

## THE JURISDICTION OF THE PATENTED MEDICINE PRICES REVIEW BOARD IS CLARIFIED

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### Introduction

Hoechst Marion Roussel Canada Inc. (HMRC) who is the exclusive distributor of Nicoderm, an aid for the cessation of smoking, was seeking judicial review of two decisions of the Patented Medicine Prices Review Board. As its title suggests, the Patented Medicine Prices Review Board has the mandate of reviewing the prices of patented medicines in Canada, pursuant to the Patent Act. The Board informed HRMC (arguably a “patentee”) in 1998 that it was investigating the pricing of Nicoderm (arguably a “medicine”) to which 3 patents and 2 *patent applications* pertained, according to the Board. The Chairperson of the Board, after reviewing the file, issued a notice of hearing to determine if the sale price of Nicoderm was excessive, the whole pursuant to sections 83 and 85 of the Patent Act. HRMC then sought to have the notice of hearing rescinded by raising a number of jurisdictional issues. The jurisdictional issues were argued in two separate motions in front of a Board panel consisting of the Chairperson and three other members.

### Patented Medicine Prices Review Board decisions

#### *Bias and procedural fairness*

In its decision rendered August 3rd, 1999, the Board Panel unanimously dismissed HMRC’s arguments with respect to the issues of institutional bias, breach of procedural fairness and lack of particulars.

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The Board Panel came to the conclusion that the Patented Medicine Prices Review Board is an expert tribunal with overlapping functions authorized by the Patent Act and that it did not exceed its jurisdiction. In addition, it concluded that the Board proceeded in a fair manner as all aspects of procedural fairness were respected.

### ***Statutory guidelines***

In a separate hearing, the Board Panel rejected HMRC's argument that Nicoderm is not a medicine for the purposes of the Act, but rather a delivery device for the administration of nicotine. The Board concluded that Nicoderm was a medicine for the purposes of subsections 83(1) and 79 (2) of the Act by relying on the fact that the term medicine is not defined and that jurisprudence has concluded that the word medicine should be interpreted broadly.

The Board Panel also decided that, except for one, the patents and patent applications in issue pertained to Nicoderm and that HMRC was a patentee within the meaning of the Act. The Board Panel ruled that it had jurisdiction over the patent applications in issue, as of the date on which they were laid open.

### **Federal Court decision (part 1)**

The first part of the application for judicial review questioned the jurisdiction of the Board on the basis of procedural fairness and bias. The following issues were raised by HMRC.

1. Did the procedure followed by the Board for conducting a hearing provide for a fair and impartial tribunal in accordance with the principles of procedural fairness and the Bill of Rights?
2. Whether or not the following factors constitute a reasonable apprehension of bias so as to justify judicial intervention:
  - a) Do the operations of the Board create an impermissible overlap of investigative and adjudicative functions by the Board and the Chairperson?
  - b) Did the Board and Chairperson predetermine certain matters that were in issue at the hearing?
  - c) Did the participation of the Chairperson in the Board Panel, having previously reviewed the Staff Report and VCU and issued the Notice of Hearing, constitute a reasonable apprehension of bias?

The Court decided that HMRC's procedural fairness rights were respected as a notice of hearing and opportunity to make representations was given. In

fact, HMRC received several letters from the Board relating to the price of Nicoderm and was given the opportunity to respond to the allegations of excessive pricing by providing additional information as well as the possibility of making a price adjustment proposal (VCU) which it did.

As for the issue of whether a reasonable apprehension of bias existed, the Court recognized that an overlap of functions does exist within the Patented Medicine Prices Review Board. This overlap of functions is authorized by statute, allowing the Board to discharge multiple functions, including investigation, prosecution and adjudication. In addition 96(2) of the Patent Act, gives the Board the possibility of adopting its own rules and procedures. Furthermore, the way the Board proceeded did not give rise to a reasonable apprehension of bias as the Chairperson's decision to hold a hearing and to participate in this hearing was in no way a determination that there was excessive pricing. The Court decided that this was a matter to be resolved in a public hearing as the function of the Chairperson at a preliminary stage is merely an administrative one.

### **Decision of the Federal Court (Part 2)**

The second part of HMRC's application for judicial review dealt with statutory guideline issues having to do with the jurisdiction of the Patented Medicine Prices Review Board. The first issue that the Court had to determine was whether Nicoderm was a medicine within the meaning of the Patent Act. The Court reiterated that the word medicine must be interpreted broadly and in its ordinary sense. The Court decided that a reasonable person could conclude, based on the evidence available to the Board, that Nicoderm is a medicine for the purposes of the Board's jurisdiction. No errors were therefore made by the Board Panel in arriving at this conclusion.

The Court also found that the Board Panel's conclusion that the patents in issue (except one) pertain to Nicoderm was reasonable. HMRC had argued that the structure of the delivery system protected by one of the patents in issue was not the system used in Nicoderm. The Court concluded that whether the patentee is making use of the patent is irrelevant. The only relevant question is whether that patent pertains to a medicine within the meaning of the Act.

While the Court agreed that the Board had jurisdiction over issued patents pertaining to Nicoderm, it concluded that the board lacked jurisdiction over patent applications as of the date on which they were laid open. The Court determined that the Board must only assume jurisdiction on patents from the date on which they are granted as no monopoly is granted to the patent holder pursuant to section 42 of the Act prior to the issuance. The existence of a laid open patent application in no way leads to the conclusion that a

patent will eventually be granted. The Court therefore quashed the part of the Board's decision dealing with the two patent applications in issue.

## Conclusion

This decision of the Federal Court of Canada clarifies issues pertaining to the jurisdiction of the Patented Medicine Prices Review Board. The Court upheld in large part the decision of the Patented Medicine Prices Review Board recognizing the broad jurisdiction and authority of the Board in relation to the pricing of medicines. Also, the procedures put in place by the Board when determining whether the price of a medicine is excessive, were recognized by the Court as being fair and impartial. However, the Court concluded that the broad jurisdiction of the Board does not extend to patent applications pertaining to medicines, as the patent has not yet been granted. Medicines that are subject to patent applications are now evidently outside of the realm of the Patented Medicine Prices Review Board.

*Hoechst Marion Roussel Canada Inc. v. Canada (Attorney General)* 2005 FC 1552 (F.C.; 2005-11-17)



