Federal Court Cour fédérale

Date: 20160623

Docket: T-1537-15

Citation: 2016 FC 716

Toronto, Ontario, June 23, 2016

PRESENT: Prothonotary Kevin R. Aalto

BETWEEN:

ALEXION PHARMACEUTICALS INC.

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

ORDER AND REASONS

I. Introduction

[1] The Applicant, Alexion Pharmaceuticals Inc., (Alexion), manufactures a drug called SOLIRIS. It is used to treat two rare life threatening medical conditions (paroxysmal nocturnal hemoglobinuria and atypical hemolytic uremic syndrome). The Patented Medicines Prices Review Board (the Board) has commenced proceedings against Alexion concerning the price at which Alexion is selling or has sold SOLIRIS in Canada.

[2] The Board is created pursuant to Section 91 of the *Patent Act*, R.S.C. 1985, c. P-4. Sections 79 through to 103 of the *Patent Act* provide for the mandate of the Board, the structure and appointment process to the Board, the jurisdiction of the Board, remedies available to the Board, enforcement of orders, production of information and the like.

[3] Alexion, in this application, seeks declaratory relief declaring that sections 80 through to 86 of the *Patent Act* and the words "in any proceeding under section 83" in section 87(1) (the Impugned Provisions) are *ultra vires* the Parliament of Canada "in that the price regulations scheme created by the Impugned Provisions exceeds the powers granted to Parliament under section 91(22), or other federal power, of the *Constitution Act, 1867*". Alexion further alleges that the Impugned Provisions violate provincial jurisdiction over property and civil rights under section 92(13) of the *Constitution Act, 1867*. The within application also seeks an order in the nature of prohibition preventing the Board from proceeding with a hearing under section 83 of the *Patent Act*.

[4] The Respondent, the Attorney General of Canada (AG) brings this motion to strike the application on the ground that it is bereft of any chance of success because there is a line of jurisprudence, the most recent of which is *Canada (Attorney General) v Sandoz Canada Inc.*, 2015 FCA 249 (*Sandoz*), which has fully and finally determined that these sections are in fact *intra vires* and constitutional. Notably, the *Sandoz* case is the subject of a leave to appeal application to the Supreme Court of Canada, which, as of the date of this decision, has not been decided.

[5] The AG's argument is simple: as the constitutionality of the provisions has already been determined in prior jurisprudence, this application is bereft of any chance of success.

[6] In contrast, Alexion argues that while the issue of constitutionality of these provisions has been adverted to in several cases, the discussion has been peripheral and has not been focused on a pith and substance analysis nor a complete and careful division of powers analysis. Thus, none of the jurisprudence to date deals with the issue head on. For that reason, this application is not bereft of any chance of success. The Impugned Provisions are set out in Schedule A attached hereto.

[7] In order to determine whether or not the Impugned Provisions are constitutional, thus making this application bereft of any chance of success, it is necessary to carefully consider the issues in play in the various cases cited by the AG and particularly the recent *Sandoz* case.

II. **Background**

[8] The proceeding before the Board giving rise to this application results from a Notice of Hearing issued January 20, 2015 by the Board notifying Alexion that the Board would "determine whether, under section 83 and 85 of the *Patent Act* … [Alexion] is selling or has sold … SOLIRIS in any market in Canada at a price that, in the Board's opinion, is or was excessive and if so, what order, if any, should be made."

[9] It is stated in the grounds of this application that "[t]he price of SOLIRIS in Canada has neither increased since it was first introduced in the Canadian market in 2009, or decreased in the

countries where the product is sold outside of Canada. Further, it is noted that in 2010 and 2011, the Board explicitly acknowledged that the introductory price of SOLIRIS was not excessive based on international pricing of the product." [Paragraph 4 Notice of Application]

III. **Position of Alexion**

[10] Alexion alleges that the Notice of Hearing of the Board directed toward pricing between 2012 and 2014 relates to exchange rate fluctuations of the value of the Canadian dollar which in turn affects the price of SOLIRIS in Canada.

[11] Alexion argues that the Board's mandate, in part, is "protecting consumers" and its mission is to ensure that prices of patented medicines are not excessive. It is argued that these objectives of protecting consumers and ensuring that the prices of patented medicines are not excessive, do not fall within federal powers and do not fall within the objective of controlling patents of invention and discovery under section 91(22) of the *Constitution Act, 1867* or any other federal power under the *Constitution Act, 1867*.

[12] Alexion has served the evidence that it intends to rely upon in support of its position on the ultimate hearing of this application. That evidence comprises the legislative history of the *Patent Act* and particularly the Impugned Provisions; an affidavit and documentary exhibits of Lionel Bentley, the Herschel Smith Professor of Intellectual Property of the Faculty of Law, University of Cambridge; and, the affidavit and documentary exhibits of Jonathan Putnum, a Professor of International Economics as Applied to Intellectual Property Law.

[13] The legislative history is extensive and canvasses the evolution of the Impugned Provisions and various aspects of the development of Canada's compulsory licensing regime. Included in the legislative history is a legal opinion dated September 14, 1992 prepared for the Canadian Drug Manufacturers Association by Dean James C. McPherson (as he then was) relating to the constitutionality of the Impugned Provisions. That opinion puts into question the constitutional validity of the Impugned Provisions.

[14] In his affidavit, Lionel Bentley describes himself as a specialist in intellectual property law and professor at the University of Cambridge. His affidavit discusses at length the relationship between patents and prices; drug price regulation; compulsory licensing; and drug price regulation in various jurisdictions. His conclusion is that the Canadian regime is unique and questions whether the Impugned Provisions are really patent law provisions as patent law is not concerned with direct price controls.

[15] In his affidavit, Jonathan Putnam describes himself as an expert in international economics as applied to intellectual property. The thrust of his affidavit, *inter alia*, relates to the purpose and effect of the Impugned Provisions and its economic impact within the administrative framework of the *Patent Act*. He concludes that the regulatory purpose of the Board in protecting consumers is, in effect, antithetical to the real purpose of the *Patent Act* which is to provide patent protection in the form of a monopoly to inventors. The regulatory regime, it is opined, "depriv[es] the inventor . . . of . . . the full enjoyment of the monopoly conferred by the patent" which may result in a detriment to the Canadian consumer as it may discourage inventors from developing new medicines.

[16] The legislative history and the affidavit evidence is argued by Alexion to provide the full record for a complete and thorough pith and substance constitutional analysis of the Impugned Provisions. Further, this evidence bolsters the position of Alexion that the Impugned Provisions are *ultra vires* as they infringe on property and civil rights. For this reason, as no court has yet had the benefit of such a complete record, the determinations of the courts which have considered the Impugned Provisions or their predecessors are open to question. Thus, argues Alexion, this application is not bereft of any chance of success.

IV. **Position of the AG**

[17] The AG argues that as the constitutionality of the Impugned Provisions has been considered in prior cases which have all upheld the Impugned Provisions as constitutional this application is bereft of any chance of success.

[18] In order to put the constitutional issue in perspective, it is necessary to review the line of cases upon which the AG relies to argue that this application is bereft of any chance of success.

A. *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 DLR (4TH) 485 (QB), aff'd (1992), 96 DLR (4TH) 606 (CA)

[19] This is the first case which the AG relies upon in support of the proposition that the constitutionality of the Impugned Provisions has been determined. It is to be noted that the *Patent Act* was subsequently amended and the specific provisions in dispute in *Manitoba Seniors* were repealed and were replaced in part, by the Impugned Provisions [*Patent Act Amendment Act*, 1992, S.C. 1993, c. 2].

[20] In *Manitoba Seniors*, the *Patent Act's* provisions in dispute were challenged on the following basis as set out in p. 486-487:

> The challenge is mounted on three fronts:
>
> (a) That the impugned provisions are *ultra vires* the Parliament of Canada in that they exceed the powers granted to Parliament pursuant to the *Constitution Act, 1867*;
>
> (b) That in both purpose and effect, the impugned provisions establish a system for regulating, controlling and fixing the prices of patented medicines being sold in provincial markets, thereby infringing upon the jurisdiction of the provinces in relation to matters of property and civil rights pursuant to s. 92(13) of the *Constitution Act, 1867*; and
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> (c) That *those* provisions of the impugned legislation, lengthening the period of patent exclusivity applicable to medicines, are so inextricably linked to those establishing a price control system, they would not have been enacted by Parliament in the absence of a system of price control; the exclusivity provisions are therefore not severable, and the entire scheme created by impugned provisions is *ultra vires*.

[21] The Applicants in *Manitoba Seniors* argued that Parliament exceeded its legislative authority by creating a price control mechanism in the pharmaceutical industry which fell within the exclusive jurisdiction of the Provinces. The Crown argued that the impugned amendments flowed from section 91(22) of the *Constitution Act, 1867*, "patents and invention and discovery".

[22] After a brief review of the legislative history of the sections under attack, Justice Dureault of the Manitoba Court of Queen's Bench made the following observations at p. 491:

> On a careful review of the impugned legislation in its totality, it does appear on a reasonable construction that in pith and substance the legislation pertains to increased patent protection for new inventions pertaining to medicines. Patent exclusivity is restored to an important degree by allowing immunity from competition of any new patented medicine for periods ranging from seven to ten

> years. While compulsory licensing is retained, the amendments introduce a prohibition against exercising any rights under the licence during the period of patent exclusivity. That is also a significant policy change.
>
> . . .
>
> The price review regime is but one component of the broader regime of patent exclusivity brought about by the impugned provisions and is essentially a device for dealing with excessive prices resulting from patent abuse. As indicated, the remedial actions are loss of patent exclusivity or reintroduction of competition through compulsory licensing. How could such actions, directing a return to the earlier regime of immediate compulsory licensing, be considered anything but the valid exercise of patent power. The fact that, as a last resort, the Board may seek enforcement of its rollback orders through a superior court process does not change the fundamental nature of the legislation from the field of patent to that of property and civil rights, i.e., price control.
>
> I conclude that in the 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.
>
> I conclude that the impugned legislation was validly enacted by the Parliament of Canada pursuant to its constitutional power in the field of patents of invention. Accordingly, the application for the declaratory relief must be denied. [emphasis added]

[23] On appeal, the Manitoba Court of Appeal upheld the decision and offered the following observation:

> In our opinion, there can be only one answer to the question in this case. The impugned legislation is in pith and substance in relation to matters within Parliament's exclusive legislative jurisdiction over patents. The fact that the legislation may have an effect upon matters within provincial jurisdiction (in this case, property and civil rights) is then of no consequence.

[24] The conclusion of the Manitoba courts, while not dealing with the current Impugned Provisions, is nonetheless persuasive of the point that control of pricing through the auspices of the *Patent Act* is constitutional.

B. *Smith, Kline & French Laboratories Ltd. v Attorney General of Canada*, [1986] 1 FC 274

[25] This case was also heavily relied upon by counsel for the AG. This case dealt with an attack on provisions of the *Patent Act* as being unconstitutional as they related to compulsory licence provisions. In particular, the AG relies upon the following observations of Justice Strayer (as he then was):

> I therefore conclude that this subsection, by making the grant of patent for medicine subject to compulsory licensing is simply limiting the scope of the property right, the monopoly, which Parliament is authorized but not obliged to grant.
>
> … But subsection 41(4) is not a law in relation to "prices" as contended by the plaintiffs. It does not purport to fix prices. One of its principal objects is, obviously, to bring about a reduction in prices through competition, but the prices are to be fixed by the vendors of drugs. Merely because the exercise of a federal power affects prices does not make it invalid. For example, the exercise of the federal taxation power in respect of excise taxes and tariffs affects in a much more precise way the prices paid by Canadians for many goods. The exercise of the federal jurisdiction over "interest" and "banking" affects the price of borrowing money. One can multiply the examples. [emphasis added]

[26] It is also interesting to note that Justice Strayer commented on the previous line of authority upholding various provisions of the *Patent Act* as follows:

> I accept, nevertheless, the submission of counsel for the plaintiffs that it might remain open to this Court to distinguish these previous decisions if the evidence in this case disclosed an object or effect that was not apparent at the time of those other decisions. It appears that there was no extrinsic evidence presented in those cases with respect to the object or effect of the Act. I must therefore consider whether the evidence in this case is such as to lead to a different conclusion at this time.

[27] This latter observation of Justice Strayer is relied upon by Alexion to support its argument that no proper evidentiary record has been put forward to deal with the constitutionality of the Impugned Provisions.

C. *Sandoz - Canada (Attorney General) v Sandoz Canada Inc.*, 2015 FCA 249

[28] This is a decision of the Federal Court of Appeal. This case engages the Impugned Provisions. There were two appeals heard together: one involving ratiopharm Inc. (ratiopharm) and one involving Sandoz Canada Inc. (Sandoz).

[29] The case involving ratiopharm related to the supply and licensing of a patented drug owned by GlaxoSmithKline (GSK) to ratiopharm. As part of the arrangement ratiopharm was granted the exclusive licence to set the price of the drug. ratiopharm applied for a Notice of Compliance (NOC) and listed GSK's patent with the proviso that the patent owner had consented "to the making, constructing, using or selling of [the drug] in Canada". ratiopharm received its NOC.

[30] Sandoz also sold various drugs as a licensee from a patent owner. The patent owner consented to Sandoz obtaining NOC's for its generic drugs and allowed Sandoz to market and sell generic versions of the drugs after other generics had entered the market.

[31] The Board commenced proceedings against ratiopharm alleging that a drug sold by ratiopharm was sold at excessive prices. The Board also sought information about the sales and pricing of the drug and also sought supply agreements relating to other drugs. As against Sandoz, the proceedings brought by the Board related to seeking sales and pricing information on a number of drugs.

[32] Orders were made by the Board against both ratiopharm and Sandoz. In the case of ratiopharm an order was made requiring ratiopharm to pay over $65 million to offset excess revenues realized by ratiopharm relating to the drug in issue. The Board also required ratiopharm to provide additional information relating to other drugs.

[33] As against Sandoz, the Board ordered Sandoz to provide information relating to five drugs.

[34] The two orders of the Board were judicially reviewed. The judicial review applications were both heard by the Honourable Mr. Justice James O'Reilly, one shortly after the other. Reasons for decision overturning the orders of the Board were issued simultaneously.

[35] Justice O'Reilly found in both cases that neither Sandoz nor ratiopharm were "patentees" within the meaning of the *Patent Act* and therefore the Board had no jurisdiction over them. The applications for judicial review were both allowed with costs and a direction was made that the Board find they were not patentees. Justice O'Reilly also made a determination of the constitutional issue and found the Impugned Provisions to be constitutional. He observed as follows:

> [28] Even though the relevant provisions of the Act have already been found to be constitutional (*Manitoba Society of Seniors Inc.*), ratiopharm argues that subsequent amendments to the Act relating to the Board's powers now place those provisions beyond federal jurisdiction over patents, encroaching on provincial jurisdiction over Property and Civil Rights.
>
> [29] Those amendments "strengthened the Board's remedial and punitive powers" to offset the effect of abolishing the prior scheme of compulsory. Their purpose was to enable the Board "to influence the pricing of patented medicines to much the same extent that the competition fostered by compulsory licensing used to influence it" licensing (*ICN Pharmaceuticals, Inc v Canada (Patented Medicines Prices Review Board)*, [1997] 1 FC 32 (CA) at para 12).
>
> [30] As I see it, the amendments giving the Board the power to address the pricing of patented medicines more directly through monetary remedies and penalties did not alter the basic purpose of the legislation or expand the Board's mandate. Therefore, I see no basis for departing from the conclusion reached in *Manitoba Society of Seniors Inc.*, that the provisions of the *Patent Act* dealing with patented medicines, properly interpreted, fall within federal jurisdiction over patents of invention; they are constitutional.

[36] The AG appealed both decisions. Both the issue of whether Sandoz and ratiopharm were "patentees" and whether the Impugned Provisions were constitutional were in play in the appeals. However, the central issue as defined by Chief Justice Marc Noël was "whether the Federal Court Judge properly held that Sandoz and ratiopharm (collectively the Respondents) fell

outside the jurisdiction of the Board as they were not "patentees" within the meaning of section 79(1). . . " [para 2].

[37] While much of the decision of the Federal Court of Appeal addresses this issue, Justice Noël, in fact, devoted some 5 pages to a discussion of the constitutional arguments. Justice Noël summarized the arguments as follows:

> [110] The gist of the respondents' constitutional argument before the Board was that the regulation of prices under sections 79-103 of the Act, and the related filing requirements, are an unconstitutional extension of Parliament's authority over patents, at least insofar as generic pharmaceutical products are concerned (Sandoz written submissions before the Board, Sandoz's Confidential Appeal Book, Vol. 11, Tab 27 at para. 201). Ratiopharm made the identical arguments but without this reservation (ratiopharm written submissions before the Board, ratiopharm's Confidential Appeal Book, Vol. 5, Tab 10 at para. 383; Transcripts of hearing before the Board, RPAB, Vol. 8, Tab 44 at p. 2210). However the notice of constitutional question which it filed before the Federal Court and before this Court uses the same language.
>
> [111] It is apparent that the respondents used that language because their argument, if accepted, could result in the entire scheme devised by Parliament being struck down. The Federal Court judge refused to declare the scheme unconstitutional insofar as patent holders are concerned (ratiopharm reasons at paras. 28 to 30; Sandoz reasons at paras. 35 to 37), but his decision leaves open the question whether the scheme might be unconstitutional with respect to persons who exercise the right to sell patented medicine without owing it.
>
> [112] The theory behind the respondents' constitutional attack before the Board was that the current regime is one of pure price regulation which intrudes into the sphere of property and civil rights. Specifically, when Manitoba Society was decided, the Board had the remedial power to "lift" the protection granted to an inventor by a patent (reference is made to paragraph 41.15(2)(d) of the Act as it then read). According to the respondents this provision, which has since been repealed, was at the heart of the decision of the Manitoba Queen's Bench in Manitoba Society upholding the constitutional validity of the scheme.

[38] After referring to the Manitoba Court of Appeal decision in *Manitoba Seniors*, Chief Justice Noël held as follows:

> [116] In my view, the Federal Court judge and the Board before him correctly held that the control of prices charged for patented medicines comes within the jurisdiction conferred on Parliament over patents under subsection 91(22) of the *Constitution Act 1867* when applied to a patent holder or owner. The respondents recognize as much when they state that the Federal Court judge's interpretation of "patentee" maintained the connection to the federal head of power, such that the reasoning in Manitoba Society remained intact (respondents' respective replies to the response by the Attorney General of Canada to the Notice of Constitutional Question (respondents' replies) at para. 46).

[39] In my view, the Federal Court of Appeal has determined explicitly that the Impugned Provisions are constitutional. This decision is binding on this Court. It may very well be, that as Alexion argues, none of these cases have conducted a proper pith and substance analysis nor has there been before those courts a full record which would include its legislative history and the impact of the Impugned Provisions. Alexion endeavoured to distinguish both *Manitoba Seniors* and *Sandoz* with other inventive arguments. Notwithstanding these efforts to distinguish those cases, in my view, having carefully reviewed all of them, as far as this application is concerned, the Federal Court of Appeal's conclusion on constitutionality prevails. Thus, this application is bereft of any chance of success and the motion of the AG should be granted.

[40] Notably, the *Sandoz* case is being appealed to the Supreme Court of Canada. No decision has been rendered yet by the Supreme Court on the leave to appeal application. However, in that leave application, the Appellants (Sandoz and ratiopharm) open their factum with the following statement:

> 1. This case raises questions of national importance in constitutional, administrative, and patent law. It presents an opportunity for this Court to address, for the first time, the scope of the federal power over "Patents of Invention and Discovery" under s. 91(22) of the *Constitution Act, 1867*. Specifically, this Court's guidance is needed to define the extent to which, if at all, this power authorizes federal price regulation of generic drugs and to identify when such regulation exceeds federal jurisdiction and encroaches impermissibly upon the exclusive provincial jurisdiction over "Property and Civil Rights" under s. 92(13) of the *Constitution Act, 1867*.

[41] This issue is repeated at paras. 18 and 19 as follows:

> 18. This case raises significant issues about the scope of the federal power over Patents of Invention and Discovery under s. 91(22) of the *Constitution Act, 1867* and, more precisely, the boundaries between this federal power and the provincial power over Property and Civil Rights under s. 92(13) of the *Constitution Act, 1867* – matters that have yet to be addressed by this Court. Ratiopharm and Sandoz, respectfully submit that price regulation of generic drugs sold by companies who are not patent holders and do not exercise monopolies is not in pith and substance related to matters within Parliament's s. 91(22) power, nor can it be held *intra vires* through the application of the ancillary powers doctrine.
>
> 19. To begin, there is no general power authorizing the federal government to regulate prices in a particular trade or industry, such as the generic pharmaceutical industry. Thus federal regulation under the "trade and commence" power must be concerned with "trade as a whole rather than with a particular industry". In the absence of a national emergency or reliance on some other head of power, the federal government and its agencies do not have the authority to engage in pure price regulations. In this case, if federal authority existed, it would have to be grounded upon the head of power over Patents of Invention and Discovery.

[42] While *Sandoz* is focused on whether or not a generic manufacturer is captured by the definition of "patentee" in the *Patent Act* and thereby is subject to the jurisdiction of the Board, should the Supreme Court of Canada grant leave to appeal, the issue of the constitutionality of

the price control regime and the jurisdiction of the Board as contained in the Impugned Provisions would be open for consideration by the Supreme Court. However, that is for the Supreme Court to decide.

V. **Conclusion**

[43] The test to be applied on a motion to strike, as noted, is whether the proceeding is bereft of any chance of success. It is a high burden. [see, *Hunt* v. *Carey Canada Inc.*, [1990] 2 S.C.R. 959; *David Bull Laboratories (Canada) Inc.* v. *Pharmacia Inc.*, [1995] 1 FC 588 (C.A.)]. In my view, that burden has been met.

[44] At first instance, the precedent set by *Sandoz* in the Federal Court of Appeal is sufficient to dispose of this motion. The conclusion of that Court is definitive and notwithstanding the very able arguments of counsel for Alexion, the doctrine of *stare decisis* applies.

[45] During the course of the argument of this motion, counsel were asked whether this matter should be stayed pending the outcome of the leave to appeal application. Neither party supported holding this motion to strike in abeyance pending the outcome of the Notice of Application for Leave. The AG argued, in effect, if leave were denied then the law would clearly be settled and if leave is granted this application becomes unnecessary. Alexion, for its part, argued that while the issue may be raised in the *Sandoz* case, it is not raised on a full and complete record in the manner which Alexion argues has been put together in support of this application and therefore this application should proceed in any event.

[46] In the end result, as no stay has been sought, the motion of the AG is granted and this application is struck with costs. If the parties are unable to agree on costs they may file written submissions limited to three single spaced pages. The AG shall file their written representations within 15 days of the date of this order and Alexion shall file their responding submission within 15 days thereafter.

[47] The Court is grateful to counsel for the excellent argument of this motion.

ORDER

THIS COURT ORDERS that:

1. The motion is granted and this application is struck.

2. If the parties are unable to agree on costs they may file written submissions limited to three single spaced pages. The AG shall file their written representations within 15 days of the date of this order and Alexion shall file their responding submission within 15 days thereafter.

"Kevin R. Aalto"
Prothonotary

SCHEDULE A

The Impugned Provisions, *Patent Act*, s. 80-83

Pricing information, etc., required by regulations	**Renseignements réglementaires à fournir sur les prix**
80 (1) A patentee of an invention pertaining to a medicine shall, as required by and in accordance with the regulations, provide the Board with such information and documents as the regulations may specify respecting	80 (1) Le breveté est tenu de fournir au Conseil, conformément aux règlements, les renseignements et documents sur les points suivants :
(a) the identity of the medicine;	a) l'identification du médicament en cause;
(b) the price at which the medicine is being or has been sold in any market in Canada and elsewhere;	b) le prix de vente — antérieur ou actuel — du médicament sur les marchés canadien et étranger;
(c) the costs of making and marketing the medicine, where that information is available to the patentee in Canada or is within the knowledge or control of the patentee;	c) les coûts de réalisation et de mise en marché du médicament s'il dispose de ces derniers renseignements au Canada ou s'il en a connaissance ou le contrôle;
(d) the factors referred to in section 85; and	d) les facteurs énumérés à l'article 85;
(e) any other related matters.	e) tout autre point afférent précisé par règlement.
Idem	**Idem**
(2) Subject to subsection (3), a person who is a former patentee of an invention pertaining to a medicine shall, as required by and in accordance with the regulations, provide the Board with such information and documents as the regulations may specify respecting	(2) Sous réserve du paragraphe (3), l'ancien titulaire d'un brevet est tenu de fournir au Conseil, conformément aux règlements, les renseignements et les documents sur les points suivants :

(a) the identity of the medicine;

(b) the price at which the medicine was sold in any market in Canada and elsewhere during the period in which the person was a patentee of the invention;

(c) the costs of making and marketing the medicine produced during that period, whether incurred before or after the patent was issued, where that information is available to the person in Canada or is within the knowledge or control of the person;

(d) the factors referred to in section 85; and

(e) any other related matters.

a) l'identification du médicament en cause;

b) le prix de vente du médicament sur les marchés canadien et étranger pendant la période où il était titulaire du brevet;

c) les coûts de réalisation et de mise en marché du médicament pendant cette période, qu'ils aient été assumés avant ou après la délivrance du brevet, s'il dispose de ces derniers renseignements au Canada ou s'il en a connaissance ou le contrôle;

d) les facteurs énumérés à l'article 85;

e) tout autre point afférent précisé par règlement.

Limitation

(3) Subsection (2) does not apply to a person who has not been entitled to the benefit of the patent or to exercise any rights in relation to the patent for a period of three or more years. 1993, c. 2, s. 7.

Prescription

(3) Le paragraphe (2) ne vise pas celui qui, pendant une période d'au moins trois ans, a cessé d'avoir droit à l'avantage du brevet ou d'exercer les droits du titulaire. 1993, ch. 2, art. 7.

Pricing information, etc. required by Board

81 (1) The Board may, by order, require a patentee or former patentee of an invention pertaining to a medicine to provide the Board with information and documents respecting

Renseignements sur les prix exigés par le Conseil

81 (1) Le Conseil peut, par ordonnance, enjoindre le breveté ou l'ancien titulaire du brevet de lui fournir les renseignements et les documents sur les points visés aux alinéas 80(1)a) à e), dans le cas du breveté, ou, dans le cas de l'ancien breveté, aux alinéas 80(2)a) à e) ainsi que sur tout autre point qu'il

précise.

(a) in the case of a patentee, any of the matters referred to in paragraphs 80(1)(a) to (e);

(b) in the case of a former patentee, any of the matters referred to in paragraphs 80(2)(a) to (e); and

(c) such other related matters as the Board may require.

Compliance with order

(2) A patentee or former patentee in respect of whom an order is made under subsection (1) shall comply with the order within such time as is specified in the order or as the Board may allow.

Respect

(2) L'ordonnance est à exécuter dans le délai précisé ou que peut fixer le Conseil.

Limitation

(3) No order may be made under subsection (1) in respect of a former patentee who, more than three years before the day on which the order is proposed to be made, ceased to be entitled to the benefit of the patent or to exercise any rights in relation to the patent.

Prescription

(3) Il ne peut être pris d'ordonnances en vertu du paragraphe (1) plus de trois ans après qu'une personne ait cessé d'avoir droit aux avantages du brevet ou d'exercer les droits du titulaire.

Notice of introductory price

82 (1) A patentee of an invention pertaining to a medicine who intends to sell the medicine in a market in Canada in which it has not previously been sold shall, as soon as practicable after determining the date on which the medicine will be first offered for sale in that market, notify the Board of its intention and of that date.

Avis du prix de lancement

82 (1) Tout breveté doit, dès que possible après avoir fixé la date à laquelle il compte mettre en vente sur un marché canadien un médicament qui n'y a jamais été vendu, notifier le Conseil de son intention et de la date à laquelle il compte le faire.

Pricing information and

Renseignements sur les prix

documents

(2) Where the Board receives a notice under subsection (1) from a patentee or otherwise has reason to believe that a patentee of an invention pertaining to a medicine intends to sell the medicine in a market in Canada in which the medicine has not previously been sold, the Board may, by order, require the patentee to provide the Board with information and documents respecting the price at which the medicine is intended to be sold in that market.

(2) Sur réception de l'avis visé au paragraphe (1) ou lorsqu'il a des motifs de croire qu'un breveté se propose de vendre sur un marché canadien un médicament qui n'y a jamais été vendu, le Conseil peut, par ordonnance, demander au breveté de lui fournir les renseignements et les documents concernant le prix proposé sur ce marché.

Compliance with order

(3) Subject to subsection (4), a patentee in respect of whom an order is made under subsection (2) shall comply with the order within such time as is specified in the order or as the Board may allow.

Respect

(3) Sous réserve du paragraphe (4), l'ordonnance est à exécuter dans le délai précisé ou que peut fixer le Conseil.

Limitation

(4) No patentee shall be required to comply with an order made under subsection (2) prior to the sixtieth day preceding the date on which the patentee intends to first offer the medicine for sale in the relevant market. 1993, c. 2, s. 7.

Prescription

(4) Une ordonnance prise en vertu du paragraphe (2) n'oblige pas le breveté avant le soixantième jour de la date prévue pour la mise en vente du médicament sur le marché proposé. 1993, ch. 2, art. 7.

Excessive Prices

Prix excessifs

Order re excessive prices

Ordonnance relative aux prix excessifs

83 (1) Where the Board finds that a patentee of an invention

83 (1) Lorsqu'il estime que le breveté vend sur un marché

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.

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.

Idem

(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:

Idem

(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 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.

Idem

Idem

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

(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 :

(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

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

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

Where policy to sell at excessive price

Cas de politique de vente à prix excessif

(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

(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

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.

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.

Excess revenues

(5) In estimating the amount of excess revenues under subsection (2), (3) or (4), the Board shall not consider any revenues derived by a patentee or former patentee before December 20, 1991 or any revenues derived by a former patentee after the former patentee ceased to be entitled to the benefit of the patent or to exercise any rights in relation to the patent.

Excédent

(5) Aux fins des paragraphes (2), (3) ou (4), il n'est pas tenu compte, dans le calcul de l'excédent, des recettes antérieures au 20 décembre 1991 ni, dans le cas de l'ancien breveté, des recettes faites après qu'il a cessé d'avoir droit aux avantages du brevet ou d'exercer les droits du titulaire.

Right to hearing

(6) Before the Board makes an order under this section, it shall provide the patentee or former patentee with a reasonable opportunity to be heard.

Droit à l'audition

6) Avant de prendre une ordonnance en vertu du présent article, le Conseil doit donner au breveté ou à l'ancien breveté la possibilité de présenter ses observations.

Limitation period

(7) No order may be made under this section in respect of a former patentee who, more than three years before the day on which the proceedings in the matter commenced, ceased

Prescription

(7) Le présent article ne permet pas de prendre une ordonnance à l'encontre des anciens brevetés qui, plus de trois ans avant le début des procédures, ont cessé d'avoir droit aux

to be entitled to the benefit of the patent or to exercise any rights in relation to the patent.

avantages du brevet ou d'exercer les droits du titulaire.

1993, ch. 2, art. 7; 1994, ch. 26, art. 54(F).

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1537-15
STYLE OF CAUSE:	ALEXION PHARMACEUTICALS INC v PATENTED MEDICINE PRICES REVIEW BOARD ET AL
PLACE OF HEARING:	TORONTO, ONTARIO
DATE OF HEARING:	FEBRUARY 9, 2016
ORDER AND REASONS:	AALTO P.
DATED:	JUNE 23, 2016

APPEARANCES:

Malcolm N. Ruby David T. Woodfield Erica Maidment	FOR THE APPLICANT
Christine Mohr Joseph Cheng	FOR THE RESPONDENT

SOLICITORS OF RECORD:

Gowling Lafleur Henderson LLP Barristers & Solicitors	FOR THE APPLICANT
Department of Justice William F. Pentney Q.C.	FOR THE RESPONDENT