Court No. T-2541-95

IN THE MATTER OF an application for Judicial Review pursuant to Section 18.1 of the *Federal Court Act* and the jurisdiction of the Patented Medicine Prices Review Board established by Section 91 of *The Patent Act;*

BETWEEN:

ICN PHARMACEUTICALS, INC.
and ICN CANADA LIMITED

Applicants

- and -

THE STAFF OF THE PATENTED MEDICINE PRICES REVIEW BOARD,
THE ATTORNEY GENERAL OF CANADA and
THE MINISTER OF CONSUMER AND CORPORATE AFFAIRS

Responmdents

- and -

THE PATENTED MEDICINE PRICES REVIEW BOARD

Intervenor

REASONS FOR ORDER

CULLEN, J.:

This is an application by ICN Pharmaceutical Inc. and ICN Canada Limited ("the applicants") for judicial review of a decision made by the Patented Medicine Prices Review Board ("the Board"), dated November 30, 1995. The matter came on for hearing before me on January 29, 30, and 31, 1996.

With consent of the parties, the style of cause is amended such that the respondents are the Staff of the Patented Medicines Prices Review Board, the Attorney General of Canada, and the Minister of Consumer and Corporate Affairs, and the Patented Medicine Prices Review Board is changed to be an intervenor. I also note that the respondent Ministers took no part in these proceedings and hereafter the Staff of the Patented Medicine Prices Review Board will be referred to as the respondent.

THE PATENTED MEDICINE PRICES REVIEW BOARD

Given that this is the first case considering the Board's jurisdiction and, indeed, one of the first cases concerning the Board before this Court, I have set out the legislative history and framework within which the Board operates.

The Patented Medicine Prices Review Board was established through the 1987 amendments to the *Patent Act*.[1] Under the Act, the Board is responsible, *inter alia*, for ensuring that prices being charged in Canada for patented medicines are not, in the opinion of the Board, excessive.

The history of the Board is set out in the decision of *Re Manitoba Society of Seniors Inc. v. Canada* (*Attorney General)* (1991), 35 C.P.R. (3d) 66 at 69-71 (Man. Q.B.), aff'd (1992), 45 C.P.R. (3d) 194 (Man. C.A.), to which I was directed by counsel for the applicants. Given that this Court has not been called upon to review many decisions of the Board, I have decided to reproduce Mr. Justice Dureault's summary in its entirety:

> A brief historical review of the patent legislation affecting medicines will be found relevant to the circumstances under which the impugned provisions were enacted. The *Patent Act*, S.C. 1923, c. 23, s. 17 allowed for compulsory licenses to be granted for the manufacture, use, and sale of patented processes. Up until 1969, when the 1923 Act was amended (S.C. 1968-69, c. 49) to permit compulsory licenses to import patented pharmaceutical products, few applications for compulsory licenses were made. Subsequent to the 1969 amendment, however, 559 licenses to import and sell have been applied for; of these, 306 have been granted, 15 have been refused or terminated, 96 have been abandoned or withdrawn, and 142 were still pending as of January 31, 1985. (See H.C. Eastman, *Report of The Commission of Inquiry on the Pharmaceutical Industry* (1985) 1-2.)
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> The 1969 amendment resulted in the licensing of brand name patented products by generic firms which then produced and marketed their own brand or copy of the patented medicine. Compulsory licensing to import medicines resulted in increased competition by generic firms against patent-holding firms. This competition was further encouraged by the provincial policy of generic substitution under their respective pharmacare plans. The result has been the growth of large and profitable Canadian-owned generic pharmaceutical firms, which in turn led to lower prices. Needless to say, this aspect of compulsory licensing permitting a competitor (generic firm) to import and produce a copy of the patent holder's product (brand name) has been the object of intense political lobbying by the patent-holding firms. There was no such thing as patent exclusivity for an invention of medicine. Indeed an applicant could apply for a compulsory license immediately upon the grant of the patent.
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> Restoration of patent exclusivity and revocation of compulsory licensing for patented medicine had for some time been the elusive goal of the patent-holding firms. Reacting to the pharmaceutical lobby, the government appointed Dr. H.C.

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[1] S.C. 1987, c.41.

> Eastman as Commissioner to inquire into and report upon the then current situation in the pharmaceutical industry in Canada. The Commissioner's report was submitted on February 28, 1985.
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> The government's response to the Eastman report was the introduction in Parliament of Bill C-22, entitled *An Act to amend the Patent Act and to provide for certain matters in relation thereto*, 33rd Parl., 2nd Sess. (1986). It was given first reading on November 7, 1986. The Bill, following its usual legislative route including several references to both the House of Commons Legislative Committee and the Special Committee of the Senate, was eventually passed by Parliament and received Royal Assent on November 19, 1987 (See S.C. 1987, c. 41, also R.S.C. 1985, c. 33 (3rd Supp.))
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> It is widely acknowledged that s. 14 of Bill C-22 created a new regime of patent exclusivity applicable to medicines. The amending provisions were designed to give back some measure of patent exclusivity to the brand name firms. While compulsory licensing was retained, it carried with it a prohibition from exercising any rights obtained under the compulsory license for periods varying generally from seven to ten years.
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> Patents in respect of medicine, as for any other patent, are issued for 17 or 20-year terms. What is exceptional about these patents, however, is the provision for their immediate compulsory licensing. The new regime does not change this unique provision. It merely prohibits a licensee from exercising the rights given under the license for a particular period of time. In other words, a monopoly is created for the patent holder for the period during which the licensee is prohibited from working the patent.
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> Under this limited monopoly, it was recognized that the price of new medicines would be introduced and maintained at higher levels than otherwise would be the case with competition under compulsory licensing. The increased financial return to the brand name firm was expected to encourage pharmaceutical research and development in Canada. From the government's standpoint, growth of this industry with enhanced employment opportunities was considered to be a desirable objective. On the other hand, legitimate concerns arose that, from the consumer's standpoint, prices might escalate to unacceptable levels during the exclusivity period. To counteract this mischief, the impugned amending provisions were also linked to a regulatory scheme to be administered by the Board referred to earlier.
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> The Board's main regulatory function is to monitor and review prices at which these new patented medicines are being sold. It is charged with the responsibility of requiring new patentees of medicines to provide information and documents with respect to a patented medicine, the selling price of the medicine, and the cost of making and marketing the medicine.
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> If the Board concludes that the medicine is being sold at a price it determines to be excessive, it can order remedial action. Moral suasion by threat of public disclosure is one of the options open to the Board or it can take the form of lifting the prohibition against a licensee in respect of the medicine in question and/or in respect of one other patent for medicine held by that firm. The result is loss of the monopoly for that or one additional patent. It may, as an alternative, direct the patent-holding firm to reduce the price of that medicine to such an extent the Board would no longer find excessive. It is further noted that, for the enforcement of its orders, the Board is clothed with the powers of a superior court (see s. 39.23(4) of the amended 1985 Act). This last measure has generated much argument, particularly the right to enforce its orders through the contempt power. Without deciding if the Board can avail itself of this last remedy, it is my view that, even if it did, it is not determinative of the issue to be decided.

As explained by Mr. Justice Dureault, the Board has considerable powers. Pursuant to sections 80, 81, 82, and 88, a patentee is required to disclose information to the Board about its patented medicines: the identity of the medicines, prices, costs or marketing and making the

medicine, and so forth. However, as pointed out by counsel for the respondent, the Board does not have investigative powers to determine, for example, if the patentee is actually using a particular patent to produce a medicine.

Based on the information obtained from the patentee, the Board has authority to determine whether the prices charged for the medicine are excessive. Subsection 83(1), which gives the Board power with respect to excessive pricing, reads 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.

The reference in subsection 83(1) to an "invention pertaining to a medicine" is discussed in subsection 79(2) of the *Patent Act*. Subsection 79(2) provides that 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 proper interpretation of this phrase, in the context of subsection 83(1), is at issue in the case at bar.

THE DECISION OF THE PATENTED MEDICINE PRICES REVIEW BOARD

By Amended Notice of Hearing dated September 28, 1995,[2] the Board gave notice that it would hold a hearing, the purpose of which was "to determine whether, under sections 83 and 85 of the *Patent Act* ("the Act"), the respondents [the applicants herein] are selling and/or have, while patentees, sold the medicine known as Virazole 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." In response to the amended notice of hearing, the applicants (the respondents before the Board) brought an Amended Notice of Motion before the Board,[3] seeking an order that the Board is without jurisdiction to investigate, hold hearings or make any Order in relation to the medicine Virazole.

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[2]The Amended Notice of Hearing is found in the Applicants' Application Record, volume IV, tab 28.

[3]The Notice of Motion is found in the Applicants' Application Record, volume III, tab 16.

The Board found that five Canadian patents pertain to Virazole; however, three have expired and only two remain at issue in the case at bar. Canadian Patent No. 1,028,264 ("the '264 Patent") was granted to ICN Pharmaceuticals Inc. on March 21, 1978 and expired on March 21, 1995. The '264 Patent describes an enzymatic process for preparing ribavirin, the active ingredient in the medicine which the applicants sell under the name "Virazole." Canadian Patent No. 1,261,265 ("the '265 Patent") was granted to Viratech Inc. (a predecessor of ICN Pharmaceuticals Inc.) on September 26, 1989 and will expire on September 26, 2006. The '265 Patent pertains to various methods of medical treatment utilizing ribavirin.

The applicants (the respondents before the Board) submitted that neither the '264 Patent nor the '265 Patent pertained to Virazole within the meaning of the *Patent Act* and, accordingly, the Board was without jurisdiction to make any order in relation to Virazole. By decision dated November 30, 1995, however, the Board concluded that both patents pertained to Virazole and it had jurisdiction.[4]

I note that in its decision, the Board also made reference to the applicants' supply of ribavirin in capsule form pursuant to the Emergency Drug Release Programme ("the EDRP"). Counsel for the applicants strongly objected to this portion of the Board's judgment, noting that an NOC has not been issued for ribavirin in the EDRP dosage and form. In my view, the reference to the EDRP is a red herring. The Board considers the EDRP under the heading "Virazole and its Recent Pricing History" and, in the end, the EDRP was irrelevant to the question of whether the '264 and '265 Patents were intended or capable of being used for medicine or for the preparation or production of medicine.

ISSUE

The question before this Court is whether the Board correctly decided that it had authority to consider whether the prices that the applicants charged for ribavirin, under the brand name Virazole, are excessive. The answer to that question flows from a determination as to whether either or both of the applicants' '264 and '265 Patents are "intended or capable of being used for medicine or for the preparation or production of medicine" within the meaning of subsection 79(2) of the *Patent Act*.

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[4]The Board's decision is found in the Applicants' Application Record, volume VIII, tab 42.

STANDARD OF REVIEW

As a preliminary matter, counsel for the Board raised the question is the appropriate standard of review, arguing that regardless of the standard, the Board's decision was correct.

Counsel directed me to *U.E.S., Local 298 v. Bibeault*, [1988] 2 S.C.R. 739, in which the Supreme Court stated that a reviewing court should ask the question, "Did the legislator intend the question to be within the jurisdiction conferred on the tribunal?" If the answer to that question is "Yes," the Board's decision is entitled to curial deference unless it is patently unreasonable. The respondent submits that the Board is a specialized tribunal and Parliament intended it to make the determinations which are in issue in this proceeding.

The applicants directed this Court to a more recent Supreme Court of Canada decision concerning standard of review: *Pezim v. British Columbia (Superintendent of Brokers)*, [1994] 2 S.C.R. 557. In this case, Mr. Justice Iacobucci advocated a "spectrum" analysis at 589-591:

> From the outset, it is important to set forth certain principles of judicial review. There exist various standards of review with respect to the myriad of administrative agencies that exist in our country. The central question in ascertaining the standard of review is to determine the legislative intent in conferring jurisdiction on the administrative tribunal. In answering this question, the courts have looked at various factors. Included in the analysis is an examination of the tribunal's role or function. Also crucial is whether or not the agency's decisions are protected by a privative clause. Finally, of fundamental importance, is whether or not the question goes to the jurisdiction of the tribunal involved.
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> Having regard to the large number of factors relevant in determining the applicable standard of review, the courts have developed a spectrum that ranges from the standard of reasonableness to that of correctness. Courts have also enunciated a principle of deference that applies not just to the facts as found by the tribunal, but also to the legal questions before the tribunal in the light of its role and expertise. At the reasonableness end of the spectrum, where deference is at its highest, are those cases where a tribunal protected by a true privative clause, is deciding a matter within its jurisdiction and where there is no statutory right of appeal. See *Canadian Union of Public Employees, Local 963 v. New Brunswick Liquor Corp.*, [1979] 2 S.C.R. 227; U*.E.S., Local 298 v. Bibeault*, [1988] 2 S.C.R. 1048, at p. 1089 (*Bibeault*), and *Domtar Inc. v. Quebec (Commission d'appel en matiere de lesions professionnelles)*, [1993] 2 S.C.R. 756.
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> At the correctness end of the spectrum, where deference in terms of legal questions is at its lowest, are those cases where the issues concern the interpretation of a provision limiting the tribunal's jurisdiction (jurisdictional error) or where there is a statutory right of appeal which allows the reviewing court to substitute its opinion for that of the tribunal and where the tribunal has no greater expertise than the court on the issue in question, as for example in the area of human rights. See for example *Zurich Insurance Co. v. Ontario (Human Rights Commission)*, [1992] 2 S.C.R. 321; *Canada (Attorney General) v. Mossop*, [1993] 1 S.C.R. 554, and *University of British Columbia v. Berg*, [1993] 2 S.C.R. 353.

The applicants urged this Court to find that the Board's decision fell into the "correctness" end of the spectrum. While there is no statutory right of appeal under the *Patent Act*, decisions of the Board are not protected by a privative clause and the case at bar concerns the interpretation of a provision limiting the Board's jurisdiction.

I have no difficulty finding that the Board is an expert tribunal. Parliament has created an appointment mechanism to ensure that the Board is composed of members who are knowledgeable about the pharmaceutical industry. Section 92 of the *Patent Act* provides that the Minister establish an advisory panel, composed of representatives of the provincial ministers of health, representatives of the pharmaceutical industry, and consumer advocates. The Minister is further obliged to consult this advisory panel before making an appointment to the Board. This expert nature indicates curial deference should be in order. However, the issue to be determined on judicial review is clearly a question of jurisdiction. While this Court can consider from a "functional and pragmatic" perspective whether Parliament intended a certain question to be within the Board's jurisdiction, in the end, the Board must answer that key question correctly or risk being overturned by the reviewing court. In my view, on the jurisdictional issue of whether the '264 and '254 Patents are "intended or capable of being used for medicine or for the preparation or production of medicine" within the meaning of subsection 79(2) of the *Patent Act*, the standard of review is correctness.

THE '264 PATENT

In the case of the '264 Patent, the applicants submit that the evidence is clear that the method of the '264 Patent is neither intended nor capable of being used for medicine or for the preparation or production of medicine because it is a research and development process. Thus, there is, no exclusionary right flowing from the '264 Patent which could conceivably give rise to excessive prices flowing from the claims of the '264 Patent.

The affidavit of Robert Orr,[5] submitted by the applicants, asserts that the applicants were the holders of Canadian Letters Patent No. 997,756 ("the '756 Patent") which expired on September 28, 1993. This patent described a process of making ribavirin and, according to the

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[5]The Orr affidavit is found in the Applicants' Application Record, volume III, tab 17.

affiant, was the process which was and is actually utilized for making the Virazole sold in Canada. The affiant further stated that the '264 Patent, which also describes a process for making ribavirin, is irrelevant to the medicine Virazole being marketed in Canada by the applicants. At paragraph 31 of his affidavit, the affiant summarizes why it would be impossible, in the practical sense, to the process of the '264 Patent to make virazole:

> (a) The world-wide supply of ribose-1-phosphate [one of chemical substances required to make ribavirin] is insufficient to produce a single dose of the medicine Virazole;
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> (b) Ribose-1-phosphate is unstable and must be stored at 0 to -18C. It would be very difficult to handle, and very costly to store, if it were available in sufficient quantities for the industrial scale reaction suitable for the preparation or production of actual dosage forms of the medicine Virazole;
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> (c) If ribose-1-phosphate were available in sufficient quantities, the cost of U.S. $4.9 million for one 20 kilogram batch [the amount of ribavirin necessary to produce sufficient quantities of Virazole in Canada for one year], would be prohibitive (i.e., would exceed the market value of the final dosage forms of the medicine Virazole);
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> (d) The cost of the nucleoside phsphoylase enzyme raw material [the catalyst for reacting the two chemical compounds used to produce ribavirin], at approximately U.S. $63 million, would be prohibitive (i.e., it would vastly exceed the market value of the dosage forms);
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> (e) The reaction vessel required for the industrial scale reaction of approximately 3,000,000 litres required to produce 20 kilograms is beyond the scope of what is available.

The evidence of Mr. Orr is supported by the affidavit of Dr. Howard Cottam,[6] also submitted by the applicants. At paragraphs 6 and 7 he states:

> 6. After having reviewed the details of the process described in the '264 Patent, it is my opinion that this process as described is suitable and practical for only small scale preparation of the nucleoside; that is, in amounts that are typically considered as research laboratory scale as opposed to industrial scale amounts. The '264 Patent, in my opinion, teaches only the process of preparation of nucleoside using the purified enzyme, and base and sugar mentioned in the patent, only on a milligram scale and does not teach a method for its large scale preparation. A milligram scale is not suitable for the preparation of even a single dose of medicine.
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> 7. It is my further opinion that if one were to attempt to use this process on a large scale, that is, in amounts useful for pharmaceutical application (i.e., kilogram amounts), the total cost would certainly be prohibitive due to the cost and limited availability of the enzyme and sugar materials. Indeed, this process, in my opinion, cannot be used for even the preparation of gram quantities of nucleoside; that is, in amounts necessary to provide for a single pharmaceutical dose of the substance which is about 6 grams.

The evidence of Mr. Orr and Dr. Cottam is not disputed by the respondent. Rather, counsel for the respondent argues that, on its face, the '264 Patent is an invention for the preparation of medicine and, secondly, it is an invention that is capable for being used for the

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[6]The Cottam affidavit is found in the Applicants' Application Record, volume III, tab 18.

preparation of medicine. Limiting the meaning of the phrase "intended or capable of being used for medicine or for the preparation or production of medicine" in the manner suggested by the applicants would be contrary to the plain and ordinary meaning of subsection 79(2). There is nothing in the subsection which would limit its application to situations where the invention is in fact being used. Indeed, the Board has no power to investigate and determine whether a patent is being actually used; if the Court adopts the applicants' definition, the jurisdiction of the Board could easily be circumvented by a patentee simply claiming that it was not using a particular patent.

Furthermore, the respondent submits that there is nothing in subsection 79(2) which would suggest that "capable of being used for medicine or for the preparation or production of medicine" should be interpreted to mean "capable of being used for medicine or for the preparation or production of medicine in quantities which the patentee deems to be commercially feasible." The applicants are advocating that this Court "read in" words which Parliament never included in the statute.

While I accept that the applicants' evidence that the '264 Patent cannot be worked, at this point in time, to create suitable quantities of ribavirin and was not intended by the patentee to be used to create industrial quantities of the ribavirin, I do not accept the applicants' submissions that the '264 Patent is not capable of preparing the medicine. The word "capable," in the context of the *Patent Act*, should not be given a meaning that is akin to "commercially feasible" or "reasonably practicable."

Sections 79 to 103 of the *Patent Act*, creating the Patented Medicine Prices Review Board, were enacted in response to the abolition of the compulsory licensing regime. Parliament's intent was certainly to address the "mischief" that the patentee's monopoly over pharmaceuticals during the exclusivity period might cause prices to rise to unacceptable levels. Accordingly, the words of these sections of the *Patent Act* should be read purposively, acknowledging that the Board has jurisdiction over all patents that are either intended or capable of preparing or producing a medicine, and not only those that the patentee insists that it is using or deems to be feasible. To adopt such a restrictive interpretation would not mesh with the legislative scheme which does not provide the Board any powers to investigate a patentee's conduct or actual use of a patent. Effectively, a patentee could avoid the Board's jurisdiction

simply by asserting that it is not using a patented process because it is commercially infeasible or that the raw materials are not available; the Board, without investigative powers, would be bound by this assertion.

That is not to say that the applicants in the case at bar are purposely seeking to avoid the Board's jurisdiction. As already mentioned, I accept their evidence that the process described by the '264 Patent was not and is not being used to produce the ribavirin used in Virazole. Parliament may not have had their particular situation in mind when drafting the subsection 79(2); however, this Court, and the applicants, are bound by the clear meaning of the phrase "intended or capable of being used for medicine or for the preparation or production of medicine." The '264 Patent is capable of being used for the preparation or production of ribavirin within the meaning of subsection 79(2) and, accordingly, is within the jurisdiction of the Board. That being said, it would be open to the Board to conclude that the applicants are not selling the medicine in Canada within the meaning of subsection 83(1) of the *Patent Act*. Such a finding, however, is best left to the Board adjudicating this matter on its merits.

THE '265 PATENT

The applicants submit that in order to find that the '265 Patent is intended for the preparation or production of medicine, there must be some rational connection between the claims of the '265 patent and the use or approved indications for Virazole and the claims in the patent. However, in the case at bar, the claims of the patent, properly construed, are not rationally related to the medicine Virazole being sold in Canada.

The applicants directed this Court to certain claims in the '265 Patent which refer to the invention as a formulation for the treatment of respiratory syncytial viruses in immunocompromised patients or in patients with severe combined immune deficiency syndrome. According to the applicants, the words "immunocompromised" and "severe combined immune deficiency syndrome" are key elements to the patent claims. However, the Virazole product monograph, which is included by the Health Protection Branch as a part of the Notice of Compliance for a New Drug Submission, does not mention these key words. Rather, the product monograph refers only to "immune deficiency" and "severe combined immune deficiency disease."

According to the evidence of Dr. Heinz-Joachim Biedermann,[7] submitted on behalf of the applicants, the information disclosed in the product monograph for Virazole was available over two years before the '265 Patent was issued. Dr. Biedermann makes particular reference to two articles by Hall[8] and Gelfand[9]; both articles refer to ribavirin as a treatment for "immune deficiency" and "severe combined immune deficiency disease." Based on this information, Dr. Biedermann concludes that "immune deficiency" and "severe combined immune deficiency disease" must mean something different than "immunocompromised" and "severe combined immune deficiency syndrome," otherwise the '265 Patent would be anticipated or rendered obvious by the prior art and *prima facie* invalid. The applicants submit that such an approach would run contrary to the purposive approach to claim construction which is to construe the patent so as to allow the patentee protection for that which he has invented.

In summary, the applicants submit that the claims in the '265 Patent do not pertain to Virazole as it is being sold in Canada. Virazole is authorized for sale for use in patients with immune deficiency and for severe combined immune deficiency disease, while the patent itself describes uses for immunocompromised patients and for the treatment of severe combined immune deficiency syndrome. There is no rational nexus between the '265 Patent and the product monograph and NOC for Virazole and, accordingly, the '265 Patent is not intended to be used for medicine or for the preparation or production of medicine.

The respondent, however, counters the applicants' submissions, primarily relying on the affidavit evidence of Dr. Raymond Corrin.[10] Although the applicants sought to impeach Dr.

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[7]The Biedermann affidavit is found in the Applicants' Application Record, volume VI, tab 35.

[8]Hall CB, McBride JT, Walsh EE, Bell D. et al. *Aerosolized ribavirin treatment of infants with respiratory syncytial viral infection.* New England Journal of Medicine 308:1443-7, 1983.

[9]Gelfand EW, McCurdy D. Rao DP, Middleton PJ. *Ribavirin treatment of viral pneumonitis in severe combined immunodeficiency disease*. Lancet ii: 732-733, 1983.

[10]The Corrin affidavit is found in the Applicants' Application Record, volume VII, tab 38, as exhibit "A" to the affidavit of Laura Reinhard.

Corrin's credentials, implying he had no specialized training in immunology or virology, I note that Dr. Corrin is a medical doctor, employed at the Ottawa General Hospital in the Immunodeficiency Clinic where he treats patients with immunodeficiencies, primarily AIDS. According to the affiant, the claims in the patent are identical to the uses approved in the NOC for Virazole. It was his evidence that while the words "immunocompromised" and "immune deficiency," and "severe combined immune deficiency disease" and "severe combined immune deficiency syndrome" are different, their meanings are the same. This evidence was unshaken on cross-examination.[11]

The respondent also pointed out that the Gelfand and Hall articles, contrary to the applicants' submissions, are dated less than two years prior to the patent application. The application for the '265 Patent was filed on May 7, 1985 and, under subsection 27(1) of the *Patent Act* as it then read, the invention must not be published two years prior to application; May 7, 1983 would, therefore, be the critical date. However, the New England Journal of Medicine article by Hall is dated June 16, 1983 and the Lancet article by Gelfand is dated September 24, 1983. I note that the applicants asserted that the Gelfand article was presented at a conference and, hence, published in March 1983, in addition to the subsequent publication in Lancet. Given my conclusions concerning the Board's jurisdiction over the '265 Patent, I find it unnecessary to resolve the dispute over publication dates.

The respondent's most convincing argument, and one on which the Board relied, is that the Board would exceed its jurisdiction if it was asked to construe the claims of the patent. At page 17 of its decision, the Board stated:[12]

> ... the Board notes that its mandate under the *[Patent] 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 [the applicants before this Court] with a view to concluding that

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[11]The examination, cross-examination and re-examination of Dr. Corrin are found in the transcript of the Board's hearing on November 2, 1995, in the Applicants' Application Record, volume VIII, tab 40, at pages 1179 to 1245.

[12]*Supra*, footnote 4, at page 1453.

> 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.

Counsel for the respondent urged me to follow the Board's lead, noting that the Court, in the context of this judicial review, should not be asked to construe the claims of the '265 Patent.

This Court is faced with a "battle of the experts," with both Dr. Biedermann and Dr. Corrin asserting different propositions. On judicial review, it is particularly difficult to choose one affiant's version of the evidence over that of the other. In the end, I have decided that such a choice is not necessary. Whether "immunocompromised" and "immune deficiency," and "severe combined immune deficiency disease" and "severe combined immune deficiency syndrome" have synonymous or differing meanings is irrelevant if I conclude that the '265 Patent is intended for the preparation or production of a medicine. Having carefully considered the evidence, I have concluded that there is no argument that the '265 Patent comprises uses for ribavirin and that ribavirin is, indeed, a medicine.

"Medicine," in the context of subsection 79(2) of the *Patent Act*, should not be interpreted to mean only the drug as described in the product monograph and for which an NOC has been issued, contrary to the applicants' submissions. The applicants urged this Court to conclude that "medicine" should be given the same definition as under the *Patented Medicines (Notice of Compliance) Regulations* since both the NOC Regulations and the Board were created to replace the compulsory licensing regime. Under the *Patented Medicines (Notice of Compliance) Regulations*, "medicine" is defined as "a substance intended or capable of being used for the diagnosis, treatment, mitigation or prevention of a disease, disorder, or abnormal physical state, or the symptoms thereof." However, I do not accept the applicants' submissions. In my view, the term "medicine" in the context of subsection 79(2) should be given the same interpretation as it was given under the former compulsory licensing provisions of the *Patent Act*. The language of subsection 79(2) is lifted from subsection 39(4) of the "old" *Patent Act* dealing with compulsory licensing; both use the phrase "intended or capable of being used for medicine or for the preparation or production of medicine." This phrase has a far broader meaning than the restrictive definition of "medicine" in the *Patented Medicines (Notice of Compliance) Regulations* and includes all medicines, not only those sold pursuant to an NOC.

It is my conclusion that the Board was correct in finding that it should not go beyond the face of the patent and construe the claims to determine if they corresponded to the NOC for Virazole. On its face, the '265 Patent is intended for the preparation or production of medicine and that finding, alone, establishes the Board's jurisdiction. However, as I stated with respect to the '264 Patent, it would be open to the Board, when considering the merits of this case, to find that the applicants are not selling the medicine Virazole in Canada, pursuant to subsection 83(1) of the *Patent Act*.

THE DISCLAIMER

Subsequent to the hearing and decision by the Board, the applicants filed a disclaimer with the Patent Office in connection with the '265 Patent; the Patent Office confirmed this filing on December 6, 1995. The Patent Office confirmed that the applicants disclaimed the following part of the '265 Patent:

> 1. A formulation for, and the use of, the chemical compound 1-_-D-ribofuranosyl-1,2,4-triazole-3-carboxamide (ribavirin) (supplied in 100 ml. glass vials of 6 grams of sterile lyophilized powder of ribavirin) for the treatment of severe Respiratory Syncytial virus infection in neonates and infants when associated with underlying cardiovascular, pulmonary or immune deficiency.
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> 2. Under independent Claims 1, 11, 17, 18, or 19 of the Patent and the dependent claims thereof, any formulation containing the chemical compound 1-_-D-ribofuranosyl-1,2,4-triazole-3-carboxamide (ribavirin) (supplied in 100 ml. glass vials of 6 grams of sterile lyophilized powder of ribavirin) for the treatment of Respiratory Syncytial Virus in neonates and infants with underlying cardiovascular, pulmonary or immune deficiency.
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> 3. Under independent Claim 20 and the dependent claims thereof, the use of the chemical compound 1-_-D-ribofuranosyl-1,2,4-triazole-3-carboxamide (ribavirin) for the manufacture of a pharmaceutical composition and compositions for the medical treatment of viral diseases, characterized in the composition and compositions are for use in neonates and infants for the treatment of viral disease caused by Respiratory Syncytial viruses in neonates and infants with underlying cardiovascular, pulmonary or immune deficiency.

The applicants submit that the Board, subsequent to the December 6, 1995 filing date, is without jurisdiction to deal with the '265 Patent since the disclaimer specifically disclaims any claims to any invention in relation to the indications for which Virazole is approved for sale in Canada.

The respondent, however, submits that the disclaimer is without force and effect for three reasons. First, even if the disclaimer is valid, the Board's authority would not terminate because the invention disclosed by the '265 Patent continues to pertain to ribavirin with the meaning of subsection 79(2) of the *Patent Act*. Given my conclusion on the meaning of "medicine" in the context of that subsection, I am in agreement with the respondent's submission.

As discussed under the heading "The '265 Patent", *supra*, I am satisfied that this patent disclosed uses and is intended to be used in the preparation or production of medicine, including medicines which are not available for sale pursuant to an NOC.

Since I have concluded that the Board's jurisdiction is not terminated by the disclaimer, there is no need to address the respondent's second and third submissions. However, in the interest of completeness, I will do so briefly.

The respondent also submits that the disclaimer does not affect the Board's authority because it does not comply with section 48 of the *Patent Act* and was filed for the improper purpose of seeking to avoid the Board's authority. Subsection 48(1) of the Act provides for the filing of a disclaimer to narrow a patent claim when a patentee has made a specification too broad "by mistake, accident or inadvertence, and without any wilful intent to defraud or mislead the public." The respondent claims that the applicants' sole motivation in filing the disclaimer is to avoid the jurisdiction of the Board. That may indeed be the applicants' intention and I can see nothing objectionable in such an action. A patentee, if he so chooses, can forsake his monopoly and organize his affairs so as to avoid price regulation by the Board. However, in the case at bar, the disclaimer does not change the fact that the '265 Patent continues to be an invention intended for medicine and, accordingly, it remains in the Board's jurisdiction.

Finally, the respondent submits that the disclaimer has no effect on the Board's authority because is was filed after the Board issued its Notice of Hearing and after it had rejected the applicants' challenge to its jurisdiction. Subsection 48(4) of the *Patent Act* provides:

> No disclaimer affects any action pending at the time when it is made, unless there is unreasonable neglect or delay in making it.

I am in agreement with the respondent's submissions on this point, however, if this were the sole ground of argument, I would have addressed the question of the validity of the disclaimer nonetheless, to provide some guidance and direction to the Board. In any event, I am satisfied, for the reasons already mentioned, that the disclaimer is invalid and does not otherwise affect the jurisdiction of the Board.

CONCLUSIONS

After having read the documents and evidence filed and considered the able submissions of counsel, I have determined that:

(1) the word "capable" in subsection 79(2) of the *Patent Act* must be given its plain and ordinary meaning; accordingly, the '264 Patent is capable of being used for the preparation or production of the medicine, ribavirin, and is within the jurisdiction of the Board;

(2) the word "medicine" in subsection 79(2) of the *Patent Act* includes all medicines and is not limited to drugs for which an NOC has been issued; accordingly, the '265 Patent is intended to be used for the preparation or production of the medicine, ribavirin, and is within the jurisdiction of the Board; and

(3) the Board's authority is not terminated by the disclaimer filed by the applicants on December 6, 1995 because the invention disclosed by the '265 Patent continues to pertain to ribavirin with the meaning of subsection 79(2) of the *Patent Act*.

The application for judicial review, as well as the within motion concerning the validity of the disclaimer, are dismissed.

OTTAWA B. Cullen

February 15, 1996 J.F.C.C.