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'UNIVERSITE MONTPELLIER II, Plaintiffs, v. GILEAD SCIENCES, INC. and GILEAD PHARMASSET LLC, Defendants.	C.A. No. 13-1987 (LPS-CJB) **JURY TRIAL DEMANDED**

DEFENDANTS' FIRST AMENDED
ANSWER AND COUNTERCLAIMS TO COMPLAINT

Defendants Gilead Sciences, Inc. ("Gilead Sciences") and Gilead Pharmasset LLC ("Gilead Pharmasset") (collectively, "Gilead" or "Defendants"), by and through their attorneys, hereby file this First Amended Answer and Counterclaims to the numbered allegations of the Complaint of 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"), setting forth their affirmative defenses thereto and alleging Counterclaims below. Gilead denies the allegations and characterizations in Plaintiffs' Complaint unless expressly admitted in the following paragraphs:

NATURE OF ACTION

1. Gilead admits that the Complaint purports to state claims for a declaration of patent infringement pursuant to 35 U.S.C. § 271 and for adjudication of Plaintiffs' priority of invention pursuant to 35 U.S.C. § 291.

THE PARTIES

2. On information and belief, Gilead admits that Idenix is a Delaware Corporation with U.S. Corporate Headquarters at 320 Bent Street, Cambridge, Massachusetts 02141.

3. On information and belief, Gilead admits that U. Cagliari is an Italian university located at Via Università 40, Cagliari, Sardinia, Italy, 09124.

4. On information and belief, Gilead admits that CNRS is a French organization located at 3, rue Michel-Ange, F-75794 Paris, Cédex 16, France. Gilead is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 4 of the Complaint, and therefore denies the same.

5. On information and belief, Gilead admits that UMII is a French university located at 2 Place Eugène Bataillon, F-34095 Montpellier Cédex 5, France.

6. Gilead admits the allegations set forth in Paragraph 6 of the Complaint.

7. Gilead admits that Gilead Pharmasset is a limited liability company organized under the laws of the State of Delaware. Gilead denies the remaining allegations set forth in Paragraph 7 of the Complaint.

JURISDICTION AND VENUE

8. Gilead admits that the Complaint purports to state claims of patent infringement that arise under the patent laws of the United States, Title 35 of the United States Code. Gilead admits that the Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202. Gilead denies that the Plaintiffs are entitled to any relief pursuant to the claims.

9. Paragraph 9 contains legal conclusions to which no answer is required. To the extent that an answer is required, Gilead admits that Gilead Sciences is subject to personal

jurisdiction in this Judicial District for the limited purposes of this action only. Gilead denies the remaining allegations of Paragraph 9 of the Complaint.

10. Gilead admits that on December 6, 2013, the United States Food and Drug Administration ("FDA") approved sofosbuvir, which is a hepatitis C nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C infection, as a component of a combination antiviral treatment regimen. Gilead admits that Gilead Sciences is marketing sofosbuvir as Sovaldi® in the United States, including in the State of Delaware. Gilead admits that Plaintiffs claim that a substantial controversy exists between Plaintiffs and Gilead Sciences, but specifically denies that Gilead Sciences will commit (or has committed) a tortious act or will infringe (or has infringed) any valid patent owned by Plaintiffs as a result of any actions in this Jurisdiction pertaining to sofosbuvir or otherwise. Gilead denies the remaining allegations of Paragraph 10 of the Complaint.

11. Gilead admits that Gilead Sciences is a corporation organized under the laws of the State of Delaware and admits that Gilead Sciences is subject to personal jurisdiction in this Judicial District for the limited purposes of this action only. Gilead denies the remaining allegations of Paragraph 11 of the Complaint.

12. Gilead admits that Gilead Pharmasset is a limited liability company organized under the laws of the State of Delaware and admits that Gilead Pharmasset is subject to personal jurisdiction in this Judicial District for the limited purposes of this action only. Gilead denies the remaining allegations of Paragraph 12 of the Complaint.

13. Gilead admits venue is proper in this Judicial District for this action.

FACTUAL BACKGROUND

14. Upon information and belief, Gilead admits that Idenix is a biopharmaceutical company conducting research in the area of human viral diseases. Gilead is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 14, and therefore denies the same.

15. Gilead admits that hepatitis C virus ("HCV") is highly contagious and can lead to serious liver damage. Gilead admits that HCV is a group of related viruses classified into at least six distinct HCV genotypes (genotypes 1-6). Gilead admits that at this time Genotype (GT) 1 is most prevalent in the United States and that GT 2 and GT 3 are also observed, while GT 4, GT 5, and GT 6 are more prevalent in Africa and Asia. Gilead denies the remaining allegations set forth in Paragraph 15 of the Complaint.

16. Gilead is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 16 of the Complaint, and therefore denies the same.

17. Gilead is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 17 of the Complaint, and therefore denies the same.

18. Gilead is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 18 of the Complaint, and therefore denies the same.

19. Gilead is without knowledge or information sufficient to form a belief as to the truth of the allegations set forth in Paragraph 19 of the Complaint, and therefore denies the same.

20. Gilead admits that a non-provisional patent application was filed that led to United States Patent No. 7,608,600 ("the '600 patent"). Gilead admits that the '600 patent purports to claim priority to Provisional Application Nos. 60/392,350, 60/466,194 and 60/470,949 but denies that the '600 patent is entitled to any of these claims of priority. Gilead

specifically denies that Gilead Sciences' drugs or the use of Gilead Sciences' drugs containing sofosbuvir infringe any valid claim of the '600 patent. Except as expressly admitted, Gilead denies the remaining allegations set forth in Paragraph 20 of the Complaint.

THE ASSERTED AND ALLEGEDLY INTERFERING PATENT

21. Gilead admits that Exhibit A to the Complaint appears to be a copy of the '600 patent, entitled "MODIFIED 2' AND 3'-NUCLEOSIDE PRODRUGS FOR TREATING *FLAVIVIRIDAE* INFECTIONS," issued on October 27, 2009, and listing Plaintiffs as the assignees. Gilead denies that the '600 patent was "duly and lawfully issued." Gilead is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in Paragraph 21 of the Complaint, and therefore denies the same.

ALLEGED INFRINGEMENT

22. Gilead admits that Gilead Sciences submitted a New Drug Application ("NDA") to the FDA for approval of sofosbuvir on April 8, 2013. Gilead also admits that on June 7, 2013, it issued a press release announcing that "the U.S. Food and Drug Administration (FDA) has granted priority review to the company's New Drug Application (NDA) for sofosbuvir, a once-daily oral nucleotide analogue inhibitor for the treatment of chronic hepatitis C virus (HCV) infection" and that "FDA has set a target review date under the Prescription Drug User Fee Act (PDUFA) of December 8, 2013." Except as expressly admitted, Gilead denies the remaining allegations of Paragraph 22 of the Complaint.

23. Gilead admits that during an October 25, 2013 meeting, the Antiviral Drugs Advisory Committee of the FDA voted unanimously (15-0) that the available data support approval of once-daily sofosbuvir in combination with ribavirin for the treatment of chronic hepatitis C in adult patients with genotype 2 and 3 infection and voted unanimously (15-0) that

the available data support approval of sofosbuvir in combination with pegylated interferon and ribavirin for the treatment of chronic hepatitis C in treatment-naïve adult patients with genotype 1 and 4 infection. Except as expressly admitted, Gilead denies the remaining allegations set forth in Paragraph 23 of the Complaint.

24. Gilead admits 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 in the Northern District of California, seeking, among other things, a declaration of non-infringement and invalidity related to U.S. Patent No. 7,105,499 and U.S. Patent No. 8,481,712. Except as expressly admitted, Gilead denies the remaining allegations of Paragraph 24 of the Complaint.

25. Gilead admits that 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, including manufacturing sufficient quantities for sale upon FDA approval." The remaining allegations in Paragraph 25 of the Complaint contain legal conclusions to which no answer is required. To the extent that an answer is required, Gilead denies the remaining allegations of Paragraph 25 of the Complaint.

26. Gilead admits that Gilead Sciences is currently marketing sofosbuvir in the United States as Sovaldi®, and that Gilead Sciences made preparations to do so prior to receiving FDA approval on December 6, 2013. Except as expressly admitted, Gilead denies the remaining allegations of Paragraph 26.

27. Gilead specifically denies that Gilead Sciences will indirectly infringe (or is indirectly infringing) any valid claims of the '600 patent based on its activities with respect to sofosbuvir. The remaining allegations in Paragraph 27 of the Complaint contain legal

conclusions to which no response is required. To the extent a response is required, Gilead denies the allegations in Paragraph 27 of the Complaint.

GILEAD PHARMASSET'S ALLEGEDLY INTERFERING PATENT

28. Gilead admits that Exhibit B to the Complaint is a copy of United States Patent No. 8,415,322 ("the '322 patent"), entitled "MODIFIED FLUORINATED NUCLEOSIDE ANALOGUES," issued on April 9, 2013 and listing Gilead Pharmasset LLC as the assignee.

29. Gilead admits that the '322 patent issued from U.S. patent application Ser. No. 12/878,262 filed on September 9, 2010, which is a continuation of U.S. patent application Ser. No. 12/240,342, filed September 29, 2008, which is a continuation of U.S. patent application Ser. No. 10/828,753, filed April 21, 2004. Gilead also admits that the '322 patent claims priority to U.S. Provisional Application No. 60/474,368, filed May 30, 2003. Except as expressly admitted, Gilead denies the remaining allegations of Paragraph 29 of the Complaint.

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

30. Gilead realleges and incorporates by reference each of its answers set forth in Paragraphs 1-29.

31. Denied.

32. Gilead admits that the FDA approved label for Sovaldi® (sofosbuvir) states that "SOVALDI is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen." Gilead denies the remaining allegations of Paragraph 32 of the Complaint.

33. Denied.

34. Denied.

35. Denied.

36. Denied.

37. Gilead admits that Gilead Sciences has knowledge of the ’600 patent. Gilead denies the remaining allegations of Paragraph 37 of the Complaint.

38. Denied.

39. Paragraph 39 contains legal conclusions to which no answer is required. To the extent that an answer is required, Gilead admits that a substantial controversy exists as to whether Gilead Sciences infringes the ’600 patent and whether the ’600 patent is invalid, but Gilead specifically denies that Gilead infringes any valid claim of the ’600 patent. Gilead denies the remaining allegations set forth in Paragraph 39 of the Complaint.

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

40. Gilead realleges and incorporates by reference each of its answers set forth in Paragraphs 1-39.

41. Denied.

42. Paragraph 42 contains legal conclusions to which no answer is required. To the extent that an answer is required, Gilead admits that Plaintiffs purport that the ’322 patent and the ’600 patent are interfering patents within the meaning of 35 U.S.C. § 291. Gilead denies the remaining allegations set forth in Paragraph 42 of the Complaint.

43. Paragraph 43 contains legal conclusions to which no answer is required. To the extent that an answer is required, Gilead admits that Plaintiffs purport that an interference-in-fact exists between one or more claims of the ’322 patent and one or more claims of the ’600 patent. Gilead denies the remaining allegations set forth in Paragraph 43 of the Complaint.

44. Gilead specifically denies that Plaintiffs are the Senior Party and Gilead Pharmasset is the Junior Party in determining priority of invention in this § 291 action. The remaining allegations in Paragraph 44 of the Complaint contain legal conclusions to which no answer is required. To the extent that an answer is required, Gilead denies the allegations of Paragraph 44 of the Complaint.

45. Denied.

46. Denied.

JURY DEMAND

47. Paragraph 47 does not require a response by Gilead.

PRAYER FOR RELIEF

Gilead denies that Plaintiffs are entitled to relief of any kind and requests that the Court deny all relief to Plaintiffs, including that requested by Plaintiffs in their Prayer for Relief.

AFFIRMATIVE DEFENSES

Gilead asserts the following affirmative defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Gilead reserves the right to amend its Answer to add additional affirmative defenses, including claims of inequitable conduct, consistent with the facts discovered in this case.

First Affirmative Defense (Invalidity)

48. The claims of the asserted ’600 patent are invalid for failure to satisfy one or more of the conditions of patentability set forth in Title 35 of the United States Code, including without limitation §§ 101, 102, 103, and/or 112, as well as relevant provisions governing proceedings before the United States Patent and Trademark Office.

Second Affirmative Defense
(Noninfringement)

49. Gilead Sciences' manufacture, use, sale, offer for sale, or importation into the United States of sofosbuvir or pharmaceutical compositions containing sofosbuvir does not and will not directly, indirectly, contributorily and/or by inducement, infringe any valid claim of the '600 patent, either literally or under the doctrine of equivalents.

Third Affirmative Defense
(Lack of Priority)

50. The '322 patent has priority of invention over the '600 patent.

Fourth Affirmative Defense
(Derivation)

51. The claims of the '600 patent are invalid under 35 U.S.C. § 102(f) because the claimed invention(s) were derived and/or misappropriated from the true inventor, Jeremy Clark.

Fifth Affirmative Defense
(Laches/Estoppel)

52. Plaintiffs' claims for relief are barred under the doctrines of laches and/or estoppel.

Sixth Affirmative Defense

(Limitation on Damages and Costs)

53. Plaintiffs' claims for relief are limited by 35 U.S.C. §§ 286, 287, and/or 288.

Seventh Affirmative Defense
(No Injunction or Enhanced Damages)

54. Plaintiffs are not entitled to injunctive relief or enhanced damages because they have failed to plead the required elements for such relief, and because Plaintiffs have an adequate remedy at law for any alleged injury.

GILEAD SCIENCES'S COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Gilead Sciences, Inc. ("Gilead Sciences") asserts Counterclaims for a declaratory judgment of non-infringement and invalidity of United States Patent No. 7,608,600 ("the '600 patent") under 28 U.S.C. §§ 2201 and 2202. Gilead Sciences reserves the right to further amend its Counterclaims, including claims of inequitable conduct, consistent with the facts discovered in the case. Gilead Sciences, for its Counterclaims, alleges as follows:

PARTIES

1. Gilead Sciences is a company organized and existing under the laws of the State of Delaware with its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

2. On information and belief, Idenix Pharmaceuticals, Inc. ("Idenix") is a Delaware Corporation with U.S. Corporate Headquarters at 320 Bent Street, Cambridge, Massachusetts. On information and belief, Idenix is a wholly-owned subsidiary of Merck & Co., Inc., a New Jersey Corporation with corporate headquarters at One Merck Drive, P.O. Box 100, Whitehouse Station, New Jersey 08889.

3. On information and belief, Universita Degli Studi Di Cagliari ("U. Cagliari") is an Italian university located at Via Università 40, Cagliari, Sardinia, Italy, 09124.

4. On information and belief, Centre National de la Recherche Scientifique ("CNRS") is a French organization located at 3, rue Michel-Ange, F-75794 Paris, Cédex 16, France.

5. On information and belief, L'Université Montpellier II ("UMII") is a French university having a location at 2 Place Eugène Bataillon, F-34095 Montpellier Cédex 5, France.

THE ’600 PATENT

6. On October 27, 2009, the ’600 patent entitled “Modified 2’ and 3’-Nucleoside Prodrugs for Treating *Flaviviridae* Infections” issued to Richard Storer, Gilles Gosselin, Jean-Pierre Sommadossi and Paola LaColla. A copy of the ’600 patent is attached as Exhibit A to the Complaint.

7. Idenix, U. Cagliari, CNRS and UMII are listed as assignees on the face of the ’600 patent.

JURISDICTION AND VENUE

8. Gilead Sciences’ counterclaims for Declaratory Judgment arise under the patent laws of the United States, 35 U.S.C. §§ 101 *et seq*. Gilead Sciences is seeking relief pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. §§ 2201(a) and 2202.

9. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338.

10. This Court has personal jurisdiction over Idenix, U. Cagliari, CNRS, and UMII (together, “Plaintiffs” or “Counterclaim Defendants”) because they have all voluntarily submitted themselves to the jurisdiction of this Court as a result of filing their Complaint for patent infringement against Gilead Sciences in this Court and a Complaint under 35 U.S.C. § 146 on January 29, 2014 against Gilead Pharmasset LLC (“Gilead Pharmasset,” a subsidiary of Gilead Sciences) Case No. 14-109 (D. Del.).

11. Venue is proper in this judicial district for Gilead Sciences’ counterclaims because Counterclaim Defendants, Idenix, U. Cagliari, CNRS, and UMII consented to this venue by asserting and filing claims of patent infringement against Gilead Sciences and Gilead

Pharmasset and by virtue of Counterclaim Defendants' admission in at least paragraph 13 of the Complaint that venue is proper in this district.

FACTUAL BACKGROUND

Gilead Sciences' Sofosbuvir Drug

12. Gilead Sciences is a research-based biopharmaceutical company that discovers, develops, and commercializes innovative medicines for life-threatening diseases in areas of unmet medical need, including treatment for HIV/AIDS, hepatitis, serious respiratory and cardiovascular conditions, cancer, and inflammation.

13. Hepatitis C virus ("HCV") is a group of related viruses that infect the liver and are classified into at least six distinct HCV genotypes (genotypes 1-6) that are spread by contact with HCV-infected blood. The prevalence of HCV infection in the U.S. has been estimated between 3.2 and 5.2 million people. Since 2007, there have been more deaths in the U.S. due to HCV than HIV. HCV infection is the cause of half of all liver cancer deaths in the U.S. and the most common indication for liver transplants. For every 100 people infected with HCV, 75-85 will develop chronic infection and 60-70 will suffer from HCV-related complications including chronic liver disease, cirrhosis, and death.

14. Traditionally, chronic HCV infection has been treated with a combination of antiviral medicines—ribavirin, interferons, and, more recently, protease inhibitors. In addition to relatively limited efficacy, these available treatments have frequent, debilitating and, at times, permanent side effects. Moreover, these treatments must be taken for prolonged periods—24 to 48 weeks—thereby exacerbating the physical and emotional toll on the infected individuals and their families, which often lead to patient discontinuation of treatment. While liver transplantation can be life-saving for HCV-infected individuals in end-stage liver disease,

transplantation presents significant risks and is not a readily available option. Even when available, transplantation is costly and requires ongoing post-procedure care, and for HCV positive transplant recipients, reinfection is almost universal.

15. Gilead Sciences has developed sofosbuvir, a hepatitis C virus nucleotide analogue NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C infection.

16. On April 8, 2013, Gilead Sciences filed a New Drug Application ("NDA") with the United States Food and Drug Administration ("FDA") seeking approval of sofosbuvir as a once-daily oral therapy for chronic HCV infection. The data submitted in the NDA support the use of sofosbuvir and ribavirin together as an oral therapy for patients with genotype 2 and 3 HCV infection, and for sofosbuvir in combination with ribavirin and pegylated interferon for treatment-naïve patients with genotype 1 and 4 HCV infection (hereinafter "sofosbuvir NDA").

17. The FDA approved once daily Sovaldi® (sofosbuvir) 400 mg tablets for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen on December 6, 2013.

Idenix and HCV

18. Idenix is a biopharmaceutical company. On information and belief, Idenix monitors the drug-development pipelines, clinical trials, and acquisitions of competitor pharmaceutical companies, including activities related to potential therapeutic products for the treatment of HCV infection. On information and belief, Idenix has monitored and continues to monitor such activities as related to Gilead Sciences.

19. Both Gilead Sciences and Idenix are active litigants against one another in the HCV space. There are pending litigations in the United Kingdom, Germany, Norway, France, Canada, Australia, and, now, the United States related to Gilead Sciences' sofosbuvir drug and to

both Idenix's and Gilead Sciences' patents on certain nucleosides and methods for the treatment of hepatitis C.

20. On December 1, 2013, Idenix filed this suit against Gilead Sciences alleging that the sale, offer for sale or distribution of sofosbuvir will infringe the claims of the '600 patent.

21. Gilead Sciences has the right to manufacture, use, offer to sell, sell and/or import sofosbuvir without a license to the '600 patent.

22. The facts alleged herein show that a substantial controversy exists between Gilead Sciences and Idenix, parties having adverse legal interests, regarding the validity and alleged infringement of the'600 patent.

23. The Court may and should exercise its broad discretion to adjudicate this action under the Declaratory Judgment Act. There is no better or more effective remedy or forum for resolving the present controversies between the parties regarding sofosbuvir. Such adjudication will serve the underlying purpose of the Declaratory Judgment Act by resolving legal disputes between Gilead Sciences and Counterclaim Defendants regarding Gilead Sciences' legal right to manufacture, sell, offer to sell, and import sofosbuvir. It will also serve the public interest by settling the adverse legal rights between Gilead Sciences and Counterclaim Defendants as it relates to the availability of a promising new treatment of chronic hepatitis C infection as a component of a combination antiviral treatment regimen. These disputes should be resolved efficiently and economically in this action, deciding the controversies between the parties with certainty, completeness, and finality.

The Pending Interferences between Gilead Pharmasset and Counterclaim Defendants

24. On February 22, 2012, the U.S. Patent and Trademark Office ("PTO") Issued a Declaration of Interference Number 105,871 ("the '871 interference" or the "first interference")

between Gilead Pharmasset's U.S. Patent No. 7,429,572 ("the '572 patent") and Counterclaim Defendants' U.S. Patent Application No. 12/131,868 ("the '868 application"). In the Declaration, Jeremy Clark, named inventor of the '572 patent, was initially identified as the junior party. Jean-Pierre Sommadossi, Paolo LaColla, Richard Storer, and Gilles Gosselin, who are named as inventors of the '868 application, were initially identified as the senior party. As detailed more fully below, as a result of motion practice in the first interference, Idenix's '868 application was denied the benefit of earlier filed applications because they failed to enable one of skill in the art to practice the embodiment disclosed in the interference count. As a result, Jeremy Clark was named as the senior party.

25. Gilead Pharmasset, Defendant in the present litigation and subsidiary of Gilead Sciences, is identified as the real party-in-interest to the '572 patent and is identified as "Clark" in the first interference.

26. Counterclaim Defendants are identified as the real parties-in-interest to the '868 application and is identified as "Sommadossi" in the first interference.

27. Gilead Pharmasset's '322 patent, the patent in the present § 291 action, is related to Gilead Pharmasset's '572 patent, the patent at issue in the first interference. The '322 patent claims priority to U.S. Provisional Application No. 60/474,368 ("the '368 application"), filed on May 30, 2003.

28. Counterclaim Defendants' '868 application at issue in the first interference purports to be related to the '600 patent, which is at issue in the § 291 proceeding before this Court. The '868 application states that it is a divisional of U.S. Patent Application No. 10/608,907 ("the '907 application"), which issued as the '600 patent. The '868 application, like

the ’600 patent, is entitled “MODIFIED 2’ AND 3’-NUCLEOSIDE PRODRUGS FOR TREATING *FLAVIVIRIDAE* INFECTIONS” and was filed on June 2, 2008.

29. During the first interference, Counterclaim Defendants filed several motions, including a motion for benefit of priority to U.S. Patent Application No. 60/392,350 (“the ’350 application”). Both the ’600 patent and the ’868 application purport to claim priority to the ’350 application.

30. During the first interference, Gilead Pharmasset filed several motions, including:

a. a motion for benefit of priority to the ’368 application (Clark Substantive Motion 1);

b. a motion to deny Counterclaim Defendants the accorded benefit of the ’907 application (Clark Substantive Motion 2);

c. a motion for judgment that all of Counterclaim Defendants’ claims are barred by repose under 135(b)(2) over U.S. Patent Application Publication No. 2005/0009737 and the ’572 patent (Clark Substantive Motion 3); and

d. a motion for judgment that Counterclaim Defendants’ claims are invalid for lack of utility under 35 U.S.C. § 101 and lack of written description and enablement under 35 U.S.C. § 112 because, *inter alia*, there is no evidence within the disclosure that the claimed compounds have anti-HCV activity, the disclosure does not teach how to synthesize any of the claimed compounds, and there is no disclosure in the specification of any specific compound that falls within the scope of the claims (Clark Substantive Motion 6);

31. On March 22, 2013, the Patent Trial and Appeal Board (“PTAB”) issued an Order deciding Counterclaim Defendants’ and Gilead Pharmasset’s motions. Specifically, the PTAB

denied Counterclaim Defendants' motion to be accorded benefit to the '350 application and granted Gilead Pharmasset's motion to deny Counterclaim Defendants the accorded benefit of the '907 application. In so doing, the PTAB concluded that the '907 application "is not enabling for an embodiment encompassed by" the Count of the first interference. (March 22, 2013 Decision on Motions, Paper 426 at 25, attached hereto as Exhibit 1)

32. The PTAB vacated the benefit accorded to Counterclaims Defendants in the Declaration of Interference as to the '907 application and denied Counterclaim Defendants benefit to the '350 application. As a result, the PTAB concluded Counterclaim Defendants were not entitled to any priority date prior to June 2, 2008—the filing date of the '868 application.

33. The PTAB granted Gilead Pharmasset's motion to be accorded benefit of the filing date of the '368 application—May 30, 2003.

34. Having determined that Counterclaim Defendants were not entitled to any priority date earlier than June 2, 2008, while Gilead Pharmasset was entitled to a priority date of May 30, 2003, the PTAB redesignated the parties. On March 22, 2013, the PTAB issued a redeclaration designating Clark (Gilead Pharmasset) senior party and Sommadossi (Counterclaim Defendants) junior party for all further proceedings in the first interference, thus shifting the burden of proof to Sommadossi.

35. On January 29, 2014 the PTAB issued a judgment against Counterclaim Defendants refusing the claims of the '868 patent that corresponded to the interference count. In the corresponding Decision, the PTO found that "Sommadossi did not conceive of the subject matter before Clark's accorded benefit date and, even if it had been the first to conceive, it was not diligent in reducing the invention to practice." (Jan. 29, 2014 Decision, Paper 1007 at 2, attached hereto as Exhibit 2.)

36. On December 3, 2013, the PTO Issued a Declaration of Interference Number 105,981 ("the '981 interference" or the "second interference") between Gilead Pharmasset's U.S. Patent Application No. 11/854,218 ("the '218 application") and the '600 patent.

37. In the '981 interference, Gilead Pharmasset has filed numerous motions, including:

a. a motion for judgment that Counterclaim Defendants' claims are invalid pursuant to 35 U.S.C. § 112 (1) for lack of enablement because, *inter alia*, there is no teaching in the patent of how to make compounds with a fluorine down and a methyl group (or substituted methyl group) up in the 2' carbon position, nor is there a basis for believing that the claimed methods using such compounds would be effective for treating HCV infection; and (2) for lack of written description because a person of skill in the art considering the application as filed would not have believed that the Counterclaim Defendants were in possession of the claimed methods, *inter alia* because the specification does not recite any of the chemical formulae (i.e., the chemical structures and substituent definitions) in the claims or disclose a single compound falling within the claims. (Clark Substantive Motion 7, Paper 154, attached hereto as Exhibit 3);

b. a motion for judgment that Counterclaim Defendants' claims are invalid for lack of utility under 35 U.S.C. § 101 and lack of enablement under 35 U.S.C. § 112 because, *inter alia*, there is no credible utility disclosed because there are no test results for any compound with a fluorine down and a methyl group (or substituted methyl group) up in the 2' carbon position, nor is there any logical reasoning to

support the utility of the claimed methods (Clark Substantive Motion 8, Paper 155, attached hereto as Exhibit 4); and

c. a motion for judgment that all of Counterclaim Defendants' claims are unpatentable under 35 U.S.C. §§ 102(e) or 103(a) over U.S. Patent Application Publication No. 2005/0009737 because Counterclaim Defendants cannot claim priority to earlier applications (Clark Substantive Motion 9, Paper 156, attached hereto as Exhibit 5).

The Norway Action involving Gilead Pharmasset and Counterclaim Defendants

38. Counterclaim Defendants and Gilead Pharmasset, and another Gilead entity (Gilead Sciences Europe Ltd.), are involved in litigation pending in Norway, Appeal Case No. 14-117680ASD-BORG/02, concerning Norwegian patent NO330,755 (a patent in the '600 patent family held by Counterclaim Defendants) and NO330,700 (held by Gilead Pharmasset).

39. The Norwegian District Court summarized the origins of this litigation as "a disagreement between the parties to the case as to who are the rightful owners of chemical substances of the pattern 2'-methyl-up, 2'-fluorine-down nucleosides with a natural N-bonded base." (Norwegian Opinion, attached hereto as Exhibit 6, at 3.)

40. On March 21, 2014, the Oslo District Court (a three-member panel consisting of one legal judge and technical expert judges in nucleoside chemistry and medicine) issued a judgment holding NO330,755 invalid because "the description in patent NO '755 is not sufficiently clear and complete as to enable a skilled person, as at the application date of 27 June 2003, to carry out the invention without undue burden or experimentation." (Norwegian Opinion, attached hereto as Exhibit 6, at 34.) The court simultaneously upheld the validity of NO330,700. (Id., at 38).

COUNT ONE
(Declaratory Judgment of Non-Infringement of the '600 Patent)

41. Gilead Sciences realleges and incorporates herein all allegations in paragraphs 1-40 of these Counterclaims.

42. Counterclaim Defendants have asserted the '600 patent against Gilead Sciences in this court alleging that Gilead Sciences' sale, offer for sale and distribution in the United States of sofosbuvir or pharmaceutical compositions containing sofosbuvir will infringe the '600 patent under 35 U.S.C. § 271(a), (b), and/or (c).

43. An actual and justiciable case or controversy exists between Gilead Sciences and Counterclaim Defendants regarding whether Gilead Sciences infringes any valid claim of the '600 patent.

44. The manufacture, use, offer for sale, sale, and/or importation of sofosbuvir and pharmaceutical compositions containing sofosbuvir has not infringed and does not infringe, directly or indirectly, any valid claim of the '600 patent, either literally or under the doctrine of equivalents.

45. Gilead Sciences is entitled to a judgment declaring that the manufacture, use, offer for sale, sale and/or importation of sofosbuvir and pharmaceutical compositions containing sofosbuvir before expiration of the '600 patent does not and will not constitute infringement of the '600 patent.

COUNT TWO
(Declaratory Judgment of Invalidity of the '600 Patent)

46. Gilead Sciences realleges and incorporates herein all allegations in paragraphs 1-45 of these Counterclaims.

47. An actual and justiciable case or controversy exists between Gilead Sciences and Counterclaim Defendants regarding the invalidity of the '600 patent.

48. The claims of the '600 patent are invalid for failure to comply with one or more provisions of Title 35 of the United States Code related to patentability, including but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112, as well as relevant provisions governing proceedings before the United States Patent and Trademark Office.

49. The claims of the '600 patent are invalid under 35 U.S.C. § 101 at least because they fail to meet the statutory utility requirement for reasons set out in the '981 and '871 interferences, including because the '600 patent fails to disclose any anti-HCV testing. (*See, e.g.*, Clark Substantive Motion 8, Paper 155, attached hereto as Exhibit 4)

50. The claims of the '600 patent are invalid for failing to meet the written description requirement under 35 U.S.C. § 112 for at least the reasons set out in the '871 interference and the '981 interference, including that the specification does not recite any of the chemical formulae in the claims or disclose a single compound falling within the claims. (See, e.g., Clark Substantive Motion 7, Papers 154, attached hereto as Exhibit 3.) The claims of the '600 patent also fail to meet the written description requirement at least because the '600 patent fails to disclose which species of compounds, if any, are effective in treating HCV.

51. The claims of the '600 patent are invalid for lack of enablement under 35 U.S.C. § 112 because the '600 patent fails to enable one of ordinary skill in the art to make and use the full scope of the claims without undue experimentation for at least the reasons set out in the '871

interference, the '981 interference, and Norwegian Opinion, including that the patent does not disclose how to synthesize a compound with a fluorine down and a methyl group up in the 2' position, and Counterclaim Defendants themselves were not able to successfully synthesize such a compound until long after the filing date of the '600 patent. (*See, e.g.*, March 22, 2013, Decision on Motions, Paper 426 at 25, attached hereto as Exhibit 1; Clark Substantive Motion 7 and 8, Papers 154 and 155, attached hereto as Exhibits 3 and 4; Norwegian Opinion, attached hereto as Exhibit 6, at 33-34.).

52. The claims of the '600 patent are invalid under 35 U.S.C. §§ 102 and 103 as anticipated or obvious over at least U.S. Patent Application Publication No. 2005/0009737 (WO 2005/003147; U.S. Patent No. 7,429,572). (*See e.g.*, Clark Substantive Motion 9, Paper 156, attached hereto as Exhibit 5.)

53. Gilead Sciences is entitled to a judicial declaration that the claims of the '600 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Gilead Sciences respectfully requests that this Court enter the following relief:

a. Enter a judgment in favor of Gilead Sciences;

b. Declare under 28 U.S.C. § 2201 that the manufacture, use, offer for sale, sale, and/or importation of sofosbuvir and pharmaceutical compositions containing sofosbuvir does not and will not infringe any valid claim of the '600 patent, whether directly, indirectly, contributorily, by inducement, literally, or under the doctrine of equivalents;

c. Declare under 28 U.S.C. § 2201 that the claims of the '600 patent are invalid;

d. Issue an injunction enjoining Plaintiffs and their agents, representatives, attorneys, employees, and those persons in active concert or participation with them who receive actual notice herefrom from threatening or initiating infringement litigation against Gilead Sciences or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers of Gilead Sciences, or charging them either orally or in writing with infringement of the ’600 patent;

e. Declare that this is an exceptional case as defined by 35 U.S.C. § 285 and award Gilead Sciences its attorneys’ fees and costs;

f. All other and further relief the Court may deem just and proper.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Gilead Sciences hereby requests a trial by jury of all issues so triable.

Dated: December 22, 2014 FISH & RICHARDSON P.C.

By: */s/ Martina Tyreus Hufnal*

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