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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.

AGILA SPECIALTIES PRIVATE
LIMITED, AGILA SPECIALTY INC.,
AGILA SPECIALTIES INC. F/K/A/
STRIDES INC., MYLAN INC.,
MYLAN PHARMACEUTICALS INC.,
MYLAN INSTITUTIONAL INC., and
MYLAN INSTITUTIONAL LLC.,

Defendants.

C.A. No. _____

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 Agila Specialties Private Limited, Agila Specialty Inc., and Agila Specialties Inc. (collectively “Agila” or the “Agila Defendants”), and Mylan Inc., Mylan Pharmaceuticals Inc., Mylan Institutional Inc., and Mylan Institutional LLC

(collectively “Mylan” or the “Mylan Defendants”) (collectively with Agila, the “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. Upon information and belief, defendant Mylan Inc. is a corporation incorporated in Pennsylvania, having its principal place of business at 1000 Mylan Blvd. Canonsburg, PA 15317. Mylan 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. Upon information and belief, defendant Agila Specialties Private Limited 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 Strides House, Bilekahalli, Bannerghatta Road, Bangalore—560076, Karnataka, India, or elsewhere in India.

7. Upon information and belief, to the extent it exists (*see* ¶ 47 below), defendant Agila Specialty Inc. is a wholly owned subsidiary of Mylan Inc., having offices at 781 Chestnut Ridge Road, Morgantown, WV 26505 and is designated by Agila Specialties Private Limited as its U.S. agent. Upon information and belief, Agila Specialty Inc. is not a West Virginia corporation or registered to do business in West Virginia.

8. Upon information and belief, defendant 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).

9. The Agila Defendants are pharmaceutical companies engaged in the world-wide development, manufacture, and marketing of generic injectable products.

10. Upon information and belief, 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.

11. Upon information and belief, defendant Mylan Pharmaceuticals Inc. is primarily responsible for the marketing, distribution and sales of Mylan Inc.'s products.

12. Upon information and belief, Mylan Institutional Inc. is a corporation incorporated in Illinois and whose registered office is at 1718 Northrock Court, Rockford, IL 61103.

13. Upon information and belief, defendant Mylan Institutional LLC is a limited liability corporation incorporated in Delaware with a principal place of business at 4901 Hiawatha Dr., Rockford, IL 61103.

14. Upon information and belief, defendants Mylan Institutional Inc. and Mylan Institutional LLC are primarily responsible for the marketing, distribution, sales and packaging of Mylan Inc.'s products to Mylan's institutional customers, such as hospitals.

NATURE OF ACTION

15. 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

16. 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).

17. This Court has personal jurisdiction over Defendants because, *inter alia*, they have committed – or aided, abetted, planned, contributed to, or participated in the commission of – tortious conduct which will lead to foreseeable harm and injury to Baxter in the State of New Jersey, and in doing so, Defendants have purposefully directed their activities at the residents of this forum.

18. This Court also has personal jurisdiction over Defendants because, *inter alia*, they have maintained continuous and systematic contacts with the State of New Jersey and this District.

19. Upon information and belief, Defendants collaborate to market and sell generic pharmaceutical products, pursuant to the abbreviated new drug application process, throughout the United States, including in the State of New Jersey, at least by making and shipping into this judicial district, or by offering to sell or selling, or causing others to offer to sell or sell, generic

pharmaceutical products. Defendants derive substantial revenue from goods used or consumed or services rendered in this judicial district.

20. Mylan is in the business of making and selling pharmaceutical drug products, including generic drug products. Upon information and belief, Mylan Inc., directly or through its subsidiaries including through Agila and the other Mylan Defendants, manufactures, imports, markets and sells generic drugs throughout the United States and in this judicial district.

21. Mylan Inc.'s 10-K claims, for instance, that Mylan holds the number one ranking in the U.S. generics prescription market in terms of sales, and number two ranking in terms of prescriptions dispensed. The 10-K further states that approximately one in every 12 prescriptions dispensed in the U.S. is a Mylan product. Upon information and belief, Mylan Inc. derives revenue from its operations in New Jersey and is registered with the State of New Jersey Division of Revenue and Enterprise Services (Entity ID 0100971292).

22. Mylan acquired Agila from Strides Arcolabes Limited in December 2013. In its promotional materials, Mylan claims that as a result of its acquisition of Agila, Mylan now commands one of the largest portfolios of injectable medications in the pharmaceutical industry, and that Mylan now has an expanded focus on essential therapies including cardiovascular treatments, as well as expanded manufacturing infrastructure and capabilities.

23. Mylan, Inc.'s 10-K similarly states that the acquisition of Agila doubles Mylan's injectables portfolio, including in the U.S. market and this judicial district.

24. Upon information and belief, Agila has over 80 abbreviated new drug applications approved by the FDA and more than 100 filed applications pending FDA approval. The FDA approved products for which Agila Specialties Private Limited is listed as the applicant holder and manufacturer include Adenosine, Ampicillin Sodium, Ampicillin Sodium/Sulbactam

Sodium, Haloperidol Decanoate, Ketorolac Tromethamine, Lidocaine Hydrochloride, MESNA, Oxacillin Sodium, Piperacillin Sodium/Tazobactam Sodium, Sumatriptan Succinate, Vancomycin Hydrochloride, and Zoledronic Acid. *See, e.g.,* <http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm>. Upon information and belief, these products are sold throughout the United States, including in this judicial district.

25. Upon information and belief, Defendants operate as a single vertically integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of generic pharmaceutical products throughout the U.S. including in this judicial district. *See e.g.,* www.mylan.com/company/about-us.

26. For example, Mylan, through its subsidiary Mylan Pharmaceuticals Inc., manufactures, markets, sells and distributes generic pharmaceutical products approved by the FDA including the products Rabeprazol Sodium and Voriconazole. Upon information and belief, Mylan Pharmaceuticals Inc., derives revenue from its operations in New Jersey and is registered with the State of New Jersey Division of Revenue and Enterprise Services (Entity ID 4302546711).

27. Similarly, upon information and belief, Mylan, through its subsidiary Mylan Institutional LLC, manufactures, markets, sells, packages and distributes generic pharmaceutical products approved by the FDA (including, for example, Esmolol Hydrochloride Injection; Cidofovir Injection, solution; Cosyntropin Injection, powder, for solution; Dexrazoxane Hydrochloride; and Fomepizole Injection, solution) to Mylan's institutional customers. Upon information and belief, Mylan Institutional LLC derives revenue from its operations in New Jersey.

28. In addition, upon information and belief, Mylan, through its subsidiary Mylan

Institutional Inc., manufactures, markets, sells, packages, and distributes institutional generic pharmaceutical products. Mylan Institutional Inc. is registered with the State of New Jersey Division of Revenue and Enterprise Services (Entity ID 4302546711).

29. Upon information and belief, Defendants intend to manufacture for distribution and distribute and sell generic equivalents of Baxter's BREVIBLOC[®] products in 10 mg/ml (250 mg) and 20 mg/ml (100 mg/ml) infusion bags (*see* description below of Defendants' ANDA relating to these products) throughout the United States and in this judicial district.

30. Upon information and belief, Defendants have previously submitted to and availed themselves of the jurisdiction of this Court for patent infringement suits. *See, e.g., Warner Chilcott Laboratories Ireland Limited et al. v. Mylan Pharmaceuticals Inc. et al.*, 2:09-cv-02073-WJM-MF; *Pfizer Inc. et al. v. Mylan Inc. et al.*, 2:10-cv-03246-DMC-JAD; *Janssen Pharmaceuticals Inc. v. Mylan Inc. et al.*, 2:10-cv-06018-SRC-CLW, *Novartis Pharma et al. v. Akorn, Inc., et al.*, 2:13-cv-05125-SDW-MCA.

THE DRUG APPROVAL PROCESS

31. 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).

32. 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”).

33. 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.”

34. 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.

35. 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 it 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

36. 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.

37. 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.

38. Baxter International and Baxter HSA are the owners of the ‘094 Patent and the ‘540 Patent.

39. 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).

40. 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”).

41. 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.

42. 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.

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

44. 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).

45. Upon information and belief, prior to September 30, 2014, Defendants 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.

46. On or about September 30, 2014, Defendants 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.

47. 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.

48. The Paragraph IV Notice advised Baxter that Defendants' ANDA included a Paragraph IV Certification stating that it was Defendants' opinion that the '094 and '540 patents are not valid. That Notice did not include any assertion that Defendants' proposed products would not infringe the claims of those patents.

49. On October 29, 2014, Baxter sent Defendants' a letter seeking confirmation that their products, if approved by the FDA and sold by Defendants in the U.S., would infringe the '094 and '540 patents, or alternatively requesting Defendants provide Baxter with a detailed statement for the basis of any non-infringement contentions, along with confidential access to the ANDA. To date, however, Defendants have not responded to that letter and have not provided access to any portion of the ANDA.

COUNT I

INFRINGEMENT OF THE '094 PATENT

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

51. Defendants' 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).

52. Upon FDA approval of ANDA No. 206608, Defendants 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 Defendants' ANDA is no earlier than the expiration date of the '094 Patent and any additional periods of exclusivity.

53. Baxter has no adequate remedy at law for Defendants' 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.

54. Upon information and belief, Defendants were aware of the existence of the '094 Patent as demonstrated by their reference to that patent in their ANDA, and were aware that the filing of their 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

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

56. Defendants' 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 '540 Patent, constitutes infringement of the '540 Patent under 35 U.S.C. § 271(e)(2)(A).

57. Upon FDA approval of Defendants' ANDA No. 206608, Defendants 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 Defendants' ANDA is no earlier than the expiration date of the '540 Patent and any additional periods of exclusivity.

58. Baxter has no adequate remedy at law for Defendants' 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.

59. Upon information and belief, Defendants were aware of the existence of the '540 Patent as demonstrated by their reference to that patent in its ANDA, and were aware that the filing of their 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), Defendants have infringed the '094 Patent;

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

C. A declaration that Defendants' 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 Defendants' 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 Defendants' 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 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 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 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 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: November 12, 2014

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CERTIFICATION OF NON-ARBITRABILITY

Pursuant to Local Civil Rule 201.1 (d)(2), the undersigned attorney for plaintiffs Baxter Healthcare Corporation and Baxter International Inc. certifies that this action is not eligible for compulsory arbitration under Local Civil Rule 201.1 because the relief sought in the Complaint primarily consists of a demand for preliminary and permanent injunctive relief, and because if Defendants were to commercially make, use, sell, offer for sale in, or import into the United States any of the Proposed ANDA Products prior to the expiration of the '094 and '540 Patents, Baxter's monetary damages would exceed \$150,000.

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned attorney for plaintiffs Baxter Healthcare Corporation and Baxter International Inc. certifies that to the best of his knowledge, the matter in controversy is not the subject of another action pending in any court or of any pending arbitration or administrative proceeding. Plaintiffs do note, however, that the patents-in-suit are the subject of another patent infringement action pending in this district, encaptioned *Baxter Healthcare Corp. et al., v. HQ Specialty Pharma Corp.*, C.A. No. 2:13-cv-6228-FSH-MAH.

DECHERT LLP
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By /s/ Robert D. Rhoad
ROBERT D. RHOAD

Dated: November 12, 2014