

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

SOUTHEASTERN PENNSYLVANIA
TRANSPORTATION AUTHORITY,
individually and on behalf of all others
similarly situated,

Plaintiff,

v.

GILEAD SCIENCES, INC.,

Defendant.

Case No. _____

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

INTRODUCTION

1. This case involves a drug manufacturer's attempt to exploit the patent laws by selectively charging exorbitant prices for its life-saving Hepatitis-C drug, Sovaldi® (sofosbuvir tablets) ("Sovaldi"). As explained herein, Defendant Gilead Sciences, Inc.'s ("Gilead" or "Defendant") limited rights as a patent holder do not translate into a license to price gouge consumers, state and federal health and welfare programs, and other third party payers under the extraordinary circumstances presented here.

2. Sovaldi is, by all accounts, a remarkably effective drug. It is the first drug approved by the Food and Drug Administration ("FDA") for certain types of Hepatitis-C infections that does not need to be injected. It can cure about 90 percent of the patients who have the most common form of Hepatitis-C in three to six months, and can do so with relatively minor side effects compared to other treatments. It is also a very lucrative drug: it has already accounted for \$5.7 billion

in sales in the first half of 2014 alone, which is about half of all of Gilead's revenue. An image of a 400 mg Sovaldi tablet and bottle they are contained in is below.



3. In the United States, the cost of a standard 12-week regimen of Sovaldi treatment costs approximately \$84,000, or \$1,000 per pill. This is in sharp contrast to the prices at which Sovaldi is being made available by Gilead in other countries. For example, it is estimated that the cost of a Sovaldi treatment in Egypt is only \$900, or about 99% below the U.S. price. Additionally, Gilead has recently announced that it had reached new licensing agreements with seven generic drug companies to manufacture and sell generic sofosbuvir – the active ingredient in Sovaldi – in 91 developing countries at deeply discounted prices. Certain large federal agencies, such as the Bureau of Prisons, have also received significant discounts on Sovaldi. This obvious paradox is being investigated by the Senate Finance Committee, which has questioned whether the market for Sovaldi “is

working efficiently and rationally,” and whether “payors of health care....can carry such a load.”

4. Gilead’s price gouging has had at least two detrimental consequences in this country. It has, obviously, resulted in the consumers and entities that have purchased Sovaldi paying significant prices for the drug. It has also effectively priced some consumers and government programs alike out of the Sovaldi market, thereby preventing needed recipients from obtaining this critical drug. Notably, there have been reports that this pricing scheme has had a disproportionately high impact on minorities and those in lower income brackets (demographics that have had historically higher incidents of Hepatitis-C infections). The average annual income of Hepatitis-C patients is \$23,000, which suggests that many of these patients likely receive their health care coverage from government programs. But even state Medicaid programs have been limiting their approval of Sovaldi for only the sickest of patients – an approach which Gilead itself discourages.

5. As discussed below, however, Gilead’s monopoly on Sovaldi is questionable, as (a) its patents are currently being challenged in infringement actions, and (b) the sale of Sovaldi infringes on the patents of others.

6. Even if it is ultimately determined that Gilead actually has a legal monopoly, Gilead is not authorized by the patent laws (or otherwise) to abuse its purported monopoly on Sovaldi by charging discriminatory prices that apparently have no rational basis other than to inflate the company’s bottom line. The biotechnology company that initially conducted the research and development which

ultimately led to the creation of Sovaldi (and which was then acquired by Gilead) had estimated that a regimen of the drug would be sold for \$36,000 per treatment in the United States. Gilead is now charging nearly two-and-a-half times that amount. And unlike other specialty drugs that come with comparable hefty price tags – but only affect a small number of patients – there are *several million* Americans living with Hepatitis-C that could benefit from this drug. If Gilead's conduct is left unchecked, many of these patients will never get access to this drug and, in those cases where they do, third party payors like Plaintiff will continue to pay exorbitant prices for Sovaldi.

7. Plaintiff, on behalf of itself and those similarly situated, brings this action to stop this unconscionable and unfair conduct, and to secure appropriate recoveries for consumers and third party payors who, like Plaintiff, have been victimized by Gilead's price gouging scheme. Plaintiff seeks appropriate relief for unjust enrichment, for violations of the federal antitrust laws and section 1557(a) of the Patient Protection and Affordable Care Act, and for breach of the duty of good faith and fair dealing as an intended third-party beneficiary.

JURISDICTION AND VENUE

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. § 1332 because the aggregate amount in controversy exceeds \$5,000,000, exclusive of interest and cost, and because members of the class are citizens of states other than Defendant. The Court also has federal question subject matter

jurisdiction based on the Sherman Act and Affordable Care Act claims asserted herein.

9. Personal jurisdiction and venue are proper because Defendant regularly transacts business within this District.

PARTIES

10. Plaintiff, the Southeastern Pennsylvania Transportation Authority (“SEPTA” or “Plaintiff”) is a regional transportation authority that operates various forms of public transit, serving Bucks, Chester, Delaware, Montgomery, and Philadelphia counties in Pennsylvania. SEPTA is headquartered at 1234 Market Street, Philadelphia, Pennsylvania. SEPTA maintains an employee health and welfare benefit plan pursuant to which it reimburses and pays for certain of its employees’ prescription drug purchases. Plaintiff has paid in excess of \$2.4 million for Sovaldi before the end of 2014 for its members, and has been injured as a result of Defendant’s conduct described herein.

11. Defendant Gilead is a corporation organized under the laws of Delaware, having a principal place of business located at 222 Lakeside Drive in Foster City, California. It has issued securities that are publicly traded on the NASDAQ exchange under the symbol “GILD.” According to its most recent form 10K filed with the Securities and Exchange Commission (“SEC”), the company recognized over \$11.2 billion in revenue for the year ended December 31, 2013, and over \$3 billion in profits.

FACTUAL ALLEGATIONS

A. Gilead and its Limited Sovaldi Patent Rights.

12. It has been estimated that there are between 2.7 and 5.2 million people in the United States infected with Hepatitis-C. The virus is transmitted by coming into contact with infected blood, such as shared needles, a blood transfusion, or sexual contact. Left untreated, it can lead to cirrhosis or liver cancer, and may require a liver transplant. Such conditions typically manifest many years after the initial infection occurs. Since 2007, there have been more deaths in the United States from Hepatitis-C than from HIV. Prior to Sovaldi, the available treatments cured only about half of Hepatitis-C patients, and often had debilitating side effects.

13. Sovaldi is a Hepatitis-C tablet that was originally developed by a company called Pharmasset, Inc. (“Pharmasset”). In November 2011, Pharmasset was acquired by Gilead. According to a press release issued by Gilead at the time, it acquired Pharmasset for \$137 per share in cash, putting the value of the transaction at approximately \$11 billion. Pursuant to the merger, Gilead acquired Pharmasset’s assets, including its patent portfolio associated with the development of Sovaldi.

14. A New Drug Application for Sovaldi was filed with the FDA on April 8, 2013. As noted above, the active ingredient in Sovaldi tablets is sofosbuvir. Sofosbuvir is a nucleotide analog that acts to inhibit the replication of the Hepatitis-C virus.

15. On October 25, 2013, an FDA committee voted to support approval of Sovaldi for treatment of Hepatitis-C genotypes 1 and 4 in combination with

pegylated interferon and ribavirin, and for treatment of Hepatitis-C genotypes 2 and 3 in combination with ribavirin.¹

16. Leading up to the anticipated approval for the commercial sale of Sovaldi, Kevin Young and Executive Vice President at Gilead, said on an October 29, 2013 investors conference call that “we feel that our commercial launch plans are where they should be to bring sofosbuvir responsibly to specialists and their patients upon regulatory approval.”

17. The FDA approved the sale of Sovaldi on or around December 6, 2013. The Orange Book currently lists five patents associated with Sovaldi, the last of which expires December 11, 2030. The Orange Book is a database maintained by the FDA that identifies, *inter alia*, patents that may be applicable to prescription drugs. According to the Orange Book, the “Exclusivity Expiration” date for Sovaldi is December 6, 2018.

18. Sovaldi is not the only Hepatitis C drug sold by Gilead at excessive prices. On or around October 10, 2014, it received FDA approval to sell an even more expensive drug, Harvoni. Unlike Sovaldi, which must be taken in conjunction with another drug, Harvoni is a complete, one-a-day pill that can be taken alone. It reportedly costs in excess of \$94,000 for a 12 week regimen. Unlike Sovaldi, Harvoni has only been approved for the main subtype of hepatitis, genotype 1. According to the Orange Book, there are ten patents associated with Harvoni, the last of which expires on December 11, 2030.

¹ Hepatitis-C is comprised of six different genotypes. Genotype 1 is the most predominant genotype in the United States, followed by genotype 2 and 3.

B. The Sovaldi Price Disparity.

19. On September 15, 2014, Gilead issued a press release revealing license agreements that it reached with seven generic drug manufacturers providing for the manufacture of the generic form of Sovaldi. These arrangements reportedly provide for the generic drug manufacturers to receive a “complete technology transfer” of the Gilead manufacturing process of Sovaldi so that cheaper, generic versions of the drug can be sold in 91 developing countries. The licensees can set their own prices for the drug and will pay a 7% royalty back to Gilead.

20. While rolling out its self-congratulatory marketing campaign about how the company is making this lifesaving drug available in third world countries, Gilead has been simultaneously gouging its U.S.-based consumers and third party payors of the drug. As noted above, Sovaldi can cost \$1,000 per pill, making the total cost of a standard treatment approximately \$84,000.

21. A handful of large purchasers of Sovaldi in the U.S. have been able to successfully negotiate discounts on the drug. For example, it has been reported that the Federal Bureau of Prisons (which houses about 9% of the nation’s inmates) receives a 44% discount on Sovaldi. The U.S. Department of Veterans Affairs reportedly receives a similar discount. However, state prison systems (which house approximately 58% of U.S. inmates) generally do not have access to these discounts. Similarly, the federal government is prohibited from negotiating lower prices for Medicare drugs.

22. State Medicaid programs have been similarly affected. For example, it has been reported that the Illinois Medicaid program has indicated that Hepatitis-C patients would need to meet “25 criteria” to qualify for Sovaldi. Other states, such as Pennsylvania, are limiting their approval for purchases of Sovaldi to only the sickest patients. For its part, however, Gilead has reportedly encouraged the *early* use of Sovaldi because doing so “yields better health and economic outcomes compared with later initiation,’ by reducing such complications as cancer and the ‘downstream costs associated with advancing [liver] disease.’”

23. Gilead’s pricing makes early use economically impossible. It was reported in March 2014 that two Medicaid patients in Pennsylvania had applied for Sovaldi in the previous month, and were not approved by the state’s Office of Medical Assistance Program. Other states are apparently reviewing applications for Medicaid coverage of the drug on a case-by-case basis.

24. On October 28, 2014, the National Association of Medicaid Directors (“NAMD”) sent a letter to eight members of Congress discussing the unique challenges that the state Medicaid programs were facing related to Sovaldi. The NAMD is a bipartisan, non-profit organization that represents the Medicaid Directors in fifty states. The NAMD letter notes that “most people living with a chronic hepatitis C infection are unaware of their infection status.” It is anticipated that the number of Americans with confirmed Hepatitis C infections will increase as additional testing is conducted, per recommendations by the Centers for Disease

Control and Prevention (“CDC”). As indicated in the letter, this will only add to the significant financial strain already placed on the Medicaid system:

The challenge Sovaldi and other new hepatitis C medications pose for the Medicaid program is the intersection of a high-cost therapy and a potentially large population eligible for the therapy. To date, several states have reported that their first quarter 2014 prescription drug expenditures for hepatitis C treatments has doubled or tripled compared to their entire 2013 spending,...

C. The Senate Finance Committee Investigation.

25. The Senate’s Committee on Finance has recently commenced an investigation into Gilead’s pricing practices. A July 11, 2014 letter to Gilead’s CEO from Senators Chuck Grassley (R-IA) and Ron Wyden (D-OR) notes that Sovaldi’s “pricing has raised serious questions about the extent to which the market for this drug is working efficiently and rationally.” The letter notes that the cost of a Sovaldi treatment regimen in Egypt (the country with the highest Hepatitis-C presence in the world) is around \$900, which is 99% less than what it costs in the U.S. The letter cites statistics about how the government could very well end up spending several billion dollars on this drug through Medicare, Medicaid and other federal programs.

26. Significantly, the Senators’ letter observes that the high price charged for Sovaldi “appears to be higher than expected given the costs of development, and production and the steep discounts in other countries.” The Senate Finance Committee has requested that Gilead produce numerous categories of documents, largely concerning the Pharmasset 2011 merger,² and the price at which

² Pharmasset had said in its SEC filings before the merger that it expected to sell

Pharmasset had anticipated selling Sovaldi. A spokesperson for Gilead said at the time that the company received the Senators' letter and "will cooperate with their request." The company's most recent Form 10-Q filed with the SEC on November 5, 2014 states that it is "cooperating with the inquiries."

D. Gilead's Windfall Profits from Sovaldi Sales.

27. Gilead's price gouging has been a remarkable financial success for the company and its shareholders. Gilead's \$2.3 billion in worldwide Sovaldi sales in the first quarter of 2014 apparently set a record for the sale of a drug during its first full quarter on the market. Approximately \$2.1 billion of these sales were in the United States. Second quarter 2014 sales of Sovaldi climbed to \$3.4 billion and third quarter sales totaled \$2.8 billion, bringing the nine month total to an astounding \$8.5 billion.

28. Gilead's exorbitant pricing practices for Sovaldi have placed Hepatitis-C patients – and the third party payors like Plaintiff who shoulder most of these prescription drug costs – in an impossible position: either (a) expend substantial amounts for Sovaldi, thereby depleting health and welfare funds and negatively impacting their continued viability, or (b) fail to provide or limit coverage for Sovaldi, effectively denying plan beneficiaries access to this highly effective drug. Indeed, some insurance companies do not even have a choice, as they are often required to provide coverage for drugs like Sovaldi that are highly effective and have no alternative equivalents.

the drug in the United States for \$36,000. The Senators' letter asks for information about this figure.

29. Gilead has attempted to justify these exorbitant prices by predicting that Sovaldi has the potential to save the health care system money by avoiding other costly Hepatitis-C treatments. John F. Milligan, the Chief Operating Officer of Gilead, said on an analysts' conference call in April 2014 that "the value of a cure, I tend to think, is underestimated in terms of the overall advantage that the health care system receives from it..." In another call in July 2014, Mr. Milligan said that the price is "an outlier because we are curing people of a horrible disease in a very rapid time frame." Mr. Milligan stated on this July call that over 70,000 people in the United States have been treated with Sovaldi-containing regimens.

30. To be sure, Sovaldi is not the only extremely expensive prescription drug on the market. However, these other drugs, referred to as orphan drugs, are designed to treat rare diseases in a relatively small population of patients. A *Wall Street Journal* article dated October 10, 2014 contained the diagram on the following page which illustrates this point:

Prices Climb | The cost of drugs is rising, especially for rare disorders.

A selection of some of the most expensive drugs, annual cost in the U.S.

Drug (company)	Treats	Typical/Annual Cost	Target patient population
Soliris (Alexion)	Type of blood disease and also a kidney disorder	\$440,000	10,000-12,000 world-wide
Naglazyme (BioMarin)	Rare enzyme disorder	\$400,000	1,100 in developed countries
Elaprase (Shire/Sanofi)	Rare enzyme disorder	\$375,000	2,000 world-wide
Cinryze (Shire)	Hereditary Angioedema	\$350,000	6,000 in U.S.
Gattex (NPS)	Short Bowel Syndrome	\$295,000	3,000-5,000 in U.S.
Harvoni (Gilead)	Hepatitis C	\$94,500	3.2 million in U.S.

Source: Sector & Sovereign Research (price changes); Needham & Co. (drugs, patient population); Centers for Disease Control and Prevention (patient population)

^aAdjusted for inflation
The Wall Street Journal

31. As noted above and depicted in the chart, there are several million people in the United States who are infected with Hepatitis-C. Indeed, during an October 28, 2014 conference call with investors, Patrick O'Brien (VP of Investor Relations at Gilead) said that "approximately 100,000 patients have been treated with Sovaldi in the United States....This represents a fraction of the estimated 185 million people in the world suffering from [Hepatitis-C], who have the potential to benefit from sofosbuvir-based regimens."

32. As the president of a major group of insurers and other third party payors has been quoted as saying, multiplying Sovaldi's "price by three million people...can torpedo the whole health insurance system." Express Scripts, the largest pharmacy benefit manager in the United States, has estimated that states would have to pay \$55 billion to treat all of their Medicaid patients and prison

inmates, calling the drug “a tax on all Americans.” Such exorbitant pricing cannot be rationally justified by any research and development costs associated with developing Sovaldi, nor by predictions of future healthcare cost-avoidance.

E. Gilead’s Sovaldi Patents May Not Even Be Valid.

33. While Gilead’s price gouging conduct described herein cannot be justified by the patent laws, it is noteworthy that the validity and applicability of some of the Sovaldi patents are currently being challenged. Indeed, Gilead’s most recent Form 10-Q acknowledges that while it owns patents “that claim sofosbuvir as a chemical entity and its metabolites,” they do “not necessarily guarantee our right to practice the patented technology or commercialize the patented product.” Several of the ongoing cases related to Gilead’s purported patents concerning Sovaldi are summarized below.

**A. *Gilead Sciences, Inc. v. Merck & Co, Inc. et al*,
No. 5:13-cv-04057-BLF (N.D. Cal.)**

34. On August 30, 2013, Gilead filed a declaratory judgment action in the United States District Court for the Northern District of California against Merck and related entities, seeking a declaratory judgment that its sale of Sovaldi would not infringe upon two patents to which the defendants were assigned – U.S. Patent 7,105,499 and 8,481,712. These two patents are entitled “Nucleoside Derivatives as Inhibitors of RNA-Dependent RNA Viral Polymerase.” According to Gilead, those two patents cover compounds which do not include, but which may relate to, sofosbuvir.

35. Gilead's action was filed shortly after Merck's director of corporate licensing had sent a letter to Gilead offering it a license related its two patents. Merck has responded to Gilead's lawsuit by filing an answer and counter-claims seeking, among other things, a declaration that Gilead's commercial sale of Sovaldi would infringe on these two patents. Gilead has filed an answer to those counter-claims. The parties are conducting discovery in that case, which is scheduled to be concluded by October 15, 2015. Trial is scheduled to begin on March 7, 2016.

36. In describing this action in its SEC filings, Gilead has stated that "[i]f the court determines that Merck's patents are valid and that we have infringed those claims, we may be required to obtain a license from and pay royalties to Merck to commercialize sofosbuvir."

**B. *Idenix Pharmaceuticals, Inc., et al. v. Gilead Sciences, Inc., et al.*,
No. 1:13-cv-01987-LPS (D. Del.)**

37. On December 1, 2013, a biopharmaceutical company that focuses on developing drugs to treat viral disease, Idenix Pharmaceuticals, Inc. and others filed a patent infringement action in the United States District Court for the District of Delaware related to Gilead's then-pending FDA approval to sell sofosbuvir. The plaintiffs in that lawsuit are alleging that (a) Gilead's sale of sofosbuvir will infringe one of their patents (U.S. Patent No. 7,608,600), and (b) one of Gilead's patents that purportedly covers sofosbuvir – U.S. Patent No. 8,415,322 – is invalid because those plaintiffs have an earlier-filed patent with priority.

38. Gilead filed an answer with counter-claims on February 6, 2014. This case is also ongoing. The court has reserved trial dates between October and December of 2016.

C. *Idenix Pharmaceuticals, Inc., et al. v. Gilead Sciences, Inc., et al., No. 1:13-cv-13052 (D. Mass.)*

39. Also on December 1, 2013, Idenix and others filed a second, related declaratory judgment action against Gilead in the United States District Court for the District of Massachusetts.³ In the Massachusetts case, Idenix alleged that Gilead infringed on two more of its patents: U.S. Patent Nos. 6,914,054 and 7,608,597. These two patents are titled “Methods and Compositions for Treating Hepatitis C Virus,” and relate to 2’ – methyl nucleosides that hinder the replication of Hepatitis C in the human body.

40. On June 30, 2014, U.S. District Court Judge Denise J. Casper issued a Memorandum and Order that granted a motion filed by Gilead to have this case transferred to the District of Delaware. Judge Casper noted that Idenix’s case in Massachusetts was filed approximately 30 minutes after its action was commenced in Delaware. She also found that the two cases concern the same patented product (sofosbuvir) and involve the pharmaceutical products designed to treat Hepatitis C and relate to 2’ –methyl nucleosides that hinder its replication in the human body. Accordingly, the Massachusetts action was transferred to Delaware, where it was related to the District of Delaware action.

³ Idenix has explained that it simultaneously filed these two cases in different courts because they involve patents “from different patent families, with different priority dates, different specifications, and different claim terms...”

41. Gilead has stated in its SEC filings that it believes “Idenix’s patents are invalid and would not be infringed by our commercialization of sofosbuvir and that we have the sole right to commercialize sofosbuvir. However, if the court disagrees with our view and determines that these patents are infringed, we may be required to obtain a license from and pay royalties to Idenix to commercialize sofosbuvir.” It also noted that Merck acquired Idenix on June 9, 2014, which Gilead noted may be significant because “Merck has greater resources than Idenix and may therefore choose to fund the litigation at higher levels than Idenix.”

CLASS ACTION ALLEGATIONS

42. Plaintiff brings this action individually, and on behalf of a class, pursuant to FED. R. CIV. P. 23(a), 23(b)(2), and/or 23(b)(3). Specifically, Plaintiff seeks to represent the following class:

All persons or entities in the United States and its territories who were harmed as a result of the excessive pricing of Sovaldi by (a) purchasing or paying for some or all of the purchase price for Sovaldi, for consumption by themselves, their families, or their members, employees, insureds, participants, or beneficiaries, other than for resale, or (b) being prevented from obtaining a needed Sovaldi regimen.⁴

43. Numerosity: The Class is so numerous that joinder of all members is impracticable. While the exact number and identities of individual Class Members are unknown at this time, such information being in the sole possession of Defendant and obtainable by Plaintiff only through the discovery process, Plaintiff believes that there are thousands of class members. As noted above, Gilead has estimated that there have been over 70,000 treatments of Sovaldi in the United

⁴ Plaintiffs reserve the right to modify this class definition.

States, and there are millions more Americans living with Hepatitis-C who have sought or may in the future seek to purchase Sovaldi.

44. Existence and Predominance of Common Questions of Fact and Law:

Common questions of law and fact exist as to all Class Members. These questions predominate over the questions affecting individual Class Members. These common legal and factual questions include, but are not limited to:

- Whether Gilead has engaged in price gouging.
- Whether Gilead has violated the statutes asserted herein.
- Whether Gilead has been unjustly enriched (and if so, in what amount).
- Whether Gilead's pricing practices can be justified or defended through its patents or otherwise.
- Whether Gilead should be ordered to cease this unconscionable conduct, or otherwise modify it.
- The extent and measurement of classwide damages, and nature of other appropriate relief.

45. Typicality: The claims of Plaintiff are typical of the claims of the Class in that Plaintiff, like all Class Members, paid exorbitant prices for Sovaldi.

Furthermore, the facts related to Gilead's misconduct are common to all Class Members and represent a common thread resulting in injury to all Class Members.

46. Adequacy: Plaintiff will fairly and adequately protect the interests of the Class Members. Plaintiff has retained attorneys experienced in the prosecution

of class actions, including healthcare, antitrust and consumer protection matters, and Plaintiff and its counsel intend to prosecute this action vigorously.

47. Superiority: Plaintiff and the Class Members have all suffered and will continue to suffer harm and damages as a result of Defendant's unlawful and wrongful conduct. A class action is superior to other available methods for the fair and efficient adjudication of the controversy. Absent a class action, most Class Members would likely find the cost of litigating their claims prohibitively high and would therefore have no effective remedy at law. Because of the relatively small size of the individual Class Members' claims, it is likely that only a few Class Members could afford to seek legal redress for Defendant's misconduct. Absent a class action, Class Members will continue to incur damages, and Defendant's misconduct will continue without remedy. Class treatment of common questions of law and fact would also be a superior method to multiple individual actions or piecemeal litigation in that class treatment will conserve the resources of the courts and the litigants, and will promote consistency and efficiency of adjudication.

48. Gilead has acted or refused to act on grounds that apply generally to the class, so that final injunctive relief or corresponding declaratory relief is appropriate respecting the class as a whole.

VIOLATIONS ALLEGED

COUNT I

Unjust Enrichment

49. Plaintiff repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

50. Plaintiff and those similarly situated conferred a benefit upon Gilead by purchasing the Sovaldi for its members. Gilead realized and appreciated this benefit.

51. Gilead's price gouging was not done in good faith and, under the circumstances, a reasonable factfinder could conclude that it would be unjust for it to retain the benefit of those excessive charges. Among other things, the prices charged by Gilead for Sovaldi were unreasonable, excessive, arbitrary, discriminatory, inflated, exorbitant and inflated.

52. As a result of Gilead's price gouging and related unfair conduct, it has been unjustly enriched at the expense of Plaintiff and the Class, in amounts to be determined at trial. Under the circumstances, Gilead's acceptance and retention of these exorbitant charges would be inequitable and unjust.

53. Plaintiffs do not have an adequate alternative remedy available at law. Gilead's pricing scheme has no end in sight and – if left unchecked – has the potential to literally bankrupt segments of the U.S. healthcare system, given the large number of Americans infected with Hepatitis-C.

COUNT II

For Declaratory and Injunctive Relief Under Section 16 of the Clayton Act for Defendant's Violations of Section 2 of the Sherman Act, 15 U.S.C. 2

54. Plaintiff repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

55. For purposes of this claim, the relevant product market is defined as the sofosbuvir indications approved by the FDA. The relevant geographic market is the United States. At all relevant times, Gilead possessed substantial market power (*i.e.*, monopoly power) in these relevant markets.

56. Gilead has engaged in the willful acquisition and maintenance of monopoly power in the market for Sovaldi through its conduct, and not through the growth or development as a consequence of a superior product, business acumen, or historic accident.

57. Gilead has engaged in predatory, exclusionary and/or unfair conduct with the specific intent to monopolize the market for Sovaldi.

58. As a direct and proximate result of Gilead's unlawful restraint of trade and unfair trade practices, Plaintiff and members of the Class were harmed as described herein.

59. Plaintiff, pursuant to FED. R. CIV. P. 57 and 28 U.S.C. § 2201(a) hereby seeks a declaratory judgment that Gilead's conduct as described herein violates Section 2 of the Sherman Act.

60. Plaintiff and the Class further seeks equitable and injunctive relief pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26, and other applicable law, to correct for the anticompetitive market effects caused by the unlawful and unfair conduct of Gilead, and other relief so as to assure that similar anticompetitive conduct does not occur in the future.

COUNT III

**Discrimination in violation of section 1557(a) of the Patient
Protection and Affordable Care Act**

63. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

64. Gilead meets the qualifications for being a “health program or activity, any part of which is receiving Federal financial assistance” under section 1557 of the Affordable Care Act. *See* 42 U.S.C. § 18116. Upon information and belief, the federal government provided grants and/or other financial assistance that contributed to the development of Sovaldi.

65. By definition, consumers and potential consumers of Sovaldi all have Hepatitis C, a debilitating disease. According to Stedman's Medical Dictionary, Hepatitis C is a viral infection that causes a progressive inflammation of the liver – a major and essential organ. The World Health Organization has described Hepatitis as “one of the most prevalent and serious infectious conditions in the world.” The CDC has stated that Hepatitis C “is the most common chronic bloodborne infection in the United States.” Hepatitis C reportedly accounts for a large percentage of cirrhosis, liver failure and liver cancer cases in the United States.

66. Given the severity of this chronic condition, Hepatitis C interferes (and inevitably will interfere) with at least one or more of the following major life activities: caring for oneself, performing manual tasks, reproducing/procreating, engaging in sexual relations, and working. Accordingly, persons infected with

Hepatitis C have a “disability” within the meaning of section 504 of the Rehabilitation Act of 1973. *See* 29 U.S.C. § 794.

67. Defendant has violated and continues to violate section 1557(a) of the Affordable Care Act by intentionally causing Plaintiffs to “be excluded from participation in, be denied the benefits of, or be subjected to discrimination under, any health program or activity, any part of which is receiving Federal financial assistance” based on their disability, which is a prohibited ground of discrimination under section 504 of the Rehabilitation Act.

68. Plaintiffs have been aggrieved and damaged by this violation of section 1557 of the Affordable Care Act.

COUNT IV

Breach of the Duty of Good Faith and Fair Dealing As an Intended Third-Party Beneficiary

69. Plaintiff hereby repeats and incorporates by reference each preceding and succeeding paragraph as though fully set forth herein.

70. As a drug manufacturer, Gilead primarily sold Sovaldi directly to wholesalers and distributors. Upon information and belief, Sovaldi patients and third-party payors for it were intended third-party beneficiaries of those contracts.

71. Every contract contains a duty of good faith and fair dealing.

72. Gilead failed to carry out its contracts with these direct purchasers of Sovaldi in good faith. Gilead abused any discretion it may have possessed related to those agreements by charging grossly excessive prices for Sovaldi. Gilead has

arbitrarily, unreasonably, and/or capriciously breached its duty of good faith and fair dealing by demanding the excessive prices it charged for Sovaldi.

73. Gilead has been able to leverage its market power and purported patent rights to successfully coerce these wholesalers to extract excessive purchase prices from third party-payors and patients alike. Both the wholesalers and end-consumers (as well as third-party payors) have no other alternative means to obtain Sovaldi, or any other alternative to treat and cure Hepatitis C. Because of this, Gilead (and the wholesalers) know that consumers must and will pay whatever exorbitant price is charged by Gilead, and passed on by the wholesalers.

74. Alternatively, the wholesalers have acted as *de facto* agents of Gilead, serving no realistic market function except to serve as a phantom middle men in the distribution scheme.

75. Gilead's conduct breached of its duty of good faith and fair dealing, and directly and proximately caused Plaintiff and other intended third party beneficiaries to be injured.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court:

- (a) Issue an order certifying the Class defined above, appointing the Plaintiff as Class representative, and designating the undersigned firm as Class Counsel;
- (b) Find that Gilead has committed the violations of law alleged herein;

- (c) Determine that Gilead has been unjustly enriched as a result of its wrongful conduct, and enter an appropriate order awarding restitution and monetary damages to the Class;
- (d) Render an award of compensatory damages, the amount of which is to be determined at trial;
- (e) Render an award of punitive and/or treble damages;
- (f) Enter judgment including interest, costs, reasonable attorneys' fees, costs, and expenses; and
- (g) Grant all such other relief as the Court deems appropriate.

Dated: December 9, 2014

Respectfully submitted,

By:



Nicholas E. Chmicles

Benjamin F. Johns

Joseph B. Kenney

CHIMICLES & TIKELLIS LLP

One Haverford Centre

361 West Lancaster Avenue

Haverford, PA 19041

Telephone: (610) 642-8500

Facsimile: (610) 649-3633

Nick@chimicles.com; BFJ@chimicles.com

Attorneys for Plaintiff and the Class