Federal Court Cour fédérale

Date: 20090710

Dockets: T-1442-08
T-1447-08

Citation: 2009 FC 719

Ottawa, Ontario, July 10, 2009

PRESENT: The Honourable Madam Justice Mactavish

Docket: T-1442-08

BETWEEN:

PFIZER CANADA INC.

Applicant

and

ATTORNEY GENERAL OF CANADA

Respondent

and

PATENTED MEDICINE PRICES REVIEW BOARD

Intervener

Docket: T-1447-08

AND BETWEEN:

**CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES,
AMGEN CANADA INC., ASTRAZENECA CANADA INC.,
BAYER INC., BRISTOL-MYERS SQUIBB CANADA INC.,
BOEHRINGER INGELHEIM (CANADA) LTD.,
ELI LILLY CANADA INC., EMD SERONO CANADA INC.,
GLAXOSMITHKLINE INC., HOFFMAN-LA ROCHE LIMITED,
JANSSEN-ORTHO INC., MERCK FROSST CANADA LTD.,
MERCK FROSST-SCHERING PHARMA PARTNERSHIP,
NOVARTIS PHARMACEUTICALS CANADA INC.,
PROCTOR & GAMBLE PHARMACEUTICALS CANADA, INC.,
SCHERING-PLOUGH CANADA INC.,
SHIRE CANADA INC., AND SOLVAY PHARMA INC.**

Applicants

and

ATTORNEY GENERAL OF CANADA

Respondent

and

PATENTED MEDICINE PRICES REVIEW BOARD

Intervener

<u>REASONS FOR JUDGMENT AND JUDGMENT</u>

[1] In August of 2008, the Patented Medicine Prices Review Board released a decision in a "Stakeholder Communiqué" which required that patentees report rebates (including rebates or

payments to third parties), discounts, free goods, free services, gifts and other benefits of a like nature, in calculating the average price of patented medicines.

[2] The applicants seek judicial review of this decision, asserting that the Board's jurisdiction is limited to reviewing prices associated with sales of patented medicines made at the "factory gate". The applicants say that the Board's jurisdiction does not extend to transactions involving third parties that may take place further downstream in the supply chain.

[3] The respondent argues that these applications are premature, as the Board has not yet started to enforce the new reporting requirements, and thus there have been no proceedings before the Board involving specific factual situations. As a result, the respondent says that there is an insufficient evidentiary record for the Court to determine the question of statutory interpretation raised by the applications. In the alternative, if the matter is not premature, the respondent submits that the Board acted within its jurisdiction in requiring that rebates or payments made by patentees to third parties be reported.

[4] The Board was given leave to intervene in these applications. It supports the applicants' position that the applications are not premature, and the respondent's position that the Board acted within its jurisdiction.

[5] For the reasons that follow, I have concluded that the applications are not premature. I have also concluded that the Board acted outside its jurisdiction in requiring the reporting of rebates or

payments made by patentees to third parties. As a consequence, the applications for judicial review will be allowed.

The Parties

[6] There are two applications for judicial review before the Court. By order of a prothonotary, the two applications were heard together, and these reasons pertain to both applications.

[7] Application T-1442-08 was commenced by Pfizer Canada Inc., an innovator pharmaceutical company which sells patented medicines in Canada. Application T-1447-08 was brought by Canada's Research-Based Pharmaceutical Companies ("Rx&D") and a number of its members. Rx&D is the trade association for innovative pharmaceutical manufacturers in Canada, and represents 50 member companies involved in the discovery, development and testing of new medicines and vaccines. The remaining applicants in T-1447-08 are patentees selling patented medicines in Canada.

[8] The Patented Medicine Prices Review Board is a quasi-judicial body established in 1987 under amendments to the *Patent Act*, R.S., 1985, c. P-4, which regulates the prices that patentees can charge for prescription and non-prescription patented medicines in Canada.

Background

[9] The 1987 amendments to the *Patent Act* expanded the intellectual property rights of patentees of patented medicines. To balance this, the Board was created to monitor the prices

charged by patentees for patented medicines, in order to ensure that these prices were not excessive: see *ICN Pharmaceutical, Inc. et al. v. Staff of the Patented Medicine Prices Review Board* (1996) 68 C.P.R. (3d) 417 (F.C.A.); *Hoechst Marion Roussel Canada Inc. v. Canada (Attorney General)*, 2005 FC 1552.

[10] In 1993, the *Patent Act* was once again amended. The period of patent exclusivity enjoyed by patentees was increased, and the compulsory licence provisions of the Act were repealed. At the same time, Parliament strengthened the Board's mandate to deal with the price abuse that could potentially result from the monopolies that it had created. Regulations were also put into place specifying the information that was to be reported to the Board by patentees with respect to the sales of patented medicines.

[11] The role of the Board is not to set prices for patented medicines in Canada. This would be beyond the legislative competence of Parliament, as the setting of retail prices is a matter within provincial jurisdiction. Rather, the role of the Board is to determine whether, taking certain specified factors into account, a patentee is selling patented medicines to its customers at an "excessive price".

[12] If it is determined that excessive prices are being charged by a patentee, then the Board has the power to make remedial orders. The Board also reports to Parliament with respect to pharmaceutical pricing trends, as well as with respect to research and development spending by pharmaceutical patentees.

[13] In order to determine whether a patentee is selling a patented medicine to its customers at an excessive price, the Board is statutorily empowered to require patentees to provide pricing information. A complete version of the relevant statutory and regulatory provisions is attached as an appendix to this decision.

[14] In particular, subsection 80(1)(b) of the *Patent Act* requires that patentees provide the Board with "such information and documents as the regulations may specify respecting … the price at which the medicine is being or has been sold in any market in Canada and elsewhere".

[15] Section 85 of the *Patent Act* identifies the factors that are to be considered in determining whether a medicine is being sold at an excessive price in any market in Canada. These factors include the prices at which the medicine has been sold in the relevant market, the prices of medicines in the same therapeutic class in the relevant market, the prices at which the medicine and other medicines in the same therapeutic class have been sold in identified comparator countries, changes in the Consumer Price Index, and such other factors as may be specified in the regulations.

[16] Paragraph 4(1)(f) of the *Patented Medicines Regulations*, SOR/94-688, stipulates that patentees must provide the Board with information identifying the medicine, and must also indicate "the quantity of the medicine sold in final dosage form and either the average price per package or the net revenue from sales in respect of each dosage form, strength and package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory".

[17] The Board's *Patentees' Guide to Reporting* identifies four classes of customers: Hospitals, Pharmacies, Wholesalers or "Other". Direct sales to "others" may include, for example, doctors in remote areas who do not have ready access to a pharmacy.

[18] The evidence before the Court suggests that the vast majority of sales made by patentees are sales to drug wholesalers.

[19] Of particular importance to these applications is subsection 4(4) of the Regulations. Paragraph 4(4)(a) deals with the reporting of the average price per package in respect of each dosage form, and provides that:

(4) For the purposes of subparagraph (1)(*f*)(i),	(4) Pour l'application du sous-alinéa (1)*f*)(i) :
(*a*) 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 benefit of a like nature* and after the deduction of the federal sales tax shall be used …	*a*) *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 …
[my emphasis]	[je souligne]

[20] In recent years, some provinces have negotiated agreements (known as “expenditure limitation agreements” or “negotiated price agreements”) with patentees whereby a patented medicine is listed on a provincial formulary at a specified price. In some cases, these payments may be made by the patentee as consideration for the province’s agreement to list the product on the provincial formulary.

[21] The amount of the payment or payments made by patentees may, in some situations, be calculated as a percentage of the units of medicine sold in the province, for which the province is required to reimburse the patient. In other cases, payment arrangements may not be as simple, and may be negotiated on the basis of factors such as the achievement of target improvements in health outcomes. Agreements may also relate to multiple drugs, both patented and non-patented: see the Board’s January 31, 2008 Discussion paper.

[22] The Board submits that payments by patentees to the provinces are part of the “commercial and economic reality” relating to the actual prices charged for patented medicines, and should, therefore, be taken into account in the Board’s determination of whether the prices charged by patentees are excessive.

[23] The question for the Court is whether the *Patent Act* and the *Patented Medicines Regulations* empower the Board to require patentees to report information regarding these payments.

Events Leading up to the Decision

[24] The Board did not initially require that payments made to the provinces under expenditure limitation agreements be reported. In April of 2000, the Board published a newsletter identifying the information that was to be reported by patentees. It noted that inquiries had been received from patentees with respect to their reporting obligations with respect to various kinds of incentives and programs, including payments made under expenditure limitation agreements between manufacturers and public drug plans.

[25] It is apparent from this newsletter that patentees had a measure of discretion in terms of the reporting requirements in relation to benefits such as rebates, and that it was the intention of the Board that its policies and procedures "not discourage a patentee from offering an incentive program or entering into an agreement which would benefit patients".

[26] The Board did stipulate that patentees must be consistent in reporting such programs "so as to avoid artificial fluctuations in the price calculated for price review purposes".

[27] In March of 2007, this Court issued its decision in *Leo Pharma Inc. v. Canada (Attorney General)*, [2007] F.C.J. No. 425. This was an application for judicial review with respect to a decision by the Board that Leo Pharma Inc. was selling its "Dovobet" medicine at an excessive price. At issue was whether the Board acted unreasonably in refusing to take the free distribution of Dovobet under a compassionate release program into account in establishing the average transaction price for the medicine.

[28] Justice Blais concluded that the Board acted unreasonably in refusing to consider the distribution of free samples of Dovobet in establishing the average price of the medicine, noting that "the fact that the distribution of free goods may benefit the patentee should not make such a distribution any less valuable to the patients who receive the free medicine". It was, in Justice Blais' view, "much more reasonable" to assume that Parliament, had sought to increase access to patented medicines for Canadians, some of whom would not have extensive drug insurance coverage.

[29] To achieve this objective, Justice Blais found that the Regulations had been drafted so as to provide incentives for patentees to distribute free medicine, by allowing them to include these goods in the average price calculation regardless of their actual intent in distributing such free goods. He concluded that "The determination of the average price per package of medicine for each period *must take into account 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*": *Leo Pharma*, at para. 69, [my emphasis].

[30] As a result of the *Leo Pharma* decision, the Board undertook a review of its reporting requirements. In April of 2007, a further newsletter was released to the industry advising that, as a result of the *Leo Pharma* decision, "all reductions or benefits" must now be included in the average transaction price calculation. The Board advised that beginning with the reporting period ending June 30, 2007, patentees could no longer exclude any reductions or benefits, including payments to third parties under expenditure limitation agreements.

[31] After the publication of the April, 2007 newsletter, discussions ensued between the Board, and its stakeholders, including Rx&D and drug patentees, as well as the provinces. Rx&D and the drug companies took the position that the *Leo Pharma* decision did not require any change to the manner in which patentees reported the sale price of patented medicines insofar as payments to the provinces were concerned. They argued that the decision did not even address the issue of payments made by patentees under negotiated price agreements, nor did it require that these payments be reported to the Board.

[32] Several provinces also took the position that payments made by patentees to the provinces should not be included in the calculation of the average price of patented medicines, and that it was beyond the mandate of the Board to require their inclusion.

[33] In May of 2007, the Board issued a further newsletter advising that the reporting requirements would remain as they had been in accordance with the April, 2000 newsletter, pending further consultation with stakeholders, and a review of possible options by the Board.

[34] After completion of its consultations and review processes, a decision was made by the five members of the Board with respect to changes to the reporting requirements which, it said, would take effect beginning with the reporting period ending June 30, 2009.

[35] This decision was communicated to the industry in an August 18, 2008 “Stakeholder Communiqué”. The decision requires that patentees report “rebates (including rebates/payments to

third parties), discounts, free goods, free services, gifts and other benefits of a like nature", in calculating the average price from sales of patented medicines.

[36] The Board subsequently delayed implementation of the new reporting requirements until January 1, 2010, as a result of these applications for judicial review.

The Central Issue

[37] The central issue in these proceedings is whether sections 4(1)(f)(i) and 4(4) of the *Patented Medicines Regulations* authorize the Board to require the reporting of rebates or payments made to third parties by the manufacturers of patented medicines so that these payments may be included in the calculation of the average price for sales for the patented medicine in question.

[38] Before turning to consider this issue, however, I must first determine whether the applications are premature.

Are the Applications Premature?

[39] As I understand the respondent's position, it is not disputed that the Board has made a final decision with respect to the change in reporting requirements. Rather, the respondent says that the applications are premature, as the Board has not yet commenced enforcing the interpretation of the Regulations set out in the August 18, 2008 "Stakeholder Communiqué".

[40] As a consequence, the respondent says that there are currently no proceedings before the Board involving payments made by a patentee to a province under a specific negotiated price agreement, nor has the Board issued any rulings in relation to any cases actually involving a negotiated price agreement between a patentee and a province.

[41] In the circumstances, the respondent says that there is a limited factual record before the Court regarding price agreements, which is insufficient for the Court to determine the question of statutory interpretation raised by the applications.

[42] In particular, there is no actual negotiated price agreement between a patentee and a province before the Court. Moreover, there is limited evidence as to how common negotiated price agreements are in the pharmaceutical industry. Other than the single blank sample agreement in the record, there is no evidence regarding the actual terms of a negotiated price agreement nor is there any evidence as to the amount or refunds of payments made by a patentee to a province under a negotiated price agreement.

[43] According to the respondent, the proper time for patentees to raise the jurisdictional question would be in the context of actual Board proceedings involving an actual negotiated price agreement between a patentee and a province.

[44] All of that said, the respondent concedes that if all the Court is being asked to do is to simply interpret the *Patent Act* and Regulations, so as to determine whether provinces can be

considered to be “customers” of the patentees, such that payments to provinces are subject to the reporting requirements established therein, it is open to the Court to do so on the basis of the existing record.

[45] The applicants point out that in order to comply with the Board’s new reporting requirements, patentees will have to devote resources to collecting and compiling the data in issue, long before the actual implementation date of January 1, 2010. According to the applicants, the Board’s reporting requirements are not only onerous and difficult to implement; they also intrude into sensitive commercial transactions that are outside the jurisdiction of the Board.

[46] As their efforts to dissuade the Board from implementing the decision that underlies these applications for judicial review were unsuccessful, the applicants say that they have been forced to commence these applications to have the Board’s decision set aside, before they are required to commit resources to collecting and compiling the information now being sought by the Board.

[47] The Board itself urges the Court to decide the issue, submitting that both it and the industry have a practical problem that requires an immediate resolution, so that all of those involved in the regulatory process know what the rules of the game are.

[48] I would start by observing that the respondent’s contention that these applications are premature, and cannot be decided in the absence of a fully developed evidentiary record is difficult to reconcile with the respondent’s argument that all of the evidence put before the Court by the

applicants (other than the extracts from Hansard) should be disregarded as “irrelevant”, given that what is involved in this case is a pure question of statutory interpretation, for which evidence is not required.

[49] Moreover, the Board has clearly made a binding decision - one which will have immediate consequences for those involved in the patented medicine industry. Having given the matter careful consideration, and recognizing the respondent’s concession that the record is sufficient to allow for an interpretation of the Act and Regulations, independent of the specific terms of any particular expenditure limitation agreements, I have determined that the applications are not premature and that it is appropriate to decide the issue now before me.

Standard of Review

[50] The first issue to be determined is how much deference should be accorded to the Board’s own interpretation of its enabling legislation.

[51] The applicants and the respondent all agree that as what is in issue is a question of statutory interpretation going to the jurisdiction of the Board, the appropriate standard of review is that of correctness. In this regard, they rely on jurisprudence which has held that correctness should be the standard of review applied to the Board’s interpretation of its own enabling legislation: see *Hoechst Marion Roussel Canada Inc.*, previously cited, at paras. 99-110, and *Shire Biochem Inc. v. Canada (Attorney General)*, [2007] F.C.J. No. 1688, at para. 19.

[52] The Board itself has made no submissions in this regard.

[53] Neither of the cases cited by the parties were decided after the Supreme Court of Canada rendered its decision in *Dunsmuir v. New Brunswick*, 2008 SCC 9. There, the Court reaffirmed that the correctness standard will not automatically apply every time a tribunal is involved in interpreting legislation, particularly where, as here, an expert tribunal is interpreting its own enabling legislation.

[54] However, what is in issue in this case is what was described in *Dunsmuir* as "a true question of jurisdiction": at para. 59. As such, I agree that the appropriate standard of review is that of correctness.

Analysis

[55] The question, then, is whether sections 4(1)(f)(i) and 4(4) of the *Patented Medicines Regulations*, SOR/94-688 authorize the Board to require the reporting of rebates or payments made to third parties by the manufacturers of patented medicines so that these payments may be included in the calculation of the average price for sales of patented medicines.

[56] At the outset, I would observe that although the Board's April, 2007 newsletter suggests that the Board interpreted Justice Blais' decision in *Leo Pharma* as requiring the reporting of rebates or payments made to third parties, I do not read the *Leo Pharma* decision as addressing the issue in this case.

[57] While Justice Blais held that the determination of the average price for a medicine must take into account 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, he did not consider whether this obligation extends to "rebates or payments to third parties".

[58] In addressing this question, the starting point must be a consideration of the constitutional limitations on what Parliament can, and cannot, do in relation to drug prices. These limitations were recognized during the legislative process leading up to the creation of the Board.

[59] In this regard, Harvie Andre, the then Minister of Consumer and Corporate Affairs, stated in committee proceedings that:

> We do not constitutionally have the ability in Canada of setting prices at the federal level. But again, it is worth repeating that it is not right to say there are not strong price control mechanisms in Canada; there are. They are at the provincial level. Through the fact that they purchase 60% of the drugs, have formularies in some provinces, and can have laws that direct that pharmacists must provide the lowest cost equivalent, and through the bulk purchasing and so on, the net result is that we do have in fact a price control system in Canada

[60] Minister Andre went on to observe that "it is not intended that the Board would be a profit-control mechanism. The Board is intended … as a watchdog on the general prices of pharmaceuticals within Canada".

[61] Similarly, during the legislative process leading up to the 1993 amendments to the *Patent Act*, Barbara Sparrow, the Parliamentary Secretary to the Minister of Health and National Welfare, noted that federal jurisdiction was confined to the regulation of the "factory-gate" prices of patented medicines. It was the provinces that had jurisdiction over retail prices and dispensing fees for patented medicines.

[62] The term "factory-gate" appears to be one that is generally understood in the industry to refer to the transaction between the patentee and the first purchaser of the patented medicine in question. As was noted earlier, this first purchaser is most commonly a wholesaler.

[63] The Board itself understands that its jurisdiction is limited to the regulation of the factory-gate prices for patented medicines, and that it has no jurisdiction over prices subsequently charged by wholesalers and retailers. The Board also recognizes that it has no jurisdiction over matters such as whether the costs of patented medicines are covered by public drug plans: see the affidavit of Barbara Ouellet, the Board's Executive Director, at paras. 4 and 5.

[64] Under subsection 83(1) of the *Patent Act*¸ the Board's remedial jurisdiction is engaged where the Board finds that *a patentee is selling a medicine* in any market in Canada at a price that is excessive in the Board's opinion. [my emphasis]

[65] In order for the Board to be able to determine whether the price of a patented medicine is or is not excessive, paragraph 80(1)(b) of the *Patent Act* requires that patentees provide the Board with

such information respecting "the price at which the medicine is being or has been sold in any market in Canada and elsewhere" as may be specified in the Regulations.

[66] Subparagraph 4(1)(f)(i) of the *Patented Medicines Regulations* states that patentees must provide the Board with information with respect to "the average price per package … *in which the medicine was sold by the patentee … to each class of customer*". [my emphasis]

[67] Thus what is clearly contemplated by the Act and the Regulations is a *sale* by a patentee to a *customer*. The question then is whether patentees "sell" patented medicines to the provinces, and whether the provinces can be considered to be "customers" of the patentees. This involves interpreting the statute and the Regulations.

[68] When addressing a question of statutory interpretation, the words of an Act are to be read 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: see *Re Rizzo and Rizzo Shoes Ltd.* [1998] 1 S.C.R. 27, at para. 21, and see Ruth Sullivan, ed., *Sullivan on the Construction of Statutes*, 5th ed. (Markham: LexisNexis., 2008), at p. 1.

[69] Moreover, where the words used are precise and unequivocal, the ordinary meaning of the words should play a dominant role in the interpretive process: see *Canada Trustco Mortgage Co. v. Canada*, [2005] S.C.J. No. 56, at para. 10.

[70] The object of the Act and Regulations, as well as the intention of Parliament in relation to their enactment, have been discussed earlier in these reasons. However, it bears repeating that the Board does not set the prices for patented medicines in Canada, nor does it control the profits made by patentees. Rather, the role of the Board is to monitor the prices charged by patentees for patented medicines, so as to ensure that these prices are not excessive.

[71] With these principles of statutory interpretation in mind, the first question is whether it can be said that patentees *sell* patented medicines to the provinces.

[72] As a starting point, I note that the *Canadian Oxford Dictionary* defines a "sale" as "the exchange of a commodity for money etc.". See also *H.W. Liebig & Co. v. Leading Investments Ltd.*, [1986] 1 S.C.R. 70, at para. 24.

[73] It is common ground that, regardless of the precise terms of the specific expenditure limitation agreements in issue, provinces never take title to patented medicines sold by the patentees under such agreements, nor do they ever take possession of them. Furthermore, provinces are not parties to the sale at the factory-gate, nor do they pay patentees for patented medicines. Indeed, in some cases, patentees are actually prohibited by law from selling patented medicines to provinces.

[74] That is, the *Food and Drug Regulations*, C.R.C. 1978, c. 870, identify who patentees can sell prescription medication to without a prescription. This list includes drug manufacturers, practitioners, wholesale druggists, registered pharmacists, and hospitals: see section C.01.043(1).

[75] Under the Regulations, sales can also be made to Departments of the Government of Canada or of a province, "*upon receipt of a written order signed by the Minister thereof or his duly authorized representative*". [my emphasis]

[76] There is no suggestion that there are any Ministerial orders permitting the sale of patented medicines to provinces in accordance with expenditure limitation agreements. Indeed, in argument, the respondent submitted that the provinces created drug benefit programs specifically because they did not want to have to purchase and dispense medications themselves, preferring instead to use the existing commercial distribution network.

[77] More importantly, however, when read in context, it is clear that what is contemplated by section C.01.043(1) is a transfer of a physical product to an entity that actually takes title to and possession of the patented medicine in question in exchange of valuable consideration – that is, a "sale" in the conventional sense.

[78] Furthermore, even giving the word a broad and purposive interpretation, to interpret the term "sale" in the manner proposed by the respondent and the Board, so as to encompass the relationship between patentees and provinces would, in my view do violence to the ordinary meaning of the term.

[79] Moreover, such an interpretation is inconsistent with the Board's own understanding of the term. Indeed, the Board's own *Patentee's Guide to Reporting* defines a "sale" as a "transfer of property rights from one person to another for money, money's worth, or other consideration".

[80] I am also not persuaded that provinces could be considered to be the "customers" of the patentees. Clearly, the role of provinces under expenditure limitation agreements is akin to that of public insurers who reimburse eligible patients for the cost of their drugs.

[81] The fact that the payments made by patentees under expenditure limitation agreements may, in some cases, be calculated as a percentage of the sales of the patented medicine in question does not make the province a customer of the patentee. By way of analogy, the rent paid by a restaurant business under the terms of a commercial lease may be calculated, in part, as a percentage of the restaurant's sales. Such a contractual term does not turn the landlord into a customer of the restaurant.

[82] Indeed, the recognition that provinces are not "customers" of the patentees is implicit in the Board's own description of them as "third parties".

[83] I would also observe that my interpretation of the *Patent Act* and the *Patented Medicines Regulations* is consistent with the constitutional limitation on the Board's ability to look beyond the factory-gate price of patented medicines, to consider contractual arrangements involving patentees and entities further down the distribution chain.

[84] Quite apart from the constitutional issues that would arise if the Board were able to go beyond an examination of the factory-gate prices charged for patented medicines, it is also clear from subsections 4(5) and 4(6) of the Regulations that the Board is only empowered to inquire into prices charged beyond the factory-gate where the factory-gate sale by the patentee is a non-arm's length transaction.

[85] Furthermore, if correct, the Board's interpretation would allow it to go well beyond the examination of the prices charged by patentees at the factory-gate for patented medicines in order to determine whether such prices were "excessive" within the meaning of the *Patent Act* and Regulations.

[86] Finally, the Board and the respondent contend that payments made to provinces under expenditure limitation agreements are "rebates", and are thus within the scope of subsection 4(4) of the Regulations. Paragraph 4(4)(a) provides that in calculating the average price of sales for the purposes of subparagraph 4(1)(f)(i), "the actual price after any reduction … in the form of rebates …. or any other benefit of a like nature … shall be used".

[87] The term "rebate" is defined in Black's Law Dictionary, 6th ed., (1990) as a "Discount; deduction or refund of money in consideration of prompt payment .... A deduction or drawback from a stipulated payment, charge, or rate ... not taken out in advance of payment, but handed back to the payer after [it] has paid the full stipulated sum": as cited in *Fourth Generation Realty Corp. v. Ottawa (City)* [2005] O.J. No. 1982 (Ont. C.A.) at para. 54.

[88] I agree with the Ontario Court of Appeal in *Fourth Generation Realty Corp.* that the term "rebate" "refers to the return of a portion of money actually paid": at para. 55. As a consequence, a "rebate" cannot be paid to a stranger to the sale transaction.

[89] Furthermore, even if the monies paid to the provinces by patentees could be considered to be a "refund", a "discount" or "any other benefit of a like nature", for the purposes of paragraph 4(4)(a) of the *Patented Medicines Regulations*, such payments still do not relate to patented medicines "sold" to a "customer" as contemplated by subparagraph 4(1)(f)(i).

Conclusion

[90] For the reasons given, I find that sections 4(1)(f)(i) and 4(4) of the *Patented Medicines Regulations* do not authorize the Board to require the reporting of rebates or payments made to third parties by the manufacturers of patented medicines. As a consequence, the applications for judicial review are allowed, and the Board's decision as communicated in the August 18, 2008 "Stakeholder Communiqué" is set aside.

JUDGMENT

THIS COURT ORDERS AND ADJUDGES that:

1. These application for judicial review are allowed, and the decision of the Patented Medicine Prices review Board is set aside;

2. The Court declares that subsections 4(1)(f)(i) and 4(4) of the *Patented Medicines Regulations* do not authorize the Board to require the reporting of rebates or payments made to third parties by the manufacturers of patented medicines.

3. The applicants shall have their costs from the respondent. No costs are awarded with respect to the intervener.

"Anne Mactavish"
Judge

APPENDIX

PATENT ACT

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

(*d*) 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.

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

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

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.

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.

(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.

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

(3) No order may be made under subsection (1) in respect of a former patentee who, more than three years before the day on which the order is proposed to be made, ceased to be entitled to the benefit of the patent or to exercise any rights in relation to the patent.
1993, c. 2, s. 7.

(3) Il ne peut être pris d'ordonnances en vertu du paragraphe (1) plus de trois ans après qu'une personne ait cessé d'avoir droit aux avantages du brevet ou d'exercer les droits du titulaire.
1993, ch. 2, art. 7.

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

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

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

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

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

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

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

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

1993, ch. 2, art. 7.

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

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

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

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

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

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

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

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

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

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

(3) Subject to subsection (4), where the Board finds that a former patentee of an invention pertaining to a medicine had, while a patentee, sold the medicine in any

(3) Sous réserve du paragraphe (4), lorsqu'il estime que l'ancien breveté a vendu, alors qu'il était titulaire du brevet, le médicament à un prix qu'il juge avoir

market in Canada at a price that, in the Board's opinion, was excessive, the Board may, by order, direct the former patentee to do any one or more of the following things as will, in the Board's opinion, offset the amount of the excess revenues estimated by it to have been derived by the former patentee from the sale of the medicine at an excessive price:

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

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

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

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

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

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

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

(5) In estimating the amount of excess revenues under subsection (2), (3) or (4), the Board shall not consider any revenues derived by a patentee or former patentee before December 20, 1991 or any revenues derived by a former patentee after the

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

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

brevet ou d’exercer les droits du titulaire.

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

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

(7) No order may be made under this section in respect of a former patentee who, more than three years before the day on which the proceedings in the matter commenced, ceased to be entitled to the benefit of the patent or to exercise any rights in relation to the patent.
1993, c. 2, s. 7; 1994, c. 26, s. 54(F).

(7) Le présent article ne permet pas de prendre une ordonnance à l’encontre des anciens brevetés qui, plus de trois ans avant le début des procédures, ont cessé d’avoir droit aux avantages du brevet ou d’exercer les droits du titulaire.

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

84**.** (1) A patentee or former patentee who is required by any order made under section 83 to reduce the price of a medicine shall commence compliance with the order within one month after the date of the order or within such greater period after that date as the Board determines is practical and reasonable, having regard to the circumstances of the patentee or former patentee.

84. (1) Le breveté ou l’ancien breveté est tenu de commencer l’exécution de l’ordonnance de réduction des prix dans le mois suivant sa prise ou dans le délai supérieur que le Conseil estime pratique et raisonnable compte tenu de sa situation.

(2) A patentee or former patentee who is directed by any order made under section 83 to pay an amount to Her Majesty shall pay that amount within one month after the date of the order or within such greater period after that date as the Board determines is practical and reasonable, having regard to the circumstances of the patentee or former patentee.

(2) Le breveté ou l’ancien breveté est tenu d’exécuter l’ordonnance de paiement à Sa Majesté dans le mois suivant sa prise ou dans le délai supérieur que le Conseil estime pratique et raisonnable, compte tenu de sa situation.

(3) An amount payable by a patentee or former patentee to Her Majesty under any order made under section 83 constitutes a debt due to Her Majesty and may be recovered in any court of competent

(3) Les sommes payables en application d’une ordonnance prise en vertu du présent article constituent des créances de Sa Majesté, dont le recouvrement peut être poursuivi à ce titre devant toute juridiction

jurisdiction.
1993, c. 2, s. 7.

compétente.
1993, ch. 2, art. 7.

85**.** (1) In determining under section 83 whether a medicine is being or has been sold at an excessive price in any market in Canada, the Board shall take into consideration the following factors, to the extent that information on the factors is available to the Board:

85**.** (1) Pour décider si le prix d'un médicament vendu sur un marché canadien est excessif, le Conseil tient compte des facteurs suivants, dans la mesure où des renseignements sur ces facteurs lui sont disponibles :

(*a*) the prices at which the medicine has been sold in the relevant market;

a) le prix de vente du médicament sur un tel marché;

(*b*) the prices at which other medicines in the same therapeutic class have been sold in the relevant market;

b) le prix de vente de médicaments de la même catégorie thérapeutique sur un tel marché;

(*c*) the prices at which the medicine and other medicines in the same therapeutic class have been sold in countries other than Canada;

c) le prix de vente du médicament et d'autres médicaments de la même catégorie thérapeutique à l'étranger;

(*d*) changes in the Consumer Price Index; and

d) les variations de l'indice des prix à la consommation;

(*e*) such other factors as may be specified in any regulations made for the purposes of this subsection.

e) tous les autres facteurs précisés par les règlements d'application du présent paragraphe.

(2) Where, after taking into consideration the factors referred to in subsection (1), the Board is unable to determine whether the medicine is being or has been sold in any market in Canada at an excessive price, the Board may take into consideration the following factors:

(2) Si, après avoir tenu compte de ces facteurs, il est incapable de décider si le prix d'un médicament vendu sur un marché canadien est excessif, le Conseil peut tenir compte des facteurs suivants :

(*a*) the costs of making and marketing the medicine; and

a) les coûts de réalisation et de mise en marché;

(*b*) such other factors as may be specified in any regulations made for the purposes of this subsection or as are, in the opinion of

b) tous les autres facteurs précisés par les règlements d'application du présent paragraphe ou qu'il estime pertinents.

the Board, relevant in the circumstances.

(3) In determining under section 83 whether a medicine is being or has been sold in any market in Canada at an excessive price, the Board shall not take into consideration research costs other than the Canadian portion of the world costs related to the research that led to the invention pertaining to that medicine or to the development and commercialization of that invention, calculated in proportion to the ratio of sales by the patentee in Canada of that medicine to total world sales.
1993, c. 2, s. 7.

(3) Pour l'application de l'article 83, le Conseil ne tient compte, dans les coûts de recherche, que de la part canadienne des coûts mondiaux directement liée à la recherche qui a abouti soit à l'invention du médicament, soit à sa mise au point et à sa mise en marché, calculée proportionnellement au rapport entre les ventes canadiennes du médicament par le breveté et le total des ventes mondiales.

1993, ch. 2, art. 7.

86**.** (1) A hearing under section 83 shall be held in public unless the Board is satisfied on representations made by the person to whom the hearing relates that specific, direct and substantial harm would be caused to the person by the disclosure of information or documents at a public hearing, in which case the hearing or any part thereof may, at the discretion of the Board, be held in private.

86. (1) Les audiences tenues dans le cadre de l'article 83 sont publiques, sauf si le Conseil est convaincu, à la suite d'observations faites par l'intéressé, que la divulgation des renseignements ou documents en cause causerait directement à celui-ci un préjudice réel et sérieux; le cas échéant, l'audience peut, selon ce que décide le Conseil, se tenir à huis clos en tout ou en partie.

(2) The Board shall give notice to the Minister of Industry or such other Minister as may be designated by the regulations and to provincial ministers of the Crown responsible for health of any hearing under section 83, and each of them is entitled to appear and make representations to the Board with respect to the matter being heard.
1993, c. 2, s. 7; 1995, c. 1, s. 62.

(2) Le Conseil avise le ministre de l'Industrie, ou tout autre ministre désigné par règlement, et les ministres provinciaux responsables de la santé de toute audience tenue aux termes de l'article 83 et leur donne la possibilité de présenter leurs observations.

1993, ch. 2, art. 7; 1995, ch. 1, art. 62.

87**.** (1) Subject to subsection (2), any information or document provided to the Board under section 80, 81 or 82 or in any proceeding under section 83 is privileged, and no person who has obtained the information or document pursuant to this

87**.** (1) Sous réserve du paragraphe (2), les renseignements ou documents fournis au Conseil en application des articles 80, 81, 82 ou 83 sont protégés; nul ne peut, après les avoir obtenus en conformité avec la présente loi, sciemment les communiquer

Act shall, without the authorization of the person who provided the information or document, knowingly disclose the information or document or allow it to be disclosed unless it has been disclosed at a public hearing under section 83.

ou en permettre la communication sans l'autorisation de la personne qui les a fournis, sauf s'ils ont été divulgués dans le cadre d'une audience publique tenue en vertu de l'article 83.

(2) Any information or document referred to in subsection (1)

(*a*) may be disclosed by the Board to any person engaged in the administration of this Act under the direction of the Board, to the Minister of Industry or such other Minister as may be designated by the regulations and to the provincial ministers of the Crown responsible for health and their officials for use only for the purpose of making representations referred to in subsection 86(2); and

(*b*) may be used by the Board for the purpose of the report referred to in section 100.
1993, c. 2, s. 7; 1995, c. 1, s. 62.

(2) Le Conseil peut communiquer les renseignements ou documents qui lui sont confiés à quiconque est chargé, sous sa responsabilité, de l'application de la présente loi, ainsi qu'au ministre de l'Industrie, ou tout autre ministre désigné par règlement, ou à un ministre provincial responsable de la santé, ou à tel de leurs fonctionnaires, à seule fin de leur permettre de présenter leurs observations au titre du paragraphe 86(2); il peut aussi s'en servir pour établir le rapport visé à l'article 100.
1993, ch. 2, art. 7; 1995, ch. 1, art. 62.

Patented Medicines Regulations

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 date on which the medicine is first sold in Canada;

(*d*) the day or period, referred to in subsection (2) or (3), to which the

Règlement sur les médicaments brevetés

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 date à laquelle le médicament est vendu au Canada pour la première fois;

d) le jour ou la période visé aux paragraphes (2) ou (3) auxquels

information pertains;

s’appliquent les renseignements;

(*e*) the drug identification number assigned under the *Food and Drug Regulations* in respect of the medicine or, if no drug identification number has been assigned, any other identification number assigned in respect of each dosage form and strength of the medicine of the patentee or former patentee; and

e) le numéro d’identification de drogue attribué en vertu du *Règlement sur les aliments et drogues* ou, à défaut d’un tel numéro, tout autre numéro d’identification attribué à chaque forme posologique et à chaque concentration du médicament du breveté ou de l’ancien breveté;

(*f*) in respect of the day or period referred to in paragraph (*d*),

f) à l’égard du jour ou de la période visé à l’alinéa *d*) :

(i) the quantity of the medicine sold in final dosage form and either the average price per package or the net revenue from sales in respect of each dosage form, strength and package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory,

(i) la quantité du médicament vendu sous sa forme posologique finale 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 a été vendu par le breveté ou l’ancien breveté à chaque catégorie de clients dans chaque province et territoire,

(ii) the publicly available ex-factory price for each dosage form, strength and package size in which the medicine was sold by the patentee or former patentee to each class of customer in each province and territory, and

(ii) le prix départ usine accessible au public de chaque forme posologique, de chaque concentration et de chaque format d’emballage dans lesquels le médicament a été vendu par le breveté ou l’ancien breveté à chaque catégorie de clients dans chaque province et territoire,

(iii) if the medicine is being sold in one or more of the countries set out in the schedule, 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.

(iii) si le médicament est vendu dans un ou plusieurs des pays mentionnés à l’annexe, le prix départ usine accessible au public de chaque forme posologique, de chaque concentration et de chaque format d’emballage dans lesquels le médicament a été vendu à chaque catégorie de clients dans chacun de ces pays.

(*g*) [Repealed, SOR/2008-70, s. 4]

g) [Abrogé, DORS/2008-70, art. 4]

(2) If the medicine is for human use and contains a controlled substance as defined in the *Controlled Drugs and Substances Act* or a substance listed or described in Schedule C or D to the *Food and Drugs Act* or Schedule F to the *Food and Drug Regulations*, the information referred to in subsection (1) shall be provided

(2) S'agissant d'un médicament destiné à l'usage humain qui contient une substance désignée au sens de la *Loi réglementant certaines drogues et autres substances* ou mentionnée ou décrite aux annexes C ou D de la *Loi sur les aliments et drogues* ou à l'annexe F du *Règlement sur les aliments et drogues*, les renseignements visés au paragraphe (1) sont fournis :

(*a*) for the day on which the medicine is first sold in Canada, within 30 days after that day; and

a) pour le jour où le médicament est vendu au Canada pour la première fois, dans les trente jours suivant ce jour;

(*b*) for each six-month period beginning on January 1 and July 1 in a year, within 30 days after the end of the period.

b) pour chaque période de six mois commençant le 1er janvier et le 1er juillet de chaque année, dans les trente jours suivant la fin de cette période.

(3) If the medicine is for human use and does not contain a controlled substance as defined in the *Controlled Drugs and Substances Act* or does not contain a substance listed or described in Schedule C or D to the *Food and Drugs Act* or in Schedule F to the *Food and Drug Regulations* or is a medicine for veterinary use, the information referred to in subsection (1), for each six-month period beginning on January 1 and July 1 of each year, shall be provided to the Board within 30 days after the date on which the Board sends a request in response to a complaint respecting the price of the medicine, and during the two years following the request, within 30 days after each six-month period.

(3) S'agissant d'un médicament destiné à l'usage humain qui ne contient aucune substance désignée au sens de la *Loi réglementant certaines drogues et autres substances* ou mentionnée ou décrite aux annexes C ou D de la *Loi sur les aliments et drogues* ou à l'annexe F du *Règlement sur les aliments et drogues* ou d'un médicament destiné à l'usage vétérinaire, les renseignements visés au paragraphe (1) doivent être fournis au Conseil pour chaque période de six mois commençant le 1er janvier et le 1er juillet de chaque année, dans les trente jours suivant l'envoi, par ce dernier, d'une demande faisant suite à une plainte concernant le prix du médicament et, au cours des deux années qui suivent la demande, dans les trente jours suivant la fin de chaque période de six mois.

(4) For the purposes of subparagraph (1)(*f*)(i),

(4) Pour l'application du sous-alinéa (1)*f*)(i) :

(*a*) in calculating the average price per package of medicine, the actual price after

a) le prix après déduction des réductions accordées à titre de promotion ou sous

any reduction given as a promotion or in the form of rebates, discounts, refunds, free goods, free services, gifts or any other benefit of a like nature and after the deduction of the federal sales tax shall be used; and

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;

(*b*) 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 benefit of a like nature and after the deduction of federal sales taxes shall be used.

b) 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.

(5) Subject to subsection (6), this section does not apply to medicine sold by a patentee or former patentee to a person with whom they do not deal at arm's length or to another patentee or former patentee.

(5) Sous réserve du paragraphe (6), le présent article ne s'applique pas au médicament vendu par le breveté ou l'ancien breveté à une personne avec qui il a un lien de dépendance ou à tout autre breveté ou ancien breveté.

(6) If the patentee or former patentee sells the medicine to a person with whom they do not deal at arm's length and who is not required to provide information under paragraphs 80(1)(*a*) or (2)(*a*) of the Act, the patentee or former patentee shall provide the information required under paragraph (1)(*f*) in respect of any resale of the medicine by the person.

(6) Si 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*) ou (2)*a*) de la Loi, il doit fournir les renseignements prévus à l'alinéa (1)*f*) à l'égard de toute revente du médicament par cette personne.

(7) For the purposes of subparagraph (1)(*f*)(iii), the price at which a medicine was sold in a country other than Canada shall be expressed in the currency of that country.

(7) Pour l'application du sous-alinéa (1)*f*)(iii), le prix auquel le médicament a été vendu dans le pays étranger doit être exprimé dans la devise de ce pays.

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

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

(9) 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.

(9) 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.

(10) [Repealed, SOR/2008-70, s. 4] SOR/98-105, s. 3; SOR/2008-70, s. 4.

(10) [Abrogé, DORS/2008-70, art. 4] DORS/98-105, art. 3; DORS/2008-70, art. 4.

Food and Drug Regulations

C.01.043. (1) A person may sell a Schedule F Drug, without having received a prescription therefor, to

(*a*) a drug manufacturer;

(*b*) a practitioner;

(*c*) a wholesale druggist;

(*d*) a registered pharmacist;

(*e*) a hospital certified by the Department of National Health and Welfare;

(*f*) a Department of the Government of Canada or of a province, upon receipt of a written order signed by the Minister thereof or his duly authorized representative; or

Règlement sur les aliments et drogues

C.01.043. (1) Est permise sans aucune ordonnance, la vente d'une drogue de l'annexe F à

a) un fabricant de drogues;

b) un praticien;

c) un pharmacien en gros;

d) un pharmacien inscrit;

e) un hôpital reconnu par le ministère de la Santé nationale et du Bien-être social;

f) un ministère d'un gouvernement, fédéral ou provincial, sur réception d'une commande écrite signée par le ministre en cause ou son représentant dûment autorisé; ou à

(*g*) any person, upon receipt of a written order signed by the Director.

(2) Where a person makes a sale authorized by paragraph (1)(*f*) or (1)(*g*), he shall retain the written order for the drug for a period of at least two years from the date of filling the order.

g) toute personne, sur réception d'une commande écrite signée par le Directeur.

(2) Quand une personne effectue une vente autorisée par les alinéas (1)*f*) ou *g*), elle doit conserver la commande écrite relative à la drogue durant une période minimum de deux ans à partir de l'exécution de ladite commande.

FEDERAL COURT

SOLICITORS OF RECORD

DOCKET:	T-1442-08 and T-1447-08
STYLE OF CAUSE:	PFIZER CANADA INC. v. AGC and PATENTED MEDICINE PRICES REVIEW BOARD and, CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES ET AL v. AGC and PATENTED MEDICINE PRICES REVIEW BOARD
PLACE OF HEARING:	Ottawa, Ontario
DATE OF HEARING:	June 16 and 17, 2009
REASONS FOR JUDGMENT AND JUDGMENT:	Mactavish, J.
DATED:	July 10, 2009

APPEARANCES:

Mr. Orestes Pasparakis	FOR THE APPLICANT (PFIZER)
Mr. Martin W. Mason	FOR THE APPLICANTS (CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES ET AL)
Mr. Alexander Gay	FOR THE RESPONDENT (AGC)
Mr. Gordon Cameron	FOR THE INTERVENER (PATENTED MEDICINE PRICES REVIEW BOARD)

SOLICITORS OF RECORD:

OGILVY RENAULT LLP Toronto, Ontario	FOR THE APPLICANT (PFIZER)
GOWLING LAFLEUR HENDERSON LLP Toronto, Ontario	FOR THE APPLICANTS (CANADA'S RESEARCH-BASED PHARMACEUTICAL COMPANIES ET AL)
JOHN H. SIMS, Q.C. Toronto, Ontario	FOR THE RESPONDENT (AGC)
BLAKE CASSELS & GRAYDON LLP Ottawa, Ontario	FOR THE INTERVENER (PATENTED MEDICINE PRICES REVIEW BOARD)