

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 DISCLOSURE

This is the decision of the Board on a motion brought by Board Staff for an order requiring Hoechst Marion Roussel Canada (“HMRC”) to produce documents said to be relevant to a motion HMRC has brought challenging the jurisdiction of the Board.

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. On April 20, 1999, the Board issued a Notice of Hearing to initiate a hearing pursuant to sections 83 and 85 of the *Patent Act* (the “*Act*”). The purpose of the hearing is to determine whether HMRC is, 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, and its actions in this regard are directed at the patentees of such medicines. 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. As detailed below, HMRC advanced grounds raising the issues of whether or not Nicoderm is a “medicine” for the purposes of the *Act*, whether HMRC is a “patentee” within the meaning of the *Act* and whether the patents in issue “pertain” to Nicoderm.

Board Staff have alleged that in order to respond to these issues, they require the disclosure of certain documents and other materials in the possession of HMRC or its affiliates and business partners. HMRC has resisted this further disclosure and thus Board Staff have brought a motion to compel the disclosure.

B. The Position of HMRC on the Patents

As stated in the Notice of Hearing, Board Staff have identified three patents alleged to pertain to Nicoderm and two patent applications alleged to be relevant to the Board's consideration of the issues raised by the Notice of Hearing.

One of the patents, Canadian Patent No. 1,338,700, is acknowledged by HMRC to pertain to Nicoderm.

Of the two other existing patents said by Board Staff to pertain to Nicoderm (Canadian Patent No. 1,331,340 and Canadian Patent No. 1,333,689), HMRC has stated in its motion that neither pertain to Nicoderm. With respect to Canadian Patent No. 1,331,340, HMRC adds that it is not a patentee within the meaning of the *Act*.

With respect to the two patent applications (Nos. 2,032,446 and 2,040,352) HMRC's position is stated very summarily, but it would appear that HMRC argues that the Board does not have jurisdiction to make any order "based on" the patent applications.

C. The Position of the Parties on Disclosure

Board Staff have filed detailed written submissions, the crux of which is that documentation in the possession of HMRC and/or its affiliates, and which is otherwise unavailable, is required in order for Board Staff to respond fully to the issues raised by HMRC. In this regard, Board Staff have focused on the relationship between HMRC and Alza Corporation USA, as established (at least in part) by the Development and License Agreement dated November 27, 1989 and the Amended Development and License Agreement dated June 28, 1996, and as that relationship may be evidenced by documentation and information concerning the rights and obligations of HMRC with respect to the patents and patent applications cited in the Notice of Hearing.

HMRC has responded with written submissions that identify several reasons why no order for further production should be made. HMRC's first line of argument is that the motion should be dismissed outright without analysis of the particular documents sought, in that:

1. Board Staff have not provided necessary evidence in support of their motion;
2. Board Staff should be required to respond to the jurisdictional challenge exclusively with the information on which they initially came to the position that the Board had jurisdiction;
3. The motion by Board Staff is premature in that HMRC has not yet filed its evidence in support of its jurisdictional challenge.

HMRC then argues, in the alternative, that no order should be made to require HMRC to produce the particular documents sought by Board Staff, given that on the proper interpretation of the contractual provisions in issue, and on the proper interpretation of the Board's powers under the *Act* as it relates to patents and patent applications, the requested documents are not relevant to HMRC's jurisdictional challenge.

D. Discussion

1. Lack of evidence in support of the motion

HMRC has argued that Board Staff should have filed affidavit evidence in support of its motion. The essence of Board Staff's response is that the documents of which production is sought are relevant to the matters raised in HMRC's jurisdictional challenge and that this relevance can be seen on the face of the record. In particular, Board Staff argue that given the allegations in the Notice of Hearing and in the grounds for HMRC's jurisdictional challenge, no evidence is necessary to debate the relevance of the documents in issue.

The Board agrees that this motion can be addressed in a satisfactory manner on the face of the record without affidavit evidence. The Board has been able to reach its conclusions on this motion without reference to any matters asserted by either party that could be said to require affidavit evidence.

2. Board Staff must be held to argue HMRC's motion on the documents and information already in their possession

HMRC has argued that since Board Staff must have come to an initial conclusion that the Board had jurisdiction over the matters raised in the Notice of Hearing, they must be limited to the information on which that conclusion was based for its response to the jurisdictional challenge brought by HMRC.

No authority was cited for this proposition and the Board sees no merit in it. The Board is interested in having the most complete record possible for its determination as to its jurisdiction. It is open to Board Staff to adduce evidence to respond to a jurisdictional challenge, just as it is open to HMRC to present evidence in support of the challenge. If the evidence on which Board Staff intends to rely is under the control of HMRC, and if it is otherwise appropriate that an order to produce documents and other information be made, the Board has the authority in the *Act* and its *Rules* to do so.

3. The motion is premature

HMRC argues that Board Staff should wait until HMRC files its evidence on the jurisdictional challenge before commencing its documentary discovery.

The Board is experienced with the issues arising from the questions “Who is the patentee?”, “Is this a medicine?” and “Does this patent pertain to the medicine?” and the information on which those questions are debated. It is apparent to the Board from the grounds for the jurisdictional challenge that complete information concerning the business relationship between HMRC and its affiliates will be relevant to the issues arising on HMRC’s motion. Other issues might arise once HMRC has filed its evidence on the motion, but it is reasonable to commence documentary disclosure at this time in areas where the Board is able to confirm relevance.

Accordingly, the Board does not consider Board Staff’s motion to be premature.

4. The merits of the motion - the documents are not relevant

HMRC argues that, given what it alleges is the proper interpretation of the relevant contractual provisions (in the agreements between Alza Corporation and HMRC) and the proper description of the Board’s jurisdiction, the documents and information sought by Board Staff are not relevant to the issues arising on HMRC’s motion. Board Staff do not accept the interpretations of the agreements or the *Act* urged upon the Board by HMRC.

Much of HMRC’s argument is premised on the very points that will be in dispute on the motion and will have to be resolved before the rights of HMRC to the benefits of the patents in issue are determinable by the Board. The purpose of the requested disclosure is to obtain evidence on these points so that the Board has a more complete record for the consideration of HMRC’s jurisdictional challenge. If the Board were able to arrive at a conclusive position on the legal entitlements as between HMRC and its affiliates, such that certain documents were plainly irrelevant, the Board would not make an order for disclosure of those documents. However, the Board is not able to reach such a conclusion at this time.

As noted, the Board is familiar with the debate in which the parties are now engaged. The issues have been discussed with many patentees and in some cases have been the subject of the same type of jurisdictional challenge now before the Board. The documents sought by Board Staff are the types of documents the Board would expect to review in the course of its consideration of the grounds for the motion brought by HMRC. With the exception discussed below, the documents and other materials sought by Board Staff appear to be relevant to the grounds relied on by HMRC in support of its motion.

It must be borne in mind that the issue at this stage in the proceedings is disclosure. There is some administrative burden but no prejudice in the mere disclosure of documents to Board Staff that appear to be relevant to the issues raised by HMRC’s motion. The documents will not form part of the record of this proceeding unless and until they are accepted by the panel of the Board hearing this matter as evidence adduced by one of the parties. Furthermore, the documents will be received by Board Staff in confidence and before they are entered onto the public record of the hearing HMRC has the right to request of the Board, pursuant to subsection 86(1) of

the *Act*, that any particular information or document remain confidential on the grounds that harm to HMRC would arise from their release to the public. If Board Staff attempt to advance evidence on the motion that HMRC considers to be irrelevant (including any of the information or documents delivered in accordance with the Board's decision on this motion), the argument for exclusion of the evidence can be made at that time.

The Board does agree with HMRC that the information sought in paragraph 8 of the motion of Board Staff (pre-1996 sales information for Nicoderm) is not relevant to the jurisdictional challenge. The Board does have the authority to order the delivery of this information, but the stated purpose of Board Staff's motion was to obtain information relevant to the jurisdictional motion and the Board does not consider it appropriate to make an order concerning the information described in paragraph 8 of Board Staff's Motion at this time.

5. Confidentiality

In its written submissions on this motion, HMRC voiced concerns about the confidentiality that should attach to the information and documentation HMRC had delivered to the Board, though no motion was brought by HMRC in that regard. This issue was resolved on consent during the hearing of the motion by the severance from the public record of certain paragraphs of the factum of Board Staff.

6. General

The order below provides for the scope of disclosure of relevant information and documents that the Board considers to be appropriate in these circumstances, for the reasons set out above. The Board would view any failure by HMRC to disclose all appropriate documents and information as a very serious matter indeed. The Board urges HMRC to conduct the disclosure in consultation with Board Staff, and in particular on any item where HMRC anticipates room for disagreement as to the obligation to disclose documents or information. Also, such consultation would be useful so that agreement can be reached, for example, on the avoidance of duplicate copies of identical documents and related matters. The Board is hopeful that thorough disclosure in accordance with the terms of the order below will obviate the need for any further proceedings in this regard.

E. Order

For the reasons set out above, the Board orders that HMRC provide Board Staff, by August 30, 1999, with copies of the documents and other materials along with an affidavit or affidavits attesting to the information described in paragraphs 1 to 7 of the Notice of Motion of Board Staff dated May 27, 1999.

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