UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA SAN JOSE DIVISION

GILEAD SCIENCES, INC., Plaintiff,

v.

MERCK & CO, INC., et al., Defendants. Case No. <u>13-cv-04057-BLF</u>

ORDER REGARDING NON-JURY LEGAL ISSUES

[Re: ECF 407, 411]

Plaintiff Gilead Sciences, Inc. ("Gilead") seeks to bar Defendants Merck & Co., Merck Sharp and Dohme Corp., and Isis Pharmaceuticals, Inc., (collectively "Merck") from maintaining their suit based on the equitable defenses of waiver and unclean hands. At trial, the jury determined that Merck's patents-in-suit are not invalid and awarded damages to Merck for infringement. Gilead's equitable defenses, however, are the province of the Court to decide.

After a thorough review of the evidence submitted at trial and in post-trial submissions, the Court finds Gilead has not shown that Merck waived its right to enforce the '499 and '712 Patents against Gilead. The record, however, reflects a pervasive pattern of misconduct by Merck and its agents constituting unclean hands, which renders Merck's '499 and '712 Patents unenforceable against Gilead.

I. BACKGROUND

On December 6, 2013, Gilead received approval from the Food and Drug Administration
to market and sell Sovaldi®, an orally-administered prescription drug containing the active
ingredient sofosbuvir, to treat chronic Hepatitis C (HCV) infection in patients. Order Construing
Claims at 2, ECF 140. Sofosbuvir is a prodrug that is inactive and has little to no therapeutic effect
until transformed by enzymes in the body into an active form. *Id*. Once inside a liver cell,

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sofosbuvir is converted into three analogs, each with different structures: a monophosphate analog, a diphosphate analog, and a triphosphate analog. *Id*. The triphosphate analog is the therapeutically effective form that can target and cure HCV infection in patients. *Id*.

Merck asserts that two of its patents, U.S. Patent No. 7,105,499 and U.S. Patent No. 8,481,712, cover sofosbuvir, and that Gilead's sales of Sovaldi® and Harvoni®, which contain the active ingredient sofosbuvir, induce and contribute to the infringement of these patents. Merck Mot. for SJ, ECF 167. The operative filing date of the '499 and '712 Patents is January 18, 2002. Exh. 22 to Gilead Mot. for SJ at Interrog. No. 1, ECF 164-16.

The '712 Patent is directed to compounds having a specific structural formula, Exh. 16 to Gilead Mot. for SJ at 143:1-146:60, ECF 165-11, while the '499 Patent relates to methods for treating HCV by administering a therapeutically effective amount of those compounds either alone or in combination with another HCV treatment. Exh. 1 to Gilead Mot. for SJ at 137:1-138:25 (claims 1 and 2).

At summary judgment, Gilead argued that the asserted claims were invalid but conceded that if they were not invalid, it infringed them. The Court denied Gilead's summary judgment motion of invalidity and granted Merck summary judgment of infringement. ECF 214. On March 20, 2016, after an eight-day trial, the jury found that the '499 and '712 Patents were not invalid. Following a three-day trial on damages, the jury awarded Merck \$200 million in damages for sales of Sovaldi® and Harvoni® through December 31, 2015. Verdict Phase 2, ECF 392. On March 30, 2016, the Court held a bench trial on Gilead's equitable defenses of unclean hands and waiver. ECF 401. On April 22, 2016, Gilead filed a motion to re-open the record and allow additional evidence. ECF 410. On April 29, 2016, the Court held a hearing on Gilead's motion where the Court granted the motion and also allowed Merck to supplement the record. ECF 418.

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II. LEGAL STANDARD

Federal Rule of Civil Procedure 52(a) requires district courts to make findings of fact in an action "tried on the facts without a jury or with an advisory jury." Fed. R. Civ. P. 52(a)(1). The Court is required to "find facts specially and state its conclusions of law separately." *Id.* "One purpose behind Rule 52(a) is to aid the appellate court's understanding of the bases of the trial

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court's decision." *Simeonoff v. Hener*, 249 F.3d 883, 891 (9th Cir. 2001) (internal citations omitted). The Court is not required to make findings on each and every fact presented at trial. *Id.*Conflicting testimony must be resolved on relevant issues. *Zivkovic v. Southern California Edison, Co.*, 302 F.3d 1080, 1090 (9th Cir. 2002).

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III. FINDINGS OF FACT

Gilead argues that Merck waived its rights to enforce the '499 and '712 Patents, or alternatively, that these patents are unenforceable by virtue of the doctrine of unclean hands. Gilead Trial Br., ECF 368; Gilead Supp. Trial Br., ECF 408. Gilead claims Merck impliedly waived its patent rights by attempting to license or acquire from Pharmasset, Gilead's predecessorin-interest, its confidential compound, PSI-6130 from 2003 to 2011. Gilead Trial Br. 8-9, ECF 368. Next, Gilead argues Merck's unclean hands bars enforcement of the patents against it because Merck improperly obtained the structure of PSI-6130 from Pharmasset, drafted patent claims covering PSI-6130, and then lied about its conduct during this proceeding. Gilead Trial Br. 2-8, ECF 368. Merck responds that it never explicitly or implicitly indicated that it would not enforce the '499 and '712 Patents against Gilead. Merck Tr. Br. 5-6, ECF 370. Merck also argues the jury's rejection of Gilead's invalidity defense forecloses Gilead's unclean hands defense and even if it did not, Merck's actions do not warrant a finding of unclean hands. Merck Trial Br. 1-6, ECF 370; Merck Supp. Trial Br., ECF 409. With that brief overview of the parties' arguments, the Court makes the following findings of fact and conclusions of law.¹

A. The 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., formerly known as Isis Pharmaceuticals, Inc. ("Ionis" or "Isis"), (collectively, "Defendants" or "Merck") are the parties in this action. Compl., ECF 1.

2. 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. Compl.

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¹ To the extent that any conclusion of law is deemed to be a finding of fact, it is adopted as such; and likewise, any finding of fact that is deemed to be a conclusion of law is so adopted.

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¶ 2, ECF 1.

3. 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. Compl. ¶ 3, ECF 1; Ans. ¶ 3, ECF 62.

4. 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. Compl. ¶ 4, ECF 1; Ans. ¶ 4, ECF 62.

> 5. MSD Corp. is a subsidiary of Merck & Co. Compl. ¶ 5, ECF 1; Ans. ¶ 5, ECF 62.

9 6. 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. Compl. ¶ 6, ECF 1; Ans. 10 ¶ 6, ECF 62.

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B. **General Background of the Litigation**

7. The patents-in-suit are U.S. Patent Nos. 7,105,499 (the "'499 Patent") and 8,481,712 (the "712 Patent"). Compl. ¶¶ 62-77, ECF 1. On August 30, 2013, Gilead filed its complaint for declaratory judgment of non-infringement and invalidity of the '499 and '712 Patents. Compl. ¶ 1, ECF 1.

8. On November 22, 2013, Merck filed its answer and amended counterclaims. Ans., ECF 62. Merck denied all allegations involving non-infringement and invalidity, *id.* at ¶¶ 66-77, and counterclaimed for a declaratory judgment of infringement of the '499 and '712 Patents, id. at ¶¶ 11-34.

9. On November 28, 2014, Merck filed its second amended and supplemental counterclaims. Second Am. Countercl., ECF 98. Merck repeated its previous counterclaims seeking declaratory judgment of infringement of the '499 and '712 Patents, and added additional counterclaims for infringement of the '499 and '712 Patents based on the fact that Gilead began commercially selling sofosbuvir on or about December 6, 2013. Id. at 1 n.1.

10. On December 15, 2014, Gilead filed its answer to Merck's second amended and 26 supplemental counterclaims. Ans. to Second Am. Countercl., ECF 101. Gilead denied all 27 28 pertinent allegations regarding infringement and invalidity, id. at ¶¶ 11-43, and asserted

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affirmative defenses based on invalidity, laches, estoppel, waiver, and unclean hands, id. at 6.

11. Merck moved for summary judgment that Gilead's products (Sovaldi® and Harvoni®) that contain the active pharmaceutical ingredient "sofosbuvir" infringe the asserted claims. Merck's Mot. for SJ, ECF 167. Gilead argued that the asserted patents are invalid but conceded that if they are not invalid, then it infringes the asserted claims. Gilead's Opp. to SJ at 1, ECF 175. On February 1, 2016, the Court granted as unopposed Merck's motion for summary judgment that the sale by Gilead of Sovaldi® and Harvoni® infringes the asserted claims. Summary Judgment Order at 8, ECF 214. The Court left to a jury trial the issue of whether the asserted patents are invalid. Id. at 9.

12. At trial, Merck asserted claims 1 and 2 of the '499 Patent and claims 1, 2, 3, 5, 7, 9, 10 and 11 of the '712 Patent. Joint Pretrial Stmt. at 3, ECF 254.

13. From March 7-16, 2016, the Court held an eight-day jury trial on Gilead's invalidity defenses under 35 U.S.C. § 112 (lack of written description and enablement) and § 102 (derivation and prior invention). ECF 305, 306, 307, 324, 325, 327, 348, 349.

14. On March 22, 2016, the jury reached a verdict, finding the '499 and '712 Patents were not invalid. Verdict Phase 1, ECF 388. Following a three day trial on damages, ECF 386, 389, 391, the jury awarded Merck \$200 million in damages for sales of Sovaldi® and Harvoni® through December 31, 2015. Verdict Phase 2, ECF 392.

19 15. On March 30, 2016, the Court held a bench trial on Gilead's equitable defenses. 20ECF 401. Prior to the bench trial, on March 22, 2016, Gilead withdrew its defenses of laches and equitable estoppel. Gilead Trial Br. at 1 n.1, ECF 368. As a result, the March 30 bench trial addressed Gilead's defenses of unclean hands and waiver. Gilead Trial Br., ECF 368; Merck Trial 22 23 Br., ECF 370.

16. On April 22, 2016, Gilead filed a motion to re-open the record and allow additional 24 evidence. ECF 410. On April 29, 2016, the Court held a hearing on Gilead's motion where the 25 Court granted the motion and also allowed Merck to supplement the record. ECF 418. 26

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Background on Hepatitis C

17. HCV was discovered in the late 1980s. Trial Tr. 191:14-17 (McHutchison). Around 170 million people in the world and 3.2 to 3.5 million people in the United States have HCV. Trial Tr. 197:22-198:1 (McHutchison).

18. HCV is a blood borne disease. Trial Tr. at 195:19-196:16 (McHutchison). Prior to 1991, blood donations were not screened for HCV and people contracted HCV through blood transfusions. *Id.* Today, HCV is spread in other ways including the sharing of a needle or a used razor. *Id.* When a person is infected with HCV, the virus attacks and invades the liver. *Id.*Damaged liver cells are replaced with scar tissue, eventually resulting in cirrhosis and potentially causing liver cancer and requiring a liver transplant. *Id.*

19. There are seven strains, or genotypes of the HCV virus. Trial Tr. 198:2-199:2
(McHutchison). In the United States, the most common type of strain is genotype 1 (affecting between 67 and 75% of infected people) followed by genotype 2 and 3. *Id.*

20. Historically, individuals with HCV genotype 1 were treated with interferon or a combination of interferon and ribavirin. Trial Tr. 199:6-17 (McHutchison). Initially such treatment consisted of three interferon injections a week for one year and subsequently improved to one injection a week with ribavirin pills twice a day. *Id.* Side effects from this treatment resembled the flu and included fevers, chills, shakes, burning muscles, and headaches. Trial Tr. 200:6-18 (McHutchison).

21. Because of the side effects, on average, 20 percent of individuals would not participate in the treatment and 20 percent of people who started the treatment could not complete it. Trial Tr. 199:18-25; 200:19-201:1 (McHutchison). Moreover, of those who successfully completed the treatment, only about 40 percent were actually cured. *Id*.

22 22. In the 1990s and 2000s, significant efforts were made by various individuals and
entities to find improved treatment options for HCV. *See, e.g.*, Trial Tr. 201:2-4 (McHutchison)
(researched HCV treatment at Scripps Clinic and Duke University); Trial Tr. 209:15-211:13
(McHutchison) (explaining Gilead's attempts to treat HCV); Trial Tr. 254:14-255:8 (Sofia)
(discussing collaboration between Roche and Pharmasset); Trial Tr. 491:19-493:1 (Otto)
(explaining Pharmasset's research regarding HCV in the early 2000s); Trial Tr. 949:18-23 (Olsen)
(discussing joint collaboration between Merck and Isis to research HCV treatments).

23. HCV is particularly difficult to treat for at least a few different reasons. Trial Tr. 197:4-21 (McHutchison). HCV has developed several different ways to evade the immune system and is constantly replicating. *Id*. For example, once infected, a person may have a trillion viruses in their body with half of those viruses being replaced every three to five hours. *Id*. In addition, drugs that may be effective against HCV in a laboratory setting may be unsuitable for humans due to toxic side effects. Trial Tr. 249:3-17 (Sofia). Even when a drug that is effective against HCV is discovered, it must still be delivered to the virus and liver without being converted into an inactive drug by the body. Trial Tr. 249:18-250:9 (Sofia).

D. The '499 and '712 Patents

24. Merck and Isis are joint assignees of the '499 and '712 Patents. Joint Pretrial Stmt. at 2, ECF 254.

25. The patents share a common specification, Stipulation, ECF 300; Trial Tr. 1787:20-24 (stipulation), and arose out of a joint collaboration between Merck and Isis dating from 1998-2003, Trial Tr. 961:10-17; 994:25-995:3 (Olsen). The purpose of the collaboration was to find nucleoside inhibitors of HCV RNA replication by targeting the NS5B polymerase. Trial Tr. 949:18-23 (Olsen).

26. Merck employees Dr. David Olsen, a research scientist, Trial Tr. 920:22-24 (Olsen), and Steve Carroll, an enzymologist, were some of the people that led the Merck-Isis collaboration, Trial Tr. 948:19-949:12 (Olsen).

2027. As part of that years-long collaboration, the Merck-Isis scientists tested more than 21 2,000 nucleoside analogs, of which at least 1,000 were novel compounds made by Isis. Trial Tr. 22 970:21-971:2 (Olsen). The group's work was guided in part by its analysis of structure activity 23 relationships, which it used to identify compounds that were likely to be active. Trial Tr. 963:4-12 24 (Olsen). The inventors tested the compounds of the invention using an NS5B polymerase 25 biochemical assay and a cell-based replicon assay. Trial Tr. 948:15-949:7, 969:21-970:11 (Olsen); 1561:7-15 (Wuest). The assays were performed in 96-well plates to test many compounds at one 26 time. Trial Tr. 948:15-949:7, 1013:9-1014:1 (Olsen). 27

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- 28. Philippe Durette, an in-house patent prosecutor at Merck, became involved with the

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Merck-Isis collaboration in late 2000. Trial Tr. 991:10-16 (Olsen). Dr. Durette has a bachelor's degree from Marquette University and a Ph.D. from The Ohio State University. Trial Tr. 412:14-15 (Durette). Dr. Durette did a post-doctoral fellowship for three years and afterwards started his career as a medicinal organic chemist at Merck. Trial Tr. 412:18-413:5 (Durette). After 25 years working in laboratory settings, Dr. Durette went to law school at Rutgers University and subsequently passed the bar exams in New Jersey and Pennsylvania in 1993 and 1994. Trial Tr. 413:4-13 (Durette).

8 29. On January 22, 2001, Dr. Durette filed U.S. Provisional Application No. 9 60/263,313. EX-0804. Subsequently, Dr. Durette filed additional provisional applications in April, June, and October of 2001. EX-0805, 0806, 0807. 10

30. The patent applications included over 150 examples depicting compounds of the invention. Trial Tr. 928:24-929:1 (Olsen).

31. On January 18, 2002, Dr. Durette filed two non-provisional patent applications having the same specification, one of which was the PCT application that led to the '499 Patent. EX-0808, 0829. These applications incorporated the provisional patent applications by reference. Trial Tr. 1587:22-1588:13 (Wuest).

32. Dr. Olsen, Dr. Carroll, Dr. Durette, and various team members were involved in drafting the 2002 patent application that eventually resulted in the '499 and '712 Patents. Trial Tr. 19 990:11-991:4 (Olsen).

33. On July 9, 2003, Dr. Durette filed U.S. Patent Application No. 10/258,873 (the "'499 application"), the specific application that resulted in the '499 Patent. EX-0829. It claims priority to the January 18, 2002, non-provisional patent application. EX-0001.

23 34. Upon initially filing the '499 application, Dr. Durette submitted a preliminary amendment presenting ten claims for prosecution. EX-0829.0247-0259. Among the ten claims 24 25 for prosecution was claim 44. Id. Pending claim 44 covered the use of a compound from among structural formula III as defined within the claim to treat HCV. EX-0829.0257-0258. The generic 26 structural formula III as defined in pending claim 44 was identical to a sub-embodiment of 27 28 structural formula III in the specification. Compare id. with EX-0001.0009. That sub-

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1 embodiment of structural formula III is limited to only single-ring, or pyrimidine, bases. Id. 2 Pending claim 44 containing generic structural formula III never issued as a patent claim. 3 35. Between July 9, 2003 and February 7, 2005, no substantive actions took place with respect to the '499 application. EX-8029.0001-1092. However, Dr. Durette did not forget about 4 the '499 application as he exchanged correspondence with the Patent Office in 2003 and 2004: 5 On October 14, 2003, Dr. Durette submitted an information disclosure 6 a. 7 statement that disclosed related applications 10/052,318 and 10/431,657. EX-8 8029.1070-76. 9 b. On December 4, 2003, the Patent Office issued a notice that that the '499 application was missing an oath or declaration of the inventors in compliance with 10 37 CFR 1.497(a) and corresponding fees. EX-8029.1077-78. 11 On January 16, 2004, Dr. Durette responded to the notice by enclosing a 12 c. 13 declaration and power of attorney executed by the inventors and the appropriate 14 fees. EX-8029.1080-88. 15 d. On February 11, 2004, the Patent Office issued a notice of acceptance for examination that the application complied with all the requirements of 35 U.S.C. § 16 371. EX-8029.1091-92. 17 18 E. The Beginning of the Pharmasset and Merck Conversations 19 36. During the early 2000s, Pharmasset was a research-based pharmaceutical company 20focused in the field of nucleoside derivatives as potential antiviral treatments, including treatments for HCV. Trial Tr. 489:21-490:3; 491:23-492:6 (Otto). 21 37. In 2001, Pharmasset and Merck explored potential collaboration opportunities. 22 23 Trial Tr. 1019:21-1020:2 (Olsen). In order to facilitate discussions, on January 29, 2001, Pharmasset entered into a Non-Disclosure Agreement ("NDA") with Merck. EX-2298. 24 38. 25 The purpose of the NDA was to permit disclosure of "certain confidential and proprietary information concerning discovery and development of antiviral agents against 26 flaviviruses, in particular hepatitis C virus (HCV)" for the purpose of "evaluating a possible 27 28 business relationship between the Parties." EX-2298.0002. 9

2 3 40. 4 5 EX-2298.0003, ¶ 6. 6 41. 7 8 9 10 11 42. 12 Northern District of California 13 43. 14 15 16 44. 17 18 19 45.

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39. Under the NDA, Merck agreed to hold the confidential information disclosed to it by Pharmasset in confidence and not to disclose any confidential information to any third party without the prior written authorization of Pharmasset. EX-2298.0003, \P 5.

40. Under the NDA, Merck agreed that it would not use Pharmasset's confidential information for any purpose other than for evaluating a potential collaboration with Pharmasset.
EX-2298.0003, ¶ 6.

41. On August 22, 2003, Pharmasset and Merck amended their NDA, again for purposes of evaluating a potential collaboration. EX-1241.0001. The August 22, 2003, Amendment stated that all terms and conditions of the January 29, 2001, Non-Disclosure Agreement would remain in full force and effect. *Id*.

42. One month later, on September 22, 2003, Pharmasset presented to Merck an overview of its HCV program. EX-2300.

43. The presentation focused on Pharmasset's evaluation of its compound identified as PSI-6130 in both the replicon assay and the HCV NS5B polymerase assay. EX-2300.0002. PSI-6130 was first recorded by Pharmasset employee Jeremy Clark on December 6, 2002. EX-2383 at 32:11-32:17, 33:05-33:14, 34:10-34:14, 36:04-36:16, 36:24-37:12.

44. During the presentation, Pharmasset also presented to Merck data on the potency of PSI-6130 in the NS5B polymerase assay. EX-2300.0014, 0017, 0019.

45. Thus, by September 22, 2003, Merck was aware that Pharmasset's lead compound, PSI-6130, was an NS5B polymerase inhibitor whose mechanism of action was to inhibit the NS5B polymerase enzyme.

46. On October 23, 2003, Pharmasset and Merck executed a Material Transfer
Agreement ("MTA") authorizing Merck to conduct testing and evaluation of ten Pharmasset
nucleosides, including PSI-6130. EX-1231.0002, .0006. The MTA referred to the "Evaluation of
Pharmasset HCV NS5B Nucleoside Inhibitor." EX-1231.0012.

47. Under the MTA, Merck agreed to limit its use of the disclosed nucleoside
compounds to testing and evaluation as set forth in the Agreement. EX-1231.0007. The MTA
also barred Merck from determining the chemical structure of the nucleosides provided for testing.

Id.

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48. On December 12, 2003, Pharmasset and Merck amended their MTA to include further evaluation of PSI-6130 as an HCV inhibitor. EX-1231.0003. The amendment described PSI-6130 as "a Nucleoside HCV NS5B Inhibitor" and as "the HCV NS5B polymerase inhibitor." EX-1231.0004.

49. Under the terms of these additional material transfer agreements, Merck knew that
Pharmasset's PSI-6130 was an NS5B polymerase inhibitor. *Id.*

50. In January 2004, Merck tested PSI-6130 and told Pharmasset that the in vitro results were "very encouraging." EX-2302.0002. Moreover, Merck requested certain information about the structure of PSI-6130. EX-2302.0003; EX-0183.0001.

51. Maintenance of confidentiality was critically important to Pharmasset. A confidential compound's structural information is a biopharmaceutical company's "crown jewels."
EX-2400 at 166:19-168:7; *see also* EX-2397 at 22:9-20.

52. Dr. Durette admitted that "[h]aving structural information is very important as to what the competition is doing in its research efforts." Durette Dep. Tr. (EX-2388) at 38:25-39:7; Trial Tr. at 359:15-18 (Durette).

53. In furtherance of the Pharmasset-Merck discussions, Merck proposed that structural information be shared with a "firewalled" Merck medicinal chemist, Dr. Wallace Ashton, to "help guide [Merck] in framing a relationship with Pharmasset in the HCV field." EX-2302.0003; EX-0183.0001.

54. In an effort to encourage Pharmasset to give Merck structural information about PSI-6130, Merck told Pharmasset that "[i]t will be very helpful to Merck if Pharmasset would consider allowing a Merck Medicinal Chemist, who is 'firewalled' from our internal HCV program, assess the lead and back-up Pharmasset compounds." EX-2302.0003.

55. A firewall is a key method to protect a confidential compound's structural
information, because it limits that confidential information to only individuals not involved with
the project at hand, therefore maintaining confidentiality. EX-2400 at 166:19-168:7.

56. Merck understood that the purpose of the firewall was to protect Pharmasset's

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confidential structural information about its lead compound, PSI-6130. EX-2302.0003; *see also* EX-2397 at 24:08-24:11, 24:14-16.

57. Pharmasset only agreed to provide more information about the structure of PSI-6130 to Merck personnel who were within the firewall (i.e., "firewalled"). EX-2302.0001-.0002.

58. A firewalled person would not have any involvement with Merck's internal HCV program. EX-2302.0001.

59. Thus, Pharmasset was willing to provide structural information about PSI-6130 to Merck because there was a confidentiality agreement in place between the parties and the information would be firewalled. EX-2302.0001.

60. On February 4, 2004, Pharmasset provided information to firewalled Merck chemist, Dr. Wallace Ashton, disclosing that PSI-6130 was a cytosine base containing nucleoside, without a N=O bond, and with a 5' hydroxyl group. EX-0046.001; EX-0047.0001-2.

61. In communicating that structural information, Pharmasset reminded Dr. Ashton that the information was only being shared with him because he was firewalled. EX-0047.0001.

62. Dr. Ashton understood that, as a firewalled chemist receiving structural information about PSI-6130, he was not permitted to communicate specifics of the compound's structure to anyone outside the firewall. EX-2397 at 24:8-26:4, 34:8-12.

63. Despite the NDA, MTA and firewall restrictions, in March 2004, Merck directed
Dr. Durette, one of its in-house patent attorneys, to participate in a due diligence call with
Pharmasset. Trial Tr. at 355:22-360:15 (Durette); EX-0153.

64. As discussed *supra* Findings of Fact ("FOF") ¶¶ 28-29, since 2001, Dr. Durette had
been the attorney responsible for prosecuting patent applications related to nucleoside analogs for
the treatment of HCV based on the Merck-Isis HCV collaboration, including the '499 application.
Trial Tr. at 328:21-24 (Durette). These patent applications disclosed NS5B polymerase inhibitors.
EX-0001; EX-0808.

65. On March 11, 2004, one month after the Patent Office issued the '499 application's
notice of acceptance for examination, Dr. Durette was copied on an e-mail from Pamela Demain, a
Merck corporate licensing specialist, regarding the upcoming March 17, 2004, due diligence call

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with Pharmasset. Trial Tr. 356:20-357:10 (Durette). The other recipients of this e-mail were 2 Mervyn Turner, Anthony Ford-Hutchinson, Barbara Yanni, Malcolm Maccoss, Daria Hazuda, 3 David Olsen, Scott Kauffman, Doug Pon, Frank Potter, Michael Rabinowitz, Durga Bobba, and Linda Stefany. The e-mail evidences Merck's intention that Dr. Durette would participate in the 4 due diligence call. 5

66. In that March 11, 2004, e-mail, Ms. Demain noted that "Pharmasset has not yet permitted us to review the structure of PSI-6130." EX-0153.0001.

67. In that March 11, 2004, e-mail, Ms. Demain wrote "[a]s a first step, Phil Durette will view the structure during a patent due diligence meeting on March 17[, 2004]." EX-0153.0001.

68. Ms. Demain's March 11, 2004, e-mail attached a proposed Merck-Pharmasset term sheet. She stated in the e-mail that the term sheet had been reviewed by Dr. Durette. Trial Tr. at 2499:1-2500:1 (Demain); EX-0153.0001.

69. The proposed term sheet that Dr. Durette reviewed stated that Pharmasset's "lead compound PSI 6130... is a chain terminator of HCV polymerase." EX- 2394.0002; Trial Tr. at 2500:5-21 (Demain).

70. A chain terminator of HCV polymerase is the same type of compound for which Dr. Durette was prosecuting patent applications for Merck, and the same type of compounds which were the subject of the Merck-Isis collaboration. Trial Tr. at 951:12-955:21 (Olsen) (describing collaboration as focused on chain terminators).

71. From his review of the term sheet and Ms. Demain's email, Dr. Durette knew, before the March 17, 2004, patent due diligence phone call with Pharmasset, that:

PSI-6130 was Pharmasset's lead compound, EX-0153.0001; EXa. 2394.0002; Trial Tr. at 1430:9-18 (Demain);

Pharmasset believed PSI-6130's value was "in excess of \$100 million b. total," EX-153.0001;

he would learn the structure of PSI-6130 during the March 17, 2004 phone 27 c. 28 call, EX-0153.0001;

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1 d. PSI-6130 was a chain terminator of the HCV polymerase, Trial Tr. at 2500:17-2501:4 (Demain); EX-2394.0002; and 2 3 PSI-6130 was an NS5B polymerase inhibitor, Trial Tr. at 2500:17-2501:4 e. (Demain); EX-2394.0002. 4 72. In light of the facts recited supra FOF ¶ 64-70, the Court finds that Dr. Durette 5 knew, before the March 17, 2004, phone call, that any information he learned about Pharmasset's 6 7 PSI-6130 nucleoside analog compound would overlap with the subject matter of his patent 8 prosecution docket for Merck, thereby creating a conflict. Trial Tr. at 354:14-355:16; 364:11-365:11, 375:7-23 (Durette). 9 73. 10 Furthermore, Dr. Durette did not qualify as a firewalled individual; he was prosecuting patents from the Merck-Isis collaboration. See, e.g., Trial Tr. 990:11-991:4 (Olsen). 11 12 74. Merck's corporate policy forbids Merck's patent prosecutors from participating in 13 licensing discussions in an area related to their prosecution work. Durette Dep. Tr. (EX-2388) at 38:25-39:7. 14 15 75. Dr. Durette knew, before the March 17, 2004, due diligence phone call with Pharmasset, that learning the structure of PSI-6130 would overlap with his responsibilities in 16 prosecuting patent applications concerning the Merck-Isis collaboration, including the '499 17 18 application and violate corporate policy. 19 Thus, in light of the facts recited supra FOF ¶¶ 64-75, the Court finds that it was 76. 20improper for Merck to plan to have its employee Dr. Durette participate on the March 17, 2004, due diligence call with Pharmasset. 21 22 F. **The Phone Call** 23 77. On March 17, 2004, a due diligence phone call was held between Merck and Pharmasset. EX-2098. 24 25 78. The Merck participants on the March 17, 2004, phone call were Dr. Durette and Dr. Pon. Id. The Pharmasset participants on the March 17, 2004, phone call were Alan Roemer, Dr. 26 27 Raymond Schinazi, and Bryce Roberts. Id. 28 79. This March 17, 2004, phone call occurred barely one month after Dr. Durette 14

received the '499 application's notice of acceptance for examination. Trial Tr. 354:24-355:16
 (Durette).

80. Mr. Roemer took notes during the call. EX-2098.

81. During the March 17, 2004, call, Dr. Durette learned the structure of PSI-6130. Trial Tr. at 431:7-14 (Roemer); Trial Tr. at 347:9-22 (Durette); EX-2098.

82. At the beginning of the call, Dr. Schinazi reminded everyone that it was a firewalled conversation. Trial. Tr. at 382:8-12 (Durette); EX-2098.0001 (RFS: "Firewall"). This meant that no one from Merck on the telephone call should have been involved in Merck's HCV program. EX-2302.0003.

83. Before Pharmasset revealed the structure of PSI-6130, Dr. Durette did not tell
Pharmasset that he was prosecuting patents in the same field of HCV nucleoside analogs. Trial
Tr. at 435:7-12 (Roemer); EX-2098; Trial. Tr. at 382:8-383:6 (Durette).

84. Merck violated its own company policy by directing Dr. Durette to participate in the due diligence phone call with Pharmasset. Durette Dep. Tr. (EX-2388) at 38:25-39:7.

85. Mr. Roemer's notes reflect that after initial information about the structure of PSI-6130 was disclosed, Dr. Durette stated that the information he learned "seems quite related to things that I'm involved with," and that he "need[ed] to have a conversation with his supervisor."
EX-2098.0002. Moreover, according to Mr. Roemer's notes, Dr. Durette clarified that he was "personally conflicted; not the company." EX-2098.

86. At the end of the call, Mr. Roemer again reminded the Merck attendees that this was a firewalled conversation, and sought confirmation that Dr. Durette and Dr. Pon were within the "firewall" of the Confidentiality Agreement. Trial Tr. 382:8-18 (Durette); Trial Tr. at 434:1-24 (Roemer); EX-2098.0002.

At the end of the call, both Dr. Durette and Dr. Pon specifically stated that each of
them was within the firewall. Trial Tr. at 434:1-20 (Roemer); EX-2098.0002.

26 88. After the March 17, 2004, call, neither Merck nor Dr. Durette ever informed
27 Pharmasset that Dr. Durette was not in fact firewalled and was in fact prosecuting Merck's patents
28 in the same field.

89. At his deposition, Dr. Durette testified that if he had learned the structure of PSI-6130, then according to Merck's procedures and policies, he would have had to turn his prosecution of Merck's HCV patents over to another attorney. Durette Dep. Tr. at 201:23-202:16, ECF 410-3.

90. Instead of withdrawing from prosecution, Dr. Durette continued to prosecute
Merck's HCV patent applications and write new claims that targeted Pharmasset's work. The new claims that targeted Pharmasset's work were based on the information he learned on the March 17, 2004, patent due diligence call.

91. The Court finds that:

a. Dr. Durette's statements to Pharmasset on the March 17, 2004, call about being within the firewall were untrue;

b. Merck, through Dr. Durette and Dr. Pon, knowingly misrepresented to Pharmasset that Dr. Durette was firewalled;

c. it was a violation of the Merck-Pharmasset firewall for Dr. Durette to participate on the March 17, 2004, call;

d. it was improper for Merck and Dr. Durette never to have informed
Pharmasset that Dr. Durette was not within the firewall and was in fact prosecuting
Merck's patents in the same field;

e. after Dr. Durette learned the structure of PSI-6130 on the March 17, 2004, phone call, Merck was required to recuse Dr. Durette from any further prosecution of the Merck-Isis patent applications, in order to comply with Merck's obligations under the NDA, EX-2298, EX-0124, and the firewall; and

f. Merck and Dr. Durette's failure to recuse Dr. Durette from further
prosecution of the Merck-Isis patent applications was an improper business practice.
92. Neither Merck nor Dr. Durette has provided any explanation for why Dr. Durette
was not excluded from further prosecution of the Merck-Isis patent applications after learning the

27 structure of PSI-6130 during the firewalled patent due diligence call.

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G. Dr. Durette's Continued Prosecution of the '499 and '712 Patents

93. On the March 17, 2004, patent due diligence call, Dr. Durette was told by Pharmasset that Pharmasset's patent application would be publishing in November 2004. EX-2098.0002.

94. Pharmasset's patent application naming Jeremy Clark as the inventor and disclosing the structure of PSI-6130 published on January 13, 2005. EX-0155.

95. As of February 1, 2005, the Patent Office had not allowed the then-pending claims of the '499 application. EX-0829.

96. On February 1, 2005, Dr. Durette cancelled all then-pending claims of the '499 application and submitted the two new, narrower claims (53 and 54) for prosecution. EX-0156.0004.

97. None of the listed inventors on the '499 Patent was involved in Dr. Durette's patent claiming strategy or the change in claims that took place on February 1, 2005. Bhat Dep. Tr. (EX-2377) at 100:11-17; Eldrup Dep. Tr. (EX-2378) at 55:24-56:6; Carroll Dep. Tr. (EX-2379) at 129:1-10; Cook Dep. Tr. (EX-2376) at 255:11-15; Olsen Dep. Tr. (EX-2380) at 213:18-21. This is despite the fact that several Merck-Isis team members had been involved with drafting the initial application. Trial Tr. 990:11-991:4 (Olsen) (explaining Dr. Olsen, Dr. Carroll, Dr. Durette, and various team members were involved in drafting the 2002 patent application that eventually resulted in the '499 and '712 Patents).

98. The then-pending claims had not been rejected by the patent examiner at the Patent Office, and the examiner had not asked Dr. Durette to narrow the claims. *See* EX-8029. Dr. Durette did that on his own. Trial Tr. at 372:18-23 (Durette).

99. The two new, narrower claims Dr. Durette submitted on February 1, 2005, do not cover any compound tested by Merck and Isis during the Merck-Isis collaboration. Stipulation, ECF 300; Trial Tr. 554:6-10 (stipulation).

100. The two narrowed claims issued as claims 1 and 2 of the '499 Patent. EX-0156.0004; *see also* EX-0001.0071.

101. Dr. Durette waited until Pharmasset published the structure of PSI-6130 and then

wrote claims to cover Pharmasset's invention. Trial Tr. at 369:24-374:4, 389:25-390:14; 417:1-19 (Durette).

102. The Court finds that Dr. Durette waited to amend the claims in the '499 Patent until Clark application was published to give the appearance that he learned it from a public source.

103. Dr. Durette has admitted that he would not have been able to associate any structure in the Pharmasset application as the structure of PSI-6130 unless he knew the structure of PSI-6130 beforehand. Durette Dep. Tr. at 53:1-6, 53:22-54:5, ECF 410-3.

104. The Court finds that Dr. Durette would not have written new claims to cover PSI-6130 in February 2005 but for his improper participation on the March 17, 2004 patent due diligence call and learning the structure of PSI-6130 ahead of the structure being published.

105. Additionally, in further violation of Merck's corporate policy and the Merck-Pharmasset firewall, it was improper for Merck to allow Dr. Durette to prosecute the '712 Patent after having participated on the March 17, 2004, call and learning the structure of PSI-6130. Dr. Durette filed the application that resulted in the '712 Patent in February 2007. EX-2375 (Bergman Dep. Tr.) at 26:16-24, 27:03-06; EX-0192.0003.

106. The '499 and '712 Patents share a common specification. Stipulation, ECF 300; Trial Tr. 1787:20-24 (stipulation).

H. **Dr. Durette's Deposition**

107. Dr. Durette was deposed in this case on May 8, 2015. Durette Dep. Tr. at 1, ECF 410-3.

108. Dr. Durette was Merck's designated Fed. R. Civ. P. 30(b)(6) corporate representative on issues related to the preparation and prosecution of the patent application leading 22 23 to the '499 patent-in-suit, including all reasons for amending any pending claim during prosecution. Durette Dep. Tr. at 181:25-182:16, ECF 410-3. 24

At the deposition, Dr. Durette was represented by Merck's outside counsel. 25 109. Durette Dep. Tr. at 7:16-19, ECF 410-3. 26

Leading up to his deposition, Dr. Durette met with Merck's outside and inside 27 110. 28 counsel for two full days of preparation, six to seven hours for each day. Durette Dep. Tr. at

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10:19-11:11, ECF 410-3.

111. Dr. Durette spent an additional 8-10 hours on his own preparing for the deposition.*Id.*

112. Dr. Durette testified at his deposition that he had the same memory of events before and after looking at documents related to the Merck HCV program. Durette Dep. Tr. at 14:815:11, ECF 410-3.

113.During the deposition, Dr. Durette was questioned about his participation in theMarch 17, 2004, patent due diligence call.Durette Dep. Tr. (EX-2388) at 30:21:31:10.

114. When asked about the March 17, 2004, call at the deposition, Dr. Durette denied
ever having been on such a call. When asked whether he was sure that he was not on the March
17, 2004, call, Dr. Durette unequivocally answered yes.

12	Q:In March of 2004 were you involved in any discussion with		
13	Pharmasset whereby you were told what the structure was for their 6130		
14	compound?		
15	A: No.		
16	Q: You're sure of that?		
17	A: Yes.		
18	Durette Dep. Tr. (EX-2388) at 30:21-31:3.		
19	115. Dr. Durette also stated that he was "positive" that the structure of PSI- 6130 was		
20	0 "never" revealed to him:		
21	Q: How are you so sure 11 years later that you were never told what the		
22	structure was for the 6130 compound?		
23	A: The structure was not revealed to me by individuals at Merck or		
24	otherwise. I'm positive of that. I never saw a structure of the Pharmasset		
25	compounds until it published later on in time.		
26	Durette Dep. Tr. (EX-2388) at 31:4-31:10.		

27 116. Dr. Durette did not say that he did not remember a call or that he could not be sure,
28 but definitively stated that he was sure he was never on the call and "positive" that he never saw

1 the structure of PSI-6130 prior to it being published later. Id. Later in the deposition, Dr. Durette also definitively stated that "I never participated 2 117. 3 in a due diligence meeting on March 17 because the due diligence component of this potential deal was assigned to another attorney, so there was-I did not participate in any meeting of due 4 diligence on March 17." Durette Dep. Tr. (EX-2388) at 37:13-18. 5 118. Dr. Durette offered several reasons why he never learned the structure of PSI-6130 6 7 in March 2004. 8 Q: How can you be so sure of that memory? 9 A: Because I was not part of the patent due diligence for the structure, so I would not have been privy to any revelation of the structure to me as a 10 patent attorney working on a related docket. So this was assigned to 11 12 another person. So I would not have participated in a phone call wherein it 13 was a potential for the revelation of the structure to Merck counsel. 14 Q: Why would that have been inappropriate for you to have been told the 15 structure of 6130? 16 A: Because I was prosecuting a docket which had potential a conflict with Pharmasset's IP positions on the subject matter. 17 18 Durette Dep. Tr. (EX-2388) at 38:1-38:13. 19 Dr. Durette acknowledged at his deposition that it was against Merck's company 119. 20policy to have a Merck patent prosecutor participate in licensing discussions in a related area. Durette Dep. Tr. (EX-2388) at 38:25-39:07. 21 22 120. Dr. Durette explained at his deposition "[h]aving structural information is very 23 important as to what the competition is doing in its research efforts. We had a policy at Merck on a particular docket area if there were potential licensing opportunities in a related area, that due 24 25 diligence would be assigned to a non – an attorney that was not prosecuting a particular docket in a related area." Durette Dep. Tr. (EX-2388) at 38:25-39:7. 26 Dr. Durette acknowledged at the deposition that learning the structure of PSI-6130 27 121. would "have tainted [his] judgment as to what claims to pursue in the Merck/Isis collaboration." 28

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1	Durette Dep. Tr. (EX-2388) at 38:21-38:24.
2	122. Pharmasset's patent application, known as the Clark application, published on
3	January 13, 2005. EX-0155. When Pharmasset's patent application published on January 13,
4	2005, it disclosed a "large collection of compounds." Durette Dep. Tr. at 52:25, ECF 419-1. In
5	Dr. Durette's words, PSI-6130 was but one structure among a "plethora of compounds" disclosed
6	in the patent application. Durette Dep. Tr. at 53:25-54:1, ECF 419-1.
7	123. Without knowing the structure of PSI-6130 in advance of the application, Dr.
8	Durette would not have been able to associate any compound in the patent application published
9	on January 13, 2005, with PSI-6130. Durette Dep. Tr. at 52:19-23, ECF 419-1.
10	Q: How is it that you know that you would not in January of 2005 have
11	realized that Paragraph 0168, that chemical structure there, was 6130?
12	A: Because this was one compound out of a plethora of compounds in the
13	publication.
14	Q: Now, if you had been told prior to this publication what the structure of
15	6130 was, then you would have been able to match it up, right?
16	A: Yes.
17	Durette Dep. Tr. at 53:25-54:5, ECF 410-3.
18	124. Having denied being on the March 17, 2004, due diligence call, Dr. Durette was
19	shown Ms. Demain's March 11, 2004 e-mail which said that he was specifically chosen by Merck
20	to receive the structure of PSI-6130 on a March 17, 2004, patent due diligence call. Durette Dep.
21	Tr. (EX-2388) at 37:02-18; EX-0153. He was asked if this refreshed his recollection. Durette
22	Dep. Tr. (EX-2388) at 37:02-18.
23	125. In the face of Ms. Demain's e-mail, Dr. Durette still denied being on the call,
24	contending "[t]hat was Pamela's evaluation of the time, but I never participated in a due diligence
25	meeting on March 17 because the due diligence component of this potential deal was assigned to
26	another attorney, so there was – I did not participate in any meeting of due diligence on March
27	17." Durette Dep. Tr. (EX-2388) at 37:13-18.
28	126. Dr. Durette was then shown a May 20, 2004, letter and asked if that letter refreshed

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his recollection about the March 17, 2004, call. Durette Dep. Tr. at 168:5-16, ECF 410-3. The May 20, 2004, letter contained a list of things Pharmasset wanted returned, including "notes from a March 17, 2004, telephone conference regarding PSI-6130 patent due diligence with [Doug Pon] and Phil Durette." Id.

Dr. Durette still denied being on the call, stating that it was his sworn testimony 127. that he was not made aware of the structure of PSI-6130 on the March 17, 2004, call, and that he remembered that clearly. Durette Dep. Tr. at 168:24-169:18, ECF 410-3.

128. At the time of his deposition, no one told Dr. Durette that Pharmasset's Alan Roemer had taken contemporaneous notes of that March 17, 2004, patent due diligence phone call. Trial Tr. at 380:22-25 (Durette). 10

Mr. Roemer was deposed by Merck's counsel on May 24, 2015. Roemer Dep. Tr. 129. at 1.

130. At Mr. Roemer's deposition, his notes were used as an exhibit, and Gilead's counsel asked Mr. Roemer about the call that occurred on March 17, 2004. Mr. Roemer testified that Dr. Durette participated in the call and that Dr. Durette was provided the structure of PSI-6130 on that call. Roemer Dep. Tr. at 233:3-22.

131. Between May 24, 2015, the date of Mr. Roemer's deposition, and March 8, 2016, the start of trial, Merck never indicated that Dr. Durette's deposition testimony was untruthful or incorrect.

20 132. In his opening statement at trial, on March 8, 2016, Merck's counsel stated that Merck would not dispute that Dr. Durette was on the March 17, 2004, call with Pharmasset. Trial 22 Tr. at 178:5-179:1 (Merck's opening statement). Counsel for Merck further told the jury that Dr. 23 Durette did not know that the compound that Pharmasset was going to disclose was within the scope of what Merck was working on. Trial Tr. 178:8-11 (Merck's opening statement). That 24 25 representation of Dr. Durette's pre-call knowledge was incorrect. See infra, FOF ¶¶ 142-143.

133. Gilead first learned of Dr. Durette's new story during Dr. Durette's examination at 26 trial. 27

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I. Dr. Durette's Trial Testimony

134. Dr. Durette was outside the subpoena power of this Court and Gilead could not force his attendance at trial. Final Pretrial Conf. Tr. at 42:5-17, ECF 280. Merck, knowing about Dr. Durette's deposition testimony, voluntarily brought Dr. Durette to trial to testify on its behalf.

135. At trial, Dr. Durette provided key testimony for Merck on validity issues, including written description of the '499 Patent. Trial Tr. 391:10-404:19 (Durette). For example, Dr. Durette testified that his amendment to the '499 Patent "was fully supported by the specification," Trial Tr. 403:15-17 (Durette), and that "[Merck] had support for written -- written description support in terms of how to make the[structure] and how to use them." Trial Tr. 410:11-15 (Durette).

136. At trial, Dr. Durette said that his memory of the March 17, 2004, patent due diligence call became refreshed in January 2016 when he reviewed the deposition exhibits in preparation for trial. Trial Tr. at 386:6-15 (Durette).

137. When confronted with his deposition testimony that he had not participated in the Pharmasset-Merck due diligence call, Dr. Durette said he was relying too much on his memory.Trial Tr. at 344:8-17 (Durette).

138. Dr. Durette attempted to explain away his deposition testimony by stating that he had a lapse in memory and "over concluded" based on his memory. Trial Tr. at 344:18-345:7, 347:9-348:1 (Durette).

139. When asked about the March 17, 2004, call at trial, Dr. Durette said that the answers he gave at the deposition were "based on my lack of recollection of the events and I over concluded that I had – that I had not seen the structure." Trial Tr. at 344:1-345:7, 347:9-22 (Durette).

140. Dr. Durette further testified at trial that Pamela Demain, Merck's director of corporate licensing, asked him to attend the March 17, 2004, call. Trial Tr. at 355:17:23, 375:12-19 (Durette).

141. Ms. Demain credibly testified that she did not ask Dr. Durette to attend the call.Trial Tr. at 1404:14-1405:8 (Demain). Instead, Ms. Demain explained she was simply acting as a

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messenger when she sent her March 11, 2004, e-mail and she did not know who asked Dr. Durette to be on that call. Trial Tr. at 1405:1-8 (Demain). The Court concludes that Dr. Durette's testimony was not credible on this point.

142. Dr. Durette also asserted at trial that before the due diligence call, while he knew PSI-6130 was a nucleoside, he did not know that PSI-6130 was an inhibitor of the NS5B polymerase. Trial Tr. at 364:13-18, 365:13-21, 367:13-368:6 (Durette).

143. Contrary to that testimony, Ms. Demain credibly testified that Merck and Dr.
Durette did know that PSI-6130 was a nucleoside NS5B polymerase inhibitor. Trial Tr. at 2498:2-4, 2499:1-2501:4 (Demain); EX-0153; EX-2394. The Court concludes that Dr. Durette's testimony was not credible on this point.

144. Dr. Durette stated at trial that he went into the March 17, 2004, call knowing that he would receive the structure of PSI-6130 but he "did not think it was going to be likely that it would be on the subject matter that was related to the – my HCV docket." Trial Tr. at 350:25-351:9 (Durette).

145. Contrary to that testimony, Dr. Durette was prosecuting patents directed to nucleoside NS5B polymerase inhibitors, Trial Tr. at 367:13-23 (Durette), and he knew going into the call that PSI-6130 was a nucleoside NS5B polymerase inhibitor. EX-0001.0001; EX-0808; EX-2394.0002; Trial Tr. at 2498:2-4, 2499:1-2501:4 (Demain). Again, the Court concludes that Dr. Durette's testimony was not credible on this point.

20146. At trial, Dr. Durette for the first time said that he had had a pre-call meeting with his manager and they had determined that it was fine for him to learn the structure of PSI-6130 21 22 because Dr. Durette was prosecuting patents related to nucleosides with a certain mechanism of 23 action, NS5B polymerase inhibitors. Trial Tr. at 360:16-361:21 (Durette); see also Trial Tr. at 24 365:13-21, 367:13-368:14 (Durette). Specifically, Dr. Durette testified that his manager and he 25 decided it was fine for Dr. Durette to learn the structure of PSI-6130 for several reasons: (1) HCV has "many different target enzymes"; (2) nucleosides for HCV is a "very broad area"; (3) 26 nucleosides that attack different enzymes can have "totally different structures" and different 27 28 "structure types" with "different overall mechanisms of action." Id. Dr. Durette offered no

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explanation for this sudden clear memory.

147. Contrary to that testimony, Merck, and Dr. Durette in particular, knew before the meeting that PSI-6130 was a nucleoside NS5B inhibitor with the same mechanism of action of the compounds for which he was seeking patent protection on behalf of Merck and Isis. EX-2300; EX-1231; EX-0153; EX-2394; EX-0090; Trial Tr. at 2498:2-4, 2500:5-2501:4 (Demain). Ms. Demain credibly testified that Dr. Durette knew this fact. Trial Tr. at 2500:5-2501:4 (Demain). The term sheet attached to the e-mail from Ms. Demain, which Dr. Durette reviewed, states that: "Until then, this amount [of the proposed license] is based on the following assumptions: ... That lead compound PSI-6130 ... is a chain terminator of HCV polymerase" EX-2394.0002. The Court concludes that Dr. Durette's testimony was not credible on this point.

J. Clark Publication

148. Pharmasset's patent application, known as the Clark application, published on January 13, 2005. EX-0155.

149. When Pharmasset's patent application published on January 13, 2005, PSI-6130 was but one structure among a number of structures disclosed in the patent application. EX- 0155.

150. At trial, Dr. Durette said that seeing the Clark application in 2005 caused him to think that any confidentiality obligations he had under the NDA had terminated. Trial Tr. at 369:24-370:14 (Durette).

19 151. Contrary to that testimony, at his deposition, Dr. Durette testified that he had no
20 memory of when he saw Pharmasset's published patent application, and that in any event, he
21 never associated that application with the structure of PSI-6130. Durette Dep. Tr. at 48:15-20,
22 51:25-52:1, ECF 410-3.

In fact, at his deposition, Dr. Durette—who was Merck's corporate representative
with respect to the February 1, 2005 claim amendment—testified that he was not sure if he saw
the Clark publication before the February 1, 2005 claim amendment:

Q: You're just not sure if you saw the Clark publication before February 1,
2005?

A: Correct.

Durette Dep. Tr. at 67:22-24, ECF 410-3; see also id. at 65:14-67:24, ECF 410-3.

153. At trial, Dr. Durette said that seeing the Pharmasset patent application must have been a triggering event that led him to reexamine his docket and look at the '499 Patent application. Trial Tr. at 390:23-391:9 (Durette).

154. Contrary to that testimony, at his deposition, Dr. Durette further testified that Pharmasset's application would have had no impact, even if he had seen the application, on his amendment of Merck's claims. Durette Dep. Tr. at 71:11-72:3.12, ECF 410-3.

155. Dr. Durette also testified at his deposition that he would not have realized that the structure disclosed in paragraph 0168 of the Pharmasset application was PSI-6130 because it was just "one compound out of a plethora of compounds." Durette Dep. Tr. at 53:22-54:5, ECF 410-3.

156. Dr. Durette further testified at his deposition that he never associated the published Clark chemical structure with PSI-6130. Durette Dep. Tr. at 52:19-23, 53:1-6, ECF 419-1.

157. Dr. Durette acknowledged at his deposition that if had he been told the structure of PSI-6130 prior to the patent publication, then he would have been able to match up PSI-6130 to the structure disclosed at paragraph 0168. Durette Dep. Tr. at 54:2-5, ECF 410-3. However, at his deposition, Dr. Durette testified he was not sure he even saw the Clerk publication before February 1, 2005. Durette Dep. Tr. at 65:14-67:24, ECF 410-3.

K. Amendment of the Claims

158. Dr. Durette canceled all pending claims in the '499 Patent application in February
2005 and drafted two new claims to cover PSI-6130. Trial Tr. 375:24-376:10 (Durette). The
Court finds that he did so because he had learned the structure of PSI-6130 on the March 17, 2004, call.

159. At deposition, Dr. Durette testified that he was not sure he saw the Clark
publication prior to amending the claims. Durette Dep. Tr. 48:10-52:1, ECF 410-3. Given the
timing of his amendment, mere days after the Clark publication, and his contradictory and evasive
testimony at trial, the Court finds Dr. Durette's deposition testimony is not credible.

27 160. At his deposition and on cross examination at trial, Dr. Durette insisted that he filed
28 the two, narrower claims in the '499 application simply to "expedite" prosecution. Trial Tr. at

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374:7-375:2 (Durette).

161. At trial, on direct examination by Merck's counsel, Dr. Durette stated that he amended the '499 claims to focus on "get[ting] allowance on the subject matter that was most important to the [Merck-Isis] collaboration." Trial Tr. at 404:14-19 (Durette).

162. Dr. Durette's changing and evasive explanations for why he narrowed the claims undermine his testimony. The Court finds his testimony to be not credible.

163. Additionally, Dr. Durette's claim that he amended the '499 claims to focus on
"get[ting] allowance on the subject matter that was most important to the [Merck-Isis]
collaboration" is contrary to the evidence and is not credible because Merck never tested any of
the claimed compounds. Stipulation, ECF 300; Trial Tr. 554:6-10 (stipulation).

164. Neither Merck nor Isis tested a single compound falling within the new claims of
the '499 Patent during the Merck-Isis collaboration that ended in 2003. Stipulation, ECF 300;
Trial Tr. 554:6-10 (stipulation).

165. Merck did not test a single compound claimed in the '499 Patent until August 2005, after Jeremy Clark's patent application published, and after Dr. Durette added the two new claims to the '499 Patent. Trial Tr. at 576:1-22 (Seeger); Stipulation, ECF 300; Trial Tr. 554:6-10 (stipulation).

18 166. Neither Merck nor Isis made a 2'-methyl up, 2'-fluoro down pyrimidine or purine
19 nucleoside compound, tested such a compound, or used such a compound during the Merck-Isis
20 collaboration that ended in 2003. Bennett Dep. Tr. (EX-2381) at 123:15-124:01, 124:06-21;
21 Duffy Dep. Tr. (EX-2382) at 46:22-25; Trial Tr. at 576:1-22 (Seeger); Stipulation, ECF 300; Trial
22 Tr. 554:6-10 (stipulation).

167. The Court finds that it is not credible that compounds that were never made, used,
or tested during a collaboration were considered by Merck to be the most important work of the
collaboration.

168. The only 2'-methyl up, 2'-fluoro down compound proposed by Merck and Isis was
never made, does not fall within the claims of the '499 Patent, and was a "lower priority." Song
Dep. Tr. (EX-2385) at 175:16-21, 177:1-5, 178:4-9, 189:10-18; *see also* Trial Tr. at 736:8-17

(Secrist); Trial Tr. at 982:9-17, 983:9-984:20 (Olsen); EX-0036.0056; EX-1543.0003; Bennet Dep. Tr. (EX-2381) at 111:2-10, 123:9-12, 124:6-9.

169. Merck did not make a 2'-methyl up, 2'-fluoro down purine or pyrimidine
compound until August 2005, seven months after Mr. Clark's patent application published, and six
months after Dr. Durette filed new patent claims to cover such compounds in February 2005. Trial
Tr. at 1130:12-17; Duffy Dep. Tr. (EX-2382) at 46:22-25.

170. The Court finds Dr. Durette's testimony that the two new, narrower claims he wrote in the '499 Patent were to protect Merck's "most important work" is not credible and is false.²

L. The '712 Patent

171. The '712 Patent was filed on February 2, 2007 as U.S. Patent Application No. 11/701,682 (the "'712 application") by Dr. Durette. EX-0002.0001; EX-0192.0003; Bergman Dep. Tr. (EX-2375) at 25:5-27:6.

172. While Mr. Jeffrey Bergman, Merck's in-house patent attorney, took over prosecution of the '712 Patent application in 2011, Dr. Durette was involved in prosecuting the application prior to that. Bergman Dep. Tr. (EX-2398.0001) at 17:1-7, 17:25-18:7.

173. Merck asserted both the '499 and '712 Patents in this action and Dr. Durette was Merck's 30(b)(6) witness on the prosecution of the '499 Patent, which shares the same specification as the '799 Patent. Durette Dep. Tr. 181:25-182:16, ECF 410-3.

M. Waiver

174. Merck and Pharmasset had discussions in 2003-2004 about the possibility of Merck
in-licensing Pharmasset's lead compound PSI-6130. Trial Tr. 1402:6-24 (Demain). Merck
scientists were interested in PSI-6130 because they believed that combination therapy was the
future of HCV treatment and that PSI-6130, if successful, might be used with Merck's own MK-

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 ² Although Gilead introduced evidence of Dr. Durette's work on a related patent application, the
 ² Although Gilead introduced evidence of Dr. Durette's work on a related patent application, the
 ² 24 Patent application, the Court did not consider it in assessing Merck's misconduct. There are various legitimate reasons why a patentee may choose to abandon a pending application and the fact that Merck and Dr. Durette chose to abandon the prosecution of the '224 Patent application is not relevant.

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0608 compound and other anti-HCV drugs. Trial Tr. 1056:25-1058:2 (Olsen).

175. There is no evidence that Merck communicated to Pharmasset that Merck was waiving its patent rights during the 2004 timeframe. And no one from Pharmasset ever communicated to Merck that it believed Merck waived its patent rights. Trial Tr. 2482:2-18 (Demain). Nothing Merck did could be construed as a waiver of patent rights in 2004.

176. Beginning in 2008 through 2011, there were several years of on-again, off-again negotiations between Merck and Pharmasset over partnering opportunities in the antiviral space including in the HIV, Hepatitis B, and Hepatitis C areas. Trial Tr. 1405:16-1406:11 (Demain). On numerous occasions, Pharmasset contacted Merck to see if Merck was interested in a deal. *Id.*; *see also* Trial Tr. 1407:5-1408:15 (Demain); EX-1675 (timeline of Merck-Pharmasset discussions).

177. In the 2008 period, the driver of discussions was Pharmasset's Hepatitis B drug Clevudine in late-stage clinical studies. Trial Tr. 1405:16-1406:11 (Demain). In October 2008, Merck offered to license Clevudine along with Pharmasset's anti-HCV program, or alternatively, to purchase Pharmasset for \$625 million. EX-1768; EX-0093 at 1-2. In its letter, Merck pointed out that one advantage of Merck acquiring Pharmasset would be that Pharmasset would get "[t]he ability to leverage Merck's intellectual property estate to reduce uncertainty and enhance the value of the Pharmasset assets going forward." EX-1768 at 2; EX-0093 at 2. Merck conveyed to Pharmasset that Pharmasset would benefit by no longer having to concern itself with the risk associated with Merck's blocking patents. Trial Tr. 1409:17-1411:1 (Demain); Trial Tr. 2483:16-2484:19 (Demain).

178. Ms. Demain testified without contradiction that Merck's patents were always in the 21 22 background of the discussions with Pharmasset. Trial Tr. 2482:2-11 (Demain). Ms. Demain dealt 23 primarily with Pharmasset's head of licensing, Abel De la Rosa. Trial Tr. 2482:19-21 (Demain). The two discussed Merck's patents generally, but there was no ambiguity that one of the patents at 24 25 issue was the '499 Patent series. Trial Tr. 2482:22-2483:2; 2520:21-2521:14 (Demain) (explaining that "there's no ambiguity" about which patents were discussed with Dr. De la Rosa "because 26 there were two patents, and it was very clear what we were speaking about"). No Pharmasset 27 witness testified to having any other understanding of these discussions. Ms. Demain conveyed to 28

Pharmasset that there was unique value in Pharmasset partnering with Merck because Pharmasset would gain access to Merck's patents. Trial Tr. 2521:2-8 (Demain).

179. The documents corroborate Ms. Demain's account. On October 8, 2009, in an internal memorandum, Pharmasset stated that "[a]ll things considered, Merck is the ideal strategic partner for PSI-7851 [sofosbuvir] and Pharmasset. Consolidating nucleos(t)ide IP would lower the legal risk of this program." EX-1770 at 2 (emphasis added), App'x at 35.

180. Beginning around October 2009, and carrying through to August 2010, Pharmasset and Merck exchanged draft term sheets that would make Merck a development and marketing partner of sofosbuvir for which Merck would pay Pharmasset, and in which Pharmasset would get a cross-license to Merck's patents. EX-1622 (October 2009); EX-1625 (December 2009 draft); EX-1630 (April 2010 draft); EX-2390 (July 2010 draft); EX-1652 (referencing forthcoming August 2010 draft); Trial Tr. 2484:20-2487:14 (Demain) (discussing draft term sheets).

181. In December 2009, Pharmasset sent a draft term sheet to Merck which provided that Merck would grant Pharmasset a co-exclusive, worldwide license under Merck's patents with respect to the licensed compound, which was sofosbuvir. EX-1625 at 2; Trial Tr. 2486:9-20 (Demain).

182. In April 2010, Pharmasset sent a term sheet to Merck that provided for a similar 17 18 license to Merck's patents. EX-1630; Trial Tr. 2486:25-2487:14 (Demain). Although these term 19 sheets did not specifically mention the '499 and '712 Patents by name, the parties contemplated 20that Pharmasset would get a license to all of Merck's patents in this space. Trial Tr. 1412:16-1413:17 (Demain) (explaining that Pharmasset was looking to license "all of the patents related to 21 22 HCV that Merck had"). At the time of these term sheet exchanges in late 2009 and 2010, the '499 23 Patent had issued and the application that led to the '712 Patent was pending with the Patent 24 Office. EX-0001; EX-0002. And although the term sheets discussed were general in nature and did not list out the particular Merck patents that would have been licensed to Pharmasset, a final 25 agreement would provide an appendix listing the licensed patents and patent applications. Trial Tr. 26 2507:18-24 (Demain). 27

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183. Consistent with Pharmasset's repeated requests, a May 25, 2010, internal Merck

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presentation about the Pharmasset term sheet indicated that Pharmasset had requested a "[n]on-exclusive, worldwide license under Merck patent rights and know how to develop, manufacture and commercialize products containing Licensed Compound [which included PSI-7977, Pharmasset's compound number for sofosbuvir]." EX-1634 at 3; Trial Tr. 2487:18-2489:3 (Demain).

184. On June 16, 2010, Merck sent Pharmasset a counter-proposal that did not include a license from Merck to Pharmasset that would provide Pharmasset freedom-to-operate with regard to Pharmasset's HCV products. EX-1636; Trial Tr. 1413:18-1414:7 (Demain) (explaining Pharmasset's proposed license was too broad and that Merck "took it out of the term sheet").

185. On August 5, 2010, Pharmasset wrote Merck in advance of sending a revised term sheet that once again sought a license to Merck's patent estate. The letter noted that "[t]he licensing of Merck Patent Rights and Know-How is specific to the development, manufacture and commercialization of PSI-7977 as a Monotherapy Product, or as the PSI-7977 component of Pharmasset Combination Products." EX-1652. While most of the term sheets exchanged during this period did not provide for a royalty to Merck, "there was one version that did have royalties going back to Merck." EX-1625 at 7; Trial Tr. 2506:23-2507:1 (Demain).

186. Around September 2010, Merck's interest in a deal changed from a collaboration to a purchase. On September 3, 2010, Merck again sent a letter that stated that one of the benefits to Pharmasset of an acquisition by Merck would include "'[t]he ability to leverage Merck's intellectual property estate to reduce uncertainty and enhance the value of the Pharmasset assets going forward." EX-0069; EX-0686 at 1-2; Trial Tr. 1414:14-1415:10 (Demain). Merck ultimately did not purchase Pharmasset.

187. In 2011, Merck executives informed Pharmasset's CEO, P. Schaefer Price, that
Pharmasset needed a license from Merck to the '499 Patent to commercialize PSI-7977
(sofosbuvir). Merck indicated that "there were claims [of the '499 Patent] that could give
Pharmasset trouble in the future." Mr. Price responded that he hoped Merck's attorney could "find
the courthouse." Price Depo Tr. (EX-2392) at 115:13-116:06. This course of events is entirely
inconsistent with a waiver of patent rights and demonstrates that Pharmasset did not hold any

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belief-much less a reasonable one-that Merck had waived its patent rights.

188. The May 2011 Merck-Roche license, to which Pharmasset consented, is also inconsistent with a waiver. When Merck did not do a deal with Pharmasset for PSI-6130 in 2004, Pharmasset ultimately did a deal with Roche. EX-0627; Trial Tr. 1415:19-1416:4 (Demain). In 2011, when PSI-6130 was in phase II clinical studies and appeared as though it would advance to the next stage of development, Roche approached Merck for an unblocking license so that Merck's patents would not stand in the way of Roche bringing PSI-6130 (then renamed RG-7128) to the market. Trial Tr. 1416:9-23 (Demain). Pharmasset remained the development partner of that product with Roche. Trial Tr. 1417:14-20 (Demain). There is no evidence that Pharmasset ever conveyed to Roche that it thought that Merck was not going to enforce its patents against them.

189. In 2011, Roche (Pharmasset's development partner with regard to certain nucleosides including PSI-6130) entered into a license agreement with Merck, whereby Merck granted Roche a license to the '499 Patent (and other to-be-issued patents including the application that issued as the '712 Patent) and Roche agreed (among other things) to pay Merck a royalty of between 9-12%. EX-1783; Trial Tr. 1416:24-1417:7 (Demain).

190. Under Roche's development agreement with Pharmasset, Pharmasset's consent to the Roche-Merck license was sought because Roche's royalty payments to Merck would reduce Roche's royalty payments to Pharmasset. EX-0627 at 2; Trial Tr. 1417:18-1418:2 (Demain).

19 191. By September 7, 2011, Pharmasset had consented to the Roche-Merck license. EX-202632. Pharmasset was informed that Pharmasset's consent to the Merck-Roche license would cause the Merck-Roche license to spring into effect. EX-0619; Trial Tr. 1419:18-1423:1

(Demain). There is no evidence that Pharmasset ever told Roche that Merck would not assert its 22 23 patents.

24 192. During the 2008 to 2011 timeframe, there is no evidence that anyone from Merck 25 communicated to Pharmasset that Merck would not assert its patents. No one from Pharmasset ever communicated to Merck that Pharmasset thought Merck waived its patent rights. Trial Tr. 26 2482:2-18 (Demain). 27

193. In February 2, 2011, Merck prepared an internal business analysis that compared

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two scenarios: one in which Merck would provide a license to Roche to develop product R-7128 and another in which Merck would buy Pharmasset and develop sofosbuvir. Trial Tr. 2514:11-2516:25 (Demain). The '499 patents are listed as intellectual property considerations for the Roche license deal, but not for the Pharmasset sofosbuvir purchase deal. EX-0099 at 27, 29. But Ms. Demain explained this difference: in the first scenario (in which Roche would have to pay for a license to Merck's patents), Merck was not contemplating a purchase of Roche; in the second scenario, in which Merck would buy Pharmasset, Merck's patents would no longer be a concern for sofosbuvir-the only concern would be third-party patents. Trial Tr. 2516:3-25 (Demain) (explaining why Merck's patents were listed on the R-7128 slide, but not the PSI-7977 slide). Ms. Demain's testimony was not contradicted at trial and in any event, there is no indication that this document or any other like it was ever communicated to Pharmasset before this litigation commenced.

194. Merck had no viable patent infringement claim until Pharmasset/Gilead's product was on the market. Trial Tr. 2483:3-7 (Demain). Given that Merck could not sue for infringement until late 2013 because Gilead's pre-commercialization work is specifically exempted from constituting infringement under the "FDA exemption," no ripe claim existed until then, and it would not be reasonable to conclude that Merck waived its patent rights before Gilead commercialized. Indeed, the '712 Patent did not issue until the summer of 2013. EX-0002. Shortly thereafter, and before Gilead's product was launched, Merck sent a letter to Gilead asking Gilead to take a license. EX-2566.

195. Furthermore, a defense of waiver cannot be asserted based on any interaction 21 between Merck and Pharmasset in 2004 because Merck's '499 patent did not issue until 22 23 September 12, 2006. EX-0001.

Gilead Response to Merck's Interrogatory No. 11 (asking for the factual and legal 24 196. basis for Gilead's defense that Merck's claims are barred by the equitable doctrine of laches 25 and/or estoppel and/or waiver) does not point to any specific communications between Merck and 26 Pharmasset, nor does Gilead's response specify any document that indicates Merck has waived its 27 28 right to assert the '499 and '712 Patents against Gilead. Gilead's Written Discovery Responses 4-

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197. Gilead's Interrogatory response points only to EX-2314 as alleged evidence that Merck delayed assertion of its patent rights was misleading to Gilead or that Gilead has suffered material prejudice. Gilead's Written Discovery Responses 4-5, ECF 231-25. This reliance is misplaced: EX-2314 is a letter from Merck to Pharmasset dated September 3, 2010 regarding the *licensing proposal provided to Merck by Pharmasset*. The letter rejects the licensing proposal and rather suggests the alternative that Merck acquire Pharmasset.

198. Contrary to Gilead's assertion, EX-2314 specifically put Pharmasset on notice that Merck would assert its patent rights. In describing the benefits to Pharmasset and its shareholders in an acquisition of Pharmasset by Merck, the letter states that one of the benefits is "[t]he ability to leverage Merck's intellectual property estate *to reduce uncertainty and enhance the value of the Pharmasset assets* going forward." EX-2314 at 2 (emphasis added). The very document cited by Gilead shows that Merck communicated to Pharmasset that Merck's intellectual property estate was a source of uncertainty for Pharmasset.

199. No witnesses from either Pharmasset or Gilead testified that they reasonably believed that Merck would not assert its patents.

IV. CONCLUSIONS OF LAW - WAIVER

18 Courts have recognized waiver as a defense to patent infringement. Qualcomm Inc. v. 19 Broadcom Corp., 548 F.3d 1004, 1019 (Fed. Cir. 2008). There are two forms of waiver-"true waiver" and "implied waiver." Id at 1020. True waiver occurs when a patentee "with full 20knowledge of the material facts, intentionally relinquished its rights to enforce [the asserted 21 22 patents]." Id. Implied waiver occurs when a patentee's "conduct was so inconsistent with an 23 intent to enforce its rights as to induce a reasonable belief that such right has been relinquished." Hynix Semiconductor Inc. v. Rambus Inc., 645 F.3d 1336, 1348 (Fed. Cir. 2011); Qualcomm, 548 24 F.3d at 1020. 25

In this case, Gilead does not contend that there was a true waiver of Merck's patent rights
and instead argues Merck impliedly waived its patent rights. *See* Gilead Trial Br. 11-12, ECF 368.
However, most courts finding an implied waiver of patents rights have done so in the context of

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standard setting organizations where (1) the patentee had a duty of disclosure to the standard setting organization and (2) the patentee breached that duty. *Barnes & Noble*, 849 F. Supp. 2d at 941-42 (citing *Hynix*, 645 F.3d at 1348); *see also Qualcomm Inc. v. Broadcom Corp.*, 2007 WL 1031373, at *6-23 (S.D. Cal. Mar. 21, 2007), *aff*^{*}d 548 F.3d at 1020-22.

Gilead has cited three cases for the proposition that implied waiver is not limited to standard setting organizations. In *Mars, Inc. v. TruRX LLC*, the Eastern District of Texas discussed the Federal Circuit's decision in *Qualcomm*, which dealt with implied waiver in the standard setting context. Case No. 6:13-cv-526-RWS, ECF 346, at *2-3 (E.D. Tex. April 29, 2016). The Court found that "nothing in the [Federal Circuit's] opinion indicated that implied waiver can only be established if a patentee is under a duty to disclose information to a standard setting organization" and noted that "the [Federal Circuit] simply held that under the particular facts of the case, the district court did not abuse its discretion by concluding that Qualcomm's 'conduct was so inconsistent with an intent to enforce its rights as to induce a reasonable belief that such right ha[d] been relinquished." *Id.* at *2. What mattered to the court was not whether a standard setting organization was implicated, but rather whether the patent holder's silence or inaction was so inconsistent with an intent to enforce its rights as to induce a reasonable belief that the patent holder had relinquished its rights.

18 In Universal Electronics Inc. v. Logitech, Inc., the Central District of California stated that 19 "implied waiver as a doctrine does not need to be limited to" the context of a standard setting organization. Case. No. 11-cv-01056-JVS(ANx), ECF 144, at *21 (C.D. Cal. May 9, 2012). 20However, the court went on to recognize that it was aware of "no law dictating that silence outside 21 of the [standard setting organization] context is 'so inconsistent' with intent to enforce" that it 22 23 could constitute an implied waiver. Id. at *22. The court further recognized that "other courts" had "impos[ed] significant barriers to establish a duty to disclose in the [standard setting organization] 24 context." Id. 25

In *Dane Technologies, Inc. v. Gatekeeper Systems, Inc.*, the final case relied upon by
Gilead, the District of Minnesota appeared to assume that implied waiver is a valid defense outside
the context of standard setting organizations. Case No. 12-cv-2730-ADM/JJK, 2015 WL 5719142,

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at *19 (D. Minn. Sept. 29, 2015). However, the court only cited cases involving standard setting organizations, and it did not analyze whether implied waiver could apply outside that context—it simply assumed so. *Id.*

While some courts have recognized implied waiver of patent rights outside the standard setting context, it is not clear that Federal Circuit caselaw dictates such a result. Assuming that implied waiver is a cognizable defense outside the standard setting context, Gilead has failed to meet its burden of proof. On that note, it is also unclear whether the burden of proof for asserting waiver is preponderance of the evidence or clear and convincing evidence. See, e.g. Hynix, 645 F.3d 1348 ("To support a finding of implied waiver in the standard setting organization context, the accused must show by clear and convincing evidence...") (quoting Qualcomm, 548 F.3d at 1020); A.C. Aukerman Co. v. R.L. Chaides Construction Co., 960 F.2d 1020, 1045-46 (Fed. Cir. 1992) (en banc) (holding that the quantum of proof for equitable estoppel is a preponderance of the evidence except where "special considerations" are implicated, such as "where the danger of deception is present ..., where a particular claim is disfavored on policy grounds ..., or where a particularly important individual interest is at stake such as one's reputation"); Oracle Am., Inc. v. Google Inc., Case No. 10-cv-03561 WHA, 2012 WL 1965778, at *2 (N.D. Cal. May 31, 2012) ("To prevail on a waiver defense, Google must show by a preponderance of the evidence..."). For purposes of this case, the Court need not decide the issue as Gilead has failed to prove implied waiver by either standard of proof.

Implied waiver requires proof that the patentee's conduct "was so inconsistent with an intent to enforce its rights as to induce a reasonable belief that such right has been relinquished." *Hynix*, 645 F.3d at 1348 (quoting *Qualcomm*, 548 F.3d at 1020)); *see also* Pretrial Conference Statement 5, ECF 254 (stipulation that waiver requires "a reasonable belief that [a] right has been relinquished"). Gilead has failed to make such a showing for at least three reasons:

First, Gilead failed to establish that it or Pharmasset reasonably believed that Merck had relinquished its patent rights. Gilead did not offer any evidence to show such a belief. In fact, the only evidence of what Pharmasset or Gilead believed supports a conclusion that they did not believe Merck had relinquished its rights. *See supra*, FOF ¶¶ 179, 187. This failure of proof alone

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compels a conclusion that implied waiver has not been shown.

Second, even if Gilead had offered evidence tending to show that Pharmasset or Gilead believed Merck had relinquished its right to assert the patents in suit, any such belief would have been unreasonable because Merck's conduct was not inconsistent with an intent to enforce its rights. From 2008 to 2011, the parties engaged in repeated discussions over partnership opportunities in the antiviral space. During such discussions, Pharmasset proposed term sheets to Merck which provided that Merck would grant Pharmasset a worldwide license to Merck's patents. In one counter-proposal, Merck sent an offer that did not provide Pharmasset with a freedom-to-operate license with respect to Pharmasset's HCV products. Furthermore, at a meeting in 2011 in which Merck informed Pharmasset that the '499 patent "could give Pharmasset trouble in the future," Mr. Price told a Merck attorney that he "hoped [the Merck attorney] found it easier to find the courthouse." See supra, ¶ 189. Such conduct would not create a reasonable belief that Merck had relinquished its rights to enforce the asserted claims. Gilead's attempt to characterize these negotiations as fundamentally inconsistent with an intent to enforce patent rights glosses over several facets of the negotiations. For example, Gilead claims in 2010 that Merck never told Pharmasset that Pharmasset should offer it different terms because Merck had patents that covered PSI-7977. However, in 2010, Merck responded to Pharmasset's proposals with counter-offers that did not provide a license for Pharmasset's HCV products. This is not the conduct of a party (Merck) that had waived its right to enforce its patents or of a party (Pharmasset) that has a "reasonable belief" that Merck had waived its patent rights.

Finally, it does not appear that Merck had an actionable claim of infringement until 21 Gilead's product was launched on the market in December 2013. Gilead's development activities 22 23 prior to the launch is protected from infringement liability under 35 U.S.C. § 271(e)(1). See generally Merck KGaA v. Integra Lifesciences I, Ltd., 545 U.S. 193, 202 (2005) (explaining the § 24 271(e)(1) safe harbor). Since Merck could not enforce its patents until Gilead's product launched, 25 Merck had no affirmative duty to take any action and its failure to take any action cannot be 26 interpreted as implied waiver. See, e.g., Bio-Tech. Gen. Corp. v. Genentech, Inc., 80 F.3d 1553, 27 28 1564 (Fed. Cir. 1996) (holding in the context of laches that "[w]ith no legal right to enforce, it

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cannot be said that Genentech unreasonably delayed during that time period [before FDA approval and launch].").

The Court concludes that Gilead has not proven its waiver defense and that Merck is not prohibited from asserting its patents on this basis.

V.

A. Background on Unclean Hands

CONCLUSIONS OF LAW – UNCLEAN HANDS

The equitable doctrine of unclean hands has long existed as a principal of patent law. It arises from the maxim, "[h]e who comes into equity must come with clean hands." *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240, 241 (1933). The party asserting the defense of unclean hands must prove it by clear and convincing evidence. *In re Omeprazole Patent Litig.*, 483 F.3d 1364, 1374 (Fed. Cir. 2007); *Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1374 (Fed. Cir. 2001). In a trio of cases in the 1930s and 1940s, the Supreme Court applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct.

First, in *Keystone*, which involved the manufacture and suppression of evidence, the plaintiff sued for patent infringement. 290 U.S. at 242. In an earlier infringement action against a different defendant, Keystone had prevailed and its three patents were declared valid. *Id.* Armed with this verdict, Keystone brought suit against the General Excavator Company and another company for infringing the same three patents and moved for a preliminary injunction. *Id.* The injunction was denied, and Keystone amended its complaint to allege infringement of two more patents. *Id.* The case then proceeded to trial. *Id.* at 242-43.

During the trial, it was discovered that after learning about a possible invalidating prior use, the patent applicant, who was Keystone's general manager and secretary, for one of the patents-in-suit paid the potential prior user to sign a false affidavit stating the prior use was an abandoned experiment, to assign any rights to the applicant, and to suppress any evidence of the prior use. *Id.* at 243. The Supreme Court framed this issue on appeal as follows:

> Plaintiff contends that the [unclean hands] maxim does not apply unless the wrongful conduct is directly connected with and material to the matter in litigation, and that, where more than one cause is joined in a bill and plaintiff is shown to have come with unclean hands in respect of only one

of them, the others will not be dismissed.

[Plaintiff] must come into court with clean hands. He must be frank and fair with the court, nothing about the case under consideration should be guarded, but everything that tends to a full and fair determination of the matters in controversy should be placed before the court...It is a principle in chancery, that he who asks relief must have acted in good faith. The equitable powers of this court can never be exerted in behalf of [one] who has acted fraudulently, or who by deceit or any unfair means has gained an advantage. To aid a party in such a case would make this court the abetter of iniquity.

Id. at 244-45 (internal quotations and citations omitted). With that in mind, the Supreme Court explained that unclean hands applies only where the "unconscionable act of one coming for relief has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation." Id. at 245. The misconduct must "affect the equitable relations between the parties in respect of something brought before the court for adjudication." Id. In Keystone, the Supreme Court stated that "it [] clearly appear[ed] that [Keystone] made the [first] case a part of his preparation in the [subsequent suits]." Therefore, Keystone's conduct with respect to one patent was sufficient to infect causes of action based on related patents and to prevent recovery on any of the asserted patents. Id. at 247.

Second, in Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238 (1944), overruled on other grounds by Standard Oil Co. v. United States, 429 U.S. 17 (1976), also involving the manufacture and suppression of evidence, Hartford alleged Hazel-Atlas infringed its patent. The District Court, finding that infringement had not been proven, dismissed the case. Id. at 241. On appeal, the Circuit Court, quoting extensively from an article written by William Clarke, an expert and former President of the Glass Workers' Union, found the patent valid and infringed. Id. at 241-42. The Circuit Court's decision caused both Hazel-Atlas and Hartford to contact Mr. Clarke, who eventually signed an affidavit that he wrote the article. *Id.* at 242-43. Hazel-Atlas then settled the patent lawsuit with Hartford. Id. at 243. In a separate anti-trust action by the United States against Hartford, seven years after the patent dispute, evidence disclosed that the patentee's attorney wrote the article to overcome issues at the Patent Office and had Mr. Clarke sign it as his

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own and publish it. Id. at 243-44.

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The Supreme Court explained that the doctrine of unclean hands "has always been characterized by flexibility which enables it to meet new situations which demand equitable intervention, and to accord all the relief necessary to correct the particular injustices involved in these situations." Id. at 248. In Hazel-Atlas, the Court found the fraud was so egregious that it found the patent unenforceable against Hazel-Atlas and denied any recovery. Id. at 249-251.

Third, in Precision Instrument Manufacturing Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806 (1945), involving perjury and suppression of evidence, Automotive sued Precision for breach of contract and patent infringement. The parties had been adversaries in a prior interference proceeding, with competing patent applications covering torque wrenches. Id. at 809-12. During the interference proceeding, Automotive learned that Precision filed a fraudulent affidavit. Id. Instead of reporting this fraud to the Patent Office, Automotive settled the interference case with Precision and Precision assigned its rights in the application to Automotive. Id. When Precision recommenced selling the allegedly infringing torque wrenches, Automotive brought suit against Precision. Id. at 814.

The Supreme Court reiterated general principals of the doctrine of unclean hands, 16 including the broad discretion an equity court has in refusing to be an accomplice to the unclean litigant. Id. at 815. Commenting that "the maxim is far more than a banality," the Court explained:

[The maxim of unclean hands] gives wide range to the equity court's use of discretion in refusing to aid the unclean litigant. It is "not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion." Accordingly one's misconduct need not necessarily have been of such a nature as to be punishable as a crime or as to justify legal proceedings of any character. Any willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim by the chancellor. Moreover, where a suit in equity concerns the public interest as well as the private interests of the litigants this doctrine assumes even wider and more significant proportions. The possession and assertion of patent rights are "issues of great moment to the public."

Id. at 815 (internal citations omitted).

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The Supreme Court found that the history of the patents-in-suit was steeped in perjury and undisclosed knowledge of perjury. Id. at 816. The Court neither found nor required a finding that any of the patents-in-suit would not have issued if Automotive had disclosed to the examiner the information provided by its former employee. Id. at 815-19. Moreover, that information plainly had no bearing whatever on the patents that issued from Automotive's own applications. Id. Yet the Court ruled that Automotive's unclean hands prevented enforcement of all of the patents-insuit. Id. at 819.

Notably, in *Hazel-Atlas* and *Precision*, the Supreme Court reversed lower courts that had been unwilling to bar suit for the described misconduct. In Keystone, the circuit court reversed the district court's finding denying the unclean hands defense which was affirmed by the Supreme Court.

Almost 70 years after *Precision*, the Federal Circuit issued its *en banc* decision in Therasense, Inc. v. Becton, Dickson & Co., 649 F.3d 1276 (Fed. Cir. 2011). Therasense addressed the separate defense of inequitable conduct—a defense that Gilead does not assert in this case but the Federal Circuit's discussion of the differences between inequitable conduct and unclean hands confirmed that unclean hands remains a viable defense to patent infringement. Id. at 1285-16 89. As the Federal Circuit explained, the doctrine of inequitable conduct grew from the older doctrine of unclean hands. Id. at 1287. Whereas unclean hands can involve improper conduct before either the Patent Office or the courts, inequitable conduct relates solely to conduct before the Patent Office. Id. Additionally, where unclean hands affects the enforceability of a patent in a particular lawsuit, inequitable conduct carries far more severe consequences for the patent For this reason, inequitable conduct requires a "finding of both intent to deceive and materiality." Id. The Federal Circuit made clear, however, that unclean hands remains a viable defense, and does not require a finding of materiality:

> This court recognizes that the early unclean hands cases do not present any standard for materiality. Needless to say, this court's development of a materiality requirement for inequitable conduct does not (and cannot) supplant Supreme Court precedent. Though inequitable conduct developed

from these cases, the unclean hands doctrine remains available to supply a remedy for egregious misconduct like that in the Supreme Court cases.

Id. Thus, the Federal Circuit's *Therasense* decision confirmed the continuing viability of the unclean hands doctrine.

B. Other Cases Involving Unclean Hands

Against this standard from the Supreme Court and Federal Circuit, other courts have applied the doctrine of unclean hands to situations involving lying under oath, unethical business conduct, or litigation misconduct.

In Aris-Isotoner Gloves, Inc. v. Berkshire Fashions, Inc., 792 F. Supp. 969, 970 (S.D.N.Y. 1992), *aff*²d, 983 F.2d 1048 (2d Cir. 1992), the Court found egregious misconduct where the Defendant's president lied under oath in a prior proceeding. In an attempt to prove detrimental reliance on Plaintiff's conduct, Berkshire President Issac Dweck testified at a contempt hearing that his company initially sold very small quantities of an infringing glove and after nothing happened—it was not sued for infringement—the company increased the amounts sold in the following years. *Id.* In a remand hearing, after being confronted with contrary evidence in interrogatory responses, Mr. Dweck testified that Berkshire sold over 50,000 dozen gloves and sales decreased, not increased, the following year. *Id.* He also admitted that his prior testimony had been incorrect even though the relevant figures had been available to him at the prior hearing. *Id.*

The court found that Mr. Dweck had fabricated his testimony in light of "the inadequately explained and obvious contradictions as to testimony of direct relevance." Id. The court also rejected Berkshire's explanation that Mr. Dweck had confused sales of the infringing glove with another glove as "wholly inconsistent" with Mr. Dweck's "original, confident story." Id. at n.2. The court also rejected Berkshire's contention that Mr. Dweck's inconsistent testimony was immaterial because regardless of which version was believed, it did not affect the outcome. Id. at 971. However, the court found that once Berkshire engaged in the egregious misconduct, the doctrine of unclean hands prevented Berkshire from obtaining relief. Id. Other courts have also found unclean hands in the presence of false testimony. See Mas v. Coca-Cola Co., 163 F.2d 505,

511 (4th Cir. 1947) (finding the plaintiff had unclean hands and upholding dismissal of plaintiff's suit where plaintiff submitted false testimony and forged documents to the Patent Office); *C.C.S. Commc 'n Control, Inc. v. Sklar*, Case No. 86-cv-7191-WCC, 1987 WL 12085, at *2-3 (S.D.N.Y. 1987) (denying request for equitable remedy because plaintiff committed perjury).

Improper business conduct can also invoke unclean hands. In *Clements Indus., Inc. v. A. Meyers & Sons Corp.*, 712 F. Supp. 317, 318 (S.D.N.Y. 1989), plaintiff attempted to extract confidential information from the defendant, not for legitimate commercial reasons, but rather to obtain the defendant's confidential trade secrets. The court found that "[t]his deceptive dealing fully supports [defendant's] contention that [plaintiff] has 'unclean hands'" and dismissed plaintiff's claims. *Id.* at 328.

Courts have found improper business dealings can invoke unclean hands in several other situations. See Worthington v. Anderson, 386 F.3d 1314, 1321-22 (10th Cir. 2004) (affirming dismissal of plaintiff's trademark claims against former business partner for unclean hands where plaintiff "threw economic obstacles in the way of" defendant's ability to comply with terms of arbitration agreement); Saudi Basic Indus. Corp. v. ExxonMobil Corp., 401 F. Supp. 2d 383, 395 (D.N.J. 2005) ("There is also caselaw to support application of the unclean hands doctrine when a business partner engages in acts of self-dealing."); FLIR Sys., Inc. v. Sierra Media, Inc., 965 F. Supp. 2d 1184, 1197 (D. Or. 2013) ("FLIR's false advertising claim . . . is barred, in light of FLIR's false advertising on the same subject matter, by the doctrine of unclean hands."); Unilogic, Inc. v. Burroughs Corp., 10 Cal. App. 4th 612, 617-621 (1992) (affirming, inter alia, that plaintiff's failure to return defendant's software and continued use of software after development agreement terminated was unclean hands barring plaintiff's legal claim for conversion); Fed. Folding Wall Corp. v. Nat'l Folding Wall Corp., 340 F. Supp. 141, 146 (S.D.N.Y. 1971) (plaintiff breaching employment contract with defendant and inducing trademark owner to cancel license to defendant was unclean hands warranting dismissal of case); Metro Publishing, Ltd. v. San Jose Mercury News, Inc., 861 F. Supp. 870, 880 (N.D. Cal. 1994) (finding plaintiff's deliberate attempt to create trademark confusion constituted unclean hands and granting summary judgment against trademark holder "on this basis alone").

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misconduct. In U.S. Ethernet Innovations, LLC v. Texas Instruments Inc., Case No. 6:11-cv-491-MHS, 2014 WL 4683252, at *6 (E.D. Tex. 2014), defendant's unprofessional conduct, including attempting to interfere with plaintiff's expert, constituted unclean hands

Courts have also found unclean hands applicable where a party has engaged in litigation

C. Application of Unclean Hands to Findings of Fact

Against this backdrop, the Court must review the facts to determine whether Merck's misconduct rises to the level of egregious misconduct sufficient to bar Merck from maintaining this suit against Gilead. All of the Court's findings are made under the standard of clear and convincing evidence.

In this case, numerous unconscionable acts lead the Court to conclude that the doctrine of unclean hands bars Merck's recovery against Gilead for infringement of the '499 and '712 Patents. Merck's misconduct includes lying to Pharmasset, misusing Pharmasset's confidential information, breaching confidentiality and firewall agreements, and lying under oath at deposition and trial. Any one of these acts—lying, unethical business conduct, or litigation misconduct would be sufficient to invoke the doctrine of unclean hands; but together, these acts unmistakably constitute egregious misconduct that equals or exceeds the misconduct previously found by other courts to constitute unclean hands. Merck's acts are even more egregious because the main perpetuator of its misconduct was its attorney.

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1. Pharmasset and Merck Interactions

The first set of unconscionable acts barring Merck's recovery from Gilead for infringement concerns the actions of Merck and its patent prosecutor, Dr. Durette, in learning the confidential structure of Pharmasset compound PSI-6130 and pursuing patent claims to cover that compound in violation of the Merck-Pharmasset firewall and Merck's own policies.

Interactions between Merck and Pharmasset began in 2001 when the companies discussed
potential collaboration opportunities. FOF ¶ 37. As part of these discussions, the companies
signed a NDA. *Id.* In 2003, pursuant to the NDA, Pharmasset gave Merck an overview of its
HCV program, including an overview of its lead compound, PSI-6130. FOF ¶¶ 42-44. Shortly
after, the companies signed a Material Transfer Agreement (MTA), which permitted Merck to test

and evaluate PSI-6130. FOF ¶ 46. After the testing revealed encouraging results, Merck requested additional information about the structure of PSI-6130. FOF ¶ 50. Merck assured Pharmasset that structural information about PSI-6130 would be firewalled and on this basis, the parties set up a phone call for March 17, 2004. FOF ¶¶ 53-59.

It was not as though Merck and Dr. Durette stumbled into that call unaware of the subject matter, or the impropriety of Dr. Durette's participation. All of this information was contained in emails and a term sheet distributed to Merck, and Dr. Durette in particular, in advance of the meeting. In these e-mails, Merck's employees were fully advised in advance that Pharmasset would disclose its closely guarded PSI-6130 compound to Merck employees bound by an NDA and firewall. Merck further knew that Pharmasset's compound was an NS5B polymerase inhibitor just like its own compounds from the Merck-Isis collaboration that formed the bases of the '499 and '712 patent applications. Dr. Durette's legal and scientific sophistication preclude the possibility that he was unaware or misunderstood the relationship of the anticipated disclosure to his own HCV work for Merck.

Compounding the problem, Merck's representatives, Dr. Durette and Dr. Pon, committed further unconscionable acts during the call. Based on the contemporaneous notes prepared by 16 Pharmasset's Alan Roemer, after learning key structural features of PSI-6130, Dr. Durette voiced concern that he might have a problem, stating "seems quite related to things I'm involved with," 19 EX-2098, but he never revealed that he was prosecuting Merck's own HCV patent applications. This was information unavailable to Pharmasset. Moreover, Dr. Durette's involvement with Merck's HCV patents violated the understanding the parties had about their firewall obligations, which excluded anyone involved with Merck's internal HCV program. EX-2302. This most certainly would include the Merck-Isis collaboration that Dr. Durette was involved with. After suggesting there might be a problem, both Dr. Durette and Dr. Pon assured Pharmasset that they were within the firewall and continued the conversation.

On that call, Dr. Durette obtained the full structure of PSI-6130 and he subsequently 26 continued to prosecute Merck's HCV patent portfolio. Although he claims to have recused 27 28 himself from the Pharmasset-Merck due diligence, that is not where the harm lay. It was, in fact,

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wrong for Merck to allow Dr. Durette to continue to prosecute the '499 and '712 Patent applications. Ironically, in the course of what the Court deems a complete fabrication of testimony at his deposition, Dr. Durette himself explained why this conduct was so egregious. As he said, having learned the structure of PSI-6130, his judgment was tainted. And, indeed it was. His February 2005 claim amendments to the '499 patent were made possible by the information he unfairly obtained in March 2004. Proper recusal would have mandated that Dr. Durette cease work on Merck's HCV patents as well. Such conduct was required by Merck's own internal policies and would have been consistent with a common understanding of recusal.

Based on the foregoing, there can be no doubt that Merck used this highly confidential information to benefit its own prosecution of its stalled '499 Patent application. Dr. Pon and Dr. Durette's deception about Dr. Durette being firewalled, and Merck's subsequent decision to allow Dr. Durette to continue to prosecute the '499 and '712 with full knowledge of the structure of Pharmasset's PSI-6130 constitute unacceptable business conduct. It is clear to this Court that Dr. Durette improperly used this information to inform his conduct in amending the '499 Patent claims a mere 18 days after the Clark application published. Those amendments related to compounds Merck never tested during its collaboration with Isis, and the amendments were not prompted by requests from the inventors or prodding by the patent examiner to narrow the claim scope. Thinking that he was now free from what he knew were his obligations under the NDA, Dr. Durette pounced on the opportunity to capitalize on what he improperly had learned a year earlier.

The Court concludes that each of the foregoing unconscionable acts has an "immediate and 21 necessary relation to...the matter in litigation" because the patents that resulted from this series of 22 23 unconscionable acts are now asserted against Gilead, Pharmasset's successor-in-interest. See Keystone, 290 U.S. at 245. The Court finds the facts in Clements analogous to Merck's 24 25 misconduct. In Clements, the court found plaintiff's deceptive dealing in learning defendant's confidential trade secrets warranted a finding of unclean hands. In a similar situation, Merck sent 26 Dr. Durette to "view the structure during a patent due diligence meeting" under deceptive 27 circumstances. EX-0153.0001. As detailed supra FOF ¶¶ 54-92, the evidence shows Dr. Durette

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lied to Pharmasset about being within the firewall, then Merck allowed Dr. Durette, with his
tainted judgment, to continue prosecuting the related Merck-Isis patents-in-suit and to draft claims
to target Pharmasset's inventions. The Court finds Merck's deceptive dealing warrants a finding
of unclean hands. *See Clements*, 712 F. Supp. at 328.

2. Litigation Misconduct

The Court concludes that the doctrine of unclean hands also bars Merck's recovery against Gilead for infringement of the '499 and '712 Patents based on additional reprehensible acts by Merck and Dr. Durette amounting to litigation misconduct, including his false testimony in this case. Based on the Court's findings *supra* FOF ¶¶ 107-170, the record shows that Dr. Durette presented inconsistent, contradictory, and untruthful testimony, and that testimony was sponsored by Merck.

Throughout the prosecution of this case, Dr. Durette continued to deceive Gilead and this Court. His trial testimony was inconsistent with his deposition testimony in numerous material and critical respects. He recanted a major portion of his prior testimony without any warning to Gilead until revealed in Merck's opening statement.³ He gave inconsistent stories about his participation on the March 2004 due diligence call and the circumstances that led to his amendments to the '499 claims. His trial testimony was not credible on significant matters related to this case.

Remarkably, when he faced the Court and jury at trial, Dr. Durette recanted his testimony
that he had not been on the Pharmasset-Merck due diligence call. At trial, he testified that he just
did not remember what had taken place 11 years ago. Trial Tr. 347:9-22 (Durette). His trial
testimony is completely inconsistent with his deposition testimony. Dr. Durette had previously
testified at his deposition that he was certain he had not participated in the call and not learned the
structure of Pharmasset's compound:

25 26 Q: How can you be so sure 11 years later that you were never told what

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 ³ Also troubling is Merck's counsel's failure to disclose to Gilead or this Court that Dr. Durette would recant his prior testimony as soon as Merck learned that Dr. Durette's prior testimony was unsustainable—wholly inconsistent with the record evidence. Opening statement was not the preferred time for such a disclosure. *See* ABA Model Rules Prof. Conduct, Rule 3.3(a).

the structure was for the 6130 compound? 1 2 A: The structure was not revealed to me by individuals at Merck or otherwise. I'm positive of that. I never saw a structure of the Pharmasset 3 compounds until it was published later on in time." 4 Durette Dep. Tr. (EX-2388) at 31:4-10. 5 **** 6 7 Q: How do you know you weren't told it? A: Because I remember that. 8 9 Q: You remember what? 10 A: That the structure was not disclosed to me Q: How do you remember that? 11 12 A: Because I do. 13 Durette Dep. Tr. at 169:10-18, ECF 410-3. 14 Further, as rationale for his memory of the events, Dr. Durette embellished his "clear" recollection during his deposition by stating confidently—even sanctimoniously: 15 Q: How can you be so sure of that memory? 16 A: Because I was not part of the patent due diligence for the structure, so 17 18 I would not have been privy to any revelation of the structure to me as a 19 patent attorney working on a related docket. So this was assigned to another person. I would not have participated in a phone call wherein it 20was a potential for the revelation of the structure to Merck counsel. 21 Q: Why would that have been inappropriate for you to have been told the 22 23 structure of 6130? A: Because I was prosecuting a docket which had potential a conflict with 24 Pharmasset's IP positions on the subject matter. 25 Durette Dep. Tr. (EX-2388) at 38:1-13. 26 **** 27 Q: Again, why would it have been inappropriate or wrong for you to have 28 48

1 been told the 6130 structure? 2 A: It would have tainted my judgment as to what claims to pursue in the Merck/Isis collaboration. 3 Q: How would it have tainted your judgment? 4 5 A: Having structural information is very important as to what the competition is doing in its research efforts. We had a policy in Merck on a 6 7 particular docket area if there were potential licensing opportunities in a 8 related area, that due diligence would be assigned to a non-an attorney that was not prosecuting a particular docket in a related area. 9 Durette Dep. Tr. (EX-2388) at 38:21-39:7. 10

Dr. Durette's trial testimony about failed memory rings hollow. By the time he appeared at trial, Dr. Durette was aware that Pharmasset's Alan Roemer had contemporaneous notes that indisputably placed him at the meeting and would expose his false testimony. But that was not the end of Merck's problems. As he tried to put a new gloss on his conduct, Dr. Durette placed blame on his colleague Pamela Demain, stating that she had instructed him to attend the due diligence call and that his supervisor approved it. However, Ms. Demain testified credibly that she did not.

He further testified untruthfully that before the meeting he had "no knowledge of what the 17 18 structure was going to be revealed to me." Trial Tr. 351:3-4 (Durette). He stated that he and his 19 supervisor concluded that there was little chance of overlap with Dr. Durette's HCV docket since 20the field of nucleosides was so broad. However, this testimony simply does not hold up against the information about Pharmasset's compound disclosed on the term sheet that Merck and Dr. Durette reviewed before the meeting. As Ms. Demain credibly testified, Merck knew going into 22 23 the meeting that Pharmasset's compound was an NS5B polymerase inhibitor just like Merck's compounds. Moreover, it is not credible to the Court that Dr. Durette had such a clear memory about a meeting with his supervisor prior to the due diligence call when he also testified that he lacked any memory of the events 11 years prior. 26

27 Further at trial, Dr. Durette spun a new tale about the genesis of the February 1, 2005, amendments to the claims in the '499 patent application. At his deposition, Dr. Durette could not 28

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recall when he had first seen the Clark patent application containing PSI-6130 that was published 2 on January 13, 2004. He averred that he might not have seen it until after he filed his amended 3 claims. Durette Dep. Tr. 51:2-15, ECF 410-3. He further testified that he did not associate the Clark patent application with PSI-6130; he explained: 4

> Q: How is it that you would know that you would not in January 2005 have realized that Paragraph 0168, that chemical structure there, was 6130?

> A: Because this was one compound out of a plethora of compounds in the publication.

Durette Dep. Tr. at 52:19-25, 53:1-6, ECF 419-1.

Although Dr. Durette professed not to recall seeing the Clark publication before his amended claims were filed, he did have a clear recollection of other publications that "pointed towards fluoro as being an important invention for HCV nucleosides...." Durette Dep. Tr. at 65:18-25, ECF 410-3. When asked at his deposition why he had amended the claims on February 1, 2005, he testified "We wanted to expedite prosecution of the application." Durette Dep. Tr. at 62:5-9, ECF 419-1. He also testified that competitors were disclosing fluoro compounds that Merck had support for in its patent applications. Durette Dep. Tr. at 63:18-64:7, ECF 419-1. However, he avoided associating his amendment with the Clark publication.

19 At trial, Dr. Durette offered different reasons for the amendments. He testified that in 20addition to wanting to expedite the examination, Merck wanted to capture the subject matter that was most important to the Merck-Isis collaboration. Trial Tr. 404:14-19 (Durette). This testimony 22 was in stark contrast to the testimony of other witnesses that Merck had never tested any of those 23 compounds during the Merck-Isis collaboration and none of the inventors had discussed the amendments with him before the amendment. Dr. Durette's testimony is not credible on this issue. 24 Additionally, at trial, Dr. Durette now recalled clearly that he did see the Clark publication before he filed the amendments. When asked when he recalled seeing the Clark publication, Dr. 26 Durette testified:

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A: I don't have a specific recollection of the timing, but I know it was

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before the filing of my second amendment because of two reasons: A, I was monitoring the competition in the area, and B, there must have been a triggering event that led me to reexamine my docket and take a look at my '499 application which had been pending for about a year and a half. So I was convinced – or I became convinced that it was the publication of the application that led me to reexamine and then file the secondary amendment, or secondary amendment 18 days later.

Trial Tr. at 390:25-391:9 (Durette).

Although Merck would ask this Court to accept the simple explanation that Dr. Durette's memory failed him and that the inconsistencies are harmless, in light of Dr. Durette's persistent pattern of falsifications, the Court cannot interpret his testimony in this manner. It is overwhelmingly clear to the Court that Dr. Durette sought at every turn to create the false impression that Merck's conduct was above board.

Knowing that he should not have been on the Pharmasset call and that upon learning the structure of PSI-6130, Dr. Durette should have recused himself from the Merck HCV docket. Instead, he first tried to deny knowledge of his role in the Pharmasset due diligence. When that did not work, he recanted his sworn testimony at trial and tried to blame others at Merck for compelling him to participate in the call. In order to first justify the propriety of the claim amendments made on the heels of the Clark publication, first he claimed not to have seen the Clark publication before he filed his amendments and when that story did not pan out he testified at trial that the Clark publication was actually the trigger that caused him to reexamine his stale '499 claims.

In sum, several important facts are clear. First, Dr. Durette provided false testimony to this Court on important issues regarding Merck's validity claims. Second, Merck sponsored and encouraged Dr. Durette's conduct in the prosecution of the '499 Patent, including Dr. Durette's improper participation on the Pharmasset call and his continued prosecution of Merck's HCV docket. Third, Merck fully aligned itself with Dr. Durette, as evidenced by its provision of legal counsel to Dr. Durette at his deposition and trial and designation of him as a Rule 30(b)(6) witness

on selected issues. Merck's counsel spent two days preparing him for his deposition and for trial. Fourth, the untruthful testimony offered by Dr. Durette in his deposition and at trial was not incidental, but rather was directed at and supported Merck's validity arguments, and went to the heart of significant issues in this case. Fifth, by making Dr. Durette a centerpiece of its case, from the opening statement to the closing argument, Merck's litigation misconduct infects the entire lawsuit, including the enforceability of the '712 Patent.

The Court concludes that Dr. Durette's testimony has an "immediate and necessary relation to . . . the matter in litigation" because Dr. Durette testified regarding the key invalidity defenses presented to the jury, and regarding how Merck obtained the patents that are now asserted against Gilead, Pharmasset's successor-in-interest. *Keystone*, 290 U.S. at 245. Dr. Durette's testimony played an influential role at trial on the critical issue of the relationship between the amended '499 claims drafted solely by Dr. Durette and the content of the earlier specification. In response to questions by Merck, he testified that the claims were fully described in the application he filed in 2002. *See supra*, FOF ¶ 135. Although other witnesses presented testimony regarding written description and enablement, Dr. Durette was a key witness on this issue and thus, such additional evidence does not absolve Merck of its unclean hands with respect to Dr. Durette's fabrications.

18 The Court finds the *Aris-Isotoner* case particularly persuasive as it relates to Merck's 19 misconduct at Dr. Durette's deposition and at trial. In Aris-Isotoner, the defendant's president 20gave testimony in one proceeding that directly contradicted his testimony in a prior proceeding. 792 F. Supp. at 970. That court found "no other conclusion can exist but that [defendant's 21 22 president] fabricated his testimony in either the instant proceedings or in the original contempt 23 proceedings." Id. That court found the witness's "half-hearted" claim that he was "confused" in the initial proceeding was "wholly inconsistent with [his] original, confident story." Id. at 970 n.2. 24 On the basis of the fabricated testimony, the court dismissed defendant's laches defense. Id. at 25 972. This Court finds these facts akin to Dr. Durette's confident explanation at his deposition, 26 recanted at trial, about why he never learned the structure of PSI-6130 from Pharmasset and his 27 28 wholly inconsistent testimony regarding the genesis of the February 1, 2005, claims amendments

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As in *Aris-Isotoner*, Dr. Durette's deposition testimony and trial testimony in this case are irreconcilable. The Court concludes that Dr. Durette lied in both proceedings. Further borrowing from *Aris-Isotoner*, this Court "lack[s] complete confidence as to which—if either—of the two testimonies is correct." *Aris-Isotoner*, 792 F. Supp. at 971. The Court concludes that Dr. Durette's fabricated deposition testimony and his false trial testimony, both of which Merck sponsored, are unconscionable acts that warrant a finding of unclean hands.

The Court also takes into account the fact that Dr. Durette was Merck's attorney. Among many important duties, attorneys have a duty of candor.⁴ The legal system requires witnesses to supply complete and truthful testimony. If a witness fabricates testimony, justice is not served and when an attorney lies under oath, the Court cannot sanction such conduct. Dr. Durette, as Merck's former employee and 30(b)(6) witness, lied repeatedly at his deposition and at trial. The Court cannot condone such conduct from any witness, let alone an attorney.

3. Merck's Arguments Against Unclean Hands

Merck argues that Gilead's theory of unclean hands is precluded by the jury's verdict. If it is not, Merck denies all misconduct and seeks to diminish Dr. Durette's testimony to the failed memory of a retired employee. Alternatively, Merck argues that even if the Court finds fabricated testimony, unethical business practices, and litigation misconduct, none of that conduct amounts to unclean hands for several reasons: (1) its misconduct is not egregious; (2) amending claims to cover a competitor's product is expressly allowed; (3) Merck and Dr. Durette did not have an intent to deceive; (4) Dr. Durette's conduct cannot be imputed to Merck; (5) there is no immediate and necessary relation between the alleged misconduct and the litigation; and (7) any misconduct did not involve the '712 Patent. The Court addresses each in turn.

⁴ The New Jersey Disciplinary Rules of Professional Conduct, Rule 3.3 which governs candor toward the tribunal, provides: "A lawyer shall not knowingly: (1) make a false statement of material fact or law to a tribunal." N.J. R.P.C. § 3.3(a)(1). Rule 4.1 governs truthfulness in statements to others, and provides: "In the course of representing a client a lawyer shall not knowingly: (1) make a false statement of material fact or law to a third person." N.J. R.P.C. § 4.1(a)(1). The Court also notes the Patent Office has promulgated the "USPTO Rules of Professional Conduct," which conforms to the Model Rules of Professional Conduct of the American Bar Association. *See* 37 C.F.R. § 11.100 *et seq.* The Patent Office's rules are virtually identical to the New Jersey Rules of Professional Conduct with respect to candor towards the tribunal and truthfulness in statements to others.

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As a threshold argument, Merck argues that the jury's verdict prevents a finding of unclean hands. Merck Proposed Conclusions of Law ("COL") 46-54, ECF 407. According to Merck, the only unclean hands theory set forth in Gilead's interrogatory responses is predicated on Merck's derivation of the inventions claimed in the '499 and '712 Patents from Pharmasset's confidential disclosures. Since the jury found the claims of the '499 and '712 Patent were not invalid for lack of written description or lack of enablement, the priority date of the asserted claims is January 18, 2002. As a result, Merck argues that it could not have derived the invention from Pharmasset in 2004 because its invention was completely conceived by January 18, 2002.

9 The Court disagrees with Merck's view of Gilead's interrogatory responses and the jury's verdict. Gilead's interrogatory responses made clear that its unclean hands defense is based on the 10 belief that Merck improperly derived information about Pharmasset's invention from Pharmasset's 12 confidential disclosures. Gilead's Supp. Response to Interrogatories 9-10, ECF 218-2. These 13 responses did not, as Merck argues, limit Gilead to a theory of unclean hands based on 35 U.S.C. § 102(f), also known "derivation," which states a person shall be entitled to a patent unless "he did 14 15 not himself invent the subject matter." If Gilead's unclean hands disclosure was interpreted as only disclosing a theory of unclean hands based strictly on § 102(f), it would be entirely redundant 16 of Gilead's § 102(f) invalidity defense. It would also allow Merck's misconduct in obtaining 17 18 Pharmasset's confidential information during the 2004 phone call and subsequent litigation 19 misconduct to go unchecked. Gilead's responses, instead, provide Gilead the ability to pursue an 20unclean hands defense covering circumstances where Merck improperly received information from Pharmasset. Thus, the jury's verdict, which did foreclose a § 102(f) invalidity defense, does 22 not prevent Gilead from pursuing a defense of unclean hands.

23 Moving to Merck's alternative arguments, first, Merck argues that cases finding unclean hands have involved repeated and egregious misconduct involving an elaborate scheme to defraud. 24 25 According to Merck, isolated instances of misconduct or conduct that is susceptible to innocuous explanations do not rise to the level of egregious misconduct. However, Merck's argument 26 glosses over the serious and outrageous conduct in this case in which Merck engaged in litigation 27 28 misconduct by presenting fabricated testimony and engaging in improper business practices. The

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1 cases Merck cites in support of its argument do not contain findings of lying, unethical business 2 practices, and litigation misconduct and instead turn on the fact the Court did not have sufficient 3 evidence to determine whether lying occurred. See Excelled Sheepskin & Leather Coat Corp. v. Oregon Brewing Co., 2014 WL 3874193, at *10 (S.D.N.Y. Aug. 5, 2014) (finding defendant 4 5 failed to present clear and convincing evidence that plaintiff's representations were inaccurate); Top Grade Construction v. Fluoresco Lighting-Sign Maintenance, 2012 WL 1122599, at *10 6 7 (N.D. Cal. Apr. 3, 2012) (denying summary judgment that plaintiff had unclean hands because 8 defendant "presented no evidence to show that [p]laintiff intentionally misrepresented" 9 information and there was a triable issue of fact as to whether plaintiff explanation for an 10 inconsistent response is credible); Lenz v. Universal Music Corp., 2010 U.S. Dist. LEXIS 16899, 11 at *15-17 (N.D. Cal. Feb. 25, 2010) (no evidence any misstatements were made in bad faith); Big 12 Lots Stores, Inc. v. Jaredco, Inc., 182 F. Supp. 2d 644, 652 (S.D. Ohio 2002) (finding conduct was 13 susceptible to more innocuous explanations because there was no evidence that a witness had lied 14 or that counsel acted wrongfully and deceitfully); In re Coordinated Pretrial Proceedings in 15 Antibiotic Antitrust Actions (Pfizer, Inc. v. Int'l Rectifier Corp.), 538 F.2d 180, 195-196 (8th Cir. 1976) (any misstatements were an oversight because "the facts so concealed were basically 16 supportive of [the concealing party's] contentions"); Helene Curtis Indus. v. Sales Affiliates, 121 17 18 F. Supp. 490, 510, 512 (S.D.N.Y. 1954) (holding unclean hands was not applicable because there 19 was no evidence that the patentee had deliberately misrepresented or omitted information).

20Merck also attempts to downplay the seriousness of its misconduct by relying on post-Therasense cases that apply the egregious misconduct prong of inequitable conduct. Merck 21 22 argues these cases find egregious misconduct in the presence of systematic and outrageous 23 deception, or in other words, conduct that is more extreme than the conduct in this case. Merck Proposed COL ¶ 45, ECF 407 (citing Apotex, Inc. v. UCB, Inc., 970 F. Supp. 2d 1297, 1328 (S.D. 24 25 Fla. 2013) (inventor's "overall pattern of misconduct" included "purposefully mislead[ing]" the Patent Office by misrepresenting invalidating prior art, withholding references, concealing 26 27 detrimental test results, fabricating results for tests that were not conducted, and facilitating the 28 submission of a misleading expert report), aff'd on other grounds, 763 F.3d 1354 (Fed. Cir. 2014);

Intellect Wireless, Inc. v. HTC Corp., 732 F.3d 1339, 1342, 1343-44 (Fed. Cir. 2013) (inventor "filed multiple unmistakably false declarations during prosecution" to overcome prior art)). What Merck's argument fails to recognize is that the conduct in this case consists of systematic and outrageous deception in conjunction with unethical business practices and litigation misconduct. As discussed above, Merck violated its understanding with Pharmasset about who would receive structural information about PSI-6130. Compounding this problem, Merck attempted to minimize and conceal this behavior with Dr. Durette's fabricated testimony at his deposition and at trial. Even if the Court credits Merck's argument that it did not control the content of Dr. Durette's deposition testimony, the Court cannot ignore the fact that Merck never sought to correct the record until trial. And even then, Merck's witness continued to lie about what he knew and when he knew it.

Further relying on post-Therasense cases, Merck argues that misleading statements are not enough to rise to the level of egregious misconduct. Of course, the Court has found more than misleading statements. The Court has found that Merck engaged in improper business practices and litigation misconduct. That said, Merck's cases do not fully support its argument that misleading statements do not rise to the level of egregious misconduct; instead, those cases found 16 that when it was ambiguous or not clear whether a statement was false, that uncertainty does not create egregious misconduct. See Smith & Nephew, Inc. v. Interlace Med., Inc., 955 F. Supp. 2d 69 (D. Mass. 2013) (finding ambiguous misrepresentation was not egregious misconduct); Network Signatures, Inc. v. State Farm Mut. Auto. Ins. Co., 2012 WL 2357307, at *7 (C.D. Cal. June 13, 2012) (not clear whether statement that delay in paying patent maintenance fee was unintentional was made to deceive the Patent Office), rev'd on other grounds, 731 F.3d 1239 (Fed. Cir. 2013); Ohio Willow Wood Co. v. Alps S., LLC, 735 F.3d 1333, 1339 (Fed. Cir. 2013) (denying summary judgment))

25 Second, Merck argues that its conduct is not improper because the law expressly allows it to file claims that cover a competitor's product. See Kingsdown Med. Consultants, Ltd. v. 26 Hollister Inc., 863 F.2d 867, 874 (Fed. Cir. 1988). In Kingsdown, the Federal Circuit stated: 27

[T]here is nothing improper, illegal or inequitable in filing a patent

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application for the purpose of obtaining a right to exclude a known competitor's product from the market; nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application. Any such amendment or insertion must comply with all statutes and regulations, of course, but, if it does, its genesis in the marketplace is simply irrelevant and cannot of itself evidence deceitful intent.

Id. (citing *State Indus., Inc. v. A.O. Smith Corp.*, 751 F.2d 1226, 1235 (Fed. Cir. 1985)). There are multiple problems with Merck's argument. First, Merck's argument relies on the assumption that it amended the claims to cover a competitor's product. But Dr. Durette testified that he amended the claims to cover the most important compounds in the Merck-Isis collaboration and not to cover Pharmasset's product. When pressed at trial, Dr. Durette refused to cleanly admit that he amended the claims to cover structures he saw in the Clark publication. Thus, Merck's argument fails to fit the evidence adduced during this case.

Even if that were not the case, the Court finds *Kingsdown*'s holding is premised entirely on the assumption that a patentee learns of a competitors' product through legal and ethical means. Here, Merck learned of PSI-6130, Pharmasset's crown jewel, during its due diligence of Pharmasset. This information was provided to Merck in a confidential setting to Merck employees who were purportedly firewalled from the prosecution of Merck's HCV patents. The Federal Circuit's holding in *Kingsdown* does not permit individuals to disregard firewalls and confidentiality agreements; holding otherwise, would bring the marketplace to a halt as companies would be weary to engage in due diligence lest a competitor uses that information to obtain patents.

Third, Merck claims Dr. Durette did not have an intent to deceive. Merck notes that "to meet the clear and convincing evidence standard, the specific intent to deceive must be the 'single most reasonable inference able to be drawn from the evidence." Merck Proposed COL ¶ 60, ECF 407 (quoting *Therasense*, 649 F.3d at 1290). According to Merck, Dr. Durette did not have an intent to deceive because he disclosed his conflict during the 2004 phone call and any further misstatements were simply the result of a lapse in memory. As support, Merck cites several cases where courts have refused to infer bad faith or intent to deceive from the fact of a

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misrepresentation, without more. Merck Proposed COL ¶¶ 64, 65, 66, 69, ECF 407 (citing 1 2 Outside the Box Innovations, LLC v. Travel Caddy, Inc., 695 F.3d 1285, 1294-95 (Fed. Cir. 2012); 3 Larson Mfg. Co. of S.D. v. Aluminart Prods. Ltd., 559 F.3d 1317, 1341 (Fed. Cir. 2009); Excelled Sheepskin, 2014 WL 3874193, at *10 (S.D.N.Y. Aug. 5, 2014); Abbott Labs. v. Sandoz, Inc., 544 4 F.3d 1341, 1354-57 (Fed. Cir. 2008); Eastman Kodak Co. v. Agfa-Gevaert N.V., 560 F. Supp. 2d 5 227, 301 (W.D.N.Y. 2008), judgment entered, 2008 WL 5115252 (W.D.N.Y. Dec. 4, 2008)). 6 7 Merck also cites cases where courts have refused to infer intent to deceive from errors that could 8 be due to memory lapses. Merck Proposed COL ¶ 67, ECF 407 (citing BASF Corp. v. Aristo, Inc., 9 872 F. Supp. 2d 758, 779 (N.D. Ind. 2012); United States v. Bailey, 123 F.3d 1381, 1395 (11th Cir. 1997)). While Merck accurately conveys the holdings of the cases it cites, these cases are 10 11 inapposite to the present facts, which involve substantially more than a "misrepresentation, 12 without more" or "errors that could be due to memory lapses." As explained throughout this 13 order, Merck's fabricated testimony was more than just an isolated incident, but happened 14 repeatedly during Dr. Durette's deposition. At trial, Dr. Durette continued to be evasive and told a 15 story that was not credible. Moreover, while perhaps a common and convenient post-fabrication excuse, a memory lapse does not explain Dr. Durette's confident and sanctimonious deposition 16 testimony, nor does it explain Dr. Durette's sudden moments of purported clarity at trial, when for 17 18 example, he magically recalled meeting with a supervisor prior to attending the 2004 phone call 19 with Pharmasset. As such, the present facts are significantly more disturbing than those in any of 20the cases cited by Merck. The evidence in this case fully supports a finding of intent to deceive.

Fourth, Merck argues that Dr. Durette's conduct cannot be imputed to Merck. It argues that a non-litigant's misconduct cannot support unclean hands unless it is attributable to the litigant. Since Dr. Durette was no longer a Merck employee at the time of his deposition, was not under Merck's control, and was not a 30(b)(6) witness as to the subject of the 2004 call, Merck argues there is no basis to impute Dr. Durette's intent and conduct. Merck also argues it did not try to hide Dr. Durette's participation on the 2004 phone call, as it acknowledged that in its opening statement.

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The Court disagrees with Merck and finds the evidence clearly supports imputing Dr.

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Durette's conduct to Merck. Dr. Durette appeared at the deposition as Merck's designated 30(b)(6) corporate representative on issues related to the prosecution of the '499 Patent, including all reasons for amending any pending claim during prosecution. At the deposition, Dr. Durette was represented by Merck's outside counsel and leading up to the deposition, Dr. Durette met with Merck's outside and inside counsel for two full days of preparation, totaling 12 to 14 hours. Moreover, although Dr. Durette was outside the subpoena power of the Court, and Merck voluntarily brought Dr. Durette to trial on its behalf. Additionally, Merck presented Dr. Durette's testimony on direct examination to support its claim of patent validity. Finally, Merck's argument that it openly acknowledged Dr. Durette's participation in the 2004 phone call overlooks that in the very next sentence, its counsel told the jury that Dr. Durette appeared on the phone call because he did not know the compound that was going to be disclosed was within the scope of the Merck patent applications he was working on which turned out to be false. Thus, through Dr. Durette, Merck directed, advised, guided, and covered up misconduct and Merck argued on behalf of Dr. Durette throughout this proceeding. Accordingly, Dr. Durette's conduct may be imputed to Merck.

Moreover, the record amply supports the conclusion that while Dr. Durette was employed by Merck, his conduct was supervised by his managers. He testified that he had a pre-call meeting with his supervisor to discuss whether his HCV patent work would overlap Pharmasset's compound and during the 2004 call, he declared he would have to discuss the same issue with his supervisor. The only reasonable inference that can be drawn is that Dr. Durette continued to prosecute the '499 Patent under the direction of Merck.

Fifth, Merck argues that there is no immediate and necessary relation between the asserted claims and alleged misconduct. Merck claims that to prevail on its unclean hands defense, Gilead must show that the alleged misconduct (1) directly related to the claims Merck asserts in the present suit, and (2) as a result Gilead suffered injury. Merck Proposed COL ¶ 78 (citing *Hynix*, 897 F. Supp. 2d at 978). Merck's reliance on *Hynix* is not persuasive. *Hynix* did not establish a two-step test for showing the "immediate and necessary relation" component of unclean hands. Instead, the Court was reiterating the notion that misconduct must relate to the party asserting the

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Onsite, 561 F.3d 983, 990 (9th Cir. 2009)). In Dream Games, the Ninth Circuit re-emphasized that under the longstanding principal of unclean hands, misconduct must relate to the party asserting the defense. Id.; see also Republic Molding Corp. v. B.W. Photo Utilities, 319 F.2d 347 (9th Cir. 1963) ("What is material is not that the plaintiff's hands are dirty, but that he dirtied them in acquiring the right he now asserts, or that the manner of dirtying renders inequitable the assertion of such rights against the defendant. As Professor Chafee suggests..., we should not by this doctrine create a rule comparable to that by which a careless motorist would be 'able to defend the subsequent personal injury suit by proving that the pedestrian had beaten his wife before leaving his home.""). Here, as the Court has explained, the misconduct relates directly to Gilead as it involves Merck's misconduct with respect to Pharmasset and this litigation.

defense and cannot be some general wrongdoing. See id. (citing Dream Games of Ariz. Inc. v. PC

Furthermore, the thrust of Merck's argument is that Gilead did not suffer any harm because Merck did not obtain patent coverage that it would not have otherwise obtained. Merck Proposed COL ¶ 79, ECF 407. However, this argument would have the effect of imposing a non-existent materiality requirement onto unclean hands and further reveals the flaw in Merck's interpretation of the "immediate and necessary relation" component of unclean hands. While misconduct must relate to the asserted claims, which it does in this case, the misconduct does not have to be material. See Therasense, 649 F.3d at 1287 ("This court recognizes that the early unclean hands cases do not present any standard for materiality."). As a result, the Court finds Merck's argument is nothing more than an attempt to import a materiality requirement into unclean hands that would be inconsistent with Supreme Court authority.

22 Sixth, Merck argues that the '712 Patent is not unenforceable due to unclean hands. Merck claims that its in-house patent prosecutor, Mr. Jeffrey Bergman began working on the '712 Patent in 2011 and was responsible for narrowing the original claims. Since Mr. Bergman narrowed the amended claims and there is no evidence that Mr. Bergman engaged in misconduct, Merck argues there is no immediate and necessary relation between Dr. Durette's misconduct and the 26 prosecution of the '712 Patent.

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Northern District of California United States District Court

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Contrary to Merck's argument, Merck and Dr. Durette's intentional litigation misconduct

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casts a darkness on this entire case that covers both patents-in-suit. Dr. Durette played a key role in the prosecution of both the '499 and '712 Patents. He was responsible for filing the application that eventually matured as the '712 Patent and this application shares the same specification as the '499 Patent. Although Merck cites several cases in support of its argument that the '712 Patent is not affected by the misconduct, these cases deal with starkly different factual situations. In all of Merck's cases, one party is trying to allege that misconduct related to a patent not-in-suit should give rise to unclean hands to an asserted patent. See, e.g., Advanced Magnetic Closures, Inc. v. Rome Fastener Corp., 2006 WL 3342655, at *1-2 (S.D.N.Y. Nov. 16, 2006) (rejecting unclean hands defense predicated on the wrongful assertion of other patents not involved in the litigation); MedPointe Healthcare Inc. v. Hi-Tech Pharmacal Co., 380 F. Supp. 2d 457, 466 (D.N.J. 2005) (rejecting an assertion of unclean hands that at best involved plaintiff's failure to disclose a prior ruling on a different, though related, patent, which was not the patent involved in the litigation); Hoffman-La Roche, Inc. v. Promega Corp., 319 F. Supp. 2d 1011 (N.D. Cal. 2004) (rejecting unclean hands defense predicated on non-asserted patent). Here both the '499 and '712 Patents were asserted in this case; Merck and Dr. Durette's litigation misconduct infected this entire case, covering both patents-in-suit. Moreover, it would be an odd result, to say the least, if Merck could engage in the substantial litigation misconduct exhibited in this case, yet face no penalty because the '712 Patent was deemed uncontaminated.⁵

19 In sum, the Court concludes that Dr. Durette knowingly misled Pharmasset regarding his 20status as being within the firewall at the March 17, 2004, due diligence call. Merck approved this misconduct both before and after the March 17, 2004, call by initially assigning its HCV patent 21 attorney to handle the Pharmasset due diligence work and thereafter, when Dr. Durette ceased his 22 23 due diligence work on Pharmasset's compound, directing him to remain active in prosecuting 24 Merck's overlapping HCV patent docket after Dr. Durette obtained the highly confidential 25 Pharmasset PSI-6130 disclosure. Moreover, the Court concludes that Dr. Durette intentionally

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²⁷ ⁵ The Court's finding of improper business conduct related to the March 2004 call was not considered by the Court in determining whether unclean hands prevented enforcement of the '712 28 Patent.

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fabricated testimony in this case and that Merck supported that bad faith conduct.

D. Balance of Equities

The last step of the unclean hands analysis is to balance the equities. "The Supreme Court has emphasized, however, that the doctrine of unclean hands 'does not mean that courts must always permit a defendant wrongdoer to retain the profits of his wrongdoing merely because the plaintiff himself is possibly guilty of transgressing the law." *Northbay Wellness Grp., Inc. v. Beyries*, 789 F.3d 956, 960 (9th Cir. 2015) (quoting *Johnson v. Yellow Cab Transit Co.*, 321 U.S. 383, 387 (1944)). As the Ninth Circuit has explained:

> Unclean hands...does not stand as a defense that may be properly considered independent of the merits of the plaintiff's claim.... In the interests of right and justice the court should not automatically condone the defendant's infractions because the plaintiff is also blameworthy, thereby leaving two wrongs unremedied and increasing the injury to the public. Rather[,] the court must weigh the substance of the right asserted by plaintiff against the transgression which, it is contended, serves to foreclose that right. The relative extent of each party's wrong upon the other and upon the public should be taken into account, and an equitable balance struck. The ultimate decision is whether the deception actually caused by plaintiff as compared with the trading methods of the defendant warrant punishment of the plaintiff rather than of the defendant.

Republic Molding, 319 F.2d at 350.

Although there is no precise set of criterion for such balancing, courts have generally considered the weight of wrongdoing of one party against the wrongdoing of the other. For example, in *Hoffman-La Roche*, the Court considered the number of false statements made by the patentees in prosecuting their patents and found the balance of the equities did not favor the patentees. 319 F. Supp. 2d at 1015-16. In *Dunlop-McCullen v. Local 1-S*, 149 F. 3d 85, 92-93 (2d Cir. 1998), a case under the Labor-Management Reporting and Disclosure Act, the court denied defendant's request to bar suit under the doctrine of unclean hands where the parties' wrongful conduct was remarkably similar in quality and extent but where, on balance, the court found that defendant's conduct was more significant so that the plaintiff was permitted to proceed with the suit. In *Northbay Wellness*, a bankruptcy case where a creditor sought by adversary proceeding to obtain a finding that a debt was nondischargeable based on theft, the Ninth Circuit was faced with

United States District Court Northern District of California balancing the seriousness of, on the one hand, an attorney's theft from his client of funds that led to his disbarment against, on the other hand, illegal marijuana sales by the other party. 789 F.3d at 960-61. Reversing the lower court, the Ninth Circuit held that the lower court had failed to conduct this balancing test and determined that unclean hands would not bar Northbay from its suit because, on balance, Northbay's board member, shared in its wrongdoing and his own culpability for theft of client funds was so egregious as to harm both Northbay and the public. *Id*.

In this case, Gilead is guilty of patent infringement. It admitted so much in response to Merck's motion for summary judgment, and on that basis, the Court granted summary judgment of infringement against Gilead. ECF 214. By contrast, Merck has engaged in business misconduct and litigation misconduct that the Court has found to be egregious.

As to Gilead's misconduct, it goes without saying that patent infringement is serious. However, in virtually every patent case where unclean hands is asserted, it comes on the heels of an infringement finding. *See Keystone*, 290 U.S. at 242; *Hazel-Atlas*, 322 U.S. 241-42; *Precision*, 324 U.S. at 814.

Merck raises a number of arguments to demonstrate that its conduct was less culpable than Gilead's. First, and foremost, Merck argues that Gilead's claim of unclean hands is weak. As described in detail above, the Court disagrees. The Court has determined that Merck engaged in a pervasive pattern of misconduct amply support by the evidence.

19 Merck further argues that there is no evidence that it intended to deceive Gilead or the 20Court. Again, the Court has found otherwise. From the evidence, it is clear to the Court that Merck's conduct during the Merck-Pharmasset discussions of allowing Dr. Durette to participate 21 22 and assuring Merck, albeit falsely, that Dr. Durette was firewalled, its decision to allow Dr. 23 Durette to continue to prosecute Merck's own HCV patent portfolio in violation of the firewall requirements and its own policy, its tainted judgment in amending the '499 claims 18 days after 24 25 the Clark application published, its litigation misconduct including Dr. Durette's lying at his deposition, recanting that testimony at trial without proper prior notice to Gilead, and further 26 untruthful testimony at trial all support the Court's conclusion that Merck did intend to deceive 27 28 Gilead and the Court.

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Next, Merck argues that the events in 2004 are irrelevant. Merck claims that Pharmasset knew that its PSI-6130 infringed Merck's patent applications. The Court has not made such a factual finding and on the record before it, cannot do so. Although there was evidence that Merck told Pharmasset that it did not have freedom to operate and that Jeremy Clark used the '499 Patent application to inform his lab work in developing PSI-6130, the evidence further shows that Pharmasset rejected Merck's accusations and that it reviewed the '499 application in order to expressly stay clear of infringement. On this record, the Court does not find the 2004 events irrelevant.

Merck further argues that it did not engage in misconduct before the PTO. While true, good behavior in one setting does not absolve Merck's misconduct in this setting. Additionally, unlike the inequitable conduct defense, misconduct is not limited to the PTO forum. *Therasense*, 649 F.3d at 1287.

Merck argues that Gilead was not harmed by its conduct. But this argument does not align with case law. The balancing of the equities analysis is not limited to the private harm caused by the misconduct. To say otherwise would impose a materiality requirement where there is none. *Id.* Rather, the focus is on the transgressions of both parties, to make sure that two wrongs are not left unpunished against the public interest. Even assuming that Merck is correct on this point, there was a significant public harm regarding false testimony and improper business conduct that permeated this suit.

Merck also argues that barring it from suit against Gilead is far too severe a penalty for its conduct. The Court acknowledges that the jury's damages award demonstrates the significance of the rights at risk. Taking that into account, however, it is the Court's determination that, on balance, Merck's persistent misconduct involving repeated fabricated testimony and improper business conduct outweigh its right to maintain this suit against Gilead.

As oft repeated, Learned Hand stated:

The doctrine is confessedly derived from the unwillingness of a court, originally and still nominally one of conscience, to give its peculiar relief to a suitor who in the very controversy has so conducted himself as to shock the moral sensibilities of the judge. It has nothing to do with the

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rights or liabilities of the parties; indeed the defendant who invokes it need not be damaged, and the court may even raise it sua sponte.

Saudi Basic Indus. Corp. v. ExxonMobil Corp., 401 F.Supp.2d 383, 392-93 (D.N.J. 2005) (quoting *Gaudiosi v. Mellon*, 269 F.2d 873, 882 (3rd Cir. 1959)). For the foregoing reasons, a balance of the equities favors Gilead, and thus, the Court concludes that Gilead has proven its defense of unclean hands by clear and convincing evidence.

VI. CONCLUSION

Candor and honesty define the contours of the legal system. When a company allows and supports its own attorney to violate these principles, it shares the consequences of those actions. Here, Merck's patent attorney, responsible for prosecuting the patents-in-suit, was dishonest and duplicitous in his actions with Pharmasset, with Gilead and with this Court, thus crossing the line to egregious misconduct. Merck is guilty of unclear hands and forfeits its right to prosecute this action against Gilead.

VII. ORDER

For the foregoing reasons, IT IS HEREBY ORDERED that Merck is barred from asserting the '499 and '712 Patents against Gilead and Merck shall take nothing by this suit.

IT IS SO ORDERED.

Dated: June 6, 2016

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BETH LABSON FREEMAN United States District Judge

United States District Court Northern District of California