Decision: PMPRB-06-D1-ADDERALL XR

IN THE MATTER OF the *Patent Act* R.S.C. 1985, c. P-4, as amended

AND IN THE MATTER OF Shire BioChem Inc. (the "Respondent") and the medicine "Adderall XR"

Introduction

The Patented Medicine Prices Review Board (the "Board") is in the course of a public hearing pursuant to the *Patent Act* (*Act*) to determine whether the medicine Adderall XR, which is used to treat Attention Deficit Hyperactivity Disorder (ADHD), was or is being sold at excessive prices.

Shire BioChem Inc. (Shire) holds a patent that pertains to Adderall XR and markets the medicine in Canada, and is thus the respondent in this hearing. Canada's Research-Based Pharmaceutical Companies (Rx&D), a national association of pharmaceutical companies whose products include patented medicines, has intervened in this hearing.

This is the decision of the Board on a motion brought by Shire and supported by Rx&D. The motion is for an order excluding the first several years that Adderall XR was sold in Canada from the time period that the Board may consider when making a determination of whether or not Adderall XR was sold at excessive prices.

Background

The regulatory mandate of the Board is to ensure that patented medicines sold in Canada are not sold at prices that are excessive. In [1987] an amendment to the *Patent Act* eliminated the compulsory licensing regime and extended patent rights. In order to ensure that the enhanced market power associated with the enhanced patent rights did not result in sales of patented medicines, at the ex-factory level, at excessive prices, the amendments included the creation of the Board. The rationale for the creation of the Board is discussed in the *Manitoba Society of Seniors Inc. v. Canada (A.G.)* case, Justice Dureault described what was, at that point, the curtailment of the compulsory licensing regime (they were later eliminated entirely) and the concomitant concerns about excessive pricing of medicines:

> [Under the new regime], it was recognized that the price of new medicines would be introduced and maintained at higher levels than otherwise would be the case with competition under compulsory licensing. The increased financial return to the brand name firm was expected to encourage

> pharmaceutical research and development in Canada. From the government's standpoint, growth of this industry with enhanced employment opportunities was considered to be a desirable objective. On the other hand, legitimate concerns arose that, from the consumer's standpoint, prices might escalate to unacceptable levels during the exclusivity period. To counteract this mischief, the impugned amending provisions were also linked to a regulatory scheme to be administered by the Board referred to earlier. …
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> The policy of the impugned amendments appears to me to be primarily directed at increasing patent protection or exclusivity for new inventions of medicines. It is intended to provide greater financial rewards for pharmaceutical firms developing new medicines. Ordinarily, it should foster greater research and development. That does not strike me as an improper use of the patent power. And while Parliament was not oblivious to the risk that patent exclusivity might result in excessive prices, it sought to deal with that incidental mischief by instituting the regulatory Board with its monitoring and reviewing powers. …
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> I conclude that in pith and substance the impugned amendments pertain to the field of patents of invention. As the legislation re-establishes exclusivity for patented medicines to an extent not enjoyed since 1931, Parliament also provided for a mechanism to deal with price abuse that may incidentally occur as a result of these monopolies it created. The Board is only empowered to deal with the excessive prices of medicines patented under the new regime. It is not a scheme of general supervision of all patented pharmaceutical inventions. It clearly deals with the potential abuse flowing incidentally from the newly created patent exclusivity. Any firm not wishing to submit to the Board's authority can do so by renouncing its right to obtain a patent. Thus, the legislation is targeted to patent and patent abuse.

Also, Justice Cullen in *ICN Pharmaceuticals, Inc. v. Canada (PMPRB)* identified the mischief that the Board's jurisdiction was created to address:

> Sections 79 to 103 of the *Patent Act*, creating the Patented Medicine Prices Review Board, were enacted in response to the abolition of the compulsory licensing regime. Parliament's intent was certainly to address the "mischief" that the patentee's monopoly over pharmaceuticals during the exclusivity period might cause prices to rise to unacceptable levels.

The *ICN* case involved, among other things, an allegation by the patentee that the patent in question did not confer market power because it was exclusively for research. The question arose as to whether the price control provisions of the *Patent Act* applied only to patents that provided actual market power, or whether those provisions applied whenever the medicine was patented. The Board and Board Staff took the position that

proof of actual market power should not be required because the Board cannot know which patents confer market power and which do not.

In its decision in *ICN*, the Federal Court of Appeal agreed, stating that the price control provisions (in particular, subsection 83(1) of the *Patent Act*) apply whenever a patent pertains to a medicine, whether or not market power can be demonstrated. The Board does not take the Federal Court of Appeal's comments on this point to detract from the quite obvious connection between the market power associated with the statutory monopoly granted by patents and the price control provisions of the *Patent Act*.

The Board, in conjunction with the pharmaceutical industry and other stakeholders, according to subsection 96 (5) of the *Act*, developed guidelines to implement the price determination factors of section 85 of the *Act* in a manner that provides patentees with specific guidance with which they can ensure that their medicines are sold at prices that will be presumed by the Board not to be excessive.

Shire's motion raises the question of the period during which a patentee is required to price its medicine at a level that is not excessive. To address the mischief for which the Board was created, the answer would be that the patentee should be required to price its medicine at non-excessive levels during the period that it could have market power associated with its patent. The issue then becomes whether or not the *Patent Act* provides the Board with the jurisdiction to prevent excessive pricing during that period; that is, whether, in the wording of the *Patent Act*, Parliament provided the Board with the tools with which to address the mischief that the Board was created to address.

By virtue of the operation of sections 10 and 55 of the *Patent Act*, a person who is granted a patent begins to acquire market power from the date that the patent application is laid open to the public. This is because potential competitors of the patentee are aware that if the patent is granted, any use of the patented invention between the time the patent application is laid open and the date the patent is granted will be treated as an infringement of the patent. Section 55 provides:

> **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.
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> …
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> (4) For the purposes of this section and sections 54 and 55.01 to 59, any proceeding under subsection (2) is deemed to be an action for the infringement of a patent and the act on which that proceeding is based is deemed to be an act of infringement of the patent.

The HMRC case

In its decision in the proceeding involving Hoechst Marion Roussel Canada ("*HMRC*"), the Board noted that the patentee in that case had purposefully delayed the grant of patent in order to have the benefit of section 55 while avoiding the jurisdiction of the Board, and that this approach could be used by any patentee. Whether or not the patentee delayed the grant of patent, the market power would not be balanced by the jurisdiction of the Board.

In the *HMRC* case, the patents for which application were made, though applied for many years earlier, had not been granted at the time of the Board's decision that it nonetheless had jurisdiction to ensure that the price of the medicine in question was not excessive. The Board's decision was reviewed by the Federal Court. An issue before the Federal Court in the *HMRC* case was whether the Board had jurisdiction to ensure that the price of the medicine in question was not excessive when an application for a patent pertaining to the medicine had been made but no patent had been granted. The Federal Court held that the Board had no such jurisdiction.

While it is evident from her reasons in the *HMRC* case that the Judge was considering the Board's jurisdiction over patent applications where no patent had been granted, it was argued by Shire and Rx&D that her decision on this point included language that argues against Board jurisdiction even if a patent has been issued.

The Judge made a number of references to the fact that she was dealing with patent applications and it appears to the Board that the Judge made it clear that a critical premise of her conclusion was that no patents had been issued. It is not at all evident to the Board that the Judge would have reached the same conclusion if she had been considering patents that had been granted at the time the Board asserted jurisdiction, when there was no doubt that a patent had issued and there was indisputably a "patentee" named in the Board's Notice of Hearing. However, if her reasons may be interpreted to imply otherwise, the Board makes the following observations.

The Judge's reasons on this point begin with an outline of the case presented by the Attorney General and the Board, and then the following observation:

> [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.

What the Judge appears to have overlooked is that there were four patents involved in the *HMRC* case; two were applied for before subsections 55(2) and 79(1) of the *Patent Act* were enacted in their present form. Accordingly, the Board in *HMRC* did not assert jurisdiction over those two patents from their respective application dates, but rather was

prepared to rely, for jurisdiction, on the dates the patents were ultimately granted. By contrast, the remaining two patents were applied for *subsequent* to the enactment of the present subsections 55(2) and 79(1) of the *Act*, justifying, in the Board's view, the assumption of jurisdiction from the dates of application, or the laid open periods for each of them.

With respect, in making distinction between the two sets of patents in relation to the timing of the two critical amendments to the *Act* referred to above, subsections 55(2) and 79(1), the Board in *HMRC*, in this panel's opinion, did not act inconsistently.

In all events, the Judge's reasons spoke to the Board's lack of jurisdiction when no patent had been granted. Once a patent has been granted, as in this case, there is no doubt that at the time of the hearing, the Board has jurisdiction over the patentee. The question in this case is the start date of the period to which the Board may have reference in making orders to remediate excessive pricing. That date could be: (1) the date the patent application was laid open, or (2) the date that the patent was granted.

Analysis

Put another way, do the provisions of the *Patent Act* pertaining to the Board give the Board jurisdiction to balance the market power in the period before the grant of patent in the same manner that the Board has jurisdiction to balance the market power of the patentee in the period after the grant of patent? While the purpose of the Board's jurisdiction is a factor in the interpretation of the *Patent Act*, the provisions of the *Act* must exist and support the implementation of that purpose.

The *Patent Act* stipulates that the Board may make remedial orders with respect to the prices at which medicines that are sold by a patentee "while a patentee":

> 83(2) Subject to subsection (4), where the Board finds that a patentee of an invention pertaining to a medicine has, **while a patentee**, sold the medicine in any market in Canada at a price that, in the Board's opinion, was excessive, the Board may, by order, direct the patentee to do any one or more of the following things as will, in the Board's opinion, offset the amount of the excess revenues estimated by it to have been derived by the patentee from the sale of the medicine at an excessive price…[emphasis added]

Section 79 of the *Act* defines "patentee"

> "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 added]

The question, then, is whether, once a patent has been granted, it can reasonably be said that the patentee was entitled to the benefit of that patent before it was granted; that is, whether, given that the patentee had the benefits arising from section 55(2) from the time after the patent application was laid open until the grant of the patent, it can be said that the patentee had the "benefit of the patent" during that laid-open period.

Shire and Rx&D argue that it is, by force of logic and language impossible for a person to have been entitled to the benefit of a patent before it was issued. However, since shortly after the amendments to the *Patent Act* the Board has taken the position that once a patent has been granted, the Board has the jurisdiction to make remedial orders pertaining to sales of the medicine from the date the patent application was laid open. The Board takes the position that the phrase "for the time being" in the definition of patentee includes the laid open period; that is, the time that the person who is now a patentee enjoyed the benefit of excluding others from the market on threat of an action in damages if the patent was issued.

The provisions of the *Patent Act* that created the Board are remedial provisions and should be interpreted purposively. The Board cannot, of course, assume powers that are not granted by its enabling legislation simply because those powers are necessary in order to address the mischief that Parliament intended to address. However, where the words of the statue can reasonably bear an interpretation that puts the intention of Parliament into effect, the Board should adopt that interpretation over an interpretation that defeats the intention of Parliament.

Discussion of the law

(i) Ordinary Meaning

As discussed in *Sullivan and Driedger on the Construction of Statutes*[1], the starting point for statutory interpretation is the ordinary meaning of the statute. Professor Sullivan summarizes the ordinary meaning approach as being composed of the following three propositions:

1. It is presumed that the ordinary meaning of a legislative text is the meaning intended by the legislature. In the absence of a reason to reject it, the ordinary meaning prevails.[2]

2. Even if the ordinary meaning is plain, courts must consider the purpose and scheme of the legislation, and relevant legal norms. They must consider the entire legal context.[3]

[1] Ruth Sullivan, *Construction of Statutes*, 4th ed. (Toronto: Butterworths, 2002)
[2] The operation of the presumption in favour of ordinary meaning is illustrated in *Thomson v. Canada* (Minister of Agriculture) [1992] 1 S.C.R. 385 at 399-400.
[3] *Chieu v. Canada (Minister of Citizenship and Immigration)* [2002] S.C.C. 3 at para 34.

3. In light of these considerations, the court may adopt an interpretation that modifies or departs from the ordinary meaning, provided the interpretation adopted is plausible and reasons for adopting it are sufficient to justify the departure from ordinary meaning.[4]

In *Rizzo and Rizzo Shoes Ltd*.[5] the Supreme Court of Canada noted that relying on what appears to be the plain meaning of legislation is unacceptable because it is incomplete. Iacobucci J. wrote:

> Although the Court of Appeal looked to the plain meaning of the specific provisions in question in the present case, with respect, I believe that the court did not pay sufficient attention to the scheme of the *Employment Standards Act*, its objective or the intention of the legislature; nor was the context of the words in issue appropriately recognized.[6]

The case of *Chieu v. Canada (Minister of Citizenship and Immigration)* supports this approach:

> The grammatical and ordinary sense of the words employed in s. 70(1)(b) is not determinative, however, as this court has long rejected a literal approach to statutory interpretation. Instead, s. 70(1)(b) must be read in its entire context. This enquiry involves examining the history of the provision at issue, its place in the overall scheme of the Act, the object of the Act itself, and Parliament's intent both in enacting the Act as a whole, and in enacting the particular provision at issue.[7]

(ii) Purposive Analysis

A purposive analysis is to be considered at every stage of the analysis and not just when there is an ambiguity. Sullivan lists three basic propositions underlying a purposive analysis:

1. All legislation is presumed to have a purpose. It is possible for courts to discover or adequately reconstruct this purpose through interpretation.

2. Legislative purpose should be taken into account in every case and at every stage of interpretation, including the determination of a text's meaning.

3. In so far as the language of the text permits, interpretations that are consistent with or promote legislative purpose should be adopted, while interpretations that defeat or undermine legislative purpose should be avoided.[8]

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[4] *Supra* note 4 at 20; in support of the ability of the court to adopt a modified interpretation Sullivan cites *Tremblay v. Daigle* [1989] 2 S.C.R. 530 at 553.
[5] [1998] 1 S.C.R. 27.
[6] *Ibid*. at 41.
[7] *Supra* note 6.
[8] *Supra* note 4 at 195. For the general proposition *McBratney v. McBratney* (1919), 59 S.C.R. 550, at 561.

In general, an interpretation that would frustrate or defeat the legislature's purpose should be rejected if there is a plausible alternative.[9] In the case of *Canadian Fishing Company Ltd. v. Smith*, purposive analysis was used to justify rejecting the ordinary meaning of language in favour of a plausible, but more expansive, meaning: "Where the usual meaning of the language falls short of the whole object of the legislature, a more extended meaning may be attributed to the words if they are fairly susceptible of it."[10] As is stated in *Sullivan and Driedger*:

> Willingness to modify meaning or sentence structure in order to avoid absurd results seems to be an unavoidable aspect of interpretation. Although the legislature is sovereign, it is not omniscient; it cannot envisage and provide for (or against) every possible application of its general rules. It must rely on official interpreters to mediate between the text and the facts in particular cases so as to ensure an outcome that does not bring the law into disrepute.[11]

(iii) Retroactivity and Retrospectivity

It was argued by Shire and Rx&D that the Board's interpretation of the *Act* would result in the *Act* having retroactive (Rx&D) or retrospective (Shire) effect, a consequence in legislation that can only result from the clearest express wording that such effect is intended.

However, the Board does not agree that either retroactive or retrospective applications of the *Act* are in issue on this motion.

In *Benner v. Canada (Secretary of State)*, Iacobucci J. quoted Driedger:

> A retroactive statue is one that operates as of a time prior to its enactment. A retrospective statute is one that operates for the future only. It is prospective, but it imposes new rules in respect of a past event. A retroactive statute *operates backwards*. A retrospective statute *operates forwards*, but it looks backwards in that it attaches new consequences *for the future* to an event that took place before the statute was enacted. A retroactive statute changes the law from what it was; a retrospective statute changes the law from what it otherwise would be with respect to a prior event. [Emphasis in original][12]

The *Patent Act* does not operate retroactively or retrospectively when a patentee is subject to the Board's jurisdiction in respect of pricing during the laid-open period.

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[9] *Supra* note 4 at 219.
[10] [1962] S.C.R. 294, at 301.
[11] Ruth Sullivan, *Construction of Statutes*, 4th ed. (Toronto: Butterworths, 2002) at 7.
[12] [1997] 1 S.C.R. 358, at para. 40.

The *Act* does not purport to operate as of a time prior to the 1987 amendments, nor to have an impact on events that took place before the enactment of the amendments. Rather, a person who is granted a patent after the enactment of the amendments is subject to the remedial powers of the Board with respect to the pricing of the medicine during the laid-open period for that patent.

Conclusion

Applying these principles to the interpretation of section 79 of the *Patent Act*, the Board concludes that a person who is granted a patent can reasonably be said to have been a "patentee" during the laid-open period. This interpretation is consistent with the language of the *Patent Act* and is necessary in order to give effect to the intention of Parliament. Indeed, as noted above, it is necessary to prevent purposeful avoidance behaviour on the part of patentees that would allow them to acquire market power and yet avoid the very counterbalance to that market power that the Board was created to provide. Shire, and all other patentees, have been aware, since shortly after the 1987 amendments, that this was the position of the Board.

Accordingly, the motion brought by Shire is dismissed. The Board, in deciding whether any remedial order is appropriate, will consider the pricing of Adderall XR from the date that the first patent pertaining to that medicine was laid open.

Board Members: Dr. Brien G. Benoit
Thomas (Tim) Armstrong

Board Counsel: Gordon Cameron

Original signed by

Sylvie Dupont
Secretary of the Board

December 15, 2006