IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IDENIX PHARMACEUTICALS, INC. and UNIVERSITA DEGLI STUDI DI CAGLIARI Plaintiffs, v. GILEAD SCIENCES, INC. Defendant.	CIVIL ACTION NO. _____ JURY TRIAL DEMANDED

PLAINTIFFS' DECLARATORY JUDGMENT COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Idenix Pharmaceuticals, Inc. ("Idenix") and Universita Degli Studi di Cagliari ("U. Cagliari") (collectively, "Plaintiffs"), for their Complaint against Defendant Gilead Sciences, Inc. ("Gilead"), hereby allege:

THE PARTIES

1. Idenix is a corporation duly organized and existing under the laws of the State of Delaware, having a principal place of business at 320 Bent Street, Cambridge, Massachusetts 02141.

2. U. Cagliari is an Italian university having a location at Via Università 40, 09124 Cagliari, Italy.

3. On information and belief, Defendant Gilead is a corporation organized under the laws of the State of Delaware. On information and belief, Gilead's principal place of business is located at 333 Lakeside Drive, Foster City, California 94404.

JURISDICTION AND VENUE

4. This action arises under the patent laws of the United States, 35 U.S.C. §§ 1 et seq. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

5. Gilead is subject to personal jurisdiction in this District because, upon information and belief, Gilead regularly and continuously transacts business in the District of Massachusetts, by making, distributing, and shipping into this Judicial District, or by using, distributing, offering to sell, or selling, or by causing others to use, offer to sell, or sell in this Judicial District, pharmaceutical products. Upon information and belief, Gilead derives substantial revenue from interstate and/or international commerce, including substantial revenue from goods used or consumed or services rendered in the Commonwealth of Massachusetts and this Judicial District.

6. On information and belief, on or before December 8, 2013, Gilead will obtain approval from the United States Food and Drug Administration ("FDA") to market and sell sofosbuvir, a 2'-methyl nucleoside, to treat the hepatitis C virus ("HCV") infection. On information and belief, upon receiving FDA approval, Gilead will import, sell, offer to sell, and distribute drugs containing sofosbuvir within the Commonwealth of Massachusetts that will be used within Massachusetts to treat HCV infections. By doing so, Gilead will be committing a tortious act within the Commonwealth of Massachusetts, which Gilead expects or reasonably should expect to have consequences in the Commonwealth of Massachusetts. As is set forth more fully herein, Gilead will infringe at least two patents owned by Plaintiffs. Given the imminence of Gilead's tortious acts, a substantial controversy exists between Plaintiffs and Gilead.

7. Venue properly exists in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400.

FACTUAL BACKGROUND

8. Idenix is a biopharmaceutical company whose primary focus is on the discovery and development of drugs to treat human viral diseases. Idenix has conducted research for antiviral drugs, including drugs to treat HCV infections, since its inception and it has discovered, developed, and gained FDA approval for antiviral drugs for the treatment of the hepatitis B virus ("HBV") and the HIV/AIDS virus. Idenix's current research and development focus is on the treatment of HCV infections.

9. HCV is an infectious disease affecting the liver. It is a heterogeneous disease comprising six different genotypes. At the current time, there are treatments available for each of the six HCV genotypes. HCV Genotype 1 is the predominant genotype in the United States, but HCV Genotype 2 and HCV Genotype 3 are also observed. HCV Genotype 4, HCV Genotype 5, and HCV Genotype 6 are more prevalent in Africa and Asia, and are rarely observed in the United States.

10. In response to the significant global need for an effective way to treat HCV infections, researchers led by Dr. Jean-Pierre Sommadossi focused on the way that HCV replicates in the body in order to find a way to stop the replication process.

11. Dr. Sommadossi co-founded a company that later became Idenix to develop HIV, HBV, and HCV treatments.

12. Idenix researchers, in collaboration with scientists at U. Cagliari, discovered and developed 2'-methyl nucleosides that hinder the replication of HCV in the body.

13. Idenix and U. Cagliari scientists made significant advances related to the treatment of HCV infections using 2'-methyl nucleosides, and several provisional patent applications were filed in the United States Patent and Trademark Office ("USPTO") describing their inventions, including Serial No. 60/206,585 (filed May 23, 2000) ("the '585 application").

14. Non-provisional patent applications were subsequently filed. These non-provisional patent applications led to United States Patent Nos. 6,914,054 and 7,608,597 (collectively, "the Asserted Patents"), each of which claims priority to the '585 application. Plaintiffs are co-owners by assignment of the Asserted Patents. Use of Gilead's drugs containing sofosbuvir infringes the Asserted Patents.

THE ASSERTED PATENTS

15. United States Patent No. 6,914,054 ("the '054 Patent"), titled "Methods And Compositions For Treating Hepatitis C Virus," was duly and lawfully issued on July 5, 2005. Plaintiffs are owners of, and have the right to enforce, the '054 Patent. A true and correct copy of the '054 Patent is attached hereto as Exhibit A.

16. United States Patent No. 7,608,597 ("the '597 Patent"), titled "Methods And Compositions For Treating Hepatitis C Virus," was duly and lawfully issued on October 27, 2009. Plaintiffs are owners of, and have the right to enforce, the '597 Patent. A true and correct copy of the '597 Patent is attached hereto as Exhibit B.

GILEAD'S IMMINENT INFRINGEMENT

17. Gilead submitted a New Drug Application ("NDA") to FDA for approval of sofosbuvir on April 8, 2013. On June 7, 2013, Gilead issued a press release announcing that FDA had granted priority review of Gilead's sofosbuvir NDA and set a target review date of December 8, 2013, by which date FDA approval is expected.

18. On October 25, 2013, FDA's Antiviral Drugs Advisory Committee held a meeting to discuss Gilead's NDA for sofosbuvir. During that meeting, the advisory committee voted, by two unanimous 15-0 votes, to support approval of sofosbuvir for treatment of HCV genotypes 1 and 4 in combination with pegylated interferon and ribavirin and for treatment of HCV genotypes 2 and 3 in combination with ribavirin. FDA's advisory committee vote is

consistent with the timeline for approval in December 2013 that Gilead expects and for which Gilead is actively preparing.

19. Gilead filed a declaratory judgment action against Merck & Co., Inc., Merck Sharp & Dohme Corp., (together, "Merck") and Isis Pharmaceuticals, Inc. ("Isis") on August 30, 2013, seeking a declaration of non-infringement and invalidity related to two patents allegedly covering sofosbuvir and its use.

20. In its declaratory judgment complaint against Merck and Isis, Gilead stated that it "has made substantial preparation to make, sell, and offer to sell sofosbuvir in the United States" and has "manufactur[ed] sufficient quantities for sale upon FDA approval." The activities Gilead has undertaken to prepare sufficient quantities for sale upon FDA approval, as described in Gilead's declaratory judgment complaint against Merck and Isis, fall outside the safe harbor provisions of 35 U.S.C. § 271(e).

21. In anticipation of FDA approval to market and sell drugs containing sofosbuvir, on information and belief, Gilead has been and is making meaningful preparations to market and sell drugs containing sofosbuvir in the United States to treat HCV, in quantities suitable for large scale distribution in the United States following approval, and not for clinical trials, including at least:

a. Manufacturing and/or importing into the United States quantities of sofosbuvir, and/or pharmaceutical compositions containing sofosbuvir, which exceed the quantity needed for Gilead's current clinical trials;

b. Hiring key management, support, and sales personnel to market and sell drugs containing sofosbuvir to treat HCV upon FDA approval of sofosbuvir in the United States;

c. Training sales personnel regarding the marketing and sales of drugs containing sofosbuvir for treating HCV in the United States;

d. Contacting gastroenterologists, hepatologists, virologists, and other physicians who treat HCV patients in the United States to solicit interest in prescribing drugs containing sofosbuvir for treating HCV upon FDA approval in the United States; and

e. Filing declaratory judgment actions against patentees such as Merck and Isis to clear the way for Gilead to market and sell drugs containing sofosbuvir for treating HCV in the United States in large quantities upon receiving FDA approval.

22. Gilead's imminent commercial sale, offer for sale, and distribution of sofosbuvir or pharmaceutical compositions containing sofosbuvir for treatment of HCV patients in the United States is outside the safe harbor provisions of 35 U.S.C. § 271(e) and will indirectly infringe claims of the '054 and '597 Patents.

COUNT I: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '054 PATENT

23. Plaintiffs reallege and incorporate by reference each of the allegations set forth in Paragraphs 1-22.

24. Gilead's imminent sale, offer for sale, and distribution in the United States of sofosbuvir or pharmaceutical compositions containing sofosbuvir will infringe the '054 Patent under one or more sections of 35 U.S.C. § 271 in this Judicial District and elsewhere in the United States.

25. On information and belief, Gilead's sale, offer for sale, and distribution of sofosbuvir or pharmaceutical compositions containing sofosbuvir will include labeling indicating

that it has been approved by FDA to treat HCV and will instruct end users to administer sofosbuvir to humans to treat HCV. On information and belief, Gilead specifically intends that sofosbuvir be used to treat HCV.

26. The use of Gilead's drugs containing sofosbuvir to treat HCV infections will directly infringe one or more claims of the '054 Patent under 35 U.S.C. § 271(a).

27. On information and belief, this infringing use of Gilead's drugs containing sofosbuvir will be at Gilead's behest, and with its intent, knowledge, and encouragement, and Gilead will actively induce, encourage, contribute to, aid, and abet this administration with knowledge that it is in contravention of the '054 Patent. On information and belief, sofosbuvir has no substantial noninfringing uses, and Gilead knows sofosbuvir is especially made or especially adapted for use in infringement of the '054 Patent.

28. As a result, Gilead will be liable for inducing and/or contributing to infringement of the '054 Patent under 35 U.S.C. §§ 271(b) and/or (c).

29. Plaintiffs will be damaged by Gilead's infringement of the '054 Patent. Plaintiffs will be permitted to recover from Gilead the damages sustained by Plaintiffs as a result of Gilead's wrongful acts.

30. Gilead's infringement will be deliberate and willful, permitting Plaintiffs to seek enhanced damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285. On information and belief, Gilead has knowledge of the Asserted Patents. Gilead's infringement of the '054 Patent will be with full and complete knowledge of the '054 Patent and its applicability to the use of drugs containing sofosbuvir without any attempt to take a license under the '054 Patent and without a good faith belief that the '054 Patent is invalid or not infringed.

31. Plaintiffs will have no adequate remedy at law to redress Gilead's infringement of the '054 Patent.

32. A substantial controversy exists of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Therefore, Plaintiffs seek a judicial determination and declaration that, upon receiving FDA approval, Gilead will contribute to and induce infringement of one or more claims of the '054 Patent by its sale, offer for sale, and distribution in the United States of sofosbuvir or pharmaceutical compositions containing sofosbuvir.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '597 PATENT

33. Plaintiffs reallege and incorporate by reference each of the allegations set forth in Paragraphs 1-32.

34. Gilead's imminent sale, offer for sale, and distribution in the United States of sofosbuvir or pharmaceutical compositions containing sofosbuvir will infringe the '597 Patent under one or more sections of 35 U.S.C. § 271 in this Judicial District and elsewhere in the United States.

35. On information and belief, Gilead's sale, offer for sale, and distribution of sofosbuvir or pharmaceutical compositions containing sofosbuvir will include labeling indicating that it has been approved by FDA to treat HCV and will instruct end users to administer sofosbuvir to humans to treat HCV. On information and belief, Gilead specifically intends that sofosbuvir be used to treat HCV.

36. The use of Gilead's drugs containing sofosbuvir to treat HCV infections will directly infringe one or more claims of the '597 Patent under 35 U.S.C. § 271(a).

37. On information and belief, this infringing use of Gilead's drugs containing sofosbuvir will be at Gilead's behest, and with its intent, knowledge, and encouragement, and

Gilead will actively induce, encourage, contribute to, aid, and abet this administration with knowledge that it is in contravention of the '597 Patent. On information and belief, sofosbuvir has no substantial noninfringing uses, and Gilead knows sofosbuvir is especially made or especially adapted for use in infringement of the '597 Patent.

38. As a result, Gilead will be liable for inducing and/or contributing to infringement of the '597 Patent under 35 U.S.C. §§ 271(b) and/or (c).

39. Plaintiffs will be damaged by Gilead's infringement of the '597 Patent. Plaintiffs will be permitted to recover from Gilead the damages sustained by Plaintiffs as a result of Gilead's wrongful acts.

40. Gilead's infringement will be deliberate and willful, permitting Plaintiffs to seek enhanced damages under 35 U.S.C. § 284 and to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285. On information and belief, Gilead has knowledge of the Asserted Patents. Gilead's infringement of the '597 Patent will be with full and complete knowledge of the '597 Patent and its applicability to the use of drugs containing sofosbuvir without any attempt to take a license under the '597 Patent and without a good faith belief that the '597 Patent is invalid or not infringed.

41. Plaintiffs will have no adequate remedy at law to redress Gilead's infringement of the '597 Patent.

42. A substantial controversy exists of sufficient immediacy and reality to warrant the issuance of a declaratory judgment. Therefore, Plaintiffs seek a judicial determination and declaration that, upon receiving FDA approval, Gilead will contribute to and induce infringement of one or more claims of the '597 Patent by its sale, offer for sale, and distribution in the United States of sofosbuvir or pharmaceutical compositions containing sofosbuvir.

JURY DEMAND

43. Plaintiffs request a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Gilead as follows:

a) Declaring that Gilead's commercial sale and offer for sale of sofosbuvir will contribute to and induce infringement of the '054 Patent;

b) Declaring that Gilead's commercial sale and offer for sale of sofosbuvir will contribute to and induce infringement of the '597 Patent;

c) For an order permanently enjoining Gilead's infringing activities;

d) For an accounting of all damages sustained by Plaintiffs as a result of Gilead's infringing activities;

e) For actual damages together with prejudgment interest;

f) For increased damages pursuant to 35 U.S.C. § 284;

g) For an award of attorneys' fees and costs pursuant to 35 U.S.C. § 285 or as otherwise permitted by law; and

h) For such other and further relief as the Court may deem just and proper.

Dated: December 1, 2013

Respectfully submitted,

IDENIX PHARMACEUTICALS, INC. AND
UNIVERSITA DEGLI STUDI DI CAGLIARI,

By their attorneys,

/s/ Christopher M. Morrison

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