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, and BROOKSHIRE BROTHERS, INC.,	§	
	§	
Defendants.	§	

MEMORANDUM OPINION AND ORDER

Before the Court is Defendant Eli Lilly and Company's Motion to Amend Its Affirmative Defenses to Add the Defense of Unclean Hands ("Motion to Amend"), Dkt. No. 153. The motion was briefed by the parties, see Dkt. Nos. 153, 158, 164, and 167, and argued during a telephonic hearing conducted on January 18, 2017. The motion is DENIED.

BACKGROUND

This action was filed on July 1, 2015. The deadline for the parties to amend their pleadings was April 7, 2016. Fact discovery closed on October 28, 2016, and expert discovery closed on December 23, 2016.

On December 5, 2016, the defendant Eli Lilly and Company ("Lilly") filed its Motion to Amend, in which it sought to raise an affirmative defense of unclean hands. Lilly's allegation of unclean hands is based on the actions of Dr. Stefan Ückert. Dr. Ückert is one of the inventors of the patent in suit in this case, U.S. Patent No. 8,791,124 ("the '124 patent"). He was also a member of the plaintiff, Erfindergemeinschaft UroPep GbR ("UroPep"), a German business organization formed by the five inventors of the '124 patent. UroPep has asserted its patent against Cialis, Lilly's commercial product that contains as its active ingredient the drug tadalafil.

Lilly's unclean hands theory is, in short, that at the same time Dr. Ückert and his colleagues were prosecuting a patent claiming the use of certain compounds, including tadalafil, to treat benign prostatic hyperplasia ("BPH"), Dr. Ückert collaborated with Lilly scientists in authoring a publication dealing with the use of tadalafil to treat BPH. In the course of that collaboration, Lilly alleges, Dr. Ückert obtained confidential information from Lilly that enabled UroPep to fashion its patent application in a way that would result in the patent reading on the use of Lilly's tadalafil product, Cialis, for the treatment of BPH. All the while, according to Lilly, Dr. Ückert concealed the fact that he and his colleagues were prosecuting the application that ultimately issued as the '124 patent.

UroPep responds that Lilly's allegations are factually unsupported and fall far short of the level of improper conduct necessary to give rise to a defense of unclean hands. Because the dispute is highly factual, the Court will set out below a detailed account of the underlying facts as the parties have presented them.

1. In November 2011, Dr. Lars Viktrup, a Lilly scientist, invited Dr. Ückert to participate as one of a number of co-authors on a review article on the mechanism by which tadalafil treats BPH. Dr. Viktrup explained that Dr. Ückert was being invited to participate based on his "interests in the field of lower urinary tract and how PDE5 inhibitors may impact" lower urinary tract symptoms. Dr. Ückert agreed to participate. As part of the undertaking, Dr. Ückert was required to sign a confidentiality agreement with Lilly, and he was advised that "Lilly complies with the authorship standards of the International Committee of Medical Journal Editors' Uniform Requirements for Manuscripts Submitted to Medical Journals ("Uniform Requirements"). Dr. Ückert was further advised that "Lilly will provide you access to the research data under its control that are necessary for you to perform your responsibilities as an

author of the disclosure." Dkt. No. 153-3, at 2-3. The Uniform Requirements provides that "[a]ll participants in the peer-review and publication process must disclose all relationships that could be viewed as potential conflicts of interest," and adds that when submitting a manuscript, authors "are responsible for disclosing all financial and personal relationships that might bias their work. To prevent ambiguity, authors must state explicitly whether potential conflicts do or do not exist." Dkt. No. 153-5, at 2.

The paper had six co-authors, two of whom (including Dr. Viktrup) were Lilly employees. Dr. Ückert was assigned one portion of the paper to write and another portion to co-author. The portion for which he was assigned sole responsibility was the section addressing "phosphodiesterase type 5 localization in the human outflow region (bladder, prostate, urethra)." The portion for which he was assigned co-authoring responsibility was the section addressing "smooth muscle relaxation." Dkt. No. 153-6, at 5, 6; see also Dkt. No. 153-3, at 10-11. Each of those two sections of the paper was approximately one page in length. Dkt. No. 153-6, at 5-7.

The paper was ultimately submitted to, and accepted for publication by, the journal European Urology. On its website, the journal provided directions "for authors," which included a section entitled "Conflicts of Interest and Financial Disclosures." Dkt. No. 153-4, at 4. That section stated, in pertinent part, as follows:

> A conflict of interest may exist when an author (or the author's institution or employer) has financial or personal relationships or affiliations that could influence (or bias) the author's decisions, work, or manuscript.
>
> Authors are expected to provide detailed information about all relevant financial interests and relationships or financial conflicts (e.g., employment/affiliation, grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received, or pending), particularly those present at the time the research was conducted and through publication, as well as other financial interests (such

> as patent applications in preparation), that represent potential future financial gain.
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> For example, authors of a manuscript about prostate cancer should report all financial relationships they have with all manufacturers of products used in the management of prostate cancer, not only those relationships with companies whose specific products are mentioned in the manuscript.
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> . . . .
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> All disclosures of any potential conflicts of interest, including specific financial interests and relationships and affiliations (other than those affiliations listed in the title page of the manuscript) relevant to the subject of their manuscript will be disclosed by the corresponding author on behalf of each co-author, if any, as part of the submission process. Likewise, authors without conflicts of interest, will be requested to state so as part of the submission process.
>
> If authors are uncertain about what constitutes a relevant financial interest or relationship, they should contact the editorial office.
>
> . . . .
>
> If an author's disclosure of potential conflicts of interest is determined to be inaccurate or incomplete after publication, a correction will be published to rectify the original published disclosure statement.

Although the European Urology conflict-of-interest policy required Dr. Ückert to disclose any "patents filed, received, or pending," Dr. Ückert did not disclose the application for the '124 patent, which was pending before the U.S. Patent and Trademark Office between December 29, 2011, and July 29, 2014.

The paper that emerged from the collaborative effort was a review article entitled The Mechanism of Action of Phosphodiesterase Type 5 Inhibitors in the Treatment of Lower Urinary Tract Symptoms Related to Benign Prostatic Hyperplasia, ("Giuliano Article"), Dkt. No. 153-6. It was published in European Urology in September 2012. The Giuliano Article assessed and summarized the published literature dealing with the proposed mechanisms of action of PDE5

inhibitors in the treatment of BPH and lower urinary tract symptoms. It concluded that PDE5 isoenzymes are highly expressed in human lower urinary tract tissues, and that PDE5 inhibition "results in smooth muscle relaxation and increased pelvic blood perfusion in these tissues and likely modulates afferent nerve activity." Dkt. No. 153-6, at 10.

The financial disclosure notice at the end of the text of the paper read as follows, Dkt. No. 153-6, at 10:

> **Financial disclosures**: François Giuliano certifies that all conflicts of interest, including specific financial interests and relationships and affiliations relevant to the subject matter or materials discussed in the manuscript (eg, employment/affiliation grants or funding, consultancies, honoraria, stock ownership or options, expert testimony, royalties, or patents filed, received or pending), are the following: François Giuliano is a consultant and lecturer for Eli Lilly and Company and a consultant and investigator for Bayer-Schering. Jay Kissel and Lars Viktrup are employees and stockholders of Eli Lilly and Company. The other authors [Dr. Ückert, Mario Maggi, and Lori Birder] have nothing to disclose.

Id.

2. Dr. Ückert's involvement with patents relating to the role of PDE5 inhibitors in treating the signs and symptoms of BPH is as follows:

In 2003, Dr. Ückert and four other inventors applied for a patent on the use of phosphodiesterase inhibitors in the treatment of prostatic diseases. That application ultimately issued as U.S. Patent No. 8,106,061 ("the '061 patent"). Claims 1 and 2 of the '061 patent claimed methods of treating a prostatic disease, including BPH, by administering a selective inhibitor of [PDE4 or PDE5] to a person having such a disease, where the selective inhibitor was one of six identified compounds. Claims 3 through 5 of the patent claimed a method of relaxing

prostatic muscles by administering one of the same six compounds to a person with BPH or lower urinary tract symptomatology.[1] The '061 patent issued on January 31, 2012.

Beginning in the summer of 2011, Dr. Ückert contacted Lilly and sought to have Lilly license the '061 patent. Dkt. No. 153-1. When he learned that the '061 patent did not cover tadalafil, however, he concluded that the '061 patent was not likely to produce any revenue and he abandoned that effort.

Meanwhile, on December 29, 2011, the same inventors filed a continuation application that ultimately issued as the '124 patent. The original claims of that application, Application No. 13/339,561 ("the '561 application") were directed to the use of the same 12 compounds that were listed in the specification of the '061 patent, for use in the prophylaxis and treatment of prostatic diseases, in particular BPH. The specified compounds did not include tadalafil. Unlike the claims of the '061 patent, the claims of the '561 application did not refer to the compounds as inhibitors of PDE IV or V. In addition, none of the claims of the '561 application recited a method of relaxing prostatic muscles, as had claims 3-5 of the '061 patent.

In March 2012, the applicants amended their claims. While several of the claims continued to be limited to the 12 specified compounds recited in the original claims of the '561 application, the first new independent claim was broader. It recited a "medicament useful in the treatment of prostatic disease comprising an inhibitor agent of PDE IV and PDE V," excluding a particular identified compound. That claim, and its dependent claims, covered tadalafil, as did at least some of the claims in all of the subsequent amendments to the application. Amendments (Mar. 19, 2012).

[1] The specification of the '061 patent identified 12 compounds as inhibitors of PDE I, IV, or V, but the claims were drawn to only 6 of those 12 compounds.

Further amendments were made in September 2012. The first independent claim recited a "method for prophylaxis or treatment of prostatic disease comprising administering to a person in need thereof an effective amount of a compound selected from the group consisting of an inhibitor of specific phosphodiesterase (sPDE) I, IV, or V." Another independent claim recited a "method of relaxing prostatic muscles" comprising administering the same compound to a person in need thereof. Amendments (Sept. 10, 2012).

In November 2012, the applicants filed new claims, narrowing the first two independent claims slightly by omitting reference to the inhibition of PDE I. The first independent claim now recited a "method for prophylaxis or treatment of prostatic disease comprising administering to a person in need thereof an effective amount of a compound selected from the group consisting of an inhibitor of phosphodiesterase (PDE) IV or PDE V." The second independent claim was now drawn to "[a] method of relaxing prostatic muscles comprising administering to a person in need thereof an effective amount of a compound selected from the group consisting of an inhibitor of PDE IV or PDE V." A third independent claim recited a "method of inhibiting a subesterase of PDE, wherein the subesterase is PDE IV or PDE V, comprising administering to a patient an effective amount of a compound selected from the group consisting of" certain identified compounds and types of compounds. Amendments (Nov. 20, 2012).

Subsequently, the examiner imposed a species election requirement that required the applicants to elect either PDE IV inhibitors or PDE V inhibitors, and to elect a single species or a grouping of patentably indistinct species of either PDE IV inhibitors or PDE V inhibitors. Office Action Summary (Feb. 21, 2013). The applicants elected the PDE V inhibitors and elected zaprinast as the single, disclosed species of PDE V inhibitor. Response to Requirement for Election of Species (July 22, 2013).

The examiner then rejected the pending claims on several grounds. First, the examiner rejected the claims based on statutory double patenting, finding that they were unpatentable over the '061 patent. Second, the examiner rejected the claims as being indefinite because they recited a method of treating "prostatic disease" but did not identify a particular disease. Third, the examiner rejected the claims as anticipated because the specification characterized "prostatic diseases" as including "impotence." For that reason, a prior art reference directed to the use of a PDE inhibitor to treat erectile dysfunction was deemed anticipating. Fourth, the examiner rejected the claims reciting a method of relaxing prostatic muscles or inhibiting PDE IV or PDE V by administering one of an identified set of compounds. Those claims were found to be anticipated by other prior art that taught the administration of two of the identified compounds. Finally, the examiner rejected all of the claims as obvious in light of several prior art references. The main problem identified by the examiner was that the specification's definition of "prostatic diseases" was so broad that it included erectile dysfunction, and the recitation of inhibitors of PDE IV and PDE V was broad enough to include inhibitors such as sildenafil and zaprinast. It would have been obvious, the examiner explained, to administer those PDE V inhibitors to treat BPH. Moreover, the examiner stated, the prior art suggested that inhibitors of PDE I, PDE IV, and PDE V led to a rise in the concentration of cyclic guanosine monophosphate ("cGMP") in the body, which can cause vasodilatory action, thus suggesting that such inhibitors could be used to treat BPH. Office Action (Sept. 5, 2013), Dkt. No. 158-10.

The applicants responded to those rejections by limiting themselves to the three claims that were ultimately allowed. Thus, the claim that became claim 1 of the issued '124 patent was amended to recite "[a] method for the prophylaxis or treatment of benign prostatic hyperplasia comprising administering to a person in need thereof an effective amount of a compound

selected from the group consisting of an inhibitor of phosphodiesterase (PDE) V excluding a compound selected from the group consisting of [certain named compounds]." Amendment (Dec. 5, 2013), Dkt. No. 158-10. The applicants explained that they had addressed the issue of indefiniteness by identifying a particular disease, BPH; they responded to the anticipation rejection by specifically excluding particular compounds from the claims, including sildenafil. And they challenged the examiner's obviousness rejection on the ground that the treatment of BPH, to which the claims were now limited, was not inherently disclosed in the prior art.

In light of the new claims, the examiner maintained the double patenting rejection but receded from the other grounds for rejection. Office Action (Feb. 5, 2014). After the applicants filed a terminal disclaimer in response to that action, Attorney Remarks (Mar. 25, 2014), Dkt. No. 158-11, the examiner allowed the claims. Notice of Allowability (Apr. 7, 2014). The '124 patent issued on July 29, 2014, and was assigned to UroPep.

Initially, UroPep sought a licensing arrangement with Lilly. When no such agreement was reached, however, UroPep filed this action in July 2015 against Lilly and a Texas company that was alleged to have distributed Cialis through its pharmacy.[2]

DISCUSSION

Under Rule 15(a)(1), Fed. R. Civ. P., a party may amend a pleading once as a matter of course more than 21 days after service of the original pleading or a responsive pleading or a motion under Fed. R. Civ. P. 12(b), (e) or (f). After that, a party may amend a pleading only with the opposing party's consent or leave of court. Fed. R. Civ. P. 15(a)(2). Leave of court is to be freely granted "when justice so requires." Fed. R. Civ. P. 15(a)(2). Although Lilly argues that the motion to amend should be granted because of the liberal standard set forth in Rule

[2] UroPep recently dismissed the action against the Texas company, Brookshire Brothers, Inc. Dkt. No. 162.

15(a)(2), the posture of Lilly's motion is quite different from a motion to amend that is filed within the time allotted by the scheduling order. In this case, because Lilly's motion was filed eight months after the deadline for filing amended pleadings, Lilly faces a much stricter standard.

Once a scheduling order has been entered in a case and a deadline has been set for filing amended pleadings, the decision whether to permit a post-deadline amendment is governed by Fed. R. Civ. P. 16(b). See Squyres v. Heico Companies, L.L.C., 782 F.3d 224, 237 (5th Cir. 2015); EEOC v. Serv. Temps Inc., 679 F.3d 323, 333-34 (5th Cir. 2012); L.G. Motorsports, Inc. v. NGMCO, Inc., No. 4:11-cv-112, 2013 WL 2543398, at *6 (E.D. Tex. June 6, 2013). Under Rule 16(b)(4), Fed. R. Civ. P., a motion to modify the scheduling order by permitting the filing of an amended pleading after the deadline in the scheduling order may be granted "only for good cause and with the judge's consent."

The party seeking to modify a scheduling order has the burden to show good cause. Squyres, 782 F.3d at 237; Self v. Quinn's Rental Servs. (USA), LLC, Civil Action No. H-15-1569, 2016 WL 6835093, at *1 (S.D. Tex. Nov. 21, 2016). Moreover, the Fifth Circuit has held that Rule 16 gives trial courts "broad discretion to preserve the integrity and purpose of the pretrial order." Geiserman v. MacDonald, 893 F.2d 787, 790 (5th Cir. 1990) (quoting Hodges v. United States, 597 F.2d 1014, 1018 (5th Cir. 1979)). That court has directed that in deciding whether to permit amendments to the pleadings after the deadline for such amendments, district courts should consider "(1) the explanation for the party's failure to [timely move for leave to amend]; (2) the importance of the [amendment]; (3) potential prejudice in allowing the [amendment]; and (4) the availability of a continuance to cure such prejudice." United States ex rel. Bias v. Tangipahoa Parish Sch. Bd., 816 F.3d 315, 328 (5th Cir. 2016) (quoting S&W Enters., L.L.C. v. SouthTrust Bank of Ala., N.A., 315 F.3d 533, 536 (5th Cir. 2003) (alterations

in original)); Filgueira v. U.S. Bank Nat'l Ass'n, 734 F.3d 420, 422 (5th Cir. 2013); Ciena Corp. v. Nortel Networks, Inc., 233 F.R.D. 493, 494 (E.D. Tex. 2006). The Court will consider each of those factors in exercising its discretion whether to grant the motion to amend.

1. Lilly's Explanation for its Untimely Motion to Amend

Lilly filed its Motion to Amend eight months after the deadline for filing amended pleadings. Lilly argues that its belated filing was justified on the ground that it needed to wait until after Dr. Ückert's deposition to "confirm" that he had not disclosed his conflict of interest to European Urology or to Lilly. The Court does not find Lilly's justification for its untimely motion to be convincing.

Even before the case was filed, Lilly was aware of both Dr. Ückert's co-authorship role with respect to the Giuliano Article and his contemporaneous activities as an inventor of the '124 patent. The patent issued in July 2014, a year before this case was instituted. UroPep contacted Lilly in 2014, seeking to license the '124 patent to Lilly, Dkt. No. 158-12, so it is clear that Lilly was aware of the '124 patent, on which Dr. Ückert was listed as a named inventor, well before this lawsuit was filed.

If Lilly had focused on the conflict-of-interest issue that it now says constituted egregious misconduct on Dr. Ückert's part, it would have been a simple matter (1) to determine whether Dr. Ückert had made a disclosure to Lilly regarding his interest in the '061 patent or the '561 application by inquiring of the Lilly representatives that had contact with Dr. Ückert during the preparation of the Giuliano Article; (2) to determine whether he had made any such disclosure to European Urology, by inquiring of that publication; or (3) to determine whether any such disclosure had been made, by seeking that information through an interrogatory or a request for admission. Although Lilly states that it was not reasonable to expect it to begin the discovery

process as early as April 2016, there was nothing that prevented Lilly from doing so. See EEOC v. Serv. Temps Inc., 679 F.3d 323, 334 (5th Cir. 2012) (upholding finding that party had failed to provide a plausible explanation for its delay in seeking to amend its pleadings when it "waited almost six months before commencing discovery, allowing the pleadings deadline to pass in the meantime"). Thus, even accepting Lilly's contention that it needed to "confirm" that Dr. Ückert had not made a conflict-of-interest disclosure to European Urology, Lilly could have obtained the information necessary to satisfy itself on that point well before the deadline for filing amended pleadings in April 2016.

In any event, there was no real need for Lilly to wait for such "confirmation" of the absence of any conflict-of-interest disclosure on Dr. Ückert's part. By its own admission, Lilly had all the information it needed to plead its unclean hands defense except for an express acknowledgement from Dr. Ückert that he had not made a conflict-of-interest disclosure of which Lilly was unaware. There was no need for Lilly to wait until the deposition of Dr. Ückert to obtain sufficient confirmation of that fact. See Squyres, 782 F.3d at 238 ("Squyres fails to show good cause for his delay. Squyres's only reason for failing to amend his complaint sooner is that he did not have the basis to allege a fraud claim until after he had deposed Frediani in mid-August 2013."). Lilly's choice to wait until after the time for amending the pleadings simply because it did not have confirmation of the absence of a disclosure from Dr. Ückert's lips is not a satisfactory excuse for the delay in moving to amend Lilly's answer.[3]

[3] Lilly attributes the delay in amending its pleading in part to the Court's stay of discovery for a period between July 6 and October 21, 2016 to permit briefing of early summary judgment motions on non-infringement and invalidity. See Dkt. Nos. 119, 120. That period of delay did not materially change Lilly's position with respect to this motion. By the time of the stay, the time for Lilly to amend its pleadings had already long since expired, and in any event, as the Court has explained, there is no persuasive reason that Lilly needed to wait for Dr. Ückert's deposition before filing its amended answer.

The "explanation for the untimely motion" factor cuts against Lilly.

2. The Importance of the Amendment

Lilly argues that allowing it to amend its answer is of critical importance because the defense of unclean hands, if successful, would dispose of this case in Lilly's favor. Of course, it is typically the case that success on the defense of unclean hands ends a patent infringement action. See Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1384 (Fed. Cir. 2006). But that is not to say that an amendment raising such a defense must invariably be regarded as important. What is called for in determining the importance of the amendment is not just an assessment of the theoretical effect of success on the defense being asserted, but a pragmatic judgment as to the likelihood that the newly asserted defense will succeed. See Filgueira, 734 F.3d at 423 ("Filgueira fails to show the importance of his amendment" because "it would not have changed the outcome of the court's ruling" on the motion to dismiss.); Sw. Bell Tel. Co. v. City of El Paso, 346 F.3d 541, 547 (5th Cir. 2003) (treating "likely failure of the proposed counterclaims on the merits" as a factor weighing against allowing untimely amendment); see also Bombardier Aerospace Corp. v. United States, 831 F.3d 268, 284 (5th Cir. 2016) (futility of amendment supports decision to deny motion to amend); Tangipahoa Parish Sch. Bd., 816 F.3d at 328 (same); Nourison Rug Corp. v. Parvisian, 535 F.3d 295, 299 (4th Cir. 2008) (same). In this case, the Court concludes that the defense of unclean hands would be highly unlikely to succeed. For that reason, the Court regards the amendment as not being of sufficient importance to justify overlooking Teva's failure to meet the filing deadline.

a. The defense of unclean hands is reserved for extreme circumstances. As Judge Payne recently explained, for a defendant in a patent case to establish the defense of unclean hands, the defendant "must show that the patentee conducted itself as to shock the moral sensibilities of the

judge, or stated otherwise, that the patentee's conduct was offensive to the dictates of natural justice." iFLY Holdings LLC v. Indoor Skydiving Germany GmbH, Case No. 2:14-cv-1080, 2016 WL 3675136, at *1 (E.D. Tex. Mar. 25, 2016); see also Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp., 343 F. Supp. 2d 272, 320 (D. Del. 2004). Moreover, a party asserting unclean hands "bears the burden of proving by clear and convincing evidence that [the opposing party] acted with unclean hands." In re Omeprazole Patent Litig., 483 F.3d 1364, 1374 (Fed. Cir. 2007); Aptix Corp. v. Quickturn Design Sys., Inc., 269 F,.3d 1369, 1374 (Fed. Cir. 2001).

Importantly, an unclean hands defense requires that there be a nexus between the improper conduct and the legal issues in the case. To successfully invoke the unclean hands doctrine, the defendant must point to an unconscionable act by the patentee that has an "immediate and necessary relation to the equity" of the relief that the patentee seeks. Keystone Driller Co. v. Gen. Excavator Co., 290 U.S. 240, 245 (1933).

That nexus requirement has been articulated in different ways. Several courts of appeals, including the Fifth Circuit, have held that proof of nexus requires a showing that the defendant was injured by the wrongful conduct. See Bailey v. TitleMax of Ga., Inc., 776 F.3d 797, 801-802 (11th Cir. 2015) ("To assert an unclean hands defense, a defendant must show that (1) the plaintiff's wrongdoing is directly related to the claim, and (2) the defendant was personally injured by the wrongdoing."); Alcatel USA, Inc. v. DGI Techs., Inc., 166 F.3d 772, 796 (5th Cir. 1999) ("To invoke the doctrine [of unclean hands] a defendant must show that he was injured by the plaintiff's acts."); Mitchell Bros. Film Grp. v. Cinema Adult Theater, 604 F.2d 852, 863 (5th Cir. 1979) ("The maxim of unclean hands is not applied where plaintiff's misconduct is not directly related to the merits of the controversy between the parties, but only where the wrongful acts 'in some measure affect the equitable relations between the parties in respect of something

brought before the court for adjudication. . . . The alleged wrongdoing of the plaintiff does not bar relief unless the defendant can show that he has personally been injured by the plaintiff's conduct."); Calloway v. Partners Nat'l Health Plans, 986 F.2d 446, 451 (11th Cir. 1993) (same); Lawler v. Gilliam, 569 F.3d 1283, 1294 (4th Cir. 1978) (defense of unclean hands "requires the defendant to show that he himself has been injured by the plaintiff's conduct"); Bambu Sales, Inc. v. Testini, No. 87 CV 3190, 1988 WL 138055, at *3 (E.D.N.Y. Dec. 21, 1988) (defendant must show "that he has been personally injured by the plaintiff's conduct."); Castle v. Cohen, 676 F. Supp. 620, 627 (E.D. Pa. 1987) (unclean hands doctrine requires that party seeking affirmative relief is guilty of unconscionable conduct that is "directly related to the matter in issue, . . . that injures the other party . . . and affects the balance of equities between the litigants"); see also John Norton Pomeroy, A Treatise on Equity Jurisprudence § 399, at 99 (5th ed. 1941) ("The party to a suit, complaining that his opponent is in court with 'unclean hands' because of the latter's conduct in the transaction out of which the litigation arose, or with which it is connected, must show that he himself has been injured by such conduct, to justify the application of the principle to the case. The wrong must have been done to the defendant himself and not some third party.").

The Federal Circuit has required a showing of "materiality" to establish the defense of unclean hands. Regents of the Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1571 (Fed. Cir. 1997); J.P. Stevens & Co. v. Lex Tex Ltd., Inc., 747 F.2d 1553, 1560 n.7 (Fed. Cir. 1984). Although the Federal Circuit stated in Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc), that "the early unclean hands cases do not present any standard for materiality," that comment simply reflects that the early cases do not provide any explicit definition for the materiality requirement, not that they do not require materiality at all.

In fact, the early cases, beginning with Keystone Driller, require that the offending act be material, but they do not define the materiality requirement with great specificity. In Keystone Driller, the Supreme Court stated that the doctrine of unclean hands does not apply "unless the wrongful conduct is directly connected with and material to the matter in litigation," 290 U.S. at 244 (emphasis added), and "in some measure affect[s] the equitable relations between the parties in respect of something brought before the court for adjudication," id. at 245. In two other early Supreme Court cases, the Court held that the nexus requirement was satisfied not because the wrongful act resulted in injury to the innocent party, but because it resulted in an unjust benefit to the offending party. In those cases, the doctrine of unclean hands was invoked to prevent the "wrongdoer from enjoying the fruits of its transgression," Precision Instrument Mfg. Co. v. Automotive Maintenance Mach. Co., 324 U.S. 806, 815 (1945); see also Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238, 251 (1944) (patent at issue was "obtained by fraud").

Other courts have found the nexus requirement satisfied where the nexus between the misconduct and the claim is "close," and the unconscionable act is "immediately related to the equity the party seeks in respect to the litigation," Highmark, Inc. v. UPMC Health Plan, Inc., 276 F.3d 160, 174 (3d Cir. 2001); where the plaintiff's actions "might have damaged" the defendant's interests, and "were directly related to the equities between the parties," Saxon v. Blann, 968 F.2d 676, 680 (8th Cir. 1992); and where the "bad conduct constituting unclean hands" has been directed "toward the party proceeded against" and has "pertain[ed] to the subject matter involved [in the action] and affect[ed] the equitable relations between the

litigants." Int'l Union, Allied Industrial Workers of Am., AFL-CIO v. Local Union No. 589, 693 F.2d 666, 672 (7th Cir. 1982).[4]

Under any of those standards, Lilly's proof of nexus falls short. Lilly has not offered any evidence that Dr. Ückert's failure to disclose the pendency of the '561 application caused injury to Lilly, any unjust benefit to Ückert or UroPep, or was otherwise material to the present litigation. As UroPep points out, Dr. Ückert's failure to comply with European Urology's conflict-of-interest policy is not related to this litigation, because the conflict-of-interest policy was designed to protect European Urology and its readers, not to protect Lilly. As the policy itself makes clear, the purpose of the disclosure requirement is to reveal any possible source of bias on the part of journal authors. See Dkt. No. 153-4, at 4 ("A conflict of interest may exist when an author (or the author's institution or employer) has financial or personal relationships or affiliations that could influence (or bias) the author's decisions, work, or manuscript."). It has nothing to do with protecting a third party such as Lilly against the possible misuse of its confidential information.[5]

[4] In support of its contention that a finding of unclean hands does not require a finding of prejudice to the party asserting the defense, Lilly cites the district court decision in Intamin, Ltd. v. Magnetar Techs. Corp., 623 F. Supp. 2d 1055, 1074-75 (C.D. Cal. 2009), and it quotes, indirectly, from a dissenting opinion of Judge Learned Hand addressed to an entirely different point. The Intamin case recognizes that many courts have adopted an injury requirement, but declined to do so, while nonetheless acknowledging that the plaintiff's conduct must "directly relate[] to the claim which it has asserted against the defendant" and "has immediate and necessary relation to the equity that he seeks in respect of the matter in litigation," 623 F. Supp. 2d at 1074, conditions that are not present here for the reasons explained in the text.

[5] For that reason, if Dr. Ückert had made a full disclosure of his interest in the '124 patent at the time of the European Urology publication, he would have satisfied his conflict-of-interest obligations under European Urology's policy, even though his disclosure would have made no difference at all to the manner in which UroPep prosecuted the '124 patent. During the oral argument, Lilly's counsel contended that if Lilly had been aware of the '124 patent at that time, it could have taken steps such as negotiating a license or other arrangement with UroPep. That argument does not have much force, however, because Lilly was already on notice of the existence of the '561 application, which was published in July 2012, before the publication of the

Lilly's argument as to the impact of Dr. Ückert's conduct is emphatic in tone, but short on substance. The picture Lilly paints is that of a patent applicant who has insinuated himself into Lilly's camp and has obtained confidential information that he has used in fashioning the patent that he plans to—and later does—assert against Lilly. Upon close examination of the facts, that scenario does not stand up.

b. The one point on which Lilly has the better of the argument is that, under the conflict-of-interest and financial disclosure policies of the journal European Urology, Dr. Ückert should have disclosed that he had patents pending (first the '061 patent and then the '124 patent) during the time he was participating in the preparation of the Giuliano Article. The journal's disclosure policy specifically refers to "patents filed, received, or pending," and the financial disclosure section at the end of the Giuliano Article refers to "patent applications in preparation" as a form of "financial interest." Dkt. No. 153-4, at 4.

UroPep's only effort to explain Dr. Ückert's failure to disclose the pendency of the '061 and '124 patents is to contend that the patents were directed not to the mechanism of action of PDE5 inhibitors in treating lower urinary tract symptoms related to BPH (the subject of the Giuliano Article), but to the treatment of BPH. That distinction is unpersuasive, particularly in light of the provision in the European Urology journal's conflict-of-interest and financial disclosure policy that explains that, for example, "authors of a manuscript about prostate cancer should report all financial relationships they have with all manufacturers of products used in the management of prostate cancer, not only those relationships with companies whose specific products are mentioned in the manuscript." Dkt. No. 153-4, at 4. That example indicates that

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Giuliano Article, and because Lilly took no steps to negotiate a license in the fall of 2014 when UroPep approached Lilly after the '124 patent was issued to invite Lilly to take a license to the patent. See Dkt. No. 153-9.

the policy was intended to be applied generously, which would clearly make Dr. Ückert's patents pertinent to the subject matter of the Giuliano Article.

In any event, that was not the excuse Dr. Ückert gave for not disclosing his pending patents. He testified that he did not do so because he thought the disclosure obligations applied only to financial interests. Dkt. No. 155-1 (Ückert deposition, Oct. 18, 2016, at 157:15-23). That answer is unsatisfactory for three related reasons. First, it is contrary to the plain terms of the disclosure policy, which is not limited to direct financial interests. Second, an ownership interest in a patent that the owner intends to enforce against a drug company such as Lilly with regard to a highly successful drug is a financial interest by any reasonable definition. And third, as noted, the European Urology conflict-of-interest and financial disclosure policy specifically defines "patent application in preparation" as a form of financial interest.[6]

So the Court concludes that Lilly is correct that Dr. Ückert failed to make the disclosure that the European Urology journal's policy required him to make. Beyond that, however, Lilly's unclean hands theory loses steam.

c. Because Dr. Ückert did not disclose to Lilly or to the publisher of the Giuliano Article that he was simultaneously seeking a patent on the use of tadalafil and other compounds for the treatment of BPH, Lilly argues that Dr. Ückert was made privy to confidential Lilly information that he could have used in the course of the prosecution of the patent. His conduct, according to

[6] Lilly argues that the Uniform Requirements of the International Committee of Medical Journal Editors imposed a second disclosure obligation on Dr. Ückert that he ignored. It is clear, however, that the financial disclosure requirement of the European Urology journal is simply an application (and a more detailed one) of the principle set forth in the Uniform Requirements. To the extent that the latter is significant, it is only because Dr. Viktrup called Dr. Ückert's attention to it in his email correspondence. It does not add anything of substance to the obligation of disclosure imposed on Dr. Ückert.

Lilly, is sufficiently grave to trigger the unclean hands doctrine and require that the '124 patent be declared unenforceable.[7]

The problem is that there is very little by way of evidence to back up that theory. What is missing from Lilly's proof of unclean hands is any evidence that Dr. Ückert's participation as a co-author of the Giuliano Article had any effect on the prosecution of the '561 application. It was Lilly's representative who invited Dr. Ückert to participate in the authorship of the Giuliano Article because of his valued expertise. Dr. Ückert did not seek to collaborate with Lilly scientists; rather, Lilly offered him the opportunity to collaborate, subject only to his willingness to sign a confidentiality agreement, which Lilly does not contend he breached.[8] Moreover, Lilly was aware, at least as of early 2012, that Dr. Ückert and his group had obtained the '061 patent. Lilly was also aware that, as early as mid-2011, Dr. Ückert had sought to license UroPep's '061 patent to Lilly on account of Lilly's interest in tadalafil. It could hardly have come as a surprise to Lilly that Dr. Ückert and his group were continuing their efforts to obtain patent protection for their research efforts. In fact, UroPep's efforts leading to the '124 patent were publicly disclosed in July 2012, when the '561 application was published, along with the entire prosecution history

[7] In its briefs, Lilly did not argue that Dr. Ückert violated the confidentiality agreement he signed with Lilly. During the oral argument, counsel for Lilly claimed that Dr. Ückert had violated the confidentiality agreement, but because that contention was not raised in Lilly's briefs and was raised for the first time during oral argument, it is waived. See Braun v. Colvin, No. 1:14-cv-744, 2015 WL 4532617, at *4 (S.D. Ind. July 27, 2015); Keys v. Dart Container Corp., Civil Action No. 1:08-cv-138, 2012 WL 2681461, at *6 (W.D. Ky. July 6, 2012) Bd. of Managers of Mason Fisk Condominium v. 72 Berry St., LLC, 801 F. Supp. 2d 30, 39 (E.D.N.Y. 2011); In any event, however, for completeness the Court will address Lilly's arguments based on the assertion that Dr. Ückert violated his confidentiality obligations to UroPep as if that argument had been preserved.

[8] In an apparent effort to put some rhetorical spin on the facts, Lilly states that Dr. Ückert "jumped" at the opportunity to collaborate with Lilly researchers on the review article. Dkt. No. 153, at 2. In fact, the evidence shows that Dr. Ückert did not even respond to Dr. Viktrup's first invitation to participate in preparing the article, and that it wasn't until Dr. Viktrup contacted him again, several weeks later, that Dr. Ückert agreed to participate. See Dkt. No. 153-3.

for the application up to that point. See Dkt. No. 167-3.[9] For that reason, Dr. Ückert's failure to disclose, prior to the publication of the Giuliano Article in September 2012, that UroPep had a pending patent application could not have affected Lilly, since the fact that Dr. Ückert had an interest in the '561 application was publicly known even earlier, in July 2012.

Even more importantly, Lilly has pointed to no evidence that in the course of preparing his sections of the Giuliano Article Dr. Ückert obtained any confidential information from Lilly that he or his colleagues used in the prosecution of the '124 patent. His role in preparing those sections of the article was to summarize the literature on two discrete subjects—the localization of PDE5 in the bladder, prostate, and urethra; and the mechanism by which enhancement of the cGMP pathway, such as by inhibiting the activity of PDE5, can affect the relaxation of smooth muscle cells in the lower urinary tract.

In his declaration, Dr. Ückert states that the Giuliano Article was simply a review of the literature on the mechanisms of action of PDE5 inhibitors and that the "evidence" supporting the article was publicly available research, "especially articles published in the ten years prior to publishing the Giuliano Article." He further states that he does not recall receiving any information, "let alone confidential information, from Dr. Viktrup or anyone else at Lilly in relation to the Giuliano Article." The only information that he could recall having been provided was draft manuscripts of the article from Dr. Giuliano. Dkt. No.158-5.

Lilly offers nothing of substance by way of rebuttal to that denial. The evidence makes it clear that, as Dr. Ückert said, the Giuliano Article was a review article that was intended to review recent medical literature on the mechanism of action of PDE5 inhibitors in the treatment

[9] By July 2012, the claims of the '561 application were broad enough to cover tadalafil. Lilly is therefore wrong in contending that the publication of the '561 application did not put it on notice that the application covered tadalafil.

of lower urinary tract symptoms, not a report of a clinical or experimental study. In fact, the email in which the Lilly representative outlined the purpose of the article explained that even though there had been several recent review articles on the same subject, including a review article focusing on tadalafil, "we believe there is a need for a simplified review focusing on a few key areas . . . incorporating newly published data and developed images," and that such a "simplified [mechanism of action] review article" would be "useful also for the non-experts."

Even though the article merely summarizes other published research papers, Lilly asserts that "Dr. Ückert's collaboration on this manuscript gave him confidential, or at least unique, insights into how Lilly had developed tadalafil as a treatment for the symptoms of BPH and how Lilly believed that tadalafil might work for that purpose." Eli Lilly & Company's Reply in Support of its Motion to Amend, Dkt. No.164, at 3. But Lilly offers no evidence that any such confidential or unique insights were provided to Dr. Ückert. Nor does Lilly point to any evidence that any such information would have assisted Dr. Ückert or UroPep in prosecuting the claims that ultimately issued in the '124 patent.

During the oral argument, Lilly's counsel argued that Lilly scientists provided confidential information to Dr. Ückert, which he exploited in prosecuting the '124 patent. In particular, counsel pointed to a November 22, 2011, email and the conclusion of the Giuliano Article for support for his contention that Lilly conveyed confidential information to Dr. Ückert during the course of the preparation of the article.

The email was sent to all of the authors of the Giuliano Article at the outset of the process of preparing the article. The pertinent portion of the email reads as follows:

> The mechanism of action for tadalafil in the treatment of signs and symptoms of BPH has continued to be an area of debate. Though there is an increasing amount of literature on the mechanistic role of NO/cGMP pathway and PDE5 inhibition in the LUT [lower

> urinary tract], insignificant peak flow rate improvement in several clinical studies and the erectogenic improvements with PDE5 inhibitors have contributed to the question of how PDE5 inhibitors (specifically tadalafil) reduce LUTS [lower urinary tract symptoms].
>
> . . . .
>
> We believe the review should focus on PDE5 localization in the LUT and associated vasculature, the role of PDE5-inhibition in smooth muscle relaxation, increased blood perfusion and modulation of afferent nerve activity in the LUT. The focus should be on tadalafil, where appropriate.

Dkt. No. 153-3, at 10.

The conclusion of the Giuliano Article, to which Lilly attaches particular significance, states that "PDE5 inhibition results in smooth muscle relaxation and increased pelvic blood perfusion in these tissues and likely modulates afferent nerve activity." The article then concludes as follows:

> We propose that the improvement in both storage and voiding urinary symptoms observed after 1-2 wk of tadalafil could be caused by the smooth muscle cell relaxation in bladder neck, prostate, and urethra, with the maintenance of effect possibly supported by the smooth muscle cell relaxation of these organs' vascular supply and increased blood perfusion and oxygenation. Modulation of the sensory output from the LUT is likely to play a role in both the short and long term.

Dkt. No. 153-6, at 10.

Lilly contends that the conclusion of the article, like the email, is indicative of the confidential information shared with Dr. Ückert. The problem with that argument is that there is nothing confidential, or even new, in either the email or the conclusion of the Giuliano Article.

The email suggests that the article should focus on the localization of PDE5 inhibitors in the lower urinary tract and associated blood vessels, and the role of PDE5 inhibitions in three areas: smooth muscle relaxation, increased blood flow, and the modulation of nerve activity in

the lower urinary tract. Dkt. No. 153-3, at 10. The article follows that outline. A section written by Dr. Ückert reviews the studies regarding the localization of PDE5 in various portions of the lower urinary tract. Dkt. No. 153-6, at 5-7. Then, in a section co-authored by Dr. Ückert, the article summarizes the research papers—many of them authored by Dr. Ückert himself—showing that PDE5 inhibition can cause the relaxation of smooth muscle cells in various parts of the lower urinary tract. Id. at 7-8. The following section reviews the research suggesting that reduced blood supply to the lower urinary tract might underlie lower urinary tract symptoms. It also notes that "preliminary findings" in the cited studies indicate that PDE5 inhibitors "might relax [lower urinary tract] vasculature and consequently increase blood supply and tissue oxygenation, therefore possibly ameliorating urinary function and reduce BPH-related [lower urinary tract symptoms]. Id. at 8. Finally, the article contains a section summarizing the evidence that certain well-known chemical processes in the body ("the NO[nitric oxide]/cGMP pathways") that are affected by PDE inhibitors "play important roles in the function of the nervous system in the lower urinary tract," such as the effect of PDE5 inhibitors in decreasing "the perception of bladder filling, thereby reducing the sensation of urgency." Id. That section concludes: "Taken together, these studies show support for NO/cGMP pathway and a [mechanism of operation] for PDE5 inhibition in the reduction of afferent nerve activity in both bladder physiology and pathophysiology." Id. at 9-10.

Aside from the assertions of Lilly's counsel during the oral argument, there is no support for Lilly's contention that the email and the contents of the Giuliano Article (or any disclosure made during the preparation of that article) reflect confidential Lilly information or "unique insights" that Dr. Ückert was able to exploit in obtaining his patent. As the preceding summary of the Giuliano Article indicates, the article broke no new ground, but was simply a synopsis of

the research on various possible mechanisms by which PDE5 affects lower urinary tract symptoms. And the tentative conclusions of the article are consistent with the research showing the effects of PDE5 inhibition on various lower urinary tract sub-systems.

Lilly argues that the applicants made changes to the claims in the course of the prosecution of the '124 patent and that those changes could have been influenced by the information that Dr. Ückert obtained from Lilly during the preparation of the Giuliano Article. In fact, however, as the earlier review of the prosecution history makes clear, most of the changes in the claims were made in response to specific comments or rejections by the examiner. In particular, it was the examiner who required the applicants to define the particular condition that was the target for treatment; it was the examiner who objected to the inclusion of some of the compounds that had been recited in the '061 patent; and it was the examiner who imposed a species election requirement that forced the applicants to focus on inhibitors of PDE5. Moreover, the changes to the claims in response to the examiner's rejections were made in December 2013, more than a year after the publication of the Giuliano Article and two years after Dr. Ückert began his work on the article. Lilly points to no evidentiary basis to support its suggestion that Dr. Ückert and his colleagues exploited Dr. Ückert's participation in the preparation of the Giuliano Article to their benefit in the prosecution process 18 months to two years later.

During the oral argument, counsel for Lilly pointed out that the claims in the original application for the '124 patent, filed on December 29, 2011, did not cover tadalafil. It was not until an amendment made on March 19, 2012, that the '561 application included a broad claim that would have encompassed tadalafil. Amendments (Mar. 19, 2012), at 1 (claim 9). Counsel contended that the amendment to include tadalafil might have been provoked by information

provided to Dr. Ückert by Lilly during Dr. Ückert's collaboration on the Giuliano Article. There is no evidence to support that supposition. It seems much more likely that the addition of claims to cover tadalafil was the result of the publication of the revised Cialis label that included treatment of the signs and symptoms of BPH, which occurred before UroPep amended its claims in early 2012. It would not be surprising (or in any way improper) that in light of that public information UroPep elected to broaden the claims of the '124 patent to cover tadalafil. It is well established that it is permissible to file, amend, or insert claims that cover a particular product when the information about that product is obtained through legal and ethical means. Kingsdown Med. Consultants, Ltd. v. Holister, Inc., 863 F.2d 867, 874 (Fed. Cir. 1988).

Lilly also argues that the change in approach between the '061 patent and the '124 patent was attributable to the information Dr. Ückert received from Lilly during his work on the Giuliano Article. Lilly notes that several of the claims of the'061 patent were directed to a particular mechanism of action (relaxing prostatic muscles), while the original claims of the '561 application were not limited in that manner. The omission of a claimed mechanism of action in the '561 application was likely triggered, according to Lilly, by Dr. Ückert's learning from Lilly that the mechanism by which PDE5 inhibitors treat the signs and symptoms of BPH is unknown. Again, that assertion is based entirely on speculation. Moreover, as noted, the revised Cialis label was approved by the Food and Drug Administration in the fall of 2011, and, the revised label stated that "[t]he mechanism for reducing BPH symptoms has not been established." Dkt. No. 158-2, at 12. Therefore, Lilly's position as to the questions about the mechanism of action of PDE5 in treating BPH was publicly known by the time that label was published; there was no need for UroPep or Dr. Ückert to rely for that information on anything that Dr. Ückert learned from Lilly in the course of preparing his sections of the Giuliano Article.

In any event, the difference in approach between the ’061 patent and the’561 application is not as great as Lilly suggests. It is true that a mechanism of action—relaxation of prostatic muscles—was claimed in claims 3-5 of the ’061 patent (but not in claims 1-2 of that patent). And it is true that no method of action was claimed in the original claims of the ’561 application or the March 19, 2012, amended claims. But the same mechanism of action (“relaxing prostatic muscles”) was claimed in the September 10, 2012, amendments to the ’561 application as well as in the November 20, 2012, amendments to the application. There is thus no plausible basis for inferring that Dr. Ückert’s collaboration with Lilly scientists on the Giuliano Article provided Dr. Ückert with information not otherwise available that caused UroPep to omit claims to a mechanism of action in the original claims of the ’561 application and the claims of the March 19, 2012, amendment to that application.

Almost as significant as the infirmities in the evidence that Lilly relies on is the absence of affirmative evidence regarding what Lilly characterizes as “Lilly’s insights and evaluation of the potential mechanisms of action for treatment of symptoms of BPH using tadalafil,” Motion to Amend at 1, Lilly’s “confidential insight and evaluation of the potential mechanisms of action regarding tadalafil,” id. at 5, and Lilly’s “confidential, or at least unique, insights into how Lilly had developed tadalafil as a treatment for the symptoms of BPH and how Lilly believed tadalafil might work for that purpose,” Eli Lilly & Company’s Reply in Support of Its Motion to Amend, at 3. Except for the emails sent by Lilly representatives to the authors (including Dr. Ückert) at the outset of the project and a few ministerial emails sent by Lilly representatives at the time the manuscript was being edited, there is no paper trail of communications from Lilly revealing any such “insights and evaluation” of the mechanisms of action regarding tadalafil. Nor has Lilly placed in the record any declarations from the two Lilly scientists (or others at Lilly) who dealt

with Dr. Ückert or the other authors of the Giuliano Article. If the Lilly representatives had provided any confidential or unique information to Dr. Ückert or the other co-authors, they would have been expected to say so. But they didn't.

Lilly complains that some of the materials obtained by Dr. Ückert during the publication process were not produced to Lilly in discovery until after Lilly filed its Motion to Amend. UroPep, however, points out that those specific materials were requested only a few days before Lilly filed its Motion to Amend. In any event, those materials consist almost entirely of drafts of the manuscript of the Giuliano Article, annotated in some cases by European Urology's peer reviewers. Lilly's representatives made only a modest number of comments on the draft manuscript, most of which were stylistic or organizational suggestions. For example, in the portion of the article authored by Dr. Ückert, the Lilly representatives' suggestions included one to add a paragraph so as to "ground the reader." Other comments included questions from the Lilly representatives and suggestions to omit certain materials that were considered outside the scope of the article. Dkt. No. 169, at 5-15. Significantly, Lilly does not cite anything from the draft manuscripts to buttress its defense of unclean hands.

As support for its unclean hands argument, Lilly cites the district court opinion in Gilead Sciences, Inc. v. Merck & Co., No. 13-cv-4057, 2016 WL 3143943 (N.D. Cal. June 6, 2016), which Lilly characterizes as a case "with facts that closely parallel the present dispute." Motion to Amend, at 9. In fact, however, that case is dramatically different from this one, in that the misconduct in that case was both extreme and had a substantial effect on the subject matter of the litigation, unlike in this case. In Gilead, the district court found that Gilead's predecessor in interest provided specific confidential information to Merck pursuant to a nondisclosure agreement and that Merck used that information to tailor its claims to cover Gilead's products.

Id. at *29. Based on those findings, the court concluded that those challenged conduct had an "'immediate and necessary relation to . . . the matter in litigation' because the patents that resulted from this series of unconscionable acts are now asserted against Gilead." Id. (quoting Keystone Driller, 290 U.S. at 245). In this case, by contrast, Lilly has pointed to no evidence that it provided any confidential information to Dr. Ückert, nor any evidence that Dr. Ückert or his co-inventors used any such confidential information in prosecuting the application that issued as the '124 patent. Gilead is therefore of no assistance to Lilly.

Notably, Lilly states that it "does not anticipate that any further discovery regarding this [unclean hands] defense will be necessary," so it appears that the evidence Lilly has set forth in its motion is the best it has on this issue. Under these circumstances, the Court feels comfortable concluding that Lilly's claim of unclean hands is quite weak, given the exacting standard of proof required to mount such a defense. Lilly's evidence is certainly not sufficient to suggest that it could satisfy the "clear and convincing evidence" standard that would apply to proof of the defense of unclean hands at trial.[10] For that reason, the Court concludes that the "unclean hands" defense would be destined to fail and thus is not important to the case.

The "importance" factor cuts against Lilly.

[10] If the unclean hands issue were for a jury to determine, this Court might be less willing to venture a judgment at this stage as to the likelihood of Lilly prevailing on its defense. But the defense of unclean hands, like the defense of inequitable conduct, is an equitable issue for the court. eTool Dev., Inc. v. Nat'l Semiconductor Corp., No. 2:08-cv-196, 2011 WL 12677158, at *1 (E.D. Tex. Dec. 12, 2011); see also Therasense, 649 F.3d at 1285; PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1318 (Fed. Cir. 2000); A.C. Aukerman Co. v. R.L. Chaides Constr. Co., 960 F.2d 1020, 1029,1041 (Fed. Cir. 1992). For that reason, the Court is less diffident about predicting how this issue would be resolved if the issue remained in the case for trial on the merits.

3. Prejudice to UroPep

Lilly contends that there would be no prejudice to UroPep if the Court were to grant Lilly's Motion to Amend. UroPep takes strong issue with that contention. The Court agrees with UroPep. Lilly's contention is that significant additional discovery would not be necessary. That may be true for Lilly, since Lilly acknowledges that it has known for some time that it was contemplating asserting an unclean hands defense, and presumably it has already assembled whatever evidence is available to support its position. But Lilly did not inform UroPep of its intention to move to amend its answer until shortly before filing its Motion to Amend. As a result, UroPep has not conducted any discovery relating to the unclean hands issue or otherwise made preparations to meet the unclean hands defense. Those preparations, UroPep points out, would include a further deposition of Lilly employees such as Dr. Ückert's co-authors, including Lilly employees Dr. Viktrup and Dr. Kissel, possible expert witnesses, and others.[11] Given that both fact discovery and expert discovery have closed and the time for trial is approaching, the burden of preparing to meet a new defense at this late hour would be substantial and constitutes prejudice to UroPep.

The "prejudice" factor cuts against Lilly.

[11] UroPep points out that Lilly did not inform it of Lilly's intention to file its Motion to Amend until after the deposition of Dr. Viktrup, thus depriving UroPep of the opportunity to question Dr. Viktrup on that subject. While Lilly offers to make Dr. Viktrup available for a supplemental deposition, requiring UroPep to conduct another deposition of the same witness is burdensome and constitutes a form of prejudice. The Court also notes that Dr. Viktrup's deposition was held on October 27, 2016, more than a week after Dr. Ückert's deposition, which Lilly says provided the critical evidence for its motion and justified Lilly's delay in filing its Motion to Amend. However, Lilly further delayed filing its motion—and informing UroPep of its intent to file the motion—until after Dr. Viktrup's deposition. This delay further cuts against Lilly with regard to the issue of justifiable delay as well as the issue of prejudice.

4. The Availability of a Continuance.

In theory, the Court could grant a continuance in this case and allow additional fact and expert discovery on the unclean hands theory Lilly seeks to raise. The trial in this case, however, has already been postponed twice, including a postponement directed by the Court over UroPep's objections. UroPep objects to any further continuance of the trial, and the Court is reluctant to delay the disposition of the case any longer. Thus, while a continuance is possible—as is true in almost any case—it would be unfair to UroPep to delay the resolution of this case any longer, and the Court is disinclined to do so without a compelling justification. Accordingly, the Court does not find that the availability of a continuance is a factor that favors granting the Motion to Amend.

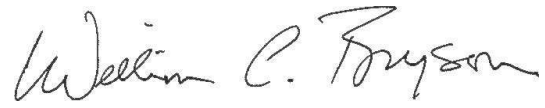
The "availability of a continuance" does not cut strongly in favor of either party, but slightly favors UroPep.

Upon weighing the factors that bear on whether to grant a motion to amend pleadings after the deadline in the Court's scheduling order, the Court concludes that none of those factors favors Lilly. The Court views the "importance of the amendment" factor as particularly significant; if Lilly had made a sufficient showing that it has a substantial "unclean hands" claim, the Court might have been inclined to grant the Motion to Amend notwithstanding Lilly's failure to make a convincing showing on the other factors. But the Court concludes that Lilly's "unclean hands" theory is quite weak. Because Lilly has acknowledged that it needs no more discovery on that issue, and because it has not suggested that there is other evidence in support of its unclean hands defense that it has not referred to in its briefs on this motion, the Court is satisfied that the unclean hands defense would fail and that there is no reason to add a new issue

to the case at this late date when the resolution of that issue appears to be so clear. Accordingly, the Motion to Amend is DENIED.

IT IS SO ORDERED.

SIGNED this 20th day of January, 2017.



WILLIAM C. BRYSON
UNITED STATES CIRCUIT JUDGE