IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS CORPORATION, NOVARTIS AG, and NOVARTIS PHARMA AG	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
ACTAVIS GROUP HF., ACTAVIS GROUP PTC EHF., ACTAVIS, INC. and ACTAVIS ELIZABETH LLC	)	
Defendants.	)	

COMPLAINT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, and Novartis Pharma AG (collectively, "Novartis") by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code. This action relates to Abbreviated New Drug Application ("ANDA") No. 203560 filed by Actavis Elizabeth LLC with the U.S. Food and Drug Administration ("FDA") for approval to market 125 mg, 250 mg, and 500 mg deferasirox tablets for oral suspension, generic versions of the 125 mg, 250 mg, and 500 mg forms of Novartis's EXJADE® drug product, prior to expiration of U.S. Patent Nos. 6,465,504 ("the '504 patent") and 6,596,750 ("the '750 patent").

PARTIES

2. Novartis Pharmaceuticals Corporation ("NPC") 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.

3. 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.

4. 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.

5. 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.

6. Upon information and belief, Actavis Group hf. ("Actavis Group") is a corporation organized and existing under the laws of Iceland, having its principal place of business at Dalshrauni 1, 220 Hafnarfirdi, Iceland.

7. Upon information and belief, Actavis Group is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for distribution in the U.S. market, including in this judicial district, through various directly or indirectly owned operating subsidiaries, including Actavis Group PTC ehf. ("Actavis PTC"), Actavis, Inc. ("Actavis U.S.") and Actavis Elizabeth LLC ("Actavis Elizabeth").

8. Upon information and belief, Actavis PTC is a corporation organized and existing under the laws of Iceland, having its principal place of business at Reykjavikurvegi 76-78, 220 Hafnarfirdi, Iceland.

9. Upon information and belief, Actavis PTC is a wholly-owned subsidiary of Actavis Group and is controlled and/or dominated by Actavis Group. Upon information and belief, Actavis PTC is in the business of, among other things, developing, manufacturing, and/or selling generic versions of branded pharmaceutical products for distribution in the U.S. market, including in this judicial district, through various directly or indirectly owned operating subsidiaries, including its wholly-owned subsidiary, Actavis U.S. Upon information and belief, such conduct is done at the direction, under the control, and for the benefit of Actavis Group.

10. Upon information and belief, Actavis U.S. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960.

11. Upon information and belief, Actavis U.S. is a wholly-owned subsidiary of Actavis PTC and is controlled and/or dominated by Actavis PTC and Actavis Group. Upon information and belief, Actavis U.S. itself, and through its wholly-owned subsidiary and agent, Actavis Elizabeth, develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district. Such conduct is done at the direction, under the control, and for the benefit of Actavis PTC and Actavis Group. Upon information and belief, Actavis Group and Actavis PTC established Actavis U.S. for the purposes of manufacturing, distributing, marketing, offering for sale and/or selling their generic drug products throughout the United States, including in this judicial district.

12. Upon information and belief, Actavis Elizabeth is a company organized and existing under the laws of Delaware, having its principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

13. Upon information and belief, Actavis Elizabeth is in the business of, among other things, developing, manufacturing, and selling generic versions of branded pharmaceutical products for the U.S. market. Upon information and belief, Actavis Elizabeth is a wholly-owned subsidiary of Actavis U.S. and is controlled and/or dominated by Actavis U.S. Upon information and belief, Actavis Elizabeth develops, manufactures and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district, at the direction, under the control, and for the benefit of Actavis U.S., Actavis PTC, Actavis Group. Upon information and belief, Actavis Group, Actavis PTC and Actavis U.S. established Actavis Elizabeth for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district.

14. Upon information and belief, Actavis Group, Actavis PTC, Actavis U.S. and Actavis Elizabeth work in concert with one another and hold themselves out as an integrated unit for purposes of developing, manufacturing, distributing, marketing, and selling generic drug products throughout the United States, including in this judicial district. For example, Actavis Group maintains a website, www.actavis.com, advertising Actavis Group's "worldwide" operations, including in the "US." In a July 21, 2011 press release announcing the launch of oxymorphone hydrochloride extended-release tablets, which are generic versions of OPANA® ER, Actavis Group stated, "Actavis Inc. is the US distributor of the product and the United States subsidiary of Actavis Group hf. Approximately one third of Actavis Group hf's sales are generated in North America, Actavis's single largest market." Press Release, Actavis Group, *Actavis US launches Oxymorphone Hydrochloride Extended-Release Tablets, CII*, (July 23, 2011), available at

http://www.actavis.com/en/media+center/newsroom/articles/oxymorphone_hcl_extended_release_us.htm (last accessed Mar. 3, 2012).

15. Upon information and belief, and consistent with their past practices, Actavis Group, Actavis PTC, Actavis U.S. and Actavis Elizabeth acted collaboratively in the preparation and submission of ANDA No. 203560.

16. Upon information and belief, and consistent with its past practices, Actavis Elizabeth's preparation and submission of ANDA No. 203560 was done at the direction, under the control, and for the direct benefit of Actavis Group, Actavis PTC, and Actavis U.S.

17. Upon information and belief, and consistent with their past practices, Actavis Group, Actavis PTC, and Actavis U.S. directed Actavis Elizabeth to submit ANDA No. 203560, in whole or in part, to shield Actavis Group, Actavis PTC, and Actavis U.S. from liability for patent infringement based upon that act.

18. Upon information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 203560, Actavis Group, Actavis PTC, Actavis U.S., and Actavis Elizabeth will work in concert with one another, and with other Actavis Group subsidiaries, to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 203560 throughout the United States, and/or import such generic drug products into the United States, including in this judicial district.

19. Actavis Group, Actavis PTC, Actavis U.S. and Actavis Elizabeth are collectively referred to hereafter as "Actavis."

JURISDICTION AND VENUE

20. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over the subject matter of this action under 28

U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

21. This Court has personal jurisdiction over Actavis because, among other things, it has committed, or aided, abetted, contributed to, or participated in the commission of, a tortious act of patent infringement in filing ANDA No. 203560 that has led to foreseeable harm and injury to NPC, a Delaware corporation.

22. This Court also has personal jurisdiction over Actavis because, among other things, as described above it manufactures, distributes, markets, and sells generic drug products throughout the United States and within Delaware. Furthermore, upon information and belief, Actavis derives substantial revenue from such conduct in Delaware. Accordingly, Actavis has persistent, systematic and continuous contacts with Delaware and therefore purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in this district.

23. This Court also has personal jurisdiction over Actavis Group because it has availed itself of the legal protections of the State of Delaware by, among other things, creating subsidiaries in Delaware (*e.g.*, Actavis U.S. and Actavis Elizabeth) and admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware (*e.g.*, *Pfizer, Inc. v. Actavis Group HF*, Civil Action No. 1:10-cv-00675 (D. Del.)).

24. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Actavis.

PATENTS IN SUIT

25. On October 15, 2002, the U.S. Patent and Trademark Office duly and legally issued the ’504 patent, entitled “Substituted 3,5-Diphenyl-1,2,4-Triazoles and Their Use as Pharmaceutical Metal Chelators.” A true and correct copy of the ’504 patent is attached hereto as **Exhibit A**. The claims of the ’504 patent are valid and enforceable. Novartis is the owner of the ’504 patent by assignment, with the right to sue for and obtain equitable relief and damages for infringement of the ’504 patent.

26. On July 22, 2003, the U.S. Patent and Trademark Office duly and legally issued the ’750 patent, entitled “Substituted 3,5-Diphenyl-1,2,4-Triazoles and Their Use as Pharmaceutical Metal Chelators.”. A true and correct copy of the ’750 patent is attached hereto as **Exhibit B**. The claims of the ’750 patent are valid and enforceable. Novartis is the owner of the ’750 patent by assignment, with the right to sue for and obtain equitable relief and damages for infringement of the ’750 patent.

27. NPC is the holder of New Drug Application (“NDA”) No. 21-882 by which the FDA granted approval for the marketing and sale of 125 mg, 250 mg and 500 mg strength deferasirox tablets for oral suspension, which NPC markets in the United States under the trade name “EXJADE®.” The composition, formulation, dosing, and method of administration for EXJADE® is covered by certain claims of the ’504 patent and the ’750 patent. The FDA’s official publication of approved drugs (the “Orange Book”) includes EXJADE® together with the ’504 patent and the ’750 patent.

INFRINGEMENT BY ACTAVIS

28. By letter dated February 7, 2012, (“the Notice Letter”), Actavis notified Novartis that Actavis had submitted ANDA No. 203560 to the FDA under Section 505(j) of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, and sale of 125 mg, 250 mg, and 500 mg generic deferasirox tablets for oral suspension before the expiration of the '504 patent and the '750 patent. Upon information and belief, Actavis intends to engage in the commercial manufacture, use, and sale of its 125 mg, 250 mg, and 500 mg generic deferasirox tablets for oral suspension promptly upon receiving FDA approval to do so.

29. By filing ANDA No. 203560, Actavis has necessarily represented to the FDA that its generic deferasirox tablets for oral suspension have the same active ingredient as EXJADE®, have the same method of administration, dosage form, and strengths as EXJADE®, and are bioequivalent to EXJADE®.

30. In the Notice Letter, Actavis notified Novartis that its ANDA contained a "Paragraph IV certification" asserting that the '504 and '750 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of Actavis's 125 mg, 250 mg, and 500 mg generic deferasirox tablets for oral suspension.

31. This Complaint is being filed before the expiration of the forty-five days from the date Novartis received the Notice Letter.

COUNT I (INFRINGEMENT OF THE '504 PATENT)

32. Each of the preceding paragraphs 1 to 31 is incorporated as if fully set forth.

33. Actavis's submission of ANDA No. 203560 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 125 mg, 250 mg, and 500 mg generic deferasirox tablets for oral suspension prior to the expiration of the '504 patent constitutes infringement of one or more of the claims of the '504 patent under 35 U.S.C. § 271(e)(2)(A).

34. Upon FDA approval of Actavis's ANDA No. 203560, Actavis will further infringe the '504 patent by making, using, offering to sell, and selling its 125 mg, 250 mg, and 500 mg generic deferasirox tablets for oral suspension in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

35. Upon information and belief, Actavis had actual and constructive knowledge of the '504 patent prior to filing ANDA No. 203560 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '504 patent.

36. If Actavis's infringement of the '504 patent is not enjoined, Novartis will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II (INFRINGEMENT OF THE '750 PATENT)

37. Each of the preceding paragraphs 1 to 36 is incorporated as if fully set forth.

38. Actavis's submission of ANDA No. 203560 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of 125 mg, 250 mg, and 500 mg generic deferasirox tablets for oral suspension prior to the expiration of the '750 patent constitutes infringement of one or more of the claims of the '750 patent under 35 U.S.C. § 271(e)(2)(A).

39. Upon FDA approval of Actavis's ANDA No. 203560, Actavis will further infringe the '750 patent by making, using, offering to sell, and selling its 125 mg, 250 mg, and 500 mg generic deferasirox tablets for oral suspension in the United States and/or importing such tablets into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

40. Upon information and belief, Actavis had actual and constructive knowledge of the '750 patent prior to filing ANDA No. 203560 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '750 patent.

41. If Actavis's infringement of the '750 patent is not enjoined, Novartis will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Novartis prays that this Court grant the following relief:

1. A judgment that one or more claims of the '504 patent and the '750 patent are valid, enforceable and infringed by Actavis's submission of ANDA No. 203560, and that Actavis's making, using, offering to sell, or selling in the United States, or importing into the United States Actavis's 125 mg, 250 mg, and 500 mg generic deferasirox tablets for oral suspension will infringe the '504 and '750 patents.

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 203560 shall be a date which is not earlier than the latest expiration date of the '504 and '750 patents, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

3. An order permanently enjoining Actavis, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States Actavis's 125 mg, 250 mg, and 500 mg generic deferasirox tablets for oral suspension until after the latest expiration date of the '504 patent and the '750 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

4. Damages or other monetary relief to Novartis if Actavis engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Actavis's 125 mg, 250 mg, and 500 mg generic deferasirox tablets for oral suspension prior to the latest expiration date of the '504 patent and the '750 patent, including any extensions and/or additional periods of exclusivity to which Novartis is or becomes entitled.

5. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

McCARTER & ENGLISH, LLP

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