Date: 20071213

Docket: T-100-07 / T-101-07

Citation: 2007 FC 1316

Ottawa, Ontario, this 13th day of December, 2007

PRESENT: The Honourable Mr. Justice Russell

BETWEEN:

T-101-07

SHIRE BIOCHEM INC.

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

and

CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES

Intervener

AND BETWEEN:

T-100-07

JANSSEN-ORTHO INC.

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

REASONS FOR JUDGMENT AND JUDGMENT

THE APPLICATIONS

[1] The Applicants, Shire Biochem Inc. (Shire) and Janssen-Ortho Inc. (Janssen-Ortho) are seeking judicial review pursuant to section 18.1 of the *Federal Courts Act*, R.S.C. 1985, c. F-7 of decisions (Decisions) made by the Patented Medicine Prices Review Board (Board) and issued December 18, 2006, in which the Board held it had jurisdiction to review the pricing of Shire's drug product Adderall XR and Janssen-Ortho's drug product Concerta for that period of time between the laying open and the granting of the relevant patents.

[2] These two matters are separate applications. However, the Board's reasons and conclusions are substantially the same for both Decisions so that, with the consent of all parties, the Court ordered that both applications should be heard consecutively on the same day.

[3] Canada's Research-based Pharmaceutical Companies (Rx&D) is an intervener in file T-100-07 and was also an intervener in the hearing before the Board below. Rx&D's arguments support and largely duplicate the arguments of the Applicants.

BACKGROUND

(i) The Patented Medicine Prices Review Board

[4] The Board is established under the *Patent Act*, R.S.C. 1985, c. P-4 as amended in 1987 by *An Act to amend the Patent Act and to provide for certain matters in relation thereto*, S.C. 1987, c. 41, s. 15. Parliament created the Board to prevent patentees from abusing the increased patent protection or exclusivity for new inventions of medicines (which were also granted protection in the 1987 amendments) by charging excessive prices. The powers of the Board were strengthened in 1993 in conjunction with further increased patent protection or exclusivity for new inventions of medicines.

(ii) Patent Applications

[5] Under section 10 of the *Patent Act*, patent applications are laid open for public inspection prior to the patent being granted. An applicant cannot prevent anyone from infringing on the application during this time. However, once a patent is granted, anyone who does infringe on the patent during the laid-open period is liable to the patentee under subsection 55(2) for reasonable compensation for any damages suffered. Also, once the patent is granted, it confers on a patentee a wider range of privileges, rights, entitlements, protection and remedies, including the ability to enjoin others from continuing to use, manufacture or sell the subject-matter of the patent.

(iii) Shire's Adderall XR

[6] Adderall XR is a drug used for the treatment of Attention Deficit Hyperactivity Disorder (ADHD)

[7] Shire's U.S. affiliate was granted Canadian Patent No. 3,348,090 on April 13, 2004. Shire is a licensee of the patent and for purposes of the proceedings before the Board and this Court is considered to be the Canadian patentee. All the parties agree that this patent is for an invention pertaining to a medicine.

[8] Shire began selling Adderall XR on September 12, 2002, about 19 months before the patent was granted. The patent application was laid open on April 27, 2000.

(iv) Janssen-Ortho's Concerta

[9] Like Adderall XR, Concerta is a medicine used for the treatment of ADHD. Janssen-Ortho began selling Concerta in Canada on August 7, 2003.

[10] Janssen-Ortho has three relevant Canadian patents which pertain to Concerta: (i) Canadian Patent No. 1,222,950 which was granted on June 16, 1987 and expired on June 16, 2004; (ii) Canadian Patent No. 2,265,668 which was granted on August 23, 2005 and will expire on November 12, 2017; and (iii) Canadian Patent No. 2,264,852 which was granted November 1, 2005

and will expire on September 16, 2017. The period in issue for Concerta is between the expiry of the first patent and the time when the second patent was granted (June 16, 2004 to August 23, 2005). During this time, the latter two patents were laid open. All the parties agree that these patents are for inventions pertaining to a medicine.

(v) History of Proceedings

[11] By Notice of Hearing dated January 18, 2006, the Board commenced a hearing into allegations that Shire was selling Adderall XR at excessive prices. Part of the period covered by the Notice of Hearing involved the laid-open period for the patent pertaining to Adderall XR.

[12] On February 26, 2006, Shire brought a motion before the Board contesting the Board's jurisdiction to make an order pertaining to the laid-open period. Janssen-Ortho and Rx&D were granted intervener status by the Board.

[13] By Notice of Hearing dated July 24, 2006, the Board commenced a hearing into allegations that Janssen-Ortho had excessively priced Concerta. As with the Shire hearing, part of the period covered by the Notice of Hearing involved the laid-open period for the patents pertaining to Concerta.

[14] Given that the same jurisdictional issue in the Shire hearing arose in the Janssen-Ortho hearing, the Applicants proposed that the Board's decision on the jurisdictional motion for the Shire

hearing would be incorporated by reference into the Janssen-Ortho hearing. The Board accepted this proposal on September 14, 2006.

[15] By order dated December 18, 2006, the Board dismissed the motion brought by Shire. The Board also issued a separate order in relation to Janssen-Ortho's Concerta hearing which stated that the reasons given in the Shire order also applied to the Concerta hearing.

[16] While the Board's order was issued on December 18, 2006, the decision itself was dated December 15, 2006. In that decision, the Board provided detailed reasons which included findings that can be summarized as follows:

1. The intention of Parliament was to control excessive pricing during periods of market power related to the patent system and the provisions of the *Patent Act* that create the Board's remedial powers should be interpreted purposively to give effect to this intent;
2. The effect of sections 10 and 55 of the *Patent Act* is that a party who is granted a patent acquires market power from the date the patent application is laid open to the public;
3. Under section 83 of the *Patent Act* the Board may make remedial orders with respect to prices at which medicines are sold by a patentee "while a patentee." Section 79 defines "patentee" for inventions pertaining to medicine as "the person for the time entitled to the benefit of the patent for that invention."

4. Once a patent has been granted, the patentee has the "benefit of the patent" from the time after the patent application is laid open. Specifically, a patentee has the benefits of subsection 55(2) once the patent application is laid open.

APPLICABLE LEGISLATION

[17] Relevant provisions from the *Patent Act,* R.S.C. 1985, c. P-4 are set out below:

10. (1) Subject to subsections (2) to (6) and section 20, all patents, applications for patents and documents filed in connection with patents or applications for patents shall be open to public inspection at the Patent Office, under such conditions as may be prescribed.	**10.** (1) Sous réserve des paragraphes (2) à (6) et de l'article 20, les brevets, demandes de brevet et documents relatifs à ceux-ci, déposés au Bureau des brevets, peuvent y être consultés aux conditions réglementaires.
[…]	[…]
R.S., 1985, c. P-4, s. 10; R.S., 1985, c. 33 (3rd Supp.), s. 2; 1993, c. 15, s. 28.	L.R. (1985), ch. P-4, art. 10; L.R. (1985), ch. 33 (3^{e} suppl.), art. 2; 1993, ch. 15, art. 28.
GRANT OF PATENTS	OCTROI DES BREVETS
42. Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and	**42.** Tout brevet accordé en vertu de la présente loi contient le titre ou le nom de l'invention avec renvoi au mémoire descriptif et accorde, sous réserve des autres dispositions de la présente loi, au breveté et à ses représentants légaux, pour la durée du brevet à compter de la date où il a été accordé, le

liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.
R.S., 1985, c. P-4, s. 42; R.S., 1985, c. 33 (3rd Supp.), s. 16.

droit, la faculté et le privilège exclusif de fabriquer, construire, exploiter et vendre à d'autres, pour qu'ils l'exploitent, l'objet de l'invention, sauf jugement en l'espèce par un tribunal compétent.
L.R. (1985), ch. P-4, art. 42; L.R. (1985), ch. 33 (3e suppl.), art. 16.

INFRINGEMENT

[…]

CONTREFAÇON

[…]

55. (1) A person who infringes a patent is liable to the patentee and to all persons claiming under the patentee for all damage sustained by the patentee or by any such person, after the grant of the patent, by reason of the infringement.

55. (1) Quiconque contrefait un brevet est responsable envers le breveté et toute personne se réclamant de celui-ci du dommage que cette contrefaçon leur a fait subir après l'octroi du brevet.

(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.

(2) Est responsable envers le breveté et toute personne se réclamant de celui-ci, à concurrence d'une indemnité raisonnable, quiconque accomplit un acte leur faisant subir un dommage entre la date à laquelle la demande de brevet est devenue accessible au public sous le régime de l'article 10 et l'octroi du brevet, dans le cas où cet acte aurait constitué une contrefaçon si le brevet avait été octroyé à la date où cette demande est ainsi devenue accessible.

(3) Unless otherwise expressly provided, the patentee shall be or be made a party to any proceeding under subsection (1) or (2).

(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.
R.S., 1985, c. P-4, s. 55; R.S., 1985, c. 33 (3rd Supp.), s. 21; 1993, c. 15, s. 48.

(3) Sauf disposition expresse contraire, le breveté est, ou est constitué, partie à tout recours fondé sur les paragraphes (1) ou (2).

(4) Pour l'application des autres dispositions du présent article et des articles 54 et 55.01 à 59, le recours visé au paragraphe (2) est réputé être une action en contrefaçon et l'acte sur lequel il se fonde est réputé être un acte de contrefaçon.
L.R. (1985), ch. P-4, art. 55; L.R. (1985), ch. 33 (3e suppl.), art. 21; 1993, ch. 15, art. 48.

PATENTED MEDICINES
INTERPRETATION

79. (1) In this section and in sections 80 to 103,

"Board"
«*Conseil* »
'Board" means the Patented Medicine Prices Review Board continued by section 91;

[…]

"patentee"
«*breveté* » ou «*titulaire d'un brevet* »
'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*

MÉDICAMENTS BREVETÉS
DÉFINITIONS

79. (1) Les définitions qui suivent s'appliquent au présent article et aux articles 80 à 103.

«breveté » ou «titulaire d'un brevet »
"*patentee*"
«breveté » ou «titulaire d'un brevet » La personne ayant pour le moment droit à l'avantage d'un brevet pour une invention liée à un médicament, ainsi que quiconque était titulaire d'un brevet pour une telle invention ou exerce ou a exercé les droits d'un titulaire dans un cadre autre qu'une licence prorogée en vertu du paragraphe 11(1) de la *Loi de 1992 modifiant la Loi sur les brevets*.
«Conseil »

Act Amendment Act, 1992, that other person in respect of those rights;
[…]

"*Board*"
«Conseil » Le Conseil d’examen du prix des médicaments brevetés prorogé au titre de l’article 91.
…]

(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.
1993, c. 2, s. 7; 1996, c. 8, s. 32.

(2) Pour l’application du paragraphe (1) et des articles 80 à 101, une invention est liée à un médicament si elle est destinée à des médicaments ou à la préparation ou la production de médicaments, ou susceptible d’être utilisée à de telles fins.
1993, ch. 2, art. 7; 1996, ch. 8, art. 32.

EXCESSIVE PRICES

PRIX EXCESSIFS

83. (1) Where the Board finds that a patentee of an invention pertaining to a medicine is selling the medicine in any market in Canada at a price that, in the Board’s opinion, is excessive, the Board may, by order, direct the patentee to cause the maximum price at which the patentee sells the medicine in that market to be reduced to such level as the Board considers not to be excessive and as is specified in the order.

83. (1) Lorsqu’il estime que le breveté vend sur un marché canadien le médicament à un prix qu’il juge être excessif, le Conseil peut, par ordonnance, lui enjoindre de baisser le prix de vente maximal du médicament dans ce marché au niveau précisé dans l’ordonnance et de façon qu’il ne puisse pas être excessif.

(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

(2) Sous réserve du paragraphe (4), lorsqu’il estime que le breveté a vendu, alors qu’il était titulaire du brevet, le médicament sur un marché canadien à un prix qu’il juge avoir été excessif, le Conseil

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:

peut, par ordonnance, lui enjoindre de prendre l'une ou plusieurs des mesures suivantes pour compenser, selon lui, l'excédent qu'aurait procuré au breveté la vente du médicament au prix excessif :

(*a*) reduce the price at which the patentee sells the medicine in any market in Canada, to such extent and for such period as is specified in the order;

a) baisser, dans un marché canadien, le prix de vente du médicament dans la mesure et pour la période prévue par l'ordonnance;

(*b*) reduce the price at which the patentee sells one other medicine to which a patented invention of the patentee pertains in any market in Canada, to such extent and for such period as is specified in the order; or

b) baisser, dans un marché canadien, le prix de vente de tout autre médicament lié à une invention brevetée du titulaire dans la mesure et pour la période prévue par l'ordonnance;

(*c*) pay to Her Majesty in right of Canada an amount specified in the order.

c) payer à Sa Majesté du chef du Canada le montant précisé dans l'ordonnance.

(3) Subject to subsection (4), where the Board finds that a former patentee of an invention pertaining to a medicine had, 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 former patentee to do any one or more of the following things as will, in the Board's opinion, offset the amount of the excess

(3) Sous réserve du paragraphe (4), lorsqu'il estime que l'ancien breveté a vendu, alors qu'il était titulaire du brevet, le médicament à un prix qu'il juge avoir été excessif, le Conseil peut, par ordonnance, lui enjoindre de prendre l'une ou plusieurs des mesures suivantes pour compenser, selon lui, l'excédent qu'aurait procuré à l'ancien breveté la vente du médicament au prix excessif :

revenues estimated by it to have been derived by the former patentee from the sale of the medicine at an excessive price:

(*a*) reduce the price at which the former patentee sells a medicine to which a patented invention of the former patentee pertains in any market in Canada, to such extent and for such period as is specified in the order; or

(*b*) pay to Her Majesty in right of Canada an amount specified in the order.

(4) Where the Board, having regard to the extent and duration of the sales of the medicine at an excessive price, is of the opinion that the patentee or former patentee has engaged in a policy of selling the medicine at an excessive price, the Board may, by order, in lieu of any order it may make under subsection (2) or (3), as the case may be, direct the patentee or former patentee to do any one or more of the things referred to in that subsection as will, in the Board's opinion, offset not more than twice the amount of the excess revenues estimated by it to have been derived by the patentee or former patentee from the sale of the medicine at an excessive price.
[…]
1993, c. 2, s. 7; 1994, c. 26, s.

a) baisser, dans un marché canadien, le prix de vente de tout autre médicament lié à une invention dont il est titulaire du brevet dans la mesure et pour la période prévue par l'ordonnance;

b) payer à Sa Majesté du chef du Canada le montant précisé dans l'ordonnance.

(4) S'il estime que le breveté ou l'ancien breveté s'est livré à une politique de vente du médicament à un prix excessif, compte tenu de l'envergure et de la durée des ventes à un tel prix, le Conseil peut, par ordonnance, au lieu de celles qu'il peut prendre en application, selon le cas, des paragraphes (2) ou (3), lui enjoindre de prendre l'une ou plusieurs des mesures visées par ce paragraphe de façon à réduire suffisamment les recettes pour compenser, selon lui, au plus le double de l'excédent procuré par la vente au prix excessif.
[…]
1993, ch. 2, art. 7; 1994, ch. 26, art. 54(F).

54(F).

ISSUES

[18] The primary issue before me is whether the Board erred in determining it had jurisdiction to review the pricing of Adderall XR and Concerta during the period when the relevant patents were laid open.

REASONS

(i) Standard of Review

[19] All parties agree that the standard of review is correctness. As noted by Justice Heneghan in *Hoechst Marion Roussel Canada Inc. v. Canada (Attorney General)*, 2005 FC 1552 at paras. 99-110 [*HMRC*], questions of jurisdiction are questions of law for which the Board does not possess more expertise than does this Court. While the *Patent Act*'s purpose is to resolve competing policy objectives, pointing to greater deference, there is no privative clause. For these reasons, I accept that the standard of review is correctness.

(ii) Application of HMRC

[20] The Applicants argue that the Board erred by failing to follow *HMRC*. In that decision, Justice Heneghan held that the Board did not have jurisdiction to review prices when a patent is laid open. However, in *HMRC*, the relevant patents had not issued; they were merely patent applications. As Justice Heneghan noted at para. 136 of her reasons, "a patent application gives rise only to the potential for a grant of a patent." As no patent had been granted, there was no patentee on the facts before her. The Board's jurisdiction is with respect to patentees, and for that reason it had no jurisdiction to review the prices in that case.

[21] In the case at bar, the patents have been granted and there is no dispute that, because the Applicants are patentees, the Board has jurisdiction to review the prices at least from the date the patents issued. Consequently, because of the important difference in the fact situations regarding the relevant patents, the decision in *HMRC* is not, in my view, determinative of whether the Board can, subsequent to the granting of a patent, review prices during the laid-open period. Hence, in my view, the Board did not err in distinguishing the case at bar from Justice Heneghan's decision in *HMRC*. My own review of *HMRC* convinces me that there is nothing in Justice Heneghan's reasons to suggest that she intended to address a situation such as exists on the facts before me where the relevant patents have been granted and the Applicants are patentees within the meaning of the *Patent Act*. Having achieved that status, the Applicants are now beyond the conceptual difficulties that confronted Justice Heneghan in *HMRC*. The question now is whether, given the fact that the

Applicants are patentees, the Board's power can be extended back to the time when the patents were laid open.

(iii) Statutory Interpretation

[22] In my view, the question of jurisdiction raised in these Applications depends upon the interpretation of the relevant provisions of the *Patent Act*. This requires a purposive analysis, giving such fair, large and liberal construction and interpretation as best ensures the attainment of the *Patent Act*'s objective in accordance with the relevant jurisprudence (*Rizzo & Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27; *Interpretation Act*, R.S.C. 1985, c. I-12, s. 12).

[23] The Federal Court has held that the purpose of the Board is "to address the 'mischief' that the patentee's monopoly over pharmaceuticals during the exclusivity period might cause prices to rise to unacceptable levels" (*ICN Pharmaceuticals, Inc. v. Canada (Patented Medicine Prices Review Board)* (1996), 108 F.T.R. 190 at para. 24, aff'd [1997] 1 F.C. 32 (F.C.A.)). It follows, then, that the provisions must, in so far as the language of the text permits, be interpreted in a manner consistent with that purpose (Ruth Sullivan, *Sullivan and Driedger on the Construction of Statutes*, 4th ed. (Toronto: Butterworths, 2002) at 195).

[24] The Federal Court of Appeal has previously held that the Board's jurisdiction is not based upon an actual or prospective effect on market power (*ICN Pharmaceuticals, Inc. v. Canada (Patented Medicine Prices Review Board*, [1997] 1 F.C. 32 at para. 76 (F.C.A.)). Parliament gave

the Board broad scope to review prices of medicines, even when the nexus to a patent was a slender thread, to ensure that pharmaceutical companies could not avoid the jurisdiction of the Board, and to avoid limiting the Board's ability to protect Canadian consumers from excessive pricing (para. 60).

(iv) Meaning of Patentee

[25] A patentee, as defined in section 79 of the *Patent Act*, "means the person for the time being entitled to the benefit of the patent for that invention."

[26] The benefit of a patent includes the patentee's rights to exercise a number of enforcement options against infringers of the patent as described in sections 54 to 59 of the *Patent Act*. Included among these enforcement options is the ability to sue for reasonable compensation under subsection 55(2) for any infringement that resulted after the patent application was laid open under section 10 of the *Patent Act*. Under subsection 55(4), that action for reasonable compensation is deemed to be an action for infringement of the patent.

[27] In essence, this means that once a patent is granted a patentee has the benefit of the patent from the date the patent was laid open in the form of an action for reasonable compensation.

[28] The Applicants argue that the term "benefit" in section 79 refers to <u>all</u> attributes of a patentee's rights under a patent. They note that, once a patent is granted, a patentee has enforcement options in addition to seeking reasonable compensation, including, for example, the right to seek

injunctions under section 57 of the *Patent Act*. As the patentee can only seek reasonable compensation during the laid-open period (and only after the patent is granted), the Applicants say that the patent holder does not have the full benefit of the patent during this period and so should not be regarded as a patentee during that period.

[29] In my view, there is nothing in the statute that suggests that "benefit" must be taken to mean every enforcement option available to a patentee under the statute. The purpose of subsection 55(2) is to extend the patent benefits to patentees during the patent application period. Once a patent application is laid open it is possible for a third party to read the published material and use the invention. Subsection 55(2) provides that anyone who does so (or otherwise infringes on the invention) is liable to pay reasonable compensation should the patent be subsequently granted. Subsection 55(4) specifically provides that any such action for reasonable compensation "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." So the *Patent Act* specifically makes the reasonable compensation right granted under subsection 55(2) part of the bundle of enforcement rights enjoyed by a patentee under the relevant patent once that patent has issued.

[30] In my view, it follows that since the patentee, once the patent issues, enjoys patent rights from the time the patent is laid open (even if not the full complement) then the patentee is deemed by the *Patent Act* to enjoy those rights as a patentee and must be taken to have sold medicines in accordance with section 83(2) "while a patentee" and as the person entitled to the benefit of the patent during that period of time.

[31] This being the case, I am convinced that the purposive analysis carried out by the Board and referred to in its Decisions is correct and that it was Parliament's intent that the Board's jurisdiction over prices for medicines should extend to the period in question between laying the patent open and the grant of the patent. This is provided, of course, that a patent is granted, as the patents were granted in this case.

(v) Whether Retroactive Application

[32] Just as a patentee cannot sue for infringement during the laid-open period until the patent has been granted, the Board cannot review prices during the laid-open period until the patent has been granted. Until the patent is granted, the patent application gives rise only to the potential for the grant of a patent (*HMRC* at para. 135) which is insufficient both for enforcement and for review of prices.

[33] The Applicants argue that this interpretation leads to a retroactive application of the *Patent Act* and that there is nothing in the statute that rebuts the strong presumption that legislation is not intended to have a retroactive effect (*Gustavson Drilling (1964) Ltd. v. M.N.R.*, [1977] 1 S.C.R. 271 at 279). They argue that while subsection 55(2) provides a retroactive or retrospective right of action once the patent is granted, there is no similar provision that provides a retroactive or retrospective right of review of prices by the Board.

[34] In my view, the provisions do not operate retroactively or retrospectively. They do not purport to operate as of a time prior to the 1987 amendments that brought them into being. Nor do they attach new consequences to an event that took place before the statute was enacted. (*Benner v. Canada*, [1998] 1 S.C.R. 358 at paras. 39-40); see also *Sullivan*, at 547 ff).

[35] Rather, the provisions have a prospective operation. Patent applicants know when they file their applications that if the patent is subsequently granted, they will have the benefit of subsection 55(2) from the date the application is laid open. Although the benefit becomes effective on a date before its existence is crystallized (the date the patent is granted), it is nevertheless prospective as it takes effect after the applicant files the application and after the enactment of the provisions.

[36] For the same reasons, the Board's ability to review prices is crystallized on the date the patent is granted but becomes effective the date the patentee obtains the benefit of the patent – the date it was laid open.

[37] Even if the provisions could be characterized as retroactive or retrospective in their operation, they nevertheless, in my view, meet the test set out in *Gustavson Drilling*. As noted above, subsection 55(2) expressly provides that the patentee has a benefit once the patent is granted during the laid-open period. By necessary implication, this means that once a patent is granted the patentee is a patentee during the laid-open period. In fact, subsection 55(4) deems any action under subsection 55(2) to be a patent infringement action. To construe the statute otherwise would, in my

view, twist the meaning of benefit beyond what the language permits and beyond what Parliament intended.

(vi) Constitutional Authority

[38] Janssen-Ortho argues that it would be *ultra vires* the power of Parliament to give the Board the power to regulate prices during the laid-open period because the regulation of prices falls normally under provincial heads of power. The argument is that Parliament may only regulate the prices of products pursuant to its exclusive legislative competence over patents and, since the relevant patents were not granted during the time in question, the Board is attempting to regulate prices in a manner beyond the patent power of Parliament. Janssen-Ortho argues that it could not have been the intent of Parliament to grant the board jurisdiction during the laid-open period because Parliament would not legislate in a way that could extend its jurisdiction.

[39] There is no dispute, however, that Parliament has legislative authority over "Patents of Invention and Discovery." Because the definition of patentee encompasses the rights enjoyed during the laid-open period once the patent is granted, the legislation is, in my view, clearly *intra vires* and so there can be no inhibition on Parliamentary intent along the lines argued.

[40] In my view, the same power that makes subsection 55(2) of the *Patent Act intra vires* also makes the power of the Board to review prices during the laid-open period *intra vires*.

(vii) Whether Evidence Required for Jurisdiction

[41] Shire argues that the Board erred because there was no evidence of "mischief" requiring it to intervene. In its Decisions, the Board stated that patent applicants could engage in "purposeful avoidance behaviour" by delaying the grant of their patents in order to extend the laid-open period and the benefits of subsection 55(2) unless the Board had subsequent jurisdiction under subsection 83(2). In the absence of any evidence that this would happen, Shire argues the Board erred in law by relying on this rationale.

[42] In my view, this argument misstates the position of the Board. The term "mischief" comes from case law (see e.g., *ICN Pharmaceuticals*) and refers to the possibility that pharmaceutical companies might seek to evade the Board's jurisdiction. There is no allegation that either of the Applicants engaged in any such mischief, and I have seen no evidence that would support such an allegation if it was made.

[43] Parliament created the Board to address the possibility of mischief. Evidence of mischief is not necessary to provide a basis for that jurisdiction. For instance, the Board does not need evidence of market power arising from a patent, or even that a patent is, in fact, used in order for it to exercise its regulatory powers. Parliament granted the Board broad jurisdiction to ensure that it could carry out its purpose of ensuring that prices are not excessive.

[44] In my view, it is irrelevant whether patentees might delay obtaining the grant of the patent in order to minimize the Board's jurisdiction. In the absence of that jurisdiction, patentees may be able to price their products excessively, using the benefit of subsection 55(2) to protect their monopoly pricing power during the laid-open period. The purpose of the Board is to address the possibility of mischief that could arise from an abuse of a patentee's monopoly power. The same possibility of mischief exists both after the date the patent is granted and during the laid-open period.

[45] Similarly, Shire argues that the Board never found that market power existed during the laid open period. However, as noted by the Federal Court of Appeal in *ICN Pharmaceuticals*, it is irrelevant whether market power exists in order for the Board to have jurisdiction. Whether the Applicants had market power during the relevant periods may be a factor for the Board to consider in determining whether the prices for the medicines were excessive. That question, though, is not before me today. In my view, the Board has the jurisdiction to consider whether the prices are excessive and, if so, to order appropriate remedies as provided for under the *Patent Act*.

(viii) Conclusion

[46] In summary, I conclude that for purposes of section 79 of the *Patent Act*, "benefit of the patent" includes the benefit of subsection 55(2) which is realized once the patent is granted. Accordingly, once the patent is granted, a patentee is a patentee from the date the application was laid open under section 10. For that reason, the Board has jurisdiction with respect to the patentee's

prices during the laid-open period under subsection 83(2). In my view, the Board made no error in law in coming to this same conclusion and thus its Decisions should stand.

JUDGMENT

UPON reviewing the material filed and hearing the submissions of counsel for both parties in Ottawa on Wednesday, November 7, 2007;

THIS COURT HEREBY ORDERS AND ADJUDGES that:

1. For the reasons given above the judicial review in both applications is hereby dismissed with costs to the Respondent.

"James Russell"

Judge

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	**T-100-07**
STYLE OF CAUSE:	**JANSSEN-ORTHO INC. v. ATTORNEY GENERAL OF CANADA**
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	November 7, 2007
REASONS FOR JUDGMENT AND JUDGMENT	**December 13, 2007**

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Department of Justice	FOR THE RESPONDENT

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	**T-101-07**
STYLE OF CAUSE:	**SHIRE BIOCHEM INC. v. ATTORNEY GENERAL OF CANADA v. CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES**
PLACE OF HEARING:	OTTAWA, ONTARIO
DATE OF HEARING:	November 7, 2007
REASONS FOR JUDGMENT AND JUDGMENT	**December 13, 2007**

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