IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THE MEDICINES COMPANY,	)	
	)	
Plaintiff,	)	
	)	
v.	)	No. 11-cv-1285
	)	
MYLAN INC., MYLAN PHARMACEUTICALS INC., and BIONICHE PHARMA USA, LLC,	)	Hon. Amy J. St. Eve
	)	
Defendants.	)	

MEMORANDUM OPINION AND ORDER

AMY J. ST. EVE, District Court Judge:

Defendants Mylan Inc., Mylan Pharmaceuticals Inc., and Bioniche Pharma USA, LLC (collectively, "Defendants") have moved to amend the Court's Amended Final Judgment in light of the United States Court of Appeals for the Federal Circuit's recent opinion in this case. (R. 676.) Plaintiff The Medicines Company ("TMC") opposes Defendants' motion and also moves for a new trial. (R. 682; R. 684.) For the following reasons, the Court grants Defendants' motion and denies TMC's motion.

BACKGROUND

I. The Patents-in-Suit

The Court assumes the parties' familiarity with this case, but summarizes the relevant facts and procedural history. TMC is the owner of U.S. Patent Nos. 7,582,727 ("the '727 Patent") and 7,598,343 ("the '343 Patent"). *Meds. Co. v. Mylan, Inc.*, 853 F.3d 1296, 1298 (Fed. Cir. 2017). The patents-in-suit concern "pharmaceutical formulations—or 'batches'—of the drug bivalirudin." *Id.* Bivalirudin is a well-known drug covered by a different TMC patent that

expired in 2015. *Id.* It is typically distributed as a dry powder that "must be compounded with a base, before being reconstituted in a clinical setting and administered to a patient as an intravenous injection." *Id.* Reconstituting bivalirudin involves dissolving the drug in powder form in an aqueous solvent. *Id.* Because dissolving bivalirudin without a base results in an acidic solution that is not suitable for injection into humans, commercial forms of bivalirudin compound the drug with a base to increase the pH of the reconstituted drug to render it acceptable for injection. *Id.* The claimed inventions of the patents-in-suit "are directed to minimizing impurities in batches of bivalirudin that have been compounded with a base." *Id.*

The claimed inventions arose out of a problem TMC encountered when manufacturing Angiomax—a base-compounded bivalirudin drug product. The Food & Drug Administration ("FDA") "required TMC to limit the level of 'Asp^{9}-bivalirudin'—an impurity generated during the compounding process that shortens bivalirudin's shelf life—to less than 1.5 percent." *Id.* at 1299. Between 2001 and 2005, TMC produced Angiomax with Asp^{9} levels normally below 0.6%, but sometimes the process TMC used resulted in variable or high levels of Asp^{9}. *Id.* After producing two batches in 2005 and 2006 with Asp^{9} levels above 1.5%, TMC investigated and identified the compounding process as the source of the problem. *Id.* One of the steps of compounding bivalirudin is mixing a bivalirudin solution (the powder bivalirudin dissolved into an aqueous solvent) with a pH-adjusting solution containing a base. *Id.* As the patents-in-suit indicate, this mixing process can result in "hotspots"—that is, certain "concentrated sites in the compounding solution that have much higher pH levels." *Id.* (quoting from the '727 Patent as an example). These hotspots in turn "catalyzed the degradation of bivalirudin to Asp^{9}-bivalirudin, resulting in the undesirable high Asp^{9} levels that TMC was at times experiencing. *Id.*

The inventions at issue in the patents-in-suit concern an "efficient mixing" process for combining the pH-adjusting solution with the bivalirudin solution that limits the formation of hotspots. *Id.* at 1299–1300 (noting that the "batch consistency of bivalirudin products compounded using 'efficient mixing' is the invention disclosed and claimed by the patents in suit, which were filed on the same day and share nearly identical specifications"). This process resulted in batches with Asp^9 levels consistently below the FDA-mandated limit of 1.5%. *Id.* at 1299. Indeed, TMC found that efficient mixing resulted in batches with Asp^9 levels that never exceeded 0.6%. *Id.* Both the '727 and the '343 Patents have a common claim limitation (the "batches limitation"): "[p]harmaceutical batches of a drug product comprising bivalirudin . . . *wherein the batches have a maximum impurity level of Asp^9-bivalirudin that does not exceed about 0.6%*." *Id.* at 1300 (quoting '727 Patent, col. 25:56–64; '343 Patent, col. 27:13–31). The patents-in-suit also defined the term "pharmaceutical batches" as follows:

> As used here, "batch" or "pharmaceutical batch" refers to material produced by a single execution of a compounding process of various embodiments of the present invention. "Batches" or "pharmaceutical batches" as defined herein may include a single batch, wherein the single batch is representative of all commercial batches, and wherein the levels of, for example, Asp^9-bivalirudin, total impurities, and largest unknown impurity, and the reconstitution time represent levels for all potential batches made by said process. "Batches" may also include all batches prepared by a same compounding process.

Id. (citation omitted) (quoting '727 Patent, col. 5:24–36; '343 Patent, col. 5:24–36).

II. Defendants' ANDA and the Litigation Before Appeal

Defendants submitted an ANDA to the FDA in 2010, seeking to market a generic version of Angiomax. *Id.* Defendants stated that they would limit the ASP^9 level of its generic drug to less than 2% and certified either (1) that their product would not infringe the patents-in-suit, or (2) that the patents-in-suit were invalid. *Id.* TMC filed the current lawsuit asserting

infringement of the ’727 and ’343 Patents under 35 U.S.C. § 271(e)(2), and Defendants filed counterclaims seeking declaratory judgments of invalidity. *Id.* The parties disputed the claim terms “pharmaceutical batches” and “efficiently mixing.” *Id.* at 1300–01. With respect to the former, this Court’s claim construction—to which both parties consented—“clarif[ies] that the definition requires a particular process.” *Id.* at 1301. With respect to the latter disputed term, the Court looked to two examples set forth in the patents’ specifications comparing TMC’s “old compounding process,” which used “inefficient mixing conditions” (Example 4), with the new “efficient mixing” process (Example 5). *Id.* The Court ultimately concluded that TMC “had disclaimed the ‘inefficient mixing conditions’ of Example 4 and adopted Mylan’s proposed construction of ‘efficiently mixing’ to require ‘not using inefficient mixing conditions such as described in Example 4.’” *Id.* at 1301 (quoting (R. 119, Aug. 6, 2012 Op., 30)).

Based on the claim construction of “efficiently mixing,” the Court granted summary judgment of non-infringement to Defendants with respect to the ’343 Patent. (R. 309, Dec. 16, 2013 Op., 18); *see also Meds. Co.*, 853 F.3d at 1301. Specifically, with respect to literal infringement, the Court explained that “[t]he only question is whether Mylan’s compounding process is as inefficient (or more inefficient) than the compounding process described in Example 4,” and “[t]he undisputed facts show that Mylan’s compounding process is more inefficient than the ‘inefficient mixing’ process described in Example 4.” (R. 309 at 19–20); *see also Meds Co.*, 853 F.3d at 1301. With respect to the doctrine of equivalents, the Court struck as untimely the declaration of TMC’s expert supporting TMC’s doctrine-of-equivalents argument. (R. 309 at 22–23.) The Court went on, however, to reason that even considering TMC’s expert’s belated opinions, TMC’s infringement claim under the doctrine of equivalents would fail under the second prong of the “function/way/result test”—that is, the test requiring that the patentee

show the accused device "performs the substantially same function in substantially the same way with substantially the same result"—because Defendants process "does not use 'efficient mixing.'" (*Id.* (quoting *Energy Transp. Grp., Inc. v. William Demant Holding A/S*, 697 F.3d 1342, 1352 (Fed. Cir. 2012)).) Furthermore, the Court concluded that "even if Mylan's compounding process did meet the function/way/result test, TMC cannot claim infringement under the doctrine of equivalents because the '343 patent specification and prosecution history expressly disclaim 'inefficient mixing' conditions such as Example 4 in order to get around anticipation by prior art." (R. 23–24 (quoting *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1307 (Fed. Cir. 2011), for the proposition that "when a specification excludes certain prior art alternatives from the literal scope of the claims and criticizes those prior art alternatives, the patentee cannot then use the doctrine of equivalents to capture those alternatives").) TMC therefore could not "claim that Mylan's compounding process, which is more inefficient than the 'inefficient mixing' process in Example 4, is substantially equivalent to the 'efficient mixing' process claimed by the '343 patent." (*Id.* at 24.)

With regard to the '727 Patent, the Court "held that 'efficiently mixing' was not a claim limitation and determined that factual disputes concerning the Asp^9 level of Mylan's ANDA product precluded summary judgment." *Meds. Co.*, 853 F.3d at 1301. The Court then conducted a bench trial with respect to infringement and validity of the '727 patent. The Court rejected Defendants' invalidity contentions and concluded that Defendants' ANDA infringed the '727 Patent as a matter of law. *Id.* With respect to infringement, the Court noted that "TMC did not advance arguments at trial regarding infringement under the doctrine of equivalents, [so] TMC's

infringement allegations for the asserted claims are treated as allegations of literal infringement." (R. 590, Oct. 27, 2014 Op., 72 n.29.)[1]

III. The Federal Circuit's Opinion on Appeal

Defendants appealed the Court's judgment of infringement and no invalidity of the '727 Patent and TMC cross-appealed the Court's summary judgment of non-infringement of the '343 Patent. The Federal Circuit first held, contrary to the Court's interpretation, that "'efficient mixing' . . . is . . . a limitation *of both* the '727 and '343 patents." *Meds. Co.*, 853 F.3d at 1302 (emphasis added). The court went on to determine what "efficient mixing" was. Looking to examples 4 and 5 in the patents-in-suit, the Federal Circuit observed that the two examples "clearly state what efficient mixing is and is not." *Id.* at 1307–08. The court proceeded to suggest its agreement with TMC's argument that the Court's reliance on Example 4 "to construe 'efficient mixing' as 'not using inefficient mixing conditions such as described in Example 4,'" was a negative construction that "fail[s] to define what 'efficient mixing' is, as opposed to what it is not."[2] *Id.* at 1308 (citations omitted). The Federal Circuit ultimately concluded that it "construe[d] the 'efficient mixing' required by the patents in suit to require using the efficient mixing conditions of Example 5." *Id.* at 1309.

Having completed its claim construction, the Federal Circuit turned to the question of infringement of both patents-in-suit. *See id.* The court concluded that "Mylan's ANDA does not

[1] In stating this information, the Court cited its summary judgment opinion in which it held that Defendants did not infringe the '346 Patent, an order in which it recognized that TMC represented that it will not pursue a doctrine of equivalents theory at trial, and a docket entry in which the Court reiterated that it had previously struck as untimely one of TMC's expert's opinions regarding infringement under the doctrine of equivalents. (R. 590 at 72 n.29 (citing R. 309 at 22–23; R. 366; R. 485).)

[2] The Federal Circuit did not, however, fully adopt TMC's argument. It simply noted that it "carri[ed] some force," and "[t]he logic of the argument suggests that we should look to the specifications only clear delineation of what 'efficient mixing' is—Example 5." *Meds. Co.*, 853 F.3d at 1308. Additionally, as noted above, the Federal Circuit expressly stated that "Examples 4 and 5 . . . clearly state what efficient mixing is and is not." *Id.* at 1307. It therefore appears that the Federal Circuit would look to Example 4 to show what falls outside the scope of the patents-in-suit, although it would construe the claim limitation of "efficient mixing" positively by reference to Example 5.

infringe the asserted claims since [it] is undisputed that, for example, Mylan does not use multiple mixing devices as required by Example 5." *Id.* The court further explained that "the undisputed facts before the district court on summary judgment foreclose the possibility that Mylan 'would likely sell an infringing' product" because "[t]here is no genuine dispute that Mylan's compounding process 'adds the PH-adjusting solution all at once' and 'uses one paddle mixer' operating at 200 rpm," unlike Example 5, which "requires multiple mixers and adds the pH-adjusting solution at a continuous rate using a peristaltic pump." *Id.* at 1310 (quoting *Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1382, 1387–88 (Fed. Cir. 2014)). In addition to this, the court explained in a footnote:

> While we also disagree with the district court's construction of "efficient mixing" as "not using inefficient mixing conditions such as described in Example 4," the district court correctly concluded that Mylan did not infringe the '343 patent under this construction because Mylan's compounding process was "more inefficient" than Example 4.

Id. at 1310 n.10 (quoting *Meds. Co. v. Mylan Inc.*, No. 11-cv-1285, 2013 WL 6633085, at *9 (N.D. Ill. Dec. 16, 2013)[3]). Accordingly, the Federal Circuit reversed the judgment of infringement with respect to the '727 patent and affirmed the Court's summary judgment of noninfringement with respect to the '343 patent. *Id.* at 1310.

The Federal Circuit opted not to reach the invalidity issues Defendants raised regarding the patents-in-suit. *Id.* at 1298, 1302 n.1. While the court acknowledged that "a finding of noninfringement cannot moot a counterclaim of invalidity," it explained that "because Mylan has agreed that a judgment of noninfringement with respect to both patents in suit 'would be tantamount to the relief sought on the merits' and that [the court] need not reach the invalidity issues, [the court] decline[d] to reach the merits of Mylan's invalidity contentions." *Id.* at 1302

[3] In the district court docket, this citation is found at (R. 309 at 18).

n.1 (quoting *Old Town Canoe Co. v. Confluence Holdings Corp.*, 448 F.3d 1309, 1318 n.2 (Fed. Cir. 2006)).

TMC then petitioned the Federal Circuit for panel rehearing and rehearing en banc. (R. 686-5.) In that petition, TMC for the first time argued that remand is necessary to determine infringement based on the court's new construction of "efficient mixing." (*Id.* at 14–16.) The Federal Circuit denied the petition without substantive discussion. (R. 686-7.)

ANALYSIS

I. The Mandate Rule

"The mandate rule, encompassed by the broader law-of-the-case doctrine, dictates that 'an inferior court has no power or authority to deviate from the mandate issued by an appellate court.'" *Banks v. United States*, 741 F.3d 1268, 1276 (Fed. Cir. 2014) (quoting *Briggs v. Pa. R.R. Co.*, 334 U.S. 304, 306 (1948)). It exists to promote finality and efficiency "by preventing relitigation of already settled issues." *SUFI Network Servs., Inc. v. United States*, 817 F.3d 773, 779 (Fed. Cir. 2016). The mandate rule precludes from further consideration "issues actually decided [on appeal]—those within the scope of the judgment appealed from, minus those explicitly reserved or remanded by the court." *Amado v. Microsoft Corp.*, 517 F.3d 1353, 1360 (Fed. Cir. 2008) (alteration in original) (quoting *Engel Indus., Inc. v. Lockformer Co.*, 166 F.3d 1379, 1383 (Fed. Cir. 1999)); *Apple Inc. v. Samsung Elecs. Co.*, No. 11-CV-01846-LHK, 2015 WL 8477855, at *3 (N.D. Cal. Dec. 9, 2015); *see also SUFI*, 817 F.3d at 779 ("After our mandate issues, the mandate rule forecloses reconsideration of issues implicitly or explicitly decided on appeal. For an issue to be implicitly decided, it must be decided by *necessary* implication." (emphasis in original) (citation omitted)). Thus, "all issues within the scope of the

appealed judgment are deemed incorporated within the mandate and thus are precluded from further adjudication." *Banks*, 741 F.3d at 1279 (quoting *Engel*, 741 F.3d at 1279).

"[A] mandate is to be construed by considering the context." *SUFI*, 817 F.3d at 780. Additionally, in interpreting the Federal Circuit's mandate, "both the letter and the spirit of the mandate must be considered." *Id.* at 779 (quoting *TecSec, Inc. v. IBM Corp.*, 731 F.3d 1336, 1341–42 (Fed. Cir. 2013)).[4]

II. The Mandate Rule Bars the Court from Ordering a New Trial and Requires the Court to Amend the Judgment

Considering the context of the current litigation—both in this Court and on appeal—following the Federal Circuit's mandate requires the Court to amend the judgment according to the appellate court's opinion and to do no more. Simply put, nothing in the Federal Circuit's opinion suggests that it contemplated that the Court would conduct subsequent substantive proceedings; rather, the Federal Circuit's opinion indicates that it believed that this case was at an end.

First, the Federal Circuit said nothing about proceedings on remand. It did not "remand for further proceedings consistent with [its] opinion. *See, e.g., Mentor Graphic Corp. v. EVE-USA, Inc.*, 851 F.3d 1275, 1301 (Fed. Cir. 2017). Nor did it "vacate the judgment and remand for a new trial." *See, e.g.*, *Avid Tech., Inc. v. Harmonic, Inc.*, 812 F.3d 1040, 1042. Instead it "reverse[d] the district court's judgment of infringement with respect to the '727 patent and affirmed the court's summary judgment of noninfringement with respect to the '343 patent." *Meds. Co.*, 853 F.3d at 1310. There is no mention of a remand, no mention of another trial, and

[4] The Court notes that there are exceptions to the mandate rule in three rare circumstances. *See Banks*, 741 F.3d at 1276. TMC does not argue that one of the exceptions applies. Instead, it argues that certain issues are outside the scope of the mandate.

no mention of anything other than the final disposition of the case. Moreover, there is no mention of the "doctrine of equivalents" or "literal infringement."

Second, the Federal Circuit's decision not to reach the question of the '727 Patent's validity strongly suggests that any further substantive proceedings in this case are beyond the scope of the mandate. Citing Defendants' counsel's agreement at oral argument that "a finding of noninfringement would render it unnecessary for the court to reach th[e] issue [of invalidity]," the Federal Circuit exercised its discretion "to limit the grounds upon which appeals are decided" even though "a finding of noninfringement cannot moot a counterclaim of invalidity." *Id.* at 1302 n.1. If the Federal Circuit had believed there was more to be done in this case, it would not have agreed with Defendants' counsel that "a judgment of noninfringement with respect to both patents in suit 'would be tantamount to the relief sought on the merits' and that [the court] need not reach the invalidity issues." *Id.* (quoting *Old Town Canoe*, 448 F.3d at 1318 n.2). As TMC would have the Court believe, the Federal Circuit remanded this case for a new trial on infringement, skipping over validity issues squarely before the court that were potentially dispositive and that would have almost certainly recurred in a subsequent appeal after remand.[5] The Court will not read the Federal Circuit's opinion to invite such needless inefficiency, especially in light of the fact that the Federal Circuit made no indication that it was remanding this case for further substantive proceedings.

Third, the Federal Circuit did not mention further proceedings and declined to reach the question of invalidity for a reason: no infringement issues remained in the case. The Court reached the question of literal infringement and the doctrine-of-equivalents with respect to the

[5] Hypothetically, if TMC prevailed on its doctrine-of-equivalents theory of infringement on remand, Defendants would likely appeal that decision as well as the district court's previous finding of patent validity. If Defendants prevailed on TMC's doctrine-of equivalents theory, TMC would likely appeal that decision and Defendants would argue patent invalidity once again before the Federal Circuit.

"efficient mixing" limitation. While it reached these issues under the '343 Patent, the "efficient mixing" claim limitation applies to *both* patents-in-suit. *See id.* at 1302 ("We agree with Mylan that 'efficient mixing' is . . . a limitation of both the '727 and '343 patents."); *id.* at 1307–08 (construing the "efficient mixing" limitation in both patents together based on Examples 4 and 5 in the specifications of both patents); *id.* at 1309 ("We therefore construe the 'efficient mixing' required by the *patents* to require using the efficient mixing conditions of Example 5." (emphasis added)). Accordingly, when the Federal Circuit reached the portion of its opinion discussing infringement, it considered whether Defendants infringed either patent-in-suit under the Federal Circuit's updated construction of the "efficient mixing" limitation and concluded that there was no infringement. *Id.* at 1309 ("The net effect of our claim construction is that to infringe either the '727 patent or the '343 patent, infringing batches must be compounded using a process that employs the efficient mixing conditions of Example 5. Under this claim construction, Mylan's ANDA does not infringe the asserted claims . . . ."). The Federal Circuit was clear that "the undisputed facts before the district court on summary judgment foreclose the possibility that Mylan 'would likely sell an infringing' product" because Mylan's compounding process materially differed from Example 5. *Id.* at 1310. Notably, the Federal Circuit discussed infringement generally; it did not use the terms "literal infringement" or the "doctrine of equivalents."

The Federal Circuit also confirmed that the Court was correct that "Mylan's compounding process was 'more inefficient' than Example 4." *Id.* at 1310 n.10. Given that the Federal Circuit concluded that (1) "[w]hether we view the patentee as having disclaimed inefficient mixing or construe 'batches' to require efficient mixing, at bottom, the compounding process must be one that uses efficient mixing," *id.* at 1305 (citation omitted), and (2) "Examples

4 and 5 [] clearly state what efficient mixing is *and is not*, *id.* at 1307 (emphasis added), the Court (and, it appears, the Federal Circuit) cannot see how Mylan could infringe the "efficient mixing" limitation under any theory. Additionally, as the Court previously concluded at the summary-judgment stage in rejecting TMC's doctrine-of-equivalents argument, "Mylan's process does not achieve its results 'in substantially the same way' as the invention at issue [because] Mylan's ANDA process does not use 'efficient mixing.'" (R. 309 at 23.)

TMC argues that the Federal Circuit's opinion and mandate "do not cover infringement under the doctrine of equivalents and therefore do not preclude a trial before th[e] Court on this issue." (R. 682 at 8; *see also* R. 687 at 1–2.) It contends that "[n]either the district court nor the Federal Circuit adjudicated infringement of the '727 patent under the doctrine of equivalents," and, "having obtained a favorable claim construction, there was no reason for [TMC] to argue infringement under the doctrine of equivalents." (R. 687 at 1.) TMC's arguments are unpersuasive. It fails to recognize that the "efficient mixing" claim limitation applies to both patents-in-suit and that the Court concluded that Defendants did not infringe the '343 Patent due to this limitation under a literal-infringement theory and under the doctrine of equivalents. Thus, the issue of whether the presence of the "efficient mixing" claim limitation precluded a finding of infringement was before this Court, resolved by this Court, and resolved on appeal. As previously noted, the mandate rule covers issues "within the scope of the judgment appealed from, minus those explicitly reserved or remanded by the [appellate court]." *Amado*, 517 F.3d at 1360; *see also Banks*, 741 F.3d at 1279 ("[A]ll issues within the scope of the appealed judgment are deemed incorporated within the mandate and thus are precluded from further adjudication." (quoting *Engel*, 741 F.3d at 1279)). Thus, the Court's doctrine-of-equivalents ruling falls within the scope of the mandate.

TMC cannot complain that the Federal Circuit's new claim construction necessitated a remand for further proceedings. The Federal Circuit clearly believed it could resolve the issue of infringement under its new claim construction without remanding the case. *See Meds. Co.*, 853 F.3d at 1309 ("Under [the Federal Circuit's] claim construction, Mylans's ANDA does not infringe the asserted claims . . . ."). Nor can TMC escape the mandate rule because it opted not to raise the issue of whether this Court properly disposed of its doctrine-of-equivalents argument. The Court determined (1) that TMC had waived its doctrine-of-equivalents argument by failing to submit timely expert evidence, and, in the alternative, (2) that the "efficient mixing" limitation precluded finding infringement under the doctrine of equivalents. TMC thus had an opportunity and motivation to raise the doctrine-of-equivalents issue on appeal. While the Court recognizes that its doctrine-of-equivalents ruling concerned the '343 Patent, the Federal Circuit's claim construction made this Court's infringement rulings related to the "efficient mixing" limitation applicable to both patents—a result well within the realm of possibility of the appeal. TMC gives no reason, nor can the Court discern one, for receiving a second opportunity to raise an issue it failed to properly raise previously in the district court *and* on appeal. Accordingly, the mandate rule precludes this Court from holding additional proceedings on infringement under the doctrine of equivalents. *See Amado*, 517 F.3d at 1360 (explaining that "[a]n issue that falls within the scope of the judgment appealed from but is not raised by the appellant in its opening brief on appeal is necessarily waived" and that "the mandate rule precludes reconsideration of any issue within the scope of the judgment appealed from—not merely those issues actually raised"); *see also ResQNet.com, Inc. v. Lansa*, 828 F. Supp. 2d 688, 696 (S.D.N.Y. 2011).

TMC also argues that the Federal Circuit's decision in *Exxon Chemical Patents, Inc. v. Lubrizol Corp.*, 137 F.3d 1475 (Fed. Cir. 1998), indicates that the mandate rule does not prevent

the Court from moving forward with a new trial on the question of the doctrine of equivalents. (*See* R. 682 at 5.) There, a jury found that the defendant literally infringed the plaintiff's patent, but the jury did not consider the doctrine of equivalents. 137 F.3d at 1477. The plaintiff had deleted the doctrine-of-equivalents jury instruction after the district court adopted its proposed claim construction. *Id.* On appeal, the Federal Circuit rejected the district court's claim construction, adopted the construction proposed by the defendant, and held that under the new claim construction, no reasonable jury could have found literal infringement. *Id.* The majority of the panel explicitly noted that the parties had not briefed the question of whether the plaintiff was entitled to a new trial on infringement under the doctrine of equivalents, and therefore the majority expressed no view on the issue. *Id.* The dissenting judge argued that the plaintiff was entitled to a new trial. *Id.* Subsequently, the plaintiff sought a new trial on infringement under the doctrine of equivalents in the district court, which the court denied. *Id.* The Federal Circuit disagreed with the district court and therefore vacated the district court's denial of the plaintiff's motion for a new trial and remanded for further proceedings. *Id.*

Exxon is distinguishable from the current case. First, in *Exxon*, the Federal Circuit in its initial opinion was explicit that (1) "the judgment under review was limited to literal infringement," and (2) it had no opinion on the question of whether a new trial under the doctrine of equivalents was appropriate. *Id.* at 1478 (quotation marks and citation omitted). In the current case, as described above, the Federal Circuit indicated that the case was at an end when it declined to consider the question of patent invalidity. Moreover, the Federal Circuit discussed infringement generally and did not explicitly limit its ruling to the question of literal infringement. *Meds. Co.*, 853 F.3d at 1309–10; *see supra*. Second, the district court in *Exxon* had not addressed the doctrine of equivalents, as the issue was not presented to the jury. *Id.* at

1477. Here, the Court addressed both literal infringement and infringement under the doctrine of equivalents as they relate to the "efficient mixing" limitation—a limitation the Federal Circuit determined applied to both patents-in-suit. In other words, as discussed above, this Court resolved the doctrine-of-equivalents issue as it related to the "efficient mixing" limitation. That issue therefore is within the scope of the mandate because it was "within the scope of the judgment appealed from" just as much as the issue of literal infringement as it pertained to the "efficient mixing" limitation. *See Amado*, 517 F.3d at 1360; *see also Banks*, 741 F.3d at 1279. This was not the case in *Exxon*. *See Tronzo v. Biomet, Inc.*, 236 F.3d 1342, 1348 (Fed. Cir. 2001) (distinguishing *Exxon* because in that case "the trial court had not addressed the contested issue and, therefore, the issue was not deemed within the scope of the judgment initially appealed").

In short, nothing in the Federal Circuit's decision indicates that it contemplated additional proceedings on the question of the doctrine of equivalents or any other issue. Instead, the decision supports that the Federal Circuit believed this case was at an end. Moreover, the issue of infringement under the doctrine of equivalents as it relates to the "efficient mixing" limitation was squarely a part of this Court's summary judgment opinion. That TMC chose to discuss literal infringement instead of the doctrine of equivalents before the Federal Circuit does not give it license for a second bite at the apple. This hard-fought case has come to an end.[6]

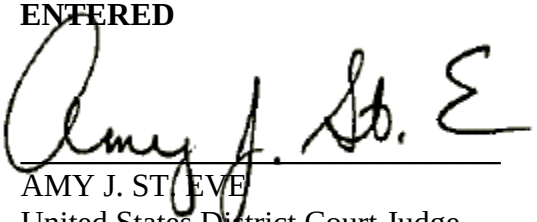
[6] The Court will not consider TMC's request for further discover into Defendants' ANDA. Discovery closed quite some time ago. Furthermore, TMC's request is akin to moving under Federal Rule of Civil Procedure 15 to amend the complaint after trial and appeal. Defendants argue "[i]f TMC believes it has a basis to file a new suit that meets the requirements of Rule 11, it may do so, but this case is at an end." (R. 686 at 6.) The Court agrees that this litigation has concluded. It has no opinion regarding TMC's ability to file another complaint or the wisdom of doing so.

CONCLUSION

For the foregoing reasons, the Court grants Defendants' motion and denies TMC's motion.

DATED: June 28, 2017

ENTERED



AMY J. ST. EVE
United States District Court Judge