NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE: CERTAIN CONSOLIDATED ROFLUMILAST CASES,	:	Civil Action No. 15-03375 (FLW) (DEA)
		OPINION

WOLFSON, United States District Judge:

Before the Court is the motion of Defendants Torrent Pharmaceuticals Ltd., Torrent Pharma Inc., Strides Pharma, Inc., Strides Pharma Global PTE Ltd., Prinston Pharmaceutical Inc., Hetero USA, Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited (collectively the "Moving Defendants") for reconsideration of this Court's October 18, 2016 Opinion and Order construing the term "roflumilast" according to its plain and ordinary meaning as "N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxybenzamide" in U.S. Patent Nos. 8,536,206 (the "'206 Patent"), 8,604,064 (the "'064 Patent"), and 8,618,142 (the "'142 Patent") (collectively, the "Patents-at-Issue"), following the *Markman* hearing in this case. The Moving Defendants contend that this Court erred in construing the term roflumilast (i) for the reasons set forth in the Moving Defendants' original claim construction briefing and at the *Markman* hearing and (ii) in light of newly discovered evidence in the form of the testimony of the inventor of the Patents-at-Issue. Plaintiffs AstraZeneca AB, AstraZeneca Pharmaceuticals LP, and AstraZeneca UK Ltd. ("Plaintiffs") oppose the motion. For the reasons set forth below, the Moving Defendants' motion is denied.

I. FACTUAL BACKGROUND & PROCEDURAL HISTORY

The facts of this matter are set forth in detail in the Court's October 18, 2016 Opinion and Order. As relevant to the present motion, the sole claim term disputed in this action, which

appears in each of the Patents-at-Issue, is "roflumilast." The Patents-at-Issue are members of the same family of patents as U.S. Patent No. 7,470,791 (the "'791 Patent"), which purportedly protects novel processes for the production of highly pure roflumilast. '206 Patent at 1:1-17; '064 Patent at 1:1-19; '142 Patent at 1:1-19; '791 Patent at 8:29-20:6. Both the '206 Patent and the '064 Patent are process patents that claim methods for the treatment of an acute or chronic airway disorder using highly pure roflumilast. '206 Patent at 8:21-10:34; '064 Patent at 8:37-10:33. The '142 Patent claims a chemical composition composed primarily of roflumilast. '142 Patent at 8:22-9:21.

Roflumilast is the international nonproprietary name ("INN") for the chemical compound N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-difluoromethoxybenzamide (the "Roflumilast Compound"). Each of the Patents-at-Issue identifies the Roflumilast Compound as "INN: roflumilast." '206 Patent at 1:14-17; '064 Patent at 1:16-19; '142 Patent at 1:16-19.
In their papers and at the *Markman* hearing, the Moving Defendants, along with Breckenridge Pharmaceutical Inc., Mylan Pharmaceuticals, Inc., Citron Pharma LLC, MSN Laboratories Private Ltd., Apotex Inc., Apotex Corp., Micro Labs USA, Inc., and Micro Labs Ltd. (collectively "Defendants"), argued that express disavowals in the specifications of the Patents-at-Issue and disclaimers that were made during the patent prosecution history require that "roflumilast" be construed more narrowly than its plain and ordinary meaning. Defendants contended that roflumilast should be construed as only the product of the process to produce roflumilast disclosed in the specifications of the Patents-at-Issue.

After a full briefing of the issue, on July 12, 2016, the Court held a *Markman* hearing at which the parties made oral argument. The Court, setting forth its reasons on the record, construed "roflumilast" as it appears in the Patents-at-Issue by its plain and ordinary meaning –

the chemical compound to which its INN corresponds. On October 18, 2016, the Court issued an Opinion and Order further setting forth its reasons. On November 11, 2016, the Moving Defendants moved for reconsideration of the Court's Opinion and Order. The remaining Defendants chose not to seek reconsideration. On May 1, 2017, the Moving Defendants requested supplementary briefing to argue the significance of the recent decision of the Federal Circuit in *The Medicines Co. v. Mylan, Inc.*, Fed. Cir. Nos. 2015-1113, 2015-1151, 2015-1181, 2017 U.S. App. LEXIS 5947 (Fed. Cir. Apr. 6, 2017) (hereinafter, "*TMC*"). The Court granted the Moving Defendants' request and received letter briefs from the Moving Defendants and Plaintiffs on May 5, 2017. The Court now considers the Moving Defendants' motion and the parties' supplementary briefing.

II. STANDARD OF REVIEW

Motions for reconsideration are governed by Federal Rule of Civil Procedure 59(e) and Local Civil Rule 7.1. Pursuant to Local Civil Rule 7.1(i), a party moving for reconsideration must "set[ ] forth concisely the matter or controlling decisions which the party believes the Judge or Magistrate Judge has overlooked[.]" L. Civ. R. 7.1(i). Motions for reconsideration are considered "extremely limited procedural vehicles." *Resorts Int'l v. Great Bay Hotel & Casino*, 830 F. Supp. 826, 831 (D.N.J. 1992). Indeed, they "are not to be used as an opportunity to relitigate the case; rather, they may be used only to correct manifest errors of law or fact or to present newly discovered evidence." *Blystone v. Horn*, 664 F.3d 397, 415 (3d Cir. 2011) (citing *Howard Hess Dental Labs., Inc. v. Dentsply Int'l Inc.*, 602 F.3d 237, 251 (3d Cir. 2010)); *see also N. River Ins. Co. v. CIGNA Reinsurance Co.*, 52 F.3d 1194, 1218 (3d Cir. 1995).

Accordingly, a judgment may be altered or amended [only] if the party seeking reconsideration shows at least one of the following grounds: (1) an intervening change in the

controlling law; (2) the availability of new evidence that was not available when the court granted the motion for summary judgment; or (3) the need to correct a clear error of law or fact or to prevent manifest injustice." *Blystone*, 664 F.3d at 415 (quotations omitted, emphasis removed, alterations in original). "A party seeking reconsideration must show more than a disagreement with the Court's decision, and 'recapitulation of the cases and arguments considered by the court before rendering its original decision fails to carry the moving party's burden.'" *G-69 v. Degnan*, 748 F. Supp. 274, 275 (D.N.J. 1990) (quoting *Carteret Savings Bank, F.A. v. Shushan*, 721 F. Supp. 705, 709 (D.N.J. 1989)). In other words, "a motion for reconsideration should not provide the parties with an opportunity for a second bite at the apple." *Tischio v. Bontex, Inc.*, 16 F. Supp. 2d 511, 533 (D.N.J. 1998) (citation omitted). Rather, a difference of opinion with the court's decision should be dealt with through the appellate process. *Florham Park Chevron, Inc. v. Chevron U.S.A., Inc.*, 680 F. Supp. 159, 162 (D.N.J. 1998). Finally, the Court will only grant such a motion if the matters overlooked might reasonably have resulted in a different conclusion. *Bowers v. NCAA*, 130 F. Supp. 2d 610, 613 (D.N.J. 2001).

III. ANALYSIS

The Moving Defendants seek reconsideration of the Court's claim construction on two bases. Firstly, the Moving Defendants recapitulate their previous claim construction argument that language in the specification common to all of the Patents-at-Issue constitutes an express disavowal of roflumilast produced by all processes except that explicitly endorsed in the specification. In their supplementary letter brief, the Moving Defendants argue that the case before the Federal Circuit in *TMC*, in which the circuit court found that a process limitation could be imported into patent claims from language in the specification, is sufficiently factually

similar to the case at bar to suggest that the same result should have been reached here. Defendants further contend that the Court must find an express disavowal in this case because failure to do so would render the Patents-at-Issue invalid due to the inclusion of ordinary roflumilast in the prior art. Secondly, the Moving Defendants argue that newly discovered evidence in the form of the deposition testimony of Dr. Bernd Mueller, the inventor of the Patents-at-Issue and Plaintiffs' designated Rule 30(b)(6) witness, operates to narrow the definition of roflumilast claimed in the Patents-at-Issue to only roflumilast produced by the process endorsed in the specification. As explained below, the Court finds that reconsideration of the October 18 Opinion and Order is not warranted and so denies the Moving Defendants' motion.

A. Defendants' Previous Arguments

It is axiomatic that "[w]here litigants have once battled for the court's decision, they should neither be required, nor without good reason permitted, to battle for it again." *Dixon v. Shinseki*, 741 F.3d 1367, 1378 (Fed. Cir. 2014) (quotation omitted). The Third Circuit, therefore, has explained that the scope of a motion for reconsideration is "extremely limited," and has enumerated only three circumstances in which reconsideration is appropriate. *Blystone*, 664 F.3d at 415.[1] Here, the Moving Defendants' first argument, that language included in the specification shared by the Patents-at-Issue, which endorses a particular process and disparages other processes acts as an express disavowal of roflumilast produced by any process other than the

[1] "Accordingly, a judgment may be altered or amended [only] if the party seeking reconsideration shows at least one of the following grounds: (1) an intervening change in the controlling law; (2) the availability of new evidence that was not available *when the court granted the motion for summary judgment;* or (3) the need to correct a clear error of law or fact or to prevent manifest injustice." *Id. Blystone*, 664 F.3d at 415 (quotation omitted) (emphasis in original).

endorsed one, was clearly raised in Defendants' original claim construction briefing and thoroughly argued at the *Markman* hearing. Dkt. No. 82, 7-21. The Moving Defendants do not offer an intervening change of controlling law relevant to this argument, nor do they cite to any newly discovered, previously unavailable *intrinsic* evidence,[2] nor have they identified a clear error of law or fact or manifest injustice that would result in the absence of reconsideration. In short, the Moving Defendants' recapitulation of their original claim construction argument does not fall within any of the categories identified by the Third Circuit and is the quintessential example of seeking reconsideration on an impermissible basis. The Court will not allow the Moving Defendants to take a "second bite at the apple" by rehashing my extensive analysis from the October Opinion and Order again here. *Dixon*, 741 F.3d at 1378.

1. The Court Would Reach the Same Conclusion on the Basis of the Intrinsic Evidence.

Even were the Court inclined to revisit its previous application of the same controlling law to the same intrinsic evidence, the result in this case would remain the same. The Moving Defendants' arguments do not alter the fact that, despite the Patents-at-Issue dedicating large

[2] In construing patent claims, courts may examine both intrinsic evidence (i.e., the patent, its claims, the specification, and prosecution history) and extrinsic evidence (i.e., expert reports, testimony, and anything else). *Pitney Bowes, Inc. v. Hewlett–Packard Co.*, 182 F.3d 1298, 1309 (Fed. Cir. 1999). It is well settled, however, that extrinsic evidence is considered only where the intrinsic evidence does not provide a sufficient description to resolve ambiguities in the scope of the claim. *See Vitronics*, 90 F.3d at 1583; *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999). Extrinsic evidence cannot be used to vary or contradict claim terms when their meanings are discernible from intrinsic evidence. *C. R. Bird, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004). In its October 18 Opinion and Order, this Court analyzed the claims, specifications, and prosecution histories of the Patents-at-Issue, and found that roflumilast should be given its plain and ordinary meaning on the basis of such intrinsic evidence alone. In their motion for reconsideration, the Moving Defendants' first argument asks the Court to review the same intrinsic evidence again and reach a different conclusion. This argument therefore does not present any newly discovered evidence for the Court's consideration. By contrast, the Moving Defendants' second argument presents newly discovered *extrinsic* evidence in the form of inventor testimony, which is discussed, *infra*.

portions of their specifications to disclosing processes for the production of roflumilast, these Patents *do not claim such processes*. Instead, the Patents-at-Issue claim methods for the treatment of airway disorders and claim a chemical composition composed primarily of roflumilast. '206 Patent at 8:21-10:34; '064 Patent at 8:37-10:33; '142 Patent at 8:22-9:21.[3] The '791 Patent, not any one of the Patents-at-Issue, claims processes for the production of roflumilast. The Patents-at-Issue merely use the word roflumilast, identified by its INN, the plain and ordinary meaning of which refers to a compound of a specific chemical composition, without regard for the process employed to produce the compound. From the very outset, therefore, the burden was on the Moving Defendants to "establish [that] the inventors demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Epistar*, 566 F.3d at 1334 (quotations and brackets omitted).

The Moving Defendants failed to meet their burden. The law is clear that the Federal Circuit "do[es] not [simply] read limitations from the embodiments in the specification into the claims." *Hill-Rom Servs. v. Stryker Corp.*, 755 F.3d 1367, 1371 (Fed. Cir. 2014). Instead, "[d]isavowal requires that the specification or prosecution history make clear that the invention does not include a particular feature, or is clearly limited to a particular form of the invention." *Id.* (quoting *SciMed Life Sys.*, 242 F.3d at 1341 and *Edwards Lifesciences LLC v. Cook Inc.*, 582

[3] As this Court observed in its Opinion and Order, "[g]enerally[,] product claims are not limited to the methods of manufacture disclosed in the specification and . . . the method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process. . . . A novel product that meets the criteria of patentability is not limited to the process by which it was made." *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1375 (Fed. Cir. 2007) (quoting *Vanguard Prods. Corp.*, 234 F.3d at 1372-73) (quotations and brackets omitted). Production process steps should only be treated as part of a product claim "if the patentee has made clear that the process steps are an essential part of the claimed invention." *Andersen*, 474 F.3d at 1375.

F.3d 1322, 1330 (Fed. Cir. 2009)) (quotations and brackets omitted). Here, the Patents-at-Issue state in pertinent part:

> None of the processes described in the international applications WO 93/25517 and WO 94/02465 for preparing piclamilast, nor the process described in WO 95/01338 for preparing roflumilast, appear to be suitable for the industrial preparation of roflumilast of high purity.
>
> Although the improved process described in Organic Process Research & Development 2, 157-168 (1998) for preparing 3-(cyclopentyloxy)-N-(3,5dichloropyrid-4-yl)-4-methoxybenzamide (INN: piclamilast) has already been optimized for feasibility on the industrial scale, when applied analogously to roflumilast it leads to the formation of more than 3% by weight of the by-product N-(3,5-dichloropyrid-4-yl)-3-cyclopropylmethoxy-4-hydroxybenzamide, which cannot be reduced even by multiple recrystallization.

'206 Patent at 2:15-28, '064 Patent at 2:19-33, '142 Patent at 2:14-27. The shared specification language thus clearly does disparage the application of two processes for the preparation of piclamilast to the preparation of roflumilast as well as one preexisting process for the preparation of roflumilast. The Court, however, cannot find, as the Moving Defendants argue, that criticisms of two particular production processes indicate that the patentee intended to explicitly disclaim *all* methods other than a single process to produce the highly pure roflumilast needed to create the composition claimed in the '142 Patent or needed to implement the processes claimed in the '206 and '064 Patents. *See also Thorner v. Sony Computer Entertainment America LLC*, 669 F.3d 1362 (Fed. Cir. 2012) ("Mere criticism of a particular embodiment encompassed in the plain meaning of a claim term is not sufficient to rise to the level of clear disavowal."). The flaw in the Moving Defendants' reasoning remains the same as that identified in the Court's original Opinion; the law does not support that disparagement of some embodiments in the specification evinces an express intent to limit the claim.

Moreover, the Moving Defendants' motion does not address this Court's thorough review of the Patents-at-Issue's prosecution history, in which the Court found that the inventors

purposefully chose not to restrict the claims in the Patents-at-Issue to roflumilast produced by the process disclosed in the patents' specifications. October 18, 2016 Opinion, 15-17. In short, the prosecution history of the family of patents including the Patents-at-Issue reveals that, while many of the initial applications for patents in the family included language expressly limiting the roflumilast utilized in the claims to roflumilast produced by a particular process, the patentees amended their applications *to remove* the express limitations. Accordingly, even were I to reconsider the Moving Defendants' prior arguments, the outcome in my Opinion and Order would remain the same in light of the clear claim language, specification language, and prosecution history of the Patents-at-Issue.

2. The *TMC* Case Does Not Affect the Court's Opinion.

The recent Opinion of the Federal Circuit in *TMC* does not change the result in this case. The patents at issue in *TMC* were directed to pharmaceutical formulations, or "batches" of the drug bivalirudin produced through a process that consistently minimized impurities. *Id.* at *2. The patents' inventors had developed an improved "efficient mixing" process, which resulted in batches that consistently satisfied the FDA's percent limitation on impurities in bivalirudin. *Id. at *6.* In the district court below, the parties had disputed the construction of the terms "batches" and "efficient mixing." Specifically, in the shared specification of the patents in issue, the term "pharmaceutical batches" was defined 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.

TMC, 2017 U.S. App. LEXIS 5947, *7-8. The patentee, TMC, proposed that “batches” should be construed according to the verbatim definition of pharmaceutical batches from the specification, while defendant Mylan insisted that additional language of "made by a compounding process" was necessary after “all commercial batches” in order to provide an antecedent for the later phrase “made by said process.” TMC argued that no antecedent was necessary because the readily discernable meaning of the definition was that “batches” referred only to “batches” “made by a compounding process of various embodiments of the present invention.” *Meds. Co. v. Mylan Inc.*, 2012 U.S. Dist. LEXIS 109749 *, 2012 WL 3234282 (N.D. Ill. Aug. 6, 2012). At oral argument, however, patentee TMC conceded that it could live with Defendant Mylan’s proposed additional language and consented to the Court’s construction of “batches” as either “(1) ‘a single batch, wherein the single batch is representative of all commercial batches . . . *made by a compounding process*, 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’; or (2) ‘all batches prepared by a same compounding process.’” *Medicines*, 2012 U.S. Dist. LEXIS 109749, 2012 WL 3234282, at *3-5 (emphasis added). *Id.* at *8-9. As the Federal Circuit Court observed on appeal, the parties in the case had thus consented to the district court’s clarification that “batches” required bivalirudin produced by “a particular process.” *9.

“With respect to ‘efficiently mixing,’ the district court relied on two examples set forth in the patents’ specifications comparing TMC’s ‘old compounding process’ using ‘inefficient mixing conditions’ (Example 4) with the improved ‘efficient mixing’ process developed by Drs. Krishna and Musso (Example 5). *See* 2012 U.S. Dist. LEXIS 109749, [WL] at *14-15; *see also* '727 patent, col. 21 l. 44-col. 24 l. 35; '343 patent, col. 22 l. 21-col. 25 l. 3. The court

ultimately agreed 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.' " *TMC*, 2017 U.S. App. LEXIS 5947, *9-10 (quoting *Medicines*, 2012 U.S. Dist. LEXIS 109749, 2012 WL 3234282, at *15).

Based on these claim constructions, the district court held that Mylan's ANDA, which employed an inefficient mixing process, did not infringe one patent, which included the efficient mixing claim limitation, but infringed the other, which lacked the efficient mixing claim limitation. *See* 2013 U.S. Dist. LEXIS 176269, [WL] at *10, *20. On appeal, defendant Mylan took the position that the efficient mixing claim limitation should have been imported into both patents in issue by virtue of their shared specification and the "batches" definition. The patentee, TMC, took the new position that "the batches limitation is not necessarily limited to a compounding process that achieves batch consistency. Instead, . . . the batches limitation is satisfied whenever an accused infringer consistently produces batches having Asp9 levels below 0.6 percent, and that the claims do not require the use of a particular process that achieves batch consistency." *TMC*, 2017 U.S. App. LEXIS 5947, *14. The Federal Circuit agreed with Mylan, holding that the "batches limitation" in both patents in issue required the production of bivalirudin through a particular process including "efficient mixing." The appellate court set forth four primary reasons for its narrowing construction.

Before this Court discusses the reasoning of the Federal Circuit in *TMC*, it is important to emphasize the extremely different factual and procedural posture of that case during the district court's claim construction. The specification in *TMC* was factually distinguishable from that in this case because the definition of "pharmaceutical batches" of bivalirudin already included a limitation that the bivalirudin be produced through a particular process. Here, by contrast,

roflumilast is identified in the specification only by its INN, without reference to a particular process. Moreover, procedurally, the question of whether the term "batches" imposed a process limitation on the claimed bivalirudin in *TMC* was never disputed before the district court because both the patentee and the defendant agreed that, on the basis of the definition in the specification, it was clear that the batches of bivalirudin had to be produced by a particular process. The parties therefore ultimately consented to the district court's construction. *Id.* at * 15. Indeed, it was the position *of the patentee* in *TMC* before the district court that the particular process called for in producing the batches claimed was clearly and unmistakably the compounding process of the patentee's present invention. *Id.* at *9. The more general language of "a particular process" was only settled upon at the insistence *of the defendant*. *Ibid.* Accordingly, the central question in this case — whether the claimed term (roflumilast) includes a process limitation due to the language of the specification — was never disputed by the parties before the district court in *TMC*. That fact alone is sufficient to distinguish *TMC* from the case at bar.

Turning to the reasoning of the Federal Circuit in *TMC* on appeal, it remains clear that the critical factors for interpreting the intrinsic evidence in that case to narrow the plain and ordinary meaning of the claims are absent here. The first[4] and most important factor the Federal Circuit observed in its claim construction was the prosecution history of the *TMC* patents in issue. The appellate court held as a threshold matter that the phrase "batches . . . [that] do[] not exceed 0.6%" impurities could not be "literally construed" to mean all batches of bivalirudin not exceeding 0.6% impurities because the patentee had been forced to disclaim that plain and ordinary meaning during prosecution due to the patentee's pre-critical-date sales of such batches.

[4] This Court does not address the Federal Circuit's reasons in the order in which they appear in the *TMC* opinion, instead presenting them in a manner which facilitates application to this case.

TMC, 2017 U.S. App. LEXIS 5947, *13. The Federal Circuit observed that the patentee "took pains to distinguish its pre-critical date sales" during prosecution, certifying that batches of bivalirudin described by the patents in suit had not been on sale for more than one year prior to the patents' filing date. *TMC*, 2017 U.S. App. LEXIS 5947, *16-17. In other words, in *TMC* it was impossible at the outset to find that "bivalirudin of a certain purity" meant "bivalirudin of a certain purity" in the patents in issue because the patentee had already been selling bivalirudin batches of that purity for over a year before its patent application. Bivalirudin of that purity was indisputably in the prior art. The appellate court also noted that, at oral argument, patentee's counsel had admitted that purity of the composition of bivalirudin alone was insufficient to distinguish the patents in issue from the prior art, requiring the consistency limitation. *Id.* at *14.

There are no such facts here. To the contrary, in this case the claimed compositions were not distinguished during prosecution based on the process by which they were made, but rather by a declaration showing that the claimed compositions were not in the prior art. *See* Decl. of Walter Palosch, ECF 82-15. Moreover, the Moving Defendants have not pointed to any disclosure in the prior art of the claimed compositions of roflumilast and the 4-hydroxy compound, only to roflumilast itself, the prior existence of which is not disputed.

Second, the Federal Circuit observed that the language of the specification in *TMC* itself, required not only a particular process, as discussed above, but also that the process "consistently generate formulations having low levels of impurities." *TMC*, 2017 U.S. App. LEXIS 5947, *15. Here, by contrast, the specification does not define roflumilast in terms of the process used in its preparation and does not tie the particular compositions of roflumilast and 4-hydroxy compound claimed to the consistency of any such process. Instead, the specification sets forth an ideal

embodiment in the form of the patentee's novel process, without expressly limiting the treatment method Patents-at-Issue to the use of roflumilast produced by that ideal process.

Third, the Federal Circuit in *TMC* held that adopting the patentee's alternative claim construction would be unworkable because "proof of infringement would necessitate forward-looking assessments of whether an accused infringer's production of future or 'potential' batches would be likely to generate [impurity] levels greater than 'about 0.6%.'" *TMC*, 2017 U.S. App. LEXIS 5947, *14-15. The appellate court explained:

> To illustrate, if a defendant using the same compounding process produced fifty batches each having an Asp^9 level below 0.6 percent, each of those fifty batches would infringe. But the defendant would not know whether any of the batches infringed until all fifty batches had been produced because if even one of those batches was determined to have an Asp^9 level higher than 0.6 percent, none of the batches would infringe. *See* Oral Argument at 17:00-19:06, *Medicines Co. v. Mylan, Inc.*, No. 15-1113 (Fed. Cir. Dec. 6, 2016). For an ongoing commercial compounding process, this approach cannot provide "reasonable certainty" regarding the scope of the asserted claims.

Id. at *15. The unworkability in *TMC* came about because mere batches with impurity levels below 0.6 percent were already in the prior art. The patentee's invention in the patents in issue was therefore dependent upon *consistently* producing batches with impurity levels below 0.6 percent. In the absence of some sort of process limitation, therefore, identifying infringement would require sampling of every batch produced to determine if a competitor was *consistently* producing batches of the requisite impurity. Here, the particular composition of roflumilast and 4-hydroxy compound of the requisite purity in the Patents-at-Issue is itself novel, such that no consistent production limitation was necessitated, nor for that matter included, in the patents' claims, specification, or prosecution history.

Fourth and finally, the Federal Circuit was swayed by *TMC*'s admission to the district court that "[w]hen viewed in the context of the specification, it is readily apparent that the

[definition of 'pharmaceutical batches'] refers to the compounding processes described in the patents-in-suit." *Medicines,* 2013 U.S. Dist. LEXIS 176269, 2013 WL 6633085, at *15." In other words, the patentee, through counsel, directly affirmed the reading of the disputed term that was supported by the intrinsic evidence. Here, the patentee's position has consistently been that the term roflumilast does not include a process limitation. As the Court held at the *Markman* hearing and explained in its October 18 Opinion and Order, that position is supported by the intrinsic evidence in this case. There is accordingly, no admission by Plaintiffs upon which to rely to undermine the clear claim language. In sum, the Federal Circuit's decision in *TMC* is clearly distinguishable from the case at bar and does not merit reconsideration of this Court's Opinion and Order.

3. The Validity Maxim

In the context of reiterating their disavowal argument, the Moving Defendants raise the issue that the Court's decision was in error because "plain and ordinary roflumilast" is in the prior art and therefore cannot be the subject of the Patents-at-Issue.[5] The Moving Defendants argue that the Court should have read the language in the specification as a disavowal of claim scope in order to avoid invalidating that Patents-at-Issue.

This court finds that recourse to the validity maxim is not warranted in this case. As the Federal Circuit has observed:

[5] To the extent that the Moving Defendants raise for the first time on reconsideration the argument that reading roflumilast according to its ordinary meaning in the Patents-at-Issue would invalidate the patents, and therefore the term should be more narrowly construed to avoid invalidity, that argument is improper and rejected by this Court. "An argument made for the first time in a motion for reconsideration comes too late and is ordinarily deemed waived." *Golden Bridge Tech., Inc. v. Apple Inc.,* 758 F.3d 1362, 1369 (Fed. Cir. 2014). "[N]ew arguments are beyond the scope of a motion for reconsideration." *Blystone,* 664 F.3d at 415.

> Claim construction should not, of course, be blind to validity issues: "claims should be so construed, if possible, as to sustain their validity." *Rhine v. Casio, Inc.*, 183 F.3d 1342, 1345 (Fed.Cir.1999). A claim that is interpreted too broadly will run into validity issues, providing motivation for the construing court to choose a narrower interpretation if possible. However, validity construction should be used as a last resort, not a first principle: "we have limited the maxim [that claims are to be construed to preserve validity] to cases in which the court concludes, after applying all the available tools of claim construction, that the claim is still ambiguous." *Phillips*, 415 F.3d at 1327 (quotation marks omitted). Construction of the claims here is not so difficult a problem as to require resort to the validity maxim.

MBO Labs., Inc. v. Becton, Dickinson & Co., 474 F.3d 1323, 1332 (Fed. Cir. 2007). Specifically, as applied in this case, the intrinsic evidence clearly supports that roflumilast should be given its plain and ordinary meaning. The Court is, therefore, not empowered to rewrite the claims in the Patents-at-Issue on the basis of validity considerations alone. *Honeywell Int'l, Inc. v. Int'l Trade Comm'n*, 341 F.3d 1332, 1341 (Fed. Cir. 2003) ("Adopting Honeywell's proffered construction would require the court to import a limitation that is not only outside the bounds of the claims, the written description, and the prosecution history, but is also outside the scope of any written publication. We may not rewrite claims to preserve validity in that manner."). Stated differently, there is no ambiguity in this case that would support weighing validity considerations. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1328 (Fed. Cir. 2005) ("In this case, unlike . . . other cases in which the doctrine of construing claims to preserve their validity has been invoked, the claim term at issue is not ambiguous. Thus, it can be construed without the need to consider whether one possible construction would render the claim invalid while the other would not. The doctrine of construing claims to preserve their validity, a doctrine of limited utility in any event, therefore has no applicability here.").

B. The Newly Discovered[6] Testimony of Dr. Mueller Does Not Change the Court's Opinion

Turning to the Moving Defendants' second argument, the discovery of new evidence that was not previously available is a permissible basis on which to seek reconsideration. Here, the Moving Defendants contend that the previously unavailable deposition testimony of Dr. Mueller, the inventor of the Patents-at-Issue and Plaintiffs' Rule 30(b)(6) witness, indicates that the Patents-at-Issue intended to disclaim roflumilast produced by all processes other than that endorsed in the Patents-at-Issue's shared specification. Dr. Mueller's testimony would not have changed and does not now change the outcome in the Court's Opinion and Order because it constitutes extrinsic evidence outside of the Court's consideration where, as here, the intrinsic evidence clearly supports a claim construction of plain and ordinary meaning. Furthermore, even were the Court to consider Dr. Mueller's inventor testimony, it would still be legally irrelevant to the Court's claim construction.

1. The Court Declines to Consider Dr. Mueller's Testimony as Extrinsic Evidence.

It is well settled that courts first look to intrinsic evidence, such as the claim, specification, and prosecution history, when interpreting disputed terms. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed .Cir. 1996). Extrinsic evidence, by contrast,

[6] The Third Circuit has "made clear that 'new evidence,' for reconsideration purposes, does not refer to evidence that a party . . . submits to the court after an adverse ruling. Rather, new evidence in this context means evidence that a party could not earlier submit to the court because that evidence was not previously available. Evidence that is not newly discovered, as so defined, cannot provide the basis for a successful motion for reconsideration." *Blystone*, 664 F.3d at 415–16 (quotation omitted). The Moving Defendants have represented that it was not possible to depose Dr. Mueller in advance of the original *Markman* briefing, and Plaintiffs have not challenged this representation. Thus, although the testimony of a party's 30(b)(6) witness and the inventor of one or more of the Patents-at-Issue would not normally qualify as newly discovered evidence, as the party seeking reconsideration clearly had knowledge of its existence, if not perhaps its specific content, prior to the original decision in this case.

includes all evidence external to the patent and prosecution history, e.g., expert and inventor testimonies, dictionaries, and learned treaties. *Markman*, 52 F.3d at 980. It is considered only where the intrinsic evidence does not provide a sufficient description to resolve ambiguities in the scope of the claim. *See Vitronics*, 90 F.3d at 1583; *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999). Ultimately, extrinsic evidence cannot be used to vary or contradict claim terms when their meanings are discernible from intrinsic evidence. *C. R. Bird, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004).

As this Court observed above, in the October 18, 2016 Opinion and Order, the Court found the term roflumilast to be unambiguous on the basis of the intrinsic evidence alone. Thus, the Moving Defendants' proffered extrinsic evidence in the form of inventor testimony could not possibly have disturbed the Court's earlier judgment, as the Court did not look to extrinsic evidence in the first instance.

2. Were the Court to Consider Dr. Mueller's Testimony it Would Not Change the Outcome.

It is well-established in the patent context that the testimony of an inventor "cannot be relied on to change the meaning of the claims." *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 983 (Fed.Cir.1995) (en banc), *aff'd*, 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996); *see also Hoechst Celanese Corp. v. BP Chems. Ltd.*, 78 F.3d 1575, 1580 (Fed.Cir.1996) ("*Markman* requires us to give no deference to the testimony of the inventor about the meaning of the claims."). In particular, the Federal Circuit has "explained that '[t]he subjective intent of the inventor when he used a particular term is of little or no probative weight in determining the scope of a claim.' *Howmedica Osteonics Corp. v. Wright Med. Tech., Inc.*, 540 F.3d 1337, 1346 (Fed. Cir. 2008) (quoting *Markman*, 52 F.3d at 985). Stated succinctly, "inventor testimony as to

the inventor's subjective intent is irrelevant to the issue of claim construction" and cannot be used to narrow claim scope. *Howmedica*, 540 F.3d at 1346–47.

The Federal Circuit has recognized an exception to this general rule, where the testimony of an inventor is offered as expert testimony, "for example, as to understanding the established meaning of particular terms in the relevant art." *Howmedica*, 540 F.3d at 1352 n.5 (Fed. Cir. 2008) (citing *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed.Cir.2005) (en banc)). In the seminal *Phillips* case, the Federal Circuit explained

> We have also held that extrinsic evidence in the form of expert testimony can be useful to a court for a variety of purposes, such as to provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field. *See Pitney Bowes, Inc. v. Hewlett–Packard Co.*, 182 F.3d 1298, 1308–09 (Fed.Cir.1999); *Key Pharms. v. Hercon Labs. Corp.*, 161 F.3d 709, 716 (Fed.Cir.1998). However, conclusory, unsupported assertions by experts as to the definition of a claim term are not useful to a court. Similarly, a court should discount any expert testimony "that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Key Pharms.*, 161 F.3d at 716.

Phillips, 415 F.3d at 1318.

The Moving Defendants contend that Dr. Mueller's testimony falls within the expert testimony exception to the exclusion of inventor testimony from claim construction because it is offered for Dr. Mueller's explanation of the state of the prior art at the time of application. *See, e.g. ArcelorMittal France v. AK Steel Corp.*, 700 F.3d 1314, 1321–22 (Fed. Cir. 2012) (inventor testimony relevant as expert testimony of the prior art). Specifically, the Moving Defendants argue that this case is distinguishable from *Howmedica* because while Dr. Mueller's testimony "is critically relevant to claim construction—how prior-art processes were disavowed as failures and only the inventors' novel process worked—this is not the litigation-driven subjective

characterization of claim language that *Howmedica* rejected." Reply 3. This Court disagrees. Dr. Mueller was asked about how he would describe the invention in the Patents-in-Suit of which he was the named inventor, Mueller Tr. 24:16-22, about his contributions to the invention, *id.* at 68:9-18, about his understanding of what was claimed in the patents, 65:23-66:3, about which parts of the specification he would include in the claim, 76:2-24, and directly about the limitations on the meaning of the term roflumilast in the claims, 116:14-20. These questions, and the answers they elicited, clearly concerned Dr. Mueller's opinions, as the inventor, about claim scope. They do not go to "background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1318 (Fed. Cir. 2005). Whereas permissible inventor expert testimony goes to the meaning of patent terms in the pertinent field, impermissible subjective inventor testimony, like that offered by the Moving Defendants here, goes to the meaning of patent terms in the particular Patents-at-Issue. Because the Court has found the intrinsic evidence to support a plain and ordinary meaning construction for the term roflumilast, the Moving Defendants may not apply the testimony of Dr. Mueller to vary from that meaning based on his subjective impression of the patent claims. *See, e.g., Unwired Planet L.L.C. v. Google, Inc.*, 660 F. App'x 974, 984 (Fed. Cir. 2016) (district court wrongly relied upon inventor's testimony about his subjective understanding of claim term in construing claim scope because inventor's testimony is irrelevant as a matter of law); *Gen. Protecht Grp., Inc. v. Int'l Trade Comm'n*, 619 F.3d 1303, 1310–11 (Fed. Cir. 2010) (the inventor testimony relied on by the judge below did not reveal that the construed term "had

a particular meaning in the art," and the "expert's subjective understanding of a patent term is irrelevant.").

3. Dr. Mueller's Status as Plaintiffs' 30(b)(6) Witness.

Finally, the Moving Defendants contend that Dr. Mueller's testimony as inventor of the Patents-at-Issue is not legally irrelevant to claim construction, despite the weight of precedent to the contrary, because Dr. Mueller was also designated as Plaintiffs' 30(b)(6) witness for the purposes of, *inter alia*, providing evidence relevant to claim construction. The Moving Defendants therefore contend that Dr. Mueller's testimony binds Plaintiffs as the admissions of a corporate representative.

The Court first notes that the Moving Defendants have not provided the Court with any authority, controlling or otherwise, indicating that the admissions of a corporate representative may be used to vary the scope of a patent claim from that established by the intrinsic evidence. Instead, the Moving Defendants primarily rely upon a general pronouncement from the Court of Federal Claims that "[t]he testimony of the inventors does not fill the same purpose as a Rule 30(b)(6) deposition because their testimony would not bind the corporation," *Exxon Research & Eng'g Co. v. US*, 44 Fed. Cl. 597, 601 n.3 (1999), and an unreported district court case from the Eastern District of Texas. *See Blue Spike, LLC v. Audible Magic Corp.*, No. 15-cv-584, 2015 U.S. Dist. LEXIS 181532, at *18-24 (E.D. Tex. Sep. 11, 2015) (granting summary judgment on the basis of inventor/30(b)(6) deponent because statements constituted admissions). *Exxon* does not speak to the question at hand — whether a 30(b)(6) witness's acknowledged capacity to bind a corporation by admissions can be used to alter claim construction — and *Blue Spike* concerned a Rule 30(b)(6) witness's testimony as to *infringement*, not claim construction. This Court does not doubt that Dr. Mueller's testimony could be used to bind Plaintiffs to admissions relevant to

infringement. The Federal Circuit has recognized the appropriate use of 30(b)(6) testimony for such purposes. *See, e.g., Welker Bearing Co. v. PHD, Inc.*, 550 F.3d 1090, 1099 (Fed. Cir. 2008); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1348 (Fed. Cir. 2003); *Nike Inc. v. Wolverine World Wide, Inc.*, 43 F.3d 644, 648 (Fed. Cir. 1994). This Court's research, along, presumably, with the Moving Defendants' own diligent search, however has failed to identify any precedent employing Rule 30(b)(6) inventor testimony to modify claim construction.

The absence of law in support of the Moving Defendants' position is unsurprising in the claim construction context, given the primacy placed by the Federal Circuit on the analysis of the intrinsic evidence concerning terms in any patents in issue. Whether or not the statement of a party to the case, inventor testimony in a deposition during claim construction is inherently extrinsic to the Patents-at-Issue. Thus, in the absence of any authority to the contrary, the Court will, as described above, apply well-established principles of claim construction to find that Dr. Mueller's testimony, in whatever capacity offered, cannot be used to vary the claim terms in the Patents-at-Issue that are unambiguous on the basis of the intrinsic evidence.

IV. CONCLUSION

For the foregoing reasons, the Moving Defendants' motion for reconsideration is **DENIED**.

Dated: 6/2/2017

/s/ Freda L. Wolfson
The Honorable Freda L. Wolfson
United States District Judge