

LITE DEPALMA GREENBERG & RIVAS, LLC

Allyn Z. Lite
Michael E. Patunas
Mayra V. Tarantino
Two Gateway Center, 12th Floor
Newark, New Jersey 07102
(973) 623-3000

SUTHERLAND ASBILL & BRENNAN LLP

John L. North
Jeffrey J. Toney
N.E.B. Minnear
999 Peachtree Street
Atlanta, Georgia 30309-3996
(404) 853-8000

*Attorneys for Plaintiffs Teva Pharmaceutical
Industries Ltd. and Teva Pharmaceuticals USA, Inc.*

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

TEVA PHARMACEUTICAL	:	
INDUSTRIES LTD. and TEVA	:	ELECTRONICALLY FILED
PHARMACEUTICALS USA, INC.,	:	
	:	
Plaintiffs	:	Civil Action No.:
	:	
v.	:	
	:	
APOTEX, INC. and APOTEX CORP.,	:	
	:	
Defendants.	:	

COMPLAINT FOR PATENT INFRINGEMENT

For their Complaint against Defendants Apotex, Inc. and Apotex Corp. (collectively, "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 an indirect wholly-owned subsidiary of Teva Ltd.

3. On information and belief, Defendant Apotex Inc. is a Canadian corporation having a place of business at 150 Signet Drive, Toronto, Canada M9L 1T9. On further information and belief, Defendant Apotex Inc. 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 Apotex Corp. is a Delaware corporation with its principal place of business at 2400 N. Commerce Parkway, Suite 400, Weston, Florida 33326. On further information and belief, Defendant Apotex Corp. 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 damages and injunctive relief under 35 U.S.C. §§ 271, 281-285.

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, including without limitation Defendant Apotex Corp.'s registration with the New Jersey Department of Health and Senior Services as a "Drug or Medical Device Manufacturing or Wholesale Drug or Medical Device Business" under registration number 5003192, and Defendant Apotex Inc.'s availing of the privilege of doing business in this District through its subsidiary and agent Defendant Apotex Corp.

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." Approved drugs listed in the Orange Book may be used as the basis of a later applicant's Abbreviated New Drug Application to obtain approval of the applicant's generic drug product under 21 U.S.C. § 355(j).

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 ended on September 5, 2007. Pursuant to this exclusivity, the FDA could not grant final approval to any Abbreviated New Drug Application ("ANDA") holders for carvedilol

during that period. After this period ended, the FDA began granting final approval to ANDA holders beginning immediately upon expiration of GSK's pediatric exclusivity period.

Defendants' Infringement of the Patents in Suit

21. On information and belief, Defendants submitted ANDA No. 78-165 to the FDA, requesting approval to market a generic version of COREG[®] in 3.125, 6.25, 12.5, and 25 mg dosage strengths.

22. On information and belief, Defendants received final approval of their ANDA from the FDA on September 5, 2007 and are able to market, offer for sale, and sell generic carvedilol tablets in the United States.

23. Defendants identify generic carvedilol tablets in their pharmaceutical product list on their websites at www.apotexcorp.com/product_frameset.html and www.apotex.com/ca/en/products.

24. Under the Hatch-Waxman 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 make the API themselves or, instead, may purchase the API from a supplier. When an ANDA holder intends to purchase API from a supplier to use in the proposed product, the ANDA holder may reference a Drug Master File ("DMF") submitted to the FDA by that supplier, instead of providing process information in the ANDA. Plaintiffs have been unable to obtain from a public source any information regarding whether Defendants make or purchase the API used in their products.

25. On information and belief, Defendants make carvedilol API or purchase carvedilol API from a third party DMF holder, to use in the manufacture of their generic carvedilol tablets ("Defendants' tablets").

26. On information and belief, Defendants engage in the commercial importation, manufacture, use, sale and/or offer for sale of generic carvedilol tablets in the United States.

27. On information and belief, Defendants are engaging in the activities described in paragraph 26 prior to the expiration of the patents in suit.

28. On information and belief, Defendants' tablets include carvedilol API that infringes or will infringe one or more claims of the patents in suit, and/or that is or will be made by a process that infringes one or more claims of the patents in suit.

29. Plaintiffs have made a reasonable effort to determine the chemical composition of the carvedilol API to be used in Defendants' tablets, as well as the process by which the carvedilol API to be used in Defendants' tablets is or will be made. On August 31, 2007, Teva USA notified Defendant Apotex Inc. of the existence of the patents in suit and sought information allowing Plaintiffs to ascertain whether Defendants' tablets and/or the API to be used in Defendants' tablets fall within the scope of one or more of the patents in suit, and/or whether the API to be used in Defendants' tablets 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 a detailed description of all processes that will be used to manufacture Defendants' tablets, all processes that will be used to make the API to be used in Defendants' tablets, samples of Defendants' tablets, and samples of the API to be used in Defendants' tablets. 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.

30. Defendants have not provided to Teva USA samples of the API to be used in Defendants' tablets, or the detailed information requested regarding the processes by which Defendants' tablets are manufactured or the API to be used in the tablets is made, despite Teva USA's offer of confidentiality. Further, Plaintiffs have been unable to obtain from a public

source samples of the API to be used in their manufacture or the detailed information regarding the processes by which Defendants' tablets are manufactured or the API to be used in the tablets is made.

31. Without the requested information, Plaintiffs are unable to determine the process actually used to produce the product in question.

32. 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 infringe the patents in suit.

33. As a direct and proximate consequence of the 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

Infringement of Patents-in-Suit

34. Plaintiffs repeat and reallege Paragraphs 1 through 33 of the Complaint as if fully set forth herein.

35. On information and belief, the importation, manufacture, use, sale and/or offer for sale by Defendants of their carvedilol tablets pursuant to ANDA No. 78-165 infringes, 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 contribute to or induce such infringement, under 35 U.S.C. § 271;

3. Declaring that Defendants' infringement is willful and that this is an exceptional case under 35 U.S.C. § 285 entitling Plaintiffs to recover treble damages and attorneys fees;

4. Permanently enjoining Defendants, their 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 damages adequate to compensate for Defendants' infringement, but in no event less than a reasonable royalty.

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

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

LITE DEPALMA GREENBERG & RIVAS, LLC

Dated: November 15, 2007

/s/ Michael E. Patunas
Allyn Z. Lite
Michael E. Patunas
Mayra V. Tarantino
Two Gateway Center, 12th Floor
Newark, New Jersey 07102
(973) 623-3000

SUTHERLAND ASBILL & BRENNAN LLP

John L. North
Jeffrey J. Toney
N.E.B. Minnear
999 Peachtree Street, N.E.
Atlanta, Georgia 30309-3996
(404) 853-8000
*Attorneys for Plaintiffs Teva Pharmaceutical
Industries Ltd. and Teva Pharmaceuticals USA, Inc.*