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PATENT DEDICATION AND THE PATENTED MEDICINE PRICES REVIEW BOARD

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INTRODUCTION

The Patented Medicine Prices Review Board (the "Board" or the "PMPRB") was established in 1987 pursuant to amendments to the *Patent Act*. The PMPRB is an independent quasi-judicial body whose mandate is to: (1) ensure that the prices charged by patentees for patented drug products are not excessive; (2) report annually on pricing trends in the pharmaceutical industry; and (3) report annually on the ratios of research and development (R&D) expenditures to sales for individual patentees and for the entire pharmaceutical sector.

The Board reviews the prices of patented medicines sold for human or veterinary use, but not of drugs for which there are no Canadian patents or of generic drugs sold under compulsory licence. The Board reviews the price at which a patentee sells the patented medicine. This is usually the "factory-gate" price to the wholesaler or to a hospital or pharmacy. Retail prices are not subject to the Board's jurisdiction.

When determining whether the price of a patented medicine is excessive, the Board is required to consider the factors set out in the *Patent Act*. These include:

- the prices at which the medicine in question and medicines in the same therapeutic class are sold in Canada and in other countries named in regulations made pursuant to the *Patent Act* (Germany, France, Italy, Switzerland, Sweden, the United Kingdom and the United States);
- changes in the Consumer Price Index (CPI); and
- other factors that may be specified by regulation.

On 15 February 1993, further amendments to the *Patent Act* came into force. Among other things, they provided the Board with new remedies and powers in relation to excessive prices.

If the Board finds that a medicine has been sold at an excessive price, it can order a price reduction. The Board can also order a further reduction in order to recapture any excess revenue that a patentee may have earned as a result of charging excessive prices. Excess revenues can also be recouped through payments to the Crown. Moreover, if the Board finds that there has been a policy of selling a medicine at an excessive price, it can order a patentee to reduce the price or pay a penalty amounting to twice the excess revenues estimated to have been derived from the excessive price.

Since the inception of the Board, there has been a marked increase in the number of drug products whose patents have been "dedicated." This is the term used to describe a patent whose patentee has surrendered its proprietary interest and dedicated that interest to the Canadian public by so notifying the Commissioner of Patents. Through the act of dedication, a patentee relinquishes its exclusive ownership of the patent and, presumably, its ability to sue other persons for patent infringement. Although the *Patent Act* does not recognize or provide for a process whereby patents can be dedicated, dedication has been practised in Canada for many years.

Until recently, the Board ceased reviewing the price of a patented medicine whose patent or patents had been dedicated. In 1995, in view of the increasing number of dedications of pharmaceutical patents, the Board changed this policy, believing that some dedications had been made to avoid the Board's jurisdiction. These notes will review the Board's recent policy statements with respect to patent dedications and the events leading to these statements.

PATENT DEDICATION DECISION

In January, 1995, the Board published for notice and comment a proposal that it would no longer cease to review prices after dedication of a patent (Patented Medicine Prices Review Board, *Bulletin*, Issue No. 15, January 1995). The Board's decision on patent dedication was published in October 1995 (*Bulletin*, Issue No.17).

Thirty-eight stakeholders provided comments to the Board. Generally, consumer

groups, provincial ministries of health and associations representing pharmacists, doctors, nurses and hospitals expressed their approval of the proposal. The patented drug manufacturers and, interestingly, the generic pharmaceutical industry opposed the proposal. The Canadian Drug Manufacturers Association, representing the generic sector, was opposed in part because it felt the proposal would discourage patentees from dedicating patents and thereby adversely affect generic competition.

A. Number of Dedications

Between 1969 and mid-1995, 637 patents applying to a variety of products were dedicated for public use. Pharmaceutical companies had dedicated 449 (71% of the total), of which 447 (99.6% of these dedications) had taken place since 1988, the first full year of operation of the PMPRB. Board statistics further revealed that pharmaceutical patents represented about 1% of the dedications prior to the creation of the Board, but 93% thereafter.

It should be noted that there may be several patents pertaining to one drug product. The well over 400 patent dedications by pharmaceutical companies relate to a smaller number of actual drug products. Data from the Board indicate that from 1989 to the end of 1994, 136 drug products had been dedicated.

Further research by the Board reveals that this rash of dedications of pharmaceutical patents appears to be taking place only in Canada, in spite of the fact that other jurisdictions (such as the United States, the United Kingdom and Australia), unlike Canada, have patent legislation that specifically authorizes the practice of dedication.

An analysis of the 136 dedicated drug products reveals that at least 43 of them had been priced above the Board's pricing guidelines for some period prior to the actual expiry date of the patent following dedication. The Board estimates that the practice of patent dedication in the pharmaceutical sector has cost Canadian society some $39.9 million for the five and one-half year period from 1 January 1989 to 1 July 1995 (see table below).

Estimated Costs to Society of Patent Dedication in Canada

1989	217 457 $
1990	1 518 936 $
1991	2 232 793 $
1992	7 478 645 $
1993	11 390 481 $
1994	11 203 929 $
1995 (Jan.1 – July 1)	5 837 237 $
Total	**39 879 478 $**

Source: PMPRB, *Bulletin*, Issue No. 17, p. 6.

B. Authority of the Board

The Board's policy of ceasing to review the prices of a patented medicine after its patents have been dedicated was stated in its *Fourth Annual Report For the Year ended December 31, 1991: "*In the event that a Canadian patentee should dedicate a patent pertaining to a drug product to the public domain, the relevant drug product ceases to be subject to price review by the Patented Medicine Prices Review Board" (p. 6).

The issue of patent dedication came to the fore in 1992 when the PMPRB issued its first Notice of Hearing in connection with the drug Activase. Shortly after the Board initiated price review proceedings in respect of Activase, the patent holders, Genetech Inc. and Genetech Canada Inc., dedicated the patents for Activase to the public domain and filed a motion with the Board disputing the PMPRB's jurisdiction on the grounds that Activase was no longer a patented medicine. In its August 1992 decision in this matter, the Board stated its concerns about using patent dedication to avoid price review:

> The Board therefore does not accept the argument that it was Parliament's intention to permit medicine patentees to abuse their patent rights by charging excessive prices and then, once the regulatory machinery created by Parliament to provide a public remedy is activated, to avoid those regulatory consequences by dedicating the relevant patents.

Subsequently, the Board obtained independent legal advice to the effect that the dedication of a patent does not eliminate the Board's jurisdiction over a patentee because the *Patent Act* does not specifically provide for the dedication of patents for public use.

> While the *Patent Act* confers rights on pharmaceutical patentees, it also confers obligations, including the obligations imposed by the regulatory scheme established in sections 79 to 101. Although a patentee may choose not to exercise its rights, it cannot unilaterally avoid its obligations. The *Patent Act* provides several ways in which a patent may be terminated before the normal expiry of the patent term; patent dedication is not one of them....
>
> The Board's jurisdiction over a patentee of a dedicated patent extends until the expiry of the patent's term, or at least until the happening of one of the events by which the Act removes the rights and benefits of the patent granted. (*Bulletin*, Issue No. 17, p. 7-8)

Effective 30 January 1995, the Board began to assert its continuing jurisdiction after the dedication of a patent until either the expiration of the patent's term or the cancellation or surrender of a patent in accordance with the *Patent Act*, whichever comes first (i.e., dedication does not affect jurisdiction). This assertion of jurisdiction may well reduce the number of pharmaceutical patents that are dedicated. It may also be open to legal challenge by patentees.