PMPRB-99-D2-NICODERM

IN THE MATTER OF the *Patent Act* R.S. 1985, c. P-4, as amended by R.S. 1985, c. 33 (3rd Supp.), and as further amended by S.C. 1993, c. 2
AND IN THE MATTER OF Hoechst Marion Roussel Canada Inc. (Respondent) and the medicine Nicoderm

DECISION ON JURISDICTION - PART I

This is the decision of the Board on two of the four grounds advanced in the motion by Hoechst Marion Roussel Canada ("HMRC") for an order that the Board rescind its Notice of Hearing dated April 20, 1999 (the "Notice of Hearing"). The order was sought on the basis that the Board is without jurisdiction to inquire into the matters raised in the Notice of Hearing.

A. Introduction

Nicoderm is the brand name of a nicotine "patch" that, when placed on the skin, delivers nicotine into the bloodstream to replace the nicotine otherwise delivered by cigarettes. It is used to assist in smoking cessation by the partial relief of nicotine withdrawal symptoms. It is sold in Canada by HMRC. The Board issued the Notice of Hearing to initiate a public hearing to determine whether HMRC was, or had been, selling Nicoderm at excessive prices, and if so whether it had done so inadvertently or pursuant to a policy adopted in that regard.

The Board's jurisdiction to prevent excessive pricing is limited to patented medicines. The Notice of Hearing sets out the allegations of Board Staff concerning the patents said to pertain to Nicoderm and the current and historical pricing of Nicoderm. This pricing was alleged to exceed the maximum allowable price determined in accordance with the Board's policies in this regard.

In accordance with the Board's *Rules of Practice and Procedure*, the Notice of Hearing called on HMRC to provide its Response within 15 days. HMRC did not file a Response, but instead filed a document titled "Conditional Response" that stipulated only that the Notice of Hearing was deficient in that it did not provide HMRC sufficient detail to prepare its Response.

On May 25, 1999, HMRC filed a Notice of Motion requesting that the Board rescind the Notice of Hearing, as the Board was without jurisdiction to have issued the

Notice. HMRC advanced four grounds in support of its position. The first was that Nicoderm is not a medicine within the meaning of the *Patent Act* (the "*Act*"). The second was that the Board was tainted by institutional bias. The third was that HMRC was not the patentee of the patents cited in the Notice of Hearing, and in any event only one of the patents pertains to Nicoderm. The fourth was that the Notice of Hearing was insufficiently detailed for HMRC to know the case it had to meet.

Board Staff argued that further documentation was needed in order for Board Staff to address the first and third grounds of HMRC's motion. HMRC resisted this further production and this has been the subject of a separate motion by Board Staff and a separate decision of the Board. In the meantime, however, the Board received evidence and argument on the second and fourth grounds for HMRC's motion, and this decision – which is Part 1 of the Board's decision on the HMRC motion - addresses those grounds.

B. The Structure and Operation of the Board

It will be useful at this stage of the decision to provide a brief description of the manner in which the Board is structured and the procedures by which it operates. The details of this outline are contained in the Board's *Compendium of Guidelines, Policies and Procedures*, (the "*Compendium*") which forms part of the public record of this proceeding.

(i) Structure

As noted in greater detail below, the Board has the statutory obligation to develop policies with respect to the pricing of patented medicines, to monitor the prices of patented medicines, to investigate instances in which the price of a patented medicine might have been excessive, and to adjudicate cases where it is alleged that there has been excessive pricing.

The Board is composed of members and has the authority under the *Act* to hire staff, and to develop policies and procedures as to how it will carry out its statutory duties in a fair and effective manner. Though the *Act* creates the Board without the separate creation of a distinct entity labeled "Board Staff", part of the process by which the Board has determined to carry out its statutory obligations has been the separation of some of the functions of the staff of the Board ("Board Staff") and the Board members.

(ii) Operation

The Board has developed policies as to how it will determine the maximum price for a patented medicine that is not excessive, and this price is termed the "maximum non-excessive price", or the "MNE" for the medicine. In developing these policies and

in its ongoing operation the Board operates with a high degree of consultation with stakeholders in the pharmaceutical industry and health care fields, as well as with individual patentees concerned with the pricing of their medicines. These pricing policies have been set out in the "Guidelines" contained in the *Compendium*.

Though not required by the *Act* to do so, the Board has introduced procedures that separate its adjudicative functions from its monitoring and investigative functions. When Board Staff encounter an instance in which the price of a patented medicine might have exceeded its MNE, the matter will be investigated by Board Staff. If Board Staff conclude that the MNE has been exceeded the patentee will be requested to lower the price to comply with the Guidelines and refund any excessive revenues that were received while the price exceeded the Guidelines. This process is discussed in greater detail below under the heading "Voluntary Compliance Undertaking". If the matter is not resolved through this process, Board Staff may recommend to the Chairperson that it be brought before a panel of the Board for determination in a public hearing.

Until the matter is brought before them at the public hearing, no Board member is involved in or aware of the results of Board Staff's investigation into an instance of alleged excessive pricing, other than the Chairperson in his management capacity as Chief Executive Officer of the Board, as discussed below. The members first learn of Board Staff's case when the Notice of Hearing is issued, and they hear the evidence adduced by Board Staff when it is put before a panel of Board members in the form of evidence adduced at a public hearing.

When Board Staff report to the Chairperson that there has been an instance of excessive pricing, the Chairperson, as Chief Executive Officer of the Board, will review the matter with the sole purpose of determining whether it is in the public interest that there be a public hearing concerning the matter. In making this determination, the Chairperson determines, among other things, whether the allegations made by Board Staff, if proven true, would establish a prima facie case of excessive pricing by a patentee under the Board's jurisdiction. The Chairperson's role in this context is as the senior management official of the Board directing its operations and ensuring that public hearings are held (and only held) in appropriate cases; it is not in any sense adjudicative and the Chairperson undertakes no analysis of whether the facts alleged by Board Staff are, or will be, proven.

If the Chairperson determines that it is in the public interest that a hearing be held, the Board issues a Notice of Hearing and the Chairperson appoints a panel of members to preside at the hearing. At the hearing Board Staff will advocate its position that there has been excessive pricing of a medicine under the Board's jurisdiction, the patentee will present its case to the contrary, and the panel of the Board will hear the evidence and issue a decision in the matter. The panel of the Board is represented by its own separate counsel throughout the hearing process.

(iii) Voluntary Compliance Undertaking

It was noted above that when Board Staff conclude that there has been an instance of excessive pricing, the patentee will be invited by the Director of Compliance and Enforcement to comply voluntarily with the Board's Guidelines by lowering the price of the medicine in question and refunding excessive revenues that have been received to date. A patentee can respond by submitting a "Voluntary Compliance Undertaking" ("VCU"), containing the patentee's proposal to reduce the price of the medicine and refund excessive revenues so that, in the view of the patentee, any past excessive pricing is remedied and any future excessive pricing is avoided. The VCU is forwarded to the Chairperson along with Board Staff's report of their investigation of the matter.

If the Chairperson determines that the VCU does not comply with the Board's policies or that it is otherwise in the public interest that a public hearing be held, the Board will issue a Notice of Hearing, setting out the allegations of Board Staff and the order that Board Staff propose the Board make if the allegations are proven. The Notice of Hearing also sets out the schedule and procedures for the hearing.

C. Institutional Bias

(i) Structure of the Board

In support of its motion, HMRC notes that, despite the manner in which the Board is structured and operates, the *Act* creates the Board as a single entity with the responsibility to investigate, prosecute and adjudicate instances of alleged excessive pricing of patented medicines. HMRC argues that as such, the *Act* gives rise to a reasonable apprehension of bias and thus deprives the patentees under its jurisdiction their right to a fair hearing.

HMRC does not dispute the extensive case law to the effect that legislators may create tribunals with overlapping functions without violating the right of a fair hearing, nor that what constitutes a "fair hearing" can vary depending on the rights and interests at stake. HMRC argues, however, that federal tribunals are subject to the *Canadian Bill of Rights*, and thus if they are to have overlapping functions such as those of the Board, the resulting denial of a fair hearing, as HMRC would put it, can only be permissible if the enabling legislation expressly provides that it applies notwithstanding the right to a fair hearing guaranteed in section 2(e) of the *Canadian Bill of Rights*.

Having considered the arguments of HMRC and Board Staff on this point, the Board concludes that HMRC's argument fundamentally misdescribes the logic and effect of the jurisprudence in this area. Parliament did not enact those provisions of the *Act* that create the Board with the assumption that the Board's overlapping functions would deprive patentees of their right to a fair hearing. What the extensive jurisprudence in this area has established is that what constitutes a fair hearing will vary depending on the rights and interests in issue, and that Parliament may create a tribunal with the features appropriate to meet the statutory duties imposed upon it without denying the right to a fair hearing.

The Board regulates the purely economic interests of patentees under its jurisdiction. It is an expert tribunal that develops and applies health care policy within the pharmaceutical industry, and in particular, policy with respect to the avoidance of excessive pricing of patented medicines. It is precisely the type of tribunal that, as noted in the jurisprudence, Parliament may create with overlapping functions without violating the right to a fair hearing.

The response to the argument of HMRC is that Parliament, in creating the Board, did not violate patentees' rights to a fair hearing such that the *Act* must be expressly stated to apply "notwithstanding" the provisions of the *Bill of Rights*. Rather, Parliament created a tribunal that provides patentees with a fair hearing given the rights and interest at stake. There is no violation of the *Bill of Rights* that must be the subject of "notwithstanding" language in the *Act*.

(ii) The Operation of the Board

In the alternative, HMRC has argued that the Board has gone beyond any overlap authorized by the *Act* in the manner in which it has carried out its statutory obligations in this case. HMRC made four specific arguments of this type.

1. <u>The "conclusive" nature of the allegations of Board Staff following its investigation into the pricing of Nicoderm</u>

HMRC complains that the Director of Compliance and Enforcement, in communicating Board Staff's concerns with HMRC's pricing of Nicoderm, made "definitive conclusions on the very matters that are to be determined by the Board after a hearing". HMRC raises this objection as if it were additional to the general complaint regarding the overlapping functions of the Board, though it is the Board's view that it is really derivative of the general complaint.

The conclusions in the correspondence were those of Board Staff's Director of Compliance, when she wrote to HMRC to communicate first, the preliminary and then the final results of Board Staff's investigation into the pricing of Nicoderm. These results are summarized in the statements set out in the Notice of Hearing as the allegations of Board Staff that will be considered by the Board during the course of the hearing.

The Board sees nothing offensive in Board Staff describing the results of its investigation as a series of conclusions. Board Staff have conducted an investigation for the very purpose of determining whether there is a *prima facie* case that there has been an instance of excessive pricing by a patentee under the Board's jurisdiction. In her correspondence the Director of Compliance and Enforcement was informing HMRC of the results of Board Staff's investigation and putting HMRC on notice that the matter would be put to the Chairperson to determine if he should issue a Notice of Hearing.

The results of Board Staff's investigation could have been cloaked with language such as "Board Staff believe that the evidence adduced at a hearing into this matter will establish that …", but this is implicit given the operation of the Board and the context of the statements. The purpose of the correspondence of Board Staff was to put HMRC on notice of the findings of the investigation and it was entirely appropriate that those findings be presented in unambiguous terms so that HMRC could respond accordingly.

The test for a reasonable apprehension of bias is:

> "*what would an informed person, viewing the matter realistically and practically – and having thought the matter through" – conclude*".[1]

As noted above, given that the conclusions are in no sense those of the panel of the Board that will be considering the matter, but only the allegations of Board Staff to be put before the panel for proof in a public hearing, the fact that they are framed as the conclusions of Board Staff does not give rise to any reasonable apprehension of bias.

2. <u>The "predetermination on key factual issues" made by the Chairperson in rejecting the VCU</u>

HMRC argues that when the Chairperson considered the VCU submitted by HMRC but elected to initiate a public hearing, he must have come to a conclusion that the VCU did not accord with the Board's policies. This, HMRC argues, amounts to a predetermination of key factual issues to be determined at the public hearing.

The complaint here is based on a misapprehension of the policies and procedures of the Board, and in particular the reasons for which the Chairperson might decide to initiate a public hearing despite having received a VCU.

As noted in the *Compendium*, in considering a VCU the Chairperson will be guided by whether or not the VCU will result in compliance with the Board's excessive pricing Guidelines, and could initiate a public hearing if it does not. However, the Chairperson may initiate a public hearing when it is in the public interest to do so, and this could be for a number of reasons, one of which is that the matter appears open to debate and the Chairperson believes that there should be a public hearing at which Board Staff, the patentee and interested parties can present evidence regarding the allegation of excessive pricing. As noted in the next section, the Chairperson's consideration at this stage is simply whether the allegations of Board Staff, if proven true, would constitute a *prima facie* case of excessive pricing. The evidence at the hearing might, or might not, bear out the allegations. There could be disagreement among reasonable persons as to whether or not the VCU will result in compliance with

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[1] Committee for Justice & Liberty v. National Energy Board, [1978] 1 S.C.R. 369 at 394-5

the Guidelines, or whether the Guidelines (which are only presumptive) are appropriate. Accordingly, the Chairperson could be concerned to give interested parties, including the Ministers of Health of the provinces, health insurers and consumers (who will pay the price for the medicine established by the VCU) the opportunity to be heard on the issue.

The decision of the Chairperson to issue a Notice of Hearing does not entail any conclusion as to the merits of the case to be heard at the hearing, but only the Chairperson's conclusion as Chief Executive Officer of the Board that it is in the public interest that there be a public hearing. Accordingly, the Board is satisfied that no informed person would form a reasonable apprehension of bias based on the Chairperson's decision to initiate a public hearing in this case despite having received a VCU from HMRC.

3. The Chairperson, having reviewed Board Staff's report and the VCU, and having decided to initiate a public hearing, should not sit on the panel hearing the matter

As noted above, in reviewing the report of Board Staff, the Chairperson is undertaking a limited assessment: that of whether it is in the public interest that the matter proceed to a public hearing. In the course of that assessment the Chairperson will consider whether the allegations made by Board Staff, if proven true, would establish a *prima facie* case of excessive pricing by a patentee under the Board's jurisdiction. However, the Chairperson undertakes no analysis of whether the facts are or will be proven. Similarly, when the Chairperson initiates a public hearing despite having received a VCU, it does not entail the conclusion that any predetermination on the matter has been made.

Given the role of the Chairperson as Chief Executive Officer of the Board, the structure and operation of the Board, and its mandate as an expert tribunal developing and applying relevant policies, the Board considers it to be useful and appropriate for the Chairperson of the Board to be available to sit on panels of the Board at its public hearings. The Board believes that, given the limited purpose of the Chairperson's review of the report of Board Staff and the VCU, there will be no reasonable apprehension of bias resulting from the Chairperson's inclusion on the panel of the Board at the public hearing.

4. The Chairperson did not afford HMRC procedural fairness in considering the VCU

HMRC argues that since acceptance of the VCU by the Chairperson would have "terminated proceedings" against HMRC, it should have been given an opportunity to make submissions to the Chairperson on whether or not its VCU would result in compliance with the Board's excessive pricing Guidelines.

Again, the Chairperson's consideration of a proposed VCU is not in any sense determinative of the patentee's rights in the matter. There is no prejudice to a patentee in the Chairperson's decision to initiate a public hearing, only the requirement that the matters in issue be presented and determined in public instead of internally by the Board alone. To the extent that any confidential information is involved in the public hearing, the *Act* and the Board's *Rules* provide for protection of the patentee.

It should be borne in mind that HMRC is entitled to submit its original VCU, or another VCU, for the consideration of the panel at any time during the course of the hearing, and to argue for its acceptance at that time.

Accordingly, the Board does not consider there to be any denial of procedural fairness in the decision of the Chairperson to initiate a public hearing without receiving the submissions of HMRC on the matter.

D. Sufficiency of the Notice of Hearing

(i) Introduction

The final point for consideration in this decision is HMRC's complaint that the Notice of Hearing does not contain sufficient detail for HMRC to know the case it has to meet.

In brief, the Notice of Hearing (including Appendices 5 and 6):

(a) recites and describes the patents alleged by Board Staff to pertain to Nicoderm;

(b) recounts the rationale for, and the specifics of, the maximum non-excessive price that the Board has established as the MNE for Nicoderm;

(c) describes such information as the Board Staff currently have as to the actual prices that have been charged for Nicoderm;

(d) based on (b) and (c), alleges that the actual prices for Nicoderm exceed the MNE and that this has resulted in excessive revenues; and

(e) in the proposed order filed by Board Staff, indicates that Board Staff advocate the lowering of the price of Nicoderm to the maximum non-excessive price, the refund of excessive revenues, and, if the Board finds that HMRC engaged in a policy of excessive pricing, a further payment to the Crown of up to twice the excessive revenues collected by HMRC.

The Notice of Hearing also deals with the order and scheduling of the procedures for the public hearing.

(ii) Purpose of the Notice of Hearing

The Notice of Hearing is only the first, and most general stage at which HMRC is apprised of "the case it has to meet". It sets out in summary form the allegations of Board Staff regarding the "material facts" of the case and the order that Board Staff proposes the Board to make, so as to allow HMRC to file a Response setting out its position on those allegations and the proposed order. The object is to identify the issues in the hearing and determine where Board Staff and HMRC agree and disagree.

Once HMRC has filed its Response, Board Staff will file evidence, describing in detail all of the facts on which they rely. Board Staff have agreed to receive and respond to HMRC's written interrogatories on this evidence before HMRC is obliged to file its evidence. At that stage (subject of course to its cross-examination of Board Staff's witnesses) HMRC will know all of the case it has to meet. Only then will HMRC be required to file its written evidence. HMRC's evidence will not be tested in the public hearing until HMRC has completed its cross-examination of the evidence of Board Staff. Accordingly, HMRC will know in precise detail the "case it has to meet" and have ample opportunity to meet that case as the hearing proceeds.

(iii) HMRC's Position

In general, HMRC's submissions on this part of its motion consisted only of a general complaint, repeated several times, that the Notice of Hearing was not sufficiently detailed. With one exception, there was no identification of what details, or what types of information generally, were necessary to enable HMRC to file its Response.

There was only one specific issue on which the Notice of Hearing was argued by HMRC to be deficient, and some background (all as contained in the *Compendium)* is required to put this point in context.

The Board establishes an MNE for each dosage of each patented medicine under its jurisdiction, using the policies set out in the *Compendium.* A patentee may presume that sales at that price will not be considered by the Board to be excessive. However, a patentee may challenge the MNE, and if a challenge is made the Board Staff has the onus of defending the MNE at the resulting public hearing.

HMRC argues that in the Notice of Hearing, Board Staff simply allege that the price of Nicoderm exceeds the MNE, without explanation of why this results in excessive pricing. HMRC stated in argument that it was completely unable to respond to this position.

In fact, in paragraphs 11 to 15 of the Notice of Hearing, Board Staff describe the rationale for the MNE for Nicoderm, making apparent Board Staff's position that the MNE is the appropriate benchmark for the Board's consideration of whether or not there has been excessive pricing. In other words, though the MNE is merely a presumption, Board Staff have defended the manner in which it was derived and now

defend the MNE. Board Staff will have to lead evidence in this regard to satisfy their onus, and if HMRC wishes to test and rebut that evidence it will have an opportunity to do so.

But at this stage, for the purpose of HMRC's Response, all that is needed is a statement from HMRC as to whether or not HMRC accepts or challenges Board Staff's position on the MNE for Nicoderm, and if so, in general terms, why. HMRC will have all of Board Staff's evidence on this point before it is obliged to file any evidence in support of its position.

(iv) Incorporation of the September 21, 1998, Letter

In his argument on this point, counsel for Board Staff noted that the material filed on the Motion demonstrated that the pricing of Nicoderm has been the topic of meetings, conversations and correspondence between HMRC and Board Staff for some time now. Furthermore, the pricing of Nicoderm in the context of the MNE was ultimately the topic of the VCU submitted by HMRC. For these reasons counsel for Board Staff voiced his doubt about HMRC's purported perplexity on this issue.

In any event, to forestall further debate on the issue, Board Staff have agreed that the allegations in Ms. Reinhard's letter of September 21, 1998, (Exhibit 2 in the material filed by HMRC on this Motion) except where superceded in the Notice of Hearing by more recent information, should be deemed to be particulars of the Notice of Hearing.

(v) Conclusion

The Board considers that, for its intended purpose, the Notice of Hearing was sufficiently detailed from its issuance. HMRC could and should have complied with the Board's *Rules* by filing a meaningful Response in accordance with the schedule in the Notice of Hearing. As it is, with the further information provided by Board Staff there should be no reason why HMRC cannot file its Response within 15 days of the date of this decision, therefore no later than August 18, 1999, and the Board so orders.

E. Conclusion

For the reasons set out above the Board concludes that the matters described in paragraphs 6, 7 and 9 of the Notice of Motion do not deprive the Board of jurisdiction in this proceeding.

The Board will now proceed to consider the balance of HMRC's motion (on the grounds in paragraphs 5 and 8 of the Notice of Motion) as Part II of its deliberations. The following schedule will apply:

HMRC is required to serve and file any affidavit evidence and a summary of any expert evidence on which it intends to rely in support of paragraphs 5 and 8 of its motion by September 10, 1999;

Board Staff is required to serve and file any affidavit evidence and a summary of any expert evidence on which it intends to rely in opposition to paragraphs 5 and 8 of the motion by September 24, 1999;

Each party is required to indicate to each other and the Board by October 1, 1999, whether it intends to cross-examine on the affidavit evidence filed by the other;

Each party will serve and file a factum together with a brief of authorities by October 15, 1999;

The motion will be heard during the week commencing October 25, 1999.

Parties should file five copies of each item with the Board and deliver one copy to Board counsel.

Board Members: Robert G. Elgie, Chairperson
Réal Sureau
Anthony Boardman
Ingrid Sketris

Board Counsel: Gordon K. Cameron

Sylvie Dupont-Kirby
Secretary of the Board

August 3, 1999