UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

COVIDIEN SALES LLC and COVIDIEN LP, and COVIDIEN, INC.,

Plaintiffs,

v.

ETHICON ENDO-SURGERY, Inc. and ETHICON ENDO-SURGERY, LLC,

Defendants.

ETHICON ENDO-SURGERY, Inc. and ETHICON ENDO-SURGERY, LLC,

Counterclaim-Plaintiffs,

v.

COVIDIEN SALES LLC and COVIDIEN LP, and COVIDIEN, INC.,

Counterclaim-Defendants.

Case No. 1:11-cv-871
JUDGE DOUGLAS R. COLE

OPINION AND ORDER

This cause comes before the Court on three motions in limine. Plaintiffs (and Counterclaim-Defendants) Covidien Sales LLC, Covidien LP, and Covidien Inc.'s (together, "Covidien") filed two of them (Docs. 228 & 229). Defendants (and Counterclaim-Plaintiffs) Ethicon Endo-Surgery, Inc. and Ethicon Endo-Surgery, LLC's (together, "Ethicon") filed the other (Doc. 227). The parties filed these motions

in anticipation of the bench trial in this patent matter currently set for January 11, 2021. All three motions claim that various different types of evidence are irrelevant to the limited issues remaining to be tried in this matter, and thus should be excluded.

For the reasons set forth more fully below, the Court **GRANTS IN PART AND DENIES IN PART** each of the three motions. More specifically, the Court **GRANTS** Ethicon's Motion to exclude evidence of alleged non-infringing alternatives (Doc. 227) to the extent that Ethicon seeks to preclude Covidien from admitting evidence of other Covidien devices as a basis for arguing that Ethicon is not entitled to lost profits for any time period prior to the time that Covidien actually released those products to market. But the Court **DENIES** the Motion to the extent that Covidien seeks to introduce such evidence for other permissible reasons, as further discussed below. Similarly, the Court **GRANTS** Covidien's Motion regarding the curved blade device (Doc. 229) to the extent that it seeks to preclude Ethicon from introducing or using such evidence for the purpose of establishing that the curved blade device infringes, but **DENIES** the Motion to the extent that Ethicon seeks to introduce such evidence for other permissible reasons. Finally, the Court likewise **GRANTS** Covidien's Motion to prohibit Ethicon from introducing evidence about Covidien's 510(k) FDA premarket submissions solely to argue that the Covidien's accused infringing devices are substantially equivalent to Ethicon products that practice the patented invention, but the Court **DENIES** the Motion to the extent that Ethicon seeks to introduce such evidence for other permissible reasons.

BACKGROUND

This case concerns Ethicon's patent number 9,168,055 ("the '055 patent"), titled "Ultrasonic Surgical Shears and Method for Sealing a Blood Vessel Using Same," which claims, as relevant here, a surgical apparatus for transecting and sealing blood vessels. Ethicon practices the patented invention in its Harmonic ultrasonic surgical device. Ethicon introduced the Harmonic product in 2005, obtained the '055 patent in 2015, and claims priority for the invention claimed in that patent back to a provisional application filed on February 27, 2004. (Ethicon's Statement of Proposed Undisputed Facts, Doc. 184-1, #11480; Doc. 227, at #17842).

In 2012, Covidien began selling its Sonicision Cordless Ultrasonic Dissection Device ("Sonicision"), which competes with Ethicon's Harmonic device. Already mired in patent litigation with Ethicon at the time, Covidien sought a declaratory judgment in 2016 that the Sonicision does not infringe Ethicon's '055 patent (or any of five other Ethicon patents). Ethicon responded by filing an infringement claim on all six patents, plus a seventh. Ultimately, the parties resolved their dispute as to all patents other than the '055 patent. The parties cross-moved for summary judgment on a variety of issues relating to that remaining claim. The Court, among other things: (1) granted Ethicon's motion for summary judgment of infringement as to claims 9, 10, and 20-25 of the '055 patent; (2) granted Covidien's motion for summary judgment of non-infringement of claims 1, 2, 4, 5, 8, and 14 of the '055 patent; and (3) granted Ethicon's motion for summary judgment as to the absence of any acceptable and available non-infringing alternatives (which is a question that arises

under the second step of the *Panduit* test for lost-profit damages). (*See generally* Order Resolving Mots. For Summ. J., ("Summary Judgment Order"), Doc. 212).

After resolving the issues presented at the summary judgment stage, the Court entered a Calendar Order setting the matter for a bench trial starting on March 30, 2020. (Order Adopting Proposed Pretrial Case Schedule, Doc. 215, #17744). Because the Court resolved the issues relating to infringement as a matter of law, the trial is limited to validity and, if the patent is valid, damages. (*See* Ethicon's Trial Br., Doc. 239, #18043). In other words, the upcoming trial will address whether claims 9, 10, and 20–25 of the '055 patent are invalid for obviousness, and if the Court finds that any of the infringed claims are valid, it will then determine damages in the form of lost profits and/or a reasonable royalty.

On January 2, 2020, this matter was reassigned to the undersigned judge. Due to a delay caused by the COVID-19 pandemic, the Court has since rescheduled the trial twice. It is currently set for January 11, 2021. In advance of trial, the parties filed the present motions in limine seeking to exclude introduction and discussion of certain evidence during the bench trial. This Order addresses those motions.

LAW AND ANALYSIS

Parties may seek to prohibit the introduction or discussion of evidence at trial by filing a motion in limine explaining why the Court should exclude that evidence. Even so, "[e]vidence which is not admissible for one purpose may be relevant and admissible for another." *United States v. Threadgil*, No. 3:11–cr–86, 2012 WL 5384813, at *2 (E.D. Tenn. Nov. 1, 2012). Accordingly, "[o]rders *in limine* which

exclude broad categories of evidence should rarely be employed." *Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975). So a district court will grant a motion to exclude evidence "only when [the] evidence is clearly inadmissible on all potential grounds." *Ohio Willow Wood Co. v. ALPS South, LLC,* No. 2:04-cv-1223, 2014 WL 3734342, at *1 (S.D Ohio July 29, 2014). "Unless evidence meets this high standard, evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *Id.* Importantly, "[t]his presumption is particularly strong in a bench trial" because "[w]ithout the fear that prejudicial or improper evidence will taint the jury, courts are even more inclined to take a wait-and-see approach." *Id.* at *2 (quoting *Bank One, N.A. v. Echo Acceptance Corp.* No. 04–CV–318, 2008 WL 1766891, at *1 (S.D. Ohio Apr.11, 2008)).[1]

Here, both parties have moved to exclude certain evidence that each believes that the other will seek to introduce for purposes that are impermissible under the Federal Rules of Evidence. As described below, though, in each case, the opposing party largely agrees that the evidence would be inadmissible for that purpose, but also claims that it is in fact seeking to introduce the evidence for a different—and

[1] The Court notes that its ruling on the parties' evidentiary motions is preliminary in nature. "Denial of a motion *in limine* does not necessarily mean that all evidence contemplated by the motion will be admitted at trial. Denial merely means that without the context of trial, the court is unable to determine whether the evidence in question should be excluded. The court will entertain objections on individual proffers as they arise at trial, even though the proffer falls within the scope of a denied motion *in limine*." *Ohio Willow Wood*, 2014 WL 3734342, at *1. "Indeed even if nothing unexpected happens at trial, the district judge is free, in the exercise of sound judicial discretion, to alter a previous *in limine* ruling." *Luce v. United States*, 469 U.S. 38, 41–42 (1984).

permissible—purpose. Given that the parties largely agree on the impermissible purposes for each type of evidence, the Court **GRANTS** the parties' Motions to exclude evidence for the particular identified purpose, as outlined below. But the Court **DENIES** the parties' broader requests to completely prohibit the introduction or discussion of the disputed evidence. In other words, the Court will not exclude evidence if the tendering party can identify an appropriate purpose, which is a question the Court will address during trial, at the time, and in the context, in which the party seeks to admit the evidence.

A. Evidence Concerning Covidien's Non-Infringing Alternative Products

The Court begins with Ethicon's Motion (Doc. 227) to limit introduction and discussion of Covidien's alleged non-infringing alternatives. Noting that the Court previously ruled in its Summary Judgment Order that Covidien was unable to show that it had any acceptable non-infringing alternatives to Ethicon's product during what the Summary Judgment Order called the "relevant time period," (Doc. 212, at #17733), Ethicon seeks to completely prohibit Covidien from discussing any alleged non-infringing alternatives during the upcoming trial. Ethicon argues the Court's earlier summary judgment ruling on the non-infringing alternative devices constitutes "the law of the case" and thus governs the remaining litigation. (Doc. 227, at #17846). According to Ethicon, that ruling makes any discussion or evidence concerning non-infringing alternatives irrelevant as a matter of law. In other words, Ethicon asserts the time for discussing non-infringing alternatives has come and

gone, so relitigating that argument would be irrelevant given the limited issues that remain in this action.

Resolving this Motion requires the Court to determine whether there is any remaining issue as to which Covidien's evidence about its other products (products that are not accused of infringement in this lawsuit) may be relevant. Per Federal Rule of Evidence 401, "[e]vidence is relevant if: (a) it has any tendency to make a fact more or less probable than it would be without the evidence; and (b) the fact is of consequence in determining the action." Under that standard, evidence offered to support a claim not at issue is irrelevant. *See In re Nat'l Prescription Opiate Litig.*, No. 1:17-md-2804, 2020 WL 6450290, at *5 (N.D. Ohio Nov. 3, 2020) (finding evidence used to support compensatory damages inadmissible as irrelevant because those claims were not at issue). In other words, it is only when evidence does not touch upon *any* matter at issue that it should be excluded as irrelevant.

Here, Covidien agrees with Ethicon that the Court has already ruled on whether Covidien possessed any available non-infringing alternatives as that term is used in the second step of the *Panduit* test, (Mem. in Opp'n, Doc. 236, at #18008), but disputes Ethicon's position that the Court's previous Order decided the broader question of whether Covidien had *any* non-infringing alternatives. (*Id.* at #18001, 18006). Covidien claims that it is not seeking to introduce these alternative designs to foreclose the availability of lost-profit damages (the issue to which the *Panduit* test is directed). Rather, it claims such evidence may be relevant for other purposes.

According to Covidien, these include "Ethicon's damages claims for products sold after December 31, 2019 and the calculation of a reasonable royalty." (*Id.* at #18006).

The Court agrees (apparently with both parties) that Covidien cannot relitigate the *Panduit* step-two issue resolved in the earlier Order (although Covidien has reserved its right to appeal that determination). But Ethicon errs in trying to read that Summary Judgment Order as a broad prohibition on introducing evidence of non-infringing alternatives that Covidien had in development, or that Covidien released to the market since the Court issued that Order.

In saying that there were no "available non-infringing alternatives," the Court was not intimating that Covidien did not have any such devices under development, but rather only that they were not close enough to release to the market to count as "available" under *Panduit*. Even devices that are not "available" for *Panduit* purposes, though, may still be relevant to the damages analysis in other ways. For example, if lost profits are not available (for whatever reason), one measure of damages is a reasonable royalty. In assessing a reasonable royalty, courts reconstruct hypothetical negotiations between a willing licensor and a willing licensee. *See, e.g.*, *Bio-Rad Labs., Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1372 (Fed. Cir. 2020) ("At trial, the parties used the hypothetical negotiation or the 'willing licensor-willing licensee' approach for calculating reasonable royalty damages. This approach attempts to calculate the royalty rate the parties would have agreed upon had they negotiated an agreement prior to the start of the infringement."). As a matter of common sense, it appears at least possible that such negotiations could be colored by

whether the licensee has developed a design (even if not ready yet to go to market) that is non-infringing. Or, at the very least, Ethicon has failed to cite any case law to the contrary.

Separately, the basis for the holding in the Summary Judgment Order was that Covidien did not have its products ready for market during the then-relevant time period for damages. Due to various delays in getting the matter to trial, though, it appears that Covidien has since released those products. Thus, the Court's prior determination that the products were not available non-infringing alternatives at the time should not prevent Covidien from arguing that *after the products were released to the market* they became available non-infringing alternatives, and thus presumably could terminate the time period during which lost-profit damages are available. The Court is not saying that *is* the case, but it certainly seems at least plausible that it *may be* the case, thus rendering evidence as to Covidien's non-infringing alternatives at least arguably relevant.

All in all, although the parties agree that the evidence at issue is not relevant for some purposes, Covidien has identified valid issues to which evidence of non-infringing alternatives could conceivably be relevant. Thus, the Court **GRANTS** Ethicon's Motion to the extent that Ethicon seeks to preclude Covidien from admitting evidence of other Covidien devices as a basis for arguing that Ethicon is not entitled to lost profits (i.e., the second *Panduit* factor) for any time period prior to the time that Covidien actually released the products to market, which Covidien suggests in its Opposition was on or about August 2020, but **DENIES** the Motion's

broader request to prohibit Covidien from introducing or discussing evidence of non-infringing alternatives for any purpose. As to any such other purposes, the Court will assess the relevance, *in context*, at the time that Covidien seeks to introduce the evidence.

B. Evidence Concerning Covidien's Curved Blade Device

Covidien's Motion seeking to exclude evidence on its curved blade device (Doc. 229) suffers from a similar defect as Ethicon's Motion about the non-infringing alternatives. Covidien first presents the clearest purpose for which Ethicon cannot use evidence about the curved blade device: making a claim that the curved blade device infringes on the '055 patent. That is because, to date, Ethicon has not asserted an infringement claim against the curved blade device, and it is far too late to do so in this matter. Moreover, an existing settlement agreement requires the parties to undergo a mediation procedure before bringing an infringement claim against a device. Accordingly, Covidien concludes that evidence regarding the curved blade device is irrelevant. (Doc. 229, at #17868).

Happily, though, Ethicon agrees with at least part of what Covidien argues. Specifically, Ethicon concurs that "[w]hether the curved-blade Sonicision infringes the '055 patent will not be in dispute at trial" and that "Ethicon does not allege claims for infringement by the curved-blade device in this litigation." (Resp. to Mot., Doc. 235, #17988). Because the parties agree that using the curved blade device as evidence of infringement would not relate to the issues at hand in the upcoming bench trial, the Court **GRANTS** Covidien's Motion to the extent that it seeks to preclude

Ethicon from introducing or using evidence regarding the curved blade product for the purpose of establishing infringement.

Even so, Ethicon argues that it can introduce and discuss evidence about the curved blade device for purposes aside from raising an infringement claim. For example, Ethicon claims that it will introduce evidence as to Covidien's curved blade device to bolster Ethicon's claims that it "is entitled to lost-profit damages." (*Id.* at #17989). Specifically, Ethicon claims that it will rely on the "introduction of the second-generation curved-blade Sonicision in 2018" to assist in "reconstruct[ing] the market as it would have developed." (*Id.*). Accordingly, Ethicon concludes that evidence about Covidien's curved blade device would be "relevant to the damages issues that will be tried, even though the devices themselves are not accused of infringement." (*Id.* at #17990).

In response, Covidien argues that Ethicon cannot offer evidence relating to the "curved blade device to support its damages theories" because: (1) Ethicon does not seek lost profits or a reasonable royalty relating to the curved blade device; (2) pricing data about the second generation curved blade device is not relevant to the accused first generation device; (3) the pricing data Ethicon relies on did not come from Covidien, but instead "derives from a third party and is incomplete and therefore unreliable;" and (4) Ethicon's expert incorrectly "assumes the curved blade device does not differ in any material respect from Sonicision" and "his opinion is factually incorrect and unsupported by any record evidence." (Doc. 229, at #17868–69).

The Court agrees with Ethicon that evidence regarding other products in the marketplace, including the curved blade product, may be relevant to the expert's efforts to reconstruct the relevant market for purposes of calculating lost profits (if the Court determines that such damages are available). *See Ericsson, Inc. v. Harris Corp.*, 352 F.3d 1369, 1377 (Fed. Cir. 2003) (finding that reconstructing a market to account for the infringing products can support a lost-profits argument). With regard to the question of whether the sales data on the curved blade products is sufficiently reliable, or whether the expert's opinion is factually inaccurate in assuming that the curved blade device does not differ from the Sonicision, the Court will reserve judgment until such time as the parties have elicited testimony at trial on those issues. In short, the Court finds that Covidien has not met the high pre-trial bar for excluding a broad category of evidence as irrelevant. Thus, the Court **DENIES** Covidien's Motion to the extent it seeks to exclude evidence relating to the curved blade device for all purposes.

C. Evidence Concerning Covidien's 510(k) Premarket Submissions To The Food And Drug Administration ("FDA")

In the remaining Motion in Limine (Doc. 228), Covidien seeks to preclude Ethicon from introducing or discussing evidence related to Covidien's 501(k) premarket submissions to the FDA. This evidence includes:

> (i) versions or excerpts of the original Sonicision 510(k) Application No. K101797 submitted to the FDA containing technical comparisons between Sonicision and ACE to support Covidien's 'substantial equivalence' claim (and applicant statements and characterizations concerning the same) (PTX-259, PTX-263, PTX-348); (ii) comparative testing and technical documents Covidien prepared in connection with 510(k) Application No. K101797 for purposes of supporting this

> 'substantial equivalence' claim (and internal Covidien communications relating to such testing and data) (PTX-009, PTX-0016, PTX-017, PTX-019); and (iii) the February 24, 2011 '510(k) Summary' reflecting FDA approval to market Sonicision based on Covidien establishing "substantially equivalence" to the ACE under governing FDA regulations (PTX-014, PTX-250).

(*Id.* at #17855–56). Covidien also seeks to exclude Mr. David Horton's May 10, 2013 deposition testimony, which touches on Covidien's 510(k) application submissions to the FDA. (*Id.* at #17856).

Covidien argues that the evidence relating to its 510(k) premarket submissions has no relevance to the issues that remain for the upcoming trial. To begin, it asserts that those materials cannot be used to raise or support patent infringement arguments because that issue has already "been decided on summary judgment." (*Id.* at #17857). The Court agrees with Covidien that the infringement issue has been resolved, and it appears Ethicon agrees as well. Ethicon admits that it "does *not* seek to introduce Covidien's 510(k) submissions to show infringement." (Resp. to Mot., Doc. 237, #18019). Thus, the Court **GRANTS** Covidien's Motion to exclude evidence relating 510(k) premarket submissions materials for the purpose of forwarding an infringement argument.

Still, Ethicon claims that it seeks to use evidence relating to Covidien's 510(k) premarket submissions for relevant and noncumulative purposes. Ethicon suggests two such reasons: (1) to show market demand during the infringement period to support Ethicon's lost-profits claim; and (2) as evidence that Covidien copied the invention from the '055 patent, which is a secondary consideration of non-obviousness. (*Id.* at #18020). Covidien responds that FDA premarket submissions

materials are not relevant to either question and, at best, offer "minimal probative value" to the questions remaining for trial. (Doc. 228, at #17859).

The Court agrees with Ethicon that information or statements in Covidien's 510(k) premarket submissions application are not irrelevant simply because they appear in that form. *Itendis GMBH v. Glenmark Pharms. Inc.*, 822 F.3d 1355, 1363 (Fed. Cir. 2016) (finding "no reason why a district court acting as a fact finder should ignore a party's representation to a federal regulatory body that is directly on point"). The Court finds, though, that, at least to date, Ethicon has failed to identify statements in the 510(k) premarket materials that provide relevant, noncumulative evidence that bears on the remaining issues.

Start with the damages issue. To be sure, Ethicon is correct that, to obtain lost-profits damages, the patentee must show that there is "demand for the patented product." (Doc. 237, #18023 (quoting *Versata Software, Inc. v SAP Am., Inc.*, 717 F.3d 1255, 1263–64 (Fed. Cir. 2013)) (in turn quoting *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152, 1156 (6th Cir. 1978))). But Ethicon has not identified any particular statement in the 510(k) materials that would substantiate market demand. And the Court frankly would find it a little surprising if such information were there. Typically, 510(k) materials describe how a product works, not what the demand for that product is. But, if Ethicon's only point in using the 510(k) materials is to show that Covidien's accused devices work similarly to Ethicon's devices that practice the '055 patent, it hardly seems that Ethicon needs to rely on the 510(k) materials for that, as the Court has already found infringement as a matter of law.

The three cases that Ethicon cites are not to the contrary. (*See* Doc. 237, #18023–24). In *Masimo Corp. v. Philips Elec. N. Am. Corp.*, No. CV 09-80-LPS, 2014 WL 4246579, at *1 (D. Del. Aug. 27, 2014), the question was whether the product described in the 510(k) materials was a "safe and effective non-infringing alternative." Here, the products described in the 510(k) material are not non-infringing alternatives, but rather the accused infringing devices themselves. In *Hologic, Inc. v. Minerva Surgical, Inc.*, No. 1:15-cv-1031, 2018 WL 3348998 (D. Del. July 9, 2018), the statement that the products were "almost dead identical" went to willfulness, which is not an issue set for the upcoming trial. *See* S.D. Ohio Pat. R. 107.2. And finally, in *Baxter Int'l, Inc. v. CareFusion Corp.*, No. 15-CV-9986, 2017 WL 1049840 (N.D. Ill. Mar. 20, 2017), the question was whether the submission showed knowledge and deceptive intent for purposes of inequitable conduct, which also is not an issue here. In sum, Ethicon has failed to identify any case in which statements in the 510(k) were deemed relevant on the issue of "market demand."

The same is true for obviousness. Ethicon correctly states that copying a patented invention is a secondary consideration of non-obviousness. (Doc. 237, #18024). Again, though, Ethicon has failed to point to any statement in the 510(k) that shows that Covidien copied Ethicon's invention. To be sure, the 510(k) arguably shows that Covidien's device worked in a substantially similar manner, but that hardly seems a key disputed issue, given the finding on infringement.

That said, the Court leaves open the possibility that there may be statements in the 510(k) materials that are relevant to the trial issues. Accordingly, the Court

DENIES Covidien's motion to exclude all evidence relating to its 510(k) premarket submissions offered for any reason, and will reserve judgment on any particular statements that Ethicon seeks to introduce from those materials until the Court better appreciates both the contents of the statements and the purpose(s) for which they are offered.

CONCLUSION

For the reasons set forth more fully above, the Court **GRANTS IN PART AND DENIES IN PART** Covidien's Motions in Limine (Docs. 228 & 229), as well as Ethicon's Motion in Limine (Doc. 227). The Court **GRANTS** the Motions to exclude evidence if introduced for the impermissible reasons outlined above, but **DENIES** the Motions to the extent they seek to exclude the admissibility of evidence for other purposes. As with all in limine rulings, these findings are subject to modification should the facts or circumstances at trial differ from those which have been presented in the pre-trial motions and memoranda.

SO ORDERED.

December 1, 2020
DATE

DOUGLAS R. COLE
UNITED STATES DISTRICT JUDGE