IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVEN PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ACTAVIS LABORATORIES UT, INC.	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Noven Pharmaceuticals, Inc. ("Noven" or "Plaintiff"), for its Complaint of patent infringement against Defendant Actavis Laboratories UT, Inc. ("ALU" or "Defendant"), alleges as follows:

THE PARTIES

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

2. Upon information and belief, Defendant ALU is a Delaware corporation with a principal place of business at 577 Chipeta Way, Salt Lake City, UT 84108.

3. Upon information and belief, Defendant ALU is 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

4. This is a civil action for infringement of U.S. Patent No. 8,231,906 ("the '906 patent") 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. 206202, which Defendant 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

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

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

7. This Court has personal jurisdiction over Defendant by virtue of its specific acts in, and its systematic and continuous contacts with, the State of Delaware.

8. Upon information and belief, Defendant is incorporated in the state of Delaware, and purposefully availed itself of this forum by making, using, importing, selling 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.

9. Upon information and belief, Defendant prepared, developed and filed ANDA No. 206202 and its underlying subject matter.

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

FACTUAL BACKGROUND

11. The '906 patent, entitled "Transdermal Estrogen Device and Delivery" was duly and legally issued by the United States Patent and Trademark Office on July 31, 2012 and certificates of corrections were issued on June 18, 2013 and July 22, 2014. Noven is the owner of all right, title, 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 A.

12. Noven is the holder of New Drug Application No. 203752 for the manufacture and sale of Estradiol Transdermal System and sells the product under the registered trademark Minivelle®. Pursuant to Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(1) ("FFD&C Act"), and corresponding FDA regulations, Noven has listed the '906 patent in the FDA's Orange Book as covering the Minivelle® drug and methods for using it.

13. Upon information and belief, pursuant to FFD&C Act, 21 U.S.C. § 505(j), Defendant filed ANDA No. 206202 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 '906 patent.

14. Upon information and belief, Defendant's ANDA No. 206202 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 '906 patent are invalid or otherwise will not be infringed by the Defendant's generic product.

15. On or about February 5, 2015, Noven received a letter from Defendant purporting to be a written notice that Defendant had filed ANDA No. 206202 seeking approval to market its generic product prior to the expiration of the '906 patent, 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 Defendant's allegations that the '906 patent is invalid, unenforceable, and/or not infringed by Defendant's generic product.

16. Defendant's submission of ANDA No. 206202, including the Paragraph IV certification, to the FDA constituted infringement of the '906 patent under 35 U.S.C. § 271(e)(2). Moreover, Defendant's anticipated commercial manufacture, use, sale, offer for sale, or

importation of the generic product upon approval and before expiration of the '906 patent will infringe at least one claim of the '906 patent under 35 U.S.C. § 271(a), (b), and/or (c).

17. Noven is commencing this action within 45 days of receiving Defendant's Paragraph IV letter.

CLAIM FOR RELIEF – INFRINGEMENT OF U.S. PATENT NO. 8,231,906

18. Paragraphs 1-17 are incorporated by reference as though fully set forth herein.

19. Defendant's submission of ANDA No. 206202 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).

20. Upon information and belief, Defendant 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. 206202.

21. Upon information and belief, Defendant 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. 206202.

22. Upon information and belief, Defendant 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. 206202.

23. 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 Defendant's infringement of the '906 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

24. Upon information and belief, Defendant was aware of the '906 patent prior to filing ANDA No. 206202, 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 it would not be liable for infringing the '906 patent.

PRAYER FOR RELIEF

WHEREFORE, Noven respectfully prays for:

A. A judgment that Defendant has infringed the '906 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 206202 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 '906 patent will constitute infringement of the '906 patent;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 206202 shall be no earlier than the date on which the '906 patent expires, 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 Defendant, its 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 its 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 '906 patent;

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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