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

Defendant Eli Lilly & Company ("Lilly") has filed a Corrected Motion to Exclude Certain Opinions of UroPep's Damages and Technical Experts. Dkt. No. 223 ("Lilly's Motion to Exclude"). Following briefing, Dkt. Nos. 223, 184, 199 & 221, the Court heard argument on Lilly's motion on February 21, 2017. The motion is DENIED as to Drs. Bell and Vellturo, and GRANTED IN PART and DENIED IN PART as to Dr. Sliwinski, as explained below.

BACKGROUND

Plaintiff Erfindergemeinschaft UroPep GbR ("UroPep") initiated this action against Lilly for infringing U.S. Patent No. 8,791,124 ("the '124 patent") by marketing the drug Cialis for treatment of the signs and symptoms of benign prostatic hyperplasia ("BPH").[1] UroPep has proposed to call several experts, including urologist Dr. Anthony M. Sliwinski, medicinal chemist Dr. Andrew Bell, and economist Dr. Christopher A. Vellturo. Lilly now moves,

[1] The Court recognizes that the Food and Drug Administration has approved the use of Cialis for treatment of "the signs and symptoms" of BPH, not for the treatment of BPH itself. For purposes of simplicity, however, the Court in this order will refer to both the treatment of BPH and the treatment of the signs and symptoms of BPH as the treatment of BPH.

pursuant to Federal Rule of Evidence 702 and Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579 (1993), to exclude (1) the opinions of Dr. Sliwinski in their entirety, (2) the infringement analysis of Dr. Bell, and (3) a portion of the damages analysis of Dr. Vellturo.

DISCUSSION

I. Legal Standard

Federal Rule of Evidence 702 provides that a witness "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."

The Supreme Court has stated that when an expert's testimony is challenged under Rule 702, the district court has a "basic gatekeeping obligation" to ensure that the expert's testimony "'is not only relevant, but reliable.'" Kumho Tire Co., Ltd. v. Carmichael, 526 U.S. 137, 147 (1999) (quoting Daubert, 509 U.S. at 589); see also United States v. Valencia, 600 F.3d 389, 423-24 (5th Cir. 2010). A district court has broad discretion when exercising its gatekeeping role under Rule 702 and making a preliminary determination of admissibility. Kumho Tire, 526 U.S. at 152; Valencia, 600 F.3d at 424 (district court "has discretion in determining which factors are most germane in light of the nature of the issue"—i.e., whether the expert's testimony is sufficiently reliable and relevant to be helpful to the finder of fact). The factors to consider are not fixed and "the reliability inquiry is flexible." Valencia, 600 F.3d at 424; see also Fed. R. Evid. 702 Advisory Committee Notes (2000) (explaining that "Daubert set forth a non-exclusive

checklist for trial courts to use in assessing the reliability of scientific expert testimony," and that "[n]o attempt has been made to 'codify' these specific factors.").

When a jury is the finder of fact, the court's role is not to supplant that of the jury but to ensure that the expert's proffered testimony is sufficiently reliable and relevant to the issues properly before the jury. See Fed. R. Evid. 702 Advisory Committee Notes (2000) ("'[T]he trial court's role as gatekeeper is not intended to serve as a replacement for the adversary system.'") (quoting United States v. 14.38 Acres of Land Situated in Leflore Cty., Miss., 80 F.3d 1074, 1078 (5th Cir. 1996)); Micro Chem., Inc. v. Lextron, Inc., 317 F.3d 1387, 1391-92 (Fed. Cir. 2003) (applying Fifth Circuit law) ("When . . . the parties' experts rely on conflicting sets of facts, it is not the role of the trial court to evaluate the correctness of facts underlying one expert's testimony."); Pipitone v. Biomatrix, Inc., 288 F.3d 239, 249-50 (5th Cir. 2002) ("[W]hile exercising its role as a gate-keeper, a trial court must take care not to transform a Daubert hearing into a trial on the merits."). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Daubert, 509 U.S. at 596.

II. Dr. Sliwinski

Lilly moves to exclude Dr. Sliwinski's opinions in their entirety. Those opinions include (1) his testimony that by prescribing Cialis for BPH he and his partners have directly infringed the '124 patent; (2) his testimony about the nature and impact of Lilly's promotional advertising for Cialis; and (3) his estimate of the number of Cialis prescriptions he has written for treating BPH. Lilly also moves to exclude Dr. Sliwinski's testimony regarding the inefficacy of natural and herbal remedies for the treatment of BPH, which appears in the background section of his report. The Court DENIES Lilly's motion to entirely exclude Dr. Sliwinski's opinions, but

GRANTS Lilly's motion to exclude any testimony by Dr. Sliwinski regarding the inefficacy of all natural and herbal remedies.

A. Infringement

Dr. Sliwinski treats BPH in his clinical practice. He estimates that he has more than 500 patients who take Cialis and that two-thirds to three-quarters of the prescriptions he writes for 5mg daily dosages of Cialis are for the treatment of BPH (or the treatment of erectile dysfunction plus BPH). He adds that based on his "experience" he has found that Cialis is "a very effective treatment for BPH in my patients," which "is consistent with" the experiences of the other physicians in his practice. Expert Report of Dr. Anthony M. Sliwinski ("Sliwinski Report"), Dkt. No. 184-2, at ¶ 49.

From his experience, Dr. Sliwinski concludes that he and his partners infringe claims 1 and 3 of the '124 patent because (1) they are prescribers who administer Cialis, (2) Cialis is a PDE5 inhibitor in that it is at least 20 times more selective in inhibiting PDE5 than PDE1 through PDE4, and (3) the 5mg dose of Cialis is an effective amount for the prophylaxis and treatment of BPH. Sliwinski Report, Dkt. No. 184-2, at ¶ 50. He also notes that he prescribes Cialis in a unit dosage form (individual tablets), which satisfies the additional limitation of claim 3. Id. ¶ 51.

Lilly argues that Dr. Sliwinski's opinion that he and other partners in his practice directly infringe the '124 patent is conclusory and not helpful to the jury. The Court disagrees. Experts commonly review a patent, apply claim limitations to a product or conduct at issue, and then, based on knowledge and experience in their field of expertise, render an opinion as to whether the product or conduct satisfies all the limitations of a particular patent claim. Dr. Sliwinski's opinion is directed at his own conduct, which is less common, but his opinion is no less relevant.

And his opinion is neither conclusory nor unhelpful to the jury, as his opinion is based on substantial clinical experience in prescribing Cialis for BPH treatment and describes the efficacy of Cialis as a treatment for BPH. His report explains in some detail why he concludes that he and his partners infringe each of the limitations of claims 1 and 3 of the '124 patent. See Sliwinski Report, Dkt. No. 184-2, at ¶¶ 19-23, 48-52. Given the detail in his explanation for that conclusion, his testimony on that issue cannot fairly be considered conclusory or lacking in "meaningful analysis," as Lilly contends.

Lilly next complains that Dr. Sliwinski's statement that Cialis's active ingredient, tadalafil, is a selective PDE5 inhibitor is entirely unnecessary because it is based on the Cialis label, which itself would be easily understood by the jury. The Court is not persuaded. The first 16 sections of the Cialis label describe, inter alia, the drug's indications and usage, administration, contraindications, warnings, adverse reactions, drug interactions, clinical pharmacology, nonclinical toxicology, clinical studies, storage instructions, and patient counseling information. Dkt. No. 177-34, at 2-3. The label is clearly directed at physicians, not patients. See, e.g., id. at 27-28 (multiple provisions of section 17, titled "Patient Counseling Information," contain directions for physicians, including stating that "Physicians should discuss with patients . . ." (four times), "Physicians should advise patients . . ." (four times), "patients should be instructed" (twice), "Physicians should instruct patients . . ." and "physicians should inform patients . . ."). The last four pages of the label are a separate incorporated document entitled, "Patient Information," which indicates that it is a separate portion of the label intended for the patient. Id. at 29-33; see also id. at 1 (referring the reader to section 17 for patient counseling information and FDA-approved patient labeling).

It may be true that some or all of the jurors would understand, without help, the short excerpts from the label on which Dr. Sliwinski based his infringement analysis—namely, that "[s]tudies *in vitro* have demonstrated that tadalafil is a selective inhibitor of PDE5," and that "the effect of tadalafil is more potent on PDE5 than on other phosphodiesterases," showing "that tadalafil is >10,000-fold more potent for PDE5 than for" PDE1 through PDE4. Dkt. No. 177-34, at 11. But the average layperson may not be familiar with the significance of "*in vitro*" studies, or know that relative potency is a proxy for selectivity, or be familiar with the mathematical symbol ">."

In that respect, this case is quite different from K-Mart Corp. v. Honeycutt, 24 S.W.3d 357, 360-61 (Tex. 2000), on which Lilly relies. See Lilly's Motion to Exclude, at 4. In that case, the Texas Supreme Court affirmed the exclusion of expert testimony that it was not unreasonable for a person to sit on the lower railing of a shopping cart corral. The court ruled that the jury was likely to be familiar with railings on shopping cart corrals and could apply the "jury's collective common sense" to determine "whether people would likely sit on the lower railing" without the need for expert testimony stating as much. The level of juror familiarity with a shopping cart corral is almost certainly much greater than the jurors' familiarity with the multi-page formal FDA-approved label for a pharmaceutical drug.

Even if the jury might be expected to understand the Cialis label without testimonial assistance, that does not mean that Dr. Sliwinski's opinion is, as Lilly argues, irrelevant and "gratuitous." Lilly's Motion to Exclude, at 4. Dr. Sliwinski's "understanding and perception" of the drug label "is entirely relevant," as physicians are the intended audience for the main portion of the label. Mauldin v. Upjohn Co., 697 F.2d 644, 648 (5th Cir. 1983) (noting that package inserts are "written to inform fully and adequately the medical practitioner who is called upon . .

. to prescribe the medication."). At minimum, testimony from a physician such as Dr. Sliwinski could be useful in reassuring the jury that its lay understanding of the label is correct. Dr. Sliwinski's testimony based on the Cialis label is therefore admissible as expert testimony.

B. Cialis Marketing and Promotion

In the background section of his report, Dr. Sliwinski explains how "Lilly markets and promotes Cialis to physicians like [himself] for use in the treatment of BPH." Sliwinski Report, Dkt. No. 184-2, ¶ 42. He states, for example, that Lilly sends pharmaceutical representatives to his practice approximately five times a month to "discuss any recent developments with respect to Cialis[] and encourage us to use Cialis for treatment of patients with BPH." Id. Lilly also "sends [him] promotional materials for Cialis at least once a week," and sends vouchers for free Cialis as well as co-pay assistance for Cialis. Id. ¶ 43; see also id. ¶¶ 44-46 (discussing a few concrete examples of the Cialis promotional materials he received from Lilly). Lilly also "sent [him] a significant number of samples of Cialis . . . on a weekly basis." Id. He further notes that patients often request treatment with Cialis based on Lilly's marketing to consumers, including television advertisements with which he is personally familiar. Id. ¶ 47.

Based on his understanding of the Cialis label and promotional materials (those directed to physicians and those directed to consumers), Dr. Sliwinski states that "Lilly's promotion and advertisement of Cialis is a reason why I prescribe it in this infringing manner"—that is, in an effective amount for the treatment of BPH. Sliwinski Report, Dkt. No. 184-2, ¶ 52.

Lilly argues that Dr. Sliwinski's testimony on the "apparent meaning and impact" of Lilly's marketing of Cialis is irrelevant. Lilly contends that UroPep should have retained a marketing or survey expert if UroPep wished to offer such testimony.

On the latter point, Lilly is correct. Expert testimony on the interpretation of advertisements and their impact on members of the public should come from a marketing expert, not a physician. In his report, Dr. Sliwinski does not "interpret" Lilly's promotional materials, which are admittedly directed to physicians, in a way that renders them accessible to the average juror; instead, he simply recites the content of the materials. See Sliwinski Report, Dkt. No. 184-2, ¶¶ 44-46. And the content of those materials, although not before the Court except in the form of Dr. Sliwinski's summaries, appears to be easily understandable without the expertise of a urologist. E.g., id. ¶ 44 ("Lilly states on the cover of Exhibit 7 . . . 'Is your erectile dysfunction (ED) patient living with benign prostatic hyperplasia (BPH) symptoms? Two conditions. One treatment. **Cialis 5 mg for once daily use.**'").

UroPep contends that "Dr. Sliwinski is offering an opinion on whether Lilly's marketing encourages physicians to prescribe Cialis," and that the opinion is expert testimony because "[a] physician who prescribes Cialis is in the best position to offer testimony on that topic." Dkt. No. 221, at 1 n.2. UroPep correctly identifies a physician as the appropriate witness to testify about the impact of Lilly's promotional materials, but UroPep incorrectly draws the conclusion that a physician testifies as an expert when doing so. A patient could testify that Lilly's television ads, directed to consumers, prompted him to ask his doctor for a Cialis prescription, but that would be lay testimony, not expert consumer testimony. The same is true for a physician offering similar testimony. A physician does not testify as an expert whenever he testifies about a fact relating to his profession. Here, it does not appear that Dr. Sliwinski used any expert knowledge to "interpret" the promotional materials or to assess the materials' effect.

While Dr. Sliwinski's statements regarding the marketing and promotion of Cialis are not competent as expert testimony, they are admissible as fact evidence. See Fed. R. Evid. 701 (lay

witness can offer opinion testimony that is "rationally based on the witness's perception," "helpful . . . to determining a fact in issue," and not based on specialized expert knowledge). Lilly's promotional materials and its representatives' actions are directed at physicians for the purpose of increasing prescription rates. As the target of Lilly's marketing efforts, Dr. Sliwinski is an appropriate fact witness to testify about his personal perception of the content and impact of those efforts, which is relevant to the issue of induced infringement.

PharmaStem Therapeutics, Inc. v. ViaCell, Inc., 491 F.3d 1342 (Fed. Cir. 2007), on which Lilly relies, does not hold otherwise. There, the court affirmed the exclusion of testimony from a cell biologist expert for two reasons. First, it was irrelevant: the "testimony was almost entirely based on an interpretation of the defendants' marketing materials and materials directed to investors, [so] any expertise on [the expert's] part as a cell biologist was of no apparent help to the jury." Id. at 1355 (emphasis added). Second, it was not reliable: The expert's "interpretation was not a reasonable one" because it was not supported by anything stated in the marketing materials. Id. Here, Dr. Sliwinski is the intended audience of the marketing materials, unlike the cell biologist in PharmaStem. Second, Dr. Sliwinski's testimony as to his perception of Lilly's marketing materials is factual and does not need to meet a Daubert reliability requirement. Dr. Sliwinski's personal experience and observations provide a sufficient basis for his lay opinion.

Finally, in its reply brief, Lilly argues that Dr. Sliwinski's factual testimony should be excluded under Fed. R. Civ. P. 37(c)(1) because UroPep did not disclose him as a fact witness. However, Lilly did not raise that objection in the initial brief, so it is waived.[2] See United States

[2] Lilly also argues in its reply brief that Dr. Sliwinski's infringement and personal experience opinions are mere ipse dixit statements. That appears to be the same argument raised in Lilly's initial brief that Dr. Sliwinski's opinions are conclusory, which the Court has addressed

v. Jackson, 426 F.3d 301, 304 n.2 (5th Cir. 2005) ("arguments raised for the first time in a reply brief are waived"); Core Wireless Licensing S.A.R.L. v. LG Elecs., Inc., No. 2:14-cv-911, 2015 WL 5786501, at *5 (E.D. Tex. Sept. 30, 2015); TracBeam, LLC v. Apple, Inc., No. 6:14-cv-680, 2015 WL 5786449, at *2 (E.D. Tex. Sept. 29, 2015); Flooring Sys., Inc. v. Chow, No. 4:12-cv-475, 2013 WL 4674667, at *1 n.2 (E.D. Tex. Aug. 29, 2013).

Even if Lilly had objected in a timely manner, Fed. R. Civ. P. 37(c)(1) provides that a witness may be excluded unless the party's failure to identify the witness "was substantially justified or is harmless." Lilly neither argues nor puts forth any evidence that Lilly was prejudiced by UroPep's failure to identify Dr. Sliwinski as a fact witness. The Court can discern none, given that Dr. Sliwinski's expert report, which contained the factual opinions in dispute, was disclosed in November 2016, and Lilly had the opportunity to obtain further details when Lilly deposed him in January 2017. See Dkt. No. 221, at 2. In addition, the expert report alone is much more detailed than what is required for fact witness disclosures. See Fed. R. Civ. P. 26(a)(3)(A); see also, e.g., Dkt. No. 207-7, at 9 (Lilly's disclosures for several proffered fact witnesses consist of single sentence summaries of general topics for testimony, such as "Prior art to the Patent-in-Suit."). In short, UroPep offered Dr. Sliwinski's testimony about the marketing materials as expert testimony; the fact that the Court has ruled that his testimony can be admitted, but only as fact evidence, does not mean that UroPep's identification of Dr. Sliwinski as an expert witness, rather than as a fact witness, requires that his testimony be excluded altogether.

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supra. To the extent that Lilly is making a separate argument, the argument is waived because it was raised too late.

C. Estimate of Cialis Prescriptions for BPH indication

As noted previously, Dr. Sliwinski "estimate[d] that between two-thirds and three-fourths of [his] 5mg daily Cialis prescriptions are written either for BPH or for [erectile dysfunction] plus BPH." Sliwinski Report, Dkt. No. 184-2, ¶ 49. Lilly contends that this "off-the-cuff" estimate is not reliable and, as summary evidence under Fed. R. Evid. 1006, limits Lilly's ability to effectively cross-examine him. Neither argument merits exclusion.

First, Dr. Sliwinski's estimate is properly viewed as factual testimony, not expert testimony, so it does not need to satisfy Daubert's reliability requirement. The number of prescriptions Dr. Sliwinski has written for patients he has previously diagnosed as suffering from BPH or for erectile dysfunction plus BPH is not an expert opinion based on technical knowledge. Rather, it is the relation of an historical fact. Dr. Sliwinski exercises his expert judgment when diagnosing a patient's condition, but not when estimating the percentage of prescriptions he has written that are directed to BPH treatment. The number of prescriptions is a factual observation of the kind commonly offered by lay witnesses. Given the number of patients diagnosed with BPH, it does not take an expert to estimate what percentage of all of the prescriptions Dr. Sliwinski wrote for 5 mg doses of Cialis were prescribed for BPH or erectile dysfunction plus BPH.

Second, Dr. Sliwinski's factual testimony is sufficiently supported. Dr. Sliwinski stated that he treats hundreds of patients with BPH and frequently prescribes Cialis in 5mg daily doses for the treatment of BPH, either alone or in conjunction with erectile dysfunction. Sliwinski Report, Dkt. No. 184-2, ¶ 49. He is certainly in a position to be able to estimate the percentage of such Cialis prescriptions he has written that were directed, in whole or in part, at the treatment of BPH.

Finally, contrary to Lilly's argument, Dr. Sliwinski's estimate does not constitute a summary exhibit that is subject to the requirements of Fed. R. Evid. 1006. That rule provides that "a summary, chart, or calculation" may be used "to prove the content of voluminous writings, recordings, or photographs that cannot conveniently be examined in court," but only if the originals or duplicates of those records are "available for examination or copying, or both, by other parties at a reasonable time and place."

Dr. Sliwinski's estimate is not a "summary, chart, or calculation." It is simply an estimate based on his recollection of how many Cialis prescriptions he has written for BPH. It is not, and does not purport to be, a summary or calculation based on his review of patient records. Lilly has not even suggested that documents exist or would be reasonably accessible from which the exact percentage of Dr. Sliwinski's Cialis prescriptions for BPH and for ED with BPH could be determined. This is therefore not a case in which Dr. Sliwinski is offering a summary of voluminous records that are shown to be in evidence or otherwise available. Instead, it is a case in which, so far as the record reflects, Dr. Sliwinski's estimate is the best available evidence of the number of such prescriptions that he has written. Nothing in the Federal Rules of Evidence (including Rule 1006) bars witnesses from making estimates of numbers such as the number of particular items sold, the number of items with certain features, and the number of patients with particular complaints. See Accent Designs, Inc. v. Jan Jewelry Designs, Inc., 827 F. Supp. 957, 971 (S.D.N.Y. 1993) (Rule 1006 inapposite where the "nature of the proof" of a particular quantity "is such that it must be established by testimonial evidence, not by writings."). Dr. Sliwinski's estimate of the number of prescriptions he has written for the treatment of BPH is no different, even though, like the other examples, it is imprecise.

D. Inefficacy of Herbal Remedies

In the background section of his expert report describing treatments for BPH, Dr. Sliwinski discusses "[n]atural and herbal remedies" for BPH, including icariin (a compound relevant to Lilly's anticipation defense, see Dkt. No. 172). He then states that, in his opinion, "these products operate largely through the placebo effect, do not function (if at all) through the inhibition of PDE5, and are not, on the whole, effective treatments for BPH." Sliwinski Report, Dkt. No. 184-2, at ¶ 33. In support of those assertions, Dr. Sliwinski cites a clinical study from the New England Journal of Medicine that reported no BPH benefit with the use of saw palmetto (a fruit extract), and the American Urological Association's guidelines for BPH treatment, which state that "[n]o dietary supplement, combination phytotherapeutic agent or other nonconventional therapy is recommended for the management of LUTS secondary to BPH." Id.

According to Lilly, Dr. Sliwinski's remarks constitute a sweeping conclusion about the inefficacy of natural and herbal remedies that is not supported by the two cited references and that is outside of Dr. Sliwinski's expertise as a clinical urologist. UroPep responds that Dr. Sliwinski's opinion is based on his personal experience as a clinical urologist and on his understanding of the guidelines of the American Urological Association.

Dr. Sliwinski is a urologist who frequently prescribes treatment for patients suffering from BPH, see Sliwinski Report, Dkt. No. 184-2, at ¶ 49, and he is a member of the American Urological Association, id. ¶ 5. His report shows that he keeps apprised of treatments for BPH and maintains an active practice, in which he makes professional judgments regarding how to treat his BPH patients. See id. ¶ 4 (he was recertified by the American Board of Urology in 2010 and his certification is current through 2023); id. ¶ 5 (he attends every annual meeting of the American Urological Association and of the Society of Sexual Medicine); id. ¶ 6 (he gives

Continuing Medical Education presentations for, among other things, men's wellness, sexual medicine, and BPH); id. ¶ 7 (over half his current practice involves the treatment of men with sexual dysfunction and prostatic conditions). UroPep therefore asserts that Dr. Sliwinski should be allowed to apply his expert knowledge and experience to offer an opinion that he is not aware, and other practitioners in his field are not aware, of natural or herbal remedies that are effective for BPH.

Dr. Sliwinski's report, however, goes a step farther than that. It states that in his opinion (1) natural and herbal remedies are not effective treatments for treat BPH, and (2) they do not function by inhibiting PDE5. See Sliwinski Report, Dkt. No. 184-2, at ¶ 33. Neither of those opinions have adequate support in Dr. Sliwinski's report. See Knight v. Kirby Inland Marine, Inc., 482 F.3d 347, 352 (5th Cir. 2007) (reliability of expert testimony "is determined by assessing whether the reasoning or methodology underlying the testimony is scientifically valid.").

As to the first opinion, Dr. Sliwinski does not suggest that he or the American Urological Association has studied all natural remedies and determined that the remedies are ineffective for the treatment of BPH. See Daubert, 509 U.S. at 590 (expert testimony "must be supported by appropriate validation—i.e., good grounds, based on what is known"). Nor do Dr. Sliwinski's references support that opinion. The American Urological Association's guidelines do not state that natural remedies are ineffective for the treatment of BPH. The guidelines say that natural remedies "are not recommended," but that could be because, as compared to known pharmaceuticals, natural remedies are less effective—not that they are completely ineffective. It could also be that natural remedies are less advisable for completely independent reasons, such as side effects or problems with patient compliance. The clinical study reported in the New

England Journal of Medicine, which Dr. Sliwinski cites, provides support only for an opinion that saw palmetto is not an effective BPH treatment; it says nothing about icariin and other natural remedies.

As for Dr. Sliwinski's second opinion that no natural remedy functions by inhibiting PDE5, he does not have the requisite experience or expertise to support such a claim. A chemist who has done extensive PDE5 inhibitor assays with natural and herbal remedies could reach such a conclusion, but Dr. Sliwinski does not purport to be such an expert or to have knowledge of such evidence. See Bryant v. 3M Co., 78 F. Supp. 3d 626, 633 (S.D. Miss. 2015) (excluding as not reliable expert testimony that product provided plaintiff with sufficient protection from silica exposure, because expert admitted that product "was effective to a certain exposure limit" but did not know plaintiff's specific exposure); see also In re Fosamax Litig., 509 F. App'x 69, 74 (2d Cir. 2013) (affirming exclusion of expert opinion regarding the comparative efficacy of bisphosphonates to drug of interest because "the opinion was not based on sufficient facts."). Neither Dr. Sliwinski's cited references nor his knowledge of urology supports that sweeping conclusion.

III. Dr. Bell

Lilly moves to exclude Dr. Bell's literal infringement analysis because Dr. Bell did not test tadalafil or analyze its structure or mechanism of action. More specifically, Lilly complains that Dr. Bell did not perform what Lilly refers to as the "peak fractionation test" that is described in the patent. See '124 patent, col. 7, line 35 through col. 8, line 16.[3] Lilly argues that Dr. Bell's

[3] In its reply brief, Lilly also argued that Dr. Bell's analysis was contrary to the Court's claim construction because he excluded PDE11 when evaluating tadalafil's selectivity. Dkt. No. 199, at 2-3. That argument is moot in light of the Court's clarified claim construction, in which the Court held that a selective PDE5 inhibitor has to be selective for PDE5 versus PDE1 through PDE4, and not against all known PDEs, see Dkt. No. 234, at 16.

reliance on the Cialis label and a scientific article to conclude that tadalafil is a selective PDE5 inhibitor under the Court's claim construction does not constitute expert testimony. According to Lilly, Dr. Bell is simply reciting what is readily apparent from evidence already in the record.

As discussed previously in the context of Dr. Sliwinski's reliance on the Cialis label, it is not the case that all the information in the label is plainly within the understanding of the average person. The same is true of the journal article cited by Dr. Bell, A. Daugan et al., The Discovery of Tadalafil: A Novel and Highly Selective PDE5 Inhibitor, 46 J. Med. Chem. 4533 (2003), Dkt. No. 177-19 ("Daugan"). Using a good measure of scientific jargon, the Daugan article reports the methods used in and results of a number of assays that the authors ran to determine the PDE5 selectivity of tadalafil and modified analogs.

Even if those two documents (particularly Daugan) were more readily accessible to lay jurors, materials need not be completely incomprehensible in order for expert testimony to be admissible. Dr. Bell's testimony would still be helpful to the jury in explaining both documents and how Dr. Bell relied on their reported results to come to his conclusion that tadalafil is a selective PDE5 inhibitor within the meaning of the Court's construction.

As for Lilly's remaining argument, Dr. Bell was not required to perform any actual tests before his testimony could be admitted. See Pipitone v. Biomatrix, Inc., 288 F.3d 239, 245 (5th Cir 2002) (reversing order excluding testimony of expert who did not conduct an epidemiological study but explained why such a study was not necessary and was inappropriate). Experts are permitted to, and often do, rely on others' testing to support their opinions. See Greatbatch Ltd. v. AVX Corp., No. 13-723-LPS, 2015 WL 9171042, at *3 (D. Del. Dec. 11, 2015) (expert permitted to rely on another lab's results to support his opinion); see also O'Neill v. Isle of Capri Casinos, Inc., No. 2:01-cv-202, 2003 WL 25773473, at *1, *3 (E.D. Tex. Aug.

18, 2003) ("[A]n expert is permitted wide latitude to offer opinions, including those that are not based on firsthand knowledge or observation."). What Daubert requires is that an expert base his or her opinion on reliable methodology, whether performed personally or by others. In this respect, Lilly does not challenge the reliability of its Cialis label and has not suggested that Daugan's results are dubious.

It is true, as Lilly contends, that Dr. Bell did not perform the "peak fractionation test," as described in the '124 patent, to test the selective PDE5 potency of tadalafil. However, "[t]he standard under Rule 702 is not whether an expert's testimony has 'proven[,]' to an optimal degree, his or her conclusion; it is whether there are 'good grounds' for the expert's conclusion." Greatbatch, 2015 WL 9171042, at *3. Lilly may challenge the weight to be afforded to Dr. Bell's conclusion in the absence of a "peak fractionation test," but the weight of Dr. Bell's testimony, in light of any such cross-examination, is a question for the jury; it does not raise an issue of admissibility. See Viterbo v. Dow Chem. Co., 826 F.2d 420, 422 (5th Cir. 1987) ("As a general rule, questions relating to the bases and sources of an expert's opinion affect the weight to be assigned to that opinion rather than its admissibility and should be left for the jury's consideration.").

The Court DENIES Lilly's Motion to Exclude as it pertains to Dr. Bell.

IV. Dr. Vellturo

In his report, UroPep's damages expert Dr. Vellturo sought to determine UroPep's reasonable royalty damages beginning in October 2014, when Lilly received notice of the '124 patent. He did so in several steps. First, he calculated the incremental profits to Lilly from the sales of Cialis for the BPH indication starting in 2011 when the Food and Drug Administration approved Cialis for the treatment of BPH. Dr. Vellturo derived the incremental profits to Lilly

from the BPH indication by comparing the sales of 5mg doses of Cialis prior to and after October 2011. He then deducted incremental costs from those sales to determine the incremental profits to Lilly from the BPH indication between October 2011 and September 2016. After obtaining this initial calculation of total incremental profits, he then subtracted from that incremental profit figure the incremental profits that Lilly earned between 2011 and October 2014, on the ground that Lilly would not be liable for infringement during that period, as that was before it was given notice of the '124 patent.

Lilly objects to the admission of Dr. Vellturo's initial calculation of the total incremental profits from 2011 through September 2016 because that figure includes "admittedly unpatented, non-infringing conduct by Lilly" before Lilly received notice of the patent in October 2014. Dkt. No. 223, at 10. According to Lilly, it is improper to include references to profits that are not attributable to infringing conduct, just to make the expert's final damages estimate appear more reasonable. See Uniloc USA, Inc. v. Microsoft Corp., 632 F.3d 1292, 1318-19 (Fed. Cir. 2011) (use of an overinflated royalty base figure as a "check" on the accuracy of the expert's damages estimate is improper).

There are several problems with Lilly's argument. Contrary to Lilly's assertions, Dr. Vellturo did not calculate Lilly's total incremental profits between 2011 and 2016 to determine the royalty base from which to calculate a reasonable royalty. Instead, he used the incremental profits for that period, as compared with the pre-2011 period, in an effort to obtain an accurate assessment of the incremental value of the BPH indication to Lilly. See Expert Report of Christopher A. Vellturo, Ph.D. ("Vellturo Report"), Dkt. No. 209-1, at ¶¶ 131-33. That initial calculation served as a necessary predicate for Dr. Vellturo's later calculation of the benefit that Lilly obtained from the BPH indication during the infringement period, from October 2014

through September 2016. The 2011 through 2016 incremental profits calculation did not serve as an independent basis for determining damages. See Vellturo Report, Dkt. No. 209-1, at ¶ 133; see also Dkt. No. 179-2 (Dr. Vellturo Dep. Tr., Jan. 17, 2017 ("Vellturo Dep. Tr.")), at 192:18 through 193:6; see also id. at 195:12-20, 198:11-12. Because Dr. Vellturo's calculation of the incremental benefit of the BPH indication to Lilly was a way of measuring the "footprint" of the BPH indication in the market, it was not improper for him to look to the 2011 through 2016 profits, compared to the pre-2011 profits, as a way of making that measurement. See Uniloc, 632 F.3d at 1317 ("To be admissible, expert testimony opining on a reasonable royalty rate must carefully tie proof of damages to the claimed invention's footprint in the marketplace.") (internal quotation mark omitted).

For the same reason, there is no merit to Lilly's argument that "Dr. Vellturo's opinion regarding the alleged value [of] the '124 Patent's invention before it even issued is improper and should be excluded," Lilly's Motion to Exclude, at 8. The economic data from the period before the issuance of the '124 patent provided a sound basis from which to determine the value of the invention that was ultimately patented. To the extent that Dr. Vellturo was able to isolate the value to Lilly of the BPH indication during the period between 2011 and 2014, that value was a useful measure of the value of the invention that was subsequently patented. A patent does not have to be in existence in order to calculate the value that the invention would have, particularly if others are already practicing the invention in the market when the patent issues.

Furthermore, contrary to Lilly's contention, Dr. Vellturo did not perform the initial calculation merely to provide a gratuitous "check" for his reasonable royalty calculation. Rather, he performed it as the first step in his process for deriving the reasonable royalty rate, a step that

was necessary to calculate the reasonable royalty damages (equal to infringing sales multiplied by the reasonable royalty rate). See Vellturo Report, Dkt. No. 209-1, at ¶ 13.

The thrust of Lilly's argument is that Lilly's sales of Cialis for BPH before October 2014 were not infringing and therefore are not relevant to any part of the damages calculation. Lilly is correct that those earlier sales were not infringing sales, and therefore may not be included as contributing to the assessment of damages. But Dr. Vellturo committed no such error.[4]

Lilly nonetheless contends that Dr. Vellturo should be barred from mentioning Lilly's profits from the pre-2014 sales of Cialis, even if his only reference to the pre-patent profits are as part of the process for deriving the value of the BPH indication for the ultimate damages calculation. As support for that argument, Lilly relies on Uniloc. There, the plaintiff's expert separately calculated the gross sales of the entire product in addition to calculating reasonable royalties for the patented feature. The plaintiff conceded that it was not entitled to royalties on the value of the entire product under the entire market value rule, which "allows a patentee to assess damages based on the entire market value of the accused product only where the patented feature creates the basis for customer demand or substantially create[s] the value of the component parts." Uniloc, 632 F.3d at 1318 (alteration in original) (internal quotation marks omitted). The plaintiff also agreed that it would not base its damages calculation on sales of the product, and gross sales of the product in fact played no role in the expert's damages calculation. Id. at 1319. The expert nevertheless presented that gross sales number—and a corresponding pie chart—to the jury as a "check" on the plaintiff's reasonable royalty damages calculation, which

[4] To be sure, Dr. Vellturo's report contains the statement that the incremental profits from 2011 through 2016 are "associated with the infringing use of the '124 patent by Lilly." Vellturo Report, Dkt. No. 209-1, at ¶ 140. During the February 21, 2017, hearing, UroPep agreed to strike that phrase from Dr. Vellturo's report and testimony. See Dkt. No. 231 (Feb. 21, 2017, Hearing Tr.), at 158-59. The Court will hold UroPep to that concession.

amounted to 2.9%—a minuscule sliver of the pie chart—of the defendant's total revenue for the product. Id. Ultimately, the district court, and the Federal Circuit on appeal, determined that the gross sales "check" was entirely irrelevant to the royalty damages calculation and that it "tainted" the jury's damages award. Id.

In contrast, Dr. Vellturo began with the number in dispute and then accounted for several other variables, including deducting noninfringing profits, before ultimately deriving his estimated reasonable royalty rate. The initial number was an essential part of Dr. Vellturo's model for calculating damages and is therefore a legitimate and relevant part of his damages analysis.

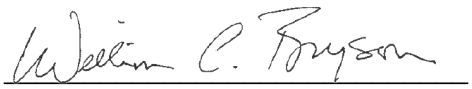
Notably, the optics of comparing Dr. Vellturo's initial calculation with the final damages calculation are not nearly as severe as was the case in Uniloc. Here, the final damages calculation is approximately 30% of the initial calculation, not 3%, as was the case in Uniloc. The Court also notes that, unlike the expert witness in Uniloc, Dr. Vellturo has not undertaken in his report or deposition to compare his final damages calculation to the number in dispute.[5] In sum, the Court is not persuaded that Dr. Vellturo's reference to the initial calculation as a part of his explanation of his analysis will "taint" the jury, as was true of the expert's pie chart in Uniloc.

The Court therefore DENIES Lilly's Motion to Exclude as it pertains to Dr. Vellturo.

[5] The Court also notes that, even if the Court required Dr. Vellturo to refrain from mentioning the initial calculation number (Lilly's profits from 2011 through September 2016) unless he first deducted the pre-notice noninfringing profits (Lilly's profits from 2011 through October 2014), Lilly would derive very little benefit from the ruling. Subtracting the latter from the former gives a result that is approximately 94 percent of the former. See Dkt. No. 209-1, at ¶¶ 172-73. That 6 percent reduction is not a reason to exclude his testimony as "tainting."

IT IS SO ORDERED.

SIGNED this 17th day of March, 2017.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE