

UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

MAYNE PHARMA LTD.,

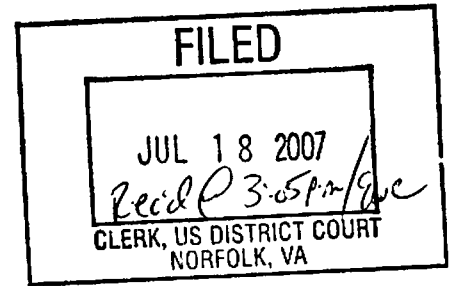
Plaintiff,

v.

SANOFI-AVENTIS U.S. LLC,

Serve: Corporation Service Company
11 South 12th Street
P.O. Box 1463
Richmond, Virginia 23218

Defendant.



Civil Action No. 3:07CV424
Judge Payne

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff, Mayne Pharma Limited ("Mayne"), for its complaint against Defendant, Sanofi-Aventis U.S. LLC ("Sanofi-Aventis"), alleges as follows:

PARTIES

1. Mayne is a corporation organized and existing under the laws of Australia with its principal place of business at Level 3, 390 St Kilda Road, Melbourne VIC 3004, Australia. Mayne is primarily in the business of the development, manufacturing and sale of injectable pharmaceutical products. Mayne's products are primarily used in hospitals in therapeutic categories including oncology, anesthesia/pain and cardiac care.

2. As it has previously advised Sanofi-Aventis, Mayne consents to jurisdiction in this district for purposes of patent disputes concerning oxaliplatin. Moreover, Mayne's regulatory agent for its oxaliplatin formulation in the U.S. is Drug Development Consultants Inc. located at 5108 Grimm Drive, Alexandria, Virginia 22304.

3. Defendant Sanofi-Aventis is the United States subsidiary of Sanofi-Aventis of France, and is a corporation organized and existing under the laws of the State of Delaware, having an office at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis manufactures and sells pharmaceutical products throughout the United States, including distributing, using and selling pharmaceutical products in the State of Virginia.

4. Sanofi-Aventis is registered to do business in Virginia, as shown on the Clerk's Information System of the Virginia State Corporation Commission. Sanofi-Aventis regularly conducts business in Virginia and in this judicial district, including selling and offering to sell pharmaceutical products to residents of the State of Virginia.

5. Sanofi-Aventis has designated Corporation Service Company, located at 11 South 12th Street, P.O. Box 1463, Richmond, Virginia 23218, as an agent for service of process in the State of Virginia, as shown on the Clerk's Information System of the Virginia State Corporation Commission.

6. Sanofi-Aventis regularly employs residents of the State of Virginia as a part of its efforts in the sale of pharmaceutical products in the State of Virginia, including hiring a regional account manager in Ruckersville, Virginia. Sanofi-Aventis has also placed employment advertisements on Internet websites seeking to hire district sales managers in Fairfax, Virginia.

7. Sanofi-Aventis is an active participant in the medical community of the State of Virginia, including: sponsoring clinical studies involving residents of Virginia from Annandale, Charlottesville, Fairfax, Newport News, Norfolk, Midlothian, Salem, Richmond, Roanoke, Virginia Beach and Williamsburg; presenting at the Virginia Academy of Physician Assistants 25th Annual Summer CME Conference held at the Hilton Virginia Beach Oceanfront Resort in Virginia Beach, Virginia; and exhibiting at the Virginia Counsel of Nurse Practitioners 33rd

Annual Conference held at the Hyatt Regency Reston in Reston, Virginia.

8. Sanofi-Aventis participates in a Patient Assistance Program in Virginia to provide free drugs to Virginia residents that meet certain qualifications, and is a member of the Virginia Association of Health Plans.

9. Sanofi-Aventis is the successor in interest to Aventis Pharmaceuticals, S.A., which is listed with an Internet business directory as having a place of business at 1780 Business Center Driver, Reston, Virginia 20190 and telephone number 703-438-3025.

JURISDICTION AND VENUE

10. This action arises under the Patent Act of 1952, 35 U.S.C. §§ 101 et seq., and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 et seq. This Court has subject matter jurisdiction to hear this action under 28 U.S.C. §§ 1331, 1338(a), 2201, 2202.

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

BACKGROUND

MAYNE'S ABBREVIATED NEW DRUG APPLICATION

12. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the U.S. Food & Drug Administration ("FDA") follows when considering the approval of applications for both brand-name and generic drugs.

13. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

14. An NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant submitted the application

and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1)(G).

15. Upon approval of the NDA, the FDA publishes patent information for the approved drug in its publication, *Approved Drug Products with Therapeutic Equivalence Evaluation* (“Orange Book”).

16. Generic drugs are versions of brand-name drugs that have been shown to be “bioequivalent” to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

17. On February 9, 2007, Mayne filed an Abbreviated New Drug Application (“ANDA”) with the FDA pursuant to 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use or sale of generic oxaliplatin injection pharmaceutical formulation that is related to an oxaliplatin product that is commercially known as Eloxatin[®]. Sanofi-Aventis is the NDA holder for Eloxatin[®].

18. The Orange Book lists four patents that Sanofi-Aventis identified with its NDA for the drug oxaliplatin: U.S. Patents Nos. 5,290,961; 5,338,874; 5,420,319; and 5,716,988. Mayne’s ANDA included a “Paragraph IV” certification pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV) that these four patents listed in the Orange Book under oxaliplatin were invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the proposed oxaliplatin drug product described by Mayne’s ANDA.

19. The filing of an ANDA creates a justiciable controversy because 35 U.S.C. § 271(e)(2)(A) states that it is an act of infringement to submit “an application under section 505(j) of the Federal Food, Drug and Cosmetic Act [21 USCS § 355(j)] or described in section 505(b)(2) of such Act [21 USCS § 355(b)(2)] for a drug claimed in a patent.”

THE '902 PATENT

20. According to the records of the U.S. Patent and Trademark Office (“USPTO”),

Sanofi-Aventis is the assignee of U.S. Patent No. 6,306,902, entitled “Oxaliplatin Formulations,” which is another patent that includes claims that encompass oxaliplatin formulations and manufacturing processes (“the ’902 Patent”). A copy of the ’902 patent is attached hereto as Exhibit A.

21. Furthermore, the ’902 Patent is the U.S. equivalent to European patent EP 0943331 (“the EP ’331 Patent”). The ’902 Patent and the EP ’331 Patent share the same specification, have nearly identical claims and are derived from the same priority application (GB 9804013). A copy of the ’331 Patent is attached hereto as Exhibit B.

22. The equivalent EP ’331 patent was the subject of litigation in Great Britain between Mayne and Sanofi-Aventis of France in which Mayne’s proposed oxaliplatin product was alleged to infringe claims of the EP ’331 patent. *See Mayne Pharma Limited et al. v. Debiopharm SA et al.*, No. HC05 C01298 (High Court of Justice, Chancery Division 2006).

23. Despite the relevance of the ’902 Patent to oxaliplatin, however, it is not listed in the Orange Book with the four other oxaliplatin patents, U.S. Patents Nos. 5,290,961; 5,338,874; 5,420,319; and 5,716,988.

24. Mayne seeks certainty as to infringement, validity and enforceability of the ’902 patent as it moves forward with its efforts to develop and market its proposed oxaliplatin formulation in the United States.

25. Infringement in the United States under 35 U.S.C. § 271(e)(2)(A) for the act of submitting an ANDA to the FDA has been characterized as a “highly artificial act of infringement” *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 678 (1990), where the actual manufacture, use or sale of a drug in violation of a patent has not occurred, but is recognized to allow parties to seek judicial adjudication of their rights, and to prevent uncertainty.

26. Furthermore, the Court of Appeals for the Federal Circuit has held that “[u]nder 35 U.S.C. § 271(e)(2)(A), submitting an ANDA, regardless of how many paragraph IV certifications it may contain, is a single act of infringement.” *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1340 (Fed. Cir. 2007).

27. Based on, *inter alia*, Sanofi-Aventis' prior allegations of infringement in the Great Britain litigation of the European equivalent of the '902 Patent, the EP '331, and the artificial act of infringement created through the filing of Mayne's ANDA with the FDA, there has been and is now an actual and justiciable controversy between Mayne and Sanofi-Aventis in the United States as to whether Mayne's proposed oxaliplatin formulation infringes, induces infringement of, or contributes to the infringement of the '902 Patent.

28. Sanofi-Aventis has shown that it will enforce its patent rights related to oxaliplatin against possible infringers. Within the last five weeks, Sanofi-Aventis has filed ten lawsuits against numerous parties for allegedly infringing patents related to the filing of ANDAs for oxaliplatin formulations.

29. Mayne has a reasonable apprehension that Sanofi-Aventis will initiate a patent infringement action against Mayne, claiming that Mayne's proposed oxaliplatin formulation infringes the '902 Patent.

CLAIM

DECLARATION OF INVALIDITY AND NON-INFRINGEMENT OF THE '902 PATENT

30. Mayne realleges and incorporates by reference the allegations set forth in paragraphs 1-29 above.

31. A conflict of asserted rights has arisen and a justiciable controversy exists between Mayne and Sanofi-Aventis with regard to the infringement, validity and enforceability of the '902 Patent.

32. Mayne has not infringed, contributed to the infringement of, or induced the infringement of any valid claim of the '902 patent and is not liable for infringement thereof.

33. The '902 patent is invalid, void and/or unenforceable against Mayne, at least, for failure to comply with the requirements of, *inter alia*, 35 U.S.C. §§ 101, 102, 103 and/or 112.

34. Mayne is entitled to declaratory judgment adjudicating its rights with respect to the '902 patent.

REQUEST FOR RELIEF

WHEREFORE, Plaintiff Mayne respectfully requests that this Court enter a Judgment and Order in its favor and against Defendant Sanofi-Aventis as follows:

A. Declaring that Mayne's proposed oxaliplatin product does not, and would not if commercially manufactured, used, sold, offered for sale, or imported into the United States, infringe any claim of the '902 patent;

B. Declaring that each claim of the '902 patent is invalid and/or unenforceable; and

C. Grant to Mayne such other and further relief as the Court may deem just, proper and equitable under the circumstances.

Dated: July 18, 2007

Respectfully Submitted,

MAYNE PHARMA LIMITED

By  _____
Of Counsel

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