

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VECTURA LIMITED,

Plaintiff;

v.

GLAXOSMITHKLINE LLC and GLAXO
GROUP LIMITED,

Defendants.

Civil Action No. 16-638-RGA

MEMORANDUM OPINION

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ANDREWS, U.S. DISTRICT JUDGE:

Currently pending before the Court is Plaintiff's motion to exclude the testimony of William O. Kerr, Ph.D. (D.I. 129). The parties have fully briefed the issues. (D.I. 129, 139, 160). At oral argument on the parties' summary judgment motions, I requested further briefing. (Hr'g Trans. at 95:20-25). The supplemental briefing was completed on March 25, 2019. (D.I. 256, 258, 265, 266). After full consideration of the parties' briefing, Plaintiff's motion is GRANTED-IN-PART and DENIED-IN-PART.

I. BACKGROUND

Plaintiff Vectura Limited sued Defendants GlaxoSmithKline LLC and Glaxo Group Limited on July 27, 2016 alleging infringement of U.S. Patent Nos. 8,303,991 ("the '991 patent") and 8,435,567 ("the '567 patent"). (D.I. 1). Plaintiff has narrowed its infringement allegations to claim 3 of the '991 patent and claim 3 of the '567 patent ("the Asserted Claims"). The patents-in-suit "relate to pharmaceutical compositions for inhalation and methods of making them." (D.I. 82 at 1). The asserted claims are dependent claims that only cover compositions where the additive is magnesium stearate. (D.I. 195 at 9).

Before this litigation, the parties had entered a license agreement on August 5, 2010 ("the 2010 Agreement"). (D.I. 256 at 6; D.I. 258 at 5). The 2010 Agreement included a covenant not to sue for certain of Plaintiff's patents and patent applications ("the Non-Assert Patents"), including the patents-in-suit. (D.I. 256 at 7; D.I. 258 at 5). The 2010 Agreement provided Defendants "with an option to license Non-Assert Patents by identifying or 'nominating' them on or before July 31, 2016." (D.I. 256 at 7; D.I. 258 at 5). On July 26, 2016, Defendants formally notified Plaintiff under the 2010 Agreement that they declined to exercise the option and thereby terminated both the covenant not to sue and the option to license. (D.I. 256 at 7; D.I. 258 at 6-7).

II. LEGAL STANDARD

Federal Rule of Evidence 702 sets out the requirements for expert witness testimony and

states:

A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if: (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue; (b) the testimony is based on sufficient facts or data; (c) the testimony is the product of reliable principles and methods; and (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702. The Third Circuit has explained:

Rule 702 embodies a trilogy of restrictions on expert testimony: qualification, reliability and fit. Qualification refers to the requirement that the witness possess specialized expertise. We have interpreted this requirement liberally, holding that a broad range of knowledge, skills, and training qualify an expert. Secondly, the testimony must be reliable; it must be based on the "methods and procedures of science" rather than on "subjective belief or unsupported speculation"; the expert must have "good grounds" for his or her belief. In sum, *Daubert* holds that an inquiry into the reliability of scientific evidence under Rule 702 requires a determination as to its scientific validity. Finally, Rule 702 requires that the expert testimony must fit the issues in the case. In other words, the expert's testimony must be relevant for the purposes of the case and must assist the trier of fact. The Supreme Court explained in *Daubert* that Rule 702's "helpfulness" standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

By means of a so-called "*Daubert* hearing," the district court acts as a gatekeeper, preventing opinion testimony that does not meet the requirements of qualification, reliability and fit from reaching the jury. *See Daubert* ("Faced with a proffer of expert scientific testimony, then, the trial judge must determine at the outset, pursuant to Rule 104(a) of the Federal Rules of Evidence whether the expert is proposing to testify to (1) scientific knowledge that (2) will assist the trier of fact to understand or determine a fact in issue.").

Schneider ex rel. Estate of Schneider v. Fried, 320 F.3d 396, 404-05 (3d Cir. 2003) (cleaned up).¹

III. DISCUSSION

Plaintiff asserts that Dr. Kerr's opinion should be excluded for two reasons: 1) he used an incorrect hypothetical negotiation date, and 2) he failed to provide an opinion based on the correct 2016 hypothetical negotiation date. (D.I. 129 at 2). Defendants argue that 2013 is the proper date for the hypothetical negotiation, and in the alternative, that Dr. Kerr's reasonable royalty opinion does not change if the hypothetical negotiation was in July 2016. (D.I. 139 at 6-7).

A. The Hypothetical Negotiation Date

One measure of damages for patent infringement is a reasonable royalty. *Georgia-Pacific Corp. v. U.S. Plywood Corp.*, 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970) provides a multitude of factors influencing the determination of the reasonable royalty. One factor is the hypothetical negotiation between the parties. *Id.*

[T]he hypothetical negotiation or the 'willing licensor-willing licensee' approach[] attempts to ascertain the royalty upon which the parties would have agreed had they successfully negotiated an agreement just before infringement began. . . . In other words, if infringement had not occurred, willing parties would have executed a license agreement specifying a certain royalty payment scheme. The hypothetical negotiation also assumes that the asserted patent claims are valid and infringed.

Lucent Techs., Inc. v. Gateway, Inc., 580 F.3d 1301, 1324-25 (Fed. Cir. 2009). The date of the hypothetical negotiation may be determined as a matter of law.² *See Boston Sci. Corp. v. Cordis Corp.*, 777 F. Supp. 2d 783, 791-94 (D. Del. 2011). Here, the parties do not dispute that the accused product was first sold in October 2013, that the parties executed the 2010 Agreement

¹ The Court of Appeals wrote under an earlier version of Rule 702, but subsequent amendments to it in 2011 were not intended to make any substantive change.

² While neither of the parties have explicitly moved for summary judgment on the date of the hypothetical negotiation, Plaintiff's motion requires that I determine the appropriate date on which the hypothetical negotiation occurred as a prerequisite to determining whether or not Dr. Kerr's opinion is based on an incorrect date. Moreover, the notice requirement under Federal Rule of Civil Procedure 56(f) has been met by both my statements at oral argument that I intended to determine the issue, and the opportunity for the parties to file further briefing on the issue.

which included a covenant not to sue, and that the covenant not to sue expired on July 26, 2016 when Defendants formally notified Plaintiff that they declined to exercise the option. (D.I. 129 at 2; D.I. 256 at 6-7; D.I. 258 at 5-7, 8 n.2).

The parties dispute the date of the hypothetical negotiation. Plaintiff asserts that the hypothetical negotiation would have occurred in July 2016 when the 2010 Agreement expired. (D.I. 129 at 4-5). Defendants argue that the hypothetical negotiation would have occurred in October 2013 because the agreement is irrelevant to whether or not the sales were infringing. (D.I. 139 at 8-9; D.I. 258 at 3 n.2). At oral argument, I requested that the parties provide further briefing on (1) the exact date of the hypothetical negotiation, assuming it took place in 2016, and (2) the impact of that date on Defendants' ability to argue that at the hypothetical negotiation, they would have been able to exercise the option that they actually declined to exercise. (Hr'g Trans. 95:20-25).

Plaintiff asserts that the correct date of the hypothetical negotiation occurs "after the July 26, 2016 termination of both" the covenant not to sue and the option to license the patents-in-suit. (D.I. 256 at 5). Plaintiff argues an earlier date "would enable Dr. Kerr to improperly argue that the parties could have continued their preexisting, actual agreement[] without considering any negotiation." (*Id.* at 9). Defendants argue that if the hypothetical negotiation occurs in July 2016 it would occur on or before July 25, 2016 or the "eve of infringement." (D.I. 258 at 7-8, 8 n.2). Defendants further argue that the date of the hypothetical negotiation does not alter the influence of the 2010 agreement, but note that they do "not argue that [they] could merely exercise the [] License Option in the hypothetical negotiation on or before July 25, 2016." (*Id.* at 11).

I agree with Plaintiff that the proper date for the hypothetical negotiation occurred in July 2016. However, I agree with Defendants that the proper date is July 25, 2016 rather than a date after infringement began.

First, 35 U.S.C. § 271(a) provides that “whoever *without authority* makes, uses, offers to sell, or sells any patented invention within the United States . . . during the term of the patent therefor, infringes the patent.” (emphasis added). As defined by § 271(a), the practice of a patented invention is only infringement when done *without authority*. Defendants argue that a time-limited covenant not to sue, like the one in the 2010 Agreement, does not “authorize” the practice of a patented invention, but merely delays the patentee’s right to seek damages. (D.I. 139 at 8). The Federal Circuit has noted, however, “a patentee, by license or otherwise, cannot convey an affirmative right to practice a patented invention by way of making, using, selling, etc.; the patentee can only convey a freedom from suit.” *TransCore, LP v. Elec. Transaction Consultants Corp.*, 563 F.3d 1271, 1275 (Fed. Cir. 2009). In other words, “a non-exclusive patent license is equivalent to a covenant not to sue” and vice versa; “both are properly viewed as ‘authorizations.’” *Id.* at 1275-76 (citing cases). As the covenant not to sue included the patents-in-suit once they issued, and was executed before the accused product was first sold, Defendants were authorized to practice the patents-in-suit, and thus no infringement could occur until the covenant expired on July 26, 2016.

Second, “[t]he hypothetical-negotiation approach to calculating reasonable-royalty damages ‘attempts to ascertain the royalty upon which the parties would have agreed had they successfully negotiated an agreement *just before infringement began.*’” *Prism Techs. LLC v. Sprint Spectrum L.P.*, 849 F.3d 1360, 1375-76 (Fed. Cir. 2017) (quoting *Lucent Techs.*, 580 F.3d at 1324) (emphasis added); *see also VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1326 (Fed.

Cir. 2014). Thus, the proper date for the hypothetical negotiation as a matter of law is July 25, 2016, the day before the covenant not to sue expired and infringement began.

However, regardless of the date of the negotiation, Defendants may not argue that they could exercise the option to license the patents-in-suit in the hypothetical negotiation. Any such argument would be improper as a matter of law.³ The hypothetical negotiation is an arms-length negotiation between a willing licensor and a willing licensee. *Lucent*, 580 F.3d at 1324-25 (one measure of infringement compensation is “the reasonable royalty [the patentee] would have received through arms-length bargaining”); *see also AstraZeneca AB v. Apotex Corp.*, 782 F.3d 1324, 1330 (Fed. Cir. 2015). While real world circumstances may be considered, they may not replace the hypothetical negotiation or impact the willingness of either the licensee or licensor. *See, e.g., Conceptus, Inc. v. Hologic, Inc.*, 771 F. Supp. 2d 1164, 1179-80 (N.D. Cal. 2010) (hypothetical negotiation is a “counterfactual exercise”); *Cummins-Allison Corp. v. SBM Co., Ltd.*, 584 F. Supp. 2d 916, 918 (E.D. Tex. 2008) (explaining “[t]he problem with . . . basing the royalty calculation entirely on a ‘real world’ view of the hypothetical negotiation”); *Tektronix, Inc. v. United States*, 552 F.2d 343, 349 (Ct. Cl. 1977) (the hypothetical negotiation “does not depend on the actual willingness of the parties”). In other words, for the hypothetical negotiation to be at arms-length, neither party can come to the table with one arm tied behind its back. Allowing Defendants to argue that the option was on the table at the hypothetical negotiation would impermissibly skew the results of the hypothetical negotiation, just as “litigation itself can skew the results of the hypothetical negotiation.” *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 872

³ I understand from Defendants’ representations at oral argument and in the supplemental briefing that they do not plan to assert to the jury that the option could be exercised at the hypothetical negotiation. (D.I. 258 at 11). I will, of course, hold Defendants to this representation at trial.

(Fed. Cir. 2010). Thus, neither Defendants nor Dr. Kerr may argue that the option to license the patents-in-suit could be exercised at the hypothetical negotiation.

B. Dr. Kerr's Opinion Is Excluded in Part

As the date of the hypothetical negotiation is July 25, 2016 as a matter of law, Dr. Kerr's opinions to the contrary will be excluded. (D.I. 259-1, Ex. H ¶¶ 59, 75-76). Furthermore, Dr. Kerr's opinions suggesting that the option could be exercised in the hypothetical negotiation will be excluded for the reasons stated above. (*Id.* ¶¶ 41, 58, 62).⁴

Plaintiff asserts that Dr. Kerr's reasonable royalty opinion should be excluded in its entirety because 1) it is based on an incorrect date of the hypothetical negotiation and 2) it violates Federal Rule of Civil Procedure 26(a)(2)(B)(i)-(ii) because he never explicitly recited a July 2016 date in his expert report. (D.I. 129 at 2, 7). Defendants assert that even if 2013 is the incorrect date, Dr. Kerr's reasonable royalty opinion does not change if the hypothetical negotiation was in July 2016. (D.I. 139 at 7). More specifically, Defendants assert that Plaintiff has not identified "any aspect of Dr. Kerr's analysis that is dependent on a hypothetical negotiation date of October 2013." (*Id.*).

First, I do not find that the entirety of Dr. Kerr's opinion is based upon the 2013 date. Dr. Kerr testified at his August 3, 2018 deposition that his opinions would apply equally to a July 2016 hypothetical negotiation date. (D.I. 259-1, Ex. G at 108:23-109:20, 111:9-22). Moreover, Dr. Kerr's opinions do not appear to be intrinsically dependent on his original assertion of the 2013

⁴ Paragraph 41 will be excluded in its entirety. The following sentence from ¶ 58 will be excluded: "One outcome involves a continuation of the 2010 Agreement between the parties, based on exercise of the options included in that agreement." (D.I. 259-1, Ex. H ¶ 49).

The following sentences from ¶ 62 will be excluded: "At the time of the hypothetical negotiation, the parties would have known that the NP License Option they agreed to in 2010 would allow them to continue to operate without any new negotiations. As such, the 2010 Agreement sets the upper bound to the terms of a reasonable royalty. The option could have been exercised by GSK at the time of the hypothetical negotiation and royalty payments begun after the transition date. Had GSK simply exercised this option, Vectura would have received royalties as described under the original 2010 Agreement." (D.I. 259-1, Ex. H ¶ 62).

date. Plaintiff's challenge to Dr. Kerr's opinions based on a failure to account for certain changes in circumstances goes to the weight and credibility of his opinions, not their admissibility. Therefore, the Court will not exclude Dr. Kerr's opinions under Rule 702. Plaintiff may challenge Dr. Kerr's conclusions at trial through cross-examination and the presentation of contrary evidence.

Second, Dr. Kerr's opinions will not be excluded for violating Rule 26(a). In determining whether a violation of Rule 26(a) was substantially justified or harmless, courts consider the following factors: (1) the importance of the information withheld; (2) the prejudice or surprise to the party against whom the evidence is offered; (3) the likelihood of disruption of the trial; (4) the possibility of curing the prejudice; (5) the explanation for the failure to disclose; and (6) the presence of bad faith or willfulness in not disclosing the evidence (the "*Pennypack* factors"). See *Konstantopoulos v. Westvaco Corp.*, 112 F.3d 710, 719 (3d Cir. 1997) (citing *Meyers v. Pennypack Woods Home Ownership Ass'n*, 559 F.2d 894, 904–05 (3d Cir. 1977)). It bears emphasis that "exclusion of critical evidence is an 'extreme' sanction, not normally to be imposed absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence." *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 791–92 (3d Cir. 1994) (internal quotation marks omitted). The determination of whether to exclude evidence is committed to the discretion of the Court. See *id.* at 749.

Dr. Kerr testified at his deposition on August 3, 2018 that the opinions in his report would apply to a 2016 hypothetical negotiation date for the same reasons they applied to a 2013 date. (D.I. 259-1, Ex. G at 108:23-109:20, 111:9-22). Plaintiff was able to further question Dr. Kerr about those opinions at that time. Trial is scheduled to begin on April 29, 2019. I determine that there is little surprise or prejudice to Plaintiff if Dr. Kerr's opinions are permitted at trial. Neither

is there a risk of disruption to the trial by permitting his opinions. Any prejudice that may have existed was cured by the ability of Plaintiff's counsel to further question Dr. Kerr about his opinions at the deposition. Finally, there is no evidence of bad faith or willful deception on the part of Defendants. Therefore, the *Pennypack* factors weigh heavily in favor of admission and I will not exclude the remainder of Dr. Kerr's reasonable royalty opinions.

IV. CONCLUSION

For the foregoing reasons, Plaintiff's Motion is GRANTED as to paragraphs 41, 59, 75-76, the second sentence of paragraph 58, and the first four sentences of paragraph 62 of Dr. Kerr's report and DENIED as to all else.

An accompanying order will be entered.