

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

IDENIX PHARMACEUTICALS LLC,
UNIVERSITA DEGLI STUDI di CAGLIARI,
CENTRE NATIONAL de la RECHERCHE
SCIENTIFIQUE, and
L'UNIVERSITÉ de MONTPELLIER,

Plaintiffs,

v.

GILEAD SCIENCES, INC. and GILEAD
PHARMASSET LLC,

Defendants.

Civil Action No. 13-1987-LPS

IDENIX PHARMACEUTICALS LLC,
UNIVERSITA DEGLI STUDI di CAGLIARI,
CENTRE NATIONAL de la RECHERCHE
SCIENTIFIQUE, and
L'UNIVERSITÉ de MONTPELLIER,

Plaintiffs,

v.

GILEAD PHARMASSET LLC,

Defendant.

Civil Action No. 14-109-LPS

IDENIX PHARMACEUTICALS LLC and
UNIVERSITA DEGLI STUDI di CAGLIARI,

Plaintiffs,

v.

GILEAD SCIENCES, INC.,

Defendant.

Civil Action No. 14-846-LPS

Steven J. Balick, John G. Day, and Andrew C. Mayo, ASHBY & GEDDES, Wilmington, DE

Calvin P. Griffith, Ryan B. McCrum, Leozino Agozzino, and Michael S. Weinstein, JONES DAY, Cleveland, OH

Anthony M. Insogna and John D. Kinton, JONES DAY, San Diego, CA

John M. Michalik and Lisa L. Furby, JONES DAY, Chicago, IL

Jennifer L. Swize, JONES DAY, Washington, DC

Tharan G. Lanier, JONES DAY, Palo Alto, CA

Attorneys for Plaintiffs.

Martina Tyreus Hufnal, Joseph B. Warden, and Santosh V. Coutinho, FISH & RICHARDSON P.C., Wilmington, DE

Frank E. Scherkenbach and Jenny Shmuel, FISH & RICHARDSON P.C., Boston, MA

W. Chad Shear and Craig E. Countryman, FISH & RICHARDSON P.C., San Diego, CA

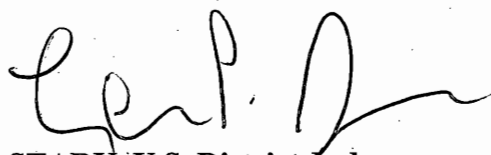
Jonathan E. Singer and Tasha M. Francis, FISH & RICHARDSON P.C., Minneapolis, MN

Corrin N. Drakulich, FISH & RICHARDSON P.C., Atlanta, GA

Attorneys for Defendants.

MEMORANDUM OPINION

November 16, 2016
Wilmington, Delaware



STARK, U.S. District Judge:

Plaintiffs Idenix Pharmaceuticals LLC, Università Degli Studi di Cagliari, Centre National de la Recherche Scientifique, and L'Université Montpellier (together, "Plaintiffs" or Idenix) filed three actions against Defendants Gilead Pharmasset LLC and Gilead Sciences, Inc. (together, "Gilead" or "Defendants"): (i) an action for a declaration of patent infringement and adjudication of Plaintiffs' priority of invention with respect to U.S. Patent No. 7,608,600¹ over U.S. Patent No. 8,415,322 (C.A. 13-1987 D.I. 1); (ii) an appeal of a decision and judgment of priority by the Patent Trial and Appeal Board ("PTAB") regarding U.S. Patent Application Serial No. 12/131,868 (C.A. No. 14-109 D.I. 1); and (iii) an action for a declaration of patent infringement of U.S. Patent Nos. 6,914,054² (the "'054 patent") and 7,608,597³ (the "'597 patent") (C.A. No. 14-846 D.I. 1).⁴

The Court previously construed a number of contested claim terms in this matter. (*See* D.I. 237) On June 1, 2016, Defendants moved for summary judgment on multiple issues, including lack of written description in the '054 and '597 patents. (*See* D.I. 287) The Court denied the motion. (*See* D.I. 367) The Court's denial was without prejudice to renew following additional claim construction, as the Court determined that a claim construction dispute was at

¹The '600 patent is entitled "Modified 2' and 3'-Nucleoside Prodrugs for Treating *Flaviviridae* Infections." It was issued on October 27, 2009. (C.A. No. 13-1987 D.I. 1, Ex. A)

²The '054 patent is entitled "Methods and Compositions for Treating Hepatitis C Virus." It was issued on July 5, 2005. (C.A. No. 14-846 D.I. 1, Ex. A)

³The '597 patent is entitled "Methods and Compositions for Treating Hepatitis C Virus." It was issued on October 27, 2009. (C.A. No. 14-846 D.I. 1, Ex. B)

⁴Hereinafter, all citations to the record are to C.A. No. 14-846.

least one of the reasons summary judgment was not warranted. (*See* D.I. 368 at 138-39) The Court ordered supplemental claim construction briefing and allowed Gilead to renew its motion if desired. (*See id.* at 138-140)

Pending before the Court is claim construction of two disputed terms in the '054 and '597 patents as well as Defendants' renewed motion for summary judgment on written description grounds. (D.I. 377) The parties completed briefing on these issues on September 16, 2016. (*See* D.I. 376, 378, 380, 390, 392, 393, 398) The Court heard oral argument on October 7, 2016. (*See* D.I. 410 ("Tr."))

I. LEGAL STANDARDS

A. Claim Construction

The ultimate question of the proper construction of a patent is a question of law. *See Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 837 (2015) (citing *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388-91 (1996)). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). "[T]here is no magic formula or catechism for conducting claim construction." *Id.* at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which is] the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a

claim term is its meaning to the ordinary artisan after reading the entire patent.” *Id.* at 1321 (internal quotation marks omitted). The patent specification “is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.” *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While “the claims themselves provide substantial guidance as to the meaning of particular claim terms,” the context of the surrounding words of the claim also must be considered.

Phillips, 415 F.3d at 1314. Furthermore, “[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent” *Id.* (internal citation omitted).

It is likewise true that “[d]ifferences among claims can also be a useful guide For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim.” *Id.* at 1314-15 (internal citation omitted). This “presumption is especially strong when the limitation in dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim.” *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that “the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor’s lexicography governs.” *Phillips*, 415 F.3d at 1316. It bears emphasis that “[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.” *Hill-Rom Servs., Inc. v. Stryker*

Corp., 755 F.3d 1367, 1372 (Fed. Cir. 2014) (internal quotation marks omitted).

In addition to the specification, a court “should also consider the patent’s prosecution history, if it is in evidence.” *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 980 (Fed. Cir. 1995), *aff’d*, 517 U.S. 370 (1996). The prosecution history, which is “intrinsic evidence,” “consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent.” *Phillips*, 415 F.3d at 1317. “[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be.” *Id.*

In some cases, “the district court will need to look beyond the patent’s intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period.” *Teva*, 135 S. Ct. at 841. Extrinsic evidence “consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises.” *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the court in determining the meaning of a term to those of skill in the relevant art because such dictionaries “endeavor to collect the accepted meanings of terms used in various fields of science and technology.” *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful “to ensure that the court’s understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field.” *Id.* Nonetheless, courts must not lose sight of the fact that “expert reports and

testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence.” *Id.* Overall, while extrinsic evidence “may be useful” to the court, it is “less reliable” than intrinsic evidence, and its consideration “is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence.” *Id.* at 1318-19. Where the intrinsic record unambiguously describes the scope of the patented invention, reliance on any extrinsic evidence is improper. *See Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999) (citing *Vitronics*, 90 F.3d at 1583).

Finally, “[t]he construction that stays true to the claim language and most naturally aligns with the patent’s description of the invention will be, in the end, the correct construction.” *Renishaw PLC v. Marposs Societa’ per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that “a claim interpretation that would exclude the inventor’s device is rarely the correct interpretation.” *Osram GmbH v. Int’l Trade Comm’n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007) (internal quotation marks omitted).

B. Motion for Summary Judgment

Pursuant to Rule 56(a) of the Federal Rules of Civil Procedure, “[t]he court shall grant summary judgment if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law.” The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 585-86 (1986). An assertion that a fact cannot be – or, alternatively, is – genuinely disputed must be supported either by citing to “particular parts of materials in the record, including depositions, documents, electronically stored information,

affidavits or declarations, stipulations (including those made for purposes of the motion only), admissions, interrogatory answers, or other materials,” or by “showing that the materials cited do not establish the absence or presence of a genuine dispute, or that an adverse party cannot produce admissible evidence to support the fact.” Fed. R. Civ. P. 56(c)(1)(A) & (B). If the moving party has carried its burden, the nonmovant must then “come forward with specific facts showing that there is a genuine issue for trial.” *Matsushita*, 475 U.S. at 587 (internal quotation marks omitted). The court will “draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence.” *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000).

To defeat a motion for summary judgment, the nonmoving party must “do more than simply show that there is some metaphysical doubt as to the material facts.” *Matsushita*, 475 U.S. at 586; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment “must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue”) (internal quotation marks omitted). The “mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;” a factual dispute is genuine only where “the evidence is such that a reasonable jury could return a verdict for the nonmoving party.” *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986). “If the evidence is merely colorable, or is not significantly probative, summary judgment may be granted.” *Id.* at 249-50 (internal citations omitted); *see also Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986) (stating entry of summary judgment is mandated “against a party who fails to make a showing sufficient to establish the existence of an element essential to that party’s case, and on which that party will

bear the burden of proof at trial”). Thus, the “mere existence of a scintilla of evidence” in support of the nonmoving party’s position is insufficient to defeat a motion for summary judgment; there must be “evidence on which the jury could reasonably find” for the nonmoving party. *Anderson*, 477 U.S. at 252.

C. Written Description

Whether a specification satisfies the written description requirement is a question of fact. See *GlaxoSmithKline LLC v. Banner Pharmacaps, Inc.*, 744 F.3d 725, 729 (Fed. Cir. 2014); see also *Alcon, Inc. v. Teva Pharms. USA, Inc.*, 664 F. Supp. 2d 443, 468 (D. Del. 2009) (“Satisfaction of the written description requirement is a fact-based inquiry, depending on ‘the nature of the claimed invention and the knowledge of one skilled in the art at the time an invention is made and a patent application is filed.’”) (quoting *Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008)). Nevertheless, the issue of invalidity for lack of written description is amenable to summary judgment under certain circumstances. See, e.g., *Carnegie Mellon*, 541 F.3d at 1126-28 (affirming summary judgment of invalidity for lack of written description); see also *Helicos Biosciences Corp. v. Illumina, Inc.*, 888 F. Supp. 2d 519, 530-31 (D. Del. 2012) (“While compliance with the written description requirement is a question of fact, the issue is ‘amenable to summary judgment in cases where no reasonable fact finder could return a verdict for the non-moving party.’”) (quoting *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1307 (Fed. Cir. 2008)).

To comply with the written description requirement, a patent’s specification “must clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed.” *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (internal brackets and

quotation marks omitted). “[T]he test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.” *Id.* “[T]he hallmark of written description is disclosure. Thus, ‘possession as shown in the disclosure’ is a more complete formulation” of the written description requirement. *Id.* “[T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art.” *Id.* “[T]he written description requirement does not demand either examples or an actual reduction to practice; a constructive reduction to practice that in a definite way identifies the claimed invention can satisfy the written description requirement.” *Id.* at 1352. However, “a description that merely renders the invention obvious does not satisfy the requirement.” *Id.*

II. CONSTRUCTION OF DISPUTED TERMS

A. “method for [the] treatment of a Hepatitis C virus infection”⁵

<p>Plaintiffs The preambles are limitations: plain and ordinary meaning. Alternatively, a method in which an HCV infection is treated.</p>
<p>Defendants Plain and ordinary meaning: given for the purpose of stopping or slowing the progression of HCV. (Non-limiting preamble)</p>
<p>Court The preambles are claim limitations and will be given their plain and ordinary meaning.</p>

The parties dispute whether the relevant claims’ preambles “limit the claims to methods in which an HCV infection is treated,” as Plaintiffs contend (D.I. 376 at 1-2), or merely recite a purpose or an intended use in a non-limiting fashion, which is Defendants’ position (D.I. 380 at

⁵This term appears in claim 26 of the ’054 patent and claim 1 of the ’597 patent.

1). Generally, a preamble is not limiting unless it recites an “essential structure or steps” or is “necessary to give life, meaning, and vitality to the claim.” *Catalina Mktg. Int'l, Inc. v. Coolsavings.com, Inc.*, 289 F.3d 801, 808 (Fed. Cir. 2002) (internal quotation marks omitted). Put another way, “[a] preamble is not limiting where a patentee defines a structurally complete invention in the claim body and uses the preamble only to state a purpose or intended use for the invention.” *Id.* (internal quotation marks omitted). “Whether to treat a preamble as a claim limitation is determined on the facts of each case in light of the claim as a whole and the invention described in the patent.” *Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 831 (Fed. Cir. 2003).

Idenix emphasizes that the “essence of the invention” is the treatment of the Hepatitis C virus infection (“HCV”) and that the specifications “expressly teach that a method using a compound that is *ineffective* (*e.g.*, it has no anti-HCV activity) is not within the bounds of the invention.” (D.I. 376 at 3) Idenix suggests that, if the preambles are not claim limitations, then “performing the method steps of the claims would be a purely academic exercise,” because the remaining steps of the claims “do not recite what the ribonucleosides are effective for.” (*Id.* at 5) Gilead responds that the preambles require at most that the nucleosides “be used to *try* to slow or stop the progression of HCV,” without regard to the actual efficacy of the compounds. (D.I. 392 at 2 (emphasis added); *see also* Tr. at 15)

The Court finds the preambles here to be claim limitations because they are “essential to understand[ing] limitations or terms in the claim body.” *Catalina Marketing*, 289 F.3d at 808. The preambles “give life” to these claims because a full understanding of the “effective amount” terms (as discussed further below) depends on what the relevant compounds must be effective

for. Put another way, the bodies of the relevant claims do not, in the absence of a limiting preamble, “define[] a structurally complete invention.” *Id.* (internal quotation marks omitted).

Gilead, pointing to the prosecution history, argues that the “‘core of the invention’ was a class of compounds.” (D.I. 392 at 2 (quoting D.I. 376-4 at 11)) But emphasizing this supposed “core” is not the most reasonable characterization of the intrinsic record as a whole. Gilead’s view is in tension with the plain language and form of the method claims at issue and with the patentees’ representation that “[a]pplicants are not aware of any prior disclosure of the *use of* a pyrimidine nucleoside with a ‘2’-branched’ carbon to treat [HCV].” (D.I. 376-4 at 11 (emphasis added))

Because “deletion of the preamble phrase[s]” would “affect the structure or steps of the claimed invention,” the preambles are not “merely duplicative.” *TomTom, Inc. v. Adolph*, 790 F.3d 1315, 1324 (Fed. Cir. 2015) (internal quotation marks omitted). The Court will construe the preambles as limitations, which are given their plain and ordinary meaning.

B. “[antivirally] effective amount”⁶

Plaintiffs Plain and ordinary meaning; an amount [of the claimed ribonucleoside (’054 patent) / ribofuranosyl nucleoside (’597 patent)] that is effective to treat HCV
Defendants an amount [of a claimed nucleoside] that produces an antiviral effect / an amount [of a claimed nucleoside] that is effective
Court an amount [of the claimed ribonucleoside (’054 patent) / ribofuranosyl nucleoside (’597 patent)] that is effective to treat HCV

⁶The term “effective amount” appears in claim 1 of the ’597 patent, and the term “antivirally effective amount” appears in claim 26 of the ’054 patent.

The parties present a related disputed over whether the “effective amount” terms “narrow the chemical structure of the nucleosides recited later in the claim[s]” to those that are in fact effective for the treatment of HCV. (D.I. 392 at 3) Idenix contends that the claims are narrowed in this manner, while Gilead disagrees. Although Gilead agrees with Idenix that the compounds “are to be used for [treatment of HCV],” Gilead nonetheless insists that these “effective amount” terms do not constrain the chemical structure of the compounds the patentee claimed. (*Id.*) In Gilead’s view, “the term refers only to *how much* of a claimed nucleoside is administered.” (D.I. 380 at 2) The Court disagrees with Gilead.

The term “[antivirally] effective” modifies the word “amount.” In a vacuum, Gilead’s view that these “effective amount” terms are solely quantitative limitations might prevail. But claim language must be construed in the context of the claim as a whole. *See IGT v. Bally Gaming Int’l, Inc.*, 659 F.3d 1109, 1117 (Fed. Cir. 2011). “Extracting a single word from a claim divorced from the surrounding limitations can lead construction astray.” *Id.* Given the Court’s finding that the preambles are limiting, the claims are explicitly directed to – and, as explained above, limited to – *methods* for the treatment of HCV. The patents’ abstracts disclose “[a] method and composition for treating a host infected with hepatitis C comprising administering an effective hepatitis C treatment amount of a described 1’, 2’, or 3’-modified nucleoside.” (*E.g.*, ’597 patent at abstract) The specifications are replete with references to treatment of HCV, including that “it is an object of the present invention to provide a compound, method and composition for the treatment of [HCV].” (*E.g.*, ’054 patent at 5:23-25)

Crucially, as Plaintiffs explain, “if no amount of a particular ribonucleoside can be administered to effectively treat HCV, then administering that ribonucleoside does not practice

the claims.” (D.I. 376 at 7) In other words, because *some amount* of the composition must be “effective,” the overall scope of the claims does *not* include compounds that are *not* effective (for the claimed purpose) at *any* amount. In this way, Plaintiffs’ proposed construction, which the Court adopts, “stays true to the claim language and most naturally aligns with the patent’s description of the invention.” *Renishaw*, 158 F.3d at 1250.

At oral argument, counsel for Gilead asserted that none of cases Idenix cites in support of its proposed construction “interprets the term ‘effective amount’ to impose a structural limitation of any kind on the claimed compound.” (Tr. at 21) But neither does Gilead direct the Court to any cases that reject such a construction.

Gilead also attacks Idenix’s construction for excluding preferred embodiments. (*See, e.g.*, Tr. at 25) Idenix disputes whether this is the result of adoption of its proposed construction. (*See* Tr. at 33 (“I don’t agree that a preferred embodiment is not covered by these claims.”)) Either way, any “reluctan[ce] to exclude an embodiment” cannot “outweigh the language of the claim, especially when the court’s construction is supported by the intrinsic evidence.” *Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1334 (Fed. Cir. 2010) (internal quotation marks omitted); *see also Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1347–48 (Fed. Cir. 2009) (“It is the claims that define the metes and bounds of the patentee’s invention. The claims, not specification embodiments, define the scope of patent protection.”) (internal citation omitted). The claims’ language logically requires that “[m]ethods that administer ineffective compounds” fall “outside the scope of the claims.” (D.I. 376 at 8)

Gilead also highlights what it contends is tension between Plaintiffs’ expert, Dr. Meier, and the disclosures of the specifications. (*See* D.I. 380 at 3 (“Idenix’s experts have used . . .

phantom limitations to exclude many compounds that the specification itself suggests are effective.”)) But even Gilead’s expert “agree[d] that the methods of the asserted claims of the ’597 patent only ‘cover compounds that are effective’ to treat HCV.” (D.I. 285-4 at 21-22, 41-42, ¶¶ 52, 96 (quoting Dr. Meier’s rebuttal report)) Given that the Court’s task at claim construction is to construe the disputed terms “as an ordinary artisan would have understood them,” *Wi-LAN USA, Inc. v. Apple Inc.*, 830 F.3d 1374, 1381 (Fed. Cir. 2016), it is significant that both sides’ experts appear to agree that the scope of the claims is limited to effective compounds.

The claims’ language requires that the Court construe the preambles and effective amount terms to limit the scope of the claims to the use of some set of compounds that are effective for treatment of HCV.

C. Indefiniteness

Gilead contends that the constructions proposed by Idenix, and now adopted by the Court, render the claims invalid as indefinite. “[A] patent is invalid for indefiniteness if its claims . . . fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.” *Nautilus, Inc. v. Biosig Instruments, Inc.*, 134 S.Ct. 2120, 2124 (2014). Gilead bears the burden of proving “any fact critical to a holding on indefiniteness” by clear and convincing evidence. *Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1366 (Fed. Cir. 2003). Gilead argues that the claims as construed fail the *Nautilus* test because the patents do not “provide sufficient guidance regarding whether a nucleoside is ‘effective’ against Hepatitis C or ‘mimics’ a natural nucleoside.” (D.I. 380 at 6) The Court is not persuaded that Gilead has proven, by clear and convincing evidence, that the claims must be deemed invalid as indefinite.

Gilead points to this Court's recent decision in *BASF Corporation v. Johnson Matthey Inc.*, 2016 WL 661407 (D. Del. Feb. 9, 2016). That case involved construction of claim language that included, for example, "material composition A effective for catalyzing NH₃ oxidation." *Id.* at *2. The Court found this language indefinite, observing that it recited "a performance property the composition must display, rather than its actual composition." *Id.*

BASF is distinguishable for numerous reasons, most prominent being the overwhelming breadth of the claim language involved there. The claim found to be indefinite in *BASF* lacked any sort of structural limitation, leading the Court to observe that "a practically limitless number of materials" existed that would exhibit the claimed performance property. *Id.* at *2 n.10. By contrast, the claims here explicitly limit the methods to use of β -D-2'-C-branched or β -D-2'-methyl-ribofuranosyl nucleosides. While this evidently captures an extremely large number of compounds, it is not "practically limitless" but is, instead, meaningfully bound by the explicit chemical structure identified in the claims.

Gilead also relies on *Geneva Pharmaceuticals, Inc. v. GlaxoSmithKline PLC*, 349 F.3d 1373 (Fed. Cir. 2003). In *Geneva*, the Federal Circuit rejected as indefinite a proposed reading of a claim that would have "ma[d]e the dosage range depend on the particular antibiotic and bacteria." *Id.* at 1384. Under such a construction, "a formulation . . . might infringe or not depending on its usage in changing circumstances;" "a given embodiment would simultaneously infringe and not infringe the claims, depending on the particular bacteria chosen for analysis." *Id.* There is no similar result here. Instead, a compound meeting the structural and other limitations of the claim that is also effective to treat HCV is within the scope of the claims, while compounds meeting only the structural limitations (but not being effective to treat HCV) are

outside the scope of the claims. Thus, the claims “afford clear notice of what is claimed.”

Nautilus, 134 S.Ct. at 2129. Accordingly, Gilead has failed to persuade the Court that the claims are invalid as indefinite.

III. SUMMARY JUDGMENT

In addition to providing supplemental claim construction briefing, Gilead has again moved for summary judgment that the claims of the '054 and '597 patents are invalid due to lack of written description. Gilead bases its motion on the lack of antiviral data in the '054 and '597 patents, along with the specifications' inclusion of a broad set of nucleosides that are ineffective against HCV, resulting in “an utter failure to describe the claimed invention.” (D.I. 378 at 1) In Gilead's view, the claims – as the Court has now construed them – cover use of a subgenus, but the specifications “provide no blaze marks that would direct the skilled artisan to this subgenus.” (D.I. 378 at 4)

Gilead faults Idenix for relying, improperly, on expert testimony to “supply the blaze marks that the specification lacks.” (D.I. 398 at 4) In Gilead's view, Idenix's expert, Dr. Meier, excludes certain embodiments, configurations, and subembodiments disclosed in the specifications, without any valid basis to do so. (*See generally* D.I. 289-7). Gilead also takes issue with the specifications' lack of “[a]ntiviral data showing which nucleosides work and which do not.” (D.I. 398 at 1) Gilead relies principally on two cases in support of its position: *Boston Scientific Corp. v. Johnson & Johnson*, 647 F.3d 1353 (Fed. Cir. 2011), and *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336 (Fed. Cir. 2013).

Idenix appears to accept that there is some inconsistency – or at least a difference in breadth – between the specifications and the scope of the claims as construed. Idenix contends

that any such discrepancy is irrelevant to the issue of written description (although allowing that it may be pertinent to the issue of enablement, which is not presently ripe for the Court's attention). In response to Gilead's arguments concerning the lack of "blaze marks," Idenix points to Dr. Meier's reliance on, among other things, the disclosure that the invention's nucleosides "may inhibit HCV polymerase activity" (D.I. 391-11 at 19 ¶ 63), his examination of the patents' formulas (*see, e.g., id.* at 22-23), and toxicity data (*see, e.g., id.* at 42-43).⁷ With respect to antiviral data, Idenix notes the specifications' discussion of assays and disclosure of "phosphorylation data, oral bioavailability data, pharmacokinetics data, and toxicity data (both bone marrow and mitochondrial)." (D.I. 390 at 13)⁸ Idenix also attempts to distinguish the *Boston Scientific* and *Novozymes* cases.

Written description is about whether the "inventor had possession of the claimed subject matter." *Ariad Pharm.*, 598 F.3d at 1351. On that point, Idenix's expert, Dr. Meier, has opined, for example, that the '054 patent "demonstrates that the inventors had possession of a definite class of compounds . . . useful in the treatment of HCV, namely those . . . that resemble the naturally occurring substrate of the HCV polymerase sufficiently to be useful for inhibiting HCV polymerase." (D.I. 391-11 at 18 ¶ 59) Dr. Meier provided a variety of reasons in support of his conclusion, asserting that "the skilled artisan reading the '054 patent would have identified as the

⁷The patents explicitly note that "[t]he compounds of this invention either possess antiviral (i.e., anti-HCV) activity, or are metabolized to a compound that exhibits such activity." (*E.g.*, '054 patent at 15:38-40)

⁸As Gilead points out, certain portions of the specifications were added in May 2001 and were not present at the original May 2000 filing date. At oral argument, the parties agreed that this distinction was not directly relevant to the binary question of whether the invention is adequately described. (*See* Tr. 52-53)

inventors' invention . . . modified ribonucleoside analogues . . . that otherwise mimic the naturally occurring ribonucleosides closely enough to be recognized and used by the HCV polymerase.” (*Id.* at 24-25 ¶ 82) A reasonable factfinder could credit Dr. Meier’s opinion and analysis and find, as he opines, that the inventors had possession of the claimed invention (as the Court has construed it). The record also contains Gilead documents, from which a reasonable factfinder might conclude that Gilead (and/or its predecessor) recognized that the inventors of the patents-in-suit were in possession of their claimed invention. (*See* D.I. 391-1 at 24 of 28; D.I. 391-3 at 27 of 36)

The Federal Circuit has explained that patents can be categorized as those relating to “generic inventions that are adequately supported, those that are merely a ‘wish’ or ‘plan’ . . . and those in between.” *Capon v. Eshhar*, 418 F.3d 1349, 1360 (Fed. Cir. 2005) (internal citation omitted). In Gilead’s view, “Idenix’s inventors didn’t know themselves which compounds would be effective,” so the patents-in-suit are invalid, as they are nothing more than “an invitation to conduct research with no blaze marks to the subgenus that Idenix has concocted in hindsight.” (D.I. 398 at 7) This appears to be one reasonable interpretation of the record, one which a reasonable factfinder might credit. But the record as a whole does not compel this as the only supportable conclusion that could be drawn by a reasonable factfinder.

Boston Scientific and *Novozymes* are of limited value to Gilead because both cases involved even less written description support than is found in the specifications here. In *Boston Scientific*, the Federal Circuit affirmed a finding of invalidity of a patent that “disclosed a genus . . . , but claimed a narrower sub-genus.” *Boston Sci.*, 647 F.3d at 1367. The Court found “nothing in [the patent] indicat[ing] that the claimed [narrower sub-genus] might be of special

interest.” *Id.* In *Novozymes*, 723 F.3d 1336, the Federal Circuit affirmed a finding of invalidity where the patent involved contained “no disclosure of any variant that actually satisfies the claims, nor . . . anything to suggest that Novozymes actually possessed such a variant at the time of filing.” *Id.* at 1348. Here, by contrast, a reasonable factfinder could agree with Dr. Meier that there is not “nothing” or “no disclosure;” instead, a reasonable factfinder could find that the specifications show the inventors were in possession of nucleosides with certain structural characteristics that were also effective to treat HCV.

Gilead has not met its burden to establish that “no finder of fact could reasonably determine that the asserted claims of the patents-in-suit contained an adequate written description.” *Boston Sci.*, 647 F.3d at 1356. Summary judgment is therefore inappropriate. The Court will deny Gilead’s motion.

IV. CONCLUSION

The Court will construe the disputed terms in the manner explained above. Gilead’s renewed motion for summary judgment will be denied. An appropriate Order follows.