Federal Court of Appeal  Cour d'appel fédérale

Date: 20151106

Dockets: A-302-14
A-303-14

Citation: 2015 FCA 249

CORAM: **NOËL C.J.**
PELLETIER J.A.
RENNIE J.A.

Docket: A-302-14

BETWEEN:

ATTORNEY GENERAL OF CANADA

Appellant

And

SANDOZ CANADA INC.

Respondent

Docket: A-303-14

AND BETWEEN:

ATTORNEY GENERAL OF CANADA

Appellant

And

RATIOPHARM INC. (NOW TEVA CANADA LIMITED)

Respondent

Heard at Ottawa, Ontario, on September 22, 2015.

Judgment delivered at Ottawa, Ontario, on November 6, 2015.

REASONS FOR JUDGMENT BY: NOËL C.J.

CONCURRED IN BY: PELLETIER, J.A.
RENNIE, J.A.

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REASONS FOR JUDGMENT

NOËL C.J.

[1] These are appeals brought by the Attorney General of Canada (the Attorney General or the appellant) from two judgments rendered by O'Reilly J. (the Federal Court judge). The first – reported at 2014 FC 501 – allowed an application for judicial review brought by Sandoz Canada Inc. (Sandoz) from a decision (PMPRB-10-D2-SANDOZ, or PMPRB Sandoz) of the Patented Medicine Prices Review Board (the Board). The second – reported at 2014 FC 502 – allowed three applications for judicial review brought by ratiopharm Inc. (ratiopharm) from two decisions of the Board (PMPRB-08-D3-ratio-Salbutamol HFA and PMPRB-08-D3-ratiopharm, or, respectively, PMPRB ratio HFA and PMPRB ratiopharm) and an order by the Board giving effect to the first of these decisions.

[2] The two appeals were heard together. The central issue in both appeals is whether the Federal Court judge properly held that Sandoz and ratiopharm (collectively the respondents) fell outside of the jurisdiction of the Board as they were not "patentees" within the meaning of subsection 79(1) of the *Patent Act*, R.S.C. 1985, c. P-4, as amended (the Act). The Attorney General maintains that in so holding, the Federal Court Judge did not give due deference to the Board's elaborate reasons for concluding that the respondents came within the ambit of that provision.

[3] For the reasons which follow, I would allow both appeals.

[4] The relevant provisions of the Act and the *Patented Medicines Regulations*, SOR/94-688 (the Regulations) are reproduced in Annex I to these reasons.

BACKGROUND

[5] At the time when these proceedings arose, both ratiopharm and Sandoz were engaged in the business of selling various medicines in Canada.

[6] Among those medicines sold by ratiopharm was an anti-asthmatic medicine called ratio-salbutamol HFA (ratio HFA). This medicine was a generic equivalent of the brand name Ventolin HFA, a patented medicine manufactured and sold in Canada by GlaxoSmithKline (GSK). Pursuant to a series of supply and licensing agreements between these two arm's length parties, GSK sold ratio HFA to ratiopharm in final packaged and labeled form. Ratiopharm was granted an exclusive licence to set the price and sell ratio HFA in Canada without any right to sub-licence. Ownership of the patent and intellectual property rights remained with GSK.

[7] When ratiopharm applied for a Notice of Compliance (NOC) to sell ratio HFA, it listed GSK's patent on the forms it submitted to Health Canada pursuant to the *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133 (the PM(NOC) Regulations), but indicated that the patent owner had consented "to the making, constructing, using, or selling of [ratio HFA] in Canada".

[8] In addition to ratio HFA, ratiopharm also sold a wider range of medicines with respect to which the patent rights were owned by other companies. In none of the agreements pursuant to which ratiopharm bought these medicines were any patent ownership rights granted to ratiopharm. In each case, ratiopharm held its own NOC obtained from Health Canada on consent from the owner of the patents in question.

[9] Sandoz was and remains a wholly owned subsidiary of Novartis Canada Inc., which is itself a wholly owned subsidiary of Novartis Pharma AG, which in turn is wholly owned by Novartis AG (Novartis). Among the medicines sold in Canada by Sandoz was a set of medicines covered by patents owned by either Novartis or one of its wholly-owned subsidiaries. The owners of these patents would generally sell their own brand name version of the medicines in question. They would also allow Sandoz to enter the market and sell a generic version of the medicines after other generics had entered the market and for that purpose, would consent to Sandoz referring to those medicines in obtaining the required NOCs. All the medicines were acquired by way of purchase orders and in no case was there any express licensing agreement linking Sandoz with the owners of the patents in question.

[10] The Board proceedings in respect of ratiopharm were initiated by the staff of the Board (the Board Staff) in July, 2008. By way of a Statement of Allegation, the Board Staff alleged that ratiopharm was selling or had sold, in a manner contrary to sections 83 and 85 of the Act, its ratio HFA product in Canada at excessive prices. A week later, the Board Staff filed an application seeking an order that ratiopharm provide the Board pursuant to sections 80, 81 and 88 of the Act certain sales and pricing information with respect to some 12 additional medicines

sold by ratiopharm, as well as an order that ratiopharm provide certain supply agreement documentation pertaining to two further medicines.

[11] The proceedings in respect of Sandoz were initiated in January, 2010. The application sought an order that Sandoz provide, pursuant to sections 80, 81 and 88 of the Act, sales and pricing information with respect to six medicines sold by Sandoz, which application would later be amended to extend to only five medicines.

[12] In the PMPRB ratio HFA reasons issued May 27, 2011, the Board affirmed the allegations made by the Board Staff, holding that ratiopharm had sold ratio HFA at excessive prices. In the PMPRB ratiopharm reasons issued June 30, 2011, the Board allowed the Board Staff's application for an order that ratiopharm provide the Board certain information with respect to 14 medicines sold by ratiopharm. On October 17, 2011, the Board gave effect to its PMPRB ratio HFA reasons, issuing an order compelling ratiopharm to pay $65,898,842.76 to offset excess revenues realized in the sale of ratio HFA.

[13] In the PMPRB Sandoz reasons issued August 1, 2012, the Board allowed the Board Staff's application for an order that Sandoz provide the Board certain information with respect to five medicines sold by Sandoz.

THE BOARD DECISIONS

[14] Among the determinations made by the Board, only two were subsequently addressed by the Federal Court judge, and I therefore restrict my summary of the Board's reasons to those two determinations.

[15] The first was that sections 79 to 103 of the Act are constitutionally valid. The second was that a person need not own the patent over a particular medicine in order to be a "patentee" in respect of that medicine within the meaning of subsection 79(1) of the Act. In each of its three decisions, the Board found that the respondent in question was a subsection 79(1) "patentee", despite not holding any patents over the medicine or medicines in question.

[16] With respect to the constitutional question, the Board rejected the argument that the Board's enabling provisions including the definition of "patentee" in subsection 79(1) were *ultra vires* Parliament. In reaching this conclusion in the ratiopharm decisions, the Board based itself on a series of prior decisions (PMPRB ratio HFA reasons at paras. 13 and 14, citing *ICN Pharmaceuticals, Inc. v. Canada (Staff of the Patented Medicine Prices Review Board)*, [1997] 1 F.C. 32 [*ICN*] approving *Manitoba Society of Seniors Inc. v. Canada (Attorney General)* (1991), 77 D.L.R. (4th) 485 (Man. Q.B.); aff'd (1992), 96 D.L.R. (4th) 606 (Man. C.A.) [*Manitoba Society*] and *Teva Neuroscience G.P. – S.E.N.C. v. Canada (Attorney General)*, 2009 FC 1155 [*Teva Neuroscience*]. This analysis was adopted without reproduction in the PMPRB ratiopharm reasons at para. 29).

[17] In PMPRB Sandoz, the Board upheld the constitutionality of these provisions once again, rejecting Sandoz's argument that "generic" drug companies fall outside Parliament's legislative authority over patents. While recognizing that most pharmaceutical companies can be broadly sorted into "name brand" or "research-based" companies that rely heavily on patent protection and "generic" companies that do not, the Board found that companies sometimes straddle this boundary and that generalizations are not helpful in determining whether a particular company has brought itself within the Parliament's legislative authority with respect to any given patent (PMPRB Sandoz reasons at paras. 19, 20 and 88).

[18] In construing the scope of the term "patentee" within the meaning of subsection 79(1) of the Act, the Board undertook to read the words of the Act "in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament" (PMPRB ratio HFA reasons at para. 35, citing *Rizzo & Rizzo Shoes Ltd. (Re)*, [1998] 1 S.C.R. 27). The Board identified the purpose of sections 79 to 103 of the Act as one of protecting consumers from unreasonable pricing of patented medicines (PMPRB ratio HFA reasons at para. 38, citing *Celgene Corp. v. Canada (Attorney General)*, 2011 SCC 1 [*Celgene*]). It further observed that the wording of subsection 79(1) did not, on its face, require ownership of a patent nor that a person be entitled to exercise "all rights in relation to a patent" (PMPRB ratio HFA reasons at para. 41). Rather, Parliament cast its language in much broader terms, capturing "any other person entitled to exercise any rights in relation to a patent" (PMPRB ratio HFA reasons at para. 41).

[19] Following the above analysis, the Board held that, in obtaining under the licensing agreement with GSK the right *inter alia* to sell ratio HFA, ratiopharm became entitled to exercise a right in relation to a patent within the meaning of subsection 79(1) of the Act (PMPRB ratio HFA reasons at para. 42). Having found comparable rights with respect to the 12 medicines identified in the Board Staff's July 15, 2008, application, the Board held that ratiopharm was a patentee within the meaning of subsection 79(1) in relation to these 12 medicines (PMPRB ratiopharm reasons at paras. 13, 14 and 26). With respect to the two medicines in respect of which the Board Staff had sought further documentation, the Board took the view that a *prima facie* demonstration of jurisdiction had been made out, and that the request for further information was warranted (PMPRB ratiopharm reasons at paras. 67 to 69).

[20] Though no express agreements linked Sandoz to Novartis or any of its patent holding subsidiaries, the Board found that Sandoz sold the medicines in question pursuant to what amounted to a series of implied licences from the patent holders in question. Specifically, Sandoz was granted the right to sell these medicines without fear of being sued for infringement (PMPRB Sandoz reasons at paras. 48 and 49). By virtue of this right, Sandoz was a patentee within the meaning of subsection 79(1) of the Act in relation to the medicines in question (PMPRB Sandoz reasons at para. 52).

[21] The Board further rejected ratiopharm's contention that construing subsection 79(1) in that manner had the effect of capturing wholesalers, hospitals and pharmacies. According to the Board, subsection 79(1) only captures persons who sell to consumer classes protected by the

Board, and wholesalers, hospitals and pharmacies do not come within that class (PMPRB ratiopharm reasons at paras. 15 and 16).

THE FEDERAL COURT DECISIONS

[22] Ratiopharm brought applications for judicial review against the decisions issued against it. These applications were consolidated by order of the Federal Court and disposed of in a single set of reasons (ratiopharm reasons). Sandoz's single application for judicial review was disposed of in a separate set of reasons (Sandoz reasons).

[23] Notices of constitutional question challenging the validity of sections 79-103 of the Act were filed prior to the hearing in conformity with section 57 of the *Federal Courts Act*, R.S.C. 1985, c. F-7, as amended.

[24] Because the four applications engaged the threshold issue as to whether ratiopharm and Sandoz were subsection 79(1) patentees and whether, if so, such a construction was constitutional, the reasons largely overlap, often echoing each other verbatim. Given the commonality of the reasons, the following is a joint summary drawn principally from the ratiopharm reasons.

[25] The Federal Court judge held that, in reviewing the Board's interpretation and application of subsection 79(1) of the Act, he was required to apply the standard of reasonableness, given the Board's familiarity with its home statute (ratiopharm reasons at para. 10, citing *Celgene* at para. 34 and *Alberta (Information and Privacy Commissioner) v. Alberta Teachers Association*, 2011

SCC 61 [*Alberta Teachers*] at para. 34). In reviewing the Board's disposition of the constitutional challenge, he applied the standard of correctness (ratiopharm reasons at para. 11).

[26] The Federal Court judge concluded that the Board's construction of the word "patentee" in subsection 79(1) of the Act was not reasonable. Because the purpose of the Act is to ensure that patent holders cannot take undue advantage of the monopolistic positions which they hold, the Board would be exceeding its role if it were to extend its price review powers to those prices charged by persons who do not own patents or hold monopolies (ratiopharm reasons at para. 15). Had the Board examined the French text of subsection 79(1), it would have seen that the definition of "patentee" is tied more closely to the rights of the owner of the patent (ratiopharm reasons at para. 25).

[27] The Federal Court judge drew additional support for this proposition from the fact that the constitutionality of the Board's enabling provisions is rooted in Parliament's exclusive jurisdiction over patents (ratiopharm reasons at para. 16, citing *Manitoba Society*). He held, "without addressing the constitutional argument directly", that where the Act is ambiguous, it should be interpreted "in a manner consistent with the federal jurisdiction over patents" (ratiopharm reasons at para. 17). Such an interpretation can be achieved by excluding from the subsection 79(1) definition of "patentee" those who do not actually hold the relevant patent, i.e.: generic companies.

[28] Elaborating on the limits of Parliament's power over patents, the Federal Court judge held that "federal jurisdiction in this area is generally understood to be confined to regulating the

'factory-gate' prices of patented medicines … [meaning] those charged by patent holders [e.g. GSK or Novartis] to their first purchasers [e.g. ratiopharm or Sandoz]" (ratiopharm reasons at para. 18, citing *Pfizer v. Canada (Attorney General)*, 2009 FC 719 [*Pfizer*] at paras. 61 to 63).

[29] Finally, the Federal Court judge added a number of practical observations relating to the pharmaceutical industry in support of his view that a "generic company" cannot come within the definition of a patentee simply because it sells a version of a medicine that is patented (ratiopharm reasons at para. 20). These observations included the following (ratiopharm reasons at paras. 20 to 22):

> "Usually, a generic company is not entitled to the principal benefit of a patent – an exclusive monopoly to make, use, or sell the patented product. Nor can a generic company typically exercise rights in relation to a patent held by another company.
>
> …
>
> Generally speaking, generic companies either help create or join a competitive marketplace, which helps keep the costs of patented medicines down.
>
> …
>
> If the term "patentee" is interpreted too broadly so as to catch a company in the position of ratiopharm [or Sandoz], there are likely few generic companies who would not be similarly placed. Most generics enter the market by comparing their products against drugs that are the subject of patents held by other companies. To that extent, they indirectly enjoy the benefits of patents and, ultimately, may be regarded as having acquired rights in relation to them".

[30] Having determined that subsection 79(1) of the Act could not reasonably be construed so as to include a party holding neither a patent nor a monopoly in respect of the medicine in question, the Federal Court judge held that the Board erred in holding that ratiopharm and Sandoz were "patentees" in respect of any of the medicines at issue.

[31] Turning to the constitutional issue, the Federal Court judge dismissed the argument that *Manitoba Society* was overtaken by a subsequent set of amendments to the Act. These amendments giving the Board the power to address the pricing of patented medicine more directly did not alter the Act's purpose or the Board's mandate, and fall, when properly interpreted, within the federal head of power over patents (ratiopharm reasons at para. 30). When regard is had to the reservation expressed by the Federal Court judge earlier on with respect to generic companies, the conclusion that he reached is that the price control scheme devised by Parliament is constitutionally valid when applied to brand name medicine, or medicine sold by the owner "un titulaire" of the patent pertaining to it.

[32] The Federal Court judge disposed of the four applications by referring the matter back to the Board with a direction that it find the respondents not to be "patentee[s]". Given this conclusion, the Federal Court judge did not address the further questions whether the patents in issue pertained to the medicine sold by the respondents and whether ratiopharm had sold HFA at excessive prices.

POSITION OF THE PARTIES ON APPEAL

[33] For ease of reference, I will refer to the memoranda of fact and law pertaining to the ratiopharm appeal for arguments that are common to both appeals. Reference will be made to the memoranda of fact and law pertaining to the Sandoz appeal for points which only arise in that appeal.

[34] Before this Court, the Attorney General seeks to have each of the judgments below set aside, and asks that in the event that its appeal is successful, the issues which the Federal Court judge did not address be sent back to the Federal Court for determination.

[35] The Attorney General argues that, although the Federal Court judge identified the correct standard of review in assessing the Board's construction of subsection 79(1) (i.e. reasonableness), he failed to show the appropriate level of deference. Though the Federal Court judge found that subsection 79(1) could not reasonably be construed so as to include those who neither own patents nor hold monopolies, the Board's reasons for finding otherwise had a solid foundation in the wording and purpose of the provisions in question, as well as the jurisprudence interpreting them.

[36] With respect to legislative purpose, both this Court and the Supreme Court of Canada have affirmed that the purpose of the Board's enabling provisions is one of consumer protection (Attorney General's ratiopharm memorandum of fact and law at paras. 56 and 57, citing *ICN* and *Celgene*). It would frustrate this purpose if patent holders could avoid the application of these provisions by merely inserting a licensee, arm's length or otherwise, in the supply chain between itself and the consumer. The Board's interpretation and application of subsection 79(1) of the Act gives effect to this purpose, and is reasonable.

[37] With respect to the plain language of the Act, the definition of "patentee" in subsection 79(1) of the Act is expansive, and says nothing about patent ownership. In both linguistic versions, the provision expressly includes persons other than the one owning the patent in

question (Attorney General's ratiopharm memorandum of fact and law at para. 72). Consideration of the legislative context reinforces the breadth of this provision's scope, as the legislator could have simply relied on the less expansive definition of "patentee" provided in section 2 of the Act (Attorney General's ratiopharm memorandum of fact and law at para. 73).

[38] Nor does the wording of the Act require proof of a monopoly. This makes sense, given that a factual monopoly, though relevant to competition law, is irrelevant to the legislative purpose, which is to limit the negative effects that result from the *statutory* monopoly resulting from the grant of a patent (Attorney General's ratiopharm memorandum of fact and law at para. 67). That the Board is in no practical position to assess the market power of a given party supports the view that it was reasonable for the Board not to view the existence of a monopoly in fact as a condition precedent for engaging the Board's jurisdiction (Attorney General's ratiopharm memorandum of fact and law at para. 71, citing *ICN, inter alia*).

[39] Finally, with respect to the issue of "factory-gate prices", the Attorney General argues that this term does not necessarily describe the price charged by patent owners, but rather the "list price" that certain purchasers are charged for the drug (Attorney General's ratiopharm memorandum of fact and law at paras. 86 and 87). In any event, this definition is not set out by statute or regulation, and only appears in the Patentees' Guide to Reporting (the Guide) (Attorney General's ratiopharm memorandum of fact and law at para. 86).

[40] The respondents for their part seek the dismissal of the appeals, principally on the basis that the Federal Court judge properly held that the Board's interpretation and application of

subsection 79(1) of the Act is unreasonable. They also reiterate the constitutional challenge put before the Board.

[41] With respect to the standard of review, the respondents argue that the Federal Court judge erred in law when he identified reasonableness as the standard of review applicable to the Board's interpretation and application of subsection 79(1). Although the Board was interpreting its home statute, the presumption from *Albert Teachers* that such decisions must be reviewed with deference can be rebutted once the factors from *Dunsmuir v. New Brunswick*, 2008 SCC 9 [*Dunsmuir*] are considered (ratiopharm's memorandum of fact and law at para. 52).

[42] Given that the Federal Court judge applied a more deferential standard than he should have and properly found the Board's interpretation of subsection 79(1) to be unreasonable, the respondents argue on a subsidiary basis that he would have reached the same result had he selected the correct standard, being correctness (ratiopharm's memorandum of fact and law at paras. 33 and 54).

[43] With respect to legislative purpose, the Board framed its own statutory mandate in terms of "'consumer protection' at large" (ratiopharm's memorandum of fact and law at paras. 64). This was unreasonable, however, as a long line of jurisprudence, running from the Board's very own decisions to those of the Supreme Court, affirms a narrower purpose, being the prevention of "abuses of the monopoly power that devolves from patent rights" [emphasis in original] (ratiopharm's memorandum of fact and law at para. 59, citing *PMPRB-06-D1-ADDERALL XR,*

Shire Biochem Inc. v. Canada (Attorney General), 2007 FC 1316, *Sanofi Pasteur Limited v. Canada (Attorney General)*, 2011 FC 859 and *Celgene*).

[44] A textual analysis supports the view that the Board interpreted subsection 79(1) unreasonably. First, because the French text (« les droits d'un titulaire »), is more precise than the English text ("any rights in relation to that patent"), the Board was required according to the shared meaning rule to limit the definition's content to this narrower definition (ratiopharm's memorandum of fact and law at para. 71). When one reviews the authorities as to what constitute the "rights of a patent holder", one finds that the key right is the right to exclude others from dealing in the patented invention (ratiopharm's memorandum of fact and law at paras. 74 to 76, citing *Black's Law Dictionary*, 8th ed.). It follows that only the right to exclude was contemplated.

[45] Second, subsection 79(1) requires that a patentee be "entitled" to exercise rights in relation to a patent. Neither respondent, however, is "entitled" to exercise any rights of exclusion. In the case of ratiopharm, the respondent was at most entitled to exercise certain contractual rights to sell the medicines in question. In conflating mere contractual rights with the rights of a patent holder, the Board reached an unreasonable conclusion (ratiopharm's memorandum of fact and law at para. 83). In the case of Sandoz, despite the Board's erroneous finding of an implied licence, the respondent had no entitlements whatsoever (Sandoz's memorandum of fact and law at para. 79).

[46] Third, when read in harmony with the original meaning rule of statutory construction, the text of subsection 79(1) can be seen to exclude generic companies. Specifically, this provision expressly excludes from the definition of patentee those persons operating under a "licence continued by subsection 11(1) of the *Patent Act Amendment Act, 1992* [the PAAA]". Subsection 11(1) expressly invoked the "compulsory licence" provisions of the Act as it read prior to February 4, 1993. When they were available, compulsory licences were granted only to generic companies (ratiopharm's memorandum of fact and law at para. 88). Though no such licences are at issue in this case, the invocation of subsection 11(1) must be read, once its original meaning is understood, as a statutory exclusion aimed at generic companies (ratiopharm's memorandum of fact and law at para. 90).

[47] Turning from the text of subsection 79(1), the respondents argue that several contextual factors support the view that the Board's interpretation and application of this provision was unreasonable. First, they argue that the Board's reasons for construing subsection 79(1) to include them were based on misinterpretations of the law of patents, including various provisions of the Act. In the case of ratiopharm, the Board erroneously concluded that ratiopharm would be entitled to bring an action under subsection 55(1) of the Act (ratiopharm's memorandum of fact and law at para. 117, citing *Signalisation de Montréal Inc. v. Services de Béton Universels Ltée*, [1993] 1 F.C. 341).

[48] Second, the respondents argue that the Parliamentary debates leading to the enactment of the Board's enabling provisions illustrate a clear intent to target "patent holding pharmaceutical firms" (ratiopharm's memorandum of fact and law at para. 99).

[49] Third, the respondents cite the Board's own conduct, observing that, for many years, the Board took the view, expressed publicly in its very own guidelines, that it had no authority to regulate generic drugs (ratiopharm's memorandum of fact and law at para. 104, citing ratiopharm's Public Appeal Book [RPAB], Vol. 1, Tab 18A).

[50] Finally, the respondents argue that the Board did not fairly consider their challenges to the constitutional validity of an interpretation of subsection 79(1) that would extend the Board's jurisdiction to generic drugs. Rather, the Board simply dismissed their arguments summarily, failing to follow relevant jurisprudence both from this Court and the Supreme Court (ratiopharm's memorandum of fact and law at paras. 121 to 126, citing *Bernard v. Canada (Attorney General)*, 2014 SCC 13 *inter alia*). As such, the Board's decision cannot stand.

[51] In addition to those arguments shared by each of the respondents, there are several arguments which they advance separately. Sandoz, for its part, argues that the Board erred in finding that it had an implied licence. Specifically, the Board merely asserted without any analysis that the sales at issue would have constituted infringement of the patents in question (Sandoz's memorandum of fact and law at para. 85). Also, the Board made findings that found no support in the record, such as the holding that Novartis "instructed" Sandoz (Sandoz's memorandum of fact and law at para. 107).

[52] There are two arguments put forward uniquely by ratiopharm. First, ratiopharm argues that the Federal Court has affirmed and the Board has long-recognized that its jurisdiction extends only to "ex-factory" or "factory gate" prices, and the Board's own guidelines define this

price as that established for "the first sale … of the product 'at arm's length' to distributors, wholesalers, hospitals, pharmacies, etc." (ratiopharm's memorandum of fact and law at paras. 108 and 109, citing the *Guide and Pfizer* at paras. 61 to 63). This definition cannot sensibly capture ratiopharm. Furthermore, if it were to capture ratiopharm, there is no principled reason it would not capture wholesalers, retailers and pharmacies that the Attorney General now asserts would not in fact be captured (ratiopharm's memorandum of fact and law at paras. 84 and 85, citing the Attorney General's ratiopharm memorandum of fact and law at para. 88).

[53] Ratiopharm argues that the unreasonableness of the Board's determination that it was a patentee can be further illustrated by its equally unreasonable determination that GSK, despite owning the patents pertaining to ratio HFA, was found not to be a patentee. The Board's treatment of GSK in respect of ratio HFA exemplifies its position with respect to all of the products in issue (ratiopharm's memorandum of fact and law at para. 112). To exclude these patent holders from the definition of "patentee" simply makes no sense.

ANALYSIS AND DISPOSITION

[54] The first issue which must be addressed is whether it was open to the Federal Court judge, applying the appropriate standard of review, to set aside the Board's conclusion that a person need not own a patent or hold a monopoly over the medicine which it sells in order to be a "patentee" within the meaning of subsection 79(1). To the extent that the answer to this question is no, the Court will also have to determine whether subsection 79(1), as it was construed by the Board, can withstand constitutional scrutiny. A further issue, which arises in the

Sandoz appeal only, and which I propose to address immediately after the first, is whether the Board erred in finding that Sandoz sold the medicines in question pursuant to an implied licence.

[55] The other questions that were raised in the judicial review application before the Federal Court judge but not addressed by him – i.e. the propriety of $65,898,842.76 pricing adjustment directed against ratiopharm to offset excess revenues realized on the sale of ratio HFA and the question in each case whether the respective patents pertain to the medicines in issue – will be referred back to the Federal Court at the joint request of the parties.

Standard of Review

[56] When this Court hears an appeal from a decision of the Federal Court disposing of an application for judicial review, it is the role of this Court to determine "whether the court below identified the appropriate standard of review and applied it correctly" (*Agraira v. Canada (Public Safety and Emergency Preparedness*), 2013 SCC 36 at para. 45, citing *Canada Revenue Agency v. Telfer*, 2009 FCA 23 at para. 18).

[57] There is no dispute that the decision of the Board, insofar as it asserts that its reading of subsection 79(1) is constitutionally valid, must be reviewed for correctness. The parties disagree, however, on the standard of review applicable to the Board's interpretation of subsection 79(1) of the Act.

[58] Although the respondents accept that the Board is interpreting its home statute, and is therefore presumptively subject to review on a reasonableness standard (*Alberta Teachers*), they argue that this presumption is rebutted once the *Dunsmuir* factors are considered. I cannot agree.

[59] Under the test set out in *Dunsmuir*, one must consider the existence of a privative clause, the nature of the administrative regime in question, the expertise of the decision-maker and the nature of the question.

[60] Though the respondents correctly observe that the Board's decisions are not protected by any privative clause, the other factors weigh in favour of deference.

[61] Under sections 79-103 of the Act, Parliament has provided for a discrete pricing regime applicable to patented medicines, the administration of which is left to the Board. Within this statutory context, the Supreme Court has recognized that the Board is a specialized tribunal which is entitled to deference (*Celgene* at para. 34). Even if this observation was offered by way of obiter, as the respondents point out, it carries authoritative force, appearing as it does in a passage intended to cast doubt on the appropriateness of reviewing the Board's interpretation of its enabling statute on a standard of correctness (*R. v. Henry*, 2005 SCC 76 at para. 57).

[62] I should add that although the meaning of patentee pursuant to subsection 79(1) gives rise to a question of law, it can hardly be considered of "central importance to the legal system". Indeed, this definition is arguably of no central importance to the Act itself, which relies on the more general definition of "patentee" provided in section 2. Subsection 79(1) ousts this general

definition for the sole purposes of applying the discrete pricing regime applicable to patented medicines. The question whether a person is "entitled to exercise any right in relation to a patent" is highly fact dependant, informed by the Board's appreciation of the pharmaceutical industry and the complex relationship between innovators and generics.

[63] As the presumption of deference from *Alberta Teachers* is not rebutted, the Federal Court judge properly concluded that the Board's interpretation of subsection 79(1) of the Act was to be reviewed on a standard of reasonableness.

[64] Finally, the Board's determination that Sandoz was granted an implied licence to sell the medicine by the patent holders within the Novartis group gives rise to a question of mixed fact and law with respect to which the Board is also owed deference.

The Board's Interpretation of Subsection 79(1) of the Act

Legislative Purpose

[65] The Board determined that the purpose of its enabling provisions was to protect consumers from the excessive pricing of patented medicines (PMPRB Sandoz reasons at para. 37). The Federal Court judge preferred a narrower characterization, however, holding that the purpose was to prevent *patent holders* from pricing their patented medicines excessively (ratiopharm reasons at para. 15). That is one of the four principal reasons relied upon by the Federal Court judge in order to justify his intervention and overturn the Board's interpretation of subsection 79(1) of the Act (ratiopharm reasons at paras. 14 and 15).

[66] In so doing, the Federal Court judge substituted his own view of the legislation's purpose without considering whether the Board's characterization met the threshold of acceptability and defensibility that separates unreasonable decisions from reasonable ones. As such, he misapplied the standard of reasonableness. Had he turned his mind to the Board's reasons, it would have been apparent that the Board's determination was based on a defensible interpretation of the Act as construed to date by the case law.

[67] Both the Federal Court judge and the Board agreed that the mischief targeted by these provisions was the excessive pricing of patented medicines. However, while the Board's construction focused on the persons in need of protection from such mischief, i.e. consumers, the Federal Court judge focused on those in a position to cause the mischief. In losing sight of the ultimate goal of the provisions in question, he failed to appreciate that the mischief sought to be prevented could be caused without the patent owner itself charging excessive prices.

Interpretation in Favour of Constitutional Validity

[68] The second basis on which the Federal Court judge overturned the Board's interpretation of subsection 79(1) was his concern that this interpretation *might* be unconstitutional. This reasoning once again ignores the standard of review which governed the question before him.

[69] The Federal Court judge appeared to be of the view that an ambiguity could be said to exist in subsection 79(1), suggesting that it might be capable of more than one interpretation (ratiopharm reasons at para. 17). Specifically, the definition of patentee might be limited to patent owners or it might not be. Though the second interpretation was the one adopted by the

Board, this interpretation could, in the Federal Court judge's view, "expose" the legislation to a constitutional challenge (Sandoz reasons at para. 22; ratiopharm reasons at para. 17). He therefore preferred the first interpretation.

[70] Reasonableness review does not invite the Court to prioritize all possible answers to a question and identify the best among them. Rather, the question to be answered is whether the conclusion reached by the decision-maker meets the threshold of acceptability and defensibility mentioned above. To the extent that the legislation was reasonably capable of bearing the interpretation given by the Board, the Federal Court judge was precluded from substituting his own view for that of the Board.

[71] I should add that regardless of the foregoing, it was not open to the Federal Court Judge to construe subsection 79(1) narrowly on the basis that the construction adopted by the Board *might* be unconstitutional since a Notice of Constitutional Question had been filed and the constitutional validity of subsection 79(1), as construed by the Board, was for him to decide (contrast *Canada (Fisheries and Oceans) v. MiningWatch Canada*, 2008 FCA 166 at para. 4).

"Ex-factory price" Issue

[72] The third basis on which the Federal Court judge overturned the Board's interpretation of subsection 79(1) was that Parliament's power over price review in connection with patents is "generally understood" to extend only to "factory-gate prices" (ratiopharm reasons at para. 18, citing *Pfizer* at paras. 61 to 63).

[73] While the Act makes no mention of factory gate prices, the term "ex-factory price" does appear in the Regulations, where paragraphs 4(1)(*f*), 4(1)(*g*) and subsection 4(10) use the term to specify the types of prices contemplated in paragraphs 80(1)(*b*) and 80(2)(*b*) of the Act. The term is not defined as such by the Regulations, but has been defined in part in the Guide as follows (PMPRB ratio HFA reasons at para. 31):

> The price established for the first sale … of the product "at arm's length" to distributors, wholesalers, hospitals, pharmacies, etc… The ex-factory price is generally the "list price" for medicines …

[74] Ratiopharm argues that this definition excludes sales between it and its suppliers, as it operates at arm's length from the patent holders from whom it bought the medicines in issue. As the Federal Court judge held, it is the price paid by ratiopharm to these companies that attracts the review jurisdiction of the Board, not the price subsequently charged by ratiopharm to its customers.

[75] In my view, this argument must be rejected for two reasons. First, it has been recognized that the Board's guidelines do not constitute binding law, and that to the extent that they conflict with the Act or the Regulations, the latter must prevail (*Teva Neuroscience* at paras. 21 to 25). The Board noted that its statutory mandate may require it to adapt to "different sales, distribution, commercial and marketing arrangements" (PMPRB ratio HFA reasons at para. 32). Indeed, the Guide describes a mode of operation in which the first arm's length sale of a patented medicine will generally be the sale at the list price. However, that is not the only mode of operation and the Board merely adapted the definition to a scenario where the list price is charged in a sale subsequent to the first arm's length sale (PMPRB ratiopharm reasons at paras.

15 and 16). Despite the respondents' claim to the contrary, I do not find this conclusion to be unreasonable.

[76] Second, current subsection 4(5) of the Regulations (formerly subsection 4(6)) recognizes that the Board can look past the first arm's length sale, provided the party whose prices would be subject to review also constitutes a subsection 79(1) "patentee" with respect to the medicine in question. As the Board concluded, in such a situation, the focus shifts to the price charged by the patentee further down the supply chain (PMPRB ratio HFA reasons at para. 47). It is not unreasonable to conclude that the price charged by this subsequent patentee constitutes the ex-factory price in these particular situations.

[77] Sandoz, for its part, did not advance any argument on the basis of the ex-factory price as set out in the Guide. However, because the Federal Court judge relied on this argument in disposing of the Sandoz appeal, it should also be addressed in that context.

[78] As Sandoz does not operate at arm's length from Novartis, the prices which it charges do not fall outside the definition of ex-factory prices provided by the Guide. Though it might be argued that, pursuant to current subsection 4(6) of the Regulations (formerly subsection 4(7)), it is Novartis who should have been reporting the prices charged by Sandoz, this would only apply where the non-arm's length party reselling the drug is not "entitled" to do so, and thus "not required to provide information" under section 80 of the Act, which only applies to patentees. However, nothing turns on this in the present case given the Board's finding that Sandoz is also a patentee based on the implied licence pursuant to which it sold the medicines in issue.

[79] There is no basis for ratiopharm's related argument that the Board's proposed definition of "patentee" is unwieldy to the point that it could capture wholesalers, retailers and pharmacies (ratiopharm's memorandum of fact and law at paras. 84 and 85). The fact that the respondents operate under a licence to sell the patented medicine whereas wholesalers, retailers and pharmacies derive their right qua owners of the products which they purchase for re-sale provides a principled basis for the distinct treatment (compare *Eli Lilly & Co. v. Novopharm Ltd.*, [1998] 2 S.C.R. 129 at paras. 48 to 51, 68 to 71 and 99 to 100).

The French Text of Subsection 79(1) of the Act

[80] The Federal Court judge considered the impact of the French text of subsection 79(1) in the part of his judgment relating to "supporting factors," which I address later in these reasons. However, because the outcome of these appeals turns on the construction of this provision, it is preferable to deal with this question now, together with the other main reasons advanced by the Federal Court judge in support of his intervention.

[81] In determining the meaning to be given to the word "patentee", the Federal Court judge contrasted the phrase "les droits d'un titulaire" in the French text with "any rights in relation to that patent" in the English text. According to him, the French text "ties the definition of 'patentee' more closely to the rights of the patent holder" than does the English text and should be preferred on that account (Sandoz reasons at para. 31).

[82] The difficulty with this reasoning is that the definition so construed would add nothing to the one found in section 2 of the Act, i.e.: "the person for the time being entitled to the benefit of

the patent", thereby imposing a redundancy that offends the presumption that Parliament does not speak in vain (*Canada (Attorney General) v. JTI-Macdonald Corp.*, 2007 SCC 30 at para. 110).

[83] Beyond this, it is worth noting that the history of this provision shows that while the words "any rights of the patentee" have remained constant in the English text over the years, the French text previously used the more indeterminate phrase "quiconque exerce des droits d'un breveté" thereby providing for a reading that is wholly consistent with the English text (these texts are reproduced in annex II to these reasons). That the words "any rights" in the English text have remained throughout suggests that a slip might have occurred in the drafting of the French text in 1992, when the word "les" was inserted instead of the word "des". As an aside, it is useful to add that for the purpose of identifying the "rights" – "les droits" – that are contemplated by subsection 79(1), the use of the plural is not to be construed as excluding the singular (subsection 33(2) of the *Interpretation Act*, R.S.C. 1985, c. I-21).

[84] The respondents advance a more extensive justification for relying on the French text in order to confine its meaning to patent holders. The entry point for the analysis which they propose is the invocation of the shared meaning rule of statutory interpretation. Because the English text leaves open the question of what constitutes a "right in relation to" a patent, argue the respondents, reference to the French text is required to clarify the matter. When one considers how "the rights of a patent holder" (the respondents' translation of the phrase "les droits d'un titulaire" in the French text) are defined by the case law and the doctrine, one finds that the essential feature is the right to exclude, a right which only a patent holder can have.

[85] I first note that this argument would require that subsection 79(1) be construed without regard to the respective rights of a patentee as these are set out in the Act itself (section 42), a most unlikely solution. This argument also assumes that there is discordance between the French and English text as to whether a right to exclude is a necessary component of the definition since recourse to the shared meaning can only be had if this discordance actually exists (*R. v. Daoust*, 2004 SCC 6 at para. 27).

[86] Turning to this point, the argument advanced by the respondents is that "les droits d'un titulaire" cannot extend to someone who has a right to sell a patented medicine without also having a right to exclude. However, one need not look beyond the French text to see that its scope cannot be so narrow. Indeed, just as in the English text, the rights at issue are clarified in the French text by the exclusion of compulsory licences continued under the PAAA. Such licences did not entitle their holders to exclude others, but did entitle them to sell the patented products or process without the consent of the patent owner. The fact that Parliament provided for this exclusion indicates that, absent the exclusion, the rights granted under these compulsory licences would have constituted "rights of the patent holder".

[87] The respondents attempted to obviate the effect of this exclusion arguing that it was inserted for greater certainty. However, the more plausible explanation is that the exclusion was inserted in order to insure that those who held the right to sell patented medicine under compulsory licences which remained in effect when the 1992 amendments were enacted, did not come within the definition of "patentee".

[88] In the end, there is no indication that the English and French texts give discordant answers to the question whether a person must have a right to exclude in order to be a "patentee".

[89] When construing provisions of the Act that frame the Board's jurisdiction, the Court should prefer the interpretation which best implements the objectives of the Act. In *Celgene*, Abella J. stressed the need for the Board to discharge its mandate "[taking] into paramount account its responsibility for ensuring that the monopoly that accompanies the granting of a patent is not abused to the detriment of Canadian patients and their insurers" (*Celgene* at para. 29).

[90] As the Board explained at length Parliament, by including in the definition of "patentee" persons who exercise any rights in relation to a patent, recognized that persons exercising selling rights can inflict on consumers the same mischief as patent holders. In both cases, the risk that excessive prices will be charged arises from the existence of the patent pertaining to the medicine being sold and its presumptive impact on the market (PMPRB Sandoz reasons at paras. 72 to 78; PMPRB ratiopharm reasons at para. 19). Simply put, nothing turns on the fact that the patent rights – specifically the right to exclude and the right to sell – are exercised by different persons.

[91] As the Board further explained, its capacity to fulfill its mandate would be greatly diminished if the narrow reading proposed by the respondents was to prevail. Having found that the words of subsection 79(1) can reasonably bear an interpretation which allows it to give effect

to Parliament's intent, the Board proceeded to adopt it (PMPRB Sandoz reasons at paras. 35 to 40, 56 and 57). I can detect no error in this regard.

Supporting Factors

[92] The Federal Court judge also highlighted a number of secondary points which he referred to as "factors", in support of his conclusion that the respondents are not patentees within the meaning of subsection 79(1) of the Act.

"Generic Companies"

[93] Beyond his reading of the French text of subsection 79(1) which I have already addressed, the main factor spoken to by the Federal Court judge is, broadly speaking, the general practices of "generic companies" in the pharmaceutical industry. He held, for instance, that generic companies "generally … either help create or join a competitive marketplace" and are "usually...not entitled to the principal benefit of a patent" (ratiopharm reasons at paras. 20 and 21). With respect, I find this line of analysis to be unhelpful.

[94] The term "generic company" appears nowhere in the Act or the Regulations. Such terms as "innovator" or "generic" are, in some contexts, used as a shorthand way for identifying legal categories that are relevant to the scheme at hand, such as, respectively, "first person" and "second person" within the meaning of the PM(NOC) Regulations. However, their use in connection with a statute that makes no reference to these distinctions only serves to create confusion.

[95] In its reasons, the Board rejected this approach explaining that (PMPRB ratiopharm reasons at para. 81):

> … the generic pharmaceutical industry is not a defined entity, in either the legal or practical sense. There are some obvious divisions between the generic and brand name pharmaceutical industries and rough lines can be drawn. However, this is not conductive to defining legal rights in the sense argued for by ratiopharm. Indeed, some generic companies could hold more patents than some brand name companies, or be entitled to rights in relation to more patents than some brand name companies.

[96] This is a reasonable holding. Put simply, the extent to which a given company relies on patent protection in its overall business model as innovator companies typically do and generic companies typically do not, is irrelevant to the question whether, with respect to a particular medicine being sold, it is acting as a patentee within the meaning of subsection 79(1) of the Act.

The Board's Finding of an Implied Licence

[97] The Federal Court judge did not consider the question whether Sandoz had an implied licence with respect to the patents in question. His decision was reached on the more general basis that Sandoz did not own the patents in question or hold a monopoly, and therefore was not a patentee within the meaning of subsection 79(1) of the Act (Sandoz reasons at para. 41). This conclusion is confirmed by the fact that, in the ratiopharm reasons, the Federal Court judge relied on the same reasoning to issue substantially the same order notwithstanding the existence of express agreements between ratiopharm and the patent holders (ratiopharm reasons at para. 34).

[98] It remains that the absence of an implied licence, if this be the case, would provide a basis for upholding the order of the Federal Court judge.

[99] The core of the Board's holding on the question of implied licences was that, with respect to each of the medicines in question, Sandoz was entitled to sell that medicine without being sued for infringement by the owners of patents for inventions pertaining to those medicines (PMPRB Sandoz reasons at para. 48). By virtue of this entitlement, Sandoz was a person entitled to exercise a right in relation to the patent in question, and therefore a patentee within the meaning of subsection 79(1) of the Act.

[100] Sandoz's most direct challenge on this point is that the Board asserted without analysis that the sales at issue would have constituted infringement of the patents in question (Sandoz's memorandum of fact and law at para. 85). In reality, claims Sandoz, most of the patents were not actually used in the medicines sold by Sandoz. The Board's "infringement" assertion reflected a "clear misapprehension of the facts" (Sandoz's memorandum of fact and law at para. 85).

[101] There are two fundamental flaws with this argument. The first is that the Board never in fact concluded that the sales in question would have amounted to infringement. Though the Board does state at one point that "[t]hese sales would be actionable patent infringement but for this authorization", it does so in a paragraph expressly dedicated to summarizing the position taken by the Board Staff (PMPRB Sandoz reasons at para. 10).

[102] The second flaw with this argument is its premise that the Board's conclusion could not have been reached unless the sales in question amounted to infringement. This premise is wrong.

[103] The entitlement identified by the Board was a right, arising out of an implied contract, to sell the medicine purchased from the licensing party *even if* doing so would, absent this right, constitute an infringement of a patent owned by the licensing party. In the Board's view, the legal force of this right could be illustrated by the fact that, were Sandoz ever sued for patent infringement by any of these parties, it could rely upon this right in defending against the suit (PMPRB Sandoz reasons at para. 50). Whether the party bringing suit in such a scenario could demonstrate that the medicine was covered by its patent is irrelevant to the question whether Sandoz would be able to rely on this right in the event of such a suit (i.e. able to show its entitlement to sell the medicine). Indeed, this first question goes to the strength of the connection between a particular invention and a particular medicine as opposed to the existence of any legal rights or claims that the party selling the medicine in question may have in relation to the patent for the invention in question.

[104] As was held by this Court in *ICN*, the Board's jurisdiction to review a given set of prices requires the existence of a rational connection between a patented invention and the medicine being sold in Canada (*ICN* at para. 46). Subsection 79(2) of the Act defines the parameters of such a connection in providing for when an invention will "pertain" to a given medicine for the purposes of applying subsection 79(1). Given the broad language in subsection 79(2), the connection can be one of "the merest slender thread" (*ICN* at para. 46). In giving effect to the language of subsection 79(2), this Court expressly rejected the idea that the Board need construe the claims of the patent, let alone determine that the sales in question would amount to patent infringement, holding that the existence of the required connection is to be assessed without going beyond the face of the patent (*ICN* at para. 46).

[105] The Board understood that, pursuant to the rule set out in *ICN*, it was not required to go beyond the face of the patent (PMPRB Sandoz reasons at paras. 72 and 75). It also understood that the question whether there exists any entitlement within the meaning of subsection 79(1) is distinct from the question whether an invention pertains to a medicine within the meaning of subsection 79(2), having addressed these questions sequentially in separate sections of its reasons (see PMPRB Sandoz reasons at paras. 31 and 58).

[106] Sandoz argued before the Board with respect to the interpretation of this latter provision that *ICN* should be distinguished or had been overtaken by subsequent jurisprudence (PMPRB Sandoz reasons at para. 73). Although the Federal Court judge did not consider this question (Sandoz reasons at para. 5), the Board addressed it extensively (PMPRB Sandoz at paras. 73 to 80). As was found in *ICN* and reiterated by the Board, the purpose of subsection 79(2) would be frustrated if a more extensive connection between the patent and the medicine in question was required.

[107] The remaining arguments advanced by Sandoz with respect to the implied licence issue must also be rejected. Sandoz argues that the Board erred in finding that "instructions" were received from the patent holders (Sandoz's memorandum of fact and law at paras. 80 and 107). It adds that the finding of an implied licence is based on a misapprehension of the evidence without however pointing to the evidence that was allegedly misapprehended.

[108] The only question which needs be answered in order to dispose of these arguments is whether the Board's conclusion as to the existence of an implied licence finds support in the

evidence. In my view, reference need only be made to the consent given by the patent holders in order to allow Sandoz to cross-reference their medicine and obtain the required NOCs, in order to find such support.

The Constitutional Challenge

[109] The respondents contend that the Board improperly dismissed on a summary basis their constitutional challenge of the Act's enabling provisions. They argue that the Board did not consider their arguments or dispose of them fairly. They refer to the arguments which they made before the Board and ask that they be given the attention which they deserve (ratiopharm memorandum at paras. 122 to 126).

[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.

[113] The respondents argued that the removal of this provision when the *Patent Act Amendment Act*, 1992 was introduced renders the Act unconstitutional. Specifically, the scheme is no longer directed at patents but at the pricing of medicine and therefore intrudes upon the provinces' jurisdiction over property and civil rights.

[114] The respondents further argued, citing the test set out in *General Motors v. City National Leasing*, [1989] 1 S.C.R. 641, that the relevant provisions of the Act are not sufficiently integrated into the federal scheme to justify this intrusion. In contrast with the situation confronting the Supreme Court in *Kirkbi AG v. Ritvik Holdings Inc.*, 2005 SCC 65, the incursion into provincial jurisdiction is highly intrusive and therefore invites a stricter test. Only a

demonstration that these provisions are necessary or integral to the federal scheme can save the constitutional validity of these provisions, and such demonstration has not been made.

[115] This contention insofar as it is aimed at patent owners was summarily dismissed by both the Federal Court judge and the Board. The Board found that the power to address excessive prices is an integral part of the scheme implemented by Parliament. Indeed, the Court of Queen's Bench noted in *Manitoba Society* that increasing patent protection for pharmaceutical firms brought with it the risk that excessive pricing might result and Parliament dealt with that concern by creating the Board and granting it monitoring and review powers over prices (*Manitoba Society* at para. 20). The capacity of the Board to cap prices was always part of the scheme and while the power to "lift" patent protection did not give rise to an intrusion into matters of provincial jurisdiction, and price control did, this was of no consequence as price control was and remains an integral part of the scheme. In the words of the Manitoba Court of Appeal which dismissed the appeal from the decision of the Manitoba Queen's Bench (*Manitoba Society* (Man. C.A.) at para. 4):

> … 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.

[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).

[117] The remaining question is whether this price control scheme retains its constitutional validity when applied to non-patent owners or holders.

[118] The argument advanced by the respondents is that including such persons severs the connection set out in *Manitoba Society*, and taken up in *ICN* (respondents' replies at para. 19). Specifically, they maintain that the constitutional soundness of the Board's jurisdiction is imperiled when persons who do not hold a patent over the medicine being sold are included in the definition of "patentee" (respondents' replies at para. 30).

[119] I cannot agree. At issue in *Manitoba Society* was the constitutional validity of section 15 of *An Act to amend the Patent Act and to provide for certain matters in relation thereto*, S.C. 1987, c. 41 (*Patent Act Amendment Act, 1987*). At the time the case was decided, the impugned provisions of the former *Act* included section 39.1, which defined the term patentee as follows:

39.1 (1) In section 39.11 to 39.25,	**39.1** (1) Les définitions qui suivent s'appliquent aux articles 39.11 à 39.25.
…	[…]
"patentee", in respect of an invention pertaining to a medicine, includes, where a person is exercising any rights of the patentee other than under a licence under section 39, that other person in respect	«breveté» ou «titulaire de brevet» lui est assimilé quiconque exerce des droits d'un breveté sur une invention liée à un médicament autres qu'une licence visée à l'article

of those rights. 39.

[120] As noted earlier, this prior definition, in both official languages, gave rise to no conceivable ambiguity as to Parliament's intent to include both patent holders and persons who, without holding a patent, exercise rights under it. Thus, it cannot be said that in upholding the constitutional validity of the pricing regime established by section 15 of the *Patent Act Amendment Act, 1987*, the Manitoba Court of Queen's Bench and the Manitoba Court of Appeal in *Manitoba Society* did not sanction the constitutional validity of the pricing regime insofar as it applied to non-patent holders.

[121] Beyond this, there is no basis for the argument that the connection with the patent ceases to be sufficient to meet the constitutional imperative when the person targeted holds a licence to sell a patented medicine without holding the patent. As was explained in *ICN*, the harm which the Act seeks to prevent arises by reason of the existence of the patent pertaining to the medicine being sold (*ICN* at para. 76), with the result that nothing turns on the fact that the person exercising the selling rights does not hold the patent itself.

[122] I therefore conclude that the Board correctly held that including persons who exercise selling rights under a patent within the ambit of subsection 79(1) does not bring that provision outside the scope of subsection 91(22) of the *Constitution Act*.

[123] For these reasons, I would allow the appeals with costs in both instances, and refer the matter back to the Federal Court judge or another judge of that Court designated by the Chief

Justice so that the two outstanding issues identified at paragraph 55 of these reasons may be addressed.

"Marc Noël"

Chief Justice

"I agree
J.D. Denis Pelletier J.A."

"I agree
Donald J. Rennie J.A."

ANNEX I

Patent Act, R.S.C., 1985, c. P-4	***Loi sur les brevets***, L.R.C. 1985, c. P-4
Definitions	**Définitions**
2. In this Act, except as otherwise provided,	**2.** Sauf disposition contraire, les définitions qui suivent s'appliquent à la présente loi.
…	[…]
"patentee" means the person for the time being entitled to the benefit of a patent;	« breveté » ou « titulaire d'un brevet » Le titulaire ayant pour le moment droit à l'avantage d'un brevet.
…	[…]
Contents of patent	**Contenu du brevet**
42. Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.	**42.** Tout brevet accordé en vertu de la présente loi contient le titre ou le nom de l'invention avec renvoi au mémoire descriptif et accorde, sous réserve des autres dispositions de la présente loi, au breveté et à ses représentants légaux, pour la durée du brevet à compter de la date où il a été accordé, le droit, la faculté et le privilège exclusif de fabriquer, construire, exploiter et vendre à d'autres, pour qu'ils l'exploitent, l'objet de l'invention, sauf jugement en l'espèce par un tribunal compétent.
Liability for patent infringement	**Contrefaçon et recours**
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.
+Definitions	**Définitions**

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

. . .

"patentee", in respect of an invention pertaining to a medicine, means the person for the time being entitled to the benefit of the patent for that invention and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a licence continued by subsection 11(1) of the *Patent Act Amendment Act, 1992*, that other person in respect of those rights;

. . .

Invention pertaining to a medicine

(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.

Pricing information, etc., required by regulations

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

(*a*) the identity of the medicine;

(*b*) the price at which the medicine is being or has been sold in any market in Canada and

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

[. . .]

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

[…]

Définition de « invention liée à un médicament »

(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.

Renseignements réglementaires à fournir sur les prix

80. (1) Le breveté est tenu de fournir au Conseil, conformément aux règlements, les renseignements et documents sur les points suivants :

a) l'identification du médicament en cause;

b) le prix de vente — antérieur ou actuel — du médicament sur les marchés canadien et étranger;

elsewhere;

(*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

(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

Idem

(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;

a) l'identification du médicament en cause;

(*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;

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

(*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;

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.

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.

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.

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

(*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.

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.

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

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

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

titulaire.

Sales and expense information, etc., to be provided

88. (1) A patentee of an invention pertaining to a medicine shall, as required by and in accordance with the regulations, or as the Board may, by order, require, provide the Board with such information and documents as the regulations or the order may specify respecting

Obligations des brevetés

88. (1) Le breveté est tenu, conformément aux règlements ou aux ordonnances du Conseil, de fournir à celui-ci des renseignements et documents sur les points suivants :

(*a*) the identity of the licensees in Canada of the patentee;

a) l'identité des titulaires des licences découlant du brevet au Canada;

(*b*) the revenue of the patentee, and details of the source of the revenue, whether direct or indirect, from sales of medicine in Canada; and

b) les recettes directes ou indirectes qu'il a tirées de la vente au Canada du médicament, ainsi que la source de ces recettes;

(*c*) the expenditures made by the patentee in Canada on research and development relating to medicine.

c) les dépenses de recherche et développement faites au Canada relativement au médicament.

Additional information, etc.

(2) Where the Board believes on reasonable grounds that any person has information or documents pertaining to the value of sales of medicine in Canada by a patentee or the expenditures made by a patentee in Canada on research and development relating to medicine, the Board may, by order, require the person to provide the Board with any of the information or documents that are specified in the order, or with copies thereof.

Renseignements complémentaires

(2) S'il estime pour des motifs raisonnables qu'une personne a des renseignements ou documents sur le montant des ventes au Canada de tout médicament ou sur les dépenses de recherche et développement supportées à cet égard au Canada par un titulaire de brevet, le Conseil peut, par ordonnance, l'obliger à les lui fournir — ou une copie de ceux-ci — selon ce que précise l'ordonnance.

Compliance with order

Délai

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

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

Information, etc., privileged

(4) Subject to section 89, any information or document provided to the Board under subsection (1) or (2) is privileged, and no person who has obtained the information or document pursuant to this Act shall, without the authorization of the person who provided the information or document, knowingly disclose the information or allow it to be disclosed, except for the purposes of the administration of this Act.

Protection des renseignements

(4) Sous réserve de l'article 89, les renseignements ou documents fournis au Conseil sont protégés; nul ne peut, après les avoir obtenus en conformité avec la présente loi, sciemment les communiquer ou en permettre la communication sans l'autorisation de celui qui les a fournis, sauf quant à l'application de la présente loi.

Report

89. (1) The Board shall in each year submit to the Minister a report setting out

(*a*) the Board's estimate of the proportion, as a percentage, that the expenditures of each patentee in Canada in the preceding year on research and development relating to medicine is of the revenues of those patentees from sales of medicine in Canada in that year; and

(*b*) the Board's estimate of the proportion, as a percentage, that the total of the expenditures of patentees in Canada in the preceding year on research and development relating to medicine is of the total of the revenues of those patentees from sales of medicine in Canada in that year.

Rapport

89. (1) Le Conseil remet au ministre un rapport annuel exposant son estimation de la proportion, exprimée en pourcentage, que les dépenses de recherche et développement en matière de médicaments, faites au Canada dans l'année précédente, représentent par rapport aux recettes tirées de la vente au Canada de médicaments pendant la même période, et ce tant pour chaque breveté que pour l'ensemble des brevetés.

Basis of report

(2) The report shall be based on an analysis of information and documents provided to the Board under subsections 88(1) and (2) and of such other information and documents relating to the revenues and expenditures referred to in subsection 88(1) as the Board considers relevant but, subject to subsection (3), shall not be set out in a manner that would make it possible to identify a person who provided any information or document under subsection 88(1) or (2).

Fondement du rapport

(2) Le rapport se fonde sur l'analyse des renseignements et documents obtenus au titre des paragraphes 88(1) ou (2) et des renseignements ou documents — que le Conseil juge pertinents — sur les recettes et dépenses mentionnées au paragraphe 88(1); par ailleurs, il est établi de manière à ne pas permettre de connaître l'identité de la personne qui a fourni ces renseignements ou documents visés aux paragraphes 88(1) ou (2).

Exception

(3) The Board shall, in the report, identify the patentees in respect of whom an estimate referred to in subsection (1) is given in the report, and may, in the report, identify any person who has failed to comply with subsection 88(1) or (2) at any time in the year in respect of which the report is made.

Exception

(3) Dans son rapport, le Conseil identifie toutefois les brevetés pour lesquels une estimation est donnée; il peut aussi identifier les contrevenants aux paragraphes 88(1) ou (2) pour l'année en cause.

Tabling of report

(4) The Minister shall cause a copy of the report to be laid before each House of Parliament on any of the first thirty days on which that House is sitting after the report is submitted to the Minister.

Dépôt au Parlement

(4) Le ministre fait déposer le rapport devant chaque chambre du Parlement dans les trente premiers jours de séance de celle-ci suivant sa remise.

Patented Medicines Regulations, SOR/94-688

(as cited by the Patented Medicine Prices Review Board in PMPRB ratiopharm reasons as Appendix "A")

Règlement sur les médicaments brevetés, DORS/94-688

(tel que cité par le Conseil d'examen du prix des médicaments brevetés dans *PMPRB ratiopharm reasons* en tant qu'*Appendix "A"*)

3. (1) For the purposes of paragraphs 80(1)(*a*) and 80(2)(*a*) of the Act,

3. (1) Pour l'application des alinéas 80(1)*a*) et (2)*a*) de la Loi, les

information identifying the medicine shall indicate

(a) the name and address of the patentee or former patentee and the address for correspondence in Canada;

(*b*) whether the reporting patentee referred to in paragraph (*a*) is the patent holder, a person holding a licence other than a licence continued by subsection 11(1) of the *Patent Act Amendment Act, 1992*, or any other person referred to in the definition "patentee" in subsection 79(1) of the Act;

(*c*) the generic name and brand name of the medicine;

(*d*) whether the medicine is for human or veterinary use;

(*e*) the therapeutic use of the medicine approved by the Minister of Health and Welfare;

(*f*) the date on which the first notice of compliance was issued to the patentee or former patentee in respect of the medicine;

(*g*) the drug identification number assigned to each strength and dosage form of the medicine under the *Food and Drug Regulations*;

(*h*) the patent number of each invention of the patentee or former patentee pertaining to the medicine, the date on which each patent was granted and the date on which each patent will expire.

renseignements identifiant le médicament doivent indiquer :

a) le nom et l'adresse du breveté ou de l'ancien breveté ainsi que son adresse postale au Canada;

b) si celui-ci détient le brevet ou est le titulaire d'une licence autre que celle prorogée en vertu du paragraphe 11(1) de la *Loi de 1992 modifiant la Loi sur les brevets*, ou toute autre personne visée par la définition de « breveté » au paragraphe 79(1) de la Loi;

c) l'appellation générique et la marque du médicament;

d) si le médicament est destiné à usage humain ou vétérinaire;

e) son usage thérapeutique approuvé par le ministre de la Santé nationale et du Bien-être social;

f) la date à laquelle le premier avis de conformité a été délivré au breveté ou à l'ancien breveté pour le médicament;

g) le numéro d'identification de drogue attribué à chaque forme posologique et à chaque concentration du médicament conformément au *Règlement sur les aliments et drogues*;

h) le numéro de brevet de chaque invention du breveté ou de l'ancien breveté liée au médicament, la date d'octroi ainsi que la date d'expiration du brevet.

(2) The information required under subsection (1) shall be provided if

(*a*) a notice of compliance has been issued in respect of the medicine; or

(*b*) the medicine is being offered for sale in Canada.

(2) Les renseignements visés au paragraphe (1) doivent être fournis :

a) soit si un avis de conformité a été délivré pour le médicament;

b) soit si le médicament est offert en vente au Canada.

(3) The information referred to in subsection (1) shall be provided within the earlier of

(*a*) 30 days after the date on which the first notice of compliance is issued in respect of the medicine, and

(*b*) 30 days after the date on which the medicine is first offered for sale in Canada.

(3) Les renseignements visés au paragraphe (1) doivent être fournis, selon la première de ces éventualités suivantes :

a) dans les 30 jours suivant la date à laquelle le premier avis de conformité est délivré pour le médicament;

b) dans les 30 jours suivant la date à laquelle le médicament est offert en vente au Canada pour la première fois.

(4) The information referred to in subsection (1) shall be up to date and any modification of that information shall be reported within 30 days after the modification.

(4) Les renseignements visés au paragraphe (1) doivent être tenus à jour, et toute modification qui y est apportée doit être présentée dans les 30 jours suivant celle-ci.

4. (1) For the purposes of paragraphs 80(1)(*b*) and (2)(*b*) of the Act, information identifying the medicine and concerning the price of the medicine shall indicate

(*a*) the identity of the patentee or former patentee;

(*b*) the generic name and brand name of the medicine;

(*c*) the time period, referred to in subsection (2), to which the information pertains;

(*d*) the drug identification number

4. (1) Pour l'application des alinéas 80(1)*b*) et (2)*b*) de la Loi, les renseignements identifiant le médicament et ceux sur son prix de vente doivent indiquer :

a) l'identité du breveté ou de l'ancien breveté;

b) l'appellation générique et la marque du médicament;

c) la période visée au paragraphe (2) à laquelle s'appliquent les renseignements;

d) le numéro d'identification de

assigned under the *Food and Drug Regulations* or, where no drug identification number has been assigned, any other identification number assigned to each dosage form and strength of the medicine of the patentee or former patentee;

drogue attribué en vertu du *Règlement sur les aliments et drogues* ou, lorsqu'aucun numéro n'a été attribué, un autre numéro d'identification attribué à chaque forme posologique et à chaque concentration du médicament du breveté ou de l'ancien breveté;

(*e*) the quantity of the medicine sold and either the average price per package or the net revenue from sales of each dosage form, strength and package size in which the medicine was sold in final dosage form by the patentee or former patentee to each class of customer in each province during the periods referred to in subsection (2);

e) la quantité du médicament vendue et soit son prix moyen par emballage, soit les recettes nettes dérivées des ventes de chaque forme posologique, de chaque concentration et de chaque format d'emballage dans lesquels le médicament était vendu sous sa forme posologique finale par le breveté ou l'ancien breveté à chaque catégorie de clients dans chacune des provinces durant les périodes visées au paragraphe (2);

(*f*) the publicly available ex-factory price for each dosage form, strength and package size of the medicine that was sold by the patentee or former patentee to each class of customer in each province during the periods referred to in subsection (2);

f) le prix départ usine accessible au public de chaque forme posologique, de chaque concentration et de chaque format d'emballage dans lesquels le médicament était vendu par le breveté ou l'ancien breveté à chaque catégorie de clients dans chacune des provinces durant les périodes visées au paragraphe (2);

(*g*) where the medicine is being sold in one or more of the countries set out in Schedule I, the publicly available ex- factory price for each dosage form, strength and package size in which the medicine was sold to each class of customer in each of those countries, during the periods referred to in subsection (2).

g) lorsque le médicament est vendu dans un ou plusieurs des pays nommés à l'annexe I, le prix départ usine accessible au public de chaque forme posologique, de chaque concentration et de chaque format d'emballage dans lesquels le médicament était vendu à chaque catégorie de clients dans chacun de ces pays au cours des périodes visées au paragraphe (2).

(2) The information referred to in

(2) Les renseignements visés au

subsection (1) shall be provided in respect of

(*a*) the 30 day period following the date of the first sale in Canada of the medicine; and

(*b*) each six month period commencing on January 1 and July 1 of each year.

paragraphe (1) sont fournis à l'égard de :

a) la période de 30 jours suivant la date à laquelle le médicament est vendu au Canada pour la première fois;

b) chaque période de six mois commençant le 1er janvier et le 1er juillet de chaque année.

(3) The information referred to in subsection (2) shall be provided within 30 days after the end of each period referred to in that subsection.

(3) Les renseignements visés au paragraphe (2) doivent être présentés dans les 30 jours suivant la fin de chaque période visée à ce paragraphe.

(4) For the purposes of paragraph (1)(*e*), in calculating the average price per package of medicine, the actual price after any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefits of a like nature and after deduction of the federal sales tax shall be used.

(4) Pour l'application de l'alinéa (1)*e*), le prix après déduction des réductions accordées à titre de promotion ou sous forme de rabais, escomptes, remboursements, biens ou services gratuits, cadeaux ou autres avantages semblables et après déduction de la taxe de vente fédérale doit être utilisé pour le calcul du prix moyen par emballage dans lequel le médicament était vendu.

(5) For the purposes of paragraph (1)(*e*), in calculating the net revenue from sales of each dosage form, strength and package size in which the medicine was sold in final dosage form, the actual revenue after any reduction in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefits of a like nature and after deduction of federal sales taxes shall be used.

(5) Pour l'application de l'alinéa (1)*e*), le montant des recettes après déduction des réductions accordées sous forme de rabais, escomptes, remboursements biens ou services gratuits, cadeaux ou autres avantages semblables et après déduction de la taxe de vente fédérale doit être utilisé pour le calcul des recettes nettes pour chaque forme posologique, chaque concentration et chaque format d'emballage dans lesquels le médicament était vendu sous sa forme posologique finale.

(6) Subject to subsection (7), this section does not apply in respect of medicine sold by the patentee or

(6) Sous réserve du paragraphe (7), le présent article ne s'applique pas à un médicament vendu par le breveté ou

former patentee to any person with whom the patentee or former patentee does not deal at arm's length, or to any other patentee or former patentee.

(7) Where the patentee or former patentee sells the medicine to a person with whom the patentee or former patentee does not deal at arm's length and the person is not required to provide information pursuant to paragraphs 80(1)(*a*) and 80(2)(*a*) of the Act, the patentee or former patentee shall provide the information required under paragraphs (1)(*e*) to (*g*) in respect of any resale of the medicine by that person.

(8) For the purposes of paragraph (1)(*g*), the price at which a medicine was sold in a country other than Canada shall be expressed in the currency of that country.

(9) For the purposes of this section, the provisions of the *Income Tax Act*, as that Act read on December 1, 1987, apply with such modifications as the circumstances require, in determining whether a patentee or former patentee is dealing at arm's length with another person.

(10) For the purposes of this section, "publicly available ex-factory price" includes any price of a patented medicine that is agreed on by the patentee or former patentee and the appropriate regulatory authority of the country in which the medicine is sold by the patentee.

5. (1) For the purposes of subsection 88(1) of the Act, information concerning the identity of any licensee in Canada of the patentee and the

l'ancien breveté à une personne avec qui il a un lien de dépendance ou à tout autre breveté ou ancien breveté.

(7) Lorsque le breveté ou l'ancien breveté vend le médicament à une personne avec qui il a un lien de dépendance et que celle-ci n'est pas tenue de fournir des renseignements en vertu des alinéas 80(1)*a*) et 80(2)*a*) de la Loi, le breveté ou l'ancien breveté doit fournir les renseignements prévus en vertu des alinéas (1)*e*) à *g*) à l'égard de toute revente du médicament par cette personne.

(8) Pour l'application de l'alinéa (1)*g*), le prix auquel le médicament était vendu dans un pays étranger doit être exprimé dans la devise de ce pays.

(9) Pour l'application du présent article, les dispositions de la *Loi de l'impôt sur le revenu* dans sa version du 1er décembre 1987 s'appliquent, compte tenu des adaptations nécessaires, à la détermination du lien de dépendance entre le breveté et une autre personne.

(10) Pour l'application du présent article, « prix départ usine accessible au public » s'entend notamment de tout prix d'un médicament breveté dont sont convenus le breveté ou l'ancien breveté et l'autorité réglementante compétente du pays dans lequel le breveté vend le médicament.

5. (1) Pour l'application du paragraphe 88(1) de la Loi, les renseignements sur l'identité des titulaires des licences découlant du brevet au Canada et sur

revenues and research and development expenditures of the patentee shall indicate

(*a*) the name and address of the patentee and the address for correspondence in Canada;

(*b*) the name and address of all licensees in Canada of the patentee;

(*c*) the total gross revenues from all sales in Canada during the year by the patentee of medicine for human and veterinary use and the total revenues received from all licensees from the sale in Canada of medicine for human and veterinary use; and

(*d*) a summary of all expenditures made during the year by the patentee towards the cost of research and development relating to medicine for human or veterinary use carried out in Canada by or on behalf of the patentee, including

(i) a description of the type of research and development and the name of the person or entity that carried out the research and development,

(ii) the expenditures of the patentee or the person or entity that carried out the research and development, in respect of each type of research and development, and

(iii) the name of the province

les recettes et les dépenses de recherche et développement du breveté doivent indiquer :

a) le nom et l'adresse du breveté ainsi que son adresse postale au Canada;

b) le nom et l'adresse des titulaires des licences au Canada;

c) les recettes brutes totales tirées de toutes les ventes de médicaments pour usage humain et vétérinaire effectuées par le breveté au Canada durant l'année et les recettes totales qui proviennent des titulaires des licences au titre des ventes au Canada de médicaments pour usage humain et vétérinaire;

d) un résumé de toutes les dépenses engagées par le breveté durant l'année pour l'exécution, au Canada par lui ou pour son compte, de recherche et développement en matière de médicaments pour usage humain ou vétérinaire y compris :

(i) une description du type de recherche et développement et le nom de la personne ou de l'entité qui les a exécutés,

(ii) pour chaque type de recherche et développement, les montants dépensés par le breveté ou par la personne ou l'entité qui a exécuté la recherche et le développement,

(iii) le nom de la province où la

in which the research and development was carried out and the expenditures in that province by the patentee or the person or entity.

recherche et le développement ont été effectués et le montant dépensé dans la province par le breveté ou par la personne ou l'entité.

(2) The information referred to in subsection (1) shall be provided for each calendar year and shall be submitted within 60 days after the end of each calendar year.

(2) Les renseignements visés au paragraphe (1) doivent être fournis pour chaque année civile et être présentés dans les 60 jours suivant la fin de l'année.

(3) The total gross revenues referred to in paragraph (1)(*c*) shall comprise revenues from sales of medicine

(3) Les recettes brutes totales visées à l'alinéa (1)*c*) sont celles qui se rapportent aux ventes de médicaments:

(*a*) for which a drug identification number has been issued under the *Food and Drug Regulations* or which has been approved for sale to qualified investigators under those Regulations;

a) auxquels un numéro d'identification de drogue a été attribué conformément au *Règlement sur les aliments et drogues* ou ceux qui ont été approuvés pour la vente à un chercheur compétent conformément à ce règlement;

(*b*) that is used in the diagnosis, treatment, mitigation or prevention of a disease, disorder or abnormal physical state or the symptoms thereof or in the modification of organic functions in humans or animals; and

b) qui sont utilisés pour le diagnostic, le traitement, l'atténuation ou la prévention de maladies, de troubles ou d'états physiques anormaux ou de leurs symptômes, ainsi que pour la modification de fonctions organiques chez les humains ou les animaux;

(*c*) the sale of which is promoted by any means to physicians, dentists, veterinarians, hospitals, drug retailers or wholesalers or manufacturers of ethical pharmaceutical products.

c) dont la vente est promue par quelque moyen que ce soit auprès des médecins, des dentistes, des vétérinaires, des hôpitaux, des détaillants ou des grossistes de drogues ou des fabricants de produits pharmaceutiques contrôlés.

(4) For the purposes of paragraph

(4) Pour l'application de l'alinéa (1)*d*),

(1)(*d*), the patentee shall specify

(*a*) the total capital expenditures on buildings and the annual depreciation of the buildings which depreciation shall be calculated at an annual rate of four per cent for a maximum of 25 years;

(*b*) the total capital expenditures on equipment; and

(*c*) the source and amount of the funds for expenditures made by the patentee towards the cost of research and development.

le breveté doit indiquer :

a) les dépenses en immobilisations totales afférentes aux immeubles et le montant de dépréciation annuelle de ceux-ci, qui est calculée à un taux annuel de 4 pour cent sur une période maximale de 25 ans;

b) les dépenses totales relatives à l'équipement;

c) la source du financement des dépenses de recherche et de développement du breveté et le montant fourni.

ANNEX II

An Act to amend the Patent Act and to provide for certain matters in relation thereto, S.C. 1987, c. 41	***Loi modifiant la Loi sur les brevets et prévoyant certaines dispositions connexes***, L.C. 1987, c. 41
(relevant provisions in force 1987-12-07)	(dispositions pertinentes en vigueur le 1987-12-07)
41.1 (1) In sections 41.11 to 41.25,	**41.1** (1) Les définitions qui suivent s'appliquent aux articles 41.11 à 41.25.
. . .	[…]
"patentee", in respect of an invention pertaining to a medicine, includes, where a person is exercising any rights of the patentee other than under a licence under section 41, that other person in respect of those rights.	«breveté» ou «titulaire de brevet» Lui est assimilé quiconque exerce des droits d'un breveté sur une invention liée à un médicament autres qu'une licence visée à l'article 41.
. . .	[…]
An Act to amend the Patent Act and to provide for certain matters in relation thereto, R.S.C. 1985 (3rd Supp.), c. 33	***Loi modifiant la Loi sur les brevets et prévoyant certaines dispositions connexes***, L.R.C. 1985 (3e supp.), c. 33
(relevant provisions in force 1988-12-12)	(dispositions pertinentes en vigueur le 1988-12-12)
39.1 (1) In sections 39.11 to 39.25,	**39.1** (1) Les définitions qui suivent s'appliquent aux articles 39.11 à 39.25.
. . .	[…]
"patentee" in respect of an invention pertaining to a medicine, includes, where a person is exercising any rights of the patentee other than under a licence under section 39, that other person in respect of those rights.	« breveté » ou « titulaire de brevet » Lui est assimilé quiconque exerce des droits d'un breveté sur une invention liée à un médicament autres qu'une licence visée à l'article 39.
. . .	[…]

Patent Act Amendment Act, 1992, S.C. 1993, c. 2	***Loi de 1992 modifiant la Loi sur les brevets***, L.C. 1993, c. 2
(relevant provisions in force 1993-02-15)	(dispositions pertinentes en vigueur le 1993-02-15)
79. (1) In this section and in sections 80 to 103,	79. (1) Les définitions qui suivent s'appliquent au présent article et aux articles 80 à 103.
. . .	[…]
"patentee", in respect of an invention pertaining to a medicine, means the person for the time being entitled to the benefit of the patent for that invention and includes, where any other person is entitled to exercise any rights in relation to that patent other than under a licence continued by subsection 11(1) of the *Patent Act Amendment Act, 1992*, that other person in respect of those rights;	« 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*.
. . .	[…]

FEDERAL COURT OF APPEAL

NAMES OF COUNSEL AND SOLICITORS OF RECORD

DOCKETS:	A-302-14 AND A-303-14
DOCKET:	A-302-14
STYLE OF CAUSE:	ATTORNEY GENERAL OF CANADA v. SANDOZ CANADA INC.
AND DOCKET:	A-303-14
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PLACE OF HEARING:	OTTAWA, ONTARIO
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