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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. SAGENT PHARMACEUTICALS INC., Defendant.	C.A. No. _____

COMPLAINT

Plaintiffs Baxter Healthcare Corporation ("Baxter Healthcare"), Baxter International Inc. ("Baxter International"), and Baxter Healthcare S.A. ("Baxter HAS") (collectively, "Baxter" or "Plaintiffs"), for their Complaint against defendant Sagent Pharmaceuticals Inc. ("Sagent" or "Defendant") 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, Sagent is a corporation incorporated in Delaware, having its principal place of business at 1901 N. Roselle Road, Suite 700, Schaumburg, Illinois 60195.

6. Upon information and belief, Sagent is a specialty pharmaceutical company focused on developing, manufacturing, sourcing and marketing injectable pharmaceutical products for sale primarily in the United States of America.

NATURE OF ACTION

7. 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

8. 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).

9. This Court has personal jurisdiction over Sagent 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, Sagent has purposefully directed its activities at the residents of this forum.

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

11. Upon information and belief, Sagent develops, manufactures, sources, and markets injectable pharmaceutical products that it sells throughout the United States, including in the State of New Jersey, including 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 in this judicial district. Upon information and belief, Sagent derives substantial revenue from goods used or consumed or services rendered in this judicial district.

12. Sagent's 10-K claims, for instance, that Sagent is a specialty pharmaceutical company focused on developing, manufacturing, sourcing and marketing injectable pharmaceutical products, which Sagent sells primarily in the United States of America. Upon information and belief, Sagent derives revenue from its sales in New Jersey and is registered

with the New Jersey Department of Health Food & Drug Safety as a wholesale drug manufacturer (Registration # 5004419).

13. Sagent's 10-K additionally claims that Sagent launched 12 products in 2013, and had 62 ANDA's under FDA review at the end of the period. According to Sagent's 10-K, Sagent's FDA approved products include "key" products Cefepime, Levofloxacin, Docetaxel, Leucovorin Calcium, Zoledronic acid, and Heparin.

14. Upon information and belief, Sagent intends, upon FDA approval to do so, to manufacture, distribute and sell the generic equivalents of Baxter's BREVIBLOC® products in 10 mg/mL 250 mL infusion bags and 20 mg/mL 100 mL infusion bags (*see* description below of Sagent's ANDA relating to these products) that Baxter accuses of infringement in this matter throughout the United States and in this judicial district.

15. Upon information and belief, Sagent has previously submitted to and availed itself of the jurisdiction of this Court for patent infringement suits. *See, e.g.*, *Astrazeneca et al. v. Sagent Pharma Inc.*, 1:14-cv-05539-RMB-KMW, *Novartis v. Actavis et al.*, 2:13-civ-1028-SDW-MCA (admitting that it sells generic versions of branded drugs in the United States, including in New Jersey).

THE DRUG APPROVAL PROCESS

16. 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).

17. 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").

18. 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."

19. 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.

20. 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

21. 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.

22. 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.

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

24. 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).

25. 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").

26. 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.

27. 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.

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

29. 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).

30. Upon information and belief, prior to January 23, 2015, Sagent submitted to the FDA Abbreviated New Drug Application Number 207107 (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 10 mg/ML 250 mL infusion bags and 20 mg/mL 100 mL infusion bags (collectively, the "Proposed ANDA Products"), referencing versions of Baxter's BREVIBLOC® in plastic container and BREVIBLOC® double strength in plastic container products.

31. On or about January 23, 2015, Sagent sent Baxter International a notice stating that Sagent had submitted ANDA No. 207107 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").

32. Baxter first received Sagent's Paragraph IV Notice on January 26, 2015.

33. The Paragraph IV Notice advised Baxter that Sagent's ANDA included a Paragraph IV Certification stating that it was Sagent's opinion that the '094 Patent is not valid. The Notice did not include any assertion that Sagent's Proposed ANDA Products would not infringe the claims of the '094 Patent. The Notice also stated that it was Sagent's opinion that claims 1-6, 8-10, and 12-16 of the '540 Patent are invalid, and that Sagent's manufacture, use, importation, sale and offer for sale of its Proposed ANDA Products would not infringe claims 7 and 11 of the '540 Patent. The Notice did not include any assertion that claims 7-8 and 11 are invalid, or that claims 1-6 and 9-16 of the '540 Patent would not be infringed by Sagent's manufacture, use, importation, sale and offer for sale of its Proposed ANDA Products.

COUNT I

INFRINGEMENT OF THE '094 PATENT

34. Baxter incorporates each of the preceding paragraphs 1-33 as if fully set forth herein.

35. Sagent's submission of ANDA No. 207107 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 '094 Patent, constitutes infringement of the '094 Patent under 35 U.S.C. § 271(e)(2)(A).

36. Upon FDA approval of ANDA No. 207107, Sagent 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 Sagent's ANDA is no earlier than the expiration date of the '094 Patent and any additional periods of exclusivity.

37. Baxter has no adequate remedy at law for Sagent'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.

38. Upon information and belief, Sagent was aware of the existence of the '094 Patent as demonstrated by its reference to that patent in its ANDA, and were 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

39. Baxter incorporates each of the preceding paragraphs 1-38 as if fully set forth herein.

40. Sagent's submission of ANDA No. 207107 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).

41. Upon FDA approval of ANDA No. 207107, Sagent 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 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 Sagent's ANDA is no earlier than the expiration date of the '540 Patent and any additional periods of exclusivity.

42. Baxter has no adequate remedy at law for Sagent'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.

43. Upon information and belief, Sagent was aware of the existence of the '540 Patent as demonstrated by its reference to that patent in its ANDA, and were 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), Sagent has infringed the '094 Patent;

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

C. A declaration that Sagent'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 Sagent'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 Sagent's ANDA No. 207107 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 Sagent, 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 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 Sagent, its 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 Sagent, 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 Sagent's ANDA No. 207107 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: March 6, 2015

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

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 other patent infringement actions pending in this district, encaptioned *Baxter Healthcare Corp. et al., v. HQ Specialty Pharma Corp.*, C.A. No. 2:13-cv-6228-FSH-MAH, and *Baxter Healthcare Corp. et al., v. Agila Specialties Private Limited*, C.A. No. 2:14-cv-07094-FSH-MAH.

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

Dated: March 6, 2015