Decision: PMPRB-95-D5/VIRAZOLE

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. 997,756, 1,028,264, 1,261,265, 1,297,057 and 1,297,058

AND IN THE MATTER OF ICN Canada Ltd. and ICN Pharmaceuticals Inc. (Respondents)

HEARING ON THE MERITS

DECISION/REASONS
PMPRB-95-D5/VIRAZOLE

INTRODUCTION

History of the Proceeding

On August 15, 1995, the Chairperson of the Patented Medicine Prices Review Board issued Notice of Hearing PMPRB-95-1 (the "Notice of Hearing"), pursuant to sections 83 and 86 of the *Patent Act* (the "*Act*"), in relation to Canadian Patents Nos. 997,756 (" '756") and 1,028,264 (" '264") granted to ICN Pharmaceuticals Inc. (U.S.A.) and expired respectively on September 28, 1993 and March 21, 1995. The Board named ICN Canada Ltd. and ICN Pharmaceuticals Inc. (hereafter the "Respondents") as Respondents in the Notice of Hearing.

The purpose of the proceeding commenced by the Notice of Hearing (the "Proceeding") was to consider whether the Respondents had, while patentees, sold the medicine known as Virazole in any market in Canada at a price that, in the Board's opinion, was excessive and, if so, what order, if any, should be made.

As in all proceedings held pursuant to sections 83 and 86 of the *Act*, the case against the Respondents 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 were thus Board Staff and the Respondents.

The Notice of Hearing scheduled a pre-hearing conference for November 7, 1995 and a hearing on the merits for December 11, 1995. By letter dated August 15, 1995 accompanying the Notice of Hearing, the Board also scheduled a hearing in respect of any preliminary matters for September 26, 1995 (subsequently postponed to September 27, 1995 at the request of the Respondents).

On September 8, 1995, the Respondents filed a Notice of Motion with the Board seeking an order that the Board is without jurisdiction to investigate, hold hearings or make any order in relation to the medicine Virazole. The Notice of Motion also sought an order providing for the confidentiality and non-disclosure of certain documents and an order amending a form relating to Virazole previously filed with the Board by ICN Canada Ltd. pursuant to the *Patented Medicines Regulations* ("*Regulations"*).

On September 27, 1995, Board Staff filed a Notice of Motion for an order to amend the Notice of Hearing by adding thereto further patents pertaining to Virazole.

These patents were Canadian Patent Nos. 1,261,265 (" '265"), 1,297,057 (" '057") and 1,297,058 (" '058"), copies of which were obtained by Board Staff on September 26, 1995. The Respondents consented to the amendment of the Notice of Hearing as requested by Board Staff and the Board postponed the hearing on preliminary matters scheduled for September 27, 1995 to November 2 and 3, 1995.

On September 28, 1995, the Board issued an Amended Notice of Hearing reflecting the addition of the '265, '057 and '058 Patents as patents pertaining to Virazole.

On October 20, 1995, the Respondents filed an Amended Notice of Motion, revised to be responsive to the Amended Notice of Hearing.

The Parties pre-filed with the Board the affidavit evidence of their witnesses together with copies of the documents to be relied on by each such witness.

On November 2 and 3, the Board heard the cross-examination of the evidence of several of the witnesses and argument on its jurisdiction with respect to the matters described in the Amended Notice of Hearing.

On November 30, 1995, the Board issued its decision with respect to its jurisdiction in this case. In summary, the Board concluded that with respect to both the '264 and '265 Patents, the Respondents are patentees of patents for inventions which pertain to the medicine Virazole. Accordingly, the Board has jurisdiction over the actions of the Respondents with respect to the price at which they have sold Virazole in any market in Canada at all times material to the issues raised by the Amended Notice of Hearing. The '756 Patent pertained and expired on September 28, 1993. With respect to the '057 and '058 Patents, Board Staff accepted that the Respondents had no rights in relation to the said patents and thus they were not relevant to the Proceeding.

It remained to be determined whether the Respondents have sold Virazole at a price that, in the Board's opinion, is or was excessive and whether the Respondents have engaged in a policy of selling Virazole at an excessive price.

On December 1, 1995, the Respondents filed a Motion with the Federal Court of Canada for judicial review of the Board's decision. On December 6, the Federal Court denied the Respondents' application to stay the Board's proceeding. The application for judicial review was heard on January 29, 1996.

The Board's hearing had been scheduled to commence on January 22, 1996 but was delayed for the imminent hearing of the application for judicial review.

On December 1, 1995, ICN Canada Ltd. disclaimed, under the *Act*, certain parts of the '265 Patent.

On February 15, 1996, the Federal Court issued its decision denying the injunctive relief sought by the Respondents and upholding the Board's decision. In addition, the Court concluded that the disclaimer by ICN Canada Ltd. with respect to the '265 Patent was invalid and did not affect the jurisdiction of the Board.

On February 21, 1996, the Respondents appealed to the Federal Court of Appeal and the appeal was heard on May 21, 1996. The decision was reserved. As of this date, the Federal Court of Appeal has not issued its decision on the appeal.

On March 22, 1996, Board Staff filed a Motion for the Board to issue an order requiring the Respondents to provide various items of information and documentation.

The Board heard the parties on March 26, 1996 and concluded on March 28 that in order to address properly the issues raised in the Amended Notice of Hearing

in this matter, and in order to determine the correctness and reasonableness of the position taken by the Respondents in their Response and in the outlines of evidence they provided, it was necessary to obtain the information and documentation requested by Board Staff in its Motion.

The hearing on the alleged excessive pricing of Virazole commenced on April 9, 1996 and concluded on July 4, 1996.

The evidence established that ICN Canada Ltd. has been selling Virazole in Canada since 1986. For the period up to September 28, 1993, the Respondents acknowledged that the Board had jurisdiction to regulate the price of Virazole in Canada. On February 1, 1994, ICN Canada Ltd. took the position that on the expiry of the '756 Patent, that is on September 28, 1993, it was no longer subject to the Board's jurisdiction. Effective January 1, 1994, the Respondents increased the price of Virazole to $750 per vial from $409 per vial, and subsequently, in late 1994, to $1,540 per vial.

THE ISSUES BEFORE THE BOARD IN THIS PROCEEDING ARE AS FOLLOWS:

1. Whether either Respondent has sold Virazole in any market in Canada at an excessive price within the meaning of section 83 of the *Act*;

2. Whether either Respondent has engaged in a policy of selling Virazole at an excessive price within the meaning of section 83 of the *Act*;

3. If the Board finds that either Respondent has sold or engaged in a policy of selling Virazole at an excessive price, the Board must consider what order, if any, is appropriate pursuant to section 83 of the *Act*.

ISSUE 1: Whether either Respondent has sold Virazole in any market in Canada at an excessive price within the meaning of section 83 of the *Act*.

(i) The Board's Guidelines

Subsection 96(4) of the *Act* allows the Board to issue guidelines with respect to any matter within its jurisdiction. The Board issued its Excessive Price Guidelines in July 1988 and has revised them from time to time. The most recent version of the Guidelines was consolidated and

issued in April, 1994, and is contained in the Board's *Compendium of Guidelines, Policies and Procedures*.

The Guidelines were established to assist patentees and Board Staff in understanding the analysis and considerations that are relevant to the Board in determining whether or not the price of a patented medicine is or will be excessive, but the Guidelines are not binding on the Board or any patentee.

The language and logic of the Guidelines is to illustrate the manner in which the Board will determine a "maximum non-excessive price" ("MNE") for a medicine. The Guidelines were established as a way to implement the criteria for determination of excess prices as set out in section 85 of the *Act*. As discussed in greater detail below, the Guidelines describe various tests which might apply depending on the circumstances of a particular medicine, but in all cases the application of the Guidelines will result in the determination of a price (the MNE) that may be presumed by the patentee not to be excessive. Conversely, sales by the patentee at a price above the MNE (on an annual average basis) can be expected to be of concern to the Board and can be expected to invoke a review by Board Staff as to whether or not the medicine is being sold at an excessive price.

If Board Staff come to a conclusion that, in their view, a patentee is selling a medicine at an excessive price, and if efforts at resolution of the matter on a voluntary compliance basis are not successful, Board Staff can request the Board to hold a hearing at which the matter will be determined.

Though Board Staff's decision to bring the matter before the Board will likely be informed by the price of the medicine relative to the MNE set in accordance with the Guidelines, the Board itself looks at the issue afresh to determine whether or not the medicine is being sold at an excessive price. Nevertheless, the Guidelines have been issued by the Board after considerable deliberation and consultation by the Board with interested parties. Accordingly the Guidelines will be given due consideration in the course of the Board's review of the matter.

The onus is on Board Staff to establish that the price at which a medicine is or has been sold is or was excessive. This is not simply a matter of Board Staff demonstrating that the price has exceeded the MNE as derived by the application of the Guidelines. The Board is examining the issue in accordance with the criteria for determination of excessive prices as set out in section 85 of the *Act*, and if the Board Staff's case is

premised on pricing which exceeds the MNE price as established by the Guidelines, it is for Board Staff to satisfy the Board that the Guidelines do and should apply with respect to the medicine in question. There is no onus on the patentee to satisfy the Board that the Guidelines should not apply.

(ii) ICN Canada Ltd.

ICN Canada Ltd. plainly has sold and does sell Virazole in Canada. Accordingly the Board must consider whether those sales are or have been at excessive prices.

(a) The Relevant Criteria

Subsection 85(1) of the *Act* provides as follows:

> 85(1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:
>
> (a) the prices at which the medicine has been sold in the relevant market;
>
> (b) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;
>
> (c) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;

> (d) changes in the Consumer Price Index; and
>
> (e) such other factors as may be specified in any regulations made for the purposes of this subsection.

It was agreed by the parties that at this time there is no other medicine in the same therapeutic class as Virazole. There have been no regulations passed for the purposes of this subsection. Accordingly the only relevant criteria are those in clauses 85(1)(a), (c) and (d).

(b) The position of the Respondents regarding the interpretation of subsection 85(1)

Counsel for the Respondents argued that subsection 85(1) of the *Act* is not restrictive, and that the Board, in coming to its conclusion on whether or not Virazole is or has been sold at an excessive price, is permitted to examine factors other than those enumerated in that subsection. In particular, the Respondents argue that the Board should, in making its determination on this matter pursuant to subsection 85(1), have regard to the costs that ICN Canada Ltd. incurs in making and marketing (which the Board takes to include "acquiring" where appropriate, as in this case) Virazole. In order to assess this argument it is necessary to examine the language of section 85 of the *Act*.

Subsection 85(1) provides that the Board "shall" determine the matter on the basis of the factors set out in that subsection, the last of which is:

> (e) such other factors as may be specified in any regulations made for the purposes of this subsection.

Subsection 85(2) of the *Act* provides as follows:

> 85(2) Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:

> (a) the costs of making and marketing the medicine; and
>
> (b) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of the Board, relevant in the circumstances.

It seems apparent to the Board, then, that it is instructed by the *Act* to first attempt to determine the matter by reference to criteria established by Parliament in subsection 85(1) of the *Act* or by regulations pursuant to that subsection, and only if that exercise is not successful should the Board consider factors such as the costs of making and marketing the medicine or other factors the Board considers appropriate pursuant to clause 85(2)(b). Accordingly the Board concludes that its deliberations pursuant to subsection 85(1) are indeed restricted to the factors set out in that subsection or in regulations passed pursuant to that subsection.

It is not appropriate for the Board, in its deliberations pursuant to subsection 85(1), to consider the costs to ICN Canada Ltd. of making and marketing Virazole.

(c) Clause 85(1)(a): The Virazole Pricing History

As noted above, the Board was established by amendments to the *Act* in December 1987. Virazole was sold in Canada by ICN Canada Ltd. before 1987, and during that period the price at which Virazole was sold was not regulated by any government authority. At that time ICN Canada Ltd. had the benefit of patents (the '756 and '264 Patents) for two processes for the production of Virazole and ICN Canada Ltd. was the only source in Canada of Virazole or any comparable antiviral medicine. Accordingly, before the establishment of the Board, Virazole was sold in Canada by ICN Canada Ltd. at a price established by ICN Canada Ltd.

The Board's Guidelines provide that the prices of medicines being sold in Canada at the time of the Board's inception will be presumed not to be excessive. This appears to be a reasonable conclusion in this case, and certainly one which is eminently fair to the Respondents.

(d) Clause 85(1)(d): Changes in the Consumer Price Index

The Guidelines provide that the initially-established non-excessive price of a medicine (in the case of Virazole, its average price in 1987) is the "benchmark price", and the MNE is the benchmark price as adjusted

(typically increased) in accordance with the Consumer Price Index ("CPI") from year to year.

Again, while the Board is not bound by its Guidelines, the Board is satisfied that in this case the Guidelines are entirely consistent with the *Act* and the Board accepts that the use of the CPI to adjust the MNE of Virazole from the benchmark price from year to year is appropriate.

Furthermore, the Board notes that ICN Canada Ltd. did not raise any objection to the establishment of its pre-regulation market price as the initial MNE and thus the benchmark price, nor to the use of the CPI to adjust that price from year to year from 1988 until these proceedings. Indeed, in June, 1990, the Board wrote to ICN Canada Ltd. to inquire as to whether ICN Canada Ltd. accepted the initial benchmark price and the use of the proposed CPI methodology. ICN Canada Ltd. responded confirming the benchmark price and indicating that the CPI methodology would be used to adjust the benchmark price.

A secondary issue arose in the hearing as a result of amendments effective January 1994, which altered the methodology by which the CPI was applied to determine the MNE from year to year. Given the change that these amendments introduced in the reference period for application of the CPI, it was possible for the amendments to have the effect of actually reducing the MNE of a medicine. This effect was not intended and so the Board applied a transitional measure stipulating that a patentee who faced a price reduction "solely" as a result of the application of the new methodology would not have to reduce its price below the pre-amendment MNE. Board Staff argued that, since ICN Canada Ltd. faced a reduction in the price of Virazole both because of the new methodology and because of its decision to increase the price of Virazole beyond the MNE, ICN Canada Ltd. should not have the benefit of the transitional measure.

The Board is satisfied that the wording of the transitional measure was not intended to deny ICN Canada Ltd. the benefit of that measure in the circumstances of this case. Accordingly the Board concludes on this issue that the MNE for Virazole should be calculated by application of the transitional measure.

(e) Clause 85(1)(c): The Price of Virazole in Other Countries

The price at which a medicine is sold in other countries will not usually be a determining factor where a benchmark price has been established

based on a history of sales in Canada. Though the Board's Guidelines do provide that the price of a medicine will be considered excessive if it is higher in Canada than in any other of the countries listed in the *Regulations* (Germany, France, Italy, Sweden, Switzerland, the United Kingdom and the United States), Virazole is not so priced and thus that factor is not material to the Board's consideration in this case.

While large and consistent deviations in the price of a medicine in other countries relative to the Canadian price could be significant to the Board, the multitude of factors that could be influencing the foreign prices, but that are not relevant to the Canadian market, makes it preferable to the Board to use the Canadian pricing history where it is available.

Nonetheless, the Board did receive evidence on the prices of Virazole in the countries listed in the *Regulations*. The evidence was not entirely satisfactory because the comparison was to the "list" prices of Virazole abroad. The Board's Guidelines do suggest reference to list prices where the foreign prices are material to the Board's deliberations because it is difficult to obtain information on actual selling prices. The list prices in Canada and abroad are often discounted and so the comparison may not be reliable.

In any event, having considered such evidence on the foreign prices as was available, the Board concludes that those prices did not differ sufficiently from the actual prices in Canada to alter the Board's conclusions based on the Canadian pricing history and the CPI.

(f) Conclusion

The Board is able to determine a MNE by the application of the criteria set out in subsection 85(1). That price is the price that the Board has established from year to year as the MNE for Virazole by the use of the benchmark price of Virazole (the average price during 1987) as adjusted by the CPI.

While this conclusion has necessarily only been reached with reference to the years 1988 to 1996, the Board cannot at this time foresee any reason why the MNE for Virazole would be determined in any other way from 1997 to 2006, at which time the '265 Patent expires.

(g) Subsection 85(2)

Having been able to determine, through the application of the criteria set out in subsection 85(1), that the price at which Virazole was sold in Canada since January 1994 was excessive, there remains the issue of the relevance, if any, of the criteria in subsection 85(2) of the *Act*. As can be seen in the sections of the *Act* set out above, unlike the mandatory "shall" of subsection 85(1), subsection 85(2) provides that the Board "may" consider the criteria set out in that subsection where the Board is unable to determine the matter on the basis of the criteria set out in subsection 85(1).

The Board has been able to make its determination on the basis of the criteria set out in subsection 85(1) and it was therefore not necessary to evaluate the evidence of ICN Canada Ltd. concerning the costs it incurs in making and marketing Virazole in Canada, nor the responding evidence of Board Staff on this issue.

However, for the benefit of patentees who are, or might in the future be, subject to the Board's jurisdiction, the Board would like to comment on the position of the Respondents that the price of Virazole could not possibly be said to be excessive if the costs of making and marketing the medicine exceeded the revenue from sales.

There would have to be compelling reasons for the Board to determine the MNE on the basis of a patentee's costs of making and marketing a medicine and it seems likely that the instances in which that analysis will be appropriate will be rare. However, it is not inconceivable that, where the criteria in subsection 85(2) were properly being considered by the Board, a patentee could present evidence which would satisfy the Board that the MNE for a medicine could be established by reference to the costs of making and marketing the medicine.

Nonetheless, even where the Board is instructed by the *Act* that it may consider such evidence, it is not axiomatic that in each case the costs of making and marketing the medicine will establish a floor for the MNE of the medicine. While each case would have to be considered on its merits, it seems probable that the Board would, pursuant to clause 85(2)(b), examine the broader context in which the situation arose before coming to a conclusion on the point. Also, it will always be for the Board itself, after consideration of the relevant evidence, to make its own determination on the identification, characterization and relevance of

each element of costs alleged by a patentee to comprise part of the costs of making and marketing the medicine.

Finally, it should be noted that, given the potentially complex and contentious nature of the financial and accounting evidence on this issue, the Board expects that the determination of a MNE by reference to the costs of making and marketing the medicine would only be possible where the Board received clear and reliable evidence on the point.

(iii) The prices at which Virazole has been sold in Canada

The history of the price of Virazole has been outlined in the comments that introduced this decision. Attached as Appendix A to this decision is a table prepared by Board Staff detailing this pricing history.

It is plain that these prices exceed the maximum non-excessive price determined in this decision, and accordingly in its finding on the first issue, the Board concludes that ICN Canada Ltd. has sold Virazole in Canada at an excessive price from January 1994 to the present time.

(iv) ICN Pharmaceuticals Inc.

For the reasons set out below regarding the policy of excessive pricing, the Board concludes that ICN Pharmaceuticals Inc. has sold Virazole in Canada at an excessive price from January 1994 to the present time.

ISSUE 2: Whether either Respondent has engaged in a policy of selling Virazole at an excessive price within the meaning of section 83 of the *Act*.

(i) ICN Canada Ltd.

Subsection 83(4) of the *Act* provides as follows:

> 83(4) Where the Board, having regard to the extent and duration of the sales of the medicine at an excessive price, is of the opinion that the patentee or former patentee has engaged in a policy of selling the medicine at an excessive price the Board may, by order, in lieu of any order it may make under subsection (2) or (3), as the case may be, direct the patentee or former patentee to do any one or more of the things referred to in that subsection as will in the Board's opinion offset not more than twice the amount of the excess revenues estimated by it to have been derived by the patentee or former patentee from the sale of the medicine at an excessive price.

The "extent" of the increases in the price of Virazole beyond its MNE was considerable, representing an approximate doubling and then redoubling of the price from 1993 to 1994. Counsel for the Respondents himself referred to these price increases as "enormous". The "duration" of the price increases has been substantial and permanent: the price increases were instituted in 1994 and have endured to the most recent period for which ICN Canada Ltd. has filed pricing information with the Board, that is to December 31, 1995.

Also, the price increases were intentional and undertaken with knowledge that the resulting price of Virazole would exceed significantly the MNE for Virazole.

The Respondents argued that, despite these factors, the price increases should not be characterized as a policy of excessive pricing because ICN Canada Ltd. believed that as of September 1993 it was no longer subject to the jurisdiction of the Board.

The evidence on this point did not satisfy the Board. ICN Canada Ltd. alleged that it obtained legal opinions in late 1993 (as regards the '265 Patent) and early 1994 (as regards the '264 Patent) to the effect that the patents did not pertain to Virazole. However, these opinions were not put on the record during the hearing and the Board does not know the wording of the opinions. It is apparent from the Securities Exchange Commission 10K filing of ICN Pharmaceuticals Inc. that the company considered itself to have the benefit of two Canadian patents which were to expire respectively in 1994 and 2006 and that these patents would provide it with material patent protection for its sales of Virazole. These two Canadian patents are undoubtedly the '264 and '265 Patents. Yet the evidence of the Respondents was that on the strength of a legal opinion obtained by ICN Canada Ltd., the decision was made not to disclose the existence of the '265 Patent to the Board, even in the face of the specific question from Board Staff as to whether or not any patents other than the '264 Patent pertained to Virazole.

It was the position of Board Staff that ICN Canada Ltd. "took a chance" by increasing the price of Virazole without waiting for a ruling by the Board or the Federal Court confirming its position that the Board did not have jurisdiction in the matter. Board Staff argued that ICN Canada Ltd. knew that there was a possibility that the Board and the courts would determine that the Board had jurisdiction and that the price increases would attract the sanctions of the *Act*.

While the Board agrees with these submissions of Board Staff, it would not be necessary for the Board to find that ICN Canada Ltd. had knowledge of the uncertainty of its position and the risks it was taking in increasing its prices. It is

the Board's view that a patentee's mistaken understanding of the law does not insulate the patentee from a finding by the Board that the patentee has engaged in a policy of excessive pricing.

Accordingly the Board concludes that ICN Canada Ltd. has engaged in a policy of excessive pricing since January 1994.

(ii) ICN Pharmaceuticals Inc.

The evidence before the Board established that ICN Canada Ltd. is the wholly owned subsidiary of ICN Pharmaceuticals Inc., and that the increases in the price of Virazole from 1994 to the present were at the direction of ICN Pharmaceuticals Inc. Indeed, the evidence of the Respondents was that the price increases were at least in part implemented in order to protect ICN Pharmaceuticals Inc.'s American market for Virazole, which, it was alleged (though without support from the evidence), might otherwise be imperiled by the "grey marketing" in the United States of Virazole purchased in Canada.

Though the wording of the *Act* does not expressly describe aiding, abetting or assisting in a policy of excessive pricing, this Board is not blinded by a corporate veil to the reality of this situation. The actions of ICN Canada Ltd. were in all relevant senses the actions of ICN Pharmaceuticals Inc. Also, through its sole ownership of ICN Canada Ltd. and as beneficiary of the Canadian price increases (as ICN Pharmaceuticals Inc. saw it) in protecting its sales of Virazole in the United States, the actions of ICN Canada Ltd. were for the exclusive benefit of ICN Pharmaceuticals Inc. ICN Pharmaceuticals Inc. was the directing mind of ICN Canada Ltd. and the Board could not effectively carry out its mandate if it could not address the actions of a parent company acting in this manner through its wholly owned subsidiary.

Accordingly, for the reasons given above with respect to ICN Canada Ltd., the Board concludes that ICN Pharmaceuticals Inc. has engaged in a policy of excessive pricing since January 1994.

The Respondents argued that they were prejudiced by what they submitted was the slow pace at which the Board dealt with the issue of whether the '264 Patent pertained to Virazole. On the evidence before the Board it is apparent that the Respondents did not suffer any such prejudice and acted throughout these events independently of any position taken by Board Staff.

ISSUE 3: What order, if any, is appropriate pursuant to section 83 of the *Act*.

Section 83 of the *Act* provides as follows:

83 (1) Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order, direct the patentee to cause the maximum price at which the patentee sells the medicine in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.

(2) Subject to subsection (4), where the Board finds that a patentee of an invention pertaining to a medicine has, while a patentee, sold the medicine in any market in Canada at a price that in the Board's opinion, was excessive, the Board may, by order, direct the patentee to do any one or more of the following things as will, in the Board's opinion offset the amount of the excess revenues estimated by it to have been derived by the patentee from the sale of the medicine at an excessive price:

(a) reduce the price at which the patentee sells the medicine in any market in Canada, to such extent and for such period as is specified in the order;

(b) reduce the price at which the patentee sells one other medicine to which a patented invention of the patentee pertains in any market in Canada, to such extent and for such period as is specified in the order; or

(c) pay to Her Majesty in right of Canada an amount specified in the order.

(4) Where the Board, having regard to the extent and duration of the sales of the medicine at an excessive price, is of the opinion that the patentee or former patentee has engaged in a policy of selling the medicine at an excessive price, the Board may, by order, in lieu of any order it may make under subsection (2) or (3), as the case may be, direct the patentee or former patentee to do any one or more of the things referred to in that subsection as will, in the Board's opinion, offset not more than twice the amount of the excess revenues estimated by it to have been derived by the patentee or former patentee from the sale of the medicine at an excessive price.

For the reasons set out above with respect to the first issue, the Board orders that the maximum non-excessive price for Virazole for the years 1994 to 1996 was and is the price calculated by Board Staff by application of the Guidelines, except that ICN Canada Ltd. shall be given the benefit of the transitional

measures with respect to the introduction in 1994 of the new methodology for the calculation of CPI adjustments.

With respect to the Board's finding that the Respondents engaged in a policy of excessive pricing, the Board concludes that the actions of the Respondents warrant the exercise of the Board's remedial power to the full extent permitted by the *Act*, that is an order which will recover twice the cumulative excess revenues received by ICN Canada Ltd. to date. Accordingly, pursuant to the provisions of subsection 83(4) of the *Act*, the Board makes the following order in lieu of an order under subsection 83(1) or (2) of the *Act*:

i) ICN Canada Ltd. shall, no later than August 5, 1996, report to the Board with respect to the volume and prices of sales of Virazole in Canada from January 1, 1996 to July 31, 1996. Within ten days of the receipt of this information, Board Staff shall calculate the total excess revenues received by ICN Canada Ltd. from January 1, 1994 to July 31, 1996, and this information shall be provided to the Board and ICN Canada Ltd.;

ii) ICN Canada Ltd. and/or ICN Pharmaceuticals Inc. shall, no later than August 26, 1996, make a payment or payments to Her Majesty in right of Canada in the total amount of $1,200,000. The obligation to make payment in this amount shall be that of ICN Canada Ltd. and ICN Pharmaceuticals Inc. jointly and severally;

iii) From and after August 1, 1996, the average price (on an annual basis) at which Virazole is sold in Canada shall be reduced to an amount that is $200 per 6 gram vial less than the MNE for Virazole in each year. For the purposes of calculating the future MNE for Virazole, sales of Virazole at prices reduced in accordance with this order shall be deemed to have been made at the applicable MNE for Virazole;

iv) The price reduction described in paragraph (iii) shall remain in effect until the earlier of December 31, 1999, or the date on which an amount equal to twice the cumulative excess revenues (as calculated pursuant to paragraph (i) above) has been offset by the sum of the amount paid pursuant to paragraph (ii) above and the cumulative price reductions pursuant to paragraph (iii) above;

v) In the event that the cumulative excess revenues have not been offset by December 31, 1999, ICN Canada Ltd. and/or ICN Pharmaceuticals Inc. shall, no later than January 31, 2000, make a payment or payments to Her Majesty in right of Canada equal to the balance of excess revenues

outstanding as at December 31, 1999. The obligation to make any payment required by this paragraph shall be that of ICN Canada Ltd. and ICN Pharmaceuticals Inc. jointly and severally;

vi) If at any time before December 31, 1999, Virazole is not reasonably available for purchase in Canada, ICN Canada Ltd. and/or ICN Pharmaceuticals Inc. shall make a payment or payments to Her Majesty in right of Canada equal to the balance of excess revenues outstanding as at the first date on which Virazole is not reasonably available for purchase in Canada. The obligation to make any payment required by this paragraph shall be that of ICN Canada Ltd. and ICN Pharmaceuticals Inc. jointly and severally.

In the event that the manner of implementing or complying with these orders requires further directions from the Board, either Board Staff or the Respondents may apply in writing for such directions.

Sylvie Dupont-Kirby
Secretary to the Board

July 26, 1996