THE NEW CANADIAN PHARMACEUTICAL COMPULSORY LICENSING PROVISIONS

or
HOW TO JUMP OUT OF THE FRYING PAN AND INTO THE FIRE

by
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INTRODUCTION

As at least most of the innovative pharmaceutical companies know, the Canadian Patent Act has always included very harsh pharmaceutical compulsory licensing provisions.

On November 18, 1987, an Act to amend the Patent Act was adopted by our Federal Parliament and given Royal Assent on the same day. This Act, whose passage into law has been marked by extensive lobbying from both the generic and innovative sectors of the pharmaceutical industry, has substantially modified the current legislation.

The compulsory licensing provisions introduced by this new Act were proclaimed on December 7, 1987, i.e. a few weeks after the Act was adopted, and the Patented Medicine Prices Review Board, which is the "police corps" in charge of enforcing the new provisions, was created on the same day, with Mr. EASTMAN as president.

The introduction of these new provisions was heavily supported by the innovative pharmaceutical companies and the revised law was welcomed with cheers by the same companies when it was enacted. The question however that we shall discuss hereinafter is whether the new Act is actually a "good deal" for these companies or whether they have merely jumped out of the frying pan and into the fire.

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After a short review of the current legislation, we shall set out the major changes recently enacted and briefly discuss their potential advantages and drawbacks, as we see them.

A. THE CURRENT LEGISLATION

Ever since 1923, the Canadian Patent Act has included compulsory licence provisions specific to patents for inventions dealing with food or medicine. These alimental or pharmaceutical compulsory licence provisions are to be distinguished from the more general compulsory licence provisions also provided by Law, whereby any interested person may obtain a licence for working a patented invention in the case of abuse of the exclusive rights under the patent, whatever be the technical domain to which the invention belongs. Here, it is obligatory to prove that there has been such abuse, for example, by failure to work the invention on a commercial scale in Canada or by failure to meet the demand for the patented invention to an adequate extent and on reasonable terms. According to the terms of the Paris Convention, such a licence may only be applied for, if at least three years have elapsed since the patent was officially granted.

In the case of patents dealing with pharmaceutical inventions (those dealing with food being in fact very few in number, only one having been made the subject matter of a compulsory licence in the last fifty years), it is not necessary to prove that there has been abuse of the exclusive rights under the patent and no grace period is applicable.

Under the present provisions of the Patent Act (which provisions have not been modified by the new Act), any interested person may, no matter when the patent was granted, ask for a compulsory licence that shall be automatically granted not only for manufacturing but also for importing the patented drug into Canada, either in bulk or in posological form. The Commissioner of Patents must grant the licence except if he sees "good reasons not to grant such a licence"[1]. In settling the terms of the licence and fixing the amount of royalty, the Commissioner must also "have regard to the desirability of making the medicine available to the public at the lowest possible price consistent with giving to the patentee due reward for the research leading to the invention".

In other words, the Canadian Patent Act as it presently stands, practically guarantees the grant of a compulsory licence to manufacture or to import into Canada a medicine to any interested person who asks for it.

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[1] Section 41(4) of the Patent Act.

Until 1969, the grant of compulsory licences was guaranteed only for the manufacture in Canada of a patented medicine, there being no compulsory licences available for importation of that medicine. However, in the years closely preceding 1969, a few schandals had arisen involving some innovative companies which, using their dominating position, had fixed the prices of their medicines at a very high level, particularly when compared to the prices at which the same medicines were sold by the same companies outside Canada. This abuse of the exclusive rights under patents became the subject of several public enquiries and led to reports such as the 1963 Report on the Manufacture, Distribution and Sale of Drugs of the RESTRICTIVE TRADE PRACTICES COMMISSION. Such reports were given greater currency because, at that time, Canada was completing nationalization of its medical services and was beginning to pay for them.

Accordingly, in 1969, the compulsory licence provisions were completely modified to allow the grant of compulsory licences to import upon request from any interested person. This was obviously in order to reduce as much as possible any further abuse by some innovative companies and to attempt a reduction in the retail price of drugs by increasing competition in the market place.

As soon as these provisions were enacted, a great number of compulsory licences to import were applied for and granted. This led to the development of a strong generic industry (some of the generic companies which actually started their operation in 1970, at present have higher sales than the Canadian subsidiaries of several multinational innovative companies). In fact, since 1969, nearly all the compulsory licences that were applied for and granted (more than four hundred), were licences to import.

Two very particular, not to say peculiar, features distinguish the Canadian pharmaceutical compulsory licence provisions from any other compulsory licence provisions known to us:

1 - almost all of the compulsory licence applications that were filed and not abandoned by their applicants since the provisions were enacted in 1969, have been granted, irrespective of the argumentation submitted by the patentee; and

2 - the amount of the royalty granted to the patentee has always been fixed at 4% of the net selling price of the drug in posological form and/or 15% of the net selling price of the drug in bulk, again irrespective of the argumentation put forward by the patentee.

In other words, since 1969, the Commissioner of Patents has never seen good reason bot to grant a compulsory licence in the pharmaceutical domain, in

spite of the numerous and various arguments that have been submitted by patentees. In fact, the only cases where compulsory licence applications have been refused are:

- where the patents listed in the compulsory licence applications had expired or did not deal with the drug for which the compulsory licence was requested; and

- where the applicant of the compulsory licence was declared bankrupt a few days before his application was filed.

The Commissioner of Patents has also never found arguments convincing enough to vary the amount of the royalty arbitrarily set at 4% of the net selling price of the drug in the first decision rendered under the provisions of 1969, in spite of numerous submissions made by patentees as to the amount of money they actually spent in research and development in Canada and/or abroad.

In addition, our Courts have never thought fit to reverse the decisions rendered by the Commissioner of Patents in spite of the invariable nature of his decisions, because, on the one hand, it was actually the intention of the legislators in 1969 to generate competition in the pharmaceutical industry in an attempt to reduce drug prices, and because, on the other hand, the decision to grant or refuse to grant a compulsory licence is exclusively an administrative decision on which a Court should not pronounce judgement, unless there is some flagrant abuse of right. In particular, otherwise sound arguments, such as, for example, the fact that the provisions enacted in 1969 are unconstitutional and/or contrary to the Canadian Charter of Rights and Liberties inasmuch as they lead to a deprivation of a property right guaranteed by Law, have been dismissed by our Courts.

B. THE NEW LEGISLATION

As political historiars have often observed, the preoccupations of a country's citizens and of their political representatives (if they have any) change with time and circumstances. In the past few decades, one of the major problems that has beset the developed countries of the world is unemployment. A popular method of obviating this problem, at least in part, is to stimulate investment in order to promote growth and thereby create jobs.

At the end of the seventies, Canada was perceived to be inhospitable to investment in the pharmaceutical industry, because of the rather unfair compulsory licence provisions of its Patent Act. It also appeared that these compulsory licence provisions had not only caused a substantial cut in the