Date: 20051117

Dockets: T-1576-99
T-1671-00

Citation: 2005 FC 1552

Ottawa, Ontario, November 17, 2005

PRESENT: THE HONOURABLE MADAM JUSTICE HENEGHAN

BETWEEN:

HOECHST MARION ROUSSEL CANADA INC.

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

and

PATENTED MEDICINE PRICES REVIEW BOARD

Intervener

REASONS FOR ORDER

INTRODUCTION

[1] Hoechst Marion Roussel Canada Inc. ("HMRC" or the "Applicant") seeks judicial review of two decisions of the Patented Medicine Prices Review Board (the "Board"). The first decision,

dated August 3, 1999 is the subject of cause number T-1576-99. The second decision dated August 8, 2000, is the subject of cause number T-1671-00.

[2] HRMC is the exclusive distributor in Canada of Nicoderm. Nicoderm is an aid to cessation of smoking. It is available in strengths of 7 mg, 14 mg and 21 mg, administered by the continuous delivery of nicotine through the skin into the circulatory system, by means of a patch. This product is manufactured in the United States by Alza Corporation. It is sold in Canada pursuant to a Notice of Compliance ("NOC") issued by Health and Welfare Canada on May 12, 1992.

[3] The Board was established pursuant to the *Patent Act*, R.S.C. 1985, c. P-4, as amended (the "Act"), in 1987. Its mandate is to review the prices of patented medicines. It obtained leave to intervene in these proceedings pursuant to the *Federal Court Rules,1998*, SOR/98-106, as amended, (the "Rules") in these proceedings by Order of Prothonotary Aronovitch dated July 13, 2001. The decision of the Prothonotary, reported as *Hoechst Marion Roussel Canada v. Canada (Attorney General)*, [2002] 1 F.C. 76 was upheld on appeal, aff'd. February 11, 2002 [unreported] (T.D.) aff'd. [2002] F.C.J. No. 1785 (C.A.).

[4] The Attorney General of Canada (the "Respondent") is named as the responding party, pursuant to Rule 303(2) of the Rules.

BACKGROUND

[5] In or about 1986, Alza Corporation commenced a joint venture with Merrell Dow Pharmaceuticals Inc., the predecessor to HMRC, to develop and market a transdermal nicotine patch. A number of agreements were made with Alza Corporation, including the following:

1) a Confidentiality Agreement dated March 21, 1986;
2) an Interim Development Agreement dated January 1, 1987;
3) a Development and Licence Agreement (the "Licence Agreement") dated November 27, 1989, amended October 25, 2995 and November 29, 1995;
4) a Nicotine Patch Supply Agreement (the "Supply Agreement") dated November 27, 1989; and
5) an Interim Development Agreement dated October 5, 1992.

[6] Alza Corporation holds several Canadian patents relating to nicotine patches, as well as a minimum of two outstanding patent applications, as follows:

- Canadian Patent No. 1,331,340 (the " '340 Patent"), a method of prolonging the shelf life of a nicotine transdermal patch, was granted to Alza Corporation on August 9, 1994 and will expire on August 9, 2011;

- Canadian Patent No. 1,333,689 (the " '689 Patent"), a nicotine transdermal patch with a method of controlling the rate of release of nicotine, was granted to Alza Corporation on December 27, 1994 and will expire on December 27, 2011;

- Canadian Patent No. 1,338,700 (the " '700 Patent"), a transdermal patch for the delivery of nicotine through the skin of a user, was granted to Alza Corporation on November 12, 1996 and will expire on November 12, 2013;

- Canadian Patent Application No. 2,032,446 (the " '446 Application"), relating to packaging material for a nicotine transdermal patch, was filed on December 17, 1990 and was laid open on June 22, 1991;

- Canadian Patent Application No. 2,040,352 (the " '352 Application"), a transdermal patch for the delivery of nicotine through the skin of a user, was filed on April 12, 1991 and was laid open on October 17, 1991.

[7] In May 1998, HMRC submitted to the Board a Form 1, dated April 9, 1998, pursuant to the provisions of the *Patented Medicine Regulations*, 1994, SOR/94-688. This was the first time that HMRC had reported Nicoderm to the Board as a patented medicine. HMRC reported that the '700 patent pertains to Nicoderm and that it held a licence other than a licence referred to under section 41 of the Act, as it stood prior to the 1993 amendments. HMRC provided the information that had been required by the Regulations, including reports on prices and sales for the period November 12, 1996 to December 31, 1997.

[8] By letter dated June 12, 1998, Ms. Laura Y. Reinhard, Director of the Board's Compliance and Enforcement Branch, advised HMRC that the Board was investigating the pricing of Nicoderm. HMRC was given the opportunity to present further information before the matter would be referred to Dr. Robert G. Elgin, the Chairperson of the Board. Ms. Reinhard, in her letter, referred to the Board's *Compendium of Guidelines, Policies and Procedures* (the "Compendium") and advised that for the purposes of that document, the price of Nicoderm should not exceed the lower of the maximum non-excessive ("MNE") prices of the comparable strengths of Habitrol and the prices for Nicoderm in the other countries that are listed in the Regulations. Habitrol is the comparable medicine for price review purposes as it is the most similar to Nicoderm.

[9] Ms. Reinhard indicated that, based upon the information provided by HMRC, the price of Nicoderm exceeded the Excessive Price Guidelines (the "Guidelines") of the Compendium during the period November 1996 to December 1997 by amounts varying between 4% and 10.7% and consequently, HMRC had received excess revenues of more than $1,000,000.00. Further, she advised that the price of Nicoderm exceeded the Guidelines prior to November 12, 1996. The Board Staff also concluded that both the '689 Patent and the '352 Application pertain to Nicoderm and that HMRC is a patentee of the '689 Patent for the purposes of the Act.

[10] HMRC responded to this letter on July 21, 1998 and provided additional documentation, including copies of the Licensing Agreement with Alza Corporation and the Supply Agreement. It submitted further material in August 1998, in response to a request from the Board Staff about the

patent status of Nicoderm. This information was considered by the Board Staff, as well as the discussion at a meeting between Board Staff and representatives of the Applicant on July 30, 1998.

[11] On September 21, 1998, Ms. Reinhard wrote a letter advising HMRC of the results of the Board's Staff Investigation into the prices of Nicoderm transdermal nicotine patches. The Board Staff had concluded that the price of Nicoderm exceeded the Guidelines and informed it that a confidential report on the Board's Staff Investigation (the "Staff Report") would be submitted to the Chairperson for consideration. She also advised that HMRC could submit to a Voluntary Compliance Understanding ("VCU"), that is a written proposal that it would adjust the price of Nicoderm. The VCU, if submitted, would be considered by the Chairperson, as well as the Staff Report. The Chairperson is authorized to accept a VCU to resolve pricing issues if satisfied that it meets the statutory objectives and conforms with the policies of the Board.

[12] On March 9, 1999, the Applicant submitted a VCU for consideration by the Chairperson. Nonetheless, the Chairperson determined that a hearing should be held, in the public interest. On April 20, 1999, the Board issued a Notice of Hearing to determine, pursuant to sections 83 and 85 of the Act, whether HMRC, as a patentee, is selling or has sold Nicoderm in Canada at a price that, in the Board's opinion, is or was excessive.

[13] HMRC filed a "Conditional Response" on May 5, 1999, objecting that the Notice of Hearing was deficient because it did not provide sufficient detail to enable it to prepare a response. On May 14, 1999, HMRC sent a letter to counsel for the Board, requesting a summary description of the proposed Order to be made against it.

[14] On May 17, 1999, the Board replied and advised that it would treat the Conditional Response and the May 14th letter as a motion for particulars of the Order to be sought by the Board at the hearing. The Board further noted that HMRC's Conditional Response asserted that the Board lacked jurisdiction to issue the Notice of Hearing. The Board indicated that if HMRC intended to challenge the Board's jurisdiction, it should do so by means of a motion before the Board at the Pre-Hearing Conference scheduled for May 28, 1999.

[15] On May 21, 1999, the Board sent a letter to HMRC, providing full particulars about the Order sought from the Board concerning the matter of excessive pricing.

[16] On May 25, 1999, HMRC filed a notice of motion requesting that the Board rescind its Notice of Hearing. A variety of jurisdictional issues were raised, as follows:

> 5) The Board is without jurisdiction to inquire into the Respondent's pricing of Nicoderm® as Nicoderm® is not a medicine for the purposes of section 83 of the *Patent Act*;
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> 6) The Board is without jurisdiction to inquire into the Respondent's pricing of Nicoderm® as an overlap of Board functions as investigator, prosecutor and adjudicator creates a reasonable apprehension of bias against the Respondent which is not excused at law and is contrary to the principles of fundamental justice and the *Canadian Bill of Rights*;
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> 7) The Board is without jurisdiction as the Notice of Hearing was issued in this case in breach of the principles of natural justice and procedural fairness. The manner in which the Board proceeded by making determinations prior to the issuance of the Notice of Hearing denied the Respondent a reasonable opportunity to be heard and gives rise to a reasonable apprehension of bias;
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> 8) In any event, the Board is without jurisdiction to inquire into the Respondent's pricing of Nicoderm® commencing with the grant of Canadian Patent No. 1,331,340, as the Respondent is not a person entitled to the benefit of that patent nor a person entitled to exercise any rights in relation to that patent. Furthermore, the only patent which pertains to Nicoderm® is Canadian Patent No. 1,338,700 granted on November 12, 1996. Any interpretation of the *Patent Act* that would

> extend the Board's jurisdiction to make orders based on the other patents, or patent applications, identified in the Notice of Hearing would be contrary to sections 91 and 92 of the *Constitution Act, 1867*;
>
> 9) The Notice of Hearing issued by the Board, including the summary of the proposed order subsequently provided, fails to provide the allegations, grounds and material facts in sufficient detail to enable the Respondent to know the case it has to meet. Proceeding on the Notice of Hearing would constitute an abrogation of the Respondent's right to natural justice and procedural fairness and would prevent the Respondent from making a full and proper response thereto;

[17] The Board Panel, consisting of the Board Chairperson and members Réal Sureau, Anthony Boardman and Ingrid Sketis dealt with the motion in two parts. It first addressed the allegations of institutional bias and procedural fairness raised in paragraphs 6, 7 and 9. The Applicant argued that, in consequence of the overlapping functions of the Board as investigator, prosecutor and adjudicator, as well as its manner of proceeding in making decisions prior to the issuance of a Notice of Hearing, a reasonable apprehension of bias was created. As well, the Applicant alleged that the Notice of Hearing lacked sufficient detail for this purpose, thereby breaching its right to procedural fairness.

[18] The Board addressed the second part of the Applicant's motion, dealing with allegations set out in paragraphs (5) and (8), in a separate hearing. The Board's decision on jurisdiction is the subject matter of cause number T-1671-00.

[19] In its first decision on jurisdiction rendered on August 3, 1999, the Board unanimously dismissed the Applicant's allegation of institutional bias, breach of natural justice and lack of particulars in the Notice of Hearing. The Board declined to end the proceedings and to rescind the Notice of Hearing. The Applicant filed its application for judicial review relative to this decision on September 3, 1999.

[20] In its reasons, the Board Panel considered the various allegations raised by the Applicant. It concluded, with respect to the issue of institutional bias, that the Board is an expert tribunal that develops and applies health care policy within the pharmaceutical industry and is the kind of tribunal that Parliament may create with overlapping functions without violating the right to a fair hearing. As well, the Board Panel found that there was no violation of the Applicant's right to a fair hearing such that the Act must be expressly said to apply "notwithstanding" the provisions of the *Canadian Bill of Rights*, S.C. 1960, c. 44, reproduced in R.S.C. 1985, App. III (the "Bill of Rights").

[21] The Board Panel also addressed the Applicant's alternative argument, that the Board had exceeded any overlap authorized by the Act in the manner in which it discharged its statutory obligations. The Board Panel considered some specific submissions raised by the Applicant in this regard.

[22] First, the Board Panel concluded that the Board Staff had conducted an investigation for the purpose of determining if there was a *prima facie* case that there has been excessive pricing. As such, the purpose of Ms. Reinhard's correspondence was to put the Applicant on notice of the findings of the investigation. The Board Panel found nothing inappropriate in the presentation of those findings in unambiguous terms since they were only the allegations of Board Staff and not the conclusions of the Board Panel.

[23] Second, the Board Panel found that the decision of the Chairperson to issue a Notice of Hearing, despite receipt of a VCU from the Applicant, does not represent any conclusion as to the merits of the case to be presented at the hearing. Rather, the issuance of the Notice of Hearing represents the Chairperson's conclusion, as Chief Executive Officer of the Board, that a public hearing would be in the public interest.

[24] Third, the Board Panel concluded that, having regard to the limited purpose of the Chairperson's preliminary review of the confidential Staff Report and the VCU, that is to determine if it is in the public interest to hold a public hearing, no reasonable apprehension of bias will arise from the Chairperson's participation in the Panel conducting the public hearing.

[25] Fourth, the Board found there was no denial of procedural fairness flowing from the Chairperson's decision to initiate a public hearing without receiving the submissions of the Applicant on that matter; that decision only required that the matters in issue be presented and decided in public rather than internally, by the Board alone.

[26] As for the Applicant's allegation about the sufficiency of the Notice of Hearing, the Board found that, for its intended purpose, the Notice of Hearing provided sufficient details from its issuance. As well, the Board Staff agreed that the allegations in Ms. Reinhard's letter of September 21, 1998, except where superseded in the Notice of Hearing by more recent information, should be deemed to be particulars of the Notice of Hearing. That being so, with the further information provided by the Board Staff, the Board Panel concluded that there should be no reason

for the Applicant to delay filing its response within fifteen days of the date of its first decision on jurisdiction.

[27] On December 8, 2000, the Board Staff filed a Notice of Motion seeking to be added as a party, either in its own name or in the name of the Board, pursuant to the Rules. Alternatively, the Board Staff sought leave to intervene. On March 7, 2001, the Board filed a Notice of Motion, seeking to be added as an intervener with limited scope or alternatively, in the event that the Board Staff was denied standing, to intervene with broader rights of participation.

[28] These motions were heard by Prothonotary Aronovitch and by Order dated July 13, 2001, the Board Staff's Motion was dismissed. The Board was granted intervener status for the limited purpose of making submissions upon the record before the Court, to explain the roles of the Chairperson and Board Staff in discharging the Board's dual mandate pursuant to its governing legislation and the Board's rules and policy, but only to the extent that such matters are not addressed by the Respondent Attorney General of Canada.

[29] On June 25, 2003, the Applicant brought a motion, seeking an order for production of documents in the possession of the Board, relevant to the application for judicial review. By Order dated November 14, 2003, the motion was dismissed, on the grounds that there was no basis to enlarge the Tribunal Record, to include the confidential Staff Report that the Board Panel would not refer to in its adjudication of the case on the merits. This decision was upheld on appeal, in *Hoechst Marion Roussel Canada v. Canada (Attorney General)*, [2004] F.C.J. No. 633 (T.D.).

[30] In the meantime, the Board Panel, consisting of the Board Chairperson and the same members heard the second part of the Applicant's jurisdictional challenge in December 1999 and June 2000. That hearing dealt with various issues relating to the statutory guidelines of the Board.

[31] On August 8, 2000, the Board Panel rendered its decision, denying most of the relief sought by the Applicant. The Board declined to terminate the proceedings and to rescind the Notice of Hearing. The Applicant then commenced a second application for judicial review in cause T-1671-00.

[32] In its reasons, the Board Panel addressed the substance of the Board's specialized jurisdiction, beginning with the Applicant's submissions that Nicoderm is not a "medicine" for the purposes of the Act, but rather a delivery device for the administration of nicotine.

[33] The Board Panel rejected this argument. Referring to subsections 83(1) and 79(2) of the Act, the Board Panel noted that the word "medicine" remains undefined, although the Federal Court of Appeal held, in *ICN Pharmaceuticals, Inc. v. Canada (Staff of the Patented Medicines Prices Review Board)*, [1997] 1 F.C. (F.C.A.), that the word "medicine" is to be interpreted broadly and in its ordinary sense, following the practice under section 39 of the former *Patent Act*, S.C. 1923, c. 23 (the "Former Act").

[34] The Board Panel considered the Applicant's arguments that reference should have been made to the decision of the Federal Court of Appeal *Glaxo Group Ltd. v. Novopharm Ltd.* (1999), 244 N.R. 199 ("*Glaxo*") where it was held that a mechanical device known as an "inhaler", used to

administer medicine in aerosol form, was not a medicine within the scope of the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the "NOC Regulations").

[35] The Board Panel concluded that *Glaxo*, *supra* did not assist, based upon the reasoning in *ICN*, *supra* where the Federal Court of Appeal held that the NOC Regulations are part of a separate regime with a distinct purpose. As such, the jurisprudence in interpreting those regulations is not helpful with respect to the Board's jurisdiction. In any event, the Board Panel concluded that in view of the integration of the elements in a transdermal patch, it would not consider a transdermal patch to be analogous to an inhaler. Further, inhalers are considered to be medicines for the purposes of the Board's mandate and in fact, the NOC issued for Nicoderm shows that Health Canada considers Nicoderm to be a drug, not a medical device, and regulates it accordingly.

[36] The Board Panel concluded that the components of the nicotine patch are integrated and integral to the drug product Nicoderm. In this regard, the Board Panel relied upon the expert evidence of Dr. Patrick du Souich, a medical practitioner, professor of clinical pharmacology and a senior medical researcher, who gave evidence on behalf of the Board Staff. He provided the opinion that together, the nicotine and layers of material of which the patch is composed, "generate the 'pharmacodynamic and pharmacokinetic characteristics' that result in Nicoderm having a therapeutic effect", likening the product to an ointment.

[37] The Board Panel also found that there was evidence to show that the Applicant itself refers to Nicoderm as a "medicine" on its labeling and packaging information. As well, it found that the Applicant accepted that Nicoderm was a medicine over which the Board had pricing jurisdiction

when it filed its Form 1 respecting the ’700 Patent. The Board Panel also noted that patentees of other nicotine transdermal patches, including Habitrol and ProStep, have filed Form 1’s and have accepted the Board’s jurisdiction to regulate the price of those patches.

[38] Following the interpretative approach set out by the Federal Court of Appeal in *ICN*, *supra*, the Board Panel observed that Ms. Joan Van Zant, a patent agent who gave evidence on behalf of the Applicant, acknowledged in cross-examination that “if she were a ‘regular person who was not involved in the intellectual property area’, she would consider Nicoderm to be medicine”. Finally, Mr. Robert Gale, inventor of the ’340 and ’700 Patents, agreed that when nicotine is imbedded in the patch, the product Nicoderm, as a transdermal patch, is medicine.

[39] In reaching its conclusion, the Board Panel held that where a substance that has no inherent therapeutic effect, such as nicotine, can become useful as a medicine when it is integrated with other substances and the manner in which those components are integrated is patented, the resulting product, here Nicoderm, is in every pertinent sense a “patented medicine” for the purposes of the Board’s jurisdiction. Accordingly, it found Nicoderm to be a medicine within the meaning of the Act.

[40] Second, the Board Panel considered whether the ’700, ’689 and ’340 Patents pertain to Nicoderm, that is whether there is a rational connection between the invention described in the patent and the medicine itself. In this regard, the Board Panel referred to *ICN*, *supra*, where the Court held there need only be the “merest slender thread” of connection between the patent and the

medicine in order to find that it is a patent pertaining to the medicine, thereby grounding the Board=s jurisdiction over pricing.

[41] The Board Panel noted that with respect to the ’700 Patent the Applicant agreed that it pertains to Nicoderm and as such, the pricing of Nicoderm has been subject to the jurisdiction of the Board since November 12, 1996, when the ’700 Patent was granted.

[42] The Board Panel also addressed the ’689 Patent. The Board Panel concluded that while this Patent describes a product differing from Nicoderm in respect of its rates of release of nicotine following application of the patch, there is still a sufficient nexus between it and Nicoderm to find that it pertains to the medicine, within the meaning of the Act. It recognized that although proof of market power is not determinative in determining the Board’s jurisdiction, in *ICN*, *supra*, the Federal Court of Appeal found that the potential for a deterrent effect, regardless of its actual effect on market power, provides the basis of the Board’s jurisdiction. The Board Panel ultimately concluded that the ’689 Patent pertains to Nicoderm because it pertains to a transdermal nicotine patch, a generic type of medicine of which Nicoderm is a particular example.

[43] With respect to the ’340 Patent, the Board Panel identified the real question as to whether, looking at the face of the patent as instructed by the Federal Court of Appeal in *ICN*, *supra*, there is sufficient reference to a nicotine patch to say that the patch pertains to Nicoderm. The Board Panel considered that the ’340 Patent does pertain to Nicoderm on its face and, in any event, it can be inferred from the language of the patent that the inventors “intended”, within the meaning of subsection 79(2) of the Act, that it would be useful for a nicotine patch.

[44] Third, having concluded that the ’700, ’689 and ’340 Patents all pertain to Nicoderm, the Board Panel proceeded to consider whether the Applicant is a “patentee” of those patents within the meaning of the Act. The Board discussed the various agreements entered into between Alza and the Applicant’s predecessor, Hoechst Marion Roussel (“HMR”). It noted that, pursuant to the Licensing Agreement and the Supply Agreement, Alza had the exclusive right to manufacture the product, subject to an exception in section 8 of the Supply Agreement that where Alza is unable to supply the product, HMR is entitled to manufacture it or to have it manufactured by another supplier. As the Canadian affiliate of HMR, the Applicant enjoys the right of HMR in Canada, pursuant to the Licensing Agreement and the Supply Agreement.

[45] For the purposes of the Board’s jurisdiction, the Board Panel found that the definition of “patentee” is deliberately expanded by subsection 79(1) of the Act to include not only the person entitled to the benefit of the patent, but also any person entitled to exercise rights relative to it. In respect of the ’700 Patent, the Board Panel found that the Applicant had acknowledged that it is a licensee for the purposes of that patent. Accordingly, the Board Panel concluded that the Applicant is a patentee of a medicine that pertains to Nicoderm, for the purposes of the ’700 Patent.

[46] The Board Panel then considered whether the Applicant was a patentee with respect to the ’689 Patent. It concluded that the inclusion of the ’689 Patent in Appendix B strongly favoured its status as a licensed patent and that its inclusion is consistent with the structure of the joint venture and various agreements made between the parties. In particular, the joint venture was an exclusive agreement. As such, Alza did not have the right to develop or market a nicotine patch using the

’689 Patent, other than with HMR. The Board Panel found that if the Applicant were not a licensee of the ’689 Patent pursuant to the Licensing Agreement, it would not be able to protect its market for Nicoderm in Canada. Accordingly, the Board Panel concluded that the Applicant was a patentee with respect to the ’689 Patent.

[47] Turning to the ’340 Patent, the Board Panel noted that it was not developed for Nicoderm or for any nicotine patch but rather to address a particular problem encountered by Alza with crystallization occurring in the liquid scopolamine in patches. The Board Panel ultimately concluded that the parties never intended to licence the ’340 Patent or the technical information it contained, to HMR. The Board Panel found that the exclusion of the ’340 Patent from Appendix B further illustrated that point that the Applicant is not nor has been a patentee of the ’340 Patent.

[48] The Chairperson wrote a dissenting opinion on this point. He found that, in view of the broad terms of the Licensing Agreement, the Applicant had, and has the benefit of the ’340 Patent and is a patentee for the purpose of the Act.

[49] Fourth, the Board Panel considered whether the Applicant has been a “patentee” of the patents for which application has been made in the ’352 and ’446 Applications, from the date on which those applications were laid open to public inspection.

[50] The Board Panel held that the ’352 Application is for a patent constituting the “inline” adhesive used in Nicoderm patches. The ’446 Application is for a patent for the pouch in which

Nicoderm is packaged and sold. The Board Panel found that the inventions described in these two applications pertain to Nicoderm.

[51] In considering whether the Applicant is a "patentee" of these two patent applications, the Board Panel concluded that once the patents are granted, they will be licenced to the Applicant for the marketing of Nicoderm. Both patent applications are listed in Appendix B. Further to the commercial arrangements between Alza and HMR, the Applicant has the rights in Canada that flow from the patent applications including the right to sell nicotine patches that use the inventions described in the two applications. As such, the Board Panel concluded that the Applicant is a "patentee" for the purposes of the '352 and '446 Applications.

[52] Fifth, the Board Panel considered whether the Board has jurisdiction on the basis of patent applications, prior to the issuance of any patent to the Board Panel. First, it concluded that while not dispositive, the payment of royalties by HMR at the higher rate under the licence agreement shows that Alza and HMR considered HMR to have patent protection in Canada from the beginning of the sale of Nicoderm in Canada in 1992. The Board Panel found this to be strong evidence of the extent to which the laid-open process provides *de facto* patent protection.

[53] The Board Panel went on to note that the laid-open patent application process creates the potential for patent applicants to charge excessive prices for medicines during the period between the laying-open of the patent application and the granting of the patent. Pursuant to the laid-open application process, the public is put on notice of a pending application and made aware that any

person who uses the invention described in the application will be liable in damages if the patent is granted.

[54] The Board Panel observed that both Alza and the Applicant are content with the *de facto* patent protection provided by the laid-open patent application process. It also noted the evidence that the Applicant and Alza have considered abandoning the patent applications. In the Board Panel's view, the only explanation for such abandonment would be to support an argument that the Board lacks jurisdiction to require the Applicant to repay any excessive revenues earned for 1992 until the date on which the first patent pertaining to Nicoderm was granted.

[55] The Board Panel then considered whether the Act grants the Board jurisdiction, in order to fulfill its mandate, with respect to the '352 and '446 patent applications. It concluded that if the Board does not have the jurisdiction to avoid excessive pricing of medicines where patent applications can be presumed to have given the applicants pricing power, the statutory purpose of the Act will not be achieved in those circumstances.

[56] The Board Panel referred to section 55 of the Act. This section provides for the retroactivity of patent protection and accordingly, the ultimate rights and interests of the parties are clear from the time the application is laid open. The Board Panel found that there is no reason why the Board should decline to investigate an allegation of excessive pricing in this type of situation, in order to wait for the inevitable grant of the patent before taking remedial steps that will be inadequate, after the fact of excessive pricing. The Board Panel found that it had jurisdiction to consider the two patent applications.

[57] In conclusion, the Board Panel determined that the pricing of Nicoderm has been subject to the jurisdiction of the Board since Nicoderm was introduced to the Canadian market in July 1992.

DISCUSSION AND DISPOSITION

I Decision on Jurisdiction – Part I

[58] In the matter of the Applicant's challenge to the first decision on jurisdiction, the following issues are addressed:

1) Did the procedure followed by the Board for conducting a hearing provide for a fair and impartial tribunal in accordance with the principles of procedural fairness and the Bill of Rights?

2) Whether or not the following factors constitute a reasonable apprehension of bias so as to justify judicial intervention:

    a) Do the operations of the Board create an impermissible overlap of investigative and adjudicative functions by the Board and the Chairperson?
    b) Did the Board and Chairperson predetermine certain matters that were in issue at the hearing?

c) Did the participation of the Chairperson in the Board Panel, having previously reviewed the Staff Report and VCU and issued the Notice of Hearing, constitute a reasonable apprehension of bias?

[59] This application for judicial review involves the issues of procedural fairness and bias. The first subject addressed by the Applicant, in respect of alleged breaches of procedural fairness, is the applicable standard of review. Both the Applicant and the Respondent Attorney General of Canada urged the view that the applicable standard of review is correctness.

[60] The Applicant referred to the recent decision in *Dr. Q v. College of Physicians and Surgeons of British Columbia*, [2003] 1 S.C.R. 226 ("*Dr. Q*") where the Supreme Court of Canada held that the pragmatic and functional analysis must be undertaken in every case where legislation delegates power to an administrative decision-maker. It submitted, however, that this approach does not necessarily apply to the procedural framework in which the decision is made. Relying on the decision of the Federal Court of Appeal in *Ha v. Canada (Minister of Citizenship and Immigration)* (2004), 236 D.L.R. (4^{th}) 485, the Applicant argues that the pragmatic and functional analysis need not be applied to questions of procedural fairness.

[61] I agree with these arguments of the Applicant. While *Dr. Q, supra* clearly states that the pragmatic and functional analysis must be applied to all questions, it is my opinion that this means it is to be applied to all substantive questions. No decision of the Supreme Court of Canada was cited to require the application of the pragmatic and functional analysis approach to procedural fairness questions. Even if that approach were applied it seems to me that the result would be the

correctness standard. The Court's relative expertise to that of a tribunal is greater when dealing with questions of procedural fairness, as these are questions of law.

[62] However, the application of the standard of correctness to procedural fairness questions does not mean that the content of that duty is absolute. The duty of fairness varies, depending upon the circumstances; see *Knight v. Indian Head School Division No. 19*, [1990] 1 S.C.R. 653 at 682. Nonetheless, once a breach of the duty is found, the decision below must be set aside; see *Congrégations des témoins de Jéhovah deSt-Jérome-Lafontaine v. Lafontaine (Village)*, [2004] 2 S.C.R. 650 at paragraph 30. There is no room for deference.

The Duty of Fairness

[63] In *Baker v. Canada (Minister of Citizenship and Immigration)*, [1999] 2 S.C.R. 817, the Supreme Court of Canada again recognized that the duty of procedural fairness is flexible and depends upon an appreciation of the context of the particular statute and the rights affected. All parties here have argued that a distinction must be drawn between those tribunals whose function tends towards the judicial end of the spectrum and those that tend to the legislative or policy-making end. In *Baker, supra*, the Supreme Court provided a non-exhaustive list of factors to be considered in determining the content of procedural fairness owed by an administrative tribunal at common law, as follows:

1) the nature of the decision being made and the process followed in making it;

2) the nature of the statutory scheme and the terms of the statute pursuant to which the body acts;
3) the importance of the decision to the individual(s) affected;
4) the legitimate expectations of the person challenging the decision; and
5) the choices of procedure made by the body itself.

[64] First, in *ICN*, *supra*, the Federal Court of Appeal commented at paragraph 12, that the 1993 amendments to the Act reinforced the Board's remedial and punitive powers. Orders of the Board carry the same force and effect as those of the Federal Court. Section 83 of the Act grants the Board statutory authority to make various remedial orders against the patentee or former patentee who is selling a patented medicine at an excessive price.

[65] As for the Board's procedural framework, subsection 96(2) of the Act allows the Board, subject to the approval of the Governor-in-Council, to make rules to regulate its practice and procedure. In my opinion, these factors tend towards more procedural protection for the Applicant.

[66] Second, concerning the nature of the statutory scheme and the statutory provision under which the Board operates, section 2.2 of the Introduction of the Board's Compendium provides that:

> 2.2 The Board is an independent and autonomous quasi-judicial body. To ensure this independence and autonomy, the Act provides no power, either expressly or implicitly, to the government to direct the Board or to review its decisions and orders. However, decisions of the Board are subject to judicial review by the Federal Court of Canada on jurisdictional or procedural grounds in accordance with administrative law principles.

[67] However, in *Ciba-Geigy Canada Ltd. v. Canada* (1994), 56 C.P.R. (3d) 377 (F.C.A.), the Federal Court of Appeal found that the Board is an administrative tribunal with economic regulatory functions and as such, law and policy require that some leeway be provided in pursuing its mandate. Further, in this case, the application for judicial review relates to a jurisdictional decision of the Board, that is its decision to proceed with a public hearing to determine to proceed with a public hearing to determine whether the Applicant has sold Nicoderm at an excessive price.

[68] In my opinion, this decision on Jurisdiction, Part I, is clearly not determinative of the issue of whether the price of Nicoderm exceeds the guidelines. Accordingly, a lower degree of procedural fairness is required.

[69] Third, as noted by the Federal Court of Appeal in *Ciba-Geigy*, *supra*, there are very serious economic consequences for an unsuccessful patentee in a section 83 hearing, including a potential negative effect on a corporation's reputation in the marketplace. However, these consequences will not arise until the formal public hearing has taken place. At that hearing, the Applicant will have the opportunity to present its evidence and arguments, and to cross-examine opposing evidence. In my opinion, the consequences of a negative decision by the Board, after a public hearing, are inherent in any situation where a corporation is alleged to be in breach of accepted standards and is called upon to defend itself in a hearing.

[70] Fourth, subsection 97(1) of the Act provides that hearings before the Board are expected to proceed as informally and expeditiously as the circumstances and considerations of fairness permit. As well, the Board is mandated to protect the public interest. In my opinion, there appears to be a

basis for finding that the Applicant has a legitimate expectation that fairness will be accorded it in the public hearing. However, that stage has not yet arrived.

[71] As for the procedure to be followed by the Board Staff in conducting investigations and the action of the Chairperson in reviewing the confidential Staff Report and the VCU submitted by the Applicant, these processes are set out, in general terms, in the Board's Policy. In my opinion, there is no indication that the investigation and the issuance of the Notice of Hearing were not carried out in accordance with the Board's Policy and consequently, I cannot say that the duty or fairness was absent or ignored.

[72] Fifth, the procedure chosen by the Board, and outlined in the Policy, was introduced to ensure a separation of functions and necessary safeguards. When the Board Staff began its investigation, the Applicant was informed of the allegations against it and given the opportunity to respond. The Act has given the Board the right to choose its own procedures. In my view, the Board is an expert tribunal with the ability to decide what procedures are appropriate, in light of the duty of fairness owed to a patentee or former patentee. While not determinative, significant weight is to be given to the choice of procedure made by the tribunal, subject to its institutional constraints; see *IWA v. Consolidated Bathurst Packaging Ltd.*, [1990] 1 S.C.R. 282, per Gonthier J.

[73] As the basis of the foregoing, I conclude that the basic requirements of procedural fairness, as described by the Supreme Court of Canada in *Lakeside Colony of Hutterian Brethren v. Hofer*, [1992] 3 S.C.R. 165, that is the right to an unbiased tribunal, the right to notice and the opportunity to make representations, apply to the Board's actions. However, I would grant a considerable

degree of flexibility to the Board in respect of the procedural requirements in light of the factors described in *Baker, supra*. Subsection 97(1) of the Act clearly states that proceedings of the Board are to be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit, providing ample room for flexibility on the part of the Board, as long as natural justice and procedural fairness are respected.

The Context of the Duty of Fairness

[74] As noted above, the basic requirements of the principles of natural justice include notice, the opportunity to make representations and an unbiased tribunal. In the present case, the Applicant's allegations relate solely to the issue of bias. It is clear that the requirements of notice and the opportunity to make representations have been respected. The Applicant received several letters from the Director of the Board's Compliance and Enforcement Branch and was given the opportunity to respond to the allegations of excessive pricing by providing additional documentation, as well as a VCU for consideration by the Chairperson. The remaining question is whether the Board is a biased tribunal.

Reasonable Apprehension of Bias

[75] In *Baker*, *supra*, the Court reiterated that procedural fairness requires that decisions be made by an impartial decision-maker and free from any reasonable apprehension of bias. The classic test for reasonable apprehension of bias was set out by De Grandpré, J. writing in dissent, in *Committee for Justice and Liberty et al. v. National Energy Board et al.*, [1978] 1 S.C.R. 369 at page 394 as follows:

> ...
> As already seen by the quotation above, the apprehension of bias must be a reasonable one held by reasonable and right minded persons, applying themselves to the question and obtaining thereon the required information ... [t]hat test is "what would an informed person, viewing the matter realistically and practically - and having thought the matter through - conclude. Would he think that it is more likely than not that [the decision maker], whether consciously or unconsciously, would not decide fairly.

[76] In *Baker*, *supra*, L'Heureux-Dubé, J. reaffirmed the well-established principle that "the standards for reasonable apprehension of bias may vary, like other aspects of procedural fairness, depending on the content and the type of function performed by the administrative decision-maker involved." The Applicant has raised these allegations of bias arising from impermissible overlap of functions, predetermination of issues and the participation by the Chairperson in the Board Panel.

Impermissible Overlap

[77] The fact that an administrative tribunal may perform multiple functions does not, by itself, create a reasonable apprehension of bias. In this regard, the Supreme Court of Canada in *Bell*

Canada v. Canadian Telephone Employees Association, [2003] 1 S.C.R. 884, made the following comments at paragraph 40:

> [O]verlapping of different functions in a single administrative agency is not unusual, and does not on its own give rise to a reasonable apprehension of bias [see *2747-3174 Québec Inc.*, *supra* at paragraphs 46-48, per Gonthier J.; *Newfoundland Telephone*, *supra*, at page 635, per Cory J.; *Brosseau*, *supra*.] As McLachlin C.J. observed in *Ocean Port*, *supra*, at para. 41, "[t]he overlapping of investigative, prosecutorial and adjudicative functions in a single agency is frequently necessary for [an administrative agency] to effectively perform its intended role."

[78] As well, in *Ocean Port Hotel Ltd. v. British Columbia (General Manager, Liquor Control and Licensing Branch)*, [2001] 2 S.C.R. 781, the Supreme Court of Canada observes that the common law does not outweigh legislative provisions that are reasonably clear, since this would have the effect of reducing procedural fairness rights. In *Ocean Port*, *supra* at paragraph 41, Chief Justice McLaughlin went on to say that "without deciding the issue, I would note that such flexibility may be appropriate in licensing schemes involving purely economic interests."

[79] In my opinion, that description is applicable to the type of regime at issue in this case. The Board is responsible for ensuring that patentees of patented medicines are not selling their products at prices that exceed the guidelines. The Board is carrying out a type of economic regulatory function, as noted by the Federal Court of Appeal in *Ciba-Geigy*, *supra*. As such, it must be accorded a degree of flexibility.

[80] Again, I refer to *Ocean Port*, *supra*, relied on by the Intervener, where the Supreme Court made the following observation at paragraph 42:

> Further, absent constitutional constraints, it is always open to the legislature to authorize an overlapping of functions that would otherwise contravene the rule against bias. Gonthier J. alluded to this possibility in *Régie*, at para. 47, quoting from the opinion of L,Heureux-Dubé J. in *Brosseau*, *supra*, at pp. 309-10:
>
> > As with most principles, there are exceptions. One exception to the "*nemo judex*" principle is where the overlap of functions which occurs has been authorized by statute, assuming the constitutionality of the statute is not in issue.
> >
> > ...
> >
> > In some cases, the legislator will determine that it is desirable, in achieving the ends of the statute, to allow for an overlap of functions which in normal judicial proceedings would be kept separate. ... If a certain degree of overlapping of functions is authorized by statute, then, to the extent that it is authorized, it will not generally be subject to the doctrine of "reasonable apprehension of bias" *per se.*

[81] The Applicant has not raised a constitutional argument in this application for judicial review.

[82] The legislative scheme here in issue specifically contemplates that the Board will discharge multiple functions, including investigation, prosecution and adjudication. Subsections 96(2) and (3) of the Act authorize the Board, subject to the approval of the Governor in Council, to make rules regulating its own practices and procedures, to make by-laws for conducting its work, for the management of its internal affairs and for the duties of its staff. The existence of this legislative scheme militates against finding the existence of inherent institutional bias or lack of impartiality.

[83] I am not persuaded by the Applicant's arguments that the Board lacks sufficient institutional impartiality as a result of overlapping functions as performed by individuals working as Board Staff or serving as members of the Board Panel. The Applicant concedes that an overlap of functions may

be authorized by statute, if validly within the power of the legislation. The Applicant also recognizes that the Board may establish its own policies and procedures.

[84] The Federal Court of Appeal in *ICN, supra* found that while the Board is required to act as both prosecutor and adjudicator in fulfillment of its statutory mandate, the Board through its Policy has decided, in fact, to operate independently of Board Staff. The Court, in *ICN, supra* noted that the relationship between the Board and its staff was described by the majority of the Board in *Genentech Canada Inc. (Re)* (1992), 44 C.P.R. (3d) 316 (P.M.P.R.B.) at p. 320 as follows:

> In conducting hearings with respect to the price of a patented medicine, the Board's staff is segregated from the Board. The Board's staff, through its own counsel, adduces evidence, tests evidence of other parties, and makes submissions on procedural, jurisdictional, legal, and substantive issues arising during the course of the proceeding.

[85] The Board's Policy serves to enforce the principles of procedural fairness and natural justice, by attempting to ensure a separation of functions and necessary safeguards beyond what is provided for by the Act itself.

Predetermination of Issues

[86] The Applicant has argued that the Chairperson's consideration of the Staff Report and the VCU, and his decision to issue a Notice of Hearing, amount to predetermination of the issues to be decided at the public hearing. In other words, according to the Applicant, in deciding to issue the Notice of Hearing, the Chairperson must have already concluded that Nicoderm was being sold at

an excessive price and that the VCU submitted by the Applicant did not accord with the Board's policies.

[87] The Board's Policy provides that the Chairperson "may" issue a Notice of Hearing if he holds the view that the investigation has shown that the price "may" be or has been excessive. This language obviously confers discretion upon the Chairperson to issue a Notice of Hearing if, after reviewing the Staff Report and the VCU, he believes that there may have been excessive pricing. This does not represent, in any way, a determination concluding that there was excessive pricing by the patentee or former patentee.

[88] In this regard, I refer to the Board's reasons in its Decision on Jurisdiction, Part I. The Board noted that in deciding whether to issue a Notice of Hearing, the Chairperson considers whether the results of the investigation, if proven true, would show a *prima facie* case of excessive pricing [emphasis added].

[89] The issue of actual excessive pricing is a matter to be resolved at the public hearing, when all interested parties are given the opportunity to lead evidence, cross-examine and make submissions. That being so, I agree with the arguments of the Respondent Attorney General of Canada and the Intervener that the issuance of the Notice of Hearing does not represent the Board's conclusion on the issue, but rather constitutes an allegation that is sufficiently substantiated to justify a hearing on the merits. I conclude that no objectionable bias has been proven in this regard.

Participation by the Chairperson in the Board Panel

[90] As noted above, the test as to whether a reasonable apprehension of bias exists in a particular set of circumstances was set out by the Supreme Court of Canada in *Committee for Justice and Liberty et al, supra* : what would an informed person, viewing the matter realistically and practically and having thought the matter through conclude?

[91] The Applicant has argued that, on the basis of *MacBain v. Canada (Human Rights Commission)*, [1985] 1 F.C. 856 (F.C.A.) and *2747-3174 Québec Inc. v. Québec (Régie des permis d'alcool)*, [1996] 3 S.C.R. 919, the fact that the Chairperson, after reviewing the Staff Report and considering the VCU submitted by the Applicant, then decided to hold a hearing and to participate in the adjudication process, gives rise to a reasonable apprehension of bias.

[92] In my opinion, this issue is closely related to the question of predetermination of key issues, discussed above. As noted above, the Chairperson, when reviewing the Staff Report and VCU, was acting in his administrative capacity as chief executive officer, for the limited purpose of deciding whether or not to issue a Notice of Hearing. I agree with the submissions of the Respondent and the Intervener that no independent analysis was conducted by the Chairperson as to whether the results of the investigation are, or may be, established.

[93] Finally, the Act does not ban the Chairperson from sitting as a member of a Board Panel, notwithstanding his role in the issuance of a Notice of Hearing. Having regard to the fact that the Board is an expert tribunal, that the Chairperson is presumably highly knowledgeable in this field,

and that the Chairperson, to date, has had no role in determining the well-foundedness of the allegation contained in the Staff Report, I see no basis upon which an informed person, viewing the matter realistically and practically, and having thought the matter through, would conclude that there is a reasonable apprehension of bias arising from the Chairperson's participation in the panel. This view is reinforced by my opinion as to the degree of flexibility to be afforded to the Board in satisfying the duty of fairness.

[94] For these reasons, the application for judicial review in respect of the Board's Decision on Jurisdiction, Part I, is dismissed.

II Decision on Jurisdiction - Part II

[95] In seeking to set aside the Board Panel's decision to proceed to a hearing, the Applicant raises the following issues:

1) What is the appropriate standard of review for decisions of the Board?
2) Is Nicoderm a "medicine" within the meaning of the Act?
3) Do the '700 and '689 Patents pertain to a medicine?
4) Is the Applicant the "patentee", of the '700 and '689 Patents.
5) Does the Act grant the Board jurisdiction on the basis of patent applications and prior to the issuance of any patent?

6) If the Act does purport to confer such jurisdiction, is it *ultra vires* the Parliament of Canada?

[96] Again, the analysis begins with consideration of the applicable standard of review. The decision under review deals with a direct challenge to the Board's statutory jurisdiction relative to Nicoderm as a patented medicine. The pragmatic and functional analysis described in *Dr. Q, supra* will apply here, in determining the applicable standard of review.

[97] Generally, there are four factors to be taken into account for each question at issue in this application for judicial review:

1. the nature of the review mechanism (privative clause);

2. relative expertise – the Court must categorize the expertise of the tribunal, compare the expertise of the tribunal to that of the Court, and identify the nature of the specific issue before the tribunal relative to that expertise;

3. the purpose of the statute; and

4. the nature of the question.

[98] Traditionally, the view was that if a question related to jurisdiction, the applicable standard was that of correctness. That view was refined in *Pushpanathan v. Canada*, [1998] 1 S.C.R. 982 and a jurisdictional question is now to be treated as another kind of legal question. It is necessary,

in light of the decision in *Dr. Q, supra*, to consider each issue in light of the pragmatic and functional analysis outlined in that decision, as follows:

The nature of the review mechanism

[99] The Board's review mechanism is set out by subsection 97(1) of the Act, as follows:

97. (1) All proceedings before the Board shall be dealt with as informally and expeditiously as the circumstances and considerations of fairness permit.	97. (1) Dans la mesure où les circonstances et l'équité le permettent, le Conseil agit sans formalisme, en procédure expéditive.

[100] As noted by the trial judge in *ICN Pharmaceuticals, Inc. v. Canada (Patented Medicine Prices Review Board)* (1996), 66 C.P.R. (3d) 45 (F.C.T.D.), decisions of the Board are not subject to a privative clause, although this factor is not determinative. There is no statutory right of appeal under the Act and decisions of the Board are amenable only to judicial review pursuant to section 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7, as amended. In my opinion, this suggests that greater deference should be afforded to the Board.

Relative Expertise of the Board

[101] In *ICN*, *supra*, the trial judge discussed the Board's expertise in paragraph 17:

> 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.

[102] The Board applies its expertise in accordance with subsection 83(1), 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.	83. (1) Lorsqu'il estime que le breveté vend sur un marché canadien le médicament à un prix qu'il juge être excessif, le Conseil peut, par ordonnance, lui enjoindre de baisser le prix de vente maximal du médicament dans ce marché au niveau précisé dans l'ordonnance et de façon qu'il ne puisse pas être excessif.

[103] In my opinion, the interpretation of specific provisions of the Act, particularly section 79 and subsection 83(1), relies greatly upon technical meaning in order to establish the Board's jurisdiction over a specific patentee. In *Barrie Public Utilities v. Canadian Cable Television Association* , [2003] 1 S.C.R. 476, Justice Bastarache in dissent, said that the interpretation of enabling legislation by a specialized tribunal is more like the administration of the statute, a core part of a tribunal's mandate.

[104] As well, the Board administers the section of the Act pertaining to the price review of patented medicines in furtherance of its policy objectives. The Board has more expertise in respect of these matters than does a generalized Court.

[105] However, the issues to be determined relate directly to the jurisdiction of the Board to inquire into the pricing of a particular patented medicine. The jurisdictional "character" of the issues suggest less deference.

The purpose of the Act

[106] I agree with the submissions of the Respondent AGC that the Act is intended to resolve and balance competing policy objectives. This means that the statutory purpose may be described as polycentric. This suggests that more deference be afforded to the Board.

The nature of the question

[107] As indicated above, the issues in this application for judicial review involve the interpretation of "medicine" as it is used in subsection 83(1) of the Act, whether certain patents "pertain to" a medicine as addressed in subsection 79(1) of the Act, whether the Applicant is a "patentee" for the purposes of subsection 79(1) of the Act, and whether patent applications are subject to the Board's jurisdiction.

[108] In my opinion, all of these issues, except the last, raise questions of mixed fact and law that are factually intensive. That suggests that more deference be afforded to the Board's findings in this regard. The last issue may be characterized more as a straight question of jurisdiction that is legally intensive, suggesting that less deference will be given to the Board on this issue.

[109] In my opinion, upon conducting a pragmatic and functional analysis of each question at issue in this application for judicial review, the appropriate standard of review applicable to the decision on jurisdiction, Part II, will vary, depending upon the issue. I conclude that the standard of reasonableness *simpliciter* applies to the following issues: is Nicoderm a "medicine" within the meaning of the Act; do the '700 and '689 Patents pertain to a medicine; and is the Applicant the "patentee" of the '700 and '689 Patents.

[110] In my opinion, the standard of correctness should apply to the question of whether patent applications are subject to the Board's jurisdiction.

Is Nicoderm a "medicine" within the meaning of the Act?

[111] For the purposes of the Act, the word "medicine" remains undefined. In *ICN*, *supra*, the Federal Court of Appeal held that the word, as used in subsection 83(1), should be interpreted in the same manner as it had been under the old section 39 of the former Act, that is, broadly and in its ordinary sense.

[112] The Applicant has referred to the Board's definition of "medicine" in its *Compendium*, which was considered by the Federal Court of Appeal in *ICN*, *supra*. Although that definition is not binding, the Court found that it clearly includes products that would typically be considered as "medicine" as that term is used in the vernacular.

[113] On the standard of review of reasonableness *simpliciter*, this Court must consider the reasons given by the Board and determine whether there is some line of analysis that could reasonably lead the Board from the evidence before it to the conclusion that it reached; see *Law Society of New Brunswick v. Ryan*, [2003] 1 S.C.R. 247.

[114] In my opinion, having reviewed the Board Panel's reasons, there is a tenable basis for its decision. Based upon the evidence that was submitted, I am satisfied that a reasonable person could move from that evidence to the result reached by the Board Panel, that is, a finding that Nicoderm is a "medicine" for the purposes of the Board's jurisdiction.

[115] Alternatively, if the appropriate standard of review is that of correctness, I am equally satisfied that the Board Panel's decision was correct, based upon the guidance given by the Federal Court of Appeal for the interpretation of the word "medicine" in *ICN*, *supra*. As well, I am not persuaded by the Applicant's argument that jurisprudence addressing the definition of "medicine" in the context of the NOC Regulations, such as *Glaxo, supra*, would be of use in the present application. The Federal Court of Appeal explicitly rejected the utility of that jurisprudence in *ICN*, *supra* as follows:

> ...The interpretation of the word "medicine" and the phrase "intended or capable of being used for" as used in section 2 of the NOC Regulations has no relevance to their interpretation under subsections 79(2) and 83(1) of the Act. The NOC Regulations are part of a separate regime with a distinct purpose.

Do the "700 and "689 Patents pertain to a medicine?

[116] As noted by the Federal Court of Appeal in *ICN*, *supra*, there must be a rational connection or nexus between a patent and the medicine in issue in order for the Board to have jurisdiction. In view of the broad scope of the words "pertaining to" and "pertains to" as used in subsections 83(1) and 79(2) of the Act, the Court found that the nexus can be one of the merest slender thread and it is unnecessary to go beyond the face of the patent to establish the required nexus.

[117] In its decision on jurisdiction, Part II, the Board Panel concludes that the '689, '700 and '340 Patents pertained to Nicoderm. It found that the Applicant was not a "patentee" of the '340 Patent and the Applicant is not challenging the finding that the '340 Patent pertains to Nicoderm. As well, the Applicant does not challenge the Board Panel's finding that the '760 Patent pertains to Nicoderm if this Court concludes that Nicoderm is a "medicine" for the purposes of the Board's jurisdiction. This means that the sole inquiry, in respect of this issue, is whether the '689 Patent pertains to Nicoderm.

[118] The Applicant has argued that the structure of the delivery system protected by the '689 Patent is not the system used in Nicoderm and accordingly, the '689 Patent is not a patent for the Nicoderm product itself or for a process for manufacturing or preparation of Nicoderm. However, in *ICN*, *supra*, both the Board and the trial judge concluded that whether a patentee is making use of the patent in question is irrelevant to the legal question of whether that patent "pertains" to a medicine within the meaning of the Act. In that case, the Trial Judge held that the Board was correct in finding that it should not go beyond the face of the patent to construe the use claims

before determining whether they correspond to the use stipulated in the notice of compliance for the medicine.

[119] On the face of the ’689 Patent, it is clear that it is a patent for a transdermal nicotine patch, that is the type of medicine of which Nicoderm is a particular example. It is intended or capable of being used for medicine such as Nicoderm. Dr. du Souich said the following in his affidavit, “The [nicotine] transdermal patch is the drug delivery system which controls the rate of release of the active ingredient, nicotine, into the blood.”

[120] The Federal Court of Appeal in *ICN, supra* has confirmed that the nexus between the patent in question and the medicine, in light of the broad language of subsections 83(1) and 79(2) of the Act, need only be of the merest slender thread. In my opinion, the fact that the ’689 Patent is for a nicotine transdermal patch system, capable of being used in the drug product Nicoderm, is a sufficient connection to support the conclusion that the ’689 Patent pertains to Nicoderm. It is irrelevant whether the ’689 Patent is actually being used in connection with the medicine Nicoderm.

[121] Applying the standard of reasonableness *simpliciter* I am satisfied that the Board Panel’s conclusion that both the ’700 and ’689 Patents pertain to Nicoderm is reasonable and withstands a somewhat probing analysis. There is no basis for judicial intervention on this issue.

Is the Applicant the “patentee” of the ’700 and ’689 Patents?

[122] Subsection 79(1) of the Act defines “patentee” as follows:

79(1) In this section and in sections 80 to 103, ... "patentee", in respect of an invention pertaining to a medicine, means the person for the time being *entitled to the benefit of the patent for that invention* and includes, where any other person is *entitled to exercise any rights in relation to that patent* other than under a licence continued by subsection 11(1) of the Patent Act Amendment Act, 1992, that other person in respect of those rights; ... [emphasis mine]	79. (1) Les définitions qui suivent s'appliquent au présent article et aux articles 80 à 103. « breveté » ou « titulaire d'un brevet » La personne *ayant* pour le moment *droit à l'avantage d'un brevet pour une invention* liée à un médicament, ainsi que quiconque *était titulaire d'un brevet pour une telle invention* ou exerce ou a exercé les droits d'un titulaire dans un cadre autre qu'une licence prorogée en vertu du paragraphe 11(1) de la Loi de 1992 modifiant la Loi sur les brevets. … [je souligne]

[123] The Applicant has argued that the only licensed patent for which it obtained a licence was that necessary or useful to make, use or sell Nicoderm, that is, the ’700 Patent. In light of my conclusion above, that Nicoderm is a “medicine” within the meaning of the Act and that the ’700 Patent pertains to Nicoderm, there is no doubt that the Applicant is a “patentee” within the meaning of section 79, with respect to the ’700 Patent. The remaining issue is whether the Applicant is a “patentee” with respect to the ’689 Patent.

[124] In assessing the reasonableness of the Board Panel’s conclusion that the Applicant is a patentee of the ’689 Patent, I must consider the language of section 79 of the Act and the relevant

facts relating to the ’689 Patent. It must be determined whether it was reasonable for the Board Panel to conclude that the Applicant was entitled to the benefit of the ’689 Patent or entitled to exercise any rights in relation to that patent. In my opinion, the Board Panel’s conclusions in that regard were reasonable.

[125] I agree with the submission of the Respondent, that the fact that the ’689 Patent was never developed or marketed is irrelevant to the question of whether the Applicant was entitled to the benefit of that patent or entitled to exercise any rights in respect of that patent. The Board Panel concluded that the Applicant had the power to prevent a competitor from entering the Canadian market with the delayed release nicotine patch, described in the ’689 Patent, that would compete with Nicoderm. That power may be considered as an exercise of rights in relation to the ’689 Patent.

[126] The parties made submissions concerning the inclusion of the ’689 Patent in Appendix B to the License Agreement. The Applicant has argued that despite the inclusion of the ’689 Patent in Appendix B, not all the patents listed there are licensed patents. Further, according to the revised Appendix B, neither the ’689 Patent nor its U.S. counterpart appears on the list.

[127] The Respondent argues that the inclusion of the ’689 Patent in Appendix B is consistent with the notion of the joint venture formed between Alza and HMR. He suggests that it would be

odd if HMR were not a licensee of the ’689, as it would have no means with which to protect its market for Nicoderm in Canada.

[128] While the ’689 Patent is actually held by Alza, under the Licence Agreement between HMC and Alza, the Applicant is authorized to exercise in Canada the rights held by its parent, HMC, under that agreement. In my opinion, a review of the Licence Agreement and Appendix B shows that all licensed patents shall be listed on Appendix B and Appendix B is clearly entitled “Licensed Patents (Section 1.6)”. Consequently, I do not see any basis upon which to conclude that the ’689 Patent was erroneously included in the Appendix.

[129] Since the Board Panel concluded that Nicoderm is a “medicine” within the meaning of the Act and that the ’689 Patent pertains to Nicoderm, the fact that the ’689 Patent was a Licensed Patent for the purposes of the Licence Agreement is enough, in my view, to support the conclusion that the Applicant was a patentee within the meaning of section 79 of the Act. Although the ’689 Patent was not developed for use in Canada, the applicant still had an enforceable right to protect its Canadian market for that product. In light of this analysis, I agree that the Board Panel’s conclusion in this regard was reasonable and there is no basis for judicial intervention.

Are patent applications subject to the Board's Jurisdiction?

[130] Having regard to the pragmatic and functional analysis undertaken previously, the appropriate standard of review to the Board Panel's decision on this issue is that of correctness.

[131] In its decision on Jurisdiction - Part II, the Board Panel addressed the implications of evidence that Alza and the Applicant had considered abandoning the patent applications here in issue. The Board Panel opined that the only possible explanation for such abandonment would be to generate an argument that the Board lacked jurisdiction to require the Applicant to repay any excessive revenues earned from 1992 until the date on which the first patent pertaining to Nicoderm was granted.

[132] The Applicant argued that section 2 of the Act defines "patent" as "letters patent for an invention" and that the definition does not include a patent application. It has been submitted that section 79 has expanded the definition of a "patentee" approaching that contained in section 2; however, even the definition in section 79 specifically relates to a patent, not a patent application.

[133] The Respondent has argued that subsection 55(2) provides a benefit to a patent-holder from the time that the application is laid open, creating significant *de facto* protection, even without the patent having been granted *de jure*. Both the Respondent and the Intervener have argued that the Board Panel was correct in asserting jurisdiction over the patent applications, in light of the

possibility that a person applying for a patent may delay the actual grant of the patent to avoid regulation by the Board.

[134] However, if this is the case, and the Board assumes jurisdiction when a patent is laid open, the question arises as to why the Board did not attempt to assert jurisdiction as of the date on which the ’700 and ’689 Patents were also laid open. In my opinion, it is inconsistent for the Board to assert jurisdiction over patent applications by reference to the dates upon which they are laid open and to assume jurisdiction over granted patents as of the date upon which they are granted.

[135] This approach ignores the critical fact that a patent is a creature of statute. The effect of the grant of a patent is a statutory monopoly, in accordance with the Act. Section 42 of the Act provides as follows:

42. Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.	42. Tout brevet accordé en vertu de la présente loi contient le titre ou le nom de l'invention avec renvoi au mémoire descriptif et accorde, sous réserve des autres dispositions de la présente loi, au breveté et à ses représentants légaux, pour la durée du brevet à compter de la date où il a été accordé, le droit, la faculté et le privilège exclusif de fabriquer, construire, exploiter et vendre à d'autres, pour qu'ils l'exploitent, l'objet de l'invention, sauf jugement en l'espèce par un tribunal compétent.

[136] In my opinion, a patent application gives rise only to the potential for the grant of a patent. In no way does the existence of a laid-open patent application support the inference that a patent will inevitably be granted. That being so, I conclude that the Board Panel erred in finding that it was authorized to assert jurisdiction over the two laid-open patent applications. Further, in my opinion, the Board Panel's reasons with respect to this issue demonstrate an attempt to justify its conclusion in that regard.

[137] In the result, I conclude that the Board erred in law in purporting to exercise jurisdiction over the two patent applications, that is the '446 and the '352 applications. Accordingly, that part of the Board's decision will be quashed.

[138] The application for judicial review relative to the Board's decision in relation to jurisdiction, Part II, is allowed in part as addressed above, and is otherwise dismissed.

[139] If the parties cannot agree on costs, brief submissions may be made no later than December 1, 2005.

[140] These reasons shall be filed in T-1576-99 and placed on the file in T-1671-00.

"E. Heneghan"

JUDGE

FEDERAL COURT

SOLICITORS OF RECORD

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REASONS FOR ORDER AND ORDER BY:	The Honourable Madam Justice Heneghan
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APPEARANCES BY:

Mr. Martin W. Mason Mr. Andrew Hayes	FOR THE APPLICANT
Mr. F.B. Woyiwada	FOR THE RESPONDENT
Mr. Gordon Cameron	FOR THE INTERVENER

SOLICITORS OF RECORD:

GOWLING LAFLEUR HENDERSON LLP	FOR THE APPLICANT
MR. JOHN H. SIMS, Q.C. DEPUTY ATTORNEY GENERAL OF CANADA	FOR THE RESPONDENT
BLAKE, CASSELS & GRAYDON LLP OTTAWA, ONTARIO	FOR THE INTERVENER