

PMPRB-94-D1/HABITROL

IN THE MATTER OF the *Patent Act* R.S. 1985, c. P-4, as amended by R.S. 1985, c. 33 (3<sup>rd</sup> Supp.), and as further amended by S.C. 1993, c. 2

AND IN THE MATTER OF Canadian Patent Nos. 1,283,053 and 1,312,800

AND IN THE MATTER OF CIBA-Geigy Canada Ltd. (Respondent)

**PRE-HEARING CONFERENCE**

**DECISIONS/REASONS  
PMPRB-94-1/HABITROL/PHC**

**BACKGROUND**

On 24 November 1993, the Patented Medicine Prices Review Board (the "Board") issued Notice of Hearing PMPRB-93-2 (the "Notice of Hearing"), pursuant to sections 83 and 86 of the *Patent Act* (the "*Act*") and the *Proposed Rules Respecting the Practice and Procedure of the Patented Medicine Prices Review Board* (the "*Rules*"), in relation to Canadian patent No. 1,283,053 granted to The Regents of the University of California (the "California Patent") and Canadian Patent No. 1,312,800 granted to LTS Lohmann Therapie-Systeme GmbH & Co. KG (the "Lohmann Patent") and the medicine S(-)- Nicotine Transdermal Therapeutic System, also known as Habitrol ("Habitrol"). The Board named as Respondent in the Notice of Hearing CIBA-Geigy Canada Ltd. ("CIBA").

Under the process established by the Board at its inception, in a proceeding held pursuant to sections 83 and 86 of the *Act*, the case is presented to the Board by a team drawn from the staff of the Board, separated from the Board members and represented by its own separate legal counsel ("Board Staff"). The Board members, in such cases, are advised by their own legal counsel. The parties to the proceeding commenced by the Notice of Hearing (the "Proceeding") are thus CIBA and Board Staff (the "Parties").

The purpose of the Proceeding is to consider whether, under sections 83 and 85 of the *Act*, CIBA is selling or has, while a patentee, sold Habitrol in any market in Canada at a price that, in the Board's opinion, is or was excessive and if so what order, if any, should be made.

The Notice of Hearing scheduled a pre-hearing conference for 18 January 1994 (the "Pre-Hearing Conference") and a hearing for 2 March 1994. Following the pre-hearing conference, the hearing was re-scheduled to commence on 24 May 1994 (the "Hearing"). The Pre-Hearing Conference was to determine, among other things, whether, pursuant to subsection 86(1) of the *Act*, the Hearing, or any part thereof, should be held in private; applications for leave to intervene in the Proceeding; requests for confidential status for information and documents filed in the Proceeding; requests for disclosure and production of information and documents; motions respecting interlocutory matters; and requests respecting the conduct of the Proceeding.

CIBA made a request for particulars on 2 December 1993 which was answered by Board Staff on 7 December 1993. CIBA filed a response to the Notice of Hearing on 13 December 1993 (the "Response") and a pre-hearing memorandum on 10 January 1994 ("CIBA's Pre-Hearing Memorandum") and Board Staff filed a Notice of Motion on 10 January 1994 (the "Notice of Motion") and a pre-hearing memorandum on 10 January 1994 ("Board Staff's Pre-Hearing Memorandum"). No statutory party indicated any intention to appear and make representations to the Board with respect to the matter being heard. Neither did the Board receive any application for leave to intervene.

This document sets out the Board's determinations on the matters raised during the Pre-Hearing Conference.

## **I. INTRODUCTION**

The issues considered at the Pre-Hearing Conference were:

- A. The question raised by CIBA in the Response and in CIBA's Pre-Hearing Memorandum whether Habitrol is an invention pertaining to a medicine and whether, therefore, the Board has any jurisdiction in the matter which is the subject of the Proceeding, which question CIBA requested be heard and determined by the Board in advance of the Hearing.
- B. A request by CIBA that certain parts of the Hearing be held in private.
- C. A request by CIBA that certain documents and information filed as supporting documents in the Proceeding not be made available to the public.
- D. Requests by the Parties for the disclosure and production of information.
- E. Procedural matters with respect to the conduct of the Proceeding.

Each issue will be addressed below.

At the Pre-Hearing Conference, submissions were made by both CIBA and Board Staff regarding the Board's nature and function when it initiates a proceeding under the *Act* to determine a question of excessive pricing, and the procedural requirements that flow from them in the conduct of such a proceeding. Such submissions were made specifically in relation to the determination of issues involving requests for confidentiality and requests for disclosure and production. The Board considers it appropriate to state its position on these issues generally before setting out its specific determinations on the matters before it.

### Confidentiality and Production

Subsection 83(6) of the *Act* requires that, before the Board makes an order regarding excessive pricing, it provide a patentee or former patentee with a reasonable opportunity to be heard. Subsection 86(1) of the *Act* requires that a hearing under section 83 be held in public unless the Board is satisfied that specific, direct and substantial harm would be caused to the person to whom the hearing relates by the disclosure of information or documents at a public hearing. The relevant provisions of the *Act* are as follows:

- 83(6)            Before the Board makes an order under this section, it shall provide the patentee or former patentee with a reasonable opportunity to be heard.
  
- 86(1)            A hearing under section 83 shall be held in public unless the Board is satisfied on representations made by the person to whom the hearing relates that specific, direct and substantial harm would be caused to the person by the disclosure of information or documents at a public hearing, in which case the hearing or any part thereof may, at the discretion of the Board, be held in private.

### **The Submissions of CIBA**

In its Pre-Hearing Memorandum and at the Pre-Hearing Conference, CIBA requested confidential status for a number of categories of documents and an order to the effect that all portions of the Hearing which deal with them or the information they contain be conducted in private, on the ground that it would suffer specific, direct and substantial harm if such documents were made available to the public.

In support of its requests for disclosure and production, CIBA claimed to be entitled to every piece of information that the Board and Board Staff have in their possession or control that bears in any way on the issues in the Proceeding, whenever obtained and whether or not imparted to the

Board, and whether or not Board Staff is intending to rely on it at the Hearing. CIBA thus requested the production of, among other things, any notes, opinions, memoranda or other documentation of a technical, scientific or legal nature in the possession of the Board or Board staff on any issue relating to Habitrol or any comparative medicine, or the pricing of Habitrol; documents, including notes, relating to discussions with the Human Drug Advisory Panel of the Board ("HDAP"), as well as all documents in the possession of the HDAP, and any Board staff document used to brief Board members, including any notes or memoranda prepared by Board members in connection with such briefings.

The yardstick relied on by CIBA for determining its right to disclosure and production is entitlement to "the fruits of the investigation" of Board Staff into the pricing of Habitrol. This standard was used by the Supreme Court of Canada in R. v. Stinchcombe, [1991] 3 S.C.R. 326 ("Stinchcombe"), a case decided in the context of a criminal proceeding. In Stinchcombe, the Crown was ordered to disclose and produce to the accused the content of the statements obtained in interviews conducted by a police officer after a preliminary inquiry and before a trial, and during the course of a trial, whether or not the Crown intended to introduce them as part of its evidence or to call the witness.

CIBA also referred the Board to Ontario Human Rights Commission v. Jeffrey House et al (Court File No. 520/93) 8 October 1993 ("House"), an unreported judgment of the Ontario Divisional Court involving a refusal by that Commission to provide to the respondents in the case the statement and identity of any witness interviewed by the Commission or its agents whom the Commission did not propose to call but whose statements might reasonably aid such respondents in answering the Commission's case. CIBA referred the Board as well to cases where the courts have found Stinchcombe to be instructive when considering the duty of disclosure in the context of administrative tribunals.

### **The Submissions of Board Staff**

Board Staff submitted that, as an administrative tribunal, the Board has a specialized mandate under the *Act*, which it characterized as economic, to monitor and review the pricing of patented medicines and to assess whether a particular patented medicine is sold in Canada at an excessive price and, if so, to order correctives. Board Staff was of the further view that, in the discharge of that mandate, the Board does not adjudicate individual rights, as do civil and criminal courts and other specialized administrative tribunals such as, for example, a human rights tribunal. It argued that, as a specialized tribunal which only occasionally holds a hearing, the Board should not assume the trappings of a court.

Based on this categorization of the Board, Board Staff argued that a person against whom an order is proposed under sections 83 and 85 of the *Act* is not entitled, in the context of a public hearing held by the Board into the matter, to the full panoply of procedural rights guaranteed by

applicable rules of procedure and related jurisprudence in a criminal or civil context. Neither is such a person entitled, Board Staff argued, to the same level of procedural rights as may be applicable in a proceeding before a quasi-judicial tribunal which adjudicates individual rights.

Board Staff considered that its view of the level of rights to which CIBA is entitled in the Proceeding is bolstered by the fact that subsection 97(1) of the *Act* requires that all proceedings before the Board be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit. It relied on that subsection to argue that the standard intended to govern procedural requirements in a hearing held by the Board is fairness, that is, enough disclosure and production to give a fair opportunity to a respondent to respond to the case against it before the Board.

Board Staff also argued that, in matters of disclosure and production, the Board has to take into consideration its dual role as an administrative tribunal, first as an ongoing monitoring body with a continuing mandate, assisted in that role by staff and, secondly as a decision-maker when an unresolved issue of excessive pricing goes to a hearing. In the view of Board Staff, the Board must weigh in the balance, when ordering disclosure in the context of a hearing, its responsibility to ensure the effective discharge of its continuing mandate. Board Staff argued that the effective role of staff in advising the Board on an ongoing basis in the furtherance of its policy objectives under its empowering statute requires the fostering of a climate where objective, candid and complete reporting and advice is provided to the Board, untrammelled by the prospect that such reporting and advice at any particular point in the development of a matter may later be disclosed in an eventual hearing.

### **The Board's View**

In the Board's view, in considering its function in the context of a hearing and the procedural rights it must afford parties to a hearing, the Board must be informed primarily by the statutory requirements of its empowering statute. Pursuant to subsections 83(6) and 86(1) of the *Act*, the Board may not make any order under section 83 without the person against whom an order is proposed to be made being given a reasonable opportunity to be heard, and without the hearing being conducted in public, except in limited circumstances. The Board considers that, in making any order granting confidential status to information which forms part of a hearing, and in adopting a standard for disclosure and production, it must be guided by these express statutory pre-conditions to the making of an order under section 83 of the *Act*.

The Board must therefore ensure that, subject to satisfying any safeguard set out in the applicable statute, any hearing it holds is held in public and there is sufficient information on the public record of a hearing to provide to any member of the public as full an understanding as possible regarding what is at stake at any point in the proceeding, and how an eventual decision was made.

Case law abounds on the subject of the steps needed to satisfy the express statutory requirement that a party be given a reasonable opportunity to be heard. The courts, including those which decided Stinchcombe and House, have generally acknowledged that the degree of disclosure required to meet the duty of natural justice or of fairness depends on the particular circumstances of each case, including the subject matter and the nature of the inquiry, the rules under which the tribunal is acting and, last but not least, the seriousness of the consequences of the inquiry for the respondent.

In the Board's view, in a hearing before it, the party to whom the hearing relates must be provided with a level of disclosure and production which ensures that the party is fully informed of the case to be made against it. Further, the procedure followed must provide the party to whom the hearing relates a reasonable opportunity to meet that case by bringing forward its own position and by correcting or contradicting any statement or evidence related to the case which is prejudicial to its position.

It is the Board's view that, in matters of the disclosure and production of information and documents in the context of a public hearing, the Board must balance its duty to give every opportunity to a respondent to be heard against its responsibility to ensure that its orders do not have the effect of limiting its ability to discharge its responsibilities in the public interest on an ongoing basis. In order to discharge such responsibilities, the Board must be confident that it is getting candid, complete and objective advice from its staff. This is particularly the case in respect of the preliminary views it receives as to whether there is sufficient evidence to justify calling a hearing into a matter. This balancing need not in any way affect the Board's duty in law to make its decisions on the basis of the evidence placed and tested before it during a hearing.

## **II. THE ISSUES**

### **A. Consideration of the issue whether Habitrol is an invention pertaining to a medicine**

Although the issue of whether Habitrol is an invention pertaining to a medicine was raised by CIBA in both its Response and its Pre-Hearing Memorandum, no notice of motion to have the issue determined had yet been filed by CIBA at the Pre-Hearing Conference. The Board heard the Parties at the Pre-Hearing Conference on whether the hearing of this issue should be postponed and directed, at the Pre-Hearing Conference, that the matter be dealt with as follows:

1. CIBA may file with the Board and serve on all parties to the Proceeding a notice of motion with respect to this issue no later than 28 January 1994, in accordance with the *Rules*, except as provided herein.
2. Board Staff may file with the Board and serve on all parties to the Proceeding a response in writing no later than 7 February 1994.

3. CIBA may file with the Board and serve on all other parties to the Proceeding a reply in writing no later than 14 February 1994.
4. Oral argument by both Parties on the motion filed will be heard as the first item on the agenda at the Hearing. The notice of motion, response and reply may be filed with the Board and served on all parties to the Proceeding by facsimile transmission or by courier.

**B. Whether any part of the Hearing should be held in private**

In light of the view of the Board expressed above regarding its mandate under subsection 86(1) of the *Act*, the Board's decisions on the information to which confidential status will be granted under section C. below, and the fact that the Board is not satisfied on the basis of the information and documents before it at this time that specific, direct and substantial harm would be caused to CIBA if the Hearing were to be held in public, the Board denies CIBA's request that certain parts of the Hearing be held in private.

The Board notes that the Parties agreed that the Hearing should be held in public to the maximum extent possible and offered to cooperate in working out how to handle any part of the Hearing that may involve information or documents to which the Board has accorded confidential status.

**C. Requests for Confidentiality**

CIBA requested that certain categories of documents, and specifically the documents listed in Schedule "B" to CIBA's Pre-Hearing Memorandum, not be made publicly available. The Board notes that the documents listed in Schedule "B" generally correspond to the documents found on the list of supporting documents, at pages 22 and 23 of the Notice of Hearing (the "List").

Dealing generally with the request, the Board is of the view first, that confidential status for documents should be granted on a document-by-document basis, and not by categories of documents. Secondly, in light of subsection 86(1) of the *Act*, the Board considers that, with a few exceptions, the documents listed in Schedule "B" of CIBA's Pre-Hearing Memorandum should be disclosed on the public record.

The Board agrees with the concerns expressed by CIBA that disclosure of sales data, by province, by market and by class of customers, filed on a privileged basis pursuant to the *Patented Medicines Regulations*, could cause specific, direct, and substantial harm to CIBA by providing valuable information and assistance to its competitors regarding its position and strategies in the market place. Moreover, the Board considers that such disaggregated information is not necessary for the determination of the issues in the Hearing. The Board has therefore decided not to make such information publicly available.

Neither will the Board make publicly available the legal opinion from Sim, Hughes, Dimock dated 29 January 1993, found at No. 15 of the List, and received in response to a letter from Laura Reinhard, dated 26 January 1993, found at No. 12 of the List, asking for written confirmation whether any of the five Canadian patents listed in the letter, or any other Canadian patent, pertains to Habitrol. The legal opinion deals with three Canadian patents which are not at issue in the Proceeding. As agreed by the Parties at the Pre-Hearing Conference, at the end of the covering letter from CIBA dated 3 February 1993, found at No. 15 of the List, to which the legal opinion was attached, will be added a paragraph to the effect that a legal opinion was forwarded to the Board by CIBA concerning three patents which are not in issue in the Proceeding.

The Board has also decided not to make publicly available the details of any proposed voluntary compliance undertaking discussed in the context of the matters before the Board in the Proceeding, in accordance with its practice, as set out in its "Compliance and Enforcement Policy". The Board will therefore not make publicly available the attachments to the Board's letter to CIBA dated 17 June 1993, found at No. 19 of the List.

The Board notes that the letter from CIBA to Laura Reinhard, dated 24 September 1993, was not included in the List.

In summary, it is the Board's decision that all documents on the List, as well as Tables 1, 2, 3, 4A, 4B and 4C, which constitute pages 10 to 15 of the Notice of Hearing, will be placed on the public record, with the exception of parts of Nos. 14, 15 and 19 of the List, as noted above.

The Board notes that both CIBA and Board Staff have access to all information and documents in respect of which confidentiality has been claimed and that, consequently, neither Party before the Board in the Proceeding has been precluded from access to any document on the ground of its confidentiality.

#### **D. Requests for Disclosure and Production**

##### **1. Board Staff**

In the Notice of Motion, Board Staff requested an order requiring the filing by CIBA of information and documentation relating to any communication or agreement between CIBA or an affiliated company and the University of California with respect to the California Patent and the sale of Habitrol in Canada; a copy of any legal opinion to the effect that the California Patent does not pertain to Habitrol if CIBA intends to rely upon this ground to deny the Board's jurisdiction; a copy of any agreement between CIBA and Lohmann or of any other document evidencing how Lohmann was and is being compensated for the use of the Lohmann Patent by CIBA; and copies of all documentation relevant to the dedication of the Lohmann Patent to the public, including advice as to whether Lohmann continued to receive any compensation from CIBA in relation to

the Lohmann Patent after the dedication.

## 2. CIBA

In its Pre-Hearing Memorandum, CIBA requested an order requiring the Board and Board Staff to provide to CIBA a list of all documents relating to any matter in issue in the Proceeding that they may have in their possession, control or power and, specifically, the documents described in Schedule "A" to CIBA's Pre-Hearing Memorandum. Schedule "A" consists of broad categories of documents, including notes relating to all communications between CIBA personnel and the Board and/or Board staff, Board and/or staff documents used to brief Board members and notes prepared by Board members in connection with any such briefings, Board and/or Board staff documents and notes relating to discussions with the members of the HDAP concerning the categorization of Habitrol and dosage equivalences with other nicotine products, Board and/or Board staff documentation and opinions and notes relating to conversations or interviews with any third party concerning legal, scientific, technical, pricing or other issues relating to Habitrol and its pricing, and all documents, including notes relating to conversations and written exchanges with the University of California, Lohmann and any of their representatives concerning patent and licensing matters relating to Habitrol.

For the reasons set out in the Introduction, particularly at pages 8, 9 and 10, and in light of the procedure proposed for the conduct of the Proceeding, such as the pre-filing of the outline of the evidence to be adduced at the Hearing, the Board denies CIBA's request for an order for the disclosure and production of all categories of documents set out in Schedule "A", except for the request for disclosure and production of information relating to the California and Lohmann patents as they may relate to Habitrol and CIBA. In the Board's view, all information relating to matters surrounding the status of those patents in Canada, and the relationship between CIBA and Lohmann and/or its affiliates, as well as the relationship between CIBA and the University of California, is central to the matters in issue in the Proceeding and should be disclosed and produced.

On the other hand, the other documents set out in Schedule "A" contain information internal to the Board that is, at most, preliminary to the matters in issue in the Proceeding. The withholding of such information would not, in the opinion of the Board, compromise the ability of CIBA to meet the case against it. The disclosure of such information would, in the opinion of the Board, adversely affect the Board's ongoing ability to discharge its mandate in the public interest.

The Board therefore orders as follows:

- (a) That CIBA file and serve on all other parties to the Proceeding, on or before 11 March 1994, the terms of supply, conditions of sales, financial compensation or any contractual arrangement and the particulars of any discussion, negotiation, understanding,

undertaking, agreement or other communication, oral or written, between CIBA, CIBA personnel, CIBA's parent or an affiliate of CIBA and

- (i) the University of California or personnel or representatives of the University of California with respect to the California Patent or the sale of Habitrol in Canada;
  - (ii) Lohmann, Lohmann personnel, Lohmann's parent or any affiliate of Lohmann with respect to the Lohmann Patent, including its dedication to the public, or the sale of Habitrol in Canada; and
  - (iii) any other party with respect to either the California Patent or the Lohmann Patent or the sale of Habitrol in Canada.
- (b) That Board Staff file and serve on all other parties to the Proceeding, on or before 11 March 1994, all documents, including notes and particulars of conversations and written exchanges between Board Staff or Board personnel and
- (i) the University of California or personnel or representatives of the University of California with respect to the California Patent or the sale of Habitrol in Canada;
  - (ii) Lohmann, Lohmann personnel, Lohmann's parent or any affiliate of Lohmann with respect to the Lohmann Patent, including its dedication to the public, or the sale of Habitrol in Canada; and
  - (iii) any other party with respect to either the California Patent or Lohmann Patent, or the sale of Habitrol in Canada.

The Board expects that any request for confidentiality with respect to any information or document disclosed or produced will be made, document by document, at the time of filing.

#### **E. Procedural Matters with Respect to the Conduct of the Proceeding**

In Board Staff's Pre-Hearing Memorandum, Board Staff requested that the Board order:

1. that the Parties pre-file an outline of the evidence of each (non-expert) witness they intend to call at the Hearing, as well as copies of all documents to be relied on by the Parties, on a date prescribed by the Board;
2. that any Party requiring formal proof of any document produced by the other advise the other party in writing of such requirement, on a date prescribed by the Board; and
3. that the Parties be entitled to file, by a date fixed by the Board, written interrogatories requesting further information from each other prior to the commencement of the Hearing.

CIBA agreed at the Pre-Hearing Conference with the pre-filing of an outline of non-expert evidence as proposed by Board Staff. Both Parties had agreed to 21 February 1994 as the filing and service date for such outlines, together with copies of all documents to be relied on. In view of the changes to the Hearing date, the Board requires the pre-filing and service on all parties to the Proceeding of such outlines, together with copies of all documents to be relied on, on or before 13 May, 1994.

Both Parties agreed to dispense with formal proof of any document produced, except where either Party makes a specific request for such proof. The Board accepts the agreed position of the Parties.

CIBA objected to the filing of written interrogatories, on the ground that an exchange of interrogatories could not be made effectively in the time frame originally proposed. The Board accepted CIBA's position at the Pre-Hearing Conference. Although the date of the Hearing has now been changed, the Board is of the preliminary view that the exchange of written interrogatories is not necessary. The Parties may however address the Board on this issue.

1 February 1994