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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

TEVA PHARMACEUTICAL INDUSTRIES LTD. and TEVA PHARMACEUTICALS USA, INC.,	:	
Plaintiffs	:	Civil Action No.
v.	:	
LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,	:	
Defendants.	:	

COMPLAINT FOR DECLARATORY JUDGMENT

For their Complaint against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. ("Defendants"), Plaintiffs Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") and Teva Pharmaceuticals USA, Inc. ("Teva USA"; collectively, "Plaintiffs") allege as to their own acts, and on information and belief as to the acts of others, as follows:

THE PARTIES

1. Teva Ltd. is a corporation organized under the laws of Israel, and maintains its principal place of business at 5 Basel Street, Petah Tiqva 49131, Israel.

2. Teva USA is a Delaware corporation with its principal place of business located at 1090 Horsham Road, North Wales, Pennsylvania, 19454-1090. Teva USA is a wholly-owned subsidiary of Teva Ltd.

3. On information and belief, Defendant Lupin Limited is an Indian corporation based in Mumbai, India. On further information and belief, Defendant Lupin Limited is engaged in the business of developing, manufacturing, and selling various pharmaceutical products, many of which are sold in New Jersey.

4. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a Virginia corporation with its principal place of business at Harborplace Tower, 111 South Calvert St., 21st Floor, Baltimore, MD 21202. On further information and belief, Defendant Lupin Pharmaceuticals, Inc. is registered to do business in New Jersey and maintains a registered agent in New Jersey. On further information and belief, Defendant Lupin Pharmaceuticals, Inc. is engaged in the business of developing, manufacturing, and selling various pharmaceutical products, many of which are sold in New Jersey.

NATURE OF THE ACTION

5. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 1 et seq., and seeking injunctive relief under 35 U.S.C. §§ 281-283.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this controversy under 28 U.S.C. §§ 1331 and 1338(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court's jurisdiction.

8. This Court has personal jurisdiction over Defendants because of, *inter alia*, Defendants' systematic, purposeful and continuous contacts in this District, Defendant Lupin Pharmaceuticals, Inc.'s registration in this District, and Defendant Lupin Limited's availment of the privilege of doing business in this District through its subsidiary and agent Defendant Lupin Pharmaceuticals, Inc.

9. Venue is proper in this judicial district based on 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b), (c), and (d).

FACTUAL BACKGROUND

The Patents in Suit

10. Teva Ltd. is the owner of all right, title and interest in United States Patent Nos. 6,699,997 ("the '997 Patent"), 6,710,184 ("the '184 Patent"), 7,056,942 ("the '942 Patent"), and 7,126,008 ("the '008 Patent"; collectively, "the patents in suit") relating to, *inter alia*, various forms of a chemical compound known as carvedilol and processes for preparing various forms of carvedilol. One polymorphic form of carvedilol is known as "Form II."

11. The '997 Patent was duly and legally issued by the United States Patent and Trademark Office ("PTO") on March 2, 2004 for an invention entitled "Carvedilol." A copy of the '997 Patent is attached as Exhibit A.

12. The '008 Patent was duly and legally issued by the PTO on October 24, 2006 for an invention entitled "Carvedilol." A copy of the '008 Patent is attached as Exhibit B.

13. The '997 and '008 Patents claim processes for preparing carvedilol.

14. The '184 Patent was duly and legally issued by the PTO on March 23, 2004 for an invention entitled "Crystalline Solids of Carvedilol and Processes for Their Preparation." A copy of the '184 Patent is attached as Exhibit C.

15. The '184 Patent claims processes for preparing carvedilol Form II.

16. The '942 Patent was duly and legally issued by the PTO on June 6, 2006 for an invention entitled "Carvedilol." A copy of the '942 Patent is attached as Exhibit D.

17. The '942 Patent claims, *inter alia*, a hydrate form of carvedilol hydrochloride.

GlaxoSmithKline's Exclusivity

18. Carvedilol is a pharmaceutical compound used in the treatment of congestive heart failure. It is the active pharmaceutical ingredient ("API") in the product sold by GlaxoSmithKline ("GSK") under the trade name COREG®. COREG® is included in the United States Food and Drug Administration's ("FDA") list of "Approved Drug Products With Therapeutic Equivalence Evaluations," also known as the "Orange Book."

19. The carvedilol compound is disclosed and claimed in U.S. Patent No. 4,503,067 ("the '067 Patent"), which is owned by GSK. The '067 Patent is listed in the FDA's Orange Book in association with COREG®. The '067 Patent expired on March 5, 2007.

20. Pursuant to 21 U.S.C. § 355a, GlaxoSmithKline was awarded a six-month period of pediatric exclusivity following the expiration of the '067 Patent. GlaxoSmithKline's pediatric exclusivity period extends from March 5, 2007 to September 5, 2007. Pursuant to this exclusivity, the FDA cannot grant final approval to any Abbreviated New Drug Application

("ANDA") holders for carvedilol during that period. The FDA may grant final approval to ANDA holders beginning immediately upon expiration of GSK's pediatric exclusivity period.

21. There are nine holders of ANDAs for carvedilol that have received tentative approval from the FDA. Final approval is expected to be granted to these ANDA holders shortly after the expiration of GSK's pediatric exclusivity period on September 5, 2007. Once each ANDA holder receives final approval, it may market carvedilol tablets in the United States.

Defendants' Imminent Infringement of the Patents in Suit

22. Under the Act, ANDA holders must provide detailed information to the FDA about how the API to be used in their proposed generic products will be made. ANDA holders may purchase API from a supplier instead of making API themselves. Suppliers of API typically are reluctant to disclose confidential information about their manufacturing processes to their customers and, instead, may submit this confidential information directly to the FDA in the form of a Drug Master File ("DMF"). ANDA filers who intend to purchase API from a given supplier may then reference the API supplier's DMF in their ANDAs. Upon receiving an ANDA referencing a DMF, the FDA will separately review the DMF as part of the ANDA approval process. Accordingly, the act of filing a DMF indicates that the present intent of the DMF filer is to supply API in the United States.

23. On information and belief, Defendants have filed DMF No. 19218 for carvedilol API with the FDA.

24. On information and belief, Defendants plan and intend to supply carvedilol API to one or more third party ANDA holder(s), with the knowledge and intent that the third party

ANDA holder(s) will engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic carvedilol tablets in the United States.

25. On information and belief, Defendants plan and intend to supply carvedilol API to the third party ANDA holder(s) with the knowledge and intent that the third party ANDA holder(s) will engage in the activities described in paragraph 24 immediately upon receiving final approval of the ANDA(s) from the FDA, and that said approval will occur shortly after GSK's pediatric exclusivity period expires on September 5, 2007.

26. On information and belief, Defendants plan and intend to supply carvedilol API to the third party ANDA holder(s) with the knowledge and intent that the third party ANDA holder(s) will engage in the activities described in paragraph 24 prior to the expiration of the patents in suit.

27. On information and belief, Defendants plan and intend to import carvedilol API into the United States for sale to third party ANDA holder(s).

28. On information and belief, Defendants' carvedilol API infringes or will infringe one or more claims of the patents in suit, and/or is or will be made by a process that infringes one or more claims of the patents in suit. Accordingly, Defendants' plans and intentions to import and sell carvedilol API in the United States constitute imminent, threatened acts of infringement under 35 U.S.C. § 271, which give rise to an actual controversy over which the Court may exercise jurisdiction.

29. On information and belief, Defendants' plans and intentions to supply carvedilol API to third party ANDA holder(s) outside of the United States for incorporation into products that it knows will be imported and sold in the United States constitutes imminent, threatened

inducement of infringement under 35 U.S.C. § 271, which gives rise to an actual controversy over which this Court may exercise jurisdiction.

30. Plaintiffs have made a reasonable effort to determine the chemical composition of Defendants' carvedilol API, as well as the processes by which Defendants' carvedilol API is or will be made. On May 8, 2007, Teva USA notified Defendants of the existence of the patents in suit and sought information allowing Plaintiffs to ascertain whether Defendants' API falls within the scope of one or more of the patents in suit, and/or whether Defendants' API is made pursuant to a process that falls within the scope of one or more of the patents in suit. In particular, Teva USA requested samples of all carvedilol API made pursuant to Defendants' DMF, and a detailed description of all processes that will be used to manufacture Defendants' carvedilol API. Teva USA offered to enter into a confidentiality agreement to protect the confidentiality of any information disclosed by Defendants. Pursuant to this offer, Teva USA supplied a proposed confidentiality agreement to Defendants.

31. Defendants have not provided to Teva USA samples of Defendants' carvedilol API or the detailed information requested regarding the processes by which Defendants' carvedilol API is made, despite Teva USA's offer of confidentiality. Further, Plaintiffs have been unable to obtain samples of Defendants' API from a public source.

32. Without the requested information, Plaintiffs are unable to determine whether Defendants' API infringes one or more compounds claimed in the patents in suit, or whether the processes by which Defendants' API is made infringe one or more methods claimed in the patents in suit. For this reason, Plaintiffs cannot conclusively determine whether Defendants

infringe each of the patents in suit unless and until Defendants provide samples of their API and disclose to Plaintiffs the processes by which the API is made.

33. In the absence of a sufficient response from Defendants, Plaintiffs have no choice but to resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, the information required to confirm their beliefs as to infringement and to present the Court evidence that Defendants will infringe the patents in suit.

34. As a direct and proximate consequence of the planned and intended infringement by Defendants, Plaintiffs will be injured in their business and property rights unless the infringement is enjoined by the Court, and will suffer injury for which they are entitled to relief.

COUNT I

Declaratory Judgment of Patent Infringement

35. Plaintiffs repeat and reallege Paragraphs 1 through 34 of the Complaint as if fully set forth herein.

36. On information and belief, the importation, manufacture, use, sale and/or offer for sale by Defendants of their carvedilol API pursuant to DMF No. 19218 will infringe, either literally or under the doctrine of equivalents, one or more claims of the '997, '184, '942, and/or '008 Patents, or will contribute to or induce such infringement, under 35 U.S.C. § 271.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Teva Ltd. and Teva USA respectfully request a judgment from the Court:

1. Declaring that the '997, '184, '942, and '008 Patents are valid and enforceable;

2. Declaring that Defendants will infringe, either literally or under the doctrine of equivalents, one or more claims of the '997, '184, '942, and/or '008 Patents, or will contribute to or induce such infringement, under 35 U.S.C. § 271;

3. Declaring that Defendants' infringement will be willful and that this is an exceptional case under 35 U.S.C. § 285;

4. Permanently enjoining Defendants, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringing the '997, '184, '942, and '008 Patents;

5. Awarding Plaintiffs their attorneys' fees, costs, and expenses; and

6. Awarding Plaintiffs such other relief that the Court deems proper, just and equitable.

LITE DEPALMA GREENBERG & RIVAS, LLC

Dated: June 21, 2007

/s/ Michael E. Patunas

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