

I. Background

In July, 2010, after receiving approval from the United States Food and Drug Administration ("the FDA"), Momenta began to market the first generic version of Lovenox (otherwise known as enoxaparin) in the United States. Enoxaparin is an anticoagulant used to prevent blood clots. Momenta is the assignee of U.S. Patent No. 7,575,886 ("the '886 patent"), issued in August, 2009, which is directed at a set of manufacturing quality control processes that ensure that each batch of generic enoxaparin includes the individual sugar chains characteristic of Lovenox.

Amphastar received FDA approval to market its generic enoxaparin product in September, 2011. Two days later, Momenta filed a complaint alleging that Amphastar infringed its '886 patent by manufacturing generic enoxaparin for commercial sale using its patented method. Momenta alleges that three of Amphastar's manufacturing control procedures infringe the '886 patent: 1) the Disaccharide Building Block ("DBB") procedure, 2) the 15-25% procedure which Amphastar performed at the time of FDA approval of its generic version of enoxaparin ("the 15-25% procedure") and 3) the revised 15-25% procedure which it adopted after FDA approval ("the revised 15-25% procedure").

In October, 2011, this Court allowed Momenta's motion for a preliminary injunction and enjoined Amphastar from advertising

or selling allegedly infringing enoxaparin products. That decision included a preliminary finding that the safe harbor provision in 35 U.S.C. § 271(e)(1) did not protect Amphastar's infringing activities because Amphastar used the patented process to test products after it had already obtained FDA approval, such that the use was not "reasonably related to the development and submission of information" to the FDA.

In August, 2012, the Federal Circuit Court of Appeals ("the Federal Circuit") vacated this Court's preliminary injunction and found that this Court applied "an unduly narrow interpretation" of the safe harbor provision. Momenta Pharm., Inc. v. Amphastar Pharm., Inc., 686 F.3d 1348, 1349 (Fed. Cir. 2012). It explained that Amphastar's post-approval use of the patented process to run quality control tests fell within the scope of the safe harbor provision because it generated information for records that Amphastar needed for continued FDA approval. Id. at 1357-61. The Federal Circuit denied Momenta's petition for a rehearing en banc in November, 2012.

In July, 2013, this Court entered summary judgment in Amphastar's favor finding, at the direction of the Federal Circuit, that its activities were protected by the safe harbor provision and therefore did not infringe. Because, apparently, no act of obeisance goes unpunished, the Federal Circuit then vacated this Court's grant of summary judgment to Amphastar and

held, in November, 2015, that the safe harbor provision did not apply to its infringing activities. Momenta Pharm., Inc. v. Teva Pharm. USA Inc., 809 F.3d 610, 613 (Fed. Cir. 2015).¹ The Federal Circuit also suggested that:

the district court may choose to reconsider on remand its denial of leave [to amend the infringement contentions] in light of our holding.

Id. at 622.

In June, 2016, this Court allowed plaintiffs' renewed motion to amend its infringement contentions with respect to the DBB test. Further litigation maneuvering ensued and, in April, 2017, this Court allowed defendants' motion to amend their non-infringement contentions as to the DBB test.

That month, defendants moved for summary judgment of invalidity and non-infringement. Plaintiffs timely opposed that motion and cross-moved for summary judgment of dismissal of the equitable defenses of waiver and estoppel or, alternatively, for a separate hearing on those defenses. This memorandum and order addresses those motions all of which, for the following reasons, will be denied.

¹In that decision, the Federal Circuit addressed the findings of this Court in both the instant case, in which Momenta alleges that Amphastar infringed the '886 patent, and the companion case, in which Momenta alleged that Teva Pharmaceuticals USA Inc. infringed the '886 patent. Id.

II. Motions for Summary Judgment

The role of summary judgment is "to pierce the pleadings and to assess the proof in order to see whether there is a genuine need for trial." Mesnick v. Gen. Elec. Co., 950 F.2d 816, 822 (1st Cir. 1991). The burden is on the moving party to show, through the pleadings, discovery and affidavits, "that there is no genuine dispute as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A fact is material if it "might affect the outcome of the suit under the governing law." Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A genuine issue of material fact exists where the evidence with respect to the material fact in dispute "is such that a reasonable jury could return a verdict for the nonmoving party." Id.

If the moving party has satisfied its burden, the burden shifts to the non-moving party to set forth specific facts showing that there is a genuine, triable issue. Celotex Corp. v. Catrett, 477 U.S. 317, 324 (1986). The Court must view the entire record in the light most favorable to the non-moving party and indulge all reasonable inferences in that party's favor. O'Connor v. Steeves, 994 F.2d 905, 907 (1st Cir. 1993). Summary judgment is appropriate if, after viewing the record in the non-moving party's favor, the Court determines that no

genuine issue of material fact exists and that the moving party is entitled to judgment as a matter of law.

A. Amphastar's Motion for Summary Judgment

Amphastar moves for summary judgment on the grounds of 1) a lack of patentable subject matter, 2) indefiniteness and 3) non-infringement.

1. Legal Standard for Patentable Subject Matter

The parties agree that the two-step framework for patentable subject matter described in Mayo Collaborative Servs. v. Prometheus Labs., Inc., 132 S. Ct. 1289, 1293 (2012), controls. First, the Court must determine whether the patent claims are "directed" to a patent-ineligible concept, such as a natural law, natural phenomenon or abstract idea. Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc., 827 F.3d 1042, 1047 (Fed. Cir. 2016) (quoting Mayo, 132 S. Ct. at 1296-97). If the claims are not so directed, they are patentable. Id. If the claims are directed to an ineligible concept, then the Court determines whether the elements of the invention, individually and combined, "transform" the claims into an application eligible for a patent. Id.

2. Application

Applying the first Mayo factor to the '886 patent, Amphastar contends that each of the four steps of the '886 patent involves non-patentable subject matter. According to

Amphastar, step one of the patent involves the digestion of enoxaparin, which is a law of nature, and in step two the outcome of that natural process is identified and separated. Amphastar further claims that steps three and four of the patent, which consist of a comparison between the tested product and a standard product, are comparisons of abstract ideas.

Momenta responds that the '886 patent claims a series of laboratory steps that establish the quality of enoxaparin by confirming the presence of its structural signature. Specifically, it claims that, at step one of the process, the exhaustive digestion of enoxaparin does not occur naturally. To facilitate the exhaustive digestion, the enoxaparin sample is exposed to a chemical cocktail for a certain time and at a specific temperature. That process results in a mixture of long and short sugar chains that do not individually exist in nature.

With respect to the second step, according to Momenta, a laboratory instrument conducts a facilitation method such as capillary electrophoresis or high performance liquid chromatography. The separation method shows enoxaparin's unique structural signature which is a result of the chemical process used to manufacture enoxaparin and does not exist in nature. Momenta submits that the inventors of the '886 patent were the first individuals to use the separation process in a way that permits the identification of enoxaparin's structural signature.

Finally, Momenta asserts that the third and fourth steps of the claimed patent involve comparing the structural signature exposed in step two to an enoxaparin reference standard. Then, relying on that determination, manufacturers take a collection of enoxaparin from the sample. According to Momenta, the inventors of the '886 patent created the four-step process to control the quality of each batch of enoxaparin.

Viewing the facts in the light most favorable to Momenta, it persuasively contends that the '886 patent "[is] directed to a new and useful method" of ensuring the quality of enoxaparin and thus Amphastar's motion for summary judgment on the basis of patent-ineligibility will be denied. See CellzDirect, 827 F.3d at 1048.

3. Legal Standard for Indefiniteness

A patent's specification must be sufficiently "definite" in that it must include at least one claim that "particularly point[s] out and distinctly claim[s] the subject matter which the applicant regards as [the] invention." 35 U.S.C. § 112 (2002). Pursuant to Nautilus, Inc. v. Biosig Instruments, Inc., 134 S. Ct. 2120, 2124 (2014),

[a] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.

Although “[s]ome modicum of uncertainty” is permissible, the “patent must be precise enough to afford clear notice of what is claimed.” Trusted Knight Corp. v. Int'l Bus. Machines Corp., No. 2016-1510, 2017 WL 899890, at *3 (Fed. Cir. Mar. 7, 2017) (quoting Nautilus, 134 S. Ct. at 2128-29).

The Federal Circuit has explained that indefiniteness is a question of law. Microprocessor Enhancement Corp. v. Tex. Instruments Inc., 520 F.3d 1367, 1374 (Fed. Cir. 2008). To the extent that the legal conclusion entails questions of fact, the party claiming invalidity by way of indefiniteness must prove those facts by clear and convincing evidence. Tech. Licensing Corp. v. Videotek, Inc., 545 F.3d 1316, 1338 (Fed. Cir. 2008).

4. Application

Amphaster contends that all claims are indefinite because they are limited to “the non naturally occurring sugar associated with peak 9 of FIG. 1” and there is no specific “FIG. 1” in the '886 patent. Momenta responds that “FIG. 1” refers to two parts of the '886 patent: “Figures 1A-1B”. Momenta further submits that, according to its expert witnesses, those skilled in the art typically refer to figures with multiple parts by one name, such as “Figure 1”. Viewing the facts in the light most favorable to Momenta, this Court agrees that those skilled in the art would be afforded clear notice of what was claimed.

Thus, Amphastar's motion for summary judgment on the grounds of indefiniteness will be denied.

5. Legal Standard for Non-infringement

An infringement analysis requires 1) the Court to determine, as a matter of law, the meaning and scope of the patent claims asserted to be infringed and 2) the trier of fact to compare the properly construed claims to the device accused of infringing. Markman v. Westview Instruments, Inc., 52 F.3d 967, 976 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). Summary judgment of non-infringement is appropriate where

on the correct claim construction, no reasonable jury could have found infringement on the undisputed facts or when all reasonable factual inferences are drawn in favor of the patentee.

Netword, LLC v. Centraal Corp., 242 F.3d 1347, 1353 (Fed. Cir. 2001).

6. Application

Amphastar contends that summary judgment on non-infringement is warranted because 1) it does not compare the peak area for the compounds in peak 9 to a reference standard and 2) Momenta's redefinitions of the claims are legally and factually wrong.

a. Reference Standard

Amphastar asserts that this Court construed "reference standard" to mean "preselected values". It further asserts that

comparing a structural signature of the compound in peak 9 to pre-selected values is a required element of all the claims and it does not make such a comparison. Therefore, contends Amphastar, summary judgment of non-infringement is appropriate.

Specifically, with respect to its 15-25% tests, Amphastar submits that Momenta alleges that the "preselected values" are that 15%-25% of the oligosaccharides in the enoxaparin have sugars including a 1,6-anhydro ring on their reducing ends. It asserts, however, that, in its 15-25% tests, the structural signature for peak 9 alone is not compared to the 15%-25%. Instead, the peak areas of all four 1,6-anhydro compounds in the sample, including peak 9, are combined to determine whether they are in the 15%-25% range.

Momenta responds that Amphastar ignores this Court's construction of the claim language by asserting that the structural signature for peak 9 alone must be the reference standard. According to Momenta, the claim limitation is

a structural signature which bears a relationship to the non-naturally occurring sugar which corresponds to Peak 9 [of Fig. 1].

Momenta submits that because the "structural signature that bears a relationship to the non-naturally occurring sugar" is a 1,6-anhydro ring structure, which is the structure that Amphastar identifies in the four compounds and compares to the 15-25% reference standard, it infringes on the claimed process.

Construing reasonable inferences in Momenta's favor, this Court agrees that a factfinder could determine that Amphastar's process infringes on the patent because the structural signature associated with peak 9, which is the 1,6-anhydro ring that is also associated with the other three compounds, is the reference point for Amphastar's test. At the least, a genuine issue of material fact persists with respect to infringement. Thus, summary judgment of non-infringement is unwarranted with respect to the 15-25% tests.

Next, with respect to the DBB test, Amphastar contends that, because it simply determines whether the peak 9 compound is detectable, it does not infringe the asserted claims because it does not compare the peak 9 compound to "preselected values". Momenta rejoins that Amphastar's own Rule 30(b)(6) witness testified that all 23 peaks, including the peaks for the four 1,6-anhydro rings, must fit into numeric ranges for the DBB test. Momenta further contends that a determination that peak 9 is detectable may infringe the '886 patent under the doctrine of equivalents.

Viewing the record in the light most favorable to Momenta and construing all reasonable inferences in its favor, a genuine issue of material fact persists with respect to whether a test that establishes the presence of the peak 9 compound constitutes

a comparison to a "preselected value". Consequently, summary judgment that the DBB test is non-infringing is unwarranted.

b. Purported Redefinitions of Claims

Amphastar also contends that Momenta is attempting improperly to broaden the scope of its claims with new constructions. Amphastar particularly takes issue with the purported redefinition of 1) the non-naturally occurring sugar depicted by peak 9 to include any compound with a 1,6-anhydro ring structure and 2) "reference standard" to include both "preselected values" (plural) and "preselected value" (singular).

With respect to the purported redefinition of the non-naturally occurring sugar at peak 9, Momenta replies that the '886 patent is not limited to one non-naturally occurring sugar but instead protects the method of using a structural signature that is associated with the non-naturally occurring sugar associated with peak 9. Thus, according to Momenta, its patent has always covered the 1,6-anhydro ring structure which is the structural signature of the non-naturally occurring sugar associated with peak 9. Momenta submits that the structural signature had not been identified as a 1,6-anhydro ring at the date of the filing of the patent but asserts that the structural signature in its patent was identified as a 1,6-anhydro ring structure after the patent issued.

Momenta's contention that it is not attempting to expand its patent but merely providing the name of the structural signature to which it refers is well taken. See Novozymes A/S v. Danisco A/S, 2011 U.S. Dist. LEXIS 157568, *40 (W.D. Wis. July 7, 2011) ("[P]laintiffs are not attempting to take advantage of new technology to expand the scope of the patent, but are simply using developments in the art to show what a Bacillus stearothermophilus alpha-amylase is and what it always has been.") (emphasis in original); Chiron Corp. v. Genentech, Inc., 266 F. Supp. 2d 1172, 1191 (E.D. Cal. 2002) ("Thus, Chiron is not claiming a different invention than that disclosed in the priority applications; Chiron is merely claiming a later-developed embodiment of the same invention.").

With respect to "preselected values", Amphastar claims that finding a detectable amount of peak 9 is not a preselected value. Amphastar also claims that this court construed "reference standard" to include only "preselected values" (plural), not "preselected value" (singular).

Momenta asserts that 1) this Court's claim construction order states that a "reference standard" is defined as a "pre-selected value" and 2) the construction of the term "reference standard" as "pre-selected values" does not preclude a reference standard that is a single value. This Court agrees that reference standard may include both singular and plural

preselected values. Thus, Amphastar is not entitled to summary judgment based upon the purported redefinitions.

B. Momenta's Motion for Summary Judgment Dismissing Amphastar's Equitable Defenses

1. Background

The United States Pharmacopeia ("USP") is a scientific, nonprofit, standard-setting organization ("SSO"). It establishes standards to identify drugs and ensure they meet certain quality prerequisites. The Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 et seq., recognizes the USP National Formulary ("USP-NF"), which is a book of pharmacopeia standards, as the official compendia for drugs sold in the United States. Drugs sold in this country must conform to USP-NF standards.

In 2006, the USP began looking for a method to test compounds with 1,6-anhydro ring structures to incorporate into the enoxaparin monograph. Although Momenta had already applied for its '886 patent, in April, 2008, it began participating on the advisory panel that chose the 1,6-anhydro test method as Chapter <207> of the USP-NF ("USP <207>"). Specifically, Zachary Shriver, the inventor of the method embodied in the '886 patent, participated as an expert on the panel. Despite the fact that the Momenta employees involved in the USP process signed a form declaring that intellectual property rights that

could create the appearance of a conflict of interest should be disclosed, Momenta and Dr. Shriver failed to disclose to the USP the '886 patent application.

In comments to the advisory panel, Momenta and Dr. Shriver opposed the adoption of USP <207> and stated that, at least, alternative methods to identify the 1,6-anhydro ring structures in enoxaparin should be allowed. The USP ultimately approved USP <207> as a way to determine whether enoxaparin conforms to the structure stated in the USP enoxaparin monograph. Although the USP announced that manufacturers would be able to use alternative tests, it stated that "the General Chapter <207> will provide the official test for 1,6-Anhydro Derivative".

Before the USP <207> test was approved, Amphastar developed its own test, the 15-25% procedure, to examine the 1,6-anhydro structures in enoxaparin. According to Amphastar, in or about 2009 or 2010, it compared its own test to the USP <207> test and determined that the tests were substantially the same. Amphastar avers that it switched to the USP <207> test with respect to its revised 15-25% procedure in 2011 because the FDA required it to use that test in order to be approved to sell its enoxaparin.

In Amphastar's view, Momenta had a duty to disclose that its '886 patent would cover USP <207> and, because it did not, the equitable defenses of waiver and estoppel apply. Momenta

retorts that it was not required to disclose the patent application. Momenta further asserts that Amphastar adopted its first 15-25% procedure before USP <207> was approved and the revised 15-25% procedure, which is more similar to USP <207>, in response to this lawsuit. Momenta moves for summary judgment on the equitable defenses of waiver and estoppel.

2. Waiver Defense

To succeed on a waiver defense, a defendant must prove either express or implied waiver by clear and convincing evidence. Qualcomm Inc. v. Broadcom Corp., 548 F.3d 1004, 1020 (Fed. Cir. 2008). Express waiver requires a showing that a plaintiff intentionally waived its right to enforce a patent.

Id. Implied waiver occurs if the behavior of the patent owner was so inconsistent with an intent to enforce its rights as to induce a reasonable belief that such right has been relinquished.

Hynix Semiconductor Inc. v. Rambus Inc., 645 F.3d 1336, 1348 (Fed. Cir. 2011) (quoting Qualcomm, 548 F.3d at 1020). The Federal Circuit has determined that a finding of implied waiver is warranted if a patent owner had 1) a duty to disclose information to an SSO and 2) breached that duty. Id.

The parties vigorously dispute whether Momenta had a duty to disclose the patent application to the USP. Momenta argues that experts like Dr. Shriver were only required to disclose a conflict of interest if it would necessitate abstaining from a

vote and that Dr. Shriver disclosed that he worked for Momenta and refrained from voting on USP <207>. Amphastar retorts that there was an express written duty, as well as an expectation, for USP members and participants to identify intellectual property interests. Viewing the facts in the light most favorable to Amphastar, a genuine issue of material fact remains with respect to whether Momenta had a duty to disclose.

Momenta also contends that summary judgement of dismissal of the waiver defense is warranted because it opposed the adoption of method <207> and supported allowing alternative methods. Amphastar rejoins that Momenta's opposition to the method and advocacy for alternative methods was simply tactical to ensure the FDA approval of its own process, which does not include USP <207>. Momenta was thus purportedly protecting its own financial interests by not disclosing its pending patent application.

This Court agrees that a genuine issue of material fact remains with respect to whether Momenta took those stances to protect its own interests in which case it should have disclosed the pending patent application. Momenta's non-disclosure may be found to have

[f]orc[ed] a party [i.e. Amphastar] to accept a license and pay whatever fee the licensor demands, or to undergo the uncertainty and cost of litigation

if it used the only standard identified by the USP for the enoxaparin quality control process. Qualcomm, 548 F.3d at 1021. Accordingly, summary judgment on waiver is unwarranted.

3. Equitable Estoppel Defense

With respect to equitable estoppel, first, the defendant must prove that the owner of the patent engaged in "misleading conduct" that resulted in the reasonable inference that the "the patentee [did] not intend to enforce its patent against the alleged infringer." Hynix, 645 F.3d at 1348 (quotation and citation omitted). Misleading conduct includes "silence where there was an obligation to speak." Id.

The parties dispute the remaining elements of an equitable estoppel defense. Amphastar, relying on Hynix, contends that, in the context of an SSO, in addition to the first element, the alleged infringer need only show a duty to disclose and a breach of that duty. See id. Momenta asserts that in addition to demonstrating 1) misleading conduct that resulted in the reasonable inference of non-enforcement, the purported infringer must also show 2) reliance and 3) that it will be materially prejudiced if the patent owner's claim is allowed. E.g., Radio Sys. Corp. v. Lalor, 709 F.3d 1124, 1130 (Fed. Cir. 2013).

This Court agrees that the three elements identified by Momenta are required and concludes that the approach of the Hynix Court can be subsumed in the reliance analysis, i.e., if

there is a duty to disclose and the patent owner breaches that duty, there may be an inference of reliance.

Momenta contends that summary judgment on the estoppel defense is warranted because 1) Momenta did not disclaim its intention to to enforce the patent and 2) Amphastar cannot show reliance because it only adopted USP <207> after Momenta had filed suit against it. Viewing the facts in the light most favorable to Amphastar and drawing reasonable inferences in its favor, those contentions are unavailing.

First, a factfinder could conclude that Momenta's failure to disclose the patent to the USP was misleading and resulted in a reasonable inference of non-enforcement. Second, genuine issues of material fact persist with respect to reliance. For instance, Momenta contends that Amphastar adopted the USP <207> procedure only after the lawsuit was filed but Amphastar submits that the USP published method <207> before it was officially adopted and that Amphastar concluded that its method and UPS <207> were essentially the same in 2009 or 2010. Moreover, Momenta contends that the FDA merely required Amphastar to use a method to identify 1,6-anhyrdo rings while Amphastar rejoins that it was specifically required to comply with USP <207>. Perhaps most compelling is Amphastar's argument that it reasonably believed it could use and rely on the method published by the USP. Consequently, there is at least a genuine

issue of material fact with respect to reliance and therefore Momenta is not entitled to summary judgment on the equitable estoppel defense.

III. Motion for a Separate Hearing

As an alternative to its motion for summary judgment, Momenta moves for a separate hearing on the equitable defenses. It asserts that the equitable defenses involve questions of law, are irrelevant to the jury issues and will be used to prejudice the jury against it.

Amphastar responds that the evidence in support of its defenses to the jury questions of infringement, validity and damages is inseparable from the evidence of its equitable defenses. For instance, according to Amphastar, Momenta's failure to disclose the '886 patent to the USP constitutes evidence that it did not believe that USP <207> was covered by that patent which is inconsistent with its allegation that Amphastar infringes the patent by using a procedure identical to USP <207>. Moreover, says Amphastar, plaintiffs made statements disparaging USP <207> which are relevant to its invalidity defense. Amphastar further suggests that the USP situation is relevant to both witness credibility and damages and that if any prejudice results, it is not unfair.

This Court agrees that there is significant overlap between the evidence of infringement, validity and damages on the one

hand, and the equitable defenses on the other hand. Courts have availed themselves of advisory jury verdicts on equitable defenses when such evidence overlaps with jury questions, see Qualcomm, 548 F.3d 1020, and bifurcated trials have been deemed unnecessary. See Genentech, Inc. v. Wellcome Found. Ltd., No. 88-330, 1990 WL 69187, at *14 (D. Del. Mar. 8, 1990). This Court is of like mind and, accordingly, will submit the equitable defenses to the jury for an advisory verdict. Fed. R. Civ. P. 39(c)(1).

IV. Recommendation

In accordance with the foregoing, defendants' motion for summary judgment (Docket No. 823) and plaintiffs' motions for summary judgment and for a separate hearing (Docket Nos. 817, 819) are **DENIED**.

ORDER

So ordered.

/s/ Nathaniel M. Gorton
Nathaniel M. Gorton
United States District Judge

Dated June 16, 2017