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

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

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

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

John M. Michalik, JONES DAY, Chicago, IL.

Attorneys for Plaintiffs.

Douglas E. McCann, Martina Tyreus Hufnal, and Santosh V. Coutinho, FISH & RICHARDSON P.C., Wilmington, DE.

W. Chad Shear, FISH & RICHARDSON P.C., San Diego, CA.

John M. Farrell and Rebecca Charnas Grant, FISH & RICHARDSON P.C., Redwood City, CA.

Rebecca Shult and Tasha M. Francis, FISH & RICHARDSON P.C., Minneapolis, MN.

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

Attorneys for Defendants.

MEMORANDUM OPINION

December 16, 2015
Wilmington, Delaware

STARK, U.S. District Judge:

Plaintiffs Idenix Pharmaceuticals, Inc. ("Idenix"), Universita Degli Studi di Cagliari ("Cagliari"), Centre National de la Recherche Scientifique ("Centre National"), and L'Université Montpellier II ("Montpellier") (collectively, "Plaintiffs") filed three actions against Defendants Gilead Pharmassett LLC and Gilead Sciences, Inc. (collectively, "Gilead" or "Defendants"): an action for a declaration of patent infringement and adjudication of Plaintiffs' priority of invention of U.S. Patent No. 7,608,600[1] ("the '600 patent") over U.S. Patent No. 8,415,322 ("the '322 patent") (C.A. 13-1987, D.I. 1), 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 ("the '868 application") (C.A. No. 14-109, D.I. 1), and an action for a declaration of patent infringement of U.S. Patent Nos. 6,914,054[2] ("the '054 patent") and 7,608,597[3] ("the '597 patent") (C.A. No. 14-846, D.I. 1).

Pending before the Court is the issue of claim construction of various disputed terms of the '600, '054, and '597 patents.[4] The parties completed briefing on claim construction on August 6, 2015. (D.I. 128, 129, 138, 140) In addition to the briefing, the parties submitted technology tutorials. (D.I. 126, 127) The Court held a Markman hearing on October 19, 2015.

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[1]The '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)

[2]The '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)

[3]The '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)

[4]Hereinafter, all citations to the record are to C.A. No. 13-1987.

("Tr.")

I. LEGAL STANDARDS

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. Conceptronic, 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." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

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) (quoting *Modine Mfg. Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1550 (Fed. Cir. 1996)).

II. CONSTRUCTION OF DISPUTED TERMS

A. The '054 Patent: "ß-D-2'-C-branched pyrimidine nucleoside"

Plaintiffs A ß-D-pyrimidine nucleoside having two non-hydrogen substituents at the 2' position, at least one of which is connected at the 2' position through a carbon-to-carbon bond.
Defendants A ß-D-pyrimidine nucleoside having two non-hydrogen substituents at the 2' position, at least one of which is connected at the 2' position through a carbon-to-carbon bond, and no fluorine at the 2' down position.
Court A ß-D-pyrimidine nucleoside having two non-hydrogen substituents at the 2' position, at least one of which is connected at the 2' position through a carbon-to-carbon bond.

The parties' only dispute with respect to this term is whether, as Defendants propose, it should be construed to include the negative limitation "and no fluorine at the 2' down position." It is undisputed that the plain and ordinary meaning of this term includes fluorine at the 2' down position. (D.I. 19 at 16; D.I. 129 at 4; Tr. at 30, 38) To depart from this ordinary meaning, the Court must find that the patentee expressed a clear intent to exclude fluorine at the 2' down position by acting as his own lexicographer or by intentionally disclaiming or disavowing fluorine at the 2' down position. *See Phillips*, 415 F.3d at 1316 (citing *SciMed Life Sys. Inc. v.*

Advanced Cardiovascular Sys. Inc., 242 F.3d 1337, 1343-44 (Fed. Cir. 2001)).

Here, Gilead does not argue that the patentee acted as its own lexicographer, but does argue that the patentee disavowed fluorine at the 2' down position. Though Gilead acknowledges that the patent does not expressly disclaim or disavow fluorine at the 2' down position (*see* Tr. at 12, 45-46), *see Abbott Labs v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1278-79 (Fed. Cir. 2003); *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352 (Fed. Cir. 2004), Gilead contends that the patentee ***implicitly*** disclaims fluorine at the 2' down position, *see Astrazeneca AB v. Mut. Pharm. Co.*, 384 F.3d 1333, 1340 (Fed. Cir. 2004); *see also SkinMedica, Inc. v. Histogen, Inc.*, 727 F.3d 1187, 1204 (Fed. Cir. 2013).

The standard for finding implicit disclaimer is "exacting." *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012). When determining whether a patent implicitly redefines a claim term, a court must be careful not to read limitations from the specification into the claims. *See id.* at 1366-67. Ultimately, an implicit disclaimer must be "so clear that it equates to an explicit one." *Id.* at 1368.

Hence, implicit disclaimers have been found only when the patentee clearly and unmistakably intends to exclude the relevant feature, such as when: (i) in describing the invention in a manner that does not include the relevant feature, the patent uses language such as "the present invention is," "the present invention requires," or "all embodiments of the present invention are," *see SciMed*, 242 F.3d at 1343-44; *Regents of Univ. of Minn. v. AGA Med. Corp.*, 717 F.3d 929, 936 (Fed. Cir. 2013); *Honeywell Int'l, Inc. v. ITT Indus., Inc.*, 452 F.3d 1312, 1316-19 (Fed. Cir. 2006); (ii) in describing a particular embodiment that does not include the relevant feature, the patent's specification makes clear that the particular embodiment

nonetheless contains another feature or element that is necessary, very important, or critical to the invention, *see Andersen Corp v. Fiber Composites, LLC*, 674 F.3d 1361, 1367 (Fed. Cir. 2007); or (iii) the patentee repeatedly disparages embodiments that include the relevant feature or otherwise makes clear that the feature cannot be part of the claimed invention, *see Chi. Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1372 (Fed. Cir. 2012); *SafeTCare Mfg., Inc. v. TeleMade, Inc.*, 497 F.3d 1262, 1269-70 (Fed. Cir. 2007); *SciMed*, 242 F.3d at 1342-45.

None of these circumstances is present here. Defendants cannot point to language in the specification to the effect that "the present invention is" or "requires" an embodiment excluding fluorine at the 2' down position. Nor do they identify anywhere the intrinsic evidence makes clear that an embodiment lacking fluorine at the 2' down position is critical to the invention. Defendants likewise fail to show where the patentee repeatedly disparaged embodiments that do or may include fluorine at the 2' down position.

Instead, Gilead points to the specification's disclosure of the preferred embodiment of 2'-C-branched ribonucleosides. The patent discloses many possible substituents for the 2' down position of this embodiment, including three of the five halogens (chlorine, bromine, and iodine), but never mentions fluorine – even though fluorine is a halogen and is disclosed as a possible substituent for the 2' up position. (*See, e.g.*, '054 patent at 43:53-44:26, 47:5-43, 50:39-51:13; Tr. at 33-35) However, the specification does not describe the preferred embodiment of 2'-C-branched-ribonucleosides as defining the invention. Rather, this section is introduced by the statement, "[t]he following ***non-limiting*** embodiments ***illustrate some*** general methodology to obtain the nucleosides of the present invention." ('054 patent at 43:50-52; '597 patent at 43:51-

53) (emphasis added)

Gilead observes that although fluorine is mentioned a total of 332 times in each specification, not one of these mentions has fluorine in the 2' down position. (*See* D.I. 128 at 17) (citing D.I. 28, Ex. B) The patent's failure to expressly disclose fluorine at the 2' down position does give the Court pause. But the patent's silence in this respect (i.e., whether fluorine ***could*** be in the 2' down position and still be within the scope of the claims) does not amount to a disclaimer. Because "[a]n invention is not limited to its examples," *Netcraft Corp. v. eBay, Inc.*, 549 F.3d 1394, 1400 (Fed. Cir. 2008); *see also Info-Hold, Inc. v. Applied Media Techs. Corp.*, 783 F.3d 1262, 1267 (Fed. Cir. 2015), "silence is not a sound basis on which to limit claims," *Honeywell Int'l, Inc. v. Nikon Corp.*, 589 F. Supp. 2d 433, 446 (D. Del. 2008).

Defendants can point to nowhere in the intrinsic record where a person of ordinary skill in the art would find "words or expressions of manifest exclusion or restriction." *Liebel-Flarsheim*, 358 F.3d at 906. The inventors stated multiple times during prosecution that the "core of the invention" is "a pyrimidine nucleoside that has two non-hydrogen substituents" without further excluding fluorine (which is a non-hydrogen substituent, and therefore within the scope of the claims). (*E.g.*, D.I. 128, Ex. 4) Additionally, when the examiner rejected a claim including non-hydrogen substituents at the 2' position in view of U.S. Patent No. 6,348,587 ("the Schinazi patent"), which disclosed fluorine at the 2' down position (*see* D.I. 129 at 6; Tr. at 48, 51), the patentee added a new claim that it distinguished from the Schinazi patent on a basis other than it not having fluorine at the 2' down position. (*See* D.I. 129, Ex. 8 at 3; D.I. 129, Ex. 6 at 13; Tr. at 51) Had the patentee understood its invention to exclude any embodiment with fluorine at the 2' down position, the patentee easily could have distinguished its patent on this basis.

In further support of its position, Gilead contends that the '054 and '597 patents fail to adequately describe or enable embodiments with fluorine at the 2' down position. (*See* D.I. 146 at 9-10; Tr. at 43) This may be so – but the Court is not at this stage addressing these issues. Generally, questions of validity such as inadequate written description or enablement are premature at the claim construction stage. *See Hill-Rom Servs., Inc. v. Stryker Corp.*, 755 F.3d 1367, 1374 (Fed. Cir. 2014) ("Enablement concerns do not justify departing from the plain and ordinary meaning of [a term]."); *Phillips*, 415 F.3d at 1327 ("While we have acknowledged the maxim that claims should be construed to preserve their validity, . . . we have certainly not endorsed a regime in which validity analysis is a regular component of claim construction. . . . Instead, we have limited the maxim to cases in which the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous.") (internal citations and quotation marks omitted).[5]

Accordingly, the Court will adopt Plaintiffs' proposed construction of this term.

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[5]Defendants rely on *Wang Labs., Inc. v. Am. Online, Inc.*, 197 F.3d 1377, 1381 (Fed. Cir. 1999), in which the Federal Circuit construed a disputed claim term in a manner that excluded features that were neither described nor enabled in the specification. This pre-*Phillips* case does not alter the Court's conclusion. In *Liebel-Flarsheim*, the Federal Circuit explained that in *Wang*, the lack of enablement was consistent with a prosecution history disclaimer, and that "*Wang* therefore does not stand for the proposition that if a patent specification describes only a particular embodiment, the claims must be limited to that subject matter." 358 F.3d at 907. Moreover, as Defendants acknowledge, the *Wang* Court had adequate extrinsic evidence before it to support exclusion of certain embodiments. (*See* Tr. at 41) Here, the record does not justify the exclusion sought by Defendants. Finally, the intrinsic evidence does not leave any ambiguity in the scope of the claim language. *See Vitronics*, 90 F.3d at 1583.

B. The '054 Patent: "ß-D-2'-C-branched pyrimidine ribonucleoside"

Plaintiffs A ß-D-pyrimidine ribonucleoside having a non-hydrogen substituent at the 3' down position and two non-hydrogen substituents at the 2' position, at least one of which is connected at the 2' position through a carbon-to-carbon bond.
Defendants A ß-D-pyrimidine ribonucleoside with a non-hydrogen substituent at the 2' up position that is connected at the 2' position through a carbon-to-carbon bond, and hydroxyl groups at the 2' down and 3' down positions. [To the extent the term is not construed to require a hydroxyl group at the 2' down position, the construction should specify that there is no fluorine in the 2' down position.]
Court A ß-D-pyrimidine ribonucleoside having a non-hydrogen substituent at the 3' down position and two non-hydrogen substituents at the 2' position, at least one of which is connected at the 2' position through a carbon-to-carbon bond.

The parties' principal dispute regarding this term is whether the 2' down and 3' down positions are limited to hydroxyl ("OH") groups, as Defendants contend. In the alternative, Defendants request a construction that at least excludes fluorine at the 2' down position. Plaintiffs oppose both of Defendants' proposals, contending that the claims encompass any non-hydrogen substituents at the 2' and 3' down positions.

It is undisputed that OH is required at the 2' and 3' down positions of a natural ribonucleoside. (D.I. 148 at 12-13; D.I. 148, Ex. 23 at 141:13-143:6, 184:21-185:1; Tr. at 98) However, the term the Court is being asked to construe does ***not*** refer to a natural ribonucleoside, and the Court is not convinced that the term is limited to a single species rather than a genus of compounds.[6] (*See* D.I. 148 at 13; Tr. at 83)

[6]Defendants provided extrinsic evidence, as well as much argument, to the effect that persons of ordinary skill in the art would understand the chemical nomenclature at the pertinent time to be consistent with Defendants' proposed construction, and not with Plaintiffs' proposal. (*See, e.g.*, D.I. 131 at 12-14, Tr. at 75-76) As the intrinsic evidence does not persuade the Court

Claims 1-24 of the '054 patent expressly require OH at the 2' and 3' down positions, but claim 26 does not. (*Compare* '054 patent at 160:2-164:35 *with id.* at 164:40-45) Defendants' contention that "[c]laim 26 simply describes the ribonucleosides depicted by claims 1-24, albeit with the potential for a wider range of modifications at the 2' up position" (D.I. 146 at 12) is unsupported. *See Vitronics*, 90 F.3d at 1583 (explaining that interpretations reading out preferred embodiments are "rarely, if ever, correct"). The specification's description of 2'-C-branched ribonucleosides includes various non-OH compounds at the 2' and 3' down positions. ('054 patent at 47:6-23; '597 patent at 47:2-23) During prosecution, the patentee referred to this description of 2'-C-branched-ribonucleoside including non-OH compounds at the 2' and 3' down positions. (D.I. 129, Ex. 6 at 11; D.I. 129, Ex. 9 at 66) Therefore, Defendants' construction would improperly exclude a preferred embodiment disclosed in the specification from the claim language.

Defendants point to the ribonucleosides depicted in Figure 1 of the specification, entitled "Chemical Structure of Illustrative Nucleosides," which show OH at the 2' and 3' down positions ('054 patent at Fig. 1; '597 patent at Fig. 1), and other parts of the specification that likewise have OH at the 2' and 3' down positions of ribonucleosides ('054 patent at 54:30-55:17 (Example 1), 159:40-62 (Table 5), 91:1-30 (Example 2), 125:24-60 (Example 3), 44:57-45:45 (Scheme 1), 46:37-65 (Scheme 2), 48:24-29 (Scheme 3), 49:47-50:31 (Scheme 4), 51:65-52:49 (Scheme 5), 53:12-54:22 (Scheme 6)) While these many embodiments are consistent with Defendants' construction, they do not constitute a disclaimer nor otherwise compel the Court to reject

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that the patentee intended to claim a species rather than a genus, the extrinsic evidence does not alter the Court's conclusion.

Plaintiffs' proposed construction. Because the Court finds the support for Plaintiffs' construction (including claim 26) to be more persuasive than the support for Defendants' construction, the Court will adopt Plaintiffs' proposal.

C. The '597 Patent: "ß-D-2'-methyl-ribofuranosyl nucleoside"

Plaintiffs A ß-D-nucleoside that includes a five member sugar ring with a methyl group in the 2' up position and non-hydrogen substituents at the 2' down and 3' down positions.
Defendants A ß-D-nucleoside that includes a five member sugar ring with a methyl group in the 2' up position and hydroxyl groups at the 2' down and 3' down positions. [To the extent the term is not construed to require a hydroxyl group at the 2' down position, the construction should specify that there is not fluorine in the 2' down position.]
Court A ß-D-nucleoside that includes a five member sugar ring with a methyl group in the 2' up position and non-hydrogen substituents at the 2' down and 3' down positions.

The parties agree that the dispute over this term is essentially the same as that over the previous term. (Tr. at 70, 73) The only additional intrinsic evidence for this term is a statement made by the patentee during prosecution identifying a compound with OH at the 2' and 3' down positions as a ß-D-2'-methyl-ribofuranosyl nucleoside. (*See* D.I. 131, Ex. H at 5) Defendants point to this as evidence that the patentee intended to limit ß-D-2'-methyl-ribofuranosyl nucleosides to compounds with OH at the 2' and 3' down positions. Again, however, this is not an unmistakable disclaimer of ß-D-2'-methyl-ribofuranosyl nucleosides with something other than OH at the 2' and 3' down positions. Accordingly, the Court will adopt Plaintiffs' proposed construction of this term.

D. The '054 and '597 Patents: "Nucleoside"

Plaintiffs A compound comprising a base linked to a sugar.
Defendants A compound comprising base and sugar moieties, with a hydroxyl group at the 5' position.
Court A compound comprising a base linked to a sugar.

The parties disagree about whether the 5' positions are limited to hydroxyl ("OH") groups, such that nucleosides exclude nucleotides, which have phosphate (a non-OH substituent) at the 5' position. It is "not disputed that a nucleotide is simply a phosphorylated version of a nucleoside." (Tr. at 106)

Plaintiffs rely on claim differentiation in support of their view that nucleosides should not be limited to compounds including OH at the 5' position. As Plaintiffs emphasize, claims 1-24 of the '054 patent expressly require OH at the 5' position, whereas claim 25 does not. (*Compare* '054 patent at 160:2-164:35 *with id.* at 164:36-39) Defendants contend that claim 25 differs from claims 1-24 because it allows for modifications at the ***2'*** position. Defendants again emphasize Figure 1 of the specifications, which shows the "Chemical Structure of Illustrative Nucleosides" and depicts OH in the 5' position ('054 patent at Fig. 1; '597 patent at Fig. 1); elsewhere, the specifications refer to the "5'-OH position of the nucleoside" ('054 patent at 40:8-9; '597 patent at 40:9-10).

However, reading selected specification references into a claim limitation requiring OH at the 5' position, while ignoring many other parts of the specification that are inconsistent with such a limitation, would be improper. *See, e.g.*, *Vitronics*, 90 F.3d at 1583. The specifications' description of 2'-C-branched ribonucleosides expressly includes embodiments with various non-

OH compounds at the 2' and 3' down positions. ('054 patent at 47:6-23; '597 patent at 47:2-23) Similarly, the specifications explain that "[t]he active nucleoside can also be provided as a 5'-phosphoether lipid or a 5'-ether lipid," neither of which have OH at the 5' position. ('054 patent at 39:48-51) Many other preferred embodiments of nucleosides also do not have OH at the 5' position. (*See, e.g.*, '054 patent at 10:10-54, 21:37-22:13, 11:41-12:17, 24:5-44, 12:22-64, 29:1-41, 13:1-38, 32:52-33:25) During prosecution, claims were presented for nucleoside embodiments having substituents other than OH at the 5' position. (D.I. 129, Ex. 6 at 11; D.I. 129, Ex. 9 at 66; D.I. 129, Ex. 5 at 7) Defendants' proposal would read various preferred embodiments out of the claim language.

Defendants also argue that because the claims of the '597 patent – unlike those of the '054 patent – explicitly refer to "nucleoside or a phosphate thereof" (*compare* '597 patent at 142:63-144:47 *with* '054 patent at 162:2-164:45), construing nucleoside to include nucleotide would (in the context of the '597 patent) render the language "or a phosphate thereof" (i.e., "or a nucleotide") superfluous. "[W]hile interpretations that render some portion of the claim language superfluous are disfavored, where neither the plain meaning nor the patent itself commands a difference in scope between two terms, they may be construed identically." *Power Mosfet Techs., L.L.C. v. Siemens AG*, 378 F.3d 1396, 1410 (Fed. Cir. 2004). Here, although Defendants' argument suggests these patents were drafted with something short of perfection, it does not persuade the Court that it should adopt Defendants' proposed constructions.

E. The '054, '597, and '600 Patents: "Administering"

Plaintiffs Making available.
Defendants Providing externally. A metabolite of an administered compound that is created by *in vivo* transformation is not administered.
Court Making available.

The parties disagree about whether administering includes *in vivo* (inside the body) administration, such that the claims cover the use of prodrugs that metabolize into pharmaceutically effective compounds once inside of the body. Defendants' proposed construction would read *in vivo* out of the claims. The Court rejects Defendants' proposal.

The claims refer to *in vivo* administration. Claim 1 of the '600 patent does so specifically. ("R^2 is . . . a pharmaceutically acceptable leaving group which when ***administered in vivo*** provides a compound wherein R^2 is H") (emphasis added) The claim language of the patents also refers to administration in a "host", a term which, according to the specification, encompasses living cells. ('054 patent at 38:50-53; '597 patent at 38:54-57, '600 patent at 109:36-39) ("The term host specifically refers to infected cells, cells transfected with all or part of the HCV genome and animals . . . .") Defendants argue that such cells must refer to cells in a petri dish, as opposed to the human body. (*See* Tr. at 110) But nothing in the patent requires such a limitation. In fact, each patent's specification explains that the claimed compounds can be administered *in vivo* ('054 patent at 10:38-41; '597 patent at 10:38-41; '600 patent at 105:1-4),

including in the form of a prodrug[7] ('054 patent at 15:38-40; '597 patent at 15:48-50, '600 patent at 109:64-67) ("The compounds of this invention either possess antiviral (i.e., anti-HCV) activity, or are metabolized to a compound that exhibits such activity.") (emphasis added); '600 patent at 38:50-54 ("The invention further provides at least one of the described 2' and 3'-prodrugs in combination or alteration with second nucleoside that exhibits activity against a Flaviviridae, including but not limited to a parent drug of any of the prodrugs defined here . . . .").

The Court does not read other parts of the specifications discussing external administration as excluding *in vivo* administration. (*See, e.g.*, '054 patent at 36:53-56; '600 patent at 110:2-5) ("The active compound can be administered as any salt or prodrug that upon administration to the recipient is capable of providing directly or indirectly the parent compound, or that exhibits activity itself.")

IV. CONCLUSION

The Court will construe the disputed claim terms of the patents-in-suit consistent with this Memorandum Opinion. An appropriate Order follows.

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[7] The patents describe a pro-drug form of the invention as "a compound that is ***metabolized***, for example hydrolyzed or oxidized, ***in the host to form the compound of the present invention***." ('054 patent at 39:2-5; '597 patent at 39:5-8; '600 patent at 109:54-57) (emphasis added)