Decision: PMPRB-95-D2/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 PRELIMINARY MATTERS
MOTION BY THE RESPONDENTS TO DETERMINE THE BOARD'S JURISDICTION

DECISIONS/REASONS
PMPRB-95-D2/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 and 1,028,264 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. (collectively "ICN") 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 ICN 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 ICN, as 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, 1,297,057 and 1,297,058, 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 Canadian Patents Nos. 1,261,265, 1,297,057 and 1,297,058 as patents pertaining to Virazole.

On October 20, 1995, 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.

Virazole and its recent pricing history

The Respondent, ICN Canada Ltd., has been selling Virazole in Canada since 1986. Virazole is supplied in 100 millilitre glass vials of sterile lyophilized powder containing 6 grams of the chemical compound 1-ß-D-ribofuranosyl-1,2,4-triazole-3-carboxamide, known as "ribavirin". ICN Canada Ltd. has also, pursuant to the Emergency Drug Release Program ("EDRP"), provided ribavirin in capsule form under the name Virazole.

In summary of the allegations in the Amended Notice of Hearing, it is alleged that for the period up to September 28, 1993, the Respondents acknowledged that they held a patent pertaining to Virazole and that the Board had jurisdiction to regulate the price of Virazole in Canada. After that date, the Respondents denied that they held such a patent and denied the Board's jurisdiction to regulate the price of Virazole.

In September 1993, the price of Virazole was $409 per vial (a 12 hour dosage in a treatment program of at least 72 hours). The Board received complaints that, effective January 1, 1994, the Respondents increased the price of Virazole to $750 per vial, and subsequently, in late 1994, to $1,540 per vial.

THE PATENTS ALLEGED TO PERTAIN TO VIRAZOLE

The Amended Notice of Hearing identified five Canadian patents as pertaining to Virazole.

The '756 Patent

The Respondents held Canadian Patent No. 997,756 (the '756 Patent) pertaining to Virazole, which expired on September 28, 1993. The '756 Patent describes a chemical process for the preparation of ribavirin. It was the undisputed evidence of the Respondents that they produced Virazole using the process described in the '756 Patent. It is acknowledged by Board Staff that the Respondents complied with their obligations under the *Act* by reporting the pricing and sales information for Virazole during the life of this patent.

The '264 Patent

The Respondents held Canadian Patent No. 1,028,264 (the '264 Patent) which expired on March 21, 1995. The '264 Patent describes an enzymatic (as opposed to chemical) process for the preparation of ribavirin.

Pursuant to the *Regulations* made on September 15, 1988, the Respondent ICN Canada Ltd. filed a "Medicine Identification Sheet" with the Board on August 4, 1988 setting out information required to be given in respect of Virazole. In that

filing, the Respondent ICN Canada Ltd. listed the '264 Patent (along with the '756 Patent) as one of its patents pertaining to Virazole.

The '265 Patent

Canadian Patent No. 1,261,265 (the '265 Patent) describes and claims a number of medicinal uses for ribavirin. The '265 Patent was granted to Viratek Inc., U.S.A., a subsidiary of ICN Pharmaceuticals Inc., U.S.A., on September 26, 1989 and will expire on September 26, 2006. Viratek Inc. was amalgamated into ICN Pharmaceuticals Inc. on November 10, 1994.

The '057 and '058 Patents

Canadian Patent Nos. 1,297,057 and 1,297,058 were granted to Genencor International, Inc., U.S.A. In its Supplementary Memorandum of Argument, Board Staff acceded to the Respondents' denial of any rights in relation to these patents.

As a consequence of the foregoing, the patents alleged to pertain to Virazole and to give rise to the remedial powers of the Board in this Proceeding are the '264 and '265 Patents.

THE ISSUE BEFORE THE BOARD

The central issue before the Board in the hearing on preliminary matters held on November 2 and 3 related to its jurisdiction under the *Patent Act*. The Respondents contend that the Board is without jurisdiction to make any Order in relation to Virazole because neither the '264 Patent nor the '265 Patent pertain to Virazole within the meaning of the *Act*.

SUBSECTION 79(2) OF THE *PATENT ACT*

The Board has jurisdiction with respect to patents for inventions pertaining to medicine. An issue which underlay much of the evidence and argument on the Respondents' motion was the interpretation of subsection 79(2) of the *Act* in this context.

Subsection 79(2) of the *Act* provides:

> *(2) For the purposes of subsection (1) and sections 80 to 101, an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine.*

The Position of the Respondents

The Respondents noted that, pursuant to the provisions of the *Food and Drugs Act*, a Notice of Compliance must be issued before a medicine can be sold in Canada. The Notice of Compliance includes the "Product Monograph" for the medicine, in which the essential characteristics of the medicine are described, including matters such as the chemicals in the medicine, the illnesses it is effective in treating (the "indications"), the proper dosages, the method of administering the medicine to the patient and the side-effects which may be experienced. (For purposes of clarity, a medicine for which a Notice of Compliance has been issued under the *Food and Drugs Act* is hereafter referred to as an "NOC Drug".)

It is the position of the Respondents that, for an invention to pertain to a "medicine" within the meaning of subsection 79(2) of the *Act*, the invention must be for "a substance which itself has therapeutic value and approved for sale in Canada". The Respondents contend that subsection 79(2) is limited in scope to medicines in respect of which pricing information is required to be filed with the Board pursuant to section 80 and the Regulations made thereunder or, in other words, to a medicine which is an NOC Drug.

The Respondents further argue that, under subsection 79(2), a medicine includes all matters concerning the NOC Drug stipulated in the Notice of Compliance, including the medicine, the dosages and ways of administering the medicine to a patient and the specific illness ("indications") for which it is appropriate.

Thus in this case, with reference to Virazole, the Respondents argue that the '264 Patent and the '265 Patent must be for an invention which is intended or capable of being used for, or for preparing, 6 grams of pure 100% ribavirin in lyophilized powder to be delivered in aerosol form in the manner stipulated in the Notice of Compliance for the indications stipulated in the Notice of Compliance. Since, on the Respondents view of these matters, neither patent meets this test, the Respondents argue that the Board does not have jurisdiction over the matters described in the Notice of Hearing.

The Position of Board Staff

It is the position of Board Staff that a patent pertains to a medicine if it is for an invention which is intended or capable of being used for, or for preparing, either a medicine or any active ingredient or necessary component of a medicine, whether or not it is an NOC Drug. With respect to these proceedings, Board Staff argue that each of the '264 and '265 Patents are for inventions which are intended or capable of being used for, or for preparing, ribavirin, that is, the

active (and indeed only) ingredient of which Virazole is comprised. Board Staff characterize Virazole as simply a brand name for ribavirin.

In answer to the Respondents' argument that, under subsection 79(2) of the *Act*, a medicine is an NOC Drug, Board Staff made particular reference to the Emergency Drug Release Program ("EDRP").

The EDRP is a program operated by Health Canada under which Health Canada may authorize the use and/or sale of a quantity of a medicine for which there is no Notice of Compliance or, in the case of an NOC Drug, for a use which is not authorized by the Notice of Compliance. In the affidavit of Dr. Corrin filed by Board Staff, Dr. Corrin describes the uses of Virazole authorized through the EDRP.

Dr. Corrin testified that in 269 cases since 1990, Virazole supplied by ICN Canada Ltd. had been approved pursuant to the EDRP for uses outside the Notice of Compliance. In 24 of these cases the approvals were for uses identical to the claims under the '265 Patent. Dr. Corrin stated that the product supplied by ICN Canada Ltd. for certain other cases within the EDRP was in capsule form rather than in the powder form described in the Virazole Notice of Compliance, but this product was nonetheless comprised of the same active ingredient (ribavirin) and was named "Virazole" by ICN Canada Ltd.

Discussion

(a) The Language of Subsection 79(2)

With regard to the Respondents' argument that the Board's jurisdiction extends only to NOC Drugs, the Board notes that the language of subsection 79(2) is not restricted in the manner suggested by the Respondents. Under subsection 79(2), an invention pertains to a medicine if that invention is intended or capable of being used for medicine or for the preparation or production of medicine. The language of the subsection is clear and makes no mention of medicines which have a price, or which are sold, or in respect of which a Notice of Compliance has been issued under the *Food and Drugs Act*. The only qualification in the subsection is that the invention must be intended or capable of being used for medicine or its preparation or production. Consequently, the Board concludes that its jurisdiction under the *Act* is not limited to patentees of inventions for NOC Drugs. This conclusion also precludes acceptance of the Respondents' submission that, for purposes of subsection 79(2), a medicine must also include all matters concerning the NOC Drug stipulated in the pertinent Notice of Compliance.

(b) The Emergency Drug Release Program

The Board considers that an interpretation of subsection 79(2) which would limit its scope to NOC Drugs would also have the effect of excluding medicines released under the EDRP from the jurisdiction of the Board. In addition to its value in treating patients in clinical situations, the EDRP is of substantial importance in the evaluation of new uses for medicines.

The EDRP consequently performs an important role in the development and marketing of medicines in Canada. In some cases it is the primary sales outlet for a medicine. The Board could not properly fulfil its mandate to ensure that patented medicines are not sold at excessive prices if it ignored sales of medicines through the EDRP and restricted itself to an examination only of the sales of NOC Drugs.

(c) Substances with Therapeutic Value

With regard to the Respondents' submission that a medicine means a substance which itself has therapeutic value, the Board notes that, while Virazole is comprised exclusively of a substance with therapeutic value, there are many cases in which a patented invention relates to only one of several components or active ingredients of a medicine. A patent may only relate to the process for administering a medicine to a patient, or to a part of the process for producing a medicine, or to any other partial aspect of a medicine.

Yet in all these cases the patentees of such patents would have the exclusive ability to produce, or to prevent the production of, a critical part of a medicine despite the fact that their patent would not, in the Respondents' submission, be for an invention which was intended or capable of being used for a medicine within the meaning of subsection 79(2) because it was not "a substance which itself has therapeutic value".

(d) Other Sections of the *Act*

The definition of an invention pertaining to a medicine in subsection 79(2) governs sections 80 to 101 of the *Act*. Under section 88 of the *Act* and the Regulations made thereunder, patentees are required to report expenditures made by them in Canada on research and development "relating to medicine." The Board is, under section 89, required to report to the Minister yearly, on an individual and aggregate patentee basis, its estimate of the expenditures made by patentees on research and development "relating to medicine" as a proportion of the revenues of those patentees from "sales of medicine" in Canada.

Since the largest research and development expenditures are made to discover and apply new processes, systems of delivery and active ingredients and their

uses and not on NOC Drugs the interpretation of the word medicine in subsection 79(2) as contended for by the Respondents would very significantly limit the expenditures on research and development that could be reported by patentees and by the Board under these sections.

CONCLUSION

The Board notes that, in the particular circumstances of this case, the only ingredient of Virazole is ribavirin. It is accordingly the Board's view that, for the purposes of subsection 79(2) in this case, the word "medicine" in the phrase "intended or capable of being used for medicine or for the preparation and production of medicine" means ribavirin. Ribavirin is the substance for which a process of production is patented in the '264 Patent and is the substance for which uses are patented in the '265 Patent. The Board therefore concludes that the '264 and '265 Patents pertain to Virazole.

THE '264 PATENT

The Position of the Respondents

Despite the filing by the Respondent ICN Canada Ltd. on August 4, 1988 listing the '264 Patent as pertaining to Virazole, Respondents took the position on the expiry of the '756 Patent on September 28, 1993 that they no longer held a patent pertaining to Virazole and that the Board did not have jurisdiction to regulate the price of Virazole. Respondents took this position because they were not actually using the process described in the '264 Patent, but rather were using the process described in the by then expired '756 Patent. Respondents ceased filing information concerning the prices at which Virazole was sold.

The Respondents argued that it is not possible to use the process described in the '264 Patent to make ribavirin in quantities sufficient for pharmaceutical applications and that the patent cannot therefore be considered to pertain to Virazole within the meaning of the *Act*.

In support of this position the Respondents relied on the affidavits of Robert Orr and Dr. Cottam to the effect that only very small quantities of ribavirin can be produced using the process described in the '264 Patent. Producing ribavirin with this process in quantities sufficient to market as Virazole is described as prohibitively expensive due to the cost and limited availability of the necessary raw materials.

The Position of Board Staff

Board staff did not file evidence to dispute the Respondents' position on the mechanics or costs of producing ribavirin with the process described in the '264 Patent because they considered those matters to be irrelevant.

Discussion

(a) "Medicine" in subsection 79(2)

As noted in the discussion above concerning subsection 79(2), the Board interpreted subsection 79(2) and concluded that the '264 Patent pertains to Virazole. During argument, counsel for the Respondents agreed that, if the Board took this position regarding the interpretation of subsection 79(2), the '264 Patent pertains to Virazole since it is a process patent for the making of ribavirin. While this is dispositive of the issue whether the '264 Patent pertains to Virazole, it is appropriate to respond to the other submissions of the Respondents concerning the '264 Patent.

(b) Actual Use and Relative Efficacy

The Board considers the actual use a patentee is making of a given patent to be irrelevant to the legal question of whether that patent pertains to a medicine with the meaning of the *Act*. The test established in subsection 79(2) is whether the patent is "intended or capable of being used for medicine". In the Board's view the use of these words in the subsection clearly broadens the scope of these provisions beyond actual use.

For the same reasons, the Board considers the relative efficacy of a patent in producing commercial quantities of a medicine to be irrelevant to the issue of whether a patent pertains to a medicine for the purposes of the *Act*.

The Board also considers that there are sound policy reasons for rejecting the Respondents' submissions on these matters. Patents pertaining to medicines granted under the *Act* give to the patentee "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used".

The reasons a patentee obtains a patent and the uses to which the patentee puts its exclusive rights are beyond the knowledge of the Board. A patentee may utilize its patent to preclude the making of medicines by others which are competitive with the patentee's products and thereby enable the patentee to price its products excessively. In this context, the actual use of a patent made

by a patentee, or the ability of the patentee to use the patent to produce commercial quantities of a medicine, represent only two potential benefits of a variety of benefits the patentee may derive from its exclusive rights.

In these circumstances, the Board considers that the broad scope of the language in subsection 79(2) of the *Act* is designed to ensure that, however the exclusive rights attached to a patent might be exercised by a patentee, they will not result in the continuing ability of a patentee to price its products in contravention of the excessive price provisions of the *Act*.

(c) The Board's Mandate

It is important in this regard to note that, contrary to the submission of the Respondents, the *Patent Act* does not require the Board to identify a complete monopoly over a given medicine as a pre-condition to its authority to carry out its mandate. Rather, in all cases in which a patent is intended or capable of being used for medicine or for its preparation and production, the mandate of the Board is to ensure that the price of the medicine is not excessive.

This Board has, since its inception, routinely reviewed the prices of patented medicines where (for example as a result of the presence of a compulsory license or a voluntary license) there is competition in Canada among two or more producers of particular medicines, or where two or more different drugs are close therapeutic equivalents. It has been the Board's experience in reviewing prices in such circumstances that the exclusive rights attached to a patent pertaining to a medicine can have a material effect on pricing even in the absence of a complete monopoly situation.

CONCLUSIONS

During the period expiring March 21, 1995, the Respondents were patentees of the '264 Patent, which gave them the exclusive rights to a process for producing ribavirin, the active and only ingredient in Virazole. The actual use and the commercial usefulness of the '264 Patent are not relevant to the determination of the Board's jurisdiction. Consequently, the Board concludes that the '264 Patent pertains to Virazole.

THE '265 PATENT

The Position of the Respondents

The Respondents have never disclosed the existence of the '265 Patent to the Board. As noted above in the Introduction, a copy of the '265 Patent was obtained by Board Staff on September 26, 1995, the day before the originally scheduled hearing on preliminary matters was to commence.

Before that time Board Staff were not aware of the existence of the patent. Indeed, at a meeting on June 26, 1995 with representatives of the Respondents, Board Staff specifically asked whether there were any patents other than the '264 Patent which pertained to Virazole. Respondents' representatives answered that there were not. The Respondents take the position that, since it is their opinion that the '265 Patent does not pertain to Virazole within the meaning of the *Act*, it was appropriate for them to answer this inquiry in this manner.

The Respondents submitted that, in determining whether the '265 Patent pertains to Virazole, the Board must ascertain whether the claims for the uses of ribavirin in the '265 Patent encompass the uses of ribavirin described in the Notice of Compliance for Virazole. With respect to those claims, the Respondents made reference to the state of the art during the relevant period prior to the application for the '265 Patent with a view to excluding from the claims of the '265 Patent the uses of ribavirin described in the Virazole Notice of Compliance. The Respondents argue that the result of an analysis made on this basis is that the '265 Patent claims, thus properly construed, could not include the uses of ribavirin described in the Virazole Notice of Compliance since they were prior art.

The evidence of the Respondents on this issue was provided primarily in the affidavit of Dr. Biedermann. Dr. Biedermann was qualified as an expert in health sciences research, but acknowledged in cross-examination that he was not medically trained.

Dr. Biedermann's evidence describes the medical and scientific literature pertaining to ribavirin prior to and surrounding the period that ICN applied for the '265 Patent. On the basis of this evidence, the Respondents argue that the uses of ribavirin described in the Virazole Notice of Compliance were "prior art" at the time of the application for the '265 Patent and that, accordingly, whatever the scope of the claims of the '265 Patent might be, they cannot include those uses.

In support of this contention, the Respondents also filed the patent prosecution file for the '265 Patent, which documents the history of the claims originally made for that patent and the patent examiner's objections to the inclusion of prior art in the claims.

The Respondents raise a second issue. The '265 Patent claims a number of medicinal uses for ribavirin. This patent does not describe or claim the substance ribavirin itself, nor a process for making ribavirin. The Respondents argue that the Board's jurisdiction must be based upon an invention pertaining to a medicine, and not a method of using a medicine.

The Position of Board Staff

The evidence of Board Staff on this issue was in the form of the affidavits of Drs. Corrin and Cooper. The focus of argument centred on the evidence of Dr. Corrin. The substance of his evidence was that the claims for the uses of ribavirin asserted in the '265 Patent were identical to or inclusive of the uses of ribavirin described in the Virazole Notice of Compliance.

DISCUSSION

(a) The '265 Patent Claims

As noted above in the discussion concerning subsection 79(2), the Board considers that its jurisdiction is not limited to NOC Drugs, that is, to medicines in respect of which a Notice of Compliance has been issued under the provisions of the *Food and Drugs Act*. Accordingly, it is not necessary for the Board to make a comparison between the claims for the uses of ribavirin in the '265 Patent and the uses of ribavirin described in the Virazole Notice of Compliance in order to make its determination as to whether the '265 Patent pertains to Virazole.

Nevertheless, the Board has considered the evidence and arguments dealing with the comparison proposed by the Respondents, and notes that the evidence of
Dr. Corrin on this point was unambiguous and unshaken on cross-examination. The Board concludes that, despite minor differences in terminology in the Virazole Notice of Compliance and the '265 Patent, a number of the claims for the uses of ribavirin asserted in the '265 Patent are in fact identical to, or inclusive of, the uses of ribavirin described in the Virazole Notice of Compliance.

(b) Construing the '265 Patent Claims

It is the Respondents' position that the '265 Patent must be construed by the Board as excluding certain claims which are described in the Virazole Notice of Compliance. Yet the Respondents have not disclaimed the '265 Patent, nor has the Patent been challenged or qualified in any court of competent jurisdiction. The Board agrees that, as was argued by Board Staff, it is not appropriate for this Board to undertake the task of construing the '265 Patent as suggested by the Respondents.

In this regard, the Board notes that its mandate under the *Act* requires it to have experience and expertise in the pricing of patented medicines. In carrying out that mandate, the Board does not consider that it has either the further mandate or the necessary experience and expertise to review a patent prosecution file, follow the history of the patent claims as they are assessed, revised and then included in the issued patent, review the medical literature extant at the time of

the patent application and then apply the voluminous case law cited by the Respondents with a view to concluding that some or all of the claims in the Patent should be limited in scope or otherwise found to mean something different from what they say.

Nonetheless, based on the evidence and argument presented to it on this issue, it appears clear to the Board that the uses of ribavirin described in the Virazole Notice of Compliance were not part of the prior art relevant to the '265 Patent.

Accordingly, if it were necessary for the Board to come to a conclusion on this issue, the Board would construe the claims in the '265 Patent without any restriction based on the prior art pertinent to the Virazole Notice of Compliance. Thus, as noted above, it is the Board's opinion that the '265 Patent includes claims for ribavirin which are identical to, or inclusive of, the uses of ribavirin described in the Virazole Notice of Compliance.

(c) A Patent for Uses of a Medicine

With regard to the Respondents' argument that a patent for the medicinal use of a medicine is not a patent pertaining to a medicine within the meaning of subsection 79(2) of the *Act*, the Board cannot identify any limitation in the language of the subsection that would narrow its scope in the manner suggested by the Respondents. On the contrary, since in any set of circumstances the Board can conceive of, a medicinal use of a medicine is or would be "intended or capable of being used for medicine", it would appear clear that a patent pertaining to such medicinal use is a patent pertaining to a medicine within the meaning of the subsection.

CONCLUSIONS

For the reasons described above, the Board concludes that the '265 Patent pertains to Virazole because it describes uses for ribavirin, the active and only ingredient in Virazole. Furthermore, if a comparison with the Virazole Notice of Compliance were appropriate, the Board would conclude that the '265 Patent describes and claims uses for ribavirin which are identical to, or inclusive of, the uses of ribavirin described in the Virazole Notice of Compliance.

CONCLUSIONS REGARDING JURISDICTION

In summary, the Board concludes 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.

It remains 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. The timing of the hearing to determine those issues is a matter of some importance to the Board given the complaints which have been received by it about the magnitude of the price increases for Virazole. As noted in the Introduction, the price of a vial of Virazole in September 1993 was $409. The minimum course of treatment with Virazole requires 6 vials so that the cost of a minimum course of treatment at that time was $2,454. The complaints received by the Board indicate that a minimum course of treatment with Virazole has now increased to $9,240. The Board also notes that Virazole is a medicine which is important in the treatment of very young children with certain illnesses which can be fatal.

Accordingly the hearing into the remaining issues to be determined by the Board will commence on January 22, 1996. An Amended Schedule of Events establishing the procedural framework for the hearing is attached.

RELATED MATTERS

Confidentiality

The Respondents sought an order requesting confidentiality for certain information provided to the Board in the course of the hearing on this motion and for certain documents described in the Amended Notice of Hearing. Board Staff did not oppose these requests and the Board finds them to be reasonable given the proprietary nature of the information in question. Accordingly the Board will order that paragraph 10(a) of the Affidavit of Robert Orr, sworn the 6th day of September 1995, and sections 3.2.2.3 to 3.3.3 at pages 558 to 599 of Exhibit "E" to the Affidavit of Dr. Heinz-J Biedermann, sworn the 20th day of October, 1995, shall not form a part of the public record in this proceeding.

Amendment of the Medicine Identification Sheet

In the Medicine Identification Sheet filed by ICN Canada Ltd. on September 15, 1988, pursuant to the *Regulations*, ICN Canada Ltd. identified the '264 Patent as one of the patents which pertained to Virazole. In their Amended Notice of Motion the Respondents sought an order of the Board pursuant to section 6(d) of the Proposed Rules Respecting the Practice and Procedure of the Board amending that document so as to delete the reference to the '264 Patent. The Respondents filed affidavit evidence stating that the reference to the '264 Patent in the Medicine Identification Sheet was an error.

Section 6 provides as follows:

> *In relation to any proceeding, the Board may:*
>
> *(d) permit the amendment of any document issued by or filed with the Board;*

The Board does not consider it appropriate to make the requested amendment to the Medicine Identification Sheet. Rule 6(d) is intended to apply to documents filed during the course of a proceeding. In any event, the Board did not rely on the contents of the Medicine Identification Sheet to reach its conclusions on the Respondents' motion.

Costs

As noted in the Introduction, the request of the Board Staff that the Notice of Hearing be amended necessitated an adjournment of the Respondents' motion. The Respondents sought their costs of the first appearance. The Board does not consider it appropriate to make any order as to costs on this motion.

Sylvie Dupont-Kirby
Secretary to the Board

November 30, 1995