William J. O'Shaughnessy
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 639-2094

Attorneys for Plaintiffs
Novartis Pharmaceuticals Corporation
and Novartis AG

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION and NOVARTIS AG, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC. Defendants.	)	Civil Action No. **COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2**

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® 100 mg Imatinib Mesylate Capsules.

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

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

9. Upon information and belief, DRL, Inc. and DRL, Ltd. operate as an integrated, unitary business.

10. Upon information and belief, DRL, Ltd., through its wholly-owned subsidiary DRL, Inc., markets, distributes and/or sells generic and branded pharmaceutical products within and throughout the United States and within the State of New Jersey, and therefore purposefully avails itself of the privilege of conducting activities within the State of New Jersey and throughout this judicial district.

11. This Court has personal jurisdiction over DRL, Inc. by virtue of, *inter alia*, its incorporation in New Jersey, its presence in New Jersey, and its systematic and continuous contacts with New Jersey. In addition, DRL, Inc. has appointed and authorized an agent to accept service of process in New Jersey for actions filed in connection with the DRL ANDA.

12. Upon information and belief, this Court has personal jurisdiction over DRL, Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with New Jersey. In addition, DRL, Ltd. has appointed and authorized an agent to accept service of process in New Jersey for actions filed in connection with the DRL ANDA.

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

THE PATENT IN SUIT

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

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

ACTS GIVING RISE TO THIS ACTION

16. 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.

17. 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.

18. By letter dated February 24, 2014 ("DRL's Notice Letter"), DRL notified Novartis that it had submitted ANDA No. 205565 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 and sale of oral capsules containing 100 mg of imatinib mesylate, Imatinib Mesylate Oral Capsules, EQ 100 mg Base (the "Imatinib Mesylate ANDA Capsules").

19. 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. 205565.

20. 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 Imatinib Mesylate ANDA Capsules prior to the expiration of the RE932 Patent which is listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the "Orange Book") as being applicable to Novartis' Gleevec® capsules. On information and belief, DRL intends to engage in the commercial manufacture, use and sale of its ANDA Imatinib Mesylate Capsules promptly upon receiving FDA approval to do so.

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

22. DRL'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 Capsules, prior to the expiration of the RE932 Patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2).

23. DRL's commercial manufacture, use, offer to sell or sale of its Imatinib Mesylate ANDA Capsules, prior to the expiration of the RE932 Patent, would constitute infringement of the RE932 Patent under 35 U.S.C. § 271.

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

25. DRL had notice of the RE932 Patent at the time of its infringement.

26. 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 RE932 Patent is valid and enforceable;

(b) a judgment and decree that DRL has infringed one or more claims of 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 Imatinib Mesylate ANDA Capsules will infringe the RE932 Patent;

(d) a judgment providing that the effective date of any FDA approval for DRL to make, use or sell its Imatinib Mesylate ANDA Capsules be no earlier than the date on which 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 Imatinib Mesylate ANDA Capsules until after expiration of the RE932 Patent, including any associated regulatory exclusivities;

(f) if DRL engages in the commercial manufacture, use or sale of its Imatinib Mesylate ANDA Capsules prior to the expiration of 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: April 10, 2014

McCARTER & ENGLISH, LLP

s/William J. O'Shaughnessy
William J. O'Shaughnessy
McCARTER & ENGLISH, LLP
Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 639-2094

David K. Barr
Tatiana N. Alyonycheva
KAYE SCHOLER LLP
425 Park Avenue

New York, New York 10022
(212) 836-7560

Sylvia M. Becker
KAYE SCHOLER LLP
McPherson Building
901 Fifteenth Street, NW
Washington, DC 20005-2327
(202) 682-3579

Attorneys for Plaintiffs
Novartis Pharmaceuticals Corporation and
Novartis AG

CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is the subject of the following actions:

- *Sun Pharma Global FZE v. Novartis Pharmaceuticals Corp., et al.*, Civil Action No. 13-cv-03542-DMC-JBC (D.N.J.)
- *Novartis Pharmaceuticals Corp., et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civil Action No. 14-cv-00157-UNA (D. Del.)
- *Novartis Pharmaceuticals Corp., et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civil Action No. 14-cv-00785-CCC-MF (D.N.J.)
- *Novartis Pharmaceuticals Corp., et al. v. Dr. Reddy's Laboratories Ltd., et al.*, Civil Action No. 14-cv-00387-LPS (D. Del.)

Dated: April 10, 2014

Respectfully,

s/William J. O'Shaughnessy
William J. O'Shaughnessy
McCARTER & ENGLISH, LLP Four Gateway Center
100 Mulberry Street
Newark, New Jersey 07102
(973) 639-2094

David K. Barr
Tatiana N. Alyonycheva
KAYE SCHOLER LLP 425 Park Avenue
New York, New York 10022
(212) 836-7560

Sylvia M. Becker
KAYE SCHOLER LLP
McPherson Building 901 Fifteenth Street, NW Washington, DC 20005-2327 (202) 682-3579

Attorneys for Plaintiffs Novartis Pharmaceuticals Corporation and Novartis AG