IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VALEANT INTERNATIONAL (BARBADOS) SRL,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
SANDOZ, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Valeant International (Barbados) SRL ("Valeant") for its Complaint against Sandoz, Inc. ("Sandoz"), to the best of its knowledge, information, and belief, alleges:

PARTIES

1. Plaintiff Valeant is an international society with restricted liability established and existing under the laws of Barbados having a principal place of business at Welches, Christ Church, Barbados, West Indies.

2. Upon information and belief, Defendant Sandoz, Inc. is a corporation organized and existing under the laws of the State of Colorado, with a place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

3. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*, and in particular under 35 U.S.C. § 271, and 28 U.S.C. §§ 2201 and 2202.

4. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

5. This Court has personal jurisdiction over Sandoz by virtue of the fact that Sandoz regularly does or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, and/or derives substantial revenue from services or things used or consumed in Delaware.

6. The Court also has personal jurisdiction over Sandoz by virtue of the fact that Sandoz is in the business of manufacturing, distributing, and selling generic pharmaceutical products throughout the United States, including in this judicial district, and is registered to distribute drugs in the State of Delaware.

7. On information and belief, Sandoz is registered with the Delaware Board of Pharmacy as a licensed "Distributor/Manufacturer CSR" (License No. DS0131) and "Pharmacy-Wholesale" (License No. A4-0000260) pursuant to Del. C. § 2540.

8. On information and belief, Sandoz has previously availed itself of this forum for purposes of litigating its patent disputes. For example, Sandoz has submitted to the jurisdiction of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. Specifically, on March 22, 2010, Sandoz consented to personal jurisdiction in Delaware and filed counterclaims in *Cephalon, Inc. v. Sandoz Inc.*, C.A. No. 10-123-SLR (D. Del.).

9. On information and belief, and consistent with its practice with respect to other generic products, following any FDA approval of its Abbreviated New Drug Application No. 203348 ("ANDA"), Sandoz will sell its generic product throughout the United States, including in Delaware.

10. On information and belief, Sandoz has derived substantial revenue from sales of pharmaceutical products in Delaware.

11. Sandoz has engaged the services of various Delaware law firms to represent it and has repeatedly entered this District to litigate its patent disputes before this Court.

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

13. An actual, substantial, and justiciable controversy exists between Valeant and Sandoz as to the infringement and validity of United States Patent Numbers 7,241,805, 7,569,610, 7,572,935, 7,585,897, 7,645,802, 7,649,019, 7,662,407, 7,671,094 and 7,553,992 (the "Patents-in-Suit").

PATENTS IN SUIT

14. Valeant is the lawful owner by assignment of exclusive rights to the Patents-in-Suit, including all right to sue and recover for infringement.

15. United States Patent No. 7,241,805 ("'805 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued July 10, 2007, naming Werner Oberegger, Fang Zhou, Paul Maes, Stefano Turchetta, Graham Jackson, Pietro Massardo, and Mohammad Ashty Saleh as inventors, claiming priority to provisional Application No. 60/693,906 filed on June 27, 2005. A copy of the '805 patent is attached as Exhibit A.

16. United States Patent No. 7,569,610 ("'610 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued August 4, 2009, naming Werner Oberegger, Paul Maes, and Mohammad Ashty Saleh as inventors. The '610 patent is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805. A copy of the '610 patent is attached as Exhibit B.

17. United States Patent No. 7,572,935 ("'935 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued August 11, 2009, naming Werner Oberegger, Paul Maes, Stefano Turchetta, Pietro Massardo, and Mohammad Ashty Saleh as inventors. The '935 patent is a continuation of Application No. 11/751,768, filed on May 22, 2007, which is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805. A copy of the '935 patent is attached as Exhibit C.

18. United States Patent No. 7,585,897 ("'897 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued September 8, 2009, naming Werner Oberegger, Fang Zhou, Paul Maes, Graham Jackson and Mohammad Ashty Saleh as inventors. The '897 patent is a continuation of Application No. 11/751,768, filed on May 22, 2007, which is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805. A copy of the '897 patent is attached as Exhibit D.

19. United States Patent No. 7,645,802 ("'802 patent"), entitled "Bupropion Hydrobromide and Therapeutic Applications," duly and legally issued January 12, 2010, naming Werner Oberegger, Paul Maes, Mohammad Ashty Saleh, and Graham Jackson as inventors. The

'802 patent is a continuation-in-part of Application No. 11/755,946, filed on May 31, 2007, now United States Patent No. 7,553,992, which is a continuation of Application No. 11/475,252, filed on June 27, 2006, now United States Patent No. 7,241,805, said Application No. 11/930,644 is a continuation-in-part of Application No. 11/751,768, filed on May 22, 2007, now United States Patent No. 7,569,610, which is a continuation of Application No. 11/475,252, filed on June 27, 2006, now United States Patent No. 7,241,805, claiming priority to provisional Application No. 60/693,906 filed on June 27, 2005. A copy of the '802 patent is attached as Exhibit E.

20. United States Patent No. 7,649,019 ("'019 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued January 19, 2010, naming Werner Oberegger, Fang Zhou, Paul Maes, Graham Jackson, and Mohammad Ashty Saleh as inventors. The '019 patent is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805. A copy of the '019 patent is attached as Exhibit F.

21. United States Patent No. 7,662,407 ("'407 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued February 16, 2010, naming Werner Oberegger, Paul Maes, Graham Jackson, and Mohammad Ashty Saleh as inventors. The '407 patent is a continuation of Application No. 11/751,768 filed on May 22, 2007, now United States Patent No. 7,569,610, which a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805, claiming priority to provisional Application No. 60/693,906 filed on June 27, 2005. A copy of the '407 patent is attached as Exhibit G.

22. United States Patent No. 7,671,094 ("'094 patent"), entitled "Bupropion Hydrobromide and Therapeutic Applications," duly and legally issued March 2, 2010, naming Robert Perry Williams and Peter Harris Silverstone as inventors. The '094 patent is a continuation-in-part of Application No. 11/751,768, filed May 22, 2007, now United States Patent No. 7,569,610; and a continuation-in-part of Application No. 11/755,946 filed on May 31, 2007, now United States Patent No. 7,553,992, both of which are continuations of Application No. 11/475,252, filed Jun. 27, 2006, now United States Patent No. 7,241,805. A copy of the '094 patent is attached as Exhibit H.

23. United States Patent No. 7,553,992 ("'992 patent"), entitled "Modified Release Formulations of a Bupropion Salt," duly and legally issued June 30, 2009, naming Werner Oberegger, Paul Maes, Stefano Turchetta, Pietro Massardo, and Mohammad Ashty Saleh as inventors. The '992 patent is a continuation of Application No. 11/475,252 filed on June 27, 2006, now United States Patent No. 7,241,805. A copy of the '992 patent is attached as Exhibit I.

APLENZIN® ER

24. Valeant is the holder of New Drug Application ("NDA") No. 22-108 for Aplenzin® (bupropion hydrobromide) ER Tablets, 174 mg, 348 mg, and 522 mg.

25. On April 23, 2008, the U.S. Food and Drug Administration ("FDA") approved NDA No. 22-108 for the manufacture, marketing, and sale of a product containing the drug bupropion hydrobromide for treatment of depression. The drug bupropion hydrobromide with the trademark Aplenzin® ER has been sold under NDA 22-108 since approval.

26. In compliance with 21 U.S.C. § 355(b)(1), Valeant certified to the FDA that the '805, '935, '897, '802, '019, '407 and '094 patent claims cover Aplenzin® ER. The '805, '935, '897, '802, '019, '407 and '094 patents are accordingly listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book"). The '610 patent is also listed in the Orange Book covering methods of using Aplenzin® ER.

PRIOR LITIGATION OF THE PATENTS-IN SUIT

27. On February 19, 2010, Valeant successfully sued Watson Pharmaceuticals, Inc., Watson Laboratories, Inc. – Florida, and Watson Pharma, Inc. in the Southern District of Florida (Case No. 10-CV-20526) for infringing (among others) the '610, '019 and '992 patents-in-suit. Following a bench trial from June 21, 2011 to June 28, 2011 the district court rejected all of Watson's invalidity defenses and entered a Final Judgment in favor of Valeant on November 8, 2011. The case is currently pending on appeal.

SANDOZ'S ANDA

28. Upon information and belief, Sandoz submitted Abbreviated New Drug Application No. 203348 ("ANDA") to the FDA, under § 505(j) of the Federal Food, Drug and

Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in commercial manufacture, use, and/or sale of bupropion hydrobromide extended-release tablets ("Sandoz's Generic Product"), a generic version of Aplenzin® ER, before expiration of the '805, '610, '935, '897, '802, '019, '407, '094 and '992 patents. Sandoz's ANDA currently includes one dosage form (348 mg) of Sandoz's Generic Product.

29. Upon information and belief, Sandoz's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging at least the '805, '935, '897, '802, '019, '407 and '094 patents listed in the FDA's Orange Book as covering Aplenzin® ER and its use are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of Sandoz's Generic Product.

30. On or about March 20, 2012 Valeant received written notification of ANDA No. 203348 under 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. 314.95 ("Paragraph IV letter"). The stated purpose of the letter was to notify Valeant that Sandoz filed a certification with the FDA under 21 C.F.R. § 314.95 in conjunction with ANDA No. 203348 for approval to commercially manufacture and sell Sandoz's Generic Product before the expiration of Valeant's Orange Book listed patents covering Aplenzin® ER and its use. The Paragraph IV letter alleges that Valeant's orange book listed patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, importation, sale or offer for sale of Sandoz's Generic Product.

31. Although Sandoz's Paragraph IV letter states that Valeant's Orange Book listed patents will not be infringed by its Generic Product, the only basis Sandoz provides for its non-infringement position is that the Orange Book Patents are invalid.

32. Upon information and belief, because Sandoz did not provide a substantive non-infringement position in its Paragraph IV letter and because Sandoz asserts that its Generic Product will be bioequivalent to Aplenzin® ER, the Sandoz Generic Product infringes Valeant's patents covering Aplenzin® ER and its use, including the Patents-in-Suit.

33. Valeant commenced this action within 45 days of receiving Sandoz's Paragraph IV letter.

COUNT I
(Infringement of the '805 Patent Under 35 U.S.C. § 271(e)(2))

34. Valeant incorporates Paragraphs 1-33.

35. By seeking approval of its ANDA No. 203348 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '805 patent before its expiration, Sandoz has infringed the '805 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT II
(Infringement of the '610 Patent Under 35 U.S.C. § 271(e)(2))

36. Valeant incorporates Paragraphs 1-35.

37. By seeking approval of its ANDA No. 203348 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '610 patent before its expiration, Sandoz has infringed the '610 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT III
(Infringement of the '935 Patent Under 35 U.S.C. § 271(e)(2))

38. Valeant incorporates Paragraphs 1-37.

39. By seeking approval of its ANDA No. 203348 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '935 patent before its expiration, Sandoz has infringed the '935 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT IV
(Infringement of the '897 Patent Under 35 U.S.C. § 271(e)(2))

40. Valeant incorporates Paragraphs 1-39.

41. By seeking approval of its ANDA No. 203348 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '897 patent before its expiration, Sandoz has infringed the '897 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT V
(Infringement of the '802 Patent Under 35 U.S.C. § 271(e)(2))

42. Valeant incorporates Paragraphs 1-41.

43. By seeking approval of its ANDA No. 203348 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '802 patent before its expiration, Sandoz has infringed the '802 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT VI
(Infringement of the '019 Patent Under 35 U.S.C. § 271(e)(2))

44. Valeant incorporates Paragraphs 1-43.

45. By seeking approval of its ANDA No. 203348 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '019 patent before its expiration, Sandoz has infringed the '019 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT VII
(Infringement of the '407 Patent Under 35 U.S.C. § 271(e)(2))

46. Valeant incorporates Paragraphs 1-45.

47. By seeking approval of its ANDA No. 203348 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '407 patent before its expiration, Sandoz has infringed the '407 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT VIII
(Infringement of the'094 Patents Under 35 U.S.C. § 271(e)(2))

48. Valeant incorporates Paragraphs 1-47.

49. By seeking approval of its ANDA No. 203348 to engage in the commercial manufacture, use, or sale of a drug product claimed in the '094 patent before its expiration, Sandoz has infringed the '094 patent under 35 U.S.C. § 271(e)(2)(A).

COUNT IX
(Declaratory Judgment of Infringement of the '992 Patent Under 35 U.S.C. § 271(a)-(c))

50. Valeant incorporates Paragraphs 1-49.

51. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 35 U.S.C. § 271.

52. A concrete, real, and immediate dispute exists between the parties creating an actual case or controversy sufficient for the Court to entertain Valeant's request for declaratory relief consistent with Article III of the United States Constitution because the actual case or controversy requires a declaration of rights by this Court.

53. Upon information and belief, Sandoz intends, soon after the FDA has approved its ANDA No. 203348, to begin manufacturing, marketing, offering to sell, or selling within the

United States Sandoz's Generic Product with a product insert directing physicians and patients in the use of Sandoz's Generic Product.

54. Upon information and belief, Sandoz has made, and will continue to make, substantial preparation in the United States to manufacture, offer for sale, or sell within the United States, and/or import into the United States Sandoz's Generic Product before expiration of the '992 patent.

55. Upon information and belief, Sandoz has made, and will continue to make, substantial preparation in the United States to actively induce or contribute to the manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Sandoz's Generic Product before expiration of the '992 patent.

56. Sandoz's actions, including without limitation the filing of ANDA No. 203348, exhibit a refusal to change the course of its action despite Valeant's patent rights.

57. Upon information and belief, commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Sandoz's Generic Product before expiration of the '992 patent, and the active inducement of and/or contribution to any of those activities, will infringe the '992 patent.

58. Valeant is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Sandoz's Generic Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Sandoz's Generic Product before expiration of the '992 patent by Sandoz or its agents, will infringe the '992 patent.

INJUNCTIVE RELIEF

59. Valeant will be substantially and irreparably damaged and harmed by Sandoz's infringing activities unless those activities are enjoined by this Court. Valeant does not have an adequate remedy at law. The relative equities, burdens and public interest weigh in favor of an injunction.

PRAYER FOR RELIEF

Valeant respectfully prays for the following relief:

a. A judgment that Sandoz has infringed the '805 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Sandoz's Generic Product before expiration of the '805 patent.

b. A judgment that Sandoz has infringed the '610 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Sandoz's Generic Product before expiration of the '610 patent.

c. A judgment that Sandoz has infringed the '935 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Sandoz's Generic Product before expiration of the '935 patent.

d. A judgment that Sandoz has infringed the '897 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Sandoz's Generic Product before expiration of the '897 patent.

e. A judgment that Sandoz has infringed the '802 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Sandoz's Generic Product before expiration of the '802 patent.

f. A judgment that Sandoz has infringed the '019 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Sandoz's Generic Product before expiration of the '019 patent.

g. A judgment that Sandoz has infringed the '407 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial

manufacture, use, offer for sale, sale in, or importation into the United States of Sandoz's Generic Product before expiration of the '407 patent.

h. A judgment that Sandoz has infringed the '094 patent under 35 U.S.C. § 271(e)(2)(A) by submitting its ANDA to the FDA to obtain approval for commercial manufacture, use, offer for sale, sale in, or importation into the United States of Sandoz's Generic Product before expiration of the '094 patent.

i. A declaration issued under 28 U.S.C. § 2201 that Sandoz would infringe one or more claims of the '992 patent under one or more of 35 U.S.C. §§ 271(a)-(c) by its manufacture, use, offer to sell, sale in, or importation into the United States of Sandoz's Generic Product, or inducement of or contribution to any of the above-listed activities, before expiration of the '992 patent.

j. An order issued under 35 U.S.C. § 271(e)(4)(A) that the earliest effective approval date of Sandoz's ANDA, if any, shall be no earlier than the date of expiration of any patent-in-suit Sandoz is found to infringe, including any extensions.

k. An injunction issued under 35 U.S.C. §§ 271(e)(4)(b) and 283 permanently enjoining Sandoz, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with them or on their behalf, from engaging in commercial manufacture, use, offers to sell, or sale within the United States, or importation into the United States, of Sandoz's Generic Product not colorably different from Sandoz's Generic Product before the date of expiration of any patent-in-suit Sandoz is found to infringe, including any extensions.

l. A declaration that Sandoz has no legal or equitable defense to Valeant's allegations of infringement.

m. An award declaring this case exceptional under 35 U.S.C. § 285 and granting Valeant its attorneys' fees.

n. An award of Valeant's costs and expenses in this action.

o. An award of damages or other monetary relief to Valeant under 35 U.S.C. § 271(e)(4)(C), including by an accounting, as appropriate.

p. An award of any further and additional relief as this Court may deem just and proper.

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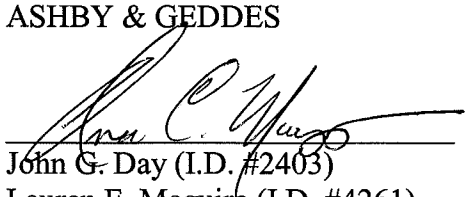

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