IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVEN PHARMACEUTICALS, INC. and HISAMITSU PHARMACEUTICAL CO., INC.	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MYLAN TECHNOLOGIES INC., MYLAN PHARMACEUTICALS INC., and MYLAN INC.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Noven Pharmaceuticals, Inc. and Hisamitsu Pharmaceutical Co., Inc. (collectively, "Noven" or "Plaintiffs"), for their Complaint of patent infringement against Defendants Mylan Technologies Inc. ("MTI"), Mylan Pharmaceuticals Inc. ("MPI") and Mylan Inc. (collectively, "Mylan" or "Defendants"), allege as follows:

THE PARTIES

1. Plaintiff Noven Pharmaceuticals, Inc. is a Delaware corporation with a principal place of business at 11960 S.W. 144th Street, Miami, Florida 33186.

2. Plaintiff Hisamitsu Pharmaceutical Co., Inc. is a Japanese corporation with a principal place of business at Saga, Tosu, Tashirodiakan-machi, 408, Japan 841-0017.

3. Plaintiff Noven Pharmaceuticals, Inc. is a wholly-owned subsidiary of Hisamitsu Pharmaceutical Co., Inc.

4. Upon information and belief, defendant MTI is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 110 Lake Street, St. Albans, Vermont 92618.

5. Upon information and belief, defendant MTI is a wholly owned subsidiary of Mylan Inc.

6. Upon information and belief, defendant MTI is engaged in the manufacture for sale of pharmaceutical products, including transdermal pharmaceutical products.

7. Upon information and belief, defendant MPI is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

8. Upon information and belief, defendant MPI is a wholly owned subsidiary of Mylan Inc.

9. Upon information and belief, defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

10. Upon information and belief, defendant Mylan, Inc. controls and/or dominates defendants MTI and MPI.

11. Upon information and belief, Defendants are in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including Delaware.

NATURE OF THE ACTION

12. This is a civil action for patent infringement of U.S. Patent Nos. 6,841,716 ("the '716 patent") and 8,231,906 ("the '906 patent") (collectively, the "patents-in-suit") arising under the United States Patent Laws, Title 35, United States Code § 100, *et. seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 206685, which Defendants filed or caused to be filed under 21 U.S.C. § 355(j) with the

United States Food and Drug Administration ("FDA"), for approval to market a generic copy of Noven's Minivelle® product, which is sold in the United States.

JURISDICTION AND VENUE

13. This is a civil action for patent infringement arising under the Patent Laws of the United States, including 35 U.S.C. § 271.

14. This Court has subject matter jurisdiction under 28 U.S.C. §§1331 and 1338(a).

15. This Court has personal jurisdiction over Defendants by virtue of their specific acts in, and their systematic and continuous contacts with, the State of Delaware.

16. This Court has personal jurisdiction over Defendants by virtue of the fact that, *inter alia*, they have committed – or aided, abetted, induced, contributed to, or participated in the commission of – the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Noven, a Delaware corporation.

17. Upon information and belief, Defendants have purposefully availed themselves of this forum by making, using, importing, selling and/or offering to sell pharmaceutical products in the State of Delaware, or causing others to do the same, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

18. Upon information and belief, each Defendant regularly conducts or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware, including through their own actions and/or the actions of their affiliates and agents, demonstrating that Defendants have continuous and systematic contacts with Delaware.

19. Upon information and belief, MPI is registered to conduct business with the State of Delaware and maintains as a registered agent Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808.

20. Upon information and belief, MPI and MTI are registered pursuant to Del. Code. Ann. Tit. 24 § 2540 to distribute generic pharmaceutical products in Delaware and hold current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy.

21. On information and belief, Mylan Inc. has previously availed itself of this forum and affirmatively invoked this Court's jurisdiction by litigating as a defendant and asserting counterclaims in at least 15 cases initiated in this jurisdiction over the past ten years, including, for example, in *Forest Laboratories, Inc.et al. v. Mylan Inc., et al.*, C.A. 13-1605-SLR (D. Del. Oct. 18, 2013) (D.I. 10).

22. Upon information and belief, Defendant MTI prepared, developed and filed ANDA No. 206685 and its underlying subject matter.

23. On or around March 12, 2015, Defendant MTI sent or caused to be sent a letter to Noven, a Delaware corporation, purporting to be a written notice that Mylan had filed ANDA No. 206685 seeking approval to market generic Estradiol Transdermal System, USP "Twice-Weekly" in 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day dosage strengths as described in Defendants' ANDA No. 206685 ("the generic product") prior to the expiration of the patents-in-suit, pursuant to FFD&C Act, 21 U.S.C. § 505(j)(2)(B)(iv) (the "Paragraph IV letter"). The Paragraph IV letter included notice of Mylan's allegations that the patents-in-suit are invalid, unenforceable, and/or not infringed by Mylan's generic product.

24. Upon information and belief, Defendants MTI, MPI and Mylan Inc. are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products throughout the United States including in Delaware, including the generic Estradiol Transdermal System, USP "Twice-Weekly" in 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day dosage strengths described in Defendants' ANDA No. 206685, which are accused of infringing the patent-in-suit.

25. Upon information and belief, Defendants MPI and Mylan Inc. acted in concert with MTI in the preparation, development, and filing of ANDA No. 206685 and its underlying subject matter.

26. Upon information and belief, Defendants MPI and Mylan Inc. acted in concert with MTI in sending, or causing to be sent, the Paragraph IV letter to Noven, a Delaware corporation.

27. If ANDA No. 206685 is approved, Defendants' generic product will, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which will have a substantial effect on Delaware.

28. Defendants know and intend that the proposed generic product will be distributed and sold in the United States, including in Delaware.

29. Plaintiff Noven Pharmaceuticals, Inc. has initiated related litigation against Actavis Laboratories UT, Inc. ("Actavis") in Delaware to enforce U.S. Patent No. 8,231,906 against Actavis' proposed generic copy of Noven's Minivelle® product, in the case styled as *Noven Pharmaceuticals, Inc. v. Actavis Laboratories UT, Inc.*, C.A. No. 15-249 (LPS).

30. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

31. The '716 patent, entitled "Patch" was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on January 11, 2005. Plaintiff Hisamitsu Pharmaceutical Co., Inc. is the owner of all title, right, and interest in and to the '716 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A copy of the '716 patent is attached as Exhibit A.

32. The '906 patent, entitled "Transdermal Estrogen Device And Delivery," was duly and legally issued by the USPTO on July 31, 2012 and certificates of correction were issued on June 18, 2013, and July 22, 2014. Plaintiff Noven Pharmaceuticals, Inc. is the owner of all title, right, and interest in and to the '906 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A copy of the '906 patent and certificates of correction are attached as Exhibit B.

33. Noven is the holder of New Drug Application No. 203752 for the manufacture and sale of Estradiol Transdermal System USP (Twice-Weekly), which it sells under the registered trademark Minivelle®. Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 355(b)(1) ("FFD&C Act") and corresponding FDA regulations, Noven has listed the patents-in-suit in the FDA's Orange Book as covering Minivelle® and methods for using it.

34. Upon information and belief, pursuant to FFD&C Act, 21 U.S.C. 505(j), Defendants filed ANDA No. 206685 with the FDA. Defendants' ANDA seeks FDA approval to market and sell within the United States a generic Estradiol Transdermal System, USP "Twice-Weekly" in 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day dosage strengths of the product (the "generic product") prior to the expiration of the patents-in-suit.

35. Upon information and belief, Mylan's ANDA No. 206685 identified Noven's Minivelle® product and included a written certification, as required by the FFD&C Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV certification"), alleging that the claims of the patents-in-suit are invalid or otherwise will not be infringed by Mylan's generic product.

36. On or about March 12, 2015, Noven received a letter from MTI purporting to be a written notice that Mylan had filed ANDA No. 206685 seeking approval to market its generic product prior to the expiration of the patents-in-suit, pursuant to FFD&C Act, 21 U.S.C. § 505(j)(2)(B)(iv) (the "Paragraph IV letter"). The Paragraph IV letter included notice of Mylan's allegations that the patents-in-suit are invalid, unenforceable, and/or not infringed by Mylan's generic product.

37. Mylan's submission of ANDA No. 206685, including the Paragraph IV certification, to the FDA constituted infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2). Moreover, upon information and belief, Mylan's anticipated commercial manufacture, use, sale, offer for sale, or importation of the generic product upon approval and before expiration of the patents-in-suit will infringe at least one claim of each of the patents-in-suit under 35 U.S.C. § 271(a), (b), and/or (c).

38. Mylan purported to include an Offer of Confidential Access ("the Mylan Offer") to Noven to ANDA No. 206685 along with its Paragraph IV Letter. Under the FFD&C Act, 21 U.S.C. § 355(j)(5)(C)(III), an Offer of Confidential Access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential information."

39. The Mylan Offer contained various restrictions, above and beyond those that would apply under a typical protective order, on who could view the ANDA and remedies in the event of a violation or breach. For example, the Mylan Offer substantially limited the fields of practice of outside and in-house counsel who might view the ANDA. In addition, the restrictions imposed by the Mylan Offer were not sufficiently directed to the purpose of protecting trade secrets and other confidential business information.

40. Since receiving Mylan's Paragraph IV letter, Plaintiffs have attempted to negotiate with Mylan to procure a copy of the ANDA and to reach agreement on the terms and conditions of the Mylan Offer. These negotiations have been unsuccessful and the parties did not reach agreement. For example, Mylan's most recent proposal continues to unduly limit the fields of practice and other activities of outside and in-house counsel who would accept access to the ANDA, and goes beyond such restrictions as would apply had a protective order been entered.

41. Plaintiffs are not aware of any other means for obtaining information regarding Mylan's proposed generic product within the 45-day statutory period. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the court evidence that Mylan's proposed generic product falls within the scope of one or more claims of the patents-in-suit.

42. Noven is commencing this action within 45 days of receiving Defendants' Paragraph IV letter.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 6,841,716

43. Paragraphs 1-42 are incorporated by reference as though fully set forth herein.

44. Mylan's submission of ANDA No. 206685 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '716 Patent constituted patent infringement under 35 U.S.C. § 271(e)(2).

45. Upon information and belief, Mylan will infringe the '716 patent under U.S.C. § 271(a) by making, using, selling, offering to sell, or importing the generic product in the United States upon the FDA's approval of ANDA No. 206685.

46. Upon information and belief, Mylan will infringe the '716 patent under U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '716 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 206685.

47. Upon information and belief, Mylan will infringe the '716 patent under U.S.C. § 271(c) by selling and offering to sell the generic product in the United States, with knowledge of the '716 patent and that there is no substantial non-infringing use of the generic product, upon the FDA's approval of ANDA No. 206685.

48. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Noven is entitled to a permanent injunction against further infringement. Noven will be substantially and irreparably harmed if Mylan's direct infringement of the '716 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

49. Upon information and belief, Mylan was aware of the '716 patent prior to filing ANDA No. 206685, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '716 patent.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 8,231,906

50. Paragraphs 1-49 are incorporated by reference as though fully set forth herein.

51. Mylan's submission of ANDA No. 206685 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '906 Patent constituted patent infringement under 35 U.S.C. § 271(e)(2).

52. Upon information and belief, Mylan will infringe the '906 patent under U.S.C. § 271(a) by making, using, selling, offering to sell, or importing the generic product in the United States upon the FDA's approval of ANDA No. 206685.

53. Upon information and belief, Mylan will infringe the '906 patent under U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '906 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 206685.

54. Upon information and belief, Mylan will infringe the '906 patent under U.S.C. § 271(c) by selling and offering to sell the generic product in the United States, with knowledge of the '906 patent and that there is no substantial non-infringing use of the generic product, upon the FDA's approval of ANDA No. 206685.

55. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Noven is entitled to a permanent injunction against further infringement. Noven will be substantially and irreparably harmed if Defendants' direct infringement of the '906 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

56. Upon information and belief, Mylan was aware of the '906 patent prior to filing ANDA No. 206685, as well as the statutory provisions and regulations set forth in 21 U.S.C. §

355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '906 patent.

PRAYER FOR RELIEF

WHEREFORE, Noven respectfully prays for:

A. A judgment that Defendants have infringed the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 206685 to the FDA, and that the commercial manufacture, use, sale, offer for sale, and/or importation of the generic product before the expiration of the patents-in-suit will constitute infringement of the patents-in-suit;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 206685 shall be no earlier than the date on which the last of the patents-in-suit will expire, including any patent term and regulatory extensions;

C. An injunction under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283, permanently enjoining Defendants, their officers, agents, servants employees, licensees, representatives, attorneys, and all other persons acting or attempting to act in active concert in participation with it or acting on their behalf, from engaging in the commercial manufacture, use, sale, offer to sell, and/or importation within the United States, of any pharmaceutical product covered by the patents-in-suit;

D. An award of damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C) and/or 35 U.S.C. § 284 as appropriate;

E. A finding that this is an exceptional case under 35 U.S.C. § 285, and that Noven be awarded reasonable attorneys' fees and costs; and

F. An award of any such other and further relief as the Court may deem just and proper.

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April 23, 2015