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

THE MEDICINES COMPANY, Plaintiff/ Counter-Defendant, v. MYLAN INC., MYLAN PHARMACEUTICALS INC., and BIONICHE PHARMA USA, LLC, Defendants/ Counter-Plaintiffs.	)	Case No. 11-cv-1285

MEMORANDUM OPINION AND ORDER

AMY J. ST. EVE, District Court Judge:

The parties in this patent infringement case dispute the construction of two claim terms in the patents-in-suit. After reviewing the parties' respective submissions and conducting a *Markman* hearing on July 30, 2012, *see Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (*en banc*), *aff'd* 517 U.S. 370, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996), the Court construes the disputed claim terms as set forth below.

BACKGROUND

The Medicines Company ("TMC") brought this lawsuit against Mylan Inc., Mylan Pharmaceuticals Inc., and Bioniche Pharma USA, LLC (collectively, "Mylan"), asserting that Mylan infringed U.S. Patent Nos. 7,582,727 (the "'727 Patent") and 7,598,343 (the "'343 Patent," and collectively with the '727 Patent, the "patents-in-suit"). The patents-in-suit pertain to pharmaceutical formulations of bivalirudin and the processes of making bivalirudin. (R. 1,

Compl.) Bivalirudin is the active ingredient in Angiomax®, which is an anticoagulant drug used in patients with unstable angina who are undergoing percutaneous transluminal coronary angioplasty. (*Id.* ¶¶ 11, 13.) TMC markets Angiomax®. (*Id.* ¶ 13.)

TMC alleges that Mylan, before the expiration of the patents-in-suit, submitted Abbreviated New Drug Application ("ANDA") No. 202471 to the U.S. Food and Drug Administration ("FDA"), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of its generic Angiomax® product. TMC avers that Mylan's ANDA No. 202471 infringes certain claims of the patents-in-suit.

I. Bivalirudin Final Drug Product

There are two main steps in making the bivalirudin final drug product. First, the bivalirudin active pharmaceutical ingredient ("API") is made. When the bivalirudin API is added to saline or water, the pH of the resulting solution is too acidic for use as an injectable medication in patients. A compounding process is therefore required to adjust the pH of the synthesized bivalirudin, as well as to add a pharmaceutically acceptable carrier, in order to make the final bivalirudin drug product. The compounding process involves, among other things, mixing a pH-adjusting solution with a solution of bivalirudin to create a compounding solution. Asp^{9}-bivalirudin, an impurity, is generated during this compounding process.

The bivalirudin final drug product that is offered for sale is supplied in single-use vials as a sterile lyophilized (i.e., freeze-dried) cake. Before injection, the cake must be reconstituted by adding water to it. The "reconstitution time" refers to the amount of time it takes the freeze-dried cake to reconstitute in a solution. Each bivalirudin cake contains 250 milligrams of

bivalirudin, 125 milligrams of mannitol (a sugar), and sodium hydroxide (a base) to adjust the pH to 5-6. The cake also contains trace impurities, including Asp^{9}-bivalirudin.

II. The Patents-In-Suit

Before the inventions in the patents-in-suit, the process for manufacturing the bivalirudin final drug product (Angiomax®) resulted in a product having inconsistent levels of the Asp^{9}-bivalirudin impurity. High levels of Asp^{9}-bivalirudin resulted in unpredictable batch failures and rejections, which was costly for TMC. The patents-in-suit are directed at consistently minimizing the amount of Asp^{9}-bivalirudin generated during the manufacture of the final bivalirudin drug product.

On September 1, 2009, the United States Patent and Trademark Office (the "PTO") issued the '727 Patent, entitled "Pharmaceutical formulations of bivalirudin and the processes of making the same," to TMC upon assignment from Gopal Krishna and Gary Musso, the named inventors.[1] (Compl. ¶ 12.) The '727 Patent is a product patent that claims

> [p]harmaceutical batches of a drug product comprising bivalirudin (SEQ ID NO: 1) and a pharmaceutically acceptable carrier for use as an anticoagulant in a subject in need thereof, wherein the batches have a pH adjusted by a base, said pH is about 5-6 when reconstituted in an aqueous solution for injection, and wherein the batches have a maximum impurity level of Asp^{9}-bivalirudin that does not exceed about 0.6% as measured by HPLC.

(R. 95, '727 Patent, col. 25, ll. 56-64.)

On October 6, 2009, the PTO issued the '343 Patent, entitled "Pharmaceutical formulations of bivalirudin and the processes of making the same," to TMC upon assignment

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[1] As the Federal Circuit has noted, "[i]nventions are created by individuals, not corporations." *MBO Labs., Inc. v. Becton, Dickinson, & Co.*, 474 F.3d 1323, 1326 n.1 (Fed. Cir. 2007). For simplicity, however, the Court refers to "TMC" as shorthand for Krishna and Musso during its discussion of the history of the patents-in-suit.

from Krishna and Musso. (Compl. ¶ 13.) The '343 Patent is a product-by-process patent that claims the same bivalirudin final drug product as the '727 Patent as well as additional limitations regarding the bivalirudin manufacturing process. (*See* R. 94, '343 Patent, cols. 27-28.) Both patents-in-suit contain largely the same specification.

III. The Disputed Terms

The parties disagree on the construction of two claim terms: "pharmaceutical batches" (in both patents-in-suit) and "efficiently mixing" (in the '343 Patent only). After submitting briefs to the Court supporting their respective positions, the parties submitted a joint claim construction chart, which details their proposed constructions. The joint chart is reproduced here for reference.

Patent/ Claim(s)	Disputed Claim Term	TMC's Proposed Construction	Mylan's Proposed Construction
'727 Patent, claims 1-3, 7-10, 17 '343 Patent, claims 1-3, 7-11	pharmaceutical batches	"[M]ay include a single batch, wherein the single batch is representative of all commercial batches (see generally, Manual of Policies and Procedures, Center for Drug Evaluation and Research, MAPP 5225.1, Guidance on the Packaging of Test Batches at 1), 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."	"[M]ay include a single batch, wherein the single batch is representative of all commercial batches (see generally, Manual of Policies and Procedures, Center for Drug Evaluation and Research, MAPP 5225.1, Guidance on the Packaging of Test Batches at 1) 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. 'Batches' may also include all batches prepared by a same compounding process."
'343 Patent, claim 1	efficiently mixing	"[M]ixing that is characterized by minimizing levels of Asp^{9}-bivalirudin in the compounding solution."	"A pH-adjusting solution and the first solution are mixed not using inefficient mixing conditions such as described in Example 4."

LEGAL STANDARD

Because the claims of a patent define the invention, claim construction—the process of giving meaning to the claim language—defines the scope of the invention. *See Phillips v. AWH Corp*., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (*en banc*) ("It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.") (citing 35 U.S.C. § 112). Claim construction is a matter of law for the court to

determine. *Markman*, 517 U.S. at 391; *Marine Polymer Techs., Inc. v. HemCon, Inc.*, 672 F.3d 1350, 1358 (Fed. Cir. 2012). The Court begins its claim construction analysis with the words of the claims themselves, giving those words their ordinary and customary meaning, which is the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips*, 415 F.3d at 1312-13; *see also InterDigital Comm'cns, LLC v. Int'l Trade Comm'n*, — F.2d —, 2012 WL 3104597, at *5 (Fed. Cir. Aug. 1, 2012).

The Federal Circuit teaches that "[i]mportantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Phillips*, 415 F.3d at 1313; *see also HTC Corp. v. IPCom GmbH & Co., KG*, 667 F.3d 1270, 1275 (Fed. Cir. 2012) (stating that the district court "should have referred to the specification to understand the claims") (citing *Phillips*, 415 F.3d at 1315). In construing a disputed claim term, courts also look to the prosecution history of the patent-in-suit. *HTC Corp.*, 667 F.3d at 1276 ("A court should look to the prosecution history when construing a claim.") (citing *Phillips*, 415 F.3d at 1317).

Although "less significant than the intrinsic record," extrinsic evidence, which consists of "all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises," may "shed useful light on the relevant art." *See Phillips*, 415 F.3d at 1317 (citations omitted); *see also HTC Corp.*, 667 F.3d at 1277 ("A court may also look to extrinsic evidence, such as dictionaries and expert opinions.") (citing *Phillips*, 415 F.3d at 1317); *Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("extrinsic sources like expert testimony cannot overcome more persuasive intrinsic evidence").

Before considering extrinsic evidence to construe a disputed claim, courts must first examine the intrinsic evidence. *Phillips*, 415 F.3d at 1317-19; *see also 01 Communique Lab., Inc. v. LogMeIn, Inc.*, — F.3d — , 2012 WL 3089367 (Fed. Cir. July 31, 2012) ("To ascertain the scope and meaning of the asserted claims, we look to the words of the claims themselves, the specification, the prosecution history, and, *if necessary*, any relevant extrinsic evidence.") (quoting *Chicago Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1366 (Fed. Cir. 2012) (emphasis added).

ANALYSIS

I. "Pharmaceutical Batches"

Patent/ Claim(s)	**Disputed Claim Term**	**TMC's Proposed Construction**	**Mylan's Proposed Construction**
'727 Patent, claims 1-3, 7-10, 17 '343 Patent, claims 1-3, 7-11	pharmaceutical batches	"[M]ay include a single batch, wherein the single batch is representative of all commercial batches (see generally, Manual of Policies and Procedures, Center for Drug Evaluation and Research, MAPP 5225.1, Guidance on the Packaging of Test Batches at 1), 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."	"[M]ay include a single batch, wherein the single batch is representative of all commercial batches (see generally, Manual of Policies and Procedures, Center for Drug Evaluation and Research, MAPP 5225.1, Guidance on the Packaging of Test Batches at 1) 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. 'Batches' may also include all batches prepared by a same compounding process."

The Court turns first to the term "pharmaceutical batches" as it appears in claims 1-3, 7-10, and 17 of the '727 Patent and claims 1-3 and 7-11 of the '343 Patent. The parties agree that the term "pharmaceutical batches" should receive the same construction in both patents. Although the parties' original proposed constructions differed rather significantly, the parties ultimately narrowed their disputes during the claim construction briefing process. In their joint claim construction chart, which is reproduced in relevant part directly above, the proposed constructions differ in only one respect: Mylan's proposal includes the phrase "made by a compounding process" before the term "wherein," but TMC's proposal does not.[2]

In support of their respective positions, both parties point to the definition of the term "pharmaceutical batches" in the specifications of the patents-in-suit. As the Federal Circuit has repeatedly held, the specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Phillips*, 415 F.3d at 1321 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009) ("When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls.") (citing *Phillips*, 415 F.3d at 1321). Indeed, the specification is the "single best guide to the meaning of a disputed term." *MBO Labs.*, 474 F.3d at 1329 (citing *Phillips*, 415 F.3d at 1314).

The text of the specification with respect to "pharmaceutical batches" is the same in both patents-in-suit. (*Compare* R. 94,'343 Patent, col. 5, ll. 24-36 *with* R. 95, '727 Patent, col. 5, ll. 24-36.) Specifically, the text provides:

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[2] Because TMC did not address this issue in its response brief, the Court, *sua sponte*, granted TMC leave to file a sur-reply on this narrow issue, which it did on June 12, 2012. (R. 117.)

> 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 (see generally, Manual of Policies and Procedures, Center for Drug Evaluation and Research, MAPP 5225.1, Guidance on the Packaging of Test Batches at 1), and wherein the levels of, for example, Asp^{9}-bivalirudin, total impurities, and largest unknown impurity, and the constitution time represent levels for all potential batches made by said process. "Batches" may also include all batches prepared by a same compounding process.

(R. 94, '343 Patent, col. 5, ll. 24-36; R. 95, '727 Patent, col. 5, ll. 24-36.)

Although Mylan concedes that TMC's proposal is a verbatim replication of the definition in the specifications, it argues that inclusion of the phrase "made by a compounding process" is necessary to (1) give meaning to the term "made by said process," which occurs later in the definition, and (2) "avoid stripping the definition [of pharmaceutical batches] of the context provided by an immediately preceding portion of the patent specification." (R. 111, Mylan Reply at 13.) Mylan further contends that TMC's proposed definition lacks an antecedent basis for the term "said process," and therefore the PTO would have rejected the claim as indefinite. (*Id.* (citing Manual of Patent Examining Procedure ("MPEP") § 2173.05(e) (8th ed. Rev. 8, July 2010) (explaining that a claim may be unclear or indefinite where it recites "said lever" or "the lever" without an earlier recitation of "lever," which is the "antecedent basis").)

TMC argues that an express antecedent basis for the term "said process" is not required because the claim has a reasonably ascertainable meaning. (R. 117, TMC Sur-reply at 1-2 (citing MPEP § 2173.05(e) (8th ed. Rev. 6, Sept. 2007) ("Obviously, however, the failure to provide explicit antecedent basis for terms does not always render a claim indefinite. If the scope of a claim would be reasonably ascertainable by those skilled in the art, then the claim is

not indefinite.")).[3]) Specifically, TMC contends that "[w]hen viewed in the context of the specification, it is readily apparent that the phrase 'made by said process' refers to the compounding processes described in the patents-in-suit." (*Id.* at 2.) In its sur-reply, TMC argued that if the Court determines that an express antecedent basis is required, Mylan's proposed inclusion of "made by a compounding process" is incomplete and misleading. Instead, according to TMC, the proper inclusion is "made by a compounding process *of various embodiments of the present invention*," which is the word-for-word antecedent basis for the term "said process." (*Id.* at 4 (emphasis added).) At the *Markman* hearing, however, TMC withdrew this alternate proposal and instead stated that TMC "could live with" Mylan's proposal of "made by a compounding process" in the event the Court determines that an express antecedent basis is necessary.

The Court adopts Mylan's proposed construction. TMC's proposed definition of "pharmaceutical batches" is a word-for-word recitation of the specification, but it does not provide an express reference to what the "said process" is. TMC is correct that "failure to provide explicit antecedent basis for terms does not always render a claim indefinite." *See Energizer Holdings, Inc. v. Int'l Trade Comm'n*, 435 F.3d 1366, 1370 (Fed. Cir. 2006) (quoting Manual of Patent Examining Procedure § 2173.05(e) (8th ed. Rev. 2, May, 2004)). The Court ultimately need not decide that issue, however, given the parties agreement that the term "said process" refers to the immediately preceding use of the word "process," as well as TMC's concession during the *Markman* hearing that it could "live with" Mylan's proposed

[3] Although TMC cited an older version of the MPEP than did Mylan, the relevant text is the same in both versions.

construction.[4] Mylan's proposed construction honors the express definition set forth in the specifications of the patents-in-suit and makes clear, in case there is any uncertainty, to precisely what "said process" refers. Accordingly, "pharmaceutical batches":

> may include a single batch, wherein the single batch is representative of all commercial batches (see generally, Manual of Policies and Procedures, Center for Drug Evaluation and Research, MAPP 5225.1, Guidance on the Packaging of Test Batches at 1) 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. 'Batches' may also include all batches prepared by a same compounding process.

II. "Efficiently Mixing"

Patent/ Claim(s)	Disputed Claim Term	TMC's Proposed Construction	Mylan's Proposed Construction
'343 Patent, claim 1	efficiently mixing	"[M]ixing that is characterized by minimizing levels of Asp^9-bivalirudin in the compounding solution."	"A pH-adjusting solution and the first solution are mixed not using inefficient mixing conditions such as described in Example 4."

The term "efficiently mixing" is found only in claim 1 the '343 Patent, which is a product-by-process patent.[5] "A 'product-by-process' claim is one in which the product is defined at least in part in terms of the method or process by which it is made." 3-8 *Chisum on Patents* § 8.05; *see also Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1293 (Fed. Cir. 2009) (*en banc*) ("'product by process claims are limited by and defined by the process'") (quoting *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1985)). "'[P]rocess terms in product-by-process claims

[4] When pressed at the hearing, TMC's counsel conceded that TMC was withdrawing its objections to Mylan's proposal.

[5] The '727 Patent does not contain the term "efficiently mixing."

serve as limitations in determining infringement.'" *Abbott*, 566 F.3d at 1293 (quoting *Atl. Thermoplastics, Inc. v. Faytex Corp*., 970 F.2d 834, 846-47 (Fed. Cir. 1992)). "In determining infringement of a product-by-process claim, . . . the focus is on the process of making the product as much as it is on the product itself." *Amgen Inc. v. F. Hoffman-LA Roche Ltd*, 580 F.3d 1340, 1370 (Fed. Cir. 2009) (citing *Abbott*, 566 F.3d at 1293). "As a result, a a product-by-process claim is not infringed by a product made by a process other than the one recited in the claim." *Id.* (citing *Abbott*, 566 F.3d at 1293).

Claim 1 of the '343 Patent claims:

> Pharmaceutical batches of a drug product comprising bivalirudin (SEQ ID NO: 1) and a pharmaceutically acceptable carrier, for use as an anticoagulant in a subject in need thereof, said batches prepared by a compounding process comprising:
>
> (i) dissolving bivalirudin in a solvent to form a first solution;
>
> (ii) *efficiently mixing* a pH-adjusting solution with the first solution to form a second solution, wherein the pH-adjusting solution comprises a pH-adjusting solution solvent; and
>
> (iii) removing the solvent and pH-adjusting solution solvent from the second solution;
>
> wherein the batches have a pH adjusted by a base, said pH is about 5-6 when reconstituted in an aqueous solution for injection, and wherein the batches have a maximum impurity level of Asp^{9}-bivalirudin that does not exceed about 0.6% as measured by HPLC.

('343 Patent, col. 27, ll. 13-31 (emphasis added).)

TMC advocates for a "functional definition" of the term "efficiently mixing"—i.e., a definition that is based on the outcome of the mixing process. Mylan, on the other hand, proposes a process-based construction of the term—i.e., a definition that informs the person of

ordinary skill in the art how to perform the process step. The Court first sets forth the parties' arguments, and then explains the reasons why it adopts Mylan's proposed construction.

A. Mylan's Proposed Construction

Mylan contends that the specification and prosecution history support its proposed construction of "efficiently mixing."

1. Specification

In support of its construction, Mylan argues that the specification expressly disclaims "inefficient mixing" from the claim scope. (R. 92, Mylan Mem. at 9-10.) In particular, Mylan contends that the specification explicitly distinguishes between "efficient" and "inefficient" mixing conditions through a comparison of large-scale studies described in "Example 4" and "Example 5." (*Id.* at 10.) "Example 4" is titled "Effects of Rapidly Adding pH Adjusting Solution to the Bivalirudin Solution Under *Inefficient Mixing* Conditions – Large Scale Study." ('343 Patent, col. 22, ll. 24-26 (emphasis added).) Example 5, on the other hand, is titled "Effects of Adding pH Adjusting Solution at a Constant Rate and Under *Efficient Mixing* Conditions – Large Scale Study." ('343 Patent, col. 23, ll. 8-10 (emphasis added).)

The specification compares the results of Examples 4 and 5 and concludes that the batches made using the methods in Example 5 "displayed significantly lower mean levels of Asp^{9}-bivalirudin, total impurities, and largest unknown impurity," which is the aim of the invention. (Mylan Mem. at 10 (citing '343 Patent at 23:56-59).) Mylan points out that Table 8 in the specification compares the mean values of Asp^{9}-bivalirudin, total impurities, largest unknown impurity, and reconstitution times for the batches made with the Example 4 and Example 5 methods. (*Id.* (citing '343 Patent at 24:6-36).) Mylan argues that the contrast

between Examples 4 and 5 in the specification "makes clear that 'efficiently mixing' does not incorporate 'inefficient mixing' as set forth in Example 4." (*Id.* at 10-11.) Relatedly, Mylan argues that interpreting the claim to include the "inefficient" mixing conditions described in Example 4 of the specification would "ensnare" prior art–namely, TMC's "old" Angiomax® drug product that is indisputably prior art to the '343 Patent. In that instance, Mylan argues, the '343 Patent claims would be anticipated by TMC's prior art Angiomax® under the strict "on sale" bar of 35 U.S.C. § 102(b). Accordingly, Mylan contends that interpreting "efficiently mixing" to ensnare the mixing conditions in Example 4 would render the claims invalid.

2. Prosecution History

Mylan also relies on the prosecution history of the '343 Patent to support its proposed construction. In particular, Mylan asserts that throughout prosecution of the '343 Patent, TMC contrasted the results of "efficient" mixing conditions with the results of "inefficient mixing" conditions, such as those described in Example 4, and by doing so, excluded Example 4's "inefficient" mixing conditions from the scope of the '343 Patent. (Mylan Mem. at 11.)

During prosecution of the '343 Patent, TMC described the prior (unclaimed) compounding process by which it mixed a pH-adjusting solution with a solution of bivalirudin to create a compounding solution:

> Applicants' prior compounding process added the pH-adjusting solution to the bivalirudin solution in an inconsistent manner, at the operator's discretion, resulting in the formation of inconsistent levels of the impurity Asp^{9}-bivalirudin; in some cases the levels of Asp^{9}-bivalirudin in the final drug product exceeded the FDA allowed limit of 1.5% w/w. The drug products generated from the old compounding process, which were sold/marketed/offered for sale for more than one (1) year prior to the filing date of the accompanying application, comprised a maximum Asp^{9}-bivalirudin level of about 3.6%, a maximum reconstitution time

of about 72 seconds, and a maximum amount of total impurities of about 3.0%.[6]

(R. 102-1, Lee Decl. Ex. 3 at MEDMYL0000163.) TMC distinguished that so-called "old compounding process," according to Mylan, with the patented invention, stating that

> [i]n the present invention, various embodiments relate to a less subjective and more consistent process for the mixing of the pH-adjusting solution with the bivalirudin solution. This process involves efficiently mixing the pH-adjusting solution and the dissolved bivalirudin solution, which is not performed in Applicants' prior compounding process.

(*Id*.) Mylan further argues that Musso distinguished Example 4's inefficient mixing process from his alleged invention of "efficient mixing" in arguing for the patentability of the '343 Patent. (Mylan Mem. at 12 (citing R. 102-4, Lee Decl. Ex. 3 at MEDMYL0000530).)

3. TMC's Arguments in Opposition to Mylan's Proposed Construction

TMC argues that Mylan's proposed construction ignores the "express functional definition" of the term "efficiently mixing" that is set forth in the specification and instead adds process steps to the term. (R. 106, TMC Resp. at 13-14.) TMC also reasons that the PTO did not require the "efficiently mixing" claim term to be limited to a specific process during prosecution of the '343 Patent, and when stating the "Reasons for Allowance," the Examiner did not refer to "efficiently mixing," only "mixing." (*Id*.) It further challenges Mylan's proposed construction on the grounds that it does not address the relationship between efficient mixing and the minimization of Asp^9-bivalirudin. (*Id.* at 14.) Finally, TMC contends that Mylan's proposed construction impermissibly construes "efficiently mixing" in terms of what it is not, rather than what it is.

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[6] During the *Markman* hearing, TMC agreed that the "old compounding process" is the same process described in Example 4 of the '343 Patent's specification and that the process in Example 4 falls outside claim 1's scope.

B. TMC's Proposed Construction and Mylan's Arguments in Opposition

TMC urges the Court to adopt its proposed "functional definition" of the term "efficiently mixing." TMC contends that it took its proposed definition directly from the specification of the '343 Patent, which "expressly defines" the term "efficient mixing" as "characterized by minimizing levels of Asp^{9}-bivalirudin in the compounding solution."[7] (R. 106, TMC Resp. at 11 (citing R. 94, '343 Patent, col. 9, ll. 34-35).) It further contends that its proposed definition is consistent with other portions of the specification that describe "efficiently mixing" as mixing that "will minimize levels of Asp^{9}-bivalirudin in the compounding solution." (*Id*. (citing R. 94, '343 Patent, col. 8, ll. 56-58).) TMC argues that the construction of the term "efficiently mixing" cannot ignore the intended result—i.e., minimizing levels of Asp^{9}-bivalirudin in the compounding solution—which is a fundamental part of the invention. (*Id.* at 14.)

According to Mylan, TMC's proposed construction impermissibly reads the process step out of the '343 Patent claims and replaces it with a non-limiting statement of the intended result of the second process step. (Mylan Mem. at 1, 9.) At the *Markman* hearing, Mylan further expanded on this criticism, arguing that TMC's proposed construction would effectively allow it to remove an element of proof from TMC's infringement claim, such that TMC would only have to prove only that Mylan's accused product is the same as the product claimed in the '343 Patent, and not that Mylan also uses the same process to make the accused product. *Cf. Amgen*, 580 F.3d at 1370 ("'[P]rocess terms in product-by-process claims serve as limitations in determining

[7] The specification of the '343 Patent expressly defines "minimize" as "the generation of a level of Asp^{9}-bivalirudin in the compounding solution that is less than about 0.6%, or less than about 0.4%, or less than about 0.3%." ('343 Patent, col. 8, ll. 58-61.)

infringement.'") (quoting *Abbott Labs*., 566 F.3d at 1293). It further submits that courts consistently disregard statements of the intended result of a claimed process as imposing no limitation on a claim. (Mylan Mem. at 13.) Mylan also contends that TMC's proposed construction runs counter to the arguments TMC made during prosecution of the patent-in-suit. (*Id.* at 14.)

C. The Court's Construction of the Term "Efficiently Mixing"

1. The Specification Does Not Expressly Define "Efficiently Mixing"

The Court first addresses, and rejects, TMC's argument that the patentees acted as their own lexicographers in defining "efficiently mixing" in the specification. In particular, TMC asserts that the use of the word "is" after the term "efficient mixing" indicates that the patentees intended the language that followed to serve as the definition of the term "efficiently mixing." (TMC Resp. at 12.) Although the Federal Circuit has recognized that a patentee's use of "is" before a term "may 'signify that a patentee is serving as its own lexicographer,'" *Sinorgchem Co., Shandong v. Int'l Trade Comm'n*, 511 F.3d 1132, 1136 (Fed. Cir. 2007) (quoting *Abbott Labs. v. Andrx Pharms., Inc*., 473 F.3d 1196, 1210 (Fed. Cir. 2007)), TMC's argument is nevertheless unconvincing.

The '343 Patent specification contains several express definitions. In each one, the patentees use a similar format: the defined term in quotation marks, followed by the terms "refers to" or "as defined herein." (*See* '343 Patent, col. 5, ll. 24-26 ("As used here, 'batch' or 'pharmaceutical batch' refers to material produced by . . ."); 27-28 ("'Batches' or 'pharmaceutical batches' as defined herein may include a single batch . . ."); 37-38 ("The term 'drug product' herein refers to an active ingredient and a pharmaceutically acceptable carrier.");

39-40 ("The term 'formulation' or 'pharmaceutical formulation' refers to a unit dose . . ."); 46-47 ("The term 'carrier' refers to any component of the pharmaceutical batch(es) . . ."); col. 8, ll. 58-59 ("'Minimize' as used herein refers to the generation of a level of . . . .").) As the Federal Circuit has explained, when a term is "set off by quotation marks" in the specification, it is "often a strong indication that what follows is a definition." *Sinorgchem*, 511 F.3d at 1136 (citing cases). The part of the specification on which TMC relies for its proposed definition of the term "efficiently mixing," however, does not contain that term in quotation marks, nor does it contain the terms "refer[s] to" or "as defined herein." Those omissions weigh strongly against TMC's argument.

As Mylan argued during the *Markman* hearing, if the patentees intended to expressly define "efficiently mixing," they could have put that term in quotation marks and inserted the words "refers to" or "as defined herein" after the term to clearly express their intent as they did with other terms, yet they did not do so. *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1371 (Fed. Cir. 2005) (holding that the patentee did not "clearly set out its own definition" of the disputed term with "'reasonable clarity, deliberateness, and precision,' and thus failed to act as its own lexicographer") (quoting *In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994)); *see also Aventis Pharms Inc. v. Impax Labs.*, No. 02-1322, 2011 WL 94188, at *3 (D.N.J. Jan. 11, 2011) (finding that the patentee had not acted as his own lexicographer in defining a disputed claim term where he did not use a "transition phrase that unambiguously imparted a definition," as he had done elsewhere in the specification). Because TMC's proposed definition from the specification does not "appear with reasonable clarity, deliberateness, and

precision," *see Abbott*, 334 F.3d at 1354, the Court finds TMC did not intend to expressly define the term "efficiently mixing" in the specification.[8]

2. The Term "Efficiently Mixing" Is Part of a Process Step and Not a Statement of Intended Result

Having rejected TMC's argument that the purported definition in the specification controls the construction of the term "efficiently mixing," the Court next considers the parties' remaining arguments. At the heart of the parties' dispute over the construction of the term "efficiently mixing" is whether the Court should construe that term functionally (i.e., in light of its intended result), as TMC argues, or as a process step, as Mylan argues.[9] For the reasons set forth below, the Court agrees with Mylan that the term "efficiently mixing," when read in context of the remainder of claim 1, is part of the second step of a three-step process for producing the claimed pharmaceutical batches and must be construed accordingly. (Mylan Reply at 4.)

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[8] During the *Markman* hearing, TMC asserted that the use of the phrase "is characterized by" (rather than simply the word "is") indicates the patentees' intent to expressly define "efficiently mixing" in the specification. In support, TMC relies on *Forest Labs. Inc. v. Cobalt Labs. Inc.*, No. 08-21-GMS-LPS, 2009 WL 1916935, at *8 (D. Del. July 2, 2009), *aff'd in relevant part*, 2009 WL 1916935, at *2 (D. Del. Sept. 21, 2009). In addition to the fact that the District of Delaware's decision in *Forest* is not binding on this Court, it also does not unequivocally support TMC's argument. While the court in *Forest* noted that the phrase "'is characterized by' *may* . . . be sufficient to call out of one of ordinary skill in the art that a claim term is being defined for purposes of the patent," *id.* at *8 (emphasis added), it does not stand for the proposition that it must always do so. Moreover, the court in *Forest* relied on the fact that the patentee had expressly identified the "is characterized by" definition in the specification during reexamination proceedings. *See id.*

[9] During the *Markman* hearing, TMC argued that its definition, too, construes the term "efficiently mixing" as part of a process step, relying on the use of the term "mixing" in its proposed construction. That argument, however, does not alter the substance of TMC's proposed construction, which seeks to describe "mixing" by the intended result of the process, rather than how to perform the process.

The words of the claim, as well as the context surrounding the term "efficiently mixing," support the conclusion that "efficiently mixing" is part of a process step—i.e., how to mix. *See 01 Communique Lab.*, 2012 WL 3089367 at *2 (courts look at the "words of the claims themselves" to ascertain the scope and meaning of asserted claims); *Phillips*, 415 F.3d at 1314 ("[T]he context in which a term is used in the asserted claim can be highly instructive."). Specifically, claim 1, in which the term is found, teaches, in relevant part that, pharmaceutical batches are "prepared by a *compounding process* comprising" three steps. ('343 Patent, Claim 1 (emphasis added).) The first step in that process is "'*dissolving*' bivalirudin in a solvent to form a first solution," the second step is "'*efficiently mixing*' a pH-adjusting solution with the first solution to form a second solution," and the third step is "'*removing*' the solvent and the pH-adjusting solution solvent from the second solution." *Id.* (emphasis added).) The terms "dissolving," "mixing," and "removing" all indicate steps in the process. As used in the claim, the term "efficiently" modifies the "mixing" process step. *See generally HTC Corp.*, 667 F.3d at 1274-75 ("Modifiers should be placed next to the words they modify.").

Adopting TMC's proposed construction—i.e., "mixing that is characterized by minimizing levels of Asp^{9}-bivalirudin in the compounding solution"—does not explain the process for mixing the solutions efficiently, i.e., *how* to mix the solutions, but rather explains the intended result of the process step. As such, it would effectively read out the "efficiently mixing" process step from the claimed process and replace it with a non-limiting intended result of the process. This, as Mylan argues, would have the effect of negating TMC's burden to prove the "process" element of a claim for infringement of product-by-process patent. *See Amgen*, 580

F.3d at 1370 ("a product-by-process claim is not infringed by a product made by a process other than the one recited in the claim") (quotation marks and citation omitted).[10]

Moreover, as Mylan submits, the Federal Circuit has held that language which recites the intended result of a positively recited process step does not impose a limitation on a patent claim. *See Minton v. Nat'l Ass'n of Secs. Dealers*, 336 F.3d 1373, 1381 (Fed. Cir. 2003) (noting that language in a whereby clause in a method claim "is not given weight when it simply expresses the intended result of a process step positively recited"); *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc*., 246 F.3d 1368, 1375 (Fed. Cir. 2001) (holding that a statement of intended result in the patent's preamble did not limit the claim).[11]

TMC concedes that its proposed definition of "efficiently mixing" construes that term functionally—i.e., by its intended result—but asserts that it is proper to do so "where, as here,

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[10] The Federal Circuit has explained that although district courts should not "prejudge the ultimate infringement analysis by construing claims with an aim to include or exclude an accused product or process, knowledge of that product or process provides meaningful context for the first step of the infringement analysis, claim construction." *Wilson Sporting Goods Co. v. Hillerich & Bradsby Co.*, 442 F.3d 1322, 1326-27 (Fed. Cir. 2006) (citing cases); *see also Every Penny Counts, Inc. v. Am. Express Co.*, 563 F.3d 1378, 1383-84 (Fed. Cir. 2009) (holding that the district court did not err in considering the accused products during its claim construction analysis).

[11] During the *Markman* hearing, TMC argued that these cases are distinguishable because they involve language in a "wherein" clause or preamble where the court found that the limitation was repetitive and therefore did not need to be construed. Although these cases are factually distinguishable from this case in some respects, their reasoning is nonetheless persuasive. Moreover, TMC's criticism of Mylan for relying on these cases is somewhat misplaced, given that TMC also relied on cases involving language from a "whereby" clause, or similar clause, in support of its argument. *See* TMC Resp. at 14; *Hoffer v. Microsoft Corp*., 405 F.3d 1326, 1329-30 (Fed. Cir. 2005) ("It is correct that a 'whereby' clause generally states the result of the patented process. However, when the 'whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention.") and *Ideal Instruments, Inc. v. Rivard Instruments, Inc*., 498 F. Supp. 2d 1131, 1208-13 (N.D. Iowa 2007) (involving terms in "whereby," "so that," or "such that" clauses).

the specification provides a functional definition and the claims and specification do not recite a specific structural or process requirement." (R. 106, TMC Resp. at 12 (citing cases).) As explained above, the Court disagrees that the specification provides a functional definition of the term "efficiently mixing." Moreover, the cases on which TMC relies are distinguishable in additional ways. Many do not involve construction of a process claim element, but rather involve claim terms relating to physical objects.[12] Additionally, *Hoffer*, 405 F.3d at 1329-30, on which TMC relies, is distinguishable because there, the Federal Circuit held that the disputed "whereby" clause did not merely state "the intended result of a process step," but was rather "part of the process itself" and "an integral part of the invention."[13] Here, the specification indicates that although "minimizing Asp[9]-bivalirudin," is undoubtedly of key importance to the '343 Patent, it is not part of the process itself, but is rather the intended result of the process. (*See, e.g.*, '343 Patent, col. 2, ll. 19-22 ("Therefore, development of a compounding process for formulating bivalidrudin that consistently generates formulations having low levels of impurities is desirable."); col. 8, ll. 56-61 ("Efficient mixing of the pH-adjusting solution with the bivalirudin solution will minimize levels of Asp[9]-bivalirudin in the compounding solution.").) Indeed, TMC's counsel acknowledged during the *Markman* hearing that "[t]he inventors

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[12] *See Innovad, Inc. v. Microsoft Corp*., 260 F.3d 1326, 1332-33 (Fed. Cir. 2001) ("small volume" as it related to a portable telephone dialer); *Ekchian v. Home Depot, Inc*., 104 F.3d 1299, 1302-03 (Fed. Cir. 1997) ("conductive liquid-like medium"); *Pall Corp. v. Micron Separations, Inc*., 66 F.3d 1211, 1215-17 (Fed. Cir. 1995) ("skinless" as it related to a membrane); *Bausch & Lomb, Inc. v. Barnes-Hind/Hyrdrocurve, Inc*., 796 F.2d 443, 450 (Fed. Cir. 1986) ("smooth" as it related to a laser mark in a contact lens).

[13] Additionally, the Federal Circuit held that "when the 'whereby' clause states a condition that is material to patentability, it cannot be ignored in order to change the substance of the invention." *Id.* at 1329. In this case, adopting Mylan's proposed construction does not "change the substance of the invention."

developed a new and improved compounding process that *resulted in* batches with more consistent levels of Asp[9] impurity."[14]

3. The Term "Efficiently Mixing" Does Not Encompass the Mixing Process Described in Example 4

Having determined that the term "efficiently mixing" must be construed as part of a process step, the Court next considers the scope and proper definition of that term. Claims must be "read in view of the specification," which is "always highly relevant to the claim construction analysis" and is usually "dispositive." *Phillips*, 415 F.3d at 1315 (quoting *Markman*, 52 F.3d at 979 and *Vitronics*, 90 F.3d at 1582); *see also Eon-Net v. Flagstar Bancorp*, 653 F.3d 1314, 1320 (Fed. Cir. 2011). The Federal Circuit has repeatedly cautioned against "import[ing] limitations onto the claim from the specification, which is fraught with 'danger.'" *MBO Labs.*, 474 F.3d at 1333-34 (citing *Phillips*, 415 F.3d at 1323, and *Comark Commc'ns, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186 (Fed. Cir. 1998)). "Limiting claims from the specification is generally not permitted absent a clear disclosure that the patentee intended the claims to be limited as shown." *Id.* at 1334 (citing *Phillips*, 415 F.3d at 1323). The Federal Circuit has offered the following guidance on distinguishing between reading a claim in light of the specification, which is permitted, and reading a limitation into the claim from the specification, which is not: "it is useful to remember that we look 'to the specification to ascertain the meaning of the claim term as it is used by the inventor in the context of the entirety of his invention,' and not merely to

[14] TMC's reliance on *Ideal Instruments*, 498 F. Supp. 2d at 1197, is also unpersuasive, as that case supports Mylan's position. There, the court distinguished *Hoffer* and held that a statement of intended result of a process step was not a substantive claim limitation. *Id.*

limit a claim term." *Interactive Gift Exp., Inc. v. Compuserve, Inc*., 256 F.3d 1323, 1331-32 (Fed. Cir. 2001) (quoting *Comark*, 156 F.3d at 1187).

The "Background of the Invention" section of the specification states that "[i]t has been shown that various compounding processes can result in formulations that have up to 12% of Asp^{9}-bivalirudin, which may affect product stability and shelf-life. Therefore, development of a compounding process for formulating bivalirudin that *consistently* generates formulations having low levels of impurities is desirable." ('343 Patent, col. 2, ll. 16-23 (emphasis added).) This language indicates that the invention is aimed at a compounding process for formulating bivalirudin that *consistently* minimizes impurities, including Asp^{9}-bivalirudin. The specification demonstrates that Example 5 achieved this goal, while Example 4 did not. Specifically, after explaining the studies in Examples 4 and 5, the specification provides that the results of the studies in Examples 4 and 5 "suggest that the process demonstrated in Example 5 produced batches *generally and consistently* having lower levels of impurities than the process of Example 4." (*Id*., col. 23, ll. 62-65 (emphasis added).) Therefore, the specification strongly indicates that the mixing process described in Example 4 is not part of the invention. *See generally Bone Care Int'l, LLC v. Pentech Pharms, Inc*., No. 08-cv-1083, 2010 WL 2266518, *12 (N.D. Ill. June 4, 2010) ("'[t]he specification * * * teaches about the problems solved by the claimed invention, the way the claimed invention solves those problems, and the prior art that relates to the invention[,] * * * [t]hese teachings provide valuable context for the meaning of the claim language'") (quoting *Eastman Kodak Co. v. Goodyear Tire & Rubber Co.*, 114 F.3d 1547, 1554 (Fed. Cir. 1997), *overruled in part on other grounds by Cybor Corp. v. FAS Techs., Inc*., 138 F.3d 1448, 1456 (Fed. Cir. 1998)); *see also Honeywell Int'l, Inc. v. IIT Indus., Inc.*, 452 F.3d

1312, 1318 (Fed. Cir. 2006) ("The written description's detailed discussion of the prior art problem addressed by the patented invention . . . further supports the conclusion that the fuel filter is not a preferred embodiment, but an only embodiment.").

The prosecution history, another form of intrinsic evidence, also "provides evidence of how the PTO and the inventor understood the claimed invention." *Advanced Fiber Techs (AFT) Trust v. J&L Fiber Servs.*, 674 F.3d 1365, 1373 (Fed. Cir. 2012) (citing *Phillips*, 415 F.3d at 1317. Although the prosecution history often lacks the clarity of the specification and is therefore relatively less useful, it "may 'demonstrat[e] how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution." *AIA Eng'g Ltd. v. Magotteaux Int'l S/A*, 657 F.3d 1264, 1272 (Fed. Cir. 2011) (quoting *Phillips*, 415 F.3d at 1317); *see also Vitronics*, 90 F.3d at 1582-83 ("the record before the Patent and Trademark Office is often of critical significance in determining the meaning of the claims") (citing *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.") (citations omitted)).

During prosecution, TMC distinguished, at length, the "old compounding process" from the new patented compounding process for making the bivalirudin final drug product. (Lee Decl. Ex. 3 at MEDMYL0000163.) Of particular relevance, TMC stated the following:

> Applicants' prior compounding process added the pH-adjusting solution to the bivalirudin solution in an inconsistent manner, at the operator's discretion, resulting in the formulation of inconsistent levels of the impurity Asp^{9}-bivalirudin; in some cases the levels of Asp^{9}-bivalirudin in the final drug product exceeded the FDA allowed limit of 1.5% w/w. The drug products generated from the old compounding process, which were sold/marketed/offered for sale for more than one (1) year prior to the filing date of the accompanying application, comprised a maximum Asp^{9}-bivalirudin level of about 3.6%, a maximum

> reconstitution time of about 72 seconds, and a maximum amount of total impurities of about 3.0%.
>
> In the present invention, various embodiments relate to a less subjective and more consistent process for the mixing of the pH-adjusting solution with the bivalirudin solution. This process involves efficiently mixing the pH-adjusting solution and the dissolved bivalirudin solution, *which is not performed in Applicants' prior compounding process*.
>
> In addition, pharmaceutical batch(es) and pharmaceutical formulation(s) of bivalirudin *formed by the new compounding process are distinguished from the batches and formulations of bivalirudin formed by the prior compounding process*. The pharmaceutical batch(es) and pharmaceutical formulation(s) associated with the present compounding process are more consistent and have a maximum level of Asp^{9}-bivalirudin of about 0.6% w/w (a decrease of about 83% compared to the batches or formulations made by the prior process), a maximum reconstitution time of about 42 seconds (a decrease of about 42% compared to the batches or formulations made from the prior process), and a maximum amount of total impurities of about 2.0% (a decrease of about 33% compared to the batches or formulations made by the prior process), for all batches or formulations made by the new process.

(*Id.* (emphasis added).) It is thus clear from the prosecution history that the claimed invention in the '343 Patent does not include the "old compounding process." *See MBO Labs.*, 474 F.3d at 1330 (observing that arguments made during prosecution that "draw distinctions between the patented invention and the prior art are useful for determining whether the patentee intended to surrender territory, since they indicate in the inventor's own words what the invention is not") (citing *Medtronic, Inc. v. Guidant Corp.*, 465 F.3d 1360, 1373 (Fed. Cir. 2006)); *Research Plastics, Inc. v. Fed. Packaging Corp.*, 421 F.3d 1290, 1296 (Fed. Cir. 2005) ("The purpose of consulting the prosecution history in construing a claim is to exclude any interpretation that was disclaimed during prosecution.") (internal quotation marks and citation omitted).

Notably, counsel for TMC conceded during the *Markman* hearing that the "old compounding process" is identical to the process described in Example 4 of the '343 Patent's

specification and that efficient mixing was not performed in the studies explained in Example 4. Accordingly, any construction of the term "efficiently mixing" that encompasses the mixing process described in Example 4 is incorrect, as evidenced not only by TMC's concession, but also by both the specification and the prosecution history. Mylan's proposed construction properly excludes the "inefficient" mixing techniques used in the old compounding process from the definition, consistent with TMC's intent.

4. TMC's Proposed Construction Impermissibly Reads Limitations Into Non-Asserted Claims and Renders Portions of Asserted Claims Superfluous

Two additional flaws in TMC's proposed construction are that it would read claim limitations into certain non-asserted claims and, at the same time, render portions of asserted claims superfluous. *See generally Phillips*, 415 F.3d at 1314 ("Other claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment as to the meaning of a claim term."). Claim 12, for example, which TMC does not assert in this case, does not recite an Asp[9]-bivalirudin limitation.[15] ('343 Patent, col. 27, l. 60 through col. 28, l. 26.) Instead, it requires that the reconstitution time for the final bivalirudin drug product does not "exceed about 42 seconds" and also requires that the batches have "a maximum total impurity level that does not exceed about 2%." (*Id*.) The claim does not mention Asp[9]-bivalirudin. Under TMC's proposed construction of the term "efficiently mixing," however, Claim 12 would include a claim limitation regarding Asp[9]-bivalirudin. The Federal Circuit has

[15] Mylan asserts that TMC was deliberate when it chose whether to include an Asp[9]-bivalirudin limitation into a claim, and that TMC only asserted claims in this case that contain such a limitation. Yet, under TMC's proposed construction, the limitation would be present in every claim.

repeatedly counseled against importing claim limitations from the specification into claims "absent a clear disclosure that the patentee intended the claims to be limited as shown." *MBO Labs.*, 474 F.3d at 1334 (citing *Phillips*, 415 F.3d at 1323); *see also Kara Tech.*, 582 F.3d at 1347-48 (declining to import limitation from the specification into the claims).

TMC's proposed construction would also render certain asserted claims of the '343 superfluous. When TMC's proposed construction is read in conjunction with what the parties agree is the definition of the term "minimize" (*see* '343 Patent, col. 8, ll. 58-61), it provides as follows:

> Mixing that is characterized by the generation of a level of Asp^{9}-bivalirudin in the compounding solution that is less than about 0.6%, or less than about 0.4%, or less than about 0.3%.

This definition renders the existing Asp^{9}-bivalirudin limitation in claim 1 of the '343 Patent (i.e., "wherein the batches have a maximum impurity level of Asp^{9}-bivalirudin that does not exceed about 0.6% as measured by HPLC") superfluous at best, and at worst, inconsistent with the remainder of the claim. Such a construction is contrary to Federal Circuit precedent, which clearly instructs that courts should construe claim terms "such that words in a claim are not rendered superfluous." *Digital-Vending Servs. Int'l, LLC v. Univ. of Phoenix, Inc*., 672 F.3d 1270, 1274-75 (Fed. Cir. 2012) (citing *Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006)). The same analysis applies to the remaining claims in the '343 Patent, many of which are dependent claims. *See generally Phillips*, 415 F.3d at 1314-15 ("the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in

question is not present in the independent claim").[16]

5. Mylan's Negative Construction of the Term "Efficiently Mixing" Is Not Improper

During the *Markman* hearing, TMC criticized Mylan's proposed definition because it defines "efficiently mixing" in the negative—i.e., in terms of what it is not, rather than what it is. Although TMC argued that such a negative construction is "facially improper," it did not provide any legal authority for such an argument. Indeed, although negative limitations, which describe the invention in terms of what it is not rather than what it is, are generally not favored, they are permissible when they are justified by clear disavowal or disclaimer. *Cf. Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1322-23 (Fed. Cir. 2003) (declining to add negative limitation where district court and accused infringer did not identify "any express disclaimer or independent lexicography in the written description that would justify adding [the] negative limitation"); *see also SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1363-64 (Fed. Cir. 2005) (Gajarsa, J. concurring) (suggesting that the patentees could have incorporated negative limitations into their claims); 3-8 Chisum on Patents § 8.06[3] ("[I]t is clear today that negative limitations are not impermissible per se . . . ."). Here, not only did TMC expressly disclaim the old compounding process described in Example 4 during the prosecution of the '343 Patent, TMC conceded repeatedly during the *Markman* hearing that Example 4 does not fall

[16] During the *Markman* hearing, TMC argued that the two respective Asp^9-bivalirudin limitations are different because the express Asp^9-bivalirudin claim 1 states that the levels are "measured by HPLC." Although TMC did not explain what "HPLC" stands for, a review of the '343 Patent indicates that the term stands for "high-performance liquid chromotography." ('343 Patent, col. 16, ll. 36-38.) TMC has not explained how one would measure the Asp^9-bivalirudin levels under its proposed construction or how such a method of measurement is different from using HPLC.

within the scope of "efficiently mixing." *Cf. RFID Tracker, Ltd. v. Wal-Mart Stores, Inc*., 342 Fed. App'x 628, 630 (Fed. Cir. 2009) ("If the applicant unequivocally disavows claim scope, the doctrine of prosecution disclaimer applies even if the disclaimer results in a negative claim limitation.") (citing *N. Am. Container, Inc. v. Plastipak Packaging, Inc*., 415 F.3d 1335 (Fed. Cir. 2005)). As such, Mylan's proposed construction, even though it defines "efficiently mixing" in the negative, is proper. For this and all of the other reasons explained above, the Court adopts Mylan's construction.

CONCLUSION

For the reasons set forth above, the Court construes the disputed claims as follows:

- **Pharmaceutical Batches**: "may include a single batch, wherein the single batch is representative of all commercial batches (see generally, Manual of Policies and Procedures, Center for Drug Evaluation and Research, MAPP 5225.1, Guidance on the Packaging of Test Batches at 1) 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. 'Batches' may also include all batches prepared by a same compounding process."

- **Efficiently Mixing**: "A pH-adjusting solution and the first solution are mixed not using inefficient mixing conditions such as described in Example 4."

Date: August 6, 2012

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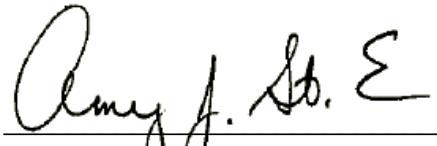

AMY J. ST. EVE
United States District Court Judge