of bona fide experiment, and not with the intention of selling and making use of the thing so made for the purpose of which a patent has been granted, but with the view of improving upon the invention the subject of the patent, or with the view of seeing wheter an improvement can be made or not, that is not an invasion of the exclusive rights granted by the patents. Patent rights were never granted to prevent persons of ingenuity exercising their talents in a fair way. But if there be neither using nor vending of the invention for profit, the mere making for the purpose of experiment, and not for a fraudulent purpose, ought not to be considered within the meaning of the prohibition,and if it were, it is certainly not the subject for an injunction."

Yet, in order to better seize the scope of this decision, we have to replace it in its context. The facts are as follow: the applicant, Micro, applied for a compulsory licence and made small quantity of the product for which he was applying for a licence. His purpose was to study the process of fabrication and to duplicate it, economically, once the licence was issued. Micro`s defence consisted in proving that the use he was making of the substance was not for profit, but served to establish the fact that he could manufacture the substance safely with a quality equivalent to that of the patentee, so the chances the Commissioner of Patents would grant him the applied for licence would better.

The trial court considered this an infringment, but the Supreme Court of Canada reversed it. The Supreme Court said that it may not always be necessary to show the Commissioner of Patents the capacity to manufacture, but it is a prudent thing to do. Moreover:

> "(...) the fact that an applicant put himself in a position to show that he is possessed of the equipment, skill and knowhow by experimentation does not, in my opinion, make him an infringer."

In other words, bona fide experimental use is the logical result of the right to apply to a compulsory licence and a prudent thing to do, as long as the applicant does not use or sell the invention for profit.

The Supreme Court seems to have put aside the springboard principle in a case of compulsory licence under a patent for a medecine (Institute of Canada, p. 459-460).

Moreover, this decision of the Supreme Court does not fully define the scope of what is an acceptable experimental use within the meaning of the law regarding patents. Following cases add to this confusion.

Recently, in the case of the Wellcome Foundation Ltd. v. Apotex Inc. (1991) 32 C.P.R.(3d) 350, F.C.T.D., the Federal Court decided that the importation of a small quantity of a patented medecine for experimental use in hospitals, in order to obtain a notice of compliance before a compulsory licence was delivered to the defendants, does not constitute a bona fide experimental use without the idea of making profit, and should therefore be considered an infringment. However, the court refused to discuss this question any further in its decision.

We conclude that the full scope of the experimental use as a defence to a claim of patent infringment has not been settled yet in Canada.