UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF FLORIDA
CASE NO._____

TEVA NEUROSCIENCE, INC., TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,

Plaintiffs,

v.

APOTEX INC. and APOTEX CORP.

Defendants.

COMPLAINT

Teva Neuroscience, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva" or "Plaintiffs") bring this action for patent infringement against Defendants Apotex Inc. and Apotex Corp. (collectively, "Apotex" or "Defendants").

1. This is an action by Teva against Apotex for infringement of United States Patent No. 5,453,446 ("'446 patent"). This action arises out of Apotex's filing of an Abbreviated New Drug Application ("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell generic versions of Azilect®, Teva's innovative oral treatment for idiopathic Parkinson's disease, prior to the expiration of the '446 patent.

THE PARTIES

Teva

2. Teva Neuroscience, Inc. ("Teva Neuroscience") is a Delaware corporation with its principal place of business at 901 E. 104th Street, Suite 900, Kansas City, Missouri 64131.

3. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

4. Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israeli company with its principal place of business at 5 Basel Street, Petach Tikva, 49131, Israel.

5. Apotex Inc. is a Canadian company with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

6. Apotex Corp. is a Delaware corporation with its principal place of business at 2400 North Commerce Parkway, Weston, Florida 33326. Apotex Corp. is a subsidiary of Apotex Inc.

7. Apotex submitted ANDA No. 201950 ("Apotex ANDA") to the FDA.

8. Apotex Corp. is the authorized U.S. agent for the Apotex ANDA.

9. Upon information and belief, the preparation and submission of the Apotex ANDA on was done collaboratively between, and for the benefit of, both Apotex Inc. and Apotex Corp.

10. Upon information and belief, Apotex Inc. and Apotex Corp. collaborate or act in concert in the development, manufacturing, testing, packaging, marketing, promoting, offering to sell, selling and distributing of generic pharmaceutical products in the United States, including this Judicial District, for the benefit of Apotex.

JURISDICTION AND VENUE

11. This action for patent infringement arises under 35 U.S.C. § 271.

12. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

13. Upon information and belief, this Court has personal jurisdiction over Apotex Inc. at least because Apotex Inc.: (1) is in the business of developing, manufacturing, marketing and/or selling generic pharmaceuticals for the global market, including the United States, and is

doing business in this Judicial District, directly and/or through its subsidiary and agent Apotex Corp.; (2) maintains and benefits from a distribution network in the United States, directly and indirectly through Apotex Corp., that results in the distribution and sale of Apotex products in the United States and in this Judicial District, and generates substantial revenue to the benefit of Apotex; (3) directly and/or through subsidiaries or agents has engaged in continuous and systematic contacts with Florida and/or purposefully availed itself of this forum by, among other things, making, shipping, using, importing, offering to sell or selling, or causing others to ship, use, import, offer to sell, or sell, Apotex generic pharmaceutical products in the United States, including in this Judicial District, either directly and/or through at least Apotex Corp.; and (4) has previously consented to personal jurisdiction in this Judicial District.

14. Upon information and belief, this Court has personal jurisdiction over Apotex Corp. at least because Apotex Corp.: (1) has its principal place of business in this Judicial District; (2) markets, distributes and sells generic pharmaceutical products in the United States and in this Judicial District; (3) has engaged in continuous and systematic contacts with Florida, including in this Judicial District, and/or purposefully availed itself of this forum by, among other things, making, shipping, using, importing, offering to sell or selling, or causing others to ship, use, import, offer to sell, or sell, pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities, and by filing claims in this Judicial District; and (4) has previously consented to personal jurisdiction in this Judicial District.

15. Venue is proper in this Judicial District under 28 U.S.C. § 1391 and 1400(b).

BACKGROUND

The Patent-in-Suit

16. The '446 patent, entitled "Use of the R-Enantiomers of N-Propargyl 1-Aminoindan Compounds for Treating Parkinson's Disease," was duly and lawfully issued on September 26, 1995 to inventors Moussa B.H. Youdim, John P. M. Finberg, Ruth Levy, Jeffrey Sterling, David Lerner, Tirtsah Berger-Paskin and Haim Yellin. The named inventors assigned the '446 patent to Teva Ltd. and the Technion Research and Development Foundation Ltd. ("Technion"). The Technion subsequently assigned to Teva Ltd. its rights in the '446 patent. Accordingly, Teva Ltd. is the sole owner by assignment of all rights, title and interest in the '446 patent. The '446 patent is listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "The Orange Book" ("Orange Book") with respect to Azilect®. The '446 patent will expire on February 7, 2017. A true and accurate copy of the '446 patent is attached hereto as Exhibit A.

The Azilect® Drug Product

17. Plaintiffs researched, developed, applied for and obtained approval to make, sell, promote and/or market rasagiline mesylate tablet products known as Azilect®.

18. Teva Neuroscience and/or Teva USA have been selling, promoting, distributing and marketing Azilect® in the United States since July 2006.

19. Azilect® is indicated to treat idiopathic Parkinson's disease, as both monotherapy and adjunct therapy with levodopa.

20. Teva Ltd. holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a), for 0.5 and 1.0 mg

Azilect® tablets for the use in treating Parkinson's disease. Teva Neuroscience is Teva Ltd.'s authorized U.S. agent for the NDA.

The Apotex ANDA

21. Apotex filed with the FDA in Rockville, Maryland an ANDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States 0.5 and 1.0 mg rasagiline mesylate tablets that Apotex asserts are generic copies of Azilect® ("Apotex's generic Azilect® products") prior to the expiration of the '446 patent.

22. The FDA assigned the Apotex ANDA the number 201950.

23. Apotex also filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '446 patent are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Apotex's generic Azilect® products ("Apotex's Paragraph IV Certification").

24. By letter dated May 10, 2011, Apotex notified Plaintiffs that it had filed an ANDA seeking approval to market Apotex's generic Azilect® products prior to the expiration of the '446 patent ("Apotex Notice Letter").

25. This action is being commenced before the expiration of forty-five days from the date of receipt of the Apotex Notice Letter.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 5,453,446

26. The allegations of paragraphs 1-25 are realleged and incorporated herein by reference.

27. The use of Apotex's generic Azilect® products is covered by one or more claims of the '446 patent.

28. The commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Apotex's generic Azilect® products would infringe one or more claims of the '446 patent.

29. Apotex infringed the '446 patent by submitting the Apotex ANDA to the FDA seeking approval to market Apotex's generic Azilect® products containing rasagiline mesylate before the expiration of the '446 patent.

30. Defendants Apotex Inc. and Apotex Corp. acted in concert and actively and knowingly assisted with, participated in, encouraged, contributed to, aided and abetted, induced and/or directed the preparation and submission of the Apotex ANDA to the FDA and the preparation to sell Apotex's generic Azilect® products in the United States.

31. Apotex was aware of the '446 patent when engaging in these knowing and purposeful activities and was aware that filing the Apotex ANDA with Apotex's Paragraph IV Certification with respect to the '446 patent constituted an act of infringement of the '446 patent.

32. Use of Apotex's generic Azilect® products in accordance with and as directed by Apotex's proposed labeling for that product would infringe one or more claims of the '446 patent.

33. Upon information and belief, Apotex intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Apotex's generic Azilect® products with its proposed labeling immediately and imminently upon approval of the Apotex ANDA.

34. Upon information and belief, Apotex plans and intends to, and will, actively induce infringement of the '446 patent when the Apotex ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

35. Upon information and belief, Apotex knows that Apotex's generic Azilect® products and the proposed labeling for Apotex's generic Azilect® products are especially made or adapted for use in infringing the '446 patent and that Apotex's generic Azilect® products and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Apotex plans and intends to, and will, contribute to the infringement of the '446 patent immediately and imminently upon approval of the Apotex ANDA.

36. The foregoing actions by Apotex constitute and/or would constitute infringement of the '446 patent, active inducement of infringement of the '446 patent and/or contribution to the infringement by others of the '446 patent.

37. Upon information and belief, Apotex acted without a reasonable basis for believing that it would not be liable for infringing the '446 patent, actively inducing infringement of the '446 patent and/or contributing to the infringement by others of the '446 patent.

38. Plaintiffs will be substantially and irreparably harmed by Apotex's infringing activities unless the Court enjoins those activities. Plaintiffs will have no adequate remedy at law if Apotex is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Apotex's generic Azilect® products.

39. Apotex's activities render this case an exceptional one, and Plaintiffs are entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests the following relief:

a. a judgment that Apotex's submission of the Apotex ANDA No. 201950 was an act of infringement of one or more claims of the '446 patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Apotex's generic Azilect® products prior

to the expiration of the '446 patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the '446 patent;

b. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Apotex ANDA No. 201950, or any product or compound the use of which infringes the '446 patent, shall be a date that is not earlier than the expiration of the '446 patent;

c. an Order permanently enjoining Apotex and all persons acting in concert with Apotex from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Apotex's generic Azilect® products, or any product or compound the use of which infringes the '446 patent, or inducing or contributing to the infringement of the '446 patent until after the expiration of the '446 patent;

d. an Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of the Apotex ANDA No. 201950 before the expiration of the '446 patent;

e. an award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Apotex engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Apotex's generic Azilect® products, or any product or compound the use of which infringes the '446 patent, or the inducement or contribution of the foregoing, prior to the expiration of the '446 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

f. a judgment that this is an exceptional case and awarding Plaintiffs their attorneys' fees under 35 U.S.C. § 285;

g. an award of Plaintiffs' reasonable costs and expenses in this action; and

h. an award of any further and additional relief to Plaintiffs as this Court deems just and proper.

Dated: June 22, 2011

Respectfully submitted,

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