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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

RECKITT BENCKISER LLC, Plaintiff, v. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD., Defendants.	Civil Action No. _____ (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Reckitt Benckiser LLC ("Reckitt Benckiser" or "Plaintiff") brings this Complaint against Defendants Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's

Laboratories, Inc. ("DRL Inc.") (collectively, "DRL" or "Defendants"), and hereby alleges as follows:

THE PARTIES

1. Plaintiff Reckitt Benckiser LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 399 Interpace Parkway, Parsippany, New Jersey 07054.

2. Upon information and belief, Defendant DRL Inc. is a company 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.

3. Upon information and belief, Defendant DRL Ltd. is a public limited liability company organized and existing under the laws of India, having its principal place of business at 8-2-337, Road No. 2, Banjara Hills, Hyderabad 500 034, Telangana, India.

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

5. Upon information and belief, the acts complained of herein were done by, at the direction of, with the authorization, cooperation, participation or assistance of, or at least in part, for the benefit of DRL Ltd. and DRL Inc.

JURISDICTION AND VENUE

6. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code §§ 100 et seq. Jurisdiction is based on 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. DRL is subject to personal jurisdiction in the State of New Jersey because, *inter alia*, DRL 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) that has led and/or will lead to foreseeable harm and injury to Plaintiff Reckitt Benckiser, which has its U.S. commercial headquarters in the State of New Jersey. DRL Inc. sent a letter dated May 18, 2015 ("Notice Letter") to Reckitt Benckiser U.S.'s commercial headquarters at 399 Interpace Parkway, Parsippany, New Jersey 07054-0225. Plaintiff's cause of action arose from DRL's contact with Reckitt Benckiser in Parsippany, New Jersey. DRL's Notice Letter states that DRL Inc. has filed, on behalf of DRL Ltd., an Abbreviated New Drug Application ("ANDA") with respect to guaifenesin and pseudoephedrine hydrochloride extended-release tablets, 600 mg/60 mg and 1.2 g/120 mg ("DRL's ANDA Products"). The Notice Letter also states that DRL intends to seek approval from the Federal Food and Drug Administration ("FDA") of the ANDA to engage in the commercial manufacture, use, or sell DRL's ANDA Products throughout the United States, including in this Judicial District, before the expiration of the U.S. patents listed in the Orange Book which are owned by Plaintiff Reckitt Benckiser.

8. This Court has personal jurisdiction over DRL Inc. because, *inter alia*, (1) DRL Inc. is a corporation organized and existing under the law of the State of New Jersey; (2) DRL Inc. has its principal place of business, is registered to do business, and does business in the State of New Jersey; and (3) DRL Inc. is licensed by the New Jersey Department of Health and Senior Services to sell generic pharmaceutical products in New Jersey.

9. Upon information and belief by virtue of, *inter alia*, DRL Ltd.'s relationship with DRL Inc., DRL's designation, in the May 18, 2015 Notice Letter, of Lee Banks of the Princeton, New Jersey office of Dr. Reddy's Laboratories, Inc., as DRL's agent for acceptance of service of process, this Court has general personal jurisdiction over DRL Ltd.

10. Upon information and belief, DRL Inc. and DRL Ltd., through DRL Inc., receive Medicaid reimbursements from drugs sold in New Jersey.

11. Upon information and belief, DRL Ltd., either directly or through one or more of its wholly owned subsidiaries and/or agents, including DRL Inc., develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this Judicial District.

12. Upon information and belief, DRL Inc., with the assistance and/or at the direction of DRL Ltd., develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this Judicial District.

13. This Court has personal jurisdiction over Defendants because, *inter alia*, Defendants DRL Inc. and DRL Ltd. have previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of the State of New Jersey by having filed suit in this jurisdiction. *See, e.g., Dr. Reddy's Laboratories, Inc., et al. v. Purdue Pharm. Prod., LP., et al.*, Civil Action No. 2:14-cv-03230 (JLL)(JAD) (D.N.J.); *Dr. Reddy's Laboratories, Ltd., et al. v. Eli Lilly & Co., et al.*, Civil Action No. 3:09-cv-00192 (GEB)(LHG) (D.N.J.); and *Dr. Reddy's Laboratories, Ltd., et al. v. AstraZeneca AB, et al.*, Civil Action No. 3:08-cv-02496 (JAP)(TJB) (D.N.J.).

14. This Court also has personal jurisdiction over Defendants because, *inter alia*, Defendants DRL Inc. and DRL Ltd. have previously submitted to the jurisdiction of this Court and have availed themselves of the legal protections of the State of New Jersey by having asserted counterclaims in this jurisdiction. *See, e.g., Sucampo AG, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 3:14-cv-07114(MAS)(DEA) (D.NJ), Answer and

Counterclaims (January 26, 2015); *Amarin Pharma, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 3:14-cv-02760(MLC)(DEA) (D.NJ), Answer and Counterclaims (July 31, 2014); *Astrazeneca AB v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 3:11-cv-02317 (JAP)(LHG)(D.NJ) Answer and Counterclaims (June 27, 2011); and *Bristol-Myers Squibb v. Dr. Reddy's Laboratories, Inc., et al.*, Civil Action No. 1:12-cv-07800 (NLH)(KMW)(D.NJ), Answer and Counterclaims (March 25, 2013).

15. This Court also has personal jurisdiction over Defendants because, *inter alia*, Defendants DRL Inc. and DRL Ltd. have admitted or otherwise conceded that each is subject to personal jurisdiction in this Court. *See, e.g., Sucampo AG, et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 3:14-cv-07114(MAS)(DEA) (D.NJ), Answer to Complaint ¶¶ 15&16 (January 26, 2015); *Amarin Pharma, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 3:14-cv-02760(MLC)(DEA) (D.NJ), Answer to Complaint ¶¶ 11, 12, 19 &20 (July 31, 2014); *AstraZeneca AB, et al. v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, 3:11-cv-02317(JAP)(DEA) (D.N.J.), Answer to Second Amended Complaint, ¶ 29 (Nov. 14, 2011); *AstraZeneca UK Ltd. and AstraZeneca Pharms. LP v. Dr. Reddy's Labs., Ltd. and Dr. Reddy's Labs., Inc.*, 3:08-cv-03237(MLC)(TJB) (D.N.J.), Answer to Complaint, ¶ 8 (July 11, 2008).

16. This Court also has personal jurisdiction over Defendants because DRL Inc. and DRL Ltd. have affiliations with the State of New Jersey that are pervasive, continuous, and systematic, including the direct marketing, distribution or sale of generic pharmaceutical drugs within the State of New Jersey and to residents of the State New Jersey.

17. Upon information and belief, Defendants, directly or through their subsidiaries, affiliates and agents, regularly conduct and/or solicit business in the State of New Jersey, engage in other persistent courses of conduct in the State of New Jersey, and/or derive substantial revenue from services or things used or consumed in the State of New Jersey.

18. Upon information and belief, Defendants act in concert to develop generic products and to seek approval from the FDA to sell generic products, including DRL's ANDA Products, throughout the United States, including within this Judicial District.

19. Upon information and belief, upon approval of the DRL's ANDA, DRL 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.

20. Upon information and belief, upon approval of the DRL's ANDA, DRL 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 product will ultimately be purchased and used by consumers in this Judicial District.

21. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

MUCINEX® D

22. Reckitt Benckiser holds approved New Drug Application ("NDA") No. 21-585 for guaifenesin and pseudoephedrine hydrochloride extended-release tablets, 600 mg/60 mg and 1.2 g/120 mg, which are sold in the United States under the trademark Mucinex® D. The FDA approved NDA No. 21-585 for Mucinex® D 600 mg/60 mg and 1.2 g/120 mg and on June 22, 2004. Mucinex® D is approved for use as an expectorant and nasal decongestant.

23. Upon information and belief, DRL's ANDA Products are copies of Plaintiff's Mucinex® D products, which are protected by Plaintiff's U.S Patent Nos. 6,372,252, 6,955,821, and 7,838,032.

THE PATENTS-IN-SUIT

24. United States Patent No. 6,372,252 (the "'252 patent," copy attached as Exhibit A) is entitled "Guaifenesin Sustained Release Formulation and Tablets" and was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on April 16, 2002. The '252 patent, *inter alia*, is directed to modified release guaifenesin tablets, covers Mucinex® D, and is listed in the FDA's Orange Book for Mucinex® D (NDA No. 21-585).

25. The '252 patent is owned by Reckitt Benckiser LLC.

26. United States Patent No. 6,955,821 (the "'821 patent," copy attached as Exhibit B) is entitled "Sustained release formulations of guaifenesin and additional drug ingredients" and was duly and legally issued by the USPTO on October 18, 2005. The '821 patent, *inter alia*, is directed to modified release guaifenesin tablets and methods of treating coughs, covers Mucinex® D and methods of using Mucinex® D pursuant to its FDA approved label, and is listed in the FDA's Orange Book for Mucinex® D (NDA No. 21-585).

27. The '821 patent is owned by Reckitt Benckiser LLC.

28. United States Patent No. 7,838,032 (the "'032 patent," copy attached as Exhibit C) is entitled "Sustained Release of Guaifenesin" and was duly and legally issued by the USPTO on November 23, 2010. The '032 patent, *inter alia*, is directed to guaifenesin drug products having immediate release and sustained release properties, covers Mucinex® D, and is listed in the FDA's Orange Book for Mucinex® D (NDA No. 21-585).

29. The '032 patent is owned by Reckitt Benckiser LLC.

ACTS GIVING RISE TO THIS SUIT

30. Upon information and belief, DRL submitted to the FDA an ANDA filed under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, offer

for sale, sale, and/or importation of DRL's ANDA Products, which are generic versions of Plaintiff's Mucinex® D products. DRL's ANDA has been assigned ANDA No. 208369.

31. Upon information and belief, DRL's ANDA No. 208369 includes a certification with respect to the patents listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for that product, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, that the listed patents are invalid, unenforceable, and/or are not infringed by the commercial manufacture, sale, or importation of DRL's ANDA products.

32. Upon information and belief, DRL sent a letter, dated May 18, 2015, to Plaintiff at its principal place of business in Parsippany, New Jersey, purporting to be a Notice of Certification for ANDA No. 208369 under 21 U.S.C. § 355(j)(2)(B) ("Notice Letter").

33. Upon information and belief, the DRL ANDA seeks FDA approval of DRL's ANDA Products for use in patients as an expectorant and nasal decongestant.

34. In its Notice Letter, and pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 C.F.R. §314.95, DRL notified Plaintiffs that it had submitted its ANDA to the FDA, seeking approval to engage in the commercial manufacture, use, or sale of DRL's ANDA Products before the expiration of Reckitt Benckiser's '252, '821, and '032 patents.

35. In its Notice Letter, DRL notified Plaintiff that, as part of the DRL ANDA, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") with respect to the '252, '821, and '032 patents. Upon information and belief, DRL certified that the '252, '821, and '032 patents are invalid, unenforceable and/or will not be infringed by the manufacture, use or sale of DRL's ANDA Products.

36. Upon information and belief, the DRL ANDA refers to and relies upon Reckitt Benckiser's NDA No. 21-585 for Mucinex® D.

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 6,372,252

37. Plaintiff repeats and realleges paragraphs 1 through 36 above as if fully set forth herein.

38. By submitting the DRL 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 throughout the United States prior to the expiration of the '252 patent, DRL committed an act of infringement of the '252 patent under 35 U.S.C. § 271(e)(2).

39. There is a justiciable controversy between the parties hereto as to the infringement of the '252 patent.

40. If DRL commercially manufactures, uses, offers to sell, or sells DRL's ANDA Products within the United States, or imports DRL's ANDA Products into the United States, or induces or contributes to any such conduct during the term of the '252 patent, it would further infringe the '252 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

41. Plaintiff will be irreparably harmed if DRL is not enjoined from infringing the '252 patent. Plaintiff does not have an adequate remedy at law.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 6,955,821

42. Plaintiff repeats and realleges paragraphs 1 through 36 above as if fully set forth herein.

43. By submitting the DRL 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 throughout the United States prior to the expiration of the '821 patent, DRL committed an act of infringement of the '821 patent under 35 U.S.C. § 271(e)(2).

44. There is a justiciable controversy between the parties hereto as to the infringement of the '821 patent.

45. If DRL commercially manufactures, uses, offers to sell, or sells DRL's ANDA Products within the United States, or imports DRL's ANDA Products into the United States, or induces or contributes to any such conduct during the term of the '821 patent, it would further infringe the '821 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

46. Plaintiff will be irreparably harmed if DRL is not enjoined from infringing the '821 patent. Plaintiff does not have an adequate remedy at law.

COUNT III

INFRINGEMENT OF U.S. PATENT NO. 7,838,032

47. Plaintiff repeats and realleges paragraphs 1 through 36 above as if fully set forth herein.

48. By submitting the DRL 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 throughout the United States prior to the expiration of the '032 patent, DRL committed an act of infringement of the '032 patent under 35 U.S.C. § 271(e)(2).

49. There is a justiciable controversy between the parties hereto as to the infringement of the '032 patent.

50. If DRL commercially manufactures, uses, offers to sell, or sells DRL's ANDA Products within the United States, or imports DRL's ANDA Products into the United States, or induces or contributes to any such conduct during the term of the '032 patent, it would further infringe the '032 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

51. Plaintiff will be irreparably harmed if DRL is not enjoined from infringing the '032 patent. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A Judgment that DRL has infringed one or more claims of the '252 patent by filing ANDA No. 208369 relating to DRL's ANDA Products before the expiration of the '252 patent;

B. A Judgment that the commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA Products will infringe the '252 patent;

C. A permanent injunction restraining and enjoining DRL, and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of DRL's ANDA Products until the expiration of the '252 patent or any later date of exclusivity to which Plaintiff and/or the '252 patent are or become entitled;

D. An Order that the effective date of any approval of DRL's ANDA No. 208369 relating to DRL's ANDA Products under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the

’252 patent or any later date of exclusivity to which Plaintiff and/or the ’252 patent are or become entitled;

E. A Judgment that DRL has infringed one or more claims of the ’821 patent by filing ANDA No. 208369 relating to DRL’s ANDA Products before the expiration of the ’821 patent;

F. A Judgment that the commercial manufacture, use, offer for sale, sale and/or importation of DRL’s ANDA Products will infringe the ’821 patent;

G. A permanent injunction restraining and enjoining DRL, and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of DRL’s ANDA Products until the expiration of the ’821 patent or any later date of exclusivity to which Plaintiff and/or the ’821 patent are or become entitled;

H. An Order that the effective date of any approval of DRL’s ANDA No. 208369 relating to DRL’s ANDA Products under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the ’821 patent or any later date of exclusivity to which Plaintiff and/or the ’821 patent are or become entitled;

I. A Judgment that DRL has infringed one or more claims of the ’032 patent by filing ANDA No. 208369 relating to DRL’s ANDA Products before the expiration of the ’032 patent;

J. A Judgment that the commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA Products will infringe the '032 patent;

K. A permanent injunction restraining and enjoining DRL, and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of DRL's ANDA Products until the expiration of the '032 patent or any later date of exclusivity to which Plaintiff and/or the '032 patent are or become entitled;

L. An Order that the effective date of any approval of DRL's ANDA No. 208369 relating to DRL's ANDA Products under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the '032 patent or any later date of exclusivity to which Plaintiff and/or the '032 patent are or become entitled; and

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

June 26, 2015

By: s/ Charles M. Lizza

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