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

**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>WATSON PHARMA, INC., WATSON LABORATORIES, INC., WATSON PHARMACEUTICALS, INC., WATSON PHARMA PRIVATE LTD. - UNIT IV, MYLAN PHARMACEUTICALS, INC., MYLAN INC., MYLAN LLC, ORCHID CHEMICALS & PHARMACEUTICALS LTD., ORCHID HEALTHCARE (a division of Orchid Chemicals & Pharmaceuticals Ltd.), and ORGENUS PHARMA INC.<br><br>*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 Watson Pharma, Inc., Watson Laboratories, Inc., Watson Pharmaceuticals. Inc. and Watson Pharma Private Ltd. - Unit IV (collectively, "Watson"); Mylan Pharmaceuticals,

Inc., Mylan Inc. and Mylan LLC (collectively, "Mylan"); and Orgenus Pharma Inc., Orchid Chemicals & Pharmaceuticals Ltd. and Orchid Healthcare (a division of Orchid Chemicals & Pharmaceuticals Ltd.) (collectively "Orchid"). Watson, Mylan and Orchid collectively are referred to as "Defendants" herein.

1. This is an action by Teva against Defendants for infringement of United States Patent No. 5,453,446 ("'446 patent"). This action arises out of Defendants' filing of Abbreviated New Drug Applications ("ANDAs") 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.

**Watson**

5. Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a Nevada corporation with its principal place of business at 311 Bonnie Circle, Corona, California 92880. Upon information and belief, Watson Pharmaceuticals conducts business at 360 Mt. Kemble Avenue, Morristown, New Jersey 07962.

6. Watson Pharma, Inc. ("Watson Pharma") is a Delaware corporation with its principal place of business at 360 Mt. Kemble Avenue, Morristown, New Jersey 07962. Upon information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals.

7. Upon information and belief, the offices of Watson Pharma in Morristown, New Jersey, are Watson's executive offices and commercial headquarters.

8. Watson Laboratories, Inc. ("WLI - NV") is a Nevada corporation with its principal place of business at 311 Bonnie Circle, Corona, California 92880. Upon information and belief, WLI – NV is a wholly-owned subsidiary of Watson Pharmaceuticals.

9. Watson Laboratories, Inc. ("WLI – FL") is a Florida corporation with its principal place of business at 4955 Orange Drive, Davie, Florida 33314. Upon information and belief, WLI – FL is a wholly-owned subsidiary of Watson Pharmaceuticals.

10. Watson Laboratories, Inc. ("WLI – DE") is a Delaware corporation with its principal place of business at 577 Chipeta Way, Salt Lake City, Utah 84108. Upon information and belief, WLI – DE is a wholly-owned subsidiary of Watson Pharmaceuticals.

11. Watson Laboratories, Inc. ("WLI – NY") is a New York corporation with its principal place of business at 1033 Stoneleigh Avenue, Carmel, New York 10512 and/or 26 Bethpage Road, Copiague, NY 11726. Upon information and belief, WLI – NY is a wholly-owned subsidiary of Watson Pharmaceuticals.

12. Watson Laboratories, Inc. ("WLI – CT") is a Connecticut corporation with its principal place of business at 131 West Street, Danbury, Connecticut 06810. Upon information and belief, WLI – CT is a wholly-owned subsidiary of Watson Pharmaceuticals.

13. "WLI" hereafter collectively refers to each and every individual WLI entity identified above that submitted, or collaborated or acted in concert with Watson in the preparation or submission of, Watson's ANDA Number 201823 ("Watson ANDA").

14. WLI conducts business at 360 Mt. Kemble Avenue, Morristown, New Jersey 07960.

15. Watson Pharma Private Ltd. - Unit IV ("WPP") is an Indian company with its principal place of business at 201/301, HDO Building, Corporate Enclave, B Wing, 100 Link Road, Chakla, Andheri (E), Mumbai, Maharashtra 400 099 India. Upon information and belief, WPP is a subsidiary of Watson Pharmaceuticals.

16. WLI submitted the Watson ANDA No. 201823 to the FDA.

17. Upon information and belief, WLI's preparation and submission of the Watson ANDA was done collaboratively with, and at least in part for the benefit of, Watson Pharmaceuticals, Watson Pharma and WPP.

18. Upon information and belief, Watson Pharmaceuticals, Watson Pharma, WLI and WPP 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 Watson.

**Mylan**

19. 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 Liberty Corner, New Jersey.

20. 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.

21. 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).

22. Mylan Pharmaceuticals submitted ANDA No. 201971 ("Mylan ANDA") to the FDA.

23. 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.

24. 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.

**Orchid**

25. Orchid Chemicals & Pharmaceuticals Ltd. ("Orchid Ltd.") is an Indian company with its principal place of business at Orchid Towers, 313 Valluvar Kottam High Road, Nungambakkam, Chennai – 600 034, Tamil Nadu, India.

26. Orchid Ltd. has a division doing business as Orchid Healthcare ("Orchid d/b/a Orchid Healthcare") with a principal place of business at Plot Nos. B5(Pt) & B6 (Pt), SIPCOT Industrial Park, Irungattukottai, Sriperumbudur – 602 105, Kancheepuram Dist., Tamil Nadu, India.

27. Orgenus Pharma Inc. ("Orgenus") is a New Jersey corporation with its principal place of business at 700 Alexander Park, Suite 104, Princeton, New Jersey 08540. Upon information and belief, Orgenus is a wholly-owned subsidiary of Orchid Pharmaceuticals, Inc., which is a wholly-owned subsidiary of Orchid Ltd.

28. Orgenus is Orchid Ltd.'s "Primary Business Contact for US and Canada" and Orchid Ltd's website directs the public to Orgenus and its Executive Vice President – Business Development & Operations, Mr. Satish Srinivasan, concerning Orchid Ltd.'s business matters in the United States.

29. Orchid d/b/a Orchid Healthcare submitted ANDA No. 201970 ("Orchid ANDA") to the FDA.

30. Orgenus is the authorized U.S. agent for the Orchid ANDA.

31. Upon information and belief, Orchid d/b/a Orchid Healthcare's preparation and submission of the Orchid ANDA was done collaboratively with, and at least in part for the benefit of, Orchid Ltd. and Orgenus.

32. Upon information and belief, Orgenus supports, collaborates or acts in concert with Orchid Ltd. and Orchid d/b/a Orchid Healthcare in obtaining regulatory approval for and the sales and distribution of Orchid products in the United States.

33. Orchid Ltd., Orchid d/b/a Orchid Healthcare and Orgenus 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 Orchid.

## JURISDICTION AND VENUE

**Subject Matter Jurisdiction**

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

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

**Personal Jurisdiction Over Watson**

36. Upon information and belief, this Court has personal jurisdiction over Watson Pharma at least because Watson Pharma: (1) has its principal place of business in New Jersey and conducts business in this Judicial District; and (2) 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, offering to sell or selling, or causing others to use, offer to sell, or sell, Watson generic pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

37. Upon information and belief, this Court has personal jurisdiction over Watson Pharmaceuticals at least because Watson Pharmaceuticals: (1) has a place of business and conducts business in this Judicial District; (2) directly and through its wholly-owned subsidiaries, including but not limited to Watson Pharma, manufactures, markets, distributes and/or sells generic Watson pharmaceuticals throughout the United States, including this Judicial District; (3) directly and through its wholly-owned subsidiaries, including but not limited to Watson Pharma, 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, offering to sell or selling, or causing others to use, offer to sell, or sell, Watson generic pharmaceutical products in this Judicial District, and deriving substantial revenue from such

activities; and (4) has previously consented to personal jurisdiction and filed claims in this Judicial District.

38. Upon information and belief, this Court has personal jurisdiction over WLI at least because WLI: (1) has a place of business in New Jersey and conducts business in this Judicial District; (2) develops, manufactures, sells and/or distributes generic Watson pharmaceutical products for the U.S. market, including this Judicial District; (3) 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, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities; and (4) has previously consented to personal jurisdiction and filed claims in this Judicial District.

39. Upon information and belief, this Court has personal jurisdiction over WPP at least because: (1) the generic pharmaceutical products that Watson distributes, markets and sells in this Judicial District for the benefit of Watson include products manufactured by WPP and (2) WPP has engaged in continuous and systematic contacts with New Jersey and/or purposefully availed itself of this forum by, among other things, assisting, collaborating or acting on concert with Watson Pharmaceuticals, Watson Pharma and/or WLI to make, use, offer to sell or sell generic Watson pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

**Personal Jurisdiction Over Mylan**

40. Upon information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals at least because Mylan Pharmaceuticals: (1) is registered to do business in New Jersey and has appointed as its agent for receipt of service of process Corporate Service

Company, 830 Bear Tavern Road, West Trenton, New Jersey 08628; (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 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, 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.

41. Upon information and belief, this Court has personal jurisdiction over Mylan Inc. at least because Mylan Inc.: (1) has a place of business in Liberty Corner, New Jersey; (2) is registered to do business in New Jersey and has appointed as its agent for receipt of service of process Corporate Service Company, 830 Bear Tavern Road, West Trenton, New Jersey 08628; (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; (5) 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, pharmaceutical products in this Judicial District, and deriving substantial revenue from such

activities, and by filing claims in this Judicial District; and (6) has previously consented to personal jurisdiction in this Judicial District.

42. 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 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, 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.

**Personal Jurisdiction Over Orchid**

43. Upon information and belief, this Court has personal jurisdiction over Orchid Ltd. at least because Orchid Ltd.: (1) is registered to do business in New Jersey and has designated an agent to accept service of process in New Jersey; (2) has designated Mr. Sathish Srinivasan of Orgenus, a New Jersey company, to accept service of process on its behalf in connection with this law suit, through its division d/b/a Orchid Healthcare; (3) 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 division d/b/a Orchid Healthcare and through Orgenus; (4) maintains and benefits from a distribution network in the United States, directly and indirectly through Orgenus, that results in the distribution and sale of Orchid products in the United States and in this Judicial District, and generates substantial revenue to the benefit of Orchid; (5) has engaged in continuous and systematic contacts with New Jersey and/or purposefully availed itself of this forum directly, through its division, Orchid Healthcare, and through Orgenus, by, among other things, making, shipping, using, offering to sell or selling, or causing others to ship, use, offer to sell, or sell,

pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities; and (6) has previously consented to personal jurisdiction in this Judicial District and has filed claims in this Judicial District.

44. Upon information and belief, this Court has jurisdiction over Orchid d/b/a Orchid Healthcare at least because Orchid d/b/a Orchid Healthcare: (1) develops, manufactures, markets, distributes and/or sells generic pharmaceutical formulations for the U.S. market and markets, distributes and/or sells generic pharmaceutical products in the United States and in this Judicial District directly and indirectly through Orgenus; (2) has designated Mr. Sathish Srinivasan of Orgenus, a New Jersey company, to accept service of process on its behalf in connection with this law suit; (3) maintains and benefits from a distribution network in the United States, directly and indirectly through Orgenus, that results in the distribution and sale of Orchid products in the United States and in this Judicial District, and generates substantial revenue to the benefit of Orchid; (4) has engaged in continuous and systematic contacts with New Jersey and/or purposefully availed itself of this forum directly and through Orgenus, by, among other things, making, shipping, using, offering to sell or selling, or causing others to ship, use, offer to sell, or sell, pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities; and (5) has previously consented to personal jurisdiction in this Judicial District.

45. Upon information and belief, this Court has personal jurisdiction over Orgenus at least because Orgenus: (1) has its principal place of business in Princeton, New Jersey and conducts business in this Judicial District; (2) is incorporated in New Jersey; (3) 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, 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 admitted personal jurisdiction in this Judicial District.

**Venue**

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

## BACKGROUND

**The Patent-in-Suit**

47. 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**

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

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

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

51. 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 Watson ANDA**

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

53. The FDA assigned the Watson ANDA the number 201823.

54. WLI 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 Watson's generic Azilect® products ("Watson's Paragraph IV Certification").

55. By letter dated September 1, 2010, WLI notified Plaintiffs that it had filed an ANDA seeking approval to market Watson's generic Azilect® products prior to the expiration of the '446 patent ("Watson Notice Letter").

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

**The Mylan ANDA**

57. 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.

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

59. 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").

60. 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").

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

**The Orchid ANDA**

62. Upon information and belief, Orchid d/b/a Orchid Healthcare 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 Orchid d/b/a Orchid Healthcare asserts are generic copies of Azilect® ("Orchid's generic Azilect® products") prior to the expiration of the '446 patent.

63. Upon information and belief, the FDA assigned the Orchid ANDA the number 201970.

64. Upon information and belief, Orchid d/b/a Orchid Healthcare 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 Orchid's generic Azilect® products ("Orchid's Paragraph IV Certification").

65. By letter dated August 18, 2010, Orchid d/b/a Orchid Healthcare notified Plaintiffs that it had filed an ANDA seeking approval to market Orchid's generic Azilect® products prior to the expiration of the '446 patent ("Orchid Notice Letter").

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

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

67. The allegations of paragraphs 1-66 are realleged and incorporated herein by reference.

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

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

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

71. Upon information and belief, Defendants Watson Pharmaceuticals, Watson Pharma, WPP and WLI 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 Watson ANDA to the FDA.

72. Defendants Watson Pharmaceuticals, Watson Pharma and WPP induced the infringement of the '446 patent by actively and knowingly aiding and abetting the preparation and submission of the Watson ANDA and in the preparation to sell Watson's generic Azilect® products in the United States.

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

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

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

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

77. Upon information and belief, Watson knows that Watson's generic Azilect® products and the proposed labeling for Watson's generic Azilect® products are especially made

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

78. The foregoing actions by Watson 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.

79. Upon information and belief, Watson 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.

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

81. Watson'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.

**COUNT II FOR INFRINGEMENT OF U.S. PATENT NO. 5,453,446 BY MYLAN**

82. The allegations of paragraphs 1-66 are realleged and incorporated herein by reference.

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

84. 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.

85. 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.

86. 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.

87. 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.

88. 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.

89. 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.

90. 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.

91. 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.

92. 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.

93. 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.

94. 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.

95. 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.

96. 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.

**COUNT III FOR INFRINGEMENT OF U.S. PATENT NO. 5,453,446 BY ORCHID**

97. The allegations of paragraphs 1-66 are realleged and incorporated herein by reference.

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

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

100. Orchid d/b/a Orchid Healthcare infringed the '446 patent by submitting the Orchid ANDA to the FDA seeking approval to market Orchid's generic Azilect® products containing rasagiline mesylate before the expiration of the '446 patent.

101. Upon information and belief, Defendants Orchid Ltd., Orchid d/b/a Orchid Healthcare and Orgenus 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 Orchid ANDA to the FDA.

102. Defendants Orchid Ltd. and Orgenus induced the infringement of the '446 patent by actively and knowingly aiding and abetting the preparation and submission of the Orchid ANDA and in the preparation to sell Orchid's generic Azilect® products in the United States.

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

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

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

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

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

108. The foregoing actions by Orchid 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.

109. Upon information and belief, Orchid 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.

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

111. Orchid'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 Watson's submission of the Watson ANDA No. 201823, Mylan's submission of the Mylan ANDA No. 201971 and Orchid's submission of the Orchid ANDA No. 201970 were acts 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 Watson's generic Azilect® products, Mylan's generic Azilect® products, or Orchid's generic Azilect® products (collectively, "Defendants' 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 Watson ANDA No. 201823, Mylan ANDA No. 201971 and Orchid ANDA No. 201970, 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 Defendants' 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 Watson ANDA No. 201823, Mylan ANDA No. 201971, or Orchid ANDA No. 201970 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 Defendants' 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: October 1, 2010

**LITE DEPALMA GREENBERG, LLC**

*/s/ Michael E. Patunas*

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