Arnold B. Calmann, Esq. (abc@saiber.com)
Jeffrey Soos, Esq. (js@saiber.com)
Rita D. Turner, Esq. (rdt@saiber.com)
Saiber LLC
One Gateway Center, 10th Floor
Newark, New Jersey 07102
Telephone: (973) 622-3333
Facsimile: (973) 286-2465

Of Counsel:
Edgar H. Haug, Esq. (ehaug@flhlaw.com)
Porter F. Fleming, Esq. (pfleming@flhlaw.com)
Angus Chen, Esq. (achen@flhlaw.com)
Mark P. Walters, Esq. (mwalters@flhlaw.com)
Frommer Lawrence & Haug LLP
745 Fifth Avenue
New York, New York 10151
Telephone: (212) 588-0800
Facsimile: (212) 588-0500

Attorneys for Plaintiff
The Medicines Company

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

THE MEDICINES COMPANY, Plaintiff, v. DR. REDDY'S LABORATORIES LTD., DR. REDDY'S LABORATORIES, INC., and GLAND PHARMA, INC. Defendants.	**COMPLAINT** No. _____ ***Document Electronically Filed***

COMPLAINT

Plaintiff The Medicines Company, by its undersigned attorneys, for its Complaint against defendants Dr. Reddy's Laboratories Ltd., Dr. Reddy's Laboratories, Inc., and Gland Pharma,

Inc. (collectively "DRL" or "Defendants"), herein 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, involving United States Patent Nos. 7,582,727 ("the '727 patent") (attached as Exhibit A hereto) and 7,598,343 ("the '343 patent") (attached as Exhibit B hereto).

THE PARTIES

2. Plaintiff The Medicines Company is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 8 Sylvan Way, Parsippany, New Jersey 07054.

3. On information and belief, Defendant Dr. Reddy's Laboratories Ltd. is an entity organized and existing under the laws of The Republic of India, with a place of business at 8-2-337, Road 3, Banjara Hills, Hyderabad - 500034, Andhra Padresh, India.

4. On information and belief, Defendant Dr. Reddy's Laboratories, Inc. is an entity organized and existing under the laws of the State of New Jersey with a place of business at 200 Somerset Corp. Blvd., Bridgewater, NJ 08807, and a wholly owned subsidiary of Defendant Dr. Reddy's Laboratories Ltd.

5. On information and belief, Defendant Gland Pharma, Inc. is an entity organized and existing under the laws of the state of Maryland, with principal places of business at 710 Ivy League Ln., Rockville, MD 20850 and at 6-3-865/1/2, Flat No. 201, Green Land Apartments, Ameerpet, Hyderabad - 500016, India.

6. On information and belief, DRL develops, manufactures, and distributes generic drugs, including injectable drugs, for sale and use throughout the United States, including within this judicial district.

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. This Court has personal jurisdiction over DRL because Defendants (i) have a continuous and systematic business presence within this judicial district and/or (ii) substantial events giving rise to acts of infringement occurred within this judicial district, including but not limited to the preparation of and/or contribution to the submission of Abbreviated New Drug Application ("ANDA") No. 201577 ("DRL's ANDA") under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to market before the expiration of the '727 and '343 patents a bivalirudin drug product that infringes the '727 and '343 patents.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b) because one or more Defendants (i) operates a permanent business location within this judicial district and can therefore be found in this judicial district and is a resident of this judicial district, and/or (ii) substantial events giving rise to acts of infringement occurred within this judicial district, including but not limited to the preparation of and/or contribution to DRL's ANDA seeking approval to market before the expiration of the '727 and '343 patents a bivalirudin drug product that infringes the '727 and '343 patents.

FACTS AS TO ALL COUNTS

10. The Medicines Company is the owner of New Drug Application ("NDA") N020873, which was approved by the FDA for the manufacture and sale of Angiomax®. Angiomax® is the trade name for bivalirudin, 250 mg/vial, for intravenous injection, which is indicated for, *inter alia*, use as an anticoagulant in patients with unstable angina undergoing percutaneous transluminal coronary angioplasty.

11. The ’727 patent, entitled “Pharmaceutical formulations of bivalirudin and processes of making the same,” was duly and legally issued on September 1, 2009, to The Medicines Company upon assignment from Gopal Krishna and Gary Musso. The ’727 patent is generally directed to bivalirudin compositions.

12. The ’343 patent, entitled “Pharmaceutical formulations of bivalirudin and processes of making the same,” was duly and legally issued on October 6, 2009, to The Medicines Company upon assignment from Gopal Krishna and Gary Musso. The ’343 patent is generally directed to bivalirudin compositions.

13. Pursuant to 21 U.S.C. § 355(b)(1), the ’727 and ’343 patents are listed in FDA’s publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “*Orange Book*”) as covering The Medicines Company’s Angiomax® product.

14. DRL prepared, submitted, and/or filed DRL’s ANDA to the FDA under § 505(j) of the FDCA seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic bivalirudin, 250 mg/vial, for intravenous injection (“DRL’s Proposed Product”) before the expiration of the ’727 and ’343 patents.

15. On information and belief, Defendant Gland Pharma was involved in the development of DRL’s Proposed Product, the preparation, submission and/or filing of DRL’s ANDA.

16. DRL sent The Medicines Company a notification for the ’727 and ’343 patents purportedly pursuant to § 505(j)(2)(B)(ii) of the FDCA regarding DRL’s Proposed Product (“DRL’s Notice Letter”).

17. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of

the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(6) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(6)(i)-(ii).

FIRST COUNT

(Infringement of the '727 Patent by DRL – ANDA No. 201577)

18. The Medicines Company repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

19. Upon information and belief, DRL seeks FDA-approval for the manufacture, use, sale, offer for sale and/or importation of DRL's Proposed Product that is the subject of ANDA No. 201577.

20. Upon information and belief, DRL's ANDA includes a paragraph IV certification to the '727 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of DRL's Proposed Product before the expiration of the '727 patent.

21. Upon information and belief, DRL will commercially manufacture, sell, offer for sale, and/or import DRL's Proposed Product immediately upon FDA-approval, including within this judicial district.

22. Upon information and belief, as of the date of DRL's Notice Letter for DRL's ANDA, DRL was aware of the statutory provisions and regulations set forth in 21 U.S.C. §

355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

23. The inclusion of a paragraph IV certification to the '727 patent in DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of DRL's Proposed Product before the expiration of the '727 patent is an act of infringement by DRL of one or more claims of the '727 patent under 35 U.S.C. § 271(e)(2)(A), directly and by inducement.

24. Upon information and belief, DRL's commercial manufacture, use, sale, offer for sale and/or importation into the United States of DRL's Proposed Product will infringe one or more claims of the '727 patent, under 35 U.S.C. § 271(a) and/or (b), directly and/or by inducement.

25. DRL admits that DRL's Proposed Product infringes the '727 patent because DRL's Notice Letter does not include a paragraph IV certification asserting non infringement of any claim of the '727 patent.

26. Upon information and belief, DRL is aware of the existence of the '727 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '727 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

27. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

SECOND COUNT

(Infringement of the '343 Patent by DRL – ANDA No. 201577)

28. The Medicines Company repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

29. Upon information and belief, DRL seeks FDA-approval for the manufacture, use, sale, offer for sale and/or importation of DRL's Proposed Product.

30. Upon information and belief, DRL's ANDA includes a paragraph IV certification to the '343 patent in DRL's ANDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of DRL's Proposed Product before the expiration of the '343 patent.

31. Upon information and belief, DRL will commercially manufacture, sell, offer for sale, and/or import DRL's Proposed Product immediately upon FDA-approval, including within this judicial district.

32. Upon information and belief, as of the date of DRL's Notice Letter for DRL's ANDA, DRL was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

33. The inclusion of a paragraph IV certification to the '343 patent in DRL's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of DRL's Proposed Product before the expiration of the '343 patent is an act of infringement by DRL of one or more claims of the '343 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or by inducement.

34. Upon information and belief, DRL's commercial manufacture, use, sale, offer for sale and/or importation into the United States of DRL's Proposed Product will infringe one or more claims of the '343 patent, under 35 U.S.C. § 271(a) and/or (b), directly and/or by inducement.

35. DRL admits that DRL's Proposed Product infringes the '343 patent because DRL's Notice Letter does not include a paragraph IV certification asserting non-infringement of

any claim of the ’343 patent.

36. Upon information and belief, DRL is aware of the existence of the ’343 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the ’343 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

37. The acts of infringement set forth above will cause The Medicines Company irreparable harm for which it has no adequate remedy at law, unless DRL is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment declaring that the ’727 patent is valid and enforceable;

(b) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 201577 with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 201577 was an act of infringement of the ’727 patent by DRL directly and/or by inducement;

(c) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), and/or 35 U.S.C. § 271(b), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 201577 prior to the expiration of the ’727 patent, including any regulatory extensions, will constitute an act of infringement by DRL directly and/or by inducement;

(d) A judgment declaring that the ’343 patent is valid and enforceable;

(e) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of ANDA No. 201577 with a paragraph IV certification to obtain approval for the

commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 201577 was an act of infringement of the ’343 patent by DRL directly and/or by inducement;

(f) A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), 35 U.S.C. § 271(a), and/or 35 U.S.C. § 271(b), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of the product that is the subject of ANDA No. 201577 prior to the expiration of the ’343 patent, including any regulatory extensions, will constitute an act of infringement by DRL directly and/or by inducement;

(g) An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of ANDA No. 201577 shall be no earlier than the date on which the ’727 and ’343 patents expire including any regulatory extensions;

(h) A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining DRL and all DRL officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 201577 until the expiration of the ’727 and ’343 patents including any regulatory extensions;

(i) A judgment awarding The Medicines Company damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if DRL commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 201577 that infringes the ’727 and ’343 patents;

(j) A judgment declaring that infringement of the ’727 and ’343 patents is willful if DRL commercially manufactures, uses, sells, offers to sell and/or imports any product that is the

subject of ANDA No. 201577 that infringes the '727 and/or the '343 patents;

(k) A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding The Medicines Company its attorneys' fees and costs;

(l) Such other and further relief as this Court may deem just and proper.

Dated: April 28, 2011

Respectfully submitted,

Saiber LLC
Attorneys for Plaintiff The Medicines Company

/s/ Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)
Jeffrey Soos (js@saiber.com)
Rita D. Turner (rdt@saiber.com)
One Gateway Center, 10th Floor
Newark, NJ 07102
Telephone: (973) 622-3333
Facsimile: (973) 622-3349

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Plaintiff The Medicines Company, by its undersigned counsel, hereby certifies pursuant to Local Civil Rule 11.2 that the matters in controversy are not the subject of any other action pending in any other court or of any pending arbitration or administrative proceeding.

Dated: April 28, 2011

Saiber LLC
Attorneys for Plaintiff The Medicines Company

/s/ Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)
Jeffrey Soos (js@saiber.com)
Rita D. Turner (rdt@saiber.com)
One Gateway Center, 10th Floor
Newark, NJ 07102
Telephone: (973) 622-3333
Facsimile: (973) 622-3349

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745 Fifth Avenue
New York, NY 10151
Telephone: (212) 588-0800
Facsimile: (212) 588-0500

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Under Local Civil Rule 201.1, Plaintiff The Medicines Company, by its undersigned counsel, hereby certifies that, at this time, Plaintiff primarily seeks injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: April 28, 2011

Saiber LLC
Attorneys for Plaintiff The Medicines Company

/s/ Arnold B. Calmann
Arnold B. Calmann (abc@saiber.com)
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