PMPRB-99-D6-NICODERM

IN THE MATTER OF the *Patent Act* R.S. 1985, c. P-4, as amended by R.S. 1985, c. 33 (3rd Supp.), and as further amended by S.C. 1993, c. 2
AND IN THE MATTER OF Hoechst Marion Roussel Canada Inc. (Respondent) and the medicine Nicoderm

DECISION ON JURISDICTION - PART II

PART I - Introduction

1. *Background*

On April 20, 1999, the Board issued a Notice of Hearing (the "Notice of Hearing") concerning allegations by Board Staff that Hoechst Marion Roussel Canada ("HMRC") had sold the medicine Nicoderm in Canada at excessive prices. On May 25, 1999, HMRC brought a motion for an order that the Board rescind the Notice of Hearing on the grounds that the Board is without jurisdiction to inquire into the matters raised in the Notice of Hearing. The motion listed a number of grounds for the relief sought and, on the agreement of all parties, the Board's consideration of the motion was divided into two distinct parts based on the grounds for the relief sought.

The first part of the motion dealt with allegations of bias and whether or not the Notice of Hearing was sufficiently detailed for its purpose. The Board issued its decision on that part of the motion on August 3, 1999, concluding that the matters that were complained of in that part of the motion did not deprive the Board of jurisdiction. The second part of the motion – considered in this decision – concerns HMRC's allegations that the Board has no statutory jurisdiction to regulate the price of Nicoderm. In particular, HMRC argues that Nicoderm is not a "medicine" within the meaning of the *Patent Act* (the "*Act*") or, if it is a medicine, then (1) only one of the patents recited in the Notice of Hearing pertains to Nicoderm; and (2) the patent applications referred to therein are not relevant to the Board's jurisdiction.

The matter of which patents pertain to Nicoderm and the relevance of the patent applications are significant because patents were granted, and applications were made and laid open, on different dates and thus there is an issue as to the date from which the pricing of Nicoderm has been subject to the Board's jurisdiction. The determination of that issue will define the period during which the Board will examine the allegations of Board Staff concerning excessive pricing by HMRC.

2. *The Product "Nicoderm"*

Nicoderm is the brand name and registered trademark for a nicotine "patch" that, when placed on the skin, delivers nicotine into the bloodstream. It is used to assist in smoking cessation by the partial relief of nicotine withdrawal symptoms. It is sold in Canada by HMRC, and has been since the introduction of the product in Canada in 1992.

3. *Issues*

The Board's jurisdiction under the *Act* to prevent excessive pricing is limited to patented medicines. In other words, for the Board to have jurisdiction over the pricing of a product, the product in question must be a "medicine" within the meaning of the *Act* and it must be sold in a market in Canada by a person who is a patentee of a patent that pertains to the product within the meaning of the *Act*.

HMRC alleges in its motion that Nicoderm is not a medicine, but a delivery device for the administration of nicotine. HMRC states that of the three patents identified in the Notice of Hearing and alleged by Board Staff to pertain to Nicoderm – the 1,338,700; 1,333,689 and 1,331,340 patents – (the '700 patent, the '689 patent and the '340 patent) only the '700 patent pertains to Nicoderm, and it is only the '700 patent of which HMRC could be said to be a "patentee" within the meaning of the *Act*. Finally, HMRC argues that the two patent applications identified in the Notice of Hearing – the 2,032,446 and 2,040,352 applications – (the '446 and '352 applications) have no bearing on the Board's jurisdiction.

4. *Summary of Conclusions*

For the reasons detailed in the respective sections of the decision that follow, the Board has reached the following conclusions with respect to the matters in issue in this proceeding:

- Nicoderm is a "medicine" within the meaning of the *Act*;
- The '700, '689 and '340 patents pertain to Nicoderm;
- HMRC is a "patentee" of the '700 and '689 patents;
- HMRC is not a "patentee" of the '340 patent. The Chairman of the panel has delivered a dissenting opinion on this conclusion;
- HMRC has been a "patentee" of the patents for which application has been made in the '352 and '446 patent applications from the date on which those applications were laid open to public inspection;
- the pricing of Nicoderm has been subject to the jurisdiction of the Board since the introduction of Nicoderm to the Canadian market in 1992.

PART II - Whether Nicoderm is a "medicine"

1. *Introduction*

The product sold under the trade name Nicoderm is a "transdermal patch". A transdermal patch consists of some substance contained within layers of appropriate material in such a manner that, when the patch is applied to and left in contact with the skin, a therapeutic dose of the substance passes through the skin into the body. As noted above, the active substance in Nicoderm is nicotine. The layers of material within which the nicotine is contained must perform several functions. They must hold and preserve the nicotine until the patch is used. They must adhere to the skin and allow the correct amount of nicotine to pass in a controlled manner through the material that is in contact with the skin and into the body. The materials must then hold any residual quantity of nicotine safely until the patch is removed and disposed of.

HMRC did not dispute that Nicoderm was used in a therapeutic way to treat a medical condition, but argued that it is the nicotine that is the medicine, with the patch being exclusively a delivery device for the administration of the medicine. Board Staff take the position that Nicoderm is a medicine because that product is a combination of substances that, as a whole, has a therapeutic effect.

2. *The Definition of "medicine"*

Section 83 of the *Act* is the section primarily concerned with the Board's authority to regulate the prices of patented medicines. Subsection 83(1) provides as follows:

> *83(1) Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board's opinion, is excessive, the Board may, by order*

Also relevant in this context is subsection 79(2) of the *Act*, which provides:

> *79(2) For the purposes of subsection (1) and sections 80 to 101, an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine.*

The question, then, is whether Nicoderm is "a medicine" within the meaning of the sections of the *Act* that describe the statutory jurisdiction of the Board. The Board was required to address the definition of "medicine" in proceedings that were ultimately reviewed by the Federal Court of Appeal in the case of *ICN Pharmaceuticals v. The Staff of the PMPRB et al*[1].

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[1] (1996) C.P.R. (3rd) 417

In the *ICN* case, Board Staff had alleged that ICN was selling its product Virazole at excessive prices. There was in the *ICN* case, as there is in the instant case, debate concerning what the "medicine" in issue was and whether or not the patents held by ICN pertained to the medicine within the meaning of the *Act*.

ICN, the patentee, argued that the "medicine" to which the patents in question must pertain for the Board to have jurisdiction was the product actually sold by ICN; that is, Virazole. The Board held that the "medicine" to which the patents in question must pertain was ribavirin, the generic name for the chemical compound of which Virazole, in its specific form and with its specific dosage, delivery method and indications, was a particular example. The issue was critical because the patents in question arguably were not useful to make or use Virazole but could be useful to make or use ribavirin.

On ICN's judicial review application the Federal Court, and then the Federal Court of Appeal, agreed with the Board that the "medicine" to which the patents had to pertain was ribavirin. Mr. Justice Robertson, speaking for the Court (at page 436), said this about the definition of "medicine" in section 83 of the *Act*:

> *For purposes of the patented medicine provisions of the Act (sections 79 to 103) the word "medicine" remains undefined. This was also true in respect of section 39 of the old Patent Act which, until its repeal, authorized the issuance of compulsory licenses. The jurisprudence with respect to section 39 made it clear that the word "medicine" was not to be regarded as a term of art and was to be interpreted broadly and in its ordinary sense: [authorities cited].*
>
> *Having regard to the earlier jurisprudence and the fact that the compulsory licensing provisions served the very same purposes that the Patented Medicine Prices Review Board provisions are intended to serve, it seems obvious to me that the word "medicine" as employed in subsection 83(1) should be interpreted in that same manner as it was under the old section 39; that is to say, interpreted broadly, not narrowly as advocated by ICN.*

In the instant case, HMRC argued that the Board should have reference to another recent case from the Federal Court of Appeal: *Glaxo Group Ltd. V. Novopharm Ltd*.[2] In the *Glaxo* case the Court held that a mechanical device known as an "inhaler", used to administer a variety of medicaments in aerosol form to be inhaled by the person taking the medication, was not a medicine within the meaning of the *Patented Medicines (Notice of Compliance) Regulations* (the "*NOC Regulations*") administered by Health Canada.

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[2] [1999] F.C.J. No. 799, May 26, 1999

For the reasons discussed below, the *Glaxo* case (and others interpreting the *NOC Regulations*) are not instructive on the scope of the Board's jurisdiction. Before discussing that point, however, it should be noted that even if the principles in *Glaxo* were applicable, there are several reasons why a case dealing with inhalers does not assist HMRC. First, given the Board's views on the integration of the elements in a transdermal patch, as discussed below, the Board would not consider a transdermal patch to be analogous to an inhaler. Second, inhalers *are* considered to be medicines for the purposes of the Board's mandate. Third, the NOC issued for Nicoderm demonstrates that Health Canada considers and regulates Nicoderm as a drug, not a medical device such as an inhaler.

In any event, it is apparent that the Board should not be governed, in its reasoning on this point, by cases interpreting the meaning of "medicine" in the *NOC Regulations*, given the decision of the Federal Court of Appeal in the *ICN* case. In response to ICN's argument that the Court should have reference to the definition of medicine under the *NOC Regulations,* Mr. Justice Robertson said (at page 437):

> *While both the 1993 amendments to the Patent Act and the NOC Regulations were enacted at the same time, and while both legislative schemes have an effect on medicines, their purposes and application are significantly different. 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(1) and 83(2) of the Act. The NOC Regulations are part of a separate regime with a distinct purpose.*

The Federal Court of Appeal in *ICN* held that, for the purposes of sections 79 to 103 of the *Act*, the term "medicine" should be interpreted in its "*ordinary, broadest sense"*, or "*vernacular*" sense. It is with this instruction from the Federal Court of Appeal that the Board has approached the question of whether Nicoderm is a "medicine" within the meaning of the *Act*.

3. ***Analysis***

The thrust of HMRC's argument was that Nicoderm is not a medicine but a delivery device for the drug nicotine. HMRC emphasized in its evidence and argument that some of the constituent elements of a transdermal patch – in the case of Nicoderm the polymer layers that hold the nicotine – remain outside the body throughout the use of the patch. This argument might derive from observation of this point – components remaining outside the body – as it relates to inhalers by the Trial Division of the Federal Court in the Glaxo case[3], but no argument was provided by HMRC as to why this was a determinative – or even a particularly relevant – consideration with respect to transdermal patches and the definition of medicine in sections 79 to 103 of the *Act*.

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[3] The Board notes that the Federal Court of Appeal did not mention this point.

Board Staff presented the evidence of Dr. Patrick du Souich on this point. He is a medical doctor, a professor of clinical pharmacology and a senior medical researcher. He is also a member of the Human Drug Advisory Panel (HDAP) of this Board, and in fact participated in the process whereby Nicoderm was assigned to a therapeutic class for the purposes of determining the appropriate maximum non-excessive price for Nicoderm. He was the only medical doctor who provided evidence on the question of whether or not Nicoderm is a medicine.

Dr. du Souich's evidence was that Nicoderm is a medicine and not merely a device for the administration of a drug. He stated that within the medical and regulatory communities, nicotine patches – which until June 1998 required a doctor's prescription – are considered to be medicine. He noted that, unlike a mere device, the nicotine and the other components of a nicotine patch are integrated and integral to the drug product Nicoderm. Together, the nicotine and the layers of material of which the patch is composed generate the "pharmacodynamic and pharmacokinetic characteristics" that result in Nicoderm having a therapeutic effect, as opposed to a toxic effect or no effect at all.

Dr. du Souich drew an analogy to ointments, where some components of ointments (their "excipients") are used as the vehicle to deliver topical medications. Some excipients of an ointment might remain outside the body while the medication passes through the skin. The fact that some elements of an ointment will never pass into the body does not make the ointment any less a medicine. Dr. du Souich also provided detailed evidence concerning the characteristics of nicotine patches and of Nicoderm in particular, and though the Board will not repeat that evidence here, it was helpful in reaching a conclusion on this issue.

The evidence also established that HMRC itself refers to Nicoderm as a "medicine" in the labeling on its packaging ("*Nicoderm is a medicine which can help you stop smoking"*) and instructions for the use of the product ("*Nicoderm patches are medicine and must be kept out of the reach of children."*) Also, the language in the product monograph filed by HMRC is consistent with the patch, and not merely the nicotine, being the medicine. Indeed, the monograph refers to "doses" of Nicoderm, not doses of nicotine:

> *Nicoderm at all doses significantly reduced the severity of withdrawal symptoms ... Nicoderm significantly reduced nicotine withdrawal symptoms compared to placebo ... all Nicoderm doses reduced withdrawal symptoms by approximately 40% when compared to placebo ...*

HMRC accepted that Nicoderm was a medicine over which the Board had pricing jurisdiction when it filed a Form 1 ("Medicine Identification Sheet") with the Board for the product in 1998 after the granting of the '700 patent in 1996. HMRC participated actively in the HDAP's "New Medicine Scientific Review", where Nicoderm was analyzed as a new version of an existing medicine. HMRC reviewed and commented on the report, discussing Nicoderm as a medicine without questioning its status as such.

The patentees of other nicotine transdermal patches – Habitrol and ProStep – have filed Form 1's and the prices of those patches are regulated by the Board, indicating that the holders of those patents and the Board have considered a transdermal nicotine patch to be a medicine within the meaning of the *Act*. Moreover, a number of other drugs are administered transdermally by patches, and the patentees of those patches have accepted that the patches are medicines and are subject to the jurisdiction of the Board.

HMRC did not present evidence that spoke directly to the issue of whether or not Nicoderm is a medicine, though the evidence of Ms. Joan Van Zant, a patent agent, as to the scope of the various patent claims, makes the point that all of the claims cover "delivery devices that remain unchanged outside the body ... and do not contain claims for any agents that enter the body", perhaps with intended reference to the *Glaxo* case, where this language is used. However, during her cross-examination, Ms. Van Zant acknowledged that if she were a "*regular person who was not involved in the intellectual property area*", she would consider Nicoderm to be medicine.

Another HMRC witness who spoke to this issue on cross-examination was Mr. Robert Gale, an inventor of two of the patents (the '340 and '700 patents) considered in this proceeding. Mr. Gale is a scientist at Alza Corporation ("Alza") in the United States. As discussed in greater detail below, Alza and HMR developed Nicoderm jointly pursuant to various agreements between them. Mr. Gale's initial view when cross-examined on this point was that nicotine was the medicine and the patch was a delivery device, but he agreed in later questioning that when the nicotine was imbedded in the patch, the product Nicoderm – and all other transdermal nicotine patches – were medicine.

4. ***Findings***

The evidence establishes that nicotine is a substance that is toxic in varying degrees in the human body in any material dosage and ultimately fatally poisonous in sufficient dosage. Nicotine does, however, have some therapeutic effect when administered appropriately. In particular, when integrated in a transdermal patch, nicotine can be delivered to the body in appropriate dosage and achieves a therapeutic effect because it helps people quit smoking, which results in improved health outcomes. The nicotine that is integrated in a transdermal nicotine patch would be ineffectual or toxic without the inert materials within which it is integrated. The materials by themselves are, of course, ineffectual for any therapeutic purpose without the nicotine with which they are integrated.

A transdermal nicotine patch such as Nicoderm includes as one of its features the fact that it effects the delivery of one of its integrated components to the body while other components remain outside the body. However, contrary to HMRC's arguments, the Board cannot accept that this fact makes Nicoderm a mere delivery device and excludes it from the definition of "medicine". Such a conclusion would not be logical, and it would not be consistent with a purposive interpretation of the *Act* and the Board's mandate thereunder.

A substance that has no therapeutic effect in itself, or cannot be used therapeutically by itself, can become useful as a medicine when it is integrated with other substances. Very often, the purpose of the mixture of the active ingredient with inert substances is to put the active ingredient in some form that can effect the delivery of the active ingredient to the body. If the manner in which the substances are integrated to become a single product is patented, the resulting product is in every pertinent sense a "patented medicine" whether it is a pill, or a liquid solution, or a transdermal patch. In all cases the combination with inert substances allows the active ingredient to be put in a form that can be administered in a therapeutic way.

There remains the question of the relevance of the evidence that HMRC itself refers to Nicoderm as a medicine and accepted that it was a medicine under the jurisdiction of the Board until these proceedings. The Board agrees with HMRC that none of these observations in itself is dispositive of the issue of whether or not Nicoderm is a medicine within the meaning of the *Act*. HMRC's own characterization of Nicoderm as a medicine and its earlier acceptance of the Board's jurisdiction cannot confer jurisdiction on the Board if jurisdiction does not arise at law. Neither can the fact that the patentees of other patches accept that a transdermal patch is a medicine and that the Board has jurisdiction to regulate the price of their products.

However, this evidence in combination with that of Dr. du Souich, demonstrates that throughout the pharmaceutical industry and the government regulation of that industry, and by the makers of the product in question and those of analogous products, and in common usage and understanding generally, a transdermal nicotine patch is understood to be a "medicine". As the Board has been instructed by the Federal Court of Appeal to define medicine broadly and in its ordinary sense, this evidence overwhelmingly supports the conclusion that Nicoderm is a medicine within the meaning of the *Act*.

Accordingly, the Board finds that Nicoderm is a medicine within the meaning of the *Act*.

PART III - Do the patents pertain to Nicoderm?

1. *Introduction*

In the *ICN* case, the Federal Court of Appeal found that, in order for the Board to have jurisdiction over a medicine to which a patent pertains – that is, to say that the patent "pertains" to the "medicine" – there must be a rational connection between the invention described in the patent and the medicine. The Court of Appeal rejected ICN's arguments that there must be a high degree of connectedness, such as an infringement test or a demonstration that the patent actually conferred some degree of market power over the pricing of the medicine. Instead, the Court of Appeal said the language of the *Act* demonstrated that there need only be the "merest slender thread" of connection between the patent and the medicine in order for it to be said that the patent pertains to the medicine such that the Board has jurisdiction over the pricing of

the medicine.

There is, of course, a logical connection between the definitions of “medicine” and “pertain” in this context, in that the answer to the question “Does this patent pertain to this medicine?” depends not only on what one means by “pertain”, but on how one defines the particular “medicine” in question. As the Court of Appeal found in the *ICN* case (at page 435), the “rational connection” between the patents in issue in that case and the product Virazole marketed by the patentee was ribavirin, the chemical substance of which Virazole was composed.

As noted above, the Board received guidance in both definitions from the Federal Court of Appeal in the *ICN* case. It is useful here to describe the background of that case in greater detail in this context. The *ICN* case involved the product “Virazole”, which provided certain specified and particular dosages of the drug ribavirin for use in treating certain specified conditions. ICN took the position that the “medicine” was the particular product that was Virazole, arguing, among other points, that Virazole – in its particular dosages and for the conditions it was designed to treat – was the only medicine that ICN was permitted by law to sell in Canada.

ICN claimed that a patent, alleged by Board Staff to pertain to Virazole, was not and could not be used to make Virazole, nor was it ever intended to make Virazole. It was intended to make minute quantities of ribavirin, the active ingredient in Virazole, for laboratory experiments. Another patent alleged by Board Staff to pertain to Virazole described a use for ribavirin that was arguably outside the scope of the permitted uses of Virazole. ICN argued that neither patent pertained to Virazole because they were not patents pertaining to the specific product sold by ICN.

The Board disagreed. The Board recognized that Virazole delivered a particular dose of ribavirin in a particular way. The Board found, however, that the “medicine” was ribavirin, that it was reasonable to interpret the *Act* to that effect, and that it was indeed necessary to interpret the *Act* to that effect in order for the Board to fulfil its mandate. The Board held that, as each of the patents pertained to ribavirin, the generic type of medicine of which Virazole was a particular example, they pertained to Virazole. As noted earlier in this decision, the Federal Court of Appeal agreed with the Board.

It remains to apply this analysis to each of the patents in question in the instant case.

2. ***The ‘700 Patent***

HMRC agrees that the ‘700 patent pertains to Nicoderm, such that if Nicoderm is a medicine within the meaning of the *Act*, (and subject to HMRC’s position on the issues dealt with by the Board in Part I of HMRC’s motion) the pricing of Nicoderm has been subject to the jurisdiction of the Board since November 12, 1996, when the ‘700 patent was granted.

3. ***The '689 Patent***

The '689 patent was granted on December 27, 1994. This patent describes a transdermal nicotine patch in which the components of which it is manufactured, and the manner in which they are combined, result in a delayed release of nicotine into the body some hours after the patch is applied. The '689 patent describes a product that is different than Nicoderm, in that Nicoderm is a nicotine patch in which the choice and assembly of materials result in an initially high rate of release of nicotine after the patch is applied, followed by a gradual release over the balance of the use of the patch.

The question is whether there is nonetheless a sufficient nexus between the '689 patent and Nicoderm to conclude that the '689 patent pertains within the meaning of the *Act*. The Board concludes that the '689 patent pertains to Nicoderm because the '689 patent is a patent for a transdermal nicotine patch, the generic type of medicine of which Nicoderm is a particular example. The Board reaches this conclusion by the logical application of the reasons that informed its decision in the *ICN* case and were accepted
– indeed expanded upon in strong language – by the Federal Court of Appeal.

In assessing the scope of its jurisdiction in the *ICN* case, the Board noted that there are many things about the motives and behaviour of patentees that the Board can never know as it sets about fulfilling its mandate. A patent is intended to give the patentee market power in a wide variety of ways, and it is reasonable for the Board to presume that in any given case it does: the Board has no investigative powers to determine one way or the other. Moreover, as confirmed in the *ICN* case, the Board's jurisdiction is not dependent on proof of market power, though the potential of a patentee to exercise market power is at the root of the rationale for the Board's existence. The Federal Court of Appeal in the *ICN* case stated at page 447:

> *It is not to be assumed, as is suggested by ICN, that simply because the patent does not pertain to the use for which a medicine is presently being sold in Canada its existence will not have a deterrent effect on potential competitors. The potential for a deterrent effect, irrespective of its actual or prospective effect on market power, is the basis of the Board's jurisdiction.*

Subsection 79(1) of the *Act*, for example, speaks of patents "intended" for the production of medicine whether or not they are actually used for the production of medicine. A patentee might not use a patent for the production of the medicine to which it relates, but rather use it to prevent others from taking advantage of the invention to develop or make that medicine or a similar medicine and compete with the patentee. For example, a pharmaceutical company could invent and patent two ways to make a medicine but use only one, using the patent on the other to prevent its competitors from entering the market by producing the medicine with the invention described in the second patent. Or, a pharmaceutical company could patent two versions of a generic medicine, but market only one, using the patent on the other to prevent its competitors from developing or marketing the competing product.

The Board cannot impose on itself the obligation of determining the motives of patentees in this context. The Board's task is to identify a medicine and a patent, and, as confirmed by the Court of Appeal in the *ICN* case, if there is a rational connection between the two such that it can be said that the patent pertains to the medicine within the meaning of the *Act*, to ensure that the price of the medicine is not excessive.

As it turns out in this case, the rational connection between the '689 patent and Nicoderm does entail a demonstrable element of potential market power, though it is not necessary for the Board to find such market power. HMRC and Alza developed the nicotine patch described in the '689 patent but later decided not to market it. Still, the '689 patent prevents any person but HMRC from producing or selling the nicotine patch described in that patent in Canada, and thus prevents potential competitors from entering the market with that product to compete directly with Nicoderm. This could enhance HMRC's market power and, depending on other competitive factors in the market, could have an effect on HMRC's ability to exact a higher price for Nicoderm.

To conclude, the '689 patent pertains to Nicoderm in that it pertains to a transdermal nicotine patch, the generic type of medicine of which Nicoderm is a particular example.

4. ***The '340 Patent***

(a) *The patent*

The '340 patent was granted on August 9, 1994. This patent describes a process for treating certain chemical substances to prevent the formation in those substances of crystals ("crystalline hydrates") that impair the utility of the substances. The process involves heating the substances in certain defined ways.

Where the substance in question is the active ingredient in a transdermal patch, the formation of crystals could have an unacceptable effect on the release rate and therapeutic effect of the ingredient, and so the patent has a particular potential usefulness for transdermal patches.

In the description of the '340 patent, the inventors of the patent state that, while the patent uses the agent scopolamine in a transdermal patch as an example of a product to which the process can be applied, the patent also applies to dispersions of any other liquid agents that form crystalline hydrates. The patent continues (at page 7):

> *Liquid agents which may have these characteristics include, without limitation, secoverine, benztropine and nicotine.*

Another similar reference to the possible usefulness of the invention for nicotine is made earlier in the patent (at page 2).

HMRC argued that the '340 patent could not be said to pertain to Nicoderm because nicotine does not form crystalline hydrates. Board Staff argued that HMRC's position requires the Board to look beyond the face of the '340 patent to look at the science concerning crystallization of liquid agents – which the Board has declined to do in the past, and as Federal Court of Appeal in the *ICN* case confirmed the Board should not do. Board Staff argue that looking just at the face of the patent it does pertain to Nicoderm, given the references in the descriptive section of the patent to its potential usefulness for nicotine.

(b) *Does the '340 patent "on its face" pertain to Nicoderm?*

Board Staff argued that the Federal Court of Appeal in the *ICN* case instructed the Board not to look beyond the face of the patent, and that it did so for good reasons that should govern the Board in this case as well. As Board Staff noted, the Court of Appeal in the *ICN* case used strong language on this point, stating that it was "impermissible" for the Board to go beyond the face of the patents to determine if they pertained to Virazole.

HMRC distinguishes the *ICN* case from the instant case on several grounds, one of which is that in the *ICN* case, it was possible to determine the substances or uses to which the patents pertained from the face of the patents. The question in that case was whether evidence was admissible to contradict the information on the face of the patents, or to construe or invalidate the patents. The direction from the Court of Appeal prohibited analysis beyond the face of the patent to contradict what was said on the face of the patent. In the instant case, HMRC argued, there is no assertion on the face of the '340 patent that the invention it describes is useful for nicotine. The references to nicotine are merely speculative, and do not actually state that a liquid dispersion of nicotine (such as is used in a nicotine patch) would benefit, in the sense for which the patent was developed, from the use of the invention.

The legal burden of establishing that the '340 patent pertains to Nicoderm lies on Board Staff. The question for the Board at this stage of the analysis is whether, looking just at the face of the patent, there is sufficient reference to a nicotine patch to say that the patent pertains to Nicoderm. While acknowledging that the question has prompted considerable argument by the parties and deliberation by the Board, the Board is satisfied that, having reference only to the face of the '340 patent, it does pertain to Nicoderm.

As was argued by Board Staff, patents are carefully, conscientiously drafted documents. Scientific or technical ideas and language are not used casually, and indeed the scientific discussion in a patent is considered to be part of the relevant literature in the field in question. Accordingly, the references in the '340 patent to its potential usefulness for a liquid dispersion of nicotine do not appear accidentally. The inventors were scientists experienced in the field – indeed, in both the chemistry and the pharmacology of transdermal patches – and it can be presumed that they had reasonable scientific grounds for including liquid dispersions of nicotine in the category of substances that could potentially benefit from the use of the invention.

While the Board does not consider it necessary to go further in order to establish that the '340 patent pertains to Nicoderm, it should also be noted that there is a separate argument in support of the position that the '340 patent, having reference only to its face, pertains to Nicoderm. As noted earlier, subsection 79(2) of the *Act* provides:

> *79(2) For the purposes of subsection (1) and sections 80 to 101, an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine*

The Board concludes that it can be inferred from the language in the patent that the inventors "intended" it to be useful for a nicotine patch. This intention was, to be clear, only applicable in the contingency that it could be useful in that regard, but the inventors considered it reasonable from a scientific point of view and appropriate from a patentee's point of view – that is, a patentee drafting a patent to stake out the scope of the patent – to give notice in the patent of its potential usefulness for nicotine patches. The Board views this intention of the inventors to bring the '340 patent within the provisions of subsection 79(2).

Accordingly, the Board concludes that, having reference only to the face of the '340 patent, that patent pertains to Nicoderm.

(c) *The evidence beyond the "face" of the '340 patent*

During the initial evidentiary portion of this phase of the jurisdiction motion, the Board did not receive evidence from either party as to the scientific issues underlying the references to nicotine in the '340 patent. Board Staff and HMRC each relied on the wording of the patent to make their arguments that the '340 patent did, or did not, pertain to Nicoderm.

After receiving evidence during the initial phase, the Board determined that it should receive further argument on whether or not it should have reference to evidence off the face of the '340 patent, and, while reserving on that legal question, the Board invited the parties to submit evidence "off the face of the patent" on the scientific issues underlying the language in the patent.

On the first point, the Board is convinced by the argument it has received, that it is not necessary in this case to have reference to evidence beyond the face of the patent, and that the Board should not rely on such evidence in this case. While there could be a case in the future where evidence beyond the patent itself is necessary to determine whether the patent pertains to a medicine, the language in the '340 patent establishes a sufficient connection between the patent and Nicoderm to avoid the need for such evidence in this case. Nevertheless, the Board did receive evidence on this point and considers it appropriate to provide the parties with its conclusions.

The evidence before the Board indicated that a necessary precondition to the creation of *crystalline* hydrates in a solution of nicotine and water is the existence of a hydrate of nicotine; that is, a state of bonding between the water molecules and the nicotine molecules (or, in the case of a large hydrate or "clathrate", a state in which the nicotine molecules influence the structure of the water molecules). The evidence established that the observation of certain characteristics demonstrated by solutions of nicotine in water is best explained by the formation of a hydrate of nicotine, though there has been some consideration given to other possible explanations. The Board was satisfied that the most probable conclusion, and the conclusion shared by many in the scientific community, is that a hydrate of nicotine does form when nicotine is in solution in water.

The next question is whether it might reasonably be expected that a solution containing hydrates of nicotine is capable of continuing to the stage of crystallization; that is, the formation of crystalline hydrates. The Board was persuaded by the evidence of Messrs. Crooks and Durst on this point, each of whom had considerable, relevant, expertise in this area. The Board is satisfied that, given the physical and chemical qualities of nicotine, it is not unreasonable to conclude that nicotine in solution can be capable of forming crystalline hydrates.

The Board appreciates that there has been a considerable period during which nicotine has been the subject of scientific observation, without any recorded occurrences of it forming crystalline hydrates. On the other hand, studies to crystallize nicotine have not been conducted with adequate methodological rigor, and the evidence established that it could take very specific, and not easily predicted, conditions for crystallization to occur. Also, the Board notes that it was not until more than 100 years after the discovery of scopolamine, and then in unexpected circumstances, that scopolamine was observed to form crystalline hydrates when in a scopolamine patch. Two more years passed before the degree of crystallization interfered with the effectiveness of the scopolamine transdermal patches, at which time the production of the patches had to be halted until development of the invention in the '340 patent, which proved to be a complete solution to the problem. If the '340 patent had been developed for some substance other than scopolamine before the sudden appearance of crystalline hydrates in scopolamine patches, there would have been a period where one would *not* have concluded that the invention was useful for scopolamine patches. Yet it is not only useful, but essential in Alza's production of scopolamine transdermal patches.

Accordingly, when one is assessing the evidence concerning the probability that a liquid dispersion of nicotine could form crystalline hydrates, the somewhat unpredictable nature of these events and the considerable usefulness of the invention if the events do occur should be borne in mind. Our experience with nicotine transdermal patches is still relatively recent and the '340 patent has a number of years yet to run.

Accordingly, the Board is satisfied that, while there can be no scientific certainty on this point, it is not unreasonable to conclude that a liquid dispersion of nicotine may be capable of forming crystalline hydrates. Thus the '340 patent has potential usefulness in the manufacture of a nicotine patch, and Nicoderm in particular. Accordingly, if the Board were to consider evidence beyond the face of the '340 patent, it would conclude that this patent does pertain to Nicoderm.

PART IV - Whether HMRC is a "patentee" of the '700, '689 or '340 patents

1. *Introduction*

In or about 1986, Alza and HMRC's predecessor corporation, Merrell Dow Pharmaceuticals Inc. (hereafter referred to as HMR), set out on a joint venture to develop and market a transdermal nicotine patch. Alza brought to this project its expertise and proprietary information concerning transdermal patches. HMR, which had been marketing chewing gum containing nicotine to people attempting to quit smoking, brought its expertise and proprietary information concerning the therapeutic use of nicotine to assist in smoking cessation.

The parties first entered into a confidentiality agreement dated March 21, 1986, and then an Interim Development Agreement effective January 1, 1987 (the "Interim Agreement"). Ultimately the parties entered into a Development and License Agreement (the "License Agreement") dated November 27, 1989, by the terms of which the parties exchanged their respective expertise and set out the terms of their collaboration. The parties agreed to cooperate to develop and commercialize the nicotine patch they had begun to develop under the Interim Agreement. Alza obtained the various patents for the product and was responsible for obtaining, or assisting HMR in obtaining, the required regulatory approvals. HMR assumed responsibility for the costs of the project. HMR was given licenses for the technical information and patents held by Alza, as discussed in greater detail below.

On the same date as the License Agreement, Alza and HMR entered into a Nicotine Patch Supply Agreement (the "Supply Agreement"), pursuant to which HMR agreed to purchase, and Alza agreed to manufacture and sell, the nicotine patch that was to be developed pursuant to the License Agreement.

An important feature of the relationship established by the License Agreement and the Supply Agreement is that, with one exception, Alza exclusively was entitled to manufacture the product. The exception, stipulated in Section 8 of the Supply Agreement, is that where Alza cannot, or does not, supply the product, HMR is entitled to manufacture the product, or have the product manufactured by some other supplier than Alza. In the "Grant of License" provisions of Sections 5 and 6 of the License Agreement, HMR is given an unqualified license to use and sell the product, but is only licensed to "make and have made" the product in accordance with Section 8 of the Supply Agreement; that is, when Alza is unable or refuses to manufacture the product. HMRC is the Canadian affiliate of HMR, and as such, exercises in Canada the rights of

HMR under the License Agreement and the Supply Agreement. Pursuant to the License Agreement, HMR is entitled to assign its licensed rights to an affiliate such as HMRC. Pursuant to the Supply Agreement, HMR's affiliates, such as HMRC, are entitled to purchase product directly from Alza and such purchases are credited to HMR for the purposes of the various pricing provisions in the Supply Agreement.

The definition of "patentee" for the purposes of the Board's jurisdiction is expressly broadened by section 79(1) of the *Act* to include not only the person entitled for the time being to the benefit of the patent but also any person entitled to exercise rights in relation to the patent. Needless to say, this expansion of the definition of patentee is necessary for the Board to fulfil its mandate. The Board must be able to prevent excessive pricing of medicines by persons taking advantage of the patent regime established by the *Act*, whether or not they are actually the holder of a patent or patents pertaining to the medicine.

Accordingly the question for the Board with respect to the patents in question is whether or not HMRC, as a result of the License Agreement or otherwise, was either a person entitled to the benefit of the patents or a person entitled to exercise any rights in relation to those patents. As noted by HMRC in argument, this is not the same analysis as the "slender thread" analysis instructed by the Federal Court of Appeal with respect to the question of whether or not a patent pertains to a medicine. This is primarily a legal question of contractual rights and/or intellectual property rights, but the analysis nonetheless involves the determination by the Board of its statutory jurisdiction and the interpretation in that regard of the relevant provisions of the *Act*.

2. ***The '700 Patent***

HMRC acknowledges that it is a licensee of the '700 patent. Given the Board's findings with respect to the status of Nicoderm as a medicine and HMRC's agreement that the '700 patent pertains to Nicoderm, the Board concludes that HMRC is a patentee of a medicine that pertains to Nicoderm.

3. ***The '689 Patent***

As noted above, the inventions described in the '689 patent are not used for the production of Nicoderm. The Board has nonetheless determined that the '689 patent pertains to Nicoderm, and so the question at this stage is whether HMRC is a "patentee" within the definition of that term in the *Act*.

HMRC argued that the '689 patent was not covered by the License Agreement and that the parties entered into a separate development agreement with respect to the nicotine patch described in the '689 patent.

Board Staff argued that the License Agreement is not specific to Nicoderm, but rather covered any nicotine patch that the parties might develop using the combined know-how and patents of the two parties. Also, Board Staff noted that the '689 patent was listed in the appendix ("Appendix B") to the License Agreement in which Licensed Patents were to be listed.

The inclusion of the ‘689 patent in Appendix B argues strongly for its status as a licensed patent because the purpose of Appendix B was to record the intentions of the parties as to which patents would be licensed, and there was no evidence that the inclusion of the ‘689 patent in Appendix B was a mistake. Its inclusion is consistent with the structure of the joint venture and the various agreements, in that at the inception of the project the parties did not know which technical information or patents would be useful for the nicotine patch they were developing, yet the licensing of the technology and patents was necessary for the joint venture to proceed. Also, the grant of licenses of the technical information and patents in the License Agreement was immediate upon execution of those agreements (presumably subject in some cases to the coming into existence of the information or patent), not contingent or delayed relative to the final development of a specific product.

Furthermore, their joint venture was an exclusive agreement. Alza did not have the right to develop or market a nicotine patch using the ‘689 patent other than with HMR. Although Alza and HMR elected not to produce the delayed release nicotine patch described in the ‘689 patent, each of them had the right to sue any person who used the invention described in the ‘689 patent to produce such a patch. HMRC had the power to prevent a competitor from entering the market in Canada with the delayed release nicotine patch (described in the ‘689 patent) that would compete with Nicoderm. It would have been a peculiar arrangement if HMR were *not* a licensee of the ‘689 patent under the License Agreement, for in that case it could not protect its market for Nicoderm in Canada.

Accordingly, the Board concludes that HMRC was a patentee with respect to the ‘689 patent.

4. ***The ‘340 Patent***

The evidence before the Board was that the ‘340 patent was developed to address a particular problem that Alza was encountering with crystallization that was occurring in the liquid scopolamine in patches. The ‘340 patent was not developed for use for Nicoderm or for any nicotine patch.

Nonetheless, Board Staff argued that HMRC was a licensee, and thus a patentee, because the terms of the License Agreement are sufficiently broad to grant the rights in this patent to HMR. The License Agreement gives HMR the rights to any patents or technical information that could be useful in the development or production of a nicotine patch. Board Staff argue that, given that the ‘340 patent appears to have some potential usefulness for nicotine patches, it would be included in the patents and/or technical information licensed to HMR.

The Board has considered the arguments of Board Staff, but is not satisfied that it was ever the intention of the parties to the License Agreement to license the ‘340 patent or the technical information it contained to HMR. It appears to the Board that this is a question of contract law; that is, of the interpretation of the License Agreement. The wording of the License Agreement does not capture a patent with only a

speculative and contingent usefulness for a nicotine patch. It does not appear ever to have been the intention of the parties to the License Agreement that the '340 patent be covered by it, and this is borne out over the life of the License Agreement by the absence of the '340 patent from Schedule B, where the licensed patents were to be listed.

Accordingly, the Board concludes that HMRC is not and has not been a patentee of the '340 patent. The dissenting opinion of the Chairman on this point appears at the conclusion of this decision.

PART V - The Patent Applications

a) *Introduction*

Board Staff argued that HMRC is now, and has been since 1992, a patentee with respect to two patent applications, the '446 application (filed in December 1990) and the '352 application (filed in April 1991), each of which was "laid open" in accordance with the provisions of the *Act* in 1991. While the patents have not yet been granted, Board Staff argued that HMRC has had the benefit of the patents or been entitled to exercise rights in relation to the patents and that it can thus be said that HMRC is now, and has been since the applications were laid open, a "patentee" within the meaning of subsection 79(1) of the *Act*[4].

This issue is only relevant if the Board can conclude that the inventions described in the applications pertain to Nicoderm, and that point will be addressed first in this section of this decision. The Board will then address the issue of whether or not HMRC is already a "patentee" of the inventions described in the applications despite the fact that the patents have not yet been granted.

b) *Whether the inventions described in the applications "pertain" to Nicoderm*

The '352 patent application is for a patent for an "in-line" adhesive (composed of polyisobutylene) that is useful in nicotine transdermal patches where the adhesive itself includes nicotine dissolved in the polyisobutylene. This is the adhesive used in Nicoderm patches.

The '446 patent application is for a patent for the pouch in which a nicotine patch can be packaged so as to avoid deterioration in the quality of the nicotine. Nicotine is highly susceptible to degradation in the presence of oxygen, light and humidity. Nicotine also dissolves the glues normally used in packaging. The pouch described in the '446 patent application contains laminates that keep the nicotine in and

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[4] This issue is not pertinent to the applications for the '700, '689 or '340 patents, because those applications were made before October 1, 1989, when the relevant amendments to the *Patent Act* came into effect. The '700, '689 and '340 patents are "Old Act" patents, whereas the '446 application and the '352 application, each filed after October 1, 1989, are for "New Act" patents.

keep the degrading elements out. This pouch is the pouch in which Nicoderm is packaged and sold.
As the nicotine-laden adhesive described in the '352 patent is the adhesive actually used in the Nicoderm product and the special pouch described in the '446 patent is the pouch in which Nicoderm is actually packaged to keep it useful as medicine, the Board has no difficulty in concluding that the inventions described in these two applications pertain to Nicoderm.

Both of these patent applications are listed on the schedule to the License Agreement in which the patents licensed to HMR by Alza are listed, though, as mere applications and not yet patents, they are listed there for reference only. The reference, of course, is to the fact that when the patents are granted, they will be licensed to HMRC for the marketing of Nicoderm. The patents for which application has been made fall squarely within the terms of the License Agreement as patents that are useful in making, using or selling Nicoderm. It is apparent that HMR is currently entitled to make Nicoderm or have it made using the adhesive and pouch described in the applications; that is, that HMR is entitled to take advantage of the technical information described in the applications. In other words, having licensed the technology to HMR, Alza will not, on the grant of the patents in question, be in a position to sue HMR for having sold nicotine patches that use the adhesive and pouch described in the applications. The commercial intent of the arrangements between Alza and HMR is that HMR have, today, the rights in Canada that flow from the patent applications, including the right to sell nicotine patches that use the inventions described in the applications without the threat to which all others are exposed of a subsequent action in damages.

c) *Whether HMRC is already a "patentee"*

(i) **The payment of "patent rate" royalties by HMRC**

Board Staff argued that the manner in which HMR and Alza structured and paid royalties under the License Agreement demonstrates that Alza and HMR considered HMR to have patent protection in Canada from the inception of the sale of Nicoderm in this country in 1992. The argument is as follows.

The License Agreement provides for the payment by HMR of royalties for the manufacture, use or sale of the product at two rates: one basic rate in consideration of the technical information licensed to HMR, and a higher rate when HMR enjoys the benefit of patent protection.

HMR has been paying the higher "patent" royalty rate provided for in the License Agreement on its sales in Canada from the outset of those sales in 1992. Thus, Board Staff argue, Alza and HMR have recognized that HMRC has had effective patent protection from 1992, consisting of the patent protection afforded by the laid open patent applications.

HMRC replied that the patent royalty rate was being paid to Alza because HMR

was having Nicoderm made (by Alza) in a jurisdiction where there was a patent already granted (in the United States), and the terms of the License Agreement mandated payment of the patent rate royalties in this situation.

In addressing HMRC's position, Board Staff noted that the purpose of a patent license is to give permission to another person to do what the patentee would otherwise exclusively be entitled to do, i.e. make, use or sell a product in circumstances that would otherwise infringe the patent. HMR was granted a license to *manufacture* Nicoderm only in very limited circumstances, none of which has arisen, so it cannot be said (as is alleged by HMRC) that patent-rate royalties must be paid for having Alza manufacture a product on HMRC's behalf. HMRC pays a separate amount to purchase the product manufactured by Alza pursuant to the Supply Agreement, as established by the formulae in the Supply Agreement, and then pays royalties based on sales at a rate determined by whether or not the product is patented in the jurisdiction where the sales occur.

The Board cannot accept HMRC's explanation for the payment of royalties at the patent rate. It does not accord with the terms of the License Agreement and the Supply Agreement in that no circumstances have arisen in which HMR would have the right (a license) to make Nicoderm, or have another party make it on HMR's behalf. The "Grant of License" in the License Agreement is unambiguous in expressly limiting the license to manufacture the product to circumstances in which Alza could not or would not do so. Alza otherwise retained to itself the exclusive right to manufacture the product. Alza has not refused or been unable to manufacture Nicoderm. Therefore, HMR does not have, and has not had, a license to have Alza manufacture Nicoderm in the circumstances to date, and thus could not be required to pay a royalty for such manufacture.

For these reasons the Board agrees with Board Staff that the correct explanation for the payment of royalties by HMR at the patent rate is the acceptance by HMR and Alza that HMR had effective patent protection; that is, market protection for Nicoderm equivalent to patent protection in Canada arising from the laid open patent applications. However, while this is strong evidence of the extent to which the laid open process provides *de facto* patent protection, it is not dispositive of the question of whether this gives rise to jurisdiction on the part of the Board.

(ii) **The Board's position on "patents pending"**

In its *Bulletin No. 15* (January 1995), the Board noted that the laid-open patent application process, whereby 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, 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. The Board observed that since the patentee benefits from retroactive patent infringement protection during the pre-grant period, it is also accountable for the price it charges during that period. The Board concluded that it has the authority under the *Act* to recover any excessive revenues

from a patentee who takes advantage of the pricing power conferred by the laid-open patent application process.

At the time the Board interpreted the *Act* with respect to this issue, the conclusion reached by the Board appeared sufficient to meet the mischief at hand and was conservative, in the sense that the Board refrained from exercising any jurisdiction until the patent was actually granted, allowing for the possibility that the patent might not be granted. The Board did not appreciate, however, the significance of the potential for patentees to take advantage of the laid-open process to secure *de facto* (and in some senses, given the right to sue retroactively for infringement, *de jure*) patent protection for an extended period of time, with two potentially irreversible adverse consequences. The first of these is that, during the period in question, the public might be forced to pay excessive prices for medicines, a situation the Board cannot remedy other than with approximate redress through the types of order it can make. The second is that some potential users of the medicines might avoid using and benefitting from them while they are priced excessively, perhaps with serious consequences. Both of these situations are undesirable from a health care policy perspective.

Also, the Board has not until this case been cognizant of the implications of the situation it faces with respect to the patent applications in question, which are applications for patents that have already been granted in the United States. The Board heard convincing evidence that it is a virtual certainty that a Canadian patent application will result in a patent grant if the equivalent patent has already been granted in the United States. In this situation, the conservative approach applied by the Board to patent applications generally – of waiting to see that the patent is actually granted – is not appropriate. The patentee and potential competitors know that it is just a matter of time before the patent issues. It seems improbable in the extreme that a competitor facing this situation would incur the expense of entering the market only to have to face an action in damages when the patent is granted.

The Board must be cognizant of the practical, and sometimes evolving, realities of the circumstances in which it must act to prevent the excessive pricing of patented medicines. In 1995 the Board noted that patentees had been dedicating patents to the public domain in an attempt to remove themselves from the definition of "patentee". The patentees did this in an effort to evade the jurisdiction of the Board. The Board, however, determined that the dedicating patentee continued to be “entitled to the benefit of the patent” beyond the date of the dedication and thus interpreted the term “patentee” in the *Act* to include a patentee in the post-dedication period.

With respect to the circumstances of this case, the Board has no difficulty in concluding on the evidence that HMRC has been taking advantage of the laid-open patent application process to secure *de facto* patent protection for Nicoderm. No potential infringers have emerged, doubtless for the reasons discussed above, and thus Alza and HMRC have been content to allow the patent applications to sit for some nine years without having been granted. It is apparent that Alza and HMRC are content with the *de facto* patent protection that the laid-open patent application process gives –

and is designed to give – HMRC.

The Board also finds that HMRC has been cognizant of the advantages this situation has brought it vis à vis the Board's potential to regulate the price of Nicoderm, in that HMRC had the *de facto* patent protection without having been subject to the Board's jurisdiction from 1992 when the product was introduced until (as HMRC would have it) 1996 when the '700 patent was granted. This cognizance of the situation on the part of HMRC and Alza is apparent from the evidence that HMRC and Alza have considered abandoning the patent applications. The Board can think of no other reason that an applicant for two patents so useful in the production and marketing of its product would abandon those applications but that this abandonment might give rise to an argument that the Board does not have jurisdiction to require HMRC to repay any excessive revenues earned from 1992 until the date on which the first patent pertaining to Nicoderm was granted.

(iii) **The Interpretation of the *Act***

The Board, then, has identified in these proceedings an instance – the use of the '352 and '446 patent applications to achieve pricing power – in which it is necessary for the Board to have jurisdiction in order to fulfil its mandate. The next question is whether the wording of the *Act* provides this jurisdiction. Can a person who has applied for, but not yet been granted, a patent be a "patentee" within the meaning of the patented medicine pricing provisions of the *Act*?

The answer to that question must begin with the observation that the Board would only very reluctantly conclude that Parliament did not, in the legislation it enacted, effectively address the mischief (excessive pricing of patented medicines) it intended to address. The very purpose of the patented medicine pricing provisions of the *Act* was to balance the enhanced patent protection being simultaneously enacted, with a process for ensuring that the resulting pricing power did not result in excessive prices for medicines. If the Board does not have jurisdiction to avoid the excessive pricing of medicines where patent applications can be presumed to have given the applicants pricing power, the *Act* will not in those circumstances achieve the purpose for which it was enacted.

Subsection 79(1) of the *Act* provides the definition of "patentee" for the purposes of the Board's jurisdiction:

> *79(1) "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 [compulsory license], that other person in respect of those rights.*

The *Act* provides for the retroactivity of patent protection in subsection 55(2):

> *55(2) A person is liable to pay reasonable compensation to a patentee and to all persons claiming under the patentee for any damage sustained by the patentee or by any of those persons by reason of any act on the part of that person, after the application for the patent became open to public inspection under section 10 and before the grant of the patent, that would have constituted an infringement of the patent if the patent had been granted on the day the application became open to public inspection under that section.*

Section 55 represents an important part of the regime put in place by the *Act*. Patent applicants are given a right to sue for damages arising during a period when they were not holders of the granted patent. Acts that did not at the time infringe the patent (because the patent had not yet been granted) are nonetheless made actionable by this section. What the applicant cannot do *pending* the grant of the patent is take action to prevent or recover damages for what would (once the patent is granted) be infringing acts, but if the applicant and potential "infringers" are confident of the eventual grant of the patent, the ultimate rights and interests of the parties are clear from the time the application is laid open.

The Board considers that the combination of these sections of the *Act* in the context of the situation facing the Board give the Board the ability to fulfil its mandate by ensuring that medicines are not excessively priced during the patent pending period. The Board has already taken the position, as noted above, that the retroactivity of patent protection creates a period prior to the grant of a patent regarding which the patentee will be subject to the jurisdiction of the Board. The proposition of Board Staff in this case is the logical extension of that position so as to allow the Board to exercise its mandate in a situation where, as here, the grant of the patent is pending, but inevitable. There is no reason why the Board should decline to investigate an allegation of excessive pricing in this type of situation and wait for the inevitable grant of the patent to take remedial steps that will be less than adequate after the fact of the excessive pricing. As discussed above, such a situation could result in the Board standing by while prices for patented medicines are charged that will inevitably be determined to be excessive, with only a limited ability to respond to the situation from a remedial point of view when the patent is granted.

Conclusion

Accordingly, the Board is able to conclude that it has had jurisdiction over the pricing of Nicoderm and the obligation to ensure that Nicoderm is not sold in Canada at excessive prices from and after July 1992 when HMRC introduced Nicoderm to the Canadian market.

PART VI - CONCLUSION

For the reasons discussed above the Board concludes that it has jurisdiction

over the pricing of Nicoderm from the date of its introduction to the Canadian market in 1992 to the present time.

This conclusion completes the Board's consideration of HMRC's motion. The Board will now proceed to consider the matters set out in the Notice of Hearing on their merits.

Board Members: Robert G. Elgie, Chairman
Réal Sureau
Anthony Boardman
Ingrid Sketris

Board Counsel: Gordon K. Cameron

Sylvie Dupont
Secretary of the Board

August 8, 2000

Partially Dissenting Opinion of Dr. Robert Elgie

I regret that I must differ from my colleagues on this panel of the Board with respect to the issue of whether or not HMRC is a patentee of the ‘340 patent within the meaning of that term in the relevant sections of the *Act*. I was persuaded by the arguments of Board Staff that, given the broad terms of the License Agreement, HMRC had, and has, the benefit of the ‘340 patent and is a patentee of that patent within the meaning of the *Act*.

I gave careful consideration to the evidence presented to the Board with respect to the genesis of the ‘340 patent as a “fix” for a problem with scopolamine patches. I accept that the initial reason this patent was developed was to assist in the manufacture of a scopolamine patch, not a nicotine patch.

However, when looking at the intention of the parties so as to interpret the License Agreement, I do not consider it appropriate to look narrowly at the question of whether, at the time of the License Agreement, the parties had the ‘340 patent in mind, or whether at the time of the development of the ‘340 patent, the parties had the License Agreement in mind. Instead, I consider it appropriate to look at the overall intentions of the parties, and in particular the fact that this was a development agreement. By its very nature, a development agreement concerns matters that are under development, such that the particular science or technology that will turn out to be relevant and useful is not necessarily known – and in this case was not known – at the outset of the project.

The scope of the License Agreement must be interpreted broadly to give effect to this feature of the parties’ respective knowledge at the time the contract is formed. In other words, given that the early stage of development prevents the parties from defining precisely which patents and what technical information Alza has or might in the future develop that could be necessary or useful in the venture, the contract must be interpreted so as to give the benefit to HMR, of whatever technology turns out to have potential usefulness for the project. This reasoning applies whether or not the parties directed their minds to the specific patent or item of information at the time the contract was entered into.

In this case, Alza came to the relationship with expertise in transdermal patches and HMR came to the relationship with expertise in the therapeutic use of nicotine. The goal was to develop a nicotine patch. It was the intention of the parties that HMR would have the benefit of whatever patents or technical information Alza owned or developed that might reasonably be necessary or useful in the development of the nicotine patch. Towards the same end, the License Agreement gives the *exclusive* right to this intellectual property to HMR, such that HMR can exclude others from developing or marketing competing products.

The Board has concluded that it is not unreasonable to expect that a liquid dispersion of nicotine (such as is used in a nicotine patch) may be capable of forming crystalline hydrates. Having reached this conclusion, I believe that it follows that the

‘340 patent could have been or could in the future be necessary or useful in developing and marketing a nicotine patch such as Nicoderm, either in the development of the product itself, or the exclusion of others from using the invention to develop their own products.

Accordingly, I find that HMRC was a patentee of the ‘340 patent, and that the Board has had jurisdiction over the pricing of Nicoderm on that account as well as the other reasons cited in the main decision.