

3. Plaintiff Baxter Healthcare SA ("Baxter HSA") is a corporation incorporated in Switzerland, having its principal place of business at Hertistrasse 2, Wallisellen, CH-8304, Switzerland.

4. On information and belief, Defendant Minrad, Inc. ("Minrad") is a corporation incorporated in Delaware, having its principal place of business at 50 Cobham Drive, Orchard Park, New York 14127.

5. On information and belief, Defendant Minrad International, Inc. ("Minrad International") is a corporation incorporated in Delaware, having its principal place of business at 50 Cobham Drive, Orchard Park, New York 14127.

6. On information and belief, Defendant Piramal Healthcare Limited ("Piramal India") is a corporation formed under the laws of the country of India, having its principal place of business at Piramal Tower, Peninsula Corporate Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

7. On information and belief, Defendant Piramal Healthcare, Inc. ("Piramal"), is a Delaware corporation and a wholly-owned subsidiary of Piramal Healthcare Limited, having its principal place of business at 379 Thornall Street, Edison, New Jersey 08837.

8. On information and belief, Piramal Healthcare Limited owns 100% of the ownership and voting interest in Piramal Healthcare, Inc.

9. On information and belief, Piramal Healthcare, Inc. owns 100% of the ownership and voting interest in Minrad, Inc.

10. On information and belief, Piramal Healthcare, Inc. owns 100% of the ownership and voting interest in Minrad International, Inc.

11. On information and belief, Piramal Healthcare Limited conducts its operations, in part, through subsidiaries in India, Europe and North America, including Piramal Healthcare, Inc., Minrad International, Inc., and Minrad, Inc.

12. On information and belief, Piramal Healthcare, Inc., Minrad International, Inc. and Minrad, Inc. are controlled and/or dominated by Piramal Healthcare Limited.

JURISDICTION AND VENUE

13. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally, and 35 U.S.C. § 271(a), (b), (c) and (e)(2) specifically.

14. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338.

15. This Court has personal jurisdiction over Minrad, Inc. because it is incorporated in Delaware.

16. This Court has personal jurisdiction over Minrad International, Inc. because it is incorporated in Delaware.

17. This Court has personal jurisdiction over Piramal Healthcare, Inc. because it is incorporated in Delaware. On information and belief, Piramal Healthcare, Inc. is also registered to do business in the State of Delaware.

18. On information and belief, Piramal Healthcare Limited regularly transacts business within Delaware, including but not limited to Piramal Healthcare Limited's direction of the operations and management of Piramal Healthcare, Inc., Minrad International, Inc., and Minrad, Inc.

19. On information and belief, Piramal Healthcare, Inc., Minrad International, Inc., and Minrad, Inc. act as agents of Piramal Healthcare Limited with respect to, at least, acts and conduct alleged in this complaint.

20. On information and belief, Piramal Healthcare Limited exercises substantially complete control over Piramal Healthcare, Inc., Minrad International, Inc., and Minrad, Inc. with respect to, at least, the acts alleged in this complaint. In related case Civil Action No. 09-054 GMS, Minrad designated witnesses employed by and or/retained by Minrad International, Inc. and Piramal Healthcare Limited in its Initial Disclosures as witnesses believed to have information regarding ANDA No. 90-363 and the development and structure of the drug product that is the subject of that ANDA, which demonstrates Piramal Healthcare Limited's control over Piramal Healthcare, Inc., Minrad International, Inc. and Minrad, Inc. with respect to, at least, the acts alleged in this complaint.

21. On information and belief, the operations of Minrad International, Inc. and Minrad, Inc. have been integrated completely with Piramal Healthcare, Inc. On information and belief, Piramal's internal communications refer to the entity composed of Piramal Healthcare, Inc. and Minrad International, Inc. as the "Piramal-Minrad combination" and the new entity has joint plans to synthesize their respective worldwide market presence and increase production of Minrad's facilities in Pennsylvania to increase Piramal-Minrad's profits.

22. On information and belief, Piramal Healthcare Limited utilizes the benefits of Delaware corporation law by incorporating its subsidiaries in Delaware, registering its subsidiaries to do business in Delaware, and conducting at least the merger transaction between Minrad International, Inc. and Piramal Healthcare, Inc. under Delaware law. On information and belief, the February 27, 2009 merger between Mayflower Acquisition Corp. (merger subsidiary),

Piramal Healthcare, Inc. and Minrad International, Inc. was consummated under Delaware corporation law.

23. This Court has personal jurisdiction over Piramal Healthcare Limited because Piramal Healthcare, Inc., Minrad International, Inc., and Minrad, Inc. maintain sufficient minimum general contacts with Delaware (including but not necessarily limited to those described in paragraphs 15 through 22 above), and/or such sufficient minimum contacts are attributable to Piramal Healthcare Limited, and the exercise of such jurisdiction is consistent with the requirements of due process and does not offend traditional notions of fair play and substantial justice.

24. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

GENERAL ALLEGATIONS

25. On April 8, 1997, the United States Patent and Trademark Office ("USPTO") issued U.S. Patent No. 5,617,906 ("the '906 Patent"). A true and correct copy of the '906 Patent is attached hereto as Exhibit A.

26. Baxter II and Baxter HSA are the owners of the '906 patent.

27. Baxter HC is the holder of the United States Food and Drug Administration ("FDA")-approved New Drug Application ("NDA") No. 20-118 and sells and distributes the drug covered by the NDA and marketed under the tradename Suprane®, the active ingredient of which is desflurane ((±)1,2,2,2-tetrafluoroethyl difluoromethyl ether) (hereinafter "Suprane®" or the "Suprane® drug product"), by exclusive license, in the United States.

28. Baxter HSA manufactures Suprane® (desflurane, USP), a nonflammable liquid administered via vaporizer and used as a general inhalation anesthetic.

29. Plaintiffs jointly own all rights, title and interest in the '906 Patent, including all rights needed to bring this action in Plaintiffs' names.

30. The '906 Patent is listed in the list of Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), maintained by the Food and Drug Administration ("FDA"), as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" Suprane®. 21 U.S.C. § 355(b)(1).

31. On information and belief, through the coordinated efforts of research and development staff in India, Europe and North America, Piramal Healthcare Limited seeks to constantly expand the range of generic products sold by it.

32. On information and belief, Minrad filed an abbreviated new drug application (ANDA) No. 90-363 with the FDA seeking approval to market a generic copy of the Suprane® drug product (hereafter "Torrane (Desflurane)").

33. On information and belief, Minrad included in its ANDA, or amended its ANDA to include, a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '906 Patent is invalid or will not be infringed by the manufacture, use, or sale of Torrane (Desflurane) covered by Minrad's ANDA.

34. Plaintiffs received a letter on or about December 12, 2008 from Minrad dated December 11, 2008, purporting to be a notice of Minrad's ANDA and "Paragraph IV" certification(s) required by 21 U.S.C. § 355(j)(2)(B)(i)-(ii).

35. On January 23, 2009, Plaintiffs brought an action for patent infringement against Minrad that is currently pending in this Court as Civil Action No. 09-054 GMS.

36. On information and belief, on June 23, 2009, Defendants filed an Amendment to abbreviated new drug application (ANDA) No. 90-363 ("amended ANDA") with the FDA seeking approval to market a generic copy of the Suprane® drug product (hereafter "Torrane (Desflurane)").

37. On information and belief, Defendants included in the amended ANDA, a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '906 Patent is invalid or will not be infringed by the manufacture, use, or sale of Torrane (Desflurane) covered by the amended ANDA.

38. Plaintiffs received a letter on or about June 23, 2009 from Minrad dated June 23, 2009, purporting to be a notice of amendment to ANDA No. 90-363 and "Paragraph IV" certification required by 21 U.S.C. § 355(j)(2)(B)(ii) attaching the "amendment to ANDA No. 90-963 [sic, ANDA No. 90-363] that was sent to the FDA on June 23, 2009."

39. On or about July 2, 2009, Plaintiffs informed Minrad that its Notice of Paragraph IV Certification Filing failed to comply with the content requirements set forth in 21 C.F.R. § 314.95(c) and therefore, constituted improper notice.

40. Plaintiffs received a letter on or about July 7, 2009 from Minrad, dated July 6, 2009, purporting to be a "Second Notice of Paragraph IV Certification Filing: Amended ANDA No. 90-363," that purported to address the deficiencies in the June 23, 2009 Notice.

COUNT ONE

(Infringement of the '906 Patent)

41. Plaintiffs incorporate and reallege paragraphs 1 through 40 above, as if set forth in full herein.

42. Pursuant to 35 U.S.C. § 271(e)(2)(A), Defendants' filing of an ANDA and amended ANDA, seeking approval to market Torrane (Desflurane) is an act of infringement of one or more claims of the '906 Patent entitling Plaintiffs to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for Defendants' ANDA be a date which is not earlier than October 8, 2014, the expiration date of the '906 Patent, including any extensions of this date.

43. Upon FDA approval of the amended ANDA, Defendants will infringe the '906 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling and or/importing Defendants' Torrane (Desflurane) in the United States, and/or by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271 (a), (b) and/or (c), unless this Court orders that the effective date of any FDA approval of the amended ANDA shall be no earlier than the expiration date of the '906 Patent and any additional periods of exclusivity.

44. Plaintiffs will be substantially and irreparably harmed by Defendants' infringing activities unless those activities are enjoined by the Court.

45. Plaintiffs have no adequate remedy at law for Defendants' infringement of the '906 Patent.

46. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorneys' fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor as follows:

(1) declaring that, under 35 U.S.C. § 271(e)(2)(A), Defendants' submission to the FDA of amended ANDA No. 90-363 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into the United States of Defendants' Torrane (Desflurane) before the expiration of the '906 Patent was an act of infringement of the '906 Patent;

(2) declaring that Defendants' commercial manufacture, use, offer for sale, or sale in, or importation into the United States by Minrad of Torrane (Desflurane) would constitute infringement of the '906 Patent;

(3) ordering that the effective date of any FDA approval of Defendants' Torrane (Desflurane) shall be no earlier than October 8, 2014, the expiration date of the '906 Patent and any additional dates of exclusivity, in accordance with 35 U.S.C. §271(e)(4)(A);

(4) enjoining Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from commercially manufacturing, using, offering for sale, or selling Defendants' Torrane (Desflurane) within the United States or importing into the United States Defendants' Torrane (Desflurane), until the expiration of the '906 Patent, in accordance with 35 U.S.C. §271(e)(4)(B);

(5) ordering that judgment be entered that Plaintiffs be awarded monetary relief if Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, commercially uses, offers for sale or sells Torrane (Desflurane) within the United States prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

(6) enjoining Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from directly infringing, contributorily infringing, or inducing infringement of the '906 Patent;

(7) enjoining Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from seeking, obtaining, or maintaining final approval of Defendants' amended ANDA No. 90-363 until the expiration of the '906 Patent;

(8) declaring this to be an exceptional case and awarding Plaintiffs their attorney fees under 35 U.S.C. § 285;

(9) awarding Plaintiffs their costs and expenses in this action; and

(10) awarding Plaintiffs any further and additional relief as this Court may deem just and proper.

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