UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

DEPOMED, INC.,	:	
	:	Civil Action No. 13-571(MLC)
Plaintiff,	:	
	:	**MEMORANDUM OPINION**
v.	:	
	:	
PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., AND PURDUE PHARMACEUTICALS L.P.,	:	
	:	
Defendants.	:	
	:	

COOPER, District Judge

This matter comes before the Court upon Defendants Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P.'s (collectively, "Purdue") Motion for Reconsideration Under Local Rule 7.1(i) or, in the Alternative, to Certify Claim Construction Order for Interlocutory Appeal Under 28 U.S.C. § 1292(b) ("the Motion"). (Dkt. 284).[1] Plaintiff Depomed, Inc. ("Depomed") opposes the Motion. The Court has considered the parties' submissions and decides the Motion without oral argument pursuant to Local Civil Rule 78.1. For the reasons discussed below, Defendants' Motion is DENIED.

[1] The Court will cite to the documents filed on the Electronic Case Filing System ("ECF") by referring to the docket entry numbers by the designation of "dkt." Pincites reference ECF pagination.

I. BACKGROUND

We will not set forth the underlying facts at length, as we have done so in previous opinions, and the Court presumes that parties are familiar with the factual background. The patents-in-suit, United States Patent Nos. 6,340,475 ("the '475 Patent") and 6,635,280 ("the '280 Patent") (together, "the patents-in-suit"), are directed to compositions and methods for the controlled delivery of a dosage form to the stomach and upper gastrointestinal system. A Markman hearing pertaining to this matter was held on November 2, 2016. (See dkt. 247.) In our April 6, 2017 Markman Opinion, we construed twelve disputed claim terms that we organized into the following categories: (1) "gastric fluid"; (2) "remains substantially intact"; (3) "until all of said drug is released"; (4) claim terms concerning swelling upon imbibition of water or gastric fluid; (5) claim terms concerning "substantially all of said drug"; and (6) claim terms concerning poly(ethylene oxide) molecular weights. See Depomed v. Purdue Pharma L.P., No. 13-571, 2017 WL 1319818 (D.N.J. Apr. 6, 2017). We adopted Depomed's proposed constructions for all of the claim terms except the term "until all of said drug is released." See id. at *13-31.

With respect to five claim terms including the phrase "substantially all of said drug," Purdue did not propose any constructions. Instead, Purdue argued that these claim terms are indefinite.[2] Depomed disagreed and argued that "substantially all of said drug"

[2] This claim term appears in all asserted claims. Claim 1 of the '475 Patent is representative, stating:

> A controlled-release oral drug dosage form for releasing a drug whose solubility in water is greater than one part by weight of

means "at least 80% of the drug." We held that these claim terms were not indefinite and adopted Depomed's proposed constructions. See id. at *25-29. In doing so, we concluded that the intrinsic record did not provide a strong indication as to the boundary of these terms. See id. at *28. We turned to the extrinsic evidence to determine the meaning of the claims in the context of the patents-in-suit. See id.

Specifically, we relied on two FDA Guidance publications which we found to be written for the person of ordinary skill in the art ("POSA"). Id. We found that the FDA Guidance publications place considerable emphasis on the 80% mark as the appropriate end point for testing dissolution of a drug. Id. at *29. We also found that the data presented in the patents-in-suit was consistent with this teaching. Id. at *29. We concluded that the FDA documents were "highly persuasive evidence that the claim term 'substantially all,' as read in light of the specification delineating the patent and prosecution history, informs, with reasonable certainty, those skilled in the art about the scope of the invention." Id. Accordingly, we adopted Depomed's proposed construction

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> said drug in ten parts by weight of water, said dosage form comprising a solid polymeric matrix with said drug dispersed therein at a weight ratio of drug polymer of from about 15:85 to about 80:20, said polymeric matrix being one that swells upon imbibition of water thereby attaining a size large enough to promote retention in the stomach during said fed mode, that releases said drug into gastric fluid by the dissolution and diffusion of said drug out of said matrix by said gastric fluid, that upon immersion in gastric fluid retains at least about 40% of said drug one hour after such immersion and releases **substantially all of said drug** within about eight hours after such immersion, and that remains substantially intact until all of said drug is released.

'475 Pat., col. 17, ll. 45-59 (emphasis added).

and concluded that the meaning of "substantially all" in the context of the patents-in-suit, as understood by the POSA, is "at least 80%." Id.

Presently, Purdue asks this Court to reconsider its construction of the "substantially all of said drug" claim terms, arguing that "the Court made a clear error of law in relying on extrinsic evidence to determine the legal construction of the claim term." (Dkt. 284-1 at 5.) More specifically, Purdue argues that we "used extrinsic evidence to attribute meaning to a claim term that does not have a well-understood meaning in the art and is ambiguous in view of the intrinsic record, but never evaluated that extrinsic evidence against the patent document." (Dkt. 289 at 4.) If we do not grant reconsideration, Purdue asks us to certify our Markman Order for interlocutory appeal under 28 U.S.C. § 1292.

II. DISCUSSION

A. Motion for Reconsideration

1. Legal Standard

A motion for reconsideration is "an extremely limited procedural vehicle" granted sparingly. Tehan v. Disability Mgmt. Servs., Inc., 111 F. Supp. 2d 542, 549 (D.N.J. 2000) (citation and quotation omitted). A court may grant a motion for reconsideration when the movant shows at least one of the following: (1) an intervening change in controlling law; (2) the availability of new evidence that was previously unavailable; or (3) it is necessary to correct a clear error of law or fact, or to prevent manifest injustice. See Shevlin v. Phoenix Life Ins. Co., No. 09-6323, 2015 WL 348552, at *1 (D.N.J. Jan. 23, 2015); Tehan, 111 F. Supp. 2d at 549.

Reconsideration is unwarranted if: (1) the movant seeks to relitigate old matters; (2) the movant seeks to raise arguments or present evidence that could have been raised; or (3) the movant seeks to express disagreement with the court's initial decision. See Boretsky v. Governor of N.J., 433 F. App'x 73, 78 (3d Cir. 2011); Shevlin, 2015 WL 348552, at *1.

2. Application

Purdue argues that reconsideration is warranted in this case "because the Court made a clear error or law when it used extrinsic evidence—primarily, the FDA Guidances—to determine the construction of the claim term 'substantially all of said drug.'" (Dkt. 284-1 at 6.) Purdue argues that the Supreme Court's decision in Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831 (2015) limited the role of extrinsic evidence in construing patent claims and assessing whether a claim is indefinite. (Id. at 6-7.)[3] Purdue contends that we failed to conduct "the proper legal inquiry of 'whether a skilled artisan would ascribe that same meaning to that term in the context of the specific patent claim under review,' i.e., the intrinsic record." (Id. at 9 (citation omitted).) Finally, Purdue asserts that we could not have concluded the claims are

[3] At certain portions, Purdue's Opening Brief may be read to suggest that the use of extrinsic evidence in claim construction and the indefiniteness analysis is prohibited. (See, e.g., dkt. 284-1 at 5-6.) Depomed understood Purdue's argument to be that under Teva, "extrinsic evidence cannot be considered when the intrinsic record is 'ambiguous.'" (Dkt. 286 at 5.) In its Reply Brief, Purdue clarified that its position is not that extrinsic evidence has no role in claim construction. (See dkt. 289 at 4.) Purdue recognizes that "extrinsic evidence may have a role in claim construction," but argues that it is limited. (See id. at 4-5.) Purdue states that the "key issue is the Court's failure to address the extrinsic evidence in the context of the asserted patents." (Id. at 4.)

definite because, according to Purdue, the extrinsic evidence contradicts the intrinsic record. Specifically, Purdue states that the 80% release marker "conflicts with the wildly variable . . . percentages disclosed in the specification and described as the invention." (Id. at 10.)

Depomed submits that there is no basis for reconsideration. Depomed argues that Purdue's reading of Teva is incorrect, and that Teva did not limit the role of extrinsic evidence in claim construction or in determining whether a claim is indefinite. (See dkt. 286 at 12-16.) Depomed argues that our analysis comports with Teva and that Purdue's position amounts to mere disagreement with our claim construction. (See id. at 6-11.) Depomed also argues that we should reject Purdue's argument because Purdue failed to raise the Teva case in its Markman submissions. (Id. at 11, n.4.)[4]

Reconsideration is not warranted in this case. Purdue has failed to identify a clear error of law or fact in our Markman opinion that would warrant reconsideration. We did not fail to "address the extrinsic evidence in the context of the asserted patents," as Purdue suggests. We turned to the extrinsic evidence because we found the intrinsic evidence inconclusive. See Depomed, 2017 WL 1319818, at *28. The term "substantially all" is not explicitly defined in the patent specification, claims, or

[4] The Court may not consider a new argument in a motion for reconsideration. See Denger v. Merret, No. 08-3454, 2011 WL 5825971, at *4 (D.N.J. Nov. 16, 2011) ("New arguments that could have been raised in [a party's] original motion are inappropriate grounds for reconsideration."). Although Purdue did not discuss the Teva case in its Markman submissions, we, albeit briefly, addressed the Teva case in our Markman Opinion. Thus, to the extent Purdue argues that we did not apply Teva correctly, it could not have previously raised that argument.

prosecution history. We carefully reviewed the FDA Guidances and expert testimony regarding the same and determined that the data collected in the patents-in-suit was consistent with the extrinsic evidence. Id. at 26-29. The FDA Guidances explain what was known to one of skill in the art at the relevant time period with regarding to dissolution testing. In this context, we determined that the FDA Guidances were "highly persuasive evidence that the claim term 'substantially all,' as read in light of the specification delineating the patent and prosecution history, informs, with reasonable certainty, those skilled in the art about the scope of the invention." Id. at 29. We concluded that the meaning of "substantially all" in the context of the patents-in-suit, as understood by the POSA, is "at least 80%." Id. We did not determine the meaning of this claim term in a vacuum with only the extrinsic evidence. We carefully evaluated the extrinsic evidence in the context of the patents-in-suit.

Teva did not limit the use of extrinsic evidence in claim construction or indefiniteness. Teva clarified the standard of review on appeal to be applied to the claim construction decisions of federal district courts. Teva, 135 S. Ct. at 841 (explaining that constructions based entirely on intrinsic evidence receive *de novo* review, and subsidiary factfinding receives clear error review). The Federal Circuit, in post-Teva cases, has sanctioned the use of extrinsic evidence. See, e.g., Akzo Nobel Coatings, Inc. v. Dow Chemical Co., 811 F.3d 1334, 1343-44 (Fed. Cir. 2016) ("The district court's determination . . . was based on extrinsic evidence. Because we see no clear error in that fact finding here, and it does not conflict with the intrinsic record, we affirm.").

We stated in our Markman Opinion that we found the extrinsic evidence to be consistent with the intrinsic record. See Depomed, 2017 WL 1319818, at *29. We considered, and rejected, Purdue's previous arguments that Depomed's proposed construction of "at least 80%" was inconsistent with the intrinsic evidence. (See, e.g., dkt. 133 at 21-23.) Thus, we view Purdue's present arguments as mere disagreement with our initial decision and an attempt to relitigate the issues we have already decided. See Boretsky, 433 F. App'x at 78; Shevlin, 2015 WL 348552, at *1. Reconsideration is unwarranted here. We will deny Purdue's motion regarding the same.

B. Motion for Interlocutory Appeal

Purdue argues, in the alternative, that interlocutory appeal to the Federal Circuit is appropriate. For the following reasons, we find that this case does not present the kind of exceptional circumstances necessary to justify interlocutory review.

1. Legal Standard

Section 1292(b), which governs interlocutory appeals, provides in relevant part:

> When a district judge, in making in a civil action an order not otherwise appealable under this section, shall be of the opinion that such order involves a controlling question of law as to which there is substantial ground for difference of opinion and that an immediate appeal from the order may materially advance the ultimate termination of the litigation, he shall so state in writing in such order. The Court of Appeals which would have jurisdiction of an appeal of such action may thereupon, in its discretion, permit an appeal to be taken from such order[.]

28 U.S.C. § 1292(b). Thus, a district court may certify a non-final order for interlocutory appeal where the order: "(1) involve[s] a controlling question of law, (2) offer[s]

substantial ground for difference of opinion as to its correctness, and (3) if appealed immediately [would] materially advance the ultimate termination of the litigation." Katz v. Carte Blanche Corp., 496 F.2d 747, 754 (3d Cir. 1974) (internal quotation marks omitted).

In determining whether an order presents a controlling question of law, the Court must look to whether (1) an incorrect disposition would constitute reversible error if presented on final appeal or (2) if the question is "serious to the conduct of the litigation either practically or legally." Id. at 755. A substantial ground for difference of opinion must arise "out of genuine doubt as to the correct legal standard." Kapossy v. McGraw-Hill, Inc., 942 F. Supp. 996, 1001 (D.N.J. 1996). Mere disagreement with the district court's ruling is not enough. Id. And, in terms of determining whether appeal would materially advance the ultimate termination of litigation, courts look to situations "where the interlocutory appeal eliminates: (1) the need for trial; (2) complex issues that would complicate trial; or (3) issues that would make discovery more costly or burdensome." F.T.C. v. Wyndham Worldwide Corp., 10 F. Supp. 3d 602, 635 (D.N.J. 2014).

The burden is on the movant to demonstrate that all three requirements are met. Piacentile v. Thorpe, No. 12-7156, 2016 WL 3360961, at *2 (D.N.J. June 8, 2016). However, even if all three criteria are met, "the district court may still deny certification, as the decision is entirely within the district court's discretion." Id. Further, Section 1292(b) "is to be used sparingly and only in exceptional circumstances that justify a departure from the basic policy of postponing review until the entry of the final order."

Acosta v. Pace Local I-300 Health Fund, No. 04-3885, 2007 WL 1074093, at *1 (D.N.J. Apr. 9, 2007) (internal quotation marks omitted); see also Kapossy, 942 F. Supp. at 1001.

2. Application

a. Controlling Question of Law

Purdue argues that the role of extrinsic evidence in proving the meaning of a claim term presents a controlling question of law. (See dkt. 284-1 at 11-12.) Purdue argues that claim construction and indefiniteness are both a matter of law, and thus the question of "whether extrinsic evidence may be used to prove the meaning of a claim and save it from indefiniteness is [ ] a pure issue of law that, if the Federal Circuit reversed, would be case dispositive." (Id.) Depomed contends that Purdue's question does not present a question of law, but rather factual findings that are reviewed for clear error. (Dkt. 286 at 17.)

As discussed above, we view Purdue's issue with our Markman Opinion as disagreement with our application, not the correct legal standard. Nevertheless, claim construction and the ultimate question of indefiniteness are questions of law. Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996); Dow Chem. Co. v. NOVA Chems. Corp., 809 F.3d 1223, 1225 (Fed. Cir. 2015). The Federal Circuit routinely reverses and remands cases on the basis of the district court's claim construction and indefiniteness opinions. Thus, an incorrect disposition regarding the indefiniteness issue would constitute reversible error if presented on final appeal. Katz, 496 F.2d at 755. Accordingly, we find that our claim construction order is a controlling issue of law. However, Purdue is unable to satisfy the remaining criteria for certification.

b. Substantial Ground for Difference of Opinion

Purdue's arguments demonstrate only disagreement with the Court's decision. Purdue argues that our ruling conflicts with precedent from the Supreme Court and Federal Circuit's Teva decisions, as well as the Supreme Court's decision in Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120 (2014). Stated differently, Purdue argues that we erred as a matter of law by applying an incorrect standard. On one hand, Purdue argues that the rule regarding extrinsic evidence is clear. (See dkt. 284-1 at 12 ("Teva makes clear that extrinsic evidence cannot be used to prove the proper or legal construction of a claim term.").) However, Purdue contradictorily states that "guidance from the Federal Circuit would be useful" on this issue. (Id.)

The correct legal standard to be applied in claim construction and indefiniteness is not in doubt. Purdue admits as much when it clarifies that the key issue is not the correctness of the standard, but rather whether we "err[ed] in failing to address the ultimate legal question of whether the patent claims are indefinite in the context of the intrinsic record (the claims, the specification, and the prosecution history)." (Dkt. 289 at 6.) The difference of opinion here is of our application; it does not arise out of the correctness of the legal standard. See Kapossy, 942 F. Supp. at 1001 (A substantial ground for difference of opinion must arise "out of genuine doubt as to the correct legal standard.").

Purdue does not cite a single case raising a conflict as to the correct legal standard. See Knopick v. Downey, 963 F. Supp. 2d 378, 398 (M.D. Pa. 2013) ("The clearest evidence of substantial grounds for difference of opinion is where there are conflicting

interpretations from numerous courts." (internal quotation marks omitted)). Purdue concedes, as it must, that the use of extrinsic evidence is not prohibited in claim construction or the indefiniteness inquiry. (See dkt. 289 at 4-5.) Purdue simply disagrees with our application of that legal standard to the evidence in this case. Accordingly, we find that Purdue has not shown that a substantial difference of opinion exists to warrant interlocutory appeal.

c. Materially Advance the Termination of the Litigation

Purdue argues that an immediate appeal would ultimately advance the termination of litigation because the issue is case dispositive. (Dkt. 284-1 at 13.) Purdue argues that if the Federal Circuit were to find "the use of extrinsic evidence to prove the meaning of the claim term" improper, there would be no valid patent claims remaining in this case, eliminating the need for trial. (Id.) Purdue also notes that expert discovery has not begun, a trial date is not yet set, and there are other motions currently before the Court. (Id. at 13-14.)

Depomed disagrees and argues that an immediate appeal will not advance this litigation. (See Dkt. 286 at 18-19.) Depomed argues that this case is in its late stages, with extensive discovery having already taken place. (Id. at 18.) This case has already been stayed for over two years while Purdue pursued petitions for *inter partes* review and an appeal to the Federal Circuit. Depomed also notes that the Federal Circuit has generally refrained from granting petitions to resolve claim construction disputes. (See id.)

We find that Purdue fails to show that an interlocutory appeal would materially advance the ultimate termination of the litigation. Here, the parties have already engaged in extensive discovery. The Court has issued a scheduling order for the remainder of the case. (See dkt. 285.) We also find that Purdue's assertions are too speculative. We do not see a reason that would justify a departure from the basic policy of postponing review until the entry of the final order. We therefore find that appellate review of our Markman Order would not advance the termination of this litigation or substantially accelerate its disposition. Accordingly, we conclude that Plaintiff fails to demonstrate that certification is appropriate and we decline to exercise our discretion to issue a certification in this instance.

III. CONCLUSION

For the reasons stated above, the Court will deny Purdue's motion for reconsideration and motion for interlocutory appeal. The Court will issue an appropriate order.

s/ Mary L. Cooper
MARY L. COOPER
United States District Judge

Dated: June 5, 2017