IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ERFINDERGEMEINSCHAFT UROPEP GbR,	§	
	§	
Plaintiff,	§	
	§	
v.	§	Case No. 2:15-CV-1202-WCB
	§	
ELI LILLY AND COMPANY,	§	
	§	
Defendant.	§	
	§	

MEMORANDUM OPINION AND ORDER

Before the Court are (1) Defendant Eli Lilly & Company's Motion and Memorandum of Law in Support of Its Motion in Limine, Dkt. No. 198, and (2) Plaintiff UroPep's Motions In Limine, Dkt. No. 207. Following briefing,[1] the Court heard argument on the motions on February 21, 2017. Beginning with the motions *in limine* of plaintiff Erfindergemeinschaft UroPep GbR ("UroPep"), and then addressing those of defendant Eli Lilly & Co. ("Lilly"), the dispositions of the individual motions *in limine* are as follows:

1. **UroPep's motion to preclude Lilly from arguing and offering evidence that the application for the '124 patent was improper or untimely.**

UroPep moves to preclude Lilly from using the application date for the '124 patent to suggest that UroPep acted improperly and filed the application only after witnessing the approval of Lilly's drug Cialis to treat the signs and symptoms of benign prostatic hyperplasia ("BPH"). UroPep argues that such use of the application date is both irrelevant and unfairly prejudicial.

[1] The parties elected not to file reply and sur-reply briefs, so the briefing was completed on February 17, 2017. See Dkt. Nos. 224, 225; see also Dkt. No. 231 (Feb. 21, 2017, Hearing Tr.), at 176.

Lilly states that it does not intend to argue that UroPep's conduct was legally improper, but that it does intend to argue that UroPep's conduct was opportunistic. Dkt. No. 231 (Feb. 21, 2017, Tr. ("Hearing Tr.")) at 165. Lilly also contends that it should be able to highlight the application date because it is relevant to damages, willful infringement, and written description. Finally, Lilly points out that the application date appears on the face of the patent and will be in front of the jury in any event.

The Court agrees that the application date will be before the jury and will likely be referenced as the parties tell the story of the invention and the emergence of Cialis. The Court will not preclude all mention of the application date.

Lilly has offered several theories as to the admissibility of the application date, but the Court is not persuaded that the evidenced is relevant to each of the issues raised by Lilly.

First, as to Lilly's intention to offer evidence to show that the UroPep inventors took improper advantage of the patent system by devising claims designed to read on the use of Cialis for BPH, the law is clear that it is not improper for patentees to seek claims in an original or continuation application with the purpose of obtaining patent rights that would cover products that have come on the market. See Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 874 (Fed. Cir. 1988) ("[T]here is nothing improper, illegal or inequitable in filing a patent application for the purpose of obtaining a right to exclude a known competitor's product from the market, nor is it in any manner improper to amend or insert claims intended to cover a competitor's product the applicant's attorney has learned about during the prosecution of a patent application. Any such amendment or insertion must comply with all statutes and regulations, of course, but, if it does, its genesis in the marketplace is simply irrelevant and cannot of itself evidence deceitful intent."); see also Liebel-Flarsheim Co. v. Medrad, Inc.. 358 F.3d 898, 909

n.2 (Fed. Cir. 2004); Tex. Instruments Inc. v. U.S. Int'l Trade Comm'n, 871 F.2d 1054, 1065 (Fed. Cir. 1989). While Lilly will be allowed to offer evidence regarding the timing of UroPep's '124 application for any purpose relevant to a claim or defense in this case, it will not be allowed to introduce such evidence simply to make the inventors appear unprincipled in the jurors' eyes, if the evidence is untethered to any claim or defense in this case.

Second, Lilly has not shown that the application date is relevant to damages. Lilly argued that it undertook efforts and made investments in Cialis for a BPH indication at a time when no patent application covered the use of the drug to treat the signs and symptoms of BPH. But UroPep is not claiming damages for that pre-patent period. In fact, UroPep is not claiming damages for any time before Lilly was notified of the '124 patent in October 2014. See Dkt. No. 184, at 10 (UroPep explains that its damages expert has calculated royalties starting in October 2014).

To the extent that Lilly is arguing that any damages should somehow be reduced as a result of its earlier investment in Cialis, Lilly has not shown how that argument depends in any way on the December 2011 filing date of the '124 patent. Lilly acknowledged at the hearing that the measure of damages in this case is not distinguishable from the measure of damages that would apply if the '124 patent had been filed in 2000, had sat quietly in the Patent & Trademark Office ("PTO") for 14 years, and then had issued in 2014, after which Lilly was notified of its existence. See Hearing Tr. at 165-66. In fact, Lilly conceded that it "may very well have continued to make those investments in Cialis" even if, as in the hypothetical scenario, the '124 patent application had been filed in 2000. Id. at 169.

Lilly's willfulness argument fails for the same reason. Lilly argued during the hearing that its earlier development and marketing of Cialis for BPH demonstrates that it acted in the

good faith belief that it was not infringing a valid patent, because it would not have expended so much time and money if it had believed it was liable for infringement. Hearing Tr. 167-68. Counsel stated that Lilly "was confronted with a patent application—a patent issuance and notification in October of 2014, after it had made all these investments and done all of this work." Id. at 167. As acknowledged by its counsel, Lilly's argument regarding its "good faith" depends on the date as of which it learned of UroPep's '124 patent, not the date that the application for that patent was filed. The cases Lilly cites in support of its argument say the same thing. See Gustafson, Inc. v. Intersys. Indus. Prods., Inc., 897 F.2d 508, 510-11 (Fed. Cir. 1990) (collecting cases standing for the proposition that "a patent must exist [i.e., must have issued] and one must have knowledge of it" to find willful infringement).

Finally, Lilly argues that the application date is relevant to its written description defense, i.e., its claim that the '124 patent is invalid because the specification does not contain an adequate written description of the claimed invention. In support of its argument, Lilly cites the Federal Circuit's decision in Gentry Gallery, Inc. v. Berkline Corp., 134 F.3d 1473 (Fed. Cir. 1998).

In Gentry Gallery, the question before the court was whether the patent in suit contained an adequate written description of the placement of the controls for an adjustable sofa. The court held that even though the claims had been amended to include placing the controls outside the console, the specification did not contain an adequate written description of that location for the controls. 134 F.3d at 1480. In the course of its opinion, the court noted that the inventor "admitted at trial that he did not consider placing the controls outside the console until he became aware that some of [his] competitors were so locating the recliner controls." Id. at 1479. The court reasoned that the inventor's admission was "not dispositive, because one can add

claims to a pending application directed to adequately described subject matter"; nonetheless, the court held that the admission was relevant to how the inventor viewed his original disclosure. Id.

Gentry Gallery is quite different from this case, because in this case there is no equivalent admission by any of the inventors regarding their lack of awareness of aspects of the claimed invention until after the BPH indication for Cialis was approved. Thus, the mere fact that in the application for the '124 patent the inventors sought new claims based on a previously filed specification does not by itself render the circumstances of the December 2011 filing relevant. However, to the extent that the filing date of the '124 patent becomes relevant to Lilly's written description defense at trial, that evidence will be admissible along with any other evidence going to the written description issue. Without knowing exactly what evidence Lilly intends to offer in support of its written description defense, the Court will not foreclose the possibility that the evidence regarding the filing date of the '124 patent will become relevant at that time.[2]

For these reasons, the Court GRANTS UroPep's first motion *in limine* in part. Lilly will be precluded from arguing that it is improper the file new claims during patent prosecution based on information obtained in the marketplace. The filing date of the '124 patent is also not relevant to the issues of damages and willfulness. The Court will not, however, foreclose the

[2] In Rambus, Inc. v. Infineon Techs. AG, 330 F. Supp. 2d 679 (E.D. Va. 2004), the court denied a motion to preclude evidence and argument that the patentee's amended claims were based on improperly obtained information. The court explained that the "genesis [of the amendment] in the marketplace is simply irrelevant and cannot *of itself* evidence deceitful intent," but that acquisition of the idea through wrongful or illegal means would not be precluded on that basis. Id. at 692. Significantly, for present purposes, the court noted that the evidence in question would be relevant to the question whether the patentee was in possession of the invention "as of the filing of the [earlier] application," and not as of the filing date of the amended claims. Rambus, 330 F. Supp. 2d at 694 n.22.

possibility that the circumstances of the filing of the '124 patent may be relevant to Lilly's written description defense.[3]

2. UroPep's motion to preclude Lilly from arguing and offering evidence that Dr. Ückert's 2007 declaration is misleading or inaccurate.

UroPep moves to preclude, as irrelevant and unfairly prejudicial, testimony from Lilly's expert Dr. David Rotella regarding a declaration that co-inventor Stefan Ückert submitted to the PTO in 2007. Specifically, Dr. Rotella in his expert report disagrees with Dr. Ückert's characterization of several prior art references and points out that Dr. Ückert did not discuss several other references and prior art teachings. Lilly contends that the 2007 declaration contains inventor admissions that Lilly is entitled to use "to support Lilly's invalidity defenses." Dkt. No. 224, at 4.[4]

The Court agrees that the 2007 declaration may be used for impeachment—for example, if Dr. Ückert is called at trial and testifies inconsistently with it. As to any further use, the Court is not at this point persuaded that the 2007 declaration is relevant. Lilly says the declaration "support[s] Lilly's invalidity defenses," but it fails to specify which defenses it supports and how it supports them. Dkt. No. 224, at 4; see also id. at 6 (arguing that the declaration should be available for Lilly's "use[] to support claims that are in the lawsuit (written description, enablement, anticipation, obviousness)."). Lilly argues that three excerpts from the declaration support its written description defense, but it does not adequately explain how. The first two

[3] The Court also notes that Gentry Gallery included a counterclaim of inequitable conduct. 134 F.3d at 1475-76. Here, even if Lilly can show that the application filing date is relevant to its written description defense, it is possible that an argument highlighting that date could be objectionable as unduly prejudicial, since Lilly has no claim of inequitable conduct or unclean hands. See Kingsdown Med. Consultants, 863 F.2d at 874.

[4] Lilly argues that this is effectively a motion to strike a portion of the expert report and is therefore untimely. However, the deadline for Daubert motions does not bar challenges to irrelevant or unduly prejudicial evidence through a motion *in limine*.

excerpts raise a question as to UroPep's decision to exclude certain examples in the specification disclosure from the claims of the '124 patent, but UroPep's decision to exclude those examples does not show that the specification fails to disclose what *is* claimed in the '124 patent. Dkt. No. 224, at 5. As for the last excerpt, Lilly argues that Dr. Ückert's statements show he did not know and sufficiently describe the mechanism by which PDE5 inhibitors treat BPH. But Lilly has not explained why the '124 patent—or the inventors—would need to know the detailed mechanism by which PDE5 inhibitors result in treatment of BPH, and the Court can discern no reason that the description of the mechanism of action would be necessary to establish the requisite written description of the claimed invention.[5]

Nor does Dr. Rotella's report clarify the relevance of the 2007 Ückert declaration. Dr. Rotella's critique of the declaration appears under its own heading, separate from his opinion regarding written description. Compare Dkt. No. 207-3, at 52-55, with id. at 56. As background for his report, Dr. Rotella appears to criticize Dr. Ückert's attempt to distinguish particular prior art references, as if the declaration were an expert report submitted by UroPep. See Hearing Tr. at 181. In the excerpted portion of Dr. Rotella's report regarding written description, Dr. Rotella does not reference anything in Dr. Ückert's declaration. Dkt. No. 207-3, at 56-57; see also Hearing Tr. at 181.

[5] Lilly's excerpted language does not accurately represent Dr. Ückert's statement in his declaration, in which Dr. Ückert disagreed with the proposition that "any compounds which stimulate NO [nitric oxide] production would be useful in treating" BPH. As Dr. Ückert explained, "any number of compounds stimulate NO activity, including cytokines, pathogens, histamine, sodium nitroprusside (SNP), [etc.], which are of minimal to no advantage in the pharmacotherapy of [BPH] and Lower Urinary Tract Symptomatology (LUTS)." Ückert Decl. ¶ 9 (citing multiple references in support). Dr. Ückert did not say that PDE4 and PDE5 inhibitors necessarily do something more than stimulate NO activity; rather, he noted that not all compounds that stimulate NO will treat BPH.

It is unclear how Dr. Ückert's 2007 declaration is relevant to Lilly's invalidity defenses. Furthermore, the Court recognizes that attacks on the 2007 declaration may unfairly prejudice UroPep by suggesting impropriety before the PTO when Lilly will not be presenting an inequitable conduct or unclean hands defense. Nevertheless, the Court is reluctant to preclude all but impeachment use of the 2007 declaration when the Court is not fully aware of the scope of Lilly's invalidity defenses. The Court therefore DENIES UroPep's second motion *in limine* to preclude Lilly from all but impeachment use of the 2007 declaration. UroPep may object at trial to any improper use of the declaration, including through Dr. Rotella.[6]

3. UroPep's motion to preclude Lilly's expert Dr. Rotella from offering testimony that the '124 patent does not satisfy the written description requirement because the patent (a) does not claim the entire genus of PDE5 inhibitors and (b) does not claim the full scope of compounds able to "selectively inhibit" PDE5.

UroPep argues that Dr. Rotella's expert testimony improperly draws legal conclusions and is irrelevant to the written description defense. The Court does not believe Dr. Rotella's testimony that UroPep did not know of the entire genus of PDE5 inhibitors is irrelevant. However, the Court agrees with UroPep that Dr. Rotella's testimony goes beyond his purview and renders improper legal conclusions, such as the following statements: "The '124 patent does not provide an adequate written description that shows the inventors were in possession of the full scope of compounds able to inhibit PDE5," and "[T]he '124 patent fails to provide an adequate written description that shows the inventors were in possession of the full scope of compounds able to 'selectively inhibit' PDE5." Dkt. No. 207-3, at 57. The Court accepts Lilly's

[6] UroPep also moves to preclude evidence of "any purported irregularities in the prosecution of the '124 patent." Dkt. No. 207, at 2. Neither the Court nor Lilly is aware of any such "purported irregularities." See Dkt. No. 224, at 4 n.3. Although the Court will not issue a blanket ban on the use of any particular prosecution history documents for such purposes, the Court will not allow Lilly to argue misconduct or impropriety in the patent prosecution unrelated to any of the defenses that Lilly has pleaded and asserted during the pretrial process.

representation during the hearing that Dr. Rotella will not offer those legal conclusions at trial. Hearing Tr. at 188-89; see also id. at 186 (counsel for Lilly stating that its experts are "not going to opine on the law and they're not going to offer an opinion along the lines of the law requires 'X.'"). Subject to that condition, the Court DENIES UroPep's third motion *in limine* to preclude Dr. Rotella from offering testimony that the '124 patent does not describe all of the compounds that are capable of inhibiting, or selectively inhibiting, PDE5.[7]

4. UroPep's motion to preclude Lilly from arguing and offering evidence related to Dr. Ückert that Lilly alleged in support of its proposed unclean hands defense.

UroPep contends that an article co-authored by Dr. Ückert and several Lilly scientists, referred to as the "Giuliano article," should be excluded on the ground that it is irrelevant and unfairly prejudicial. See Dkt. No. 153-6 (The Mechanism of Action of Phosphodiesterase Type 5 Inhibitors in the Treatment of Lower Urinary Tract Symptoms Related to Benign Prostatic Hyperplasia, 63 European Urology 506 (2013)). Lilly argues that the Giuliano article supports Lilly's written description defense by showing that the state of the art as of the priority date of UroPep's patent application was unclear regarding the mechanism by which PDE5 inhibitors treat BPH.

Although the Giuliano article does not appear to be particularly strong evidence in support of Lilly's written description defense, the Court recognizes that it is at least marginally relevant to the lack of certainty in the art even after the priority date of the patent. In addition to relevance, Lilly contends that the article goes to Dr. Ückert's credibility and bias because he collaborated with Lilly scientists and had access to Lilly's confidential information when

[7] As it did regarding the previous motion *in limine*, Lilly also contends that the motion is untimely and should have been brought as a Daubert motion to strike expert testimony. Even if UroPep raised the issue three weeks late, the Court finds that Lilly has suffered no prejudice, as the Court has denied the motion and would have sustained an objection at trial to any testimony by Dr. Rotella offering legal conclusions.

participating in the drafting of the article, while not disclosing his pending application for the '124 patent. But as the Court previously found when denying Lilly's motion to add a defense of unclean hands based on the same assertions, Lilly's allegations lack affirmative support and are contradicted by evidence in the record. Dkt. No. 181, at 20-28 & n.8. For its part, UroPep is concerned that Lilly will use the Giuliano article to suggest that Dr. Ückert acted improperly when he participated in writing the article along with several Lilly scientists, while at the same time prosecuting a patent directed at Cialis.

The Court agrees with UroPep that Lilly should not be allowed to use the Giuliano article to suggest the theft of confidential information or other related improper conduct. The Court therefore GRANTS UroPep's fourth motion *in limine* to preclude use of the article to suggest impropriety by Dr. Ückert. Lilly may use the article for any other legitimate purpose, such as to establish the knowledge of a person of skill in the art at the time of the article's publication.

5. UroPep's motion to preclude Lilly from offering testimony by Dr. Florio regarding his 2005 declaration.

One of Lilly's experts, Dr. Claus Roehrborn, relies on the 2005 declaration of Dr. Vincent Florio, Dkt. No. 205-5, which concerns testing methods for the activity of various PDE5 inhibitors, including icariin. The Florio declaration was submitted in an unrelated *ex parte* reexamination proceeding. UroPep argues that any testimony by Dr. Florio about his declaration would be expert testimony and therefore inadmissible because Dr. Florio was not disclosed as an expert witness. Lilly does not address the timeliness issue but contends that Dr. Florio will not testify as an expert. Lilly states that he will simply authenticate his prior declaration and testify as "to his personal knowledge regarding the facts of the work that he performed that is specifically documented in the Florio declaration." Dkt. No. 224, at 12-13.

UroPep is not challenging the authenticity of the declaration. Hearing Tr. at 201. Moreover, Dr. Florio's testimony, even if limited to the contents of his declaration, would constitute expert testimony, as the declaration consists of explanations of his scientific research and conclusions. The declaration begins with three paragraphs setting forth Dr. Florio's background and qualifications, turns to his experience conducting inhibitor assays, recites the results he obtained when testing icariin, and then defends his results in light of challenges to his methods. Dkt. No. 205-5; see also, e.g., id. at 6 n.10 (extensive footnote explaining the dose response model he applied to the data he obtained in his PDE5 inhibitor assays). Given the content of the declaration, Lilly's attempt to cast Dr. Florio's testimony as purely factual is not persuasive. Fed. R. Evid. 701 (for lay witnesses, "testimony in the form of an opinion is limited to one that is . . . not based on scientific, technical, or other specialized knowledge within the scope of Rule 702.").[8]

Lilly also contends that Dr. Florio's testimony is akin to inventor testimony about the patent at issue. That is not the case here. An inventor can often provide factual background regarding the development of the patent in suit based on his or her personal knowledge. These facts may be relevant to, *inter alia*, validity. Lilly does not suggest that Dr. Florio has any personal knowledge relevant to the '124 patent or any related patent.

The Court GRANTS UroPep's fifth motion *in limine* to preclude Dr. Florio from testifying regarding the contents of his 2005 declaration.

[8] Innogenetics, N.V. v. Abbott Laboratories, 512 F.3d 1363 (Fed. Cir. 2008), does not indicate otherwise. There, the district court determined that the author of prior art references was not properly disclosed as an expert and could not offer expert testimony. Id. at 1375. The court therefore limited his testimony "to the actual words and content" of the references. Id. Here, even if Dr. Florio were to read his declaration verbatim, the effect would be to provide expert testimony. In any event, Lilly can make at least that much use of the declaration through the testimony of its properly disclosed expert Dr. Claus Roehrborn, who relies on the Florio declaration in his expert report. See Dkt. No. 207-6, at 81.

6. UroPep's motion to preclude Lilly from offering evidence regarding Lilly's character.

At the motions hearing, the parties offered to meet and confer and to provide the Court with an agreed stipulation. Hearing Tr. at 206-07. The Court therefore holds in abeyance UroPep's sixth motion *in limine*, regarding Lilly's character.

* * *

1. Lilly's motion to exclude evidence of alleged litigation misconduct.

As discussed in the Court's previous order regarding the parties' motions for summary judgment, Dkt. No. 234, at 20 n.8, the Court will not permit UroPep to offer its proposed evidence of alleged litigation misconduct, as none of Lilly's actions cited by UroPep rise to the level of litigation misconduct. See Forest Labs., Inc. v. Abbott Labs., 339 F.3d 1324, 1329-30 (noting that "bad faith requires not misleading pre-litigation conduct, but vexatious, unjustified, or frivolous litigation," such as "falsifying evidence" or "pursuing a baseless claim of infringement"). The Court GRANTS Lilly's first motion *in limine*.

2. Lilly's motion to exclude argument regarding patents that are unrelated and not prior art.

At the motions hearing, the parties agreed to submit a joint statement to the Court after a meet-and-confer to narrow the scope of the patents in dispute. Hearing Tr. at 224-25. The Court will therefore hold in abeyance Lilly's second motion *in limine*.

3. Lilly's motion to exclude UroPep from referring to the "presumption of validity."

Lilly contends that the phrase "presumption of validity" is potentially confusing to the jury and should not be used at trial. UroPep disagrees. The parties have cited several district court cases on each side of the question whether to allow the use of the phrase "presumption of validity" at trial. What is clear from the case law, however, is that prohibiting the use of that

phrase is not error. See Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1258-59 (Fed. Cir. 2004).

In the Court's judgment, the use of the phrase "presumption of validity" would add little to the jury's understanding of the burden of proof on the validity issues. Moreover, the phrase might be confusing to the jury, to the extent that the jury is required to consider both that phrase and the Court's instructions on the burden of proof. At minimum, the use of the term "presumption" would require a further definitional instruction by the Court, without leading to any greater insight on the jury's part as to the nature of the burden of proof on the validity issues. Accordingly, the Court will exclude the use of the phrase "presumption of validity" and instead will address the burden of proof in its instructions to the jury. The Court therefore GRANTS Lilly's third motion *in limine*.

IT IS SO ORDERED.

SIGNED this 13th day of March, 2017.

WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE