IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC., GILEAD PHARMASSET LLC, and GILEAD SCIENCES LIMITED,

Plaintiffs,

v.

ABBOTT LABORATORIES, INC., and ABBVIE, INC.,

Defendants.

C.A. No. 13-2034

JURY TRIAL DEMANDED

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COMPLAINT

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Gilead Sciences Limited

INTRODUCTION

1. This case involves a scheme by two large pharmaceutical companies, Defendants Abbott Laboratories, Inc. ("Abbott") and AbbVie, Inc. ("AbbVie"), to attempt to eliminate competition and dominate the market of drugs to treat the hepatitis C virus, known as "HCV." To execute their scheme, the defendants falsely and knowingly represented to the United States Patent and Trademark Office ("PTO") that they invented highly valuable methods of treating HCV that were, in fact, invented by plaintiffs Gilead Sciences, Inc. Gilead Pharmasset LLC, Gilead Sciences Limited, and their predecessor Pharmasset, Inc. (collectively "Gilead") and others. Defendants made these representations despite the knowledge that the inventions for which they claimed ownership had, in fact, been developed by their competitors

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2. In the past few years, many leading pharmaceutical companies, including Gilead and Defendants, have sought to develop new methods of treating chronic HCV, a debilitating virus that attacks the liver and can cause death. Until recently, the standard of care treatment for HCV included the administration of an injectable medication called pegylated interferon for up to 12 months. Treatments employing interferon have a variable cure rate, and the drug can cause serious and sometimes permanent side effects, including severe flu-like symptoms, hemolytic anemia, worsening of cardiac disease, weight loss, skin rashes, hair loss, muscle or bone pain, diarrhea, and vomiting.

3. Based on recent scientific advancements, it is now believed that millions of HCV sufferers worldwide can be cured by the use of a combination of drugs called Direct Acting

Antivirals ("DAAs"), administered in pill form without interferon. These therapies promise high cure rates—90% and higher—much shorter treatment durations—as little as 8 weeks—and dramatically reduced side effects.

4. Given these benefits, there has been intense competition in the pharmaceutical industry to bring the first such innovative combination therapy to market, including between Gilead and Defendants. As of the date of this complaint, Gilead and Defendant AbbVie are widely recognized as being the two companies most likely to first bring an all-oral, interferon free combination therapy to market.

5. Gilead's combination therapy is the two drugs, Sofosbuvir, also known as PSI-7977 or GS-7977, and Ledipasvir, also known as GS-5885 (together, "the Gilead Combination"). Sofosbuvir is what is known as a NS5B inhibitor, while Ledipasvir is what is known as an NS5A inhibitor. Gilead acquired Sofosbuvir in 2011 when it acquired Pharmasset. Gilead developed Ledipasvir independently.

6. The Gilead Combination promises to revolutionize the treatment of HCV, offering the ability to cure HCV within as short as 8 weeks with all-oral interferon-free therapy. No longer will patients be required to endure nearly a year of therapy with inferior drugs like interferon that may not work at all. Notably, the promise of Sofosbuvir has already been partially realized. On December 6, 2013, just 8 months after Gilead filed a new drug application for Sofosbuvir, the FDA approved Sofosbuvir as a treatment for HCV in combination with certain other drugs for durations as short as 12 weeks. This approval was hailed throughout the scientific and popular press, including in the *New York Times* and the *Wall Street Journal*. Gilead is marketing Sofosbuvir as SOVALDI^{TM}, in 400 mg tablets.

7. The opportunity to combine Sofosbuvir with Ledipasvir or other Gilead NS5A or third-party compounds deemed appropriate for patients was the primary reason Gilead acquired Pharmasset, for which it paid $11 billion.

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Gilead ultimately announced its acquisition of Pharmasset on November 21, 2011, and completed the transaction on January 17, 2012.

10. While discussions in support of the Gilead-Pharmasset acquisition were ongoing, on September 16, 2011, Gilead filed a provisional patent application covering the Gilead Combination that disclosed that it could be used for as little as 12 weeks. In late 2011 and early 2012, after the transaction with Pharmasset had closed, Gilead publicly disclosed its intention to

conduct clinical studies of the Gilead Combination, including studies of the combination for a12-week treatment duration.

11. During this same time frame, Abbott (now AbbVie) published results from clinical trials of its proposed combination, which is far less patient-friendly than Gilead's. AbbVie's proposed combination therapy is a combination of four drugs. In addition to the potential patient inconvenience of possibly taking more pills, more drugs mean more potential drug-drug interactions and side effects for patients.

12. On information and belief, REDACTED

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13. On information and belief, Abbott executives and "inventors" conspired and carried out the initial steps of the company's scheme by filing serial fraudulent patent applications asserting that Abbott had invented methods of treating HCV using PSI-7977 as well as the Gilead Combination (as well as thousands of combinations of Abbott's other competitors' HCV compounds). The first of these applications is dated October 21, 2011.

14. Gilead first learned of the defendants' fraud in the days after Abbott's patent applications first published on April 25, 2013. At that time, Gilead learned not only of the applications' existence for the first time but also the speed with which AbbVie (Abbott's successor-in-interest) had sought to receive patents based on those applications. At the time Gilead learned of the applications, the applications were already in condition for allowance.

15. On May 1, 2013, the same date that the PTO issued notices of allowances for the first two of AbbVie's patents, Gilead notified AbbVie of its legal obligation to inform the PTO of Gilead's prior pending patent application covering the Gilead Combination. AbbVie failed to do so. The PTO then issued Patent Nos. 8,466,159 (the '159 patent) [attached hereto as Exhibit A] and 8,492,386 (the '386 patent) [attached hereto as Exhibit B] to AbbVie on June 18 and July 23, 2013, respectively, to the following AbbVie "inventors":

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16. These two patents purport to claim, as AbbVie's invention, methods of treating HCV genotype 1 that comprise administering PSI-7977 and GS-5885 to HCV patients for 12 weeks, with and without ribavirin. But AbbVie invented no such thing. That combination therapy is the invention of Gilead and Pharmasset, not AbbVie.

17. Indeed, AbbVie cannot make, use or sell the Gilead Combination without violating the United States patent laws. Both PSI-7977 and GS-5885 are protected by United States Patents Nos.7,964,580, 8,334,270, and 8,580,765 (PSI-7977) and 8,088,368, 8,273,341, and 8,575,118 (GS-5885), respectively, owned by Gilead Pharmasset LLC. Any attempt by AbbVie to make, use or sell the Gilead Combination in the United States would infringe those patents, willfully so.

18. Despite this, and despite its knowledge of Gilead's prior application for the Gilead Combination, AbbVie continues to this day to assert that it invented the Gilead Combination, both in the United States and abroad. For example, since securing the fraudulent allowance of the '159 and '386 patents, AbbVie has pursued additional claims regarding other potential combination therapies that employ Sofosbuvir. On December 16, 2013, the PTO

allowed Application Number 13/656,012, which claims, as AbbVie's invention, 12-week methods of treatment for HCV using PSI-7977 and any NS5A inhibitor; AbbVie paid the issue fee the very next day. Again, AbbVie invented no such thing.

19. Similarly in Europe, AbbVie has pursued a patent application covering the use of Sofosbuvir and GS-5885 for 12-week treatment of HCV genotype 1. In so doing, it presented Gilead's clinical trial data on the Gilead Combination to the European Patent Office and asserted that Gilead "adopted" AbbVie's "invention." There is no truth to such claims.

20. Because AbbVie cannot lawfully manufacture the Sofosbuvir-containing therapies claimed in the '159 and '386 patents and the allowed '012 application, its patenting activity for those therapies has only one potential purpose—to enforce them against the Gilead Combination or future Gilead combinations, either to attempt to block them from the market or to extract royalties from Gilead.

21. As detailed further herein, AbbVie's conduct in pursuing this conspiracy is fraudulent, intentional and in willful violation of the Patent Laws of the United States, the Delaware Deceptive Trade Practices Act and common law of Slander of Title and Tortious Interference with Prospective Business Relations, REDACTED

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. As detailed herein, Gilead seeks restitution and damages for this unlawful conduct forthwith, as well as the invalidation of the currently issued AbbVie patents that claim therapies using Sofosbuvir and an injunction against any further attempts by AbbVie to claim methods of treating HCV using Sofosbuvir, or combinations of Sofosbuvir and Ledipasvir, as AbbVie "inventions."

THE PARTIES

22. Gilead is a company organized under the laws of the State of Delaware with its principal place of business at 333 Lakeside Drive, Foster City, California. Its mission is to advance the care of patients suffering from life-threatening diseases worldwide, including human immunodeficiency virus (HIV), HCV, liver diseases, serious cardiovascular and respiratory conditions, cancer, and inflammation.

23. 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, and is the owner of the patents related to Sofosbuvir and Ledipasvir, including but not limited to the following issued U.S. Patents: 7,964,580, 8,334,270, and 8,580,765 (PSI/GS-7977 - Sofosbuvir) and 8,088,368, 8,273,341, and 8,575,118 (GS-5885-Ledipasvir).

24. 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.

25. On information and belief, Abbott is a company organized under the laws of the State of Illinois with its principal place of business at 100 Abbott Park Road, Abbott Park, Illinois. Abbott is involved in the discovery, development, manufacture, and sale of health care products. On January 1, 2013, Abbott separated into two companies: Abbott and AbbVie.

26. On information and belief, AbbVie is organized 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 global, research-based biopharmaceutical company.

JURISDICTION AND VENUE

27. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq.* and with respect to the state law claims, under the laws of the State of Delaware

28. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338 and 35 U.S.C. § 1, *et seq.*, based on an actual controversy between Gilead, on the one hand, and Defendants, on the other hand, for declaratory judgment of patent non-infringement, invalidity and unenforceability under 28 U.S.C. §§ 2201 and 2202.

29. This Court has exclusive jurisdiction over those of Gilead's state law claims that for their determination depend on one or more substantial issues of federal patent law over which this Court has exclusive jurisdiction under 28 U.S.C. § 1338.

30. This Court has supplemental jurisdiction under 28 U.S.C. 1367(a) over those of Gilead's state law claims that form part of the same case or controversy under Article III of the United States Constitution.

31. This Court has personal jurisdiction over Abbott because Abbott is registered with the Delaware Department of State to transact business in Delaware and, on information and belief, regularly transacts business in Delaware.

32. This Court has personal jurisdiction over AbbVie because AbbVie is organized under the laws of Delaware and, on information and belief, regularly transacts business in Delaware.

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

34. On information and belief, Abbott and AbbVie are each subject to personal jurisdiction in this judicial district, and thus reside in this judicial district under 28 U.S.C. § 1391(b)(1) and (c)(2).

35. In short, three of the five parties to this lawsuit are entities created under Delaware law and a fourth, Abbott Laboratories, Inc., an Illinois corporation, is subject to personal jurisdiction in Delaware and thus, under 28 U.S.C. § 1391 (c)(2), is deemed to reside there, creating proper venue under 28 U.S.C. § 1391(b)(1) since all defendants reside in the District of Delaware.

FACTUAL ALLEGATIONS COMMON TO ALL COUNTS AND TO THE EXISTENCE OF A CASE OR CONTROVERSY

A. Hepatitis C

36. Hepatitis C virus ("HCV") is a group of related viruses classified into at least six distinct HCV genotypes (GT 1-6). The most prevalent type of HCV in the United States is GT 1. HCV is highly contagious and is spread by contact with HCV-infected blood. It can cause serious liver damage, including cirrhosis, liver cancer, and liver failure requiring liver transplant surgery.

37. The prevalence of HCV infection in the U.S. has been estimated between 3.2 and 5.2 million people. Since 2007, more people have died from HCV than from HIV in the U.S. HCV infection is the cause of half of all liver cancer deaths in the U.S. and the most common indication for liver transplants.

38. Most HCV-infected individuals carry the virus for life and thereby remain contagious and able to transmit the virus to others. This is true irrespective of whether an individual's HCV infection progresses to chronic form.

39. Traditionally, chronic HCV infection has been treated with a combination of antiviral medicines—ribavirin, interferon, and, more recently, protease inhibitors. This course of therapy may involve several pills taken throughout the day as well as interferon injections. These medicines have relatively limited efficacy and must be taken for prolonged periods—24 to 48 weeks—thereby exacerbating the physical and emotional toll on the infected individuals and their families, which can cause patients to discontinue treatment.

40. These treatments also can have serious side effects with those associated with interferon being most prevalent. Side effects associated with interferon are frequent and can be permanent, and may include flu-like symptoms, serious hemolytic anemia, worsening of cardiac disease, weight loss, skin rashes, hair loss, muscle or bone pain, diarrhea, and vomiting.

41. Recently, scientists have discovered drugs that can directly attack the virus, without the need for interferon. These drugs are known as direct acting anti-viral agents, or "DAAs." Treatment with these DAAs will hopefully obviate the need to use either interferon or ribavirin, and will allow physicians to cure their patients of HCV after as little as 8 weeks of treatment.

42. Several pharmaceutical companies have discovered and developed various potential DAAs, including those in the form of inhibitors of the non-structural proteins NSR, NS3, NS4A, NS4B, NS5A and NS5B. Of these, nucleotide and nucleoside polymerase inhibitors are considered the most powerful potential agents. HCV scientists often refer to nucleotide and nucleoside polymerase inhibitors as "Nucs." PSI-7977 is a Nuc.

43. These non-structural protein inhibitors combat HCV by suppressing the replication of viral RNA and directly interfering with the HCV life cycle. "Nucs," while

powerful, are also almost universally highly toxic at the concentrations necessary for effective disease treatment. PSI-7977, however, is not.

Pharmasset's Development of PSI-7977 (GS-7977) for Short Duration HCV Therapy

44. By no later than late 2010, Pharmasset's PSI-7977 had emerged as the leading Nuc in development by any pharmaceutical company. Different aspects of the compound and its use for treatment of HCV are protected by several United States patents, including U.S. Patent Nos. 7,964,580, 8,334,270, and 8,580,765.

45. Before being acquired by Gilead, Pharmasset spent many years of intensive effort and millions of dollars developing and testing PSI-7977 for use in the treatment of HCV. Well before any possible priority date of the fraudulent Abbott patents, Pharmasset recognized that 7977 could be used in an effective, short duration therapy, including in a short duration combination therapy.

46. No later than May 2009, for example, Pharmasset discussed internally that "small-molecule combination therapies" combining PSI-7851 with other compounds, may be able to suppress the HCV virus to undetectable levels and achieve "complete SVR" (sustained virological response) in as little as 12 weeks.

47. PSI-7851 is what is known as a "racemic" mixture. A racemic mixture is a mixture of two molecules in which each compound's three-dimensional structure is not superimposable upon its mirror image compound, much like our hands.. In this case, the so-called "enantiomers" that make up that racemic mixture PSI-7851 are PSI-7976 and PSI-7977.

48. On January 21, 2010, Pharmasset publicly announced its intention to conduct a 12-week Phase 2 clinical study of PSI-7977 in late 2010.

49. In August 2010, after receiving a "Fast track" designation from FDA, Pharmasset began "PROTON," a 12-week dosing study of PSI-7977 in treatment-naïve patients with HCV Genotypes 1, 2, and 3. According to the FDA, "Fast track is a process designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier."

50. On January 10, 2011, Pharmasset and Bristol Myers-Squibb ("BMS") announced a clinical collaboration agreement for testing PSI-7977 in combination with BMS's BMS-790052 (Daclatasvir). BMS-790052, like Gilead's GS-5885, is an NS5A inhibitor.

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The addition of 12-week subgroups to the Pharmasset–BMS trials was publicly announced on November 4, 2011.

52. On September 6, 2011, Pharmasset released results from its Phase 2b PROTON study of PSI-7977 showing that it achieved a 90% SVR (i.e. it had reduced the virus to undetectable levels in 90% of patients) over a 12-week course of treatment.

53. Paragraphs 46-52 state just a few of the examples of Pharmasset's understanding of short duration therapies employing Sofosbuvir. Indeed, when FDA approved Sofosbuvir on December 6, 2013, it approved a labeled indication that includes a 12-week course of treatment for both HCV genotypes 1 and 2, the latter without any interferon. As such, Sofosbuvir is the first HCV treatment to be approved for use in patients for durations as short as 12 weeks.

54. Despite understanding the potency of Sofosbuvir, Pharmasset lacked the resources to develop it fully on its own. Accordingly, throughout its development and testing of PSI-7977, Pharmasset explored license agreements and/or partnerships with larger pharmaceutical companies that could help Pharmasset market and distribute its compound, or that could offer their own compounds to develop combination treatments with PSI-7977. As word spread about the promise of PSI-7977, several large pharmaceutical companies expressed strong interest in obtaining license rights to PSI-7977 or in acquiring Pharmasset.

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Gilead's HCV Drug Program and Development of GS-5885

72. For many years, Gilead has expended significant resources to discover and develop methods of treating HCV that have high SVR rates and low toxicity to patients. As part of this effort, Gilead sought to develop NS5A and NS5B inhibitors.

73. One compound that Gilead discovered and developed is the highly effective NS5A inhibitor, Ledipasvir (GS-5885). Gilead filed a patent application for compounds including GS-5885 on May 13, 2009. On January 3, 2012, the PTO issued U.S. Patent No. 8,088,368 ("the '368 patent") on GS-5885. The compound was not identified by the name GS-5885 in the patent, nor, on information and belief, was the structure of GS-5885 associated with the name GS-5885 in any public documents and/or disclosures until April, 2012.

74. In August 2010, Gilead conducted a Phase 1 clinical trial with GS-5885 in patients with chronic HCV GT 1. In October 2010, Gilead publicly announced results of the Phase 1 clinical trial with GS-5885, including favorable safety results and once daily dosing potential.

75. As of fall 2010, Gilead's HCV treatment pipeline included five compounds in clinical trials and two additional compounds slated to enter clinical trials in early 2011. One of these compounds included a nucleotide analog NS5B polymerase inhibitor of HCV GTs 1-6 called GS-6620, which was highly effective in in vitro tests as well as in in vivo tests in certain mammals.

76. Early in 2011, Gilead conducted a further Phase 1 three-day clinical trial to study the safety, pharmacokinetics and antiviral activity of GS-5885. The sustained viral response rate of the single drug treatment was 50 percent. By early 2011, Gilead had approved a plan to launch a Phase 2 study later in 2011, in which it would combine GS-5885 with its NS5B polymerase inhibitor, GS-6620, without pegylated interferon and both with and without ribavirin, to determine whether a 12-week course of treatment would be effective and tolerated in patients.

Gilead Acquires Pharmasset in Order to Develop a 12-Week Combination Therapy for HCV With GS-5885 and PSI-7977

77. On information and belief, by at least as early as June 2011, Gilead strongly believed that an all-oral regimen combining GS-5885 with PSI-7977 (eliminating interferon, and administered with or without ribavirin) for a duration of 12 weeks or less would successfully treat HCV patients, including GT 1 patients. Such a combination treatment would revolutionize the treatment of HCV, allowing for a much shorter duration of treatment and far fewer side effects.

78. Accordingly, Gilead's management recommended to its Board of Directors the acquisition of Pharmasset for the purpose of acquiring PSI-7977. Gilead's management believed that PSI-7977 would be the key component of its future HCV treatments across all genotypes and, in combination with GS-5885, would result in a highly effective, all-oral interferon-free and shorter duration HCV drug therapy.

79. Gilead pursued the acquisition of Pharmasset and sought to protect its intellectual property rights and significant anticipated financial investment in the combination.

80. While the discussions of the Gilead-Pharmasset acquisition were ongoing, Gilead filed a provisional patent application with the PTO on September 16, 2011. This application disclosed a method for treating HCV, including but not limited to GT 1, by administering, over a 12-week period, the combination of "Compound 6" and "Compound 10," with Compound 6 corresponding to the structure of GS-5885 and Compound 10 corresponding to the structure of PS-7977. The provisional application disclosed administering the "combination compounds" with and without ribavirin, but not interferon, to treat HCV.

81. On November 21, 2011, Gilead and Pharmasset jointly announced the acquisition of Pharmasset by Gilead for approximately $11 billion.

82. The main purpose of the acquisition, according to the press release issued jointly by Gilead and Pharmasset, was to advance Gilead's efforts to develop an all-oral regimen for the treatment of HCV, specifically with Pharmasset's "lead product candidate" PSI-7977. This press release, as well as an accompanying slide presentation detailing Gilead's plans for GS-5885 and PSI-7977, were exhibits to Gilead's November 21, 2011 Form 8-K filing with the Securities and Exchange Commission ("SEC"). A true and accurate copy of Gilead's Form 8-K filing dated November 21, 2011 (with accompanying exhibits) is attached as Exhibit E.

83. On November 21, 2011, M. Ian Somaiya and Do G. Kim, research analysts at Piper Jaffray & Co., commented on this acquisition in their analyst report: "[b]ased on strength of Phase II data, we expect Gilead to pursue Phase III trials in genotype 1 patients with PSI-7977 + ribavirin AND PSI-7977 + Gilead's NS5A and/or protease inhibitor +/- ribavirin."

84. Following the acquisition, PSI-7977 became known as GS-7977.

85. In January 2012, Gilead continued to evaluate the safety and efficacy of GS-5885 and GS-7977, including through clinical testing of the combination.

86. On February 2, 2012, Gilead held a public earnings call with stock analysts for the fourth quarter of 2011. During the call, Gilead's President and Chief Operating Officer, John F. Milligan, PhD, stated, "In keeping with our philosophy to develop best-in-class drugs, we acquired Pharmasset in order to bring PSI-7977 to our portfolio."

87. During the call, Norbert W. Bischofberger, Gilead's Chief Scientific Officer, commented specifically on Gilead's ongoing testing of the combination of GS-7977 and GS-5885.

88. Gilead stated that, "[a]s Gilead has pioneered in HIV, we expect to bring forward next generation single tablet regimens for the treatment of hepatitis C also. To that end, direct

[*sic*; drug-drug] interactions will be carried out with 7977 and GS 5885 and other internal candidates, which will be followed by Phase 2 clinical studies." Gilead publicly indicated that treatment was expected to last for 12 weeks.

89. In response to questions asked by analysts, Gilead stated, "so, we are currently pursuing a drug interaction study 7977, 5855. That will then be followed by a fairly small Phase II study to simply show that you can use together – the two together that you get reasonable SVR rates. And that would then lead to a Phase III study. And that's probably about six months behind 7977 by itself."

Defendants' Unlawful Scheme to Keep Gilead's Combination and Other Competitors' HCV Treatments from Reaching Patients

90. REDACTED In October 2011, Abbott reported that it was developing a 12-week interferon-free regimen to treat HCV using four separate compounds: the protease inhibitor ABT-450; ritonavir, an inhibitor of cytochrome P450; NS5A inhibitor ABT-267/ABT-072; and non-nucleoside polymerase inhibitor ABT-333.

91. On information and belief, Abbott's (now AbbVie's) proposed combination is inferior to the Gilead Combination that employs GS-7977. In contrast to the Gilead Combination, which comprises two drugs, the Abbott/AbbVie combination involves four drugs. A combination that requires more drugs per day is problematic for patient convenience and compliance, as well as increasing the potential drug-drug interactions and side effects.

92. On information and belief, Abbott was also concerned that its combination might also prove inferior to other companies' potential therapies. Other pharmaceutical companies that are attempting or have attempted to develop short-duration HCV treatments include, but are not limited to: Achillion, Alios BioPharma, Anadys, Avila, Arrow Therapeutics, BioCryst,

Boehringer-Ingelheim, BMS, Conatus, GlaxoSmithKline, Incivec, Inhibitex, InterMune, Janssen, Medivir, Merck, Novartis, Phenomix, Presidio, Roche, Schering-Plough, Tibotec, Vertex, ViraChem, and Virobay.

93. On information and belief, in 2011 if not earlier, Abbott determined to eclipse its competitors, not through innovation or the advancement of science, but through a carefully planned fraudulent scheme. The scheme was based on fraudulently seeking to procure patents on various combinations of its competitors' HCV treatment compounds. The ultimate goal for Abbott had nothing to do with the advancement of science or the welfare of individuals afflicted with HCV, but rather to delay, deter, and/or block competitors' superior treatments from entering the market and reaching patients.

94. In most, if not all, cases, the companies targeted by Abbott already had obtained or filed for patents on the individual compounds comprising their combination therapies. Thus, even if Abbott obtained a patent on a competitors' novel combination therapy, Abbott would not be able to make or sell that combination treatment without the permission/license of the owners of the patents to the individual compounds.

95. On information and belief, Abbott's intention was not to make or sell its competitors' combination therapies. Instead, Abbott merely sought to obtain patents on its competitors' inventions. Through such patents, Abbott intended to (1) block its competitors from obtaining patents on their own proprietary drug combinations and (2) make it commercially unfeasible for those competitors to continue to develop, test clinically, obtain regulatory approval for, and eventually market and sell their own combination drug therapies.

96. Abbott's first target was the Gilead Combination and any other therapy that employed PSI-7977. On information and belief, understanding that combinations with PSI-7977

would be superior to any Abbott combination, Abbott defrauded the United States Patent Office, Pharmasset, and Gilead by filing for patents that falsely claimed inventorship of the combination of PSI-7977 and GS-5885, the combination of PSI-7977 and any other NS5A inhibitor, and even the use of PSI-7977 as monotherapy.

97. As set forth in more detail below, Abbott's unlawful scheme included passing off Pharmasset's and Gilead's work as its own, and attempting to monopolize the compounds developed by Pharmasset and Gilead, as well as compounds developed by its other competitors.

1. Abbott's October 21, 2011 Provisional Patent Applications

98. A key step in Abbott's illicit plot was its filing of two provisional patent applications, No. 61/550,352 and No. 61/550, 360 with the PTO on October 21, 2011. These virtually identical provisional patent applications contained claims covering potentially thousands of combinations of HCV compounds invented by Abbott's competitors. Although Abbott met and spoke with investors and stock market analysts about its HCV regimen on that very day, it never mentioned its alleged invention of thousands of combination therapies (using its competitors' proprietary compounds) for the treatment of HCV.

99. Abbott's October 21, 2011 provisional patent filings recited virtually every DAA in development by all major Abbott competitors, including, without limitation, the following seventy (70) DAAs:

(1)	ACH-1095	Achillion	(10)	AZD-2836	Astra-Zeneca
(2)	ACH-1625	Achillion	(11)	AZD-7295	Astra-Zeneca
(3)	ACH-2684	Achillion	(12)	AVL-181	Avila
(4)	ACH-2928	Achillion	(13)	AVL-192	Avila
(5)	ALS-2158	Alios BioPharma/Vertex	(14)	BCX-4678	BioCryst
(6)	ALS-2200	Alios BioPharma/Vertex	(15)	BI-201335	Boehringer Ingelheim
(7)	ANA-598	Anadys	(16)	BI-207127	Boehringer Ingelheim
(8)	A-689	Arrow Therapeutics	(17)	BILB-1941	Boehringer Ingelheim
(9)	A-831	Arrow Therapeutics	(18)	BMS-650032	Bristol-Myers Squibb

(19)	BMS-790052	Bristol-Myers Squibb
(20)	BMS-791325	Bristol-Myers Squibb
(21)	BMS-824393	Bristol-Myers Squibb
(22)	GS-5885	Gilead
(23)	GS-6620	Gilead
(24)	GS-9132	Gilead
(25)	GS-9190	Gilead
(26)	GS-9256	Gilead
(27)	GS-9451	Gilead
(28)	GS-9669	Gilead
(29)	GL-59728	Glaxo
(30)	GL-60667	Glaxo
(31)	GSK-62336805	GlaxoSmithKline
(32)	GSK-625433	GlaxoSmithKline
(33)	IDX-102	Idenix
(34)	IDX-136	Idenix
(35)	IDX-184	Idenix
(36)	IDX-316	Idenix
(37)	IDX-320	Idenix
(38)	IDX-375	Idenix
(39)	Telaprevir	Incivek
(40)	INX-189	Inhibitex
(41)	ITX-4520	iTherX
(42)	ITX-5061	iTherX
(43)	TMC-64912	Medivir
(44)	boceprevir	Merck
(45)	MK-0608	Merck
(46)	MK-3281	Merck
(47)	MK-5172	Merck
(48)	Vaniprevir	Merck
(49)	NM-811	Novartis
(50)	alisporovir	Novartis/Debiopharm
(51)	PF-00868554	Pfizer
(52)	Filibuvir	Pfzier
(53)	PSI-7977	Pharmasset
(54)	PSI-938	Pharmasset
(55)	PHX-1766	Phenomix
(56)	PPI-1301	Presidio
(57)	PPI-461	Presidio
(58)	danoprevir	Roche
(59)	RG-7128	Roche
(60)	narlaprevir	Schering-Plough
(61)	SCY-635	Scynexis
(62)	TMC-435	Tibotec
(63)	TMC-647055	Tibotec
(64)	VX-222	Vertex
(65)	VX-500	Vertex
(66)	VX-813	Vertex
(67)	VX-985	Vertex
(68)	VCH-759	Vertex/ViraChem
(69)	VCH-916	Vertex/ViraChem
(70)	VBY-708	Virobay

100.

REDACTED

101. In the "Claims" section of the 61/550,352 and 61/550,360 provisional patent applications, Abbott represented that it had invented a method of treating HCV by administering at least two (and possibly more) DAAs with ribavirin for a duration of 12 weeks or less. As drafted, this broad claim attempted to encompass the invention of virtually thousands of combinations of the above seventy (70) DAAs. Although Abbott did not expressly mention the specific Gilead Combination, its claims in the '352 and '360 provisional applications were so broadly drafted that they included the combination of PSI-7977 and GS-5885, along with potentially thousands of other drug combinations.

102. While Abbott's '352 and '360 provisional patent applications provided the chemical structures of several of the above compounds, they did not provide the chemical structure of GS-5885. In fact, although the chemical structure of GS-5885 had been disclosed, along with the chemical structures of many other compounds, in the '368 patent, it had not been identified there with the Gilead research identifier GS-5885. Abbott's provisional application therefore did not contain the chemical structure of GS-5885, which Gilead had not made publicly available when Abbott filed the applications in October 2011.

103. The provisional patent applications, which were filed by REDACTED of Abbott's legal department on October 21, 2011, identified the following five individuals as inventors of the claims:

REDACTED

104.

REDACTED

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106.

107.

REDACTED

108. While Abbott's October 21, 2011 provisional patent applications provided clinical test data involving its own proprietary compounds, Abbott disclosed no data or other basis to support its claims regarding the combination of any of the 70 compounds of its competitors, including Gilead's GS-5885 and PSI-7977 (now GS-7977).

109. When it filed the October 21, 2011 provisional applications, Abbott knew that its subterfuge would be hidden from its competitors—including Gilead—as well as Abbott's shareholders and the general public, because provisional patent applications are unavailable publicly for up to 18 months under the federal patent laws.

110. Abbott's machinations extended beyond the PTO, reaching even the securities markets. Abbott was always careful to conceal its plot when answering questions about its HCV treatment pipeline and those of its competitors during its quarterly conference calls with stock analysts.

111. Abbott's management consistently stated that Abbott was relying on its internal pipeline to develop its HCV program, carefully avoiding any mention of its scheme to claim inventorship of treatment methods employing the use of thousands of combinations of its competitors' products

REDACTED

For example, during its Fourth Quarter 2011 earnings call with stock analysts on January 25, 2012, held after Abbott

filed its provisional patent application claiming combinations of Gilead's and other competitors' DAA compounds for the treatment of HCV, Abbott REDACTED stated:

> As we discussed in October, we made significant progress on our pipeline over the past several years . . . and successfully advancing internal programs. One of these internal programs is HCV where our data to-date have shown that we are in the running to have a leadership position in this category . . . we have all the types of assets we need.

2. Abbott's February 17, 2012 Provisional Patent Applications

112. Abbott's next major step in furtherance of its unlawful scheme occurred on February 17, 2012, shortly after Gilead announced its Phase 1, 2 and 3 clinical trials of the combination of GS-5885 and GS-7977 for 12-week HCV therapy in the February 2, 2012 quarterly conference call with stock analysts. On February 17, 2012, Abbott filed provisional patent application Nos. 61/600,276 and 61/600,468 with the PTO, titled "Methods for Treating HCV," which now increased the number of individuals named as inventors of the claims from five to eleven. They included:

REDACTED

113. REDACTED

114. The February 17, 2012 provisional patent applications falsely asserted in Claim 34 that Abbott invented the use of the Gilead Combination for treating HCV ("The method of claim 29, wherein said at least two DAAs comprise PSI-7977 and GS-5885.").

REDACTED

115. Like the October 21, 2011 provisional patent applications, the February 17, 2012 provisional patent applications were fraudulent in many material respects, including, without limitation, the following:

- They falsely represented that Abbott invented the use of the Gilead Combination to treat HCV;
- They falsely represented that Abbott invented the use of PSI-7977 to treat HCV;
- They did not provide the chemical structure of GS-5885, showing that Abbott did not even know the chemical composition of one of two Gilead Compounds comprising the combination treatment. In fact, GS-5885 was not commercially available and its chemical structure still was not publicly known;
- They failed to describe how to make GS-5885;
- REDACTED

- They included no working examples or data relating to the use of PSI/GS-7977 in combination with GS-5885 to treat patients suffering from HCV.

116. Rather than provide clinical data support for its alleged invention, Abbott instead allegedly relied on predictions regarding the SVRs of combinations of two and three DAAs allegedly derived from its so-called "mechanistic model."

3. Abbott's May 11, 2012 Provisional Application

117. The next major step in furtherance of Abbott's unlawful scheme was the filing of provisional patent application No. 61/645,696 titled "Solid Compositions" on May 11, 2012. This provisional patent application claimed the invention of PSI-7977 as well as Gilead's Combination in solid (pill) form, along with the solid forms of Abbott's other competitors HCV treatment compounds. The 61/645,696 provisional patent application is the first Abbott filing with the PTO to include the chemical structure of GS-5885, which, by that time, Gilead had made public.

118. The 61/645,696 provisional patent application was filed by attorney and listed two inventors REDACTED who are not listed as inventors of Abbott's other HCV treatment patents claiming the invention of Gilead's combination.

119. This was yet another flagrant act by which Abbott fraudulently claimed entitlement to PSI-7977 as well as the Gilead Combination.

4. Abbott's June 6, 2012 Provisional Patent Applications

120. The next major step in furtherance of Abbott's unlawful scheme was the filing of its June 6, 2012 provisional patent application Nos. 61/656,251 and 61/656,253. These applications listed REDACTED as inventors.

121. REDACTED

122. Abbott again included the chemical structure of GS-5885 in the provisional patent application.

123. Although Abbott and AbbVie claimed a priority date of October 21, 2011 for the '159 and '386 patents, its "mechanistic model" that purported to use clinical data generated by their competitors to predict the results of various combinations of drugs for HCV treatment was not described in any of its provisional applications until the filling of its provisional application Nos. 61/600,276 and 61/600,468 on February 17, 2012. The "mechanistic model" also was not applied to the Gilead Combination in any of the Abbott provisional applications until June 6, 2012, the date of filing of provisional application Nos. 61/656,251 and 61/656,253.

124. The Abbott/AbbVie model was dependent on data from Gilead's past clinical trial results for its "modeling" of the "predicted" performance of the Gilead Combination. Indeed, the model relied upon Gilead's published "[d]ata from Phase 1 and Phase 2 studies of GS-5885 and GS-7977 (PSI-7977)." '159 patent at col. 108, lines 56-60; '386 patent at col. 102. The Phase 1 and Phase 2 studies were studies that Gilead conducted on PSI-7977 and GS-5885.

125. During prosecution, Abbott and AbbVie relied on Gilead's clinical data, from later Gilead studies that were mentioned by Gilead in its earnings calls, to support their model and their claim to the use of the Gilead Combination to treat HCV. Neither Abbott nor AbbVie contributed any of their own clinical work on the Gilead Combination, despite their claims to have invented the combination.

126. While Abbott was trying to identify GS-5885 and decide how it could use Gilead's clinical data to obtain a patent on HCV treatment methods using the Gilead Combination, Gilead's HCV research and development teams were, at great expense, mounting a concerted clinical research initiative to test its Combination.

127. By the time Abbott filed provisional application Nos. 61/656,251 and 61/656,253, its "model" contributed nothing novel regarding the Gilead Combination or Sofosbuvir and was a sham.

5. The Abbott Inventors' False Declarations to the PTO

128. In August 2012, each of the 11 individuals named as inventors on the provisional patent applications claiming the Gilead Combination

REDACTED signed a declaration affirming that they (1) were the original and first and joint inventor of the subject matter claimed; (2) reviewed and understood the contents of all the claims; and (3) had a duty to disclose to the PTO all information known to be material to patentability as set forth in 37 C.F.R. § 1.56.

129. The alleged inventors further declared that all statements made on their own knowledge were true and acknowledged any willful false statements would be punishable by fine or imprisonment under 18 U.S.C. § 1001.

130. Finally, they acknowledged that any willful false statements may jeopardize the validity of the application or any patent issued based on the Application.

131. One or more of Abbott's alleged inventors willfully made material misrepresentations and omissions in their declarations.

132. Despite their affirmations, one or more of the alleged inventors knew, among other undisclosed facts, that (1) they were not the original, first, or joint inventor of the subject

matter claimed, e.g., the Gilead Combination and (2) they failed to disclose materials relevant to patentability about which they were keenly aware.

133.

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134. Thus, one or more of the alleged inventors willfully made material representations to the PTO and withheld material information from the PTO.

6. Abbott's September 4, 2012 Utility Patent Applications

135. On September 4, 2012, Abbott filed fraudulent utility patent applications, Nos. 13/603,022 and 13/603,006 ("the '022 application" and "the '006 application"), claiming the invention of the Gilead Combination in claims 18–21 and PSI-7977 in claims 29 and 30.

136. Seeking to obtain patent protection on the Gilead Combination as soon as it possibly could, Abbott requested that these utility applications proceed on a Track One, or expedited, basis, and the PTO granted its request.

137. The declarations referenced in paragraphs 128–133, above, were filed in support of these September 4, 2012 patent applications. The alleged inventors claimed benefit of, among others, Abbott provisional applications Nos. 61/550,352 and 61/550,360.

7. Abbott's October 19, 2012 Utility Patent Application

138. On October 19, 2012, Abbott filed another fraudulent utility patent application, No. 13/656,012 ("the '012 application"), again claiming the Gilead Combination. This new

application listed the same eleven inventors as the applications that were filed on September 4, 2012. The alleged inventors claimed benefit of, among other, Abbott provisional application No. 61/656,253.

139. On November 20, 2013, Abbott filed declarations of inventorship from the eleven alleged inventors. These declarations contained the very same false representations as the declarations described in paragraphs 128 to 133.

140. During prosecution of the ’012 application, Abbott broadened its claims, seeking patent coverage for a method of treating HCV for 12 weeks comprising the administration of PSI-7977 and any HCV NS5A inhibitor.

141.

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8. AbbVie’s Formation and Continuation of the Unlawful Scheme

142. On or around October 19, 2011, Abbott announced that it would separate into two publicly-traded companies, one in diversified medical products (Abbott) and the other in research-based pharmaceuticals (AbbVie). AbbVie was to absorb Abbott’s then-current portfolio of proprietary pharmaceuticals and biologics, including its HCV treatment pipeline.

143. On or around January 2, 2013, the announced separation of Abbott and AbbVie into two separate, publicly-traded companies took effect.

144.

REDACTED

145. On information and belief, REDACTED was fully knowledgeable of and instrumental in executing Abbott's scheme and continued to further that scheme on behalf of the newly formed AbbVie.

146. Shortly after the formation of AbbVie, the defendants continued to defraud the PTO.

147. On or around April 11, 2013, AbbVie stated under 37 CFR 3.73(b) that it was the owner to the entire right, title, and interest in Abbott's patent application Nos. 13/603,022 and 13/603,006. AbbVie attorney REDACTED signed the ownership statement, certifying that he was authorized to act on behalf of AbbVie.

148. On or around April 25, 2013, Abbott's (now AbbVie's) '022 and '006 patent applications were published by the PTO and thus, made publicly available for the first time.

149. Gilead learned of AbbVie's fraudulent '022 and '006 patent applications shortly after their publication.

150. On or around May 1, 2013, the day that the PTO issued its notice of allowance for AbbVie's first two patents, Gilead contacted REDACTED by email, attaching Gilead's PCT publication WO 2013/040492 A2 ("Gilead's PCT Publication"), entitled "Methods for Treating HCV," which has a priority date of September 16, 2011 and discloses the Gilead Combination of GS-7977 and GS-5885.

, was copied on the email. Gilead encouraged REDACTED to comply with 37 CFR 1.56 and disclose the reference to the PTO, given the close nature of Gilead's PCT Publication to Abbott/AbbVie's pending application. Neither REDACTED nor REDACTED , nor any other AbbVie representative, disclosed this reference to the PTO before

issuance of the '159 and '386 patents, despite Gilead informing them of the importance of the reference.

151. Gilead's PCT Publication was filed on September 14, 2012 and published on March 21, 2013. It claims priority to a provisional application (U.S.S.N. 61/535,885) ("Gilead's Provisional Application") filed September 16, 2011. Gilead's PCT application is prior art to the AbbVie Patents because the priority date of Gilead's PCT Publication is before the October 2011 filing of AbbVie's first provisional applications, before the February 2012 filing of AbbVie's first provisional applications to mention the Gilead Combination of GS-7977 and GS-5885, and before the June 2012 filing of AbbVie's first provisional applications to include the structure of GS-5885.

152. Gilead's PCT Publication and Provisional Application to which it claims priority disclose a method for treating HCV genotype 1 by administering the combination of "Compound 6" and "Compound 10":

> This invention relates to combinations of therapeutic molecules useful for treating hepatitis C virus infection. The present invention relates to methods, uses, dosing regimens, and compositions ….
> HCV is a genetically diverse virus. Within a single infected patient, many variant viruses can be identified, leading to the description of 'viral swarm', or viral quasispecies. Within the global human population, HCV is also genetically diverse, with at least 6 major 'genotypes' identified (Genotypes 1-6), and numerous subtypes (i.e., HCV Genotype 1a and 1b). HCV genotypes are defined by genomic phylogenetic analysis, and diagnosed (in a given patient) by HCV RNA sequence-based diagnostic assays ….
> Another aspect of the present invention includes a composition, e.g. a pharmaceutical composition, the composition comprising Compound 6 and further comprising a second compound selected from the group consisting of Compound 1, Compound 2, Compound 3, Compound 4, Compound 5, Compound 7, Compound 9, Compound 10 and Compound 11 …. In one specific embodiment of the invention, the second compound may be Compound 10.

153. The structure of "Compound 6" is set forth on p. 8 of Gilead's PCT Publication and Provisional Application. This structure corresponds to the structure of GS-5885 set forth at cols. 83–84 of the '159 patent and cols. 79–80 of '386 patent.

154. The structure of "Compound 10" is set forth on p. 9 of Gilead's PCT Publication and Provisional Application This structure corresponds to the structure of PSI-7977 set forth at col. 80 of the '159 patent and col. 78 of the '386 patent.

155. Gilead's PCT Publication and Provisional Application define "combination compounds" as follows:

> As used herein the term "Combination Compounds" refers to Compound 1, Compound 2, Compound 3, Compound 4, Compound 5, Compound 6, Compound 7, Compound 9, Compound 10 and Compound 11.

156. Gilead's PCT Publication and Provisional Application disclose administering the "combination compounds" with ribavirin but not interferon to treat HCV:

> Combinations of Two or more of the Combination Compounds with Ribavirin but not Interferon
>
> As discussed above, some current HCV treatments include the administration of interferon, but this treatment typically produced unwanted side effects. Therefore it would be desirable to find effective HCV treatments that do not require the administration [of] interferon.
>
> One aspect of the present invention provides for compositions, methods, uses and the like for the treatment of HCV comprising administering two or more of the Combination Compounds or pharmaceutically acceptable salts thereof and ribavirin, without administering one or more interferons. This aspect of the invention may be particularly useful because it allows for the effective treatment of HCV without the side effects associated with the administration of one or more interferon.

157. Gilead's PCT Publication and Provisional Application explain that using ribavirin is an option, but is not required. The PCT Publication and Provisional Application also contemplate the combination of Compounds 6 and 10 without ribavirin:

> The term "combination therapy" means combinations or methods or uses or the like that incorporate two or more of the Combination Compounds. Combination therapy may also incorporate other active ingredients in addition to the two or more of the Combination Compounds including, but not limited to, ribavirin.

158. Gilead's PCT Publication and Provisional Application disclose administering the treatment for 12 weeks:

> The course of treatment can extend, for example, from about 12 weeks to about 48 weeks or longer, for example, from about 12 weeks to about 24 weeks.

159. By letter dated May 2, 2013, Gilead again provided REDACTED with Gilead's PCT Publication WO 2013/040492 A2, noting its specific relevance to AbbVie's pending patent application Nos. 13/603,006, 13/656,012, 13/603,022, and 13/656,024, amongst others. Gilead copied REDACTED on the letter, in which Gilead, once again, encouraged AbbVie to comply with 37 CFR 1.56 and disclose the reference to the PTO. Neither REDACTED nor AbbVie responded to Gilead regarding this communication.

160. On May 2, 2013, just one day after the PTO issued its notice of allowance and despite AbbVie's awareness of the Gilead PCT Publication, AbbVie, nonetheless, paid the issue fee on the '022 application, further advancing its illegal scheme. The '159 patent issued from Application No. 13/603,022 on June 18, 2013. The '386 patent later issued from Application No. 13/603,006 on July 23, 2013, again with no disclosure of the Gilead PCT Publication and Provisional Application to the PTO.

161. On or around May 2, 2013, Gilead sent an email to REDACTED REDACTED, as well as REDACTED, citing Gilead's PCT application and describing, in detail, its relevance to (and impact on the validity of the claims relating to Gilead's Combination) in AbbVie's patent application No. 13/603,022. Gilead also noted that despite its previous

communication to AbbVie in which Gilead drew AbbVie's attention to Gilead's PCT application and its priority date of September 16, 2011, AbbVie had, nonetheless, subsequently paid the issue fee on its Applications.

162. In response to Gilead's email, REDACTED responded on behalf of AbbVie, stating not that she recognized the seriousness of AbbVie's duty to disclose Gilead's PCT application to the PTO, but rather, "Thank you for your email. Please direct your correspondence to my colleague REDACTED ."

163. On information and belief, despite its awareness of the Gilead PCT Publication (WO 2013/040492) and its obligation to disclose material information to the PTO, AbbVie never disclosed the Gilead PCT Publication, or any of Gilead's patent applications claiming Gilead's combination HCV treatment, as references to the PTO during prosecution of the '159 and '386 patents. In particular, REDACTED , who had a duty of candor and good faith to the PTO as a registered patent attorney and as the patent attorney prosecuting the AbbVie applications, paid the issue fee for the '159 and '386 AbbVie Patents without disclosing the Gilead PCT Publication despite having been personally informed of the Publication's existence and relevance on multiple occasions.

164. The disclosure described above in Paragraphs 152 to 158 is included in both Gilead's PCT Publication and the September 16, 2011 Provisional Application to which it claims priority. Thus, the Gilead PCT Publication qualifies as prior art under 35 U.S.C. § 102(e) against the AbbVie Patents' claims to the Gilead Combination (in particular, claims 13–16) because the subject matter of claims 13–16 "was described in an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent …."

165. The Gilead PCT Publication, and the Provisional Application to which it claims priority, is material to the claims of the AbbVie Patents. If the PTO examiner had been aware of the Gilead PCT Publication and Provisional Application during prosecution of the AbbVie Patents, the claims would not have issued because they are anticipated under 35 U.S.C. § 102(e).

166. Indeed, on December 9, 2013, the European Patent Office issued an examination report concluding that Abbott's pending European claims to a combination of PSI-7977 and GS-5885 lacked novelty over, among other things, the Gilead PCT Publication.

167. The materiality of the Gilead PCT Publication, which is entitled to priority to the Gilead Provisional Application, to claims 13–16 of the AbbVie Patents is demonstrated in the charts below. The Gilead PCT Publication and Provisional Application disclose each and every limitation of claims 13–16 of each patent.

REDACTED

The '159 Patent Claims	The Gilead PCT Publication and Provisional Application
13. A method of treatment for HCV, comprising administering at least two direct acting antiviral agents (DAAs) and ribavirin to an HCV patient infected with HCV genotype 1, wherein said treatment does not include administration of interferon to said patient,	"This invention relates to combinations of therapeutic molecules useful for treating hepatitis C virus infection. The present invention relates to methods, uses, dosing regimens, and compositions …. HCV is a genetically diverse virus. Within a single infected patient, many variant viruses can be identified, leading to the description of 'viral swarm', or viral quasispecies. Within the global human population, HCV is also genetically diverse, with at least 6 major 'genotypes' identified (Genotypes 1-6), and numerous subtypes (i.e., HCV Genotype 1a and 1b). HCV genotypes are defined by genomic phylogenetic analysis, and diagnosed (in a given patient) by HCV RNA sequence-based diagnostic assays …. Another aspect of the present invention includes a composition, e.g. a pharmaceutical composition, the composition comprising Compound 6 and further comprising a second compound selected from the group consisting of Compound 1, Compound 2, Compound 3, Compound 4, Compound 5, Compound 7, Compound 9, Compound 10 and Compound 11 …. In one specific embodiment of the invention, the second compound may be Compound 10." Provisional Application at p. 1, lines 5–7 and 28–34; p. 17, lines 17–30. "As used herein the term "Combination Compounds" refers to Compound 1, Compound 2, Compound 3, Compound 4, Compound 5, Compound 6, Compound 7, Compound 9, Compound 10 and Compound 11." Provisional Application at p. 6, lines 4-6. "<u>Combinations of Two or more of the Combination Compounds with Ribavirin but not Interferon</u>

The '159 Patent Claims	The Gilead PCT Publication and Provisional Application
	As discussed above, some current HCV treatments include the administration of interferon, but this treatment typically produced unwanted side effects. Therefore it would be desirable to find effective HCV treatments that do not require the administration [of] interferon. One aspect of the present invention provides for compositions, methods, uses and the like for the treatment of HCV comprising administering two or more of the Combination Compounds or pharmaceutically acceptable salts thereof and ribavirin, without administering one or more interferons. This aspect of the invention may be particularly useful because it allows for the effective treatment of HCV without the side effects associated with the administration of one or more interferon." Provisional Application at p. 60, lines 18–29.
wherein said at least two DAAs comprise PSI-7977 and GS-5885,	The structure of "Compound 6" is set forth at p. 7, line 15 to p. 8, lines 1–4 of the Provisional Application. This structure corresponds to the structure of GS-5885 set forth at cols. 83–84 of the '159 patent. The structure of "Compound 10" is set forth at p. 9, lines 8–10 of the Provisional Application. This structure corresponds to the structure of PS-7977 set forth at col. 80 of the '159 patent.
and wherein said treatment lasts for 12 weeks.	"The course of treatment can extend, for example, from about 12 weeks to about 48 weeks or longer, for example, from about 12 weeks to about 24 weeks." Provisional Application, at p. 60, lines 3–4.
14. The method of claim 13, wherein said patient is a treatment-naïve patient.	There are only two types of patients: treatment-naïve and treatment experienced. Because there are only two types of patients, a person of ordinary skill, reading the disclosure

The '159 Patent Claims	The Gilead PCT Publication and Provisional Application
	in the Gilead PCT Publication and Provisional Application of a treatment for "HCV infection," would understand this to mean that the treatment applied to both types of patients.
15. The method of claim 13, wherein said patient is infected with HCV genotype 1a.	"This invention relates to combinations of therapeutic molecules useful for treating hepatitis C virus infection. The present invention relates to methods, uses, dosing regimens, and compositions …. HCV is a genetically diverse virus. Within a single infected patient, many variant viruses can be identified, leading to the description of 'viral swarm', or viral quasispecies. Within the global human population, HCV is also genetically diverse, with at least 6 major 'genotypes' identified (Genotypes 1–6), and numerous subtypes (i.e., **HCV Genotype 1a** and 1b). HCV genotypes are defined by genomic phylogenetic analysis, and diagnosed (in a given patient) by HCV RNA sequence-based diagnostic assays." Provisional application at p. 1, lines 5–7 and 28–34.
16. The method of claim 14, wherein said patient is infected with HCV genotype 1a.	"This invention relates to combinations of therapeutic molecules useful for treating hepatitis C virus infection. The present invention relates to methods, uses, dosing regimens, and compositions …. HCV is a genetically diverse virus. Within a single infected patient, many variant viruses can be identified, leading to the description of 'viral swarm', or viral quasispecies. Within the global human population, HCV is also genetically diverse, with at least 6 major 'genotypes' identified (Genotypes 1–6), and numerous subtypes (i.e., **HCV Genotype 1a** and 1b). HCV genotypes are defined by genomic phylogenetic analysis, and diagnosed (in a given patient) by HCV RNA sequence-based diagnostic assays." Provisional Application at p. 1, lines 5–7 and 28–34

The '386 Patent Claims	The Gilead PCT Publication and Provisional Application
13. A method of treatment for HCV, comprising administering at least two direct acting antiviral agents (DAAs) to an HCV patient infected with HCV genotype 1,	"This invention relates to combinations of therapeutic molecules useful for treating hepatitis C virus infection. The present invention relates to methods, uses, dosing regimens, and compositions …. HCV is a genetically diverse virus. Within a single infected patient, many variant viruses can be identified, leading to the description of 'viral swarm', or viral quasispecies. Within the global human population, HCV is also genetically diverse, with at least 6 major 'genotypes' identified (Genotypes 1–6), and numerous subtypes (i.e., HCV Genotype 1a and 1b). HCV genotypes are defined by genomic phylogenetic analysis, and diagnosed (in a given patient) by HCV RNA sequence-based diagnostic assays …. Another aspect of the present invention includes a composition, e.g. a pharmaceutical composition, the composition comprising Compound 6 and further comprising a second compound selected from the group consisting of Compound 1, Compound 2, Compound 3, Compound 4, Compound 5, Compound 7, Compound 9, Compound 10 and Compound 11 …. In one specific embodiment of the invention, the second compound may be Compound 10." Provisional Application at p. 1, lines 5–7 and 28–34; p. 17, lines 17–30. "As used herein the term "Combination Compounds" refers to Compound 1, Compound 2, Compound 3, Compound 4, Compound 5, Compound 6, Compound 7, Compound 9, Compound 10 and Compound 11." Provisional Application at p. 6, lines 4–6.
wherein said treatment does not include	The term "combination therapy" means

The '386 Patent Claims	The Gilead PCT Publication and Provisional Application
administration of either interferon or ribavirin to said patient,	combinations or methods or uses or the like that incorporate two or more of the Combination Compounds. Combination therapy ***may*** also incorporate other active ingredients in addition to the two or more of the Combination Compounds including, but not limited to, ribavirin. Provisional Application at p. 11, lines 16–19.
wherein said at least two DAAs comprise PSI-7977 and GS-5885,	The structure of "Compound 6" is set forth at p. 7, line 15 to p. 8, lines 1–4 of the Provisional Application. This structure corresponds to the structure of GS-5885 set forth at cols. 79–80 of the '386 patent. The structure of "Compound 10" is set forth at p. 9, lines 8-10 of the Provisional Application. This structure corresponds to the structure of PS-7977 set forth at col. 78 of the '386 patent.
and wherein said treatment lasts for 12 weeks.	"The course of treatment can extend, for example, from about 12 weeks to about 48 weeks or longer, for example, from about 12 weeks to about 24 weeks." Provisional Application, at p. 60, lines 3–4.
14. The method of claim 13, wherein said patient is a treatment-naïve patient.	There are only two types of patients: treatment-naïve and treatment experienced. Because there are only two types of patients, a person of ordinary skill, reading the disclosure in the Gilead PCT Publication and Provisional Application of a treatment for "HCV infection," would understand this to mean that the treatment applied to both types of patients.
15. The method of claim 13, wherein said patient is infected with HCV genotype 1a.	"This invention relates to combinations of therapeutic molecules useful for treating hepatitis C virus infection. The present invention relates to methods, uses, dosing regimens, and compositions …. HCV is a genetically diverse virus. Within a single infected patient, many variant viruses can be identified, leading to the description of 'viral swarm', or viral quasispecies. Within

The '386 Patent Claims	The Gilead PCT Publication and Provisional Application
	the global human population, HCV is also genetically diverse, with at least 6 major 'genotypes' identified (Genotypes 1–6), and numerous subtypes (i.e., **HCV Genotype 1a** and 1b). HCV genotypes are defined by genomic phylogenetic analysis, and diagnosed (in a given patient) by HCV RNA sequence-based diagnostic assays." Provisional Application at p. 1, lines 5–7 and 28–34.
16. The method of claim 14, wherein said patient is infected with HCV genotype 1a.	"This invention relates to combinations of therapeutic molecules useful for treating hepatitis C virus infection. The present invention relates to methods, uses, dosing regimens, and compositions …. HCV is a genetically diverse virus. Within a single infected patient, many variant viruses can be identified, leading to the description of 'viral swarm', or viral quasispecies. Within the global human population, HCV is also genetically diverse, with at least 6 major 'genotypes' identified (Genotypes 1–6), and numerous subtypes (i.e., **HCV Genotype 1a** and 1b). HCV genotypes are defined by genomic phylogenetic analysis, and diagnosed (in a given patient) by HCV RNA sequence-based diagnostic assays." Provisional Application at p. 1, lines 5–7 and 28–34

168. If REDACTED or anyone else acting on behalf of AbbVie had disclosed the Gilead PCT Publication and Provisional Application to the PTO, the Examiner would not have allowed at least claims 13–16 to issue because these claims are anticipated under 35 U.S.C. § 102(e). Thus, REDACTED and AbbVie knowingly failed to disclose material prior art.

169. A specific intent to deceive can be inferred because REDACTED REDACTED and AbbVie were specifically informed of the relevance of the Gilead PCT

Publication and Provisional Application to the AbbVie applications before they issued as the AbbVie Patents and still failed to disclose it.

170. On or around June 13, 2013, AbbVie management, including REDACTED —a named inventor on the '159 and '386 patents and REDACTED —presented at Goldman Sachs 45th Annual Global Healthcare Conference. When asked about AbbVie's progress on developing its HCV regimen as compared to Gilead's, stated, "I'll say that it is a very tight race and like I said we're executing extremely well and I think we've got a very good shot at being first, but it's close."

171. At the time of REDACTED statements, the PTO had already notified AbbVie of its Notices of Allowance for the '159 and '386 patents, which issued on June 18, 2013 and July 23, 2013, respectively.

172. AbbVie did not, however, disclose to investors or the public that it had secured patents covering the Gilead Combination.

173. AbbVie continued with its scheme of deception after the issuance of the '159 and '386 patents. On October 18, 2013, during prosecution of its European applications on the same GS-5885 / PSI -7977 combination, AbbVie, to support the patentability of its claims, argued that the "importance of the shortened treatment method continues to be underscored, even after the present invention was published and after it was quickly adopted by others – see Exhibit 1 hereto, page 1, last but one full paragraph (Press Release dated May 2, 2013, reporting on the LONESTAR study)." The attached press release related to Gilead's clinical studies on the GS-5885 / PSI-7977 combination. Thus, AbbVie told the European Patent Office that Gilead had "adopted" its claimed treatment method, despite AbbVie's knowledge that the situation was actually reversed, with AbbVie attempting to "adopt" Gilead's work for AbbVie's own patents.

As described in detail above, REDACTED and AbbVie REDACTED ,

REDACTED

174. It was not until September 2013, during prosecution of the ’012 application that has been allowed but not issued, that AbbVie finally disclosed the existence of the Gilead PCT Publication to the PTO. This disclosure was well after the ’159 and ’386 patents had already issued, and nearly a year into the prosecution of the ‘012 application.

175. Even though the Gilead PCT Publication was disclosed in prosecution of the ’012 application, AbbVie’s unclean hands from its earlier failure to disclose infects the later prosecution as well. The ’012 application descends from the same June 2012 provisional application as the ’386 patent and claims highly related subject matter. Indeed, the claims asserted in the ‘012 application are broader than the claims of the ’159 and ’386 patents, covering the use of PSI-7977 with any NS5A inhibitor rather than just its use with GS-5885.

176. Moreover, even though the Gilead PCT Publication was listed on an Information Disclosure Statement to the PTO in prosecution of the ‘012 patent application, AbbVie still continued with its deception. During the prosecution of the ‘012 patent application, AbbVie sought even broader claims, seeking to cover the use of PSI-7977 with any NS5A inhibitor, not just with GS-5885, for 12-week treatment, even though AbbVie itself has done no work with any PSI-7977 combination.

REDACTED

177. AbbVie has also continued to use Gilead’s clinical data to support these broad claims. On September 18, 2013, AbbVie attempted to support its claims to the use of PSI-7977

with any NS5A inhibitor without interferon for 12-week treatment of HCV by citing to Gilead data of 12-week clinical studies on PSI-7977 without interferon.

178. On November 20, 2013, two months after listing the Gilead PCT Publication on the Information Disclosure Statement, AbbVie's alleged inventors filed the declarations of inventorship discussed in paragraphs 128 to 134, falsely claiming that they were the original and first inventors of the claimed subject matter.

179. As discussed in paragraphs 128 to 134, these declarations were knowingly false. The submission of such false declarations to the PTO constitutes affirmative egregious misconduct.

180. AbbVie has obtained these patents on the Gilead Combination despite the fact that AbbVie itself would not be permitted to make, use, or sell the Gilead Combination without violating the U.S. Patent Law. Gilead Pharmasset LLC owns U.S. Patent No. 7,964,580, which covers PSI-7977, and U.S. Patent No. 8,088,368, which covers GS-5885. Any attempt by AbbVie to make, use, or sell the Gilead Combination would infringe both of these patents.

181. Despite Gilead's own patents, and despite its knowledge of Gilead's prior PCT application for the Gilead Combination, AbbVie has continued to assert, both before the U.S. PTO and in Europe, that it invented the Gilead Combination and other potential combinations that involved Sofosbuvir.

182. AbbVie willfully deceived the PTO, millions of HCV sufferers and its own investors as part of its scheme to prevent Gilead from bringing its HCV cure to market. AbbVie's pattern of deception constitutes affirmative egregious misconduct.

ADDITIONAL FACTS RELATED TO PRESENCE OF CASE OR CONTROVERSY

183. The AbbVie Patents claim as AbbVie's "invention," the Gilead Combination for the treatment of HCV GT1, with and without the use of ribavirin. Because this "invention"

covers only a product that would be marketed by Gilead, and because AbbVie would be prohibited from marketing such a product because of Gilead's own patents, there is no purpose to obtaining these patents except to either: a) attempt to block Gilead's product from the market; or b) extract royalties from Gilead through the litigation process or the threat of the litigation process.

184. The Gilead Compounds have, separately and as the Gilead Combination, been clinically tested in thousands of individuals in Phase 1, 2 and 3 clinical trials and have been shown to be generally safe and well tolerated, raising no serious safety issues and they have shown a high degree of efficacy in a variety of patients infected with a variety of HCV genotypes, including treatment naïve patients with HCV GT-1.

185. In particular, the Gilead Compounds and the Gilead Combination have been extensively and successfully tested in clinical trials of treatment-naïve HCV GT-1 patients with a treatment duration of twelve weeks or less, both with and without ribavirin. The same is true of the combination of Sofosbuvir and Gilead's next generation pan-genotypic NS5A inhibitor, GS-5816.

186. All of Gilead's Phase III clinical trials of the Gilead Combination necessary for seeking regulatory approval are completed or nearly completed.

187. Gilead is preparing to file, and has publicly announced that it plans to file, a New Drug Application ("NDA") submission to the FDA for the first quarter of 2014. Gilead expects that the FDA will act on its NDA within about eight months from the date it is filed.

188. Gilead has invested $11 billion to acquire Pharmasset, plus at least $200 million in the development of the Gilead Combination, and will expend millions of dollars and vast human resources during the final FDA review process and during preparation for launching these

drugs. Thus, Gilead has conspicuously engaged in meaningful preparation for making, selling and using the Gilead Combination.

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

190. On information and belief, AbbVie has monitored and continues to monitor the progress and outcome of Gilead's clinical trials of the Gilead Combination. If approved, the Gilead NDA drug product comprising the Gilead Combination will directly compete against AbbVie's own all-oral DAA products that are the subject of AbbVie's own impending NDA in the HCV all-oral, interferon-free DAA market.

191. On information and belief, AbbVie has demonstrated a willingness to protect the market position of its proprietary drugs against competitors through patent infringement litigation. On October 25, 2013, REDACTED during a call with market analysts, stated "We certainly feel good about the patent portfolio that we have . . . . I believe it does and will provide a significant level of protection. And we certainly intend to enforce our patents and make sure no one violates those patents." Consistent with this, despite its relative short existence, on information and belief, AbbVie has been the plaintiff in eighteen patent cases filed in this judicial district, either those that it has filed itself or those in which it succeeded to Abbott's filing.

192. On information and belief, Abbott and AbbVie have sought patent protection on their competitors' proprietary developmental drugs so that they can assert those patents to eliminate competition for any AbbVie product.

193. On information and belief, AbbVie has a present intent to sue Gilead for infringement of the '159 and '386 patents. On information and belief, AbbVie secured issuance of those two patents on Track 1 status at the United States Patent Office for the specific purpose of enforcing them against Gilead.

LEGAL CLAIMS (FEDERAL LAW)

COUNT 1

(Declaratory Judgment – Invalidity of Claims 13-16 of the '159 Patent)

194. Gilead incorporates by reference the allegations contained in paragraphs 1–193 of this Complaint.

195. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, regarding the invalidity of claims 13–16 of the '159 patent.

196. Claims 13–16 of the '159 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. § 1, *et seq.*, including §§ 102(e), 102(f), 102(g)(2), 103, and 112.

197. Gilead is entitled to a judgment declaring that claims 13–16 of the '159 patent are invalid under 35 U.S.C. §§ 102(e), 102(f), 102(g)(2), 103, and 112.

198. This is an exceptional case entitling Gilead to an award of its attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT 2

(Declaratory Judgment – Unenforceability of the '159 Patent)

199. Gilead incorporates by reference the allegations contained in paragraphs 1–193 of this Complaint.

200. The ’159 patent is unenforceable due to inequitable conduct before the PTO. This conduct includes the submission of knowingly false declarations of original inventorship to claims 13–16 by REDACTED (collectively, the “Named AbbVie Inventors”) and the intentional failure of at least REDACTED to disclose material prior art—i.e., the Gilead PCT Publication and the Provisional Application to which the Gilead PCT Publication claims priority—to the PTO during prosecution of the ’159 patent with specific intent to deceive.

201. On or around August 15–29, 2012, each of the Named AbbVie Inventors signed declarations that declared that they believed each of them to be an original and first and joint inventor of the subject matter claimed in the ’159 patent, which includes the specific combination of GS-5885 and GS-7977, without interferon for 12 weeks, for the treatment of HCV genotype 1.

202. On information and belief, the Named AbbVie Inventors intentionally misrepresented to the PTO the identities of the true original inventors of claims 13–16 in the ’159 patent. This misrepresentation was material to patentability under 35 U.S.C. §§ 102(f), 111, and 115.

203. The inventors’ specific intent to deceive the PTO can be inferred from the facts described above and the fact that claims to the Gilead Combination do not appear in the application until after Gilead acquired Pharmasset and announced its intentions for 7977 and until after Gilead announced clinical trials were planned for the Gilead Combination. This intent to deceive can further be inferred from the fact that no AbbVie inventor had any knowledge of and/or access to any clinical data relating to the use of GS-7977 in combination with GS-5885 to treat patients suffering from HCV, as late as the filing date of Abbott/AbbVie’s

patent application number 61/656,251. The submission of such knowingly false declarations constitutes affirmative egregious misconduct before the PTO.

204. On information and belief, at least REDACTED intentionally failed to disclose the Gilead PCT Publication and the Provisional Application to which the Gilead PCT Publication claims priority to the PTO as prior art under 37 C.F.R. § 1.56. This misrepresentation and/or omission was material to patentability under 35 U.S.C. §§ 102(e) and 103.

205. An intent to deceive the PTO can be inferred from the fact that, on or around May 1, 2013 and May 2, 2013, prior to the issuance of the '159 patent, AbbVie received multiple instances of correspondence from Gilead encouraging AbbVie to disclose the Gilead PCT Publication to the PTO and bring it to the examiner's attention, but chose not to do so.

206. An intent to deceive the PTO can further be inferred from the fact that during the prosecution of the '159 patent, AbbVie relied on Gilead's clinical data to support its claim to the use of GS-5885 and GS-7977 to treat HCV in a March 6, 2013 Supplemental Response to the PTO, yet failed to disclose Gilead's patent applications to the PTO.

207. But for these misrepresentations and omissions to the PTO, claims 13–16 of the '159 patent would not have issued as detailed above.

208. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, regarding the unenforceability of the '159 patent.

209. The '159 patent is unenforceable due to Abbott/AbbVie's fraud on the PTO.

210. Gilead is entitled to a judgment declaring that the '159 patent is unenforceable due to Abbott/AbbVie's fraud on the PTO.

211. This is an exceptional case entitling Gilead to an award of its attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT 3

(Declaratory Judgment – Invalidity of Claims 13–16 of the '386 Patent)

212. Gilead incorporates by reference the allegations contained in paragraphs 1–193 of this Complaint.

213. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, regarding the invalidity of claims 13–16 of the '386 patent.

214. Claims 13–16 of the '386 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in 35 U.S.C. § 1, *et seq.*, including §§ 102(e), 102(f), 102(g)(2), 103, and 112.

215. Gilead is entitled to a judgment declaring that claims 13–16 of the '386 patent are invalid under 35 U.S.C. §§ 102(e), 102(f), 102(g)(2), 103, and 112.

216. This is an exceptional case entitling Gilead to an award of its attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

COUNT 4

(Declaratory Judgment – Unenforceability of the '386 Patent)

217. Gilead incorporates by reference the allegations contained in paragraphs 1–193 of this Complaint.

218. The ’386 patent is unenforceable due to inequitable conduct before the PTO. This conduct includes the submission of knowingly false declarations of original inventorship to claims 13–16 by REDACTED (collectively, the “Named AbbVie Inventors”) and the intentional failure of at least REDACTED to disclose material prior art—i.e., the Gilead PCT Publication and the Provisional Application to which the Gilead PCT Publication claims priority—to the PTO during prosecution of the ’386 patent with specific intent to deceive.

219. On or around August 15–29, 2012, each of the Named AbbVie Inventors signed declarations that declared that they believed each of them to be an original and first and joint inventor of the subject matter claimed in the ’386 patent, which includes the specific combination of GS-5885 and GS-7977, without interferon for 12 weeks, for the treatment of HCV genotype 1.

220. On information and belief, the Named AbbVie Inventors intentionally misrepresented to the PTO the identities of the true original inventors of claims 13–16 in the ’386 patent. This misrepresentation was material to patentability under 35 U.S.C. §§ 102(f), 111, and 115.

221. The inventors’ specific intent to deceive the PTO can be inferred from the facts described above and the fact that claims to the Gilead Combination do not appear in the application until after Gilead acquired Pharmasset and announced its intentions for 7977 and until after Gilead announced clinical trials were planned for the Gilead Combination. This intent to deceive can further be inferred from the fact that no AbbVie inventor had any knowledge of and/or access to any clinical data relating to the use of GS-7977 in combination with GS-5885 to treat patients suffering from HCV, as late as the filing date of Abbott/AbbVie’s

patent application number 61/656,251. The submission of such knowingly false declarations constitutes affirmative egregious misconduct before the PTO.

222. On information and belief, at least REDACTED intentionally failed to disclose the Gilead PCT Publication, and the Provisional Application to which the Gilead PCT Publication claims priority, to the PTO as prior art under 37 C.F.R. § 1.56. This misrepresentation and/or omission was material to patentability under 35 U.S.C. §§ 102(e) and 103.

223. An intent to deceive the PTO can be inferred from the fact that, on or around May 1, 2013 and May 2, 2013, prior to the issuance of the ’386 patent, AbbVie, received multiple instances of correspondence from Gilead encouraging AbbVie to disclose the Gilead PCT Publication to the PTO and bring it to the examiner’s attention, but chose not to do so.

224. An intent to deceive the PTO can further be inferred from the fact that during the prosecution of the ’386 patent, AbbVie relied on Gilead’s clinical data to support its claim to the use of GS-5885 and GS-7977 to treat HCV in a March 6, 2013 Supplemental Response to the PTO, yet failed to disclose Gilead’s patent applications to the PTO.

225. But for Abbott and/or AbbVie’s misrepresentations and omissions to the PTO, claims 13–16 of the ’386 patent would not have issued.

226. As a result of the acts described in the foregoing paragraphs, there exists an actual and justiciable controversy of sufficient immediacy and reality, within the meaning of the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, regarding the unenforceability of the ’386 patent.

227. The ’386 patent is unenforceable due to Abbott/AbbVie’s fraud on the PTO.

228. Gilead is entitled to a judgment declaring that the '386 patent is unenforceable due to Abbott/AbbVie's fraud on the PTO.

229. This is an exceptional case entitling Gilead to an award of its attorneys' fees incurred in connection with this action pursuant to 35 U.S.C. § 285.

LEGAL CLAIMS (STATE LAW)

230. Gilead incorporates by reference the factual allegations contained in paragraphs 1–193 of this Complaint as if reproduced herein in full.

231. As described more fully in paragraphs 90-182 above, Abbott and AbbVie made knowing and intentional misrepresentations to the PTO, and intentionally failed to disclose material information to the PTO, all in support of their scheme to misappropriate and exploit the immense and years-long clinical research investment of Gilead and Pharmasset by fraudulently claiming the Gilead Combination and other combinations of GS/PSI-7977 with NS5A inhibitors as Abbott and AbbVie's own inventions. Pursuant to this deliberately planned and carefully executed scheme to defraud the PTO and damage Gilead, Abbott and AbbVie knowingly and affirmatively did the following:

a. Abbott supported its false claims of inventorship with unmistakably false affidavits of inventorship executed at Abbott's direction by the following persons acting within the course and scope of their employment by Abbott and conspiring with Abbott and later AbbVie to engage in the unlawful, unfair or fraudulent business acts described herein

REDACTED

. Also conspiring with AbbVie in the

commission of these unfair, unlawful or fraudulent acts or practices was AbbVie's employee and legal representative, REDACTED, who, acting in concert with Abbott/AbbVie, knowingly, willfully and deliberately caused these false affidavits to be filed with the PTO. Each of these individuals who, claiming to be an inventor of the inventions claimed in the AbbVie Patents, signed under oath an affidavit on a form prescribed by the PTO, or who caused such affidavits to be signed or filed (particularly, as noted hereinabove, the "inventors" REDACTED), were on notice that the making and filing of a false declaration to the PTO constitutes a violation of 18 U.S.C. § 1001(a), which provides, in pertinent part:

> * * * [W]hoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—
>
> (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;
>
> (2) makes any materially false, fictitious, or fraudulent statement or representation; or
>
> (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry;
>
> shall be fined under this title, imprisoned not more than 5 years * * *

b. Before each of the AbbVie Patents issued, Abbott and AbbVie knew that Gilead was the true inventor of the inventions related to GS-7977 and the combination of GS-7977 and GS-5885, and that Abbott and AbbVie and their assignors were not the true inventors, but Abbott and AbbVie nonetheless

knowingly and intentionally both misrepresented and withheld this information from the patent examiner. More specifically, Abbott and AbbVie knew that in its February 2, 2012, public earnings call, the written transcript of which was published on or about that same date, Gilead made a clear disclosure of the use of a combination of GS-7977 and GS-5885 in a twelve week treatment regimen that would assess efficacy in the absence of ribavirin and interferon in genotype 1 patients. This disclosure came just over two weeks before Abbott first filed its February 17, 2012, provisional application claiming for the first time the combination of these two Gilead Compounds, and over four months before Abbott first filed any provisional application disclosing the chemical structure of GS-5885 and applying the Abbott/AbbVie "model" to the GS-5885/GS-7977 combination.

c. Abbott and AbbVie also deceived the PTO and improperly exploited the fruits of Gilead's research investment in the course of prosecuting the AbbVie Patents. In the June 6, 2012 provisional patent application, and nine months later in a response to the patent examiner on March 6, 2013, Abbott and AbbVie relied on Gilead's clinical data to support their claims to the use of the Gilead Combination. That clinical data had been developed only through the expenditure of substantial sums of Gilead's money and the investment of extensive and costly clinical research by Gilead and its predecessor-in-interest Pharmasset into the combination of PSI/GS-7977 and GS-5885. Thus, Abbott and AbbVie misappropriated Gilead's idea for the Gilead Combination, having expended not one speck of their own financial or clinical research

resources in furtherance of clinical testing of the Gilead Combination, and exploited Gilead's enormous clinical research investment to help secure their ill-gotten patents.

d. In addition, with a specific intent to defraud the PTO, Abbott/AbbVie intentionally made a deliberate decision not to disclose to the PTO one or more material prior art references, including Gilead's PCT Publication WO 2013/040492, which AbbVie deliberately decided not to disclose to the PTO despite having received written notice from Gilead of said publication on two occasions prior to issuance of the AbbVie Patents. It was not until September 18, 2013, when, in connection with its then-pending application USSN 13/656,012, AbbVie finally filed an Initial Disclosure Statement with its Response to the Non-Final Rejection and Amended Claims citing Gilead's PCT Application (WO 2013/040492). This belated disclosure was, of course, too little and too late to reverse the effects of AbbVie's and Abbott's longstanding fraudulent conduct respecting their assertion of claims of inventorship regarding the Gilead Claims, and their claim to have invented the combination of GS-7977/Sofosbuvir and all NS5A inhibitors, which was also a clearly false and fraudulent assertion.

e. The foregoing fraudulent acts or omissions were each, and in combination with the others, material, in that the PTO would not have issued the AbbVie Patents but for the foregoing fraudulent acts or omissions.

232. As described more fully in Paragraphs 44–89, 194–198, and 212–216 above, Abbott and AbbVie's patent claims to GS/PSI-7977, GS-5885, and their various combinations are invalid, because these inventions were made by Gilead and Pharmasset, not Abbott/AbbVie:

a. Abbott and AbbVie derived the invention of the Gilead Claims from Gilead – it was Gilead, not AbbVie, that conceived the use of the Gilead Combination and Sofosbuvir itself to treat Genotype 1 HCV treatment naïve patients with a treatment duration of twelve weeks. Under 35 U.S.C. § 102(f), AbbVie's Gilead Claims are invalid.

b. The invention of the Gilead Claims and PSI/GS-7977 itself was made by Gilead and/or its predecessor-in-interest Pharmasset in the United States before the date Abbott/AbbVie purported to have invented it – *i.e.*, Gilead conceived of said invention and reduced it to practice before Abbott/AbbVie's purported date of invention, and Gilead did not, thereafter, abandon, suppress or conceal said invention. Quite the contrary: Gilead filed its '885 provisional application claiming the invention over a month before Abbott first filed any patent application even mentioning GS-5885 and PSI/GS-7977 and over five months before Abbott filed its first provisional application claiming the specific Gilead Combination on February 17, 2012. Gilead not only conceived of the invention of Abbott's Gilead Claims and GS-7977 itself, but reduced it to practice before Abbott's purported date of invention. Under these circumstances, Abbott's Gilead Claims are invalid pursuant to 35 U.S.C. § 102(g)(2).

c. The AbbVie Patents fail adequately to disclose sufficient information to teach persons skilled in the art how to make and use said invention without undue experimentation. Abbott did not even disclose the chemical structure of GS-5885 in any of this family of patent applications until it filed its provisional application Nos. 61/656,251 and 61/656,253 on June 6, 2012. Even then, Abbott based its invention of the Gilead Claims on a "mechanistic model" using past clinical trial data that would not enable a person skilled in the art to predict that the Gilead compound would be successful in curing Genotype 1 HCV patients with twelve weeks of treatment. Under 35 U.S.C. § 112(a), these failures render the patent invalid as to the Gilead Claims.

233. Abbott and AbbVie's fraudulent conduct before the PTO, and their efforts to obtain and assert spurious and invalid patent claims in order to block Gilead from bringing its life-saving anti-HCV combination therapy to market, have injured Gilead in violation of state law as described in Counts 5–8 below. Because these state law claims necessarily depend on the determination of the validity and enforceability of AbbVie's patents, they give rise to substantial, disputed questions of federal patent law and accordingly come within the subject matter jurisdiction of this Court pursuant to 28 U.S.C. § 1338(a).

COUNT 5

(Violation of 6 Del. Code § 2532. Deceptive Trade Practices)

234. Gilead incorporates by reference the factual allegations contained in paragraphs 1–233 of this Complaint as if reproduced herein in full.

235. 6 Del. Code § 2532 provides, in pertinent part:

(a) A person engages in a deceptive trade practice when, in the course of a business, vocation, or occupation, that person:

(2) Causes likelihood of confusion or of misunderstanding as to the source, sponsorship, approval, or certification of goods or services;

(3) Causes likelihood of confusion or of misunderstanding as to affiliation, connection, or association with, or certification by, another

(5) Represents that goods or services have sponsorship, approval, characteristics, ingredients, uses, benefits, or quantities that they do not have, or that a person has a sponsorship, approval, status, affiliation, or connection that the person does not have;

(8) Disparages the goods, services, or business of another by false or misleading representation of fact; [or]

(12) Engages in any other conduct which similarly creates a likelihood of confusion or of misunderstanding.

236. Abbott's and AbbVie's misrepresentations to the PTO and intentional failure to disclose material information to the PTO constitute deceptive trade practices under one or more of the foregoing provisions of 6 Del. Code §2532. Before each of the AbbVie Patents issued, Abbott and AbbVie knew that Gilead was the true inventor of the inventions related to GS-7977, the combination of GS-7977 and GS-5885 and that Abbott and AbbVie and their assignors were not the true inventors, but Abbott and AbbVie nonetheless knowingly and intentionally both misrepresented and withheld this information from the patent examiner. In doing so, Abbott and AbbVie and their assignors violated one or more of the above-quoted provisions of 6 Del. Code § 2532. Claiming to have invented the Gilead Combination in light of Abbott's and AbbVie's knowledge of the falsity of such claims likewise constituted a violation of one or more of the foregoing provisions of 6 Del. Code § 2532. Abbott's and AbbVie's prosecution of the AbbVie Patents was also deceptive and misleading in violation of one or more of the foregoing

provisions of 6 Del. Code § 2532 because, among other reasons, in the June 6, 2012 provision application and nine months later in a response to the patent examiner on March 6, 2013, Abbott and AbbVie relied on Gilead's clinical data to support their own claim to have invented the Gilead Combination. Thus, Abbott and AbbVie not only misappropriated Gilead's idea for the Gilead Combination, but also, having expended not one speck of their own financial or clinical research resources in furtherance of clinical testing of the Gilead Combination, exploited Gilead's enormous clinical research investment to help secure their ill-gotten patents. Doing so constituted a violation of one or more of the foregoing provisions of 6 Del. Code § 2532.

237. Abbott and AbbVie's fraudulent, inequitable, and unfair conduct before the PTO disparages Gilead's rightful claim to its HCV combination therapies, and creates a likelihood of confusion or misunderstanding as to Gilead's ability to bring these therapies to market. As a result, Gilead is likely to be damaged by Defendants' conduct.

238. AbbVie should be enjoined from asserting the AbbVie Patents.

239. In addition, Gilead is entitled to an award of triple the amount of actual damages proven at trial under any other state law cause of action based on the same facts alleged herein.

COUNT 6

(Slander of Title/Injurious Falsehood)

240. The factual allegations set forth in paragraphs 1–239 above are incorporated herein by reference as if reproduced in full.

241. Gilead is the owner of valuable property interests in (i) its issued patents on the compounds GS-5885/Sofosbuvir and PSI/GS-7977/Ledipasvir; (ii) its rights to the FDA-approved compound GS-7977 (Sofosbuvir); (iii) its rights to its impending New Drug Application seeking FDA approval of the Gilead Combination of Sofosbuvir and Ledipasvir for

treatment of, among others, treatment-naïve Genotype 1 HCV patients for durations of twelve weeks or less; and (iv) its pending patent application asserting the Gilead Claims.

242. More specifically, Gilead is the owner of and has a valuable property interest in issued patents covering each of the Gilead Compounds, as set forth in Paragraph 23 hereinabove, including, among others U.S. Patent No. 7,964,580 B2 ("the Gilead '580 patent") and U.S. Patent No. 8,088,368 B2 ("the Gilead '368 patent"). The Gilead '580 patent, which was originally issued to Pharmasset on June 21, 2011, covers the GS-7977/Sofosbuvir compound, and the Gilead '368 patent, which covers GS-5885/Ledipasvir, was issued to Gilead on January 3, 2012. The present value of Gilead's property interests in these issued patents on these particular compounds is based in significant part on the potential use of GS-5885/Ledipasvir in combination with GS-7977/Sofosbuvir for the treatment of, among other conditions, Genotype 1 HCV patients for a treatment duration of 12 weeks or less.

243. Sofosbuvir was approved by the FDA for use in combination with certain other drugs for treatment of patients with chronic HCV on December 6, 2013. Gilead is the owner of all rights to any and all current and future revenues flowing from the use by clinicians of Sofosbuvir, either alone or in combination with other drugs. Upon approval by the FDA of GS-5885/Ledipasvir, Gilead's rights will then include the right to any revenues generated by the use by clinicians of Sofosbuvir in combination with GS-5885/Ledipasvir. Part of the present value of Gilead's rights in the FDA-approved drug, Sofosbuvir is, necessarily, its value derived from its potential for use with GS-5885/Ledipasvir in the future. The safety and efficacy of the specific combination of Sofosbuvir and Ledipasvir for use in treating Genotype 1 treatment-naïve HCV patients has already been established in Phase 1–3 clinical trials and is the subject of Gilead's New Drug Application which will be filed in the very near future with the FDA.

244. Gilead's United States patent application relating to the Gilead Claims was published as PCT Publication WO 2013/040492 (the "Gilead PCT Publication"), entitled "Methods of Treating HCV", a true copy of which is filed herewith as Exhibit F and is incorporated herein by reference as if reproduced in full. Gilead's PCT Application was filed on September 14, 2012, was published on March 13, 2013, and claims priority to Gilead's provision application No. 61/535,885 ("Gilead's/the Gilead '885 Provisional Application") filed on September 16, 2011, over a month before Abbott's provisional application No. 61/550,360, was filed on October 21, 2011. The Gilead '885 Provisional Application and the Gilead PCT Publication claim methods of treatment of HCV using Compounds 6 and 10, which are identified by their respective chemical structures.

245. Gilead's property interests in these patent applications and patents are immensely valuable. In early 2012—about a month before Abbott filed its provisional application No. 61/600,267 on February 17, 2012, claiming for the first time the specific combination of GS-7977 and GS-5885—Gilead closed on its acquisition of Pharmasset, for which it paid over $11 billion, primarily to acquire the rights to PSI/GS-7977 (Sofosbuvir). As detailed in paragraphs 93–182 above, Abbott and AbbVie falsely claimed to have invented treatment methods for the treatment of HCV using the specific Gilead Combination and even using GS-7977 itself, when, in fact, Abbott and AbbVie had not done so, as part of a deliberately planned and careful scheme to defraud the PTO.

246. Under Delaware law, "slander of title" occurs when a person, without a privilege to do so, knowingly publishes a false statement that disparages or casts doubt upon another's title to a property interest, including intangible or personal property such as Gilead's property interests in the above-described Gilead patents and applications and the above-described FDA-

approved drug Sofosbuvir. By falsely claiming to have invented treatment methods for the treatment of HCV using the specific Gilead Combination when, in fact, Abbott and AbbVie had not done so for the reasons set forth hereinabove, Abbott and AbbVie committed knowing and willful acts and omissions that, separately and taken together, constitute a slander of title and were knowingly and willfully and maliciously committed by Abbott/AbbVie and its co-conspirators without any good faith privilege or justification to do so. Gilead has suffered and will continue to suffer damage as a result of Abbott and AbbVie's said knowing and willful acts and omissions.

247. Gilead asks that the Court remedy the aforementioned slander of title by Abbott and AbbVie by:

a. Declaring that Abbott's and AbbVie's claim to have invented treatment methods for the treatment of HCV using the specific Gilead Combination and/or Sofosbuvir itself, was false for the reasons set forth above, that Abbott's and AbbVie's acts or omissions set forth above were committed willfully and knowingly, and that, in fact, Abbott and AbbVie had not invented the Gilead Combination or Sofosbuvir;

b. Declaring that in willfully and knowingly making its false claim to have invented the Gilead Combination and/or Sofosbuvir itself, Abbott and AbbVie disparaged, slandered and cast a cloud over Gilead's property interests in the applications and patents described hereinabove, and did so without any justification or privilege, causing Gilead to sustain pecuniary loss and damage;

c. Awarding Gilead its damages; and

d. Enjoining AbbVie from asserting or enforcing any patent rights under the AbbVie Patents against Gilead or its affiliates, distributors, customers, or end users with respect to the Gilead Claims.

COUNT 7

(Tortious Interference with Prospective Business Relations)

(Delaware law)

248. The factual allegations set forth in paragraphs 1–247 above are incorporated herein by reference.

249. Gilead had a reasonable, valid expectation that, upon completion of clinical trials and FDA approval of its combination therapy of PSI/GS-7977 (Sofosbuvir) and GS-5885 (Ledipasvir), as well as any other combinations it might pursue involving PSI/GS-7977, it would enter into economically advantageous business relationships with various marketers, distributors, insurers, and health-care providers in order to manufacture, market, distribute, and provide the combination therapies to HCV patients.

250. Abbott and AbbVie were well aware of Gilead's valid business expectancies with respect to the Gilead Combination and other potential combination therapies, and have intentionally and wrongfully interfered with those business expectancies by filing fraudulent patent applications, supported by false declarations of inventorship, that wrongfully attempt to lay claim to Gilead's combinations of Gilead's own compounds. Abbott and AbbVie's intent in doing so was to prevent Gilead's therapies from competing with their own anti-HCV compounds, to the detriment not only of Gilead but of millions of HCV patients who could be denied access to these life-saving treatments.

251. Abbott and AbbVie's intentional acts of interference were independently wrongful and unlawful, insofar as they involved (1) false statements to the U.S. Patent Office in

violation of 18 U.S.C. § 1001(a), (2) slander of Gilead's property interest in its issued patents and pending patent applications, and (3) deceptive, unlawful, and unfair business practices in violation of the Delaware Deceptive Trade Practices Act, 6 Del. Code § 2532.

252. Abbott and AbbVie's conduct has in fact interfered with Gilead's reasonable expectations of prospective business relations, insofar as their spurious patent claims over the Gilead Combination and other anti-HCV combinations have hindered and will hinder Gilead's ability to form business relationships with third parties. Manufacturers, marketers, and distributors may be deterred from doing business with Gilead by the potential risk of liability for infringing AbbVie's patents. More importantly, if AbbVie enforces its patents so as to prevent Gilead from manufacturing, marketing, and distributing its combination therapies, then Gilead's prospective business relationships with health care providers and prescribers will be disrupted because Gilead will be unable to supply them with the treatments for the patients who need them and they will be unable to prescribe such combination therapies.

253. As a result of Abbott and AbbVie's intentional and unlawful acts of interference, Gilead has been, and, in reasonable probability, will continue to be, damaged in an amount to be proven at trial.

COUNT 8

REDACTED

254. The factual allegations set forth in paragraphs 1–253 above are incorporated herein by reference.

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PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Gilead respectfully request that this Honorable Court:

(1) Issue a declaratory judgment on Count 1 that claims 13–16 of the ’159 patent are invalid.

(2) Issue a declaratory judgment on Count 2 that the ’159 patent is unenforceable due to the inequitable misconduct of Defendants, who obtained the patent through fraud on the PTO.

(3) Issue a declaratory judgment on Count 3 that claims 13–16 of the ’386 patent are invalid.

(4) Issue a declaratory judgment on Count 4 that the ’386 patent is unenforceable due to the inequitable misconduct of Defendants, who obtained the patent through fraud on the PTO.

(5) Award Gilead its attorney’s fees incurred in connection with Counts 1 through 4.

(6) Enter judgment in favor of Gilead and against Defendants on Count 5 for violating 6 Del. Code § 2532, issue a permanent injunction barring Defendants from ever enforcing the AbbVie Patents, and award triple the amount of actual damages proven at trial under any other state law cause of action, as well as attorney’s fees.

(7) Enter judgment in favor of Gilead and against Defendants on Count 6 for Slander of Title, and award Gilead damages in an amount to be proven at trial.

(8) Enter judgment in favor of Gilead and against Defendants on Count 7 for Tortious Interference with Prospective Business Relations, and award Gilead damages in an amount to be proven at trial.

(9) REDACTED

(10) Enter such other relief as the Court may deem just and proper.

DEMAND FOR JURY TRIAL BY JURY

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

Dated: December 18, 2013

FISH & RICHARDSON P.C.

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