Douglas S. Eakeley, Esq.
LOWENSTEIN SANDLER PC
65 Livingston Avenue
Roseland, New Jersey 07068
(973) 597-2500

Attorney for Plaintiff

George F. Pappas, Esq.
Christopher N. Sipes, Esq.
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004
(202) 662-6000

Elena M. DiMuzio, Esq.
Alexa R. Hansen, Esq.
COVINGTON & BURLING LLP
1 Front Street
San Francisco, California 94111
(415) 591-6000

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BRISTOL-MYERS SQUIBB COMPANY, Plaintiff, v. DR. REDDY'S LABORATORIES, LTD. AND DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT**

PLAINTIFF BRISTOL-MYERS SQUIBB COMPANY'S COMPLAINT

Plaintiff Bristol-Myers Squibb Company ("Bristol-Myers Squibb" or "Plaintiff"), having a principal place of business at 345 Park Avenue, New York, New York, 10154, brings this action for patent infringement against Defendants Dr. Reddy's Laboratories, Ltd. ("DRL Ltd."), having a principal place of business at Bachupally, 500 090, India and Dr. Reddy's Laboratories, Inc. ("DRL Inc."), having a principal place of business at 200 Somerset Corporate Blvd.,

Bridgewater, New Jersey 08807 (collectively, "DRL" or "Defendants"). Plaintiff alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the patent laws of the United States, Title 35, United States Code, arising out of Defendants' filing of Abbreviated New Drug Application ("ANDA") No. 20-4303 with the United States Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiff's successful Ixempra® kit product prior to the expiration of U.S. Patent Nos. 6,670,384, 7,022,330 and RE41,393.

THE PARTIES

2. Plaintiff Bristol-Myers Squibb is a company organized and existing under the laws of the State of Delaware. Bristol-Myers Squibb operates multiple Research and Development sites, including sites in Lawrenceville, Hopewell, and New Brunswick, New Jersey, among others. Bristol-Myers Squibb manufactures and brings to market innovative medicines and technologies.

3. Upon information and belief, Defendant Dr. Reddy's Laboratories, Ltd. is an entity organized and existing under the laws of India. Upon information and belief, DRL Ltd. develops and markets generic drug products for sale and use throughout the United States, including for sale and use in the State of New Jersey.

4. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. is a company organized and existing under the laws of the State of New Jersey. Upon information and belief, DRL Inc. markets a wide range of generic drug products and regularly conducts business throughout the United States, including in the State of New Jersey. Upon information and belief, DRL Inc. is a wholly-owned subsidiary of DRL Ltd.

5. Upon information and belief, DRL Ltd. prepared and submitted ANDA No. 20-4303 in collaboration with DRL Inc.

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Defendants by virtue of the fact that, among other things, each Defendant has continuous and systematic contacts with New Jersey. Defendants have committed, or aided, abetted, contributed to and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Plaintiff, which manufactures numerous drugs for sale and use throughout the United States, including this judicial district. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. On information and belief, both DRL Ltd. and DRL Inc. have previously consented to personal jurisdiction in this judicial district in several cases as plaintiffs and defendants.

9. This Court also has jurisdiction over DRL Inc. because, among other things, it has a principal place of business in the State of New Jersey and thus has submitted itself to the personal jurisdiction of the courts in New Jersey.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), (c) and 1400(b).

BACKGROUND

11. Bristol-Myers Squibb developed and manufactures the Ixempra® kit pursuant to New Drug Application No. 022-065, which was approved by the FDA. The Ixempra® kit

delivers a microtubule inhibitor, and is indicated for both monotherapy and combination therapy breast cancer treatment. As a monotherapy, the Ixempra® kit is indicated for the treatment of metastatic or locally advanced breast cancer in patients after the failure of an anthracycline, a taxane, and capecitabine. As a combination therapy, the Ixempra® kit is indicated in combination with capecitabine for the treatment of metastatic or locally advanced breast cancer in patients after the failure of anthracycline and a taxane.

12. Upon information and belief, DRL seeks approval to market a generic version of the Ixempra® kit for at least one of the uses approved by the FDA.

13. United States Patent No. 6,670,384 (the "'384 patent"), entitled "Methods of Administering Epothilone Analogs for the Treatment of Cancer," was duly and legally issued by the United States Patent and Trademark Office on December 30, 2003, to inventors Bandyopadhyay et al. The '384 patent is owned by Bristol-Myers Squibb.

14. The FDA-approved product and use of the Ixempra® kit is covered by one or more claims of the '384 patent, and the '384 patent was listed in connection with the Ixempra® kit in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the "Orange Book."

15. United States Patent No. 7,022,330 (the "'330 patent") entitled "Parenteral Formulation for Epothilone Analogs," was duly and legally issued by the United States Patent and Trademark Office on April 4, 2006 to inventors Bandyopadhyay et al. The '330 patent is owned by Bristol-Myers Squibb.

16. The FDA-approved product and use of the Ixempra® kit is covered by one or more claims of the '330 patent, and the '330 patent was listed in connection with the Ixempra® kit in the Orange Book.

17. United States Patent No. RE41,393 (the "'393 patent") entitled "Treatment of Refractory Tumors Using Epothilone Derivatives," was duly and legally reissued by the United States Patent and Trademark Office on June 22, 2010 to inventor Lee. The '393 patent is a reissue of United States Patent No 6,686,380, which was duly and legally issued by the United States Patent and Trademark Office on February 3, 2004 to inventor Lee. The '393 patent is owned by Bristol-Myers Squibb.

18. The FDA-approved use of the Ixempra® kit is covered by one or more claims of the '393 patent, and the '393 patent was listed in connection with the Ixempra® kit in the Orange Book.

19. Upon information and belief, DRL submitted ANDA No. 20-4303 under 21 U.S.C. § 355(j)(2) in order to obtain FDA approval to engage in the commercial manufacture, use, and/or sale of a generic version of the Ixempra® kit, to be used in infringing manners, prior to the expiration of the '384, '330 and '393 patents.

20. By letter dated November 13, 2012, Defendants notified Plaintiff that DRL had submitted ANDA 20-4303 concerning its proposed drug product of ixabepilone for injection ("DRL's ANDA product") as required by § 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act ("FDC Act"). *See* 21 U.S.C. § 355(j)(2)(B)(ii).

21. DRL's letter further notified Plaintiff that DRL had filed with the FDA, pursuant to § 505(j)(2)(A)(vii)(IV), a certification with respect to the '384, '330, and '393 patents ("Paragraph IV certification"), alleging, along with the letter, that the '384, '330, and '393 patents are invalid and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of DRL's ANDA product.

22. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Bristol-Myers Squibb's receipt of DRL's Notice Letter.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 6,670,384

23. Plaintiff re-alleges and incorporates by reference paragraphs 1–22, above.

24. Bristol-Myers Squibb is the owner by assignment of the '384 patent and has the right to sue for infringement thereof. A true and correct copy of the '384 patent is attached as Exhibit A.

25. DRL's ANDA product, or use thereof, would directly infringe one or more of the claims of the '384 patent.

26. DRL's submission of ANDA No. 20-4303 seeking approval for the commercial manufacture, use, offer for sale, and/or sale of DRL's ANDA product before the expiration of the '384 patent constitutes an act of infringement of one or more claims of the '384 patent under 35 U.S.C. § 271(e)(2)(A).

27. The commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA product would infringe and/or contribute to and/or induce infringement of one or more claims of the '384 patent.

28. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA product, with its proposed prescribing information, immediately and imminently upon approval of ANDA No. 20-4303.

29. Upon information and belief, immediately upon approval of ANDA No. 20-4303, DRL will infringe the '384 patent by making, using, offering to sell, selling, and/or importing DRL's ANDA product in the United States under 35 U.S.C. §§ 271(a) and/or (g), and/or by actively inducing and/or contributing to infringement by others under 35 U.S.C. §§ 271(b) and/or

(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 20-4303 shall be no earlier than the expiration date of the '384 patent.

30. DRL has knowledge of the '384 patent; DRL's ANDA product constitutes a material part of at least one or more claims of the '384 patent; DRL knows that its product is especially made or adapted for use in a manner infringing at least one or more claims of the '384 patent; and DRL's ANDA product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

31. The offering to sell, sale, and/or importation of DRL's ANDA product would contributorily infringe one or more claims of the '384 patent.

32. DRL has knowledge of the '384 patent and specifically intends to encourage infringement by providing prescribing information and/or through other labeling and promotional activities for DRL's ANDA product, and knows that its prescribing information and/or other labeling and promotional activities for DRL's ANDA product will induce use of DRL's ANDA product by doctors and/or patients in a manner that directly infringes of one or more claims of the '384 patent.

33. The offering to sell, sale, and/or importation of DRL's ANDA product would actively induce infringement of one or more claims of the '384 patent.

34. Unless DRL is enjoined from infringing the '384 patent, actively inducing infringement of the '384 patent, and/or contributing to the infringement by others of the '384 patent, Plaintiff will be substantially and irreparably harmed. Plaintiff has no adequate remedy at law.

COUNT II
INFRINGEMENT OF U.S. PATENT NO. 7,022,330

35. Plaintiff re-alleges and incorporates by reference paragraphs 1–34, above.

36. Bristol-Myers Squibb is the owner by assignment of the '330 patent and has the right to sue for infringement thereof. A true and correct copy of the '330 patent is attached as Exhibit B.

37. DRL's ANDA product, or use thereof, would directly infringe one or more of the claims of the '330 patent.

38. DRL's submission of ANDA No. 20-4303 seeking approval for the commercial manufacture, use, offer for sale, and/or sale of DRL's ANDA product before the expiration of the '330 patent constitutes an act of infringement of one or more claims of the '330 patent under 35 U.S.C. § 271(e)(2)(A).

39. The commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA product would infringe and/or contribute to and/or induce infringement of one or more claims of the '330 patent.

40. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA product, with its proposed prescribing information, immediately and imminently upon approval of ANDA No. 20-4303.

41. Upon information and belief, immediately upon approval of ANDA No. 20-4303, DRL will infringe the '330 patent by making, using, offering to sell, selling, and/or importing DRL's ANDA product in the United States under 35 U.S.C. §§ 271(a) and/or (g), and/or by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and/or (c), unless this Court orders that the effective date of any FDA approval of ANDA No. 20-4303 shall be no earlier than the expiration date of the '330 patent.

42. DRL has knowledge of the '330 patent; DRL's ANDA product constitutes a material part of at least one or more claims of the '330 patent; DRL knows that its product is

especially made or adapted for use in a manner infringing at least one or more claims of the '330 patent; and DRL's ANDA product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

43. The offering to sell, sale, and/or importation of DRL's ANDA product would contributorily infringe one or more claims of the '330 patent.

44. DRL has knowledge of the '330 patent and specifically intends to encourage infringement by providing prescribing information and/or through other labeling and promotional activities for DRL's ANDA product, and knows that its prescribing information and/or other labeling and promotional activities for DRL's ANDA product will induce use of DRL's ANDA product by doctors and/or patients in a manner that directly infringes of one or more claims of the '330 patent.

45. The offering to sell, sale, and/or importation of DRL's ANDA product would actively induce infringement of one or more claims of the '330 patent.

46. Unless DRL is enjoined from infringing the '330 patent, actively inducing infringement of the '330 patent, and/or contributing to the infringement by others of the '330 patent, Plaintiff will be substantially and irreparably harmed. Plaintiff has no adequate remedy at law.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. RE41,393

47. Plaintiff re-alleges and incorporates by reference paragraphs 1–46, above.

48. Bristol-Myers Squibb is the owner by assignment of the '393 patent and has the right to sue for infringement thereof. A true and correct copy of the '393 patent is attached as Exhibit C.

49. Use of DRL's ANDA product would directly infringe one or more of the claims of the '393 patent.

50. DRL's submission of ANDA No. 20-4303 seeking approval for the commercial manufacture, use, offer for sale, and/or sale of DRL's ANDA product before the expiration of the '393 patent constitutes an act of infringement of one or more claims of the '393 patent under 35 U.S.C. § 271(e)(2)(A).

51. The commercial manufacture, use, offer for sale, sale and/or importation of DRL's ANDA product would infringe and/or contribute to and/or induce infringement of one or more claims of the '393 patent.

52. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, and/or importation of DRL's ANDA product, with its proposed prescribing information, immediately and imminently upon approval of ANDA No. 20-4303.

53. Upon information and belief, immediately upon approval of ANDA No. 20-4303, DRL will infringe the '393 patent by actively inducing and contributing to infringement by others under 35 U.S.C. §§ 271(b) and/or (c), unless this Court orders that the effective date of any FDA approval of ANDA No. 20-4303 shall be no earlier than the expiration date of the '393 patent.

54. DRL has knowledge of the '393 patent; DRL's ANDA product constitutes a material part of at least one or more claims of the '393 patent; DRL knows that its product is especially made or adapted for use in a manner infringing at least one or more claims of the '393 patent; and DRL's ANDA product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

55. The offering to sell, sale, and/or importation of DRL's ANDA product would contributorily infringe one or more claims of the '393 patent.

56. DRL has knowledge of the '393 patent and specifically intends to encourage infringement by providing prescribing information and/or through other labeling and promotional activities for DRL's ANDA product, and knows that its prescribing information and/or other labeling and promotional activities for DRL's ANDA product will induce use of DRL's ANDA product by doctors and/or patients in a manner that directly infringes of one or more claims of the '393 patent.

57. The offering to sell, sale, and/or importation of DRL's ANDA product would actively induce infringement of one or more claims of the '393 patent.

58. Unless DRL is enjoined from actively inducing infringement of the '393 patent, and/or contributing to the infringement by others of the '393 patent, Plaintiff will be substantially and irreparably harmed. Plaintiff has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(1) a judgment that, under 35 U.S.C. § 271(e)(2)(A), DRL's submission to the FDA of ANDA No. 20-4303 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of DRL's ANDA product before the expiration of the '384 patent was an act of infringement of one or more claims of the '384 patent;

(2) a declaratory judgment that, under 35 U.S.C. § 271(a), (b), (c), and /or (g), the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of DRL's ANDA product before the expiration of the '384 patent will be an act of infringement of one or more claims of the '384 patent;

(3) a judgment that, under 35 U.S.C. §§ 271(e)(2)(A), DRL's submission to the FDA of ANDA No. 20-4303 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of DRL's ANDA product before the expiration of the '330 patent was an act of infringement of one or more claims of the '330 patent;

(4) a declaratory judgment that, under 35 U.S.C. §§ 271(a), (b), (c), and /or (g), the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of DRL's ANDA product before the expiration of the '330 patent will be an act of infringement of one or more claims of the '330 patent;

(5) a judgment that, under 35 U.S.C. § 271(e)(2)(A), DRL's submission to the FDA of ANDA No. 20-4303 to obtain approval for the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of DRL's ANDA product before the expiration of the '393 patent was an act of infringement of one or more claims of the '393 patent;

(6) a declaratory judgment that, under 35 U.S.C. §§ 271 (b) and/or (c), the commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of DRL's ANDA product before the expiration of the '393 patent will be an act of infringement of one or more claims of the '393 patent;

(7) an order that the effective date of any FDA approval of DRL's ANDA product shall be no earlier than the expiration of the '384 patent, and any pediatric or other extensions thereof, in accordance with 35 U.S.C. § 271(e)(4)(A);

(8) an order that the effective date of any FDA approval of DRL's ANDA product shall be no earlier than the expiration of the'330 patent, and any pediatric or other extensions thereof, in accordance with 35 U.S.C. § 271(e)(4)(A);

(9) an order that the effective date of any FDA approval of DRL's ANDA product shall be no earlier than the expiration of the'393 patent, and any pediatric or other extensions thereof, in accordance with 35 U.S.C. § 271(e)(4)(A);

(10) a permanent injunction enjoining DRL, its affiliates and subsidiaries, and all persons and entities acting in concert with DRL from commercially manufacturing, using, offering for sale, or selling DRL's ANDA product within the United States, or importing DRL's ANDA product into the United States, until the expiration of the '384 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(11) a permanent injunction enjoining DRL, its affiliates and subsidiaries, and all persons and entities acting in concert with DRL from commercially manufacturing, using, offering for sale, or selling DRL's ANDA product within the United States, or importing DRL's ANDA product into the United States, until the expiration of the '330 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(12) a permanent injunction enjoining DRL, its affiliates and subsidiaries, and all persons and entities acting in concert with DRL from commercially manufacturing, using, offering for sale, or selling DRL's ANDA product within the United States, or importing DRL's ANDA product into the United States, until the expiration of the '393 patent, in accordance with 35 U.S.C. § 271(e)(4)(B);

(13) an award of damages or other relief if DRL engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, and/or importation of DRL's ANDA product, or any product that infringes the '384 patent, prior to the expiration of the '384 patent, in accordance with 35 U.S.C. § 271(e)(4)(C);

(14) an award of damages or other relief if DRL engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, and/or importation of DRL's ANDA product, or any product that infringes the '330 patent, prior to the expiration of the '330 patent, in accordance with 35 U.S.C. § 271(e)(4)(C);

(15) an award of damages or other relief if DRL engages in the commercial manufacture, use, offer to sell, sale, marketing, distribution, and/or importation of DRL's ANDA product, or any product that infringes the '393 patent, prior to the expiration of the '393 patent, in accordance with 35 U.S.C. § 271(e)(4)(C);

(16) a declaration that this is an exceptional case, and an award of attorneys' fees to Plaintiff, in accordance with 35 U.S.C. § 285;

(17) an award to Plaintiff of their costs and expenses in this action; and

(18) such further and additional relief as this Court deems just and proper.

Dated: December 21, 2012

Respectfully submitted,

By: s/Douglas S. Eakeley

Douglas S. Eakeley, Esq.
LOWENSTEIN SANDLER PC
65 Livingston Avenue
Roseland, New Jersey 07068
(973) 597-2500

Attorney for Plaintiff

Of Counsel
George F. Pappas, Esq.
Christopher N. Sipes, Esq.
COVINGTON & BURLING LLP
1201 Pennsylvania Avenue, NW
Washington, DC 20004
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Elena M. DiMuzio, Esq.
Alexa R. Hansen, Esq.
COVINGTON & BURLING LLP
1 Front Street
San Francisco, California 94111
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Attorneys for Plaintiff