UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

PAR PHARMACEUTICAL, INC., Plaintiff, v. NOVARTIS PHARMACEUTICALS CORP., NOVARTIS AG, and AJINOMOTO CO., INC., Defendants.	:	Civil Action No. _____

COMPLAINT

Plaintiff Par Pharmaceutical, Inc. ("Par"), for its Complaint against Defendants Novartis Pharmaceuticals Corp. ("NPC"), Novartis AG ("Novartis AG"), and Ajinomoto Co., Inc. ("Ajinomoto") (NPC, Novartis AG, and Ajinomoto are collectively referred to as "Defendants") alleges as follows:

NATURE OF ACTION

1. Par seeks declaratory judgment of invalidity and noninfringement of U.S. Patent Nos. 5,463,116; 5,488,150; 6,559,188; 6,641,841; 6,844,008; and 6,878,749 pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq.*

JURISDICTION

2. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), and 2201(a), 21 U.S.C. § 355(j)(5)(C)(i)(II), and 35 U.S.C. § 271(e)(5).

This Court has personal jurisdiction over Defendants, as they reside or engage in significant business activities in this judicial district, including selling products in this district, soliciting business in this district, and deriving substantial revenue from this district.

VENUE

3. Venue is proper in this judicial district under 28 U.S.C. § 1391(b) and (c) and 21 U.S.C. § 355(j)(5)(C)(i)(II), as Defendants reside or engage in significant business activities in this district.

PARTIES

4. Par is a corporation organized under the laws of New Jersey, with its principal place of business in Woodcliff Lake, New Jersey.

5. Upon information and belief, NPC is a corporation organized under the laws of Delaware, with its principal place of business in East Hanover, New Jersey.

6. Upon information and belief, Novartis AG is a corporation organized under the laws of Switzerland, with its principal place of business in Basel, Switzerland and subsidiaries or business units located within this judicial district.

7. Upon information and belief, Ajinomoto is a corporation organized under the laws of Japan, with its principal place of business in Tokyo, Japan.

FACTUAL BACKGROUND

8. U.S. Patent No. 5,463,116 ("the '116 patent"), entitled "Crystals of N-(trans-4-isopropylcyclohexylcarbonyl)-D-phenylalanine and methods for preparing them," issued on October 31, 1995.

9. U.S. Patent No. 5,488,150 ("the '150 patent"), entitled "Crystals of N-(trans-4-isopropylcyclohexylcarbonyl)-D-phenylalanine and methods for preparing them," issued on January 30, 1996.

10. U.S. Patent No. 6,559,188 ("the '188 patent"), entitled "Method of treating metabolic disorders, especially diabetes, or a disease or condition associated with diabetes," issued on May 6, 2003.

11. U.S. Patent No. 6,641,841 ("the '841 patent"), entitled "Tablet composition," issued on November 4, 2003.

12. U.S. Patent No. 6,844,008 ("the '008 patent"), entitled "Tablet composition," issued on January 18, 2005.

13. U.S. Patent No. 6,878,749 ("the '749 patent"), entitled "Method of treating metabolic disorders, especially diabetes, or a disease or condition associated with diabetes," issued on April 12, 2005.

14. Novartis AG is the named assignee of the '188 and '749 patents.

15. Ajinomoto is the named assignee of the '116, '150, '841, and '008 patents.

16. Upon information and belief, NPC is a licensee of the '116, '150, '188, '841, '008, and '749 patents.

17. Upon information and belief, NPC holds New Drug Application No. 21-204 ("NDA 21-204") for oral nateglinide tablets, 60 mg and 120 mg, marketed under the brand name Starlix®. In connection with NDA 21-204, NPC caused the Food and Drug Administration ("FDA") to list the '116, '150, '188, '841, '008, and '749 patents (collectively, the "Listed Patents") in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book"). By doing so, NPC represented that a claim of patent infringement could reasonably be

asserted against any unlicensed manufacture, use or sale of oral nateglinide tablets. By listing the Listed Patents in the Orange Book, NPC created a reasonable apprehension that it would file a patent infringement action against applicants seeking regulatory approval for generic oral nateglinide tablets.

18. Par submitted Abbreviated New Drug Application No. 77-463 ("ANDA 77-463") in order to obtain regulatory approval to engage in the commercial manufacture, use, or sale of generic oral nateglinide tablets, 60 mg and 120 mg, before the expiration of the Listed Patents. Par's proposed drug product is bioequivalent to NPC's Starlix® product and has the same active ingredient, strength, dosage form, and route of administration. Par made a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") that each of the '116, '150, '188, '841, and '008 patents is invalid or will not be infringed by the commercial manufacture, use, or sale of the oral nateglinide tablets that are the subject of ANDA 77-463. Par was not required to make a paragraph IV certification as to the '749 patent, which issued and was listed in the Orange Book after Par's submission of ANDA 77-463.

19. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), on January 19, 2005 and March 7, 2005, Par provided notice of the paragraph IV certifications that it filed with ANDA 77-463.

20. Par's notification triggered a 45-day statutory period during which Defendants had the first opportunity to initiate patent infringement litigation. Defendants did not bring an action for patent infringement during the 45-day statutory period.

21. Where no action for patent infringement is filed within the statutory period, 21 U.S.C. § 355(j)(5)(C)(i)(II) and 35 U.S.C. § 271(e)(5) provide for a civil action to obtain patent certainty and allow Par to obtain a declaratory judgment with respect to the Listed Patents.

22. Par has received tentative approval from the FDA to engage in the commercial manufacture, use, or sale of generic oral nateglinide tablets. Upon information and belief, but for NPC's listing of the Listed Patents in the Orange Book, Par would receive final approval from the FDA on September 8, 2009 or shortly thereafter. Par has made substantial preparations for the commercial manufacture, use, or sale of generic oral nateglinide tablets.

COUNT ONE

(Declaratory Judgment Regarding U.S. Patent No. 5,463,116)

23. Par reasserts and realleges paragraphs 1-22 above as if fully set forth herein.

24. The claims of the '116 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

25. The submission of ANDA 77-463 does not infringe any valid claim of the '116 patent.

26. The commercial manufacture, use, offer for sale, sale, or importation of Par's generic oral nateglinide product would not infringe any valid claim of the '116 patent.

27. An actual and justiciable controversy exists between the parties with respect to the '116 patent, and Par is entitled to a declaratory judgment that the '116 patent is invalid and not infringed.

COUNT TWO

(Declaratory Judgment Regarding U.S. Patent No. 5,488,150)

28. Par reasserts and realleges paragraphs 1-22 above as if fully set forth herein.

29. The claims of the '150 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

30. The submission of Par's generic oral nateglinide product does not infringe any valid claim of the '150 patent.

31. The commercial manufacture, use, offer for sale, sale, or importation of Par's generic oral nateglinide product would not infringe any valid claim of the '150 patent.

32. An actual and justiciable controversy exists between the parties with respect to the '150 patent, and Par is entitled to a declaratory judgment that the '150 patent is invalid and not infringed.

COUNT THREE

(Declaratory Judgment Regarding U.S. Patent No. 6,559,188)

33. Par reasserts and realleges paragraphs 1-22 above as if fully set forth herein.

34. The claims of the '188 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

35. The submission of ANDA 77-463 does not infringe any valid claim of the '188 patent.

36. The commercial manufacture, use, offer for sale, sale, or importation of Par's generic oral nateglinide product would not infringe any valid claim of the '188 patent.

37. An actual and justiciable controversy exists between the parties with respect to the '188 patent, and Par is entitled to a declaratory judgment that the '188 patent is invalid and not infringed.

COUNT FOUR

(Declaratory Judgment Regarding U.S. Patent No. 6,641,841)

38. Par reasserts and realleges paragraphs 1-22 above as if fully set forth herein.

39. The claims of the '841 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

40. The submission of ANDA 77-463 does not infringe any valid claim of the '841 patent.

41. The commercial manufacture, use, offer for sale, sale, or importation of Par's generic oral nateglinide product would not infringe any valid claim of the '841 patent.

42. An actual and justiciable controversy exists between the parties with respect to the '841 patent, and Par is entitled to a declaratory judgment that the '841 patent is invalid and not infringed.

COUNT FIVE

(Declaratory Judgment Regarding U.S. Patent No. 6,844,008)

43. Par reasserts and realleges paragraphs 1-22 above as if fully set forth herein.

44. The claims of the '008 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

45. The submission of ANDA 77-463 does not infringe any valid claim of the '008 patent.

46. The commercial manufacture, use, offer for sale, sale, or importation of Par's generic oral nateglinide product would not infringe any valid claim of the '008 patent.

47. An actual and justiciable controversy exists between the parties with respect to the '008 patent, and Par is entitled to a declaratory judgment that the '008 patent is invalid and not infringed.

COUNT SIX

(Declaratory Judgment Regarding U.S. Patent No. 6,878,749)

48. Par reasserts and realleges paragraphs 1-22 above as if fully set forth herein.

49. The claims of the '749 patent are invalid for failure to satisfy the requirements of Title 35 of the United States Code, including without limitation one or more of 35 U.S.C. §§ 101, 102, 103, and 112.

50. The submission of ANDA 77-463 does not infringe any valid claim of the '749 patent.

51. The commercial manufacture, use, offer for sale, sale, or importation of Par's generic oral nateglinide product would not infringe any valid claim of the '749 patent.

52. An actual and justiciable controversy exists between the parties with respect to the '749 patent, and Par is entitled to a declaratory judgment that the '749 patent is invalid and not infringed.

PRAYER FOR RELIEF

WHEREFORE, Par respectfully requests that this Court enter judgment in its favor and against Defendants and grant the following relief:

A. Declare that the claims of the '116 patent are invalid;

B. Declare that the manufacture, use, offer for sale, sale, or importation of Par's generic oral nateglinide product would not infringe the claims of the '116 patent;

C. Declare that the claims of the '150 patent are invalid;

D. Declare that the manufacture, use, offer for sale, sale, or importation of Par's generic oral nateglinide product would not infringe the claims of the '150 patent;

E. Declare that the claims of the '188 patent are invalid;

F. Declare that the manufacture, use, offer for sale, sale, or importation of Par's generic oral nateglinide product would not infringe the claims of the '188 patent;

G. Declare that the claims of the '841 patent are invalid;

H. Declare that the manufacture, use, offer for sale, sale, or importation of Par's generic oral nateglinide product would not infringe the claims of the '841 patent;

I. Declare that the claims of the '008 patent are invalid;

J. Declare that the manufacture, use, offer for sale, sale, or importation of Par's generic oral nateglinide product would not infringe the claims of the '008 patent;

K. Declare that the claims of the '749 patent are invalid;

L. Declare that the manufacture, use, offer for sale, sale, or importation of Par's generic oral nateglinide product would not infringe the claims of the '749 patent;

M. Award Par its costs and reasonable attorney fees; and

N. Award Par such other and further relief as the Court deems just and proper.

Respectfully submitted,

Dated: April 15, 2009

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