IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PRONOVA BIOPHARMA NORGE AS, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	)	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Pronova BioPharma Norge AS ("Pronova"), by way of Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd."), 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, Teva USA is a corporation organized under the laws of the State of Delaware, and its principal place of business is located at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

3. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd. Upon information and belief, Teva Ltd. is a corporation under the laws of Israel, and its principal place of business is located at 5 Basel Street, St. Petach Tikva 49131, Israel.

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 Teva USA'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 Teva USA. Upon information and belief, Teva USA directly, or indirectly, manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, Teva USA purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Teva USA's generic products. Teva USA has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction and by asserting counterclaims in other civil actions initiated in this jurisdiction.

7. Upon information and belief, this Court has jurisdiction over Teva Ltd. Upon information and belief, Teva Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Teva Ltd. directly, or through its wholly-owned subsidiaries (primarily Teva USA), conducts business within the judicial district. Upon information and belief, Teva Ltd. directly, or through its wholly-owned subsidiaries (primarily Teva USA), manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Teva Ltd. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction and 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, Teva USA filed with the FDA ANDA No. 91-028 under Section 505(j) of the Act, 21 U.S.C. § 355(j).

16. Upon information and belief, Teva USA's ANDA No. 91-028 seeks FDA approval to engage in the manufacture, use or sale in the United States of generic products containing omega-3-acid ethyl esters ("Teva USA's generic products").

17. On March 12, 2009, Pronova received a letter from Teva USA dated March 9, 2009, purporting to be a Notice of Certification for ANDA No. 91-028 ("Teva USA's 91-028 letter") under Section 505(j)(2)(B)(ii) of the Act and 21 C.F.R. § 314.95(c).

18. Teva USA's 91-028 letter alleges that Teva USA's generic products for which it seeks approval contain omega-3-acid ethyl esters.

19. Upon information and belief, Teva USA'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), Teva USA has infringed at least one claim of the '077 patent by submitting, or causing to be submitted to the FDA, ANDA No. 91-028 seeking approval for the commercial marketing of Teva USA's generic products before the expiration of the '077 patent.

21. Upon information and belief, Teva USA's actions relating to Teva USA'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 Teva Ltd.

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, Teva USA’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), Teva USA has infringed at least one claim of the ’667 patent by submitting, or causing to be submitted to the FDA, ANDA No. 91-028 seeking approval for the commercial marketing of Teva USA’s generic products before the expiration of the ’667 patent.

30. Upon information and belief, Teva USA’s actions relating to Teva USA’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 Teva Ltd.

WHEREFORE, Plaintiff Pronova respectfully requests that the Court enter judgment in its favor and against Defendants Teva USA and Teva Ltd. (collectively "Teva") 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), Teva has infringed at least one claim of the '077 patent through Teva USA's submission of ANDA No. 91-028 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Teva USA's generic products before expiration of the '077 patent;

2) order that the effective date of any approval by the FDA of Teva USA'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 Teva from the commercial manufacture, use, import, offer for sale and/or sale of Teva USA's generic products until the expiration of the '077 patent, or such later date as the Court may determine;

4) enjoin Teva and all persons acting in concert with Teva, from seeking, obtaining or maintaining approval of Teva USA's ANDA No. 91-028 until expiration of the '077 patent;

5) enter judgment that, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed at least one claim of the '667 patent through Teva USA's submission of ANDA No. 91-028 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of Teva USA's generic products before expiration of the '667 patent;

6) order that the effective date of any approval by the FDA of Teva USA'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 Teva from the commercial manufacture, use, import, offer for sale and/or sale of Teva USA's generic products until the expiration of the '667 patent, or such later date as the Court may determine;

8) enjoin Teva and all persons acting in concert with Teva, from seeking, obtaining or maintaining approval of Teva USA's ANDA No. 91-028 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, P.A.

/s/ *John G. Day*

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