December 16, 2008

Decision: PMPRB-99-D9-NICODERM
- **Motion for Particulars and Production**

IN THE MATTER OF the *Patent Act* R.S. 1985, c. P4, 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

1. On November 21, 2008, the panel of the Board that is seized with this proceeding (the "Panel") heard a preliminary motion that was brought by the Respondent sanofi-aventis Canada Inc. ("sanofi-aventis", the "Respondent"). The motion sought two categories of relief: (1) further particulars of the allegations and evidence of Board Staff; and (2) the production of documents in the possession of Board Staff. This is the decision of the Panel on the motion.

A. Further particulars

2. This proceeding has followed an unusual path. The Notice of Hearing was issued on April 20, 1999. As a result of litigation before the Panel and in the Federal Court, and subsequent appearances before the Panel, the matter is only now coming to a hearing.

3. As its expert evidence in the proceeding, Board Staff proposes to rely on the affidavit of Dr. Patrick du Souich that Board Staff filed when the case commenced in 1999.

4. sanofi-aventis, concerned that Board Staff may have more to say about the case than appears in the affidavit of Dr. du Souich, and that this further information will appear in what will ostensibly be Board Staff's "reply" evidence, sought either confirmation that the 1999 affidavit of Dr. du Souich constituted all of the expert evidence on which Board Staff would be relying, or production of such further evidence as Board Staff intended to call.

5. In oral argument of the motion, counsel for Board Staff made comments that the Panel took as confirmation that Board Staff rely exclusively on the affidavit of Dr. du Souich, subject to legitimate reply evidence on issues that could not be anticipated from the position of sanofi-aventis as set out in the Consolidated Response to the Notice of Hearing.

6. The Panel is not convinced that Board Staff has fully addressed the concerns of sanofi-aventis. For example, though the affidavit of Dr. du Souich was sworn several weeks after the Respondent filed its Consolidated Response, neither his affidavit nor the will-say of Ms. Tognet addresses the issue raised by the Respondent at paragraph 4(a) of the Consolidated Response (appropriateness of the price of the comparator Habitrol). Perhaps Board Staff considers this to be a pure matter of argument, but if not, this point and any others reasonably discernable from the Consolidated Response should be addressed by Board Staff in evidence at this time.

7. However, the Panel has other concerns with the affidavit of Dr. du Souich and the will-say of Ms. Tognet.

8. In the nine years since Dr. du Souich swore his affidavit, the principles of evidence-based medicine have evolved and it is possible that further studies have been done that would be relevant to the topics addressed by Dr. du Souich as they apply to the comparators that were available at the time. The Panel does not wish to manage the case to be called by Board Staff, but it does have the expectation that a thorough examination of the current literature, undertaken using current standards of evidence-based medicine, will be presented to the Panel as part of Board Staff's case. Now is the time for expert evidence to that effect to be filed.

9. Also, since the filing of Dr. du Souich's affidavit, the Board has attempted to emphasize to the parties that a pricing hearing is not a review of the process by which Board Staff concluded that a medicine was excessively priced. The deliberations and conclusions of the Human Drug Advisory Panel (the "HDAP") and the communications between Board Staff and the patentee (which topics form the structure of Dr. du Souich's observations) are not central, and are often not even germane, to the issue of whether a medicine was or is excessively priced.

10. A panel of the Board in a pricing hearing should hear expert evidence concerning the scientific basis for the allegations of Board Staff. In this regard, the panel cannot put much weight, if any, on the fact that the HDAP reached a certain conclusion on those scientific matters, or how the HDAP reached those conclusions. Needless to say, Board Staff may consider it efficient to call a member of the HDAP to give evidence as to the scientific issues underlying the allegation of excessive pricing, given that the member will likely have already reviewed the literature when it was before the HDAP. That convenience, however, should not affect the content of the witness's expert evidence.

11. sanofi-aventis also queried the unelaborated statement in the will-say of Ms. Tognet to the effect that she would "address how the price of ...Nicoderm was considered [by Board Staff] to be excessive." sanofi-aventis sought an outline of the substance of Ms. Tognet's evidence on this topic. At the hearing of the motion, Board Staff advised that Ms. Tognet would address this topic by application of the Board's pricing guidelines (the Guidelines) to the tables of Nicoderm prices attached to her will-say.

12. In order to conclude that Nicoderm was excessively priced, the Panel will have to be satisfied – and Board Staff bears the burden in this regard – that the Guidelines represent an appropriate implementation of the relevant terms of the *Patent Act* in the circumstances of this case. The Panel will give due weight to the Guidelines, given their provenance in extensive consultation and their value to all stakeholders in bringing consistency to the Board's work, and the Panel will be able to bring its expertise to the task of determining whether the Guidelines properly apply the *Patent Act* in this case. Furthermore, the appropriateness of the Guidelines in this case might be addressed in some measure in argument. However, Board Staff risks a finding that it has not met its burden if, at the close of the hearing, all that has been established is that the pricing of the medicine has been excessive in the terms of the Guidelines.

13. For the foregoing reasons, the Panel requests that Board Staff reconsider its pre-filed evidence in light of the comments herein and advise the Panel and sanofi-aventis on or before January 7, 2009 if Board Staff intends to file any additional evidence. If additional evidence is to be filed, it should be filed within 120 days of the date of this decision (on or before April 14, 2009), and a new schedule will be issued accordingly.

B. Production

14. sanofi-aventis has made a broad request for information and documentation related to Board Staff's consideration of the price of Nicoderm and other nicotine replacement therapies. Board Staff took the position that it had no obligation to provide such information or production, and that sanofi-aventis was attempting to have Board Staff make the Respondent's case for them.

15. To some extent, the Panel agrees with Board Staff. The Panel does not consider it necessary for Board Staff to provide sanofi-aventis with information that sanofi-aventis can obtain itself for use in its evidence, or extract from witnesses at the hearing. Unless the parties agree otherwise, there is no general discovery process in advance of a pricing hearing.

16. However, the Panel does agree that Board Staff and patentees should be treated equally with respect to production of documents, and that if there are relevant documents in the possession of Board Staff, then they should be produced to the patentee if the patentee requests, subject of course to privilege and confidentiality. A patentee should not be entitled to go on a fishing expedition through the files of Board Staff, but certain of the requests of sanofi-aventis are appropriately focused and appear to describe relevant documents.

17. In this regard, the Panel orders Board Staff to produce, within 30 days (on or before January 19, 2008), any documents in its possession, subject to redaction for privilege and confidentiality as required, pertaining to the issues described in paragraphs III (3) and (4) of the Notice of Motion.

Board Members:	Dr. Robert G. Elgie Réal Sureau Dr. Ingrid Sketris Professor Anthony Boardman
Board Counsel:	Gordon Cameron

Appearances

Board Staff:	Nadia Effendi, Counsel
For the Respondent:	Martin Mason Graham Ragan

Sylvie Dupont
Secretary of the Board