IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IDENIX PHARMACEUTICALS, INC., UNIVERSITA DEGLI STUDI DI CAGLIARI, CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE and L'UNIVERSITE MONTPELLIER II, Plaintiffs, v. GILEAD SCIENCES, INC. and GILEAD PHARMASSET LLC, Defendants.	PUBLIC VERSION C.A. No. 13-1987-LPS
IDENIX PHARMACEUTICALS, INC., UNIVERSITA DEGLI STUDI DI CAGLIARI, CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE and L'UNIVERSITE MONTPELLIER II, Plaintiffs, v. GILEAD PHARMASSET LLC, Defendant.	PUBLIC VERSION C.A. No. 14-109-LPS
IDENIX PHARMACEUTICALS, INC. and UNIVERSITA DEGLI STUDI DI CAGLIARI, Plaintiffs, v. GILEAD SCIENCES, INC. Defendant.	PUBLIC VERSION C.A. No. 14-846-LPS

DEFENDANTS' OPENING BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT

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I. NATURE AND STAGE OF THE PROCEEDINGS

This case implicates Gilead's revolutionary new Hepatitis C treatments and Idenix's attempt to ensnare them with three paper patents stemming from work that never yielded an approved drug. Hepatitis C is an epidemic—it afflicts over 170 million worldwide and is the primary cause of liver cancer and liver transplants. Traditional therapy had low success rates and severe side effects. When Gilead's predecessor invented the nucleoside compound at issue here (sofosbuvir), its discovery changed everything. Gilead's life-saving drugs Sovaldi® and Harvoni® incorporate sofosbuvir into a once-daily pill that cures Hepatitis C virus in as little as 8 weeks, without the side effects of prior therapies. Having failed to develop its own therapy, Idenix now seeks to extract a windfall from Gilead through litigation. But, as explained below, Idenix has not identified any dispute of material fact sufficient to avoid summary judgment.

II. SUMMARY OF THE ARGUMENT

1. Idenix's U.S. Patent Nos. 6,914,054 and 7,608,597 are invalid as a matter of law for lack of written description. Idenix convinced the Court to construe these patents to include Hepatitis C treatment methods that include billions of nucleosides. Yet Idenix has admitted that the patents' specification does not describe many of these nucleosides, including 2'-fluoro down nucleosides like Gilead's sofosbuvir. The specification instead describes its invention as several identified classes of nucleosides, all of which exclude 2'-fluoro nucleosides and many others covered by the claims as construed. The claims are thus invalid because they have been expanded to cover far more than the specification describes. Indeed, Idenix does not even try to defend validity under the Court's construction, instead offering expert testimony only under a narrower construction that contradicts both the Court's and Idenix's own prior argument. That irrelevant testimony does not create a genuine dispute over a material issue.

2. Idenix's infringement case on the '054 and '597 patents, which is based only on induced and contributory infringement, fails as a matter of law. *Commil* and *Global-Tech* hold that a defendant is not liable where it has a good faith belief it does not infringe, such as when the defendant "reads the patent's claims differently from the plaintiff, and that reading is reasonable." Gilead explained at *Markman* why the '054 and '597 patents, as properly construed, do not cover a 2'-fluoro down nucleoside like sofosbuvir. Although the Court disagreed, that reading was (and continues to be) reasonable, precluding infringement liability.

3. Idenix's U.S. Patent No. 7,608,600 and the '054 and '597 patents are all invalid based on prior nucleoside work done by Idenix's parent company, Merck, who has sued Gilead in another patent case in California. Idenix and Merck have erroneously sought to ensnare Gilead in their invalid patents in multiple jurisdictions. Their assertions are all unfounded, but, at a minimum, because both say they invented the same general thing, only one of those two companies can be first relative to the other. The undisputed facts show that, as between the two related corporate entities, Merck was first, and its work thus invalidates Idenix's patents.

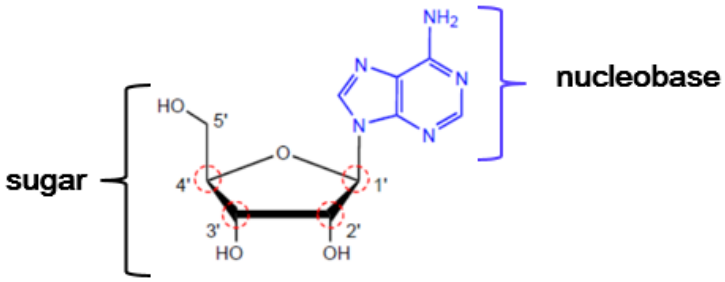
4. Idenix's willfulness allegations fail as a matter of law based on Gilead's good faith belief that it is not infringing any valid claim. Gilead's good faith belief for the '054 and '597 patents flows from, for example, the written description, prior invention, and claim construction defenses just discussed; Gilead's good faith belief for the '600 patent is based on prior invention and the Patent Office's recent cancellation of all its asserted claims.

5. These cases include an appeal from a Patent Office interference that awarded Gilead priority of invention over a class of 2'-methyl up, 2'-fluoro down nucleosides. The Court should adopt the Patent Office's definition of the interference "count," *i.e.*, the description of the parties' overlapping subject matter, as Idenix's experts do not dispute its definition.

III. STATEMENT OF THE FACTS

A. Technology Background on Nucleoside Compounds.

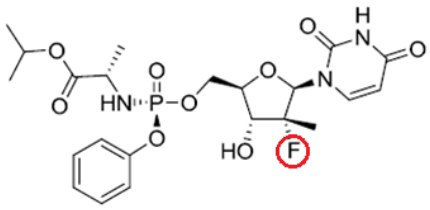
Before turning to Idenix's patents, a refresher on the terminology used to describe the nucleoside compounds at issue may be helpful. Nucleosides consist of a "base" and a five-membered sugar ring, in which each carbon atom is assigned a number from 1' to 4':



[redacted] Each carbon has chemical groups that are attached either above ("up") or below ("down") the plane of the sugar ring. The image above shows "hydroxyl" (-OH) groups attached at the 2'-down and 3'-down positions. [redacted] There are two large classes of bases—pyrimidines and purines—which are defined by whether they have a single-ring or double-ring structure, respectively. [redacted] The image above shows a purine base.

A nucleoside's activity against Hepatitis C and its toxicity vary greatly depending on which chemical groups are attached at a particular carbon on the sugar ring and whether a given group is attached in the "up" or "down" position at that carbon. Redacted Many companies, including Gilead's precedessor (Pharmasset), Idenix, and its parent, Merck, were searching for a nucleoside with the perfect chemical structure for safely treating Hepatitis C virus in the late 1990s and early 2000s. There were a seemingly endless number of options, based on the many different possible chemical groups that could be attached at either the up or down position of each carbon and the many different modified nucleobases. Redacted [redacted]

Gilead's precedessor, Pharmasset, was the first one to find and make the breakthrough nucleoside. Redacted [redacted] Sofosbuvir's chemical structure is shown below, including the fluorine at the 2'-down position circled in red:



Redacted [redacted] This case is Idenix's attempt to capture 2'-fluoro down nucleosides like sofosbuvir with patents that either never described them, never enabled making them, or both.

B. Idenix's '054 and '597 Patents.

Idenix's earliest two asserted patents, U.S. Patents 6,914,054 and 7,608,597, did little to focus the search for the right nucleoside. (Exs. 2 & 3.) The patents disclose "modified nucleoside" compounds that can supposedly be used to treat Hepatitis C. (Ex. 2 at Abstract.) The patents both claim priority to a May 2000 provisional and the May 2001 utility application that became the '054 patent. (*Id.*)

The Court has, at Idenix's urging, construed the claims of the '054 and '597 patents to broadly include billions of compounds. Idenix now asserts only claims 26 and 27 of the '054 patent, which have been construed to include ***any*** nucleoside with a pyrimidine base and two non-hydrogen substituents at the 2'-position. (Ex. 2 at 164:40-45; D.I. 248 at 5-11.) [redacted]

[redacted]. Idenix asserts claims 1, 2, 4-14, 16, 17, 19, 23, and 28-31 of the '597 patent, which have been construed to include any nucleoside with a 2'-methyl up and any non-hydrogen group at the 2'- and 3'-down positions. (Ex. 3 at 142:63-143:3, 143:7-41, 143:45-49, 144:3-4, 144:11-13, 144:26-38; D.I. 248 at 12.) The Court's construction places no limits on what may be attached at the 1'-down, 3'-up, and 4'-down positions.[redacted] And it barely limits what can be placed at 2'-down and 3'-down—it can be anything other than hydrogen. (D.I. 248 at 5-12.)

The '054 and '597 patents' specification, while itself quite broad, is significantly narrower than the claims. The specification explains, in the "Summary of the Invention," that it is directed only to the modified nucleosides shown in a specific set of formulas that follow:

> Compounds, methods and compositions for the treatment of hepatitis C infection are described that include an effective hepatitis C treatment amount of a β-D- or β-L-nucleoside ***of the Formulas (I)-(XVIII)***, or a pharmaceutically acceptable salt or prodrug thereof.

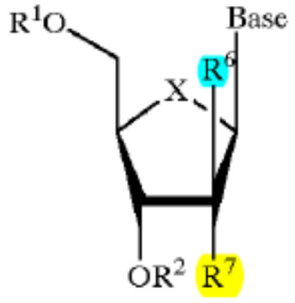
(Ex. 2 at 5:27-32.) The "Detailed Description of the Invention" includes a similar limitation, noting that "the invention as disclosed" is a compound or method of treating Hepatitis C virus that includes "β-D- or β-L-nucleoside ***as described herein***," not every conceiveable β-D- or β-L-nucleoside:

> ***The invention as disclosed herein is*** a compound, method and composition for the treatment of hepatitis C in humans or other host animals, that includes administering an effective HCV treatment amount ***of a β-D- or β-L-nucleoside as described herein*** or a pharmaceutically acceptable salt or prodrug thereof, optionally in a pharmaceutically acceptable carrier.

(*Id*. at 15:32-40; *see also id.* at 15:41-67 (emphasis added).) Idenix originally included 129 claims with the May 2001 application that became the '054 patent, and all were limited to treatment methods using a compound from one of the 18 formulas recited in the specification. (Ex. 4;[redacted]

The Formulas impose several limitations that Idenix later removed from the asserted claims as construed. For example, the Formulas describe only compounds with a hydrogen at the 4'-down position, even though all the asserted claims cover ***any*** substitution at the 4'-down position. (*See, e.g.*, Ex. 2 at 5:33-13:38.) Likewise, most of the Formulas describe only compounds with a hydrogen or methyl at the 1'-down position, and the few Formulas that show something else include a list of potential substitutions, rather than allowing every possible substitution. (*Id.*) The same is true of the 2'-down and 3'-down positions—all the Formulas list potential subsitutions, rather than opening those positions up to any non-hydrogen group. (*Id.*)

One example of the mismatch between Idenix's claims as construed and the narrower specification is that none of the formulas in the '054 and '597 patents includes a modified nucleoside with a 2'-down fluorine. (Ex. 2 at 5:33-13:38.) In fact, the Formulas that come closest specifically omit fluorine from the potential options at the 2'-down position, even though they include the other halogens: chlorine, bromine, and iodine. (*See, e.g.*, *id.* at 110:10-15, 10:48-54 (Formula XI); *see also id.* at 11:38-50, 12:5-9, 12:21-30, 12:53-59, 13:1-10, 13:30-34 (same for Formulas XVI, XVII, and XVIII).) The example below from Formula XI is representative of the problem and shows the omission of fluorine from the list of halogens at the 2'-down position (shown in yellow):



R^6 is hydrogen, hydroxy, alkyl (including lower alkyl), azido, cyano, alkenyl, alkynyl, Br-vinyl, —C(O)O(alkyl), —C(O)O(lower alkyl), —C(acyl), —O(lower acyl), —O(alkyl), —O(lower alkyl), —O(alkenyl), chloro, bromo, fluoro, iodo, NO_2, NH_2, —NH(lower alkyl), —NH(acyl), —N(lower alkyl)$_2$, —N(acyl)$_2$;
R^7 is hydrogen, OR^3, hydroxy, alkyl (including lower alkyl), azido, cyano, alkenyl, alkynyl, Br-vinyl, —C(O)O(alkyl), —C(O)O(lower alkyl), —O(acyl), —O(lower acyl), —O(alkyl), —O(lower alkyl), —O(alkenyl), chlorine, bromine, iodine, NO_2, NH_2, —NH(lower alkyl), —NH (acyl), —N(lower alkyl)$_2$, —N(acyl)$_2$; and

(Ex. 2 at 10:10-15, 10:48-54.) The patents' omission of fluorine at the 2'-down position is all the more striking because they specify that ***other positions*** of the described nucleosides may include fluorine, including the 2'-up position of the very same Formula XI (shown in blue above), as well as the, 1'-down, and 3'-up positions in other Formulas. (*See, e.g*, *id.* at 10:10-14, 10:42-49 (2'-up can be fluoro); 11:66-12:4 (1'-down); 13:1-10, 13:25-30 (3'-up).)

There is no dispute that the '054/'597 specification lacks any disclosure of any 2'-fluoro down nucleosides. Idenix's lawyer admitted as much during the *Markman* hearing in this case:

> THE COURT: You agree you failed to disclose fluorine at the 2 down position in the patents-in-suit in front of me. Correct?
>
> MR. GRIFFITH: Yes. I wouldn't call it a failing but, ***yes, it's not disclosed***.

(D.I. 224 at 25:24-26:2; *see also id*. at 18:24-25 ("It just doesn't say use fluorine at the 2 position. It doesn't have an example of doing that.").) And it's not only that the '054 and '597 patents lack a specific example of a 2'-fluoro down nucleoside—while pursuing claims in a later, unrelated patent application that ***were*** specifically directed to 2'-fluoro down nucleosides, Idenix told the Patent Office that ***nothing*** in the '054/'597 specification suggested a 2'-fluoro down nucleoside. In particular, Idenix responded to a rejection of then-pending claim 44 of its U.S. Application 12/131,868 based on the '054 patent by amending that claim to limit it to 2'-fluoro down nucleosides, and then arguing that the "rejection is moot in view of the above amendments to the claims, in which R^7 [the 2'-down position] has been amended to recite 'F' in each of the independent claims." (D.I. 147-3 at 12; *see also id.* at 4 (amending claim); Doc. No. 147-2 at 7 (examiner's rejection).) Again, the meaning of these statements isn't in dispute—Idenix's lawyer admitted at the *Markman* hearing that Idenix was telling the Patent Office that the patents-in-suit don't disclose 2'-fluoro down nucleosides:

> THE COURT: And you don't dispute that if I go study the prosecution history of the '868, ***it will very clearly have your client saying we never disclosed fluorine at the 2 down position in our earlier '054 and '597. Right***?
>
> MR. GRIFFITH: ***That's correct, Your Honor***.

(D.I. 224 at 24:25-25:4.)

It is no surprise that the '054/'597 patent specification does not disclose a 2'-fluoro down nucleoside Redacted

Given the absence of any disclosure of 2'-fluoro down nucleosides in the '054/'597, one might wonder how those patents ended up with claims that cover them Redacted

Redacted

Ms. Knowles then added new claims to the pending '054 patent application in October 2003 that issued as asserted claims 26 and 27, and that this Court subsequently construed to cover 2'-fluoro down nucleosides. (Ex. 4 at 10-14 (adding claims 183-85); D.I. 248 at 5-9.)

The resulting '054 and '597 patent claims cover a vast swath of compounds under the Court's construction. A conservative estimate is that the '054 patent's asserted claims cover at least 2 billion nucleosides, while the '597 patent's asserted claims cover at least 4 billion. Redacted And, although we have been focusing on the fact that the claims were broadened to encompass a set of 2'-fluoro down nucleosides that are missing from the specification, it bears repeating that they have also been broadened to sweep in nucleosides with any modification at the 1'-down, 3'-up, and 4'-down positions as well, even though the specification never describes many, many such nucleosides.

C. The '600 Patent

1. Idenix's third asserted patent, U.S. Patent No. 7,608,600, descends from a series of later applications that are unrelated to those that yielded the '054 and '597 patents; the earliest was filed in June 2002. (Ex. 12.) Unlike the '054 and '597 patents, the '600 patent's specification includes chemical formulas with nucleosides that include a 2'-down fluorine as a potential option. (*See, e.g.*, Ex. 12 at 59:47-60:4 (formula (IV), where R^6 is CH_3, R^7 is F).) But even this was hardly a pointer to the special nucleoside that eventually became sofosbuvir—the '600 patent buries whatever mention of 2'-fluoro down it contains among a specification that

includes billions of putative nucleoside compounds and over 100,000 examples, not one of which has a 2'-fluoro down. Idenix's earliest alleged conception date for the '600 patent is December 2001. (Ex. 7 at 9-10.)

It is unnecessary to say much more about the '600 patent, because the Patent Trial and Appeal Board has cancelled all its asserted claims in an interference proceeding between it and a Gilead patent application. (Ex. 14.) The Board concluded that the '600 patent failed to enable the skilled artisan to make its claimed 2'-fluoro down nucleosides, citing the utter absence of any disclosure in either the specification or the prior art, and the fact that Idenix itself tried and failed to make any claimed 2'-fluoro down nucleoside for years after its 2002 filing date. (*Id*. at 9-40.) Indeed, it was not until Idenix's scientists saw Gilead's published patent application in 2005, which included an exact synthetic route for making the desired 2'-fluoro down nucleoside, that they could make it. (*Id*. at 14-19.) The Board's decision is on appeal to the Federal Circuit, and the briefing was completed in April 2016. Gilead focuses largely on the '054 and '597 patents here, because it expects the Federal Circuit will affirm the Board's well-reasoned decision, eliminating Idenix's infringement claim on the '600 patent.

D. Merck's Earlier Work with Some of Idenix's Later-Claimed Nucleosides.

Idenix was not the only company to try and fail to find a nucleoside that would cure Hepatitis C. Redacted [redacted] Merck filed broad patent applications of its own, and, like Idenix, has been trying to extract a windfall from Gilead's success through litigation. *See Gilead Sciences, Inc. v. Merck & Co, Inc.*, Case No. 13-cv-04057 (N.D. Cal.). Gilead disputes that either Merck or Idenix had invented anything close to sofosbuvir by the time of their filing dates. [redacted]

Redacted

Redacted

Merck also contended in the California litigation that it had thought that 2'-methyl up, 2'-fluoro down nucleosides had activity against Hepatitis C virus since at least April 2001. (Ex. 22 at 982:2-983:9; .) Redacted and Merck filed a provisional patent application in October 2001 that it says covered and claimed 2'-methyl up, 2'-fluoro down pyrimidine nucleosides. (Ex. 22 at 400:4-11, 989:8-12.) Redacted

IV. ARGUMENT

A. The Asserted '054 and '597 Claims Are Invalid Because the Patents Fail to Describe the Full Scope of What is Claimed.

Idenix's '054 and '597 patents are invalid as a matter of law because of the disparity in scope between the claims, as broadly construed, and the far narrower set of nucleosides disclosed in the specification. This Court, at Idenix's urging, construed the claims to cover treatment methods using any pyrimidine nucleoside with a 2'-methyl up and non-hydrogen substituents at the 2'- and 3'-down positions. Idenix intended this construction to cover nucleosides that it

admits are not described by the specification, including 2'-fluoro down nucleosides. Yet, having received this broad construction, Idenix has not even tried to raise a factual dispute that the specification describes the billions of nucleosides it covers. Redacted

[redacted]

1. Federal Circuit Precedent Requires a Patent to Describe the Full Scope of the Claims Either Expressly or Inherently.

A patent is invalid under 35 U.S.C. § 112 if it fails to provide adequate written description for the claimed invention. "[T]he applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and demonstrate that by disclosure in the specification of the patent." *Centocor Ortho Biotech, Inc. v. Abbott Labs.*, 636 F.3d 1341, 1347 (Fed. Cir. 2011). That disclosure must be either express or inherent—it is not enough that the specification render the claims obvious or that the skilled artisan could fill in what the specification is missing. *See, e.g.*, *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571-72 (Fed. Cir. 1997) ("The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification."); *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008) ("This requires that the written description actually or inherently disclose the claim element."). Requiring that the claims be commensurate in scope with what the specification actually describes ensures that the claims do not "overreach [their] contribution to the field of art as described in the patent specification." *Centocor*, 636 F.3d at 1353. The Court assesses compliance by "an objective inquiry into the four corners of the specification" and can find the patent invalid "based solely on the face of the

patent specification." *Id*. "Compliance with the written description requirement is a question of fact but is amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the nonmoving party." *PowerOasis*, 522 F.3d at 1307.

The Federal Circuit has frequently invalidated claims as a matter of law where, as here, a patentee's claims were broadened during prosecution to sweep in subject matter that was never disclosed in the specification. *See, e.g.*, *Atlantic Research Marketing Sys., Inc. v. Troy*, 659 F.3d 1345, 1355-56 (Fed. Cir. 2011) (invalidating claims to a firearm handguard assembly that permitted a variety of types of attachment where the specification disclosed only two specific types of attachment); *Anascape, Ltd. v. Nintendo of Am. Inc.*, 601 F.3d 1333, 1335-41 (Fed. Cir. 2010) (invalidating claims to videogame controls that covered using either multiple inputs or a single input where the specification uniformly described only single-input controllers); *ICU Med., Inc. v. Alaris Med. Sys., Inc.*, 558 F.3d 1368, 1377-79 (Fed. Cir. 2009) (invalidating claims to a medical valve that could transmit fluids through any type of structure where the specification's disclosure was limited to valves that transmitted fluid through a sharp, pointed spike); *PowerOasis*, 522 F.3d at 1308-11 (holding that claims that covered a vending machine with a display that could be in one of multiple places were not described by an application that uniformly showed the display only on the machine); *Tronzo v. Biomet, Inc.*, 156 F.3d 1154 (Fed. Cir. 1998) (invalidating claims to a prosthetic hip socket with a cup of any shape where the specification uniformly disclosed only devices with a cone-shaped cup); *Gentry Gallery, Inc. v. Berkline Corp.*, 134 F.3d 1473, 1478-80 (Fed. Cir. 1998) (invalidating claims to a sectional sofa with recliner controls that could be located anywhere on the unit where the specification showed only examples where the controls were in a center console).

The Federal Circuit has applied the same principles in biotechnology cases, invalidating claims as a matter of law if they are not commensurate in scope with the disclosure in the specification. *See, e.g.*, *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1354-58 (Fed. Cir. 2010) (en banc) (reversing denial of JMOL and invalidating claims that covered any method of reducing NF-ʁB activity as not adequately described when the specification suggested only a few specific methods of reducing such activity); *Carnegie Mellon Univ. v. Hoffman-LaRoche Inc.*, 541 F.3d 1115, 1123-28 (Fed. Cir. 2008) (affirming summary judgment that claims to a gene that performed a particular function from any bacterial source were invalid where the specification described using only a gene from *e. coli* bacteria). The Court has also stressed that patentees cannot create written description after the fact by mixing and matching pieces of the disclosure in ways never discussed in the specification. *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1346-51 (Fed. Cir. 2013) (affirming JMOL invalidating claims where the specification disclosed individual limitations but did not disclose the claimed thermostable alpha-anylase variants as a whole).

2. Idenix's Asserted Claims Are Invalid Because They Reach Well Beyond What is Disclosed in Its Specification.

Idenix's asserted '054 and '597 patent claims are invalid as a matter of law under the Federal Circuit precedent just cited. The claims, as construed, cover nearly any nucleoside with an unlimited number of modifications at the 1'-down, 3'-up, and 4'-down positions, and with a virtually unlimited number of modifications at the 2'-down and 3'-down positions, which can be anything but hydrogen, including a 2'-fluoro down. (D.I. 248 at 5-12.) But the specification, by Idenix's own admission fails to describe such nucleosides and in fact describes the alleged invention much more narrowly, as a modified nucleoside falling within one of 18 Formulas, each of which is shown in detail and for which the possible chemical groups that can be placed at each

position on the nucleoside are identified. (Ex. 2 at 5:27-32, 5:33-13:38.) For example, every Formula shows a hydrogen at the 4'-down position, and they give various lists of potential groups at the 1'-down, 2'-down, 3'-up, and 3'-down positions. (*Id*.) The specification never describes a nucleoside that is not covered by one of those Formulas. It never describes a nucleoside with a substituent at one of those positions that is not listed in the Formulas. And the specification never asserts that that every β-D-2'-C-branched nucleoside effective against Hepatitis C is covered. Instead, the specification ties the invention to only the nucleosides within 18 recited Formulas. (Ex. 2 at 5:27-32.) The asserted claims as construed are thus invalid because they cover many billions of nucleosides beyond what the specification describes. *See, e.g.*, *Ariad*, 598 F.3d at 1352 ("[A] propyl or butyl compound may be made by a process analogous to a disclosed methyl compound, but, in the absence of a statement that the inventor invented propyl and butyl compounds, such compounds have not been described and are not entitled to a patent."); *Regents of Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568 (Fed. Cir. 1997) ("A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials."); *see also Carneige Mellon*, 541 F.3d at 1123-28; and the other cases cited above.

The fact that the asserted claims as construed cover nucleosides with a fluorine at the 2'-down position underscores how far they overreach the specification. The specification scrupuoulsy omits all 2'-fluoro down nucleosides, and that omission can only be deliberate given the explicit inclusion of fluorine at other positions, including 2' up. (Ex. 2 at 11:38-50, 12:5-9, 10:10-15, 10:48-54, 12:21-30, 12:53-59, 13:1-10, 13:30-34 (omitting fluorine at 2'-down).) Fluorine groups appear as potential options for other positions, including the 2'-up position, yet

they are notably omitted as an option for the 2'down position. (*Id*. at 10:10-14, 10:42-49 (showing that 2'-up can be fluoro); 11:66-12:4 (1'-down); 13:1-10, 13:25-30 (3'-up).) Idenix has repeatedly admitted that the specification does not contain ***any*** example of a 2'-fluoro down nucleoside. (*See, e.g.*, D.I. 224 at 18:24-25, 24:25-25:4, 25:24-26:2.) And nothing in the specification suggests modifying any nucleoside to include a 2'-fluoro down. Indeed, Idenix told the Patent Office that the '054/'597 specification does not contain any other express or inherent disclosure of a 2'-fluoro down nucleoside by arguing that its amendment of the claims of a later filed Idenix application, to narrow them to 2'-fluoro nucleosides, "mooted" the Office's anticipation rejection of those claims. (D.I. 147-3 at 4, 12; D.I 147-2 at 7; D.I. 224 at 24:25-25:4.) The rejection would not have been "moot" if there were either an express or inherent disclosure of a 2'-fluoro nucleoside in the '054/'597 patent specification, because a prior art reference anticipates if it either expressly or inherently discloses the claimed invention. *In re Montgomery*, 677 F.3d 1375, 1379-80 (Fed. Cir. 2012). Idenix certainly knew how to specifically include a fluorine as an option in the 2'-down position, as the June 2002 application that led to its later '600 patent did just that. (Ex. 12, '600 patent at 59:47-60:4 (formula (IV), where R^6 is CH_3, R^7 is F).) But Idenix didn't include 2'-fluoro down as an option in the '054/'597 specification, and it shouldn't be permitted to capture them, or any of the other undisclosed nucleoides, now.

Idenix's asserted claims are the classic example of what the written description requirement prohibits. The requirement ensures that the patentee can only claim what it has actually invented as of its filing date, preventing it from writing claims that "overreach [its] contribution to the field of art as described in the patent specification." *Centocor*, 636 F.3d at 1353. That is exactly what Idenix is trying to do here. Redacted

Redacted

Idenix should not be permitted to now pass off Gilead's invention as Idenix's own by seeking priority to patent applications that never mention 2'-fluoro down nucleosides.

Redacted

under the Court's construction, the claims cover administering ***any*** 2'-methyl up nucleoside with two non-hydrogen substituents at the 2'- and 3'-down positions, regardless of whether it is biologically active or not. (D.I. 248 at 5, 12.) The Court's construction did not

impose any further limits, such as excluding nucleosides that had those structural characteristics but lacked antiviral activity. (*Id.*) In fact, the Court specifically rejected imposing further limits, disagreeing with Gilead's position that the 2'- and 3'-down positions were limited to hydroxyl substituents. (*Id.*) Redacted [redacted] Idenix has thus failed to raise a genuine dispute of ***material*** fact that could preclude summary judgment. Redacted [redacted] The written description doctrine precludes Idenix from doing so and renders all the asserted claims invalid as a matter of law.

B. Idenix's Claims for Inducement and Contributory Infringement Are Precluded Because Gilead Has Held, and Continues to Hold, a Good Faith Belief in Non-infringement for the '054 and '597 Patents.

Idenix's allegations against Gilead on the '054 and '597 patents are based entirely on induced or contributory infringement, because its asserted claims cover treatment methods that would be performed, if at all, by a doctor or patient. But Gilead has held a reasonable belief that it does not infringe the patents since December 6, 2013, the first day it began selling the first accused product (Solvaldi®), through the present based on its claim construction positions. The Court should thus grant summary judgment of non-infringement.

1. A Good Faith Belief is a Complete Defense to Induced and Contributory Infringement, Even if It Turns Out to Be Mistaken.

A good faith belief in non-infringement is a complete defense to both types of indirect infringement. A plaintiff who seeks to prove induced infringement must show that "the

defendant knew of the patent and that the induced acts constitute patent infringement." *Commil USA, LLC v. Cisco Sys., Inc.*, 135 S. Ct. 1920, 1926 (2015). A plaintiff cannot meet this burden where the defendant holds a reasonable belief in non-infringement based on its own claim construction. *Id.* at 1928 (finding that liability is precluded where "the defendant reads the patent's claims differently from the plaintiff, and that reading is reasonable"). The same is true for contributory infringement. *See e,g.*, *id.* at 1926 ("Like induced infringement, contributory infringement requires knowledge of the patent in suit and knowledge of patent infringement."); *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 763-64 (2011) ("[A] violator of § 271(c) must know that the combination for which his component was especially designed was both patented and infringing and as we explain below, that conclusion compels this same knowledge for liability under § 271(b).").

2. Gilead Has Held, and Continues to Hold, a Reasonable Belief that the Claims Do Not Cover Sofosbuvir Under Its Claim Construction.

Gilead has held a reasonable, good faith belief that it does not infringe any of the patents-in-suit since the day it began marketing the first of the accused products (Solvaldi®), on December 6, 2013, through the present. This case was filed on December 1, 2013. (D.I. 1.) Gilead immediately retained outside counsel who filed answers denying infringement. (*Idenix Pharms, Inc. v. Gilead Scis., Inc.*, No. 1:13-cv-13052, D.I. 13 at ¶¶ 47-48 ('054 and '597 patents); D.I. 9 at ¶ 50 ('600 patent).) Gilead's belief in non-infringement is based on claim construction. For example, Gilead believes that the asserted claims of the '054 and '597 patents do not cover sofosbuvir because all of the asserted claims are properly construed to reflect the common specification's omission of fluorine at the 2' down position. (D.I. 128 at 8, 13, 16-21; D.I. 146 at 1-10, 16-17; D.I. 224 at 30:17-48:15, 59:1-60:16.) As discussed above, and at the *Markman* stage, the '054 and '597 patents meticulously list potential substituents for the 2' down

position but always omit fluorine as a possibility, even though the specification mentions fluorine in over 300 other places as a potential substituent at different positions on the nucleoside. (*Id*.) This seemingly deliberate exclusion of fluorine from the 2' down position along with Idenix's own characterization of this patent as they distinguished their later claims to 2'-fluoro down nucleosides justify Gilead's good faith belief that nucleosides with fluorine at the 2' down position, such as sofosbuvir, had been implicitly excluded from the patent claims. *See, e.g.*, *SkinMedica, Inc. v. Histogen Inc.*, 727 F.3d 1187, 1204 (Fed. Cir. 2013) (adopting narrow construction where the patent "affected a clear implicit disclaimer of culturing with beads from the scope of their claimed invention"); *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1096-97 (Fed. Cir. 2013) (limiting claims to exclude more than what the applicant's statements during prosecution suggested the patent covered).

Gilead's claim construction position was certainly reasonable, even though it did not prevail. This Court's questions and comments to Idenix's counsel at the *Markman* hearing suggested that there were fair arguments to be made for construing the claims narrowly. (*See, e.g.*, D.I. 224 at 14:6-9 ("But the fact that fluorine is talked about but never talked about in this position, doesn't that at least begin to suggest something on the order of an implicit disclaimer?"); *see also id*. at 53:9-11 ("[B]ut this is a patent that has, by your own admission, no disclosure of the embodiment that you're asking me to read into your claims."). Moreover, Idenix conceded significant ground at the hearing, admitting that its patents did not disclose any example of a 2'-fluoro down nucleoside and that it previously told the Patent Office that they did not disclose one. (*Id*. at 18:24-25, 24:25-25:4, 25:24-26:2.) And the Court's *Markman* order flatly stated that "[t]he patent's failure to expressly disclose fluorine at the 2' down position does give the Court pause," suggesting that Gilead's position was at least reasonable. (D.I. 248 at 10.)

This case thus squarely falls into *Commil*'s holding that a defendant will not be liable for indirect infringement where "the defendant reads the patent's claims differently from the plaintiff, and that reading is reasonable." *Commil*, 135 S. Ct. at 1928. Although this Court disagreed with Gilead's proposed constructions, Gilead continues to have a reasonable, good faith belief that it may prevail on them at the Federal Circuit. Idenix cannot create a dispute of material fact on this issue because it has identified no evidence that Gilead does not believe its claim construction positions in good faith (and there is no such evidence). This Court should thus grant summary judgment of no induced or contributory infringement.

C. Merck's Work on 2'-Methyl Up, 2'-Fluoro Down Nucleosides is Prior Art that Invalidates the Asserted Claims of the '054, '597, and '600 Patents.

Idenix's patents are all anticipated under 35 U.S.C. § 102(g)(2) or obvious [redacted]

"Section 102(g) operates to ensure that a patent is awarded only to the 'first' inventor in law." *Apotex USA, Inc. v. Merck & Co., Inc.*, 254 F.3d 1031, 1035 (Fed. Cir. 2001). "[I]f a patentee's invention has been made by another, prior inventor who has not abandoned, suppressed, or concealed the invention, § 102(g) will invalidate that patent." *Id*. "[P]riority of invention goes to the first party to reduce an invention to practice unless the other party can show that it was the first to conceive the invention and that it exercised reasonable diligence in later reducing that invention to practice." *Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1577 (Fed. Cir. 1996). Here, [redacted] Merck's work thus anticipates or renders obvious all the asserted claims.

1. [redacted]

The asserted '054 and '597 claims cover, among other things, treating a host with a nucleoside that has a 2'-methyl up and non-hydrogen substituents at the 2'- and 3'-down positions. Most of the '597 claims cover treatment using such nucleosides with either a purine or pyrimidine base and are not limited to humans; claims 2, 17, and 19 of the '597 patent and claims 26-27 of the '054 patent are limited to nucleosides with pyrimidine bases. (Ex. 2; Ex. 3.) Many of the claims broadly cover administration to any "host," although others are specific to humans or have specific requirements regarding dosage form, amount, and co-administration with other drugs that were standard in human treatments. (*Id.*) Redacted

Start by considering the broader claims that cover methods using either purine or pyrimidine nucleosides and administration to any "host." [redacted] "In order to establish an actual reduction to practice, the inventor must prove that: (1) he constructed an embodiment or performed a process that met all the limitations of the [claimed invention]; and (2) he determined that the invention would work for its intended purpose." *Cooper v. Goldfarb*, 154 F.3d 1321, 1327 (Fed. Cir. 1998). Redacted

Redacted

The Merck work therefore anticipates the broader claims. *Mahurkar*, 79 F.3d at 1577. Redacted Merck's entire purpose in investigating these nucleosides was to find a Hepatitis C virus treatment for humans. (Ex. 22 at 949:18-950:21.)

In particular, Idenix's expert Dr. Damha has previously opined that "given" a nucleoside with a natural purine base, it would have been obvious to try natural pyrimidine bases. (*See, e.g.*, Ex. 29 at ¶¶ 124-34.) So, applying the logic of Idenix's expert and the alleged behavior by Merck (whose scientists were at least skilled artisans at the relevant time), it would

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Before closing this section, it is important to reiterate that Gilead disagrees with many of the positions taken by Merck and its subsidiary Idenix . But Idenix and its parent, Merck, are bound by these positions. And, given those positions, the '054 and '597 claims are invalid as a matter of law .

2. The '600 Patent's Asserted Claims Are Anticipated Based on Merck's Contentions Regarding Reduction to Practice of a 2'-Methyl Up, 2'-Fluoro Down Nucleoside.

The asserted '600 claims all cover, among other things, using a 2'-methyl up, 2'-fluoro down nucleoside to treat Hepatitis C virus. (Ex. 12 at 2221:10-2222:11, 2222:22, 2222:31, 2223:21-62, 2223:64, 2224:1, 2224:11, 2224:39-54 (claims 1-9, 12, 20, 50, 52, 54, 64, 77-83).) Parent Merck argued in the California litigation that it had reduced to practice the idea of using a 2'-methyl up, 2'-fluoro down nucleoside to treat Hepatitis C virus by the time it filed its October

25, 2001 provisional patent filing. (Ex. 34; Ex. 22 at 400:4-11.) The broad formulas in Merck's provisional do indeed cast a wide net expansive enough to capture a 2'-methyl up, 2'-fluoro down nucleoside (along with billions of other nucleosides), and the Merck application states that they can be used in "the method of inhibiting RNA-dependent RNA viral polymerase," which the application says is allegedly useful for treating Hepatitis C virus. (Ex. 34.) The Merck provisional further discloses all the additional limitations of the '600 patent's dependent claims, including a dosage unit containing 50-1,000 mg of the nucleoside in a table or capsule for administration to a human, where at least 95% by weight is the β-D-isomer and the base is uracil. (*See* Ex. 34 at 47:1-35, 48:16-29, 49:1-10, 11:29-13:18, 16:24-19:20.) Therefore, accepting Merck's contentions as true, Merck's October 2001 provisional reduced to practice each of the '600 patent claims before Idenix's earliest alleged reduction to practice in June 2002, which gives Merck priority, unless Idenix can show an earlier conception. *Mahurkar*, 79 F.3d at 1577.

Idenix cannot identify any evidence showing that it conceived before the October 25, 2001 provisional. Redacted

See, e.g., *Mahurkar*, 79 F.3d at 1577 ("This court has developed a rule requiring corroboration where a party seeks to show conception through the oral testimony of an inventor."). Redacted It is thus barred as a matter of law from establishing an earlier conception, and, as a result, all the asserted '600 claims are invalid as anticipated.

D. The Court Should Grant Summary Judgment that Gilead Is Not Willfully Infringing Any of the Patents-in-Suit.

This Court should also eliminate willfulness from the case because Gilead's positions on all three patents-in-suit are objectively reasonable and held in good faith. The current standard for willfulness requires proof that the alleged infringer acted despite (1) an "objectively high likelihood that its actions constituted infringement of a valid patent" and (2) "this objectively-defined risk (determined by the record developed in the infringement proceeding) was either known or so obvious that it should have been known to the accused infringer." *In re Seagate Tech., LLC*, 497 F.3d 1360, 1371 (Fed. Cir. 2007) (*en banc*). The Supreme Court is currently reviewing the *Seagate* test in *Halo Electronics, Inc. v. Pulse Electronics, Inc.*, 769 F.3d 1371 (Fed. Cir. 2014), *cert. granted* 136 S. Ct. 356 (2015), and it may change the standard. But whatever the Supreme Court does, it is likely to follow its own precedent, which precludes enhanced damages where the defendant holds a good faith belief it does not infringe a valid patent. *See, e.g.*, *Seymour v. McCormick*, 57 U.S. 480, 488 (1854) (explaining that it was "manifestly unjust" to allow treble damages against a defendant "who acted in ignorance or good faith" because this would treat it the same as "the wanton and malicious pirate"). Gilead has at all times acted in good faith, and the Court should thus eliminate willfulness from the case.

Gilead's good faith is plain with respect to the '600 patent. The Patent Office has held all the asserted claims of the '600 patent unpatentable in an interference proceeding, explaining that Idenix's specification does not enable the skilled artisan to make and use the claimed method of treatment with 2'-fluoro down nucleosides. (Ex. 14 at 9-40.) That decision follows another Patent Office decision that held the '600 patent specification does not enable Idenix's other claims to the 2'-fluoro down nucleosides themselves. (Ex. 35.)

The Patent Office was in good company—every tribunal to consider the issue, including courts in the United Kingdom, Canada, Australia, Germany, and Norway, and the European Patent Office, has reached the same result on the foreign counterparts to the '600 patent. All these tribunals have correctly decided the issue, because not only was both Idenix's '600 patent specification and all the prior art devoid of any teaching about how to make the claimed tertiary 2'-fluoro down nucleoside, but Idenix itself tried and failed to do so for years, including well after the filing date of its patent. (Ex. 14 at 9-40.) In fact, it was not until after Idenix saw Gilead's published patent application, which disclosed the exact synthesis for the desired 2'-fluoro nucleoside, that Idenix's scientists could make it. (*Id*.) Gilead is confident that it will prevail in Idenix's Federal Circuit appeal challenging the cancellation of the '600 patent's asserted claims, and, if it does, that will eliminate Idenix's infringement claim here. Nevertheless, Gilead has at least a good faith belief that its invalidity position is correct and that is enough to preclude a finding of willful infringement as a matter of law, under any proper formulation. And, perhaps more to the point, Idenix cannot point to any evidence of bad faith that could create a disputed issue of material fact on this issue given the Patent Office's decision cancelling the asserted '600 patent claims. In addition, Merck's prior work is an independent reason that the '600 patent is invalid and also an independent basis for Gilead's good faith belief.

Gilead's good faith is also plain with respect to the '054 and '597 patents. The written description section above establishes that the asserted claims of these patents are all invalid based on Federal Circuit precedent that prohibits the very type of belated broadening that Idenix has attempted with these patents. And Idenix's position that it was the first to invent the claimed subject matter conflicts with that of its parent company, Merck, who says that it was first. Likewise, if, as the Patent Office correctly found, the '600 patent does not enable making a 2'-

methyl up, 2'-fluoro nucleoside, then the earlier '054 and '597 patents certainly do not do so either, even though such a nucleoside is within the claims as construed. At a minimum, Gilead's positions on these issues are reasonable and held in good faith, which should preclude any charge of willfulness. Moreover, as noted in the prior section on indirect infringement, Gilead also continues to hold a good faith belief that it will prevail on claim construction at the Federal Circuit and thus does not infringe. Idenix cannot point to any evidence suggesting that Gilead does not believe its defenses in good faith, so willfulness should be out of the case for these patents as well.

E. The Court Should Adopt the Patent Office's Definition of the Count for the Interference if It Invalidates the '600 Patent.

Gilead's final issue relates to Idenix's appeal from its loss in a Patent Office interference proceeding involving whether a Gilead patent (No. 7,429,572) or an Idenix patent application (No. 12/131,868) was entitled to priority of invention for the overlapping subject matter they both claimed. Gilead asks this Court to define the "count" to be used in adjudicating this appeal, which is the description of the common subject matter claimed in both parties' patents or applications. *See, e.g.*, *Genetics Inst., LLC v. Novartis Vaccines and Diagnostics, Inc.*, 687 F. Supp. 2d 486, 495 (D. Del. 2010) ("the court must define the 'count,' or the common subject matter between the claims"); 37 C.F.R. § 41.201 (2004) ("Count means the Board's description of the interfering subject matter that sets the scope of admissible proofs on priority."). "Patent interference count construction is a matter of law." *Adang v. Fischhoff*, 286 F.3d 1346, 1353 (Fed. Cir. 2002). The count construction is ripe for resolution, and the Court should adopt the same definition of the count that the Patent Office used.

The Patent Office defined the "count" for this interference, which it called "Count I," to include a group of 2'-methyl up, 2-fluoro down nucleosides. (*See* Ex. 35 at 2.) Idenix had urged

the Patent Office to define the count more broadly (as what Idenix called either "Count C" or "Count D"), in the hopes that it would allow Idenix to sweep in more evidence showing earlier work on compounds that were not within the scope of Count I. (Ex. 36 at 1, Appx. 3-1, Appx. 4-1-2.) But the Patent Office adhered to its Count I. (Ex. 35 at 2.) After Idenix appealed to this Court, Gilead asked the Court to define the count in conjunction with the *Markman* ruling. (D.I. 133, 136.) Idenix opposed, arguing that the count definition "implicates complex patent issues normally decided after fact discovery, after expert discovery, and often after a trial," (D.I. 135 at 1), and complained that it would "require expert testimony on the state of the art and analysis of prior art, among other issues." (*Id*. at 3.) The Court ultimately declined to construe the count at that time.

Discovery is now complete, and Idenix has not attempted to challenge the Patent Office's definition of the count. Idenix's expert reports never attempted to argue that the Patent Office had erred in defining the count as Count I, nor did they advocate for Idenix's previously preferred definition (Count D). The Court should thus streamline its review of the Patent Office's interference decision by adopting the Patent Office's definition of the count, which can be found in the cited portion of its opinion. (Ex. 35 at 2.)

V. CONCLUSION

For the reasons above, this Court should grant Gilead's summary judgment motions and dismiss this suit with prejudice.

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