

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

GILEAD SCIENCES, INC. and
EMORY UNIVERSITY,

Plaintiffs,

v. // CIVIL ACTION NO. 1:14CV99
(Judge Keeley)

MYLAN INC. and MYLAN
PHARMACEUTICALS INC.,

Defendants.

MEMORANDUM OPINION AND ORDER GRANTING
PLAINTIFFS' MOTION TO DEFER CONSIDERATION OF
MYLAN'S INDEFINITENESS ARGUMENT [DKT. NO. 119]

On February 19, 2015, the plaintiff, Gilead Sciences, Inc., ("Gilead"), filed its opening claim construction brief, proposing its construction of three disputed claims (Dkt. No. 100).¹ On March 12, 2015, the defendants, Mylan Inc. and Mylan Pharmaceuticals, Inc. ("Mylan"), filed an answering brief, arguing that one of Gilead's patent claims is indefinite, regardless of how the Court construes that claim (Dkt. No. 107).

Gilead has moved to defer consideration of Mylan's indefiniteness argument until summary judgment, or, in the alternative, for leave to file a reply brief (Dkt. No. 119). Mylan opposes Gilead's request, contending that its indefiniteness argument is integral to claim construction. It has agreed,

¹ Although both Gilead and Emory University are named plaintiffs, Gilead alone filed a claim construction brief because Emory does not own or hold an interest in either patent (Dkt. No. 100 at 6, fn. 6).

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however, to Gilead's request to submit a reply brief (Dkt. No. 125).

The dispute between Gilead and Mylan stems from their competing interpretations of the claim term "less than [10%/1%/0.1%/0.01%] degradation of tenofovir disoproxil fumarate over a 24-hour period," contained in U.S. Patent Nos. 8,592,397 ("the '397 Patent") and 8,716,264 ("the '264 Patent") (Dkt. No. 100 at 20). Gilead contends that "a" means "one or more," an interpretation generally accepted by the United States Court of Appeals for the Federal Circuit. Id. Gilead urges the Court to reject Mylan's construction that "a" in this context means "any," further interpreted to mean "every." Id.

Mylan argues that, no matter which of the two interpretations the Court chooses, the disputed claim term "less than [10%/1%/0.1%/0.01%] degradation of tenofovir disoproxil fumarate over a 24-hour period," is fatally indefinite, because "nothing in the patents or the prosecution histories discloses the conditions at which the degradation analysis should be conducted, or even, which 24-hour period should be tested." (Dkt. No. 107 at 12). Mylan further contends that, even if the Court were to adopt its

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construction, the claim term would remain indefinite. Id. at 17, 19, fn. 6.

In asking the Court to defer consideration of Mylan's indefiniteness argument until after the conclusion of fact and expert discovery, Gilead argues that Mylan is "clearly [attempting an] end-run around the Court's Scheduling Order," which notifies the parties that dispositive motions are to be filed after the close of discovery.² Id. at 2, 4.

While acknowledging that indefiniteness is a validity defense usually deferred until summary judgment, Mylan argues that the Court can, and should, consider the issue as part of the claim construction proceedings, because "the claim terms being construed are at the heart of the indefiniteness argument." (Dkt. No. 125 at 2). According to Mylan, "[n]o amount of discovery will change the fact that the patent and its prosecution history" are silent as to the disputed claim terms, thus making it impossible for a person of ordinary skill in the art to determine what was meant by those claims. Id.

² To be clear, Mylan had previously argued that Gilead's proposed interpretation of its claim term would render the claim indefinite (Dkt. No. 100 at 22, fn. 7; Dkt. No. 119 at 3). In its answering brief, however, Mylan has argued for the first time that the claim would be indefinite under any interpretation (Dkt. No. 119 at 3).

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Generally, "the weight of the jurisprudence disfavors indefiniteness determinations at the Markman stage of patent litigation." CSB-System Intern. Inc. v. SAP America, Inc., 2011 WL 3240838 at *17, 20, fn. 16 (E.D. Pa. July 28, 2011). Although a court may find a claim term invalid for indefiniteness after construing the term, it is clear that what a "term means to a person of ordinary skill in the art is a separate question from whether it is sufficiently definite to put others in the field on notice regarding the bounds of the claims" Chiron Corp. v. Genentech, Inc., 2002 WL 32123928 at *2 (E.D. Cal. June 24, 2004).

Several principles mitigate against ruling on indefiniteness at the Markman stage: first, the high burden of proof on the party challenging a patent claim for indefiniteness; second, the fact that a claim is not indefinite merely because the parties dispute its meaning; and, finally, the dispositive effect of a ruling on indefiniteness, which invalidates the claim entirely. See CBS-System Intern., 2011 WL 3240838 at *17-18. For these reasons, many judges have elected to wait and tackle indefiniteness at the summary judgment stage. See, e.g., CBS-System Intern. Inc. v. SAP America, Inc., 2011 WL 3240783 at *2 (E.D. Pa. July 28, 2011) (denying the defendant's indefiniteness argument without prejudice,

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subject to renewal during summary judgment); Mannatech, Inc. v. TechMedia Health, Inc., 2009 WL 3614359 at *15 (N.D. Tex. Oct. 29, 2009) (determining that consideration of the indefiniteness issue was not appropriate at the claim construction phase). But see Interval Licensing LLC v. AOL, Inc., 766 F.3d 1364, 1377-78 (Fed. Cir. 2014) (upholding the district court's judgment of invalidity due to indefiniteness during claim construction).

The Court recognizes that it is well within its power to consider indefiniteness as part of the claim construction process, if it make sense to do so. e-Plus, Inc. v. Lawson Software, Inc., 700 F.3d 509, 517 (Fed. Cir. 2012). Indeed, in Dey, L.P. v. Teva Parenteral Medicines, Inc., 2011 WL 2461888 at *3-4 (N.D. W. Va. June 17, 2011), it considered defendant Teva's argument that plaintiff Dey's proposed construction would render its claim indefinite. There, the Court looked to the specifications and prosecution histories of the patents-in-suit before concluding that Dey's proposed construction was correct, but that the patent term was not indefinite. See id. at *6-7.

In the present case, however, it does not make sense to consider indefiniteness during claim construction. In contrast to the situation in Dey, Mylan has argued that, even if its proposed

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construction is correct, the claim is indefinite (Dkt. No. 107 at 19). The Court finds persuasive Gilead's argument that discovery could uncover information relevant to the issue of indefiniteness.

For the reasons discussed above, therefore, the Court **GRANTS** Gilead's motion to defer consideration of Mylan's indefiniteness argument (Dkt. No. 119). Mylan has leave to reassert that argument following the conclusion of fact and expert discovery. Gilead's motion in the alternative for leave to file a reply brief is **DENIED** as moot.³

It is so **ORDERED**.

The Court directs the Clerk to transmit copies of this Order to counsel of record.

DATED: April 6, 2015.

/s/ Irene M. Keeley
IRENE M. KEELEY
UNITED STATES DISTRICT JUDGE

³ Both parties also address whether parts of the claim preamble regarding a separate claim, "fixed-dosage combination," are limiting (Dkt. No. 119 at 5; Dkt. No. 125 at 4). This issue is part of claim construction, and has no bearing on the issue of indefiniteness. Therefore, the Court need not address it at this time.