IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PRONOVA BIOPHARMA NORGE AS, Plaintiff, v. PAR PHARMACEUTICAL, INC., and PAR PHARMACEUTICAL COMPANIES, INC., Defendants.	)	C.A. No. 10-801-UNA **REDACTED PUBLIC VERSION**

ANSWER AND COUNTERCLAIMS

Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Par") answer the Complaint of Pronova BioPharma Norge AS ("Pronova") 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.

Answer: Par lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 and therefore denies them.

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.

Answer: Par admits the allegations in paragraph 2.

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.

Answer: Par admits the allegations in paragraph 3.

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.

Answer: Par admits that Pronova purports to bring this action under the patent laws of the United States relating to an ANDA that Par filed under Section 505(j) of the Act. Par denies that Pronova properly states a claim for patent infringement. Par further denies any infringement of the '488 patent.

JURISDICTION AND VENUE

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

Answer: Par states that it does not contest subject matter jurisdiction.

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.

Answer: Par states that it does not contest this Court's personal jurisdiction over Par Pharmaceutical, Inc. for the purposes of this action. Par avers that Par Pharmaceutical, Inc.'s business is not limited to generic drugs.

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.

Answer: Par states that it does not contest this Court's personal jurisdiction over Par Pharmaceutical Companies, Inc. for the purposes of this action. Par admits that Par Pharmaceutical Companies, Inc. is in the business of manufacturing, marketing, and selling pharmaceutical drug products, including generic drug products.

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

Answer: Par states that it does not contest venue in this judicial district for the purposes of this action.

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.

Answer: Par admits the allegations of paragraph 9.

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.

Answer: Par lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 10 and therefore denies them.

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

Answer: Par states that the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") entry for New Drug Application ("NDA") No. 21-654 lists the '488 patent as expiring on January 30, 2025. Par further states that the expiration date of a patent is a legal matter to which no response is required, and that such date may change under certain circumstances. To the extent a response is required, Par lacks knowledge or information sufficient to form a belief as to the truth of the allegations of paragraph 11 and therefore denies them.

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.

Answer: Par states that the '488 patent document speaks for itself. Par denies the allegations in paragraph 12 to the extent that Par understands them.

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.

Answer: Par admits that Pronova and/or the holder of NDA No. 21-654 caused the '488 patent to be listed in the Orange Book and that the FDA published the patent listing administratively without review. Par admits that NDA No. 21-654 was approved on November 10, 2004. To the extent that paragraph 13 contains any additional allegations, Par denies them.

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®.

Answer: Par lacks knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 14 and therefore denies them.

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).

Answer: Par admits the allegations in paragraph 15.

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").

Answer: Par admits that in ANDA No. 91-018, Par seeks FDA approval to engage in the commercial manufacture, use, or sale of pharmaceutical products containing omega-3-acid ethyl esters. Par denies any remaining allegations in paragraph 16.

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.

Answer: Par admits that Par Pharmaceutical, Inc. notified Pronova by letter dated August 5, 2010 of Par's certification under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. § 314.95 for ANDA No. 91-018. Par lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in paragraph 17 and therefore denies them.

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.

Answer: Par admits that Par Pharmaceutical, Inc.'s letter states that it seeks approval for pharmaceutical products containing omega-3-acid ethyl esters. Par denies any remaining allegations in paragraph 18.

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.

Answer: Par denies the allegations in paragraph 19.

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.

Answer: Par denies the allegations in paragraph 20.

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.

Answer: Par denies the allegations in paragraph 21.

RESPONSE TO PRAYER FOR RELIEF

Par denies that Pronova is entitled to any of the relief it seeks in its Complaint.

SEPARATE DEFENSES

1. The '488 patent is invalid under 35 U.S.C. § 1 *et seq.*

2. No valid claims of the '488 patent will be infringed by the manufacture, use, sale, or offer to sell the proposed drug products under ANDA No. 91-018.

3. The '488 patent is unenforceable for inequitable conduct during prosecution of the patent.

4. The Complaint fails to join an indispensable party.

5. The Complaint fails to state a claim for which relief can be granted.

6. The relief requested in the Complaint is barred by the doctrines of estoppel, waiver, laches, or unclean hands.

COUNTERCLAIMS

Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Par") assert the following counterclaims against Pronova BioPharma Norge AS ("Pronova"):

THE PARTIES

1. Par Pharmaceutical, Inc. is a Delaware corporation having a place of business at One Ram Ridge Road, Spring Valley, New York 10977.

2. Par Pharmaceutical Companies, Inc. is a Delaware corporation having a place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

3. Pronova asserts in its Complaint that it is a corporation organized and existing under the laws of Norway with its corporate headquarters located at Vollsveien 6, 1366 Lysaker, Baerum, Norway.

NATURE OF THE ACTION

4. Par seeks a declaratory judgment under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, that U.S. Patent No. 7,732,488 ("the '488 patent") is invalid, unenforceable, and not infringed.

JURISDICTION

5. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201(a), and 2202.

6. This Court has personal jurisdiction over Pronova by its choice of forum.

VENUE

7. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(c), 1400(b), and Pronova's choice of forum.

BACKGROUND

8. The '488 patent, entitled "Pharmaceutical composition comprising low concentrations of environmental pollutants," issued on June 8, 2010.

9. U.S. Patent No. 5,502,077 ("the '077 patent"), entitled "Fatty acid composition," issued on March 26, 1996.

10. U.S. Patent No. 5,656,667 ("the '667 patent"), entitled "Fatty acid composition," issued on August 12, 1997.

11. U.S. Patent No. 7,678,930 ("the '930 patent"), entitled "Process for decreasing the amount of cholesterol in a marine oil using a volatile working fluid," issued on March 16, 2010.

12. U.S. Patent No. 7,718,698 ("the '698 patent"), entitled "Process for decreasing environmental pollutants in an oil or a fat," issued on May 18, 2010.

13. Pronova is the named assignee of the '488, '077, '667, '930 and '698 patents.

14. On information and belief, GlaxoSmithKline ("GSK") is the holder of New Drug Application No. 21-654 ("NDA 21-654") for oral omega-3-acid ethyl ester capsules, 1 g, marketed under the brand name Lovaza®. In connection with NDA 21-654, GSK and Pronova caused the Food and Drug Administration ("FDA") to list the '077 and '667 patents in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

15. Par submitted Abbreviated New Drug Application No. 91-018 ("ANDA 91-018") to obtain regulatory approval to engage in the commercial manufacture, use, or sale of generic oral omega-3-acid ethyl ester capsules, 1 g, before the expiration of the '077 and '667 patents. Par made a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") that the '077 and '667 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the oral omega-3-acid ethyl ester capsules that are the subject of ANDA 91-018.

16. On March 17, 2009, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Par notified GSK and Pronova of Par's paragraph IV certification regarding the '077 and '667 patents filed with ANDA 91-018. The notice included an offer of confidential access to ANDA 91-018.

17. On April 29, 2009, Pronova filed a Complaint alleging infringement of the '077 and '667 patents by Par, thereby initiating the co-pending action, Case No. 1:09-cv-00305-SLR-MPT ("No. 09-305").

18. On May 19, 2009, Par filed an Answer, asserting the affirmative defenses of invalidity and noninfringement of the '077 and '667 patents, as well as unenforceability of the '667 patent. Par also filed counterclaims for declaratory judgment, alleging the invalidity and noninfringement of both patents and the unenforceability of the '667 patent.

19. On May 25, 2010, Pronova filed its First Amended Complaint in No. 09-305 alleging infringement of the '077, '667, and '930 patents by Par.

20. On July 20, 2010, Pronova filed its Second Amended Complaint in No. 09-305 alleging infringement of the '077, '667, '930, and '698 patents by Par ("the Related Litigation").

21. Sometime between June 8, 2010 and August 5, 2010, GSK caused the FDA to list the '488 patent in the Orange Book in connection with NDA 21-654.

22. Par submitted to FDA a paragraph IV certification that the '488 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the oral omega-3-acid ethyl ester capsules that are the subject of ANDA 91-018.

23. On August 5, 2010, Par notified GSK and Pronova of Par's paragraph IV certification as to the '488 patent filed for ANDA No. 91-018. The notice included an offer of confidential access to ANDA No. 91-018, as defined in 21 U.S.C. § 355(j)(5)(C)(i)(III).

24. In a letter dated August 20, 2010, Par notified Pronova of Par's willingness to include the '488 patent in the Related Litigation. Par received no response from Pronova.

25. On September 20, 2010, Pronova filed its Complaint in the instant action alleging infringement of the '488 patent by Par.

COUNT ONE

(Declaratory Judgment of Invalidity Regarding U.S. Patent No. 7,732,488)

26. Par realleges paragraphs 1-25 of the Counterclaims as if fully set forth herein.

27. The claims of the '488 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

28. An actual and justiciable controversy exists between the parties with respect to the '488 patent, and Par is entitled to a declaratory judgment that the '488 patent is invalid.

COUNT TWO

(Declaratory Judgment of Noninfringement Regarding U.S. Patent No. 7,732,488)

29. Par realleges paragraphs 1-25 of the Counterclaims as if fully set forth herein.

30. The submission of ANDA 91-018 does not infringe any valid claim of the '488 patent.

31. The commercial manufacture, use, offer for sale, sale, or importation of Par's generic oral omega-3-acid ethyl ester product would not infringe any valid claim of the '488 patent.

32. An actual and justiciable controversy exists between the parties with respect to the '488 patent, and Par is entitled to a declaratory judgment that the '488 patent is not infringed.

COUNT THREE

(Declaratory Judgment of Unenforceability Regarding U.S. Patent No. 7,732,488)

33. Par realleges paragraphs 1-32 of the Counterclaims as if fully set forth herein.

34. Finnegan, Henderson, Farabow, Garrett & Dunner LLP ("Finnegan") acted as patent counsel for Pronova in prosecuting the applications that issued as the '488, '930, and '698 patents. Pronova filed a "Revocation of Power of Attorney and Grant of New Power of Attorney" with the U.S. Patent and Trademark Office ("Patent Office") on February 28, 2007 authorizing Finnegan to represent Pronova before the Patent Office in the prosecution of the applications that issued as the '488, '930, and '698 patents.

35. Finnegan has also acted as litigation counsel for Pronova with respect to the Related Litigation since before the filing of Pronova's Complaint on the '077 and '667 patents.

36. Finnegan was familiar with the prosecution of the '488, '930, and '698 patents as well as with the Related Litigation.

37. **REDACTED**

38. The '488 patent relates to the subject matter of the Related Litigation. The '488 patent issued from the parent application of the '698 patent and shares the same disclosure. Pronova has caused the '488 patent to be listed in the Orange Book for Lovaza, along with the '077 and '667 patents in suit in the Related Litigation.

39. The Related Litigation was material to the prosecution of the '488 patent because a reasonable examiner would want to know whether the subject matter for which a patent is

being sought is involved in litigation and whether any material information arose in the litigation, such as possible prior art or allegations of inequitable conduct.

40. Anthony Tridico participated in the prosecution of the application that issued as the '488 patent, signing papers responding to Office Actions, signing Information Disclosure Statements, and meeting with the Patent Examiner on behalf of Pronova.

41. Anthony Tridico also signed the papers submitted to the Patent Office with the original application filed on May 1, 2008 and later issued as the '698 patent.

42. Anthony Tridico was also a signatory to Pronova's Complaint against Par in the Related Litigation. Anthony Tridico was admitted to the Court *pro hac vice* in August of 2009.

43. Anthony Tridico and other attorneys at Finnegan had a duty of candor under 37 C.F.R. § 1.56 to disclose the Related Litigation to the Patent Office.

44. Pronova, its inventors, attorneys and employees, also had a duty of candor under 37 C.F.R. § 1.56 to disclose the Related Litigation to the Patent Office.

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REDACTED

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REDACTED

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51. During the prosecution of the application that issued as the '488 patent, on or about March 12, 2007, Pronova and its counsel submitted to the Patent Office a "Preliminary Amendment" disclosing the marine oil compositions comprising EPA ethyl ester and DHA ethyl ester called "EPAX" and asserting to the Patent Office that the EPAX products were not prior art.

52. Pronova and its counsel stated to the Patent Office that EPAX products were sold in the United States prior to the effective U.S. filing date of the '488 patent.

53. Pronova and its counsel stated to the Patent Office that the EPAX products do not fall within the scope of the claims of the application that issued as the '488 patent because the claims required "a pharmaceutically effective concentration to therapeutically treat hypertriglyceridaemia" and represented that the EPAX products were not therapeutically effective in treating hypertriglyceridaemia.

54. Pronova and its counsel asserted that the claimed invention was patentable because the EPAX products were not effective in reducing triglyceride levels.

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66. More than one year before the priority date for the '488 patent, the U.S. National Marine Fisheries Service ("NMFS") was producing a highly-concentrated omega-3 fish oil with reduced levels of environmental pollutants.

67. More than one year before the priority date for the '488 patent, the NMFS work was public.

68.

REDACTED

69. REDACTED

70. On October 10, 2003, Breivik signed a declaration stating that "I hereby declare that I believe I am the original, first and sole (if only one inventor is listed below) or joint (if more than one inventor is listed below) inventor of the subject matter which is claimed and for which a patent is sought." Breivik's inventorship declaration was false.

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72. REDACTED

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76. **REDACTED**

PRAYER FOR RELIEF

WHEREFORE, Par respectfully requests that this Court enter judgment in its favor and against Pronova and grant the following relief:

A. Declare that the claims of the '488 patent are invalid;

B. Declare that the manufacture, use, offer for sale, sale, or importation of Par's generic oral omega-3-acid ethyl ester product would not infringe the claims of the '488 patent;

C. Declare that the '488 patent is unenforceable;

D. Award Par its costs and reasonable attorney fees; and

E. Award Par such other and further relief as the Court deems just and proper.

/s/ Steven J. Fineman

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Dated: September 27, 2010

CERTIFICATE OF SERVICE

I hereby certify that on September 27, 2010, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing and have electronically mailed to the following:

Steven J. Balick
Tiffany Geyer Lydon
Caroline Hong
Ashby & Geddes
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Wilmington, DE 19801

/s/ Steven J. Fineman
Steven J. Fineman (#4025)
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CERTIFICATE OF SERVICE

I hereby certify that on October 4, 2010, I electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing and have electronically mailed to the following:

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