IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACTAVIS ELIZABETH LLC, Plaintiff, v. NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, NOVARTIS AG, and NOVARTIS PHARMA AG, Defendants.	C.A. No. 16-604-RGA

FIRST AMENDED COMPLAINT

Plaintiff Actavis Elizabeth LLC ("Actavis"), for its First Amended Complaint against Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, and Novartis Pharma AG (collectively, "Novartis"), alleges as follows:

NATURE OF ACTION

1. Actavis seeks declaratory judgment of noninfringement and invalidity of U.S. Patent No. 9,283,209 (the "Patent-in-Suit") 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*.

PARTIES

2. Actavis is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

3. Upon information and belief, Novartis Pharmaceuticals Corporation is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at One Health Plaza, East Hanover, New Jersey.

4. Upon information and belief, Novartis Corporation is a corporation existing under the laws of the State of New York, with its principal place of business at 608 5th Avenue, New York, New York.

5. Upon information and belief, Novartis AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

6. Upon information and belief, Novartis Pharma AG is a corporation organized and existing under the laws of Switzerland, having an office and place of business at Lichtstrasse 35, CH-4056 Basel, Switzerland.

JURISDICTION AND VENUE

7. 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).

8. This Court has personal jurisdiction over Novartis based on, *inter alia*, Novartis's filing of related lawsuits in this jurisdiction, in *Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, and Novartis Pharma AG v. Actavis, Inc. and Actavis Elizabeth LLC*, C.A. No. 12-336-CJB (D. Del.) and *Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, and Novartis Pharma AG v. Actavis, Inc. and Actavis Elizabeth LLC*, C.A. No. 15-1219-RGA (D. Del.).

9. This Court also has personal jurisdiction over Novartis based on Novartis's significant transaction of business and commercialization of its pharmaceutical products in this judicial district. Upon information and belief, Novartis markets, distributes, and sells its

products, including JADENU®, throughout the United States and in Delaware. Novartis has purposefully availed itself of this forum by systematically and continuously advertising and selling its pharmaceutical products in this judicial district, deriving substantial revenues from such activities.

10. 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 the Court has personal jurisdiction over Novartis and Novartis has a regular and established place of business in this judicial district.

FACTUAL BACKGROUND

11. The Patent-in-Suit, entitled "Oral Formulations of Deferasirox," issued on March 15, 2016. A copy of the Patent-in-Suit is attached hereto as Exhibit A. The claims of the Patent-in-Suit are directed to tablets for oral administration consisting of 90, 180, and 360 mg deferasirox with precise amounts of seven other excipients: microcrystalline cellulose, poly vinyl pyrrolidone K-30, crospovidone, poloxamer, fumed silica, magnesium stearate, and seal-coat. The Patent-in-Suit claims priority to provisional application Nos. 61/774,893, filed March 8, 2013, and 61/824,435, filed May 17, 2013.

12. Upon information and belief, Novartis AG is the named assignee of the Patent-in-Suit.

13. Upon information and belief, Novartis Pharmaceuticals Corporation holds New Drug Application No. 206910 for deferasirox tablets, 90, 180, and 360 mg, marketed under the brand name JADENU®. In connection with NDA 206910, Novartis caused the FDA to list the Patent-in-Suit in the Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"). By doing so, Novartis represented that a claim of patent infringement could reasonably be asserted against any unlicensed manufacture, use, or sale of deferasirox tablets, 90, 180, and 360 mg.

14. Upon information and belief, Novartis sought and obtained the Patent-in-Suit specifically for the purpose of limiting competition from generic deferasirox tablets.

15. Actavis has submitted ANDA No. 208697 to the FDA in order to obtain regulatory approval to engage in the commercial manufacture, use, or sale of deferasirox tablets, 90, 180, and 360 mg (the "Actavis deferasirox product"), before the expiration of the Patent-in-Suit. The Actavis deferasirox product is bioequivalent to Novartis's JADENU® product and has the same active ingredient, strength, dosage form, and route of administration. Actavis made a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "paragraph IV certification") that the Patent-in-Suit is invalid and/or will not be infringed by the commercial manufacture, use, or sale of the generic deferasirox tablets, 190, 180, and 360 mg, that are the subject of ANDA 208697.

16. Actavis has made preparations for the commercial manufacture, use, and sale of the Actavis deferasirox product.

17. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), by a letter sent to Novartis on April 21, 2016, Actavis provided notice to Novartis of the paragraph IV certification that it filed with ANDA 208697, together with an Offer of Confidential Access to ANDA 208697 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). This notice included a detailed statement of the factual and legal basis why the Patent-in-Suit is invalid and/or will not be infringed by the commercial manufacture, use, or sale of the generic deferasirox tablets, 190, 180, and 360 mg, that are the subject of ANDA 208697.

18. Actavis's notification triggered a 45-day statutory period during which Novartis had the first opportunity to initiate patent infringement litigation. Novartis failed to bring an action for patent infringement during the 45-day statutory period. By listing the Patent-in-Suit in

the Orange Book but failing to bring an action for patent infringement, Novartis has injected uncertainty and insecurity into Actavis's pursuit of regulatory approval and subsequent commercialization of the Actavis deferasirox product.

19. Where no action for patent infringement is filed within the 45-day 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 ANDA filers to obtain a declaratory judgment with respect to patents listed in the Orange Book. All of the conditions specified in 21 U.S.C. § 355(j)(5)(C)(i) for filing an action for declaratory judgment have been satisfied.

COUNT ONE

(Declaratory Judgment of Non-Infringement of the Patent-in-Suit)

20. Actavis reasserts and realleges paragraphs 1-19 above as if fully set forth herein.

21. The submission of ANDA 208697 does not infringe, directly or indirectly, any valid claim of the Patent-in-Suit.

22. The commercial manufacture, use, offer for sale, sale, or importation of the Actavis deferasirox product would not infringe, directly or indirectly, any valid claim of the Patent-in-Suit.

23. Independent claim 1 of the Patent-in-Suit requires that the deferasirox tablet formulation consists of, *inter alia*, 53.61 mg microcrystalline cellulose and 4.86 mg seal-coat.

24. The Actavis deferasirox product will not contain 53.61 mg microcrystalline cellulose or 4.86 mg seal-coat.

25. Independent claim 2 of the Patent-in-Suit requires that the deferasirox tablet formulation consists of, *inter alia*, 107.23 mg microcrystalline cellulose and 9.72 mg seal-coat.

26. The Actavis deferasirox product will not contain 107.23 mg microcrystalline cellulose or 9.72 mg seal-coat.

27. Independent claim 3 of the Patent-in-Suit requires that the deferasirox tablet formulation consists of, *inter alia*, 215.45 mg microcrystalline cellulose and 19.44 mg seal-coat.

28. The Actavis deferasirox product will not contain 215.45 mg microcrystalline cellulose or 19.44 mg seal-coat.

29. Therefore, the Actavis deferasirox product would not literally infringe any claim of the Patent-in-Suit.

30. The Actavis deferasirox product will differ more than insubstantially from the claimed deferasirox tablet formulations of the Patent-in-Suit because each of the Actavis deferasirox products contains amounts of microcrystalline cellulose and seal-coat that are well outside the required claim amounts for these two components.

31. A finding of equivalence between the Actavis deferasirox product and the claims of the Patent-in-Suit would vitiate the claim limitations directed to amounts of microcrystalline cellulose and seal-coat.

32. The Patent-in-Suit discloses deferasirox tablet formulations having broader ranges of excipient amounts than are claimed, particularly for microcrystalline cellulose and seal-coat.

33. The application of the doctrine of equivalents to expand the scope of the claims of the Patent-in-Suit to read on the Actavis deferasirox product is precluded by prosecution history estoppel.

34. Upon information and belief, during prosecution of the Patent-in-Suit, Novartis originally claimed deferasirox tablet formulations not limited by specific types or amounts of excipients. However, in order to gain allowance of the claims, Novartis narrowed the claims of the Patent-in-Suit by adding limitations on the specific types and amounts of excipients, including microcrystalline cellulose and seal-coat.

35. Therefore, the Actavis deferasirox product would not infringe any claim of the Patent-in-Suit under the doctrine of equivalents.

36. Under all the circumstances, an immediate, real, substantial, and justiciable controversy exists between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment with respect to the Patent-in-Suit. Actavis is entitled to a declaratory judgment that the Patent-in-Suit is not infringed.

COUNT TWO

(Declaratory Judgment of Invalidity of the Patent-in-Suit)

37. Actavis reasserts and realleges paragraphs 1-36 above as if fully set forth herein.

38. The claims of the Patent-in-Suit are invalid under one or more of 35 U.S.C. §§ 102, 103, and/or the doctrine of obviousness-type double patenting. Upon information and belief, if the claims of the Patent-in-Suit are construed to cover and/or include the amounts of microcrystalline cellulose and seal-coat in the Actavis deferasirox products, then the claims of the Patent-in-Suit are invalid under 35 U.S.C. § 112.

39. As noted above, the Patent-in-Suit claims priority to provisional applications filed on March 8, 2013 and May 17, 2013, respectively.

40. WIPO Patent Publication No. WO 97/49395, entitled "Substituted 3,5-diphenyl-1,2,4-triazoles and Their Use as Pharmaceutical Metal Chelators," to Rene Lattmann and Pierre Acklin, and published December 31, 1997 (the "Lattmann Publication," attached hereto as Exhibit B), discloses deferasirox tablets for oral administration with a number of the excipients claimed in the Patent-in-Suit, including cellulose preparations, poly vinyl pyrrolidone, crospovidone, silica, magnesium stearate, and coatings, in ranges insubstantially different from the amounts claimed in the Patent-in-Suit. WIPO Patent Publication No. WO 2005/097062, entitled "Deferasirox Dispersible Tablets," to Catherine Beauchamp *et al.*, and published

October 20, 2005 (the "Beauchamp Publication," attached hereto as Exhibit C), discloses deferasirox tablets for oral administration with the excipients claimed in the Patent-in-Suit in ranges insubstantially different from the amounts claimed in the Patent-in-Suit. The differences between the claims of the Patent-in-Suit and the prior art, including the Lattmann and Beauchamp Publications, are such that the subject matter as a whole would have been anticipated or obvious, either on its own or in combination with other references, to a person of ordinary skill in the art at the time of the alleged invention.

41. As noted above, the claims of the Patent-in-Suit are directed to tablets for oral administration consisting of 90, 180, and 360 mg deferasirox with precise amounts of seven other excipients: microcrystalline cellulose, poly vinyl pyrrolidone K-30, crospovidone, poloxamer, fumed silica, magnesium stearate, and seal-coat.

42. As noted above, each of the Actavis deferasirox products contains amounts of microcrystalline cellulose and seal-coat that are well outside the claimed amounts for these two components set forth in the claims of the Patent-in-Suit.

43. Upon information and belief, if the claims of the Patent-in-Suit are construed to include the amounts of microcrystalline cellulose and seal-coat in the Actavis deferasirox products, then the Patent-in-Suit fails to convey to a person of ordinary skill in the art that the inventors were in possession of the full scope of the claimed invention at the time of the alleged invention. The Patent-in-Suit would fail to describe with specificity those claimed amounts, as construed by Novartis, from which a person of ordinary skill in the art would conclude that the inventors were not in possession of the full scope of the claimed invention at the time of the alleged invention.

44. Upon information and belief, if the claims of the Patent-in-Suit are construed to include the amounts of microcrystalline cellulose and seal-coat in the Actavis deferasirox products, then the Patent-in-Suit does not enable a person of ordinary skill in the art to practice the claimed invention absent undue experimentation. The Patent-in-Suit fails to provide a person of ordinary skill in the art with any guidance in selecting the amounts of microcrystalline cellulose and seal-coat in the Actavis deferasirox products. A person of ordinary skill in the art has no way of selecting, in the absence of undue experimentation, the amounts of microcrystalline cellulose and seal-coat in the Actavis deferasirox products.

45. Under all the circumstances, an immediate, real, substantial, and justiciable controversy exists between the parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment with respect to the Patent-in-Suit. Actavis is entitled to a declaratory judgment that the claims of the Patent-in-Suit are invalid.

PRAYER FOR RELIEF

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

A. Declare that Actavis has not directly or indirectly infringed any valid claim of the Patent-in-Suit;

B. Declare that the manufacture, use, offer for sale, sale, or importation of the Actavis deferasirox product would not directly or indirectly infringe any valid claim of the Patent-in-Suit;

C. Declare that every claim of the Patent-in-Suit is invalid;

D. Award Actavis its costs and reasonable attorneys' fees; and

E. Award Actavis such other and further relief as the Court deems just and proper.

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