August 1, 2012 **Decision: PMPRB-10-D2-SANDOZ - Merits**

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

AND IN THE MATTER OF Sandoz Canada Inc. (the "Respondent")

Introduction and Overview

1. This proceeding was commenced by a Notice of Application (the "Application") issued by the staff of the Board ("Board Staff") in which Board Staff sought an order pursuant to sections 81 and 88 of the *Patent Act* (the "Act") requiring the Respondent, Sandoz Canada Inc. ("Sandoz") 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").

2. The Board regulates the maximum average price at which patented medicines may be sold in Canada. The information that Board Staff believes Sandoz is obliged to file relates primarily to the average prices at which Sandoz has sold medicines that Board Staff allege are patented medicines. In the normal course, Board Staff would analyze this information to determine whether the medicines in question have been sold at "excessive" prices, in the sense of that term in the Act.

3. There is no issue in this proceeding as to whether the pricing of any medicine sold by Sandoz is or has been excessive. The only issue is whether Sandoz is obliged to file the information that would enable Board Staff to form an opinion on that point. If this panel of the Board (the "Panel") orders that the information in question be filed and if Board Staff, on reviewing the information, forms the opinion that none of the medicines in question is or has been excessively priced during the periods in question, that will be the end of the matter insofar as those medicines and the periods in question are concerned.

4. However, if Board Staff forms the opinion that any of the medicines are or have been excessively priced, discussions likely will ensue between Board Staff and Sandoz. If no resolution of the matter is reached, Board Staff will ask the Chairperson of the Board to commence a proceeding so that the matter can be considered by a panel of the Board. If, on reviewing the information presented by Board Staff, the Chair decides that such a proceeding is in the public interest, the Chair will appoint a panel

of the Board and a hearing will ensue, in which the question of whether or not the medicine is or has been excessively priced will be examined.

5. Only a “patentee” of an invention pertaining to medicine, as defined in the Act, is obliged to file the information in question, and price their medicines in accordance with the Act.

6. Section 2 of the Act provides the general definition of “patentee” as "the person for the time being entitled to the benefit of a patent". This is not, however, the definition that is specific to persons who are required to provide the information in question to the Board.

7. Subsection 79(1) of the Act provides a specific definition of “patentee” for those who are subject to the jurisdiction of the Board; that is, patentees in respect of inventions pertaining to medicines. The definition begins with the wording of section 2, and then expands on the category of persons who are patentees for the purposes of the Board’s jurisdiction:

> “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;

8. Subsection 79(2) then provides that, for the purposes of subsection 79(1) and sections 80 to 101, "an invention pertains to a medicine if the invention is intended or capable of being used for medicine".

9. Board Staff takes the position – and has the burden of establishing – that Sandoz is a person “entitled to the benefit of” and/or “entitled to exercise any rights in relation to” certain patents that pertain to medicines, and is thus a patentee within the expanded definition of patentee in subsection 79(1) of the Act. The position of Board Staff is that Sandoz is a patentee with respect to five patented medicines. Hence Board Staff seeks the sales and pricing information required to be filed by such a patentee.

10. Sandoz does not, so far as the Panel is aware, hold any patents, and Board Staff does not allege otherwise. The position of Board Staff may be summarized as follows: Sandoz is a wholly owned subsidiary of Novartis Canada Inc., which is itself a wholly owned subsidiary of Novartis AG. Novartis AG holds the patents in question, either directly or through other subsidiaries that it owns or controls. Novartis Pharma AG, also a wholly owned subsidiary of Novartis AG, holds most or

all of the patents owned by the Novartis Group. Novartis AG mandates and authorizes Sandoz to sell medicines in Canada, including medicines to which patents held directly or indirectly by Novartis AG pertain. These sales would be actionable patent infringement but for this authorization. Therefore Sandoz is a "patentee" within the meaning of that term in subsection 79(1) of the Act because it is "entitled to the benefit" of and/or is "exercising any rights in relation to" those patents.

11. Board Staff argues that this position is supported both by the plain meaning of subsection 79(1) and by the purpose of the Act: if a patentee such as Novartis AG would be subject to the Board's jurisdiction if it directly sold a patented medicine in Canada, it cannot avoid the Board's jurisdiction simply by creating a wholly-owned or controlled subsidiary through which the medicine is sold.

12. At this point some background is in order. In two previous cases, a panel of the Board was called on to interpret subsection 79(1)[1] [footnote proper names of ratio-salbutamol and ratiopharm jurisdiction cases]. In those cases, Board Staff argued that although (as in this case) the alleged patentee, ratiopharm Inc., did not hold any patents, the commercial agreements between the patent holders and ratiopharm, in the context of the pharmaceutical distribution chain, brought ratiopharm within the ambit of the definition of "patentee" in subsection 79(1). The panel hearing those cases agreed that ratiopharm was a person "entitled to the benefit of" or "entitled to exercise any rights in relation to" the patents in question, despite the fact that ratiopharm did not itself hold any patents pertaining to the medicines in question.

13. The instant case raises a similar, but different issue. Unlike the ratiopharm cases, the evidence in this case establishes that there are no express licenses or distribution agreements between Sandoz and a patentee (Novartis AG or otherwise) that could entitle Sandoz to the benefit of, or to exercise rights in relation to, patents pertaining to a medicine.

14. Nonetheless, Board Staff takes the position that the very relationship of Novartis AG (the ultimate parent) to Sandoz (a wholly owned subsidiary) and the manner in which the Novartis group of companies operate regarding the sale of patented medicines in Canada, bring Sandoz within the definition of patentee in subsection 79(1).

15. As to subsection 79(2), patents pertaining to medicines, Board Staff identified several drugs in respect of which it alleged that Sandoz was a patentee: Sandoz Cyclosporine, Sandoz Ondansetron, Sandoz Famciclovir, Sandoz Estradiol Derm, Sandoz Azithromycin and Sandoz-Terbinafine. As Sandoz is not filing information in relation to these medicines with the Board, the identification of these medicines was

[1] PMPRB-08-D3-ratio-Salbutamol HFA, May 27, 2011; PMPRB-08-D3-ratiopharm, June 30, 2011

at the time of the Application tentative. By the time of final argument Board Staff was satisfied that Sandoz Ondansetron did not belong on the list.

16. Sandoz takes the contrary position. It notes that Sandoz does not own any patents, is not the express licensee of any patents and should not be considered the implied licensee of any patents. Sandoz notes that Novartis AG has expressly licensed its patents to Novartis Canada Inc., and argues that this contradicts the proposition of Board Staff that the corporate relationship and manner of dealing with the patents and the medicines between Sandoz and Novartis AG makes Sandoz a patentee within the meaning of subsection 79(1). Sandoz notes that it has never behaved like a patent holder or licensee in any way, including the fact that it has never sued anyone for patent infringement or alleged that anyone is infringing a Novartis patent.

17. With respect to the subsection 79(2) and the question of whether any of the patents identified by Board Staff pertain to the medicines in question, Sandoz provided several arguments as to why they did not. These are summarized later in these reasons.

18. Sandoz also challenges the constitutionality of the provisions of the Act that established the Board insofar as Board Staff attempt to apply them in the context of the generic drug industry.

19. It is a fair generalization to say that the pharmaceutical industry is divided between "research-based" (or "name brand") companies that focus on research activity aimed at the development and marketing of new, typically patented medicines, and "generic" companies that typically focus on marketing medicines that have come off-patent.

20. These are not however, water-tight categories. Some "generic" companies hold patents. Some "brand name" companies participate in the generic market by licensing or making similar arrangements with arms-length generic companies to market generic versions of their patented medicines. Some companies, such as Novartis AG, participate in the generic markets both through arrangements with arms-length parties and through affiliates. In the case of Novartis AG, its Sandoz group of subsidiary companies is used for its primary participation in markets for generic medicines.

21. Sandoz is a "generic" drug company; that is, the type of pharmaceutical company that typically sells medicines when the medicines have come off patent. Sandoz does not argue that a generic drug company cannot be a patentee. Indeed, Sandoz once held a patent and when it did so it filed the requisite sales and pricing information with the Board. However, Sandoz argues that, among other things, its status as a generic drug company is relevant to a purposive interpretation of the Act,

and subsection 79(1) in particular, because the purpose of the Act (Sandoz argues) is to control the prices of patented medicines sold by name brand companies and not to control the prices of patented medicines sold by generic drug companies.

The Issues

22. Though the evidence and arguments were voluminous, the issues in the case are quite narrow. The parties agreed that there are two issues before the Panel:

    i. Is Sandoz a patentee within the meaning of subsection 79 of the Act, such that it has reporting obligations with respect to its sales of patented medicines?

    ii. Are the sections of the Act that established the Board constitutional insofar as they are sought to be applied to (as Sandoz describes itself) "a reseller of therapeutically equivalent generic medicines as a second or subsequent market entrant in a provincially price-regulated, competitive market"?

The Evidence

23. The evidence in this proceeding was by way of production, affidavits and cross-examination on the affidavits.

Board Staff presented the affidavits of three witnesses:

a. Ginette Tognet, a senior member of Board Staff, provided evidence on the manner in which the Board operates, the corporate relationship between Novartis Canada Inc. and Sandoz, the relationship of Sandoz to patents alleged to pertain to the medicines in question, and the fact that Sandoz was not filing patentee information with the Board;

b. Daniel Sher, a patent agent, provided evidence on the manner in which each of the patents in question "pertains" to a medicine being sold by Sandoz in Canada; and

c. Dr. Richard Schwindt, an economist, replied to evidence tendered by Sandoz regarding how generic companies hold patents and participate in the market.

24. Board Staff also examined (under the authority of a subpoena issued by the Board) a representative of Novartis Canada Inc., its Associate General Counsel Thea Discepola, and obtained documents (pursuant to a Board order) from Sandoz and Novartis Canada Inc.

25. Sandoz presented the affidavits of three witnesses:

    a. Christian Danis responded primarily to the affidavit of Ms. Tognet, addressing matters such as the corporate structure and relationships between Sandoz, its affiliates and their parent;

    b. Leonard Arsenault responded primarily to the evidence of Mr. Sher regarding the connections between the patents and the medicines in question; and

    c. Dr. Jonathan Putnam, an economist, who discussed the purpose of the patented medicine price regulation provisions of the Act and whether Sandoz should be considered a patentee within the meaning of subsection 79(1) of the Act.

26. With great respect to the effort that the parties put into this evidence, and the credentials of the witnesses, the Panel did not find that it needed or ought to rely on the opinion portions of the evidence of the second and third of each parties' witnesses; that is, the evidence as to whether (i) the patents in question pertained to the medicines in question; and (ii) whether generic pharmaceutical companies have or exercise market power.

27. In terms of whether the patents in question pertain to the medicines at issue, the Panel was able to come to the conclusions outlined in these reasons without relying on any expert (or putative expert) opinions. This matter is discussed in greater detail later in these reasons.

28. As to whether generic pharmaceutical companies have or exercise market power, we refer to the case of *ICN Pharmaceuticals*. Market power has been addressed in several Board and Federal Court decisions since. The conclusions are as follows:

    a. The jurisdiction of the Board to regulate the price of patented medicines is premised on the potential that a patentee could exercise market power and thereby charge excessive prices for a patented medicine;

    b. However, the only finding that the Board must make in order to have jurisdiction over the price of a medicine is that a patent pertains to the medicine;

c. The Board is not required to determine whether, in the case of a particular patented medicine for a particular period of time, the patentee had and/or was exercising market power such as would have allowed the patentee to influence the pricing of the medicine;

d. The Act contains no such requirement and the Courts have not purported to impose it;

e. Such a requirement would create an onerous, and likely often impossible, burden for Board Staff to meet; and

f. Such a requirement could call for expertise that the Board does not have.

29. The Act does not differentiate between generic patented medicines and brand name patented medicines. The only concept in the Act relevant to this discussion is that of a patent for an invention pertaining to a medicine. The Panel can see no reason why the discussion above regarding market power would not apply equally to generic patented medicines and brand name patented medicines. Once a person is a patentee of a patent that pertains to a medicine, that person has the potential to exercise market power in relation to that medicine and potentially charge excessive prices whether the medicine is generic or brand name. As noted above, some generic pharmaceutical companies hold patents and some brand name companies sell generic medicines that are protected by patents.

30. Accordingly, having considered the evidence and argument in relation to the opinions in the affidavits and cross-examinations of Messrs. Sher, Schwindt, Arsenault and Putnam, these reasons will focus on the facts in the evidence of those witnesses and in the evidence of Ms. Tognet and Mr. Danis.

Discussion

(i) Is Sandoz a Patentee Within the Meaning of s. 79 of the Act.

(a) Is Sandoz Entitled to a Benefit or Rights in Relation to Patents?

31. This case is primarily one of statutory interpretation. There were relatively few facts in dispute. The question of statutory interpretation is whether the corporate relationship of Sandoz to, and its manner of dealing with, its parent and its parent's affiliates (those who uncontentiously could be "patentees" within the meaning of subsection 79(1) of the Act), makes Sandoz itself a patentee within the meaning of subsection 79(1) of the Act.

32. Sandoz took the position that (a) it cannot be; and (b) it is not, a patentee within the meaning of subsection 79(1) of the Act. The submissions of Sandoz on the interpretation of subsection 79(1) included a very extensive discussion of its

individual words and phrases, including those in the French version of the Act. Without attempting to do justice to the comprehensiveness of the submissions, the Panel observes that the thrust of the position is that a company in the position of Sandoz, holding neither patents nor licenses to patents, cannot be said to have the benefit of, or to be able to exercise any of the rights in relation to, patents. Sandoz adds that it would not be in a position to exercise any market power or have any impact on the market such as might engage the purposes for which the Board was created.

33. Sandoz further argued that its status as an ultimately wholly-owned subsidiary of Novartis AG could not, on its own, give rise to "patentee" status in relation to patents held directly or indirectly by Novartis AG. Sandoz argued that it is incorrect to imply a grant of "rights in relation to" a patent from the patent holder to a subsidiary in the absence of an agreement to that effect or conduct that implies such a grant. Sandoz notes (and Board Staff does not allege otherwise) that there are no agreements between Sandoz and any Novartis company regarding any patents.

34. Sandoz emphasized, correctly in the Panel's view, that the question before the Panel was not, as Board Staff sometimes discussed it in oral argument, whether Sandoz was, in the course of selling patented medicines, receiving benefits in relation to patents, but whether it was entitled to benefits, or to exercise rights, in relation a patent.

1. Approach to Interpretation

35. Both parties agreed that the Panel must take a purposive approach to the interpretation of the Act, and of subsection 79(1) in particular. The submissions of Sandoz on this topic were comprehensive and Board Staff did not disagree with most of either the factual or legal propositions that were asserted by Sandoz.

36. Sandoz repeated numerous times that it did not hold patents and was not a licensee of patents, that it received medicines in finished form on the same terms as those same medicines were supplied to other, arms-length, parties. Board Staff argued, however, and the Panel agrees, that a very large part of the submissions of Sandoz were simply not material to the question before the Panel. Board Staff could concede all of the factual assertions and most of the legal analysis (though not the conclusions) of Sandoz and maintain its position that Sandoz is a patentee within the meaning of subsection 79(1) of the Act.

37. An important consideration in a purposive interpretation of the Act is an examination of the purpose and mandate of the Board. This requires a brief discussion of the structure of the Act. There is a balance inherent in (a) the patent-granting provisions of the Act; and (b) the provisions of the Act that created the Board.

The patent-granting provisions of the Act are intended to give patent-based monopoly protection for inventions, including those pertaining to medicines. The provisions within the Act that created the Board, on the other hand, are intended to ensure that those monopoly rights, insofar as they apply to inventions pertaining to medicines, cannot be used to price the medicines excessively. Indeed, the Board was created in conjunction with the granting of enhanced patent protection to patentees. Both aspects of the Act benefit consumers of medicines, in the sense that the patent-granting provisions encourage the development of new and/or improved medicines, and the pricing provisions protect consumers from excessive prices for those medicines.

38. Accordingly, and as was noted by the Federal Court of Appeal in the *ICN Pharmaceuticals*[2] ("*ICN*") case, and confirmed more recently by the Supreme Court of Canada in the Celgene case[3], the Board has a "consumer protection" mandate.

39. If the position of Sandoz is found to be correct, the provisions of the Act that created the Board could be easily evaded and consumers would not be protected from excessive prices for patented medicines. A holder of a patent that pertains to a medicine would need only to incorporate a wholly-owned or controlled subsidiary through which it sells the patented medicine in order to evade the application of the Act. In such a scenario, as the patent holder would not be selling the medicines, it likely could be outside the jurisdiction of the Board.[4] Further, the subsidiary holding neither patents nor express licenses nor agreements in relation to the medicines, would also be outside the jurisdiction of the Board. The mere use of a subsidiary of the patent holder for sales of the medicine would defeat the jurisdiction of the Board.

40. The question for the Panel is thus whether the words of the Act reasonably can bear an interpretation that implements its purpose. If so, the position of Sandoz cannot prevail.

2. Is Sandoz Receiving a Benefit or Exercising Rights?

41. In submissions that are much more elaborate than their description here, Sandoz argued that a subsidiary does not direct its parent and this subservient status leads to the conclusion that it cannot be "entitled" to benefits from, or to exercise rights in relation to, patents held by its parent or affiliates. Sandoz, as a subsidiary, could not order its parent or affiliates to grant Sandoz rights or permissions to sell medicines in

[2] *ICN Pharmaceuticals Inc. v. Canada (Patented Medicine Prices Review Board),* [1997] 1 F.C. 32 (FCA)
[3] *Celgene Corp. v. Canada (Attorney General), 2011 SCC 1*
[4] The Panel does not purport to preclude an argument that the Board should "pierce the corporate veil" and find that a parent is selling a medicine through the actions of its subsidiary.

Canada. Sandoz has no contractual rights to insist on the delivery of, or the right to sell, medicines to which its parent's or affiliates held pertaining patents.

42. The Panel agrees that a subsidiary company stands in a subservient status relative to its parent, but disagrees with the conclusions that Sandoz posits as the consequence that flows from that relationship. In support of its reasons, the Panel utilizes two extracts from the submissions of Sandoz, in which the evidence concerning the operating relationship between Sandoz and Novartis AG (and its affiliates) is discussed.

43. First, Sandoz led evidence that its interests and those of its parents and/or affiliates were not aligned, in the sense that there was competition among each of them to maximize their profits. Sandoz, accurately reflecting the evidence in this case, stated in its written argument (emphasis added):

> 13. The relationship between the companies in Canada is adversarial, each company pressing for the state of affairs that best suits its interests. <u>The Novartis patent holders do not permit Sandoz Canada to enter the market until other companies have entered the market for a given product.</u> This is for the simple reason that brand profits far outstrip generic profits in every case and so it will always be in the overall interests of the group to maintain exclusivity against all companies, including Sandoz Canada for as long as possible. Even the loss of a few days' profits is an extraordinary event that Novartis Pharmaceuticals Canada takes very seriously.
> …
>
> 68. The evidence before this Panel establishes the corporate practice of Novartis is <u>not to authorize Sandoz Canada</u> to launch a Novartis product until there are other generic companies on the market.

44. While the Board would disagree with the description of the relationship among Sandoz, its parent and other affiliates as "adversarial", these summaries of the evidence contained in the argument of Sandoz make the very case that Board Staff presented to the Panel. The Novartis parent/patent holders tell Sandoz, a wholly owned subsidiary, when it is to enter the market. The fact that those patent holders wait until they have maximized profits before telling Sandoz to enter the market – a sound business strategy for the Novartis group of companies – does not detract from the fact that the Novartis patent holders then instruct Sandoz to do so.

45. In effect, Novartis AG says to Sandoz and its other affiliates: "when the licensed affiliate has fully exploited the brand name market and generics start to appear, such that it is timely for Sandoz to enter with a generic, that is what Sandoz is to do."

46. The Panel is of the view that the wording of subsection 79(1) of the Act does bear an interpretation that implements the purpose of the Act. The question is, as Sandoz correctly framed it, whether Sandoz, despite being a subsidiary and thus subservient to the patent holder, can be said to be "entitled" to the benefit of, or to exercise rights related to, the patents held by its parent or a controlled affiliate of its parent.

47. It can be observed that Sandoz is not, merely by being a subsidiary of a patent holder, "entitled" to the benefit of, or any rights relation to, the relevant patents because the patents are held by its parent or a company controlled by its parent. Sandoz could not simply identify a patent held by Novartis AG and insist on exercising rights in relation to that patent.

48. However, as discussed below, the evidence in this proceeding established that the very reason that Novartis AG operates Sandoz in Canada is to sell generic medicines, including (indeed, wherever possible), medicines regarding which Novartis AG holds pertaining patents. In these circumstances, the Panel concludes that Sandoz is indeed entitled to the benefit of, and to exercise rights in relation to, that patent: it is entitled to sell the medicine without being sued for infringement.

49. The Panel considers that it should not be the subject of serious debate that a controlled subsidiary with instructions from its parent to sell a medicine to which the parent's (or a company controlled by the parent) patent pertains, exercises rights in relation to that patent when it follows such instructions, whether this is referred to as an "implied license" (which is a fair characterization) or not.

50. In particular, if Sandoz, complying with a mandate established by its parent Novartis AG were to sell a medicine for which Novartis AG held (directly or through a controlled affiliate) a pertaining patent, and then was sued by Novartis AG for infringement, Sandoz would have a complete defence—as complete as the defence of an express licensee. In its defence, Sandoz would say "The plaintiff is our parent and one of the very purposes for which the plaintiff established us was to sell medicines protected by the plaintiff's patents. We had the permission from, the direction from, and indeed were caused by the plaintiff, which completely controls us, to sell the medicine."

51. In other words, as Board Staff framed the point in their argument, once Novartis AG (or its controlled affiliate or the licensee of the patent) instructs Sandoz to enter the market, by general or specific mandate, to sell a medicine to which the patent(s) in question pertains, Sandoz is an implied licensee of the patent and is entitled to all of the benefits and to exercise all of the rights of an express licensee.

52. The fact that this arrangement – effectively an implied license – is accomplished through corporate control and a business model (a manner of operating and

marketing through parent and affiliates) and not by an express license does not diminish the significance of the benefits and rights that accrue to Sandoz nor qualify the sense in which Sandoz is a "patentee" within the definition of that term in subsection 79(1) of the Act.

53. A second item of evidence strongly supports this conclusion. The annual report filed in 2010 by Novartis AG with the Securities and Exchange Commission ("SEC") in the United States contains a detailed description of the manner in which Novartis AG participates in the generic market[5]. Novartis AG is the ultimate parent company of a large network of subsidiaries and affiliates. Novartis Pharma AG, a wholly owned subsidiary of Novartis AG, holds most or all of the patents owned by the Novartis group. The whole discussion of the "Sandoz Division" of Novartis AG in the SEC filing is instructive, but the following excerpt is particularly apposite (emphasis added):

> **SANDOZ**
>
> Our Sandoz Division is a world leader in developing, manufacturing and marketing generic pharmaceutical products, follow-on biopharmaceutical products and drug substances that are not protected by valid and enforceable third-party patents. As of December 31, 2009, affiliates of the Sandoz Division employed 23,423 full-time equivalents associates worldwide in more than 130 countries. In 2009, our Sandoz Division achieved consolidated net sales of $ 7.5 billion, 17% of the Group's total net sales.[…]
>
> **Intellectual Property**
>
> Wherever possible, our generic products are protected by our own patents. Among other things, patents may cover the products themselves, including the product's active substance and its formulation. Patents may also cover the processes for manufacturing a product, including processes for manufacturing intermediate substances used in the manufacture of the products. Patents also may cover particular uses of a product, such as its use to treat a particular disease or its dosage regimen. It is our policy to seek the broadest possible protection for significant product developments in all major markets. […]

54. The Panel finds two points from this excerpt to be useful in understanding the manner in which Sandoz operates in the Novartis group of companies. First, the

[5] Exhibit F to the affidavit of Ginette Tognet, page 64f

products that the Sandoz Division is said to be marketing are those that are not protected by "third party" (i.e. non-Novartis) patents. Second, wherever possible, the Sandoz generic products are protected by Novartis AG patents.

55. The business model of Novartis AG is to use its Sandoz Division to market, wherever possible, generic medicines that are protected from competition by the existence of Novartis AG patents. This is an understandable business model: Novartis AG participates actively in the growing generic market but, to the extent possible, it does so with patent protection. Understandably, Novartis AG is not shy about this business model because it enhances its competitive position in the generic market and thus improves its likelihood of success and profits in that market. Its SEC filing assures investors that even its generic Sandoz business obtains the maximum possible patent protection from Novartis AG patents.

56. The Panel believes that it is precisely the mandate of the Board to protect Canadians from the risk of the excessive pricing of patented medicines in this type of situation.

57. For these reasons, the Panel concludes that Sandoz is a patentee, within the meaning of subsection 79(1) of the Act, of any patent owned directly or indirectly by Novartis AG, where that patent is for an invention pertaining to a medicine that Sandoz is authorized by its parents to sell in Canada.[6]

(b) Do the patents in question pertain to medicines sold in Canada by Sandoz?

1. Approach to the Evidence Submitted by the Parties.

58. Following disclosure and examinations on affidavits, Board Staff took the position that, with respect to the following five medicines, Sandoz was the patentee of thirty-two pertaining patents:

- Sandoz Cyclosporine (the 827, 091, 509, 792, 018, 963, 150, 775 and 933 patents);
- Sandoz Famciclovir (the 503, 376, 383, 462, 268, 756, 238, 505 and 392 patents);
- Sandoz Azithromycin (the 639 and 007 patents);
- Sandoz Estradiol (the 660, 914, 530, 170, 132 and 384 patents); and

[6] While the burden of establishing each element of its case is on Board Staff, on the question of whether Sandoz is authorized by its parents to sell a medicine in Canada, in the absence of evidence to the contrary, the Panel considers this burden to be met when it is shown that Sandoz is in fact selling the medicine in Canada without evident objection from its parent companies.

- Sandoz Terbinafine (the 229, 341, 957, 651, 971 and 919 patents).

59. Board Staff had also investigated the connection between Sandoz and a sixth medicine, Ondansetron, but concluded that the patent that Board Staff believed to pertain to that medicine was not held by an affiliate of, nor was expressly or impliedly licensed to, Sandoz. Accordingly Board Staff did not seek an order in relation to Sandoz and the medicine Ondansetron.

60. Sandoz, while maintaining other defenses in relation to Famciclovir, acknowledged that the 756 and 503 patents pertained to Famciclovir.

61. In the case of all but five[7] of the patents that were alleged to pertain to the medicines in question, Board Staff provided the affidavit evidence of Daniel Sher, a patent agent, regarding the "rational connection or nexus" (to use the term from *ICN*) between the patents and the medicines. Mr. Sher, who has qualifications both as a chemist and a lawyer/patent agent, provided two types of evidence in his affidavit: (a) scientific information relating the information on the product monographs and the patents in question (the rational connections between the inventions described in the patents and the associated medicines); and (b) opinions as to whether in each case these connections resulted in a conclusion that the invention described in the patents pertains to the associated medicines.

62. On the question of the connection between the relevant patents and medicines, Sandoz provided the affidavit of Mr. Arsenault, who is the Vice President, Scientific Affairs, of Sandoz. Originally an executive with Rhoxal Pharma Inc., since acquired by Sandoz, he has had extensive involvement with the regulatory and patent support work of Sandoz. As an employee of Sandoz, and without qualifications (other than his extensive career experience) that would qualify him to provide other than relevant facts, Mr. Arsenault was not an independent or expert witness. His affidavit properly, in the Panel's view, purported to refrain from providing opinion evidence on the question of whether or not a given patent pertained to a given medicine. However, the Panel found his evidence on this point, in his affidavit and in the cross-examination on that affidavit to cross the boundary he purported not to cross. Other than the factual information that he provided, the Panel did not put any weight on the evidence of Mr. Arsenault with respect to the question of whether or not patents pertained to medicines.

63. As alluded to earlier in these reasons, the Panel is of the view that the question of whether or not a given patent describes an invention that pertains to a medicine[8] is

[7] For Famciclovir, the 505 and 392 patents; for Cyclosporine the 150, 775 and 933 patents.

[8] It is common to use compressed expressions such as whether a "patent pertains to a medicine". This captures the intermediate concept of a patent being for an "invention", and thus incorporates the language in the definitions in

one for the Panel to decide. Accordingly, the Panel has not placed any weight on Mr. Sher's or Mr. Arsenault's opinion on the legal question of "whether the patent pertains" to the medicine in question.

64. The Panel is assisted by Mr. Sher's evidence regarding the facts providing the connection or nexus between the patents in question to the medicines in question. However, and without disrespect for Mr. Sher's qualifications, the Panel is able to draw the same conclusions that he draws – albeit more laboriously – by examining the exhibits to his affidavit, principally the product monographs for the medicines in question and copies of the actual patents said to pertain to those medicines.

65. This should not to discourage Board Staff and patentees from leading this type of evidence, because it truly is of assistance to have, for example, a person with qualifications as a chemist and a patent agent, walk a panel through the polysyllabic and often abstruse scientific language of the patents and link the elements of the patents to the particulars of the medicines in issue. The Panel merely wishes to note that it did not need to rely on this evidence to reach its own conclusions on the documents to which Mr. Sher referred, and the conclusions that could be drawn from them.

2. The Test to Assess Whether a Patent Pertains.

66. Subsection 79(2) of the Act provides as follows:

> (2) For the purposes of subsection (1) and sections 80 to 101, an invention pertains to a medicine if the invention is intended or capable of being used for medicine or for the preparation or production of medicine.

67. The scope and application of this test, and its interpretation in the case law (most particularly the *ICN* case) were the subject of extensive written and oral submissions by the parties. These reasons will discuss the jurisprudence related to this provision of the Act, but two preliminary points are evident from the wording of the subsection itself.

68. First, an invention pertains to a medicine if it is "intended" or "capable" of being used. What is plainly <u>not</u> required is that a patent have been used or be in use. This is because the mere holding of a patent prevents others from exploiting the invention that it describes, and this could be to the advantage of the patentee. The patent

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section 2 of the Act, the language of subsection 79(1) ("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 subsection 79(2) ("…an invention pertains to a medicine if the invention…)

might prevent a competitor from developing a medicine that is competitive with another medicine that the patentee markets or could market.

69. Second, in this subsection the intention or capability of the invention is stated to be related to "medicine", not "*the* medicine". The wording of the subsection – the transition from "a medicine" to "medicine' – suggests that there must be a nexus or rational connection between the patent and the medicine in question, but that the connection need not be that the patent is intended or capable of being used to produce the very medicine that is being sold by the patentee.

70. Turning to the relevant jurisprudence, and the leading case of *ICN,* the Panel considers it fair to begin by observing that Board Staff's submissions relied heavily on the test established by *ICN*, whereas Sandoz, for the most part, argued that the test was wrong or should be interpreted in ways that, in the Panel's view, would effectively require the Panel to disregard *ICN*.

71. In *ICN*, the Federal Court of Appeal noted the very broad language of subsection 79(2) and the consumer protection mandate of the Board and held that a relatively modest degree of connection between the patent and the medicine ("the merest slender thread") was sufficient for the conclusion that the invention described in the patent pertained to the medicine in question.

72. *ICN* provided at least six important conclusions about the manner of determining whether or not the invention described in a patent pertains to a medicine:

    a. There must be a "rational connection or nexus" between the invention and the medicine;

    b. The connection between the invention and the medicine can be one of the "merest slender thread";

    c. In ascertaining whether there is a connection between the invention and the medicine, the Board should not go beyond the face of the patent (such as by engaging in patent or claims construction or infringement analysis);

    d. There is no requirement that the invention actually have been used or be in use (in relation to the medicine or otherwise) for there to be a connection between the invention and the medicine;

    e. The rational connection between a patent and a medicine can be the medicine itself; and

    f. There is no requirement that the patent provide any market power or monopoly to the patentee – the existence of the patent creates a presumption of market power, which is all that the statute requires.

73. Sandoz attempts to distinguish or challenge *ICN* on several grounds. The first ground of distinction is that ICN was holder of the patent whereas Sandoz is not a patent holder. The Panel recognizes this distinction, but considers it to be irrelevant to the issues in this proceeding. The fact that in *ICN* the patentee was the patent holder (as opposed to otherwise being within the definition of "patentee") was not at all relevant to the findings of the Federal Court of Appeal on the issues that arise in this proceeding. The Panel does not consider it appropriate to distinguish between patentees who are patent holders and persons who are otherwise within the definition of "patentee". The Panel considers the Act to apply with equal force to any entity that falls within the definition of patentee in subsection 79(1) of the Act.

74. Second, focusing on the conclusion of the Federal Court of Appeal that the Board need not conduct a detailed analysis of the patent beyond its face, Sandoz argued that:

> The Federal Court of Appeal was not called upon to conduct a more detailed review, because "on the face of the patent" the pharmaceutical end products of the inventions in those patents monopolized important aspects of making and using ribavirin, the only active ingredient in the medicine being sold by ICN in Canada.

75. This argument is not consistent with the detailed reasoning of the Federal Court of Appeal as to why it was not appropriate for the Board to go beyond the face of the patent when determining if the patent pertained to the medicine. The position taken by Sandoz simply does not engage the careful and emphatic reasoning of the Federal Court of Appeal on this point and so the Panel does not consider this argument to have any force.

76. Furthermore, the description provided by Sandoz in the extract above is not accurate. An important aspect of the *ICN* case as it was litigated, including at the Federal Court of Appeal, and a fact that gives the *ICN* case significant force, is that one of the patents in issue in that case (the 264 patent) precisely did not monopolize an important aspect of making and using Virazole (the medicine in issue in that case). The 264 patent was not used for making Virazole and its invention could not be used to make even enough Virazole for a single dose. The 264 patent was for a method of making microscopic quantities of ribavirin (the active ingredient in Virazole) in a laboratory setting for experimental purposes. ICN argued at all levels that, for these reasons, there was no connection between the medicine in issue and the '264 patent. Despite these arguments, the Federal Court of Appeal disagreed with ICN on this point and did so forcefully, finding that even in these circumstances the wording of the Act and the mandate of the Board required the conclusion that the

patent pertained to the medicine. This demonstrates the importance and the force of the "slender thread" analysis in the decision of the Federal Court of Appeal.

As Parliament recognized in the wording of the Act, the potential for market power can arise from patents other than those required to produce the medicine in question.

77. While discussing *ICN* and the 264 patent, it can be noted here in response to another issue raised by Sandoz, for each of the medicines in question in this case, the 264 patent was manifestly not pertinent to the dosage, delivery form or use of the medicine Virazole that was being sold by ICN (or anyone).

78. On this point, the Panel considers it important to note the Federal Court of Appeal's conclusion that a given patent need not be demonstrated to provide monopoly control over the production or marketing of the particular *dosage or delivery form* of the medicine in question. The Panel considers this to have been established in *ICN*, but in addition to the reasoning in that case, it should be noted that the Board cannot know (and the question will often not be answerable) whether and to what extent the patent in question provides potential market power by keeping, or having kept, other dosage or delivery forms or variations of the medicine off the market, or delaying them from coming onto the market. (The same could have been said of the 264 patent in *ICN*: it would have been difficult or impossible to know whether the invention described in the 264 patent could have been useful to potential competitors attempting to produce small quantities of ribavirin to do tests or for some other use in the development of a competing medicine.)

79. Sandoz further argued that *ICN* had been superseded by subsequent jurisprudence at the Board and at the Supreme Court of Canada. With particular reference to the jurisprudence of the Board, Sandoz noted that in *ICN* the Federal Court of Appeal had agreed with the Board that the Board should not, and did not have the expertise to engage in the construction of claims in patents that might pertain to a medicine. Sandoz pointed out that, since *ICN*, the Board had heard many expert witnesses and was considered to be an "expert tribunal".

80. The Panel does not believe that there has been a material evolution in this regard since *ICN*. The Board remains an "expert tribunal", in the sense that its membership and experience bring knowledge and expertise beyond that held by laypersons, but this has always been the case. The ICN panel consisted of a professor of economics, a neurosurgeon and a chartered accountant. Expert witnesses were heard in the ICN proceeding before the Board. Nothing in these areas has changed. The point in *ICN* was that the Board should not be expected to come to legal conclusions regarding claims construction and infringement. The Panel continues to hold that view.

81. The post-*ICN* jurisprudence cited by Sandoz relates to patent litigation, and while the Panel does not dispute the assertions made by Sandoz with respect to that jurisprudence in the context of patent litigation, the Panel does not consider it to be relevant to the Panel's mandate and, within that mandate, the Board's consideration of patents. Indeed, it is arguable (and Board Staff did argue) that the evolution in the law of claims construction (towards more rigorous construction) makes the *ICN* reasoning apply *a fortiori*: if the Board was not expected to undertake a less rigorous claims construction process, this is even more true when the process has become more rigorous.

82. In summary, the rationale for the position taken by the Federal Court of Appeal in *ICN* remains that same today as it was in 1996: the language of the Act remains the same, the Board's consumer protection mandate remains the same and the capabilities of the Board remain the same. The scope of the *ICN* test has not been problematic. The Panel does not consider it appropriate to depart from *ICN* and does not consider *ICN* distinguishable from the facts in this case.

83. For these reasons, the Panel considers that the arguments made by Sandoz in this case to the effect that the patents identified by Board Staff did not pertain to the medicines in question – such as that no monopoly was created by the patent, that the patent was not used, or not used for the medicine, that the medicine did not infringe the patent – are unsupportable.

84. These arguments were in large measure made in response to the evidence of Mr. Sher, or at least the allegations of Board Staff that he supported concerning the connections between the patents and the medicines in question. These facts established, to the satisfaction of the Panel, both from Mr. Sher's evidence and the Panel's own review of the relevant documents to which he made reference, that in the case of each of the patents he examined and each of the medicines in question, the connection between them was the medicine itself, and was sufficient to satisfy the "rational connection" test in *ICN*.

85. With respect to the five patents that Mr. Sher did not examine in detail, the Panel was able to conclude from the relevant documents in evidence that there was a rational connection between the patents and the medicines in question; in particular, the connection was, again, the medicine in question.

(ii) Constitutionality

86. Sandoz argued that the Board's regulation of prices under sections 79-103 of the Act, and its related filing requirements are, insofar as generic pharmaceutical products are concerned, an unconstitutional extension of Parliament's authority over

patents into a sphere (property and civil rights) left to the provinces by the Constitution.

87. Among other points made by Sandoz, it was argued that generic pharmaceutical companies operate in a different environment from the brand-name pharmaceutical companies. Sandoz noted that the majority of the sales of generic pharmaceutical companies are regulated (in a sense) by provincial formularies that stipulate that the generic product must be sold at a lower price than the brand-name equivalent. Generic pharmaceutical companies tend not to depend on patent protection but, rather, challenge the patents of brand companies to enable them to compete in the market.

88. The Panel does not see any basis, in the wording of the Act or the intent of the provisions that established the Board, to distinguish between patentees that are "brand name" pharmaceutical companies and patentees that are "generic" pharmaceutical companies. When a generic pharmaceutical company, or its parent or affiliate using the generic company to market the medicine, holds a patent pertaining to medicine such that the purposes of the Act are engaged, the implications are the same as for a brand name company.

89. Accordingly, the Panel cannot accept the argument of Sandoz that the provisions of the Act are unconstitutional insofar as generic pharmaceutical companies are concerned.

Conclusion

90. For the reasons above, the Panel will issue the order attached to these reasons, and in particular will order that Sandoz file the information and documents referred to in sections 80, 81 and 88 of the Act and in sections 3, 4, and 5 of the Regulations with respect to each of the following medicines, for the periods during which any of the following patents (as they were referred to in these proceedings)were in force:

    a. Sandoz Cyclosporine (the 827, 091, 509, 792, 018, 963, 150, 775 and 933 patents);
    b. Sandoz Famciclovir (the 503, 376, 383, 462, 268, 756, 238, 505 and 392 patents);
    c. Sandoz Azithromycin (the 639 and 007 patents);
    d. Sandoz Estradiol (the 660, 914, 530, 170, 132 and 384 patents); and
    e. Sandoz-Terbinafine (the 229, 341, 957, 651, 971 and 919 patents).

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