June 30, 2011 **Decision: PMPRB-08-D3-ratiopharm - Merits**

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

AND IN THE MATTER OF ratiopharm Inc. ("ratiopharm")

DECISION

Introduction

1. This is the decision of the hearing panel (the "Panel") concerning an application filed by the staff of the Board (Board Staff) on July 15, 2008 (the "Application") pursuant to sections 81 and 88 of the *Patent Act* (the *"Act")* requiring the Respondent, ratiopharm Inc. ("ratiopharm"), to provide the Board with the information and documents referred to in sections 80, 81 and 88 of the *Act* and in sections 3, 4 and 5 of the *Patented Medicines Regulations* (the "Regulations"*)*. These provisions of the *Act* and Regulations require "patentees", as that term is defined in subsection 79(1) of the *Act*, to file information and documents identifying and providing sales and pricing information and any related matters with respect to patented medicines sold in Canada, and providing revenues from, and research and development expenditures relating to, medicine. Extracts from the *Act* and Regulations containing the main statutory provisions applicable in this context are set out in Appendix "A" to these reasons.

2. Evidence and oral argument were heard on October 13 and 14, 2009, and written submissions were filed in October and November, 2009. Because the issues raised in this proceeding were related to some of those raised in an excessive-pricing proceeding involving ratiopharm and the medicine ratio-Salbutamol HFA, heard by the same Panel, the Panel reserved its decision in this proceeding until it had decided the matter involving ratio-Salbutamol, the reasons and order for which were released on May 27, 2011 (the ratio-Salbutamol Decision).

The issues and the general analysis

3. The Application sought an order that ratiopharm file the prescribed information with respect to all patented medicines that ratiopharm sells in Canada. At the outset of the Application, Board Staff had some information that gave them grounds to believe that ratiopharm was a patentee with respect to several

medicines and potentially many more. By the conclusion of the proceeding, as a result of evidence and documentary production during the proceeding, Board Staff took the position that 14 medicines should be the subject of an order arising out of this proceeding.

4. ratiopharm does not hold patents with respect to any of these medicines. Broadly speaking, Board Staff took the position that for 12 of the medicines, ratiopharm, having been authorized to sell the medicines in Canada by the holders of patents pertaining to the medicines, was a "patentee" within the meaning of that term in subsection 79(1) of the *Act*. For two of the medicines, Board Staff took the position that there was at least enough evidence on the record for the Panel to order ratiopharm to file patent and supply agreement documentation so that a determination could be made by Board Staff as to whether or not they would take the position that ratiopharm was or is a patentee with respect to those medicines.

5. The main issue in this proceeding revolved around the definition of "patentee" in subsection 79(1) of the *Act*. For the purposes of the Board's jurisdiction, subsection 79(1) expands the definition of "patentee" beyond the definition in section 2 of the *Act*. Section 2 provides as follows:

> "patentee" means the person for the time being entitled to the benefit of a patent;

6. Subsection 79(1) provides as follows:

> "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 … that other person in respect of those rights;

7. Broadly speaking, Board Staff take the position that a pharmaceutical distributor that (1) has an agreement with a person who holds a patent that pertains to a medicine to purchase the medicine from that person and resell it to others; and (2) holds its own Notice of Compliance (NOC) for that medicine, is entitled to a right (the right to sell the medicine) "in relation to" the pertaining patent. Accordingly, such a pharmaceutical distributor is a patentee within the meaning of that term in subsection 79(1) of the *Act*. Board Staff argue that ratiopharm is a patentee with respect to the medicines that are the subject of these reasons. Board Staff made several other arguments and applied their position to each of the 14 medicines regarding which they seek an order in this proceeding.

8. ratiopharm takes the contrary position. ratiopharm argues that the arrangements by which it was and is entitled to sell the medicines, which do not grant ratiopharm ownership of any patent rights, and the position it occupies in the distribution chain of the medicines, do not make it a "patentee" within the meaning of that term in subsection 79(1) of the *Act*. Accordingly, ratiopharm argues, the Board does not have jurisdiction over ratiopharm in relation to any of the medicines that are the subject of these reasons.

9. In its written final rebuttal submissions, ratiopharm framed the issue in this proceeding as being: "whether a generic pharmaceutical company who neither manufactures nor holds patents on the products in question, and who sells the products under supply agreements that expressly provide that it has no patent rights, has a duty to report". In oral submissions, ratiopharm answered the question this way: "ratiopharm is not a patentee because it is not entitled to exercise any rights in relation to the patent because the licensor has specifically retained all patent rights."

10. The specific circumstances surrounding the sale of each medicine regarding which Board Staff seek an order must be considered, because the ratio-Salbutamol Decision did not address the particulars of the Board's potential jurisdiction with respect to the specific medicines discussed in these reasons. Also, though this application was heard before the ratio-Salbutamol proceeding, the parties raised some additional arguments in this application or expressed their positions differently, and these reasons attempt to deal with those additional issues.

11. However, the principles applicable to the circumstances in which a person who is not the patent holder, but is "entitled to exercise any rights in relation to" a patent pertaining to a medicine were canvassed in the ratio-Salbutamol Decision. The consideration of this matter in the ratio-Salbutamol Decision addressed a business model by which ratiopharm, a generic pharmaceutical company, acquired ratio-Salbutamol pursuant to agreements with GlaxoSmithKline, who manufactured ratio-Salbutamol, held the patents pertaining to ratio-Salbutamol and (in the agreements between GlaxoSmithKline and ratiopharm) expressly disclaimed any grant of patent rights to ratiopharm.

12. Accordingly, the ratio-Salbutamol Decision provides guidance in this proceeding, at least with respect to the principles governing the interpretation of subsection 79(1) of the *Act* and related legal issues, such as the potential applicability of the decision of the Federal Court in the *Pfizer* case, to the Board's jurisdiction over a person selling a medicine in the circumstances in which ratiopharm was selling ratio-Salbutamol. By way of a summary, the ratio-Salbutamol Decision concluded (to frame the issue as it was framed by ratiopharm in this proceeding)

that it is not necessary for a person such as ratiopharm in its position in the pharmaceutical distribution chain to manufacture a medicine or hold a patent pertaining to the medicine in order to be subject to the jurisdiction of the Board. By virtue of the definition of patentee in subsection 79(1), a person is subject to the jurisdiction of the Board if it is entitled to "any rights in relation to" a patent pertaining to a medicine that is or was sold in Canada.

Rights in relation to a patent

13. Subsection 79(1) does not refer only to persons entitled to the benefit of the patent, but also persons entitled to exercise rights "in relation to" the patent. When one person entitled to the benefit of a patent grants another person the right to sell the medicine in the circumstances applicable to ratiopharm in relation to the medicines in issue in the proceeding, the Panel concludes that the latter person is entitled to exercise a right or rights (to sell the medicine and arguably to claim damages for infringement of the patent) that is "in relation to" the patent. This is so whether or not the agreement under which the right is granted disclaims the actual granting of patent rights.

14. Put another way, the holders of the patent rights who entered into licensing or distribution agreements with ratiopharm to sell the medicines regarding which Board Staff seek an order in this proceeding would not have agreed to supply ratiopharm with the medicines absent an agreement. The holders of those patent rights had, by virtue of those rights, the power and authority to require ratiopharm to enter into the agreements as a precondition to supplying ratiopharm with the medicines. ratiopharm had to obtain the right to sell the medicines from the holders of patents pertaining to the medicines. The holders of the patent rights pertaining to the medicines had the power to control to whom they sold their medicines for resale by virtue of their patent rights. While, as it is often said in the jurisprudence of the Board and the Federal Court, the demonstration of market power is not a precondition to the Board's jurisdiction, the potential for market power that arises from the monopoly conferred by a patent is at the root of the Board's mandate. A patent holder is not obliged to license others to sell a medicine to which the patent pertains. When the holder of a patent decides whether or not to supply ratiopharm with a medicine to which the patent pertains, the patent holder is exercising market power by virtue of its patent rights. Therefore, ratiopharm's right to sell the medicine is a right to which ratiopharm is entitled "in relation to" the pertaining patents.

Ex-factory prices and the first sale of the medicine

15. The ratio-Salbutamol Decision dealt with the expressions "ex-factory price", an undefined[1] term in the Regulations and "first sale", an expression that has been used to describe the Board's typical approach to distinguish between the manufacturing level and the wholesale / retail level. The Board does not regulate prices charged by wholesalers and retailers. It could be that, as argued by ratiopharm, in accordance with the concept of exhaustion in patent law, each person in the chain of distribution down to the retail level could be considered a patentee on the Board's interpretation of subsection 79(1). But the Board does not regulate the prices of medicines beyond the first sale into one of the consumer classes (wholesalers, hospitals and pharmacies) protected by the Board. It is patentees who sell patented medicines into those markets that are under the Board's jurisdiction. It is not relevant for these purposes if the definition catches other persons as, technically speaking, patentees.

16. The market has evolved to include arrangements such as those discussed in the ratio-Salbutamol Decision and in this decision, where ratiopharm (like a manufacturer but unlike wholesalers, pharmacies and hospitals) – holds the NOCs and Drug Identification Numbers (DINs) of the medicines it sells, and sells those medicines to the customer classes protected by the Board. ratiopharm's sales to wholesalers, pharmacies and hospitals are the first sales of the medicines to the classes of customer that the Board protects, thus making them equivalent to factory gate sales for the very purposes of the Board's mandate.

Notices of Compliance

17. It is not insignificant that ratiopharm holds the NOCs for these medicines, in at least two respects. First, the NOC application includes a process by which the positions of holders of related patents is indicated or made open to dispute. Where ratiopharm believes that the medicine it intends to sell is protected by a patent and ratiopharm has an agreement with the patent holder, this will be indicated on the application for the NOC. ratiopharm represents to Health Canada (as it did with respect, for example, to ratio-Omeprazole) that it has the patent holder's consent to the "making, constructing, using or selling the drug in Canada", language that mirrors the rights of the patent holder as stipulated in section 42 of the *Act*: the exclusive right to "making, constructing and using the invention and selling it to others".

[1] Other than the stipulation that, for medicines sold outside of Canada, the term includes a price agreed between the patentee and the applicable regulator.

18. ratiopharm properly observes that, though the NOC process identifies ratiopharm as the manufacturer, ratiopharm is not the manufacturer of the medicines in question in the normal sense of this word. However, in the Panel's view this does not aid ratiopharm's argument. The *Food and Drug Regulations* use the term "manufacturer" for a person in ratiopharm's position that is selling its own brand of a medicine and has been issued a DIN for the medicine. This is distinct from the "fabricator", the person who makes the medicine. Holding the NOCs for the subject medicines makes ratiopharm responsible, among other things, for compliance with the safety and effectiveness requirements of the medicine, even though it is not made by ratiopharm, and entitles ratiopharm to sell the medicines to the customer classes protected by the Board. Customers (for the Board's purposes, wholesalers, pharmacies and hospitals) purchase from the person classified as the manufacturer of a medicine, not the fabricator.

19. It is of course possible for a person to hold an NOC without being entitled to any rights in relation to a patent, but a person who holds an NOC and is entitled to rights in relation to a patent occupies the same position with respect to the Board's mandate as the patent holder. Interpreted this way, which is consistent both with the plain meaning of the words and the intent of the *Act*, subsection 79(1) allows the Board to fulfill its mandate.

20. To repeat a point made in the ratio-Salbutamol Decision, the Board's mandate would be easily defeated if the Board allowed the pricing of medicines to which a patent pertains to be uncontrolled simply because of the insertion, in the distribution structure, of an entity that sets the price and makes the first sale to the customer classes that the Board protects. Persons who set the prices for the first sales to the customers the Board protects are the very persons the *Act* was intended to be subject to the Board's jurisdiction, whether they are manufacturers or distributors supplied by manufacturers. The expanded definition of patentee in subsection 79(1) of the *Act* would have little point if the *Act* were interpreted to allow such unregulated pricing.

Signalisation de Montréal Inc. v Services de Béton Universels Ltée

21. An issue that received rather more attention in this proceeding than in the ratio-Salbutamol proceeding was the relevance of the decision of the Federal Court of Appeal in *Signalisation de Montréal Inc. v. Services de Béton Universels Ltée.*[2] Both parties relied on this case. In this case, the patent holder granted a license for North American sales and the licensee appointed the plaintiff as its sales representative for Quebec and Ontario. The decision notes that the agreement between the licensee and the plaintiff made no specific reference to the patent, though the patent did cover the product[3] that the plaintiff was, by the representation agreement, entitled to sell. Not only was there no grant or transfer of patent rights to the plaintiff, the licensee was prohibited by the terms of its license with the patentee from doing so. The Court specifically noted that "The fact that [the licensee] could not assign its rights under its licence … nor transfer the licence … is nothing to the point. [The licensee] was clearly entitled by the [license] to sell the invention and in fact did so, and that is the source of appellant's right.[4]"

22. The Court found that the plaintiff, as a bare sales representative of a licensee (that is, the plaintiff having no grant of patent rights) was itself properly termed a licensee, and could bring an action in damages under subsection 55(1) of the *Act* against a person who infringed the patent, as a person claiming under the patentee. The licensee has this right whether the license is exclusive or non-exclusive.[5]

23. ratiopharm argued that *Signalisation* stands for the proposition that one must look to the contractual agreements between the parties to determine whether or not patent rights were granted, the point being (though not in every case conceded by Board Staff) that with respect to the medicines sold by ratiopharm, such rights were not granted and their grant was often expressly disclaimed. It is to be noted, however, that the agreement in issue in *Signalisation* did not grant any patent rights and in fact circumscribed the representative's rights to resale only. Indeed, the thrust of *Signalisation* is that there need not be an express grant of patent rights originating with the patentee in order for a person to have standing to bring an action under subsection 55(1). The Federal Court of Appeal made the distinction by reference to the decision of the Supreme Court of Canada in *Armstrong Cork Canada Ltd. v. Domco Industries Ltd.*[6], quoting from the case as follows: "A licensee relying on this subsection is not claiming against

[2] [1993] 1 F.C. 341
[3] More precisely, a method for using a machine and a product
[4] Paragraph 14
[5] Paragraphs 17 and 18
[6] [1982] 1 S.C.R. 907

the infringer for infringement of his rights under the licence, he is claiming for the damage he has sustained in consequence of the infringement of the patent."

24. Thus the Panel considers Board Staff's reliance on *Signalisation* to be more persuasive. Board Staff argue that a second manner in which ratiopharm could be said to be entitled to rights "in relation to" patents pertaining to the subject medicines is the potential right to bring an action under subsection 55(1), albeit perhaps not often for substantial damages where ratiopharm does not have an exclusive right to sell the medicine in question. The potential situation envisioned by Board Staff's argument is this: a patent holder grants ratiopharm the right to sell the patented medicine. A person then commences infringing the patent and competing with ratiopharm, causing ratiopharm to suffer losses. In this situation ratiopharm would have standing to bring an action in damages against the infringer pursuant to subsection 55(1). ratiopharm would not be suing for infringement as an owner of patent rights, but for damages arising out of infringement of a patent held by another. Since ratiopharm's entitlement to bring this action is premised on the existence of a patent and ratiopharm's agreement with the patent holder, it is a "right in relation to" the patent. It is also a material right in the context of the Board's jurisdiction, because it allows ratiopharm to exercise market power in the manner of a patent holder. The Panel considers this to be a tenable basis for the proposition that ratiopharm is a subsection 79(1) patentee with respect to the medicines in issue in this application. However, given the reasons stated earlier in this decision, it is not necessary for the Panel to rely on this point.

Summary of Conclusions

25. In this proceeding ratiopharm provided extensive submissions, both as to the general proposition it framed as the issue in the proceeding and the particulars of how that proposition applied to each of the medicines at issue in the proceeding (albeit before this Panel issued the ratio-Salbutamol Decision). These reasons do not always address each of ratiopharm's submissions in detail because, in some measure, they are answered by the analysis in the ratio-Salbutamol Decision. Correspondingly, these reasons do not always address each of Board Staff's submissions on the general issues or the particular circumstances under which each of the medicines in question is sold by ratiopharm. However, the detailed oral and written submissions of both parties were very helpful to the Panel in understanding the facts and applying the law to the particulars of the medicines at issue in this proceeding.

26. For the reasons below, the Panel is satisfied on the evidence before it that, for the 12 medicines listed in paragraph 1 of the Order attached to these reasons, and for each of the medicines identified in paragraph 1 of the Order with a separate DIN, ratiopharm is or was a patentee with respect to one or more patents that pertained to those medicines, and is or was selling the medicines in any market in Canada. There is no dispute that ratiopharm sells these medicines in Canada, and for each of the 12 medicines, the evidence presented by Board Staff (relating to pertaining patents, NOCs, sales agreements and other documentation related to the right of ratiopharm to sell the medicines in Canada) establishes that ratiopharm is a "patentee" within the meaning of subsection 79(1) of the *Act*.

27. The Panel is also satisfied on the evidence before it that, with respect to the two medicines identified in paragraph 2 of the attached Order, there is sufficient evidence that the Board could have jurisdiction in relation to the medicines to require ratiopharm to file further information concerning the patent status and licensing (or similar arrangements) of the medicines in order to allow Board Staff to take a position as to whether or not ratiopharm is a patentee with respect to those medicines. Alternatively, if ratiopharm accepts that, on the basis of these reasons, it is a patentee within the meaning of the *Act*, it may, of course, simply file the Form 1 and Form 2 information for those medicines.

28. The Panel also concludes that, as a patentee, ratiopharm is obliged by section 88 of the *Act* to report its research and development expenditures to the Board. The *Act* is explicit on this point and the Panel's conclusion is consistent with the policy and intent of section 88. To address a legitimate concern of ratiopharm in this regard, Board Staff have undertaken that such expenditures by generic pharmaceutical companies will be separately identified when the Board reports pharmaceutical expenditures on research and development to Parliament.

29. ratiopharm also challenged the constitutionality of the Board's jurisdiction over its sales of the medicines in question, a challenge that was disposed of by this Panel in the ratio-Salbutamol Decision.

The medicines for which Board Staff seeks an order to file

30. Having reviewed the evidence and documentary production in this proceeding, Board Staff seek an order requiring ratiopharm to file pricing and sales information with respect to 12 medicines sold by ratiopharm:

1. ratio-Omeprazole
2. ratio-Ketorolac
3. ratio-Brimonidine
4. ratio-Paroxetine
5. ratio-Cefuroxime
6. ratio-Lamotrigine
7. ratio-Acyclovir
8. ratio-Ramipril
9. ratio-Diltiazem
10. ratio-Simvastatin
11. ratio-Sertraline
12. ratio-Quetiapine

31. For each of these medicines, Board Staff alleges that there are or were patents that pertain to the medicines, and that ratiopharm is entitled to exercise rights in relation to those patents. As noted, the Panel agrees. The Panel does not intend to recite all of the evidence and the arguments for or against the proposition that at least one patent pertains to each of the medicines and that ratiopharm is entitled to exercise rights in relation to the patents, but a brief discussion is provided below of the salient points of the evidence and the positions of the parties for each of the medicines. In these reasons the discussion pertains to each of the DINs (dosage forms for the medicines) identified in the attached Order, though reference is made only to the names of the medicines. Also, to avoid unnecessary repetition, these reasons sometimes incorporate for one medicine the analysis that the Panel has applied to other medicines or that appears in the ratio-Salbutamol Decision.

ratio-Omeprazole

32. AstraZeneca markets a brand name medicine known as Losec, regarding which it reports its sales and pricing information to the Board. The significance of AstraZeneca reporting to the Board with respect to Losec is that pharmaceutical companies report to the Board when they believe that a patent pertains to the medicine in question. Thus the fact that AstraZeneca reports to the Board regarding Losec is evidence that AstraZeneca believes that a patent pertains to Losec. It is possible that AstraZeneca is mistaken about the patent status of its medicine, but this is a speculative and remote possibility. In a few instances patentees report to the Board under protest, but this would be known to Board Staff and would have been reported to the Panel as part of Board Staff's case (as Board Staff did report in several cases involving reporting by generic companies.)

33. Accordingly, in the absence of evidence to the contrary, the Panel believes that a very compelling inference allows the Panel to conclude that a patent pertains to Losec. If the patent pertains to Losec, it pertains to an equivalent medicine sold under a different name. The same inference applies to each of the medicines for which the evidence establishes that the vendor of the brand name medicine reports to the Board with respect to that medicine.

34. ratiopharm obtains a medicine equivalent to Losec from AstraZeneca and markets it as ratio-Omeprazole. The agreement between ratiopharm and AstraZeneca for the supply of ratio-Omeprazole lists ten patents – the same patents that ratiopharm reported to Health Canada when obtaining the NOC for ratio-Omeprazole, declaring to Health Canada that it has the consent of the patent holder to the selling of ratio-Omeprazole in Canada. This is reflected in the agreement between ratiopharm and AstraZeneca, which grants ratiopharm a non-exclusive licence to sell ratio-Omeprazole in Canada. The Panel concludes that the patents described above pertain to ratio-Omeprazole.

35. Among other arguments, ratiopharm points out that its agreement with AstraZeneca reserves all patent rights to AstraZeneca, which, in ratiopharm's submission, has the legal consequence that ratiopharm cannot be a patentee within the meaning of subsection 79(1) of the *Act*. Board Staff point out that the agreement by which AstraZeneca supplied ratiopharm with ratio-Omeprazole demonstrates that those parties considered the right to resell the medicine to be a right related to the patent:

> ratiopharm shall have, pursuant to this Agreement, no licence from AstraZeneca or its Affiliates in respect of the Patent Rights, <u>other than the right to resell</u>, in accordance with the strict terms and conditions of this Agreement, Product sold by AstraZeneca to ratiopharm pursuant to this Agreement. [emphasis added]

36. This is some evidence to support the point, but in all events, it is for the Panel (as opposed to the parties to the agreement) to determine whether the right to resell held by a person in the position of ratiopharm amounts to a right "in relation to" a patent pertaining to a medicine sold in Canada, and for the reasons set out here and in the ratio-Salbutamol Decision, the Panel concludes that the agreement between ratiopharm and AstraZeneca did entitle ratiopharm to exercise a right in relation to the patents that pertain to ratio-Omeprazole. ratiopharm was and is a patentee in relation to ratio-Omeprazole. Operating as it does in the distribution chain of ratio-Omeprazole it is subject to the jurisdiction of Board. ratiopharm is obliged to report its sales and pricing information with respect to ratio-Omeprazole.

ratio-Ketorolac

37. Allergan markets a medicine in Canada under the brand name Acular, and reports its sales and pricing information in relation to Acular to the Board. ratiopharm obtains an equivalent product from Allergan and markets it as ratio-Ketorolac. Allergan has advised ratiopharm that Allergan holds Canadian patents with respect to Acular. Allergan is the exclusive distributor of Acular in Canada pursuant to an agreement with Syntex. Syntex has agreed with Allergan that ratiopharm has the consent of the patent holder to sell ratio-Ketorolac in Canada, which consent, as Board Staff points out, would not be necessary if the patents did not pertain to ratio-Ketorolac. The Panel is satisfied on all of the evidence that patents pertain to ratio-Ketorolac.

38. The agreement between ratiopharm and Allergan (which ratiopharm inherited from Altimed (a ratiopharm predecessor company) and which agreement was extended to cover ratio-Ketorolac provides ratiopharm with the exclusive right to market ratio-Ketorolac in Canada. ratiopharm argues that its agreement with Allergan specifically reserves the intellectual property related to ratio-Ketorolac. However, for the reasons set out here and in the ratio-Salbutamol Decision, the Panel concludes that ratiopharm, having the right to sell ratio-Ketorolac in Canada, is entitled to exercise rights in relation to patents that pertain to ratio-Ketorolac and thus was or is a patentee with the meaning of subsection 79(1) of the *Act*. ratiopharm is subject to the jurisdiction of Board and is obliged to report its sales and pricing information with respect to ratio-Ketorolac.

ratio-Brimonidine

39. Allergan markets a medicine in Canada under the name of Alphagan, and reports its sales and pricing information in relation to Alphagan to the Board. ratiopharm obtains an equivalent product from Allergan and markets it as ratio-Brimonidine. As with Acular / ratio-Ketorolac, Allergan has advised ratiopharm that Allergan has Canadian patents with respect to Alphagan. The Panel is satisfied that patents pertain to ratio-Brimonidine.

40. The agreement between ratiopharm and Allergan (the same agreement discussed above with respect to Acular / ratio-Ketorolac) provides ratiopharm with the exclusive right to market ratio-Brimonidine in Canada. Here too ratiopharm argues that its agreement with Allergan specifically reserves the intellectual property related to ratio-Brimonidine. However, for the reasons set out above with respect to ratio-Ketorolac, the Panel concludes that ratiopharm is subject to the jurisdiction of Board and is obliged to report its sales and pricing information with respect to ratio-Brimonidine.

ratio-Paroxetine, ratio-Cefuroxime, ratio-Lamotrigine and ratio-Acyclovir

41. GlaxoSmithKline (GSK) markets medicines in Canada under the brand names Paxil, Ceftin, Lamictal and Zovirax and reports (or in the case of Ceftin, reported until 2008 when the pertaining patent expired) its sales and pricing information in relation to those medicines to the Board. ratiopharm obtains equivalent medicines from GSK that it sells in Canada under the names ratio-Paroxetine (GSK's Paxil), ratio-Cefuroxime (GSK's Ceftin), ratio-Lamotrigine (GSK's Lamictal) and ratio-Acyclovir (GSK's Zovirax) from GSK. These four medicines are covered by a single agreement between GSK and ratiopharm.

42. GSK informed ratiopharm of the eight patents that relate to ratio-Paroxetine and the three single patents that relate to each of ratio-Cefuroxime, ratio-Lamotrigine and ratio-Acyclovir.

43. With respect to ratio-Cefuroxime and ratio-Acyclovir, ratiopharm argued that the patents related to those medicines that are listed in the agreement between GSK and ratiopharm expired more than three years before the commencement of this proceeding, with the effect that, pursuant to subsection 81(3) of the *Act*, the Board does not have jurisdiction over the pricing of ratio-Cefuroxime.

44. However, the evidence includes correspondence in which GSK identified to ratiopharm a further patent related to ratio-Cefuroxime that did not expire until April 2008, and consistent with this, GSK reported to the Board with respect to Ceftin, the medicine that is equivalent to ratio-Cefuroxime, until 2008. Also, GSK identified a further patent related to ratio-Acyclovir that will not expire until January 2012, and GSK still reports to the Board with respect to Zovirax, the medicine that is equivalent to ratio-Acyclovir.

45. ratiopharm also argued that, with respect to ratio-Lamotrigine, there was a conflict in the evidence as to the expiry date of the pertaining patent: 1999 vs. 2012, with the effect that there was uncertainty in the evidence with respect to whether any patent could have pertained to this medicine. However, the Panel interprets the evidence differently. The evidence indicates not a patent with alternate expiry dates, but that GSK identified a separate patent that pertained to ratio-Lamotrigine that expires in 2012 and that the Panel concludes pertains to ratio-Lamotrigine. Again, GSK still reports to the Board with respect to Lamictal, the medicine that is equivalent to ratio-Lamotrigine.

46. Accordingly, the Panel is satisfied that patents pertain (or in the case of ratio-Cefuroxime, pertained within three years of the commencement of this proceeding) to each of these medicines.

47. The agreement between GSK and ratiopharm that covers these four medicines gives ratiopharm an exclusive license to market and sell the medicines in Canada. ratiopharm points out that the agreement includes a number of terms by which it is stipulated that GSK retains and is not assigning or otherwise granting to ratiopharm any of GSK's intellectual property.

48. Again, however, for the reasons set out here and in the ratio-Salbutamol Decision, the Panel concludes that the agreement between ratiopharm and GSK did entitle ratiopharm to exercise rights in relation to the patents that pertain to these four medicines. Thus ratiopharm was and is a patentee in relation to these medicines and, operating as it does in the distribution chain of these medicines it is subject to the jurisdiction of Board. ratiopharm is obliged to report its sales and pricing information with respect to them.

ratio-Ramipril

49. sanofi-aventis sells a medicine in Canada with the brand name Altace and reports its sales and pricing information with respect to Altace to the Board. sanofi-aventis supplies ratiopharm with an equivalent medicine, ratio-Ramipril, pursuant to an agreement that grants ratiopharm the right to sell ratio-Ramipril in Canada. By correspondence in September 2008, sanofi-aventis informed ratiopharm that Altace was a patented medicine regarding which sanofi-aventis reported to the Board.

50. As with the other medicines, ratiopharm argues that it is not a patentee because, in its agreement with sanofi-aventis, sanofi-aventis expressly retains ownership of its intellectual property rights. ratiopharm adds that it does not have an exclusive license to sell ratio-Ramipril, in that sanofi-aventis is entitled to sell the same medicine.

51. The Panel is satisfied that at least one patent pertained to ratio-Ramipril within three years before the commencement of this proceeding and that, for the reasons described above for the other medicines identified by Board Staff, ratiopharm is or was a patentee obliged to report sales and pricing information to the Board with respect to ratio-Ramipril.

ratio-Diltiazem

52. Apotex Pharmachem Inc. ("Apotex") holds a patent (issued in 1999 and expiring in 2015) for a process in the manufacturing of Diltiazem, a medicine equivalent to ratio-Diltiazem. Unlike the previously-mentioned suppliers to ratiopharm, Apotex is (like ratiopharm) commonly referred to as a “generic” pharmaceutical company. From 2001 to 2008, Apotex supplied ratiopharm with ratio-Diltiazem and ratiopharm sold ratio-Diltiazem in Canada. Apotex has not been reporting its sales and pricing information with respect to Diltiazem and for that reason is subject to a failure-to-file application by Board Staff similar to the one that commenced this proceeding.

53. Pursuant to the agreement between ratiopharm and Apotex, inherited by ratiopharm from Altimed (as with the agreement pertaining to ratio-Ketorolac), ratiopharm has a non-exclusive right to sell ratio-Diltiazem in Canada. In the agreement there was no reservation by Apotex of any intellectual property rights.

54. ratiopharm argued that there was no evidence that there were any intellectual property rights associated with ratio-Diltiazem; that is, no evidence that a patent pertained to ratio-Diltiazem, pointing to the fact that Apotex was a generic pharmaceutical company. Board Staff pointed to the process patent held by Apotex for the manufacturing of the medicine as the pertaining patent.

55. In the case of this medicine, there is no inference that a patent pertains to the medicine that arises out of a patentee reporting to the Board in respect of an equivalent medicine. However, the Panel is satisfied that the evidence establishes that Apotex holds a process patent with respect to Diltiazem and that, given the decision of the Federal Court of Appeal in the *ICN* case, this is sufficient for the Panel to conclude that the patent pertains to ratio-Diltiazem. Despite the fact that Apotex is a generic pharmaceutical company, it has patent rights pertaining to a medicine that it supplies to ratiopharm and permits ratiopharm to sell. For the reasons described above for the other medicines identified by Board Staff, the Panel concludes that ratiopharm is or was a patentee obliged to report sales and pricing information to the Board with respect to ratio-Diltiazem.

ratio-Simvastatin

56. The facts related to ratio-Simvastatin are similar to those relating to ratio-Diltiazem. ratio-Simvastatin is another medicine that ratiopharm acquires from Apotex and sells in Canada. Apotex holds a process patent for manufacturing the active ingredient in Simvastatin, valid from 1998 to 2014. As with Diltiazem, Apotex is not reporting to the Board regarding Simvastatin and in that regard is

subject to a failure-to-file application similar to the instant application. The agreement between Apotex and ratiopharm grants ratiopharm a license to sell ratio-Simvastatin in Canada.

57. The positions of ratiopharm and Board Staff with respect to ratio-Simvastatin were similar to those with respect to ratio-Diltiazem: ratiopharm argued that there was no intellectual property associated with ratio-Simvastatin and Board Staff pointed to the process patent pertaining to Simvastatin held by Apotex. For the reasons described above for the other medicines identified by Board Staff, and in particular ratio-Diltiazem, the Panel concludes that ratiopharm is or was a patentee obliged to report sales and pricing information to the Board with respect to ratio-Simvastatin.

ratio-Sertraline

58. Pfizer Canada sells a medicine in Canada under the brand name Zoloft, and reports to the Board with respect to that medicine. Pfizer holds a current patent for a therapeutic use of Zoloft, a patent that is registered on the Health Canada Patent Register with respect to Zoloft. Pfizer and Pharmascience have an agreement allowing Pharmascience to sell Sertraline, a medicine equivalent to Zoloft, in Canada, and to licence those rights to others. In compliance with that agreement with Pfizer, Pharmascience supplies an equivalent medicine to ratiopharm, which ratiopharm sells in Canada under the name ratio-Sertraline.

59. The agreement between Pharmascience and ratiopharm is another of the agreements that ratiopharm inherited when it merged with Altimed. It authorizes ratiopharm to manufacture, distribute and sell ratio-Sertraline in Canada.

60. Board Staff made submissions with respect to the fact that the agreement between Pfizer and Pharmascience arose out of the settlement by Pfizer and Pharmascience of an attempt by Pfizer to prevent Health Canada from granting Pharmascience an NOC for Sertraline until Pfizer's patent expired. Part of that settlement agreement includes the covenant of Pfizer not to bring patent infringement proceedings against Pharmascience or its licensees, provided that such licensees agreed to be bound by the terms of the agreement between Pfizer and Pharmascience (which ratiopharm did as part of its agreement with Pharmascience. Board Staff argued that tracing ratiopharm's rights back to a dispute over whether or not a Pfizer patent covered the medicine in question was further evidence that ratiopharm had rights in relation to the patent.

61. However, the Panel approaches this evidence with caution, first because the positions that Pfizer, Pharmascience and ratiopharm took as to whether the sale of Sertraline and/or ratio-Sertraline would infringe the patent held by Pfizer is not evidence of significant weight on the point, and second because settlement agreements and contracts often contain covenants that a party does not feel legally obliged to make, but makes in order to achieve an acceptable settlement or commercial arrangement.

62. On balance of the evidence, however, the Panel concludes that the Pfizer patent pertaining to Zoloft pertains to ratio-Sertraline and, though there is a third party (Pharmascience) in the chain by which ratiopharm is entitled to rights in relation to a patent, for the reasons given above with respect to the previously-discussed medicines, that ratiopharm is and was a patentee obliged to report sales and pricing information to the Board with respect to ratio-Sertraline.

ratio-Quetiapine

63. AstraZeneca sells a medicine in Canada with the brand name Seroquel and reports to the Board with respect to that medicine. ratiopharm obtains an equivalent medicine from AstraZeneca and markets it as ratio-Quetiapine.

64. The agreement by which AstraZeneca supplies ratiopharm with ratio-Quetiapine describes an applicable patent, and though that patent expired in 2008, AstraZeneca continues to report to the Board with respect to Seroquel as a result of a later and currently valid patent.

65. Board Staff noted that the agreement between AstraZeneca and ratiopharm grants ratiopharm the right to resell ratio-Quetiapine, and contains the same clause by which AstraZeneca supplies ratiopharm with ratio-Omeprazole, discussed above. Board Staff also notes that when ratiopharm enquired of AstraZeneca as to whether AstraZeneca was reporting to the Board with respect to the brand name versions of any of the medicines that it supplies to ratiopharm for sale as a generic medicine, AstraZeneca responded in respect of ratio-Quetiapine: “ratiopharm was granted the enumerated patent rights under the agreement to Canadian patent 1,288,428 only.” Again, however, the question of whether ratiopharm was “entitled to exercise any rights in relation” to a pertaining patent is for the Panel to determine on all of the evidence, and the parties’ characterization of the situation in the language used in agreements or correspondence is not determinative.

66. ratiopharm argues, as with the other medicines, that the agreement expressly reserves and does not transfer any intellectual property rights to ratiopharm. However, for the reasons described above for the other medicines identified by Board Staff, the Panel concludes that ratiopharm is or was a patentee obliged to report sales and pricing information to the Board with respect to ratio-Quetiapine.

The medicines for which Board Staff seeks an order for further production

67. As noted above, Board Staff did not believe that the evidence and documents produced to them with respect to two medicines was sufficient for Board Staff to decide what position to take with respect to whether or not the Board had jurisdiction regarding the two medicines. Board Staff submits that the documents provide *prima facie* evidence that the Board has jurisdiction, and request an order for further inquiries and production by ratiopharm.

68. ratiopharm opposes this request for relief, arguing that Board Staff has failed to establish that the Board has jurisdiction with respect to the two medicines and that should be the end of the matter.

69. However, it is the Panel's view that Board Staff's request is appropriate. The Panel would not characterize Board Staff's prosecution of the application to have included a failed attempt to establish the Board's jurisdiction over the medicines. Board Staff sought documents respecting every medicine sold by ratiopharm, but did not feel that the documentation with respect to two of the medicines allowed them to take a position on the Board's jurisdiction with respect to those medicines. Board Staff could have commenced a fresh application for further inquiries and information (that is, an application for an order requiring the relief sought in paragraph 2 of the Order attached to these reasons), but the Panel believes that it is efficient for both parties and the Board for the Panel to dispose of Board Staff's request now, when the evidence has been reviewed and Board Staff's request for further relief with respect to the two medicines has been debated before the Panel. The Panel sees no point in a multiplicity of proceedings when Board Staff is engaged in what is essentially an information gathering process with a view to taking a position on the Board's jurisdiction.

ratio-Fenofibrate

70. Fournier Pharma sells a medicine in Canada with the brand name Lipidil and reports its sales and pricing information to the Board. The generic equivalent medicine is Fenofibrate, which is sold to ratiopharm by Galephar Pharmaceutical. The agreement between ratiopharm and Galephar grants ratiopharm the exclusive right to make and sell ratio-Fenofibrate in Canada and to do so using

all of the intellectual property associated with ratio-Fenofibrate, including "all patents" and a long list of other types of intellectual property. What is missing is direct evidence (though there is an inference, as discussed below) that Galephar actually holds any patent rights that it can license to ratiopharm and that would be breached if ratiopharm sold ratio-Fenofibrate in the absence of its agreement with Galephar.

71. The Panel concludes that there is a very strong inference that a patent pertains to Lipidil because Fournier reports its sales and pricing information with respect to Lipidil to the Board. Given that Lipidil and ratio-Fenofibrate are equivalent medicines there is a corresponding inference that a patent pertains to ratio-Fenofibrate. Also, given that Galephar appears able to grant ratiopharm the right to make and sale ratio-Fenofibrate without objection from Fournier, there is a reasonable inference that Galephar does have patent rights, such that it can grant ratiopharm the right to make and sell ratio-Fenofibrate. The information and documentation sought by Board Staff should establish whether or not these inferences are supported by evidence that can meet the burden of proof of jurisdiction.

ratio-Tamsulosin

72. Boehringer Ingelheim Canada sells a medicine in Canada with brand name Flomax and is reporting its sales and pricing information to the Board. The equivalent generic medicine is Tamsulosin, which is sold to ratiopharm by Synthon. The agreement between Synthon and ratiopharm grants ratiopharm an exclusive licence "under the Patents" to sell ratio-Tamsulosin in Canada, the "Patents" being any patents owned by Synthon or regarding which Synthoon has the right to grant the licence to ratiopharm.

73. The Panel concludes that the same reasonable inferences described above with respect to ratio-Fenofibrate arise from these facts with respect to ratio-Tamsulosin, and that again the information and documentation sought by Board Staff should establish whether or not these inferences are supported by evidence that can meet the burden of proof of jurisdiction.

74. Board Staff sought an order requiring ratiopharm to take certain specific steps to ascertain the patent status of these two medicines and report back to the Board. The Panel agrees that a structured process in this regard is appropriate, though the attached order makes substantive changes relative to the draft order proposed by Board Staff.

The reporting of revenues and research and development expenditures

75. Section 89 of the *Act* requires the Board to report information to Parliament regarding the proportion of patentees' revenues from sales of medicine that is spent by patentees on research and development. The Board obtains this information from patentees pursuant to patentees' obligations to report the information pursuant to section 88 of the *Act*.

76. Subsection 88(1) of the *Act* provides as follows:

> **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
> (*a*) the identity of the licensees in Canada of the patentee;
> (*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
> (*c*) the expenditures made by the patentee in Canada on research and development relating to medicine.

77. Board Staff requested an order requiring ratiopharm to report in accordance with section 88 of the *Act*. ratiopharm responded with several arguments concerning the purpose of sections 88 and 89 of the *Act*, which was said to be to ensure that what is referred to as the brand name pharmaceutical industry met its commitment to make a substantive investment in research and development in exchange for the extended patent protect provided by the 1987 amendments to the *Act*. ratiopharm argues that the *Act* should not be interpreted to cover what it referred to as the "generic pharmaceutical industry", and notes that all of its research and development expenditures pertain to generic (that is, non-patented) medicines.

78. The Panel has three difficulties with ratiopharm's position: (1) the clarity of the language in the *Act*, and (2) the lack of clarity in expressions such as "the generic pharmaceutical industry"; and (3) the policy expressed in the *Act* of obtaining this information from "patentees", which the Panel has concluded includes a company in the position of ratiopharm with respect to the medicines discussed in these reasons.

79. The language of subsection 88(1) is clear and does not distinguish between patentees that are brand-name pharmaceutical companies and patentees that are generic pharmaceutical companies holding patents or entitled to rights in relation to patents.

80. The reference in paragraphs 88(1)(*b*) and (*c*) to "medicine" is clear and quite certainly a purposeful distinction from "patented medicines". This applies equally to patentees whether they might tend to be characterized as being in the brand name pharmaceutical industry or the generic pharmaceutical industry, and whether their research and development relates to patented or non-patented medicines.

81. Furthermore, 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 conducive 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.

82. The Board takes a purposive approach to the interpretation of its *Act*. With respect to the policy behind sections 88 and 89, a company that sells medicines regarding which it is entitled to rights in relation to patents is participating in the industry that Parliament has regulated with the patented medicines provisions of the *Act*. The Panel does not agree with ratiopharm that a company in its position is not caught by the intent of sections 88 and 89.

83. ratiopharm raised a point that the Panel would describe as a legitimate but non-legal concern with the prospect of generic companies reporting research and development expenditures. The concern was that this would artificially inflate the amounts that Parliament would perceive the brand name companies to be expending on research and development. Board Staff has proposed a practical way to address this concern: the figures for companies that might reasonably be labelled part of the "generic" component of the industry will be broken out and reported as such to Parliament.

The constitutionality of the Board's jurisdiction over ratiopharm

84. This Panel disposed of ratiopharm's constitutional challenge to the provisions of the *Act* as they pertain to the Board in the ratio-Salbutamol Decision.

Conclusion

85. For the reasons above, the Panel makes the Order attached hereto requiring ratiopharm to report to the Board pursuant to sections 80, 81 and 88 of the *Act* respecting the medicines and dosage forms listed therein, and to provide a report to the Board with respect to ratio-Fenofibrate and ratio-Tamsulosin as stipulated in the Order.

Board Members: Dr. Brien Benoit
Anne Warner La Forest

Board Counsel: Gordon Cameron

Appearances

Board Staff:	David Wilson, Counsel Leslie Milton, Counsel Marisa Victor, Counsel
For the Respondent:	Gavin MacKenzie, Counsel Benoit Duchesne, Counsel Judith Parisien, Counsel

Original signed by

Sylvie Dupont
Secretary of the Board

Appendix "A" to PMPRB-08-D3-ratiopharm – Reasons of the Board, June 30, 2011 Statutory Provisions Related to Filing Requirements

PATENT ACT

INTERPRETATION

Definitions

2. In this *Act*, except as otherwise provided, "patentee" means the person for the time being entitled to the benefit of a patent;

GRANT OF PATENTS

Contents of patent

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.

INFRINGEMENT

Liability for patent infringement

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.

INTERPRETATION

Definitions

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;

PRICING INFORMATION

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 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;
(*d*) the factors referred to in section 85; and
(*e*) any other related matters.

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

(*a*) the identity of the medicine;
(*b*) the price at which the medicine was sold in any market in Canada and elsewhere during the period in which the person was a patentee of the invention;
(*c*) the costs of making and marketing the medicine produced during that period, whether incurred before or after the patent was issued, where that information is available to the person in Canada or is within the knowledge or control of the person;
(*d*) the factors referred to in section 85; and
(*e*) any other related matters.

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.

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.

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.

Limitation

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

SALES AND EXPENSE INFORMATION

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

(*a*) the identity of the licensees in Canada of the patentee;
(*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
(*c*) the expenditures made by the patentee in Canada on research and development relating to medicine.

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.

Compliance with order

(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.

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*.

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.

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).

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.

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.

PATENTED MEDICINES REGULATIONS, 1994[1]

INFORMATION RESPECTING THE IDENTITY AND PRICE OF MEDICINES

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

[1] The *Patented Medicines Regulations, 1994*, now the *Patented Medicines Regulations*, were amended in 2008 and are available at http://laws-lois.justice.gc.ca/eng/acts/P-4/index.html

(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.

(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.

(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. (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 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;
(*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);
(*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);
(*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).

(2) The information referred to in 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.

(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.

(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.

(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.

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

REVENUES AND RESEARCH AND DEVELOPMENT EXPENDITURES

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

(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.

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

(*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*;
(*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
(*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.

(4) For the purposes of paragraph (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.