PMPRB-94-D2/HABITROL

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 Canadian Patent Nos. 1,283,053 and 1,312,800

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

MOTION FOR AN ORDER APPROVING A VOLUNTARY COMPLIANCE UNDERTAKING AND TERMINATING THE PROCEEDING

DECISIONS/REASONS
PMPRB-94-D2/HABITROL

INTRODUCTION

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*"), in relation to Canadian Patent No. 1,283,053 granted to The Regents of the University of California and due to expire on 16 April 2008 (the "California Patent") and Canadian Patent No. 1,312,800 granted to LTS Lohmann Therapie-Systeme GmbH & Co. KG and due to expire on 19 January 2010 (the "Lohmann Patent") (collectively the "Patents") and the medicine S(-)- Nicotine Transdermal Therapeutic System, also known as Habitrol ("Habitrol"), sold in Canada in formats of 7 mg, 14 mg and 21 mg of active ingredient. The Board named CIBA-Geigy Canada Ltd. ("CIBA") as Respondent in the Notice of Hearing.

As in all proceedings held pursuant to sections 83 and 86 of the *Act*, the case was 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 parties to the proceeding commenced by the Notice of Hearing (the "Proceeding") were thus CIBA and Board Staff (the "Parties").

The purpose of the Proceeding was to consider whether, under sections 83 and 85 of the *Act*, CIBA is selling or has sold Habitrol, while a patentee, in any market in Canada, beginning 18 September 1992, 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 on the merits for 2 March 1994. Following the Pre-Hearing Conference, the hearing was eventually re-scheduled to commence on 18 October 1994 (the "Hearing"), in part due to an application for judicial review of the Board's Pre-Hearing Conference decision and a subsequent appeal launched by CIBA in the Federal Court of Canada. The Hearing was expected to last three weeks.

The Parties pre-filed with the Board, between 15 September and 7 October 1994, the affidavit evidence of each witness to be called at the Hearing, together with copies of the documents to be relied on by each such witness.

On 17 October 1994, Board Staff filed with the Board a Notice of Motion, returnable on 18 October 1994, for a Board order approving a Voluntary Compliance Undertaking (the "VCU") given by the Respondent with respect to the matters set out in the Notice of Hearing and terminating the Proceeding on the basis of such approval (the "Motion"). The Respondent filed a written consent to the proposed order.

On 18 October 1994, the Board heard both Parties on the Motion prior to the commencement of the Hearing. Following the hearing of the Motion, the Board approved the VCU and terminated the Proceeding, with reasons to follow. The Board's order to that effect (the "Order") was filed with the Federal Court of Canada on 19 October 1994 pursuant to section 99 of the *Act*.

THE LAW AND THE BOARD'S GUIDELINES, POLICIES AND PROCEDURES

The *Act*

Section 83 of the *Act* empowers the Board, where it finds that a patentee of an invention pertaining to a medicine is selling or has sold the medicine, while a patentee, in any market in Canada, at a price that, in the Board's opinion, is excessive, *inter alia*, to order the patentee:

a) to cause the maximum price at which it sells the medicine in that market to be reduced to such level as the Board considers not to be excessive; and

b) to offset the amount of the excess revenues estimated by the Board to have been derived by the patentee from the sale of the medicine at an excessive price by

   (i) reducing the price at which the medicine is sold in any market in Canada for a specified period; and/or

(ii) paying to her Majesty in right of Canada an amount specified in the order.

Section 85 establishes the factors that the Board must take into consideration when determining whether a medicine is being sold or has been sold in any market in Canada at an excessive price. The factors relevant to the Proceeding are as follows:

a) the prices at which the medicine has been sold in the relevant market;
b) the prices of other medicines in the same therapeutic class in the relevant market;
c) the prices of the medicine and of other medicines in the same therapeutic class in other countries; and
d) changes in the Consumer Price Index.

Subsection 96(4) authorizes the Board, following consultation with the Minister responsible under the *Act* (the "Minister"), the provincial ministers responsible for health and representatives of the pharmaceutical industry and of consumer groups, to issue guidelines with respect to any matter within its jurisdiction, although such guidelines are not binding on the Board or on any patentee.

Subsection 97(1) requires that all proceedings before the Board be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit.

***Patented Medicines Regulations* (the "*Regulations*")**

The *Regulations* were made pursuant to section 101 of the *Act*. They require patentees of inventions pertaining to medicines sold by them in any market in Canada to file with the Board, on an ongoing basis, *inter alia*, the sales, expense and pricing information with respect to such medicines, which provides the Board with the data necessary to discharge its statutory mandate.

Excessive Price Guidelines (the "Guidelines")

In order to reduce uncertainty and attendant costs and to promote consistency, and as authorized by subsection 96(4) of the *Act*, the Board has developed the Guidelines, following consultation with the industry, the provinces and interested parties. The Guidelines establish criteria derived from the wording of the *Act* that assist patentees in establishing, in advance, prices that may be presumed not to be excessive and that outline the methodology and factors to be used by the Board in determining whether the price of a medicine may be found to be excessive at any time.

The Guidelines provide that a category 3 medicine, that is, a medicine which provides moderate, little or no therapeutic advantage over other comparable medicines, will be presumed to be excessive if it exceeds the prices of all medicines in the same therapeutic class. However, if for any reason a reliable

therapeutic class comparison ("TCC") cannot be completed, the Board will conduct an international price comparison ("IPC") and the price of the medicine will be presumed to be excessive if it exceeds the median international price of the same medicine in the seven countries identified in the *Regulations*. The TCC requires the selection of comparable medicines with comparable dosage forms which in turn requires a determination of comparable dosage regimens for the medicines compared.

Human Drug Advisory Panel (the "HDAP")

The HDAP was established by the Board, pursuant to the *Act* and the Guidelines, to provide, *inter alia*, recommendations to the Board with respect to the categorization of new drug products which determines the test to be used in ascertaining whether a new product is, or is not, excessively priced, the selection of comparable drug products and the selection of comparable dosage regimens for the purpose of conducting a TCC.

Compliance and Enforcement Policy

The purpose of the Board's Compliance and Enforcement Policy found in the Board's Compendium of Guidelines, Policies and Procedures is to ensure that the prices of patented medicines are not excessive, in part by encouraging patentees to undertake voluntarily to adjust their price to a maximum non-excessive level and to take other remedial action as may be appropriate at any time.

Voluntary compliance undertakings are central to the Board's enforcement policies. Paragraph 7 of the Compliance and Enforcement Policy emphasizes that a patentee may make a voluntary compliance undertaking to adjust its price and to take any other remedial action as may be appropriate at any time, including after a hearing has been initiated in a matter. Paragraph 7.3 adds that, in such a case, the voluntary compliance undertaking may be approved by the Board as a basis for terminating the proceeding following an opportunity for submissions by the parties.

Paragraph 7.5 of the Compliance and Enforcement Policy stresses that a voluntary compliance undertaking should be consistent with the Guidelines and policies of the Board and, where appropriate, should stipulate the means by which the patentee proposes to return to consumers the excess revenues earned during the period that the price of a medicine was outside the Guidelines.

Paragraph 7.7 provides that the proposal of a voluntary compliance undertaking does not constitute an admission by the patentee that the price of the drug concerned is, or was, excessive.

THE MATTERS IN ISSUE

Several matters relating to establishing the Board's jurisdiction over the price of Habitrol under the *Act* for the relevant period and to the making of a finding of excessive pricing with respect to the sale of Habitrol in Canada by CIBA remained in issue between the Parties when their evidence was pre-filed.

The jurisdictional issues included the question of whether Habitrol was an invention pertaining to a medicine and whether the Patents that might pertain to Habitrol disclosed an invention pertaining to a medicine under subsection 79(2) of the *Act*. They also included whether CIBA was a patentee within the meaning of subsection 79(1) of the *Act* for the period during which excessive pricing was alleged by Board Staff. Subsection 79(1) defines a "patentee", in respect of an invention pertaining to a medicine as, in part, the person for the time being entitled to the benefit of the patent for that invention, including any other person entitled to exercise any rights in relation to that patent. CIBA denied being a patentee under the California Patent at any time. While CIBA acknowledged being a patentee under the Lohmann Patent beginning 19 January 1993, it claimed to have ceased being such a patentee on 10 September 1993, the date on which the Lohmann Patent was dedicated to the public. It was therefore CIBA's position that the Board's jurisdiction over the price of Habitrol was limited, at most, to the period 19 January 1993 to 10 September 1993.

The pricing issues revolved around the appropriate test and the appropriate components of such test to be applied to determine whether Habitrol was and/or is excessively priced. The Parties disagreed, *inter alia*, on whether Habitrol was a category 2 or category 3 new medicine under the Guidelines, on whether a TCC test should be used in preference to an IPC test to establish whether Habitrol was excessively priced and, should a TCC test be relied upon, the comparator(s) and the dosage regimen(s) to be used in conducting the test. More particularly, CIBA contested Board Staff's submission that Nicorette, a nicotine polacrilex gum already on the Canadian market in a 2 mg and 4 mg format at the time CIBA began its sales of Habitrol in Canada, should be considered as a comparator to Habitrol and not Nicoderm, Nicotrol or Prostep, all of which are unpatented transdermal nicotine patches the prices of which were not reviewed by the Board, and which have been marketed in Canada, beginning either at approximately the same time or after Habitrol was marketed in Canada by CIBA. CIBA also contested the appropriateness of the dosage regimen for Nicorette recommended to Board Staff by the HDAP. CIBA filed extensive scientific evidence in support of its position on the matter.

Board Staff, although it recommended to the Board reliance on an IPC test as the preferred mechanism in making a finding of excessive pricing in the circumstances of the case, nevertheless calculated how a finding of excessive pricing based on a TCC test could be made in the alternative.

The comparator(s) used, the test applied and the dosage regimen adopted in determining whether a medicine is, and if it is, to what extent it is, excessively priced yield significantly different results. Furthermore, the period during which sales of Habitrol may have been made at an excessive price by CIBA as a patentee also has a significant impact on the revenues taken into consideration in any Board order under section 83 of the *Act*.

The initial price at which Habitrol was sold in 1992 was $3.71 per patch. Habitrol is currently sold by CIBA at $3.46 for the 7 mg patch, $3.59 for the 14 mg patch and $3.62 for the 21 mg patch.

THE VOLUNTARY COMPLIANCE UNDERTAKING

The VCU approved by the Board consists of two main elements: (1) an undertaking by CIBA to reduce the prices at which Habitrol is sold, effective on 1 January 1995, so that, effective on that date, the prices at which Habitrol is sold in Canada do not exceed $3.16 for the 7 mg patch, $3.28 for the 14 mg patch and $3.31 for the 21 mg patch, and to maintain the price of Habitrol within the Board's Guidelines as amended from time to time during the period in which the VCU is in effect, and (2) an undertaking by CIBA to pay to Her Majesty in right of Canada, within one month of the date of a Board order approving the VCU, $2,950,000.00 and, no later than 31 January 1997, a further $651,595.00 plus the amount of revenues received by CIBA from prices for Habitrol above the Guidelines for the period 1 July to 31 December 1994, unless the latter two amounts are offset by CIBA selling Habitrol during the period 1 January 1995 and 31 December 1996 at prices set below the maximum prices to come into effect on 1 January 1995.

In the VCU, CIBA also undertook to abide by the provisions of the *Act* and of the *Regulations* applicable to a patentee during the period in which the VCU is in effect. In particular, CIBA undertook to continue to file the price and sales information with regard to Habitrol required of patentees by the *Regulations*.

The VCU is to remain in effect until the later of 19 January 2010 or such other date as any Canadian patent pertaining to Habitrol expires.

The VCU provides expressly that it constitutes no admission by CIBA that the prices of Habitrol are or were excessive.

THE SUBMISSIONS OF BOARD STAFF

Board Staff submitted that the VCU is responsive to the Notice of Hearing and in conformity with the objectives of the *Act*. In its view, the VCU respects the Board's Guidelines and policies and, although clearly a compromise, is a compromise which constitutes, in the circumstances of the case, a reasonable,

fair and efficient resolution of the matter before the Board. It is therefore in the public interest.

Specifically, Board Staff also submitted that the VCU addresses the two categories of possible orders set out in the Notice of Hearing: a reduction of the price of Habitrol in the future and a remedial order in the form of a repayment of excessive revenues earned in the past. Board Staff also submitted that the VCU meets the two principal mandates of the Board under the *Act*: the duty to ensure that patented medicines are not sold at excessive prices and the responsibility to require that excessive revenues earned from the sale of patented medicines are returned to the public. In Board Staff's view, the VCU meets as well the express requirement in the *Act* that proceedings before the Board be dealt with informally and expeditiously by providing a reasonable basis for achieving a settlement of the matter before the Board and avoiding a costly hearing on the merits and a potentially protracted final resolution of any disputed issue.

Board Staff submitted further that, for the following reasons, the VCU respects the Board's Guidelines and enforcement policies:

(a) the VCU respects the requirement that future pricing and past revenues both be addressed in any voluntary compliance undertaking;
(b) the VCU is based on a TCC test in accordance with the Guidelines;
(c) Nicorette was used as the comparator in conducting the TCC test which was used in arriving at the VCU, as recommended by the HDAP and Board Staff;
(d) the consensus reached by the Parties for the purposes of settlement regarding the dosage regimen used to arrive at a cost per course of treatment and a cost per day in conducting the TCC test for the VCU is based on the recommendation of the Board's HDAP;
(e) reliance on the TCC test was one of the alternatives recommended by Board Staff, in accordance with the Guidelines; and
(f) voluntary compliance forms a very important element of the Board's policies, as evidenced by the reference, at paragraph 17 of the Notice of Hearing, that the Respondent had not provided, as of that date, a voluntary compliance undertaking which conforms to the Guidelines, and by paragraph 1.1 of the Compliance and Enforcement Policy which states:

> "The purpose of this policy is to ensure that the prices of patented medicines are not excessive by encouraging and facilitating voluntary compliance by pharmaceutical patentees with the Act".

Board Staff also alluded to the difficult issues remaining in dispute between the Parties with respect to the sale of Habitrol in Canada by CIBA and stressed the benefit to the public of CIBA effectively acceding to the jurisdiction of the Board with respect to the sale of Habitrol, at least until the year 2010, despite these unresolved issues. It also noted that the reduction in the price of Habitrol as of 1 January 1995 represents a reduction in such price of approximately 14% relative to the introductory price of Habitrol in 1992 and stressed the significance of the amount of the repayment by CIBA to the Government of Canada, by far the largest of any obtained by the Board to date. At pages 49 and 50 of the transcript of the hearing of the Motion, counsel for Board Staff stated:

> "For the purposes of obtaining a VCU, which in all its most material respects the Board [S]taff was confident it respected the Act, the objectives of the Act and the Guidelines, the Board [S]taff was willing to compromise and forgo the alleged excess revenues earned in 1992. And that was because in return for that, for giving three and a half months of excess revenues, we got a price reduction which lasted at least 15 years and we also got excess revenues of a minimum of $3.6 million, which is not an insignificant amount."

CONCLUSION

In deciding to accept the proposed VCU and to terminate the Proceeding, the Board has taken into consideration the submissions of Board Staff at the hearing of the Motion and the written consent of CIBA to the order proposed. The Board notes that extensive conflicting evidence has been filed with it on a number of fundamental matters before it in the Proceeding. In the Board's view, it is in the public interest to accept a reasonable settlement of this case on the basis of the VCU, which is consistent with its statutory mandate, its Guidelines and its policies, as well as with the recommendations of its HDAP and of its staff, rather than to pursue these matters to a conclusion. Such acceptance also meets, in the circumstances of this case, Parliament's express requirement in the *Act* that all proceedings before the Board be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit. It is also in accordance with the Board's own emphasis on encouraging voluntary compliance.

The acceptance of the proposed VCU enables the Board to ensure that the price of Habitrol will be subject to its jurisdiction at least until 2010, the date on which the Lohmann Patent expires, despite the dedication of such patent to the public. It also ensures that a significant amount of revenues earned from the sale of Habitrol in Canada will be returned to the public by CIBA. Moreover, in the Board's view, there is a reasonable expectation that the price of other products used as temporary aids to facilitate smoking cessation sold in Canada will decrease as a result of the VCU accepted by the Board, to the benefit of the public.

Sylvie Dupont-Kirby
Secretary to the Board

October 24, 1994