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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. HQ SPECIALTY PHARMA CORPORATION, Defendant.	C.A. No. _____

COMPLAINT

Plaintiffs Baxter Healthcare Corporation ("Baxter Healthcare"), Baxter International Inc. ("Baxter International"), and Baxter Healthcare S.A. ("Baxter HSA") (collectively, "Baxter"), for their Complaint against defendant HQ Specialty Pharma Corporation ("HQ Specialty Pharma") 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, HQ Specialty Pharma is a corporation incorporated in New Jersey, having its principal place of business at 120 Route 17 North, Suite 130, Paramus, NJ 07652. HQ Specialty Pharma touts itself as a specialty pharmaceutical company that develops products for the hospital market.

NATURE OF ACTION

6. 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

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

8. This Court has personal jurisdiction over HQ Specialty Pharma because, *inter alia*, HQ Specialty Pharma is incorporated in this district and maintains it principal place of business in this district.

THE DRUG APPROVAL PROCESS

9. A company seeking to market a new pharmaceutical drug in the United States must first obtain approval from the U.S. Food and Drug Administration ("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 to FDA information on all patents claiming the drug that is the subject of the NDA, or a method of using that drug, and FDA then lists that 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).

10. Alternatively, a company may seek approval to market a new drug product by filing an NDA under 21 U.S.C. § 355(b)(2) (a "§ 505(b)(2) application") which refers to and relies in part on the safety and efficacy findings of a previously approved drug, typically one approved under an original NDA filed pursuant to 21 U.S.C. § 355(b)(1).

11. By allowing an applicant to piggy-back off of the innovator company's investment in clinical or other studies relating to the previously approved, reference listed drug, the abbreviated § 505(b)(2) application process can provide a shorter and less costly drug development pathway for the applicant than exists for an applicant filing an original NDA.

12. In conjunction with this § 505(b)(2) application process, Congress has put in place a process for resolving patent disputes relating to § 505(b)(2) application products, pursuant to which a § 505(b)(2) applicant must provide certifications addressing each of the patents listed in the Orange Book for the reference listed drug. *See* 21 U.S.C. § 355(b)(2)(A). *See also* 21 C.F.R. §§ 314.50(i), 314.54. The applicant may certify, for instance, that it believes a patent is invalid or will not be infringed by the manufacture, use, or sale of the § 505(b)(2) application product. *See* 21 U.S.C. § 355(b)(2)(A)(iv). *See also* 21 C.F.R. §

314.50(i)(1)(i)(A)(4). This is known as a "Paragraph IV Certification."

13. A § 505(b)(2) applicant that includes a Paragraph IV Certification with its application must also provide notice thereof to both the owner 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 § 505(b)(2) application product. *See* 21 U.S.C. § 355(b)(3). *See also* 21 C.F.R. § 314.52.

FACTUAL BACKGROUND

14. 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.

15. 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.

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

17. 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).

18. 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").

19. 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.

20. 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.

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

22. Baxter Healthcare submitted information regarding the '094 and '540 Patents to the FDA for listing in its publication, the *Approved Drug Products with Therapeutic Equivalence Evaluations* (referred to as 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).

23. Upon information and belief, prior to September 5, 2013, HQ Specialty Pharma submitted to the FDA paperwork purporting to constitute a § 505(b)(2) application (No. 205-703), seeking approval to engage in the commercial manufacture, use, and sale of proposed Esmolol Hydrochloride Premixed Injection products in dosages of 2500mg/250mL (10mg/mL strength) and 2000mg/100mL (20 mg/mL strength) (collectively, "Proposed HQ Specialty Pharma Products"), referencing versions of Baxter's BREVIBLOC® Premixed Injection

Products.

24. On or about September 5, 2013, HQ Specialty Pharma sent Baxter Healthcare and Baxter International a notice stating that it had submitted § 505(b)(2) application No. 205-703 seeking approval to manufacture, use, or sell the Proposed HQ Specialty Pharma Products prior to the expiration of the '094 Patent and the '540 Patent (the "HQ Paragraph IV Notice"). Baxter received the HQ Paragraph IV Notice on September 9, 2013.

25. The HQ Paragraph IV Notice advised Baxter that HQ Specialty Pharma's § 505(b)(2) application included a Paragraph IV Certification stating that it was HQ Specialty Pharma's opinion that the proposed manufacture, importation, use, sale, or offer for sale of the Proposed HQ Specialty Pharma Products described in its § 505(b)(2) application No. 205-703 would not infringe any claim of the '094 Patent or the '540 Patent and/or that these patents were invalid.

COUNT I

INFRINGEMENT OF THE '094 PATENT

26. Baxter incorporates each of the preceding paragraphs 1 to 25 as if fully set forth herein.

27. HQ Specialty Pharma's submission of § 505(b)(2) application No. 205-703 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 HQ Specialty Pharma Products prior to the expiration of the '094 Patent, constitutes infringement of the '094 Patent under 35 U.S.C. § 271(e)(2)(A).

28. Upon FDA approval of HQ Specialty Pharma's § 505(b)(2) application No. 205-703, HQ Specialty Pharma 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 Proposed HQ Specialty Pharma 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 HQ Specialty Pharma's § 505(b)(2) application is no earlier than the expiration date of the '094 Patent and any additional periods of exclusivity.

29. Baxter has no adequate remedy at law for HQ Specialty Pharma'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.

30. Upon information and belief, HQ Specialty Pharma was aware of the existence of the '094 Patent as demonstrated by its reference to that patent in its NDA, 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

31. Baxter incorporates each of the preceding paragraphs 1 to 30 as if fully set forth herein.

32. HQ Specialty Pharma's submission of § 505(b)(2) application No. 205-703 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 HQ Specialty Pharma Products prior to the expiration of the '540 Patent, constitutes infringement of the '540 Patent under 35 U.S.C. § 271(e)(2)(A).

33. Upon FDA approval of HQ Specialty Pharma's § 505(b)(2) application No. 205-703, HQ Specialty Pharma 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 HQ Specialty Pharma 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 HQ Specialty Pharma's § 505(b)(2) application is no earlier than the expiration date of the '540 Patent and any additional periods of exclusivity.

34. Baxter has no adequate remedy at law for HQ Specialty Pharma'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.

35. Upon information and belief, HQ Specialty Pharma was aware of the existence of the '540 Patent as demonstrated by its reference to that patent in its NDA, 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), HQ Specialty Pharma has infringed the '094 Patent;

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

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

D. A declaration that HQ Specialty Pharma's commercial manufacture, use, offer for sale, sale in or importation into the United States of its Proposed HQ Specialty Pharma 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 HQ Specialty Pharma's NDA No. 205-703 and/or of the Proposed HQ Specialty Pharma 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 HQ Specialty Pharma, its 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 HQ Specialty Pharma 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 HQ Specialty Pharma, its officers, agents, servants and employees, and those persons in active concert or participation with any of them, commercially makes, uses, sells, offers for sale in, or imports into, the United States, any of the Proposed HQ Specialty Pharma 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 HQ Specialty Pharma, its 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 HQ Specialty Pharma's 505(b)(2) application No. 205-703 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: October 17, 2013

/s/ Robert D. Rhoad
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ATTORNEYS FOR PLAINTIFFS BAXTER HEALTHCARE CORPORATION, BAXTER INTERNATIONAL INC., and BAXTER HEALTHCARE S.A.

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 HQ Specialty Pharma were to commercially make, use, sell, offer for sale in, or import into the United States any of the Proposed HQ Specialty Pharma 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.

DECHERT LLP
Attorneys for Plaintiffs
Baxter Healthcare Corporation,
Baxter International Inc., and
Baxter Healthcare S.A.

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

Dated: October 18, 2013