IN THE UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

PRONOVA BIOPHARMA NORGE AS, Plaintiff, v. PAR PHARMACEUTICAL, INC., and PAR PHARMACEUTICAL COMPANIES, INC., Defendants.	)	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Pronova BioPharma Norge AS ("Pronova"), by way of Complaint against Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc., alleges as follows:

THE PARTIES

1. Pronova is a corporation organized and existing under the laws of Norway with its corporate headquarters at Vollsveien 6, 1366 Lysaker, Baerum, Norway. Pronova is engaged in the research, development, manufacture and sale of pharmaceutical products.

2. Upon information and belief, Par Pharmaceutical, Inc. is a corporation organized under the laws of the State of Delaware, and its principal place of business is located at One Ram Ridge Road, Spring Valley, New York 10977.

3. Upon information and belief, Par Pharmaceutical Companies, Inc. is a corporation organized under the laws of the State of Delaware, and its principal place of business is located at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Upon information and belief, Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc.

NATURE OF THE ACTION

4. This is an action for infringement of U.S. Patent No. 5,502,077 ("the '077 patent") and U.S. Patent No. 5,656,667 ("the '667 patent"), arising under the United States patent laws, Title 35, United States Code, §100 *et seq.*, including 35 U.S.C. §§ 271 and 281. This action relates to Par Pharmaceutical, Inc.'s filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market generic pharmaceutical products.

JURISDICTION AND VENUE

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

6. Upon information and belief, this Court has jurisdiction over Par Pharmaceutical, Inc. Upon information and belief, Par Pharmaceutical, Inc. is incorporated in Delaware and directly, or indirectly, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Par Pharmaceutical, Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Par Pharmaceutical, Inc.'s generic products. Par Pharmaceutical, Inc. has previously submitted to the jurisdiction of this Court and has further

previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

7. Upon information and belief, this Court has jurisdiction over Par Pharmaceutical Companies, Inc. Upon information and belief, Par Pharmaceutical Companies, Inc. is incorporated in Delaware and is in the business of manufacturing, marketing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Par Pharmaceutical Companies, Inc. directly, or through its wholly-owned subsidiaries (primarily Par Pharmaceutical, Inc.), conducts business within this judicial district. Upon information and belief, Par Pharmaceutical Companies, Inc. directly, or through its wholly-owned subsidiaries (primarily Par Pharmaceutical, Inc.), manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Par Pharmaceutical Companies, Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

8. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

FIRST COUNT FOR PATENT INFRINGEMENT

9. The U.S. Patent and Trademark Office ("PTO") issued the '077 patent on March 26, 1996, entitled "Fatty Acid Composition." A copy of the '077 patent is attached as Exhibit A.

10. The '077 patent is assigned to Pronova. Pronova is the owner of the '077 patent as recorded by the PTO at Reel 019795, Frame 0594.

11. The '077 patent expires on March 26, 2013.

12. The '077 patent claims, *inter alia*, methods of using omega-3-acid ethyl esters.

13. The '077 patent is listed in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for New Drug Application ("NDA") No. 21-654, which the FDA approved on November 10, 2004.

14. Omega-3-acid ethyl esters manufactured by Pronova are sold in the United States under the trademark Lovaza®.

15. Upon information and belief, Par Pharmaceutical, Inc. filed with the FDA ANDA No. 91-018 under Section 505(j) of the Act, 21 U.S.C. § 355(j).

16. Upon information and belief, Par Pharmaceutical, Inc.'s ANDA No. 91-018 seeks FDA approval to engage in the commercial manufacture, use or sale in the United States of generic products containing omega-3-acid ethyl esters ("Par Pharmaceutical, Inc.'s generic products").

17. On March 20, 2009, Pronova received a letter from Par Pharmaceutical, Inc. dated March 17, 2009, purporting to be a Notice of Certification for ANDA No. 91-018 ("Par Pharmaceutical, Inc's 91-018 letter") under Sections 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 C.F.R. § 314.95.

18. Par Pharmaceutical, Inc.'s 91-018 letter alleges that Par Pharmaceutical, Inc.'s generic products for which it seeks approval contain omega-3-acid ethyl esters.

19. Upon information and belief, Par Pharmaceutical, Inc.'s generic products will, if approved and marketed, infringe at least one claim of the '077 patent.

20. Under 35 U.S.C. § 271(e)(2)(A), Par Pharmaceutical, Inc. has infringed at least one claim of the '077 patent by submitting, or causing to be submitted to the FDA, ANDA No.

91-018 seeking approval for the commercial marketing of Par Pharmaceutical, Inc.'s generic products before the expiration of the '077 patent.

21. Upon information and belief, Par Pharmaceutical, Inc.'s actions relating to Par Pharmaceutical, Inc.'s ANDA No. 91-028 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and, at least in part, for the benefit of Par Pharmaceutical Companies, Inc.

SECOND COUNT FOR PATENT INFRINGEMENT

22. Pronova realleges, and incorporates in full herein, paragraphs 9-21.

23. The PTO issued the '667 patent on August 12, 1997, entitled "Fatty Acid Composition." A copy of the '667 patent is attached as Exhibit B.

24. The '667 patent is assigned to Pronova. Pronova is the owner of the '667 patent as recorded by the PTO at Reel 019795, Frame 0594.

25. The '667 patent expires on April 10, 2017.

26. The '667 patent claims, *inter alia*, omega-3-acid ethyl ester compositions and methods of using omega-3-acid ethyl esters.

27. The '667 patent is listed in the Orange Book for NDA No. 21-654.

28. Upon information and belief, Par Pharmaceutical, Inc.'s generic products will, if approved and marketed, infringe at least one claim of the '667 patent.

29. Under 35 U.S.C. § 271(e)(2)(A), Par Pharmaceutical, Inc. has infringed at least one claim of the '667 patent by submitting, or causing to be submitted to the FDA, ANDA No.

91-018 seeking approval for the commercial marketing of Par Pharmaceutical, Inc.'s generic products before the expiration of the '667 patent.

30. Upon information and belief, Par Pharmaceutical, Inc.'s actions relating to Par Pharmaceutical, Inc.'s ANDA No. 91-028 complained of herein were done at the direction of, with the authorization of, and with the cooperation, the participation, the assistance of, and, at least in part, for the benefit of Par Pharmaceutical Companies, Inc.

WHEREFORE, Plaintiff Pronova respectfully requests that the Court enter judgment in its favor and against Defendants Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par") on the patent infringement claims set forth above and respectfully requests that this Court:

1) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Par has infringed at least one claim of the '077 patent through Par Pharmaceutical, Inc.'s submission of ANDA No. 91-018 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Par Pharmaceutical, Inc.'s generic products before expiration of the '077 patent;

2) order that the effective date of any approval by the FDA of Par Pharmaceutical, Inc.'s generic products be a date that is not earlier than the expiration of the '077 patent, or such later date as the Court may determine;

3) enjoin Par from the commercial manufacture, use, import, offer for sale and/or sale of Par Pharmaceutical, Inc.'s generic products until the expiration of the '077 patent, or such later date as the Court may determine;

4) enjoin Par and all persons acting in concert with Par, from seeking, obtaining or maintaining approval of Par Pharmaceutical, Inc.'s ANDA No. 91-018 until expiration of the '077 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Par has infringed at least one claim of the '667 patent through Par Pharmaceutical, Inc.'s submission of ANDA No. 91-018 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Par Pharmaceutical, Inc.'s generic products before expiration of the '667 patent;

6) order that the effective date of any approval by the FDA of Par Pharmaceutical, Inc.'s generic products be a date that is not earlier than the expiration of the '667 patent, or such later date as the Court may determine;

7) enjoin Par from the commercial manufacture, use, import, offer for sale and/or sale of Par Pharmaceutical, Inc.'s generic products until the expiration of the '667 patent, or such later date as the Court may determine;

8) enjoin Par and all persons acting in concert with Par from seeking, obtaining or maintaining approval of Par Pharmaceutical, Inc.'s ANDA No. 91-018 until expiration of the '667 patent;

9) declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Pronova costs, expenses and disbursements in this action, including reasonable attorney fees; and

10) award Pronova such further additional relief as this Court deems just and proper.

ASHBY & GEDDES

/s/ *John G. Day*

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