Liza M. Walsh
Eleonore Ofosu-Antwi
WALSH PIZZI O'REILLY FALANGA LLP
One Riverfront Plaza
1037 Raymond Blvd., Suite 600
Newark, New Jersey 07102
(973) 757-1100
lwalsh@walsh.law
eofosuantwi@walsh.law

Additional Counsel on Signature Page

Attorneys for Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd. and Teva Neuroscience, Inc.

OF COUNSEL:

David M. Hashmall
Elizabeth J. Holland
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018-1405
(212) 813-8800
dhashmall@goodwinlaw.com
eholland@goodwinlaw.com

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

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES LTD., and TEVA NEUROSCIENCE, INC., *Plaintiffs,* v. DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., *Defendants.*	Civil Action No. _____ *Electronically Filed*

COMPLAINT

Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., and Teva Neuroscience, Inc. (collectively "Plaintiffs" or "Teva") bring this action for patent infringement and declaratory judgment against defendants Dr. Reddy's Laboratories, Ltd. ("DRL Ltd."), Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (collectively "DRL"), and herein allege as follows:

NATURE OF THE ACTION

1. This is an action by Teva for infringement of United States Patent No. 9,155,775 ("the '775 patent") arising under the patent laws of the United States, Title 35, United States Code. This action arises out of DRL's ongoing attempt to market, manufacture and sell a generic version of COPAXONE® 40 mg/mL, 1 mL syringe, injection ("COPAXONE®"), Teva's innovative treatment for patients with relapsing-remitting forms of multiple sclerosis, prior to the expiration of the '775 patent.

THE PARTIES

Teva

2. Teva Pharmaceuticals USA, Inc. ("Teva USA") is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

3. Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is an Israeli company with its principal place of business at 5 Basel Street, P.O. Box 3190, Petah Tikva, 49131, Israel.

4. Teva Neuroscience, Inc. ("Teva Neuroscience") is a Delaware corporation with its principal place of business at 11100 Nall Ave, Overland Park, KS 66211.

DRL

5. Upon information and belief, Dr. Reddy's Laboratories Ltd. is a corporation organized and existing under the laws of India with its principal place of business at 8- 2- 337, Road No. 3, Banjara Hills, Hyderabad, Telangana 500 034, India.

6. Upon information and belief, Dr. Reddy's Laboratories Inc. is a corporation organized and existing under the laws of New Jersey with its principal place of business at 107 College Road East, Princeton, NJ 08540, and is a wholly-owned subsidiary of Dr. Reddy's Laboratories 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), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

10. Teva sells COPAXONE® throughout the United States, including within the State of New Jersey.

Personal Jurisdiction Over DRL Ltd.

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

12. Upon information and belief, DRL Ltd. markets, distributes and/or sells generic drugs within the State of New Jersey and throughout the United States.

13. Upon information and belief, DRL Ltd. has engaged in and maintained systematic and continuous business contacts within the State of New Jersey, and has purposefully availed itself of the benefits and protections of the laws of New Jersey rendering it at home in New Jersey.

14. Upon information and belief, DRL Ltd. routinely files Abbreviated New Drug Applications ("ANDAs") with the U.S. Food & Drug Administration ("FDA") and markets dozens of generic pharmaceutical products in the State of New Jersey, including, *inter alia*, alendronate sodium, donepezil hydrochloride, duloxetine hydrochloride, irbesartan, montelukast sodium, and paricalcitol.

15. Upon information and belief, DRL Ltd. has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of

New Jersey, including, *inter alia*, alendronate sodium, donepezil hydrochloride, duloxetine hydrochloride, irbesartan, montelukast sodium, and paricalcitol.

16. Upon information and belief, DRL Ltd. has committed or will imminently commit acts that aid, abet, contribute to and/or constitute tortious patent infringement that will harm and injure Teva, which manufactures COPAXONE® 40 mg/mL product for sale and use throughout the United States, including the State of New Jersey.

17. Teva sells COPAXONE® 40 mg/mL product in the State of New Jersey.

18. Upon information and belief, DRL Ltd. has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in New Jersey.

19. Upon information and belief, DRL Ltd. will market, sell, and offer for sale its proposed generic version of COPAXONE® 40 mg/mL product in the State of New Jersey following FDA approval of that product.

20. Upon information and belief, as a result of DRL Ltd.'s marketing, selling, or offering for sale of its generic version of COPAXONE® 40 mg/mL product in the State of New Jersey, Teva will lose sales of COPAXONE® 40 mg/mL product and be injured in the State of New Jersey.

21. Upon information and belief, this Court also has personal jurisdiction over DRL Ltd. because it previously has admitted to personal jurisdiction in this district, brought a civil action in this district, been sued in this district, did not challenge this Court's assertion of personal jurisdiction over it, and availed itself of the rights, benefits, and privileges of this forum by asserting counterclaims for the purpose of litigating patent infringement disputes. *See, e.g.*, *Novartis Pharmaceuticals Corporation v. Actavis LLC et al.*, C.A. No. 13-01028 (D.N.J.); *Dr.*

Reddy's Laboratories, Inc. et al. v. Purdue Pharmaceutical Products L.P. et al., C.A. No. 14-03230 (D.N.J.); *Genzyme Corp. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 13-06827 (D.N.J.); *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 14-02760 (D.N.J.); *Novartis Pharmaceuticals et al. v. Dr. Reddy's Laboratories, Ltd. et al*., C.A. No. 14-00785 (D.N.J.).

22. Upon information and belief, this Court has personal jurisdiction over DRL Ltd. for the reasons stated herein, including, *inter alia*, DRL Ltd.'s activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render DRL Ltd. at home in this forum.

Personal Jurisdiction Over DRL Inc.

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

24. Upon information and belief, DRL Inc. is a company that is incorporated in the State of New Jersey.

25. Upon information and belief, DRL Inc. is a company with its principal place of business in the State of New Jersey.

26. Upon information and belief, DRL, Inc. markets, distributes and/or sells generic drugs within the State of New Jersey and throughout the United States.

27. Upon information and belief, DRL, Inc. has engaged in and maintained systematic and continuous business contacts within the State of New Jersey, and has purposefully availed itself of the benefits and protections of the laws of New Jersey rendering it at home in New Jersey.

28. Upon information and belief, DRL Inc. routinely files ANDAs and markets dozens of generic pharmaceutical products in the State of New Jersey, including, *inter alia*,

amoxicillin, meloxicam, nefazodone hydrochloride, pravastatin sodium, and rivastigmine tartrate.

29. Upon information and belief, DRL Inc. has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of New Jersey, including, *inter alia*, amoxicillin, meloxicam, nefazodone hydrochloride, pravastatin sodium, and rivastigmine tartrate.

30. Upon information and belief, DRL Inc. has committed or will imminently commit acts that aid, abet, contribute to and/or constitute tortious patent infringement that will lead to harm and injury to Teva, which manufactures COPAXONE® 40 mg/mL product for sale and use throughout the United States, including the State of New Jersey.

31. Teva sells COPAXONE® 40 mg/mL product in the State of New Jersey.

32. Upon information and belief, DRL Inc. has applied for FDA approval to market and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in New Jersey.

33. Upon information and belief, DRL Inc. will market, sell, and offer for sale its proposed generic version of COPAXONE® 40 mg/mL product in the State of New Jersey following FDA approval of that product.

34. Upon information and belief, as a result of DRL Inc.'s marketing, selling, or offering for sale of its generic version of COPAXONE® 40 mg/mL product in the State of New Jersey, Teva will lose sales of COPAXONE® 40 mg/mL product and be injured in the State of New Jersey.

35. Upon information and belief, this Court also has personal jurisdiction over DRL Ltd. because it previously brought a civil action in this district, has been sued in this district,

admitted to personal jurisdiction in this Court, did not challenge this Court's assertion of personal jurisdiction over it, and availed itself of the rights, benefits, and privileges of this forum by asserting counterclaims for the purpose of litigating patent infringement disputes. *See, e.g.*, *Novartis Pharmaceuticals Corporation v. Actavis LLC et al.*, C.A. No. 13-01028 (D.N.J.); *Helsinn Healthcare S.A et al.. v. Dr. Reddy's Laboratories, et al.*, C.A. No. 13-05815 (D.N.J.); *Dr. Reddy's Laboratories, Inc. et al. v. Purdue Pharmaceutical Products L.P. et al.*, C.A. No. 14-03230 (D.N.J.); *Genzyme Corp. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 13-06827 (D.N.J.); *Amarin Pharma, Inc. et al. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 14-02760 (D.N.J.); *Novartis Pharmaceuticals et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, C.A. No. 14-00785 (D.N.J.).

36. Upon information and belief, this Court has personal jurisdiction over DRL Inc. for the reasons stated herein, including, *inter alia*, DRL Inc.'s activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render DRL Inc. at home in the forum.

37. Upon information and belief, following any FDA approval of DRL's ANDA, DRL Inc. and DRL Ltd. will work in concert with one another to make, use, import, offer to sell, and sell a generic version of COPAXONE® 40 mg/mL product throughout the United States, including in New Jersey.

38. Upon information and belief, DRL Ltd. will manufacture DRL's proposed generic version of COPAXONE® 40 mg/mL product on behalf of DRL Inc., and DRL Inc. will act as the agent of DRL Ltd. for importation and sale of that product in the United States, including New Jersey.

BACKGROUND

The ’775 Patent

39. The ’775 patent, entitled “Process for Manufacturing Glatiramer Acetate Product,” was duly and legally issued to Teva Ltd. by the United States Patent and Trademark Office on October 13, 2015, and expires on January 28, 2035. The ’775 Patent has 27 claims.

40. Rakefet Cohen, Sasson Habbah, and Muhammad Safadi are named inventors of the ’775 patent.

41. Teva Ltd. is the sole owner, by assignment, of all rights, title and interest in the ’775 patent.

42. Teva Ltd. has granted Teva USA an exclusive license under the ’775 patent to use, offer to sell, sell and import the COPAXONE 40 mg/mL product in the United States.

43. A true and correct copy of the ’775 patent is attached as Exhibit A.

Teva’s COPAXONE® 40 mg/mL Product

44. Plaintiffs researched, developed, applied for and obtained FDA approval to manufacture, sell, promote and/or market COPAXONE® 40 mg/ml product.

45. Teva USA is the holder of New Drug Application (“NDA”) number 20-622, approved by the United States Food and Drug Administration (“FDA”) for the use of glatiramer acetate 40 mg/mL three times per week, marketed as COPAXONE® 40 mg/mL, for the treatment of patients with relapsing forms of multiple sclerosis such as relapsing-remitting multiple sclerosis.

46. Teva’s innovative COPAXONE® 40 mg/mL product is supplied as single-dose prefilled syringes that contain 40 mg/ml glatiramer acetate for injection, manufactured by Teva Ltd., and marketed and sold in the United States by Teva Neuroscience.

47. The active drug ingredient in COPAXONE® 40 mg/mL is glatiramer acetate. Glatiramer acetate is a complex mixture of polypeptide chains made from four amino acid building blocks. The individual polypeptide chains in glatiramer acetate vary in length and the sequence in which the amino acids are connected together.

48. The invention claimed in the '775 patent reflects, in part, the discovery that filtering pharmaceutical preparations of glatiramer acetate at temperatures of above 0° C to 17.5° C improves the filtration process used to manufacture pharmaceutical preparations and facilitates the commercial production of COPAXONE® 40 mg/mL.

49. Teva practices at least one of the claims of the '775 patent in manufacturing COPAXONE® 40 mg/mL. In manufacturing COPAXONE® 40 mg/mL, Teva, *inter alia*, filters an aqueous pharmaceutical solution of glatiramer acetate and mannitol at a temperature of above 0° C to 17.5° C to produce a filtrate with improved filterability compared to the filterability of the solution at room temperature.

The DRL ANDA

50. DRL filed an ANDA under 21 U.S.C. § 355(j) seeking FDA approval to manufacture, use, offer for sale, sell in and import into the United States glatiramer acetate injection, 40 mg/mL, purported to be generic to Teva's COPAXONE® 40 mg/mL product ("DRL's Glatiramer Acetate Product" or "Defendants' Glatiramer Acetate Product").

51. FDA assigned the ANDA for DRL's Glatiramer Acetate Product the number 206767.

52. Upon information and belief, DRL Inc. and DRL Ltd. submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 206767.

53. In order to be approved by the FDA, the drug product described in an ANDA must be equivalent to the innovator drug product in dosage form, strength, route of administration, quality, performance characteristics, and intended use.

54. In order to be approved by the FDA, the active ingredient in an ANDA product must be "the same as" the innovator's active ingredient. Thus, generic applicants must scientifically demonstrate that the active ingredient in their product is "the same as" the active ingredient in the innovator's product.

55. Given its complexity, COPAXONE® 40 mg/mL cannot be fully characterized. Moreover, the method of action of COPAXONE® 40 mg/mL has not been fully elucidated. Thus, while COPAXONE® 40 mg/mL has been demonstrated to be a safe and effective treatment for relapsing- remitting multiple sclerosis, the specific attributes of the product responsible for this safe and efficacious treatment have not been fully identified.

56. It is believed that the method of manufacturing COPAXONE® plays a role in the composition of, and therefore the action and effectiveness of Teva's COPAXONE® 40 mg/mL product.

57. Upon information and belief, DRL has begun to manufacture and/or import commercial batches of Defendants' Glatiramer Acetate Product.

58. Upon information and belief, Defendants must produce their generic glatiramer acetate product using a process that infringes at least one of the claims of the '775 patent in order for the product to be determined by the FDA to be the same as Teva's COPAXONE® 40 mg/mL and to meet any other requirements for FDA approval of Defendants' Glatiramer Acetate Product.

59. Upon information and belief, the processes claimed in the ’775 patent are the only commercially feasible means of producing commercial scale quantities of COPAXONE® 40 mg/mL.

60. Upon information and belief, Defendants intend to launch Defendants’ Glatiramer Acetate Product upon receiving FDA approval which may occur as early as the first quarter of 2017, prior to the expiration of the ’775 patent. Defendants have stated that they are working toward January 28, 2017 as their target for ANDA approval. *See In re Copaxone 40 mg Litigation*, C.A. No. 14-1171-GMS (D. Del.), Trial Tr. at 1729:3-5, 10-16, 20-23; *see also* Dr. Reddy’s Laboratories Inc. Q2 2017 Earnings Conference Call October 25, 2016, p. 13 (“The third question, Copaxone 20 mg, the validation batches are complete, it looks good. Compilation of the response is going on, we are behind schedule by a couple of weeks, but because the amount of analytical data to be generated is fairly heavy. But we again feel good about the way the whole thing has panned out, I think the work done is good and this would be hopefully, by let us say by second week of next month we should respond back on the DMF and this is the same DMF for 40 mg.”)

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 9,155,775 BY DEFENDANTS

61. The allegation of the preceding paragraphs 1-60 are realleged and incorporated herein by reference.

62. Upon information and belief, DRL Inc. currently infringes and has infringed one or more claims of the ’775 patent under at least sections (a)-(c) and/or (g) of 35 U.S.C. § 271 by the manufacture, marketing, sale, offer to sell and/or importation of the DRL Glatiramer Acetate Product.

63. Upon information and belief, DRL Ltd. currently infringes and has infringed one or more claims of the ’775 patent under at least sections (a)-(c) and/or (g) of 35 U.S.C. § 271 by the manufacture, marketing, sale, offer to sell and/or importation of the DRL Glatiramer Acetate Product.

64. Upon information and belief, Defendants have acted in concert by assisting with, participating in, encouraging, contributing, aiding and abetting and/or directing the manufacture, marketing, sale, offer to sell and/or importation of the DRL Glatiramer Acetate Product.

65. Upon information and belief, Defendants’ infringement is willful and continues despite knowledge of the ’775 patent. Upon information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ’775 patent.

66. Teva will be substantially and irreparably harmed by Defendants’ infringing activities unless the Court enjoins those activities. Teva will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of the DRL Glatiramer Acetate Product. Defendants’ activities render this case an exceptional one, and Teva is entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

COUNT II FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 9,155,775 BY DEFENDANTS

67. The allegations of the preceding paragraphs 1-66 are realleged and incorporated herein by reference.

68. Upon information and belief, Defendants intend to manufacture, market, sell, offer to sell and/or import Defendants’ Glatiramer Acetate product upon receiving FDA approval, as early as the first quarter of 2017.

69. Such conduct will constitute direct infringement of the ’775 patent under 35 U.S.C. § 271(a), inducement of infringement of the ’775 patent under 35 U.S.C. § 271(b), contributory infringement under 35 U.S.C. § 271(c), and/or infringement of the ’775 patent under 35 U.S.C. § 271(g).

70. As a result of the foregoing facts, there is an imminent, real, substantial, and continuing justiciable controversy between Teva and Defendants as to liability for the infringement of the ’775 patent. Defendants’ actions have created in Teva a reasonable apprehension of irreparable harm and loss resulting from Defendants’ threatened imminent actions.

71. Upon information and belief, Defendants will knowingly and willfully infringe the ’775 patent.

72. Teva will be substantially and irreparably harmed by Defendants’ infringing activities unless the Court enjoins those activities. Teva will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of the DRL Glatiramer Acetate Product. Defendants’ activities render this case an exceptional one, and Teva is entitled to an award of their reasonable attorneys’ fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Teva respectfully requests the following relief:

(a) a judgment that the ’775 patent is infringed, not invalid, and enforceable;

(b) a judgment that the making, using, offering to sell, selling, marketing, distributing, or importing of Defendants’ Glatiramer Acetate Product prior to the expiration of

the ’775 patent will infringe, actively induce infringement, and/or contribute to the infringement of one or more claims of the ’775 patent;

(c) an Order pursuant to 35 U.S.C. § 283 preliminarily and permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants’ Glatiramer Acetate Product, or any product or compound the use or manufacture of which infringes the ’775 patent, or inducing or contributing to the infringement of the ’775 patent until after the expiration of the ’775 patent;

(d) an award of Teva’s damages or other monetary relief to compensate Teva if Defendants engage in the commercial manufacture, use, offer to sell, sale, or marketing or distribution in, or importation into the United States of Defendants’ Glatiramer Acetate Product, or any product or compound the use or manufacture of which infringes the ’775 patent, or the inducement or contribution of the foregoing, prior to the expiration of the ’775 patent in accordance with 35 U.S.C. § 284;

(e) a judgment that this is an exceptional case and an award to Teva of its attorneys’ fees under 35 U.S.C. § 285;

(f) a judgment that Defendants’ infringement of the ’775 patent is willful;

(g) an award of Teva’s reasonable costs and expenses in this action; and

(h) an award of any further and additional relief to Teva as this Court deems just and proper.

Dated: January 25, 2017

Respectfully submitted,

WALSH PIZZI O'REILLY FALANGA LLP

By: *s/ Liza M. Walsh*

Liza M. Walsh
Eleonore Ofosu-Antwi
Walsh Pizzi O'Reilly Falanga LLP
One Riverfront Plaza
1037 Raymond Blvd., Suite 600
Newark, New Jersey 07102
(973) 757-1100
lwalsh@walsh.law

Attorneys for Plaintiffs Teva Pharmaceuticals USA, Inc., Teva Pharmaceutical Industries Ltd., and Teva Neuroscience, Inc.

OF COUNSEL:

David M. Hashmall
Elizabeth J. Holland
GOODWIN PROCTER LLP
The New York Times Building
620 Eighth Avenue
New York, NY 10018-1405
(212) 813-8800
dhashmall@goodwinlaw.com
eholland@goodwinlaw.com

Daryl L. Wiesen
John T. Bennett
Nicholas K. Mitrokostas
GOODWIN PROCTER LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000
dwiesen@goodwinlaw.com
jbennett@goodwinlaw.com
nmitrokostas@goodwinlaw.com

William G. James
GOODWIN PROCTER LLP
901 New York Ave. NW
Washington, DC 20001
(202) 346-4000
wjames@goodwinlaw.com

CERTIFICATION PURSUANT TO RULES 11.2 AND 40.1

I hereby certify that the matter in controversy is related to patent infringement action suit *Teva Pharmaceuticals USA, Inc. et al. v. Sandoz Inc. et al*, Civ. A. No. 17-275 because it involves the same patent. That case has been assigned to the Honorable Freda L. Wolfson, U.S.D.J., and the Honorable Douglas E. Arpert, U.S.M.J.

I further certify that, to the best of my knowledge, I am not aware of any pending arbitrations or administrative proceedings involving the matter in controversy. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: January 25, 2017

WALSH PIZZI O'REILLY FALANGA LLP

s/ Liza M. Walsh
Liza M. Walsh

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: January 25, 2017

WALSH PIZZI O'REILLY FALANGA LLP

s/ Liza M. Walsh
Liza M. Walsh