IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SHIRE ORPHAN THERAPIES LLC and SANOFI-AVENTIS DEUTSCHLAND GMBH,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
INNOPHARMA, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Shire Orphan Therapies LLC and Sanofi-Aventis Deutschland GmbH (collectively "Plaintiffs"), by their undersigned attorneys, for their Complaint against defendant InnoPharma, Inc. ("InnoPharma" or "Defendant") herein allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 5,648,333 ("the '333 patent"), attached hereto as Exhibit A.

THE PARTIES

2. Plaintiff Shire Orphan Therapies LLC is a limited-liability company organized and existing under the laws of the State of Delaware, and its principal place of business is located at 300 Shire Way, Lexington, Massachusetts 02421. Shire Orphan Therapies LLC was formerly known as Shire Orphan Therapies, Inc.

3. Plaintiff Sanofi-Aventis Deutschland GmbH is a company organized and existing under the laws of Germany, and its principal place of business is located at Brüningstrasse 50, D-65926, Frankfurt am Main, Germany.

4. Upon information and belief, Defendant InnoPharma is a corporation organized and existing under the laws of the State of Delaware, and its principal place of business is located at 10 Knightsbridge Road, Piscataway, NJ 08854.

5. Upon information and belief, InnoPharma is in the business of, *inter alia*, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including throughout the State of Delaware.

JURISDICTION AND VENUE

6. This Court has subject-matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over InnoPharma because, *inter alia*, InnoPharma is a corporation organized under the laws of the State of Delaware and InnoPharma has a registered agent for service of process in Delaware. This Court therefore has general personal jurisdiction over InnoPharma.

8. This Court also has personal jurisdiction over InnoPharma because, *inter alia*, upon information and belief, InnoPharma: (1) has previously submitted to the jurisdiction of this Court and has availed itself of the legal protection of the State of Delaware, having consented to jurisdiction in this Court, *see, e.g.*, *Cephalon, Inc. v. InnoPharma, Inc.*, 1:14-cv-01238-GMS (D. Del. Sept. 25, 2014); *Cadence Pharmaceuticals Inc. et al. v. InnoPharma Licensing LLC et al.*, 1:14-cv-01225-LPS (D. Del. Sept. 24, 2014); *Celgene Corporation et al. v. InnoPharma, Inc.*, 1:14-cv-01188-RGA (D. Del. Sept. 12, 2014); *Cephalon, Inc. v. InnoPharma, Inc.*, 1:14-cv-00590-GMS (D. Del. May 9, 2014); *Cephalon, Inc. v. InnoPharma, Inc.*, 1:13-cv-02081-GMS (D. Del. Dec. 20, 2013); *Cumberland Pharmaceuticals Inc. v. InnoPharma, Inc.*, 1:12-cv-00618-LPS (D. Del. May 17, 2012); and *Spectrum Pharmaceuticals, Inc. et al v. InnoPharma, Inc.*, 1:12-cv-00260-RGA-CJB (D. Del. March 2, 2012); and (2) conducts business within the State of

Delaware and maintains extensive systematic contacts within the State of Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical drugs to Delaware residents.

9. This Court also has personal jurisdiction over InnoPharma because, *inter alia*, InnoPharma has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including Shire Orphan Therapies LLC, a Delaware limited-liability company. InnoPharma prepared, submitted, and filed with the United States Food and Drug Administration ("FDA"), pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)), Abbreviated New Drug Application ("ANDA") No. 208879 ("ANDA No. 208879") seeking approval to engage in the commercial manufacture, use, and/or sale of Icatibant Injection, 10 mg/mL, 3 mL single-use pre-filled syringes ("InnoPharma's ANDA Product") before the expiration of the '333 patent throughout the United States, including in this judicial district.

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

BACKGROUND FACTS

11. Shire Orphan Therapies LLC owns New Drug Application No. 022150 for icatibant acetate, which was approved on August 25, 2011 and is marketed under the name FIRAZYR®. FIRAZYR is sold as a single-use, prefilled syringe for subcutaneous administration, each prefilled syringe delivering 3 mL of a solution equivalent to a 30 mg icatibant (free base) dose.

12. FIRAZYR (icatibant) is a bradykinin B2 receptor antagonist indicated for treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.

13. The ’333 patent, entitled “Peptides Having Bradykinin Antagonist Action,” was duly and legally issued by the United States Patent and Trademark Office on July 15, 1997. Sanofi-Aventis Deutschland GmbH owns the ’333 patent. Shire Orphan Therapies LLC is the exclusive licensee of the ’333 patent.

14. Pursuant to 21 U.S.C. § 355(b)(1), the ’333 patent is listed in the FDA’s publication titled “Approved Drug Products with Therapeutic Equivalence Evaluations” (commonly known as the “*Orange Book*”) as covering FIRAZYR.

15. InnoPharma prepared, submitted, and filed ANDA No. 208879 under § 505(j) of the FDCA (codified at 21 U.S.C. § 355(j)), seeking approval from the FDA to engage in the commercial manufacture, use, or sale of icatibant. InnoPharma included in ANDA No. 208879 a “paragraph IV” certification seeking such approval before the expiration of the ’333 patent. And upon information and belief, upon approval of ANDA No. 208879, InnoPharma will be involved, directly and/or indirectly, in the manufacture, use, sale, offer for sale, and/or importation of InnoPharma’s ANDA Product.

16. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” Likewise, 21 C.F.R. § 314.95(c)(6) requires that such a letter include “[a] detailed statement of the factual and legal basis of the applicant’s opinion that the patent is not valid, unenforceable, or will not be infringed.” The detailed statement must include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full

and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(6)(i)-(ii).

17. Plaintiffs received a letter dated May 10, 2016 that was purportedly sent pursuant to § 505(j)(2)(B)(ii) of the FDCA, 21 U.S.C. § 355(j)(2)(B)(ii) regarding InnoPharma's ANDA Product and the '333 patent (the "May 10 Notice Letter").

18. The May 10 Notice Letter does not include any non-infringement contention with respect to claims 1, 2, 4-6, 12-14, 25, and 27 of the '333 patent.

19. The May 10 Notice Letter included an Offer of Confidential Access ("OCA") purportedly pursuant to 21 U.S.C. § 355(j)(5)(C). Plaintiffs objected to certain provisions of InnoPharma's OCA as unreasonable and in violation of 21 U.S.C. § 355(j)(5)(C)(i)(III). By way of example only, InnoPharma's OCA contains FDA and patent prosecution bars, even though no facts have been provided to show that there is good cause to impose such bars.

CLAIM FOR RELIEF
(Infringement of the '333 Patent)

20. Plaintiffs repeat and re-allege each of the foregoing Paragraphs as if fully set forth herein.

21. Upon information and belief, InnoPharma has submitted ANDA No. 208879 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of InnoPharma's ANDA Product—a product claimed and the use of which is claimed in the '333 patent—before the expiration of the '333 patent.

22. Upon information and belief, InnoPharma included in ANDA No. 208879 a paragraph IV certification in an attempt to obtain approval to engage in the commercial manufacture, use, or sale of InnoPharma's ANDA Product before the expiration of the '333 patent.

23. Upon information and belief, InnoPharma will commercially manufacture, use, sell, offer for sale, and/or import its ANDA Product upon, or in anticipation of, FDA approval.

24. The submission of ANDA No. 208879 with a paragraph IV certification for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of InnoPharma's ANDA Product before the expiration of the '333 patent was an act of infringement by InnoPharma—directly and/or indirectly—of one or more claims of the '333 patent under 35 U.S.C. § 271(e)(2).

25. Upon information and belief, InnoPharma's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of InnoPharma's ANDA Product that is the subject of ANDA No. 208879 would infringe, directly and/or indirectly (including by inducement and/or contributory infringement), one or more claims of the '333 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

26. Upon information and belief, the sale or offer for sale of InnoPharma's ANDA Product by InnoPharma would induce and/or contribute to third party infringement of one or more claims of the '333 patent under 35 U.S.C. § 271.

27. Upon information and belief, by making, using, selling, offering for sale, and/or importing into the United States InnoPharma's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, InnoPharma will encourage, advise, instruct, urge, aid, and otherwise induce third parties (e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists), to make, use, sell, offer for sale, and/or import into the United States products that infringe the claims, or the use of which infringes the claims, of the '333 patent. Upon information and belief, InnoPharma intends such inducement by third parties, as it is in the business of developing,

manufacturing, marketing, selling, and distributing generic pharmaceutical products throughout the United States. Upon information and belief, InnoPharma knows that its actions will induce direct infringement of claims of the '333 patent by, e.g., wholesalers, distributors, retailers, subjects, patients, caretakers, medical practitioners, physicians, and/or pharmacists.

28. Upon information and belief, by offering for sale or selling within the United States or importing into the United States InnoPharma's ANDA Product and/or distributing the corresponding labeling, package insert, and/or medication guide, InnoPharma will contribute to infringement of claims of the '333 patent by third parties because: (i) InnoPharma's ANDA Product constitutes a material part of the methods of treatment claimed in the '333 patent; (ii) InnoPharma knows or should know that InnoPharma's ANDA Product will be made for uses that directly infringe the methods of treatment claimed in the '333 patent; and (iii) InnoPharma's ANDA Product is not a staple article or commodity of commerce suitable for substantial noninfringing uses.

29. InnoPharma's infringement of the '333 patent will cause Plaintiffs to suffer irreparable harm. InnoPharma's infringement will continue unless enjoined by the Court. Plaintiffs have no adequate remedy at law and thus preliminary and permanent injunctions are appropriate to prohibit InnoPharma from infringing the '333 patent.

30. At least as of the date of the May 10 Notice Letter, InnoPharma was aware of the existence of the '333 patent—as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95—and acted without a reasonable basis for believing that it would not infringe one or more claims of the '333 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of ANDA No. 208879 with a paragraph IV certification for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, or sale of InnoPharma's ANDA Product—a product (1) that is claimed in the '333 patent and (2) whose use is claimed in the '333 patent—before the expiration of the '333 patent—constitutes an act of infringement of the '333 patent by InnoPharma;

B. A Judgment declaring that, pursuant to 35 U.S.C. §§ 271(a), (b), and (c), the commercial manufacture, use, sale, offer for sale and/or importation in the United States of InnoPharma's ANDA Product before the expiration of the '333 patent will constitute an act of direct infringement and/or indirect infringement, including by inducement and/or contributory infringement of the '333 patent, by InnoPharma;

C. An Order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of InnoPharma's ANDA Product shall be no earlier than the date on which the '333 patent expires, including any regulatory extensions;

D. Injunctive relief pursuant to 35 U.S.C. § 271(e)(4)(B) precluding InnoPharma from manufacturing, using, selling, offering to sell, or importing InnoPharma's ANDA Product prior to the date on which the '333 patent has expired, including any regulatory extensions;

E. A Judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Plaintiffs their attorneys' fees;

F. A Judgment awarding Plaintiffs their costs under Fed. R. Civ. P. 54(d) and 28 U.S.C. § 1920; and

G. Such other and further relief as this Court may deem just and proper.

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June 17, 2016