IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG	)	
Plaintiffs,	)	Civil Action No.
v.	)	
DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs, Novartis Pharmaceuticals Corporation and Novartis AG (collectively "Novartis"), by their attorneys, for their Complaint against Dr. Reddy's Laboratories, Ltd. ("DRL, Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL, Inc.") (collectively "DRL") 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 DRL 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 07396.

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, DRL, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 107 College Road East, Princeton, NJ 08540.

5. Upon information and belief, DRL, Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at 7-1-27, Ameerpet, Hyderabad 500 016, Andhra Pradesh, India.

6. Upon information and belief, Defendant DRL, Inc. is a wholly-owned subsidiary of DRL, Ltd., and is controlled by DRL, Ltd.

JURISDICTION AND VENUE

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

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

9. Upon information and belief, this Court has personal jurisdiction over DRL, Ltd. and DRL, Inc.

10. Upon information and belief, DRL, Inc. and DRL, Ltd. are in the business of developing and manufacturing generic and branded pharmaceutical products.

11. Upon information and belief, DRL, Inc. and DRL, Ltd. directly, or indirectly through their subsidiaries and/or distributors, market, distribute, and sell their generic and branded pharmaceutical products within and throughout the United States, including in the State of Delaware and throughout this judicial district.

12. Upon information and belief, DRL, Inc. purposefully avails itself of the privilege of doing business in the State of Delaware by 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.

13. Upon information and belief, DRL, Ltd., through its wholly-owned subsidiary DRL, Inc., 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.

14. Upon information and belief, DRL, Ltd., through its wholly-owned subsidiary DRL, Inc., has formed one or more subsidiary companies under Delaware law and therefore purposefully has availed itself of the privilege of conducting activities within the State of Delaware. For example, in DRL, Ltd.'s Form 20-F for the fiscal year ended March 31, 2013 filed with the Securities and Exchange Commission, DRL, Ltd. represented that it is the parent company of Dr. Reddy's Laboratories Louisiana, LLC and Dr. Reddy's Laboratories Tennessee, LLC, both of which are limited liability companies formed and existing under Delaware law. In the same Form 20-F, DRL, Ltd. represented that Dr. Reddy's Laboratories Louisiana, LLC and Dr. Reddy's Laboratories Tennessee, LLC are indirect subsidiaries of DRL, Ltd. owned through DRL, Inc. In the same Form 20-F, DRL, Ltd. represented that "[w]e market our products through our subsidiaries in the United States[.]" Accordingly, upon information and belief, DRL, Ltd. and DRL, Inc. manufacture, market, distribute and/or sell generic drugs throughout the United States, including without limitation in the State of Delaware and throughout this judicial district, through one or more entities formed and existing under Delaware law.

15. Upon information and belief, this Court also has personal jurisdiction over DRL, Inc. and DRL, Ltd. 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 in at least fifteen cases since 2004, including, without limitation: *Teijin Limited, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, C.A. No. 1:13-cv-01780 (D. Del. filed Oct. 30, 2013); *Genzyme Corporation, et al. v. Dr. Reddy's Laboratories Ltd., et al.*, C.A. No. 1:13-cv-01506 (D. Del. filed Aug. 29, 2013); *Pfizer Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, C.A. No. 1:13-cv-00989 (D. Del. filed Jun. 4, 2013); *Fresenius Kabi USA LLC v. Dr. Reddy's Laboratories, Ltd., et al.*, C.A. No. 1:13-cv-00925 (D. Del. filed May 23, 2013); *Pfizer Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, C.A. No. 1:09-cv-00943 (D. Del. filed Dec. 08, 2009), and *Novartis Pharmaceuticals Corp. and Novartis AG v. Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc.*, Civ. A. No. 1:14-00157-LPS (D. Del. filed Feb. 5, 2014).

16. In *Genzyme Corporation, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, C.A. No. 1:13-cv-01506 (D. Del. filed Aug. 29, 2013), DRL, Inc. and DRL, Ltd. admitted that they were "subject to personal jurisdiction in the district."

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

THE PATENTS IN SUIT

18. 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.

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

20. 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.

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

ACTS GIVING RISE TO THIS ACTION

22. Plaintiff NPC holds an approved New Drug Application ("NDA") No. 021335 for Gleevec® oral capsules containing 50 mg and 100 mg imatinib mesylate, which was approved by the FDA on May 10, 2001. The 50 mg Gleevec® capsules were discontinued in 2003 and the 100 mg capsules were discontinued in 2005.

23. Plaintiff NPC also holds approved NDA No. 21588 for Gleevec® tablets containing 100 mg and 400 mg imatinib mesylate, which was approved by the FDA on April 18, 2003.

24. By letter dated August 27, 2014 ("DRL's Notice Letter"), DRL notified Novartis that it had submitted ANDA No. 206898 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 capsules containing 400 mg of imatinib mesylate, Imatinib Mesylate Capsules, EQ 400 mg Base (the "400 mg Imatinib Mesylate ANDA Capsules").

25. Upon information and belief, both DRL, Inc. and DRL, Ltd. submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 206898.

26. As stated in its Notice Letter, DRL's ANDA was submitted to obtain FDA approval to engage in the commercial manufacture, use and sale of DRL's 400 mg Imatinib Mesylate ANDA Capsules 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, DRL intends to engage in the commercial manufacture, use and sale of its 400 mg Imatinib Mesylate ANDA Capsules promptly upon receiving FDA approval to do so.

27. In its Notice Letter, DRL notified Novartis that its ANDA contained a "paragraph IV certification" that in DRL'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 DRL's 400 mg Imatinib Mesylate ANDA Capsules.

28. DRL's filing of its ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell or sale of its 400 mg Imatinib Mesylate ANDA Capsules, 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).

29. DRL's commercial manufacture, use, offer to sell or sale of its 400 mg Imatinib Mesylate ANDA Capsules, 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.

30. Upon FDA approval of DRL's ANDA, DRL will infringe the '051 Patent and the RE932 Patent by making, using, offering to sell, and selling its 400 mg Imatinib Mesylate ANDA Capsules in the United States unless enjoined by this Court.

31. DRL had notice of the '051 Patent and the RE932 Patent at the time of its infringement.

32. Novartis will be substantially and irreparably damaged and harmed if DRL'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 DRL 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 DRL's making, using, selling, offering to sell or importing its 400 mg Imatinib Mesylate ANDA Capsules will infringe the '051 Patent and the RE932 Patent;

(d) a judgment providing that the effective date of any FDA approval for DRL to make, use or sell its 400 mg Imatinib Mesylate ANDA Capsules 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 DRL from making, using, selling, offering to sell, or importing its 400 mg Imatinib Mesylate ANDA Capsules until after expiration of the '051 Patent and the RE932 Patent, including any associated regulatory exclusivities;

(f) if DRL engages in the commercial manufacture, use or sale of its 400 mg Imatinib Mesylate ANDA Capsules 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: October 8, 2014

McCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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