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, L' UNIVERSITÉ MONTPELLIER II Plaintiffs, v. GILEAD PHARMASSET LLC, Defendants.	)	C.A. No. _____

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 Defendant Gilead Pharmasset LLC ("Gilead"), hereby allege:

NATURE OF ACTION

1. This is an action under 35 U.S.C. §146 for review and correction of the decision and judgment of priority by the Patent Trial and Appeal Board ("PTAB") of the United States Patent and Trademark Office ("USPTO") in Interference No. 105,871 ("the '871 Interference") between U.S. Patent Application Serial No. 12/131,868 ("the '868 Application") assigned to Plaintiffs and filed in the names of Jean-Pierre Sommadossi, Paolo La Colla, Richard Storer, and Gilles Gosselin ("Sommadossi") and U.S. Patent No. 7,429,572 ("the '572 Patent") (attached hereto) purportedly assigned to Gilead and filed in the name of Jeremy Clark ("Clark") and to decide all issues that were before the USPTO in the '871 Interference.

2. The parties to the ’871 Interference were Sommadossi for the ’868 Application, and Clark for the ’572 patent.

3. 35 U.S.C. §146 permits a real party in interest to bring suit against another real party in interest to challenge the decision and judgment of the PTAB in an interference.

4. The real parties in interest for Sommadossi are Plaintiffs, and the real party in interest for Clark is Gilead.

THE PARTIES

5. 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.

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

7. 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.

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

9. On information and belief, Defendant Gilead is a limited liability company organized under the laws of the State of Delaware. On information and belief, Gilead’s principal place of business is located at 303-A College Road East, Princeton, New Jersey 08540. On information and belief, Gilead’s registered agent for service of process in Delaware is the Corporation Trust Company, whose address is 1209 Orange Street, Wilmington, DE 19801.

JURISDICTION AND VENUE

10. 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 2202, and 35 U.S.C. § 146.

11. Gilead is subject to personal jurisdiction in this District because, on information and belief, Gilead is a Delaware Limited Liability Company and because, upon information and belief, Gilead regularly and continuously transacts business in the District of Delaware.

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

INVENTION BACKGROUND

13. Idenix was founded by Dr. Jean-Pierre Sommadossi as Novirio Pharmaceuticals Limited[1] in May 1998. 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 hepatitis C virus ("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.

14. Idenix worked collaboratively with scientists at CNRS, UMII and U. Cagliari in its antiviral research and development efforts.

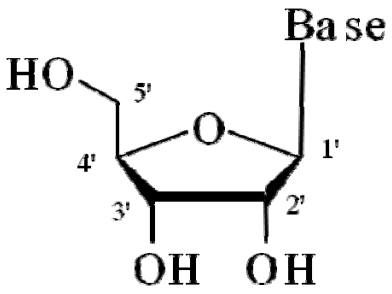
15. HCV is a single stranded RNA virus that causes hepatitis C, a chronic disease of the liver that can lead to cirrhosis and liver cancer. It is estimated that over 150 million people worldwide are infected with HCV.

[1] Novirio Parmaceuticals Limited ("Novirio") was incorporated in the Cayman Islands in May 1998. Novirio changed its name to Idenix Pharmaceuticals, Inc. on May 28, 2002, and domesticated in the state of Delaware on May 30, 2002. For purposes of this complaint, reference to Idenix also includes Novirio.

16. In response to the significant global need for an effective way to treat HCV, a team of researchers led by Dr. Sommadossi focused on the way that HCV RNA replicates in the body in order to find a way to stop the replication process.

17. RNA is comprised of a chain of compounds call nucleosides. The naturally occurring nucleosides in RNA comprise a 5-member sugar ring linked to bases called purines or pyrimidines.

18. The general structure of an RNA nucleoside can be depicted as follows:



19. In such a depiction, called a Haworth projection, the carbon atoms on the sugar ring are represented by vertices, and their locations referenced as 1' through 5'. Groups that are shown above the plane of the ring (e.g. the Base at the 1' position) are said to be in the "up" position, and groups that are shown below the plane of the ring (e.g. the OH at the 2' position) are said to be in the "down" position.

20. U.S. provisional Patent Application Serial No. 60/392,350 ("the '350 Application") was filed on June 28, 2002 disclosing, *inter alia*, nucleosides with modifications at the 2' carbon on the sugar ring, including 2'-Me (up)-2'-F (down) nucleosides.

21. On June 27, 2003, U.S. Patent Application Serial No. 10/608,907 ("the '907 Application") was filed, claiming priority to the '350 Application.

22. On June 2, 2008, the ’868 Application was filed as a divisional of the ’907 Application. The ’868 Application claims priority to the ’907 Application and to the ’350 application.

23. The ’868 Application claims nucleosides with modifications at the 2' carbon position on the sugar ring, including 2'-Me (up)-2'-F (down) nucleosides.

24. Idenix, U. Cagliari, CNRS, and UMII are co-owners by assignment of the ’868 Application.

PHARMASSET BACKGROUND

25. At some point, Pharmasset began investigating nucleosides for anti-HCV activity, which, upon information and belief, occurred after Idenix began investigating nucleosides for anti-HCV activity.

26. On May 30, 2003, U.S. provisional Patent Application No. 60/474,368 (“the ’368 Application”) was filed naming Jeremy Clark and Pharmasset biologist, Lieven Stuyver, as the inventors and disclosing a 2'-Me (up)-2'-F (down) nucleoside.

27. On April 21, 2004, U.S. Patent Application Number 10/828,753 (“the ’753 Application”) was filed claiming priority to the ’368 Application and disclosing a 2'-Me (up)-2'-F (down) nucleoside.

28. The ’753 Application issued as the ’572 Patent on September 30, 2008 with Jeremy Clark named as the sole inventor.

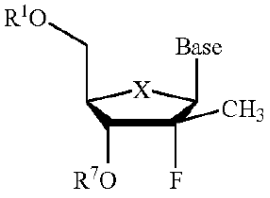
29. On January 17, 2012, Gilead Sciences, Inc., acquired Pharmasset for approximately $11.2 Billion.

INTERFERENCE BACKGROUND

30. On February 22, 2012, the USPTO declared the ’871 Interference between the ’868 Application and the ’572 Patent.

31. The USPTO defined the Count of the ’871 Interference as:

A compound of the formula:



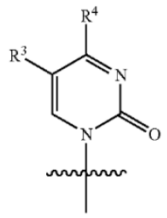
or a pharmaceutically acceptable salt thereof, wherein:

X is O;

R^1 is H, a monophosphate, a diphosphate, a triphosphate, an alkyl, an alkyl sulfonyl, or an arylalkyl sulfonyl;

R^7 is H, a monophosphate, a diphosphate, a triphosphate, an alkyl, an alkyl sulfonyl, or an arylalkyl sulfonyl; and

Base is a pyrimidine represented by the following formula:



wherein,

R^3 is H; and

R^4 is NH_2 or OH.

32. On April 11, 2012, both Sommadossi and Clark filed lists of substantive motions they requested authorization to file.

33. On April 24, 2012, the PTAB issued an Order Authorizing Motions.

34. The Order Authorizing Motions authorized Clark to file certain motions and Sommadossi to file certain motions.

35. On June 18, 2012, the PTAB issued an order authorizing Sommadossi to file a motion in response to Clark's Substantive Motion 6.

36. On July 16, 2012, the PTAB issued an order authorizing Sommadossi to file a miscellaneous motion seeking to amend the specification of the '868 Application.

37. On October 23, 2012, Sommadossi filed Sommadossi Miscellaneous Motion 8 to exclude evidence, and Clark filed Clark Miscellaneous Motion 7 to exclude evidence.

38. On March 22, 2013, the PTAB issued a "Decision on Motions," deciding motions filed in the substantive motions phase of the interference, and a "Redeclaration" ("the Motions Decision").

39. In the Motions Decision, the PTAB ruled on the motions as follows:

Clark Substantive Motion 1: Granted;

Clark Substantive Motion 2: Granted;

Clark Substantive Motion 3: Denied- in-part and dismissed-in-part;

Clark Substantive Motion 6: Dismissed;

Clark Miscellaneous Motion 7: Dismissed-in-part and denied-in-part;

Sommadossi Substantive Motion 1: Denied;

Sommadossi Responsive Motion 6: Dismissed as moot;

Sommadossi Miscellaneous Motion 7: Dismissed as moot; and

Sommadossi Miscellaneous Motion 8: Dismissed.

40. On April 15, 2013, Sommadossi filed a Request for Rehearing, requesting reconsideration of the Motions Decision on Sommadossi Motions 1, 6 and 7 and Clark Motion 2.

41. On April 23, 2013, the PTAB issued a Decision declining to modify its Motions Decision on Clark Motion 2, Sommadossi Motion 1, and Sommadossi Motion 7, but granting reconsideration of Sommadossi Motion 6, but denying the relief sought in it ("the Rehearing Decision").

42. Both the Motions Decision and the Rehearing Decision were erroneous for various reasons, including because they were inconsistent with each other and because they relied on testimony that could not reliably support the holdings.

43. On January 29, 2014, the PTAB issued a "Decision – Priority Bd. R 125(a)" deciding motions in the priority phase of the interference and "Judgment Bd. R. 127" (collectively "the Priority Phase Decision").

44. Plaintiffs are dissatisfied with decisions in the interference, including the Motions Decision, the Rehearing Decision and the Priority Phase Decision.

COUNT I

45. Plaintiffs reallege and incorporate by reference each of the allegations set forth in Paragraphs 1-44.

46. Pursuant to 35 U.S.C. §146, Plaintiffs have elected to file suit in this Court to review and reverse the PTAB's decisions and Judgment and to decide all issues raised before the PTAB. Plaintiffs have not sought review of the PTAB's Decisions by the United States Court of Appeals for the Federal Circuit.

47. The PTAB erred in its decisions in the interference, including in rulings in the Motions Decision, the Rehearing Decision and the Priority Phase Decision.

48. The PTAB's decisions, rulings and Judgment in the '871 Interference are erroneous and, based on the record before the PTAB and any additional evidence Plaintiffs may

introduce in this action, Plaintiffs are entitled to judgment correcting the erroneous decisions and Judgment of the PTAB.

JURY DEMAND

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment against Gilead as follows:

a) Reversing the Board's Decisions and Judgment adverse to Plaintiffs;

b) Awarding priority to Sommadossi et al. with respect to the subject matter of Count 1 the '871 Interference;

c) That all Sommadossi et al. claims corresponding to Count 1 the '871 Interference are patentable to Sommadossi et al.

d) That all Clark claims corresponding to Count 1 of the '871 Interference are not patentable to Clark;

e) Awarding Plaintiffs their costs and fees incurred in this action; and

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

ASHBY & GEDDES

/s/ John G. Day

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