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

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| TEVA NEUROSCIENCE, INC., TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,<br><br>*Plaintiffs*,<br><br>v.<br><br>SANDOZ INC.<br><br>*Defendant.* | Civil Action No.:<br><br>**COMPLAINT** |

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

1. This is an action by Teva against Sandoz for infringement of United States Patent No. 5,453,446 ("'446 patent"). This action arises out of Sandoz'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. Sandoz is a Colorado corporation with its principal place of business at 506 Carnegie Center, Suite 400, Princeton, NJ 08540.

6. Sandoz submitted ANDA No. 201892 ("Sandoz ANDA") to the FDA.

## JURISDICTION AND VENUE

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

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

9. Upon information and belief, this Court has personal jurisdiction over Sandoz at least because Sandoz: (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; (2) directly and/or through subsidiaries or agents has engaged in continuous and systematic contacts with New Jersey 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, Sandoz generic pharmaceutical products in the United States, including in this Judicial District; and (3) has previously admitted that it is subject to this Court's jurisdiction.

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

## BACKGROUND

### The Patent-in-Suit

11. 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**

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

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

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

15. 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 Sandoz ANDA**

16. Sandoz 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 Sandoz asserts are generic copies of Azilect® ("Sandoz's generic Azilect® products") prior to the expiration of the '446 patent.

17. The FDA assigned the Sandoz ANDA the number 201892.

18. Sandoz 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 Sandoz's generic Azilect® products ("Sandoz's Paragraph IV Certification").

19. By letter dated March 13, 2012, Sandoz notified Plaintiffs that it had filed an ANDA seeking approval to market Sandoz's generic Azilect® products prior to the expiration of the '446 patent ("Sandoz Notice Letter").

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

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

21. The allegations of paragraphs 1-21 are realleged and incorporated herein by reference.

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

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

24. Sandoz infringed the '446 patent by submitting the Sandoz ANDA to the FDA seeking approval to market Sandoz's generic Azilect® products containing rasagiline to treat Parkinson's disease before the expiration of the '446 patent.

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

26. Upon information and belief, use of Sandoz's generic Azilect® products in accordance with and as directed by Sandoz's proposed labeling for that product would infringe one or more claims of the '446 patent.

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

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

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

30. The foregoing actions by Sandoz 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.

31. Upon information and belief, Sandoz 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.

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

33. Sandoz'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 Sandoz's submission of the Sandoz ANDA No. 201892 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 Sandoz'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 Sandoz ANDA No. 201892, 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. In the event that Sandoz obtains final approval for Sandoz's generic Azilect® products prior to judgment being entered in this action, enjoining, including preliminarily enjoining, Sandoz from the commercial manufacture, use, offer to sell, sale or importation of Sandoz's generic Azilect® products in the United States before the date of expiration of the '446 patent in accordance with 35 U.S.C. § 283;

d. an Order permanently enjoining Sandoz and all persons acting in concert with Sandoz from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sandoz'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;

e. an Order enjoining Sandoz and all persons acting in concert with Sandoz from seeking, obtaining, or maintaining approval of the Sandoz ANDA No. 201892 before the expiration of the '446 patent;

f. an award of Plaintiffs' damages or other monetary relief to compensate Plaintiffs if Sandoz engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Sandoz'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);

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

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

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

**LITE DEPALMA GREENBERG, LLC**

Dated: April 26, 2012

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**CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2**

Plaintiffs Teva Neuroscience, Inc., Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd., by their attorneys, hereby certify that the matter in controversy is also the subject of the following actions:

| **Caption** | **Civil Action No.** |
|---|---|
| *Teva Neuroscience, Inc., et al. v. Watson Laboratories, Inc., et al.* | 10-5078 (CCC)(JAD) |
| *Teva Neuroscience, Inc., et al. v. Apotex Corp., et al.* (Consolidated) | 11-3076 (CCC)(JAD) |

I hereby certify that the following statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: April 26, 2012

**LITE DEPALMA GREENBERG, LLC**

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