IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG,	)	
Plaintiffs,	)	Civil Action No.
v.	)	
WOCKHARDT BIO AG and WOCKHARDT USA LLC,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Novartis Pharmaceuticals Corporation and Novartis AG (collectively "Novartis"), by their attorneys, for their Complaint against Wockhardt Bio AG and Wockhardt USA LLC (collectively "Wockhardt") 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, Sections 100 *et seq.* This action relates to an Abbreviated New Drug Application ("ANDA") filed by Wockhardt with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Novartis' Gleevec® drug product.

THE PARTIES

2. Plaintiff Novartis Pharmaceuticals Corporation ("NPC") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 59 Route 10, East Hanover, New Jersey 07936.

3. Plaintiff Novartis AG ("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.

4. Upon information and belief, defendant Wockhardt Bio AG is a company organized and existing under the laws of Switzerland, having a principal place of business at Grafenauweg 6, 6300 Zug, Switzerland.

5. Upon information and belief, defendant Wockhardt USA LLC is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Waterview Boulevard, Parsippany, New Jersey 07054.

6. Upon information and belief, Wockhardt USA LLC is a wholly-owned subsidiary of Morton Grove Pharmaceuticals, Inc., which is a wholly-owned subsidiary of Wockhardt Holding Corp., which is a wholly-owned subsidiary of Wockhardt Bio AG. Upon information and belief, Morton Grove Pharmaceuticals, Inc. and Wockhardt Holding Corp. are organized and existing under the laws of the State of Delaware.

7. Upon information and belief, Wockhardt USA LLC is controlled by Wockhardt Bio AG and acts as the U.S. agent for Wockhardt Bio AG in connection with the filing of ANDAs with the FDA and with the sale of pharmaceutical products in the United States, including in the State of Delaware and throughout this judicial district.

8. Upon information and belief, Wockhardt USA LLC is the authorized U.S. agent for ANDA No. 208429 that is the subject of this action.

JURISDICTION AND VENUE

9. This action for patent infringement arises under 35 U.S.C. § 271.

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. Upon information and belief, Wockhardt Bio AG and Wockhardt USA LLC are in the business of manufacturing, marketing, and selling pharmaceutical products, including generic pharmaceutical products.

12. Upon information and belief, Wockhardt Bio AG and Wockhardt USA LLC directly, or indirectly through their affiliates and/or distributors, market, distribute, and sell their pharmaceutical products within and throughout the United States, including in the State of Delaware and throughout this judicial district.

13. Upon information and belief, this Court has personal jurisdiction over Wockhardt USA LLC because Wockhardt USA LLC purposefully avails itself of the privilege of doing business in the State of Delaware by being formed and existing under the laws of Delaware and continuously and systematically placing goods in the stream of commerce for distribution throughout the United States, including the State of Delaware, and/or by selling directly or through its agents, pharmaceutical products in the State of Delaware, and deriving substantial revenue from such activities. Wockhardt USA LLC is registered to conduct business in the State of Delaware, Department of State: Division of Corporations, under file number 3769747 and maintains as a registered agent, Corporation Service Company, registered at 2711 Centerville Rd. Suite 400, Wilmington, DE 19808.

14. Upon information and belief, this Court has personal jurisdiction over Wockhardt Bio AG because, among other things, it purposely avails itself of the rights and benefits of the laws of Delaware by engaging in systematic and continuous contacts with Delaware such that it

should reasonably anticipate being haled into court here. On information and belief, Wockhardt Bio AG has persistent, systematic and continuous contacts with Delaware as set forth below.

15. Upon information and belief, this Court has personal jurisdiction over Wockhardt Bio AG because it purposefully avails itself of the privilege of conducting activities within the State of Delaware, including by causing its wholly-owned subsidiaries Wockhardt USA LLC, Morton Grove Pharmaceuticals, Inc., and Wockhardt Holding Corp. to be incorporated in Delaware. Upon information and belief, Wockhardt Bio AG directs the operations, management and activities of Delaware-incorporated Wockhardt USA LLC.

16. Upon information and belief, this Court has personal jurisdiction over Wockhardt Bio AG because Wockhardt Bio AG, through its indirect, wholly-owned Delaware subsidiary and agent Wockhardt USA LLC, files ANDAs with the FDA and markets, distributes, and/or sells generic drugs throughout the United States and within the State of Delaware and therefore purposefully avails itself of the privilege of conducting activities within the State of Delaware.

17. Upon information and belief, this Court also has personal jurisdiction over Wockhardt Bio AG under Federal Rule of Civil Procedure 4(k)(2).

18. Upon information and belief, Wockhardt Bio AG and Wockhardt USA LLC are aware of the process contemplated by the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch-Waxman Act"), by which a company filing an ANDA can challenge a branded pharmaceutical company's patents by filing a certification under 35 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification"), and sending notice of such certification to that branded pharmaceutical company, after which the parties might engage in patent litigation arising from this process.

19. Upon information and belief, with knowledge of the Hatch-Waxman process, pursuant to 21 U.S.C. § 355(j)(2)(B)(iii) Wockhardt directed a letter including a paragraph IV certification to Novartis, including NPC which is a Delaware corporation, and deliberately challenged Novartis' patent rights, knowing that such certification could trigger a patent infringement suit from Novartis under the Hatch-Waxman Act. Moreover, upon information and belief, Wockhardt knew that other Hatch-Waxman infringement actions relating to the same patents had been brought and litigated in Delaware.

20. Upon information and belief, this Court has personal jurisdiction over Wockhardt Bio AG and Wockhardt USA LLC because they have committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to NPC, a Delaware corporation, such that Wockhardt should anticipate being haled into court in this judicial district.

21. Upon information and belief, Wockhardt Bio AG and Wockhardt USA LLC will manufacture, market, and/or sell within the United States the generic version of Gleevec® tablets described in ANDA No. 208429 if FDA approval is granted. If ANDA No. 208429 is approved, the Wockhardt generic version of Gleevec® 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/or used by persons in Delaware, all of which would have a substantial effect on Delaware.

22. Upon information and belief, this Court also has personal jurisdiction over Wockhardt Bio AG and Wockhardt USA LLC because they have been sued previously in this district, did not challenge this Court's assertion of personal jurisdiction over them, and availed themselves of this forum by seeking affirmative relief in this jurisdiction by answering

Complaints and asserting counterclaims for the purpose of litigating a patent infringement dispute, including, without limitation: *Cephalon, Inc. v. Dr. Reddy's Labs. Ltd., et al.*, C.A. No. 15-179-GMS (D. Del.) (did not contest jurisdiction and filed counterclaims); *Cephalon, Inc. v. Wockhardt Bio AG et al.*, C.A. No. 14-1332-GMS (D. Del.) (did not contest jurisdiction and filed counterclaims); *AstraZeneca AB v. Wockhardt Bio AG et al.*, C.A. No. 14-667-GMS (D. Del.) (did not contest jurisdiction and filed counterclaims); *Forest Labs., Inc., et al v. Teva Pharms. USA, Inc., et al.*, C.A. No. 14-121-LPS (D. Del.) (did not contest jurisdiction and filed counterclaims); and *Alcon Research, Ltd. v. Wockhardt Ltd, et al.*, C.A. No. 13-2040 (D. Del.) (did not contest jurisdiction and filed counterclaims).

23. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) & (c) and 1400(b).

THE PATENTS IN SUIT

24. United States Patent No. 6,894,051 (the "'051 Patent") duly and legally issued on May 17, 2005 to inventors Jürg Zimmermann, *et al*. A true and correct copy of the '051 Patent is attached hereto as Exhibit A.

25. The '051 Patent is assigned to Novartis AG, and NPC is an exclusive licensee under the '051 Patent.

26. United States Reissue Patent No. RE43,932 (the "RE932 Patent") duly and legally issued on January 15, 2013 to inventors Jürg Zimmermann, *et al*. A true and correct copy of the RE932 Patent is attached hereto as Exhibit B.

27. The RE932 Patent is assigned to Novartis AG, and NPC is an exclusive licensee under the RE932 Patent.

ACTS GIVING RISE TO THIS ACTION

28. Plaintiff NPC holds an approved New Drug Application ("NDA") No. 21588 for Gleevec® tablets containing 100 mg and 400 mg imatinib mesylate, which was approved by the FDA on April 18, 2003.

29. By letter dated December 15, 2015 ("Wockhardt's Notice Letter"), Wockhardt notified Novartis that it had submitted ANDA No. 208429 to the FDA under Section 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, offer to sell or sale of tablets containing 100 mg and 400 mg of imatinib mesylate (the "Imatinib Mesylate ANDA Tablets"). Upon information and belief, Wockhardt stated in its ANDA that its Imatinib Mesylate ANDA Tablets are bioequivalent to Novartis' 100 mg and 400 mg imatinib mesylate Gleevec® tablets.

30. As stated in its Notice Letter, Wockhardt's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, use and/or sale of Wockhardt's Imatinib Mesylate ANDA Tablets prior to the expiration of the '051 Patent and the RE932 Patent which are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as being applicable to Novartis' Gleevec® tablets. On information and belief, Wockhardt intends to engage in the commercial manufacture, use and/or sale of Wockhardt's ANDA Imatinib Mesylate Tablets promptly upon receiving FDA approval to do so.

31. In its Notice Letter, Wockhardt notified Novartis that its ANDA contained a "paragraph IV certification" that in Wockhardt's opinion, the '051 Patent and the RE932 Patent are invalid, unenforceable or will not be infringed by the manufacture, use, sale, or offer to sell of Wockhardt's Imatinib Mesylate ANDA Tablets.

32. Wockhardt's filing of its ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell or sale of its Imatinib Mesylate ANDA Tablets, prior to the expiration of the '051 Patent and the RE932 Patent, constitutes infringement of one or more of the claims of those patents under 35 U.S.C. § 271(e)(2).

33. Wockhardt's commercial manufacture, use, offer to sell or sale of Wockhardt's Imatinib Mesylate ANDA Tablets, prior to the expiration of the '051 Patent and the RE932 Patent, would constitute infringement of the '051 Patent and the RE932 Patent under 35 U.S.C. § 271.

34. Upon FDA approval of Wockhardt's ANDA, Wockhardt will infringe the '051 Patent and the RE932 Patent by making, using, offering to sell, and/or selling Wockhardt's Imatinib Mesylate ANDA Tablets in the United States unless enjoined by this Court.

35. Wockhardt had notice of the '051 Patent and the RE932 Patent at the time of its infringement.

36. Novartis will be substantially and irreparably damaged and harmed if Wockhardt's infringement is not enjoined. Novartis does not have an adequate remedy at law.

WHEREFORE, Novartis respectfully requests the following relief:

(a) a judgment and decree that the '051 Patent and the RE932 Patent are valid and enforceable;

(b) a judgment and decree that Wockhardt has infringed one or more claims of the '051 Patent and the RE932 Patent in violation of 35 U.S.C. § 271;

(c) a judgment declaring that Wockhardt's making, using, selling, offering to sell or importing Wockhardt's Imatinib Mesylate ANDA Tablets will infringe the '051 Patent and the RE932 Patent;

(d) a judgment providing that the effective date of any FDA approval for Wockhardt to make, use or sell Wockhardt's Imatinib Mesylate ANDA Tablets be no earlier than the date on which last-expiring patent of the '051 Patent and the RE932 Patent expires, including any associated regulatory exclusivities;

(e) a judgment permanently enjoining Wockhardt from making, using, selling, offering to sell, or importing Wockhardt's Imatinib Mesylate ANDA Tablets until after expiration of the '051 Patent and the RE932 Patent, including any associated regulatory exclusivities;

(f) if Wockhardt engages in the commercial manufacture, use or sale of Wockhardt's Imatinib Mesylate ANDA Tablets prior to the expiration of the '051 Patent and the RE932 Patent, a judgment awarding Novartis damages resulting from such infringement, increased to treble the amount found or assessed, together with interest;

(g) a judgment awarding Novartis attorneys' fees in this action pursuant to 35 U.S.C. § 285;

(h) a judgment awarding Novartis costs and expenses in this action; and

(i) a judgment awarding Novartis such further and other relief as this Court may deem just and proper.

Dated: January 26, 2016

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

Michael P. Kelly (#2295)
Daniel M. Silver (#4758)
Benjamin A. Smyth (#5528)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
mkelly@mccarter.com
dsilver@mccarter.com
bsmyth@mccarter.com

Attorneys for Plaintiffs
Novartis Pharmaceuticals Corporation and
Novartis AG

OF COUNSEL:

David K. Barr
Tatiana N. Alyonycheva
Katherine G. O'Brien
KAYE SCHOLER LLP
250 West 55th Street
New York, New York 10019
(212) 836-7560
david.barr@kayescholer.com
tatiana.alyonycheva@kayescholer.com
katherine.obrien@kayescholer.com