IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC., Plaintiff, v. GILEAD SCIENCES, INC., GILEAD PHARMASSET LLC and GILEAD SCIENCES LIMITED, Defendants.	)	C.A. No. _____ **JURY TRIAL DEMANDED** REDACTED - PUBLIC VERSION

COMPLAINT

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Plaintiff, AbbVie Inc. ("AbbVie") asserts and alleges as follows against Defendants Gilead Sciences, Inc., Gilead Pharmasset LLC, and Gilead Sciences Limited (collectively "Gilead").

NATURE OF THE ACTION AND FACTUAL ALLEGATIONS

1. This lawsuit is about Gilead's intention to willfully infringe AbbVie's patents covering a revolutionary method of curing patients infected with hepatitis C virus ("HCV").

2. Gilead's intended infringement will be willful, for it is fully aware of AbbVie's patents, yet has taken no steps to seek a license from AbbVie, change paths, or mitigate its intended infringement. Instead, focused on profits and determined to be the first to market with this new category of HCV treatment, Gilead proceeded full speed ahead, knowing that its product will infringe AbbVie's patents. Gilead has no reasonable justification for its unlawful behavior.

3. AbbVie has pioneered treatments and cures for dozens of diseases, and invests more than $2.8 billion per year in research and development. AbbVie's focus is on innovation and bettering the lives of patients. One example of AbbVie's commitment to this is in the area of HCV, where AbbVie has spent millions of dollars searching for a cure to this devastating disease, with remarkable results.

4. The United States Patent and Trademark Office ("PTO") has recognized AbbVie as the rightful inventor of certain methods of treating the most difficult type of HCV with a combination of drugs called direct acting antiviral agents ("DAA's") in short durations, such as 8 weeks or 12 weeks, without the debilitating side effects caused by the previous standard treatment.

5. There is no question that Gilead's planned drug combination of two DAA's administered over 8 weeks or 12 weeks without a drug called interferon will infringe AbbVie's patents. Gilead has essentially admitted this. Gilead's only excuse for its planned infringement is its assertion that AbbVie's patents are invalid or unenforceable. But its arguments have already been rejected by the PTO, which allowed the patent-in-suit after considering those very arguments. As such, Gilead will not only infringe, but will do so willfully.

6. On information and belief, Gilead's willful conduct here is consistent with its conduct elsewhere, as evidenced by the suits that have been filed by several other companies, including arbitration over the ownership of one of its HCV drugs, and sharp criticism from HCV patient advocacy groups, who have charged Gilead with, for example, being "more concerned about profits than human lives."

7. As a result of its infringement of AbbVie's patent, Gilead will owe substantial damages, including but not limited to the profits that AbbVie would have made through the sale of its own patented combination HCV products. And AbbVie will ask for those damages to be tripled, as provided for under 35 U.S.C. § 285, and an award of attorneys' fees. Such remedies are particularly appropriate here, given Gilead's deliberate conduct.

A. AbbVie's Invention Of An Innovative Treatment Method For HCV

8. HCV is a devastating, life-threatening disease that afflicts millions of people worldwide. Chronic HCV can lead to liver disease, liver cancer, and death. There are at least six different genotypes of HCV, but genotype 1 is the most prevalent in the United States. Unfortunately, genotype 1 is also the hardest type to treat.

9. For years, HCV patients faced limited, lengthy, and difficult treatment options. The primary option was a combination of two drugs, interferon and ribavirin, administered over

the course of 48 weeks. Not only was this regimen lengthy, but interferon also has to be injected and causes many unwelcome side effects. Patients commonly experience flu-like symptoms, as well as nausea, fatigue, depression, and diarrhea throughout the nearly year-long course of treatment.

10. Many patients simply could not tolerate the treatment and stopped. Others never started, either because of the likely side effects or because coexisting medical conditions prevented them from even trying the regimen. And even for those genotype 1 patients who endured the lengthy treatment regimen, fewer than half were cured.

11. In search of better options, AbbVie and others began developing a new class of drugs for treatment of HCV: direct-acting antiviral agents. AbbVie had particular and extensive experience in virology based on years of work discovering and developing successful HIV drugs. AbbVie turned this experience, expertise, and passion to the problem of HCV.

12. AbbVie's goal was to revolutionize HCV therapy. To meet its goal, AbbVie assembled a highly-skilled group of scientists and clinicians. AbbVie challenged its team to come up with the shortest, most effective, treatment for HCV that would spare patients from the debilitating side effects of interferon.

13. AbbVie began developing its own proprietary DAA's, which would form the core for its own all-oral combination therapy.

14. At this time, many in the scientific community did not believe HCV genotype 1 could be treated in a short duration without interferon. Indeed as other companies began developing DAA's, they still thought interferon would be necessary and that treatment, while shortened, would still need to last at least 24 weeks. Early clinical trials for DAA treatment regimens included interferon and results indicated that it would be a high hurdle to remove.

DAA's like telaprevir and boceprevir demonstrated improved sustained virological response ("SVR") rates (a measure of efficacy showing the elimination of the virus from the bloodstream) when administered with interferon in treatment regimens lasting 24 weeks or longer. This led to approval by the U.S. Food and Drug Administration ("FDA") of each compound for the treatment of HCV when administered with interferon. But, neither drug filled the need for short duration treatment without interferon in patients suffering from HCV genotype 1.

15. Despite the skepticism, AbbVie pressed forward with its clinical program, devoting substantial resources to its efforts. AbbVie intensified its studies of HCV viral dynamics and the effects of drug intervention. As part of the development of this new method of treating HCV, AbbVie scientists created a sophisticated computer model used to show the relationship between DAA exposures and antiviral efficacy in HCV-infected subjects. The model was used to conduct clinical trial simulations of various DAA combination regimens without interferon. The model predicted the duration of treatment needed to eliminate the virus from the blood, using various combinations. The model also accounted for the problem of naturally-arising mutant virus strains and could estimate the amount of virus well below the ordinary limit of detection. The ability to perform what were essentially computerized clinical trials rather than trials in patients allowed AbbVie to move forward more quickly in identifying the best combinations of drugs and shortest dosing regimens and, more importantly, meant patients did not have to test regimens unlikely to be effective.

16. AbbVie's model predicted the effectiveness of numerous DAA combinations in interferon-free, short-duration therapies, predicting that multiple-drug combinations could cure over 90% of HCV genotype 1 patients.

17. Indeed, the model was able to predict not only the success of AbbVie's proprietary compounds, but also the success of administering drugs developed by others that had never previously been administered in combination.

18. When AbbVie confidentially told key opinion leaders of its plans to run a clinical trial with a combination of two of its DAA's—ABT-450 and ABT-072—and ribavirin for twelve weeks without interferon in patients with HCV genotype 1, many were skeptical. The only prior attempt at such short-duration, interferon-free therapy for HCV genotype 1 had failed so badly that the clinical trial was halted for safety reasons.

19. AbbVie persevered despite such skepticism. In June 2010, AbbVie submitted to the FDA a draft synopsis of its protocol for a clinical trial proposing 12-week, interferon-free therapy. The FDA had been skeptical of short duration treatments and had expressed concern about combination DAA treatment in the absence of interferon for durations of 12–24 weeks. According to the FDA, the optimal duration of therapy for combination DAA treatment without interferon was unknown and could be 48 weeks or longer.

20. By October 2010, AbbVie was treating patients with HCV genotype 1 with a combination of two of its proprietary drugs (ABT-450 and ABT-072) and ribavirin, without interferon, for 12 weeks.

21. The clinical trial was a success. Nine out of eleven patients in AbbVie's clinical trial achieved sustained undetectable levels of HCV after the 12-week treatment regimen. The results of this clinical study validated AbbVie's modeling approach, showing that combination treatment with certain DAA's for short duration, interferon-free could achieve SVR in patients with HCV genotype 1.

22. AbbVie quickly launched a second trial with a different combination of drugs. Patients infected with HCV genotype 1 received a combination of AbbVie proprietary drugs (ABT-450 and ABT-333) and ribavirin, without interferon, for 12 weeks.

23. Once again, the results were remarkable, as this new AbbVie combination cured 95 percent of patients receiving a higher dose of ABT-450, and 93 percent of previously untreated patients receiving a lower dose.

24. On October 21, 2011, AbbVie announced its news to the scientific community, publishing results of its trials showing that HCV patients could achieve SVR in only 12 weeks of treatment, without interferon. AbbVie's two trials received substantial praise from the HCV community, and were later published in the Journal of Hepatology and the New England Journal of Medicine.

25. In addition to announcing the results of its trials on October 21, 2011, AbbVie filed two patent applications (U.S. Provisional Application Nos. 61/550,352 and 61/550,360), disclosing its treatment regimen for curing HCV genotype 1 patients with combinations of DAA's, and without interferon, for short treatment durations. AbbVie disclosed a list of suitable DAA's, including its own compounds, and PSI-7977 (sofosbuvir) and GS-5885 (ledipasvir), both of which were specifically identified among a short list of "preferred" DAA's in their respective classes of DAA's that could be used in the inventive therapy.

26. The PTO has awarded AbbVie three patents to date based in part on these provisional applications. Specifically, the PTO issued U.S. Patent No. 8,466,159 ("the '159 patent") on June 18, 2013 and U.S. Patent No. 8,492,386 ("the '386 patent") on July 23, 2013. These patents are the subject of a lawsuit filed by AbbVie against Gilead on February 18, 2014

(Civil Action No. 14-209-GMS). The PTO additionally issued U.S. Patent No. 8,680,106 ("the '106 patent," attached as Exhibit 1) on March 25, 2014.

27. After AbbVie's development of short-duration, interferon-free treatment regimens, other companies began trials with interferon-free, short duration regimens of combinations of DAA's. Certain ongoing trials were even amended mid-stream to include interferon-free, short duration arms.

28. As others followed suit, AbbVie continued investing millions of dollars to further develop combination DAA therapies for use without interferon for short duration in genotype 1 patients, as well as specific patient populations with unmet needs. For example, AbbVie carried out clinical trials in patients with severe manifestations of HCV infection, such as compensated cirrhosis, and individuals co-infected with HIV.

29. AbbVie continued to refine its combination of DAA's, until it arrived at its current combination: ABT-450 / ritonavir, ABT-333, and ABT-267 ("AbbVie Combination"). This combination has shown extraordinary promise for short duration, interferon-free treatment of HCV genotype 1 patients. AbbVie has even shown the efficacy of its combination therapy in dedicated studies for the most difficult to treat subgroups of patients.

30. AbbVie's phase III clinical program ultimately included over 2300 patients in more than 25 countries, demonstrating outstanding efficacy. The outcomes of AbbVie's studies demonstrate how the AbbVie Combination performs across a broad spectrum of genotype 1 HCV patients, including those with compensated liver cirrhosis (scarring of the liver), those who had never been treated ("treatment-naïve") and those who had been treated previously but nevertheless remained infected with HCV ("treatment-experienced"), and those with genotype 1a and genotype 1b.

31. For example, AbbVie's TURQUOISE-II clinical study was the first phase III study completed exclusively in genotype 1 cirrhotic patients without interferon. The study evaluated the AbbVie Combination with ribavirin in cirrhotic, genotype 1a and genotype 1b, and treatment-naive and treatment-experienced patients. Patients were treated for either 12 or 24 weeks. In the 12-week arm, 92 percent of patients achieved SVR.

32. Further, in 12-week, interferon-free studies of the AbbVie Combination in patients in treatment-naïve and treatment-experienced patients with HCV-genotype 1b, 99 percent and 100 percent of patients, respectively, achieved SVR.

33. Not only did the AbbVie Combination show remarkable efficacy in Phase III studies, but also excellent tolerability and low rates of discontinuation. The AbbVie Combination has been designated as a Breakthrough Therapy by the FDA. AbbVie has announced its intention to file a New Drug Application ("NDA") for the AbbVie Combination in the second quarter of this year, and expects approval to occur later this year. AbbVie hopes and believes that its combination of drugs will be transformative in the fight against HCV.

B. Gilead's Use Of AbbVie's Invention

34. As AbbVie developed its own DAA's, it also considered partnering with other companies. While AbbVie had a broad portfolio of its own compounds with a variety of mechanisms of action, it recognized that partnering with other companies could provide additional options for patients.

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40. REDACTED , Gilead announced its intention to purchase Pharmasset in November 2011. The acquisition was finalized in January 2012. On information and belief, Gilead paid an inflated price of $11 billion for Pharmasset. Analysts have noted that Gilead needs to maximize its profits on its combination product to try to recover its investment.

41. Prior to Gilead's acquisition of Pharmasset, Pharmasset and Bristol-Myers Squibb ("BMS") had begun Phase II clinical trials using PSI-7977 and BMS-790052 for 24 weeks. On information and belief, Pharmasset and BMS added a 12-week arm to the trial after AbbVie announced the groundbreaking results of its 12-week, interferon-free study in October 2011.

42. Despite the Phase II clinical success of the PSI-7977/BMS-790052 combination and BMS's desire to continue the collaboration, Gilead discontinued trials of this combination after acquiring Pharmasset.

43. Then, Gilead substituted its own compound, GS-5885, even though it lagged in development behind BMS-790052. HCV patients, desperate for a cure, and recognizing Gilead's financial incentive to discontinue development of a combination with a competitor's drug, filed a White House petition in 2012 stating that Gilead is "more concerned about profits than human lives" and asking Gilead to stop withholding the PSI-7977/BMS-790052 combination in its attempt to corner the HCV market. On information and belief, because Gilead refused to cooperate, only after the FDA approval of PSI-7977 as a monotherapy could BMS continue on with phase III trials, causing a delay of nearly two years.

44. On information and belief, on or about May 7, 2012, well after AbbVie had announced the results of its groundbreaking 12-week, interferon free studies, and well after AbbVie filed its applications for the patents at issue in this case disclosing 8-week and 12-week interferon free treatment, Gilead added a 12-week, interferon-free combination arm (PSI-7977 and GS-5885) to an ongoing trial of PSI-7977 alone. On information and belief, in November 2012, Gilead added an 8-week, interferon-free combination arm (PSI-7977 and GS-5885).

45. On February 10, 2014, Gilead submitted an NDA to the FDA seeking approval to practice the method of treatment for HCV that AbbVie invented and for which AbbVie currently holds three patents. Specifically, Gilead's NDA seeks approval for ledipasvir (GS-5885) and sofosbuvir (PSI-7977) for the treatment of HCV genotype 1 for durations of 8 or 12 weeks without interferon. These methods of treatment are claimed by AbbVie's patents, including the

'106 patent. Therefore, Gilead, by submitting its NDA despite knowing of these patent families, has announced its intent to infringe AbbVie's patents.

C. Additional Facts Related To Case Or Controversy

46. Gilead is currently involved in contentious proceedings with at least three other companies—Roche, Merck, and Idenix—regarding the ownership of PSI-7977 and patent infringement. Notably, Roche and Gilead are engaged in an ongoing arbitration over Roche's rights to PSI-7977, REDACTED. Idenix is also suing Gilead, alleging that Gilead's sale of PSI-7977 will willfully infringe three Idenix patents related to the treatment of HCV infections using nucleosides (the class of drug to which PSI-7977 belongs). And Merck and Gilead are engaged in litigation over whether Gilead infringes two Merck patents relating to nucleosides.

47. On December 18, 2013, without provocation, Gilead filed a declaratory judgment action, C.A. No. 13-2034 ("Gilead Litigation"), against AbbVie and Abbott Laboratories Inc. ("ALI"), a subsidiary of AbbVie's predecessor Abbott Laboratories ("Abbott"), showing a justiciable controversy between AbbVie and Gilead. The lawsuit does not contest that Gilead's combination will infringe AbbVie's patents, but alleges that the '159 and '386 patents are invalid and unenforceable. On March 14, 2014, Gilead "amended"[1] its complaint alleging that the '106 patent, which had not yet issued, and two other AbbVie patent applications are invalid and

[1] Gilead's so-called "Amended Complaint" is, in fact, a supplemental complaint because it adds numerous allegations regarding transactions or occurrences that took place after the filing of the original complaint. Gilead's supplemental complaint is improper because Gilead did not ask for or receive permission from the court before filing it in accordance with Federal Rule of Civil Procedure 15(d).

unenforceable.[2] Gilead's original complaint and "amended" complaint also contain several baseless state law causes of action. In addition, the complaints slanders AbbVie's HCV drugs, its corporate integrity, and the integrity of its scientists and its attorneys, and overall seeks to disparage AbbVie's scientific reputation. Indeed, they make numerous statements that Gilead would not be permitted to make outside a privileged litigation pleading without incurring liability for slander or reprisal from FDA.

48. For example, Gilead accuses AbbVie, who has pioneered treatments and cures for dozens of diseases, and who invests more than $2.8 billion per year in research and development, of being disinterested in the "advancement of science" and unconcerned with the welfare of patients suffering from HCV. That assertion is baseless. Moreover, Gilead is leveling that assertion, even though its own decision to stop developing combination HCV treatments with BMS's drug has drawn sharp criticism from patient advocacy groups.

49. Likewise, Gilead disparages AbbVie's phase III HCV drugs as allegedly "inferior," knowing that far from being "inferior," AbbVie's has the largest all-oral, interferon-free HCV clinical program in genotype 1 patients ever conducted. Moreover, the Phase III results demonstrate that HCV genotype 1 patients achieve high rates of SVR with AbbVie's combination. And AbbVie has broken down its data to show that these high treatment rates can be seen even in the most difficult to treat subgroups, e.g. treatment-experienced patients and a particularly difficult-to-treat subtype of genotype 1 called genotype 1a. AbbVie also ran a dedicated study for patients with compensated cirrhosis, which showed 92 percent of patients

[2] Gilead's allegations that the patent application leading to the '106 patent and the other two AbbVie patent applications are invalid and unenforceable lack subject matter jurisdiction. Issued patent claims are a necessary prerequisite to litigation of a patent declaratory judgment action.

reached SVR with only 12 weeks of treatment without interferon. In view of this evidence, Gilead's assertion that AbbVie's combination will be "inferior" is just wrong.

50. And Gilead repeatedly suggests that there was something sinister about AbbVie pursuing and securing claims that cover Gilead's products, characterizing AbbVie's decision to do so as a "fraudulent scheme." But it knows full well that there is nothing wrong with pursuing such claims. After all, Gilead did the very same thing, filing claims covering PSI-7977 before it acquired Pharmasset. As the Federal Circuit explained more than 25 years ago in *Kingsdown Medical Consultants v. Hollister, Inc.*:

> It should be made clear at the outset of the present discussion that ***there is nothing improper, illegal or inequitable in filing a patent 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***.

863 F.2d 867, 874 (Fed. Cir. 1988) (emphasis added) (citations omitted).

51. AbbVie vigorously disputes all of Gilead's allegations, and has filed a motion to dismiss the state law causes of action and an anti-SLAPP motion against those state law causes of action sounding in tort.

52. Undeterred by AbbVie's patents and the numerous allegations against it by other parties, Gilead is proceeding with the development of its infringing product. In fact, Gilead's complaint in the Gilead Litigation represented that "[a]ll of Gilead's Phase III clinical trials of the [PSI-7977/GS-5885 combination] necessary for seeking regulatory approval are completed or nearly completed." On information and belief, Gilead initiated clinical trials using a combination

of PSI-7977 and GS-5885 in genotype 1 patients in May 2012. These trials included treatment arms using the PSI-7977/GS-5885 combination with and without interferon and/or ribavirin for 12 weeks or less. Furthermore, Gilead added an 8-week arm testing an interferon-free combination of PSI-7977 and GS-5885 in genotype 1 patients in November 2012.

53. As stated above, on February 10, 2014, after it filed its complaint against AbbVie and ALI, Gilead submitted its NDA for PSI-7977 and GS-5885, seeking approval of 8-week and 12-week regimens. And Gilead's complaint alleges that "Gilead expects that the FDA will act on its NDA within about eight months from the date it is filed."

54. Gilead's complaint and its public statements further affirm that its NDA seeks approval for treating HCV genotype 1 patients using the combination of PSI-7977 and GS-5885 for 8 weeks and 12 weeks, a method of treatment covered by claims 6–12 and 17–20 of the '106 patent. Accordingly, on information and belief, Gilead's label will include instructions to administer the PSI-7977/GS-5885 combination to HCV genotype 1 patients without interferon for 8 and/or 12 weeks.

55. Gilead's only excuse for its planned infringement is its assertion that AbbVie's patents are invalid or unenforceable. But its arguments have already been rejected by the PTO, which issued the '106 patent after considering those very arguments and even Gilead's complaint.

THE PARTIES

56. Plaintiff AbbVie is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois. AbbVie is a biopharmaceutical company dedicated to advancing the treatment

of complex diseases, and was formed in January 2013 from the proprietary pharmaceutical arm of Abbott.

57. On information and belief, Defendant Gilead Sciences, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 333 Lakeside Drive, Foster City, California.

58. On information and belief, Defendant Gilead Pharmasset LLC is a limited liability corporation organized under the laws of the State of Delaware with its principal place of business at 333 Lakeside Drive, Foster City, California.

59. On information and belief, Defendant Gilead Sciences Limited is a private limited liability company incorporated under the laws of Ireland with its registered offices at IDA Business & Technology Park, Carringtonhill, Co. Cork, Ireland.

JURISDICTION AND VENUE

60. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C., §§ 2201–02.

61. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a), and declaratory judgment jurisdiction exists under 28 U.S.C. §§ 2201 and 2202.

62. This Court has personal jurisdiction over Gilead Sciences, Inc. because Gilead Sciences, Inc. is registered with the Delaware Department of State to transact business in Delaware and has purposefully availed itself of this Court's jurisdiction by filing suit in the Gilead Litigation.

63. This Court has personal jurisdiction over Gilead Pharmasset LLC because Gilead Pharmasset LLC is registered with the Delaware Department of State to transact business in

Delaware and has purposefully availed itself of this Court's jurisdiction by filing suit in the Gilead Litigation.

64. This Court has personal jurisdiction over Gilead Sciences Limited at least because it has purposefully availed itself of this Court's jurisdiction by filing suit in the Gilead Litigation.

65. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

COUNT I
DECLARATORY JUDGMENT – INFRINGEMENT OF CLAIMS 6–12 AND 17–20 OF THE '106 PATENT

66. AbbVie incorporates by reference paragraphs 1–65 of this Complaint as if fully set forth herein.

67. The '106 patent was duly and legally issued by the PTO on March 25, 2014. AbbVie holds all substantial rights in the '106 patent and has the right to sue for infringement thereof. A true and correct copy of the '106 patent is attached as Exhibit 1.

68. Gilead has been aware of the '106 patent family since at least May 1, 2013, and has been monitoring prosecution of this family. For example, in Gilead's August 1, 2013 10Q filing with the Securities and Exchange Commission, Gilead acknowledges that "AbbVie Inc. (AbbVie) recently obtained United States Patent Nos. 8,466,159 and 8,492,386, which claim the use of a combination of sofosbuvir and ledipasvir for the treatment of HCV." Gilead has been aware of the application that led to the '106 patent, including the allowed claims, since at least March 14, 2014. Despite this knowledge, and with reckless disregard for the consequences of its actions, Gilead is actively preparing to infringe the '106 patent by seeking to market in the United States a combination of PSI-7977 (sofosbuvir) and GS-5885 (ledipasvir) ("the PSI-

7977/GS-5885 Combination"), for 8-week or 12-week interferon-free treatments of HCV genotype 1 patients.

69. Claims 6–11 of the '106 patent recite methods of treating HCV genotype 1 patients using the PSI-7977/GS-5885 Combination and ribavirin without interferon for 8 weeks. Claims 12, and 17–20 of the '106 patent recite methods of treating HCV genotype 1 patients using combinations of DAAs, including the PSI-7977/GS-5885 Combination and the AbbVie Combination, and ribavirin without interferon for 8, 9, 10, 11, or 12 weeks.

70. On information and belief, Gilead is developing the PSI-7977/GS-5885 Combination with ribavirin for short-duration treatment of HCV genotype 1, without interferon. On information and belief, Gilead has initiated phase III clinical trials including administration of the PSI-7977/GS-5885 Combination to HCV genotype 1 patients for 8 weeks or 12 weeks, without interferon, and with or without ribavirin.

71. Gilead has publicly announced that it submitted an NDA seeking FDA approval to market the PSI-7977/GS-5885 Combination for treating HCV genotype 1 patients without interferon. Gilead has publicly announced that its NDA seeks approval for a fixed-dose combination of the PSI-7977 and GS-5885 consisting of 90 mg of GS-5885 400 mg of PSI-7977 that will be administered once daily. On information and belief, Gilead will seek approval of a label including instructions for doctors to prescribe to HCV genotype 1 patients the PSI-7977/GS-5885 Combination for durations of 8 weeks and 12 weeks. Gilead has stated its expectation that the FDA will make a decision on the approval of its NDA, and proposed prescribing information, approximately eight months after the filing of its NDA for the PSI-7977/GS-5885 Combination.

72. Thus, Gilead has made substantial preparations to commercially manufacture, import into, market, offer for sale, and sell in the United States this combination product, and intends to commence the commercial manufacture, importation into, marketing, offering for sale, and sale in the United States of the PSI-7977/GS-5885 Combination immediately upon approval of Gilead's NDA for combination therapy.

73. On information and belief, once approved by the FDA, the PSI-7977/GS-5885 Combination will be prescribed and administered in the same or substantially similar manner as directed by the Gilead's proposed product label, which will constitute infringement of the '106 patent either literally or under the doctrine of equivalents. On information and belief, these uses will occur with Gilead's specific intent and encouragement, and will be uses that Gilead will actively induce, encourage, aid, and abet, as a consequence of, at least, the product labeling associated with the PSI-7977/GS-5885 Combination. Moreover, Gilead knows that these uses will infringe AbbVie's '106 patent.

74. Based on the facts alleged herein, there is an actual and continuing controversy between AbbVie and Gilead as to Gilead's infringement of the '106 patent.

PRAYER FOR RELIEF

WHEREFORE, AbbVie respectfully requests that this Court enter judgment in its favor as follows:

(1) declaring that, if Gilead markets its PSI-7977/GS-5885 Combination for use in an 8-week or 12-week, interferon-free treatment for HCV genotype 1 patients, Gilead will induce infringement of one or more claims of the '106 patent;

(2) entry of an injunction, prohibiting Gilead and any of its officers, agents, employees, assigns, representatives, privies, successors, and those acting in concert or participation with them from infringing and/or inducing infringement of the '106 patent;

(3) a "speedy hearing" on AbbVie's declaratory-judgment action as authorized by Fed. R. Civ. P. 57;

(4) entering of an order compelling Defendants to compensate AbbVie for any ongoing and/or future infringement of the '106 patent, in an amount and under terms appropriate under the circumstances;

(5) declaring or ordering that Defendants' infringement will be willful and/or an order increasing damages under 35 U.S.C. § 284;

(6) declaring this to be an exceptional case and awarding AbbVie its attorneys' fees under 35 U.S.C. § 285;

(7) awarding AbbVie its costs and expenses in this action; and

(8) awarding AbbVie any further and additional damages and relief as this Court deems just and proper.

DEMAND FOR TRIAL BY JURY

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

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