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

TIBOTEC INC., TIBOTEC PHARMACEUTICALS and G.D. SEARLE, LLC Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES, LTD. Defendants.	)	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Tibotec Inc. and Tibotec Pharmaceuticals (collectively, "Tibotec"), and G.D. Searle, LLC ("Searle") (collectively, "Plaintiffs") for their Complaint against defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries, Ltd. ("Teva Industries") (collectively, "Defendants" or "Teva"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent Nos. 5,843,946 ("the '946 Patent") and 7,700,645 ("the '645 Patent") (collectively, "the patents-in-suit") arising under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. This action arises out of Defendants' filing of an Abbreviated New Drug Application ("ANDA") seeking approval to sell generic versions of plaintiff Tibotec's highly successful PREZISTA® (darunavir) 75 mg, 150 mg, 400

mg, and 600 mg products prior to the expiration of patents owned by and exclusively licensed to Plaintiffs.

THE PARTIES

2. Plaintiff Tibotec Inc. is a corporation organized under the laws of the State of Delaware, having its headquarters and principal place of business at 1020 Stony Hill Road, Suite 300, Yardley, PA 19067.

3. Plaintiff Tibotec Pharmaceuticals (formerly known as Tibotec Pharmaceuticals Ltd.) is an Irish corporation having its principal place of business at Eastgate Village, Eastgate, Little Island, County Cork, Ireland.

4. Plaintiff G.D. Searle, LLC is a Delaware limited liability company having a principal place of business at 235 East 42nd Street, New York, New York 10017.

5. On information and belief, Teva Industries is an Israeli corporation, having a principal place of business located at 5 Basel St., Petach Tikva 49131, Israel. On information and belief, Teva Industries is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market through various operating subsidiaries, including Teva USA.

6. On information and belief, Teva USA is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania, 19454. On information and belief, Teva USA is in the business of manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market. Teva USA is a wholly owned subsidiary of Teva Industries.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

8. On information and belief, this Court has personal jurisdiction over Teva USA because Teva USA has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Teva USA has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

9. On information and belief, this Court has personal jurisdiction over Teva Industries because Teva Industries has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Teva Industries has had persistent and continuous contacts with this judicial district, including developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

10. On information and belief, Teva USA and Teva Industries operate and act in concert as an integrated, unitary business. For example, Teva Industries includes within its Annual Report the activities of Teva USA, including revenue earned.

11. On information and belief, Teva USA is registered to do business in New Jersey.

12. On information and belief, Teva USA retains a registered agent in this judicial district.

13. Teva Industries and Teva USA have stipulated and/or consented to personal jurisdiction in this district in numerous prior patent cases.

14. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

15. On December 1, 1998, the United States Patent and Trademark Office ("the PTO") issued the '946 Patent, entitled "α- and β-Amino Acid Hydroxyethylamino Sulfonamides Useful as Retroviral Protease Inhibitors". A true and correct copy of the '946 Patent is attached hereto as Exhibit A.

16. Plaintiff Searle holds title to the '946 Patent.

17. Plaintiff Tibotec Pharmaceuticals (formerly known as Tibotec Pharmaceuticals Ltd.) has an exclusive license under the '946 Patent.

18. The '946 Patent expires on December 1, 2015.

19. On April 20, 2010, the PTO issued the '645 Patent, entitled "Pseudopolymorphic Forms of a HIV Protease Inhibitor". A true and correct copy of the '645 Patent is attached hereto as Exhibit B.

20. Tibotec Pharmaceuticals holds title to the '645 Patent.

21. The '645 Patent expires on December 26, 2026.

22. The United States Food and Drug Administration ("FDA") has requested pediatric studies in support of pediatric exclusivity for PREZISTA® but pediatric exclusivity has not yet been awarded.

23. Tibotec Inc. is the holder of approved New Drug Application ("NDA") No. 21-976 for PREZISTA®.

24. PREZISTA® is included in FDA's list of "Approved Drug Products With Therapeutic Equivalence Evaluations" also known as the "Orange Book." Approved drugs may be used as the basis of a later applicant's ANDA to obtain approval of the ANDA applicant's drug product under the provisions of 21 U.S.C. § 355(j).

25. The FDA's "Orange Book" also lists patents associated with approved drugs. The '946 and '645 Patents are listed in the "Orange Book" in association with PREZISTA®. The claims of the '946 and '645 Patents cover PREZISTA® and its use.

26. On information and belief, Teva Industries, itself and/or through its subsidiary, agent and alter ego, Teva USA, submitted ANDA No. 202-118 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, offer for sale, and sale of generic versions of PREZISTA® 75 mg, 150 mg, 400 mg and 600 mg tablets ("Teva's Generic Tablets").

27. On information and belief, Teva Industries and Teva USA collaborated in the research, development, preparation and filing of ANDA No. 202-118 for Teva's Generic Tablets.

28. On information and belief, Teva USA will market and/or distribute Teva's Generic Tablets if ANDA No. 202-118 is approved by the FDA.

29. On information and belief, Teva Industries participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 202-118.

30. On or about February 1, 2011, Defendants received a letter dated January 31, 2011 ("the Teva Paragraph IV Letter") stating that Teva had submitted ANDA No. 202-118 seeking approval to manufacture, use and sell Teva's Generic Tablets prior to the expiration of the patents-in-suit.

31. The Teva Paragraph IV Letter also states that the Teva ANDA No. 202-118 included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '946 Patent is invalid and that the '645 Patent is not infringed.

32. In the Teva Paragraph IV Letter, Teva did not dispute that the commercial manufacture, use or sale of Teva's Generic Tablets would infringe the '946 Patent.

33. In the Teva Paragraph IV Letter, Teva did not dispute that the '645 Patent is valid.

34. On information and belief, Teva Industries and Teva USA continue to collaborate in seeking approval of ANDA No. 202-118 from the FDA and intend to collaborate in the commercial manufacture, marketing and sale of Teva's Generic Tablets (including the commercial marketing and sale of such products in the State of New Jersey) in the event that the FDA approves ANDA No. 202-118.

35. Plaintiffs commenced this action within forty-five days of the date they received Teva's Paragraph IV Notice of ANDA No. 202-118 containing the Paragraph IV certifications.

COUNT I

Infringement of the '946 Patent

36. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 35 hereof, as if fully set forth herein.

37. Under 35 U.S.C. § 271(e)(2)(A), Teva has infringed the '946 patent by submitting ANDA No. 202-118 with a Paragraph IV certification and seeking FDA approval of ANDA No. 202-118 prior to the expiration of the '946 Patent.

38. Teva does not dispute that it infringes the '946 patent.

39. Teva had actual and constructive notice of the '946 Patent prior to filing ANDA No. 202-118.

40. Plaintiffs have no adequate remedy at law to redress the infringement by Teva.

41. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing or actively inducing or contributing to infringement of the '946 Patent.

COUNT II

Patent Infringement of the '645 Patent

42. Plaintiffs repeat and reallege each and every allegation contained in paragraphs 1 through 41 hereof, as if fully set forth herein.

43. Under 35 U.S.C. § 271(e)(2)(A), Teva has infringed the '645 patent, either literally or under the doctrine of equivalents, by submitting ANDA No. 202-118 with a Paragraph IV certification and seeking FDA approval of ANDA No. 202-118 prior to the expiration of the '645 Patent.

44. Teva had actual and constructive notice of the '645 Patent prior to filing ANDA No. 202-118.

45. Plaintiffs have no adequate remedy at law to redress the infringement by Teva.

46. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing or actively inducing or contributing to infringement of the '645 Patent.

PRAYER

WHEREFORE, Plaintiffs respectfully request relief and judgment as follows:

(a) a judgment that Teva has infringed the '946 and '645 Patents under 35 U.S.C. § 271(e)(2)(A);

(b) a judgment, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Teva's ANDA No. 202-118 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date which is not earlier than the expiration of the '946 and '645 Patents, and any additional periods of exclusivity that may be granted;

(c) a judgment declaring that the making, using, selling, offering to sell, or importing of the generic darunavir tablets described in ANDA No. 202-118 would constitute infringement of the '946 and '645 Patents, or inducing or contributing to such conduct, by Teva pursuant to 35 U.S.C. § 271(a), (b) and/or (c);

(d) a judgment permanently enjoining Teva and each of its officers, agents, servants and employees, and those persons in active concert or participation with them, from commercially manufacturing, selling or offering for sale, using, or importing the generic darunavir tablets described in ANDA No. 202-118 until the expiration of the '946 and '645 Patents, and any additional periods of exclusivity that may be granted;

(e) a declaration that this case is exceptional;

(f) an award of Plaintiffs' costs, expenses, reasonable attorneys' fees and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

(g) such other and further relief as the Court may deem just and proper.

Respectfully submitted,

s/John E. Flaherty

John E. Flaherty
MCCARTER & ENGLISH, LLP
100 Mulberry Street
Four Gateway Center
Newark, New Jersey 07102
Tel: (973) 639-7903
Fax: (973) 297-3971
Attorneys for Plaintiffs

Of Counsel:
Gregory L. Diskant
Eugene M. Gelernter
Irena Royzman
PATTERSON BELKNAP
WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036
Tel.: (212) 336-2000
Fax: (212) 336-2222

Dated: March 16, 2010

CERTIFICATION PURSUANT TO L.CIV.R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding. This action alleges infringement of two patents, one of which is at issue in *Tibotec Inc. and Tibotec Pharmaceuticals v. Lupin Limited, Lupin Pharmaceuticals Inc., Mylan Pharmaceuticals Inc., and Mylan Inc.*, D.N.J., 10-cv-5954-WHW-MAS.

s/John E. Flaherty
John E. Flaherty
MCCARTER & ENGLISH, LLP