IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC. and GILEAD SCIENCES IRELAND UNLIMITED COMPANY, Plaintiffs, v. ABBVIE, INC., Defendant.	C.A. No. _____ JURY TRIAL DEMANDED

COMPLAINT FOR DECLARATORY JUDGMENT

Douglas E. McCann (#3852)
Gregory R. Booker (#4784)
Susan Morrison Coletti (#4690)
222 Delaware Avenue, 17th Floor
P.O. Box 1114
Wilmington, DE 19899
Telephone: (302) 652-5070
Facsimile: (302) 652-0607
dmccann@fr.com; booker@fr.com;
coletti@fr.com

Attorneys for Plaintiffs Gilead Sciences, Inc. and Gilead Sciences Ireland Unlimited Company

Gilead Sciences, Inc. and Gilead Sciences Ireland Unlimited Company (collectively, "Gilead") file this complaint for declaratory judgment against AbbVie, Inc. ("AbbVie") and allege as follows:

NATURE OF THE ACTION

1. This is an action for a declaratory judgment of invalidity of United States Patent No. 9,034,832 ("the '832 patent") under 35 U.S.C. § 1 et seq. and 28 U.S.C. §§ 2201 and 2202. Defendant AbbVie continues to obtain patents that do not protect its inventions, but rather attempt to cover the products of its more successful competitors. *See e.g., Gilead Sciences, Inc., et al v. AbbVie, Inc.*, C.A. No. 13-2034 (D. Del.). In this instance, AbbVie obtained a patent on formulations for tablets containing Gilead's Ledipasvir molecule, which is part of Gilead's revolutionary Hepatitis C treatment, HARVONI®. AbbVie did this despite the "inventors" of its patent not knowing the molecular structure of Ledipasvir at the time they filed for their "inventions." This latest abuse of the patent system by AbbVie should be rejected by this Court, and the '832 patent should be declared invalid.

THE PARTIES

2. Gilead Sciences, Inc. 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), hepatitis C virus (HCV), liver diseases, serious cardiovascular and respiratory conditions, cancer, and inflammation.

3. Gilead Sciences Ireland Unlimited Company is an unlimited liability company organized under the laws of Ireland with its principal place of business at IDA Business & Technology Park, Carringtonhill, Co. Cork, Ireland.

4. On information and belief, AbbVie, Inc. 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.

5. On information and belief, AbbVie is the assignee of the '832 patent.

JURISDICTION AND VENUE

6. This action arises under the Patent Laws of the United States of America, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

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

8. This Court has personal jurisdiction over AbbVie because AbbVie is organized under the laws of Delaware, has subjected itself to this Court's jurisdiction in related litigations involving the same products and parties at issue here (*e.g.*, Civil Action Nos. 13-2034-GMS, 14-209-GMS, and 14-379-GMS), and, on information and belief, regularly transacts business in Delaware.

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

10. On information and belief, AbbVie is subject to personal jurisdiction in this judicial district, and thus resides in this judicial district under 28 U.S.C. § 1391(b)(1) and (c)(2).

GILEAD'S INVENTION OF BREAKTHROUGH THERAPIES AND ABBVIE'S UNLAWFUL RESPONSE

11. In the past few years, many leading pharmaceutical companies, including Gilead and AbbVie, have sought to develop new drugs for 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 and another drug called ribavirin for up to 12 months. Treatments employing interferon and ribavirin 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.

12. Based on recent scientific advancements, millions of HCV sufferers worldwide can be cured with a combination of drugs called Direct Acting Antivirals ("DAAs"), administered in pill form without interferon. These therapies have high cure rates—90% and higher—much shorter treatment durations—as little as 8 weeks—and dramatically reduced side effects.

13. Given these benefits, there has been intense competition in the pharmaceutical industry to bring DAA combination therapies to market, including between Gilead and AbbVie. Gilead, however, is widely recognized as being the first company to bring an all-oral, interferon free combination therapy to market.

14. Gilead's combination therapy (HARVONI®) contains two DAAs: Sofosbuvir (also known as PSI-7977 or GS-7977 and marketed separately as SOVALDI®) and Ledipasvir (also known as GS-5885). Gilead acquired Sofosbuvir in 2011 when it acquired Pharmasset, Inc. Gilead Pharmasset LLC owns U.S. Patent No. 7,964,580, which covers PSI-7977.

15. Gilead developed Ledipasvir separately from Pharmasset. Gilead Pharmasset LLC owns U.S. Patent No. 8,088,368, which covers a compound with the chemical structure of GS-5885 and pharmaceutical compositions comprising that compound and conventional excipients such as copovidone and a pharmaceutically acceptable surfactant.

16. Gilead's HARVONI® and SOVALDI® products have revolutionized the treatment of HCV by offering the ability to cure HCV within as little as 8 weeks with all-oral, interferon-free therapy, and in the case of HARVONI®, interferon and ribavirin-free therapy. No longer are patients required to endure nearly a year of therapy with inferior drugs that may not work at all. The FDA approved SOVALDI® on December 6, 2013, and, just 10 months later, approved HARVONI® on October 10, 2014.

17. Upon their launch, both SOVALDI® and HARVONI® achieved immediate medical and commercial success.

18. AbbVie's competitive product to HARVONI® is known as VIEKIRA PAK®, which the FDA approved on December 19, 2014, well after both SOVALDI® and HARVONI®. VIEKIRA PAK® is less patient-friendly than HARVONI®. VIEKIRA PAK® is a combination of four drugs, which, in most cases, must be taken with a fifth drug, ribavirin. In addition to the potential patient inconvenience of taking more pills several times a day, more drugs mean more potential drug-drug interactions and side effects for patients.

19. On information and belief, recognizing its competitive disadvantage in the market for HCV therapies, AbbVie embarked on an unlawful scheme designed to attempt to block HARVONI® from reaching patients by obtaining patents directed solely at HARVONI®. These patents do not protect *any* aspect of AbbVie's products. They are simply an attempt by AbbVie to appropriate Gilead's rightful ownership of its groundbreaking therapies. This way, AbbVie could try to dominate the HCV all-oral treatment market, even if its combination product was inferior to those of its competitors.

20. On information and belief, AbbVie executives and "inventors" conspired and carried out steps of the company's unlawful scheme by filing serial patent applications around

the world asserting that AbbVie and its predecessors had invented solid oral dosage forms of Gilead's drugs, namely the Ledipasvir component of HARVONI®, and methods of using it to treat HCV. But AbbVie invented no such things. They are the property of Gilead.

ABBVIE RUSHES TO PROSECUTE A PATENT AIMED SOLELY AT GILEAD'S LEDIPASVIR COMPOUND

21. On May 19, 2015, the '832 patent issued, containing 5 claims. It claims as AbbVie's "invention" a solid oral dosage form comprising a solid solution which includes a compound with the chemical structure of GS-5885—one of the two DAAs in HARVONI®--copovidone, and optionally a pharmaceutically acceptable surfactant. *Compare* '832 patent at Claim 1, *with* U.S. Patent No. 8,088,368 (disclosing the chemical structure of GS-5885). It also claims, similar to the patents involved in the currently pending global litigations between Gilead and AbbVie, a method of using the solid oral dosage form of GS-5885 to treat HCV. A true and correct copy of the '832 patent is attached to this Complaint as Exhibit "A."

22. The '832 patent issued from United States Patent Application No. 14/507,267 ("the '267 application"), entitled "Solid Compositions," which AbbVie filed on October 6, 2014. The '267 application is a continuation-in-part of United States Patent Application No. 13/717,993, which was filed on December 18, 2012 and claims priority to United States Provisional Patent Application Nos. 61/581,146 ("the '146 application") and 61/645,696 ("the '696 application"), which were filed on December 29, 2011 and May 11, 2012, respectively.

23. The first-filed provisional application, the '146 application, however, did not contain any claims aimed at GS-5885—the composition claimed in the '832 patent—and it did not disclose the chemical structure of GS-5885. Indeed, AbbVie invented no such thing. Instead, AbbVie first added "GS-5885" to the claims and the chemical structure of GS-5885 to the specification when it filed the '696 application on May 11, 2012; less than one month after

Gilead announced that chemical structure was associated with the name "GS-5885" at the April 2012 ICAR conference in Sapporo, Japan.

24. On April 7, 2014, FDA announced it had granted priority review and a Breakthrough Therapy designation to Gilead's HARVONI® product. Less than three months later, on July 2, 2014, AbbVie amended its claims to cover only GS-5885. Upon information and belief, AbbVie drafted the claims in the '267 application for the sole purpose of targeting Gilead's HARVONI® product.

25. Further, AbbVie filed the '267 application as a "Track 1" patent application, meaning that it would be given expedited and "prioritized examination" at the United States Patent and Trademark Office. As a result, AbbVie obtained a Notice of Allowance for the '267 application roughly six months after filing.

26. On March 20, 2015, three days before the '267 application was scheduled to issue, AbbVie filed a petition to withdraw the application from issuance and submitted four new dependent claims for examination. The new dependent claims further recite a solid oral dosage form that "is a tablet," a solid oral dosage form "wherein said tablet is film coated," a solid dosage form that "further comprises another anti-HCV agent," and "[a] method of treating HCV [by] administering the solid oral dosage form." All of these claims are directed solely at GS-5885 as used in HARVONI®. On May 19, 2015, the '832 patent issued with five allowed claims.

THERE IS AN IMMEDIATE AND REAL CONTROVERSY BETWEEN GILEAD AND ABBVIE REGARDING THE '832 PATENT

27. Because the '832 patent covers a formulation and a method of treating HCV that can be marketed only by Gilead, and because AbbVie would be prohibited from marketing such a formulation and method of treatment in view of Gilead's own patents, AbbVie's only purpose

in obtaining the ’832 patent is either to: a) attempt to block Gilead’s products from the market; or b) extract royalties from Gilead through the litigation process or the threat of the litigation process.

28. Given that AbbVie directed the ’832 patent squarely at Gilead’s HARVONI® product, and AbbVie’s other actions directed against that product, there is an actual controversy between Gilead and AbbVie with respect to whether Gilead’s making, using, selling, and offering to sell HARVONI® infringes any valid and enforceable claim of the ’832 patent.

29. Indeed, as stated above, the ’832 patent is just the latest in AbbVie’s ongoing attempts to patent technology that it does not own, and then use those patents in an unlawful attempt to drive Gilead’s HARVONI® product from the market or extract royalties from Gilead through the litigation process. In December 2013, Gilead initiated Civil Action No. 13-2034-GMS against AbbVie to defend its rights, enforce a confidentiality agreement that AbbVie breached, and invalidate AbbVie’s fraudulently obtained patents (*i.e.*, U.S. Patent Nos. 8,446,159, 8,492,386, 8,680,106, 8,685,984, and 8,809,265), which, like the ’832 patent, were drafted by AbbVie to block Gilead’s HARVONI® product from reaching patients.

30. In response, AbbVie then filed a series of infringement lawsuits against Gilead in this Court asserting multiple patents. First, on February 18, 2014, AbbVie filed a complaint claiming that Gilead infringed the ’159 and ’386 patents, and requesting, *inter alia*, a declaration “that, if Gilead markets [HARVONI®] for use in a 12-week, interferon-free treatment for HCV genotype 1 patients, Gilead will induce infringement of one or more claims of the ’159 and/or ’386 patents” and requesting “entry of an injunction, prohibiting Gilead and any of its officers, agents, employees, assigns, representatives, privies, successors, and those acting in concert or

participation with them from infringing and/or inducing infringement of the ’159 and/or ’386 patents.” That lawsuit is pending under Civil Action No. 14-209-GMS.

31. On March 25, 2014, AbbVie filed a second lawsuit against Gilead in this Court the same day AbbVie’s ’106 patent issued, seeking a declaratory judgment that Gilead infringes the ’106 patent and requesting similar relief. That lawsuit is pending under Civil Action No. 14-379-GMS. As soon as AbbVie’s ’984 patent issued, AbbVie amended its complaint in Civil Action No. 14-379-GMS to add allegations of infringement of the ’984 patent. Both of the Civil Actions that AbbVie filed, C.A. No. 14-209-GMS and 14-379-GMS, have been consolidated with C.A. No 13-2034 filed by Gilead in December 2013.

32. The ongoing cases between Gilead and AbbVie in Delaware represent only a subset of the global patent dispute between the parties relating to Gilead’s HARVONI® product. Gilead and AbbVie are currently litigating in Austria, Germany, Sweden, and Switzerland patent issues related to AbbVie’s blocking patenting strategy. And AbbVie has related patents granted and/or patent applications pending in at least Australia, Canada, Denmark, Japan, Portugal, Spain, Turkey, and the European Patent Office.

33. In view of AbbVie’s actions in prosecuting the ’832 patent, the similarities in claimed subject matter between the ’832 patent and previous patents currently asserted by AbbVie against Gilead, and the existence of global, ongoing patent litigations between the parties related to Gilead’s HARVONI® product (including in this District), there is an actual controversy between Gilead and AbbVie with respect to whether Gilead’s making, using, selling and offering to sell HARVONI® infringes any valid and enforceable claim of the ’832 patent.

COUNT 1

(Declaratory Judgment – Invalidity of the '832 Patent)

34. Gilead incorporates by reference the allegations contained in paragraphs 1–33 of this Complaint.

35. Claims 1-5 of the '832 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 §§ 101, 102, 103, and 112. For example, Claims 1-5 of the '832 patent are invalid under 35 U.S.C. §§ 102 and/or 103, at least in view of PCT Publication No. WO 2010132601, PCT Publication No. WO 2010097229, PCT Publication No. WO 2010017432, and C. Leunner and J. Dressman, "*Improving drug solubility for oral delivery using solid dispersion*," Eur. J. of Pharm. Biopharm., vol. 50(1), pp. 47-60 (2000) alone or in combination with other prior art. Additionally, Claims 1-5 of the '832 patent are invalid under 35 U.S.C. § 112 because they lack, for example, an adequate written description and are not enabled.

36. 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.*, to warrant the issuance of a declaratory judgment that Claims 1-5 of the '832 patent are invalid.

37. A judicial declaration is necessary and appropriate so that Gilead may ascertain its rights regarding the '832 patent.

38. 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.

PRAYER FOR RELIEF

WHEREFORE, Gilead respectfully request that this Honorable Court:

(1) Issue a declaratory judgment on Count 1 that Claims 1-5 of the '832 patent are invalid.

(2) Award Gilead its attorneys' fees incurred in connection with Count 1.

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

DEMAND FOR 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: May 19, 2015

FISH & RICHARDSON P.C.

By: */s/ Susan Morrison Coletti*

Douglas E. McCann (#3852)
Gregory R. Booker (#4784)
Susan Morrison Coletti (#4690)
222 Delaware Avenue, 17th Floor
P.O. Box 1114
Wilmington, DE 19899
Telephone: (302) 652-5070
Facsimile: (302) 652-0607
dmccann@fr.com; booker@fr.com;
coletti@fr.com

Jonathan E. Singer
singer@fr.com
John C. Adkisson
adkisson@fr.com
FISH & RICHARDSON P.C.
60 South Sixth Street, Suite 3200
Minneapolis, MN 55402
Telephone: (612) 335-5070
Facsimile: (612) 288-9696

Juanita R. Brooks
brooks@fr.com
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070
Facsimile: (858) 678-5099

Tommy Jacks
One Congress Plaza, Suite 810
111 Congress Avenue
Austin, TX 78701
Telephone: (512) 472-5070

Attorneys for Plaintiffs
Gilead Sciences, Inc. and Gilead Sciences Ireland Unlimited Company