IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

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. 7,732,488 ("the '488 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 '488 patent on June 8, 2010, entitled "Pharmaceutical Composition Comprising Low Concentrations of Environmental Pollutants." A copy of the '488 patent is attached as Exhibit A.

10. The '488 patent is assigned to Pronova. Pronova is the owner of the '488 patent as recorded by the PTO at Reel 016754, Frame 0279.

11. The '488 patent expires on January 30, 2025.

12. The '488 patent claims, *inter alia*, pharmaceutical compositions comprising marine oil which comprises eicosapentaenoic acid ethyl ester and docosahexaenoic acid ethyl ester, also known as omega-3-acid ethyl esters, with low concentrations of environmental pollutants and methods of using said pharmaceutical compositions.

13. The '488 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. Pharmaceutical compositions comprising marine oil which comprises eicosapentaenoic acid ethyl ester and docosahexaenoic acid ethyl ester, also known as omega-3-acid ethyl esters, with low concentrations of environmental pollutants 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 August 10, 2010, Pronova received a letter from Par Pharmaceutical, Inc. dated August 5, 2010, 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 '488 patent.

20. Under 35 U.S.C. § 271(e)(2)(A), Par Pharmaceutical, Inc. has infringed at least one claim of the '488 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 '488 patent.

21. Upon information and belief, Par Pharmaceutical, Inc.'s actions relating to Par Pharmaceutical, Inc.'s ANDA No. 91-018 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 '488 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 '488 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 '488 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 '488 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 '488 patent;

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

ASHBY & GEDDES

/s/ Steven J. Balick

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