

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

JURISDICTION – PART II

INTERIM ORDER

Introduction

The Board has received evidence and argument on the second part of a motion by Hoechst Marion Roussel Canada (“HMRC”) challenging the jurisdiction of the Board. The Board is issuing this interim order because the Board wishes to offer the parties the opportunity to present evidence and argument on two points that, given the Board’s deliberations on the matters in issue to date, are considered by the Board, and might be considered by the parties, to require further evidence and argument.

1. The 1,331,340 ('340) Patent

For reasons that will, if necessary (that is, depending on the Board’s findings on other issues), be detailed in the Board’s decision on HMRC’s motion, the Board would like to provide Board Staff and HMRC with the opportunity to present evidence on the question of whether, having regard to evidence beyond the “face of the patent”, the '340 patent pertains to Nicoderm. The particular point of interest to the Board at this stage is whether, as a question of scientific fact, nicotine does or might reasonably be expected to form crystalline hydrates.

The Board does not lightly re-open the evidentiary record in any proceeding. In this instance, however, the parties might have relied on the *ICN* case in assuming that evidence beyond the face of the patent would not be required or appropriate with respect to the issue of whether or not the '340 patent pertains to Nicoderm. However, and allowing that the Board has not reached a conclusion on this point, it would appear arguable that the scope of certain patents is not determinable from the face of the patent because the patent protects uses of its invention not specified therein, and in particular, new uses “discoverable by persons skilled in the art”. Such a patent could protect the use of inventions capable of being used for medicine despite being silent as to that fact on its face.

The issue discussed in the preceding paragraph was not addressed during the hearing of HMRC's motion and the Board would consider its analysis of this matter to be more complete if it received the submissions of parties on this issue and evidence on the factual question concerning the formation of crystalline hydrates in nicotine.

Given that some evidence was filed by HMRC on the factual question, the Board considers it appropriate to make some comments that should be of assistance to both parties in the event that further evidence on this point is presented. The following comments should not be taken as critical of the evidence called by HMRC on this issue. The Board appreciates that HMRC was responding to Board Staff, who bore the legal burden on the point and elected not to call evidence.

The evidence of Mr. Robert M. Gale, one of the inventors of the '340 patent, was very careful (and properly so, given that he had not researched the point) in limiting the scope of his conclusions regarding whether or not nicotine formed crystalline hydrates to his own observations and his knowledge of the literature. No evidence at all was advanced by any witness as to whether there was any scientific reason to doubt the reasonableness of the inventors' opinion, as expressed in the '340 patent, that the invention might be useful with respect to nicotine. The speculation in the '340 patent as to its potential usefulness for the treatment of nicotine presumably was not accidental: the inventors had some reason to believe that nicotine and the other substances mentioned in company with nicotine shared certain physical properties with scopolamine such that there was a potential that they, like scopolamine, would form crystalline hydrates.

The Board would expect the evidence on this issue to be that of an independent medicinal chemist. The evidence would include an account of searches of the literature and databases, and appropriate inquiries made with scientists working in the field, presumably including those in the industry and at Health Canada and the FDA in the United States. The conclusions of this investigation would include observations on at least the two points the Board would expect to be relevant to this inquiry, that is, (1) whether there are recorded instances of the formation of crystalline hydrates in liquid dispersions of nicotine, and (2) whether, given its physical and chemical qualities, a liquid dispersion of nicotine might reasonably be expected to form crystalline hydrates.

2. The Confidentiality and Relevance of Specific HMRC Documents and Information

As an adjunct to its consideration of HMRC's motion, the Board is considering submissions by HMRC and Board Staff as to the confidentiality and relevance of the documentation and information it has provided to Board Staff in the course of Board Staff's investigation and the Board's consideration of HMRC's motion.

In the event that the Board does not accept HMRC's position that the Board has not been conducting a public hearing such that all of the documentation and information it has provided is necessarily confidential and privileged, or does accept that position and is found on review of its decision to have been wrong, it will be necessary to address the question of the confidentiality of particular documents or items of information.

It has been open to HMRC to date to present evidence as to specific, direct and substantial harm that could arise from the disclosure of any of the evidence the Board considered on its hearing of HMRC's motion. HMRC did not present evidence on this point, but invited the Board either to make the assessment of confidentiality on its own or to allow evidence to be presented on that issue.

The Board is reluctant to make its own assessment of the confidentiality of HMRC's documents and information and believes that it must have evidence on this issue before it can make any finding. The wording of section 86 of the *Patent Act* makes it clear that there is a significant onus on HMRC to establish the basis for departing from the overall requirement of public access to matters before the Board.

Having said this, it appears that there has been a misunderstanding between Board Staff and HMRC on this point: Board Staff state that HMRC had its opportunity to present evidence on confidentiality during the motion and missed that opportunity. HMRC states that it did not realize that such evidence would be required in that context.

The Board is very sensitive to the need to carry out its mandate without compromising the confidentiality of proprietary or commercially sensitive information. The Board would not want to expose such information to public scrutiny on the basis of a misunderstanding between the parties as to a point of process. The Board cannot accept the submission of Board Staff that HMRC has missed its opportunity to present evidence on this issue.

Accordingly, the Board will accept evidence and argument from HMRC on the confidentiality and/or privilege of specific documents and information, and responding evidence and argument from Board Staff.

Conclusion

It appears to the Board that further submissions and evidence on these two issues can be received in writing, and that if cross-examinations in the presence of the Board are not required, it will not be necessary to convene a further sitting of the panel. Whatever the case, the Board is hopeful that the schedule and process for such further steps as are necessary can be settled among counsel, by March 24, 2000, failing which the Board will make the required order.

Board Members: Robert G. Elgie, Chairperson
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 Anthony Boardman
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Sylvie Dupont
Secretary of the Board

March 13, 2000