United States District Court,
M.D. North Carolina.

PFIZER INC,
Plaintiff.
v.
SYNTHON HOLDING, B.V.; Synthon, B.V.; Synthon Pharmaceuticals, Ltd .; and Synthon Laboratories, Inc,
Defendants.

No. 1:05CV39

March 7, 2006.

Betty A. Ryberg, Daniel Boglioli, Gerald Sobel, Joseph V. Saphia, Milton Sherman, Richard G. Greco, Sapna Walter, Kaye Scholer, L.L.P., New York, NY, W. Andrew Copenhaver, Womble Carlyle Sandridge & Rice, Winston-Salem, NC, for Plaintiff.

Aimee Noelle Soucie, Cecil Kyle Musgrove, John Worthington Bateman, Kenyon & Kenyon, Washington, DC, Joseph Robert Beatty, R. Thompson Wright, Hill Evans Duncan Jordan & Beatty, PLLC, Greensboro, NC, Michael William Johnson, Thomas J. Meloro, Willkie Farr & Gallagher, LLP, New York, NY, for Defendants.

MEMORANDUM OPINION

BEATY**, District Judge.**

This case is a patent infringement action brought by Plaintiff Pfizer Inc. ("Pfizer") against Defendants Synthon Holding, B.V., Synthon, B.V., Synthon Pharmaceuticals, Inc., and Synthon Laboratories, Inc. ("Defendants" or "Synthon"). The matter is presently before the Court on three issues: competing claim construction briefs filed by the parties [Documents85, 89, 93, 97]; a Motion by Pfizer to Strike the Reply Declaration of Gert Jan Ettema [Document # 102]; and a Joint Motion for Leave to Supplement the Record as to Claim Construction [Document # 108], in which both sides seek to submit depositions of their experts, among other documents.

For the reasons more fully discussed below, the Court finds that the correct interpretation of the phrase "the besylate salt of amlodipine" contained within U.S. Patent No. 4,879,303 (the "'303 patent") is "any salt that contains the positively charged amlodipine cation and the negatively charged besylate anion, without limitation to any particular physical form of the salt." The Court will not read the term "anhydrous" FN1 into the phrase.

FN1. The term "anhydrous" means the compound described does not contain any water molecules. *See* Hawley's Condensed Chemical Dictionary, p. 76 (13th ed.).

I. FACTUAL BACKGROUND

Pfizer holds two patents related to its heart medication Norvasc(R): the ' 303 patent and U.S. Patent No. 4,572,909 ("the '909 patent"). The '909 patent, which claims "amlodipine" and discloses as a best mode to combine amlodipine, a 1,4-dihydropyridine compound, with maleic acid, creating thereby the salt of amlodipine maleate, expires on January 31, 2007. The ' 909 patent is not currently at issue in this litigation.FN2

FN2. Since the Complaint was filed, Pfizer and Defendants have agreed to be bound by the final judgment in *Pfizer Inc. v. Mylan Laboratories, Inc. et. al.,* No. 02-1628, which is currently pending in the U.S. District Court for the Western District of Pennsylvania, with respect to the infringement of the '909 patent. (*See* Joint Rule 26(f) Report, at 5.)

The '303 patent, which is at issue here, claims "the besylate salt of amlodipine," and expires on September 28, 2007. Synthon filed an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA") for a generic equivalent to Norvasc(R) on March 5, 2004. The ANDA was accepted by FDA for substantive review on December 23, 2004. The ANDA included a "Paragraph IV certification" alleging that the '909 patent is invalid and that the '303 patent is not infringed by Synthon's generic product, which is amlodipine besylate monohydrate. Based upon this filing Pfizer sued Defendants, alleging that Defendants have infringed Pfizer's patents.

Pfizer asserts that amlodipine was invented by Pfizer scientists in Sandwich, England. As previously stated, Pfizer thereafter patented the invention of amlodipine, first in an application in the United Kingdom on March 11, 1982, and later in the United States on February 25, 1986. Pfizer had initially selected the maleate salt form for development, which was also the preferred embodiment disclosed in '909.FN3 However, while working with the amlodipine maleate, Pfizer scientists discovered problems concerning amlodipine maleate's poor processibility, also known as stickiness, as well as a problem with degradation in both capsule and tablet form. Accordingly, Pfizer scientists decided to look for an improved salt of amlodipine. Scientists discovered that "amlodipine besylate" was superior over amlodipine maleate in four key areas: stability, processibility, solubility, and non-hygroscopicity. Subsequently, Pfizer sought a patent on "the besylate salt of amlodipine." The priority application for the ' 303 patent was filed on April 4, 1986 in the United Kingdom, and a corresponding U.S. patent application was filed on March 25, 1987. That U.S. patent application claimed priority back to the United Kingdom patent application.

FN3. Amlodipine is a chemical base. In the pharmaceutical industry, a base is often combined with an acid to create a salt, which is a dosage form that can be easily administered to a patient. Salt forms are used because they often can improve physicochemical properties of a drug, such as chemical stability and processing characteristics. (*See* Decl. of McGinity, Document # 86, at 3-4.)

A salt is a compound formed by a positive and negative ion, usually from an acid and a base, ionically bound to each other. The negatively charged ion (formed from the acid) is called an "anion," and the positively charged ion (formed from the base) is called a "cation." Id.
On October 6, 1987, the U.S. Patent and Trademark Office ("PTO") rejected all 12 claims of the '303 patent, on the ground of obviousness, in light of the '909 patent disclosing amlodipine. In response to this rejection,

Pfizer argued that the besylate salt of amlodipine was not *prima facie* obvious because it was not suggested in the prior art. On June 17, 1988, the PTO again rejected all of the claims as obvious. On October 13, 1988, Pfizer filed a continuation application and abandoned the original application. Along with this continuation application, Pfizer argued again that the claims were not *prima facie* obvious. Additionally, Pfizer submitted a declaration of James Wells, a co-inventor, that argued that even if amlodipine besylate were *prima facie* obvious, that showing of obviousness was rebutted by showing that amlodipine besylate had unexpected qualities superior to the prior art preferred embodiment of amlodipine maleate. Without stating its reasons for allowance, the PTO issued a notice of allowability on July 3, 1989. The '303 patent issued on November 7, 1989.

The '303 patent has 12 claims, two of which are independent: Claims 1 and 9. Claim 1 is: "The besylate salt of amlodipine." Claims 2 through 8 are dependent claims describing tablet and capsule dosage formulations containing the besylate salt of amlodipine. Claim 9 states: "A sterile aqueous solution comprising an antihypertensive, antiischaemic or angina-alleviating effective amount of the besylate salt of amlodipine for parenteral administration." Claims 10 and 11 are dependent upon Claim 9 and also concern aqueous solutions.

The written description of the '303 patent has five examples of the besylate salt of amlodipine. Examples 1 and 5 describe the making of an amlodipine besylate salt. Examples 2 and 3 describe making tablets and capsules comprising amlodipine besylate. Example 4 is an aqueous solution of amlodipine besylate also containing sodium chloride and propylene glycol.

Based upon these facts, and the submissions by the parties, the Court will first review general principles of claim construction and then will seek to apply those principles to the sole phrase at issue, "the besylate salt of amlodipine," as that phrase is used in the twelve claims.

II. CLAIM CONSTRUCTION

A claim construction hearing is also known as a *Markman* hearing, after the Supreme Court's ruling in Markman v. Westview Instruments, 517 U.S. 370, 116 S.Ct. 1384, 134 L.Ed.2d 577 (1996). In that case, the Supreme Court affirmed a Federal Circuit Court ruling that patent claim construction is a matter to be decided solely by the trial judge, and not by a jury. Id. at 372. Thus, after *Markman,* a trial judge construes the meaning of disputed claims within a patent.

In construing a patent claim, this Court must first look to the words of the claims themselves. *See* Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed.Cir.2005) ("[T]he claims of a patent define the invention to which the patentee is entitled the right to exclude ."), *cert. denied, AWH Corp. v. Phillips,* No. 05-602, 2006 U.S. LEXIS 1154 (U.S. Feb. 21, 2006). Unless otherwise defined by the patentee, the words of the claim must be given "their ordinary and customary meaning." *Id.* That ordinary and customary meaning is 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." Id. at 1313. This 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 the specification." Id. at 1312. Additionally, this definition by the person of ordinary skill in the art should be that which such a person could ascertain from the "intrinsic evidence in the record." Id. at 1314. Intrinsic evidence in the record includes the words of the patent claim, the specification, and the prosecution history. *Id.*

Of particular importance is the specification. The specification may reveal that the inventor gave a patent term a particular definition that differs from the meaning it would otherwise possess. *Id*. Additionally, the specification may make it clear that the inventor disclaimed or disavowed a particular claim scope. *Id*. "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id*. at 1316. "[T]here is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification." Liebel-Flarsheim Co. v. Medrad Inc., 358 F.3d 898, 904 (Fed.Cir.2004).

Part of the specification is a specific embodiment of the invention. A court should not automatically confine the claim to any disclosed embodiments. Phillips, 415 F.3d at 1323. For example, if a patent describes a single embodiment, that does not mean the patent should be limited to that preferred embodiment. *Id.; see also* Gemstar-TV Guide Int'l, Inc. v. ITC, 383 F.3d 1352, 1366 (Fed.Cir.2004). This is because "persons of ordinary skill in the art rarely would confine their definitions of terms to the exact representations depicted in the embodiments." Phillips, 415 F.3d at 1323. The question for the Court then becomes "whether the patentee is setting out specific examples of the invention to ... [enable one skilled in the art to make and use the invention] or whether the patentee instead intends for the claims and the embodiments in the specification to be strictly coextensive." *Id.; see also* SciMed Life Sys. v. Advanced Cardiovascular Sys., 242 F.3d 1337, 1341 (Fed.Cir.2001).

This Court may also consider extrinsic evidence to determine the meaning of a disputed claim term. Extrinsic evidence is all evidence external to the patent and prosecution history, such as expert and inventor testimony, dictionaries, and learned treatises. Extrinsic evidence, by its very nature, is less reliable than intrinsic evidence in determining how to read a particular patent claim. Phillips, 415 F.3d at 1318. A court must discount expert testimony that is "clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent." *Id*. As such, while extrinsic evidence can be particularly helpful to a court to understand what a person of ordinary skill in the art would understand claim terms to mean, it must still be considered in the context of the intrinsic evidence. *Id*. at 1319.

The Court will now apply these general tenets while considering the arguments made by the parties.

III. PARTY ARGUMENTS CONCERNING CLAIM CONSTRUCTION

Defendant Synthon seeks to limit Pfizer's patent to the " *anhydrous* besylate salt of amlodipine." In this way, Synthon's product would not literally infringe Pfizer's patent. As stated previously, Synthon's product is amlodipine besylate *monohydrate*. The difference between anhydrous amlodipine besylate and amlodipine besylate monohydrate is an attached H2O group. In contrast to Synthon's claim construction, Pfizer argues that "the besylate salt of amlodipine" simply means a salt in the form of an amlodipine cation attached ionically to a benzene sulphonic acid anion. This claim term therefore identifies the base (amlodipine) and acid (benzene sulphonic acid) that forms the salt, but leaves unspecified the physical form that the salt takes (hydrates, solid solutions, different crystal structures, different morphological shapes of a crystal structure) and whether any other molecules, if any, are associated with it, such as water.

Synthon makes a number of arguments as to why Pfizer's patent should be limited to the anhydrous version of amlodipine besylate. For example, Synthon points to the use of singular language in Claim 1 itself, "The

besylate salt of amlodipine," which uses such words as "the" and "salt" as opposed to "salts." Synthon points to the fact that this use of singular language must indicate that only one specific compound is covered by the claim. Moreover, Synthon argues that amlodipine besylate monohydrate is a different salt than anhydrous amlodipine besylate. As part of this same argument, Synthon posits that the claim specification indicates that the patent is limited to a single compound. This is because the specification states that "[i]t has now unexpectedly been found that the benzene sulphonate salt (hereafter referred to as the besylate salt) has a number of advantages over the known salts of amlodipine and, additionally, has unexpectedly been found to have a unique combination of good formulation properties which make it particularly suitable for the preparation of pharmaceutical formulations of amlodipine." Again, Synthon points to language indicating a singular, unique compound and not a variety of compounds.

In response, Pfizer states that the construction "the [salt] of [base]" is commonly used by scientists and is not used to signify anything more than that a particular acid-base pair constitutes a salt. As such, hydrates of that particular acid-base pair are still considered to be that same "salt." Pfizer also submits to the Court an expert declaration that states that whether a compound is anhydrous or a monohydrate does not change the kind of salt that is formed. (*See* McGinity Decl., Document # 86, at 5.) Thus, Pfizer argues that the use of a singular noun "salt" does not preclude the claim from including both the anhydrous formation and the monohydrate.

Synthon's second argument is that Pfizer was only able to get the '303 patent, which was initially rejected by the PTO for "obviousness," by arguing that this particular salt had previously unknown good qualities that were not evident in the '909 patent. Synthon argues that Pfizer tested the monohydrate in 1985 but rejected it as "not a suitable form for development" because it was hygroscopic, that is, that it had a tendency to take up or to lose water in excess of any water already in the compound. Accordingly, Synthon argues that either the patent does not include the monohydrate, or that Pfizer must have misrepresented to the patent office the scope of its invention by not reporting that the monohydrate was unsuitable for development and thereby receiving a patent broader than Pfizer's testing would support.

In response to this argument, Pfizer states that the language pointed to by Synthon, "not a suitable form for development," was only available in its nonpublic New Drug Application filed in December 1987 with the FDA. Accordingly, such information should not be considered by this Court during claim construction, and cannot constitute a disclaimer of the subject matter of claims in the '303 patent, because it was not available to a practitioner of ordinary skill in the art on the date that Pfizer filed its patent application in 1986. Moreover, and more importantly, Pfizer states that such language only concerned using the monohydrate for the pill or tablet form of the drug and not as an aqueous solution, such as that disclosed in Claim 9, in which the hygroscopicity of the substance is not important. Finally, Pfizer states that it was not inequitable conduct not to report test data as to the monohydrate because while a patent applicant has a duty to report the "best mode," to the PTO, an inventor need not disclose every possible way in which an invention could be practiced, including less desirable modes. *See* Rexnord Corp. v. Laitram Corp., 274 F.3d 1336, 1344 (Fed.Cir.2001) ("Our case law is clear that an applicant is not required to describe in the specification every conceivable and possible future embodiment of his invention.").

Synthon's third and primary argument is, although the patent does not state as such, that Pfizer only used anhydrous amlodipine besylate in its testing and development of Norvasc(R), and relatedly, that the patent specification teaches that any hydrate is unsuitable. Pfizer admits that its marketed product Norvasc(R) only uses anhydrous amlodipine besylate. Moreover, Pfizer's patent specification states that, "Although amlodipine is effective as the free base, in practice it is best administered in the form of a salt of a

pharmaceutically acceptable acid. In order to be suitable for this purpose the pharmaceutically acceptable salt must satisfy the following four physiochemical criteria: (1) good solubility; (2) good stability; (3) non-hygroscopicity; (4) processibility for tablet formulation." The patent then goes on to discuss the solubility of various salts, the stability of various salts, the hygroscopicity of various salts, and the stickiness of various salts. None of these charted salts differentiates between anhydrous, monohydrates, and dihydrates as part of the listed name in the patent. Synthon emphasizes, however, that the words "must satisfy" are in the patent specification statement, therefore indicating a clear disclaimer by Pfizer of any substance that does not contain those four qualities. Synthon then states that Synthon's expert's own testing of the monohydrate shows it to be quite sticky. Thus, Synthon argues that Pfizer stated that this particular compound "must satisfy" those four criteria, but that the monohydrate version does not satisfy all four criteria, so therefore Pfizer has disclaimed the monohydrate.

Synthon submitted the expert declaration of Walter Chambliss [Document # 90] in order to show that Pfizer did not test amlodipine besylate monohydrate when developing the '303 patent. This expert opined that the various weights of "the besylate salt of amlodipine" used in testing indicate that only the anhydrous form of the salt was utilized in that testing. Accordingly, Synthon argues that the patent teaches that only the anhydrous form is proper for producing a salt that improves upon the prior art salt of amlodipine maleate, and that "hydrates" in general must be rejected. Synthon further emphasizes that the patent specification of '303 states that,

Only the maleate, tosylate and besylate salts do not pick up any moisture when exposed to 75% relative humidity at 37degree C. for 24 hours. Even when exposed to 95% relative humidity at 30 degree C. for 3 days both the besylate and maleate *remain anhydrous* whilst *the tosylate formed the dihydrate salt*. Therefore the besylate salt can be considered to be non-hygroscopic and thus provides stale formulations while minimising the risk of intrinsic chemical breakdown."

(Patent No.4,879,303, filed April 4, 1986 (emphasis added).)

This statement, according to Synthon, is also a clear disclaimer of any hydrates in this invention.

However, Pfizer denies that it ever clearly disclaimed amlodipine besylate monohydrate in this patent. Pfizer points out that the patent specification must not be read without considering the language in all of the claims, and not just the claims referring to tablets and capsules. More specifically, Pfizer points to Claim 9 of the patent, which states, "A sterile aqueous solution comprising an antihypertensive, antiischaemic or angina-alleviating effective amount of the besylate salt of amlodipine for parenteral administration." Pfizer argues that an aqueous solution cannot by its very nature employ an anhydrate, because once the salt is dissolved in the water it is no longer "anhydrous." Moreover, Pfizer states that there is no advantage (or disadvantage) obtained by starting with anhydrous amlodipine besylate over a hydrate form when both forms of the salt are in a water-based solution. Accordingly, Pfizer states that it is impossible that the invention claimed in all aspects of the claims is limited to the physical form of salt known as anhydrous amlodipine besylate,FN4 and accordingly, the word "anhydrous" should not be read into any of the claims, including Claims 1 through 8. In response to this last point by Pfizer, Synthon's only response appears to be that, based upon the weight of the salt tested, it is presumed that Pfizer only dissolved anhydrous amlodipine besylate in solution, and not the monohydrate. Accordingly, Synthon argues that the patent does not teach one of ordinary skill in the art that use of the monohydrate form is possible within the ' 303 patent context.

FN4. Moreover, Pfizer states that the preferred quality non-hygroscopicity as stated in the patent

specification as a "must satisfy" quality is simply irrelevant to amlodipine besylate in an aqueous solution.

IV. COURT FINDINGS AS TO CLAIM CONSTRUCTION

As previously discussed, this Court must start its analysis of the correct interpretation of the phrase "the besylate salt of amlodipine" by examining the words of the claims themselves. *See* Phillips v. AWH Corp., 415 F.3d at 1312 (Fed.Cir.2005). Unless the patent otherwise provides, a claim term should not be given a different meaning in the various claims of the same patent. *See* Georgia-Pacific Corp. v. United States Gypsum Co., 195 F.3d 1322, 1331 (Fed.Cir.1999); Fin Control Sys. Pty Ltd. v. OAM Inc., 265 F.3d 1311, 1318 (Fed.Cir.2001); *Patents and the Federal Circuit,* Robert L. Harmon, s. 6.7(b). Interpretation of a disputed claim term thus requires reference to the other claims. *Id*. The Court has examined the patent specification, and finds that it does not either define the contested phrase, "the besylate salt of amlodipine," nor does it teach that the phrase "the besylate salt of amlodipine" should be read differently as between Claim 1 and Claim 9. Accordingly, the Court finds that any interpretation given to the contested phrase should be the same in both Claim 1 and Claim 9. Because the Court finds that the meaning of the phrase in Claim 9 will shed light on the meaning of the phrase in Claim 1, the Court will examine the words of Claim 9 first.

The Court notes that as Pfizer clearly argued during the *Markman* hearing in this matter, Claim 9 is *not* a process claim. It does not attempt to teach one skilled in the art how to make such a substance, but instead, claims the substance itself. Claim 9 states, "A sterile aqueous solution comprising an antihypertensive, antiischaemic or angina-alleviating effective amount of the besylate salt of amlodipine for parenteral administration." The term "comprising" is generally understood by patent attorneys to have the same meaning as the term "including ." *See* Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp., 123 F.3d 1445, 1451 (Fed.Cir.1997); *Patents and the Federal Circuit,* Robert L. Harmon, s. 6.2(d) ("The claim term 'including' is synonymous with 'comprising,' thereby permitting the inclusion of unnamed components.") It does not mean, as Synthon urged during the *Markman* hearing, "made from," and the Court does not find any evidence within the patent itself to indicate that the term "comprising" does not mean "including."

Experts for both parties appear to agree that when a salt is in an aqueous solution, it would be meaningless to term it as being "anhydrous." (*See* McGinity Decl., Document # 86, at 23 ("[T]he salt in solution is in the form of ions surrounded by water, and cannot be anhydrous."); Chambliss Dep., Document # 109, at 84 ("Q: Well if you have pure amlodipine besylate monohydrate in an aqueous solution, the amlodipine ion and the besylate anion are no longer physically joined; is that correct? A. Yes. They've separated. Q. And they are separated by water, if it's a pure water solution? A. Just in water, yes. Q. And if you have amlodipine besylate that started off as anhydrous in solution, you'd also have a separate amlodipine anion-or a cation and a besylate anion? A. Yes. Q. Surrounded by water, correct? A. Correct. Q. And those two, the monohydrate and the anhydrate surrounded by water would be, from all appearances, identical ... if that's all there is, completely pure material? A. They are going to be separated. I don't know how from what you mean by appearances, how. Q. Well if you analyze both solutions, they would appear to be identical? A. If you're analyzing for the besylate and you're analyzing for amlodipine, you should get the same result.").) Accordingly, based upon the record before the Court, the Court finds that it would be error to read the term "anhydrous" into Claim 9, because Claim 9 concerns an aqueous solution including the besylate salt of amlodipine, which cannot be "anhydrous." Therefore, because Claim 9 cannot be read as anhydrous, Claim 1, which only claims "The besylate salt of amlodipine," also cannot be read as requiring the modifier "anhydrous."

Accordingly, there is no need in this matter to move beyond the language of the claims themselves in order to determine the meaning of the phrase "the besylate salt of amlodipine." However, the Court has also considered the language of the specification, which also teaches that Synthon's preferred interpretation, requiring the insertion of the word "anhydrous," still does not hold up to close scrutiny. For example, while Synthon argues that Pfizer specifically disclaimed hydrates by stating in the specification that "both the besylate and maleate remain anhydrous whilst the tosylate formed the dihydrate salt," the Court does not find this to be a clear disclaimer of all hydrates, nor more specifically of amlodipine besylate monohydrate. *See* Eolas Techs., Inc. v. Microsoft Corp., 399 F.3d 1325, 1336 (Fed.Cir.2005) ("[A]bsent a clear disclaimer in the specification, the embodiments in the specification do not limit broader claim language."), *cert. denied,* 546 U.S. 998, 126 S.Ct. 568, 163 L.Ed.2d 499 (2005). Amlodipine besylate monohydrate and its particular properties are not distinguished within patent number '303. In much of the patent specification, it remains unclear to this Court whether Pfizer tested anhydrous, monohydrate, or dihydrate versions of various salts. However, even assuming that Pfizer only tested the anhydrous form, Pfizer created the monohydrate form by dissolving the salt in water to test for solubility. (*See* McGinity Decl., Document # 86, at 6 ("[A]mlodipine besylate hydrate is formed when the besylate salt of amlodipine is precipitated from water. It follows that a saturated aqueous solution of the besylate salt of amlodipine will produce the hydrate form of amlodipine besylate as water is evaporated from solution. The '303 patent refers to a measurement of solubility of amlodipine besylate. Because such measurements are necessarily run with a saturated solution of the amlodipine besylate, the hydrate form of amlodipine besylate would form as water is evaporated from the saturated solution.).) Accordingly, the Court finds that it cannot say as a matter of law that Pfizer either disclaimed the monohydrate form of amlodipine besylate or that Pfizer did not use the monohydrate form in its testing of this substance. *See* Phillips, 415 F.3d at 1323 ("[A]lthough the specification often describes very specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments.")

Therefore, based upon the language of the claims and the patent specification, it does not appear that Pfizer specifically disclaimed the monohydrate form of the salt, and in fact claimed a version of the salt within an aqueous solution in Claim 9, which by its very nature cannot be anhydrous. Thus, the Court will adopt this claim construction for the phrase "the besylate salt of amlodipine," as "any salt that contains the positively charged amlodipine cation and the negatively charged besylate anion, without limitation to any particular physical form of the salt."

V. PFIZER'S MOTION TO STRIKE REPLY DECLARATION OF GERT JAN ETTEMA & JOINT MOTION TO SUPPLEMENT THE RECORD

Pfizer seeks to strike the Reply Declaration of Gert Jan Ettema because the Reply Declaration states that Mr. Ettema has recently tested the various properties of amlodipine besylate monohydrate against anhydrous amlodipine besylate (concluding that the monohydrate is hygroscopic and stickier than amlodipine maleate, the subject of the '909 patent). Given that counsel made reference to the Gert Jan Ettema Declaration at the *Markman* hearing and Pfizer did not further object to discussion of the Declaration, the Court must note that it has considered all of the evidence before it, including the Reply Declaration of Gert Jan Ettema. However, as the Court did not ultimately need to go beyond the claims themselves in order to properly construe the claim, the Reply Declaration of Gert Jan Ettema, which concerned solely extrinsic evidence, became moot. Therefore, Pfizer's Motion to Strike the Reply Declaration of Gert Jan Ettema [Document # 102] is DENIED AS MOOT.

Prior to the *Markman* hearing, counsel on either side submitted the Joint Motion for Leave to Supplement the Record as to Claim Construction [Document # 108]. Attached to this Joint Motion were various documents, most particularly the full depositions of either side's principal experts, and documents that the experts referenced during their testimony. The Court finds that these depositions were not available for inclusion into the record until after the parties had submitted their Responsive Briefs concerning claim construction. Accordingly, the Joint Motion for Leave to Supplement the Record is GRANTED.

VI. CONCLUSION

For the reasons as stated in this memorandum opinion, after considering the competing claim construction briefs filed by the parties [Documents # # 85, 89, 93, 97] and hearing oral argument in this matter, the Court will construe the phrase "the besylate salt of amlodipine," as "any salt that contains the positively charged amlodipine cation and the negatively charged besylate anion, without limitation to any particular physical form of the salt." Moreover, the Motion by Pfizer to Strike the Reply Declaration of Gert Jan Ettema [Document # 102] is DENIED AS MOOT; and the Joint Motion for Leave to Supplement the Record as to Claim Construction [Document # 108] is GRANTED.

As an additional matter, the Court having reviewed its trial schedule for the April Master Calendar will set this matter for the week beginning April 10, 2006.

An Order consistent with this Memorandum Opinion will be filed contemporaneously herewith.

ORDER

For the reasons stated in the Memorandum Opinion filed contemporaneously herewith,

IT IS HEREBY ORDERED THAT after considering the competing claim construction briefs filed by the parties [Documents85, 89, 93, 97] and hearing oral argument in this matter, the Court will construe the phrase "the besylate salt of amlodipine," as "any salt that contains the positively charged amlodipine cation and the negatively charged besylate anion, without limitation to any particular physical form of the salt." Moreover, the Motion by Pfizer to Strike the Reply Declaration of Gert Jan Ettema [Document # 102] is DENIED AS MOOT; and the Joint Motion for Leave to Supplement the Record as to Claim Construction [Document # 108] is GRANTED.

As an additional matter, the Court having reviewed its trial schedule for the April Master Calendar will set this matter for the week beginning April 10, 2006.

M.D.N.C.,2006.
Pfizer Inc. v. Synthon Holding B.V.

Produced by Sans Paper, LLC.