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ATTORNEYS FOR PLAINTIFFS BAXTER HEALTHCARE CORPORATION,
BAXTER INTERNATIONAL INC., AND BAXTER HEALTHCARE S.A.

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BAXTER HEALTHCARE CORPORATION, BAXTER INTERNATIONAL INC., and BAXTER HEALTHCARE S.A., Plaintiffs, v. MYLAN LABORATORIES LTD. and MYLAN PHARMACEUTICALS INC., Defendants.	C.A. No. 1:14-cv-07094-JBS-JS

AMENDED COMPLAINT

Plaintiffs Baxter Healthcare Corporation ("Baxter Healthcare"), Baxter International Inc. ("Baxter International"), and Baxter Healthcare S.A. ("Baxter HSA") (collectively, "Baxter" or "Plaintiffs"), for their Complaint against defendants Mylan Laboratories Ltd., successor by merger to Agila Specialties Private Limited, and Mylan Pharmaceuticals Inc. (collectively "Mylan" or the "Mylan Defendants"), allege as follows:

PARTIES

1. Plaintiff Baxter International is a corporation incorporated in Delaware, having its principal place of business at One Baxter Parkway, Deerfield, IL 60015.

2. Plaintiff Baxter Healthcare is a corporation incorporated in Delaware, having its principal place of business at One Baxter Parkway, Deerfield, IL 60015. Baxter Healthcare is a wholly owned subsidiary of Baxter International.

3. Plaintiff Baxter HSA is a corporation incorporated in Switzerland, having its principal place of business at Hertistrasse 2, Wallisellen, CH-8304, Switzerland. Baxter HSA is a wholly owned subsidiary of Baxter International.

4. Baxter is a global healthcare company that develops, manufactures and markets products for people with hemophilia, immune disorders, infectious diseases, kidney disease, trauma, and other chronic and acute medical conditions.

5. Mylan Inc. is a corporation incorporated in Pennsylvania, having its principal place of business at 1000 Mylan Blvd. Canonsburg, PA 15317. Mylan Inc. touts itself as one of the world's leading generics and specialty pharmaceutical companies, with sales in approximately 140 countries and territories and providing medicine to 7 billion people worldwide.

6. Agila Specialties Private Limited was a wholly owned subsidiary of Mylan Inc., and was a corporation organized and operating under the laws of India with its principal place of

business at Strides House, Bilekahalli, Bannerghatta Road, Bangalore—560076, Karnataka, India, or elsewhere in India.

7. Agila Specialties Inc. (formerly known as Strides Inc.) is a wholly owned subsidiary of Mylan Inc., and is a corporation incorporated in New Jersey with its principal place of business at 201, South Main Street, Suite 3, Lambertville, NJ 08530. Agila Specialties Inc. is registered with the State of New Jersey Division of Revenue and Enterprise Services (Entity ID 0100791546).

8. Defendant Mylan Pharmaceuticals Inc. is a wholly owned subsidiary of Mylan Inc., and is a corporation incorporated in West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505.

9. Upon information and belief, defendant Mylan Pharmaceuticals Inc. is primarily responsible for the marketing, distribution and sales of Mylan Inc.'s products. Mylan Pharmaceuticals Inc. is the U.S. registered agent for Mylan Laboratories Ltd. with respect to the Mylan ANDA (described below).

10. Upon information and belief, defendant Mylan Laboratories Ltd. is a wholly owned subsidiary of Mylan Inc., and is a corporation organized and operating under the laws of India with its principal place of business at Bilekahalli, Bannerghatta Road, Bangalore—560076, Karnataka, India.

11. Upon information and belief, Mylan Laboratories Ltd. is the successor by merger to Agila Specialties Private Limited.

NATURE OF ACTION

12. This is an action for infringement of United States Patent Nos. 6,310,094 ("the '094 Patent") and 6,528,540 ("the '540 Patent") (collectively, "the Patents-in-Suit"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*.

JURISDICTION AND VENUE

13. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) (patent infringement). Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c) and 1400(b).

14. This Court has personal jurisdiction over the Mylan Defendants by virtue of the fact that, among other things, the Mylan Defendants have consented to the exercise by this Court of jurisdiction over them for purposes of this action. Agila Specialties Private Limited and Agila Specialties Inc. previously consented to the exercise by this Court of jurisdiction over them for purposes of this action.

THE DRUG APPROVAL PROCESS

15. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from FDA, typically through the filing of a New Drug Application ("NDA"). *See* 21 U.S.C. §355(a). The sponsor of the NDA is required to submit information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, to FDA, and FDA then lists such patent information in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." *See* 21 U.S.C. §355(b)(1) and (c)(2).

16. On the other hand, a company seeking to market a generic version of a previously approved drug is not required to submit a full NDA. Instead, it may file an Abbreviated New Drug Application ("ANDA"). *See* 21 U.S.C. §355(j). The generic drug approval process is considered "abbreviated" because the generic manufacturer may piggyback on the innovator company's data and FDA's prior finding of safety and efficacy by demonstrating, among other things, that the generic product is bioequivalent to the previously approved drug (the "listed drug" or "branded drug").

17. In conjunction with this "abbreviated" application process, Congress has put in place a process for resolving patent disputes relating to generic drugs, pursuant to which an ANDA filer must provide certifications addressing each of the patents listed in the Orange Book for the branded drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12). An ANDA filer may certify, for instance, that it believes a patent is invalid or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12)(i)(A)(4). This is known as a "Paragraph IV Certification."

18. The filer of an ANDA with a Paragraph IV Certification must also provide notice to both the owners of the listed patents and the holder of the NDA for the referenced listed drug. This "Paragraph IV Notice" must include a detailed statement of the factual and legal bases for the applicant's belief that the challenged patent is invalid or not infringed by the proposed generic product. 21 U.S.C. § 355(j)(2)(B); 21 C.F.R. §314.95.

19. If the patentee or NDA holder files a patent infringement action within 45 days of receiving a Paragraph IV Notice from an ANDA filer, final approval of the ANDA is generally subject to a 30-month stay. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 21 C.F.R. § 314.107(b)(3). The 30-month stay is important to the innovator companies because it protects them from the severe financial harm that could otherwise ensue from the FDA granting approval to a potentially infringing product without first providing an opportunity for the infringement case to be resolved. Put another way, the innovator company is assured of a 30-month period during which in may try to enforce its intellectual property rights and resolve any patent dispute before the generic product enters the market. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

FACTUAL BACKGROUND

20. On October 30, 2001, the United States Patent and Trademark Office ("PTO") duly and legally issued the '094 Patent, entitled "Ready-to-Use Esmolol Solution," to Baxter International as assignee. A true and correct copy of the '094 Patent is attached as Exhibit A.

21. On March 4, 2003, the PTO duly and legally issued the '540 Patent, entitled "Esmolol Formulation," to Baxter International as assignee. A true and correct copy of the '540 Patent is attached as Exhibit B.

22. Baxter International and Baxter HSA are the owners of the '094 Patent and the '540 Patent.

23. On February 16, 2001, the FDA approved Baxter Healthcare's supplemental NDA No. 19-386/S-018 for BREVIBLOC® Premixed Injection (esmolol HCl in sodium chloride) in 2500mg/250mL IntraVia Containers, under § 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b).

24. On January 27, 2003, the FDA approved Baxter Healthcare's supplemental NDA No. 19-386/S-020 for BREVIBLOC® Double Strength Premixed Injection (esmolol hydrochloride) 20 mg/mL in 100 mL Containers, under § 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(b) (collectively with the above BREVIBLOC® Premixed Injection (2500mg/250mL IntraVia Containers), "BREVIBLOC® Premixed Injection Products").

25. The BREVIBLOC® Premixed Injection Products are indicated, among other things, for the rapid control of the heart rate in patients with atrial fibrillation or atrial flutter in perioperative, postoperative, or other emergent circumstances where short term control of the heart rate with a short-acting agent is desirable.

26. Baxter Healthcare is the holder of the NDAs for each of the BREVIBLOC® Premixed Injection Products. It makes and sells the BREVIBLOC® Premixed Injection Products to hospitals and other healthcare providers, by exclusive license under the Patents-in-Suit, throughout the United States.

27. Plaintiffs jointly own all rights, title and interest in the Patents-in-Suit, including all rights needed to bring this action in Plaintiffs' names.

28. Baxter Healthcare submitted information regarding the '094 and '540 Patents to the FDA for listing in the "Orange Book" with respect to the BREVIBLOC® Premixed Injection Products. The FDA thereafter listed the '094 and '540 Patents in the Orange Book with respect to those products, pursuant to 21 C.F.R. § 314.53(e).

29. Upon information and belief, prior to September 30, 2014, Agila Specialties Private Ltd. submitted to the FDA Abbreviated New Drug Application Number 206608 (the "ANDA") pursuant to 35 U.S.C. § 355(j), seeking approval to engage in the commercial

manufacture, use, and sale of proposed Esmolol Hydrochloride in Sodium Chloride Solution products in dosages of 10mg/ml (250 mg) and 20 mg/ml (100 mg/ml) (collectively, the "Proposed ANDA Products"), referencing versions of Baxter's BREVIBLOC® in plastic container and BREVIBLOC® double strength in plastic container products.

30. On or about September 30, 2014, Agila Specialties Private Ltd. sent Baxter Healthcare and Baxter International a notice stating that Agila Specialties Private Limited had submitted ANDA No. 206608 seeking approval to manufacture, use, or sell the Proposed ANDA Products prior to the expiration of the '094 Patent and the '540 Patent (the "Paragraph IV Notice"). The Paragraph IV Notice was written on Mylan letterhead, identified Agila Specialties Private Limited as a "Mylan Company", and was signed by Samir Patel, VP Global IP Operations of Mylan.

31. The Paragraph IV Notice also specifically identified Agila Specialty Inc. as U.S. agent for Agila Specialties Private Limited. Baxter has investigated the corporate status of Agila Specialty Inc., but has been unable to locate any records regarding the place of incorporation, locations of any offices, or corporate existence of Agila Specialty Inc. Upon information and belief, Agila Specialty Inc. may not exist, and the reference in the Paragraph IV Notice may have been intended to refer instead to Agila Specialties Inc., which as noted above is a New Jersey corporation with its principal place of business in New Jersey.

32. The Paragraph IV Notice advised Baxter that Agila Specialties Private Ltd.'s ANDA included a Paragraph IV Certification stating that it was Agila Specialties Private Ltd.'s opinion that the '094 and '540 patents are not valid. That Notice did not include any assertion

that Agila Specialties Private Ltd.'s proposed products would not infringe the claims of those patents.

33. On October 29, 2014, Baxter sent Agila Specialties Private Limited and Mylan Inc. a letter seeking confirmation that their products, if approved by the FDA and sold by Agila Specialties Private Limited and/or Mylan Inc. in the U.S., would infringe the '094 and '540 patents, or alternatively requesting that they provide Baxter with a detailed statement for the basis of any non-infringement contentions, along with confidential access to the ANDA. Agila Specialties Private Limited and Mylan Inc. did not respond to that letter.

34. In August 2014, the High Court of India ordered that Agila Specialties Private Limited be merged into Mylan Laboratories Ltd. Upon information and belief, Agila Specialties Private Limited has been merged into Mylan Laboratories Ltd. and no longer exists as a separate entity.

35. Mylan Laboratories Ltd. is now listed as the Applicant for ANDA 206608 and Mylan Pharmaceuticals Inc. is now listed as the Authorized U.S. Agent for the Applicant.

COUNT I

INFRINGEMENT OF THE '094 PATENT

36. Baxter incorporates each of the preceding paragraphs 1 to 49 as if fully set forth herein.

37. Mylan's submission of ANDA No. 206608 to the FDA, including the Paragraph IV Certification submitted therewith, which seeks FDA approval to engage in the commercial manufacture, use, and sale of Proposed ANDA Products prior to the expiration of the '094 Patent, constitutes infringement of the '094 Patent under 35 U.S.C. § 271(e)(2)(A).

38. Upon FDA approval of ANDA No. 206608, Mylan will directly or indirectly infringe the '094 Patent under 35 U.S.C. § 271(a), (b) and/or (c) by engaging in the commercial manufacture, use, offer for sale, sale in and/or importation into the United States of the ANDA Products, and/or by actively inducing and contributing to infringement of others engaging in such activities, unless this Court orders that the effective date of any FDA approval of Mylan's ANDA is no earlier than the expiration date of the '094 Patent and any additional periods of exclusivity.

39. Baxter has no adequate remedy at law for Mylan's infringement of the '094 Patent, and will be substantially and irreparably harmed by any such infringing activities unless those activities are enjoined by this Court.

40. Upon information and belief, Mylan was aware of the existence of the '094 Patent as demonstrated by its reference to that patent in its ANDA, and was aware that the filing of its Paragraph IV Certification with respect to the '094 Patent constitutes infringement of that patent. This is an exceptional case within the meaning of 35 U.S.C. § 285.

COUNT II

INFRINGEMENT OF THE '540 PATENT

41. Baxter incorporates each of the preceding paragraphs 1 to 40 as if fully set forth herein.

42. Mylan's submission of ANDA No. 206608 to the FDA including the Paragraph IV Certification submitted therewith, which seeks FDA approval to engage in the commercial

manufacture, use, and sale of its Proposed ANDA Products prior to the expiration of the '540 Patent, constitutes infringement of the '540 Patent under 35 U.S.C. § 271(e)(2)(A).

43. Upon FDA approval of ANDA No. 206608, Mylan will directly or indirectly infringe the '540 Patent under 35 U.S.C. § 271(a), (b) and/or (c) by engaging in the commercial manufacture, use, offer for sale, sale in and/or importation into the United States of the Proposed ANDA Products, and/or by actively inducing and contributing to infringement of others engaging in such activities, unless this Court orders that the effective date of any FDA approval of Mylan's ANDA is no earlier than the expiration date of the '540 Patent and any additional periods of exclusivity.

44. Baxter has no adequate remedy at law for Mylan's infringement of the '540 Patent, and will be substantially and irreparably harmed by any such infringing activities unless those activities are enjoined by this Court.

45. Upon information and belief, Mylan was aware of the existence of the '540 Patent as demonstrated by its reference to that patent in its ANDA, and was aware that the filing of its Paragraph IV Certification with respect to the '540 Patent constitutes infringement of that patent. This is an exceptional case within the meaning of 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Baxter respectfully requests the following relief:

A. A judgment that, pursuant to 35 U.S.C. § 271(e)(2)(A), Mylan has infringed the '094 Patent;

B. A judgment that, pursuant to 35 U.S.C. § 271(e)(2)(A), Mylan has infringed the '540 Patent;

C. A declaration that Mylan's commercial manufacture, use, offer for sale, sale in or importation into the United States of the Proposed ANDA Products would infringe the '094 Patent;

D. A declaration that Mylan's commercial manufacture, use, offer for sale, sale in or importation into the United States of its Proposed ANDA Products would infringe the '540 Patent;

E. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Mylan's ANDA No. 206608 and/or of the Proposed ANDA Products shall not be earlier than the expiration date of the '094 and '540 Patents, including any extensions;

F. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining the Mylan Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, from infringement of the '094 and '540 Patents for the full terms thereof (including any extensions), including without limitation, enjoining such persons from commercially making, using, selling, or offering to sell any of the Proposed ANDA Products within the United States, or importing any such products into the United States, during the terms of those patents;

G. An order that judgment be entered awarding Baxter monetary relief if the Mylan Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, commercially make, use, sell, offer for sale in, or import into, the United States, any of the ANDA Products prior to the expiration of the '094 and '540 Patents for the full terms thereof (including any extensions), and that any such monetary relief be awarded with prejudgment interest;

H. A permanent injunction restraining and enjoining the Mylan Defendants, their officers, agents, servants and employees, and those persons in active concert or participations with any of them, from seeking, obtaining or maintaining final approval of The Mylan Defendants' ANDA No. 206608 until expiration of the '094 and '540 Patents;

I. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

J. Costs and expenses in this action; and

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

DECHERT LLP

Dated: August 19, 2015

/s/ Robert D. Rhoad
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