

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

AMGEN INC.,

Plaintiff,

v.

**AMNEAL PHARMACEUTICALS LLC,
et al.,**

Defendants.

:
:
:
:
:
:
:
:
:
:
:
:

**Civ. No. 16-853-MSG
CONSOLIDATED**

Goldberg, J.

April 19, 2018

MEMORANDUM OPINION

This is a consolidated case for patent infringement brought by Plaintiff Amgen Inc. (“Amgen”) against Defendants Amneal Pharmaceuticals LLC and Amneal Pharmaceuticals of New York LLC (together, “Amneal”), Piramal Healthcare UK Ltd. (“Piramal”), Watson Laboratories, Inc., Actavis, Inc., and Actavis Pharma, Inc. (together, “Watson”), and Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd. (together, “Zydus,” and collectively with all other defendants, “Defendants”).¹ Amgen claims that Defendants infringed United States Patent No. 9,375,405 (“the ’405 patent”) titled “Rapid Dissolution Formulation of a Calcium Receptor-Active Compound.” Trial on Amgen’s infringement claims was held between March 5, 2018 and March 9, 2018.²

¹ On May 18, 2017, Chief Judge D. Brooks Smith of the United States Court of Appeals for the Third Circuit designated me as a visiting judge for the District of Delaware, pursuant to 28 U.S.C. § 292(b), to handle this and other Delaware cases.

² All Defendants have filed counterclaims alleging invalidity. For scheduling reasons, trial on the infringement claims proceeded first.

Presently before the court are two motions filed around the start of trial: (i) Amgen's Motion for Reargument of the Court's February 27, 2018 Memorandum and Order which construed the meaning of the Markush groups in the '405 patent; and (ii) Zydus' Motion in Limine to preclude the introduction of a new theory of infringement—the doctrine of equivalents—which was not asserted against it before trial. (D.I. 323, D.I. 307). For the reasons set forth below, Amgen's Motion for Reargument is denied, and Zydus' Motion in Limine is granted.

I. MOTION FOR REARGUMENT

A. Background

In its Motion for Reargument, Amgen contends that the court “misconstrued [its] position on claim construction” and “misapprehended the claim construction issue.” (D.I. 323 at 1-2). A brief recitation of the procedural history in this matter and the court's prior rulings on claim construction are necessary to provide the proper context for Amgen's motion.

1. The '405 Patent

The '405 patent issued from U.S. Patent Application No. 12/942,646 (the “'646 application”), filed on November 9, 2010. (D.I. 293-1, Ex. 1 ¶ 7). The parties have agreed that infringement in this case will be decided based on claim 1 of the '405 patent, which states:

- (1) A pharmaceutical composition comprising:
 - (a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg;
 - (b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrans, and mixtures thereof;
 - (c) from about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof; and

(d) from about 1% to 10% by weight of at least one disintegrant selected from the group consisting of crospovidone (sic), sodium starch glycolate, croscarmellose sodium, and mixtures thereof,

wherein the percentage by weight is relative to the total weight of the composition, and wherein the composition is for the treatment of at least one of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

(D.I. 294-1, Ex. 7 at 4; D.I. 336).

2. Procedural History of Claim Construction

The Honorable Gregory M. Sleet held a Markman hearing in this matter in the spring of 2017. The only claim construction dispute presented to and resolved by Judge Sleet at that time was the meaning of “relative to the total weight of the composition,” which appears in claim 1’s “wherein clause.” (D.I. 186). By the fall of 2017, however, the parties had another claim construction dispute that had not been resolved. That dispute involved the Markush groups for the binder and disintegrant elements in claim 1.³ (D.I. 356 at 1069:15-17). The parties became aware of the claim construction dispute when they exchanged expert reports. Some of Defendants’ experts opined that there was no literal infringement, because the ANDA product contained binders or disintegrants not listed in the Markush groups. (See, e.g., D.I. 355 at 642:13-643:8; *Id.* at 780:20-782:22). No party, however, sought a further claim construction ruling from the court.

³ “A Markush group ‘lists alternative species or elements that can be selected as part of the claimed invention.’” Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp., 831 F.3d 1350, 1357 (Fed. Cir. 2016)). “It is typically expressed in the form: ‘a member selected from the group consisting of A, B and C.’” Abbott Labs. V. Baxter Pharm. Prods., Inc., 334 F.3d 1274, 1280 (Fed. Cir. 2003)).

On January 24, 2018, Amgen's expert, Dr. Davies, was deposed. Dr. Davies testified that Defendants with unlisted binders or disintegrants still literally infringed, because the "comprising language" in the preamble of claim 1 permitted unlisted binders or disintegrants. (D.I. 356 at 1067:16-23). Despite the fact that there was no claim construction to support this opinion, Amgen did not seek a second claim construction from the court or make clear that, for those defendants against whom it had only asserted literal infringement, it would now also assert the doctrine of equivalents in the alternative. (D.I. 354 at 458:18-23).

On February 5, 2018, the parties filed a Proposed Joint Pretrial Order, which made clear that the claim construction dispute over the Markush groups was still in play.⁴ (D.I. 293; D.I. 294). In the section setting forth the parties' proposed findings of fact and conclusions of law, Defendants asked the court to construe the Markush groups as closed to unlisted excipients. (D.I. 294-1, Ex. 7.1 at 316-22). Defendants also explained why they thought three arguments they expected Amgen to make should fail. (Id.). Defendants expected Amgen to argue that the Markush groups were not closed due to (1) the term "comprising" in the preamble, (ii) the phrase "at least one" before the Markush group elements, and (iii) the phrase "mixtures thereof" in the Markush group elements. (Id.).

In its part of the Proposed Joint Pretrial Order, Amgen did not make all of the arguments Defendants expected. Instead, Amgen primarily argued that Defendants should be precluded from raising the claim construction dispute, because it was "not raised at the Markman hearing."

⁴ On February 6, 2018, the case was reassigned from Judge Sleet to me, due to his pending retirement. I did not reschedule the trial, because Amgen urged that an expeditious ruling was necessary to avoid a launch at risk. (Hr'g Tr. 17-20).

(See D.I. 294-1, Ex. 8 at 1). Amgen also argued that the Markush groups were not closed sets due to the claim term “comprising.” (*Id.*; see also D.I. 294-1, Ex. 7 at 226 (citing Mannesmann Demag Corp. v. Engineered Metal Prods. Co., 793 F.2d 1279, 1282-1283 (Fed. Cir. 1986) and In re Crish, 393 F.3d 1253, 1257 (Fed. Cir. 2004))). Finally, Amgen teed-up the claim construction dispute for the court by identifying it as one of the “Evidentiary Issues [Amgen] Wishes to Raise at the Pre-Trial Conference.” (D.I. 294-1, Ex. 8 at 1).

At the pre-trial conference, Amgen argued that the claim construction dispute should not be resolved, because it was untimely. (Hr’g Tr. at 79-80). Amgen also directed the court to the case law it cited in the Proposed Joint Pretrial Order regarding the term “comprising.” (*Id.* at 81-82). Finally, representing that it was not prepared to present argument on the issue, Amgen was given the opportunity to submit a three-page letter on the issue. (*Id.*). The court granted this request, expecting Amgen to elaborate on the only arguments it had presented so far, i.e., timeliness and the meaning of the term “comprising.”

On February 20, 2018, Amgen submitted its letter (the “February Letter”). (D.I. 298). The introduction set forth three arguments: (i) Defendants “waived their right to assert these non-infringement defenses because they failed to raise these issues long ago during claim construction briefing as set forth in the Scheduling Order;” (ii) “the claims at issue—which use the open-ended transitional phrase ‘comprising’—do not exclude additional excipients that function as diluents, binders, or disintegrants;” and (iii) even if the Markush groups were not open-ended, Amgen could still assert the doctrine of equivalents. (*Id.* at 1). The body of the February Letter had two separate sections: one addressing the doctrine of equivalents and the other addressing the case law cited by the parties regarding the term “comprising.” (*Id.* at 2-3

(discussing Mannesmann, 793 F.2d at 1282-1283; In re Crish, 393 F.3d at 1257; Bristol-Myers Squibb Co. v. Mylan Pharms. Inc., 2013 U.S. Dist. LEXIS 188207, at *23 (D. Del. Oct. 17, 2013); and Maxma v. ConocoPhillips, Inc., 2005 WL 1690611 (E.D. Tex. July 19, 2005))).

On February 27, 2018, the court issued its Memorandum construing the meaning of the Markush groups for the binder and disintegrant elements of claim 1. (D.I. 300). Relying primarily on Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp., 831 F.3d 1350 (Fed. Cir. 2016), the court found that “the Markush groups for the binder and disintegrant elements are closed to unrecited binders and disintegrants.” (D.I. 300 at 6). Thus, there could be no literal infringement if the Defendants’ ANDA product contained an unrecited (or unlisted) binder or disintegrant. (Id.). The court’s Memorandum also stated that “Amgen is not precluded from relying on the doctrine of equivalents to prove that a defendant infringed the binder or disintegrant limitations, even though the Markush group for those elements are closed.” (Id. at 9).

On March 6, 2018, Amgen filed its Motion for Reargument asserting that the court misunderstood its position on claim construction. (D.I. 323 at 1-2). Amgen now urged that the point of the Markush groups is not to determine literal infringement of a claim element, but to “define the binders and disintegrants considered in the weight percentage calculations.” (Id.). According to Amgen:

So long as the weight percentage is met by one of the listed binders or disintegrants, the presence of an additional excipient that functions as a binder or disintegrant does not take the Defendants’ products outside the literal scope of the claims.

(Id.). In practice, claim 1 calls for “from about 1% to about 5% by weight of at least one binder selected from the group consisting of” (D.I. 294-1, Ex. 7 at 4). Thus, under Amgen’s

proposed construction, a hypothetical ANDA product using 4% of a listed binder and 6% of an unlisted binder would still literally infringe, even though it had 10% of binder total, because it had a listed binder within the “about 1% to about 5%” weight range. According to Amgen, the 6% of unlisted binder would be irrelevant. When asked where Amgen had previously presented this construction to the court, Amgen pointed to a single sentence in the February Letter that was in the middle of a paragraph discussing cases that construed the claim term “comprising.” (D.I. 356 at 1072:7-10). “The ‘consisting of’ Markush group only limits the binders that may be used to satisfy the ‘from about 1% to about 5% of at least one binder’ claim element.” (D.I. 298 at 3).

B. Standard of Review

“The decision to grant a motion for reargument lies within the discretion of the district court.” Chemipal Ltd. v. Slim-Fast Nutritional Foods Int’l, Inc., 2005 WL 1384695, at *1 (D. Del. May 12, 2005). Such motions are granted “sparingly.” D. Del. L.R. 7.1.5. A motion for reargument may only be granted if the court has “patently misunderstood a party, made a decision outside the adversarial issues presented by the parties, or made an error not of reasoning but of apprehension.” Sussex Cty. Senior Serv., Inc. v. Carl J. Williams & Sons, Inc., 2000 WL 1726527, at *1 (D. Del. Mar. 31, 2000); Schering Corp. v. Amgen, Inc., 25 F. Supp. 2d 293, 295 (D. Del. 1998). A motion for reargument is not an opportunity to “accomplish repetition of arguments that were or should have been presented to the court previously.” Karr v. Castle, 768 F. Supp. 1087, 1093 (D. Del. 1991).

C. Discussion

Contrary to Amgen’s contentions, the court does not misunderstand its position on claim construction. (D.I. 323 at 1-2). Before the Motion for Reargument, Amgen’s arguments

consistently focused on whether the Markush groups were “not closed sets” due to the term “comprising” in the preamble. (D.I. 294-1, Ex. 8 at 1; D.I. 294-1, Ex. 7 at 226; D.I. 323). Since filing the Motion for Reargument, Amgen has confirmed that “our position was and always has been that the ‘comprising’ at the beginning of claim 1 opens things up to things beyond the Markush groups.” (D.I. 356 at 1064:13-16). This is the argument the court carefully considered and rejected in its February 27, 2018 Memorandum. (See, e.g., D.I. 300 at 4).

Amgen never fairly presented the proposed construction it now seeks, i.e., that the Markush groups “define the binders and disintegrants considered in the weight percentage calculations.” (D.I. 323 at 2). The single sentence on which Amgen’s Motion for Reargument rests was obscured in the middle of a paragraph analogizing the language of claim 1 to the language of patents a court construed as open to unrecited elements due to the term “comprising.” (D.I. 298 at 3). Thus, Amgen’s Motion for Reargument essentially raises a new argument. The court’s colloquy with Amgen’s counsel clearly confirms this point:

THE COURT: Do you agree that the first time you suggested that construction was ... in your motion for reargument?

LAWYER: That is correct, Your Honor.

(D.I. 356 at 1070:17-23).

A new argument is not the proper subject of a motion for reargument. Davis v. Mountaire Farms, Inc., 2005 WL 1800054, at *1 (D. Del. July 29, 2005). “It is simply an attempt ‘to argue new facts or issues that inexcusably were not [fairly] presented to the court in the matter previously decided.’” Id. (quoting Brambles USA, Inc. v. Blocker, 735 F. Supp. 1239, 1240 (D. Del. 1990)); Chemipal, 2005 WL 1384695, at *3 (denying a motion for reconsideration where plaintiff raised a new argument that “could have been, and thus certainly should have

been, presented in the first instance”). “On this ground alone, [the] motion for reconsideration should be denied.” Ryan v. Asbestos Workers Union Local 42 Pension Fund, 2000 WL 1239958, at *8 (D. Del. Aug. 25, 2000).

Even if the court were to consider Amgen’s new construction, however, it fails on the merits. This is because Amgen’s claim construction requires the court to ignore the criticality of the weight ranges for the binder and disintegrant elements, which does not comport with the prosecution history. (D.I. 333 at 1).

When construing patent claims, the court considers “[t]he claims, the specification, and the prosecution history.” Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (quoting Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991). As Amgen explained in the prosecution history, “the amount of binder is relevant” and “the ratio [of binder to diluent] is relevant.”⁵ (JTX 5 at -526).

The amendments in the prosecution history of the ’405 patent further shows that Amgen acted consistent with its understanding that the weight ranges are critical to the invention. Amgen claimed the same specific weight ranges in every patent amendment, regardless of whether a Markush group was present or not. Specifically, in the amendments dated November

⁵ Calcium-receptor active compounds, such as cinacalcet HCl, may be “insoluble or sparingly soluble in water” which “can result in low bioavailability of the active compound.” (Id. at -520). According to Amgen, the inventive step in the ’405 patent was the development of a pharmaceutical composition with cinacalcet HCl that had a rapid dissolution profile. (Id.). “The more rapid the dissolution was, the better.” (Id. at -355). Testing by Amgen included in the prosecution history showed that the desired dissolution profile “can be obtained if the amount of diluent is at least 45% and the amount of binder is limited to at most 5%.” (Id. at -526). Thus, “[t]he ranges for the components ... are ... not arbitrarily chosen, but lead to the described technical effects.” (Id.; see also Id. at -354).

15, 2011 and December 15, 2014, which did not have Markush groups for the binder and disintegrant elements, Amgen claimed “from about 1% to about 5% by weight of at least one binder” and “from about 1% to about 10% by weight of at least one disintegrant.” (JTX 5 at -258). In the Examiner’s Amendment dated March 25, 2015, Amgen claimed those same weight ranges but added Markush groups. (Id. at -333 to -334). If Amgen is correct that the first Request for Continuing Examination dated June 23, 2015 withdrew the first Notice of Allowance dated March 25, 2015 and the Examiner’s Amendment contained therein, the second Notice of Allowance dated August 18, 2015 allowed claims that kept the same weight ranges but eliminated the Markush groups for the binder and disintegrant elements. (D.I. 294-1, Ex. 7 at 128; JTX 5 at -345 to -347, -1064 to -1071). The third Notice of Allowance dated December 10, 2015, allowed claims that still kept those same specific weight ranges but added back the Markush groups. (Id. at -1092 to -1094, -1577 to -1583, and -1587 to -1595). Thus, the prosecution history demonstrates that the one invariable constant of the ’405 patent was the specific weight ranges for the diluent, binder, and disintegrant elements. This suggests that the weight ranges in the ’405 patent are critical to the invention and, therefore, not subject to a construction that results in their vitiation.

Amgen also argues that its claim construction is necessary to give meaning to the example in the ’405 patent. (D.I. 323 at 7). The court is not persuaded. As the following table shows, if the court looked no further than the face of the patent, claim 1 covers the example:

Claim 1	Example
From about 10% to about 40% by weight of cinacalcet.	18.367% Cinacalcet HCl
From about 45% to about 85% by weight of a diluent selected from the group consisting of selected from the group consisting of microcrystalline cellulose, starch , dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrans, and mixtures thereof;	33.378% Pregelatinized Starch 6.678% Microcrystalline Cellulose (intragranular) 34.300% Microcrystalline Cellulose (extragranular) 74.356% Total
From about 1% to about 5% by weight of at least one binder selected from the group consisting of povidone , hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof;	2.044% Povidone
From about 1% to about 10% by weight of at least one disintegrant selected from the group consisting of crospovidone (sic), sodium starch glycolate, croscarmellose sodium, and mixtures thereof....	1.233% Crospovidone

Amgen argues that claim 1 does not cover the example, because it was common knowledge to a person of ordinary skill in the art (“POSA”) that pregelatinized starch could have one or more functions. (D.I. 323 at 8). According to Amgen, a POSA would read the pregelatinized starch in the example as a binder, but pregelatinized starch is not listed in the Markush group for binders. (*Id.*). Therefore, claim 1 needs to be open to unlisted binders. (*Id.*).

The ’405 patent, however, does not teach that pregelatinized starch has more than one function. It teaches that pregelatinized starch has only one function – as a diluent. The ’405 patent contains three Markush groups and each Markush group contains several members, but no member is present in more than one group. (D.I. 294-1, Ex. 7 at 4).

In addition, as Amgen stated in the prosecution history, “the skilled person realizes that binders are used in small amounts and diluents in big amounts.” (JTX 5 at -351). The example contains 33.378% by weight of pregelatinized starch, which is a “big” amount when compared to claim 1’s “about 5%” weight limit for binders. Finally, if a POSA treated the pregelatinized starch in the example as a binder, then the example would be left with an insufficient amount of diluent to meet the limitations of claim 1. It would have only 40.978% of diluent, when claim 1 requires a minimum of about 45% by weight of a diluent.” (D.I. 324 at 5).

For all of these reasons, the patent teaches that the pregelatinized starch in the example is acting as a diluent, not a binder. Therefore, Amgen’s argument regarding the example is without merit. (D.I. 323).

II. MOTION IN LIMINE

A. Standard of Review

“A district court judge is granted broad discretion in determining what is admissible under the Federal Rules of Evidence.” Flickinger v. Toys R Us-Delaware, Inc., 492 F. App’x 217, 222, (3d Cir. 2012) (quoting Carden v. Westinghouse Elec. Corp., 850 F.2d 996, 1001 (3d Cir.1988)). When a party does not comply with its discovery obligations, the court considers the “Pennypack factors” in deciding whether to exclude the evidence. Those factors are:

(1) the surprise or prejudice to the moving party; (2) the ability of the moving party to cure any such prejudice; (3) the extent to which allowing the testimony would disrupt the order and efficiency of trial; (4) bad faith or willfulness in failing to comply with the court's order; and (5) the importance of the testimony sought to be excluded.

Sheehan v. Del. & Hudson Ry. Co., 439 F. App’x 130, 132 (3d Cir. 2011) (citing Meyers v. Pennypack Woods Home Ownership Ass’n, 559 F.2d 894, 904–05 (3d Cir. 1977)).

B. Discussion

Zydus filed a Motion in Limine seeking an order precluding Amgen from asserting the doctrine of equivalents against it. (D.I. 307). Amgen filed a response the same day and then, unprompted, filed a supplemental response twenty-seven days later. (D.I. 301; D.I. 350). The supplemental response was unsolicited and filed without any procedural grounds permitting such filing. And all of the arguments in the supplemental response are based on facts that Amgen had in its possession at the time it filed its original response. There is no reason why Amgen could not have raised these arguments previously. Consequently, the court will disregard Amgen's supplemental response. (D.I. 350).

Zydus argues that Amgen should be precluded from asserting the doctrine of equivalents against it, because Amgen did not assert that theory before trial. (D.I. 308 at 1). Amgen does not dispute that, before trial, it only asserted literal infringement against Zydus. (D.I. 310 at 2 (“Prior to the [claim construction order], Amgen had asserted literal infringement by Zydus.”)). Amgen makes several arguments, however, as to why it should now be permitted to assert this new theory.

First, Amgen argues that it has to assert a new infringement theory against Zydus, because Zydus “intends to raise a new non-infringement defense to literal infringement.” (*Id.*). This is not accurate. Zydus raised the same non-infringement defenses at trial that it set forth in expert discovery. A review of discovery in this case supports this conclusion.

During discovery, Amgen's expert, Dr. Davies, opined that where other defendants used pregelatinized starch as a diluent, the cold water soluble portion functioned as a binder. (D.I. 353 at 169:18-23; *Id.* at 220:12-221:5; D.I. 354 at 250:21-251:8). Because claim 1 does not list

pregelatinized starch in the Markush group for binders, Dr. Davies further opined that the cold water soluble portion was equivalent to povidone, a listed binder. (D.I. 353 at 220:12-221:5; D.I. 354 at 250:21-251:8). Zydus' ANDA product uses pregelatinized starch as a diluent. (D.I. 353 at 169:17-18; D.I. 294-1, Ex. 7.1 at 200). Accordingly, Zydus's expert, Dr. Roth, adopted Dr. Davies' opinion that the cold water soluble portion of pregelatinized starch functioned as a binder, and then asserted that Zydus could not literally infringe, because it had an unlisted binder. (D.I. 356 at 909:18-22; Id. at 911:24-912:12). Amgen acknowledges that the reason it needs to assert the doctrine of equivalents against Zydus "is because their expert, Dr. Roth, accepted and incorporated all of Dr. Davies' opinions on this very issue." (D.I. 353 at 172:24-173:4). Thus, Amgen has been aware of Zydus' noninfringement theories since the exchange of expert reports. Zydus is not asserting new defenses to noninfringement, and Amgen cannot use that excuse to assert new theories of infringement.

Second, Amgen suggests there would be no prejudice in allowing it to now assert the doctrine of equivalents against Zydus, because Amgen will use the same evidence and expert opinions against Zydus that it has used against other defendants. (D.I. 310 at 2). The court disagrees that there will be no prejudice. There are multiple ways Zydus could have taken a different approach to litigation had Amgen timely asserted the doctrine of equivalents against it, from having its own expert opine on the theory to pursuing different avenues of discovery. (D.I. 353 at 170:8-171:7). As demonstrated at trial, none of the defendants to whom Amgen has asserted its theory regarding pregelatinized starch have responded with the same defenses. There is no reason to assume that Zydus would have adopted their arguments. The fact that other

defendants have had the opportunity to test Amgen's theories regarding pregelatinized starch does not cure the prejudice to Zydus.

Third, Amgen argues that the court's claim construction Memorandum, issued in the week before trial, left it with the belief that "it was free to assert infringement by equivalents" against any defendant. (D.I. 310 at 2). Amgen has unreasonably misconstrued the court's ruling. The operative Opinion does state that "Amgen is not precluded from relying on the doctrine of equivalents to prove that a defendant infringed the binder or disintegrant limitations, even though the Markush group for those elements are closed." (D.I. 300 at 8). But this ruling did not give Amgen the right to assert new infringement theories without proper notice. It simply stated that Amgen was not prevented from asserting infringement theories it had previously preserved.

Finally, Amgen argues that it "should be permitted to adjust its infringement theory and testimony to meet the constructions in the [claim construction Memorandum]," and asks for leave of the court to do so. (D.I. 310 at 2). Amgen, however, waited until the eve of trial to make this request, which left no time for Zydus to take any discovery that could have cured the prejudice against it. Amgen had several days to act after the court issued the Memorandum.⁶ Amgen was asked why it did not alert Zydus shortly after receiving the Memorandum that it was going to expand the scope of its expert report based on the ruling, and replied that it "[did not] have a good reason for it." (D.I. 353 at 172:12-20). Given all of the above, Zydus' Motion in

⁶ Amgen also did not have to wait until receiving the court's claim construction Memorandum to request relief. There were two weeks between the pre-trial conference and trial in which Amgen could have taken steps to assert the doctrine of equivalents against Zydus in case the court issued an unfavorable claim construction.

Limine is granted. Amgen is precluded from asserting a doctrine of equivalents theory against Zydus.

III. CONCLUSION

For the foregoing reasons, Amgen's Motion for Reargument of the Court's February 27, 2018 Memorandum and Order (D.I. 323) is denied. Zydus' Motion in Limine to preclude the assertion of the doctrine of equivalents against it (D.I. 307) is granted. An order consistent with this memorandum opinion will be entered.