The Scope of the PMPRB's Jurisdiction: When Does a Patent Pertain to a Medicine?

The *Patent Act* gives the PMPRB jurisdiction over a "patentee of an invention pertaining to a medicine". For greater certainty, an "invention pertaining to a medicine" is defined in subsection 79 (2) of the *Patent Act*, which reads as follows:

For the purposes of subsection (1) and sections 80 to 101, an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine.

The term "medicine" is defined in s.1 of the Preamble to the PMPRB's *Compendium of Guidelines, Policies, and Procedures* (Compendium):

1.5 A medicine is defined as any substance or mixture of substances made by any means whether produced biologically, chemically or otherwise that is applied or administered in vivo in humans or in animals to aid in the diagnosis, treatment, mitigation or prevention of disease, symptoms, disorders, abnormal physical states, or modifying organic functions in humans or animals, however administered.

1.6 For greater certainty, this definition includes vaccines, topical preparations, anaesthetics and diagnostic products used in vivo, regardless of delivery mechanism (e.g. transdermally, capsule form, injectable, inhaler, etc.). This definition excludes medical devices, in vitro diagnostic products and disinfectants that are not used in vivo.

Section 1 of the Preamble also states that for the purposes of its jurisdiction, the PMPRB considers as a patent, any Canadian patent of invention that pertains to a medicine. This includes, but is not restricted or limited to, patents with the following status:

- patents for active ingredients;
- patents for processes of manufacture;
- patents for a particular delivery system or dosage form that are integral to the delivery of the medicine;
- patents for indications; and
- patents capable of being used, whether or not they are being worked.

A full analysis of the issue of whether a patent pertains to a medicine was given by the Federal Court of Appeal in *ICN Pharmaceuticals Inc.* v. *Canada (Staff of the Patented Medicine Prices Review Board) (C.A.)* (1997) 1 F.C. 32 (*ICN*), where the Court set out a three-part test to determine whether the PMPRB has jurisdiction over patents pertaining to a medicine:

- the PMPRB must determine that a party is a patentee of an invention;
- the patentee's invention must pertain to the medicine:
  - (a) the pharmaceutical end product in question, must qualify as a medicine – the term "medicine" must be interpreted broadly, not narrowly;
  - (b) there must be a rational connection or nexus between the invention described in the patent and the pharmaceutical end product, that is between the invention described in the patent and the medicine:
    - (i) one does not have to, and ought not to, go beyond the face of a patent to establish the required nexus;
    - (ii) the nexus can be one of the "merest slender threads".
  - (c) the invention must be intended or capable of being used for medicine or for the preparation or production of medicine;
  - (d) there is no requirement that the invention described in the patent actually be used for the medicine or for the preparation or production of the medicine; and
- the patentee must be selling the medicine in any market in Canada.

The application of the second branch of the test, and in particular sub tests (b) and (c) under this branch, often involves issues of interpretation based on the facts of the specific situation.

In *ICN*, the Court rejected submissions that would have narrowed or restricted the Board's jurisdiction and instead found that the broad language of ss. 79(2) and ss. 83(1) (the latter subsection deals with the order the Board may make when it finds that a "patentee of an invention pertaining to a medicine" is selling the medicine in Canada at an excessive price) of the *Patent Act* clearly evinced Parliament's intention that it is unnecessary to go

beyond the face of the patent when establishing the required nexus, or rational connection between the patent and the medicine in question, which can be of the "merest slender thread". The Federal Court of Appeal also explained why this threshold is so low:

> "…subsection 83(1) of the Act is concerned only with the existence of a related patent and not its potential or actual effect on the ability of potential competitors to enter a market, or for that matter the ability of patent holders to exercise market power… the phrase, **an invention pertaining to a medicine** [emphasis added], and in particular the word pertaining, evinces a clear intention that the nexus between the patent and the medicine is of broad import. For example, there is no requirement that the patent actually be used in the production of the medicine. Nor could subsection 83(1) be reasonably construed to support such a construction. Furthermore, the Board's jurisdiction extends not only to patents which contain product claims (a claim for the medicine itself), but also patents which contain "process" and "use" claims. The law might be otherwise if subsection 83(1) had been drafted to read, for example, "an invention for a medicine". That the word pertaining invites a broad construction is reinforced by subsection 79(2) which expands upon the notion of when a patent pertains to a medicine."[1]

> "There is nothing to suggest that it [ss. 79(2)] is to be interpreted restrictively… There need only be a slender thread of a connection between a patented invention and the medicine sold in Canada in order to satisfy the test for a nexus. The legislative reason for this is simple. Requiring a stronger nexus would provide a window of opportunity for pharmaceutical companies to avoid the jurisdiction of the Board, and would limit the ability of the Board to protect Canadian consumers from excessive pricing."[2]

> "…the broad language found in subsections 83(1) and 79(2) of the Act clearly evinces an intention on the part of Parliament that it is unnecessary to go beyond the face of a patent when establishing the required nexus. The validity of this conclusion is reinforced by the fact that the Board's statutory mandate is limited to the pricing of patented medicines. Its members have neither the experience nor the expertise to engage in the task of patent construction… the matter of patent or claims construction is a question of law to be decided by the Court. It is simply unrealistic to expect the Board to engage the services of expert witnesses for the purpose of assessing evidence proffered by parties such as ICN, and then for the Board itself to assess opposing expert evidence. Recognizing that the Board is charged with both the prosecution (through its staff) and adjudication of each case as opposed to being a neutral arbiter of evidence presented by two opposing parties, ICN's rational connection test (based on patent construction) is impractical…"[3]

In order to establish the required nexus or rational connection between an invention described in a patent and a medicine, the patent must first be read as a whole and, in particular, all the claims of the patent must be examined as a whole to determine the invention the patent describes on its face. Considering the fact that the nexus can be "the merest slender thread", the required nexus between the invention described in the patent and the medicine is easily established. For example, in many cases the patent on its face describes an invention, which makes reference to the therapeutically active ingredient found in the medicine itself. This therapeutically active ingredient is the rational connection or nexus between the invention described in the patent and the medicine, even though all of the elements of the invention described in the patent may not be found in the medicine as it currently exists. The Federal Court of Appeal in *ICN* noted that the chemical formulation of a therapeutically active agent found in a medicine, the generic name of this agent, and the trade or brand name of a medicine containing this agent are often all synonymous and interchangeable so that any of these names can be used to establish a rational connection or nexus between the invention described in the patent and the medicine:

> "If we examine the '756 patent, which expired on September 28, 1993, it discloses several chemical processes to produce a substance with the chemical formulation 1-8-D-ribofuranosyl-1,2,4-triazole-3-carboxamide. The '756 patent lists this chemical formulation as the preferred nucleoside of the '756 invention. The '264 describes a method for the enzymatic synthesis of the same formulation and makes explicit reference to the '756 patent. Neither patent, however, contains the word "ribavirin". However, the '265 patent outlines several uses of the same chemical formulation, and refers to it as "Ribavirin (non-proprietary name adopted by the United States Adopted Names Council)":

1 *ICN Pharmaceuticals Inc. v. Canada (Staff of the Patented Medicine Prices Review Board) (C.A.)* [for 1997] 1 F.C. 32 (*ICN*) at para. 57

2 *ICN* at para. 60

3 *ICN* at para. 61

see Appeal Book, Vol. 1, at page 81. Turning to the notice of compliance and product monograph both refer to Virazole as the registered trade name for ribavirin. As is obvious, it is not difficult to establish a nexus between the two patents and the medicine being sold in Canada. For all intents and purposes, the chemical formulation outlined in the patents and the names ribavirin and Virazole are synonymous and interchangeable."[4]

After the PMPRB has determined that there is a rational connection or nexus between the invention described in a patent and the medicine, the PMPRB must next examine whether the invention described in the patent is **intended or capable** of being used for the medicine or for the preparation or production of the medicine. [Emphasis added]. It is irrelevant whether the patent is **actually being used** for the medicine or for the preparation or production of the medicine. [Emphasis added]

In *ICN*, the Federal Court of Appeal noted that, on its face, one of the patents in issue, the '264 patent, described a method for the production of ribavirin, the therapeutically active agent in the medicine, Virazole. Even though, on its face, the invention described in the '264 patent was not "capable" of producing ribavirin in sufficient quantities for pharmaceutical application, it was "intended" to produce ribavirin and so the '264 patent pertained to the medicine, Virazole. The Court noted:

> "On its face, the '264 patent does not teach that it is intended to serve solely as a research and development process or that it is only capable of producing minute quantities of ribavirin.
>
> On its face the '264 patent outlines an enzymatic process which is "intended" to produce ribavirin. According to subsection 79(2) it is not necessary that a patent be "capable" of producing that chemical substance, as long as that is the "intended" result."[5]

Even if the invention described in the patent is not ever used or is never intended to be used for the medicine or for the preparation or production of the medicine, it may be **capable** of being used for the medicine or the preparation or production of the medicine. [Emphasis added] In *ICN*, the Federal Court Trial Division noted that the word "capable", in the context of the *Patent Act* "should not be given a meaning that is akin to "commercially feasible" or "reasonably practicable".[6] Also in the recent case of *Hoechst Marion Roussel Canada Inc.* v. *Canada (Attorney General)* [2005] F.C.J. No. 1928 (T.D.) ("*Hoechst*"), in which the Federal Court Trial Division affirmed and applied the three-part test set out in *ICN*, the Court rejected the patentee's argument that on its face, the patent, which was for a transdermal nicotine delivery system, did not pertain to the medicine Nicoderm, because the structure of the delivery system protected by the patent was not the system used in Nicoderm. The Court noted:

> "…in ICN, supra, both the Board and the trial judge concluded that whether a patentee is making use of the patent in question is irrelevant to the legal question of whether that patent "pertains" to a medicine within the meaning of the Act."[7]
>
> "On the face of the '689 Patent, it is clear that it is a patent for a transdermal nicotine patch, that is the type of medicine of which Nicoderm is a particular example. It is …capable of being used for medicine such as Nicoderm."[8]
>
> "… the fact that the '689 Patent is for a nicotine transdermal patch system, capable of being used in the drug product Nicoderm, is a sufficient connection to support the conclusion that the '689 Patent pertains to Nicoderm. It is irrelevant whether the '689 Patent is actually being used in connection with the medicine Nicoderm."[9]

In light of the foregoing discussion, patentees should be aware of the fact that any patents that pertain to modified release formulations of a medicine may also pertain to regular formulations of the same medicine. Patentees should avoid making unilateral decisions as to whether a patent pertains. Rather than failing to disclose the existence of a patent based on the view that it does not pertain, patentees should advise the PMPRB as to any decisions made in this regard, as well as the reasons supporting the decision. In this regard, the Federal Court of Appeal in *ICN* underlined the importance for the pharmaceutical industry to be mindful of its reporting obligations under the *Patent Act* and its Regulations and warned patentees that where they unilaterally fail to disclose the existence of a patent on the basis that it does not pertain to a medicine, they may be undermining their credibility and that of their witnesses before the PMPRB in addition to making it more difficult for the PMPRB to fulfill its legislated mandate.[10] ■

4 *ICN* at para. 67

5 *ICN* at para. 63

6 [1996] F.C.J. No. 206 (T.D.) at para. 23

7 *Hoechst Marion Roussel Canada Inc.* v. *Canada (Attorney General)* [2005] F.C.J. No. 1928 (T.D.) ("*Hoechst*") at para. 118

8 *Hoechst* at para.119

9 *Hoechst* at para. 120

10 *ICN* at para. 78