United States District Court
District of Massachusetts

MOMENTA PHARMACEUTICALS, INC. and SANDOZ INC.,	)	
Plaintiffs,	)	
v.	)	**Civil Action No. 11-11681-NMG**
AMPHASTAR PHARMACEUTICALS, INC. and INTERNATIONAL MEDICATION SYSTEMS, LTD.,	)	
Defendants.	)	

MEMORANDUM & ORDER

GORTON, J.

In July, 2017, after a nine-day trial, the jury returned a verdict in favor of defendants Amphastar Pharmaceuticals, Inc. and International Medication Systems, Ltd. (collectively, "Amphastar" or "defendants"). Although that jury found that Amphastar had infringed the patent held by plaintiffs Momenta Pharmaceuticals, Inc. and Sandoz Inc. (collectively, "Momenta" or "plaintiffs") during the course of defendants' manufacture and sale of generic enoxaparin, it also found that the infringed patent claims were invalid because they were not enabled and had inadequate written descriptions.

In the same case, this Court sought an advisory verdict from the jury with respect to the equitable defenses of waiver and estoppel and the jury found in favor of defendants as to

both defenses. Amphastar's motion for the Court to adopt the jury's advisory verdict with respect to the equitable defenses is currently pending before the Court. For the reasons that follow, that motion will be allowed, in part, and denied, in part.

I. Background

A. The Patent and Infringing Procedures

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. The individual sugar chains are referred to in the patent as "a structural signature associated with the non naturally occurring sugar associated with peak 9" and have since been identified as 1,6-anhydro rings.

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 alleged 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").

B. Momenta's Non-Disclosure of the '886 Patent to the United States Pharmacopeia

The United States Pharmacopeia ("USP") is a scientific, standard-setting organization ("SSO"). Pursuant to the Federal Food, Drug, and Cosmetics Act, 21 U.S.C. § 301 et seq., drugs sold in the United States must conform to USP National Formulary ("USP-NF") standards. In 2006, the USP began looking for a method to test compounds with 1,6-anhydro rings 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 '886 patent, participated in the panel. Momenta did not disclose to the USP the '886 patent application.

Momenta and Dr. Shriver opposed the adoption of USP <207> and stated that, at least, alternative methods should be allowed. The USP ultimately approved USP <207> as the official test to determine whether enoxaparin conforms to the structure in the USP monograph but also announced that manufacturers would be able to use alternative tests. 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.

C. Procedural History

In October, 2011, this Court enjoined Amphastar from advertising or selling the allegedly infringing enoxaparin. 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. In August, 2012, the Federal Circuit Court of Appeals ("the Federal Circuit") vacated the 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.

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

In April, 2017, defendants moved for summary judgment of invalidity and non-infringement and plaintiffs cross-moved for summary judgment of dismissal of the equitable defenses of waiver and estoppel or, alternatively, for a separate hearing on those defenses. In June, 2017, this Court denied all three motions. The nine-day jury trial in July, 2017 resulted in a verdict as previously described.

II. Motion for the Court to Adopt the Jury's Advisory Verdicts

A. Advisory Jury Verdict

Where a trial is held before a district court with an advisory jury, the court must support its determination with sufficiently comprehensive factual findings. Transmatic, Inc. v. Gulton Indus., Inc., 53 F.3d 1270, 1275 (Fed. Cir. 1995). Under Fed. R. Civ. P. 52(a),

> [i]n all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon.

Fed. R. Civ. P. 52(a). A court can permissibly give to a jury a legal issue for an "advisory" resolution whose "ultimate determination is reserved for the court". Kinetic Concepts, Inc.

v. Smith & Nephew, Inc., 688 F.3d 1342, 1358 (Fed. Cir. 2012) (reviewing the district court's order granting judgment as a matter of law after an advisory verdict on nonobviousness) (citing Spectralytics, Inc. v. Cordis Corp., 649 F.3d 1336, 1341-42 (Fed. Cir. 2011)). While the Court must make its own findings of fact and conclusions of law, the findings of the jury made in an advisory capacity are entitled to some deference. See e.g., Felker v. Pepsi-Cola Co., 899 F. Supp. 882, at 888-89 (D. Conn. 1995) (noting that "it would be purposeless to have an advisory jury unless some degree of deference was shown to its opinions").

Accordingly, as required by Fed. R. Civ. P. 52(a), this Court will make findings of fact and conclusions of law with reference to the jury's advisory verdict.

B. Waiver

i. Legal Standard

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 1) had a duty to disclose information to an SSO and 2) breached that duty. Id. In evaluating whether such a duty existed, the Federal Circuit has adopted a two-step approach, first examining whether the policies of the SSO unambiguously impose a duty to disclose on participants and second, if the policies are ambiguous, evaluating whether participants in the SSO understood them to impose a duty to disclose. Qualcomm, 548 F.3d at 1012. Courts apply an objective standard when evaluating whether a duty to disclose existed, asking whether the patent at issue "reasonably might be necessary" to comply with the standard. Id. 1018 (quoting Rambus Inc. v. Infineon Techs. Ag, 318 F.3d 1081, 1100 (Fed. Cir. 2003)).

ii. Application

Amphastar avers that Momenta waived by implication the right to enforce its patent by failing to disclose to the USP the '886 patent application while participating in the advisory panel that chose the 1,6-anhydro test method as USP <207>. Momenta responds that 1) there was no duty to disclose the '886 patent, 2) there was no evidence of an intentional violation of

any disclosure requirement, 3) USP <207> is not a standard with which drug manufacturers are required to comply and 4) waiver cannot apply to Amphastar's use of its DBB procedure because the procedure is not standard-compliant. In its advisory verdict, the jury found that Amphastar proved, by clear and convincing evidence, that Momenta had waived its right to enforce the '886 patent with respect to both of Amphastar's procedures.

Applying the Qualcomm standard, this Court agrees that Momenta had a duty to disclose to the USP the '886 patent application. Although the USP's written policies are arguably ambiguous, testimony during the trial demonstrated that participants in the USP understood the policies as imposing a duty to disclose. This Court further finds that Dr. Shriver's non-disclosure breached his duty and Momenta therefore waived its right to enforce the '886 patent. Because the DBB test does not comply with USP <207>, however, the scope of the waiver is limited to the 15-25% procedure.

1. The USP Written Policies

Turning first to the USP's written policies, the parties agree that "the Rules and Procedures of the USP Council of Experts" ("the USP Expert Rules") applied to Dr. Shriver. In § 2.05(a), those rules, which became effective in January, 2008, state

> [n]o member of the Council of Experts, an Expert Committee or ad hoc Advisory Panel who has a financial or other interest that may conflict, or may appear to conflict, with his or her duties and responsibilities with respect to a particular matter, shall vote on such matter. An employee's interest shall be presumed to coincide with that of his or her employer.

The USP Expert Rules also require, in § 2.06(a), that advisory panel members

> shall submit to USP a statement of all employment, professional research, organizational memberships, and financial interests that relate either directly or indirectly to his or her duties and responsibilities.

To comply with the USP Expert Rules, participants are required to fill out the USP conflict of interest statement.

The conflict of interest statement reminds participants that, pursuant to § 2.07 of the USP Expert Rules, individuals involved in expert committees may not vote on matters in which they have a financial interest. The conflict of interest statement then requires the participant to list 1) his or her current employer, 2) sources of funding for research and 3) companies known to him or her that may be affected by USP standards. It concludes with a catch-all question that requires the disclosure of other professional or financial interests, including intellectual property rights, “that may result in a conflict of interest or the appearance of a conflict of interest”. Dr. Shriver submitted his conflict of interest form to the USP in February, 2008.

In addition to the USP Expert Rules, a third written policy, the USP Guidelines, is relevant to the determination of whether a duty to disclose existed. The USP revised its guidelines in April, 2009. The revised version of the guidelines states that

> USP requests Sponsors to disclose in their Request for Revision whether any portion of the methods or procedures submitted are subject to patent or other IP rights.

The revision occurred before USP <207> was open to public comment and eight months before it was officially adopted.

Momenta contends that Dr. Shriver had no obligation to disclose the '886 patent application because USP had no explicit disclosure rule and the evidence does not support a finding that panel members understood that USP imposed a duty to disclose relevant patents. Furthermore, Momenta submits that there is no evidence of intentional violation of any disclosure requirement because Dr. Shriver 1) identified Momenta as his employer on his conflict of interest statement and all of his potential conflicts, including the '886 patent application, stemmed from his employment with Momenta and 2) he abstained from the only vote on USP <207>. Amphastar responds that Dr. Shriver was required to disclose the patent in the conflict of interest statement and that, because Momenta was a sponsor of USP <207>, he was also required to disclose the patent under the USP Guidelines.

This Court finds that the disclosure obligation in the written USP policies is ambiguous. On the one hand, Dr. Shriver complied with the policies by stating that he worked for Momenta, the assignee of the '886 patent application, and by abstaining to vote. Because the catchall provision at the end of the conflict of interest form requires participants to "[l]ist any other professional or financial interests" (emphasis added) it arguably did not require Dr. Shriver again to list his employment with Momenta, the assignee of the '886 patent application. On the other hand, the requirement in the catchall provision to disclose any interest that would result in the "appearance of a conflict of interest" indicates an expectation of broad and thorough disclosure, including any interest in intellectual property.

Turning to the USP Guidelines, Amphastar's contention that Momenta was required to disclose the '886 patent application because it was a "sponsor" of USP <207> is without merit. Susan de Mars, a USP representative, submitted a sworn declaration that states that the only sponsor of USP <207> was Sanofi-Aventis.

Because the USP Expert Rules and conflict of interest requirements are ambiguous with respect to whether Dr. Shriver had a duty to disclose the '886 patent application, this Court proceeds to examine whether USP participants understood the

policies to include a duty to disclose. Qualcomm, 548 F.3d at 1012.

2. Participants' Understandings of the USP Policies

Each party called a witness to testify as to their understanding of the USP disclosure policies. Amphastar's witness, Jon Clark, a former USP employee, testified that 1) USP participants understood the policies to require disclosure of pending patents and 2) the disclosure "responsibility falls on the committee member". Mr. Clark specifically stated that

> the common thing to do and the right thing to do is to compel or obligate the volunteer to disclose [conflicts] himself [] or herself.

He further informed the jury that abstention from voting does constitute adequate disclosure of potential conflicts.

In addition to testifying as to his understanding of the written disclosure policies, Mr. Clark testified about a November, 2008 meeting of the USP advisory panel in which Dr. Shriver participated. At that meeting, the USP informed the panel that it had communicated with Sanofi-Aventis, which may have had patents that could cover USP <207> or related tests, and that Sanofi-Aventis was consequently going to allow one of its patents to lapse. Also at that meeting, an individual stated that, because Sanofi was allowing the patent to lapse, "USP is not aware of any patent issues that may cover the

[<207>] test." That statement indicates that USP participants expected that they would be made aware of any patents that might cover USP <207>.

Finally, Mr. Clark testified that a representative of Momenta asked the USP to request that Sanofi affirmatively abandon its patent that might cover USP <207> instead of simply allowing it to lapse. In response to Momenta's request, the USP asked Sanofi-Aventis to abandon its patent and it did so. Momenta's expectation that another pharmaceutical company should abandon a patent that potentially covered USP <207> indicates that Momenta itself, a participant in the USP, acknowledged its own obligation to disclose and abandon like patents.

To rebut Mr. Clark's testimony, Momenta called Mr. Andrew Updegrove, an attorney who has experience working with SSOs. Mr. Updegrove testified that his understanding of the USP written policies was that they did not require the disclosure of a patent. On cross examination Mr. Updegrove conceded, however, that he has never been employed by, advised or engaged in legal work for the USP. In fact, Mr. Updegrove testified that he never dealt with anything related to the USP before he testified at the trial in this case.

It appears that the jury accepted the testimony of Mr. Clark, an individual who had experience working at the USP and testified about a specific USP meeting attended by Dr. Shriver,

while rejecting that of Mr. Updegrove, who had no experience whatsoever with the USP. Similarly, this Court finds the testimony of Mr. Clark relative to USP disclosure policies more convincing than that of Mr. Updegrove given the differential in their experiences.

Moreover, Momenta's contention that USP <207> is not a mandatory test and that it opposed its adoption does not negate its duty to disclose. Although alternatives to USP <207> are permitted, Mr. Clark testified that the

> USP standards are intended to be public standards available for the use and benefit of all parties.

This fits with an expectation that Momenta was obliged to disclose a patent application for a patent that might cover the USP standard. Momenta's contention that it opposed USP <207> is also unavailing. It had a financial interest in opposing the mandatory adoption of USP <207> because it uses a different test to ensure the quality of its own enoxaparin. Regardless of its opposition to the standard, it had a duty to disclose.

Momenta contends that this case falls outside of the Qualcomm paradigm because there, the existence of a mandatory standard was essential to the Federal Circuit's determination that the plaintiff had "carefully orchestrated" a patent trap. Because the USP, in this case, approved USP <207> as one scientifically acceptable way to determine compliance with a

structural requirement, Momenta suggests it was not a required standard and nondisclosure did not "trap" Amphastar or others, thereby distinguishing this case from the facts in Qualcomm.

In Qualcomm, the SSO was tasked with creating a single industry standard for video compression technology that would be required in the industry. Qualcomm, 548 F.3d at 1008-09. The district court held the patents unenforceable after finding that Broadcom's equitable defenses were applicable. Id. Because the standard was compulsory, the patent-holder in that case effectively "h[eld] hostage the entire industry". Id. at 1010. Momenta's contention that its conduct differs because the USP made USP <207> optional is belied by testimony proffered by Amphastar that it was required to comply with USP <207> by the FDA.

Furthermore, the fact that the jury found that the 15-25% procedure, which is almost identical to USP <207>, infringes the '886 patent supports an inference that use of the invention disclosed by the '886 patent "reasonably might be necessary" to comply with USP <207>. Qualcomm, 548 F.3d at 1018 (quoting Rambus Inc., 318 F.3d at 1100).

Because 1) Mr. Clark testified that there was a common understanding at the USP that there was a duty to disclose conflicts of interest, including patents, and 2) use of the method in the '886 patent reasonably might be necessary to

comply with USP <207>, this Court finds that Dr. Shriver had a duty to disclose the pending '886 patent application.

3. Breach

Having established that there was a duty to disclose, the next inquiry is whether a breach of that duty occurred. There is no dispute that Dr. Shriver did not disclose to the USP the '886 patent application. Accordingly, the Court finds that he breached his duty to disclose a potential conflict of interest.

iii. Scope of the Equitable Remedy

If a Court renders a patent unenforceable due to waiver it must ensure that the "unenforceability remedy is properly limited in relation to the underlying breach." Qualcomm, 548 F.3d at 1026. In the SSO context, a remedy is properly limited in scope if it applies to products that comply with the standard at issue that also have an "obvious connection" with the allegedly infringing patent. Id. Thus, to determine the appropriate scope of the remedy in this case, the Court must determine whether the 15-25% procedures and DBB procedure comply with USP <207>.

Here, both USP <207> and the infringing 15-25% procedures use an equation that determines whether 15-25% of the sugar chains in an enoxaparin sample end up in 1,6-anhydro rings. Momenta contends the 15-25% procedures are distinct from USP <207> because different separation conditions and different

quantities of digestive enzyme are used. Those differences are, however, minor parts of an elaborate laboratory procedure that is otherwise identical. Consequently, this Court finds that Amphastar's 15-25% procedures comply with USP <207> and accordingly, Momenta may not enforce the '886 patent with respect to those procedures.

Conversely, the DBB procedure is distinct from USP <207>. Unlike USP <207>, the DBB procedure examines the 23 building blocks of enoxaparin. For 13 of those building blocks, it measures the peaks of the substances in the enoxaparin. For the other 10, including 1,6-anydro rings, it simply establishes that the substance is present in the batch.

Amphastar relies on the testimony of Mr. Zhou, its executive vice president of production and senior vice president of scientific affairs, in support of its contention that the DBB procedure is the same as USP <207>. Mr. Zhou stated that the DBB test and USP <207> are "fundamentally . . . the same." Yet he further testified that "DBB is still our own method" but the revised 15-25% procedure conforms to USP <207>. He also conceded, at a deposition before trial, that the DBB was not the USP method.

The understanding that the DBB procedure is distinct from USP <207> is also supported by the testimony of another Amphastar witness, Dr. Lindhardt. Dr. Lindhardt testified about

the differences between Amphastar's USP <207> test and the DBB procedure, including the fact that the DBB test identifies the 23 building blocks of enoxaparin instead of determining whether 15-25% of the sugar chains in an enoxaparin sample have 1,6-anhdyro rings. Momenta's expert, Dr. Liu, agreed, testifying that "the DBB procedure is quite different from the 15 to 25 percent procedure".

Given the agreed-upon differences in the subject procedures, the Court declines to adopt the advisory jury verdict with respect to the DBB procedure. It finds that the DBB procedure does not comply with USP <207> and therefore Momenta has not waived its right to enforce the '886 patent with respect to the DBB procedure.

C. Equitable Estoppel Defense

i. Legal Standard

With respect to equitable estoppel, first, a 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.

In addition to showing 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). If there is a duty to disclose a patent to an SSO and the patent owner breaches that duty, that may constitute misleading conduct that supports an inference that the patent owner does not intend to enforce the patent. Hynix, 645 F.3d at 1348. Furthermore, reliance may be shown if the alleged infringer then adopts the standard that has been set with the understanding that it is available for public use.

ii. Application

The jury found, by advisory verdict, that Amphastar proved by a preponderance of the evidence that Momenta was equitably estopped from enforcing the patent against the infringing procedures.

1. Misleading Conduct

With respect to the first element, misleading conduct, as addressed above, Momenta had a duty to disclose its patent to the USP and it breached that duty through silence. Consequently, it engaged in the misleading conduct that gives rise to equitable estoppel. Hynix, 645 F.3d at 1348.

Whether Amphastar then relied on the standard that was set, USP <207>, is a closer question that was vigorously disputed at trial. Three witnesses for Amphastar testified that it relied

on USP <207> and that the FDA expected that it would use that standard.

Mr. Zhou testified that Amphastar began using its 15-25% procedure in 2006 and became aware of USP <207> in 2009. According to Mr. Zhou, Amphastar's initial 15-25% procedure was "[f]undamentally . . . the same" as USP <207>. Mr. Zhou stated that Amphastar waited to switch to the official USP <207> test until after it launched the commercial product in 2011. He further testified that the

> FDA wanted [Amphastar] to follow the USP, [and] proposed the USP when USP bec[a]me official.

Mr. Zhou's understanding was that "[e]verybody can use [USP <207>]".

Diane Gerst, Amphastar's executive vice president of quality assurance and regulatory affairs, testified that her understanding is that the FDA requires Amphastar to perform the infringing tests. She further stated that the USP-NF is

> a public reference book . . . that prescribe[s] the testing that should be performed to consistently demonstrate quality and that everyone can refer to it and use it as a standard.

Mr. Peters, the CFO of Amphastar and the president of International Medication Systems, testified that it was his understanding that "the FDA sent us a letter saying we should use USP 207, and we told them we would."

During the trial Momenta asserted that Amphastar did not rely on USP <207>. In support of that assertion, Momenta elicited testimony during Mr. Zhou's cross examination that Amphastar did not become aware of USP <207> until 2009 which was three or four years after it had submitted its initial 15-25% procedure to the FDA. During cross examination, Mr. Zhou also admitted that when he was deposed he stated that "the FDA basically approved" Amphastar's initial 15-25% procedure in 2007. Momenta ultimately argued that Amphastar did not revise its 15-25% procedure to comply with USP <207> until November, 2011 and only did so then because Momenta had filed a lawsuit against it.

Whether Amphastar relied on USP <207> ultimately comes down to an evaluation of the witnesses' credibility. Here, the jury apparently found credible the testimony of Amphastar's witnesses, Mr. Zhou, Mr. Peters and Ms. Gerst, that Amphastar used the revised 15-25% procedure in reliance on USP <207> and was required by the FDA to do so. Moreover, Mr. Zhou's testimony that the initial and revised procedures are both fundamentally the same as USP <207> supports an inference that Amphastar relied on UPS <207> in continuing to use the initial 15-25% procedure and adopting the revised 15-25% procedure. This Court agrees that there was credible testimony supporting the inference that Amphastar relied on USP <207> for its

continued use of the 15-25% procedures. Accordingly the reliance requirement for equitable estoppel is met.

Having found that Amphastar relied on USP <207>, the final question with respect to equitable estoppel is whether defendants will be materially prejudiced if plaintiff's claim is allowed. The Federal Circuit has determined that "investment in new products" can support a finding of economic prejudice. Radio Sys. Corp. v. Lalor, 709 F.3d 1124, 1130 (Fed. Cir. 2013). In this case, Amphastar, relying on its ability to use methods that comply with USP <207>, substantially invested in developing its capacity to manufacture, produce and market enoxaparin. Therefore, it has shown that it would be economically prejudiced if Momenta were permitted to enforce the patent against it.

2. Scope of the Equitable Remedy

Because the DBB procedure does not comply with USP <207>, Momenta is only equitably estopped from enforcing its patent against the 15-25% procedures. Qualcomm, 548 F.3d at 1026.

ORDER

In accordance with the foregoing, Amphastar's motion for judgment that the equitable defenses of waiver and estoppel apply is, with respect to the 15-25% procedures, **ALLOWED** but, with respect to the DBB procedure, **DENIED.**

So ordered.

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

Dated February 7, 2018