IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INTENDIS GMBH, INTRASERV GMBH & CO. KG and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
GLENMARK GENERICS LIMITED and GLENMARK GENERICS INC., USA,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Intendis GmbH, Intraserv GmbH & Co. KG and Bayer HealthCare Pharmaceuticals Inc. (collectively "Plaintiffs"), by and through their undersigned counsel, bring this Complaint for patent infringement against Defendants Glenmark Generics Limited and Glenmark Generics Inc., USA ("Defendants") and allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.* This action relates to Abbreviated New Drug Application ("ANDA") No. 204637, filed by Glenmark Generics Limited, with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Plaintiffs' Finacea® drug product.

THE PARTIES

2. Plaintiff Intendis GmbH ("Intendis") is a corporation organized and existing under the laws of the Federal Republic of Germany, with a principal place of business at Max-Dohrn-Strasse 10, Berlin, D-10589, Germany.

3. Plaintiff Intraserv GmbH & Co. KG ("Intraserv") is a partnership organized and existing under the laws of the Federal Republic of Germany, having a principal place of business at Lilienthalstrasse 4, 12529 Schönefeld OT Waltersdorf, Germany.

4. Plaintiff Bayer HealthCare Pharmaceuticals Inc. ("Bayer HealthCare Pharmaceuticals") is a corporation organized and existing under the laws of the state of Delaware, having a principal place of business at 6 West Belt, Wayne, NJ 07470.

5. Upon information and belief, defendant Glenmark Generics Limited is a corporation organized and existing under the laws of the Republic of India, with a place of business at Glenmark House, HDO–Corporate Building, Wing -A , B. D. Sawant Marg, Chakala, Off Western Express Highway Andheri [East], Mumbai 400099, India.

6. Upon information and belief, defendant Glenmark Generics Inc., USA is a corporation organized and existing under the laws of the state of Delaware, having a place of business at 750 Corporate Drive, Mahwah, NJ 07430.

7. Upon information and belief, Glenmark Generics Inc., USA is a wholly-owned subsidiary of Glenmark Generics Limited and participated in, assisted and cooperated with Glenmark Generics Limited in all of the acts complained of herein.

8. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 204637, Defendants will act in concert to distribute and sell the ANDA product (described below in ¶ 18)

throughout the United States and within Delaware. Upon information and belief, Defendants know and intend that the ANDA product will be distributed and sold in the United States and within Delaware.

JURISDICTION AND VENUE

9. This is an action arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq*. and this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

10. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants have purposefully availed themselves of the rights and benefits of the laws of this State such that they should reasonably anticipate being haled into court here, including, for defendant Glenmark Generics Inc., USA, incorporating in this State. Upon information and belief, Defendants have also engaged in and currently engage in continuous and systematic contacts with this State, and derive substantial revenue through such contacts.

11. Venue is proper in this District under 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

BACKGROUND

12. Finacea® (azelaic acid) Gel, 15% is the subject of New Drug Application ("NDA") No. 21470, which was approved by the FDA. Finacea® is indicated for the topical treatment of inflammatory papules and pustules of mild to moderate rosacea. Bayer HealthCare Pharmaceuticals is the holder of NDA No. 21470.

13. United States Patent No. 6,534,070 (the "070 patent"), entitled "Composition With Azelaic Acid," was duly and legally issued by the United States Patent and Trademark Office on March 18, 2003. The named inventors are Patrick Franke, Clemens

Gunther and Jutta Riedl. A true and correct copy of the '070 patent is attached to this Complaint as Exhibit A.

14. The '070 patent is listed in the FDA "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) as covering Finacea®.

15. Intraserv is the assignee of the '070 patent.

16. Intendis holds an exclusive license under the '070 patent.

17. Bayer HealthCare Pharmaceuticals is the exclusive distributor of Finacea®.

18. Upon information and belief, Defendant Glenmark Generics Limited submitted ANDA No. 204637 to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of a generic Azelaic Acid Gel, 15% formulation (the "ANDA product") based on the Reference Listed Drug ("RLD") Finacea®, before the expiration of the '070 patent.

19. Upon information and belief, ANDA No. 204637 contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '070 patent is "invalid and/or will not be infringed."

20. By letter dated January 30, 2013 ("Notice letter"), Defendant Glenmark Generics Inc., USA informed Plaintiffs Intendis and Bayer HealthCare Pharmaceuticals, and "Bayer HealthCare (Dermatology)," that an ANDA had been filed with the FDA and alleged that the ANDA product would not infringe any claims of the '070 patent.

COUNT I
(INFRINGEMENT OF U.S. PATENT 6,534,070 BY DEFENDANTS)

21. Plaintiffs expressly incorporate by reference paragraphs 1 through 20, inclusive, as if fully set forth herein.

22. Defendants' submission of ANDA No. 204637 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation into the United States of the ANDA product is an act of infringement of one or more claims of the '070 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

23. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation into the United States of the ANDA product would infringe one or more claims of the '070 patent.

24. Upon information and belief, Defendants will engage in the commercial manufacture, use, offer for sale, sale and/or importation of the ANDA product immediately and imminently upon any approval of ANDA No. 204637.

25. Acts of infringement by Defendants will cause Plaintiffs irreparable harm for which they have no adequate remedy at law and will continue unless enjoined by the Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the Court to enter judgment in their favor and grant the following relief:

(a) A judgment that Defendants have directly infringed one or more claims of the '070 patent by filing ANDA No. 204637;

(b) A judgment that Defendants' making, using, selling, offering for sale and/or importing into the United States the ANDA product would infringe one or more claims of the '070 patent;

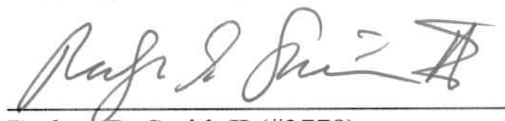
(c) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 204637, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), is to be a date not earlier than the date of expiration of the '070 patent;

(d) A judgment and order permanently restraining and enjoining Defendants and their directors, officers, agents, servants, employees, attorneys, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all persons in active concert or privity with them, and their successors and assigns, from infringing any claims of the '070 patent by making, using, selling, offering for sale and/or importing the ANDA product in the United States;

(e) A finding that this case is exceptional under 35 U.S.C. § 285, warranting an award to Plaintiffs of their costs, including attorneys' fees and other expenses incurred in connection with this action; and

(f) Such further relief as this Court deems just and appropriate.

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