PATENTED MEDICINE PRICES REVIEW BOARD

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")

NOTICE OF APPLICATION

TAKE NOTICE THAT Board Staff will bring an application before the Patented Medicines Prices Review Board (the "Board") for hearing on a date to be determined by the Board.

THE APPLICATION IS FOR 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 information and documents referred to in sections 80, 81 and 88 of the *Act* and in sections 3, 4, and 5 of the *Patented Medicine Regulations*, (the "*Regulations*"), on the terms set out in the Draft Order at Appendix 1.

THE GROUNDS FOR THE MOTION ARE:

1. Sandoz is a "patentee" within the meaning of subsection 79(1) of the *Act*. Sandoz is a wholly owned subsidiary of Novartis AG and as such is an express or implied licensee of Novartis patents. Sandoz is also entitled to exercise rights of all patents owned by other parties for which Sandoz has an express or implied license.

2. Sandoz has obtained Notices of Compliance ("NOC") in respect of medicines to which patents pertain including but not limited to Cyclosporine, Ondansetron, Azithromycin, Famciclovir, Estradiol, and Terbinafine.

3. Sandoz has sold or is selling patented medicines in a market in Canada, including but not limited to Cyclosporine, Ondansetron, Azithromycin, Famciclovir, Estradiol, and Terbinafine.

4. The Board has jurisdiction with respect to the pricing of any patented medicines sold in any market in Canada by Sandoz.

5. Pursuant to sections 80 and 88 of the *Act*, and sections 3, 4 and 5 of the *Regulations*, Sandoz is required to identify all medicines in respect of which Sandoz is or was a patentee, the price at which the medicines are being or have been sold in any market in Canada, information respecting the identity of any licensees in Canada, and the revenues and research and development expenditures of the patentee.

6. Sandoz has not complied with its obligations and as such, Sandoz is in breach of the reporting requirements under the *Act* and *Regulations*.

The Board's Jurisdiction

7. Board Staff's position is that the Board has jurisdiction with respect to Sandoz because:

    a. Sandoz is a patentee within the meaning of subsection 79(1) of the *Act*;

    b. in respect of inventions pertaining to medicines; and

    c. Sandoz has sold or is selling those patented medicines in a market in Canada.

8. Under subsection 79(1) of the *Act*, a "patentee" in respect of an invention pertaining to a medicine refers to the person for the time being entitled to the benefit of a patent, including any person entitled to exercise any rights in relation to that patent. The "patentee" definition is not confined to the patent owner, but includes anyone entitled to exercise any rights in relation to a patent, for example, through a licensing agreement or consent from the patent owner.

9. Under subsection 79(2) of the *Act*, an invention is deemed to pertain to a medicine if the invention is intended or capable of being used for medicine or for the production of medicine. The *Act* does not require that the patent actually be used for the medicine or for production of the medicine.

10. As set out below, Sandoz is a wholly owned subsidiary of Novartis, the owner of several patents pertaining to drug products sold by Sandoz, and as such, Sandoz is a patentee pursuant to subsection 79(1) of the *Act*.

11. Sandoz Cyclosporine, Sandoz Ondansetron, Sandoz Azithromycin, Sandoz Famciclovir, Sandoz Estradiol Derm, and Sandoz Terbinafine, among others, are medicines within the meaning of the *Act*. Sandoz is or was entitled to exercise patent rights in respect of these, and other, medicines as it has an express or implied license to at least one patent which pertains to each of these, and other, drugs.

12. Sandoz sells or has sold Sandoz Cyclosporine, Sandoz Ondansetron, Sandoz Azithromycin, Sandoz Famciclovir, Sandoz Estradiol Derm, and Sandoz Terbinafine among other patented medicines, in Canada.

13. Board Staff's position is that the Board has jurisdiction with respect to the pricing of any patented medicines sold in any market in Canada by Sandoz, including medicines sold pursuant to agreements with patent holders, as is the case with Sandoz Cyclosporine, Sandoz Ondansetron, Sandoz Azithromycin, Sandoz Famciclovir, Sandoz Estradiol Derm, and Sandoz Terbinafine. As is set out below, Sandoz has failed to provide Board Staff with this pricing information despite repeated requests.

<u>Sandoz is an Express or Implied Licensee of Novartis Patents</u>

14. Sandoz is a wholly owned subsidiary of Novartis AG ("Novartis"), a large multi-national drug company. As such, Sandoz is an express or implied licensee of all patents owned or licensed by Novartis. Sandoz is therefore entitled to exercise rights in relation to patents owned by Novartis, and therefore falls within the definition of "patentee" of all Novartis owned or licensed patents, pursuant to subsection 79(1) of the *Act*.

15. Further, Sandoz is also entitled to exercise rights and is therefore a "patentee" of all patents owned by other parties, and for which Sandoz has an express or implied license.

16. Board Staff is aware of at least six drug products sold by Sandoz which fall under the Board's jurisdiction as will be set out below. These products are Cyclosporine, Ondansetron, Azithromycin, Famciclovir, Estradiol, and Terbinafine.

17. These drug products are only examples. This Application is not limited to these drug products but extends to all drug products presently or previously sold by Sandoz and in respect of which Sandoz is or was a "patentee" under s. 79 of the Patent *Act*.

18. This Application is not limited to the patents set out below but extends to all other patents owned by Sandoz or Novartis, and to all other patents owned by third parties pursuant to which Sandoz is entitled to exercise rights, that pertain to drug products presently or previously sold by Sandoz. Other patents identified so far, and which may pertain to Sandoz drug products are listed at Appendix 2.

Sandoz' Patented Drug Products

Cyclosporine

19. Sandoz obtained a Notice of Compliance ("NOC") for a Cyclosporine product on or about October 28, 1994 and has sold a Cyclosporine product since on or about October 28, 1994 and possibly even earlier.[1]

20. Canadian Patent No. 2,224,792 (the "792 Patent") claims formulations of cyclosporin A.[2] The 792 Patent therefore pertains to the drug product Cyclosporine. The 792 Patent has a laid open date of January 3, 1997 and issued on January 7, 2003.

21. The owner of the 792 Patent is Hexal AG, (Germany). Novartis Pharmaceuticals Inc. purchased Hexal AG in 2005 and integrated it into the Sandoz division of Novartis. As such, Sandoz falls within the definition of "patentee" of the 792 Patent pursuant to subsection 79(1) of the *Act*.

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[1] Sandoz has obtained a NOC for Cyclosporine under the brand name Sandimmune on October 28, 1994, under the brand name Sandimmune Neoral as of January 13, 1995 as well as under the brand name Neoral as of December 2, 1996. Most recently, Sandoz obtained a NOC for Sandoz Cyclosporine on February 17, 2006. We refer to all Sandoz cyclosporine products as "Sandoz Cyclosporine".

[2] Cyclosporin A (the former British Approved Name) and cyclosporine (the United States Adopted Name) are the same medicine.

22. Despite its obligation to report it price and sales data from January 3, 1997, Sandoz has failed to report to the Board on any sales of Sandoz Cyclosporine.

Ondansetron

23. Sandoz obtained NOC for Sandoz Ondansetron on or about April 19, 2006 and has sold an Ondansetron product since on or about April 19, 2006 and possibly even earlier.

24. Canadian Patent No. 2,186,844 (the "844 Patent") claims the use of ondansetron for fibromyalgia. The 844 Patent has a laid open date of October 19, 1995 and issued on January 9, 2007. The 844 Patent therefore pertains to the drug product Ondansetron.

25. The owner of the 844 Patent is Novasearch AG, (Switzerland). Sandoz was the applicant for the 844 Patent and is a licensee of the patent. As such, Sandoz falls within the definition of "patentee" of the 792 Patent pursuant to subsection 79(1) of the *Act*.

26. Despite its obligation to report its price and sales data from April 19, 2006, Sandoz has failed to report to the Board on any sales of Sandoz Ondansetron.[3]

Azithromycin

27. Sandoz obtained a NOC for Sandoz Azithromycin on or about March 7, 2006 and has sold an Azithromycin product since on or about March 7, 2006, and possibly even earlier.[4]

28. Canadian Patent No. 2,330,007 (the "007 Patent") claims a process for the production of azithromycin. The 007 Patent therefore pertains to the drug product

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[3] Sandoz has also obtained a NOCs for Ondansetron under the brand name Sandoz Ondansetron Injection USP and Ondansetron HCl Dihydrate Injection on April 19, 2006. We refer to all Sandoz Ondansetron products as "Sandoz Ondansetron".

[4] Sandoz obtained an NOC for azithromycin monohydrate hemiethanolate on March 7, 2006 and for azithromycin monohydrate on September 8, 2009. Both products are sold under the brand name "Sandoz Azithromycin" and we will refer to them as such.

Azithromycin. The 007 Patent has a laid open date of November 18, 1999 and issued on July 8, 2008.

29. The owner of the 007 Patent is Sandoz AG, (Switzerland). As such, Sandoz falls within the definition of "patentee" of the 007 Patent pursuant to subsection 79(1) of the *Act*.

30. Despite its obligation to report its price and sales data from March 7, 2006, Sandoz has failed to report to the Board on any sales of Sandoz Azithromycin.

Famciclovir

31. Sandoz obtained a NOC for Sandoz Famciclovir on March 29, 2006 and has sold a Famciclovir product since on or about March 29, 2006, and possibly even earlier.

32. Canadian Patent 2,086,756 No. (the "756 Patent") to Novartis International Pharmaceutical Ltd. (Bermuda) claims the use of Famciclovir for HIV-1 infection. The 756 Patent therefore pertains to the drug product Famciclovir. The 756 Patent has a laid open date of January 23, 1992 and issued on April 8, 2003

33. Despite its obligation to report its price and sales data from March 29, 2006, Sandoz has failed to report to the Board on any sales of Sandoz Famciclovir.

Estradiol Derm

34. Sandoz obtained a NOC for Sandoz Estradiol Derm on January 11, 2006 and has sold an Estradiol product since on or about January 11, 2006, and possibly even earlier.

35. Canadian Patent No. 1,338,660 (the "660 Patent") issued and was made public on October 22, 1996, and covers an adhesive dermal composition in which estrogen is dissolved or dispersed. Canadian Patent No. 2,044,170 (the "170 Patent"), which has a laid open date of July 26, 1990 and issued March 27, 2001, covers a breathable backing for transdermal drug preparation. Canadian Patent No. 2,110,914 (the "914 Patent"), which has a laid open date of January 7, 1993 and issued December 5, 2000, covers a polymer that modulates delivery of drug from transdermal drug delivery system. Canadian Patent No. 2,044,132 (the "132

Patent"), which has a laid open date of July 12, 1990 and issued May 6, 1997, covers a trandermal delivery system that can load high or low amounts of drug. The 660 Patent, 170 Patent, 914 Patent and 132 Patent therefore pertain to the drug product Estradiol Derm.

36. All four of these patents are owned by Noven Pharmaceuticals Inc. (U.S.). Noven Pharmaceuticals Inc. licensed Estradot (a transdermal 17-beta estradiol product) to Novartis in 2002. As such, Sandoz falls within the definition of "patentee" of the 660, 170, 914 and 132 Patents pursuant to subsection 79(1) of the *Act*.

37. Despite its obligation to report its price and sales data from January 11, 2006, Sandoz has failed to report to the Board on any sales of Sandoz Estradiol Derm.

38. The precise time period during which Sandoz sold these and other patented medicines in a market in Canada is not specifically known to Board Staff, but is known to Sandoz.

Terbinafine

39. Sandoz obtained a NOC for Sandoz Terbinafine on December 10, 2004 and has sold a Terbinafine product since on or about December 10, 2004, and possibly even earlier.

40. Canadian Patent No. 2,015,919 (the "919 Patent") to Novartis Inc. claims the use of terbinafine as an antifungal agent. The 919 Patent therefore pertains to the drug product terbinafine. The 919 Patent has a laid open date of November 3, 1990 and issued on November 23, 1999.

41. Despite its obligation to report its price and sales data from December 10, 2004, Sandoz has failed to report to the Board on any sales of Sandoz Terbinafine.

Applicable Regulations

42. The *Act* and *Regulations* impose the following reporting requirements on patentees and former patentees:

a. Paragraphs 80(1)(a) and 80(2)(a) of the *Act* and section 3 of the *Regulations* require patentees and former patentees to provide to the Board prescribed information identifying the medicine (PMPRB Form 1). Pursuant to subsections 3(2) and 3(3) of the *Regulations*, the prescribed information must be provided (i) either if a notice of compliance has been issued with respect to the medicine, or if the medicine is being offered for sale in Canada; and (ii) seven days after the first notice of compliance is issued in respect of the medicine or after the medicine is first offered for sale in Canada, whichever occurs first.

b. Paragraphs 80(1)(b) and 80(2)(b) of the *Act* and section 4 of the *Regulations* require patentees and former patentees to provide to the Board prescribed information identifying the medicine and concerning the price of the medicine (PMPRB Form 2). Pursuant to subsection 4(2), this information must be provided, for the date of first sale in Canada, within 30 days after that date, and subsequently after each six month period commencing on January and July 1 of each year.

c. Subsection 88(1) of the *Act* and section 5 of the *Regulations* requires patentees to report to the Board prescribed information concerning the identity of any licensee in Canada and the revenues and research and development expenditures of the patentee (PMPRB Form 3). This information must be provided within 60 days after the end of each calendar year, in respect of the preceding calendar year.

43. Pursuant to paragraphs 81(1)(a) and (b) of the *Act*, the Board has the authority to require a patentee or former patentee of an invention pertaining to a medicine to provide the Board with information and documents respecting, among other things, the identity of the medicine (PMPRB Form 1) and the price at which the medicine is being or has been sold in any market in Canada and elsewhere (PMPRB Form 2). Pursuant to subsection 88(1) of the *Act*, the Board may require a patentee to provide the Board with information and documents respecting the identity of any licensee in Canada and the revenues and research and development expenditures of the patentee (PMPRB Form 3).

44. In addition, the Board has the authority pursuant to paragraph 81(1)(c) of the *Act* to require a patentee or former patentee of an invention pertaining to a medicine to provide the Board with information and documents respecting other related matters as the Board may require.

Sandoz' Failure to Report

45. Sandoz has provided the prescribed information further to sections 3 and 4 of the *Regulations* for its sales of only one product: Vasotec I.V., which was licensed from Merck Frosst Canada who previously provided regulatory filings to the Board. However, as of the date of this Notice of Application, Sandoz has failed to report on the sales of any other drug product in respect of which it is a patentee, further to section 5 of the *Regulations*. In addition, Sandoz has never reported on its revenues or research and development expenditures, further to section 5 of the *Regulations*.

46. Sandoz' obligations to report sales on various drug products, including Sandoz Cyclosporine, Sandoz Ondansetron, Sandoz Azithromycin, Sandoz Famiclovir, Sandoz Estradiol Derm, and Sandoz Terbinafine were triggered when either the following patents issued or NOCs were obtained:

    a. the 792 Patent, which issued on January 7, 2003 and pertains to Cyclosporine;

    b. the 844 Patent, which issued on January 9, 2007 and pertains to Ondansetron;

    c. the 007 Patent, which issued on July 8, 2008 and pertains to Azithromycin;

    d. the NOC obtained on March 29, 2006 for Sandoz Famciclovir;

    e. the NOC obtained on January 11, 2006 for Sandoz Estradiol Derm; and

    f. the NOC obtained on December 10, 2004 for Sandoz Terbinafine.

47. Sandoz must report sales of these and all other drug products in respect of which Sandoz is a patentee from the publication or laid-open date of each of the patents until sales ceased or until the present if sales have not ceased.

48. Sandoz has disputed the Board's jurisdiction since as early as July 14, 2008.

49. In a May 7, 2009 letter, Board Staff inquired about a number of drug products in respect of which it believed Sandoz to be a patentee, including Sandoz Cyclosporine, Sandoz Ondansetron, Sandoz Azithromycin, Sandoz Famciclovir, Sandoz Estradiol Derm, and Sandoz Terbinafine. However, on June 8, 2009, Sandoz responded by setting out the basis to its opposition of the Board's jurisdiction over the sales of those products.

50. In its most recent correspondence on September 20, 2009, Board Staff responded disagreeing with Sandoz' position on most of the products. Board Staff requested submission of all required regulatory filings by October 11, 2009, in respect of Cyclosporine, Ondansetron, Azithromycin, Famciclovir, and Estradiol Derm, and any other drug product sold by Sandoz and in respect of which Sandoz is a "patentee" under s. 79 of the *Patent Act*, failing which the matter would be referred to the Board Chairperson without further notice to Sandoz. This correspondence is attached to this Notice of Application.

51. Board Staff did not pursue Terbinafine in that letter because the relevant patent known to Board Staff at the time had expired prior to any sales of the Sandoz product. However, Board Staff has since identified a number of other non-expired Novartis patents, including the 919 Patent, which it believes pertain to Sandoz Terbinafine.

52. Sandoz has not complied with its obligations and as such, Sandoz is in breach of the reporting requirements under the *Act* and *Regulations*.

THE FOLLOWING DOCUMENTARY EVIDENCE will be used at the hearing of the Application:

1. One or more affidavits to be sworn;

2. The pleadings and proceedings herein; and

3. Such further or other documentary evidence as counsel may advise and the Board may permit.

Dated at Toronto this 11th day of January, 2010.

Original signature redacted

Tim Gilbert

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Counsel to Board Staff

APPENDIX 1

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")

ORDER

Within 30 days of the date of the Board's Order, Sandoz shall in accordance with subsections 81(1) and 88(1) of the *Patent Act* (the "*Act*"):

I. Provide the Board with a list of all drug products in respect of which Sandoz is or was entitled to exercise patent rights, whether by virtue of ownership of a patent or license, and which Sandoz has sold or is selling in any market in Canada (the "Sandoz Patented Medicines").

II. Provide to the Board with a copy of any and all agreements between Sandoz and a patent holder pursuant to which Sandoz is or was entitled to exercise rights in Canada in relation to one or more patents pertaining to a medicine that Sandoz has sold or is selling in any market in Canada.

III. Provide to the Board the prescribed information identifying each Sandoz Patented Medicine for the period of time during which each Sandoz Patented Medicine was sold in any market in Canada, in accordance with section 3 of the *Patented Medicines Regulations, 1994* (the "*Regulations*").

IV. Provide to the Board the prescribed information identifying each Sandoz Patented Medicine and concerning the price of each Sandoz Patented Medicine for the period of time during which each Sandoz Patented Medicine was sold in any market in Canada, in accordance with section 4 of the *Regulations* for each reporting period during the Relevant Period.

V. Provide to the Board the prescribed information concerning the revenues and research and development expenditures of Sandoz in accordance with section 5 of the *Regulations* for each calendar year since the date of first sale of each Sandoz Patented Medicine sold by Sandoz in any market in Canada. Such information is to include:

a. the total gross revenues from all sales in Canada during each calendar year by Sandoz 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

b. a summary of all expenditures made during each calendar year by Sandoz towards the cost of research and development relating to medicine for human or veterinary use carried out in Canada by or on behalf of Sandoz.

APPENDIX 2

Patents That May Pertain to Sandoz Drug Products

Drug	Patent No.	Title	Owner
Cyclosporine	2,106,827	PHARMACEUTICAL COMPOSITIONS CONTAINING CYCLOSPORINS	Novartis
	2,226,091	CYCLOSPORIN-CONTAINING SOFT CAPSULE PREPARATIONS	Novartis
	2,072,509	CYCLOSPORIN EMULSION COMPOSITIONS FOR ORAL ADMINISTRATION	Novartis
Azithromycin	2,429,639	STABLE AZITHROMYCIN MONOHYDRATE	Sandoz
	2,330,007	IMPROVEMENTS IN MACROLIDE PRODUCTION	Sandoz
Famciclovir	2,207,503	USE OF AMINOPURINE ANTIVIRAL AGENTS FOR THE TREATMENT AND PROPHYLAXIS OF LATENT HERPESVIRUS INFECTIONS	Novartis
	2,176,376	USE OF 2-AMINO PURINE DERIVATIVES FOR THE TREATMENT AND PROPHYLAXIS OF HUMAN HERPES VIRUS 6 INFECTIONS	Novartis
	2,245,383	FAMCICLOVIR MONOHYDRATE	Novartis
	2,240,462	HIGH-CONTENT FAMCICLOVIR TABLETS	Novartis
	2,244,268	NUCLEOSIDE ANALOGS IN COMBINATION THERAPY OF HERPES SIMPLEX INFECTIONS	Novartis
	2,086,756	PENCICLOVIR AND FAMCICLOVIR AND RELATED GUANINE DERIVATIVES FOR THE TREATMENT OF THE HIV-1 INFECTIONS	Novartis
	2,011,238	PHARMACEUTICAL TREATMENT	Novartis
Terbinafine	2,219,651	ANTIFUNGAL COMPOSITION	Novartis
	2,068,957	PHARMACEUTICAL COMPOSITION	Novartis
	2,062,341	USE OF HYDROPHILIC PENETRATING AGENTS IN DERMATOLOGICAL COMPOSITIONS FOR THE TREATMENT OF ONYCHOMYCOSIS, AND CORRESPONDING COMPOSITIONS	Novartis

	2,399,971	PHARMACEUTICAL COMPOSITION COMPRISING SQUALENE EPOXIDASE INHIBITOR AND MACROLIDE IMMUNOMODULATOR	Novartis
Estradiol Derm	1,305,384	USER-ACTIVATED TRANSDERMAL THERAPEUTIC SYSTEM	Sandoz