Exhibit 2

PFIZER INC., PFIZER LTD., and PFIZER IRELAND PHARMACEUTICALS, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.

Civil No. 2:10cv128

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF VIRGINIA, NORFOLK DIVISION

2011 U.S. Dist. LEXIS 27886

March 17, 2011, Decided
March 17, 2011, Filed

SUBSEQUENT HISTORY: Motion denied by, Dismissed by, in part *Pfizer, Inc. v. Teva Pharms. USA, Inc., 2011 U.S. Dist. LEXIS 90021 (E.D. Va., Aug. 12, 2011)*

PRIOR HISTORY: *Pfizer Inc. v. Teva Pharms. USA, Inc., 2011 U.S. Dist. LEXIS 90762 (E.D. Va., Jan. 18, 2011)*

COUNSEL: [*1] For Pfizer Inc., Pfizer Limited, Pfizer Ireland Pharmaceuticals, Plaintiffs: Aaron Stiefel, Alan Michael Fisch, Marc Nathan Zubick, Soumitra Deka, PRO HAC VICE, Coke Morgan Stewart, Daniel Peter DiNapoli, Kaye Scholer LLP, New York, NY; Brett Alexander Spain, Conrad Moss Shumadine, Willcox & Savage PC, Wells Fargo Center, Norfolk, VA; Roy William Sigler, Kaye Scholer LLP, Washington, DC.

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For Pfizer Inc., Pfizer Ireland Pharmaceuticals, Counter Defendants: Aaron Stiefel, Alan Michael Fisch, Soumitra Deka, PRO HAC VICE, Coke Morgan Stewart, Daniel Peter DiNapoli, Kaye Scholer LLP, New York, NY; Brett Alexander Spain, Conrad Moss Shumadine, Willcox & Savage PC, Wells [*2] Fargo Center, Norfolk, VA; Roy William Sigler, Kaye Scholer LLP, Washington, DC.

JUDGES: Rebecca Beach Smith, United States District Judge.

OPINION BY: Rebecca Beach Smith

OPINION

MEMORANDUM OPINION

This matter comes before the court for claim construction. On December 13, 2010, the court conducted a hearing pursuant to *Markman v. Westview Instruments, Inc., 517 U.S. 370, 372, 116 S. Ct. 1384, 134 L. Ed. 2d 577 (1996)* ("Markman hearing"), and heard argument from all parties as to the meaning of the terms in the disputed claims of the patent at issue. This Memorandum

Opinion details the court's claim construction and explains its reasoning. See *MercExchange LLC v. eBay, Inc., 401 F. 3d 1323, 1329 (Fed. Cir. 2005).*

I. Procedural History

This case involves the alleged infringement of *United States Patent No. 6,469,012* (filed May 13, 1994) (issued Oct. 22, 2002) ("the *'012 patent*"). Pfizer Inc., Pfizer Ltd., and Pfizer Ireland Pharmaceuticals (collectively "Pfizer") filed suit against Teva Pharmaceuticals USA, Inc. ("Teva") on March 24, 2010, [1] seeking injunctive and declaratory relief against imminent infringement of Pfizer's *'012 patent* entitled "Pyrazolopyrimidinones for the Treatment of Impotence. " The *'012 patent* claims a number of chemical compounds [*3] for the treatment of erectile dysfunction ("ED"), one of which is the active ingredient in the drug Viagra. Pfizer alleges that Teva will infringe the *'012 patent* by manufacturing a generic version of Viagra. [2] On April 29, 2010, Teva answered the complaint and filed a counterclaim against Pfizer seeking a declaration that the claims of the *'012 patent* are invalid and Teva's planned drug will not infringe any patentable claim. Pfizer answered Teva's counterclaim on May 20, 2010.

1 Pfizer 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.

2 As evidence, Pfizer cites Teva's filing of an Abbreviated New Drug Application with the FDA for the sale of such a generic drug. The FDA granted tentative approval of the application in April 2007.

Pursuant to this court's scheduling order and a subsequent order extending filing times, the parties submitted their initial claim construction briefs on August 30, 2010, their reply claim construction briefs on September 20, 2010, and their joint claim construction [*4] brief on September 27, 2010. On September 8, 2010, this court scheduled a Markman hearing for December 13, 2010, to aid the court in construing the disputed terms of the patent. [3]

3 On October 13, 2010, this court entered the joint consent order concerning the procedures that would be followed during the Markman hearing.

Subsequently, on November 12, 2010, Teva moved to amend its answer and counterclaim to add an allegation of invalidity because of inequitable conduct. Pfizer responded in opposition to Teva's motion on November 29, 2010, and Teva replied on December 6, 2010. On December 8, 2010, Pfizer filed a supplemental notice with the court, alerting the court to the execution of a covenant not to sue Teva on the animal claims of the patent, Claims 1-23, which claims are the subject of Teva's inequitable conduct assertion. [4] On December 8, 2010, this court notified the parties that it would hear that motion at the same time as the Markman hearing.

4 A copy of the covenant not to sue was attached to the notice filed with the court. See Docket # 64.

The court held the Markman hearing on December 13, 2010, and heard argument on both the issue of claim construction and amendment of pleadings [*5] by Teva. At the end of the hearing, the court took both issues under advisement. The court granted Teva's motion to amend on January 18, 2011, but ordered that Teva file a revised amended answer and counterclaim within ten days reflecting only the claims at issue before the court, Claims 25 and 26. [5] Teva did so on January 26, 2011, and Pfizer answered the amended counterclaim on February 2, 2011.

5 See Docket #77. In its Memorandum Order, the court ordered that all references to the "animal claims" be removed from Teva's answer and counterclaim, as the parties agreed that only Claims 25 and 26 were at issue.

II. Factual Background

The *'012 patent* is entitled "Pyrazolopyrimidinones for the Treatment of Impotence" and consists of twenty-six claims, [6] all of which claim certain chemical compounds for the treatment of impotence. Claims 25 and 26, the claims at issue in this proceeding, read:

> 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 [*6] 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, 11. 1-39. One of the particular chemical compounds claimed in Claim 25 is called "sildenafil." Sildenafil citrate is the active ingredient in Viagra. [7] The *'012 patent* is set to expire on October 22, 2019.

> 6 Claim 24 was ruled invalid by the Patent and Trademark Office ("PTO") and is not asserted by Pfizer here.
>
> 7 Pfizer also holds another patent specifically for sildenafil in *United States Patent No. 5,250,534*, which expires on March 27, 2012. Pyrazolopyrimidinone Antianginal Agents, *United States Patent No. 5,250,534* {filed May 14, 1992) (issued Oct. 5, 1993) ("the **534 patent*"). This patent is different than the **012 patent* because the *'012 patent* is a method patent for a number of different chemical compounds for the treatment of ED, while the *'534 patent* is a compound patent that claims sildenafil as a newly discovered chemical compound.

In the late 1980s, Pfizer researchers in the United Kingdom were working on a new drug, which they aimed to [*7] use to treat angina, a heart condition. During the first phase of human testing of the drug in 1992, male volunteers in the study reported penile erections as a side effect. This led to the discovery that the chemical compounds Pfizer was testing could be used to treat ED. As a result, Pfizer began human testing of one such compound, sildenafil, in 1993, [8] which in March 1998 was approved by the FDA as the drug Viagra to treat ED. As it is currently approved for use by the FDA, a dose of Viagra is to be taken in anticipation of sexual activity on an as-needed, single dose basis. [9]

> 8 Multiple dose testing began in July 1993, while single dose clinical trials commenced in early 1994.
>
> 9 As approved by the FDA, a dose of Viagra is 25 mg, 50 mg, or 100 mg taken once per day before anticipated sexual activity. See infra note 11.

Sildenafil works to treat ED by inhibiting an enzyme known as PDE5. An erection is caused by the relaxation of the arterial smooth muscle tissue of the penis which allows more blood to flow into the organ. The increased blood flow signals to the rest of the smooth muscle tissue, composed of two hollow tubes on each side of the penis called the corpora cavernosa, to relax [*8] and fill with blood. As the penis fills with blood, the vein therein is pinched, preventing blood from flowing out and causing an erection.

To initially relax the smooth muscle tissue, which in turn sets off the chain reaction, the nervous system reacts to sexual stimuli by producing nitric oxide. This nitric oxide reacts with guanylate cyclase, an enzyme, producing cyclic guanosine monophosphate ("cGMP"). cGMP is the activator on the smooth muscle tissue that cues it to relax. cGMP can be inhibited, however, by another enzyme, PDE5. Thus, if there is too much PDE5, cGMP can be inhibited and the whole process of smooth muscle tissue relaxation can be thwarted. This is where Viagra comes in, when an individual's ED is caused by this imbalance in PDE5 and cGMP. [10] The way Viagra works, then, is to inhibit excess PDE5 so that cGMP can work the way that it is supposed to.

> 10 ED has many causes, both psychological and physical. In regard to physical causes, when ED is not the result of by any particular physical injury to the body, such as paralysis or certain lower back injuries, then it is often caused by an imbalance at the cellular level between PDE5 and cGMP. In this type of case, Viagra [*9] is effective.

III. Claim Construction

Claim construction is a matter of law to be decided by the court. *Markman, 517 U.S. at 372*. The goal of such construction is to "discern the meaning of [a] term in the context of [the] invention and field of art." *Curtiss-Wright Flow Control Corp. v. Velan, Inc., 438 F.3d 1374, 1379 (Fed. Cir. 2006)*. In performing this function, the court need only construe disputed terms of disputed claims of the patent to the extent necessary to

resolve the controversy. See *NTP, Inc. v. Research In Motion, Ltd., 418 F.3d 1282, 1311 (Fed. Cir. 2005)* (citing *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc., 200 F.3d 795, 803 (Fed. Cir. 1999))*.

Sitting en banc, the Federal Circuit gave an overview of claim construction in *Phillips v. AWH Corp., 415 F.3d 1303 (Fed. Cir. 2005)*. Overall, claim construction aims to determine the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." IcL. *at 1313* (emphasis added). In some instances, a term's ordinary meaning "may be readily apparent even to lay judges, and claim construction in such cases involves [*10] little more than the application of the widely accepted meaning of commonly understood words." *Id. at 1314*. However, when the term's meaning is not readily apparent, courts must consult "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." Id. (citation and internal quotation marks omitted). Those sources include both intrinsic evidence, such as the claims, specification and prosecution history, and extrinsic evidence, such as technical dictionaries, treatises and expert testimony. *Chamberlain Group, Inc. v. Lear Corp., 516 F.3d 1331, 1335 (Fed. Cir. 2008)*. Intrinsic evidence is considered to be "more reliable" than extrinsic evidence, id., and thus it should be the court's "primary focus in determining the ordinary and customary meaning." *Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 996 (Fed. Cir. 2006)*.

The claim construction process begins with the words of the claims themselves, *Old Town Canoe Co. v. Confluence Holdings Corp., 448 F.3d 1309, 1315 (Fed. Cir. 2006)*, focusing on the context in which the term is used. *Phillips, 415 F.3d at 1314*. "It is a bedrock principle of patent law that the [*11] claims of a patent define the invention to which the patentee is entitled the right to exclude." *Id. at 1312* (citation and internal quotation marks omitted). Each disputed term is to be given its "ordinary and customary meaning." Id. In seeking the plain meaning, the court is concerned with fair notice to the public concerning the scope of the claims. *Johnson & Johnston Assocs, Inc. v. R.E. Service Co., Inc., 285 F.3d 1046, 1052 (Fed. Cir. 2002)*. Because claim terms are normally used consistently throughout the patent, other claims, both asserted and unasserted, may be instructive as to the meaning of the disputed term. *Phillips, 415 F.3d at 1314*. Differences among claims may also be helpful, as limitations in dependent claims can clarify the independent claims from which they derive. *Id. at 1314-15*.

The claims, however, "do not stand alone" and must be "read in view of the specification, of which they are a part." *Id. at 1315* (citation and internal quotation marks omitted). The entirety of the specification is relevant to claim construction, including the abstract, summary and preferred embodiment. See generally *Lucent Techs., Inc. v. Gateway, Inc., 525 F.3d 1200 (Fed. Cir. 2008)* (examining [*12] the entirety of the specification in performing claim construction). The specification "is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." *Phillips, 415 F.3d at 1315* (citation and internal quotation marks omitted). Further, if the specification reveals "a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess," then "the inventor's lexicography governs." *Id. at 1316*; see, *Edwards Lifesciences LLC v. Cook, Inc., 582 F.3d 1322, 1329 (Fed. Cir. 2009)*. The patentee must, however, "clearly express that intent in the written description." *Helmsderfer v. Bobrick Washroom Equip., Inc., 527 F.3d 1379, 1381 (Fed. Cir. 2008)*. The specification may also limit the scope of the invention through an intentional disclaimer or disavowal. *Phillips, 415 F.3d at 1316*. Nevertheless, it is important that the court "avoid the danger of reading limitations from the specification into the claim," as "persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments." *Id. at 1323*.

In [*13] addition to the claims and specification, the court may also consider the prosecution history, which "consists of the complete record of the proceedings before the [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Id. at 1317*. Although the prosecution history provides evidence of how the Patent and Trademark Office ("PTO") and the inventor understood the patent, the court must keep in mind that because it "represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes." Id.

As far as extrinsic evidence, the court is not "barred from considering any particular sources or required to analyze sources in any specific sequence, as long as those sources are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence." *Id. at 1324*. The district court, in its discretion, may admit extrinsic evidence to help educate itself about the field of the invention in order to determine how a person of ordinary skill in the art would understand the claim terms. [*14] *Id. at 1319*. [11]

11 The court notes one piece of extrinsic evidence that it does not consider in relation to the construction of the claim terms is the FDA approval of Viagra and its provisions on dosage, method of usage, and purpose. The reason for this exclusion is that the filing of the *'012 patent* application predated the application to and approval by the FDA, and the court considers the state of the art and the meaning of the terms at the time the patent is filed. See *Phillips, 415 F.3d at 1313*. Thus, the FDA approval is not relevant to the court's instant task, though the court notes that such information may become relevant at trial as regards secondary considerations of non-obviousness. See *Graham v. John Deere Co., 383 U.S. 1, 17-18, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966)*.

IV. Claim Terms

The court construes the following five terms in Claims 25 and 26: [12] (1) "erectile dysfunction," (2) "treating erectile dysfunction," (3) "a male human in need of such treatment," (4) "an effective amount, " and (5) "a method of treating erectile dysfunction in ... a male human in need of such treatment." [13] To reiterate, those claims read:

> 25. A method of treating erectile dysfunction in a male human, comprising orally administering [*15] to a male human in need of such treatment an effective amount of a compound selected from:
>
> [listing nine different chemical compounds]
>
> 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, 11. 1-39.

12 Claim 26 is a dependent claim of Claim 25, as it refers to the method in Claim 25 and then relates it to another chemical compound, so the construction that the court must engage in for both claims is the same. See *Felix v. Am. Honda Motor Co., 562 F.3d 1167, 1177-78 (Fed. Cir. 2009)* (noting that normally the same terms have the same meaning throughout the patent).

13 The parties do not agree on what language in the claims should be considered a "term" for construction purposes. Pfizer initially argued that Term 3 ("a male human in need of such treatment") is not a claim term, and Teva submitted the same for Term 5 ("a method of treating erectile dysfunction in ... a male human in need of such treatment"). However, each party proposed [*16] a construction of the respective term in its reply brief in response to the opposing party's construction, and the court considers all five terms.

At the outset, the court sets forth the contours of the parties' fundamental disagreement, as this disagreement informs how each party approaches the construction of each term. At a base level, the parties disagree as to the scope of the patent. Pfizer argues that the *"012 patent* covers all dosing regimens, including daily use or on an as-needed basis, using the chemical compounds claimed as method for treating ED. By contrast, Teva argues that Pfizer only patented the method of using the chemical compounds claimed like the drug Cialis, that is to say by taking a dose every day to prophylactically prevent ED at all times. [14] Thus, Teva argues that making a generic version of Viagra for as-needed use would not infringe the *'012 patent* because that method was not claimed. With this background framing the analysis, the court now turns to the specific terms of the patent requiring construction.

14 This suit does not concern the drug Cialis, and the court has no specialized knowledge concerning how Cialis operates and differs from Viagra. However, [*17] both of the parties referenced Cialis as an example of an everyday, prophylactic treatment for ED, and the court references it only for this limited, illustrative purpose.

A. "Erectile dysfunction"

As to the first term for construction, "erectile dysfunction," Pfizer proposes "an inability to obtain or sustain an erection adequate for intercourse." Teva proposes "an inability to obtain or sustain an erection adequate for sexual intercourse when sexually stimulated, also known in the art as impotence." The court begins its analysis by looking at the claims themselves. However, no description of what is meant by "erectile dysfunction" is to be found therein, so the court must turn to other intrinsic evidence. Pfizer derives its definition directly from the language of the specification, which provides "erectile impotence or dysfunction may be defined as an inability to obtain or sustain an erection adequate for intercourse." *'012 patent* col. 1, 11. 11-14. Pfizer argues that the court need look no further, given that the definition is expressly provided by the patent. Teva is in agreement that the explicit definition should be adopted, but urges that the definition be expanded to reflect [*18] what a person of ordinary skill in the art understood about ED at the time of filing. In particular, Teva argues that reference should be made to sexual stimulation because the scientific community agreed that ED only occurred when sexual stimulation was present. Additionally, Teva argues that at the time of the filing of the patent, erectile dysfunction was used interchangeably with impotence and thus it should be included in the term definition.

Looking to the specification, the court agrees with Pfizer, as it is clear that the explicit definition stated in the patent should be used and no further construction is necessary. As the Federal Circuit held in Phillips, if the patent itself gives a special definition for a term in the specification, "the inventor's lexicography governs." *415 F.3d at 1316*. Here, the patentee has met the requirement that the intent to create a specialized definition be clear. The definition of ED, "an inability to obtain or sustain an erection adequate for intercourse," is introduced in the *'012 patent* by the words "[m]ore specifically, erectile impotence or dysfunction may be defined." col. 1, 11. 11-12 (emphasis added). What a person of ordinary skill in [*19] the art would understand the term to mean is easily answered here, because any concerns about prior art and scientific consensus are obviated by the patentee's specific limitation of the definition. Thus, the addition of "when sexually stimulated" to the express definition is contrary to the law of claim construction.

Similarly, the addition of "also known in the art as impotence" is not supported by the intrinsic evidence. It is true that the patent refers to impotence in the specification, and indeed the patent title. However, in doing so it defines the larger category of dysfunctions, which involves both ED and failure to ejaculate. The patent defines impotence as "a lack of power, in the male, to copulate and may involve an inability to achieve penile erection or ejaculation, or both." *'012 patent* col. 1, 11. 9-11 (emphasis added). The patent then continues with the definition discussed above, namely, "[m]ore specifically, erectile impotence or dysfunction may be defined as an inability to obtain or sustain an erection adequate for intercourse." *'012 patent* col. 1, 11. 11-14 (emphasis added). It is therefore apparent that the patent draws a distinction between the overall umbrella [*20] of "impotence," which it defines first, and the specific disorder of ED, which it introduces with the words "more specifically." As above, any understanding of the state of the art at the time of filing, upon which the court expresses no opinion, is again beside the point when the patentee has provided the definition of a term in the specification itself.

Thus, this court holds that "erectile dysfunction" means "an inability to obtain or sustain an erection adequate for intercourse. "

B. "Treating erectile dysfunction"

As to the second term for construction, "treating erectile dysfunction," Pfizer proposes that construction is not necessary because the plain meaning of the term is clear. However, Pfizer argues that if the court finds that construction is required, the term should be defined as "medically caring for or dealing with erectile dysfunction." Teva proposes "preventing an inability to obtain or sustain an erection adequate for sexual intercourse from returning whenever sexually stimulated." [15] Turning first to the claims themselves, there is no indication therein as to what is meant by "treating" in the case of erectile dysfunction. [16] Pfizer argues that the claim language "treating [*21] erectile

dysfunction" is readily understandable to both the court and a person ordinarily skilled in the art and requires no construction, so the court must use the plain meaning of the terms. See *Phillips, 415 F.3d at 1313*. Teva, by contrast, argues that the intrinsic evidence of the patent prosecution history demonstrates that "treating" has a specialized meaning given to it by the patent. Specifically, Teva points to a submission by Pfizer to the PTO in 1996 after the PTO had rejected several proposed claims for a method of curing ED. Therein, Pfizer defined its understanding of "treating" as keeping ED from returning, or preventing it. Teva concludes that this represents an express definition by the patenting party which overrides the ordinary and customary meaning of the word. Pfizer counters that the language that Teva cites was merely a reservation of rights in case of reconsideration, and the final patent included only claims for the treatment of ED, not prevention or curing.

15 At the outset of the discussion of this term, the court notes that it need not consider the part of Teva's construction concerning sexual stimulation. As settled in the construction of "erectile dysfunction" [*22] above, sexual stimulation is not part of the definition of ED in the patent, per its express definition. See supra Part IV. A.

16 The court primarily discusses the meaning of "treating" in this section, as "erectile dysfunction" has already been construed. See supra Part IV. A.

The court looks first to Teva's express definition argument. It is clear from the law concerning patentee as lexicographer, [17] that the evidence pointed to by Teva does not establish the intent to express a special meaning. A patentee's understanding of the definition of a term in a pre-approval submission to the PTO, an understanding which is not embodied in the final patent, cannot form the basis of a "special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess." *Phillips, 415 F.3d at 1316*. The court is well-advised in this instance to remember that communications between the patentee and the PTO are part of an ongoing negotiation, *id. at 1317*, and there is no other evidence that suggests Pfizer intended "treating" to have the particular specialized meaning suggested by Teva in the patent as approved by the PTO. [18] E.g., *Glaxo Group Ltd. v. Teva Pharms. USA, Inc., No. 07-713, 2009 U.S. Dist. LEXIS 37494, 2009 WL 1220544, at *3 (D. Del. Apr. 30, 2009)* [*23] (unpublished) (citing *Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1327 (Fed. Cir. 2002))* (noting that the court should not read a restriction into a patent's terms unless the restriction has been clearly demonstrated). Indeed, Pfizer specifically deleted references in patented claims to curing or preventing ED. Those meanings cannot be read back into the patent.

17 See supra Part III. at 9.

18 Even if the court were to accept that the single piece of evidence pointed to by Teva demonstrates an express definition, Pfizer's submission itself does not support Teva's conclusion. In its response to the PTO, Pfizer states that when it used the words "cure" and "prevent," they were not used in the sense of curing "for all time." Pfizer Reply Claim Construction Br. 13 (citing Teva Opening Claim Construction Br. Ex. 25 at 2 (Ex. 25 being Pfizer's Apr. 23, 1997, amendment in response to PTO Office Action of Oct. 9, 1996)). Thus, Teva's suggestion that "treating" should mean "preventing" ED "whenever sexually stimulated," is not borne out by the record.

The court next looks to the specification. The patent states its purpose: "[T]hese disclosed compounds are useful in the treatment of erectile [*24] dysfunction," *'012 patent* col. 1, 11. 61-63, and can be used "for the manufacture of a medicament for the curative or prophylactic treatment of erectile dysfunction." *'012 patent* col. 2, 11. 55-57. The patent again repeats this, stating "[t]hus the invention includes a pharmaceutical composition for the curative or prophylactic treatment of erectile dysfunction." *'012 patent* col. 6, 11. 10-12. No further elucidation is given as to what is meant by "curative or prophylactic treatment."

Teva argues that this meaning is clarified by the preferred embodiment in the specification, which states: The "preferred dosing regimen for a typical man is 5 to 7 5 mg of compound three times daily." *'012 patent* col. 5, 11. 65-67. Teva thus concludes that "treating" means administering daily multiple doses to keep ED from occurring at all times. The Federal Circuit's precedent, however, is conclusive on this issue: "When the [*25] specification describes a single embodiment to enable the invention, this court will not limit broader claim language to that single application unless the patentee has demonstrated a clear intention to limit the claim scope

using words or expressions of manifest exclusion or restriction." *Abbott Labs, v. Sandoz, Inc., 566 F.3d 1282, 1288 (Fed. Cir. 2009)* (citation and internal quotation marks omitted). The court therefore considers the preferred embodiment, as it does the entire specification, but such embodiment is not determinative of the claimed method of treating.

Instead the court is of the opinion that "treating erectile dysfunction" does not require construction because its ordinary and customary meaning would be clear to a person ordinarily skilled in the art reading the entirety of the patent which describes the invention, its purpose, and its use. *ICU Med., Inc. v. Maris Med. Sys., Inc., 558 F.3d 1368, 1374 (Fed. Cir. 2009)* (citation and internal quotation marks omitted) ("[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including [*26] the specification." (emphasis added)); *Phillips, 415 F.3d at 1313.*

The court, therefore, holds that "treating erectile dysfunction" requires no construction.

C. "A male human [animal] in need of such treatment"

For the third term, "a male human [animal] in need of such treatment," Pfizer proposes the construction to be "a male human in need of treatment for erectile dysfunction." Teva proposes "a male human [animal] who requires a pharmaceutical composition to prevent an inability to obtain or sustain an erection adequate for sexual intercourse from returning whenever sexually stimulated." Teva's definition of this term is dependent on its definitions of "treating" and "erectile dysfunction" as discussed above. Having defined those terms, [19] this discussion does not bear repeating in the construction of this term. As the court has already held that "treating erectile dysfunction" requires no construction and should receive its ordinary and customary meaning, [20] "such treatment" in this term refers back to "treating erectile dysfunction" and itself requires no construction.

19 See supra Part IV. A. & B.
20 See supra Part IV. B.

The court, therefore, is of the opinion that the meaning of the [*27] term is clear and adopts the construction "a male human in need of treatment for erectile dysfunction."

D. "An effective amount"

As to "an effective amount," Pfizer proposes that no construction is necessary because the plain meaning of the term is clear. If the court does find that the term must be construed, Pfizer proposes "an amount sufficient to produce the desired effect." Teva proposes "an amount sufficient to prevent an inability to obtain or sustain an erection adequate for sexual intercourse from returning whenever sexually stimulated." Teva and Pfizer agree that "an effective amount" generally means an amount sufficient to have the desired effect, but they differ on whether and how the construction should take account of that desired effect, and indeed what the desired effect is. Teva's construction of this term is dependent on its construction of "treating erectile dysfunction," as such treatment is the desired effect, and Teva again points to the preferred embodiment as evidence that an effective amount must mean an amount sufficient to prevent ED at all times. [21] The court has already found these arguments to be unavailing. [22]

21 Tellingly, Teva does not take the next logical [*28] step and propose that "an effective amount" be "5 to 75 milligrams of compound three times daily." *'012 patent* col. 5, 11. 65-66.
22 See supra Part IV. B. at 19.

The court holds that "an effective amount" requires no construction because a person ordinarily skilled in the art reading the patent would understand its ordinary and customary meaning.

E. "A method of treating erectile dysfunction in ... a male human in need of such treatment"

As to the final term, "a method of treating erectile dysfunction in ... a male human in need of such treatment," Pfizer proposes "a method practiced for the purpose of treating erectile dysfunction." Teva, though it maintains that the term proposed by Pfizer is not actually a claim term, appears to agree with this logic in general, as its definition sets out what it believes the purpose to be. Teva proposes "a method that prevents an inability to obtain or sustain an erection adequate for sexual intercourse from returning in a male human whenever sexually stimulated." Again, the parties' interpretations are dependent on their earlier construction of the claim terms.

Pfizer argues that prior cases have held that this claim language states the purpose of the [*29] invention, and this term should be interpreted accordingly. See, e.g., *Jansen v. Rexall Sundown, Inc., 342 F.3d 1329, 1333 (Fed. Cir. 2003)* (holding that a method of treating ... a male human in need of such treatment means a method practiced for the stated purpose). [23] The court finds this purposiveness argument persuasive, especially given the entire context of the patent which consists of method claims.

> 23 Pfizer additionally argues that the court should look to the prosecution history. During the prosecution, Pfizer had to overcome the PTO's concern that the earlier patent for sildenafil, the *'534 patent*, see supra note 7, inherently disclosed the inventions of the *'012 patent*. Pfizer did so by successfully arguing that while sildenafil had been previously patented, the *'012 patent* was unique because it patented sildenafil, along with other chemical compounds, specifically as a method claim for treating ED.

Thus, the court holds that "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."

V. Conclusion

Therefore, given the construction of the disputed terms, the operative language [*30] of Claims 25 and 26 reads:

> A method practiced for the purpose of treating an inability to obtain or sustain an erection adequate for intercourse in a male human, comprising orally administering to a male human in need of treatment for erectile dysfunction an effective amount of a compound selected from:
>
> [listing chemical compounds]
>
> or a pharmaceutically acceptable salt thereof;
>
> or a pharmaceutical composition containing either entity.

The court **DIRECTS** the Clerk to send a copy of this Memorandum Opinion to counsel for the parties.

IT IS SO ORDERED.

Norfolk, Virginia

March 17, 2011

/s/

Rebecca Beach Smith

United States District Judge

Rebecca Beach Smith

United States District Judge