

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VIIV HEALTHCARE COMPANY,
SHIONOGI & CO., LTD., and VIIV
HEALTHCARE UK (NO. 3)
LIMITED,

Plaintiffs,

v.

GILEAD SCIENCES, INC.

Defendant.

Civil Action No. 18-224-CFC

Michael P. Kelly, Daniel M. Silver, Alexandra M. Joyce, MCCARTER & ENGLISH
LLP, Wilmington, Delaware; John M. Desmarais, Justin P.D. Wilcox, Todd L.
Krause, Laurie N. Stempler, Lindsey E. Miller, Michael D. Jenks, Kyle G. Petrie,
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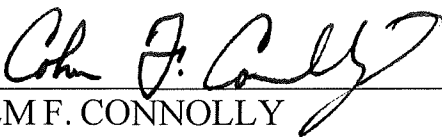
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Counsel for Defendant

MEMORANDUM OPINION

August 3, 2020
Wilmington, Delaware


COLM F. CONNOLLY
UNITED STATES DISTRICT JUDGE

Plaintiffs ViiV Healthcare Company; Shionogi & Co., Ltd.; and ViiV Healthcare UK (No. 3) Limited (collectively, ViiV) filed this lawsuit accusing Defendant Gilead Sciences, Inc. of infringing United States Patent Number 8,129,385 (the #385 patent). The #385 patent covers pharmaceutical compounds for treating the human immunodeficiency virus (HIV).

ViiV alleges that Gilead's HIV drug product Bictegravir infringes claim 6 of the #385 patent under the doctrine of equivalents. That doctrine provides that "a product or process that does not literally infringe upon the express terms of a patent claim may nonetheless be found to infringe if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 21 (1997).

Bictegravir has a benzyl ring with three fluorines. D.I. 256 ¶ 2; D.I. 269 ¶ 2. Claim 6 of the #385 patent claims four compounds, and pharmaceutically acceptable salts thereof, each with a benzyl ring that has two fluorines. D.I. 256 ¶ 3; D.I. 269 ¶ 3. Gilead has moved pursuant to Federal Rule of Civil Procedure 56 for summary judgment of noninfringement. D.I. 255. Gilead argues that summary

judgment is warranted because the two-fluorines limitation in claim 6 specifically excludes compounds with three fluorines.

I. Legal Standard for Summary Judgment

Regional circuit law governs a court's review of motions for summary judgment in patent cases. *Brilliant Instruments, Inc. v. GuideTech, LLC*, 707 F.3d 1342, 1344 (Fed. Cir. 2013). A court must 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." Fed. R. Civ. P. 56(a). The moving party bears the burden of demonstrating the absence of any genuine issues of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the burden of persuasion at trial would be on the non-moving party, then the moving party may satisfy its burden of production by pointing to an absence of evidence supporting the non-moving party's case, after which the burden of production then shifts to the non-movant to demonstrate the existence of a genuine issue for trial. *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986); *Williams v. Borough of West Chester, Pa.*, 891 F.2d 458, 460–61 (3d Cir. 1989).

Material facts are those "that could affect the outcome" of the proceeding. *Lamont v. New Jersey*, 637 F.3d 177, 181 (3d Cir. 2011). "[A] dispute about a material fact is genuine if the evidence is sufficient to permit a

reasonable jury to return a verdict for the nonmoving party.” *Id.* (internal quotation marks omitted). A non-moving party asserting that a fact is genuinely disputed must support such an assertion by: “(A) citing to particular parts of materials in the record, including depositions, documents, electronically stored information, affidavits or declarations, stipulations, . . . admissions, interrogatory answers, or other materials; or (B) showing that the materials cited [by the opposing party] do not establish the absence . . . of a genuine dispute” Fed. R. Civ. P. 56(c)(1). The non-moving party’s evidence “must amount to more than a scintilla, but may amount to less (in the evaluation of the court) than a preponderance.” *Williams*, 891 F.2d at 460–61.

The court must view the evidence in the light most favorable to the non-moving party and draw all reasonable inferences in that party’s favor. *Wishkin v. Potter*, 476 F.3d 180, 184 (3d Cir. 2007). “[T]he facts asserted by the nonmoving party, if supported by affidavits or other evidentiary material, must be regarded as true” *Aman v. Cort Furniture Rental Corp.*, 85 F.3d 1074, 1080 (3d Cir. 1996). If “there is any evidence in the record from any source from which a reasonable inference in the [nonmoving party’s] favor may be drawn, the moving party simply cannot obtain a summary judgment.” *Id.*

II. Analysis

“[B]y defining the claim in a way that clearly exclude[s] certain subject matter, the patent[ee] implicitly disclaim[s] th[at] subject matter[.]” *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1346 (Fed. Cir. 2001). This implicit disclaimer—known as the specific exclusion principle—precludes a finding of equivalency infringement when a feature of the accused product is “the opposite of, or inconsistent with, [a] recited limitation” of the asserted claim. *Augme Techs., Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1335 (Fed. Cir. 2014) (citing *SciMed Life Sys.*, 242 F.3d at 1346–47).

Not every difference between a claim and an accused product gives rise to specific exclusion. The whole point of the doctrine of equivalents is to prevent “the unscrupulous copyist [from] mak[ing] unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of the law.” *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 607 (1950). The principle of specific exclusion would nullify the doctrine of equivalents if it were triggered by any difference between the accused product’s features and the limitations in the asserted claim. Accordingly, when the Federal Circuit has applied the specific exclusion principle, it has emphasized the mutual exclusivity of the accused product’s features and the corresponding claim limitations.

For example, in *Moore U.S.A., Inc. v. Standard Register Co.*, 229 F.3d 1091 (Fed. Cir. 2000), the Federal Circuit held that “the term ‘majority’ [was] not entitled to a scope of equivalents covering a minority” because “it would defy logic to conclude that a minority—the very antithesis of a majority—could be insubstantially different from a claim limitation requiring a majority[.]” 229 F.3d 1091, 1106. In *Augme Technologies*, the Federal Circuit held that “embedded code does not include externally linked code” because the “Augme patents make clear that embedded and linked code are opposites[.]” *Augme Technologies*, 755 F.3d at 1335. And in *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945 (Fed. Cir. 2006), the Federal Circuit held that the shapes “frusto-conical” and “concave” were “clearly contrary to, and thus excluded by, the patentee’s characterization of its abutment as having a convex, frusto-spherical shape.” 441 F.3d 945, 955–56. These cases make it clear that when the Federal Circuit uses the phrase “opposite of or inconsistent with” to describe the test for specific exclusion, it means inconsistent in the sense of being “not compatible with” a claim limitation. *Inconsistent*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/inconsistent>. In other words, specific exclusion applies only when “the scope of the claim [i]s limited in a way that plainly *and necessarily* exclude[s] a structural feature” *SciMed Life Sys.*, 242 F.3d at 1346 (emphasis added).

It is undisputed that claim 6 of the #385 patent teaches a chemical compound that has among other things a benzyl ring with two fluorines (a difluoro benzyl ring) and that Bictegravir has a benzyl ring with three fluorines (a trifluoro benzyl ring). It is also undisputed that a difluoro benzyl ring is not the same thing as a trifluoro benzyl ring. But it is not clear from the claims or written description of the #385 patent that a difluoro benzyl ring necessarily excludes a trifluoro benzyl ring. And although Gilead argues that a difluoro benzyl ring “stands in contrast to” and is “inconsistent” with a trifluoro benzyl ring, D.I. 257 at 29, 32; it has neither alleged nor submitted record evidence such as an expert affidavit to establish that a difluoro benzyl ring is the opposite of or incompatible with a trifluoro benzyl ring. ViiV, on the other hand, has alleged, and has submitted an expert affidavit to establish, that a trifluoro benzyl ring is not the opposite of and not incompatible with a difluoro benzyl ring. Accordingly, the specific exclusion principle does not bar ViiV from alleging that Bictegravir infringes claim 6 under the doctrine of equivalents.¹

¹ Gilead argues that because claim 1 of the #385 patent recites a benzyl ring with one, two, or three fluorines, summary judgment in its favor is required under *Malta v. Schulmerich Carillons, Inc.*, 952 F.2d 1320 (Fed. Cir. 1991). According to Gilead, under *Malta*, claim 1’s broader fluorine limitation specifically excludes ViiV from asserting that a trifluoro benzyl ring is the equivalent of a difluoro benzyl ring. There is language in *Malta* that supports Gilead’s reading of the case. *See id.* (“In the present case, where Malta employs a broad term in one claim, but a narrower term . . . in another claim, the implication is that infringement of the

III. Conclusion

For the foregoing reasons, I will deny Gilead's Motion for Summary Judgment (D.I. 255).

The Court will issue an Order consistent with this Memorandum Opinion.

second claim can be avoided by not meeting the narrower term.”). But I am unable to conclude that *Malta* stands for the proposition that specific exclusion applies any time a broader limitation is recited in another claim. *Malta* makes no mention of specific exclusion and has never been cited by a court for the proposition that a broader limitation in one claim specifically excludes a patentee from alleging equivalency infringement of a narrower limitation in another claim. Moreover, such a proposition could not be reconciled with the Supreme Court's seminal decision in *Graver Tank*, which applied the doctrine of equivalents to a narrower claim to capture scope that was encompassed in a broader claim. *See* 339 U.S. at 610–12.