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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.

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