UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
Norfolk Division

PFIZER INC., PFIZER LTD.,

and

PFIZER IRELAND PHARMACEUTICALS UNLIMITED LIABILITY CO.,

Plaintiffs and Counterclaim Defendants,

v. **Civil No. 2:10cv128**

TEVA PHARMACEUTICALS USA, INC.,

Defendant and Counterclaim Plaintiff.

OPINION AND FINAL ORDER

On March 24, 2010, Pfizer, Inc., Pfizer, Ltd., and Pfizer Ireland Pharmaceuticals Partnership[1] (collectively "Pfizer")[2] filed suit in this court against Teva Pharmaceuticals USA, Inc. ("Teva")[3]

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[1] Upon Motion by Pfizer, and over Teva's objection, this court added Pfizer Ireland Pharmaceuticals Unlimited Liability Co. as a plaintiff on June 30, 2011, see Docket # 406, and Pfizer filed an Amended Complaint on the same day. See Docket # 407. The court, by agreement of the parties, dismissed Pfizer Ireland Pharmaceuticals Partnership from this suit on July 14, 2011. See Docket #434; infra note 31.

[2] This Opinion consistently refers to the plaintiffs as a whole as Pfizer; however, when necessary, particularly in Section III, this court refers to specific plaintiffs with reference to their full name.

[3] Pfizer initially brought suit against two defendants: Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. The complaint against Teva Pharmaceutical Industries, Ltd. was dismissed without prejudice upon agreement of the parties on May 4, 2010. See Docket # 26.

alleging imminent infringement of Pfizer's United States Patent No. 6,469,012 ("the '012 patent"), entitled "Pyrazolopyrimidinones for the Treatment of Impotence." United States Patent No. 6,469,012 (filed May 13, 1994) (issued Oct. 22, 2002), Plaintiff's Exhibit (hereinafter referred to as "PTX") 0001. The '012 patent claims the use of certain chemical compounds as a method of treating erectile dysfunction ("ED"). Only Claims 25 and 26 of the '012 patent are in dispute in this case. See Pfizer, Inc. v. Teva Pharms. USA, Inc., No. 2:10cv128, __ F. Supp. 2d __, slip. op. at 9-10 (E.D. Va. Jan. 18, 2011) (noting that only these claims are at issue in this case), Docket # 77.[4]

One of the especially preferred compounds of the '012 patent is sildenafil, the active ingredient in the ED drug Viagra.[5] On October 25, 2004, Teva filed an Abbreviated New Drug Application with the Food and Drug Administration ("FDA") seeking approval to market a generic equivalent of Viagra containing sildenafil citrate. See PTX 238. On April 24, 2007, the FDA granted Teva tentative approval to do so.[6] Pfizer alleges in its Amended Complaint that Teva's

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[4] Pfizer executed a covenant not to sue Teva on Claims 1-23 of the '012 patent on December 8, 2010, see Docket # 64, and the parties agree that only Claims 25 and 26 are at issue now.

[5] Viagra is made of sildenafil citrate, a pharmaceutically acceptable salt of sildenafil.

[6] Teva was granted permission to begin marketing its generic version of Viagra after the expiration of United States Patent Number 5,250,534 ("the '534 patent"), on March 27, 2012. See PTX 244;

planned generic drug will infringe the '012 patent, and seeks a declaration from the court to that effect.

On April 29, 2010, Teva answered the Complaint and filed a Counterclaim against Pfizer seeking a declaration that Teva's planned drug will not infringe the '012 patent and that the claims of the '012 patent are invalid. Teva subsequently sought, and was granted, leave of the court to file an Amended Answer and Counterclaim, which amendment added an allegation that the '012 patent is invalid because of inequitable conduct committed during its prosecution before the Patent and Trademark Office ("PTO").[7] On December 13, 2010, this court held a hearing pursuant to Markman v. Westview Instruments, Inc., 517 U.S. 370, 372 (1996), and issued an opinion on March 17, 2011, construing the disputed terms of the patent. See Pfizer, Inc. v. Teva Pharms. USA, Inc., __ F. Supp. 2d __, 2011 W.L. 996794 (E.D. Va. 2011).

A bench trial in this case commenced on June 15, 2011, lasting for twelve days. At trial, Teva stipulated to infringement, and therefore this issue is not before the court. See Docket # 330. On July 17, 2011, after final arguments had concluded, this court took

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United States Patent No. 5,250,534 (filed June 20, 1990) (issued Oct. 5, 1993). The '534 patent is a compound patent which claims the invention of sildenafil, among other compounds. See infra Section I.C.

[7] Teva's subsequent Motion for Leave to File Proposed Second Amended Answer and Counterclaim, see Docket # 345, is currently pending before this court. See infra Section III.

all outstanding issues under advisement. This Opinion and Final Order addresses and resolves all remaining motions and merits determinations.

I. Factual Overview

The patent in suit in this case is the '012 patent, and in particular Claims 25 and 26, which claim:

> **25.** A method of treating erectile dysfunction in a male human, comprising orally administering to a male human in need of such treatment an effective amount of a compound selected from:
>
> [listing nine different chemical compounds]
>
> or a pharmaceutically acceptable salt thereof;
> or a pharmaceutical composition containing either entity.
>
> **26.** A method as defined in claim **25**, wherein said compound is [listing a chemical compound] or a pharmaceutically acceptable salt thereof, or a pharmaceutical composition containing either entity.

'012 patent col. 10, lines 1-39, PTX 0001.[8] Thus, these claims of the patent teach the oral administration of sildenafil and other

[8] In its decision on claim construction, the court construed the following terms of Claims 25 and 26: (1) "erectile dysfunction" means "an inability to obtain or sustain an erection adequate for intercourse"; (2) "treating erectile dysfunction" requires no construction because a person ordinarily skilled in the art reading the patent would understand its ordinary and customary meaning; (3) "a male human [animal] in need of such treatment" means "a male human in need of treatment for erectile dysfunction"; (4) "an effective amount" requires no construction because a person ordinarily skilled in the art reading the patent would understand its ordinary and customary meaning; and (5) "a method of treating erectile dysfunction in . . . a male human in need of such treatment" means "a method practiced for the purpose of treating erectile dysfunction." Pfizer, Inc. v. Teva Pharms. USA, Inc., 2011 W.L. 996794 at *9.

compounds for the treatment of ED.[9] The '012 patent will expire on October 22, 2019. See Final Pretrial Order ¶ 9, Docket # 267.[10]

As the patent in suit concerns the treatment of ED, bringing with it a host of technical terminology and a background of underlying knowledge, this court will first review the biology and physiology of erections[11] and then will move to a description of the invention and patents concerned.

A.[12]

The penis of a male human contains erectile tissue called the corpus cavernosum, consisting of two corpora cavernosa that run its length. The corpus cavernosum is smooth muscle tissue that is spongy and composed of cavernosal spaces which can expand and fill with blood to produce an erection. The corpus cavernosum is surrounded by fibrous tissue known as the tunica albuginea. When the penis is in a flaccid state, the corpus cavernosum is contracted. An erection is produced when the corpus cavenosum relaxes so that it expands and

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[9] Sildenafil is the compound named in Claim 26 of the '012 patent.

[10] The provisions of the '012 patent will be discussed further, infra, in Section I.C.

[11] In reviewing the biology of erections, the court relies on the testimony of Teva's and Pfizer's urology experts, Dr. Culley C. Carson III and Dr. Irwin Goldstein, respectively.

[12] This Subsection contains information which would not have been available at the time the '012 patent was filed; the court includes it for context. The state of the art at the time of the filing of the application for the '012 patent, with relation to knowledge concerning erectile function, will be addressed, infra, in Section IV.

fills with blood. As the corpus cavernosum relaxes, the tunica albuginea compresses the veins that drain blood from the penis, thus preventing blood from flowing out and raising pressure inside the penis, producing an erection. Detumescence of the penis occurs when the corpus cavernosum contracts and bloods flows out of the penis.

An erection is controlled by the nervous system. There are three neurotransmission pathways in the human body: the adrenergic nerves; the cholinergic nerves; and the non-adrenergic, non-cholinergic ("NANC") nerves. The NANC nerves control erectile function. When a male human reacts to sexual stimuli, the NANC nerves send a signal to the penis. The neurotransmitter in this case is nitric oxide ("NO").[13] Thus, when the NANC nerves send a signal to the penis, they synthesize NO from L-arginine in the endothelial cells of the vascular system. The NO travels into the smooth muscle cells of the corpus cavernosum where it activates an enzyme known as guanylate cyclase. Guanylate cyclase synthesizes another enzyme, cyclic guanosine monophosphate ("cGMP") by interacting with guanosine triphosphate. cGMP is the signaling enzyme that cues smooth muscle tissue, in this case the corpus cavernosum, to relax.[14]

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[13] NO is also referred to as endothelium-derived relaxing factor.

[14] There is also smooth muscle tissue in the vascular system; so at the same time the smooth muscle in the corpus cavernosum relaxes to allow the penis to fill with blood, the arteries into the penis likewise relax, thereby increasing blood flow into the penis.

This entire process is known as the L-arginine-nitric oxide-cyclic GMP pathway.

cGMP is a cyclic nucleotide, a form of enzyme. Enzymes, as is evident from cGMP's function in the smooth muscle described above, are proteins that catalyze chemical reactions in the body. cGMP is degraded by cGMP phosphodiesterase ("PDE"), another enzyme, which binds to cGMP and breaks it down into GMP. GMP does not have the same signaling effect in smooth muscle as cGMP. At the time the '012 patent was filed, there were five known types of PDEs: PDE1, PDE2, PDE3, PDE4, and PDE5. PDE1 and PDE5 both degrade cGMP and, thus, are termed cGMP PDEs.[15]

cGMP PDE can be inhibited by cGMP PDE inhibitors. An inhibitor functions in the same was that cGMP PDE itself functions with cGMP, by binding to it to block or decrease the activity of the enzyme. In other words, cGMP PDE inhibitors bind to cGMP PDE so that it, in turn, cannot bind to cGMP. The effectiveness of a PDE inhibitor is measured in terms of its potency, the amount of the inhibitor required to effectively inhibit the PDE,[16] and its selectivity, i.e., the ratio at which the inhibitor prefers one PDE over another.[17]

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[15] PDE5 is also termed cGMP specific PDE because it only degrades cGMP. PDE1, by contrast, also degrades cyclic andosine monophosphate ("cAMP"), another cyclic nucleotide.

[16] Potency is measured by the half-maximal inhibitory concentration ("IC_{50}") of the compound which measures the concentration of the

B.

Beginning in 1985, Pfizer researchers in Sandwich, England were working on the creation of cGMP PDE inhibitor drugs to treat cardiovascular diseases such as hypertension and angina. Dr. Peter Ellis was the head of the team of biologists on the project, while Dr. Nicholas Terrett led the chemists. Pfizer hoped that cGMP PDE inhibitors would be able to treat these cardiovascular diseases by causing relaxation of the smooth muscle tissue in the arteries, thereby lessening stress on the cardiovascular system. In particular, Pfizer aimed to create compounds that would inhibit cGMP PDEs, thereby enhancing the action of cGMP within smooth muscle and causing smooth muscle relaxation.

The project first started with the chemistry team creating compounds. Such compounds were based off other compounds known to inhibit cGMP PDE, and the chemistry team worked to make such compounds more selective, in terms of which enzyme they inhibited, and more potent in their inhibitory capability.[18] Once the compounds were made, the biology team tested the compounds in assays it designed

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compound required to inhibit 50% of the activity of the PDE. Thus, a lower IC_{50} value indicates a more potent inhibitor.

[17] In order to determine the selectivity of a compound between two PDEs, the ratio between the IC_{50} values for each PDE is determined.

[18] Dr. Terrett testified that Pfizer began with the known cGMP PDE inhibitors zaprinast and a Warner Lambert compound. Trial Tr. 982:1-11.

to determine their selectivity and potency for cGMP PDE. The chemistry team then received feedback and modified the compounds further, if necessary, to improve their biological activity. The chemistry team also ran tests to assess the safety of the compounds, while the pharmacokinetic team studied the compounds to determine their absorption, distribution, metabolism, and excretion in the human body.

The chemistry team first synthesized sildenafil in 1989, and it quickly became a "lead compound," after the biology and pharmacokinetic tests had been run.[19] The results were so encouraging that the team working on the project recommended that Pfizer begin clinical development of sildenafil for the treatment of angina. See PTX 354. A year later, in July 1991, Pfizer began its first clinical trial using sildenafil, Study 201. Trial Tr. 695:21-697:14. As this clinical trial was a Phase I study, the subjects were healthy volunteers, in this case males, and the goal was to assess the safety of the drug and further determine its pharmacokinetic properties. This initial study, and several others after it, all tested single doses of sildenafil.

In 1992, Pfizer began a multiple dose study of sildenafil, again using healthy male volunteers, Study 207. Trial Tr. 697:21-699:9.

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[19] While it was in development at Pfizer, sildenafil was referred to by its compound number, UK-92,480.

The volunteers were administered three doses of sildenafil or a placebo daily for ten days. At the conclusion of the study, volunteers reported several side effects; the most common were myalgia, [20] headaches, and spontaneous erections. The Early Candidate Management Team ("ECMT"), the team charged with the initial testing and development of sildenafil that included Dr. Ellis, was surprised to hear that a common side effect was spontaneous erections, as such a side effect had never been previously reported in Pfizer clinical trials. As a result of this report from the volunteers, the ECMT decided to run a clinical trial with sildenafil directed toward the treatment of ED.

The first Phase II clinical study with sildenafil, Study 350, began on July 28, 1993, and concluded on November 15, 1993. See PTX 471. As it was a Phase II study, its volunteers were males with the targeted disease, i.e., men who suffered from ED. The volunteers were orally administered either sildenafil or a placebo three times a day for seven days. They recorded any erectile activity experienced during the first six days. On the seventh day, while each volunteer was provided sexual stimulation by watching an erotic video, rigidity and circumference of his penis was measured using

[20] Myalgia means muscle pain.

a Rigiscan.[21] The results showed that sildenafil significantly improved erections for those men in the test with ED.

Pfizer then commenced a single dose Phase II study, Study 351, on February 24, 1994, concluding May 30, 1994. Trial Tr. 706:21-707:20. In this study, male volunteers with ED were given a single dose of sildenafil on one occasion, and a Rigiscan was administered. The same volunteers were then given sildenafil once a day for seven days, and they made note of their erectile activity. The results were encouraging and showed a correlation between the administration of sildenafil and improved erectile function for men with ED.

Based on the results of the studies described, Pfizer applied to the FDA for approval of Viagra, sildenafil citrate. Viagra was approved by the FDA in 1998 in New Drug Application No. 20-895 as a drug to treat ED. Viagra works, as the '012 patent states, because it is a PDE5 inhibitor that prevents PDE5 from binding to cGMP and rendering cGMP inactive in the L-arginine-nitric oxide-cyclic GMP pathway, thus increasing the level of cGMP in the corpus cavernosum. Viagra's introduction on the market in 1998 generated a flurry of publicity and interest from scientists and consumers alike. Experts from both parties admitted that Viagra revolutionized the treatment

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[21] A Rigiscan is a medical device which measures penile rigidity and circumference using two loops placed on the penis, one at the base and one near the tip.

of ED, making the treatment both more effective and accessible. Since its introduction in 1998, Viagra has generated cumulative sales of over $10 billion.

C.

After successfully creating sildenafil and other related compounds, Pfizer filed a series of applications for patents.[22] Initially, Pfizer filed several compound patents. The first was European Patent Number 0463756A1 ("EP '756") entitled "Pyrazolopyrimidinone Antianginal Agents," filed June 7, 1991, and published February 1, 1992. PTX 0352. EP '756 first disclosed sildenafil, among other compounds, and claimed such compounds as selective cGMP PDE inhibitors[23] which elevate the levels of cGMP. See EP '756, 3:5-7, PTX 0352. The specification of the patent discloses:

> [T]he compounds have utility in the treatment of a number of disorders, including stable, unstable and variant (Prinzmetal) angina, hypertension, congestive heart failure, atherosclerosis, conditions of reduced blood vessel patency e.g. postpercutaneous transluminal coronary angioplasty (post-PTCA), peripheral vascular disease, stroke, bronchitis, chronic asthma, allergic asthma, allergic rhinitis, glaucoma, and diseases

[22] This Subsection of the Opinion does not exhaustively set out each of the patents referenced at trial. Here, it is sufficient to give an overview of the structure of the patents for sildenafil and its related compounds for contextual purposes. The court will analyze other relevant patents during the discussion of the issues in the case which specifically involve those patents.

[23] The patent stated that the claimed compounds inhibited both types of cGMP PDE: PDE1 and PDE5.

> characterized by disorders of gut motility, e.g. irritable bowel syndrome (IBS).

EP '756, 3:9-14, PTX 0352. Of the compounds in Claims 25 and 26 of the patent in suit, EP '756 disclosed five, including sildenafil.[24]

Pfizer next filed European Patent Number 0526004A1 ("EP '004"), also entitled "Pyrazolopyrimidinone Antianginal Agents," on February 7, 1992. EP '004 was published on March 2, 1993. PTX 0066. EP '004 claimed additional potent and selective cGMP PDE inhibitors useful in the treatment of:

> [S]table, unstable and variant (Prinzmetal) angina, hypertension, pulmonary hypertension, congestive heart failure, atherosclerosis, conditions of reduced blood vessel patency e.g. postpercutaneous transluminal coronary angioplasty (post-PTCA), peripheral vascular disease, stroke, bronchitis, chronic asthma, allergic asthma, allergic rhinitis, glaucoma, and diseases characterized by disorders of gut motility, e.g. irritable bowel syndrome (IBS).

EP '004, 2:10-14, PTX 0066. EP '004 disclosed four of the compounds in Claim 25 of the '012 patent.[25]

Finally, Pfizer filed United States Patent Number 5,250,534 ("the '534 patent") on May 14, 1992. PTX 0002. The '534 patent is the U.S. equivalent of EP '756 and, thus, is also entitled "Pyrazolopyrimidinone Antianginal Agents" and shares the same

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[24] EP '756 will be discussed further in this Opinion as its disclosures relate to Teva's claim that the '012 patent is void for obviousness. See infra Section IV.

[25] EP '004 will be discussed further as concerns obviousness. See infra Section IV.

specification and characteristics of EP '756 described above, including the diseases the compounds were believed to be useful in treating. The '534 patent likewise covers five of the compounds listed in Claims 25 and 26 of the '012 patent, including sildenafil. The '534 patent issued on October 5, 1993.[26] Each of these compound patents – EP '756, EP '004, and the '534 patent – disclosed oral administration of the relevant compounds.

After Pfizer had filed the compound patents for sildenafil and the other cGMP PDE inhibitors, it filed the patent in suit directed to a method of treating ED using some of the compounds from EP '756 and EP '004. Claims 25 and 26 specifically claim oral treatment of ED, and the specification of the patent states that oral administration is the preferred route. '012 patent, col. 5, lines, 62-65, PTX 0001.[27] In the specification of the patent, Pfizer discloses that the compounds of the '012 patent have been found to be potent and selective inhibitors of PDE5 such that they enhance cGMP levels in the corpus cavernosum. Id. col. 5, lines 33-35,

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[26] The '534 patent will also be discussed further as concerns obviousness. See infra Section IV; supra notes 24 and 25.

[27] The preferred dosing regimen disclosed is 5 to 75 mg of the compound three times a day. '012 patent, col. 5, lines 65-66. But see Pfizer, Inc. v. Teva Pharms, 2011 W.L. at *7 (holding that the preferred dosing regimen is not a claim limitation).

39-44, PTX 0001.[28] The '012 patent issued, after overcoming numerous rejections, on October 22, 2002.

With the pertinent factual underpinnings of the case set out, this court turns to the substantive issues remaining before it.

II. Teva's Motion to Dismiss for Lack of Standing

During trial on July 6, 2011, Teva filed a Motion to Dismiss for Lack of Standing. See Docket # 412. Teva argues that Pfizer has failed to carry its burden to demonstrate that each plaintiff has standing to sue for infringement of the patent in suit because it has failed to prove that any plaintiff has sufficient interest in the patent to sue for infringement. Per a briefing schedule set by the court, Pfizer responded in opposition on July 15, 2011, see Docket # 435, and Teva replied on July 20, 2011, see Docket # 451. The motion is now ripe for decision.

A.

The issue of standing in this case is bound up with the evidence on the issue of ownership,[29] and thus the court reviews the evidence

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[28] Pfizer identified the predominant PDE in the corpus cavernosum as PDE5. '012 patent, col. 5, lines 29-32, PTX 0001.

[29] To the extent that the issue of ownership was preserved for trial, this Section of the Opinion resolves questions of ownership as well as standing. However, the court notes that Teva did not preserve ownership as a triable issue in the Final Pretrial Order as to the '012 patent. See Final Pretrial Order, at 277, Docket # 276. Pfizer did so preserve the question, and thus the court addresses it because Pfizer, as the plaintiff, has the burden to prove ownership of the patent in suit, Tyco Healthcare Grp. L.P. v. Ethicon Endo-Surgery,

as to both presented at trial.[30] Looking first to the patent in suit itself, Pfizer, Inc. is named as the owner-assignee on the face of the '012 patent. PTX 0001. Pfizer, Inc. received the assignment of rights to the patent from the patent's inventors, Drs. Nicholas Terrett and Peter Ellis, on October 10, 1995. PTX 0363. In the assignment, Drs. Terrett and Ellis agreed to:

> [S]ell, assign, and transfer unto PFIZER, INC. . . . the entire right, title, and interest in and to our application for Letters Patent of the United States . . . entitled PYRAZOLOPYRIMIDINONES FOR THE TREATMENT OF IMPOTENCE and our entire right, title, and interest in the United States in and to all our inventions, whether joint or sole, disclosed in said application for Letters Patent, and in all and to all United States patents granted on the foregoing inventions.

Id. at 1. On the same day, Pfizer, Ltd., whose employment of Drs. Terrett and Ellis entitled it to claim full rights to the patentable inventions, consented to the assignment, noting that "PFIZER LIMITED desires that PFIZER INC. receive the full benefits of the foregoing assignment by its aforesaid employee(s)." Id. at 3.

Inc., 587 F.3d 1375, 1378 (Fed. Cir. 2009), even though such ownership was not challenged by Teva until trial, raising serious questions concerning waiver.

[30] Pfizer's Vice President and Assistant General Counsel, Mr. Gregg Benson, testified on the first day of trial as to matters of ownership. See Trial Tr. 63:17-98:8. The court does not reference his testimony directly because it, in substance, merely confirmed the terms of the documentary evidence referenced herein, and the court finds the documentary evidence authoritative over the testimony, as the interpretation of the agreements and their relation to standing are questions for the court to decide.

Previously on August 9, 1993, Pfizer, Inc. and Pfizer, Ltd. entered into a Patent Filing Agreement. PTX 0322. The Patent Filing Agreement memorialized "the procedures to be applied in respect of the filing of patent applications resulting from research carried out under the Cost Sharing Agreement [between Pfizer, Inc. and Pfizer, Ltd.] and the procedure applicable to patent applications resulting from other research carried on by LIMITED." Id. at 2. Specifically:

> LIMITED Property patent applications will be filed by PFIZER [INC.] in the USA. . . . In filing such applications, PFIZER [INC.] will act as agent for LIMITED, so that such applications and any patents issued thereon shall be held by PFIZER [INC.] in trust for LIMITED, as the beneficial owner thereof.

Id. at 3-4. In addition, to effectuate the filing of patents, Pfizer, Ltd. agreed that it would be "deemed to assign PFIZER [INC.] . . . all rights necessary . . . to file patent applications hereunder." Id. at 5. In consideration for its filing of the patent applications, Pfizer, Inc. could receive from Pfizer, Ltd. "a non-exclusive license . . . with respect to any such LIMITED Property in the USA." Id. at 6.

After the application for the '012 patent was filed, but before it was issued by the PTO, Pfizer, Ltd. executed a license agreement with Pfizer Pharmaceuticals Production Corporation, effective as of January 1, 1997. PTX 0324. The license agreement concerned patents for sildenafil, either issued or currently pending, including both

the '534 patent and the '012 patent. Id. at 13. Therein, Pfizer, Ltd. granted to Pfizer Pharmaceuticals Production Corporation "(1) an exclusive license under the U.S. Patent Rights to make, use, sell, and offer for sale Licensed Product in the Commercial Territory, and to import Licensed Product into the Commercial Territory and (2) an exclusive license to use the Technical Information in the Commercial territory in connection with the activities referred to [above]." Id. at 4. "Commercial Territory" was defined as the United States of America, id. at 2, and "Licensed Product" was defined as "any drug for human use containing the Compound, [sildenafil]." Id. at 3. Thus, Pfizer Pharmaceuticals Production Corporation received, in essence, an exclusive license to manufacture and sell sildenafil in the United States. This exclusive license was subject to Pfizer, Ltd.'s retained "Conversion Right," the right "to convert the exclusive license granted . . . to a non-exclusive license" at any time when at least 20% remains on the patent term. Id. at 2-4. In return for the exclusive license, Pfizer Pharmaceuticals Production Corporation would pay Pfizer, Ltd. royalties based on net sales in a schedule set out in the agreement. Id. at 6. In the case of infringement of any of the patents covered by the agreement, Pfizer, Ltd. had "the initial right to bring suit in its own name" with Pfizer Pharmaceuticals Production Corporation's cooperation, but if Pfizer, Ltd. failed to bring suit within thirty (30) days, Pfizer

Pharmaceuticals Production Corporation could bring suit in its own name, joining Pfizer, Ltd. and Pfizer, Inc. as necessary. Id. at 7-8.

The license agreement for sildenafil has since "changed hands" several times due to changes in ownership of the entity holding it. First, on January 15, 1998, Pfizer Pharmaceuticals Production Corporation entered into a Sale Agreement with Pfizer Pharmaceuticals Production Corporation, Ltd. for the "entire Irish business and Irish assets of Pfizer Pharmaceuticals Production Corporation." PTX 0325, at 1. As part of the Sale Agreement, Pfizer Pharmaceuticals Production Corporation transferred all of its assets, including all licenses. Id. at 2, 4. The license for sildenafil was specifically noted as one of the licenses that would transfer to the new entity. Id. at 13.

Subsequently, on November 14, 2000, Pfizer Pharmaceuticals Production Corporation, Ltd. entered into an "Agreement for Sale of Business and Assets" with Pfizer Ireland Pharmaceuticals. PTX 0326. Again, as part of this Agreement for Sale, Pfizer Pharmaceuticals Production Corporation, Ltd. transferred to Pfizer Ireland Pharmaceuticals all assets, id. at 4, including contracts and agreements, id. at 5, one of which was the license agreement for sildenafil. Id. at 10.

The license was transferred yet again on November 28, 2003, via an "Agreement for Sale of Business and Assets" between Pfizer Ireland Pharmaceuticals and Pfizer Ireland Pharmaceuticals Partnership. PTX 0209. Pfizer Ireland Pharmaceuticals agreed to transfer to Pfizer Ireland Pharmaceuticals Partnership all of its assets and business, including contracts. Id. at 5. Contracts was defined to include all license agreements undertaken by Pfizer Ireland Pharmaceuticals. Id. at 2. This Agreement for Sale did not, however, list the particular licenses to be transferred.

Finally, on January 10, 2011, Pfizer Ireland Pharmaceuticals Partnership sold all of its assets to Pfizer Ireland Pharmaceuticals Unlimited Liability Co. ("Pfizer Ireland Pharmaceuticals Co."). PTX 0210. Pfizer Ireland Pharmaceuticals Partnership agreed to transfer all of its assets, including its interest in contracts, id. at 7, which was defined to include all license agreements. Id. at 2. Again, there was no schedule listing the specific license agreements transferred. Pfizer Ireland Pharmaceuticals Co. currently holds the license for sildenafil in the United States.

B.

Standing is a jurisdictional requirement for any federal case and may never be waived by the parties. E.g., Sicom Systems, Ltd. v. Agilent Techs., Inc., 427 F.3d 971, 975 (Fed. Cir. 2005); Pandrol USA, L.P. v. Airboss Ry. Prods., Inc., 320 F.3d 1354, 1367 (Fed. Cir.

2003) ("It is well-established that any party, and even the court sua sponte, can raise the issue of standing for the first time at any stage of the litigation, including on appeal."). The party asserting the infringement has the burden to prove that it has standing to do so. Mentor H/S, Inc. v. Med. Device Alliance, Inc., 240 F.3d 1016, 1017 (Fed. Cir. 2001) (per curiam). In patent cases, the law of standing has its sources both in constitutional law and the Patent Act. Beam Laser Sys., Inc. v. Cox Commc'ns, Inc., 117 F. Supp. 2d 515, 520 (E.D. Va. 2000). The Patent Act provides: "A patentee shall have remedy by civil action for infringement of his patent." 35 U.S.C. § 281 (2006). "Patentee" is defined under the Act to include "not only the patentee to whom the patent was issued but also the successors in title to the patentee." Id. at § 100; see also Morrow v. Microsoft, 499 F.3d 1332, 1339 (Fed. Cir. 2007) ("The 'successor[] in title' is the party holding legal title to the patent." (emphasis in original)). Beyond the requirement that a plaintiff must be a "patentee" under the statute to sue for infringement, there is also the constitutional requirement that the party alleging infringement show an injury-in-fact. Morrow, 499 F.3d at 1339.

The Federal Circuit has held that there are three types of parties for standing purposes as concerns patents: "those that can sue in their own name alone; those that can sue as long as the patent

owner is joined in the suit; and those that cannot even participate as a party to an infringement suit." Id. There are three entities that meet the requirements for the first category. It is clear from the statute that the patentee, owner of the patent, is a party that may sue on its own for infringement. 35 U.S.C. § 281; Sicom, 427 F.3d at 976. Additionally, if a patentee assigns its rights in a patent, the assignee may sue for infringement in its own name, Sicom, 427 F.3d at 976, as the assignee has legal title to the patent. Morrow, 499 F.3d at 1339. Finally, an exclusive licensee who has all substantial rights in the patent is treated like an assignee for the purposes of standing. Sicom, 427 F.3d at 976. The court must look to the license agreement to determine if the licensee in fact holds all substantial rights. Ortho Pharm. Corp. v. Genetics Inst., Inc., 52 F.3d 1026, 1030 (Fed. Cir. 1995).

The second category, parties who may sue if the owner of the patent is joined, includes exclusive licensees that do not have all substantial rights in the patent. Indep. Wireless Tel. Co. v. Radio Corp. of Am., 269 U.S. 459, 468 (1926); Sicom, 427 F.3d at 980; Abbott Labs. v. Diamedix Corp., 47 F.3d 1128, 1132 (Fed. Cir. 1995). "An exclusive licensee receives more rights than a nonexclusive licensee, but fewer than an assignee. An example of an exclusive licensee is a licensee who receives the exclusive right to practice an invention but only within a given limited territory." Sicom, 427

F.3d at 976 (citing Rite-Hite Corp. v. Kelley Co., Inc., 56 F.3d 1538, 1552 (Fed. Cir. 1995)). Thus, crucial to the determination of whether an entity is an exclusive licensee is whether the licensee holds exclusionary rights to the patent, the right to "prevent others from practicing the invention." Morrow, 499 F.3d at 1340. "To have co-plaintiff standing in an infringement suit, a licensee must hold some of the proprietary sticks from the bundle of patent rights, albeit a lesser share of rights in the patent than for an assignment and standing to sue alone." Ortho Pharm., 52 F.3d at 1031. In other words, to have standing at all, a licensee must have "beneficial ownership of some of the patentee's proprietary rights." Id. at 1034. Again, the court looks to the license agreement to determine if a licensee is an exclusive licensee.

The final type of entity for standing purposes is a nonexclusive licensee that cannot even join an infringement suit. The Federal Circuit has been clear that "[a] holder of such a nonexclusive license suffers no legal injury from infringement and, thus, has no standing to bring suit or even join in a suit with the patentee." Ortho Pharm., 52 F.3d at 1031. Nonexclusive licensees are "those that hold less than all substantial rights to the patent and lack exclusionary rights under the patent statutes to meet the injury-in-fact requirement." Morrow, 499 F.3d at 1340. Such entities do not meet

the statutory or constitutional requirements of standing and may not join with other parties in pursuing an infringement suit.

The three categories of plaintiffs enumerated above are well-settled in Federal Circuit precedent for establishing standing in suits at law for damages. Moreover, there is one other type of entity that may have standing to sue in equity, in other words for injunctive relief. In Arachnid, Inc. v. Merit Industries, Inc., 939 F.2d 1574 (Fed. Cir. 1991), the Federal Circuit distinguished between entities with standing in law and entities with standing in equity. It held that when an entity has equitable ownership of a patent, that entity may seek only prospective relief in equity, not damages for infringement. Id. at 1579. A party "seeking to recover money damages for infringement of a United States patent (an action 'at law') must have held the legal title to the parent during the time of the infringement." Id. (emphasis omitted). Conversely, if a party only has equitable title, "a federal district court has jurisdiction to consider claims for equitable relief stemming from the alleged infringement." Id. at 1580 (emphasis omitted). This court has recognized the Federal Circuit precedent supporting the conclusion that a party having equitable title to a patent may sue in equity to prevent further infringements. Beam Laser, 117 F. Supp. 2d at 520. With these legal underpinnings, the court turns to the standing issue raised by Teva.

c.

Teva argues that all of the remaining Pfizer entities[31] lack standing to sue for infringement of the patent. For the sake of clarity, the court will consider each of the parties individually.[32] First, Teva argues that Pfizer has failed to prove that Pfizer, Inc. has standing to sue because it has not shown Pfizer, Inc. has an ownership interest in the patent sufficient to establish standing. In particular, Teva submits that the Patent Filing Agreement between Pfizer, Inc. and Pfizer, Ltd., in which Pfizer, Inc. holds the filed patents in trust for Pfizer, Ltd. as the beneficial owner, demonstrates that Pfizer, Inc. has no substantial ownership rights in the patent. Pfizer responds that such ownership is evident and unassailable from the fact that Pfizer, Inc. is listed on the face of the '012 patent as the assignee of the inventors and, thus, is recognized as owner of the patent.

The court agrees with Pfizer, as it is not open for debate that Pfizer, Inc. is the legal owner of the '012 patent. The assignment agreement, as reflected in the patent itself, rendered Pfizer, Inc.

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[31] As a result of an agreement of the parties and by Order on the final day of trial, July 13, 2011, the court dismissed Pfizer Ireland Pharmaceuticals Partnership from the case for lack of standing. See Docket #433; supra note 1.

[32] Overall, however, the court notes that Teva's argument boils down to the contention that essentially no entity owns the '012 patent and no party has a sufficient interest in the patent to sue for infringement.

the legal title holder of the patent. See 35 U.S.C. § 100. Furthermore, there is no evidence that Pfizer, Inc. has assigned its interest to any other party such that it would lose its presumptive right to enforce the patent. Accordingly, Pfizer, Inc. has standing to sue in its own name on the patent.

Next, Teva argues that Pfizer, Ltd. lacks standing to sue on the patent, either because Pfizer has failed to demonstrate that the Patent Filing Agreement was utilized for the application for the '012 patent, or because Pfizer has failed to establish that Pfizer, Ltd., as a beneficial owner of the patent, has sufficient proprietary rights to enforce it. Pfizer responds that Pfizer, Ltd. has standing to enforce the patent, both because it is the equitable owner of the patent seeking equitable relief, and because per the explicit terms of the Patent Filing Agreement, it has the right to exclude others from practicing the invention.

At the outset, the court disagrees with Teva that the assignment and application for the '012 patent were done outside the parameters of the Patent Filing Agreement. The evidence in this case demonstrates that the assignment and application specifically were done in keeping with the Patent Filing Agreement. In particular, the inventors, whose invention would normally have been property of their employer, Pfizer, Ltd., assigned all of their rights in the invention to Pfizer, Inc. for the purposes of filing a patent

application. See PTX 363. This assignment follows the terms of the Patent Filing Agreement, because therein the parties agreed that the inventions, which would be the property of Pfizer, Ltd., would be held in trust by Pfizer, Inc., so that Pfizer, Inc. could prosecute the patent in the United States. See PTX 0322, at 3-4. In order to facilitate this process, Pfizer, Ltd. consented to the assignment. In other words, the evidence of an assignment is not proof that the Patent Filing Agreement was ignored by the parties; rather it is proof that it was in effect, because without the assignment from the inventors, Pfizer, Inc. could not have prosecuted the application for Pfizer, Ltd.

Although the court has determined that the '012 patent is subject to the Patent Filing Agreement, it remains for the court to determine what rights Pfizer, Ltd. retained in the patent under that agreement and whether such rights are sufficient to create standing. As stated in the Patent Filing Agreement, Pfizer, Ltd. is considered the "beneficial owner" of the patent. See PTX 0322, at 4. Additionally, Pfizer, Ltd. retained the right to grant licenses to the patents prosecuted. Id. at 6. Finally, both Pfizer, Ltd. and Pfizer, Inc. have the right to enforce patents and agreed to cooperate in doing so. Id. at 5.

"Beneficial owner" is not defined in the Patent Filing Agreement,[33] and it specifically provides that it is to be interpreted under the laws of England. Id. at 8.[34] The court has undertaken a review of English law and found that "beneficial owner" is often used to describe an entity that gathers the benefits of an asset, business, or agreement without necessarily holding legal title. E.g., AK Investment CJSC v. Kyrgyz Mobil Tel Ltd., [2011] 1 C.L.C. 205, 211 (P.C.) (referring in the recitation to the facts to the differences between the "beneficial owner" and the "ultimate owner"); Shell U.K., Ltd. v. Total U.K. Ltd., [2010] 1 C.L.C. 343 (Ct. of App.) (discussing the ability of a beneficial owner to recover in tort for damage caused

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[33] Teva has made much of the fact that in his testimony Mr. Benson said he did not know what "beneficial owner" means in the Patent Filing Agreement. Trial Tr. 77:14-22. This is entirely beside the point because the term "beneficial owner" in a contract is a legal term for the court to decide. See supra note 30.

[34] The court notes that again Teva seems to be ignoring proper procedural notice requirements. See supra note 29. Federal Rule of Civil Procedure 44.1 requires that when a party intends to raise an issue of foreign law, that party "must give notice by a pleading or other writing." Fed. R Civ. P. 44.1. As Teva has raised the question of what "beneficial ownership" means under the laws of England, it was required to give such notice to the court and the opposing party, which it did not do in any pretrial pleading. See, e.g., Final Pretrial Order, Docket # 276 (failing even to raise the issue under English law in the final order governing trial issues); supra note 29. Moreover, at trial and in post-trial briefing, Teva has likewise merely raised the issue without affording the court any benefit of analysis or facts concerning the interpretation of the Patent Filing Agreement under the laws of England.

by negligence).[35] From the court's research, it appears that the term "beneficial owner" has similar meanings in both English and American law. This is not surprising given that "beneficial owner" in both countries sounds in equity, which evolved from mutual roots in the common law. Black's Law Dictionary, noting the term's origins in the Eighteenth Century, defines "beneficial owner" as "[o]ne recognized in equity as the owner of something because use and title belong to that person, even though legal title may belong to someone else . . . . Also termed equitable owner. . . . A person or entity who is entitled to enjoy the rights in a patent, trademark, or copyright even though legal title is vested in someone else." Black's Law Dictionary 1214 (9th ed. 2009); see also Beam Laser, 117 F. Supp. 2d at 520. Further, "[t]he beneficial owner has standing to sue for infringement." Black's Law Dictionary 1214. Thus, it appears that, under the general definition of "beneficial owner," such an entity has most to all of the traditional property rights of the owner, except for actual legal title to the property.

The terms of the Patent Filing Agreement do not contradict this meaning of the rights of a beneficial owner. Under that agreement,

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[35] This court's review of the laws of England is pursuant to Federal Rule of Civil Procedure 44.1 which provides that "[i]n determining foreign law, the court may consider any relevant material or source, including testimony, whether or not submitted by a party or admissible under the Federal Rules of Evidence. The court's determination must be treated as a ruling on a question of law." Fed. R. Civ. P. 44.1.

Pfizer, Inc. holds the patents in trust for Pfizer, Ltd., while Pfizer, Ltd. has the right to grant licenses and enforce the patent. Therefore, this court concludes that Pfizer, Ltd. has sufficient proprietary rights in the patent to confer standing to sue in its name alone. However, even if the court were to conclude otherwise, Pfizer, Ltd. certainly has sufficient proprietary rights to sue for infringement in concert with the owner of the patent, as it has done here with Pfizer, Inc.

Finally, Teva argues that Pfizer Ireland Pharmaceuticals Co. does not have standing to sue, either because the license it holds for sildenafil is invalid because Pfizer, Ltd. lacks the right to grant licenses, or because it is only a nonexclusive licensee. Pfizer replies that the Patent Filing Agreement clearly contemplated that Pfizer, Ltd. would grant licenses such that this particular license is valid, and Pfizer Ireland Pharmaceuticals Co.'s exclusive license to make and sell sildenafil in the United States renders it an exclusive licensee with standing to sue in concert with the owner of the patent.

First, the court has already concluded that the Patent Filing Agreement explicitly gave Pfizer, Ltd. the power to grant licenses. PTX 0322, at 6. Thus, there is no basis for the assertion that the

license itself is null and void ab initio.[36] Second, the court must determine if the license granted to Pfizer Ireland Pharmaceuticals Co. constitutes an exclusive license such that it has standing to join a suit where the owner of the patent, Pfizer, Inc., is a party. As recounted above, the Federal Circuit has held that "[a]n exclusive licensee receives more rights than a nonexclusive licensee, but fewer than an assignee. An example of an exclusive licensee is a licensee who receives the exclusive right to practice an invention but only within a given limited territory." Sicom, 427 F.3d at 976 (emphasis added). The Federal Circuit has directed courts considering this question to carefully parse the license agreement and the rights granted to the licensee, paying attention to whether the licensee has exclusive rights in a territory, id.; Ortho Pharm., 52 F.3d at 1031-32; whether the licensor has retained the right to grant further licenses, Morrow, 499 F.3d at 1342; whether the licensee has the right to sue for infringement, Sicom, 427 F.3d at 979; and whether the licensor retains rights to develop and market the invention. Fieldturf, Inc. v. Southwest Recreational Indus., Inc., 357 F.3d 1266, 1269 (Fed. Cir. 2004). None of these factors are individually

[36] Likewise, there is no basis for Teva to assert, as it did during the trial proceedings and in post-trial briefing, that there was insufficient evidence of the license agreement passing with each Agreement of Sale between the various Pfizer entities. The court finds it clear that the license transferred at each sale to the new holder of the assets and business. Two of the sale agreements even specifically list the license agreement as transferring. See PTX 0325, at 13; PTX 0326, at 10.

determinative, and the court must make a fact-specific decision of whether the license creates an exclusive license. Sicom, 427 F.3d at 976.

In this case, it is clear that Pfizer Ireland Pharmaceuticals Co. is not an assignee because it has not received all substantial rights in the patent. It is a close question, however, whether it has sufficient rights to be considered an exclusive licensee under the Federal Circuit's precedent. The factors cut both ways. First, Pfizer Ireland Pharmaceuticals Co. has the exclusive right to make and sell sildenafil within the United States. Second, it has the right to enforce the patent and compel the participation of other parties necessary for the suit. Both of these facts favor Pfizer Ireland Pharmaceuticals Co. being considered an exclusive licensee because it has the right to exclude and the right to enforce the patent. However, there are two considerations that cut the other way. First, Pfizer Ireland Pharmaceuticals Co.'s exclusive license is subject to Pfizer, Ltd.'s retained "Right of Conversion;" Pfizer, Ltd., at any time when there is at least 20% remaining in the patent term, may revoke the exclusive license to create a nonexclusive license for the remaining term of the patent. See PTX 0324, at 2-4. Second, while Pfizer Ireland Pharmaceuticals Co. has a right to enforce the patent, that right is subject to Pfizer, Ltd.'s primary right of enforcement, as Pfizer, Ltd. has the initial right to enforce

the patent and ultimate control over the litigation. Pfizer Ireland Pharmaceuticals Co. may only bring its own suit, joining Pfizer, Ltd. and Pfizer, Inc., if Pfizer, Ltd. fails to bring suit within thirty (30) days from the discovery of the infringement. See id. at 8.

On the balance, the court finds that under the Federal Circuit's precedent, Pfizer Ireland Pharmaceuticals Co. does not have sufficient proprietary rights in the '012 patent to be joined in the suit as an exclusive licensee. Rather, the court finds that Pfizer Ireland Pharmaceuticals Co. is a nonexclusive licensee that does not meet the injury-in-fact requirement for standing. While at the time of this suit, Pfizer Ireland Pharmaceuticals Co. enjoys an exclusive license to make and sell the invention in the United States and is joined in a consensual suit to challenge infringement by Teva, these rights are ephemeral, as Pfizer, Ltd. could revoke the exclusive license at any time, and it wields ultimate control over the litigation.

D.

For the reasons stated above, the court **FINDS** that Pfizer, Inc. and Pfizer, Ltd. have standing to sue for infringement of the '012 patent, while Pfizer Ireland Pharmaceuticals Co. lacks such standing. Accordingly, the court **DENIES IN PART** and **GRANTS IN PART** Teva's Motion to Dismiss for Lack of Standing and **DISMISSES** Pfizer Ireland Pharmaceuticals Co. from the litigation.

III. Teva's Motion for Leave to File its Proposed Second Amended Answer and Counterclaim

The other outstanding motion the court must take up is Teva's Motion for Leave to File its Proposed Second Amended Answer and Counterclaim ("Second Motion to Amend"), filed at the end of the third day of trial, Friday, June 17, 2011. See Docket # 345. Teva sought leave from the court to again amend its Answer and Counterclaim to change the allegations therein concerning inequitable conduct. On a briefing schedule set by the court, Pfizer responded in opposition on June 24, 2011, see Docket # 378, and Teva replied on June 27, 2011. See Docket # 398. By oral order during trial, the court denied the Second Motion to Amend, in part, on June 29, 2011,[37] and in its entirety on July 6, 2011.[38] The court memorialized its denial of the Second Motion to Amend in a written Order on July 7, 2011, and reserved the option to issue a written opinion detailing its ruling. See Docket # 428.[39]

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[37] See Trial Tr. 1050:20-1055:4.

[38] See Trial Tr. 1176:14-25.

[39] After the court denied Teva's Second Motion to Amend at trial, Teva submitted an "Offer of Proof" with respect to the denied amendment on July 7, 2011, see Docket # 423, to which Pfizer objected on July 11, 2011. See Docket # 431. The court has reviewed the "Offer of Proof" and finds nothing therein which would lead it to reconsider its denial of the Second Motion to Amend.

A.

On November 12, 2010, Teva filed its first Motion for Leave to File an Amended Answer and Counterclaim ("First Motion to Amend"). See Docket # 55. In particular, Teva sought leave of the court to amend its Answer and Counterclaim to add the allegation that the '012 patent was invalid because Pfizer engaged in inequitable conduct during the patent's prosecution and reexamination. After the First Motion to Amend was fully briefed and argued, the court issued an opinion allowing the amendment on January 18, 2011. Pfizer, Inc. v. Teva Pharms. USA, Inc., No. 2:10cv128, __ F. Supp. 2d __, slip op. (Jan. 18, 2011), Docket #77. Specially, the court found that, "[t]hough it [was] a close question, . . . Teva ha[d] met the [pleading] requirements of [Federal] Rule [of Civil Procedure] 9(b)." Id., slip op. at 7. The court held that Teva had specifically named the who, what, and when of the alleged misrepresentation before the PTO and that the allegations concerning intent to deceive the PTO, while tenuous, were sufficient at the initial pleading stage. Id. at 7-8. Thus, the court directed Teva to file its Amended Answer and Counterclaim.

On June 17, 2011, Teva again moved to amend its Answer and Counterclaim, seeking to change its allegations regarding the inequitable conduct claim. Previously, in its First Amended Answer and Counterclaim, Teva alleged that four individuals — Dr. Peter

Ellis, an inventor of the '012 patent; Gregg C. Benson and James T. Jones, internal counsel for Pfizer; and Gerard M. O'Rourke, Pfizer's external counsel – committed inequitable conduct during the prosecution of the '012 patent.[40] The substance of the inequitable conduct claim was that "Pfizer actively prosecuted the '012 patent to include claims that the treatment would benefit a 'male animal' with ED." Pfizer, Inc. v. Teva Pharms. USA, Inc., No. 2:10cv128, slip op. at 5. This allegedly amounted to "inequitable conduct because Pfizer knew that the animal claims were overbroad and unpatentable; Pfizer withheld information from the PTO that demonstrated the unpatentability of the claims; and Pfizer continued to espouse the animal claims in the reexamination of the patent." Id. at 5-6. As evidence of this knowledge of overbreadth, Teva pointed to the fact that Pfizer disclaimed the animal claims in the Canadian version of the '012 patent when challenged in a Canadian court. These facts are the basis of the inequitable conduct claim currently before the court.[41]

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[40] See infra note 41.

[41] In its Memorandum of Law in Support of its Motion for Leave to File a Second Amended Answer and Counterclaim and again during trial, Teva admitted that it found no evidence of any wrongdoing by three of the four individuals named in the First Amended Answer and Counterclaim: Mr. Benson, Mr. Jones, and Dr. Ellis. As a result, the court entered an Order on July 1, 2011, finding insufficient evidence existed to proceed with any inequitable conduct claim against these individuals, dismissing them from the First Amended Answer and

Teva now seeks to amend the factual allegations concerning inequitable conduct. The content of the inequitable conduct claim is still generally the same, as it is tied to the disclaimer of the animal claims in Canada, but the individuals and the specifics of their actions are different. Teva now details two separate, but related, courses of inequitable conduct. First, Teva alleges that "Pfizer in-house attorneys Watson McMunn and Dr. Peter Richardson, and Pfizer's outside counsel Daniel DiNapoli of the Kaye Scholer law firm, engaged in inequitable conduct during the prosecution of the application for the '012 patent." Mem. of Law in Supp. of Mot. for Leave to File Proposed Second Am. Ans. & Countercl., Ex. A, Proposed Second Am. Countercl. ¶ 15, Docket # 347. Specifically, Mr. McMunn, Dr. Richardson, and Mr. DiNapoli were aware that a Pfizer competitor, Bayer Aktiengesellschaft and Bayer, Inc., filed a claim in Canada ("the Bayer Statement of Claim"), arguing that the claims of the Canadian patent directed to the treatment of non-human animals were invalid for overbreadth. Id. With the knowledge that these challenged claims were identical to the claims in the '012 patent, these individuals did not disclose to the PTO that the claims in the '012 patent were overbroad. Id. at ¶ 16. This information was allegedly material and should have been disclosed to the PTO, but instead Mr. McMunn, Dr. Richardson, and Mr. DiNapoli intentionally

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Counterclaim, and leaving Mr. O'Rourke as the sole person named in the First Amended Answer and Counterclaim. See Docket # 409.

withheld the information from the PTO so that the '012 patent would issue as soon as possible. Id. at ¶¶ 17-18.[42] Teva alleges that, if the information had been disclosed, the PTO would not have allowed Claims 1-19 and 21-23 of the '012 patent to issue. Id. at ¶ 65.

The second course of inequitable conduct Teva now alleges concerns Mr. O'Rourke, who was named in the First Amended Answer and Counterclaim, and Rudolph Hutz, both partners at the time at the law firm of Connolly Bove Lodge & Hutz ("Connolly Bove"). Id. at ¶ 19.[43] Connolly Bove was hired by Pfizer during the prosecution of the '012 patent to submit documents to the PTO pursuant to the duty of disclosure. Id. Initially, Teva alleges, Mr. O'Rourke and Mr. Hutz committed inequitable conduct by "dumping" documents on the PTO without regard to the materiality of the documents. Id. Teva alleges that this practice changed after Mr. Hutz and Mr. O'Rourke learned that the patent examiner was going to allow the claims of the '012 patent, in that they no longer submitted any disclosures to the PTO. Id. Teva states that this was inequitable conduct

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[42] Paragraphs 25-64 of the Amended Counterclaim detail the specific actions allegedly taken by the individuals named in regard to the filing of the Bayer Statement of Claim in Canada, the consideration of a disclaimer of the animal claims in Canada, and the eventual filing of said disclaimer in the Canadian litigation. See Mem. of Law in Supp. of Mot. for Leave to File Proposed Second Am. Ans. & Countercl., Ex. A, Proposed Second Am. Countercl. ¶¶ 25-64. These allegations do not bear repeating in detail herein.

[43] Mr. O'Rourke is now with the law firm of Ratner Prestia. O'Rourke dep. 22:3-4 (as played at trial).

because it was a system of "willful blindness," the object of which was to avoid awareness of any information that would normally be disclosed to the PTO to prevent delaying the issuance of the '012 patent. Id. at ¶ 20.[44]

B.

Federal Rule of Civil Procedure 15(a)(1)(A) provides, in pertinent part, that "[a] party may amend its pleading once as a matter of course . . . before being served with a responsive pleading." However, if a party seeks to amend its pleading at any other time, it may only do so "with the opposing party's written consent or the court's leave." Fed. R. Civ. P. 15(a)(2). The rules require that a "court should freely give leave when justice so requires," and the Fourth Circuit has held that "leave to amend a pleading should be denied only when the amendment would be prejudicial to the opposing party, there has been bad faith on the part of the moving party, or the amendment would have been futile." Laber v. Harvey, 438 F.3d 404, 426 (4th Cir. 2006) (emphasis added) (citing Johnson v. Oroweat Foods Co., 785 F.2d 503, 509 (4th Cir.

[44] Again, Paragraphs 82-128 detail the specifics of the actions allegedly taken by the named individuals, and do not bear repeating herein. Mem. of Law in Supp. of Mot. for Leave to File Proposed Second Am. Ans. & Countercl., Ex. A, Proposed Second Am. Countercl. ¶¶ 82-128; see supra note 42.

1986) and Foman v. Davis, 371 U.S. 178, 182 (1962)).[45] Delay is another important factor for the court to consider, Foman, 371 U.S. at 182, but delay alone, without prejudice, is an insufficient reason to deny a motion to amend. Davis v. Piper Aircraft Corp., 615 F.2d 606, 613 (4th Cir. 1980). Conversely, "prejudice resulting to the opponent by a grant of leave to amend is reason sufficient to deny amendment." Id. Overall, Foman directs the court's attention to prejudice, futility, and bad faith because such concerns are related to the protection of the system or other litigants. Davis, 615 F.2d at 613. Importantly, "conjecture about the merits of the litigation should not enter into the decision whether to allow the amendment." Id.

To avoid questions of bad faith or prejudice, "a motion to amend should be made as soon as the necessity for altering the pleading becomes apparent." Deasy v. Hill, 833 F.2d 38, 41 (4th Cir. 1987) (citation and internal quotation marks omitted). Motions to amend made on the day of or close to trial "may be particularly disruptive, and may therefore be subject to special scrutiny." Id. However, "the mere fact that an amendment is offered late in the case is not enough to bar it." Sweetheart Plastics, Inc. v. Detroit Forming,

[45] The standard for whether a motion to amend should be granted in a patent case is a matter of the relevant circuit's law in the district where the case is pending, not that of the Federal Circuit. Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1318 (Fed. Cir. 2009).

Inc., 743 F.2d 1039, 1044 (4th Cir. 1984); see also Davis, 615 F.2d at 613.

As regards futility, a party seeking to amend its pleadings must meet the pleading requirements for the particular cause of action it seeks to bring to avoid denial on the basis of futility. The Federal Circuit has previously held that a party asserting a claim of inequitable conduct must plead it with the specificity required by Federal Rule of Civil Procedure 9(b). Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1328 (Fed. Cir. 2009); see Fed. R. Civ. P. 9(b).[46] Failure to plead a claim of inequitable conduct with the specificity required by Rule 9(b) will result in the amendment's denial as futile. Exergen, 575 F.3d at 1331; United States ex rel. Wilson v. Kellogg Brown & Root, Inc., 525 F.3d 370, 376 (4th Cir. 2008). Thus, the Federal Circuit has held that the party alleging inequitable conduct must "identify the specific who, what, when, where, and how of the material misrepresentation or omission committed" before the PTO to satisfy Rule 9(b). Exergen, 575 F.3d at 1328. In other words, the pleadings "must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or the falsity of the material misrepresentation, and

[46] In patent cases before the district court, Federal Circuit law determines whether inequitable conduct has been pleaded with the particularity required. Exergen, 575 F.3d at 1328.

(2) withheld or misrepresented this information with a specific intent to deceive the PTO." Id. at 1328-29.

C.

As an initial question, the court must decide whether Exergen, decided in 2009, continues to state the standard for pleading inequitable conduct, or whether its holding has been modified by the Federal Circuit's recent en banc decision in Therasense, Inc. v. Becton, Dickinson & Co., __ F.3d __, 2011 W.L. 2028255 (Fed. Cir. May 25, 2011) (en banc).[47] In Therasense, the Federal Circuit granted rehearing en banc to consider "the problems created by the expansion and overuse of the inequitable conduct doctrine." Id. at *4. Before Therasense, a party alleging inequitable conduct had to prove by clear and convincing evidence that (1) material information was not disclosed to the PTO, and (2) the non-disclosure was done with the intent to deceive the PTO. Id. at *6. Those two elements were then put on a sliding scale where a strong showing of one element, either materiality or intent, could override a weaker showing of the other. Id. at *7.

However, because of concerns about the expansion of the use of an inequitable conduct allegation as a strategic tool, the Federal

[47] The court will discuss Therasense in greater detail later in Section VI, infra, when it decides whether Teva has made out a case of inequitable conduct on the merits. Thus, the court in this Subsection of the Opinion gives only an overview of Therasense's holding as it pertains to the requirements for pleading under Rule 9(b).

Circuit revisited and recrafted the requirements for a showing of inequitable conduct. The en banc court held that "the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." Id. at *9 (emphasis added). The court also heightened the required showing for both materiality and intent to deceive, where a party alleging inequitable conduct must now show "but-for materiality" and that the intent to deceive is "the single most reasonable inference able to be drawn from the evidence." Id. at *10-11 (citation and internal quotation marks omitted). In only one instance may the court find materiality without the requisite "but-for" causation, when "the patentee has engaged in affirmative acts of egregious misconduct." Id. at *12.

Thus, it is clear that Therasense significantly heightened the requirements for a showing of inequitable conduct on the merits, but the question remains as to whether it had any effect on the pleading standards for inequitable conduct under Rule 9(b).[48] Rule 9(b) provides that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally." Fed. R. Civ. P. 9(b). In pleading the

[48] See Jersey Asparagus Farms, Inc. v. Rutgers University, No. 10-2849, 2011 W.L. 2148631, at * 14 (D.N.J. May 31, 2011) (unpublished) (noting that Therasense does not directly address the initial pleading stage).

intent prong, the court evaluates whether a sufficient showing has been made under the standards of Federal Rule of Civil Procedure Rule 8(a), Ashcroft v. Iqbal, __ U.S. __, 129 S. Ct. 1937, 1954 (2009), which requires that a party state a claim for relief that is "plausible on its face." Id. at 1949; see Bell Atl. Corp. v. Twombly, 550 U.S. 544, 555 (2007) (Rule 8(a) pleading standard clarified by Iqbal); Adiscov, L.L.C. v. Autonomy Corp., 762 F. Supp. 2d 826, 829 (E.D. Va. 2011) (applying the Twombly and Iqbal standards in a patent case). To comply with Rule 9(b), Exergen held that a party alleging inequitable conduct "must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." Exergen, 575 F.3d at 1328-29.

After reviewing all of this precedent, the court finds that Exergen still states the correct elements required for pleading inequitable conduct after Therasense. A party must still "identify the specific who, what, when, where, and how of the material misrepresentation or omission committed." Exergen, 575 F.3d at 1328. Additionally, a party must allege intent to deceive the PTO, such that the specific intent is plausible from the facts alleged pursuant to Rule 8(a). However, the court does note that after

Therasense, a mere recitation that "X" individual, at "X" time, failed to turn over "X" information to the PTO that would have been material to the prosecution, with the specific intent to deceive the PTO, is insufficient under Rule 9(b). Instead, in alleging those elements, a party must make an initial showing from which it may be plausibly inferred that: (1) the individual knew of the information not disclosed; (2) the information not disclosed was but-for material to the prosecution of the patent; and (3) the intent to deceive is the single most likely explanation for the non-disclosure. See Iqbal, 129 S. Ct. at 1954 (plausibility); Therasense, 2011 W.L. 2028255, at *9 (specificity); Exergen, 575 F.3d at 1328 (Rule 9(b) pleading requirements).

The court is mindful that at the pleading stage a party is not required to meet the clear and convincing evidence standard that applies on the merits. However, as made clear in Therasense, courts must take an active role in examining the propriety of inequitable conduct claims, Therasense, 2011 W.L. 2028255, at *9, and without incorporating allegations of the specific elements to be proven on the merits at the pleading stage, albeit at a lower standard of plausibility at this initial juncture, courts cannot perform this function.

D.

With these standards in mind, the court now looks to Teva's Second Motion to Amend. Teva argues that its Second Motion to Amend should be granted because it meets the pleading requirements of Rule 9(b); there was no delay in filing for the amendment because Teva did so as soon as it received the pertinent information; and the amendment would not prejudice Pfizer because Pfizer had notice of the substance of the allegations a month beforehand. Mem. of Law in Supp. of Mot. for Leave to File Proposed Second Am. Ans. and Countercl. at 21. Pfizer replies that the delay, which is indefensible because Teva had the information much before June 17, 2011, seriously prejudices Pfizer by forcing it to try a completely different case than the one for which it prepared. Mem. in Opp'n Mot. for Leave to File Second Am. Ans. and Countercl. at 20. Additionally, Pfizer argues that Teva's motion should be denied as futile. Id. at 7.

Beginning with considerations of delay, Teva attributes the timing of the filing of the motion to the fact that discovery concluded on June 10, 2011, five days before trial began. Teva argues that Pfizer's discovery practices delayed Teva's receipt of the information underlying the proposed amended inequitable conduct claim. In particular, Pfizer's limited waiver of attorney-client privilege on February 23, 2011, Teva represents, subsequently

required Teva to litigate with Pfizer to force the discovery of documents relevant to the Canadian disclaimer. Teva specifically asserts that it did not find out about the role that Dr. Richardson played until May 20, 2011, and then it was forced to make a motion to take Dr. Richardson's deposition after discovery had concluded. Pfizer responds that Teva knew of each of the individuals in the Proposed Second Amended Answer and Counterclaim well before June 17, 2011, such that there is no excuse for this late filing.

Discovery has been fully litigated before the United States Magistrate Judge in this case, and the court does not rehash it here. It suffices to say that the United States Magistrate Judge, who was deeply involved in this case and well-versed in the law of discovery, specifically declined to find that Pfizer had violated any provisions of the discovery rules and denied Teva's Motion for Sanctions. See Docket # 286. Thus, this court does not engage with the question of whether Pfizer's productions were timely or not, but rather focuses on when Teva learned of the facts underlying its current Second Motion to Amend. Teva deposed Mr. O'Rourke on April 1, 2011, Mr. McMunn on April 8, 2011, and Mr. Hutz on May 4, 2011. Additionally, in March 2011, Teva served a subpoena on Mr. DiNapoli. In responding to Pfizer's Motion to Quash the subpoena, see Docket # 117, Teva responded that it was seeking to depose Mr. DiNapoli because of information Pfizer had turned over in discovery regarding

Mr. DiNapoli's involvement with the decision to disclaim the animal claims in Canada. See Docket # 143. The basic facts Teva offered in support of its subpoena were the same facts which underlie the current inequitable conduct claim involving Mr. DiNapoli.[49]

Further, it is true that Teva did not seek a deposition of Dr. Richardson until May 23, 2011, as part of its Motion to Continue the Trial to allow for further depositions to be taken. See Docket # 253. Teva argues that it made such a motion for a deposition after discovery had concluded, because it had just received the information which revealed Mr. Richardson's role. However, it is unclear for two reasons why this should be, or is, the scenario. First, Dr. Richardson's name is on the face of the '012 patent as one of its prosecuting attorneys, such that his role in its prosecution has been evident from the inception of the litigation in this court. See PTX 0001, at 1. Second, during Mr. Richardson's deposition on June 10, 2011, counsel for Teva conducting the deposition, in a question posed to Mr. Richardson, stated:

> In response to an interrogatory that Teva propounded in this lawsuit to Pfizer, in which Teva asked Pfizer to identify all the individuals associated with the filing or prosecution of the application for the '012 patent, other than the named inventors, Pfizer answered with respect to you, Dr. Richardson that Peter C. Richardson, a former Senior Vice President and Associate General Counsel at Pfizer New York as in-house U.S. patent counsel

[49] Teva again reiterated those facts in its Memorandum in Support of its Motion to Reconsider the United States Magistrate Judge's Order quashing the subpoena. See Docket # 217.

> for Pfizer supervised the prosecution of U.S. patent application number 08/549792.

Richardson dep. 30:12-31:08 (emphasis added) (as played at trial). Thus, Teva's direct words undermine its contention that it did not know Dr. Richardson's role until May 20, 2011, as interrogatories are among the initial steps in discovery.

Most telling to the court, however, is Teva's argument in its brief concerning why Pfizer would not be prejudiced by the amendment:

> Pfizer is well aware of the inequitable conduct allegations detailed in Teva's proposed Second Amended Answer and Counterclaim. Teva described those allegations in detail in its May 12, 2011 Motion and Supporting Memorandum to Reconsider the Court's Order quashing Teva's subpoena of Pfizer's trial counsel, and in its May 23, 2011 Memorandum and June 2, 2011 Reply Memorandum in Support of its Motion for Sanctions.

Mem. of Law in Supp. of Mot. for Leave to File Proposed Second Am. Ans. & Countercl. at 21 (emphasis added). The court is left wondering why, if Teva asserts on the one hand that it previously revealed all of its allegations concerning inequitable conduct as far back as May 12, 2011, that it now with a "straight face" can also assert that it has brought this Second Motion to Amend during trial on the grounds that it did not have access to the requisite information beforehand. This kind of double-talk does not fool the court, when the plain facts before it are otherwise. The court thus finds that Teva delayed unnecessarily in filing the Second Motion to Amend.

However, as recounted above, delay alone is an insufficient reason to deny a motion to amend; rather a court must determine whether prejudice flows from such delay. The court finds it beyond doubt that both Pfizer and the individuals Teva seeks to name in its Second Amended Answer and Counterclaim would be seriously prejudiced were the amendment to be allowed. Inequitable conduct is a serious charge against an individual, indeed it amounts to an allegation of fraud. It can be a career-ending finding by the court for those against whom it is alleged, if proven on the merits. Thus, a court considering whether to allow a claim of inequitable conduct to go forward must strictly enforce the pleading requirements of Rule 9(b) to protect those named in such an accusation. In particular, the court must consider whether allowing the amendment would give these individuals time to seek out and engage their own counsel, if they so desire. In this case, allowing Teva yet again to amend its Answer and Counterclaim, this time after the trial was ongoing, to add allegations against Mr. Hutz, Mr. DiNapoli, Mr. McMunn, and Mr. Richardson would prejudice each of these individuals.[50] It is hard to fathom how these individuals would have time to prepare sufficiently for trial, when they are added once the trial has begun.[51]

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[50] Because Mr. O'Rourke was named in the First Amended Answer and Counterclaim, these concerns do not pertain to him.

[51] See infra notes 52 and 53 and accompanying text.

Furthermore, to allow amendment at this late date would severely prejudice Pfizer. First and foremost, to allow amendment to add a claim of inequitable conduct against Mr. DiNapoli could likely have necessitated a declaration of a mistrial, because it would require Mr. DiNapoli to withdraw from representation of Pfizer after serving as one of two lead counsel since the inception of this suit.[52] Second, amendment at this late date would require Pfizer to try a different case than it had prepared for, and a different case than was memorialized in the Final Pretrial Order, see Docket # 276, which Order governs the parties and the court regarding the remaining issues for trial as well as the presentation of evidence at trial on these issues. While Teva asserts that Pfizer already knew of the substance of the inequitable conduct allegations in the Proposed Second Amended Answer and Counterclaim, this assertion has no bearing on whether Pfizer would be prejudiced, as it would still have to try a newly proposed case on inequitable conduct, simply because Teva did not seek to amend its Answer and Counterclaim in an timely manner, i.e., when it initially received the information. Thus, the court finds that Teva's Second Motion to Amend should be denied in its entirety because to allow amendment at this juncture would severely

[52] Teva has stated that it does not seek the disqualification of Mr. DiNapoli, even if the Proposed Second Amended Answer and Counterclaim were filed. The court finds this assertion, that Mr. DiNapoli could be the subject of a claim of fraud and still act as co-lead counsel in the case, to be incredible.

prejudice both Pfizer and the individuals named in the Proposed Second Amended Answer and Counterclaim.[53]

Beyond the issue of prejudice, the court finds that Teva's Motion to Amend should be denied for futility. As the court held above, Teva must make a plausible showing with the specificity required by Rule 9(b): (1) that the individual alleged knew of the information not disclosed; (2) that the information disclosed was but-for material to the prosecution of the patent; and (3) the intent to deceive is the single most likely explanation for the non-disclosure.[54] Teva has failed to meet this standard for two reasons. First, Teva has failed to make a plausible showing that two of the individuals that it named had any duty of disclosure to the PTO such that they could have had any intent to deceive the PTO. Neither Mr. McMunn nor Mr. DiNapoli is admitted to practice before the PTO and thus can have no duty of disclosure thereto. McMunn dep. 16:13-16 (as played at trial); Mem. in Opp'n Mot. for Leave to File Second Am. Ans. and Countercl. at 12. Mr. McMunn is a patent agent registered in the United Kingdom, while Mr. DiNapoli is a litigator

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[53] This ruling does not even take into account the effect on the court's docket, as the filing of a Second Amended Answer and Counterclaim during trial would clearly have necessitated, at minimum, a continuance, and, most likely, a mistrial. See supra note 52 and accompanying text. To reschedule a long-set patent trial of this magnitude would wreak havoc on a court's trial docket and cause hardship and additional costs to other litigants.

[54] See supra at 45 (citing Iqbal, 129 S. Ct. at 1954; Therasense, 2011 W.L. 2028255, at *9; Exergen, 575 F.3d at 1328).

in the United States. Mem. in Opp'n Mot. for Leave to File Second Am. Ans. and Countercl. at 12. Neither of them were listed as prosecuting attorneys of the '012 patent. See PTX 0001. Therefore, Teva has failed to meet Exergen's requirement that the pleading provide a "factual basis to infer that any specific individual, who owed a duty of disclosure in prosecuting the ['012] patent" knew of any material information that was not disclosed to the PTO. Exergen, 575 F.3d at 1330 (emphasis added). Moreover, a failure to prove that an individual owed a duty of candor to the PTO is likewise a failure to make a showing of specific intent to deceive the PTO.

Second, and importantly, Teva's amendment is also futile because Teva has failed to make any plausible showing of but-for materiality of the information not disclosed to the PTO. With respect to Mr. Hutz and Mr. O'Rourke[55] and Teva's allegation that they failed to turn over the Bayer Statement of Claim to the PTO, Teva has made no showing that such statement of claim was but-for material to the issuance of the '012 patent. Even at the pleading stage, the court cannot imagine how a generalized complaint against Pfizer that its Canadian patent was "covetous" under Canadian law could have had any bearing whatsoever on the issuance of the '012 patent under the

[55] This non-disclosure and materiality issue with respect to Mr. O'Rourke will be discussed further in Section VI, infra, concerning inequitable conduct on the merits of the First Amended Answer and Counterclaim.

law of the United States. See Defendant's Exhibit (hereinafter referred to as "DX") 2018, at 7. As to Mr. DiNapoli, Mr. McMunn, and Dr. Richardson, given that the disclaimer in Canada was done pursuant to Canadian law after the '012 patent issued,[56] it is difficult to see any materiality such disclaimer would have in the United States patent prosecution. The disclaimer in Canada was done in response to the Bayer Statement of Claim on the belief that the animal claims were too broad under Canadian law. The disclaimer had no relation to overbreadth under United States law. Further, the disclaimer in Canada occurred after the '012 patent issued in the United States, such that at the time the Canadian Disclaimer was made, there was no duty of disclosure to the PTO; prosecution of the '012 patent had ceased. See Trial Tr. 1121:5-7 (testimony of Teva's expert in patent law and procedure, Cameron Weiffenbach, Esq., stating the duty to disclose applied from the filing of the application to the issue of the patent.)[57] Therefore, the court also denies Teva's Second Motion to Amend because the amendment it proposes is futile.

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[56] The '012 patent issued October 22, 2002, see PTX 0001, while the disclaimer in Canada was filed November 14, 2002. See PTX 817.

[57] The reexamination of the '012 patent did not begin until September 23, 2003, and is not at issue here.

E.

For the reasons stated above and on the record during trial, the court **DENIES** Teva's Motion for Leave to File its Proposed Second Amended Answer and Counterclaim on the grounds of both prejudice and futility.

IV. Obviousness

Teva makes three arguments concerning the validity of the '012 patent, the first of which is that the '012 patent's claims are obvious in light of the prior art and earlier-issued Pfizer patents. In particular, Teva argues that the prior art, in view of EP '756, either alone or combined with EP '004 and the '534 patent, makes the claims of the '012 patent obvious to a person ordinarily skilled in the art ("POSITA"), such that a POSITA would try using sildenafil to treat ED. Pfizer disagrees and argues that the prior art references do not teach that oral administration of sildenafil would have any expectation of success in treating ED. Additionally, Pfizer argues that secondary considerations of non-obviousness demonstrate that the invention was not obvious.

A.

At the time of the application for the '012 patent, May 13, 1994,[58] the treatment of ED was still in a nascent stage, but

[58] The actual application in the United States was filed on March 4, 1996, PTX 0004, but the priority date of the application is May 13, 1994. PTX 0001.

there was a sense of building momentum in the field of erectile function research. In 1994, the cutting edge treatment for ED involved the injection of vasodilators directly into the penis, referred to as intercavernosal injections because they were administered into the corpus cavenosum. Each of the drugs used for this purpose, most commonly papaverine, phentolamine, and prostaglandin E1, either alone or in combination, was also used to treat other conditions such as hypertension.[59] All of these drugs were known to relax smooth muscle tissue and, when injected directly into the penis, produced erection. Researchers at the time attributed the effectiveness of the injections to their being administered locally, which resulted in a high concentration of the drug in the penis and avoided systemic side effects. Robert J. Krane, et al., Medical Progress: Impotence, 321 New Eng. J. Med. 1648, 1654 (1989), PTX 0029. When administered systemically, however, these drugs had no effect on treating ED. Indeed, as Teva's and Pfizer's experts testified, many hypertension drugs actually induced ED when administered systemically. See, e.g., Serge Carrier, et al., Erectile Dysfunction, 23 Endocrinology & Metabolism

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[59] In their normal use for other conditions, such as hypertension, these drugs were systemically, not locally, administered. Systemic administration refers to administration of the medicine such that it reaches the entire body, for example by oral or intravenous routes.

Clinics of N. Am. 773 (1994), PTX 0046; Krane, Medical Progress: Impotence, 321 New Eng. J. Med. 1648, PTX 0029.

Because of the drawbacks of injection treatments, including pain, scarring, and patient preference, researchers at the time were actively trying to develop substances that could be applied topically to the penis, such as a cream, which would then diffuse to reach the smooth muscle tissue. For example, one researcher applied nitroglycerine, normally used systemically to treat hypertension, topically to the penis and found that it induced erection. James A. Owen et al., Topical Nitroglycerine: A Potential Treatment for Impotence, 141 J. Urology 546 (1989), PTX 0042. Indeed, Pfizer's impotence project in the late 1980s and early 1990s was focused on development of such a topical treatment, testing Pfizer's known cardiovascular drugs to determine whether they induced erections upon topical application to the penis. See PTX 0188.

In addition to the injection treatments, there were oral treatments that were tried for ED, but they had little efficacy. For example, urologists would prescribe yohimbine, a psychoactive compound found in plants, for the treatment of ED. Yohimbine was thought to work on the central nervous system, but, as Teva's and Pfizer's experts agreed,[60] yohimbine was not effective in the general population. In addition, doctors sometimes prescribed tradazone,

[60] See supra note 11.

a drug used to treat psychiatric conditions, for the oral treatment of ED. Again, both experts agreed that it was not effective. Overall, the December 1992 National Institutes of Health ("NIH") Consensus Statement on Impotence summarized the state of the art with respect to treatment of ED, noting that further research was required to "[d]evelop[] . . . new therapies, including pharmacologic agents, and with an emphasis on oral agents, that may address the cause of male erectile dysfunction with greater specificity." PTX 0018, at 27.

At the same time as these treatments were being administered, researchers were engaged in further studies to identify the causes of ED and to learn more about erectile function generally. The early 1990s were a period of gathering momentum when researchers began to build a base of knowledge about erectile function that had been previously absent. Before 1990, the scientific community was aware that that corpus cavernosum of the penis was made up of smooth muscle, the function of which was essential for an erection. By 1990, it was known that nitric oxide ("NO") is the chemical messenger in the body that mediates smooth muscle relaxation by activating the enzyme guanylate cyclase to form cGMP. DX 2258A. It was also known that cGMP PDEs break down cGMP to GMP. Additionally, researchers had isolated the PDE enzymes in human corpus cavernosum and reported that it contained PDE3, PDE4, and PDE5. Akmal Taher, et al.,

Phosphodiesterase Activity in Human Cavernous Tissue and the Effect of Various Selective Inhibitors, 149 J. Urology 285A (1993), DX 2172A. Thus, after 1990, researchers conducted experiments aimed at determining the chemical pathway involved in the relaxation of smooth muscle tissue in the corpus cavernosum to better understand erectile function.[61]

First, in 1990, Dr. Louis Ignarro reported the results of an in vitro experiment on rabbit corpus cavernosum tissue strips mounted in an organ bath.[62] Louis L. Ignarro, et al., Nitric Oxide and Cyclic GMP Formation Upon Electrical Field Stimulation Cause Relaxation of Corpus Cavernosum Smooth Muscle, 170 Biochemical & Biophysical Res. Comm. 843 (1990), PTX 0073.[63] Once the rabbit tissue strips were stretched and mounted and a pressure transducer was attached, the adrenergic and cholinergic nerve systems were blocked using chemicals added to the bath, and the tissue was stimulated by using a high-volt electrical current. The experiment itself involved

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[61] This Opinion does not discuss in detail every prior art reference presented at trial but instead focuses on the three references Teva relies on for its obviousness argument. However, the court has reviewed and considered all of the references in forming its opinion as to what a POSITA would have understood at the time.

[62] An organ bath is an artificial laboratory environment where tissue strips are mounted in an artificial blood solution and oxygen is bubbled into the solution.

[63] Teva does not specifically rely on Ignarro for its obviousness argument, but its discussion is warranted as it sets the groundwork for later studies. See supra note 61.

adding chemicals to the organ bath to inhibit the production of NO, which prevented smooth muscle relaxation upon electrical stimulation, thereby confirming that NO is indeed the chemical messenger for such relaxation. In addition, Ignarro added an inhibitor of guanylate cyclase, which in turn prevented smooth muscle relaxation upon electrical stimulation, confirming the role of guanylate cyclase and cGMP in such relaxation. Ignarro concluded that the study results confirmed that smooth muscle relaxation is mediated by the NANC nerve system and its formation of NO. Id. at 848.

Shortly thereafter, Dr. Jacob Rajfer reported on another in vitro experiment on human corpus cavernosum tissue strips mounted in an organ bath. Jacob Rajfer, et al., Nitric Oxide as a Mediator of Relaxation of the Corpus Cavernosum in Response to Nonadrenergic, Noncholinergic Neurotransmission, 326 New Eng. J. Med. 90 (1992), PTX 0077. As in the previous experiment, the adrenergic and cholinergic nervous systems were blocked using chemicals, the tissue was stimulated by using a high-volt electrical current, and various inhibitors of NO and guanylate cyclase were added,. This time, however, zaprinast, a known inhibitor of cGMP PDE, was added to the organ bath, and the researchers observed that it potentiated the effect of smooth muscle relaxation in response to electrical

stimulation.[64] This experiment supported the conclusion that by inhibiting the breakdown of cGMP by cGMP PDEs, smooth muscle relaxation is enhanced.[65] Rajfer concluded that his research confirmed the role of the NANC NO pathway in the mediation of erections and suggested that "[d]efects in [the NANC] pathway may case some forms of impotence." Id. at 90.

In 1993, Dr. Margaret Bush published her doctoral thesis, which summarized the findings and methods behind the previous experiments described in the Ignarro and Rajfer articles and drew further conclusions.[66] Margaret A. Bush, The Role of the L-Arginine-Nitric-Oxide-Cyclic GMP Pathway in Relaxation of Corpus Cavernosum Smooth Muscle (1993), PTX 0070. Bush's overall conclusion was the L-arginine-nitric oxide-cGMP pathway is responsible for the relaxation of the smooth muscle in the corpus

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[64] Potentiation refers to when two signals act in concert in a chemical pathway and their cumulative effect on the pathway is greater than would be expected by simply adding their separate effects together. See Trial Tr. 138:1-16.

[65] Another researcher conducted a similar experiment in vivo using anesthetized dogs. Flavio Trigo-Rocha, et al., Nitric Oxide and cGMP: Mediators of Pelvic Nerve-Stimulated Erection in Dogs, 264 Am. J. Physiology H419 (1993), PTX 0080. Zaprinast was administered to the dog by intercavernosal injection; researchers then electrically stimulated the dog's pelvic nerve, observing that zaprinast multiplied the effects of smooth muscle relaxation. Id. at H420. However, zaprinast only had this effect when administered at a very high dose. Id.

[66] Dr. Bush was a doctoral research student in Dr. Ignarro's and Dr. Rajfer's laboratory and was a co-author on the previously mentioned articles. See PTX 0073; PTX 0077.

cavernosum, though she cautioned that "penile erection is a complex neurovascular event, the mechanism of which is not clearly understood." Id. at 7. Thus, she concluded that her research had set the groundwork for future studies of erectile function and ED. Id. at 161. In particular, Bush suggested the use of nitrovasodilators by injection to treat ED, and commented that "clinical development of a specific cyclic GMP phosphodiesterase inhibitor should be considered for the treatment of impotence" because "[a] specific cyclic GMP phosphodiesterase inhibitor could enhance corporal smooth muscle relaxation by inhibiting the breakdown of cyclic GMP, thus having a direct and specific effect on the L-arginine-nitric oxide-cGMP mediated relaxation process." Id. at 159-60.

Finally, Dr. Kenneth Murray published a review article which recounted recent research on PDE5 inhibitors. Kenneth J. Murray, Phosphodiesterase V_A Inhibitors, 6 D. N. & P. 150 (1993), PTX 0076. In particular, Murray identifies the location of $PDEV_A$ in the body, describes known $PDEV_A$ inhibitors, and discusses those inhibitors effects in the body.[67] $PDEV_A$ is a cGMP specific PDE, which is located

[67] PDE5 and PDEV refer to the same enzyme. Previously roman numerals were used to refer to the classes of PDEs, but now Arabic numbers are standard. Trial Tr. 311:22-312:1 (Corbin testimony). The A in $PDEV_A$ refers to the fact that the article is about non-retinal PDEV, as retinal PDEV is $PDEV_{B\&C}$. Murray, Phosphodiesterase V_A Inhibitors, 6 D. N. & P. at 151; Trial Tr. 311:19-21.

in the lung, spleen, platelets, and various smooth muscle tissues, giving it, Murray states, "limited tissue distribution." Id. at 150-151. Murray then discusses zaprinast as a $PDEV_A$ inhibitor, though he notes that its selectivity between $PDEV_A$ and PDEI has not been well-established. Id. at 151. Zaprinast was known to inhibit $PDEV_A$ and cause relaxation in a number of smooth muscle tissues, including human corpus cavernosum. Id. at 152-53.[68] In evaluating the potential therapeutic uses of these inhibitors, Murray concluded that "[s]mooth muscle relaxation appears to be the most promising of the potential uses of $PDEV_A$ inhibitors, and possible therapeutic uses could include vasodilation, bronchodilation, modulation of gastrointestinal motility and treatment of impotence." Id. at 154-55. Murray states the selective action of these inhibitors "could be achieved" in tissues with a high level of guanylate cyclase activity, though he makes no mention of any such tissues. Id. at 155.

Therefore, in May 1994, a POSITA would have known that in vitro experiments taught that the relaxation of the smooth muscle tissue in the corpus cavernosum was controlled by the NANC nerve system with

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[68] Murray does note that the only in vivo studies with zaprinast were through systematic administration either in rats, dogs, or guinea pigs to study its effects on blood pressure, Murray, Phosphodiesterase V_A Inhibitors, 6 D. N. & P. at 153, or in humans to study its effects on asthma. Id. at 154. But see supra note 65 (Trigo-Rocha experiment involving intercavernosal injections in dogs). Both the Murray and the Trigo-Rocha studies were published in 1993. See PTX 0076; PTX 0080.

NO as a mediator to stimulate the production of cGMP. Further, a POSITA would have understood that cGMP PDE breaks down cGMP and the inhibition of cGMP PDE increases the production of cGMP. Finally, a POSITA would have been aware that Bush and Murray had suggested that a specific cGMP PDE inhibitor could potentially be useful in the treatment of impotence.

B.

A patent is presumed valid, thus "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282 (2006). This burden exists at every stage of the litigation and does not shift. Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc., 134 F.3d 1085, 1088 (Fed. Cir. 1998). Invalidity is a defense to infringement that must be proven by clear and convincing evidence. Microsoft Corp. v. i4i Ltd. P'ship, __ U.S. __, 131 S. Ct. 2238, 2252 (2011) (reaffirming that the clear and convincing evidence standard applies in all cases involving arguments of invalidity).[69]

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[69] Pfizer cites to Tokai Corp. v. Easton Enterprises, Inc., 632 F.3d 1358, 1367 (Fed. Cir. 2011), for the rule that when a party attacking the validity of the patent relies only on prior art that was already considered by the PTO, that party has an "enhanced burden" to prove obviousness. It is unclear whether this decision survives under the Supreme Court's recent holding in Microsoft, so the court does not apply any enhanced burden to Teva, even though it appears that all of the prior art on which Teva relies was before the PTO. See infra note 78. Furthermore, as this court holds herein that Teva cannot meet its burden to show invalidity by clear and convincing evidence, consideration of such an enhanced burden is unnecessary.

The defense of invalidity on the basis of obviousness is codified in the Patent Act, which provides that a patent shall not issue "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103(a) (2006). Obviousness then is focused on the scope of the patent in suit, not the patentee's goal in creating the patent. KSR Int'l Co. v. Teleflex, Inc., 550 U.S. 398, 419 (2007). The Supreme Court has set forth the factors a court must consider when evaluating a claim of obviousness:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy.

Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (1966) (emphasis added). This is a flexible, commonsense, and broad inquiry. KSR, 550 U.S. at 415 (disavowing the Federal Circuit's restrictive "teaching, suggestion, or motivation" test); but see Procter & Gamble Co. v. Teva Pharms. USA, Inc., 566 F.3d 989, 994 (Fed. Cir. 2009) (stating that the "teaching, suggestion or

motivation" test provides helpful insight into the obviousness question so long as it is not applied rigidly" (citing KSR, 550 U.S. at 419)).

A patent is obvious, if it is a "predictable use of prior art elements according to their established functions." KSR, 550 U.S. at 417. When a known problem exists "and there are a finite number of identified predictable solutions, a person of ordinary skill has good reason to pursue the known options . . . . [and] [i]f this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense." Id. at 421. The issue, thus, is whether the invention was "obvious to try." Id. The Federal Circuit has held that a way of analyzing this question is whether "a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so." Proctor & Gamble, 566 F.3d at 994 (citing Pfizer, Inc. v. Apotex, Inc., 480 F.3d 1348, 1361 (Fed. Cir. 2007)).

A patent is not obvious, however, if it was "obvious to explore a new technology or general approach . . . [but] the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it." Proctor & Gamble, 566 F.3d 989 (internal quotation marks omitted) (quoting In re O'Farrell, 853 F.2d

894, 903 (Fed. Cir. 1988)); see Abbott Labs. v. Sandoz, 544 F.3d 1341, 1352 (Fed. Cir. 2008) ("Slight reflection suggests, we think, that there is usually an element of 'obviousness to try' in any research endeavor, that is not undertaken with complete blindness but rather with some semblance of a chance of success." (citing Publication of Tomlinson, 363 F.2d 928, 931 (1966))). Furthermore, if the prior art "teaches away from combining certain known elements, discovery of a successful means of combining them is more likely to be nonobvious." KSR, 550 U.S. at 416. In determining the teaching of the prior art, the court must be aware of and avoid any distortion of hindsight. Id. at 421. Additionally, a "judge must not pick and choose isolated elements from the prior art and combine them so as to yield the invention in question if such combination would not have been obvious at the time of the invention." Dennison Mfg. Co. v. Panduit Corp., 475 U.S. 809, 810 (1986). Overall, the court must keep in mind that obviousness is a fact-specific inquiry where "[e]ach case must be decided in its particular context, including the characteristics of the science or technology, its state of advance, the nature of the known choices, the specificity or generality of the prior art, and the predictability of results in the area of interest." Abbott Labs., 544 F.3d at 1352; see id. at 1351-52 ("The evaluation of choices made by a skilled scientist, when such choices lead to the desired result, is a challenge to judicial

understanding of how technical advance is achieved in the particular field of science of technology.").

If a party challenging a patent makes out a prima facie case of obviousness, the party defending the patent may offer evidence of secondary considerations of non-obviousness, though secondary considerations of non-obviousness may not overcome a strong prima facie case. Wyers v. Master Lock Co., 616 F.3d 1231, 1246 (Fed. Cir. 2010). Such secondary considerations are, among others, "commercial success, long felt but unsolved needs, [and] failure of others." Graham, 383 U.S. 17-18. The patentee must show, however, that there is a nexus between the commercial success of the product and the claims in the patent. "A prima facie case of nexus is made out when the patentee shows both that there is commercial success, and that the product that is commercially successful is the invention disclosed and claimed in the patent." Crocs, Inc. v. Int'l Trade Comm'n, 598 F.3d 1294, 1311 (Fed. Cir. 2010). In other words, "commercial success or other secondary considerations may presumptively be attributed to the patented invention only where the marketed product embodies the claimed features and is coextensive with them." Muniauction, Inc. v. Thomson Corp., 523 F.3d 1318, 1328 (Fed. Cir. 2008) (internal quotation marks omitted) (citing Ormco Corp. v. Align Tech., Inc., 463 F.3d 1299, 1311-12 (Fed. Cir. 2006)). Once this prima face nexus is demonstrated, the burden shifts to the

party challenging the patent to prove that such a nexus does not exist. Id.

c.

Given the foregoing standards for obviousness, this court first looks to the Graham factors and evaluates whether Teva has shown by clear and convincing evidence that the '012 patent is obvious. Teva argues that the prior art, especially the Rajfer, Bush, and Murray studies, together with the EP '756, EP '004, and '534 patents,[70] renders the claims of the '012 patent obvious. In particular, Teva argues that given a POSITA's underlying knowledge of the role of cGMP in the erectile process, and the fact that these three patents disclosed potent and selective PDE5 inhibitors, it was obvious to try those inhibitors to treat ED. Pfizer counters that there is nothing in the prior art that teaches that an oral treatment with a PDE5 inhibitor would be effective for ED, when the details of the erectile process were unknown, the causes of ED were not established, and no in vivo testing had been done. Pfizer argues, to the contrary, that the prior art taught away from the use of sildenafil because other vasodilators actually caused ED when administered systemically.

[70] Each of these patents is discussed, supra, in Section I.C.

This court has already set out the parameters of the first Graham factor, the "scope and content of the prior art,"[71] and now turns to the question of what is the "level of ordinary skill in the pertinent art." Graham, 383 U.S. at 17. Both Teva's and Pfizer's experts offered a definition of what would constitute a POSITA in this case. The consensus was that a POSITA would have knowledge and skill in several scientific disciplines and would comprise a team of scientists with Ph.D.s or M.D.s with knowledge of medicinal chemistry, pharmacology, and urology. See Trial Tr. 140:17-25 (Corbin testimony); 891:25-892:8 (Goldstein testimony). The POSITA would have knowledge of the mechanism of erection and detumescence, ED and its treatment, and PDEs and PDE inhibitors. The POSITA would certainly be aware of the prior art recounted above and presented at trial. The court agrees with this definition and sees no way in which it should be changed.

The final Graham factor, and the key inquiry, is a determination of the "differences between the prior art and the claims at issue." Graham, 383 U.S. at 17. In contrast to many cases involving obviousness, there is no one reference that speaks to all of the elements of the claims. Claims 25 and 26 of the '012 patent claim a number of compounds, all of which are potent and selective inhibitors of cGMP PDE, for the oral treatment of ED in a male human.

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[71] See supra Section IV.A.

'012 patent, col. 1, lines 46-50, PTX 0001. Two prior patents, EP '756 and EP '004, disclose all of the compounds that are the basis of the method claims at issue in the '012 patent.[72] Further, EP '756 and EP '004 both disclose that the claimed compounds are vasodilators, which are highly potent and selective for cGMP PDEs[73] and elevate cGMP levels. EP '756, 3: 1-14, DX 2074; EP '004, 2:1-14, DX 2006.[74] Finally, EP '756 and EP '004 disclose that the compounds may be administered orally. EP '756, 7:23-32, DX 2074; EP '004, 9:11-15, DX 2006.

The '534 patent is the counterpart in the United States to EP '756, and its specification is substantially the same. Five of the especially preferred compounds of the '534 patent, including sildenafil, are in Claims 25 and 26 of the '012 patent. During the prosecution of the '534 patent, Dr. Ellis submitted an affidavit to the PTO on March 23, 1992, which gave selectivity information for PDE5 over PDE3 for numerous compounds, including twenty of the

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[72] EP '756, DX 2074, discloses sildenafil and four other compounds of Claim 25, while EP '004, DX 2006, discloses the other four. See supra Section I.C.

[73] These compounds are all potent and selective inhibitors of cGMP PDEs, both PDE1 and PDE5, over PDE3.

[74] EP '004 additionally contained a table with selectivity and potency of thirteen compounds in EP '004 for PDE5 over PDE3. EP '004, 26:1-35, DX 2006; see infra note 75.

compounds of the '534 patent. DX 2240.[75] Dr. Ellis's affidavit disclosed that these twenty compounds of the '534 patent, including sildenafil, were highly potent and selective for PDE5 over PDE3.[76]

Each of these prior patents discloses that the compounds are useful in the treatment of various cardiovascular illnesses, including angina and hypertension, as well as for the treatment of bronchitis and irritable bowel syndrome, among others, through the elevation of cGMP levels; ED was not included. Thus, from the patents, a POSITA would be aware of the existence of potent and selective cGMP PDE inhibitors that could enhance cGMP levels. In addition, a POSITA would understand that twenty of the compounds in the '534 patent and thirteen compounds in EP '004 were potent and selective inhibitors of PDE5 in particular.

The other prior art, from Rajfer, Bush, and Murray, all discusses the chemical messengers for erectile function, as demonstrated in tissue bath experiments. In particular, Rajfer and Bush document their research into the importance of NO as the chemical messenger for the corpus cavernosum by acting as a signaling agent

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[75] Dr. Corbin, Teva's expert, testified that a POSITA would have understood calcium/calmodulin independent cyclic GMP PDE to mean PDE5 and cGMP-inhibited cAMP PDE to mean PDE3. Trial Tr. 332:1-8, 13-14.

[76] This affidavit and the table in EP '004 did not disclose the compounds' selectivity and potency for PDE5 over PDE1, as they only compared selectivity between calcium/calmodulin independent cyclic GMP PDE and cGMP-inhibited cAMP PDE. See supra note 75.

for guanylate cyclase and cGMP. Murray adds to this discourse by summarizing research on PDE5 and PDE5 inhibitors. As PDE5 is a cGMP PDE, it inhibits the production of cGMP. If a substance in turn inhibits PDE5, it boosts production of cGMP and thereby enhances smooth muscle relaxation. Through Rajfer, Bush, and Murray, a POSITA would have been aware that zaprinast was a cGMP PDE inhibitor and that research had shown that it potentiated the relaxation of smooth muscle tissue stimulated with electric current.

None of these references, however, gives any relevant data on in vivo studies in humans for ED. The one in vivo study in humans of zaprinast was for the treatment of asthma and the relaxation of the smooth muscle of the lungs. Murray, Phosphodiesterase V_A Inhibitors, 6 D. N. & P. at 154, PTX 0076. Further, the one in vivo study in dogs testing zaprinast's effect on erections showed that it was only effective at extremely high doses when injected into the corpus cavernosum. Trigo-Rocha, Nitric Oxide and cGMP, 264 Am. J. Physiology H419, PTX 0080.[77] Some of the articles, particularly those of Bush and Murray, did, however, suggest that a cGMP PDE inhibitor could be used to treat ED, though there was no particular discussion of an oral treatment.

[77] See supra note 65.

Against all of these factors, the court assesses obviousness.[78] In this case, it is helpful to consider whether the prior art provided motivation to try sildenafil for the treatment of ED and whether it predicted a reasonable expectation of success in doing so; though the court notes that pursuant to KSR, it uses this analysis only as a tool to bring out evidence of obviousness and not for setting rigid requirements. Teva argues that these articles and the patents that disclosed potent cGMP PDE inhibitors made it "obvious to try" the use of sildenafil, or another compound in Claims 25 and 26 of the '012 patent, for the treatment of ED. As evidence of how a POSITA would connect the dots, Teva points to a handwritten note by Dr. Peter Ringrose, then head of Pfizer drug discovery, at the top of a copy of Rajfer's article,[79] which article and note were circulated to other members of the Pfizer team.[80] The note states: "Should we not try

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[78] The court does note that all of the references relied on by Teva were disclosed and considered by to the PTO, see '012 patent, at 2-7, PTX 0001; Teva Post-Trial Findings of Fact and Conclusions of Law on Standing and Validity ¶ 330, Docket # 411.

[79] Teva could not establish with particularity when Dr. Ringrose wrote the notation and circulated the article, but Dr. Ringrose testified that it was likely soon after the article was published. Ringrose dep. 124:8-20 (as played at trial).

[80] Teva references other contemporaneous evidence as illustrations of what a POSITA would have understood at the time. In particular, Teva presented evidence from Dr. Jackie Corbin, its expert in the fields of pharmacology and enzymology, who discovered PDE5 in 1976. Dr. Corbin testified that when he saw the Rajfer article, he understood that PDE5 inhibitors could be used to treat ED. The court finds such evidence interesting, though not highly probative, first

out UK 92,480 [sildenafil] in impotence? Have we seen any beneficial s/e's?".[81] DX 2109. Pfizer argues in opposition that the disclosure of the compounds and the prior art references is insufficient to demonstrate that there would be any motivation to try sildenafil, or any other cGMP PDE inhibitor, because there was not enough information on how such a compound would work in the body.

In KSR, the Supreme Court held that a patent is likely obvious when it is obvious to try a combination of elements from prior art. KSR, 550 U.S. at 421. The question is not whether there would be some motivation to try, or even substantial motivation to try, but rather whether it would have been obvious to a POSITA to try, as judged on a clear and convincing evidence standard. The answer here is in the negative. The court finds that it certainly was not so obvious as Teva contends during the pre-Viagra era of the early to mid-1990's. First, Teva has overstated the level of knowledge concerning erectile function during the relevant time period. While several experiments, among them those of Ignarro and Rajfer, had reported

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because the evidence offered concerning the letters Dr. Corbin wrote to Vanderbilt University and GlaxoSmithKline were not in the public domain such that a POSITA would be aware of them, see DX 2275; DX 2455; DX 2267; and, second, because the court's task is to determine what a POSITA would have understood, not what one particular scientist understood. The court is also mindful that Dr. Corbin's primary area of research for his life's work is in PDEs. Trial Tr. 110:22-25.

[81] Dr. Ringrose testified that "s/e's" meant "side effects." Ringrose dep. 123:22-23 (as played at trial).

findings that NO was the messenger from the NANC nerve system to the smooth muscle tissue and that cGMP caused smooth muscle relaxation, all of those experiments were conducted in a tissue bath environment with artificially contracted tissue, artificial blood, and a high level of oxygen. This is not to discount the scientific validity and importance of tissue bath experiments, but rather to note their limitation in predicting results in the human body and to recognize that they are often only an initial step in conducting research. The Federal Circuit has noted that motivation and predictability in the chemical arts are particularly difficult, Procter & Gamble, 566 F.3d at 996, because of the difference between in vitro data and in vivo behavior in the human body. Abbott Labs., 544 F.3d at 1348. Thus, while multiple experiments noted the significance of NO and cGMP, it is important to remember that such experiments were in vitro with all other systems besides the NANC nerve system blocked. Thus, in May 1994, a POSITA lacked substantive knowledge about the function of the erectile system and whether other factors outside of the NANC nerve system played a significant role in the relaxation of the corpus cavernosum.

Second, again Teva overestimates the import of the function of zaprinast in the in vitro experiments. The fact that zaprinast potentiated smooth muscle relaxation in electrically stimulated precontracted tissue in vitro did not necessarily give any

information about its function in vivo. This is borne out by Dr. Trigo-Rocha's experiment with anesthetized dogs where only a very high dose of zaprinast injected intercavernosally had any effect on smooth muscle relaxation. PTX 0080.[82] Thus, such experimental results informed a POSITA in 1994 that zaprinast had an effect on smooth muscle relaxation in vitro, which effect had not yet been repeated in vivo at a sustainable dose in animals or humans.

Third, the fact that Murray and Bush suggested that a selective cGMP PDE or PDE5 inhibitor could be used to treat ED provides only some motivation to try such a known inhibitor. While it is to be expected that researchers will use conditional language such as "could" or "potentially" in suggesting avenues of future research, the mere fact that the course of treatment was suggested is not sufficient to demonstrate that it would have been obvious to try. Here in particular, in May 1994, there was little knowledge of the causes of ED. Rajfer suggested that perhaps a defect in the pathway caused ED, but that could have involved either a lack of NO, guanylate cyclase, or cGMP, or conversely an overabundance of cGMP PDE. Indeed, the 1992 NIH Consensus Statement on Impotence concludes that "important information on many aspects of erectile dysfunction is lacking; major research efforts are essential to the improvement of our understanding of the appropriate diagnostic assessments and

[82] See supra note 65.

treatments of this condition." PTX 0018, at 29. Thus, a POSITA could have been motivated to try a cGMP PDE inhibitor to treat ED, but such motivation would seem to come more from a willingness to try a "longshot" rather than from the treatment being the obvious logical step.

Even if a POSITA was motivated to try one of the compounds in EP '756 or EP '004, he would have had no reasonable expectation of success in the endeavor. Teva again argues that the in vitro experiments showing the effect of zaprinast, the suggestion that a cGMP PDE inhibitor could treat ED, and the number of known selective and potent cGMP PDE inhibitors from EP '756 and EP '004, would give rise to a reasonable probability of success. Pfizer again counters that there was very little suggestion that a cGMP PDE inhibitor would be effective in general, and particularly when administered orally, given that vasodilators generally caused ED, rather than preventing or treating it. The court finds that in May 1994 there was no reasonable expectation that oral administration of a compound from EP '756 or EP '004 would have been successful in treating ED.

Specifically, it was disclosed in the EP '756, EP '004, and '534 patents that the compounds claimed therein were vasodilators with the potential to treat various cardiovascular diseases. This disclosure would have taught away from using the compounds to treat ED because, as noted by researchers in the field at the time,

vasodilators used to treat hypertension often caused ED. See J. David Curb et al., Antihypertensive Drug Side Effects in the Hypertension Detection and Follow-Up Program, 11 Hypertension 51, 51 (1988) (reporting that in a study of over 5,000 people "[a]mong the known side effects of antihypertensive drugs, sexual problems in males are often of major concern. Impotence was the most frequently reported problem for all drugs."), PTX 0047. Moreover, there was little research on whether cGMP PDE inhibitors could actually have any effect on the relaxation of the corpus cavernosum. The in vitro studies, the limitations of which were discussed above, and the Trigo-Rocha intercavernosal study, likewise did not indicate that the compounds would have the desired effect in the human body and thus a reasonable probability of success.[83]

Finally, and most importantly, there was no basis for a POSITA to believe that the administration of a cGMP PDE inhibitor orally would have the desired effect. A cGMP PDE had never been administered orally to treat ED; indeed, the only oral study in humans concerned the treatment of asthma. Murray, Phosphodiesterase V_A Inhibitors, 6 D. N. & P. at 154, PTX 0076. The only cGMP PDE inhibitor study conducted to determine treatment for ED in vivo was by intercavernosal injection in dogs. Trigo-Rocha, Nitric Oxide and

[83] Furthermore, contrary to Teva's repeated assertions, the court finds no evidence that a POSITA in 1994 had any knowledge that the penis contained a large amount of PDE5. A POSITA knew PDE5 was present in the penis, but not in any relative amount.

cGMP, 264 Am. J. Physiology H419, PTX 0080. The state of the art at the time was to treat ED with a vasodilator applied locally, either through the practice of injection or the emerging topical treatments, so that a sufficient concentration of the medicine existed in the local area. Again, as discussed above, systemic administration was avoided so as not to cause side effects and to prevent the medication from causing vascular steal away from the penis. [84]

The court, therefore, finds that Teva has failed to establish by clear and convincing evidence that the '012 patent is void for obviousness, as the claims in suit are undoubtedly "more than the predictable use of prior art elements according to their established functions." KSR, 550 U.S. at 417. The court does not deny that there is some evidence which would tend to show motivation to try one of these compounds, but a POSITA would have no expectation that oral administration of such compounds would be successful in treating ED, and thus such method was not obvious to try. This conclusion is supported by Dr. Ringrose's note. His suggestion "[s]hould we not try out UK 92,480 [sildenafil] in impotence?" bespeaks of a "well, why not try" attitude, rather than a belief that "this will definitely work." In addition, it is emblematic of the accepted understanding

[84] Vascular steal refers to when a vasodilator is administered systemically, thereby relaxing the entire vascular system, and blood is diverted away from the penis because of increased blood flow all over the body; there is then insufficient blood flow to sustain an erection. Trial Tr. 905:15-906:1.

at the time that systemic application was a dead end; when Pfizer did test sildenafil as part of its impotence program, it did so through intercavernosal injection in monkeys. Trial Tr. 710:3-716:5. Because Teva did not prove even a prima facie case of obviousness, this court need not consider Pfizer's arguments concerning secondary considerations of non-obviousness.[85]

D.

Therefore, this court **FINDS** that Teva has not shown by clear and convincing evidence that the '012 patent is invalid because of obviousness and, therefore, **DIRECTS THE CLERK TO ENTER JUDGMENT** for Pfizer on Teva's Amended Counterclaim to this effect.

V. Double Patenting

The second argument Teva makes concerning the validity of the patent is that the patent is invalid for obviousness-type double patenting. In particular, Teva argues that Claims 25 and 26 of the '012 patent are not patentably distinct from Claim 1 of Pfizer's earlier-issued United States Patent Number 6,100,270 ("the '270 patent"). United States Patent No. 6,100,270 (filed Oct. 16, 1995)

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[85] Before the court, Pfizer presented evidence concerning the sales of Viagra, that it met a long-felt need, and that it had inspired other copycat drugs as proof that it was not an obvious invention. See Trial Tr. 1011:24-1046:5 (testimony of Henry Grabowski, Pfizer's expert in the economics of the pharmaceutical industry).

(issued Aug. 8, 2000), DX 2066.[86] Pfizer counters that there are fundamentally important distinctions between the '012 patent and the '270 patent, most importantly in terms of structure of the compounds and their method of administration, such that the '012 patent is distinct and valid.

A.

The '270 patent, entitled "Bicyclic Heterocyclic Compounds for the Treatment of Impotence," was filed on October 16, 1995, over a year after the '012 patent was filed, but it issued two years before the '012 patent. Compare '012 patent, PTX 0001, with '270 patent, DX 2066. Thus, the '270 patent is considered an earlier-issued patent for the purposes of double patenting. Claim 1 of the '270 patent claims: "A method of treating male erectile dysfunction comprising administering to a male human in need of such treatment an effective amount of a compound of formula (I)." '270 patent, col. 8, lines 8-10, DX 2066. The patent disclosed that the formula created compounds that are potent and selective inhibitors of cGMP PDE, id. at col. 1, lines 47-50, DX 2066, and that some compounds of the formula were tested and found to be potent and selective inhibitors of PDE5 over PDE3. Id. at col. 7, lines 9-11, DX 2066.

[86] Earlier Teva argued that the '012 patent was invalid for double patenting based on both the '270 patent and United States Patent Number 6,534,511, but at trial limited its double patenting claim to the '270 patent. Trial Tr. 508:1-12.

The specification states that the preferred route of administration of the compounds is oral, id. at col. 7, lines 22-23, DX 2066, though Claim 1 does not name a method of administration.

The formula in the '270 patent was initially disclosed in World Intellectual Property Organization Patent Number 93/06104 ("WO '104"), filed September 4, 1992, with a publication date of April 1, 1993. See DX 2068. WO '104, entitled "Pyrazolopyrimidinone Antianginal Agents," disclosed a group of compounds according to the formula that were selective and potent inhibitors of cGMP PDEs over cAMP PDEs. WO '104 stated that the compounds were useful in the treatment of "cardiovascular disorders, such as angina, hypertension, heart failure and atherosclerosis." WO '104, at 1, DX 2068. Additionally, WO '104 included a table which listed selectivity and potency data for PDE5 over PDE3 for four examples of compounds of the formula. Id. at 18-19, DX 2068. WO '104 discloses that the compounds may be administered orally. Id. at 8-9, DX 2068.

B.

The law concerning obviousness-type double patenting is well-settled. "The judicially-created doctrine of obviousness-type double patenting . . . prohibit[s] a party from obtaining an extension of the right to exclude through claims in a later patent that are not patentably distinct from claims in a

commonly owned earlier patent." Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 967 (Fed. Cir. 2001) (en banc). Obviousness-type double patenting "prevent[s] claims in separate applications or patents that do not recite the 'same' invention, but nonetheless claim inventions so alike that granting both exclusive patent rights would effectively extend the life of patent protection." Perricone v. Medicis Pharm. Corp., 432 F.3d 1368, 1373 (Fed. Cir. 2005). The question, thus, is whether the later invention is a "slight variant" of the earlier. Geneva Pharms., Inc. v. GlaxoSmithKline P.L.C., 349 F.3d 1373, 1378 (Fed. Cir. 2003).

The court must undertake a two-step analysis in determining whether a patent is void for double patenting. "First, as a matter of law, a court construes the claim in the earlier patent and the claim in the later patent and determines the differences. Second, the court determines whether the differences in subject matter between the two claims render the claims patentably distinct." Eli Lilly, 251 F.3d at 968 (citation omitted). "A later patent claim is not patentably distinct from an earlier patent claim if the later claim is obvious over, or anticipated by, the earlier claim." Id. As stated above as relates to obviousness, the party challenging the patent bears the burden of proving that the patent is invalid by clear and convincing evidence. Microsoft, 131 S. Ct. at 2252.

c.

Teva argues that because the compounds of the '012 patent, as informed by EP '756 and EP '004, have the same properties as the formula of the '270 patent, as informed by WO '104, they are not patentably distinct. In particular, Teva argues that all of the compounds in the '012 and the '270 patents are selective and potent inhibitors of cGMP PDE, all may be administered orally, and all have the same pyrazolopyrimidinone nucleus with an alkoxy substituent at the 2-position of the phenyl ring. Pfizer argues in opposition that there are two important patentable differences between the two patents: First Claims 25 and 26 of the '012 patent specify oral administration of the compounds while Claim 1 of the '270 patent does not; and second the differences in structure of the compounds in each patent render them patentably distinct.

Turning to the first step in the analysis mandated by Eli Lilly, the court construes the claims at issue in both the earlier patent and the patent in suit and determines their differences. This court has already construed Claims 25 and 26 of the '012 patent as part of its claim construction analysis. See Pfizer, Inc. v. Teva Pharms. USA, Inc., __ F. Supp. 2d __, 2011 W.L. 996794 (E.D. Va. 2011). Thus, Claim 1 of the '270 patent remains to be construed. Claim 1 of the '270 patent claims, in pertinent part: "A method of treating male erectile dysfunction comprising administering to a male human in need

of such treatment an effective amount of a compound of formula (I)." '270 patent, col. 8, lines 8-10, DX 2066. As this claim has many of the same terms as in the '012 patent, it is construed under the court's previous claim construction order as:[87] "A method practiced for the purpose of treating an inability to maintain or sustain an erection adequate for intercourse comprising administering to a male human in need of such treatment an effective amount of a compound of formula (I)." Comparing Claims 25 and 26 of the '012 patent and Claim 1 of the '270 patent, it is clear that the only differences between the claims are: (1) the '012 patent specifies that administration of the effective amount of the compound shall be oral; and (2) the compounds named in the claims are not the same. Given these differences, the court looks to the second part of the Eli Lilly analysis and determines whether the differences between the two claims render them patentably distinct.

Pfizer and Teva squarely disagree as to whether the addition of "orally administering" to the claims in the '012 patent in and of itself renders the claims patentably distinct. Teva argues that because WO '104 disclosed that the compounds of the formula of the '270 patent could be administered orally, and because the

[87] The court sees no indication in the specification and claims of the '270 patent that would indicate its terms had any different meaning from the terms of the '012 patent. Indeed, the '270 and the '012 patent share the same definition of erectile dysfunction. See '270 patent, col. 1, 13-16, DX 2066; '012 patent, col. 1, lines 11-14, PTX 0001.

specification of the '270 patent itself states that the preferred route of delivery is oral, then there is no difference in the methods of administration of the claims. Pfizer argues that given the knowledge of a POSITA at the time the '270 patent was filed, the method of administration is critical, because a POSITA would assume local application given the issues experienced with systemic administration of vasodilators.[88]

The court finds that there is no patentable difference between the '270 and the '012 patents on this metric alone. While it is true that Claim 1 of the '270 patent does not itself specify oral administration, the patent's specification mentions oral administration as the preferred route and does not mention local application, either topically or through intercavernosal injection. In fact, each of the routes of administration mentioned – oral, sublingual, or buccal – are all systemic administrations of the drug. Therefore, the court finds unavailing Pfizer's argument that a POSITA would have understood the '270 patent to provide for local administration of the compounds of the formula.

Therefore, it remains to be determined whether the claims are patentably distinct by the fact that they claim different compounds for the treatment of ED, or if they are only "slight variants" of one another. Geneva Pharms., 349 F.3d at 1378. Teva argues that

[88] See supra Section IV.A.

the differences between the compounds are minimal and do not have any effect on their pharmacologic properties and activity in the body. Pfizer, by contrast, contends that even small changes in the structure of a compound can make significant and unpredictable changes to their effectiveness and function. Looking to the formula in Claim 1 of the '270 patent and the compounds in Claims 25 and 26 of the '012 patent, Teva's and Pfizer's experts agree that the ring structure of the compounds is the same in both cases, and only the substrates are different. Compare '012 patent col. 10, lines 5-30, 35-37, PTX 0001, with '270 patent col. 2, lines 2-21, DX 2066.

Dr. Nicholas Terrett, Pfizer's expert in medicinal chemistry, compared the structures of the formula in the '270 patent and the compounds in the '012 patent and discussed two differences between the substrates. Trial Tr. 969:6-1010:24.[89] First, where the '270 patent has a methyl group, a one carbon chain, the '012 patent has a propyl chain, a three carbon group. Trial Tr. 989:4-13. He testified that a propyl group in that position helps the compound bind better with cGMP PDE. Trial Tr. 989:13-16. Additionally, in another substrate location, the formula of the '270 patent has a sulfonamide group containing a sulfur, two oxygens, and a nitrogen, in a chain structure. Trial Tr. 989:20-22. The '012 patent's compounds also have a sulfonamide group at that substrate location,

[89] The court finds Dr. Terrett to be an extremely credible witness.

but its elements form a ring structure. Trial Tr. 990:1-5. Dr. Terrett testified that the structure of the sulfonamide group was particularly important for determining how the compound interacts with the body. Trial Tr. 990:6-11. Overall, Dr. Terrett testified that when dealing with protein inhibitors, the structure of the compound is particularly important because the protein binds with the inhibitor via a three-dimensional binding site on the protein itself. Trial Tr. 976:25-977:13. How well the inhibitor binds with the protein determines its potency and selectivity. Trial Tr. 992:5-8.

Teva does not challenge that these structural differences exist, but maintains that they are unimportant when the compounds have the same properties: They are potent and selective inhibitors of cGMP PDE. The court, however, disagrees that its task in determining whether a pharmaceutical, "drug" patent is void for obviousness-type double patenting is to only look at broad properties of pharmaceutical compositions. Instead, the court must examine the details of the structure and function of the claimed compounds to determine if they are patentably distinct. In this case, it is clear from the expert testimony of Dr. Terrett that the structural differences between the formula in Claim 1 of the '270 patent and the compounds in the '012 patent render them patentably distinct. While these compounds may have had the same general function, changes

in the structure of the compounds can have significant effects on their function within the body. Trial Tr. 992:5-8. The court further observes that, as the trier of fact, the table included in WO '104, admitted into evidence as DX 2068, lists the potency and selectivity values for four examples of compounds from the formula. Three of the examples show differences only within the sulfonamide substrate, but their selectivity ratios range from 250 to 3830. WO '104, at 18-19, DX 2068.[90] This table demonstrates that as the three-dimensional structure of the molecule changes, its selectivity for PDE5 over PDE3 changes.[91] Additionally, there is no evidence that the effects on selectivity caused by these changes in structure were in any way predictable.

The court finds no merit to Teva's argument that the differences in structure of the compounds make them only slight variants, as such changes have unpredictable and sometimes significant effects on the compounds function within the body, and thus Claims 25 and 26 of the '012 patent are patentably distinct from Claim 1 of the '270 patent.

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[90] While the court is not an expert chemist, these factual observations are clear from the exhibit itself. Moreover, the court does not consider Example 1 because it appears "on its face" to have an additional difference in another of the substrates. WO '104, 18, DX 2068.

[91] The court does note, from the face of the exhibit, that the potency of the compounds remains relatively constant. WO '104, 18-19, DX 2068.

D.

Therefore, this court **FINDS** that Teva has not shown by clear and convincing evidence that the '012 patent is invalid because of obviousness-type double patenting and **DIRECTS THE CLERK TO ENTER JUDGMENT** for Pfizer on Teva's Amended Counterclaim to this effect.

VI. Inequitable Conduct

Teva makes a third and final claim concerning the enforceability of the '012 patent. Teva argues that the patent should be invalidated in its entirety because of inequitable conduct committed during its prosecution and reexamination. In particular, Teva argues that Gerard M. O'Rourke, one of Pfizer's outside counsel during the prosecution of the '012 patent, committed inequitable conduct by failing to disclose information to the PTO.[92] Pfizer does not dispute any of the facts or evidence presented by Teva at trial, but argues that as a matter of law the conduct alleged does not constitute inequitable conduct. The court agrees with Pfizer.

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[92] The involvement of additional parties was alleged in the Amended Answer and Counterclaim, but, as previously noted by the court, upon stipulation by Teva, these additional parties were dismissed from consideration. See supra note 41. Thus, the only allegations which remain before the court, and upon which evidence was presented at trial, concern Mr. O'Rourke.

A.[93]

Mr. O'Rourke was a partner at the Delaware law firm Connolly Bove Lodge & Hutz ("Connolly Bove"),[94] which firm was engaged by Pfizer to manage disclosure of certain information to the PTO during the prosecution of the '012 patent. He testified that his particular duties were to send Information Disclosure Statements ("IDS") to the PTO during the prosecution of the patent. Teva's patent law and procedure expert, Cameron Weiffenbach, Esq., testified that pursuant to the continuing duty of disclosure to the PTO, a patent applicant must send an IDS to the PTO to bring new information to the patent examiner's attention after the application has been filed. Trial Tr. 1110:06-22. The duty of disclosure arises from the duty of candor and good faith contained in Rule 56 of the Rules of Practice in Patent Cases. Trial Tr. 1120:21-1121:7.[95] The Rules provide that

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[93] The facts in this Subsection are found from the credible testimony, via videotape deposition played at trial, of Mr. O'Rourke, Mr. Hutz, Mr. Jones, Mr. McMunn, and Mr. Richardson, as well as the agreed exhibits in the case.

[94] See supra note 43.

[95] Rule 56 provides, in pertinent part: "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56(a). An "individual associated with the filing and prosecution of a patent application" is defined as: "(1) Each inventor named in the application; (2) Each attorney or agent who prepares or prosecutes the application; and (3) Every other person who is substantively involved in the preparation or

a patentee has a continuing duty of disclosure to the PTO with respect to information material to patentability of the application. Trial Tr. 1121:22-1122:11.[96]

Connolly Bove and Mr. O'Rourke were hired to fulfill this obligation with regard to sending the PTO information concerning prosecution in foreign jurisdictions of the subject matter of the '012 patent. See DX 2183 (letter from James Jones of Pfizer requesting that Connolly Bove set up a system for disclosing documents from foreign jurisdictions to the PTO). Initially Pfizer handled the foreign disclosures itself, but eventually the volume became such that the use of outside counsel was necessary. Jones dep. 78:13-22 (as played at trial). Mr. O'Rourke was assigned to

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prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." Id. at § 1.56(c).

[96] "Information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and:

> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
>
> > (i) Opposing an argument of unpatentability relied on by the Office, or
> >
> > (ii) Asserting an argument of patentability."

Id. § 1.56(b).

the project by Rudolph Hutz, a more senior partner at Connolly Bove, and they worked together to submit the IDS forms and materials. DX 2118 (power of attorney of February 9, 1998, from Pfizer granting Mr. Hutz power of attorney to prosecute the '012 patent on its behalf); DX 2012 (power of attorney of November 13, 2000, from Pfizer granting Mr. O'Rourke power of attorney to prosecute the '012 patent on its behalf). Mr. Hutz explained to Mr. O'Rourke the general subject matter of the patent and then told Mr. O'Rourke that Mr. O'Rourke would be responsible for gathering the foreign documents and determining which ones should be disclosed to the PTO. Hutz dep. 38:25-39:24 (as played at trial). In total, Mr. O'Rourke submitted three IDS disclosures to the PTO – one in November 2000, DX 2128; one in March 2001, DX 2129; and one in February 2002, DX 2130 – all of which submitted documents from foreign prosecutions. Mr. Hutz reviewed these IDS before they were sent to the PTO. Id. at 28:13-16.

Mr. O'Rourke obtained the foreign documents in two ways, either directly from the foreign counsel prosecuting and defending the patent overseas, or from Watson McMunn, an internal United Kingdom patent counsel at Pfizer who was in charge of worldwide prosecution of the subject matter of the '012 patent. O'Rourke dep. 38:12-15 (as played at trial). Mr. McMunn and the foreign attorneys, following Pfizer policy, sent Mr. O'Rourke every document from every foreign proceeding and then left it up to him to determine what needed

to be disclosed to the PTO. McMunn dep. 55:20-56:04 (as played at trial). As a patent agent admitted only in the United Kingdom, Mr. McMunn was unfamiliar with the PTO rules and relied on counsel in the United States to correctly comply with them. Id. at 56:09-12. In order to fulfill his duty of disclosure and comply with Pfizer policy, Mr. O'Rourke testified that he looked at each document that came in and determined whether to turn it over to the PTO. Before May 2002, Mr. O'Rourke turned over all documents that were substantively relevant, leaving out only those documents that were purely procedural. O'Rourke dep. 53:23-54:05 (as played at trial).[97]

After May 2002, however, Mr. O'Rourke's practice changed as a result of instructions he received from Mr. Hutz. Beyond reviewing the IDS, Mr. Hutz also attended meetings with the patent examiner on behalf of Pfizer. At one such meeting on May 7, 2002, the patent examiner notified Mr. Hutz that the claims of the '012 patent were going to be allowed, so long as Pfizer submitted a written request for reexamination. See DX 2183 (interview notes from patent examiner indicating that the claims were in condition for allowance). Also at the interview, Mr. Hutz testified that the examiner indicated he was not interested in the foreign materials of the type Pfizer had been submitting. Hutz dep. 137:12-18 (as played at trial). As

[97] Mr. O'Rourke built a database with every document received from Mr. McMunn and the foreign attorneys and kept track of everything he turned over to the PTO. O'Rourke dep. 47:03-05 (as played at trial).

a result of this meeting, Mr. O'Rourke testified that he met with Mr. Hutz, who asked Mr. O'Rourke if there were any foreign materials that were any different than those previously submitted. When Mr. O'Rourke answered in the negative, Mr. Hutz told him that the claims were being allowed, and the examiner was not interested in anymore similar foreign materials, so no further IDS needed to be sent. O'Rourke dep. 60:8-17 (as played at trial).

Therefore, after approximately May 7, 2002, Mr. O'Rourke, while he continued to receive documents from Mr. McMunn and the foreign attorneys, did not review such documents as he had before. Instead, when a document came in, he would determine which country it was from, tell his paralegal to enter the document into the running database of documents received,[98] and then have it filed it in a box with the rest of the documents from that country. O'Rourke dep. 61:5-10 (as played at trial). Mr. O'Rourke did not review the documents in any way to determine if they were material, and he testified that he expected that if something was truly important, Mr. McMunn would have brought it to his attention. Id. at 71:7-15, 74:18-20.[99] Thus, after May 7, 2002, no one from Pfizer reviewed documents from foreign litigations to determine if they should be disclosed to the PTO.

[98] See supra note 97.

[99] Mr. McMunn, on the other hand, testified that he turned everything over to United States counsel, Mr. O'Rourke, so that Mr. O'Rourke could follow United States law and determine what needed to be disclosed. McMunn dep. 67:14-19 (as played at trial).

One document that Mr. O'Rourke received after May 7, 2002, which he did not review, was a Statement of Claim from Canada in which Bayer Aktiengesellschaft and Bayer, Inc. (collectively "Bayer") sued Pfizer on the Canadian version of the '012 patent.[100] In that Statement of Claim, filed June 5, 2002, in the Federal Court of Canada Trial Division, Bayer argued that Pfizer's Canadian patent was invalid. See DX 2018. Smart & Biggar, Pfizer's designated representatives for service of process in Canada, were served with the claim on June 11, 2002. They then forwarded it to Mr. McMunn on June 12, 2002, which he apparently received in the United Kingdom Patent Department on June 17, 2002. DX 2020. On July 9, 2002, Mr. McMunn forwarded the Statement of Claim to Mr. O'Rourke. PTX 0365.

Meanwhile, on May 22, 2002, the PTO sent Pfizer a "Notice of Allowance and Fee(s) Due," which notified Pfizer that the claims of the '012 patent were going to be allowed and payment of the issue fee was due by August 2, 2002. DX 2125. On June 12, 2002, Pfizer transmitted the issue fee to the PTO, which apparently received it on June 20, 2002. DX 2126. The '012 patent issued on October 22, 2002. PTX 0001.

B.

The court's determination of whether Mr. O'Rourke's actions constitute inequitable conduct is controlled by the Federal

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[100] See supra Section III.A.

Circuit's recent en banc decision in Therasense, Inc. v. Becton, Dickinson & Co., __ F.3d __, 2011 W.L. 2028255 (Fed. Cir. 2011) (en banc). Therein, the Federal Circuit redefined the required showing to invalidate a patent on the grounds of inequitable conduct. The Federal Circuit significantly narrowed the number of instances in which a court may find inequitable conduct, and thus an in-depth explanation of Therasense's holdings is warranted.

In Therasense, Becton, Dickinson & Co. ("Becton Dickinson") sued Therasense, Inc. and Abbott Laboratories (collectively "Abbott") seeking a declaratory judgment of non-infringement of Abbott's patent for glucose blood test strips. Beyond arguing non-infringement, Becton Dickinson claimed that the patent in suit was void and unenforceable because of inequitable conduct committed during its prosecution. The actions alleged constituting inequitable conduct arose from Abbott's prosecution of the patent in the United States and the position it took in that prosecution with respect to a prior patent prosecuted in Europe. The earlier European patent claimed another glucose test strip, preferably, it stated, with a membrane over the sensory electrode. When defending the instant patent in the United States, Abbott had to overcome an obviousness argument from the PTO which referenced the prior European patent. Abbott's attorney and the patent's inventor submitted affidavits to the PTO which stated that the previous patent only

taught a glucose test strip with a membrane, while the instant patent specifically stated that a membrane was not used in the invention. However, in the earlier prosecution of the European patent, Abbott had argued that the European patent provided for a glucose test strip with or without a membrane. Abbott then did not disclose that previous position to the PTO in the prosecution of the new patent in the United States, an action Becton Dickinson claimed constituted inequitable conduct.

On this evidence, the district court invalidated the patent for inequitable conduct. See Therasense, Inc. v. Becton, Dickinson & Co., 565 F. Supp. 2d 1088 (N.D. Ca. 2008). On appeal, a panel of the Federal Circuit affirmed. Therasense, Inc. v. Becton, Dickinson & Co., 593 F.3d 1289 (Fed. Cir. 2010). However, recognizing "the problems created by the expansion and overuse of the inequitable conduct doctrine, [the Federal Circuit] granted [Abbott's] petition for rehearing en banc," then reversed and remanded the case for further proceedings. Therasense, Inc. v. Becton, Dickinson & Co., __ F.3d __, 2011 W.L. 2028255, at *4 (Fed. Cir. May 25, 2011) (en banc).[101]

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[101] In granting rehearing en banc, the Federal Circuit posed the following six questions:

> 1. Should the materiality-intent-balancing framework for inequitable conduct be modified or replaced?

"Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent. This judge-made doctrine evolved from a trio of Supreme Court cases that applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct." Id. Early inequitable conduct cases involved the manufacture or suppression of evidence before the PTO, but the doctrine then evolved to encompass not only affirmative fraud but also nondisclosure of information to the PTO. Id. at *6. What stayed constant was that a party arguing inequitable conduct was required to prove both intent to deceive the PTO and materiality of the non-disclosed information. Id. The standards for finding

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2. If so, how? In particular, should the standard be tied directly to fraud or unclean hands? If so, what is the appropriate standard for fraud or unclean hands?

3. What is the proper standard for materiality? What role should the United States Patent and Trademark Office's rules play in defining materiality? Should a finding of materiality require that but for the alleged misconduct, one or more claims would not have issued?

4. Under what circumstances is it proper to infer intent from materiality?

5. Should the balancing inquiry (balancing materiality and intent) be abandoned?

6. Whether the standards for materiality and intent in other federal agency contexts or at common law shed light on the appropriate standards to be applied in the patent context.

Therasense, Inc. v. Becton, Dickinson & Co., 374 Fed. Appx. 35, 35-36 (Fed. Cir. Apr. 26, 2010) (unpublished).

intent, however, fluctuated over time, where at one time a finding of gross negligence or negligence was sufficient. E.g., Driscoll v. Cebalo, 731 F.2d 878, 885 (Fed. Cir. 1984). Materiality was judged from the broad viewpoint of a reasonable examiner. E.g., Am. Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1362-63 (Fed. Cir. 1984). Those two elements were considered together on a sliding scale where a strong showing of one element, either materiality or intent, would balance out a weaker showing of the other and prove inequitable conduct occurred. Id. at 1362.

The Federal Circuit found that while the more flexible standard for showing inequitable conduct had been put in place to encourage disclosure to the PTO, the expansion of the doctrine had unintended consequences. Therasense, 2011 W.L. 2028255, at *7. The most troubling of these consequences was that pleading inequitable conduct had become a litigation strategy because it "conveniently expands discovery into corporate practices before patent filing and disqualifies the prosecuting attorney from the patentee's litigation team." Id. Furthermore, "[b]ecause the doctrine focuses on the moral turpitude of the patentee with ruinous consequences for the reputation of his patent attorney, it discourages settlement and deflects attention from the merits of validity and infringement issues." Id. Additionally, "[i]nequitable conduct disputes also increase the complexity, duration and cost of patent infringement

litigation that is already notorious for its complexity and high cost." Id. (citation and internal quotation marks omitted). Finally, compounding concerns about the far-reaching consequences of the doctrine, "the remedy for inequitable conduct is the 'atomic bomb' of patent law," whereby "inequitable conduct regarding any single claim renders the entire patent unenforceable." Id. at *8.

For all these reasons, the Federal Circuit revisited the requirements for a showing of inequitable conduct, "tighten[ing] the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public." Id. at *9. Therefore, after Therasense, in order to substantiate a claim of inequitable conduct, "the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." Id. Additionally, the court did away with the sliding scale test, requiring instead that each element, intent and materiality, be proven by clear and convincing evidence and that neither may be inferred from a strong showing of the other. Id. at *10.

On the intent prong in particular, the Federal Circuit held that courts may infer intent from direct and circumstantial evidence, but that such intent must be "the single most reasonable inference able to be drawn from the evidence." Id. (emphasis added) (citation and

internal quotation marks omitted). "When there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found." Id. For materiality, the court held that "the materiality required to establish inequitable conduct is but-for materiality." Id. at *11 (emphasis added). Thus, the court must determine "whether the PTO would have allowed the claim if it had been aware of the undisclosed reference." Id. If the party challenging the patent shows each of these elements by clear and convincing evidence, the party defending the patent may offer a good faith defense. Id. at *10.

The court did recognize one exception to the "but-for" causation required for materiality. When "the patentee has engaged in affirmative acts of egregious misconduct," materiality may be assumed. Id. at *12. Willfully filing a false affidavit is an example of such egregious misconduct. Id. The court made clear, however, that "mere nondisclosure of prior art references to the PTO [or] failure to mention prior art references in an affidavit" does not constitute affirmative egregious misconduct. Id. The Federal Circuit approved of the egregious misconduct exception because its roots are in the original "unclean hands" cases and it allows for flexibility when a willful fraud is perpetrated upon the PTO. Id. at *13.

c.

Turning to the specific facts in this case, Teva argues that Mr. O'Rourke's failure to turn over the Bayer Statement of Claim constituted inequitable conduct because the reference proved the invalidity of the animal claims in the patent, and it was withheld with the specific intent to deceive the PTO and to speed the issuance of the '012 patent. Further, Teva maintains that this is a case of affirmative egregious misconduct because Mr. O'Rourke was engaged in a scheme of willful blindness to prevent his discovery of material information that would need to be turned over to the PTO. The court, therefore, determines whether Teva has shown by clear and convincing evidence that the Bayer Statement of Claim was but-for material and the intent to deceive the PTO is the single most reasonable inference from the facts.

The court finds that there is utterly no evidence as to either of these elements.[102] On materiality, the Bayer Statement of Claim

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[102] Indeed, there is such little evidence in this case of any wrongdoing by Mr. O'Rourke, the court must question Teva's conduct in pursuing this case, particularly after the Federal Circuit's decision in Therasense. A party asserting a claim in litigation represents that such claim (1) is not made for an improper purpose such as to harass or needlessly increase the cost of litigation; and (2) is warranted by existing law. Fed. R. Civ. P. 11(b). The court finds that Teva has overreached in this case, and while it makes no intimations concerning sanctions, finds this case approaches the line between an argument which is quite a stretch, and an argument that is so devoid of support as to give rise to questions about that party's intent in pursuing it. See Fed. R. Civ. P. 11(c)(3).

hardly approaches the but-for materiality required by Therasense where "the PTO would not have allowed a claim had it been aware of [it]." Therasense, 2011 W.L. 2028255, at *11. First, the Bayer Statement of Claim concerned a patent under Canadian law, law which has not been shown to have anything in common with or any bearing on the law of the United States as regards validity of patents.[103] Indeed, the Statement of Claim states as a cause of action that the claims of the Canadian are "covetous," DX 2018, at 7, which Robert MacFarlane, a Canadian patent attorney with the firm of Bereskin & Parr, testified means that the patent claims more than it describes. MacFarlane dep. 44:15-20 (as played at trial).[104] Under this explanation, the doctrine of covetousness does not seem to have a clear equivalent in the law of patents in the United States. Second, the Bayer Statement of Claim related to the Canadian patent, a patent which was issued under different standards than the '012 patent in

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[103] There is a dispute between the parties as to whether foreign litigation documents can ever be material such that they would need to be disclosed. The Manual of Patent Examining Procedure Section 2001.06 provides: "Where the subject matter for which a patent is being sought is or has been involved in litigation, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the U.S. Patent and Trademark Office." M.P.E.P. § 2001.06(c). The parties dispute whether such litigation includes litigation concerning foreign patents in foreign countries. The court need not resolve this dispute to determine materiality under Therasense, but makes note of the fact that the PTO guidelines are at least unclear on that point.

[104] See supra note 35 concerning foreign law.

the United States. Third, the Bayer Statement of Claim appears to be merely a rote recitation of causes of action and does not contain any factual contentions or references which could have informed the patent examiner in the United States. Fourth, and finally, it is emblematic of how little relevance the Bayer Statement of Claim has to the prosecution of the '012 patent in the United States that the patent examiner specifically requested not to receive any other foreign references similar to those already submitted. [105] Therefore, this court finds that Teva has failed to show any materiality of the nondisclosed reference material.

On intent, Teva's contentions fare just as poorly, as there is no evidence to suggest that Mr. O'Rourke had any intent to deceive the PTO in failing to disclose the Bayer Statement of Claim because (1) he had no such duty in the first place, and (2) such intent is hardly the single most likely inference from his actions. Teva's own patent law expert testified that while an applicant has a duty of candor and good faith to the PTO, an applicant may not continue to freely disclose information to the PTO, once there has been a notice of allowance. Trial Tr. 1111:8-23. Instead, an applicant may only disclose information, if such reference demonstrates the "unpatentability of one or more claims," 37 C.F.R. § 1.313, or as

[105] Mr. Hutz testified that the Bayer Statement of Claim was quite similar in form and substance to the other challenges to foreign patents already submitted to the PTO. Hutz dep. 187:02-16 (as played at trial).

part of a request for continued examination. 37 C.F.R. § 114. Once the issue fee has been paid, however, the only way an applicant can file additional information is if such information shows that the claims are unpatentable. 37 C.F.R. § 114(a)(1).

The evidence before the court is that Mr. O'Rourke did not receive the Bayer Statement of Claim until July 9, 2002, but the issue fee was paid on June 20, 2002; thus, the information could have only been disclosed, pursuant to Rule 313, if it demonstrated the unpatentability of one or more claims. This standard is certainly not met for all the reasons concerning materiality set out above. At base, the Bayer Statement of Claim is just a rote recitation of the bases for invalidity of patents under Canadian law, law that is not controlling on the patent process in the United States; and the Bayer Statement of Claim has no facts that would lead the examiner to reexamine his conclusions on issuance of the claims. Thus, Mr. O'Rourke had no duty to disclose this Statement of Claim in the first place and, as such, could not have had the requisite intent to deceive.

Second, Therasense commands the court to determine whether the party challenging the patent has made a showing by clear and convincing evidence that intent to deceive the PTO is "the single most reasonable inference able to be drawn from the evidence." Therasense, 2011 W.L. 2028255, at *10. The only inference the court

can draw from the evidence presented at trial was that Mr. O'Rourke was a busy young law partner who devised a somewhat "sloppy" system for sorting foreign litigation material.[106] Teva unendingly repeats the incantation that Mr. O'Rourke engaged in "scheme of willful blindness."[107] It is as if Teva hopes to conjure up the flame of inequitable conduct from thin air. Instead, the court sees this claim of inequitable conduct for what it is: an attempt to induce the court to believe that if enough smoke is created, there must be a fire. The court sees through this smokescreen and finds that Teva has failed to bring any evidence to the court's attention which shows that Mr. O'Rourke acted with the specific intent to deceive the PTO.[108]

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[106] While the court notes that it may not have adopted or approved of the sorting system and practice followed by Mr. O'Rourke, his actions do not rise to the level of specific intent to deceive the PTO. Moreover, while the court discounts Teva's extreme arguments that allowing Mr. O'Rourke's behavior would lead, in essence, to the downfall of the patent system, the court is mindful that his practice was not a model for compliance with the PTO's directives. However, the court also notes that Mr. O'Rourke created a system that worked well through May 2002. See supra note 97 and accompanying text.

[107] See infra note 108.

[108] Teva's argument that Mr. O'Rourke's actions were affirmative egregious misconduct such that materiality may be assumed meet a similar fate. Again, Teva argues that Mr. O'Rourke's actions amount to a "scheme of willful blindness." The court finds otherwise because (1) there was no indication that any of the foreign litigation materials which had been collected over years could ever rise to the materiality required by Rule 313 by demonstrating that the claims were patentable; and (2) on the facts of this case, Mr. O'Rourke's actions are more akin to mere nondisclosure of a reference rather than affirmative actions of fraud covered by the "unclean hands" doctrine. Therasense, 2011 W.L. 2028255, at *12.

D.

In sum, this court finds that this case is the archetype of the action the Federal Circuit was aiming to curtail with the tightening of the standards in Therasense. Pfizer's initial behavior of disclosing all substantive documents from every foreign patent prosecution and litigation is understandable, particularly now in hindsight, given the unfounded, costly, and time-consuming accusations, which have resulted from not turning over one completely non-material document after the time for disclosures had passed, except in the most extreme of cases, with this not being one.[109] The court refuses to read Therasense in any way other than how the Federal Circuit intended, as a bulwark against the waste of resources by both the judiciary and litigants, as has occurred in this case. For all of the reasons stated above, the court **FINDS** that Pfizer did not commit inequitable conduct in the prosecution of the '012 patent and, therefore, **DIRECTS THE CLERK TO ENTER JUDGMENT** for Pfizer on Teva's Amended Counterclaim to this effect.

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[109] "With inequitable conduct casting the shadow of a hangman's noose, it is unsurprising that patent prosecutors regularly bury PTO examiners with a deluge of prior art references, most of which have marginal value." Therasense, 2011 W.L. 2028255, at *9.

VII. Conclusion

For the reasons set out in this Opinion and Final Order, the court hereby **GRANTS IN PART** Teva's Motion to Dismiss for Lack of Standing and **ORDERS** Pfizer Ireland Pharmaceuticals Co. **DISMISSED** from the litigation. Additionally, the court **DENIES** Teva's Motion for Leave to File its Proposed Second Amended Answer and Counterclaim. Finally, the court **FINDS** that Teva's proposed generic equivalent of Viagra would **INFRINGE** the '012 patent and **FINDS** the '012 patent is **VALID** and **ENFORCEABLE**. Therefore, the Clerk is **DIRECTED** to enter judgment for Pfizer on the Amended Complaint and Amended Counterclaim in this case, in accordance with this Opinion and Final Order.

The court further **DIRECTS** the Clerk to send a copy of this Opinion and Final Order to all counsel in this case.

IT IS SO ORDERED.

Rebecca Beach Smith

Rebecca Beach Smith
United States District Judge

Norfolk, Virginia
August 12, 2011