IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

GILEAD SCIENCES, INC., Plaintiff, v. SIGMAPHARM LABORATORIES, LLC, Defendant.	Case No.:

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Gilead Sciences, Inc. ("Gilead") for its Complaint against Defendant Sigmapharm Laboratories, LLC ("Sigmapharm"), hereby alleges as follows:

Nature of Action

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code.

The Parties

2. Gilead is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

3. On information and belief, Defendant Sigmapharm is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 3375 Progress Drive, Bensalem, Pennsylvania 19020.

Jurisdiction and Venue

4. This action arises under the patent laws of the United States of America and the Food and Drug Laws of the United States, Titles 35 and 21 of the United States Code. This Court has jurisdiction over the subject matter of this action based on 28 U.S.C. §§ 1331 and 1338(a).

5. On information and belief, this Court has personal jurisdiction over Sigmapharm.

6. On information and belief, Sigmapharm resides in this District and derives substantial revenue from selling various products and doing business throughout the United States, including this District.

7. On information and belief, Sigmapharm manufactures bulk pharmaceuticals and pharmaceutical products which products are placed into interstate commerce by Sigmapharm and are thereafter sold throughout the United States, including this District.

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

Background

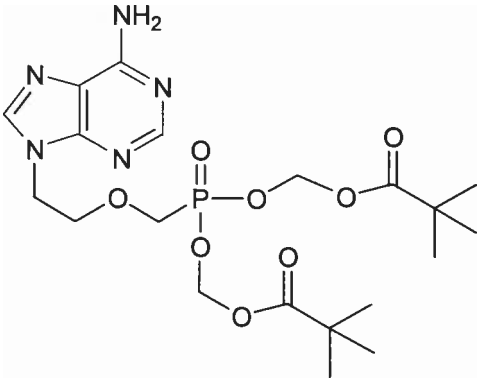
9. Gilead is the holder of New Drug Application ("NDA") No. 21-449 for Hepsera® tablets which contain 10 mg of the active pharmaceutical ingredient adefovir dipivoxil. On September 20, 2002, the United States Food and Drug Administration ("FDA") approved the use of the Hepsera® tablets described in NDA No. 21-449 for the treatment of chronic hepatitis B.

10. Gilead is also the owner of United States Patent No. 6,451,340 ("the '340 Patent," copy attached as Exhibit A), entitled "Nucleotide Analog Compositions," which was duly and legally issued by the United States Patent and Trademark Office on September 17, 2002.

11. The named inventors on the '340 Patent are Murty N. Arimilli, Daphne E. Kelly, Thomas T. K. Lee, Lawrence V. Manes, John D. Munger, Jr., Ernest J. Prisbe, and Lisa M. Schultze.

12. The '340 Patent claims various crystalline forms of adefovir dipivoxil, the active ingredient in the Hepsera® tablets described in NDA No. 21-449, as well as pharmaceutical compositions containing adefovir dipivoxil and methods of preparing adefovir dipivoxil.

13. Adefovir dipivoxil is nucleotide reverse transcriptase inhibitor having molecular formula of $C_{20}H_{32}N_5O_8P$. The chemical structure of adefovir dipivoxil is set forth below:



14. Adefovir dipivoxil can be referred to by any of several chemical names. The chemical name provided for adefovir dipivoxil in the Hepsera® labels is "9-[2-[[bis[(pivaloyloxy)methoxy]-phosphinyl]-methoxy]ethyl]adenine."

15. The '340 Patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Hepsera®.

16. Gilead is also the exclusive licensee of United States Patent No. 5,663,159 ("the '159 Patent," copy attached as Exhibit B), entitled "Prodrugs of Phosphonates," which patent was duly and legally issued by the United States Patent and Trademark Office on September 2, 1997.

17. The named inventors on the '159 Patent are John E. Starrett, Jr., Muzammil M. Mansuri, John C. Martin, David R. Tortolani, and Joanne J. Bronson.

18. The '159 Patent claims various chemical compounds, including adefovir dipivoxil, the active ingredient in the Hepsera® tablets described in NDA No. 21-449. The '159 Patent is listed in the FDA Orange Book for Hepsera®.

COUNT 1
Infringement of U.S. Patent No. 6,451,340

19. Plaintiff repeats and realleges paragraphs 1-18 above as if set forth herein.

20. On information and belief, Sigmapharm submitted or caused to be submitted an Abbreviated New Drug Application ("ANDA"), specifically ANDA No. 202051, to the FDA seeking approval to engage in the commercial manufacture, use, sale, offer to sell or importation of tablets containing 10 mg of adefovir dipivoxil within or into the United States (hereinafter referred to as "Sigmapharm's ANDA Product").

21. On information and belief, Sigmapharm, with ANDA No. 202051, seeks approval to manufacture, use, sell, offer to sell and/or import adefovir dipivoxil for the purpose of treating chronic hepatitis B.

22. By letter dated August 17, 2010 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "August 17, 2010 Hepsera® Notice Letter"), Sigmapharm notified Plaintiff that it had submitted ANDA No. 202051 to the FDA seeking approval to engage in the commercial manufacture, use, or sale of tablets containing 10 mg of adefovir dipivoxil prior to the expiration of the '340 Patent.

23. In its August 17, 2010 Hepsera® Notice Letter, Sigmapharm notified Plaintiff that, as a part of ANDA No. 202051, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '340 Patent. This statutory section requires, *inter alia,* certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '340 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed factual statement of the factual and legal basis of the applicant's opinion that

the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

24. Sigmapharm alleged in its August 17, 2010 Hepsera® Notice Letter that the claims of the '340 Patent would not be infringed by Sigmapharm's ANDA Product or the method of making the adefovir dipivoxil used in Sigmapharm's ANDA Product. Sigmapharm's August 17, 2010 Hepsera® Notice Letter does not allege that the '340 Patent is invalid or unenforceable.

25. By filing ANDA No. 202051 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale, offer to sell, and/or importation Sigmapharm's ANDA Product before the expiration of the '340 Patent, Sigmapharm has committed an act of infringement of the '340 Patent under 35 U.S.C. § 271(e)(2).

26. On information and belief, the commercial manufacture, use, sale, offer to sell, and/or importation of Sigmapharm's ANDA Product will infringe, induce infringement, or contributorily infringe one or more claims of the '340 Patent.

COUNT 2
Infringement of U.S. Patent No. 5,663,159

27. Plaintiff repeats and realleges paragraphs 1-18, 20 and 21 above as if set forth herein.

28. By letter dated August 17, 2010 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "August 17, 2010 Hepsera® Notice Letter"), Sigmapharm notified Plaintiff that it had submitted ANDA No. 202051 to the FDA seeking approval to engage in the commercial

manufacture, use, or sale of tablets containing 10 mg of adefovir dipivoxil prior to the expiration of the ’159 Patent.

29. In its August 17, 2010 Notice Letter, Sigmapharm notified Plaintiff that, as a part of its ANDA No. 202051, it had filed a Paragraph IV certification with respect to the ’159 Patent. This statutory section requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the ’159 Patent, “is invalid or will not be infringed by the manufacture, use or sale of the new drug for which this application is submitted . . . .” The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to “include a detailed factual statement of the factual and legal basis of the applicant’s opinion that the patent is not valid or will not be infringed.” The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)(ii)) further require that the detailed statement include, “[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations.”

30. Sigmapharm alleged in its August 17, 2010 Hepsera® Notice Letter that Claims 1, 3, 5, 7-9, 13 and 18 of the ’159 Patent are invalid and that Claims 2, 4, 6, 9-12, and 14-18 of the ’159 Patent would not be infringed by Sigmapharm’s ANDA Product. Sigmapharm’s August 17, 2010 Hepsera® Notice Letter does not allege that the ’159 Patent is unenforceable.

31. By filing ANDA No. 202051 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale, offer to sell, and/or importation of tablets containing 10 mg of adefovir dipivoxil before the expiration of the ’159 Patent, Sigmapharm has committed an act of infringement of the ’159 Patent under 35 U.S.C. § 271(e)(2).

32. On information and belief, Sigmapharm lacked a good faith basis for alleging invalidity of the ’159 Patent when ANDA No. 202051 was filed and when the Paragraph IV certification was made. Sigmapharm’s ANDA with its Paragraph IV certification is a wholly unjustified infringement of the ’159 Patent.

33. On information and belief, the commercial manufacture, use, sale, offer to sell, and/or importation of Sigmapharm’s ANDA Product will infringe, induce infringement, or contributorily infringe one or more claims of the ’159 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(a) A judgment, pursuant to 35 U.S.C. § 271(e)(4), declaring that the effective date of any approval of Sigmapharm’s ANDA No. 202051 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the ’340 Patent or any later date of exclusivity to which Plaintiff is or becomes entitled;

(b) A judgment, pursuant to 35 U.S.C. § 271(e)(4), declaring that the effective date of any approval of Sigmapharm’s ANDA No. 202051 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the ’159 Patent or any later date of exclusivity to which Plaintiff is or becomes entitled;

(c) A judgment declaring that the ’340 Patent remains valid, enforceable and has been infringed by Sigmapharm;

(d) A judgment declaring that the ’159 Patent remains valid, enforceable and has been infringed by Sigmapharm;

(e) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Sigmapharm, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of compositions as claimed in the ’340 Patent, including, without limitation, compositions made by the methods claimed in the ’340 Patent;

(f) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Sigmapharm, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, and their successors and assigns, from engaging in the commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of compositions as claimed in the ’159 Patent;

(g) A judgment that Sigmapharm made a baseless certification to the FDA which makes this case exceptional under 35 U.S.C. § 285, and Gilead, therefore, is entitled to an award of reasonable attorneys fees;

(h) To the extent that Sigmapharm has committed any acts with respect to the subject matter claimed in the ’340 Patent, other than those acts expressly exempted by 35 U.S.C. § 271 (e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(i) To the extent that Sigmapharm has committed any acts with respect to the subject matter claimed in the ’159 Patent, other than those acts expressly exempted by 35 U.S.C. § 271 (e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(j) Costs and expenses in this action; and

(k) Such other relief as this Court may deem proper.

September 29, 2010

Respectfully submitted,

s/Alexander Kerr
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