

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA**

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

Plaintiffs,

v.

MYLAN PHARMACEUTICALS INC.,
MYLAN INC., and
MYLAN LLC,

Defendants.

Civil Action No. _____

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 Mylan Pharmaceuticals Inc., Mylan Inc. and Mylan LLC (collectively, “Mylan” or “Defendants”).

1. This is an action by Teva against Mylan for infringement of United States Patent No. 5,453,446 (“’446 patent”). This action arises out of Mylan’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

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. Mylan Inc. (“Mylan Inc.”) is a Pennsylvania corporation with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Upon information and belief, Mylan Inc. conducts business in Morgantown, West Virginia.

6. Mylan Pharmaceuticals Inc. (“Mylan Pharmaceuticals”) is a West Virginia corporation with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc.

7. Mylan LLC (“Mylan LLC”) is a Delaware corporation with its principal place of business at Lot 24, Caguas West Industrial Parkway 156, Caguas, Puerto Rico 00725. Upon information and belief, Mylan LLC is a subsidiary of Mylan Inc. Upon information and belief, Mylan LLC was formerly known as Mylan Inc. (Puerto Rico).

8. Mylan Pharmaceuticals submitted ANDA No. 201971 (“Mylan ANDA”) to the FDA.

9. Upon information and belief, Mylan Pharmaceuticals’ preparation and submission of the Mylan ANDA on was done collaboratively with, and at least in part for the benefit of, Mylan Inc. and Mylan LLC.

10. Upon information and belief, Mylan Pharmaceuticals, Mylan Inc. and Mylan LLC collaborate or act in concert in the development, manufacturing, testing, packaging, marketing,

promoting, selling and distributing of generic pharmaceutical products in the United States, including this Judicial District, for the benefit of Mylan.

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 Mylan Pharmaceuticals at least because Mylan Pharmaceuticals: (1) is incorporated in West Virginia and 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 West Virginia, 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.

14. Upon information and belief, this Court has personal jurisdiction over Mylan Inc. at least because Mylan Inc.: (1) has a place of business in Morgantown, West Virginia; (2) is registered to do business in West Virginia and has appointed as its agent for receipt of service of process Corporation Service Company, 209 West Washington Street, Charlestown, West Virginia 25302; (3) develops, manufactures, markets, promotes, sells and/or distributes generic pharmaceutical products in the United States and this Judicial District directly and/or through Mylan Pharmaceuticals, Mylan LLC and/or other agents or subsidiaries; (4) maintains and

benefits from a distribution network in the United States, directly and indirectly through its agents and subsidiaries, including Mylan Pharmaceuticals, that results in the distribution and sale of Mylan products in the United States and in this Judicial District, and generates substantial revenue to the benefit of Mylan; and (5) has engaged in continuous and systematic contacts with West Virginia, including 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.

15. Upon information and belief, this Court has personal jurisdiction over Mylan LLC at least because Mylan LLC has engaged in continuous and systematic contacts with West Virginia, including 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, Mylan generic pharmaceutical products in the United States, including in this Judicial District, either directly and/or through at least Mylan Inc. and/or Mylan Pharmaceuticals.

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

BACKGROUND

The Patent-in-Suit

17. 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

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

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

20. Azilect[®] is indicated to treat idiopathic Parkinson’s disease, as both monotherapy and adjunct therapy with levodopa.

21. 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 Mylan ANDA

22. Mylan Pharmaceuticals 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 Mylan Pharmaceuticals asserts are generic copies of Azilect[®] (“Mylan’s generic Azilect[®] products”) prior to the expiration of the ’446 patent.

23. The FDA assigned the Mylan ANDA the number 201971.

24. Mylan Pharmaceuticals 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 Mylan's generic Azilect[®] products ("Mylan's Paragraph IV Certification").

25. By letter dated August 27, 2010, Mylan Pharmaceuticals notified Plaintiffs that it had filed an ANDA seeking approval to market Mylan's generic Azilect[®] products prior to the expiration of the '446 patent ("Mylan Notice Letter").

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

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

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

28. The use of Mylan's generic Azilect[®] products is covered by one or more claims of the '446 patent.

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

30. Mylan Pharmaceuticals infringed the '446 patent by submitting the Mylan ANDA to the FDA seeking approval to market Mylan's generic Azilect[®] products containing rasagiline mesylate before the expiration of the '446 patent.

31. Upon information and belief, Defendants Mylan Inc., Mylan LLC and Mylan Pharmaceuticals acted in concert and actively and knowingly caused to be submitted, assisted

with, participated in, encouraged, contributed to, aided and abetted and/or directed the submission of the Mylan ANDA to the FDA.

32. Defendants Mylan Inc. and Mylan LLC induced the infringement of the '446 patent by actively and knowingly aiding and abetting the preparation and submission of the Mylan ANDA and in the preparation to sell Mylan's generic Azilect[®] products in the United States.

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

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

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

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

37. Upon information and belief, Mylan knows that Mylan's generic Azilect[®] products and the proposed labeling for Mylan's generic Azilect[®] products are especially made or adapted for use in infringing the '446 patent, and that Mylan's generic Azilect[®] products and the proposed labeling are not suitable for substantial noninfringing use. Upon information and

belief, Mylan plans and intends to, and will, contribute to the infringement of the '446 patent immediately and imminently upon approval of the Mylan ANDA.

38. The foregoing actions by Mylan 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.

39. Upon information and belief, Mylan 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.

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

41. Mylan'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 Mylan's submission of the Mylan ANDA No. 201971 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 Mylan'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 Mylan ANDA No. 201971, 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 Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Mylan'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 Mylan ANDA No. 201971 before the expiration of the '446 patent;

e. an award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Defendants engage in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Mylan'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.

Respectfully submitted,

Dated: October 5, 2010

By: /s/ John Porco
SCHRADER BYRD & COMPANION, PLLC

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