

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

Dockets.Justia.com

whether there was a duty to disclose the '886 patent to the United States Pharmacopeia ("the USP") and whether Momenta breached that duty. Amphastar contends that there is substantial commonality between the evidence of its defenses to Momenta's claims and the evidence of equitable defenses. Because the Court agrees that there is a substantial overlap rendering separation of the evidence problematic, the defendants will be permitted to offer evidence relative to their equitable defenses at the trial.

I. Legal Standard

Equitable defenses involve matters of law and thus "factual issues [underlying such defenses] ordinarily are not jury questions." Baxter Healthcare Corp. v. Spectramed, Inc., 49 F.3d 1575, 1584 (Fed. Cir. 1995). Although the Federal Circuit Court of Appeals ("Federal Circuit") has stated that it is "not the preferred course", it upholds a district court's decision to "delegate aspects of the inequitable conduct inquiry to juries" as long as such delegation does not result in prejudice or an unfair trial. Rothman v. Target Corp., 556 F.3d 1310, 1322-23 (Fed. Cir. 2009).

Bifurcation is warranted if the claims and equitable defenses "are distinct and without commonality either as claims or in a relation to the underlying fact issues." DeKalb Genetics Corp. v. Syngenta Seeds, Inc., 2008 WL 382385, at *2 (E.D. Mo.

Feb. 12, 2008) (quoting Old Town Canoe Co. v. Confluence Holdings Corp., 448 F.3d 1309, 1322 (Fed.Cir. 2006)).

Conversely, when there is "overlapping of evidence on all issues," courts have conducted one trial with respect to the claims and equitable defenses. Genentech, Inc. v. Wellcome Found. Ltd., No. 88-330, 1990 WL 69187, at *14 (D. Del. Mar. 8, 1990). When evidence of equitable defenses overlaps with matters that are clearly for the jury to decide, such as issues of infringement, validity and damages in this case, courts have availed themselves of advisory jury verdicts. See Qualcomm Inc. v. Broadcom Corp., 548 F.3d 1004, 1009 (Fed. Cir. 2008). Nevertheless, the equitable defenses ultimately remain a question of law for the Court to decide. See id.

II. Application

Amphastar contends that the evidence as to equitable defenses significantly overlaps with the jury questions. Its argument addresses five specific examples.

A. Whether the Failure of Momenta and Dr. Shriver to Disclose the '886 Patent is an Admission of Non-Infringement

In Amphastar's view, Momenta did not disclose the '886 patent to the USP for either of two reasons: 1) it did not believe the patent covered the <207> method or 2) it knew that the patent covered <207> but did not disclose it anyway. Thus,

argues Amphastar, the non-disclosure is relevant to both its non-infringement and its waiver and equitable estoppel defenses.

Momenta replies that 1) Amphastar's argument assumes that there was a duty to disclose, 2) Amphastar concedes that the so-called DDB procedure is not the equivalent of UPS <207> and thus the waiver defense does not apply to it and 3) Amphastar's contention that the allegedly infringing 15-25% procedures are essentially the same as USP <207> is part of its waiver defense, not an undisputed fact.

Momenta further asserts that the only relevant comparison for infringement is 1) the language of the claims as construed by the Court and 2) Amphastar's conduct. In its view, Dr. Shriver's opinions are irrelevant to infringement. Amphastar responds that, in support of its invalidity defense, it plans to seek testimony from Dr. Shriver about whether the specification of the '886 patent would "allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." See Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (internal quotations and citations omitted).

Amphastar's contention that its claim of non-infringement and its equitable defenses of estoppel and waiver are inextricable is well taken. While the existence of a duty to disclose is factually disputed, if there was such a duty, Dr.

Shriver's non-disclosure bears on whether a person of ordinary skill in the art would understand what the patentee invented.

B. Willful Infringement

Amphastar also asserts that its contention that it practices USP <207> is relevant to the issue of willful infringement. Momenta responds that it will not claim willful infringement at trial. Yet Momenta opposes Amphastar's in limine motion to exclude evidence of willful infringement, asserting that it has

the right to introduce evidence of what Amphastar knew, when Amphastar knew it, and what Amphastar chose to do. This evidence is relevant to other issues, such as damages and estoppel.

Docket No. 986 at 1. Specifically, Momenta asserts that willful infringement is relevant to 1) Amphastar's claim that it relied on USP <207>, which is an element of equitable estoppel, and 2) Amphastar's failure to seek an alternative to performing the accused procedures.

This Court agrees that there is significant overlap of the evidence with respect to willful infringement. Momenta will be allowed to introduce the evidence of willful infringement identified in its opposition to Amphastar's in limine motion to exclude evidence of willful infringement, Docket No. 986, but Amphastar will be permitted, in rebuttal, to offer evidence that it relied on USP <207>.

C. Whether Momenta's Action at the USP is Evidence of Invalidity

Next, Amphastar claims that Momenta's statements to the USP are relevant to Amphastar's contention that the '886 patent lacks enablement and written description. Amphastar's expert, Dr. Linhardt, relied on Momenta's statements to the USP that method <207> 1) is inadequately defined and 2) leads to inaccurate results in reaching his conclusion that the '886 patent is not enabled because it contains even less description than USP <207>. Similarly, Dr. Linhardt uses statements made by Momenta to the USP as evidence that the '886 patent lacks written description because it neither describes the structure of "peak 9" nor identifies the peak 9 structure as a 1,6-anhydro ring.

Momenta responds that its statements as to USP <207> are irrelevant to Amphastar's enablement and written description defenses because those defenses examine 1) whether the specification of the '886 patent teaches a person of ordinary skill in the art the claimed method and 2) whether there is an adequate written description of the invention. This Court concludes that there is an overlap between the Amphastar's enablement and written description defenses and the USP events.

D. The Relevance of Momenta's Actions at the USP to Damages

According to Amphastar, the facts underlying its equitable defenses are also relevant to damages for lost profits and for reasonable royalties. To evaluate the calculation of reasonable royalties, the jury will have to consider the licensor's policy and marketing program to maintain a patent monopoly. Amphastar asserts that the facts that Momenta 1) offered a royalty-free license for a heparin-related patent if the USP adopted a different method and 2) demanded that Sanofi abandon a patent application because it was implicated in a USP standard rebut Momenta's contention that it does not have a policy with respect to intellectual property related to USP standards.

Momenta counters that it does not sell heparin and would not license a patent for a product it sells. Furthermore, Momenta asserts that evidence about its offer of a royalty-free license for heparin does not require instructing the jury about Momenta's non-disclosure to the USP. This Court concludes that there is at least some overlap between events that occurred at the USP and evidence of damages.

E. Whether the Conduct of Momenta Employees Before the USP Implicates the Credibility of Its Witnesses

Finally, Amphastar asserts that the events involving the USP implicate the credibility of 1) Dr. Shriver, the inventor of the '886 patent, who Amphastar intends to call as an individual

skilled in the art to testify about infringement, validity and damages, and 2) Dr. Capila, who Momenta plans to call to testify about infringement.

Momenta retorts that it does not intend to call Dr. Shriver unless the Court allows the introduction of evidence of equitable defenses and, furthermore, Amphastar does not have the right to call him merely to challenge his credibility. Momenta also contends that Dr. Capila joined a USP advisory panel that did not review method <207> and signed his form after <207> had been issued.

The Court agrees with Amphastar that it may call Dr. Shriver to testify as a person of ordinary skill in the art if it so chooses and that Dr. Capila's credibility could be implicated by the USP events. Thus, there is some overlap between the USP events and witness credibility.

In sum, the evidence relevant to the issues of infringement, validity and damages is so intertwined with the putative evidence of equitable defenses that bifurcation is unwarranted. Genentech, Inc., 1990 WL 69187, at *14. Moreover, although the Court will ultimately determine whether the equitable defenses are determinative, it will seek an advisory jury verdict thereon in the first instance. See Qualcomm Inc., 548 F.3d at 1009.

III. Avoiding Prejudice

To guard against prejudice, this Court cautions Amphastar to avoid (and to instruct its witnesses to avoid) pejorative words such as "deception", "concealed", "improper" and "unethical" in their description of the USP events. Such inflammatory terminology is improper and will not be permitted. It may also result in a reprimand and a limiting instruction to the jury.

Moreover, because the parties do not dispute that Momenta failed to disclose the patent application to the USP, such evidence might more properly be introduced by stipulation and should not be the subject of cumulative testimony. The Court will also consider a limiting instruction to the jury to be given at the outset of the case that the jury will hear evidence relative to both the plaintiffs' claims of infringement, validity and damages and the defendants' equitable defenses which they are to consider and decide separately. The Court invites counsel to submit their own version of such an instruction by the close of business on Monday, July 3, 2017.

ORDER

In accordance with the foregoing, the evidence relative to the equitable defenses will be admissible at the impending jury trial.

So ordered.

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

Dated June 29, 2017