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.

C.A. No. 13-1987-LPS

[redacted]

REDACTED VERSION

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.

C.A. No. 14-109-LPS

[redacted]

REDACTED VERSION

IDENIX PHARMACEUTICALS, INC. and UNIVERSITA DEGLI STUDI DI CAGLIARI,

Plaintiffs,

v.

GILEAD SCIENCES, INC.

Defendant.

C.A. No. 14-846-LPS

[redacted]

REDACTED VERSION

DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR RENEWED SUMMARY JUDGMENT MOTION

Dated: August 22, 2016

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I. INTRODUCTION

The undisputed lack of antiviral data in Idenix's patents exemplifies why they lack written description as a matter of law under either party's construction. The specification sets forth a broad set of nucleosides and suggests, without support, that they are all effective against Hepatitis C virus (HCV). Yet Idenix now admits this is wrong. [redacted] But Idenix's patents don't say any of this. The patents never suggest, [redacted] of the billions of nucleosides they disclose are active. The patents never say that the 2'- and 3'-down positions are functionally limited [redacted]; in fact, most of the possibilities the patents disclose for those positions admittedly ***do not*** [redacted]. And the patents include no antiviral data for any nucleoside, so there is nothing to help the skilled artisan distinguish between what works and what doesn't. The result is an utter failure to describe the claimed invention, a failure that no claim construction can fix.

II. ARGUMENT

A. The Claims Are Invalid Under Idenix's Construction Because The Written Description Does Not Identify the Subgenus that Idenix Says is Claimed.

We start with Idenix's narrower construction because, if the claims are invalid under it, they are certainly invalid under Gilead's construction. Idenix argues the "effective amount" term is a "functional limitation," (D.I. 380 at 81:21-24), that narrows the claims to a subset of [redacted] "effective" nucleosides out of the billions shown in the patents. [redacted] But, when pressed at the last hearing, Idenix could not identify anything in the patent that would support such a limitation. (D.I. 380 at 74:24-81:7.) That is insufficient under Federal Circuit precedent, which imposes strict

requirements on claims to such a subgenus: the patents must include "blaze marks," such as data, formulas, preferred embodiments, or examples, directing the skilled artisan to the subgenus. Idenix's patents lack all of those potential blaze marks, rendering them invalid as a matter of law.

The Federal Circuit's law on subgenus claims is an application of the more general requirement that the patent show "possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). When a subgenus is claimed, the patent must include "blaze marks" directing the skilled artisan to it—"simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses." *Boston Scientific Corp. v. Johnson & Johnson*, 647 F. 3d 1353, 1367 (Fed. Cir. 2011). To put the rule in more illustrative terms, "one cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention." *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320, 1326 (Fed. Cir. 2000). The reason is simple: a patent "is not a reward for the search, but compensation for its successful conclusion," so "the written description requirement prohibits a patentee from 'leaving it to the … industry to complete an unfinished invention.'" *Novozymes A/S v. DuPont Nutrition Biosciences APS*, 723 F.3d 1336, 1350 (Fed. Cir. 2013).

A couple examples will show how the Federal Circuit has applied these principles to invalidate claims like Idenix's as a matter of law. In *Boston Scientific*, the Court dealt with a patent that "disclosed a genus (analogs of rapamycin), but claimed a narrower sub-genus (macrocyclic triene analogs of rapamycin)" of compounds that could bind a particular protein. *See* 647 F.3d at 1367. Nothing in the patent suggested the subgenus "might be of special interest," and, "given the nascent state" of the technology, the "lack of such blaze marks in the '662 patent prevents any conclusion that the patent contains sufficient written description of the

claimed triene analogs of rapamycin." *Id*. The patent's failure to "disclose the sub-genus of 'macrocyclic triene analogs' by name, by functionality, or even by implication," and the fact it disclosed "no results from the testing of analogs" justified summary judgment. *Id*. at 1369.

In *Novozymes*, the patent claimed an enzyme with certain amino acid mutations that had "increased thermostability," and, although the specification mentioned each requirement in different places, it never tied them all together or disclosed a specific group of enzymes that met them. *See* 723 F.3d at 1348. After reciting the general written description standards, the Court noted that it had "often applied those fundamental concepts to hold claims invalid in cases where a patent's written description disclosed certain subject matter in terms of a broad genus but its claims specified a particular subgenus or species contained therein." *Id*. at 1346. This was another such case because there was no data or other guidance to the claimed subset—the patent "nowhere describes the actual functioning, thermostable alpha-amylase variants" and lacked "any 'blaze marks' that would lead an ordinarily skilled investigator toward such a species among a slew of competing possibilities." *Id*. at 1349. Providing such "blaze marks" would have required "actually making and testing individual variants or at least identifying subclasses of variants that could be expected to possess the claimed properties." *Id*. at 1350.

Earlier cases have likewise stressed that a patent must itself direct the skilled artisan to the claimed subgenus. *See, e.g., Fujikawa v. Wattanasin*, 93 F.3d 1559, 1570-71 (Fed. Cir. 1996) (no written description for claims to a subgenus because, although the proposed substitution "might seem simple and foreseeable" in hindsight, the specification never indicated that a given position on the molecule "would be a better candidate for substitution than any other"); *Flynn v. Eardley*, 479 F.2d 1393,1395 (C.C.P.A. 1973) (no written description despite some disclosure that "would tend to head one in the general direction of the claimed compounds"

because there were "a large number of choices," some parts of the disclosure pointed in other directions, and there was no "working example"); *In re Ruschig*, 379 F.2d 990, 995 (C.C.P.A. 1967) (no written description where the specification included only broad formulas covering thousands of compounds without any "guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made").

Idenix's patents have the same deficiencies as in *Boston Scientific*, *Novozymes*, and the other cases. Idenix says that its claims cover use of a subgenus—"antivirally effective" β-D-2′-C-branched pyrimidine ribonucleosides ('054 patent) or β-D-2′-methyl-ribofuranosyl nucleosides ('597 patent)—[redacted] But the patents provide no blaze marks that would direct the skilled artisan to this subgenus. (Ex. 3 at ¶ 82; Ex. 4 at ¶ 57.) The patents instead disclose billions of compounds and say they are all effective against HCV, (*id.*), [redacted] No language in the patents directs skilled artisans to select groups at particular positions based on any functional limitation, [redacted] In fact, the patents point ***away*** from what Idenix now identifies as the claimed subgenus, because, as explained at pp. 3-4 of Gilead's claim construction brief, its "principal embodiment[s]" and "preferred subembodiment[s]" include a laundry list of substituents [redacted] The patents never identify a further narrowed set of nucleosides that excludes these inoperative embodiments. And Idenix's lawyers [redacted] admit that the patents never provide any antiviral data (whether for HCV or any other virus) for ***any*** nucleoside. (*See, e.g.,* [redacted] D.I. 380 at 79:23-80:1; [redacted].) Without data directing the skilled artisan to the allegedly claimed subgenus

of antivirally effective nucleosides, and without any other language pointing explicitly to that subgenus, Idenix cannot meet the standard for written description under its construction, just as in the cases above. If anything, Idenix's claims are worse than those in the prior cases, as Idenix's subgenus includes nucleosides that are admittedly nowhere in the patent (like 2'-fluoro down nucleosides) without ***anything*** to suggest that these are also included, while the claims in prior cases were at least restricted to a subgenus entirely within a patent's generic disclosure.

The absence of data or other blaze marks to the claimed subgenus is particularly problematic because, as in *Boston Scientific* and *Novozymes*, the field was in a nascent state. [redacted] Idenix's specification also omits the most important active nucleosides to date—2'-fluoro down nucleosides—[redacted] Idenix's patents are thus a classic attempt to "preempt the future before it has arrived." *Ariad*, 598 F.3d at 1353.

Idenix's answer appears to be that examples and data are not required because its patents disclose testing methods a skilled artisan could use to determine which of its nucleosides are effective. But *Novozymes* rejected that argument as a matter of law, holding the patentee "misses the point" in arguing that a skilled artisan "would have known how to test every possible variant at that position and thus would have found the claimed variants as a matter of course." *See* 723 F.3d at 1350. The patent itself must disclose the claimed invention "specifically, as something [the patentee] actually invented." *Id*. So it is not enough for the patent to disclose "a roadmap

for producing candidate" molecules so others can test which "might exhibit" the desired property. *Id*. Idenix's inclusion of suggested testing methods rather than actual antiviral data or other blaze marks leaves the skilled artisan with a "mere wish or plan for obtaining the claimed invention," which "is not adequate written description." *Boston Scientific*, 647 F.3d at 1362.

[redacted] But written description is assessed by "an objective inquiry into the four corners of the specification," *Ariad*, 598 F.3d at 1351, and the specification never mentions any such relationship, instead including and even preferring mostly embodiments [redacted] It does not matter whether it would have been obvious how to narrow the disclosure if, as here, the patent does not do so: "[o]bviousness simply is not enough; the subject matter must be disclosed to establish possession." *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1310 (Fed. Cir. 2008).

B. The Claims Are Invalid Under Gilead's Construction, Too, Because They Cover Far More Than is Described and Most Embodiments Are Inoperative.

Idenix's patents are equally invalid if the Court rejects Idenix's additional claim limitations, as the claims would then implicate the billions of compounds within the existing construction of the "ribonucleoside" terms. (D.I. 248 at 5-12.) Gilead's prior briefing shows that Idenix did not adequately describe such claims, because the specification does not contain either a description of that entire genus or representative examples. (D.I. 299 at 12-19; D.I. 351 at 2-10.) The specification's admitted lack of antiviral data underscores both problems, as it shows that Idenix did not really have possession of using ***any*** nucleoside to treat HCV, [redacted].

The Federal Circuit has invalidated claims where, as here, the claims broadly seek to tie up a large class of compounds that is supposedly useful for a particular result, yet the

specification provides no supporting data or other evidence to establish the patentee actually possessed so broad an invention. For example, in another part of *Boston Scientific*, the Federal Circuit affirmed summary judgment of no written description against claims to a coronary stent with a therapeutic agent of "rapamycin, or a macrocyclic lactone analog thereof" that "is present in an amount effective to inhibit neointimal proliferation." *See* 647 F.3d at 1362-67. These claims were broader than the subgenus claims invalidated in the other part of the opinion, as they covered use of any analog, not a subset. Just like Idenix's patents, the specification there did not identify the full genus of such analogs and provided no example with efficacy data for a specific analog that worked. *Id*. The Court explained that "[a]lthough examples are not always required to satisfy the written description requirement, the lack of any disclosure of examples may be considered when determining whether the claimed invention is adequately described." *Id*. at 1364. The Court then concluded the claims were invalid because they covered tens of thousands of compounds, yet the specification provided no working examples, no guidance on how to identify the analogs, and the field was "nascent" and unpredictable. *Id*. at 1366-67.

The facts here are even worse than those in *Boston Scientific.* Idenix's claims involve billions of nucleosides, including many (like 2'-fluoro down) that are never mentioned in the specification, yet Idenix's patents do not include any antiviral data in [redacted] Most of those compounds are inoperative, yet the specification never provides any data or guidance regarding which compounds work and which don't—instead, it says—incorrectly— that they all do. There are no formulas, no preferred embodiments, no definition of "effective amount," no antiviral data, and no particular structures or characteristics known to impart anti-HCV activity. The claims are thus invalid as a matter of law.

III. CONCLUSION

For these reasons, Gilead requests that the Court grant summary judgment of invalidity.

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