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.	)	
MYLAN INC. AND MYLAN PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis Corporation, Novartis AG, and Novartis Pharma AG (collectively, "Novartis"), for its Complaint against Defendants Mylan Inc., and Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals") (collectively, "Mylan"), hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement of U.S. Patent Nos. 6,465,504 ("the '504 Patent") and 6,596,750 ("the '750 Patent"), arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281.

2. This action relates to Abbreviated New Drug Application ("ANDA") No. 206585 filed by Mylan Pharmaceuticals 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 ("Mylan Generic Deferasirox Tablets"), generic versions of the 125 mg, 250 mg, and 500 mg Novartis EXJADE® drug product.

PARTIES

3. Plaintiff 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.

4. 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. 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. 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.

7. Upon information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. Upon information and belief, Mylan Inc. develops, manufactures, and sells generic pharmaceutical products for the United States market through various directly or indirectly owned operating subsidiaries, including its wholly owned subsidiary, Mylan Pharmaceuticals.

8. Upon information and belief, Defendant Mylan Pharmaceuticals is a corporation organized and existing under the laws of the State of West Virginia, with a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Inc. established Mylan Pharmaceuticals, its wholly owned subsidiary, for the purposes of distributing, marketing, offering for sale and selling its generic drugs throughout the United States.

9. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals work in concert with one another, and with other Mylan subsidiaries, to develop, manufacture, and market pharmaceutical products throughout the United States, including in this judicial district. Upon information and belief, Mylan Inc. directs the operations, management and activities of Mylan Pharmaceuticals in the United States.

10. Upon information and belief, following any FDA approval of ANDA No. 206585, Mylan Inc. and Mylan Pharmaceuticals will work in concert, and with other Mylan subsidiaries, to make, use, offer to sell, and/or sell the generic products that are the subject of ANDA No. 206585 throughout the United States, and/or import such generic products into the United States.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America, 35 U.S.C. §§ 100, *et seq.* This Court has subject matter jurisdiction over 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).

12. This Court has personal jurisdiction over Mylan Inc. and Mylan Pharmaceuticals because, among other things, they have each committed, or aided, abetted,

actively induced, contributed to, or participated in the commission of a tortious act of patent infringement in filing ANDA No. 206585 that has led to foreseeable harm and injury to NPC, a Delaware corporation.

13. This Court also has personal jurisdiction over Mylan Inc. and Mylan Pharmaceuticals because, among other things, they have purposely availed themselves of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware such that they should reasonably anticipate being hauled into court here. On information and belief, Mylan Inc. and Mylan Pharmaceuticals have persistent, systematic and continuous contacts with Delaware as set forth below.

14. Upon information and belief, Mylan Pharmaceuticals is registered to conduct business in the State of Delaware, and maintains as a registered agent, Corporation Service Company, registered at 2711 Centerville Road, Suite 400, Wilmington, Delaware 19808. Mylan Pharmaceuticals is therefore subject to personal jurisdiction in the State of Delaware.

15. Upon information and belief, Mylan Pharmaceuticals is registered pursuant to Del. Code Ann. tit. 24, § 2540 to distribute its generic pharmaceutical products in Delaware and holds current and valid "Distributor/Manufacturer CSR" (License No. DM-0007571) and "Pharmacy-Wholesale" (License No. A4-0001719) licenses from the Delaware Board of Pharmacy.

16. Upon information and belief, Mylan Inc. maintains the website www.mylan.com, advertising the generic pharmaceutical products it manufactures and/or sells in the United States. According to Mylan Inc.'s website, Mylan is "one of the largest generics and specialty pharmaceutical companies in the world," "with sales in approximately

140 countries and territories." According to Mylan Inc.'s website, Mylan "leverage[s] a broad network of local and global access channels that include physicians, institutions, governments, retailers and wholesalers."

17. Upon information and belief, Mylan distributes for sale hundreds of drug products through the United States, including in this judicial district.

18. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals regularly do business in Delaware and have engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals have done so with each other's authorization, participation, and assistance, or acting in concert with each other.

19. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals operate as an integrated, unitary generic pharmaceutical business. For example, Mylan Inc. includes within its Annual Report the activities of its wholly owned subsidiary Mylan Pharmaceuticals, including the revenues earned. Mylan Inc. is divided into several business units, including the "Generics" business. Upon information and belief, Mylan Pharmaceuticals, in whole or in part, comprises this "Generics" business, particularly within the United States.

20. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals derive substantial revenue from generic pharmaceutical products that are sold, used, and/or consumed within Delaware.

21. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals have previously availed themselves of the rights and privileges of this forum for the purpose of litigating patent disputes. For example, Mylan Inc. and Mylan Pharmaceuticals filed suit and sought relief in at least *Mylan Pharmaceuticals Inc. and Mylan Inc. v. Eurand, Inc.*, C.A. No. 10-306-SLR (D. Del.); and Mylan Pharmaceuticals additionally filed suit and sought relief in at least *Mylan Pharmaceuticals Inc. v. Ethylpharm S.A.*, C.A. No. 10-1064-LPS (D. Del.), and *Mylan Pharmaceuticals Inc. v. Galderma Laboratories, Inc.*, C.A. No. 10-892-LPS (D. Del.). Mylan Inc. and Mylan Pharmaceuticals have also submitted to this Court's jurisdiction by asserting counterclaims in other civil actions in this jurisdiction. Specifically, Mylan Inc. and Mylan Pharmaceuticals admitted jurisdiction for the purpose of the litigation and filed counterclaims in at least *Forest Laboratories, Inc. et al v. Mylan Inc. and Mylan Pharmaceuticals Inc.*, C.A. No. 13-1605-SLR (D. Del.), *Santarus, Inc. et al v. Mylan Inc. and Mylan Pharmaceuticals Inc.*, C.A. No. 13-145-RGA (D. Del.), and *Alcon Research Ltd. v. Mylan Inc. and Mylan Pharmaceuticals Inc.*, C.A. No. 13-1332-SLR (D. Del.); and Mylan Pharmaceuticals admitted jurisdiction for the purpose of the litigation and filed counterclaims in at least *Teijin Limited et al. v. Mylan Pharmaceuticals, Inc*, C.A. No. 13-1781-SLR (D. Del.), *Roche Palo Alto LLC et al v Mylan Pharmaceuticals Inc.*, C.A. No. 13-1532-GMS (D. Del.), *Eisai Co. Ltd. et al v. Mylan Pharmaceuticals Inc.*, C.A. No. 13-1282-LPS (D. Del.), and *AbbVie Inc. et al v. Mylan Pharmaceuticals Inc.*, C.A. No. 13-1072-RGA (D. Del.), all of which are currently pending in this District. Mylan Inc. and Mylan Pharmaceuticals have also submitted to this Court's jurisdiction by asserting counterclaims in at least ten (10) additional civil actions filed in this jurisdiction since 2010.

22. Upon information and belief, Mylan Inc. participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 206585.

23. Upon information and belief, Mylan Inc. and Mylan Pharmaceuticals will manufacture, market, and/or sell within the United States the Mylan Generic Deferasirox Tablets described in ANDA No. 206585 if FDA approval is granted. If ANDA No. 206585 is approved, the Mylan Generic Deferasirox Tablets charged with infringing the Patents-in-Suit, would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

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 Mylan.

EXJADE®

25. Novartis holds approved 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®". EXJADE® was approved by the FDA on November 2, 2005.

26. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the following patents are listed in the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") with respect to EXJADE®: the '504 Patent and the '750 Patent.

27. The ’504 Patent and the ’750 Patent are collectively referred to herein as the “Patents-in-Suit.”

PATENTS-IN-SUIT

28. 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.

29. Novartis is the owner of the entire right, title and interest in the ’504 Patent by assignment, and possesses the right to sue for and obtain equitable relief and damages for infringement of the ’504 Patent.

30. 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.

31. Novartis is the owner of the entire right, title and interest in the ’750 patent by assignment, and possesses the right to sue for and obtain equitable relief and damages for infringement of the ’750 Patent.

32. The composition, formulation, dosing, and method of administration for EXJADE® is covered by certain claims of the ’504 Patent and the ’750 Patent.

INFRINGEMENT BY MYLAN

33. By letter dated May 13, 2014 (“the Notice Letter”), Mylan notified Novartis that it had submitted ANDA No. 206585 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 Patents-in-Suit. Upon information and belief, Mylan 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.

34. By filing ANDA No. 206585, Mylan has necessarily represented to the FDA that the Mylan Generic Deferasirox Tablets have the same active ingredient as EXJADE®, have the same method of administration, dosage form, and strengths as EXJADE®, and are bioequivalent to EXJADE®.

35. In the Notice Letter, Mylan notified Novartis that its ANDA contained a "Paragraph IV certification" asserting that, in Mylan's opinion, certain claims of the Patents-in-Suit are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and sale of the Mylan Generic Deferasirox Tablets.

36. Mylan has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2) by filing ANDA No. 206585 under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use and/or sale of the Mylan Generic Deferasirox Tablets before the expiration of the term of the Patents-in-Suit.

37. The sale or offer for sale of the proposed Mylan Generic Deferasirox Tablets for which Mylan seeks approval in its ANDA will infringe, actively induce infringement and/or contributorily infringe one or more claims of the Patents-in-Suit.

38. Novartis is entitled under 35 U.S.C. § 271(e)(4) to full relief from Mylan's acts of infringement, including an Order by this Court ensuring that the effective

date of any approval of ANDA No. 206585 relating to the proposed Mylan Generic Deferasirox Tablets shall not be earlier than the expiration of the Patents-in-Suit.

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

COUNT ONE: INFRINGEMENT OF THE '504 PATENT

40. Novartis hereby realleges and incorporates by reference the allegations of paragraphs 1-39 of this Complaint.

41. Mylan's submission of ANDA No. 206585 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Mylan Generic Deferasirox Tablets 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).

42. Upon FDA approval of Mylan's ANDA No. 206585, Mylan 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.

43. If Mylan'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 TWO: INFRINGEMENT OF THE '750 PATENT

44. Novartis hereby realleges and incorporates by reference the allegations of paragraphs 1-43 of this Complaint.

45. Mylan's submission of ANDA No. 206585 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Mylan Generic

Deferasirox Tablets 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).

46. Upon FDA approval of Mylan's ANDA No. 206585, Mylan will further infringe the '750 Patent by making, using, offering to sell, and selling the Mylan Generic Deferasirox Tablets in the United States and/or importing such tablets into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271(a)-(c) unless enjoined by the Court.

47. Upon information and belief, by selling and offering for sale the proposed Mylan Generic Deferasirox Tablets, Mylan will actively encourage and/or instruct others on how to use the proposed the Mylan Generic Deferasirox Tablets in a way that infringes at least one claim of the '750 Patent. Upon information and belief, Mylan knows, will know, or should know, that its encouragement and/or instructions will result in infringement of at least one claim of the '750 Patent.

48. Upon information and belief, Mylan had actual and constructive knowledge of the '750 Patent prior to filing ANDA No. 206585 and was aware that filing of the aforementioned ANDA with the FDA constituted an act of infringement of the '750 patent.

49. If Mylan'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 Mylan has infringed one or more claims of the '504 Patent and the '750 Patent, and Mylan's submission of ANDA No. 206585, and Mylan's making,

using, offering to sell, or selling in the United States, or importing into the United States the Mylan Generic Deferasirox Tablets will infringe one or more claims of the ’504 Patent and the ’750 Patent;

2. A judgment that the ’504 Patent and the ’750 Patent are valid and enforceable;

3. An order pursuant to 35 U.S.C. §271(e)(4)(A) providing that the effective date of any approval of ANDA No. 206585 shall be a date which is not earlier than 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. An order restraining and enjoining Mylan, its officers, agents, attorneys and employees, and those acting in privity or concert with Mylan, from engaging in the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of the Mylan Generic Deferasirox Tablets, 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;

5. Damages or other monetary relief to Novartis if Mylan engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Mylan Generic Deferasirox Tablets before 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;

6. Costs and reasonable attorneys’ fees relating to this action pursuant to 35 U.S.C. §§ 271(e)(4) and 285; and

7. Such other and further relief as the Court may deem just and proper.

Dated: June 25, 2014

McCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*

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