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

growth and investment of research and development in Canada, but had also led some innovative companies to move abroad, thereby reducing the number of jobs available in the pharmaceutical field to high-level graduates from Canadian Universities.

In June 1983, a working paper was published by the Minister of Consumer and Corporate Affairs, calling for a change to the compulsory licencing provisions of the Patent Act in order "to rebalance the 1969 policy" and "generate further growth in this industry". In April 1984, a report arising from a Commission of Enquiry named eponymously after its President, Mr. EASTMAN, suggested firstly the legislation of a guaranteed period of pharmaceutical patent protection for innovative companies and secondly an increase in the royalty rate for compulsory licences to import, from 4 to 14%.

The additional compulsory licence provisions introduced into the Patent Act by the new Act follow these suggestions. As stated in a press-release published in 1986 by the Minister of Consumer and Corporate Affairs, the amendments that were adopted on November 1987 and which came into force on December 7, 1987, have the following objectives:

> "1) To transform Canada's pharmaceutical sector into a world-class, innovative industry led by an unprecedented increase in investment and jobs in pharmaceutical research and development...
>
> 2) To ensure fair-priced drugs for Canadians through the creation of an independent Drug Prices Review Board.
>
> 3) To guarantee that the pharmaceutical industry's commitments for research and development are met. If they are not, the proposed period of protection will be reduced or eliminated.
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> 4) To maintain opportunities for growth for generic companies in Canada.
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> 5) To bring Canada's Intellectual Property Laws into conformity with international practices."

1. MAINTENANCE OF THE EXISTING PROCEDURES

The new Act[2] does not repeal nor modify the existing procedures. It only adds a few limitations in order to delay the grant of compulsory licences to generic

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[2]Section 15 of the new Act.

companies asking for them, and, simultaneously, to induce the innovative companies to transfer a substantial part of their research to Canada.

Accordingly, unless the existing Rules are substantially amended or unless the present policy of the Commissioner of Patents is reversed by a Court, both of which we doubt, the compulsory licence applications that are filed after the period of exclusivity now guaranteed, should be granted as easily as they are today and for the same consideration, namely an amount of royalty invariably fixed at 4% of the net selling price of the patented drug in its posological form.

2. EXISTING LICENCES TO BE RESPECTED

Newly introduced sub-section 41.11(4) of the Patent Act provides that any compulsory licence granted before June 27, 1986 (i.e. the originally intended Parliamentory tabling date of the Bill which led to the new Act) will remain unmodified, provided however that the licencee actually obtained his Notice of Compliance on his drug also before June 27, 1986 (the Notice of Compliance or N.O.C. is the authorization given by the Government to a drug manufacturer to sell his product in Canada after the product has been proved to meet various requirements pertaining to safety and efficacy).

In other words, any compulsory licence that was in force on June 27, 1986 and whose object was actually worked at the same date, will remain in force and will not be open to review.

In addition, new Section 41.12 of the Patent Act provides that any compulsory licence to import, granted or filed on the day this portion of the new Act came into force (that is on December 7, 1987) is assumed to have as its object, not only the importation but also the manufacture in Canada of the drug forming its subject matter. Accordingly, we cannot even say that there is a status-quo, as the already granted licences not only remain in force, but are broadened in scope to cover the manufacture of the licensed drugs.

3. INTRODUCTION OF GUARANTEED PERIODS OF EXCLUSIVITY

Although the new Act does not change much in the existing procedure and provisions and does not affect the compulsory licences that were in force on June 27, 1986, it does add new provisions to the Patent Act in order to guarantee a minimum of exclusivity to any innovative company that obtains or has already obtained a patent on a new drug. These guarantees are a function of:

- the kind of licence applied for (manufacture or importation);

- the date of grant of the patent; and

- the date of issue of the Notice of Compliance to the innovative company by the Minister of Health and Welfare.

Before specifying the duration of the period of exclusivity guaranteed to patentees as a function of the above mentioned factors, it is worth mentioning that such periods of exclusivity are only given to the "base" patent disclosing and claiming a new drug. There is no protection at all against the grant of a compulsory licence with immediate effect under any patent covering a new process of manufacturing a drug that is already patented or know *per se*[3].

Thus, for example, a patentee having obtained a patent on a new process of manufacturing a drug forming the subject matter of another patent already expired, will not have any period of exclusivity guaranteed in any way.

It is also worth mentioning that these periods of exclusivity are not to be substituted for the seventeen or twenty years of protection afforded by the patent. These periods of exclusivity apply only within the normal period of protection afforded by a patent, it being understood that the guaranteed exclusivity will, in every case, expire as soon as the "base" patent expires or, in the next future, is not maintained through non-payment of annuities.

a) Licence to manufacture

If the compulsory licence applied for is to manufacture a patented drug in Canada, the period of exclusivity which will be granted to the patentee before the compulsory licence comes into force is 7 years starting from the date of issue of the first Notice of Compliance on the drug, provided however that this Notice of Compliance issued after June 27, 1986[4].

Accordingly, we may deduce *a contrario* that there will be no period of exclusivity against the coming into force of a licence to manufacture a patented drug in Canada if the first Notice of Compliance issued before June 27, 1986.

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[3] *vide t*he combined effect of new Sections 41.11(3) and 41.13 of the Patent Act; see also new Section 41.12 of the Patent Act.

[4] new Section 41.14(1) of the Patent Act.

b) Licence to import

If the compulsory licence applied for is exclusively to import the patented drug into Canada, the period of exclusivity which will be granted to the patentee before the licence comes into force is:

- 7 years from the date of issue of the first Notice of Compliance if (1) this Notice issued after June 27, 1986 and (2) a licence was granted before June 27, 1986 to a generic company but this generic company had not already obtained, at that date, its own Notice of Compliance or, alternatively, this generic company has obtained a Notice of Compliance before June 27, 1986 but the licence application was still pending[5];

- 8 years from the date of issue of the first Notice of Compliance if (1) this Notice issued before June 27, 1986 and (2) no compulsory licence and no other Notice of Compliance was granted or had been issued at that date[6]; and
- 10 years from the date of issue of the first Notice of Compliance if this date is subsequent to June 27, 1986[7].

Once again, we may deduce a contrario that there will be no period of exclusivity guaranteed to a patentee against the coming into force of a compulsory licence to import if (1) a first Notice of Compliance on the patented drug had already been issued by June 27, 1986, (2) a compulsory licence has already been granted to a generic company and (3) this generic company had, on June 27, 1986, already obtained its own Notice of Compliance. This is, of course, in conformity with the political decision to which we have already alluded, namely that the compulsory licences already granted and in force will be respected.

c) An exception: Canadian pharmaceutical inventions

In order to induce innovative companies to invest in Canada and to increase their commitments to research and development, the new Act has also introduced new provisions to the Canadian Patent Act, whereby a very particular status of protection is given to any new drug that is discovered and developed in Canada[8].

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[5] new Sections 41.11(1) and 41.11(2)(a) of the Patent Act.

[6] new Sections 41.11(1) and 41.11(2)(b) of the Patent Act.

[7] new Sections 41.11(1) and 41.11(2)(c) of the Patent Act.

[8] new Section 41.16 of the Patent Act; see also sections 5 to 8 of the Patented Medicine Regulations.

According to these new provisions[9], any patentee whose invention relates to a new drug that has been invented and developed in Canada, may, by supplying sufficient evidence and information in support of his request, ask the Commissioner of Patents officially to declare his new drug as being a Canadian invention and thereby deserving of a particular status.

Having this status, the patented drug cannot be made the subject matter of any compulsory licence to import for the entire duration of the patent[10]. Such an invention furthermore cannot be made the subject matter of a compulsory licence to manufacture[11], unless it appears that, seven years after the date on which the Notice of Compliance has issued to the patentee, the same is not capable of completely or substantially supplying the Canadian market for that drug[12] or refuses to comply with an order from the Patented Medicine Prices Review Board (which we will more extensively discuss hereinafter), and, more particularly, refuses to comply with an order of the board requesting a reduction in the selling price of the patented drug[13].

In order to preserve the particular status, "Canadian invention" for a patented drug, the patentee is also bound to answer any request from the Commissioner of Patents for information on his manufacturing activity[14]. Failure to answer such a request will lead to the revocation of the special status, so subjecting the invention thereafter to the grant of any compulsory licence to manufacture or import[15].

4. ESTABLISHMENT OF THE PATENTED MEDICINE PRICES REVIEW BOARD

The new Act establishes a "Patented Medicine Prices Review Board"[16], whose powers are very broad and discretionary and whose ostensible purpose is to control the selling price of marketed drugs.

The introduction of such a control on retail drug prices is not surprising in itself, especially if we consider that (1) health services are nationalized in Canada and (2) the above discussed compulsory licence provisions were amended in 1969 (to facilitate the grant of compulsory licences to import) precisely because of the excessive price of some drugs. What is original, surprising and,

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[9] subsection 41.16(1).

[10] subsection 41.16(2) of the Patent Act.

[11] subsection 41.16(3) of the Patent Act.

[12] subsection 41.16(4) of the Patent Act.

[13] subsections 41.16(5) and (6) of the Patent Act.

[14] subsection 41.16(9) of the Patent Act.

[15] subsections 41.16(9) and 41.16(2) of the Patent Act.

[16] new Sections 41.18 to 41.24 of the Patent Act.

we think, incongruous, is the fact that such a price control system has been incorporated into the Patent Act and therefore applies exclusively to patented drugs. This will penalize the innovatice companies which will, from now on, always have to justify their prices, contrary to the generic companies which, provided their selling prices are lower than those of the innovative companies (something that is very easy for them to achieve in practice because generic companies usually have no research and development costs), will not be similarly required to justify their prices or profit margins.

The Patented Medicines Prices Review Board recently established, consists of not more than 5 members[17], appointed for a period of 5 years[18] at the suggestion of an advisory panel of persons chosen from consumer groups and the pharmaceutical industry[19].

The first task of this Board is to prepare every year and submit to the Minister of Consumer and Corporate Affairs, a report giving a summary of pricing trends in the pharmaceutical industry and the names of the patentees about whom enquiries were made[20]. The Board must also prepare a more specific report from information obtained from all drug patentees, indicating, as a percentage, the amount spent by each patentee on research and development in Canada as a proportion of the revenue of the same patentee from drug sales in Canada. The same report must also give a compilation of the data obtained from each patentee to give, as a percentage, the expeditures of all the patentees active in pharmaceutical research and development in Canada, as a proportion of the total revenue of all of these patentees from their drug sales in Canada[21].

From a practical point of view, the purpose of the latter report is, we think, to allow the Government to check whether the innovative companies respect the commitment made by their professional association, the Pharmaceutical Manufacturers Association of Canada (PMAC), to the Minister of Consumer and Corporate Affairs several years ago, in order to "push" him to mitigate the then prevailing compulsory licence provisions. This commitment of the innovative companies, disclosed in a press-release entitled "Patent Act Reform-Pharmaceutical Policy", published by the Minister of Consumer and Corporate Affairs in November 1986, was to increase the ratio of research and development to sales from the current 5% to at least 10% by 1995.

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[17] new Section 41.18(1) of the Patent Act.

[18] new Section 41.19(1) of the Patent Act.

[19] Section 41.19(1).

[20] new Section 41.24.

[21] new Section 41.25(4).

The second task of the Board is, of course, to control prices of patented drugs and to deal severely with any abuse.

The provisions introduced by the new Act into the current Patent Act[22], enjoin the owner of any patent dealing with a given medicine to provide the Board every six-months, with:

1) the price at which the medicine is being sold in Canada;

2) the price at which the medicine is being sold abroad; and

3) the cost of making and marketing the medicine.

Each patentee must also provide the Board every year, with:

4) the name of any licencee of the patentee in Canada;

5) the quantity of sales made by the patentee, whether directly or indirectly in Canada, of the medicine; and

6) the amount of expenditure by the patentee in Canada on research and development[23].

The Board may request a patentee to justify any increase in the price of a drug, within a period of 30 days[24], if this increase is higher than the percentage increase in the Consumer Price Index for that period, as published by Statistics Canada[25].

If the patentee refuses or omits to provide the Board with the above mentioned information or the Board considers that the price of a drug remains excessive in view of a plurality of factors listed in various sub-sections of the Patent Act[26] and the patentee still refuses to reduce his price within the next month, the Board may revoke the period of exclusivity guaranteed to the patentee against the grant of compulsory licences to import and/or manufacture, not only for the patented drug forming the subject matter of the particular enquiry, but also for any <u>other</u> patented drugs sold by the patentee in Canada. Alternatively, if the Board does not deem it necessary

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22[22]see Sections 41.15(1) and 41.16(5) of the Patent Act and Rule 4 of the Patented Medicine Regulations.

23new Section 41.25(1) of the Patent Act and Rule 9 of the Patented Medicine Regulations.

24Rule 3.2 of the Patented Medicine Prices Reivew Board Rules.

25new Sections 41.15(1.1) and 41.16(5) of the Patent Act.

26new Sections 41.15(5) and 41.16(7).

to revoke the period of exclusivity guaranteed to the patentee, it may order that the price of the drug be reduced to an "acceptable" value[27].

To determine whether the price of the patented medicine is excessive or not, the Board must take into account the following factors:

- the price(s) at which the patentee sold the medicine in Canada and abroad during the five (5) years immediately preceeding the current determination;

- the price(s) of other medicines in the same therapeutic class on the market in Canada and abroad during the same 5 years; and

- the Consumer Price Index[28].

The Board may also take into account the cost of making and marketing the medicine[29]. It may not however take into account the worldwide cost of research leading to the patented drug. Rather, it may only take into account the Canadian portion of the world cost related to the research leading to the invention, along with the cost of its development and commercialisation as a medicine, calculated in proportion to the ratio of Canadian sales to world sales by the patentee of that medicine[30].

From a practical point of view, the Board has quasi-judiciary powers. It may hold hearings to which it may subpoena any person to testify[31], including, in particular, the patentee, to "explain" any excessive increase in the selling price of a given drug.

These hearings will be public, unless the Board is satisfied that direct and substantial harm would be caused to the patentee by the disclosure of information or documentation during the hearing[32]. However, any specific information submitted to the Board during an enquiry on the price of a drug shall remain confidential[33].

The Board must give notice to the Minister of National Health and Welfare and the Minister responsible for Health in each Province of any such hearing and each such Minister is entitled to appear and make representation to the

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[27] new Sections 41.15(2) and 41.16(6).

[28] new Section 41.15(5) of the Patent Act.

[29] new Section 41.15(6) of the Patent Act.

[30] new Section 41.15(7) of the Patent Act.

[31] Rule 10 of the Patented Medicine Prices Review Board.

[32] new Section 41.17(1) of the Patent Act.

[33] new Sections 41.17(2), 41.25(3) and 41.25(5) of the Patent Act.

Board[34]. In this connection, nothing is known about whether the provincial Ministers responsible for health will actually make any such representation. However, in the case of the Minister of National Health and Welfare of Canada, it is doubtful that he will make any representation as he has never done so in the last 20 years for any of the great number of compulsory licences that have been applied for, despite having such a right[35].

It is worth mentioning that no leave to appeal is provided for in the case where a patentee desires to oppose an order of the Board. This is rather surprising and serious if we consider the great subjectivity of the decisions that might be taken. We assume however that any decision amounting to an obvious abuse of right, even if it is only administrative, will be open to appeal to the Federal Court, as provided for at Common Law.

5. REVISION OF THE NEW PROVISIONS WITHIN 4 YEARS

The new Act gives the Government the right to amend Section 41 of the Patent Act without referring to Parliament, in order to:

- either reduce the period of exclusivity guaranteed to the patentees (this presumably would follow if, in the long term, drug prices substantially increase or if the innovative industry does not respect its commitments);

- or completely repeal Section 41, which would remove any special status from patents dealing with medicines[36].

In any case, it is provided by Law that the new provisions introduced into the Patent Act and their consequences shall be reexamined by Parliament within 9 years from the day they came to force[37], i.e. before December 7, 1996.

C. DISCUSSION

As indicated hereinabove, the new pharmaceutical compulsory licence provisions came into force on December 7, 1987 and the Patented Medicine Prices Review Board was created on the same day, with Mr. EASTMAN as its President.

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[34]new Section 41.15(8) of the Patent Act.

[35]see Rule 124(2) of the Canadian Patent Rules.

[36]new Section 41.26 of the Patent Act.

[37]subsection 41.26(3) of the Patent Act.

In a Bulletin dated July 1988, the Board published a "Compliance Policy" setting out its approach to securing compliance with the new legislation by the patentees. It also published "Guidelines" describing how it will determine whether the price of a patented medicine is excessive. The Compliance Policy is apparently based on the premise that maximum compliance can only be achieved through effective dissemination of information "to ensure that the patentees know what the rules are, what they must do to comply and how the Board will proceed if a price appears to be excessive". This approach whose aim is presumably to achieve "voluntary" compliance by the patentees, appears to be rather fair and open-minded under the circumstances.

The criteria set forth in the Board's guidelines to assess whether the current retail price of a given patented medicine is excessive, are twofold.

Firstly, for patented medicines already on sale in Canada prior to the proclamation of the new Act, the Board has decided, in our opinion, quite fairly, to compare the current price of a given medicine (at the time of the appraisal) with the so-called "benchmark" price of this medicine adjusted for the cumulative change in the Consumer Price Index (CPI), the benchmark price being the retail price of the medicine in question on December 7, 1987 (the Act's proclamation date). In practice, the Board will hold that the current price is excessive if it is greater than this CPI adjusted price.

The criteria set forth by the Board to assess whether the current price of every new medicine is excessive is however much more subjective. Indeed, in this case, the Board has decided that, "unless there is significant evidence to the contrary, the current prices (of the new medicines) will be presumed to be not excessive if they do not exceed the lesser of the median international price and the therapeutically adjusted price".

The "median international price" is the median selling price of the medicine in West Germany, France, Italy, Sweden, Switzerland, United Kingdom and the United States[38]. The "therapeutically adjusted price" is the "value-adjusted price of the medicine relative to other medicines available in Canada which treat the same disease and symptoms".

Clearly the price of any goods or services in any country depends on numerous factors that are specific to the country: capital investments, salaries, charges, distribution costs, medical assistance costs in the case of drugs, etc... Even if the standard of living in all the above mentioned countries are comparable, the respective costs of living are very different and capital investment by patentees may vary greatly on crossing international

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[38]Schedule II of the Patented Medicine Regulations.

frontiers. All this will obviously affect the prices of medicines being sold in these various states. Therefore, we are not convinced that any comparison with a median international price to assess the price of a new medicine to be sold in Canada is actually fair or even meaningful.

The other price yardstick, the concept of "therapeutically adjusted price", seems equally meaningless and is at best highly subjective and its application will no doubt be left to some administrative "rules of thumb" which we await apprehensively. This concept is also unfair inasmuch as the price of the new drug will be compared to the prices of all the similar drugs available in the market, including generic copies of the patented drugs.

As a matter of fact, we actually wonder why it is so important to control the introduction price of a new drug placed on the Canadian market? Is it really harmful to leave the innovative companies free to fix the introduction prices of their new products? Indeed, if the medicine is very expensive and no better than any other in the same category, it will probably not be commercially successful and the patentee will himself have to reassess his price.

Coming back to the new Act, what will be the advantages and drawbacks of the new compulsory licensing provisions?

Personnaly speaking, we do think that the decision of our legislators to guarantee some period of exclusivity to the owners of pharmaceutical patents, is good and fulfils a clear need that has arisen in the past few years. We are not entitled to judge whether the introduction of a price control system into the very specific field of patented pharmaceuticals is good or even whether it was actually necessary. However, we do think that the incorporation of such a price control system into the Patent Act is incongruous and discriminatory. Indeed, only the innovative companies applying for patents will be subjected to such price control and will suffer the administrative decisions of the Patented Medicine Prices Review Board. Moreover, we note that the provisions introduced by the new Act are extremely constraining, especially in view of the kind and quantity of information that may have to be provided to the Board by the innovative companies owning drug patents. In this connection, we note that the Patented Medicine Regulations enacted on September 28, 1988 call for the completion of Forms with a very great deal of information and data which may be difficult to extract from a standard management data base. Thus, by way of example, Rule 4 calls for the submission of the ex-factory price at which the medicine is sold for each dosage form, strength and package size, to each class of customer in each province. Assuming that there are only three classes of customers, *viz* drugstores, wholesalers and hospitals, thirty (30) prices (3 classes multiplied by 10 provinces) will have to be given for each

formulation and each such price will have to be the actual price, i.e. the price "after any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefits of a like nature"[39]. And what happens to these figures if the drugs are returned to the companies or removed from the market place, for example because of their expiration date?

Therefore, we actually wonder whether the innovative companies, originally so anxious to see the passage of the new Act, have not merely fallen out of the frying pan and into the fire.

From a practical point of view, we do believe also that the result our legislators are seeking could have been obtained in a much simpler and more efficient manner, if the successive Commissioners of Patents had enforced, with greater finesse, the provisions of Section 41(4) of the current legislation, rather than systematically and inflexibly applying the same administrative "recipe" for more than 20 years.

As pointed out by Mr. Justice Thurlow in *Charles Pfiffer and Co. Inc.* v. *Novopharm Ltd.*, 65 C.P.R. 132:

> "What impressed me much more from the argument was the fact that notwithstanding such obvious difference as existed between the cases, as for example, differences in the drugs with which the inventions were concerned and in the patents in respect of which licences were sought, differences as well in the case of drugs to which the inventions applied and differences in the levels of prices and proposed prices therefor, the result reached by the Commissioner in all cases was 4% of the selling price in final dosage forms. While I think it is incumbent on the Commissioner to deal with the matter on the facts of the particular case, I do not think there is any sound objection to his approaching a problem of this nature, the solution of which depends to a considerable extent on the application of the "broad axes" principle, by the initial application of such a rule of thumb approach, provided that due consideration is thereafter given to how far the facts of the particular case indicate that an alteration should be made in the percentage which the rule of thumb suggests" (underlining ours).

In spite of this statement, made in the beginning of the 70's, none of the patentees who, over the last twenty years, has desperately tried to oppose the grant of Compulsory Licenses on their drugs, has ever been able to put forward facts proving that their new drug was actually revolutionary in its category and, because of the tremendous amount of research carried out to

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[39] Rules 4(9) and (10).

develop it, was thus deserving of some "extra-protection" compared to all the other new, yet more "ordinary" drugs. Moreover, none of the patentees has ever been able to convince the Commissioner that the amount of money spent in research and development in Canada on a given drug, deserved a higher amount of royalty than other such drugs.

With due respect to the Court and Commissioner of Patents, we do believe that there has been, and still is, something wrong with the "system" even though none of the Commissioner's decisions to grant compulsory licences was ever revised by the Courts. More particularly, we do believe that it would have been far preferable for our Commissioner of Patents to have found under certain circumstances some "good reasons" not to grant compulsory licences. He should, we believe, also have modified the amount of royalty in some cases, to take into account the actual amount of money spent in research and development by the patentee.

Therefore, it seems to us that the implementation of the new provisions which are rather complicated and constraining, could have been avoided if our successive Commissioners of Patents had interpreted, in a fairer manner, the exact wording of section 41(4) of the current Act.