

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,
DESMARAIS LLP, New York, New York

Counsel for Plaintiffs

Jack B. Blumenfeld, Jeremy A. Tigan, MORRIS, NICHOLS, ARSHT & TUNNELL
LLP, Wilmington, Delaware; Adam K. Mortara, J. Scott McBride, Mark S.
Ouweleen, Matthew R. Ford, Nevin M. Gewertz, Tulsi E. Gaonkar, Rebecca T.
Horwitz, BARTLIT BECK LLP, Chicago, Illinois; Meg. E. Fasulo, BARTLIT BECK
LLP, Denver, Colorado; Nao Takada, TAKADA LEGAL, P.C., Forest Hills, New
York

Counsel for Defendant

MEMORANDUM OPINION

February 5, 2020
Wilmington, Delaware


COLMF. 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 claims 2 and 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).

Gilead has moved pursuant to Federal Rule of Civil Procedure 12(c) for judgment on the pleadings. D.I. 103. Regional circuit law governs a court's review of motions for judgment on the pleadings in patent cases. *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288, 1293 (Fed. Cir. 2016). Under Third Circuit law, a court may grant a Rule 12(c) motion only where "the movant clearly establishes that no material issue of fact remains to be resolved and [the movant] is entitled to judgment as a matter of law." *Rosenau v. Unifund Corp.*, 539 F.3d 218,

221 (3d Cir. 2008). In considering a Rule 12(c) motion, the court must accept as true all well-pleaded allegations in the non-movant's pleadings and draw all reasonable inferences in the non-movant's favor. *Zimmerman v. Corbett*, 873 F.3d 414, 417–18 (3d Cir. 2017).

Gilead argues that it is entitled to judgment as a matter of law because (1) the disclosure-dedication rule bars ViiV from alleging that Bictegravir equivalently infringes claim 6 of the #385 patent and (2) the specific exclusion principle bars ViiV from alleging that Bictegravir equivalently infringes claim 2 of the patent. Whether the disclosure-dedication rule bars an infringement claim is a question of law. *See Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1333 (Fed. Cir. 2004). Whether the specific exclusion principle bars an infringement claim is also a question of law. *MorphoSys AG v. Janssen Biotech, Inc.*, 385 F. Supp. 3d 354, 362 (D. Del. 2019). Resolution of these questions is therefore appropriate in the context of a Rule 12(c) motion.

I. Disclosure-Dedication Rule

A. Legal Standards

Section 112(b) of Title 35 provides that a patent's "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention." This requirement codifies the "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) (en banc) (internal quotation marks and citations omitted); *see also Univ. of Rochester v. G.D. Searle & Co.*, 375 F.3d 1303, 1325 (Fed. Cir. 2004) (Linn, J., dissenting from the court’s decision not to hear the case en banc) (“Surely there is no principle more firmly established in patent law than the primacy of the claims in establishing the bounds of the right to exclude.”) (citations omitted); *Ariad Pharms., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1347 (Fed. Cir. 2010) (en banc) (“Claims define the subject matter that, after examination, has been found to meet the statutory requirements for a patent.”) (citation omitted). It is the claims—not the patent’s written description—that define the invention and provide the measure of the patentee’s right to exclude others from using it. *See Milcor Steel Co. v. George A. Fuller Co.*, 316 U.S. 143, 146 (1942) (“Out of all the possible permutations of elements which can be made from the specifications, he reserves for himself only those contained in the claims.”) (citation omitted). “Claims define and circumscribe[;] the written description discloses and teaches.” *Ariad Pharms.*, 598 F.3d at 1347; *see also Univ. of Rochester*, 375 F.3d at 1326 (“The primary role of the written description is to support the claims, assuring that persons skilled in the art can make and use the claimed invention.”) (citation omitted).

A corollary to the principle that only the claims define the scope of a patented invention is the disclosure-dedication rule.¹ That rule precludes a finding of infringement that is based on subject matter disclosed in the written description but not claimed. As the Federal Circuit held in *Johnson & Johnston Associates Inc. v. R.E. Service Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc), “when a patent drafter discloses but declines to claim subject matter . . . [she] dedicates that unclaimed subject matter to the public.”

The rule was first articulated by the Supreme Court in 1881 in *Miller v. Bridgeport Brass Co.*, 104 U.S. 350, 352 (1881) (“[T]he claim of a specific device or combination, and an omission to claim other devices or combinations apparent on the face of the patent, are, in law, a dedication to the public of that which is not claimed.”). Three years later, in *Mahn v. Harwood*, 112 U.S. 354 (1884), the Court offered this explanation of the rule:

Of course, what is not claimed is public property. The presumption is, and such is generally the fact, that what is not claimed was not invented by the patentee, but was known and used before he made his invention. But, whether so or not, his own act has made it public property, if it was not so before. The patent itself, as soon as it is issued, is the evidence of this. The public has the undoubted right to use, and it is to be presumed does us[e], what is not specifically claimed in the patent.

¹ The Federal Circuit refers to the rule both as the “disclosure-dedication rule,” see, e.g., *Eli Lilly & Co. v. Hospira, Inc.*, 933 F.3d 1320, 1334 (Fed. Cir. 2019), and the “dedication-disclosure rule,” see, e.g., *Toro*, 383 F.3d at 1331.

112 U.S. at 361.

The disclosure-dedication rule “applies equally” to literal and equivalence infringement claims. *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098, 1107 (Fed. Cir. 1996). As the Federal Circuit noted in *Johnson*, the claims provide notice of an invention’s scope not only to the public (and thus potential competitors), but also to the examiner at the U.S. Patent and Trademark Office (PTO). 285 F.3d at 1052. Thus, application of the disclosure-dedication rule helps to prevent a patentee from narrowly claiming an invention to avoid prosecution scrutiny by the PTO, and then, after the patent issues, using the doctrine of equivalents to “extend[] the coverage of an exclusive right to encompass more than that properly examined by the PTO.” *Id.* at 1055 (citation omitted).

B. Analysis

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). Bicitgravir has a benzyl ring with three fluorines (a trifluoro benzyl ring). ViiV alleges that “the difluoro benzyl ring in claim 6 and the equivalent trifluoro benzyl ring in [Bicitgravir] perform substantially the same function.” D.I. 1 ¶85.

The compound recited in claim 6 is a species of the compound genus recited in claim 2 of the patent. Claim 2 discloses a compound with a trifluoro benzyl ring. Gilead argues that the disclosure of the trifluoro benzyl ring in claim 2

triggers the disclosure-dedication rule and bars ViiV from alleging that Bictegravir infringes claim 6 under the doctrine of equivalents. According to Gilead, “[u]nder the disclosure-dedication doctrine, a patentee is barred from calling a structure an ‘equivalent’ of an asserted claim element if that structure is disclosed elsewhere in the written description *or other claims*.” D.I. 104 at 4 (citations omitted) (emphasis added).

A disclosure made in a claim, however, cannot trigger the disclosure-dedication rule. The rule has effect only when the patentee “*declines to claim* subject matter” that is disclosed in the written description. *Johnston*, 285 F.3d at 1054 (emphasis added); *see also Toro*, 383 F.3d at 1333 (“[T]he disclosure-dedication rule applies to cases in which technology is both in existence and recognizably described in the written description of the patent, yet left unclaimed.”). By definition, a disclosure in a claim is *not* dedicated to the public. A patent’s claims define the inventor’s right to exclude the public from being able to practice the invention; thus, the claims do the exact opposite of dedicating the invention to the public. Accordingly, the disclosure-dedication rule does not bar ViiV from alleging equivalence infringement of claim 6 of the #385 patent.

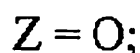
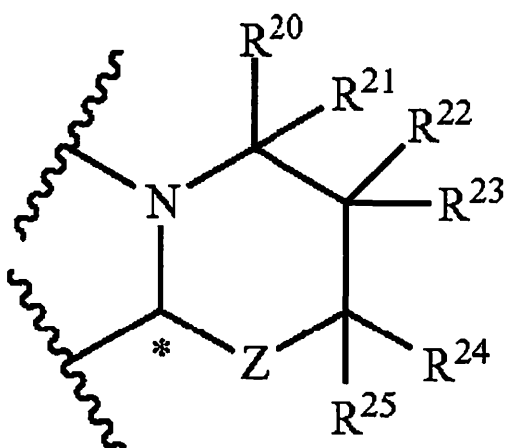
II. Specific Exclusion Principle

A. Legal Standards

A patentee cannot allege that a structure is equivalent to a claimed limitation when the limitation specifically excludes that structure. *See Augme Techs., Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1335 (Fed. Cir. 2014). “[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). The Federal Circuit has “found ‘specific exclusion’ where the patentee seeks to encompass a structural feature that is the opposite of, or inconsistent with, the recited limitation.” *Augme Techs.*, 755 F.3d at 1326 (citing *SciMed Life Sys.*, 242 F.3d at 1346–47).

B. Analysis

As noted above, ViiV alleges that Bictegravir equivalently infringes claim 2 of the #385 patent. Claim 2 is dependent on claim 1, which discloses a chemical compound that has the following “ring A” in its structure:



#385 Patent 177: 45–67. Each of the six “R^x’s” (my terminology) in the disclosed ring is a placeholder for a substituent (i.e., an atom or group of atoms). (Think of R²⁰ as being the placeholder in position #20 in the claimed structure, R²¹ as being the placeholder in position #21, and so on.) Claim 1 recites the following limitation with respect to the R placeholders:

R²⁰, R²¹, R²², R²³, R²⁴ and R²⁵ are independently hydrogen, C₁-C₈alkyl, C₆-C₁₄aryl, C₁-C₈alkyl, C₆-C₁₄aryl, or alkoxy;

#385 patent, claim 1, at 178:1–3.

Going into the *Markman* hearing last spring,² Gilead argued that “are independently” means that each R^x is “separate from and not connected to” any other R^x. D.I. 71 at 29. ViiV argued that “are independently” does not “impose[]

² See *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996) (“the construction of a patent, including terms of art within its claim, is exclusively within the province of the court”).

[a] limitation on the interconnection of” the R^x’s. D.I. 71 at 30. ViiV proposed that I construe “are independently” to mean that each R^x “may be the same or different from any other [R^x].” D.I. 71 at 29.

After the *Markman* hearing, I thought I may have come upon a solution to harmonize the parties’ competing constructions. And so, I asked the parties if they could agree to the following construction of the disputed limitation:

R²⁰, R²¹, R²², R²³, R²⁴ and R²⁵ are each hydrogen, C₁-C₈alkyl, C₆-C₁₄arylC₁-C₈alkyl, C₆-C₁₄aryl, or alkoxy, where (1) each of R²⁰, R²¹, R²², R²³, R²⁴ and R²⁵ may be the same as or different from any other R²⁰, R²¹, R²², R²³, R²⁴ or R²⁵ and (2) the hydrogen, C₁-C₈alkyl, C₆-C₁₄arylC₁-C₈alkyl, C₆-C₁₄aryl, or alkoxy that comprise each of R²⁰, R²¹, R²², R²³, R²⁴ or R²⁵ are distinct from the hydrogen, C₁-C₈alkyl, C₆-C₁₄arylC₁-C₈alkyl, C₆-C₁₄aryl, or alkoxy that comprise any other R²⁰, R²¹, R²², R²³, R²⁴ or R²⁵;

The parties agreed to this construction, and I entered an order on May 13, 2019 adopting it. *See* D.I. 84.

My belief that this construction was a workable compromise was short-lived. The briefing and oral argument on the pending motion made clear that the agreed-upon construction did not bridge the gap between the parties’ competing constructions of “are independently.” The crux of the problem is that “distinct” lends itself to competing interpretations.

Gilead argues that the agreed-upon construction of the “are independently”

limitation specifically excludes ViiV from alleging that Bictegravir equivalently infringes claim 2 because Bictegravir has substituents that are located at two R^x's but that are bonded to each other as well as to the ring and therefore are not distinct from one another. ViiV argues that even though the substituents are connected to each other they are distinct because one can distinguish them from one another.

Meriam-Webster's Dictionary defines "distinct" as "distinguishable to the eye or mind as being discrete (see DISCRETE sense 1) or not the same: SEPARATE" and as "readily and unmistakably apprehended." *Distinct*, MERRIAM-WEBSTER, <https://www.merriam-webster.com/dictionary/distinct>. Here, Gilead is interpreting "distinct" to mean separate, whereas ViiV is interpreting it to mean "distinguishable to the mind or eye" and "readily and unmistakably apprehended." Thus, for Gilead, R²⁰ and R²⁴ are not distinct if they are bonded together because they are not separate from one another. But for ViiV, R²⁰ and R²⁴ can be distinct even if they are bonded together because one would distinguish and readily apprehend them as two substituents at two R^x's.

Given the parties' fundamental disagreements about the meaning of the agreed-upon construction of "are independently," I have decided that it is necessary to revisit claim construction. *Cf. Pfizer, Inc. v. Teva Pharm., USA, Inc.*, 429 F.3d 1364, 1377 (Fed.Cir.2005) ("[D]istrict courts may engage in rolling claim construction, in which the court revisits and alters its interpretation of the claim

terms as its understanding of the technology evolves.”) (quotation marks and citation omitted). I have also decided that extrinsic evidence, including expert testimony, would be useful for me to determine what a person of ordinary skill in the art would have understood “are independently” to mean at the time of the invention. *See Phillips*, 415 F.3d at 1319 (“[B]ecause extrinsic evidence can help educate the court regarding the field of the invention and can help the court determine what a person of ordinary skill in the art would understand claim terms to mean, it is permissible for the district court in its sound discretion to admit and use such evidence.”). Both sides argue that I should give “are independently” its plain and ordinary meaning, but they differ on what the plain and ordinary meaning is. Both sides argued in their claim construction briefing and at the *Markman* hearing that I could construe the disputed term based solely on the intrinsic evidence; but “are independently” is not defined in the claims or the written description of the #385 patent, and neither side has persuaded me that the conflicting intrinsic evidence weighs in favor of its respective proposed construction.

Accordingly, I will vacate the claim construction order of May 13, 2019 (D.I. 84) and schedule an evidentiary hearing at which the parties can present extrinsic evidence, including expert testimony, on the issue of what a person of ordinary skill in the art would have understood “are independently” to mean at the

time of the invention. That evidence should also address the meaning of “independent” and “substituent.” To be clear, the parties are not precluded from arguing for the constructions they proposed previously.

Because Gilead’s specific exclusion argument is premised on its interpretation of the May 13, 2019 claim construction order, I will deny its motion. But I will permit Gilead to refile its motion after I have construed the “are independently” limitation.

III. Conclusion

For the reasons discussed above, I will deny Gilead’s motion for judgment on the pleadings (D.I. 103) and convene an evidentiary hearing on the construction of the “are independently” limitation.

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