IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOVARTIS PHARMACEUTICALS CORPORATION, NOVARTIS AG, NOVARTIS PHARMA AG and LTS LOHMANN THERAPIE-SYSTEME AG, Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	:	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG and LTS Lohmann Therapie-Systeme AG, for their Complaint against defendants Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively "DRL" or "Defendants") allege as follows:

NATURE OF ACTION

1. This is an action for patent infringement.

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. Plaintiff Novartis Pharma AG ("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.

5. Plaintiff LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of Germany, having an office and place of business at Lohmannstraße 2, D-56626 Andernach, Germany.

6. On information and belief, defendant DRL Ltd. is a corporation organized and existing under the laws of India with a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034, India.

7. On information and belief, defendant DRL Inc. is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business located at 107 College Road East, Princeton, NJ 08540.

8. On information and belief, DRL Inc. is a wholly owned subsidiary of DRL Ltd., and DRL Inc. is controlled by, and acts on behalf of and as the agent for DRL Ltd. with respect to the activities alleged in this complaint.

9. On information and belief, DRL Ltd. and DRL Inc. acted collaboratively in the preparation and submission of an abbreviated new drug application ("ANDA") No. 208318. On information and belief, DRL Inc.'s preparation and submission of ANDA No. 208318 was done at the direction, under the control, for the direct benefit and on behalf of DRL Ltd.

10. On information and belief, following any FDA approval of ANDA No. 208318, DRL Inc. as well as DRL Ltd., itself and through its subsidiaries and agents, including DRL Inc., will make, use, offer to sell, and/or sell the generic products that are the subject of

ANDA No. 208318 (hereinafter DRL's ANDA Products) throughout the United States, including in the State of New Jersey, and/or import such generic products into the United States for sale and use throughout the United States, including in the State of New Jersey.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

12. This Court has personal jurisdiction over DRL Inc. On 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, New Jersey 08540. On information and belief, DRL Inc. is registered as a domestic business entity with the New Jersey Department of Treasury under the business entity identification number 0100518911. On information and belief, DRL Inc. conducts business in the State of New Jersey under the alternate name Reddy-Cheminor, Inc. On information and belief, Reddy-Cheminor, Inc. is also registered as a domestic business entity with the New Jersey Department of Treasury under the business entity identification number 0100518911. On information and belief, Reddy-Cheminor, Inc. is registered to conduct the business activity of distributing generic pharmaceuticals. On information and belief, Reddy-Cheminor, Inc. maintains a corporate agent for service of process at 66 South Maple Avenue, Ridgewood, New Jersey 07460. On information and belief, Reddy-Cheminor, Inc. is an agent, affiliate, or subsidiary of DRL Inc.

13. On information and belief, DRL Inc. directly or through its affiliates and agents develops, formulates, manufactures, markets, imports, and sells pharmaceutical products, including generic drug products, which are copies of products invented and developed by

innovator pharmaceutical companies, throughout the United States, including in this Judicial District. On information and belief, DRL Inc. holds an active wholesale drug and medical device license for the State of New Jersey under License No. 5002312.

14. On information and belief, DRL Inc. has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, DRL Inc. engages in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of New Jersey and to the residents of the State of New Jersey, and maintains corporate agents in the State of New Jersey.

15. On information and belief, DRL Inc. regularly conducts and/or solicits business in the State of New Jersey, engages in other persistent courses of conduct in the State of New Jersey, and/or derives substantial revenue from services or things used or consumed in the State of New Jersey.

16. On information and belief, DRL Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted claims in this jurisdiction, including in the matter of *Dr. Reddy's Labs., Inc. et al. v. Purdue Pharm. Pdts. L.P. et al.*, Civil Action No. 14-3230 (JLL)(JAD) (D.N.J. May 20, 2014). On information and belief, DRL Inc. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction, including in the matters of *Sanofi-Aventis U.S. LLC et al. v. Dr. Reddy's Labs Inc., et al.*, Civil Action No. 15-02522 (MAS-LHG), D.I. 15 at 4-6, 15-20 (D.N.J., June 26, 2015); *Sucampo AG et al. v. Dr. Reddy's Labs., Inc. et al.*, Civil Action No. 14-7114 (MAS)(DEA), D.I. 16 at 2-3, 18-25 (D.N.J. Jan. 26, 2015); *Helsinn Healthcare S.A. et al. v. Dr. Reddy's Labs., Inc. et al.*, Civil Action No. 14-4274 (MLC)(DEA), D.I. 13 at 3, 8-12

(D.N.J. Sep. 5, 2014); *Amarin Pharma, Inc. et al. v. Dr. Reddy's Labs., Inc. et al.*, Civil Action No. 14-2760 (MLC)(DEA), D.I. 27 at 3, 34-48 (D.N.J. Jul. 31, 2014); *Genzyme Corp. et al. v. Dr. Reddy's Labs., Inc. et al.*, Civil Action No. 13-6827 (JEI)(KMW), D.I. 17 at 6, 16-21 (D.N.J. Jan. 21, 2014).

17. DRL Inc. is also subject to personal jurisdiction in the State of New Jersey because, *inter alia*, it has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) out of which this suit arises and that has led and/or will lead to foreseeable harm and injury to NPC, having commercial headquarters in the State of New Jersey. DRL Inc. sent its September 24, 2015 notice letter pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) ("Notice Letter") to NPC's commercial headquarters at 59 Route 10, East Hanover, New Jersey 07936. Plaintiffs' cause of action arose from DRL Inc.'s contact with NPC in East Hanover, New Jersey.

18. On information and belief, upon approval of DRL's ANDA, DRL Inc. and/or its subsidiaries, affiliates, or agents will market, sell, and/or distribute DRL's ANDA Products throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

19. On information and belief, upon approval of DRLs ANDA, DRL Inc. and/or its subsidiaries, affiliates, or agents will place DRL's ANDA Products into the stream of commerce with the reasonable expectation or knowledge and the intent that such products will ultimately be purchased and used by consumers in this Judicial District.

20. This Court has personal jurisdiction over DRL Ltd. On information and belief, DRL Ltd. directly or through its affiliates and agents develops, formulates, manufactures, markets, imports, and sells pharmaceutical products, including generic drug products, which are

copies of products invented and developed by innovator pharmaceutical companies, throughout the United States, including in this Judicial District. On information and belief, DRL Ltd. is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products.

21. On information and belief, DRL Ltd. has affiliations with the State of New Jersey that are pervasive, continuous, and systematic. On information and belief, DRL Ltd. engages in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of New Jersey and to the residents of the State of New Jersey, and maintains corporate agents in the State of New Jersey.

22. On information and belief, DRL Ltd. regularly conducts and/or solicits business in the State of New Jersey, engages in other persistent courses of conduct in the State of New Jersey, and/or derives substantial revenue from services or things used or consumed in the State of New Jersey.

23. On information and belief, DRL Ltd. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted claims in this jurisdiction, including in the matter of *Dr. Reddy's Labs., Inc. et al. v. Purdue Pharm Pdts. L.P. et al.*, Civil Action No. 14-3230 (JLL)(JAD) (D.N.J. May 20, 2014). On information and belief, DRL Ltd. has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of New Jersey, having asserted counterclaims in this jurisdiction, including in the matters of *Sanofi-Aventis, et al. v. Dr. Reddy's Laboratories, Inc., et al.*, Civil Action No. 15-02522 (MAS-LHG), D.I. 15 at 7-9, 15-20 (D.N.J. June 26, 2015); *Sucampo AG et al. v. Dr. Reddy's Labs., Inc. et al.*, Civil Action No. 14-7114 (MAS)(DEA), D.I. 16 at 2-3, 18-25 (D.N.J. Jan. 26, 2015); *Helsinn Healthcare S.A. et al. v. Dr.*

Reddy's Labs., Inc. et al., Civil Action No. 14-4274 (MLC)(DEA), D.I. 13 at 3, 8-12 (D.N.J. Sep. 5, 2014); *Amarin Pharma, Inc. et al. v. Dr. Reddy's Labs., Inc. et al.*, Civil Action No. 14-2760 (MLC)(DEA), D.I. 27 at 3, 34-48 (D.N.J. Jul. 31, 2014); *Genzyme Corp. et al. v. Dr. Reddy's Labs., Inc. et al.*, Civil Action No. 13-6827 (JEI)(KMW), D.I. 17 at 6, 16-21 (D.N.J. Jan. 21, 2014).

24. In the alternative, DRL Ltd. is subject to jurisdiction in the United States under the principles of general jurisdiction, and specially in the State of New Jersey pursuant to Fed. R. Civ. P. 4(k)(2). DRL Ltd. has contacts with the United States by, *inter alia*, its having filed an ANDA with the FDA.

25. On information and belief, upon approval of DRL's ANDA, DRL Ltd. and/or its subsidiaries, affiliates, or agents will market, sell, and/or distribute DRL's ANDA Products throughout the United States, including in this Judicial District, and will derive substantial revenue therefrom.

26. On information and belief, upon approval of DRL's ANDA, DRL Ltd. and/or its subsidiaries, affiliates, or agents will place DRL's ANDA Products into the stream of commerce with the reasonable expectation or knowledge and the intent that such products will ultimately be purchased and used by consumers in this Judicial District.

27. DRL Ltd. is also subject to personal jurisdiction in the State of New Jersey because, *inter alia*, it has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) out of which this suit arises and that has led and/or will lead to foreseeable harm and injury to NPC, having commercial headquarters in the State of New Jersey. DRL Ltd. sent its September 24, 2015 Notice Letter pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) to NPC's commercial headquarters at 59

Route 10, East Hanover, New Jersey 07936. Plaintiffs' cause of action arose from DRL Ltd.'s contact with NPC in East Hanover, New Jersey.

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

29. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c) and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF – PATENT INFRINGEMENT

30. NPC holds an approved new drug application ("NDA") No. 22-083 for Exelon® Patch (rivastigmine transdermal system or extended release film) (4.6 mg/24 hr, 9.5 mg/24 hr and 13.3 mg/24 hr dosage strengths), which patch contains the active ingredient rivastigmine. Exelon® Patch (4.6 mg/24 hr and 9.5 mg/24 hr dosage strengths) was approved by the FDA on July 6, 2007, and Exelon® Patch (13.3 mg/24 hr dosage strength) was approved by the FDA on August 31, 2012. Exelon® Patch is indicated for the treatment of mild to moderate dementia of the Alzheimer's type and mild to moderate dementia associated with Parkinson's disease. Exelon® Patch (4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths) is sold in the United States by NPC.

31. Rivastigmine is known chemically as (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate.

32. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,316,023 ("the '023 patent"). The '023 patent was duly and legally issued on November 13, 2001.

33. The '023 patent claims pharmaceutical compositions, *inter alia*, comprising 1 to 40 weight percent of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-

carbamate in the form of a free base or acid addition salt, 0.01 to 0.5 weight percent of an antioxidant, and a diluent or carrier, wherein the weight percents are based on the total weight of the pharmaceutical composition, as well as transdermal devices. A true copy of the ’023 patent is attached hereto as Exhibit A.

34. Plaintiffs Novartis AG and LTS are the owners of United States Letters Patent No. 6,335,031 (“the ’031 patent”). The ’031 patent was duly and legally issued on January 1, 2002.

35. The ’031 patent claims pharmaceutical compositions, *inter alia*, comprising: (a) a therapeutically effective amount of (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form; (b) about 0.01 to about 0.5 percent by weight of an antioxidant, based on the weight of the composition, and (c) a diluent or carrier, as well as transdermal devices and methods of stabilizing (S)-N-ethyl-3-[(1-dimethylamino)ethyl]-N-methylphenyl-carbamate in free base or acid addition salt form. A true copy of the ’031 patent is attached hereto as Exhibit B.

36. The ’023 and ’031 patents were initially assigned to Novartis AG and LTS Lohmann Therapie-Systeme GmbH & Co. KG, which subsequently changed its legal form to become Plaintiff LTS.

37. On information and belief, DRL submitted to the FDA an ANDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, and sale of a rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths (“DRL’s ANDA Products”)”) before the expiration of the ’023 and ’031 patents.

38. On information and belief, DRL made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '023 and '031 patents are invalid and/or will not be infringed. DRL did not allege that any of the '023 or '031 patent claims were unenforceable.

39. Plaintiffs received written notification of DRL's ANDA and its accompanying 21 U.S.C. § 355(j)(2)(A)(vii)(IV) certification by DRL's Notice Letter dated September 24, 2015.

40. This action was commenced within 45 days of receipt of DRL's Notice Letter.

41. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of DRL's ANDA Products before the expiration of the '023 and '031 patents, DRL has committed an act of infringement under 35 U.S.C. § 271(e)(2).

42. On information and belief, when DRL filed its ANDA, it was aware of the '023 and '031 patents and that the filing of its ANDA with the request for its approval prior to the expiration of the '023 and '031 patents was an act of infringement of those patents.

43. On information and belief, the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Products will infringe and/or induce infringement of one or more claims of the '023 and '031 patents.

44. On information and belief, the commercial manufacture of DRL's ANDA Products will involve direct infringement of the '023 patent. On information and belief, this will occur at DRL's active behest, and with DRL's intent, knowledge, and encouragement. On

information and belief, DRL will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the rights under the '023 patent.

45. On information and belief, the commercial manufacture of DRL's ANDA Products will involve direct infringement of the '031 patent. On information and belief, this will occur at DRL's active behest, and with DRL's intent, knowledge, and encouragement. On information and belief, DRL will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of the rights under the '031 patent.

46. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of the aforementioned ANDA relating to DRL's ANDA Products be a date that is not earlier than January 8, 2019, the expiration date of the '023 and '031 patents, and an award of damages for any commercial sale or use of DRL's ANDA Products and any act committed by DRL with respect to the subject matter claimed in the '023 and '031 patents, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

47. On information and belief, DRL has taken and continues to take active steps towards the commercial manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA Products, including seeking approval of that product under DRL's ANDA.

48. There is a substantial and immediate controversy between Plaintiffs and DRL concerning the '023 and '031 patents. Plaintiffs are entitled to declaratory judgment under 28 U.S.C. §§ 2201 and 2202 that DRL will infringe and/or induce infringement of one or more claims of the '023 and '031 patents.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Judgment that DRL has infringed and induced infringement of one or more claims of the ’023 and ’031 patents by filing the aforesaid ANDA relating to DRL’s rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths;

B. A permanent injunction restraining and enjoining DRL and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of a rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths, as claimed in the ’023 and ’031 patents;

C. An order that the effective date of any approval of the aforementioned ANDA relating to DRL’s rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths, be a date that is not earlier than the expiration of the right of exclusivity under the ’023 and ’031 patents;

D. Declaratory judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of DRL’s rivastigmine transdermal system, 4.6 mg/24 hr, 9.5 mg/24 hr, and 13.3 mg/24 hr dosage strengths, will infringe one or more claims of the ’023 and ’031 patents and that DRL will induce infringement of one or more claims of the ’023 and ’031 patents;

E. Damages from DRL for the infringement and inducement of infringement of the ’023 and ’031 patents;

F. The costs and reasonable attorney fees of Plaintiffs in this action; and

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

Dated: November 6, 2015

MCCARTER & ENGLISH, LLP

s/ William J. O'Shaughnessy

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CERTIFICATION PURSUANT TO LOCAL RULE 11.2

Plaintiffs Novartis Pharmaceuticals Corporation, Novartis AG, Novartis Pharma AG and LTS Lohmann Therapie-Systeme AG, by their attorneys, hereby certify pursuant to Local Rule 11.2 that the matter in controversy is the subject of the following pending actions:

Novartis Pharms. Corp. et al. v. Dr. Reddy's Labs., Ltd., 15-01026 (D. Del.).

Novartis Pharms. Corp. et al. v. Amneal Pharms. LLC et al., 15-01025 (D. Del.).

Novartis Pharms. Corp., et al. v. Noven Pharms., Inc., 2015-2053 (Fed. Cir.).

Novartis Pharms. Corp., et al. v. Noven Pharms., Inc., 2015-2051 (Fed. Cir.).

Mylan Pharms., Inc. v. Novartis AG et al., Case IPR2015-00268 (U.S.P.T.O.).

Mylan Pharms., Inc. v. Novartis AG et al., Case IPR2015-00265 (U.S.P.T.O.).

Novartis Pharms. Corp., et al. v. Zydus Noveltech Inc., 14-cv-5405-RMB-JS (D.N.J.).

Noven Pharms., Inc. et al. v. Novartis AG et al., Case IPR2014-00550 (U.S.P.T.O.).

Noven Pharms., Inc. et al. v. Novartis AG et al., Case IPR2014-00549 (U.S.P.T.O.).

Novartis Pharms. Corp., et al. v. Noven Pharms., Inc., 14-cv-111-RGA (D. Del.).

Novartis Pharms. Corp., et al. v. Noven Pharms., Inc., 13-cv-527-RGA (D. Del.).

I hereby certify that the following statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false, I am subject to punishment.

Dated: November 6, 2015

MCCARTER & ENGLISH, LLP

/s/ William J. O'Shaughnessy

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