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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
SAN JOSE DIVISION

GILEAD SCIENCES, INC.,

Plaintiff,

v.

MERCK & CO, INC., MERCK SHARP & DOHME CORP. and ISIS PHARMACEUTICALS, INC.,

Defendants

Case No. 5:13-cv-04057-BLF/PSG

~~[PROPOSED]~~ JOINT PRETRIAL STATEMENT AND ORDER

I. THE ACTION

A. Parties

Plaintiff Gilead Sciences, Inc. ("Plaintiff" or "Gilead") and Defendants Merck & Co., Inc. ("Merck & Co."), Merck Sharp & Dohme Corp ("MSD Corp."), and Ionis Pharmaceuticals, Inc. ("Ionis"), formerly known as Isis Pharmaceuticals, Inc., (collectively, "Defendants" or "Merck") are the parties that will appear at trial.

B. Substance of the Action

Gilead manufactures and sells sofosbuvir, the active ingredient of orally administered drugs prescribed for the treatment of chronic hepatitis C ("HCV") infection. Merck & Co. is the corporate parent of MSD Corp. MSD Corp. and Ionis are joint assignees of two patents: U.S. Patent Nos. 7,105,499 ("the '499 patent") and 8,481,712 ("the '712 patent") (collectively, "Merck Patents"), both titled "Nucleoside Derivatives as Inhibitors of RNA-Dependent RNA Viral Polymerase." On August 30, 2013, Gilead initiated this action for declaratory judgment pursuant to 28 U.S.C. §§ 2201 and 2202. In its complaint, Gilead alleged that the manufacture, use, offer for sale, and/or importation of sofosbuvir and the drug product that is the subject of the first sofosbuvir NDA has not infringed, does not infringe, and would not, if marketed, infringe, directly or indirectly, any valid claim of the '499 or '712 patents and that the '499 and '712 patents are invalid. (ECF No. 1.) MSD Corp. and Ionis (collectively, "Counterclaimants") asserted counterclaims, seeking declaratory judgment that Gilead's marketing of sofosbuvir, following FDA approval, would induce and contribute to infringement of the '499 and '712 patents and seeking compensatory damages for infringement arising from any commercial sale and offer for sale of sofosbuvir by Gilead. (ECF Nos. 51, 62.) On December 6, 2013, the FDA approved Gilead's NDA 204671 for sofosbuvir (SOVALDI®) used in combination with other drugs as a once daily oral therapy for chronic HCV infection. On October 10, 2014, the FDA approved Gilead's NDA 205834 for sofosbuvir used in combination with ledipasvir (HARVONI®) as a once daily oral therapy for chronic HCV infection. Gilead makes, sells, and offers to sell sofosbuvir (SOVALDI® and HARVONI®) in the United States for treatment of HCV infection. On

November 28, 2014, the Counterclaimants filed amended and supplemental counterclaims seeking a judgment that Gilead's marketing of sofosbuvir induces and contributes to infringement of the '499 and '712 patents and seeking damages for infringement from Gilead's commercial sale and offer for sale of its sofosbuvir products. (ECF No. 98).

Counterclaimants contend that Gilead's marketing and sale of SOVALDI® and HARVONI® induces and contributes to direct infringement of claims 1 and 2 of the '499 patent and claims 1–3, 5, 7, and 9–11 of the '712 patent by patients and caregivers who use these products.[1] Induced infringement under 35 U.S.C. §271(b) is present when a person actively induces infringement of a patent, knowing of the patent and that the acts induced constitute infringement. Contributory infringement under 35 U.S.C. § 271(c) is present when a person offers to sell or sells within the United States a component of a patented manufacture or composition, or a material for use in practicing a patented process, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use. On February 1, 2016, this Court granted summary judgment of infringement. (ECF No. 214).[2] The Court further determined that, whether the jury should be informed of this Court's entry of judgement of infringement, and if so, how it should be presented, are issues better left for the final pretrial conference. (ECF No. 214).

Gilead alleges that each of the asserted claims of the patents-in-suit are invalid on the following grounds:[3]

- The asserted claims of the '499 patent and the '712 patent are invalid for failure to meet the enablement requirement of 35 U.S.C. § 112, ¶ 1. Gilead's position is that, a patent's description of the claimed invention must be sufficiently full and clear to

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[1] Defendants' infringement allegations are found in their Second Amended and Supplemental Counterclaims (ECF No. 98) and in their Amended Disclosure of Asserted Claims and Infringement Contentions, served on Gilead on June 6, 2016.

[2] Gilead objects to the Court's claim construction of the term "administering" in the claims of the '499 patent (ECF No. 140), and reserves the right to appeal or otherwise contest that construction in further proceedings in this litigation. The Court adopted the parties' agreed construction of the term "compound" as used in the asserted claims of the '712 patent.

[3] Gilead's invalidity defenses are found in its Complaint, (ECF No. 1, ¶¶ 68, 76), and in Gilead's Amended Invalidity Contentions, served on Defendants on June 16, 2015.

enable a person of ordinary skill in the field at the time of filing to make and use the full scope of the claimed invention, and must disclose a practical utility for the claimed invention. Merck's position is that a patent's description of the claimed invention must be sufficiently full and clear as to enable a person of ordinary skill in the field at the time of filing to practice the claimed invention, and must disclose a practical utility for the claimed invention. Gilead contends that the asserted claims of the Merck Patents fail to satisfy the "how-to-make," "how-to-use," and practical utility subconditions of the enablement requirement.

- The asserted claims of the '499 patent and the '712 patent are invalid for failure to meet the written description requirement of 35 U.S.C. § 112, ¶ 1. To satisfy the written description requirement, the applicant must reasonably convey to those skilled in the art that, as of the priority date, he or she was in possession of the claimed invention.
- The asserted claims of the '499 patent and the '712 patent are invalid for derivation and lack of inventorship under 35 U.S.C. § 102(f) and (g). Under § 102(f), a person is not entitled to a patent if "he did not himself invent the subject matter sought to be patented." Under § 102(g), a person is not entitled to a patent if, before the person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it.
- The asserted claims of the '499 patent and the '712 patent are invalid as anticipated by U.S. Patent Application Publication No. 2005/0009737 ("Clark"), under 35 U.S.C. § 102, to the extent the claims are not entitled to a priority date before Clark published on January 13, 2005. For a claim to be invalid as anticipated, all of its requirements must have existed in a single device or method that predates the claimed invention, or must have been described in a single previous publication or patent that predates the claimed invention.
- The asserted claims of the '712 patent are invalid as anticipated by Sofia et al., "Discovery of a β-D-2'Deoxy-2'-α-fluoro-2'-β-C-methyluridine Nucleotide Prodrug

(PSI-7977) for the Treatment of Hepatitis C Virus," J. Med. Chem., 53:7202–7218 (2010) ("Sofia"), under 35 U.S.C. § 102, to the extent the claims are not entitled to a priority date before Sofia published on September 16, 2010. For the claim to be invalid as anticipated, all of its requirements must have existed in a single device or method that predates the claimed invention, or must have been described in a single previous publication or patent that predates the claimed invention.

- The asserted claims of the '499 patent are invalid as indefinite under 35 U.S.C. § 112, ¶ 2. A claim is invalid for indefiniteness if its language, when read in light of the specification and the prosecution history, fails to inform, with reasonable certainty, those skilled in the art about the scope of the claimed invention.

Merck denies Gilead's allegations of invalidity, and asserts that Gilead cannot meet its burden of proving by clear and convincing evidence that the asserted claims of the patents-in-suit are invalid. Merck also asserts that some of these invalidity grounds are not cognizable in this case as a matter of law.

As identified in its Answer to Defendants' Amended Counterclaims, (ECF No. 67), Gilead also asserts equitable defenses to the counterclaims of infringement. These equitable defenses as asserted by Gilead are:

- Laches. Laches requires that (a) the patentee's delay in bringing suit was unreasonable and inexcusable, and (b) the alleged infringer suffered material prejudice attributable to the delay.
- Waiver. Waiver requires that a patentholder, with full knowledge of the material facts, intentionally relinquish its patent enforcement rights or act in a manner that is so inconsistent with an intent to enforce its rights as to induce a reasonable belief that such right has been relinquished.
- Estoppel. Equitable estoppel requires that (a) the patentholder, through misleading conduct, leads the alleged infringer to reasonably infer that the patentholder does not intend to enforce its patent against the alleged infringer; (b) the alleged infringer relies

on that conduct; and (c) due to its reliance, the alleged infringer will be materially prejudiced if the patentee is allowed to proceed with its claim.

- Unclean hands. A showing of unclean hands requires that one coming for relief have committed some unconscionable act immediately and necessarily related to the equity that he seeks in respect of the matter in litigation.

Merck denies these Gilead allegations and asserts that Gilead cannot meet its burden of proving them. Merck also asserts that some of these equitable defenses are not cognizable in this case as a matter of law.

C. Relief Sought

Gilead's Position

Gilead seeks the following relief (described in its Complaint, ECF No. 1):

- A declaration that the asserted claims of the '499 patent and the '712 patent are invalid under 35 U.S.C. §§ 102 and/or 112.
- A declaration that the asserted claims of the '499 patent and the '712 patent are unenforceable against Gilead under the equitable doctrines of laches, waiver, estoppel, and/or unclean hands.
- A declaration that Gilead does not infringe any valid claim of the '499 patent or the '712 patent.
- An injunction enjoining Defendants 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 or its customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors or customers of Gilead, or charging them either orally or in writing with infringement of the '499 or '712 patents.
- A finding that Defendants are not entitled to any damages.

- A judgment that this is an "exceptional case" justifying the award of Gilead's reasonable attorneys' fees, expenses, and costs in this action under 35 U.S.C. § 285 both until the time of trial and thereafter.

Merck's Position

Merck seeks the following relief (described in the Second Amended and Supplemental Counterclaims, ECF No. 98):

- A judgment that Gilead's commercial sale and offer for sale of sofosbuvir induces and contributes to infringement of the '499 patent and the '712 patent.
- An Order dismissing Gilead's complaint with prejudice and entering judgment in favor of Merck.
- Damages adequate to compensate Merck for past infringement from Gilead's commercial sale and offer for sale of sofosbuvir, in the form of a reasonable royalty on past U.S. sales of SOVALDI® and HARVONI® and including pre- and post-judgment interest.
- A reasonable royalty for Gilead's ongoing and future infringement.
- A judgment that this case is "exceptional" justifying an award of Merck's reasonable attorneys' fees, expenses and costs under 35 U.S.C. § 285, both until the time of trial and thereafter.

D. Federal Jurisdiction and Venue

The Parties agree that this Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338. Personal jurisdiction and venue are not disputed.

II. FACTUAL BASIS FOR ACTION

A. Undisputed facts

1. Gilead 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. Merck & Co. is a company organized under the laws of the State of New Jersey with its principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100.

3. MSD Corp. is a company organized under the laws of the State of New Jersey with its principal place of business at One Merck Drive, P.O. Box 100, Whitehouse Station, NJ 08889-0100.

4. MSD Corp. is a subsidiary of Merck & Co.

5. Ionis is a company organized under the laws of the State of Delaware with its principal place of business at 2855 Gazelle Court, Carlsbad, CA 92010.

6. MSD Corp. and Ionis are co-owners of the '499 patent.

7. The '499 patent issued on September 12, 2006.

8. MSD Corp. and Ionis are the co-owners of the '712 patent.

9. The '712 patent issued on July 9, 2013.

10. In this action, Merck relies on a priority date of January 18, 2002 for the '499 and '712 patents.

11. The applications that ultimately issued as the '499 and '712 patents-in-suit were filed by Merck on January 18, 2002.

12. All facts admitted to in the Requests For Admissions identified in Appendix D and Appendix E to this pre-trial order.

13. All facts admitted to in the Joint Stipulation filed September 29, 2015 (Dkt. No. 153).

14. All facts admitted to in the parties' statements of undisputed facts in their summary judgment papers. (Dkt. Nos. 167-1 and 177-22).

B. Disputed Facts

Gilead's Statement

1. Whether there is clear and convincing evidence that the inventions in each of the asserted claims of the ’499 patent were derived from information disclosed to Merck by Pharmasset regarding the work of Jeremy Clark.

2. Whether there is clear and convincing evidence that the inventions in each of the asserted claims of the ’712 patent were derived from information disclosed to Merck by Pharmasset regarding the work of Jeremy Clark.

3. Whether any delay by Merck in asserting the ’499 patent was unreasonable and inexcusable and, if so, whether Gilead suffered a material prejudice as a result of any such delay.

4. Whether any delay by Merck in asserting the ’712 patent was unreasonable and inexcusable and, if so, whether Gilead suffered a material prejudice as a result of any such delay.

5. Whether Merck’s conduct during its interactions with Pharmasset was misleading, whether that misleading conduct led Pharmasset and Gilead to a reasonable belief that Merck did not intend to assert any patent rights and, if so, whether Pharmasset and Gilead relied upon that conduct and have suffered material prejudice as a result of that reliance.

6. Whether there is clear and convincing evidence that the inventions claimed by the ’499 patent had first been made in the United States by Jeremy Clark, and whether Jeremy Clark abandoned, suppressed, or concealed his invention.

7. Whether there is clear and convincing evidence that, as of January 18, 2002, the specification for the ’499 patent did not teach a person of ordinary skill in the art to make the compounds and all of their prodrugs encompassed by the full scope of the asserted claims of the ’499 patent, without undue experimentation.

8. Whether these is clear and convincing evidence that, as of January 18, 2002, the specification for the’499 patent did not teach a person of ordinary skill in the art how to use the compounds and all of their prodrugs encompassed by the full scope of the asserted claims of the ’499 patent, according to the method described by the asserted claims, without undue experimentation.

9. Whether there is clear and convincing evidence that, as of January 18, 2002, the specification for the ’499 patent did not disclose to a person of ordinary skill in the art a pratical utility for using the compounds and all of their prodrugs encompassed by the full scope of the asserted claims of the ’499 patent according to the method described by the asserted claims.

10. Whether there is clear and convincing evidence that, as of January 18, 2002, the specification for the ’499 patent did not disclose to a person of ordinary skill in the art that the inventors of the ’499 patent had possession of a method of treating HCV infection by administering the claimed genus of compounds and all possible prodrugs either alone or in combination with the active agents listed in claim 2 of the ’499 patent.

11. Whether there is clear and convincing evidence that the inventions claimed by the ’712 patent had first been made in the United States by Jeremy Clark, and whether Jeremy Clark abandoned, suppressed, or concealed his invention.

12. Whether there is clear and convincing evidence that, as of January 18, 2002, the specification for the ’712 patent did not teach a person of ordinary skill in the art to make the compounds encompassed by the full scope of the asserted claims of the ’712 patent, without undue experimentation.

13. Whether these is clear and convincing evidence that, as of January 18, 2002, the specification for the ’712 patent did not teach a person of ordinary skill in the art how to use the compounds encompassed by the full scope of the asserted claims of the ’712 patent without undue experimentation.

14. Whether there is clear and convincing evidence that, as of January 18, 2002, the specification for the ’712 patent did not disclose to a person of ordinary skill in the art a pratical utility for the compounds encompassed by the full scope of the asserted claims of the ’712 patent.

15. Whether there is clear and convincing evidence that, as of January 18, 2002, the specification for the ’712 patent did not disclose to a person of ordinary skill in the art that the inventors of the ’712 patent had possession of the claimed compounds.

16. Whether Merck's delay in asserting its patent rights or in making any claim of rights to PSI-6130 or PSI-7977 amounted to a knowing relinquishment of its patent rights or induced a reasonable belief in Gilead that such rights had been relinquished.

17. If the '499 patent is found to be valid and enforceable, the amount of the reasonable royalty to which Merck is entitled.

18. If the '712 patent is found to be valid and enforceable, the amount of the reasonable royalty to which Merck is entitled.

Merck's Statement

19. Whether there is clear and convincing evidence that a person of ordinary skill in the art would not have been able to practice any of the asserted claims of the '499 patent without undue experimentation as of January 18, 2002.

20. Whether there is clear and convincing evidence that the inventions in each of the asserted claims of the '499 patent had first been made in the United States by Jeremy Clark before January 18, 2002, and whether Jeremy Clark abandoned, suppressed, or concealed any such alleged invention.

21. Whether there is clear and convincing evidence that the specification of the '499 patent, as filed on January 18, 2002, does not convey to a person of ordinary skill in the art that the inventors were in possession of the invention as claimed in any of the asserted claims of the '499 patent.

22. Whether there is clear and convincing evidence that, as of January 18, 2002, a person of ordinary skill in the art would not have been able to practice any of the asserted claims of the '712 patent without undue experimentation.

23. Whether there is clear and convincing evidence that the inventions in each of the asserted claims of the '712 patent had first been made in the United States by Jeremy Clark before January 18, 2002, and whether Jeremy Clark abandoned, suppressed, or concealed any such alleged invention.

24. Whether there is clear and convincing evidence that the specification of the ’712 patent, as filed on January 18, 2002, does not convey to a person of ordinary skill in the art that the inventors were in possession of the invention as claimed in any of the asserted claims of the ’712 patent.

25. Whether there is clear and convincing evidence that each of the asserted claims of the ’499 patent is not supported by a practical utility.

26. Whether there is clear and convincing evidence that each of the asserted claims of the ’712 patent is not supported by a practical utility.

27. Whether Merck delayed in asserting the ’499 patent after Gilead’s infringement of that patent had begun and Gilead suffered material prejudice as a result.

28. Whether Merck delayed in asserting the ’712 patent after Gilead’s infringement of that patent had begun and Gilead suffered material prejudice as a result.

29. Whether any delay by Merck in asserting its patent rights amounted to a knowing and intentional relinquishment of its patent rights or was so inconsistent with an intent to enforce its rights that it induced a reasonable belief in Gilead that such rights had been relinquished.

30. The amount of the reasonable royalty to which Merck is entitled to compensate for Gilead’s past, ongoing, and future infringement of the ’499 and ’712 patents.

III. DISPUTED LEGAL AND EQUITABLE ISSUES

The parties are in agreement as to the disputed legal issues relevant to most claims and defenses, and those agreed-to areas of dispute are listed in the “Joint Statement,” below. The parties do not agree as to the disputed legal issues relevant to some of Gilead’s invalidity defenses and, therefore, have included separate statements regarding those defenses.

Joint Statement

1. Whether any of the asserted claims of the ’499 patent are entitled to a priority date of January 18, 2002.

2. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the ’499 patent is invalid under 35 U.S.C. § 112 for failure to disclose a practical utility for the claimed methods.

3. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the ’499 patent is invalid under 35 U.S.C. § 112, for indefiniteness.

4. Whether any of the asserted claims of the ’712 patent are entitled to a priority date of January 18, 2002.

5. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the ’712 patent is invalid under 35 U.S.C. § 112 for failure to disclose a practical utility for the claimed compounds.

6. Whether Gilead can meet its burden of proving that Merck’s claims for infringement are barred by the doctrine of laches.

7. Whether Gilead can meet its burden of proving that Merck’s claims for infringement are barred by the doctrine of waiver.

8. Whether Gilead can meet its burden of proving that Merck’s claims for infringement are barred by the doctrine of equitable estoppel.

9. Whether Gilead can meet its burden of proving that Merck’s claims for infringement are barred by the doctrine of unclean hands.

10. Whether Gilead is entitled to an injunction enjoining Merck and its agents from threatening or initiating infringement litigation against Gilead or its customers, dealers, or suppliers or charging them either orally or in writing with infringement of the ’499 or ’712 patents.

11. Whether Merck is entitled to an Order dismissing Gilead’s Complaint with prejudice and entering judgment in favor of Defendants and Counterclaim Plaintiffs;

12. Whether this is an exceptional case justifying the award of Gilead’s or Merck’s reasonable attorneys’ fees, expenses, and costs in this action under § 285.

13. Whether Merck is entitled to any damages, including past damages and an ongoing royalty, and, if so, the amount of damages.

Gilead's Statement

14. If any asserted claim of the '499 patent is not entitled to a priority date of January 18, 2002, whether Gilead can show by clear and convincing evidence that it is invalid as anticipated by Clark.

15. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the '499 patent is invalid under 35 U.S.C. § 102(f) for being derived from the invention of Jeremy Clark.

16. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the '499 patent is invalid under 35 U.S.C. § 102(g) for having first been made in the United States by Jeremy Clark, who did not abandon, suppress, or conceal his invention.

17. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the '499 patent is invalid under 35 U.S.C. § 112 for failure to enable a person of ordinary skill in the art to make the compounds and all of their possible prodrugs encompassed by the asserted claims.

18. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the '499 patent is invalid under 35 U.S.C. § 112 for failure to enable a person of ordinary skill in the art to use the claimed methods.

19. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the '499 patent is invalid under 35 U.S.C. § 112 for lacking a written description of the claimed methods.

20. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the '712 patent is invalid under 35 U.S.C. § 102(f) for being derived from the invention of Jeremy Clark.

21. If any asserted claim of the ’712 patent is not entitled to a priority date of January 18, 2002, whether Gilead can show by clear and convincing evidence that it is invalid as anticipated by Clark.

22. If any asserted claim of the ’712 patent is not entitled to a priority date of January 18, 2002, whether Gilead can show by clear and convincing evidence that it is invalid as anticipated by Sofia.

23. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the ’712 patent is invalid under 35 U.S.C. § 102(g) for having first been made in the United States by Jeremy Clark, who did not abandon, suppress, or conceal his invention.

24. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the ’712 patent is invalid under 35 U.S.C. § 112 for failure to enable a person of ordinary skill in the art to make the claimed compounds.

25. Whether Gilead can show by clear and convincing evidence that each of the asserted claimed of the ’712 patent is invalid under 35 U.S.C. § 112 for failure to enable a person of ordinary skill in the art to use the claimed compounds.

26. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the ’712 patent is invalid under 35 U.S.C. § 112 for lacking a written description of the claimed compounds.

27. Whether Merck may rely on infringement by or mode of action of sofosbuvir as evidence of practical utility for the asserted claims.

28. Whether Merck may rely on sofosbuvir’s commercial success as evidence of practical utility for the asserted claims.

Merck’s Statement

29. Whether as a matter of law Gilead may assert that the asserted claims of the ’499 patent are invalid under 35 U.S.C. § 102(f) for being derived from the work of Jeremy Clark, which post-dates Merck’s filing date of January 18, 2002.

30. Whether as a matter of law Gilead may assert that the asserted claims of the ‘’499 patent are invalid under 35 U.S.C. § 102(g) for alleged prior invention by Jeremy Clark, whose alleged date of invention post-dates Merck’s filing date of January 18, 2002.

31. Whether as a matter of law Gilead may assert that the asserted claims of the ’499 patent are invalid as anticipated by Clark, which was filed and was published after Merck’s filing date of January 18, 2002.

32. Whether as a matter of law Gilead may assert that the asserted claims of the ’499 patent are invalid as anticipated by Sofia, which was filed and was published after Merck’s filing date of January 18, 2002.

33. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the ’499 patent is invalid under 35 U.S.C. § 112 for failure to enable a person of skill in the art to practice the claimed invention.

34. Whether as a matter of law Gilead may assert that the asserted claims of the ’712 patent are invalid under 35 U.S.C. § 102(f) for being derived from the work of Jeremy Clark, which post-dates Merck’s filing date of January 18, 2002.

35. Whether as a matter of law Gilead may assert that the asserted claims of the ‘712 patent are invalid under 35 U.S.C. § 102(g) for alleged prior invention by Jeremy Clark, whose alleged date of invention post-dates Merck’s filing date of January 18, 2002.

36. Whether as a matter of law Gilead may assert that the asserted claims of the ’712 patent are invalid as anticipated by Clark, which was filed and was published after Merck’s filing date of January 18, 2002.

37. Whether as a matter of law Gilead may assert that the asserted claims of the ’712 patent are invalid as anticipated by Sofia, which was filed and was published after Merck’s filing date of January 18, 2002.

38. Whether Gilead can show by clear and convincing evidence that each of the asserted claims of the ’712 patent is invalid under 35 U.S.C. § 112 for failure to enable a person of skill in the art to practice the claimed invention.

IV. ESTIMATE OF TRIAL TIME

The parties anticipate that trial will take two weeks.

The parties are in disagreement as to the order in which trial should proceed. It is Gilead's position that because this Court has entered judgment of infringement, the case should commence with Gilead's invalidity defense and that Gilead, as the party with the burden of proof, should present first and should be permitted to present a rebuttal presentation on invalidity. It is also Gilead's position that because there is no liability for an invlaid claim, the issue of damages should only be presented after liability. It is also Gilead's position that it should be permitted to call live or by deposition adverse witnesses during its case in chief regardless of whether Merck intends to call the same witness live or by deposition during its case in chief.

It is Merck's position that Merck should present first because it is the patentee and has the burden of proof on damages. It is also Merck's position that regardless of the order at trial, Merck should be permitted to present a rebuttal case on damages. It is Merck's position that deposition testimony should not be presented at trial for any witness who is testifying live at trial. It is also Merck's position that if Gilead wishes to cross-examine a Merck witness it should be permitted to do so only after that witness has testified on direct examination in Merck's case, with the understanding that such cross-examination need not be limited to the scope of the direct examination. The reciprocal arrangement would apply to Merck's cross-examination of Gilead's witnesses.

V. TRIAL ALTERNATIVES AND OPTIONS

A. Settlement Discussion

Pursuant to the ADR L.R. 3-2 and 3-4(b), the parties stipulated to Private ADR in the form of direct discussions between the parties; the Court approved the parties' stipulation. (ECF Nos. 64, 65.) The parties filed a Joint Notice of ADR Compliance on January 21, 2014, reporting that Private ADR was conducted as stipulated and ordered. (ECF No. 70.) The parties were not able to reach a resolution. Moreover, pursuant to the Court's Jury Pretrial Standing Order, lead trial counsel met and conferred on February 5, 2016 to discuss the possibility of settlement.

B. Amendments or Dismissals

Neither Gilead nor Defendants have any proposed amendments to the pleadings. Neither Gilead nor Defendants seek to dismiss any claims or counterclaims.

C. Bifurcation or Separate Trial of Issues

Indefiniteness

As described above, Gilead maintains that each of the asserted claims of the '499 patent is invalid as indefinite. The parties agree that claim indefiniteness is a matter of law for the Court's adjudication that turns on underlying facts. Gilead's position is that while the evidence concerning indefiniteness can be presented simultaneously with the other matters within the jury's purview, Gilead would move the Court to rule as a matter of law at the close of evidence If the Court determines to adopt Merck's position, Gilead asks that that ruling applies only to evidence that is relevant exclusively to Gilead's indefiniteness defense.

Merck's position is that any evidence pertaining to this defense should be presented outside the presence of the jury, and that the defense be reserved for resolution by the Court.

Gilead's Equitable Defenses

Gilead proposes that these defenses be addressed in briefing following trial and that, if there is a need for the Court to hear further evidence, that can also be discussed post-trial. If the Court determines to adopt Merck's position, Gilead asks that that ruling applies only to evidence that is relevant exclusively to resolution of Gilead's equitable defenses.

It is Merck's view that any evidence pertaining to these defenses should be presented outside the presence of the jury, and that these defenses be reserved for resolution by the Court.

VI. APPENDICES TO PRETRIAL ORDER

The following Appendices are attached hereto:

Gilead's Witness List	Appendix A
Defendants' Witness List	Appendix B
Gilead's Exhibit List (and objections)	Appendix C-2
Defendants' Exhibit List (and objections)	Appendix C-3

Gilead's Discovery Responses	Appendix D-1
Gilead's Deposition Designations (and objections)	Appendix D-2
Defendants' Discovery Responses	Appendix E-1
Defendants' Deposition Designations (and objections)	Appendix E-2

VII. STIPULATIONS

The following stipulations were agreed upon by the parties as discussed below, and are made a part of this Pretrial Order.

A. Trial Exhibits & Demonstratives

1. The listing of a document on a party's exhibit list is not an admission that such document is relevant or admissible when offered by the opposing party for the purpose that the opposing party wishes to admit the document. Each party reserves the right to object to the relevancy or admissibility of any evidence offered by the other party, at the time such evidence is offered, in view of the specific context in which such evidence is offered.
2. The parties will each provide to each other's counsel of record via email a list of witnesses that it intends to call in Court, live or by deposition, by 7:00 p.m. two calendar days before the witness will testify. For witnesses testifying by deposition, each party will also provide a transcript (and video, if applicable) of those portions of the deposition it intends to play.
3. Although the parties have made good-faith efforts to identify the sponsoring witness or witnesses through which they expect to introduce exhibits at trial, neither party is precluded from using or introducing an exhibit with a different witness. Unless otherwise agreed to by the parties during trial, the parties will each provide to each other's counsel of record via e-mail a written list of exhibits, by exhibit number, for each witness that it intends to call in Court by 7:00 p.m. two calendar days before the day the witness will testify. Objections to any of the

disclosed exhibits shall be made by no later than 7:00 p.m. the following day, and the parties will meet and confer regarding any objections by 9:00 p.m. that same evening.

4. The parties will provide, by e-mail, any demonstrative exhibits (in color as applicable) they anticipate using on direct examination of a witness at trial to the other party's counsel of record. Gilead proposes that such an exchange occur no later than 7:00 p.m. on the calendar day before the witness is called. Merck proposes that such an exchange occur no later than 8:00 a.m. on the calendar day before the witness is called. Any objections to demonstrative exhibits shall be made by 9:00 p.m. that same day, and the parties shall meet and confer as soon as possible thereafter to resolve such objections. Any disputes as to demonstrative exhibits shall be raised with the Court as appropriate before trial resumes on the day of their anticipated use.
5. Demonstrative exhibits exchanged will not be used by the opposing party prior to being used by the disclosing party.
6. The parties agree that demonstrative exhibits that the parties intend to use at trial need not be included on their respective lists of trial exhibits.
7. The Federal Judicial Center video entitled "The Patent Process: An Overview for Jurors" will be shown to the jurors after jury selection, before opening arguments.
8. The foregoing notice provisions regarding demonstrative exhibits shall not apply to demonstrative exhibits created in the courtroom during live testimony at trial or to the enlargement, highlighting, ballooning, or excerpting of trial exhibits that have been admitted in evidence or trial testimony. Mere enlargement, highlighting, ballooning, or excerpting of trial exhibits admitted in evidence or trial testimony does not create a demonstrative exhibit.

VIII. BINDING EFFECT OF THE JOINT PRETRIAL STATEMENT AND ORDER

The foregoing admissions having been made by the parties, and the parties having specified the foregoing issues of fact and law remaining to be litigated, this order shall supplement the pleadings and govern the course of trial of this action, unless modified to prevent manifest injustice.

Dated: February 11, 2016

FISH & RICHARDSON P.C.

By: */s/ Douglas E. McCann*
Douglas E. McCann

Attorneys for Plaintiff
GILEAD SCIENCES, INC.

Dated: February 11, 2016

WILLIAMS & CONNOLLY LLP

By: */s/ Jessamyn Berniker*
Jessamyn Berniker
Attorneys for Defendants
MERCK & CO., INC.; MERCK SHARP & DOHME CORP.; ISIS PHARMACEUTICALS, INC.

SIGNATURE ATTESTATION

Pursuant to Civil Local Rule 5.1(i)(3), I attest under penalty of perjury that concurrence in the filing of this document has been obtained from its signatory

/s/ Doulas E. McCann

SO ORDERED

February 25, 2016

HONORABLE BETH LABSON FREEMAN