IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER LIMITED, PFIZER IRELAND PHARMACEUTICALS, C.P. PHARMACEUTICALS INTERNATIONAL C.V.,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
SANDOZ INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Pfizer Inc., Pfizer Limited, Pfizer Ireland Pharmaceuticals, and C.P. Pharmaceuticals International C.V. (collectively "Pfizer"), for their Complaint, allege as follows:

1. This is an action for infringement of U.S. Patent Nos. 6,632,803 ("the '803 patent") and 5,364,938 ("the '938 patent"). This action arises out of the submission by defendant Sandoz Inc. ("Sandoz") of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Pfizer's injectable VFEND®, a prescription medication used for the treatment of certain serious fungal infections, prior to the expiration of the '803 and '938 patents.

PARTIES

2. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of Delaware and has a place of business at 235 East 42nd Street, New York, New York 10017.

3. Plaintiff Pfizer Limited is a private limited company organized under the laws of the United Kingdom, having a place of business at Ramsgate Road, Sandwich, Kent, CT13 9NJ, England, United Kingdom. Pfizer Inc. is the ultimate parent of Pfizer Limited.

4. Plaintiff Pfizer Ireland Pharmaceuticals is a partnership organized under the laws of Ireland, having a place of business at Pottery Road, Dun Laoghare, Co. Dublin, Ireland. Pfizer Inc. is the ultimate parent of Pfizer Ireland Pharmaceuticals.

5. Plaintiff C.P. Pharmaceuticals International C.V. ("CPPI CV") is a limited partnership organized under the laws of the Netherlands, having its registered seat in Rotterdam, and is represented by its general partners, Pfizer Manufacturing LLC, a limited liability company organized under the laws of the State of Delaware and having a place of business at 235 East 42nd Street, New York, New York 10017 and Pfizer Production LLC, a limited liability company organized under the laws of the State of Delaware, and having a place of business at 235 East 42nd Street, New York, New York 10017, jointly acting, each in its capacity as a general partner for and on behalf of CPPI CV. Pfizer Inc. is a limited partner of and is the ultimate parent of all other partners of CPPI CV.

6. On information and belief, defendant Sandoz is a Colorado corporation with a place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540 and a manufacturing facility at 2555 West Midway Boulevard, Broomfield, Colorado 80038.

JURISDICTION AND VENUE

7. Jurisdiction is proper in this judicial district pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

9. On information and belief, this Court has personal jurisdiction over Sandoz because Sandoz has purposely availed itself of the benefits and protections of this forum such that it should reasonably anticipate being haled into court here. On information and belief,

Sandoz has had persistent and continuous contacts with this judicial district, including developing and/or manufacturing pharmaceutical products that are sold in this judicial district.

10. According to Sandoz's website, Sandoz "endeavor[s] to make [its] medicines available to everyone, everywhere. Our portfolio of approximately 1 000 molecules is already available in more than 90% of the world's population and we continue to work hard to further increase global access."

11. On information and belief, Sandoz regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

12. On information and belief, Sandoz manufactures in the United States and sells its generic pharmaceutical products throughout the United States, including, on information and belief, products that are intended for sale, and sold, in Delaware.

13. On information and belief, Sandoz is registered to distribute its generic pharmaceutical products in Delaware and is registered with the Delaware Board of Pharmacy as a licensed "Distributor/Manufacturer CSR" (License No. DS0131) and "Pharmacy-Wholesale" (License No. A4-0000260) pursuant to 24 Del. C. 2540.

14. On information and belief, Sandoz's generic pharmaceutical products are used within and throughout the United States, including in Delaware.

15. On information and belief, Sandoz derives substantial revenue from generic pharmaceutical products that are used within Delaware.

16. On information and belief, a central feature of Sandoz's business model is litigating patents covering FDA-approved branded drug products. For example, a recent Sandoz

press release of June 28, 2010 makes clear the extent to which litigation is a central feature of Sandoz's business model: "Sandoz celebrated this week the formal launch of its new product development center [which] . . . will be a key site for Sandoz US development of generic medicines, with an emphasis on 'first-to-file' applications with the FDA." On information and belief, the "first-to-file" opportunities referred to in Sandoz's press release are Paragraph IV challenges to brand pharmaceutical company patents, such as the one in this case. To pursue its strategy of litigation, upon information and belief, Sandoz regularly relies upon the services of the federal courts in Delaware.

17. On information and belief, Sandoz has previously availed itself of this forum such that it should reasonably anticipate being haled into court here. In particular, Sandoz has brought at least one suit in this judicial district within the last year: *Sandoz Inc. v. Pfizer, Inc.*, No. 10 Civ. 104 (D. Del.).

18. On information and belief, Sandoz regularly consents to jurisdiction in this District and asserts counterclaims, and has done so in at least the following cases: *Abbott Labs. v. Sandoz Inc.*, No. 10 Civ. 538 (D. Del.); *Genzyme Corp. v. Sandoz Inc.*, No. 10 Civ. 429 (D. Del.); *Cephalon, Inc. v. Sandoz Inc.*, No. 10 Civ. 123 (D. Del.); *Allergan Inc. v. Sandoz Inc.*, No. 10 Civ. 024 (D. Del.); *Abbott Labs. v. Sandoz Inc.*, No. 09 Civ. 972 (D. Del.); *Wyeth Holdings Corp. et al. v. Sandoz Inc.*, No. 09 Civ. 995 (D. Del.); *Daiichi Sankyo Co., LTD v. Sandoz Inc.*, No. 09 Civ. 898 (D. Del.); *Allergan, Inc. et al. v. Sandoz Inc.*, No. 09 Civ. 882 (D. Del.); *Pfizer Inc. et al. v. Sandoz Inc.*, No. 09 Civ. 742 (D. Del.); *Aventis Pharma S.A. v. Sandoz Inc.*, No. 09 Civ. 810 (D. Del.); *Bone Care Int'l LLC v. Sandoz Inc.*, No. 09 Civ. 524 (D. Del.); *Pfizer Inc. v. Sandoz Inc.*, No. 09 Civ. 310 (D. Del.); *Abbott Labs v. Sandoz Inc.*, No. 09 Civ. 215 (D. Del.); *Medicis Pharms. Corp. v. Mylan Inc. et al.*, No. 09 Civ. 033 (D. Del.); *Endo Pharm. Inc. v.*

Sandoz Inc., No. 08 Civ. 534 (D. Del); *Wyeth v. Sandoz Inc.*, No. 08 Civ. 317 (D. Del.); and *AstraZeneca Pharm. LP v. Sandoz Inc.*, No. 07 Civ. 807 (D. Del.).

19. In these and other cases, Sandoz has engaged the services of various Delaware law firms for its representation and has repeatedly entered into this District to litigate its patent disputes before this Court.

BACKGROUND

20. VFEND® is a pharmaceutical agent used for the treatment of certain fungal infections. Pfizer sells VFEND® in the United States in various formulations, including as a lyophilized powder for solution for injection pursuant to New Drug Application ("NDA") No. 021-267, approved by the FDA (hereafter "VFEND® I.V."). VFEND® is indicated for the treatment of invasive aspergillosis, candidemia in nonneutropenic patients and certain other *Candida* infections, esophageal candidiasis, and serious fungal infections caused by *Scedosporium apiospermum* and *Fusarium spp.* including *Fusarium solani*, in patients intolerant of, or refractory to, other therapies.

21. The '803 patent, entitled "Pharmaceutical Formulations Containing Voriconazole" (Exhibit A hereto), was duly and legally issued on October 14, 2003 to Pfizer Inc., as assignee.

22. The '938 patent, entitled "Triazole Antifungal Agents" (Exhibit B hereto) was duly and legally issued on November 15, 1994 to Pfizer Inc., as assignee.

23. Pfizer has all right, title, and interest in the '803 patent and the '938 patent, including the right to sue for infringement thereof.

24. VFEND® I.V. is covered by one or more claims of the '803 patent and the '938 patent, which have been listed in connection with VFEND® in the FDA's publication

Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

25. By letter dated November 5, 2008 (hereafter the "2008 Notice Letter"), Sandoz notified Pfizer that it had submitted to the FDA ANDA No. 90-862, for Voriconazole for Injection, 200 mg/vial, a generic version of VFEND® I.V. (hereafter "Sandoz's ANDA Product"). The purpose of the ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Sandoz's ANDA Product prior to the expiration of, *inter alia*, the '803 patent.

26. In the 2008 Notice Letter, Sandoz also stated that, as part of its ANDA, it had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. 355(j)(2)(A)(vii)(VI) ("Paragraph IV certification") asserting that no valid claim of the '803 patent will be infringed by the manufacture, use, sale or importation of Sandoz's ANDA Product.

27. By letter dated November 24, 2010, (hereafter the "2010 Notice Letter"), Sandoz notified Pfizer that as part of ANDA No. 90-862, it had filed an additional Paragraph IV certification with respect to the '938 patent, asserting that no valid claim of the '938 patent will be infringed by the manufacture, use, sale or importation of Sandoz's ANDA Product.

28. This action is being commenced before the expiration of forty-five days from the date of Pfizer's receipt of the 2010 Notice Letter.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 6,632,803 BY SANDOZ'S SUBMISSION OF ANDA NO. 90-862

29. Pfizer repeats and realleges each and every allegation contained in paragraphs 1 through 28 hereof, as if fully set forth herein.

30. Sandoz's ANDA Product is covered by one or more claims of the '803 patent.

31. The 2008 Notice Letter does not provide any contention that or explanation why the claims of the '803 patent are not infringed by Sandoz's ANDA Product, as would be required by 21 C.F.R. § 314.95(c)(6)(i) if Sandoz contended that the claims were not infringed.

32. Sandoz's submission of ANDA No. 90-862 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Sandoz's ANDA Product before expiration of the '803 patent was an act of infringement of the '803 patent under 35 U.S.C. § 271(e)(2)(A).

33. Upon information and belief, Sandoz has acted with full knowledge of the '803 patent and without a reasonable basis for believing that it would not be liable for infringing the '803 patent.

34. Unless Sandoz is enjoined from infringing the '803 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law to redress such injury.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 6,632,803

35. Pfizer repeats and realleges each and every allegation contained in paragraphs 1 through 34 hereof, as if fully set forth herein.

36. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would infringe one or more claims of the '803 patent.

37. Upon information and belief, the use of Sandoz's ANDA Product as described in and/or directed by Sandoz's proposed labeling, ANDA, and other corporate documents for that product would infringe one or more claims of the '803 patent.

38. Upon information and belief, Sandoz knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '803 patent, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use.

39. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, and/or distribution within the United States, and/or importation into the United States, of Sandoz's ANDA Product immediately and imminently upon approval of ANDA No. 90-862.

40. The foregoing actions by Sandoz will constitute infringement of the '803 patent under 35 U.S.C. § 271(a), active inducement of infringement of the '803 patent under 35 U.S.C. § 271(b), and/or contribution to the infringement by others of the '803 patent under 35 U.S.C. § 271(c).

41. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer, on the one hand, and Sandoz, on the other, regarding Sandoz's infringement of the '803 patent, active inducement of infringement of the '803 patent, and/or contributing to the infringement by others of the '803 patent.

42. Upon information and belief, Sandoz acted without a reasonable basis for believing that it would not be liable for infringement of the '803 patent, for actively inducing infringement of the '803 patent, and for contributing to the infringement by others of the '803 patent.

43. Unless Sandoz is enjoined from infringement of the '803 patent, from actively inducing infringement of the '803 patent, and from contributing to the infringement by

others of the '803 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law to redress such injury.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 5,364,938 BY SANDOZ'S SUBMISSION OF ANDA NO. 90-862

44. Pfizer repeats and realleges each and every allegation contained in paragraphs 1 through 43 hereof, as if fully set forth herein.

45. Sandoz's ANDA Product is covered by one or more claims of the '938 patent.

46. The 2010 Notice Letter does not provide any contention that or explanation why the claims of the '938 patent are not infringed by Sandoz's ANDA Product, as would be required by 21 C.F.R. § 314.95(c)(6)(i) if Sandoz contended that the claims were not infringed.

47. Sandoz's submission of ANDA No. 90-862 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Sandoz's ANDA Product before expiration of the '938 patent was an act of infringement of the '938 patent under 35 U.S.C. § 271(e)(2)(A).

48. Upon information and belief, Sandoz has acted with full knowledge of the '938 patent and without a reasonable basis for believing that it would not be liable for infringing the '938 patent.

49. Unless Sandoz is enjoined from infringing the '938 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law to redress such injury.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 5,364,938

50. Pfizer repeats and realleges each and every allegation contained in paragraphs 1 through 49 hereof, as if fully set forth herein.

51. The commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's ANDA Product would infringe one or more claims of the '938 patent.

52. Upon information and belief, the use of Sandoz's ANDA Product as described in and/or directed by Sandoz's proposed labeling, ANDA, and other corporate documents for that product would infringe one or more claims of the '938 patent.

53. Upon information and belief, Sandoz knows that its ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '938 patent, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use.

54. Upon information and belief, Sandoz will engage in the manufacture, use, offer for sale, sale, marketing, and/or distribution within the United States, and/or importation into the United States, of Sandoz's ANDA Product immediately and imminently upon approval of ANDA No. 90-862.

55. The foregoing actions by Sandoz will constitute infringement of the '938 patent under 35 U.S.C. § 271(a), active inducement of infringement of the '938 patent under 35 U.S.C. § 271(b), and/or contribution to the infringement by others of the '938 patent under 35 U.S.C. § 271(c).

56. The Court may declare the rights and legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because there is a case of actual controversy between Pfizer, on the one hand, and Sandoz, on the other, regarding Sandoz's infringement of the '938 patent,

active inducement of infringement of the '938 patent, and/or contributing to the infringement by others of the '938 patent.

57. Upon information and belief, Sandoz acted without a reasonable basis for believing that it would not be liable for infringement of the '938 patent, for actively inducing infringement of the '938 patent, and for contributing to the infringement by others of the '938 patent.

58. Unless Sandoz is enjoined from infringement of the '938 patent, from actively inducing infringement of the '938 patent, and from contributing to the infringement by others of the '938 patent, Pfizer will suffer irreparable injury. Pfizer has no adequate remedy at law to redress such injury.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Sandoz has infringed the '803 patent and the '938 patent, will infringe the '803 patent and the '938 patent, will actively induce infringement of the '803 patent and the '938 patent, and will contribute to the infringement by others of the '803 patent and the '938 patent;

(b) A judgment ordering that the effective date of any FDA approval for Sandoz to commercially make, use, offer to sell, sell, or import into the United States Sandoz's ANDA Product, be not earlier than the latest of the expiration dates of the '803 patent and the '938 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Sandoz, and all persons acting in concert with Sandoz, from infringing, actively inducing the infringement of, or contributing to the infringement by others of the '803 patent and the '938 patent through the making, using, selling, offering for sale, or importing into the United States of Sandoz's ANDA

Product, or any product or compound that infringes the '803 patent and the '938 patent, prior to the latest of the expiration dates of the '803 patent and the '938 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

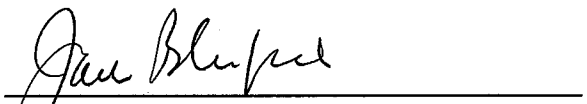
(d) A judgment declaring that the making, using, selling, offering for sale, or importing into the United States of Sandoz's ANDA Product, or any product or compound that infringes the '803 patent and the '938 patent, prior to the expiration date of the respective patent, will infringe, actively induce infringement of, and will contribute to the infringement by others of the '803 patent and the '938 patent;

(e) A declaration that this is an exceptional case, and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) Costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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