IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IDENIX PHARMACEUTICALS, INC., UNIVERSITA DEGLI STUDI DI CAGLIARI, CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE, and L' UNIVERSITÉ MONTPELLIER II,	)	C.A. No. _____
Plaintiffs,	)	JURY TRIAL DEMANDED
v.	)	
GILEAD SCIENCES, INC. and GILEAD PHARMASSET LLC,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Idenix Pharmaceuticals, Inc. ("Idenix"), Universita Degli Studi di Cagliari ("U. Cagliari"), Centre National de la Recherche Scientifique ("CNRS"), and L' Université Montpellier II ("UMII") (collectively, "Plaintiffs"), for their Complaint against Defendants Gilead Sciences, Inc. ("Gilead Sciences") and Gilead Pharmasset LLC ("Gilead Pharmasset"), hereby allege:

NATURE OF ACTION

1. This is an action for a declaration of patent infringement pursuant to 35 U.S.C. § 271 and for the adjudication of Plaintiffs' priority of invention pursuant to 35 U.S.C. § 291.

THE PARTIES

2. 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.

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

4. CNRS is a French organization under the responsibility of the French Ministry of Higher Education and Research having a location at 3, rue Michel-Ange, F-75794 Paris, Cédex 16, France.

5. UMII is a French university having a location at 2 Place Eugène Bataillon, F-34095 Montpellier Cédex 5, France.

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

7. On information and belief, Defendant Gilead Pharmasset is a limited liability company organized under the laws of the State of Delaware. On information and belief, Gilead Pharmasset's principal place of business is located at 303-A College Road East, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

8. 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.

9. Gilead Sciences is subject to personal jurisdiction in this District because, upon information and belief, Gilead Sciences regularly and continuously transacts business in the District of Delaware, 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 Sciences derives substantial revenue from interstate and/or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of Delaware and this Judicial District.

10. On information and belief, on or before December 8, 2013, Gilead Sciences 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 Sciences will import, sell, offer to sell, and distribute drugs containing sofosbuvir within the State of Delaware that will be used within Delaware to treat HCV infections. By doing so, Gilead Sciences will be committing a tortious act within the State of Delaware, which Gilead Sciences expects or reasonably should expect to have consequences in the State of Delaware. As is set forth more fully herein, Gilead Sciences will infringe a patent owned by Plaintiffs. Given the imminence of Gilead Sciences' tortious acts, a substantial controversy exists between Plaintiffs and Gilead Sciences.

11. Gilead Sciences is also subject to personal jurisdiction in this District because, upon information and belief, Gilead Sciences is a Delaware corporation.

12. Gilead Pharmasset is subject to personal jurisdiction in this District because, upon information and belief, Gilead Pharmasset is a Delaware limited liability company.

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

FACTUAL BACKGROUND

14. 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.

15. 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.

16. 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.

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

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

19. Idenix, U. Cagliari, and CNRS 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. 60/392,350 (filed June 28, 2002); Serial No. 60/466,194 (filed April 28, 2003); and Serial No. 60/470,949 (filed May 14, 2003) (collectively, "the Priority Applications").

20. Non-provisional patent applications were subsequently filed. One of these non-provisional patent applications led to United States Patent No. 7,608,600 ("the '600 Patent"),

which claims priority to the Priority Applications. Plaintiffs are co-owners by assignment of the ’600 Patent. Use of Gilead Sciences’ drugs containing sofosbuvir infringes the ’600 Patent.

PLAINTIFFS’ ASSERTED AND INTERFERING PATENT

21. The ’600 Patent, titled “Modified 2' and 3' Nucleoside Prodrugs For Treating *Flaviviridae* Infections,” was duly and lawfully issued on October 27, 2009. Plaintiffs are owners of, and have the right to enforce, the ’600 Patent. A true and correct copy of the ’600 Patent is attached hereto as Exhibit A.

GILEAD SCIENCES’ IMMINENT INFRINGEMENT

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

23. On October 25, 2013, FDA’s Antiviral Drugs Advisory Committee held a meeting to discuss Gilead Sciences’ 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 Sciences expects and for which Gilead Sciences is actively preparing.

24. Gilead Sciences 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.

25. In its declaratory judgment complaint against Merck and Isis, Gilead Sciences 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 Sciences has undertaken to prepare sufficient quantities for sale upon FDA approval, as described in Gilead Sciences' declaratory judgment complaint against Merck and Isis, fall outside the safe harbor provisions of 35 U.S.C. § 271(e).

26. In anticipation of FDA approval to market and sell drugs containing sofosbuvir, on information and belief, Gilead Sciences 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 Sciences' 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 Sciences to market and sell drugs containing sofosbuvir for treating HCV in the United States in large quantities upon receiving FDA approval.

27. Gilead Sciences' 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 '600 Patent.

GILEAD PHARMASSET'S INTERFERING PATENT

28. On information and belief, United States Patent No. 8,415,322 ("the '322 Patent"), titled "Modified Fluorinated Nucleoside Analogues," issued on April 9, 2013. Gilead Pharmasset is listed as assignee on the face of the '322 Patent. A true and correct copy of the '322 Patent is attached hereto as Exhibit B.

29. The '322 Patent matured from application Serial No. 12/878,262 (filed September 9, 2010), which is a continuation of application Serial No. 12/240,342 (filed September 29, 2008), which is a continuation of application Serial No. 10/828,743 (filed April 21, 2004). The '322 Patent also purports to claim priority to provisional application Serial No. 60/474,368 (filed May 30, 2003).

COUNT I: DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '600 PATENT

30. Plaintiffs reallege and incorporate by reference each of the allegations set forth in Paragraphs 1-29.

31. Gilead Sciences' imminent sale, offer for sale, and distribution in the United States of sofosbuvir or pharmaceutical compositions containing sofosbuvir will infringe the '600

Patent under one or more sections of 35 U.S.C. § 271 in this Judicial District and elsewhere in the United States.

32. On information and belief, Gilead Sciences' 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 Sciences specifically intends that sofosbuvir be used to treat HCV.

33. The use of Gilead Sciences' drugs containing sofosbuvir to treat HCV infections will directly infringe one or more claims of the '600 Patent under 35 U.S.C. § 271(a).

34. On information and belief, this infringing use of Gilead Sciences' drugs containing sofosbuvir will be at Gilead Sciences' behest, and with its intent, knowledge, and encouragement, and Gilead Sciences will actively induce, encourage, contribute to, aid, and abet this administration with knowledge that it is in contravention of the '600 Patent. On information and belief, sofosbuvir has no substantial noninfringing uses, and Gilead Sciences knows sofosbuvir is especially made or especially adapted for use in infringement of the '600 Patent.

35. As a result, Gilead Sciences will be liable for inducing and/or contributing to infringement of the '600 Patent under 35 U.S.C. §§ 271(b) and/or (c).

36. Plaintiffs will be damaged by Gilead Sciences' infringement of the '600 Patent. Plaintiffs will be permitted to recover from Gilead Sciences the damages sustained by Plaintiffs as a result of Gilead Sciences' wrongful acts.

37. Gilead Sciences' 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 Sciences has

knowledge of the ’600 Patent. Gilead Sciences’ infringement of the ’600 Patent will be with full and complete knowledge of the ’600 Patent and its applicability to the use of drugs containing sofosbuvir without any attempt to take a license under the ’600 Patent and without a good faith belief that the ’600 Patent is invalid or not infringed.

38. Plaintiffs will have no adequate remedy at law to redress Gilead Sciences’ infringement of the ’600 Patent.

39. 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 Sciences will contribute to and induce infringement of one or more claims of the ’600 Patent by its sale, offer for sale, and distribution in the United States of sofosbuvir or pharmaceutical compositions containing sofosbuvir.

COUNT II: DECLARATION OF INTERFERENCE BETWEEN THE ’600 PATENT AND THE ’322 PATENT PURSUANT TO 35 U.S.C. § 291

40. Plaintiffs reallege and incorporate by reference each of the allegations set forth in Paragraphs 1-39.

41. The claimed invention of the ’600 Patent was conceived at least as early as December 18, 2001 and was reduced to practice upon filing of the U.S. Provisional Patent Application Serial No. 60/392,350 on June 28, 2002.

42. On information and belief, the ’322 Patent and the ’600 Patent are interfering patents, within the meaning of 35 U.S.C. § 291, in that at least one claim of each patent claims the same or substantially the same subject matter.

43. An interference-in-fact exists between one or more claims of the ’600 Patent and one or more claims of the ’322 Patent.

44. Plaintiffs' '600 Patent has an earlier effective filing date than the purported effective filing date for Gilead Pharmasset's '322 Patent. In patent interferences for the determination of priority by the USPTO, the party with the earlier filing date is the Senior Party and is presumed to be the first to invent. 37 C.F.R. § 41.207(a)(1) ("Parties are presumed to have invented interfering subject matter in the order of the dates of their accorded benefit for each count."); 37 C.F.R. §41.201 ("*Senior party* means the party entitled to the presumption under § 41.207(a)(1) that it is the prior inventor. Any other party is a *junior party*."). Accordingly, Plaintiffs are the Senior Party and Gilead Pharmasset is the Junior Party in determining priority of invention in this § 291 action.

45. Plaintiffs have priority of invention for the claims of the '600 Patent over the claims of the '322 Patent.

46. Because the '600 Patent has priority of invention over the '322 Patent, all of the interfering claims of the '322 Patent are invalid.

JURY DEMAND

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Gilead Sciences and Gilead Pharmasset as follows:

a) Declaring that Gilead Sciences' commercial sale and offer for sale of sofosbuvir will contribute to and induce infringement of the '600 Patent;

b) For an order permanently enjoining Gilead Sciences' infringing activities;

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

d) For actual damages together with prejudgment interest;

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

f) That Plaintiffs be adjudged to be the owner of the invention claimed in the claims of the ’600 Patent;

g) That the ’600 Patent and the ’322 Patent are interfering patents;

h) That the ’600 Patent has priority of invention over the ’322 Patent;

i) That because the ’600 Patent has priority of invention over the claims of the ’322 Patent, the interfering claims of the ’322 Patent are invalid;

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

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

ASHBY & GEDDES

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