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

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

MEMORANDUM OPINION AND ORDER

Before the Court is Plaintiff UroPep's Motion to Strike Previously Undisclosed Prior Art and a Non-Prior Art Reference from Lilly's Second Amended Invalidity Contentions, Dkt. No. 253; an objection by plaintiff Erfindergemeinschaft UroPep GbR ("UroPep") to the admissibility of trial exhibits related to some of the prior art references that are the subject of the previous motion, see Dkt. No. 268, at 7; and an objection by UroPep to the admissibility, as substantive evidence, of two exhibits related to the prosecution of patent application serial no. 11/545,173, see Dkt. No. 268, at 13-15. The Court received briefing on the motion and held a hearing on April 11, 2017, on the motion and objections. The motion is GRANTED, and the objections are SUSTAINED.

I. Motion to Strike

UroPep has moved the Court to prohibit the defendant, Eli Lilly and Company ("Lilly"), from introducing or otherwise using at trial two references that Lilly recently disclosed in its second amended invalidity contentions. The first reference is a translated Chinese publication, which Lilly identifies as Prostate Hypertrophy, Clinical Curative Effect Observation of 34 in Benign Hyperplasia, 7-89:7, Shanghai Journal of Chinese Medicine and Medicinals. Dkt. No.

256-5; Dkt. No. 271-14. Lilly refers to that publication as the "Shanghai reference." The second reference consists of two applications, a Patent Cooperation Treaty ("PCT") application, WO 98/49166, Dkt. No. 253-2, and an earlier application filed in the United Kingdom to which the PCT application claims partial priority, Dkt. No. 256-1. Lilly refers to those two applications collectively as "the Bunnage applications."

Lilly proposes to use the Shanghai reference in support of its anticipation argument. It offers the Bunnage applications not as prior art, but as relevant evidence of "simultaneous invention," an objective consideration that bears on the issue of obviousness. UroPep objects to the admission or other use of the Shanghai reference on the ground that it was not timely disclosed as a prior art reference. UroPep objects to the admission or other use of the Bunnage applications on the grounds that Lilly did not timely disclose a theory of simultaneous invention in support of its obviousness defense and that, although the PCT application was disclosed early in the proceedings, neither of the Bunnage applications was addressed in any of Lilly's expert reports.

A. The Shanghai reference

The Shanghai reference was not included in Lilly's original invalidity contentions. The Shanghai reference is cited in another reference on which Lilly relies for its anticipation argument, a 1994 book authored by C.S. Cheung and K. Deaton entitled "TCM Management Benign Prostate Hyperplasia-Long Bi (Prostatism)." That reference is known as the Cheung reference.

In its second amended invalidity contentions, submitted on March 16, 2017, Lilly asserted that the Shanghai reference is independently invalidating prior art, apart from Cheung.

UroPep objects to that use of the reference on the ground that it was not disclosed until a month before trial, in violation of the Local Patent Rules and without justification.

Lilly contends that the late disclosure is justified because Lilly had no reason to rely on the Shanghai reference until recently. In UroPep's response to Lilly's motion for summary judgment of anticipation, Dkt. No. 187 (filed on January 31, 2017), UroPep argued that the Cheung reference did not qualify as a printed publication. Lilly states that it was surprised by that argument and that it now seeks to use the Shanghai reference to buttress its anticipation defense in light of UroPep's challenge to the Cheung reference. Because the "printed publication" argument arose only at the time of the summary judgment proceedings, Lilly argues that it should not be barred from relying on the Shanghai reference, even though the reference was not disclosed in Lilly's original invalidity contentions.

That argument is not persuasive. First, while it is true that the printed publication argument was raised only in response to Lilly's motion for summary judgment of anticipation, Lilly should not have been caught entirely unawares by UroPep's printed publication defense to Lilly's reliance on the Cheung reference as anticipating prior art. Given the obscurity of the Cheung reference, it is not surprising that UroPep would raise an issue as to whether the Cheung publication was sufficiently in the public domain to qualify as prior art.[1] Second, and as explained in more detail below, the Shanghai reference, which predates Cheung, is not relevant to the question of whether Cheung qualifies as a printed publication.

The Court holds that Lilly's notice of its intent to use the Shanghai reference was untimely and that Lilly's untimeliness was not justified by UroPep's opposition, in the summary

[1] The Court has accommodated Lilly's concern about the late raising of the printed publication argument by allowing Lilly to supplement the record with untimely submissions regarding Cheung's status as a printed publication. See Dkt. No. 234, at 23 n.10. The Shanghai reference, however, does not speak to that issue.

judgment proceedings, to the use of Cheung as an anticipating reference. Nothing prevented Lilly from citing both Cheung and the Shanghai reference in its original invalidity contentions. In light of Lilly's failure to make a timely disclosure of the Shanghai reference as invalidating prior art, the Court will not permit Lilly to use the Shanghai reference for that purpose at trial.

Lilly makes a second argument that the Shanghai reference should at minimum be allowed as rebuttal evidence. That argument fares no better than the first. The Shanghai reference would not rebut UroPep's argument that Cheung is not a qualifying printed publication, because the fact that Cheung cited the Shanghai article says nothing about whether the Cheung reference was publicly available as of the critical date of the UroPep patent, U.S. Patent No. 8,791,124 ("the '124 patent"). In addition, it is unclear how the Shanghai reference would bolster the scientific reliability of the Cheung reference, at least absent further evidence that the Shanghai publication and the study reported therein is more reliable than the Cheung reference. In fact, Lilly suggests that the study reported in the Cheung reference is simply taken from the Shanghai reference. Lilly Response, Dkt. No. 256, at 6-7 (Shanghai reference "describes a study that Dr. Cheung discussed in the 'Cheung reference,' which was the focus of Lilly's prior motion for summary judgment"). The cited Shanghai reference would therefore seem to be of very little value as rebuttal evidence.

On the other hand, permitting the use of the Shanghai reference for any purpose would create the risk that the jury would use that reference for the improper purpose of finding that the Shanghai reference was itself an anticipating reference, regardless of any value it might have in helping the jury evaluate the Cheung reference. Indeed, Lilly explains that it planned to use the Shanghai reference in rebuttal and not as prior art, but wished "to put UroPep on notice that, if appropriate and reasonably supported, Lilly may make a motion to conform the pleadings to the

proof at trial." Defendant Eli Lilly and Company's Response in Opposition [to] Plaintiff Erfindergemeinschaft UroPep GbR's Motion to Strike ("Lilly Response"), Dkt. No. 256, at 7. That is, Lilly seeks to reserve the right to use the Shanghai reference as invalidating prior art by itself, independent from Cheung, once introduced in rebuttal.

Beyond that, contrary to Lilly's contention, it would be highly prejudicial to UroPep for Lilly to be allowed to use the Shanghai reference after having raised it for the first time only a few weeks before trial and after the close of discovery. The reference is a Chinese publication; determining the extent to which the publication is disseminated would require some effort on UroPep's part, as would determining whether the contents of the publication read on UroPep's patent. Lilly's only argument on the issue of prejudice is that the Shanghai reference was cited and discussed in the Cheung reference and "does not add a new invalidity theory." Lilly Response, Dkt. No. 256, at 7.

Lilly's argument ignores the burden that addressing the Shanghai reference would impose. To place that burden on UroPep this close to the trial date would be manifestly prejudicial. UroPep's motion to strike the Shanghai reference from Lilly's second amended invalidity contentions is GRANTED. Lilly will not be allowed to use the Shanghai reference at trial, either as independent evidence of anticipation or as rebuttal evidence.[2]

B. The Bunnage applications

Lilly originally suggested that it wished to use the Bunnage applications to mount a priority challenge to UroPep's patent, but it has now withdrawn what it refers to as its

[2] Lilly expresses concern that UroPep will take advantage of the exclusion of the Shanghai reference by suggesting to the jury that Dr. Cheung "made up the clinical study that is discussed in the Cheung reference." Lilly Response, Dkt. No. 256, at 7. The Court's ruling excluding the use of the Shanghai reference is, of course, subject to the normal condition that if UroPep should open the door to the use of the Shanghai reference, the Court will reconsider its ruling as to the reference's admissibility.

"contingent designation of Bunnage as prior art." That is, Lilly no longer argues that it should be allowed to use the Bunnage applications to invalidate the UroPep patent directly. Instead, Lilly argues that the Bunnage applications are "admissible and relevant evidence" that it intends to use to show "simultaneous invention," a secondary consideration that bears on the issue of obviousness. See Geo M. Martin Co. v. Alliance Mach. Sys. Int'l LLC, 618 F.3d 1294, 1305 (Fed. Cir. 2010); Ecolochem, Inc. v. S. Cal. Edison Co., 227 F.3d 1361, 1379 (Fed. Cir. 2000).

Unlike in the case of the Shanghai reference, Lilly disclosed one of the Bunnage applications, PCT application WO 98/49166 ("the PCT application"), to UroPep early in the proceedings, listing it as "additional relevant art" in its initial invalidity contentions. Dkt. No. 256-3. UroPep complains, however, that Lilly did not timely disclose a theory of simultaneous invention, that Lilly did not comply with the Local Patent Rules of this Court by charting either of the Bunnage applications, see E.D. Tex. Local Patent Rule 3-3(c), and that Lilly's experts did not address either Bunnage application. For those reasons, UroPep argues that Lilly should be barred from using the Bunnage applications for any purpose at trial.

It is true, as UroPep argues, that a party may not have an expert testify to matters that do not appear in the expert's report. See Jones v. Harley-Davidson, Inc., Case No. 2:14-cv-694, 2016 WL 5340264, at *1 (E.D. Tex. Sept. 23, 2016); Tyco Healthcare Grp. LP v. Applied Med. Res. Corp., Civil Action No. 9:09-cv-176, 2011 WL 7563868, at *2 (E.D. Tex. Sept. 23, 2011); Witt v. Chesapeake Expl., L.L.C., No. 2:10-cv-22, 2011 WL 2790174, at *2 (E.D. Tex. July 14, 2011; Smith & Nephew, Inc. v. Arthrex, Inc., Civil Action No. 2:07-335, 2010 WL 457142, at *8 (E.D. Tex. Feb. 5, 2010). For that reason, Lilly's experts would not be allowed to testify regarding the Bunnage applications. Therefore, even if the Bunnage applications were

admissible, it is not clear what mechanism, if any, Lilly could use to introduce the applications, as no Lilly expert would be allowed to testify about it.

As for UroPep's argument that Lilly did not chart the Bunnage applications, that failure is not fatal because Lilly does not intend to use the Bunnage applications as prior art, and the Local Patent Rules require such measures only for "prior art." As evidence of simultaneous invention, the Bunnage applications do not serve as prior art, but serve to show that others were engaged in similar inventive activities at the same time as the inventors of the patent in suit, a fact that tends to show that the invention "was the product only of ordinary mechanical or engineering skill." Concrete Appliances Co. v. Gomery, 269 U.S. 177, 184 (1925); see also Ecolochem, 227 F.3d at 1379 (citing The Int'l Glass Co. v. United States, 408 F.3d 395, 405 (Ct. Cl. 1969) ("[T]hough not determinative of statutory obviousness, [simultaneous invention] is strong evidence of what constitutes the level of ordinary skill in the art.").

Even so, the governing Discovery Order that covers this case requires more. Under that order, Lilly needed to provide in its initial disclosures "the legal theories and, in general, the factual bases of the disclosing party's claims or defenses (the disclosing party need not marshal all evidence that may be offered at trial)." Dkt. No. 64, at 1; see also id. at 6 (duty to supplement initial disclosures). Lilly's initial disclosures were due December 29, 2015. See Dkt. No. 65, at 3; Dkt. No. 66. The Court has only been able to identify a single generic reference to secondary considerations amid boilerplate language in Lilly's original invalidity contentions and under the heading "Introduction and Reservation of Rights." See Dkt. No. 226-2, at 8 ("Defendants contend that the Asserted Claims are invalid as anticipated by prior art under 35 U.S.C. 102 and/or as obvious in view of the prior art, the knowledge of a person having ordinary skill in the art, and/or secondary factors of obviousness under 35 U.S.C. 103."). The Bunnage PCT

application was disclosed as "additional relevant art" in Lilly's original invalidity contentions, without further explanation. Dkt. No. 256-3, at 1. Beyond that, the original invalidity contentions identified only references to be used in support of Lilly's general obviousness defense. See Dkt. No. 226-2. And the United Kingdom application was not disclosed at all.

Meanwhile, UroPep has represented in its papers and represented at the hearing on April 11, 2017, without contradiction from Lilly, that Lilly did not assert a theory of simultaneous invention until March 16, 2017, when Lilly provided its second amended invalidity contentions. See Dkt. No. 253, at 1. The Court has seen no evidence to the contrary.

The Court finds that the theory of simultaneous invention was not disclosed to UroPep until a month before trial, in violation of Lilly's obligations under the Discovery Order, and that UroPep had no reason to expect that Lilly would assert this theory based on Lilly's disclosures in its invalidity contentions.[3] Because Lilly has provided no justification for the delay, and because introducing a new theory now would severely prejudice UroPep, the Court will not allow admission of the Bunnage references as evidence of simultaneous invention. Nor will the Court allow, more generally, any affirmative use of the UK application, as it was not disclosed until the deposition of Dr. Bell on January 27, 2017, long after the date on which Lilly's references in support of its invalidity contentions were supposed to be disclosed.

Lilly has not offered any other permissible affirmative use of the Bunnage PCT application and, as previously stated, no Lilly expert will be allowed to testify about it. The

[3] UroPep also argues that it was unaware of the proposed use of the Bunnage reference because Lilly was obligated to disclose the Bunnage PCT application in response to an interrogatory requesting information concerning "all testing performed concerning the use of PDE V [inhibitors] to treat the signs and symptoms of BPH before August 1997." Dkt. No. 281-1, at 15. As the Court relies on Lilly's obligation under the Discovery Order to disclose its simultaneous invention theory, the Court does not reach the question of whether Lilly was required to disclose Bunnage in the interrogatory response.

Court therefore GRANTS UroPep's motion to exclude the evidence of the Bunnage references, although Lilly will be permitted to make use of that evidence for impeachment to the extent UroPep opens the door by offering contrary testimony. See, e.g., Dkt. No. 256-2, at 5 (testimony by UroPep's expert that Pfizer had not filed an application "making any comments about BPH" as a target condition for PDE5 inhibitors before the priority date of the patent in suit).

II. UroPep's Objection to Lilly Trial Exhibits Related to Bunnage References

UroPep objects to the admissibility of Lilly Trial Exhibits 1403 (Bunnage international PCT application PCT/EP98/02257), 1413 (Bunnage UK application), 1414 (Bunnage international PCT application PCT/IB99/00519), and 1609 (published Bunnage international patent), on the same grounds. For the reasons identified previously regarding the Bunnage PCT and UK applications, the objection is SUSTAINED.

III. UroPep's Objection to Prosecution History and Wyllie Exhibits

One of UroPep's proposed trial exhibits is an abandoned Lilly patent application, filed on October 10, 2006, that discloses "[a] method of treating symptoms of benign prostatic hypertrophy and a method of treating lower urinary tract symptoms." Dkt. No. 266-5, at 1 (UroPep Exhibit 191); see also Dkt. No. 266-17 (UroPep Exhibit 306, which is a provisional application filed by Lilly in October 2005 that covers similar material). In the "Background of the Invention" section, the Lilly patent application states that "U.S. Patent Publication 2003/0199517 discloses use of PDE1, PDE4, and PDE5 inhibitors in the treatment of prostatic diseases." Dkt. No. 266-5, at 1, ¶12; accord Dkt. No. 266-17, at 4 (same). The patent in suit, the '124 patent, is a continuation of U.S. Patent Publication 2003/0199517.

UroPep wishes to use Lilly's patent application as a party admission for the inference that Lilly recognizes the UroPep patent's contribution in disclosing "PDE5 inhibitors in the treatment

of prostatic diseases." Lilly contends that, if UroPep is able to present that evidence, then Lilly "must be permitted to rely upon and introduce (1) the prosecution history of the Lilly application (Lilly Exhibit 161[1]) and (2) Wyl[l]ie et al. Patent Publ. EP 1020190 A2 (Lilly Exhibit 161[0], 'Wyl[l]ie')." Dkt. No. 266, at 8. Lilly contends that (1) Wyllie is independently admissible as evidence of simultaneous invention, (2) Wyllie and the prosecution history are needed to rebut UroPep's implication that Lilly abandoned its application because Lilly's patent application read on UroPep's patent, and (3) Wyllie is needed to rebut UroPep's cross-examination of Lilly's expert regarding the state of the art in 1998.

For the same reasons explained previously regarding the Bunnage references, Wyllie cannot be used as evidence of the untimely disclosed theory of simultaneous invention.

As for UroPep's use of the Lilly patent application, UroPep had represented that it plans to use the patent application only to suggest Lilly's recognition of UroPep's contribution, not to suggest that Lilly abandoned its application in light of a challenge based on an earlier UroPep patent. Indeed, the latter would make little sense, as Lilly was well aware of and disclosed the earlier UroPep patent in Lilly's patent application. Wyllie and the prosecution history are not relevant as rebuttal evidence given the proposed use of the Lilly patent.

Finally, Wyllie is not admissible as rebuttal evidence to rehabilitate Lilly's expert. UroPep plans to confront Lilly's expert with a 1998 patent that he authored, which includes a list of conditions that may be treated with PDE5 inhibitors. BPH does not appear on that list. See Dkt. No. 264, at 2-6. This is appropriate impeachment evidence given the expert's opinion that it was obvious to persons of skill in the art in 1997 to use PDE5 inhibitors to treat BPH.

Wyllie simply stands for the proposition that, as of Wyllie's priority date of October 1998, some in the art were aware that PDE5 inhibitors could be used to treat BPH. This is not

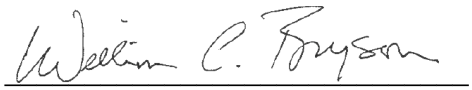
disputed; indeed, UroPep's patent stands for that same proposition. Therefore, Wyllie's value as rebuttal evidence, if it has any, is extremely limited.

Meanwhile, there is a risk of jury confusion and time waste in admitting more technical references, particularly ones that are cumulative. Those risks outweigh any probative value that the evidence may have.

For those reasons, UroPep's objection to Lilly's proposed trial exhibits 1610 and 1611 is SUSTAINED.

IT IS SO ORDERED.

SIGNED this 13th day of April, 2017.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE