

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IDENIX PHARMACEUTICALS LLC,)
UNIVERSITA DEGLI STUDI DI)
CAGLIARI,)
CENTRE NATIONAL DE LA)
RECHERCHE SCIENTIFIQUE,)
UNIVERSITÉ DE MONTPELLIER)

Plaintiffs,)

v.)

GILEAD PHARMASSET LLC,)

Defendants.)

C.A. No. _____

COMPLAINT

Plaintiffs Idenix Pharmaceuticals LLC (“Idenix”), Universita Degli Studi di Cagliari (“U. Cagliari”), Centre National de la Recherche Scientifique (“CNRS”), and Université de Montpellier (“UM”) (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. 105,981 (“the ’981 Interference”) between U.S. Patent No. 7,608,600 (“the ’600 Patent”) (attached hereto as Exhibit A) assigned to Plaintiffs and filed in the names of Richard Storer, Gilles Gosselin, Jean-Pierre Sommadossi, and Paolo La Colla, and (“Storer”) and U.S. Patent Application Serial No. 11/854,218 (“the ’218 Application”) (attached hereto as Exhibit B) purportedly assigned to Gilead and filed in the name of Jeremy Clark (“Clark”) and to decide all issues relating to the ’981 Interference.

2. The parties to the '981 Interference were Storer for the '600 Patent, and Clark for the '218 Application.

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 Storer are Plaintiffs, and the real party in interest for Clark is Gilead.

THE PARTIES

5. Idenix is a limited liability company 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. UM is a French university having a location at 163 Auguste Broussonnet 34090 Montpellier, 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 333 Lakeside Drive, Foster City, California. 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. § 146.¹

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 Limited² 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

¹ As alleged, Plaintiffs believe that, under a proper reading of the Patent Act, the Court has jurisdiction over this case pursuant to 35 U.S.C. § 146. Plaintiffs are aware that the May 7, 2015 decision of the U.S. Court of Appeals for the Federal Circuit in *Biogen MA, Inc. v. Japanese Foundation for Cancer* may be read as precluding this Court’s jurisdiction. However, the time for filing a petition for panel or en banc rehearing in the *Biogen* case, or for U.S. Supreme Court review of that decision, has not yet run. In addition, the *Biogen* decision may be reversed or modified in another case, including this one. Accordingly, Plaintiffs file this complaint in order to exercise and preserve their right to pursue a Section 146 action. Out of an abundance of caution, Plaintiffs also intend to file a notice of appeal for review of the '981 Interference by the U.S. Court of Appeals for the Federal Circuit under 35 U.S.C. § 141 in order to preserve that alternate avenue of relief in the event that relief under Section 146 is unavailable.

² Novirio Pharmaceuticals 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. Idenix Pharmaceuticals, Inc. converted to Idenix Pharmaceuticals LLC on April 27, 2015. For purposes of this complaint, reference to Idenix also includes Novirio.

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.

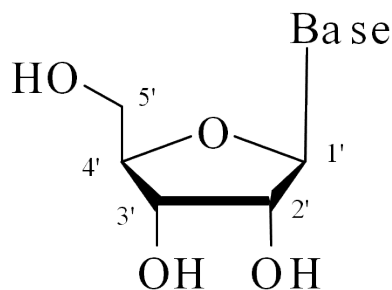
14. Idenix worked collaboratively with scientists at CNRS, UM³ and U. Cagliari in its antiviral research and development efforts.

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.

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

³ L' Université Montpellier II recently combined with Université Montpellier I to form a single entity, Université de Montpellier. Université de Montpellier assumed all goods, rights and obligations of L' Université Montpellier I and II.

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 April 28, 2003, U.S. Provisional Application No. 60/466,194 (“the ’194 Application”) was filed.

22. On May 14, 2003, U.S. Provisional Application No. 60/470,949 (“the ’949 Application”) was filed.

23. On June 27, 2003, U.S. Patent Application Serial No. 10/608,907 (“the ’907 Application”) was filed, claiming priority to the ’949 Application, the ’194 Application, and the ’350 Application.

24. On October 27, 2009, the ’907 Application issued as the ’600 Patent.

25. The ’600 Patent claims methods for using nucleosides with modifications at the 2' carbon position on the sugar ring, including 2'-Me (up)-2'-F (down) nucleosides.

26. Idenix, U. Cagliari, CNRS, and UM are co-owners by assignment of the ’600 Patent.

PHARMASSET BACKGROUND

27. 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.

28. 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.

29. 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.

30. On September 12, 2007, the ’218 Application was filed claiming priority to the ’368 Application and disclosing a 2'-Me (up)-2'-F (down) nucleoside.

31. The ’218 Application named Jeremy Clark as the sole inventor.

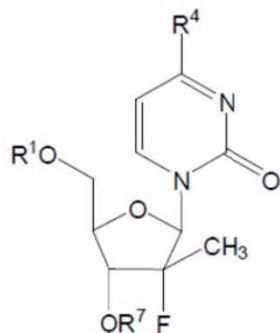
32. On January 17, 2012, Gilead Sciences, Inc., acquired Pharmasset for approximately \$11.2 Billion.

INTERFERENCE BACKGROUND

33. On December 3, 2013, the USPTO declared the ’981 Interference between the ’600 Patent and the ’218 Application.

34. The USPTO defined the Count of the ’981 Interference as:

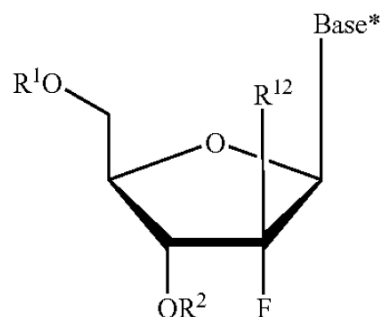
A method for the treatment of hepatitis C infection, which comprises:
administering to a mammal in need thereof an antivirally effective amount of a
(2'R)-2'-deoxy-2'-fluoro-2'-C-methyl nucleoside (β -D or β -L) or its
pharmaceutically acceptable salt of the structure:



wherein R¹ and R⁷ are independently H, a monophosphate, a diphosphate, a triphosphate, a H-phosphonate, an alkyl, an alkyl sulfonyl, or an arylalkyl sulfonyl; and R⁴ is NH₂ or OH.

or

A method for the treatment of a host infected with a hepatitis C virus, comprising administering to the host infected with a hepatitis C virus an effective amount of a compound having the formula:



or a pharmaceutically acceptable salt thereof, wherein:

R¹ is H; mono-, di- or triphosphate; acyl; an amino acid ester; a carbohydrate; a peptide; or a pharmaceutically acceptable leaving group which when administered in vivo provides a compound wherein R¹ is H or phosphate;

R² is H; acyl; an amino acid ester; a carbohydrate; a peptide; or a pharmaceutically acceptable leaving group which when administered in vivo provides a compound wherein R² is H;

Base* is selected from the group consisting of adenine, N⁶-alkylpurine, N⁶-acylpurine, N⁶-benzylpurine, N⁶-halopurine, N⁶-vinylpurine, N⁶-acetylenic purine, N⁶-acyl purine, N⁶-hydroxyalkyl purine, N⁶-alkylaminopurine, N⁶-thioalkyl purine, N²-alkylpurine, N²-alkyl-6-thiopurine, thymine, cytosine, 5-fluorocytosine, 5-methylcytosine, 6-azapyrimidine, 6-azacytosine, 2- and/or 4-mercaptopyrimidine, uracil, 5-halouracil, 5-fluorouracil, C⁵-alkylpyrimidine, C⁵-benzylpyrimidine, C⁵-halopyrimidine, C⁵-vinylpyrimidine, C⁵-acetylenic pyrimidine, C⁵-acyl pyrimidine, C⁵-hydroxyalkyl purine, C⁵-amidopyrimidine, C⁵-cyanopyrimidine, C⁵-iodopyrimidine, C⁶-iodo-pyrimidine, C⁵-Br-vinyl pyrimidine, C⁶-Br-vinyl pyrimidine, C⁵-nitropyrimidine, C⁶-amino-pyrimidine, N²-alkylpurine, N²-alkyl-6-thiopurine, 5-azacytidinyl, 5-azauracilyl, triazolopyridinyl, imidazolopyridinyl, pyrrolopyrimidinyl, pyrazolopyrimidinyl, guanine, hypoxanthine, 2,6-diaminopurine, and 6-choropurine;

R¹² is C(Y³)₃; and

Y³ is independently H or F.

35. On January 7, 2014, both Storer and Clark filed lists of substantive motions they requested authorization to file.

36. On January 16, 2014, the PTAB denied Storer's request to enter into the record in the '981 Interference an Order by the Federal Court of Canada that "addressed issues concerning inventorship of the object of the interfering claims and Storer's allegations of inequitable

conduct and derivation of the claimed invention.” The PTAB’s denial was without prejudice as to the “Canadian order being relied upon as evidence only after a relevant motion has been authorized.”

37. On January 21, 2014, the PTAB issued “Order Motion Times Bd.R. 104(c)” (“January 21, 2014 Order”).

38. The January 21, 2014 Order authorized Clark to file certain motions and Storer to file certain motions. The January 21, 2014 Order also deferred authorization for Clark to file certain motions and Storer to file certain motions. This included deferring authorization to file Storer Motion No. 3 as to designating certain Storer claims as not corresponding to Count 1 because Storer invented the claims before Clark’s earliest possible date of invention for certain Clark claims (“Storer Motion No. 3”). This also included deferring authorization to file Storer Motion No. 4, which is contingent on Storer Motion No. 3 and sought to substitute Count 1 with proposed Count A (“Storer Motion No. 4”). In addition, the January 21, 2014 Order denied authorized for Clark to file certain motions.

39. On January 28, 2014, the PTAB issued “Order—Miscellaneous—Bd.R. 104(a)” (“January 28, 2014 Order”).

40. The January 28, 2014 Order clarified that the motions deferred in its January 21, 2014 Order are not authorized for any later time period and authorization from the Board must be sought prior to filing them. The January 28, 2014 Order also deferred all proposed motions with respect to inventorship and corresponding discovery until the priority phase of the ’981 Interference. In addition, the January 28, 2014 Order stayed, pending final judgment in Interference No. 105,871, any decisions with respect to Clark’s proposed motion addressing the

benefit claimed by Storer in Interference No. 105,871 and Storer's request for reconsideration of the deferral of Storer Motion No. 3 and Storer Motion No. 4.

41. On January 29, 2014, the PTAB issued a "Decision – Priority Bd. R 125(a)" deciding motions in the priority phase of Interference No. 105,871 and "Judgment Bd. R. 127" (collectively "the Priority Phase Decision").

42. Dissatisfied with decisions in Interference No. 105,871, including the Priority Phase Decision and the PTAB's rulings denying or dismissing Storer's Substantive, Responsive, and Miscellaneous Motions, Plaintiff appealed to this Court in the currently pending Case No. 1:14-cv-00109-LPS, filed on January 29, 2014.

43. On February 4, 2014, Storer requested rehearing of the January 21, 2014 Order and the January 28, 2014 Order, such that the PTAB "authorize" Storer Motion No. 3 and Storer Motion No. 4 and that the PTAB deem "not authorized" Clark's requested motions attacking Storer's inventorship and addressing the benefit claimed by Storer in Interference 105,871.

44. On February 5, 2014, the PTAB issued "Order to Show Cause – Bd.R. 104(a); 127(a)" ("Show Cause Order").

45. The Show Cause Order estopped Storer from presenting additional evidence to show that it is entitled to priority benefit of the '907 application based on the Priority Phase Decision in the Interference No. 105,871. The Show Cause Order also ordered Storer to show cause why judgment should not be entered against it in the '981 Interference.

46. On February 21, 2014, Storer moved for leave to file a Request for Certificate of Correction to correct typographical errors made by the USPTO in the '600 Patent ("Miscellaneous Motion No. 13").

47. On February 27, 2014, the PTAB granted Storer's request for rehearing of the January 21, 2014 Order but denied the request to reverse ("February 27, 2014 Order"). The February 27, 2014 Order further denied authorization for Storer to file Motion No. 3 and Storer Motion No. 4.

48. On March 10, 2014 Storer filed a response to the Show Cause Order.

49. On April 11, 2014, the PTAB issued an order finding that Storer had shown sufficient cause why judgment should not be entered against it.

50. On January 16, 2015, the PTAB issued a Decision on Motions, deciding motions filed in the substantive motions phase of the interference ("the Motions Decision").

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

Clark Substantive Motion 1 to deprive Storer of the benefit of its U.S. Appl. No.

60/392,350: GRANTED;

Clark Substantive Motion 2 to deprive Storer of the benefit accorded with respect to

Count 1 of its U.S. Appl. No. 60/466,194: GRANTED;

Clark Substantive Motion 3 to deprive Storer of the benefit accorded with respect to

Count 1 of its U.S. Appl. No. 60/470,949: GRANTED;

Clark Substantive Motion 7 for judgment against Storer's US Patent No. 7,608,600 B2 on

the grounds of unpatentability under 35 U.S.C. § 112, 1st paragraph, for lack of enablement and written description: GRANTED;

Clark Substantive Motion 10 to deprive Storer of the benefit accorded with respect to

Count 1 of US Appl. No. 10/6018,907: NOT DECIDED;

Clark Substantive Motion 5 to substitute Clark's proposed count 2 or, alternatively,

Clark's proposed count 3, for Count 1: NOT DECIDED;

Clark Substantive Motion 8 for judgment against Storer's US Patent No. 7,608,600 B2 on the ground of unpatentability under 35 U.S.C. § 101, for lack of utility and, accordingly, under 35 U.S.C. § 112, 1st paragraph, for lack of enablement: DISMISSED;

Clark Substantive Motion 9 for judgment against Storer's US Patent No. 7,608,600 B2 on the ground of unpatentability under 35 U.S.C. §§ 102(e) or 103 as being either anticipated by, or obvious over, Clark's US Appl. No. 10/828,753: NOT DECIDED;

Storer Substantive Motion 5 to substitute proposed count B for Count 1: DENIED;

Storer Substantive Motion 11 for judgment against Clark on the grounds of unpatentability of all of Clark's involved claims as anticipated under 35 U.S.C. § 102(e) and/or 103: DENIED;

Storer Contingent Motion 14 to add a new claim to the interference: DENIED; and

Storer Contingent Motion 15 to add an application to the interference: NOT DECIDED.

52. On January 16, 2015, the PTAB issued a "REDECLARATION — BD.R. 203(c)" ("Redeclaration").

53. The Redeclaration designated Clark as the senior party and Storer as the junior party. The Redeclaration also redefined the count as the method of 11/854,218, claim 164.

54. On January 16, 2015, the PTAB issued a second "Order to Show Cause – Bd.R. 104(a)" ("Second Show Cause Order").

55. The Second Show Cause Order ordered Storer to show cause why judgment should not be entered against Storer's involved claims of Patent 7,608,600 based on the priority determination in Interference 105,871.

56. On February 20, 2015, Storer filed a response to the Second Show Cause Order.

57. On February 27, 2015, Storer emailed the PTAB to advise Judge New that Storer would not be filing a priority motion.

58. On March 23, 2015, the PTAB issued Judgment against Storer's involved claims of Patent 7,608,600 ("Judgment").

59. Plaintiffs are dissatisfied with decisions in the '981 Interference, including the Motions Decision and the PTAB's January 21, 2014, January 28, 2014, and February 27, 2014 Orders.

COUNT I

60. Plaintiffs reallege and incorporate by reference each of the allegations set forth in Paragraphs 1-59.

61. 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 relating to the '981 Interference. As of this date, Plaintiffs have not sought review of the PTAB's Decisions by the United States Court of Appeals for the Federal Circuit (*see* footnote 1).

62. The PTAB erred in its decisions in the interference, including in rulings in the Motions Decision and the PTAB's January 21, 2014, January 28, 2014, and February 27, 2014 Orders.

63. The PTAB's decisions, rulings and Judgment in the '981 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

64. 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 Storer et al. with respect to the subject matter of the '981

Interference;

- c) That all relevant Storer et al. claims are patentable to Storer et al.
- d) That all relevant Clark claims 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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Dated: May 21, 2015