IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC, and HOFFMAN-LA ROCHE INC.,	:	**UNSEALED ON JANUARY 9, 2012**
Plaintiffs,	:	
v.	:	C.A. No. 08-cv-627-LPS, 11-cv-81-LPS
TEVA PHARMACEUTICALS USA, INC.,	:	
Defendant.	:	

WARNER CHILCOTT COMPANY, LLC, and HOFFMAN-LA ROCHE INC.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 09-cv-143-LPS, 10-cv-1111-LPS
APOTEX, INC. and APOTEX CORP.,	:	
Defendants.	:	

WARNER CHILCOTT COMPANY, LLC, and HOFFMAN-LA ROCHE INC.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 10-cv-285-LPS, 11-cv-286-LPS
MYLAN PHARMACEUTICALS INC.,	:	
Defendant.	:	

WARNER CHILCOTT COMPANY, LLC, and HOFFMAN-LA ROCHE INC.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 09-cv-61-LPS, 10-cv-1085-LPS
SUN PHARMA GLOBAL, INC.,	:	
Defendant.	:	

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MEMORANDUM OPINION

December 29, 2011
Wilmington, Delaware.

STARK, U.S. District Judge:

I. INTRODUCTION

In these consolidated Hatch-Waxman actions, Plaintiffs Warner Chilcott Company, LLC and Hoffman-La Roche Inc. ("Plaintiffs") allege that Defendants Teva Pharmaceuticals USA, Inc., Apotex, Inc., Apotex Corp., Mylan Pharmaceuticals Inc., and Sun Pharma Global, Inc. ("Defendants") infringe U.S. Patent Nos. 7,192,938 ("the '938 patent") and 7,718,634 ("the '634 patent") (together, "the patents-in-suit"). (*See* 08-cv-627-LPS D.I. 1; 11-cv-81-LPS D.I. 1; 09-cv-143-LPS D.I. 1; 10-cv-1111-LPS D.I. 1; 10-cv-285-LPS D.I. 1; 11-cv-286-LPS D.I. 1; 09-cv-61-LPS D.I. 1; 10-cv-1085-LPS D.I. 1) Plaintiffs also assert U.S. Patent No. 6,165,513 ("the '513 patent") against Defendant Teva Pharmaceuticals USA, Inc. (*see* 08-cv-627-LPS D.I. 1), and Defendants Apotex, Inc. and Apotex Corp. assert counterclaims of non-infringement, invalidity, and unenforceability of the '513 patent (*see* 09-cv-143-LPS D.I. 1). Presently before the Court is the matter of claim construction. Briefing on claim construction was completed on June 2, 2011. (*See* D.I. 156; D.I. 178; D.I. 168; D.I. 173; D.I. 150; D.I. 153; D.I. 163; D.I. 164) The Court held a *Markman* hearing on June 14, 2011. *See* Claim Construction Hr'g Tr., June 14, 2011 (D.I. 205) (hereinafter "Tr.").[1]

II. LEGAL STANDARDS

"It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (internal quotation marks omitted). Construing the claims of a patent presents a

[1]On December 9, 2011, the Court granted the Stipulation of Dismissal Relating to U.S. Patent No. 5,583,122 and U.S. Patent No. 6,165,513 (D.I. 288), which, among other things, withdrew the parties' request to construe disputed terms of the '513 patent.

question of law. *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 977-78 (Fed. Cir. 1995), *aff'd*, 517 U.S. 370, 388-90 (1996). "[T]here is no magic formula or catechism for conducting claim construction." *Phillips*, 415 F.3d at 1324. Instead, the court is free to attach the appropriate weight to appropriate sources "in light of the statutes and policies that inform patent law." *Id.*

"[T]he words of a claim are generally given their ordinary and customary meaning . . . [which 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 1312-13 (internal citations and quotation marks omitted). "[T]he ordinary meaning of a claim term is its meaning to the ordinary artisan after reading the entire patent." *Id.* at 1321 (internal quotation marks omitted). The patent 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." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996).

While "the claims themselves provide substantial guidance as to the meaning of particular claim terms," the context of the surrounding words of the claim also must be considered. *Phillips*, 415 F.3d at 1314. Furthermore, "[o]ther claims of the patent in question, both asserted and unasserted, can also be valuable sources of enlightenment . . . [b]ecause claim terms are normally used consistently throughout the patent . . . ." *Id.* (internal citation omitted).

It is likewise true that "[d]ifferences among claims can also be a useful guide . . . . For example, the presence of a dependent claim that adds a particular limitation gives rise to a presumption that the limitation in question is not present in the independent claim." *Id.* at 1314-15 (internal citation omitted). This "presumption is especially strong when the limitation in

dispute is the only meaningful difference between an independent and dependent claim, and one party is urging that the limitation in the dependent claim should be read into the independent claim." *SunRace Roots Enter. Co., Ltd. v. SRAM Corp.*, 336 F.3d 1298, 1303 (Fed. Cir. 2003).

It is also possible that "the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. It bears emphasis that "[e]ven when the specification describes only a single embodiment, the claims of the patent will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction." *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004) (internal quotation marks omitted), *aff'd*, 481 F.3d 1371 (Fed. Cir. 2007).

In addition to the specification, a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980. The prosecution history, which is "intrinsic evidence," "consists of the complete record of the proceedings before the PTO [Patent and Trademark Office] and includes the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. "[T]he prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.*

A court also may rely on "extrinsic evidence," which "consists of all evidence external to the patent and prosecution history, including expert and inventor testimony, dictionaries, and learned treatises." *Markman*, 52 F.3d at 980. For instance, technical dictionaries can assist the

court in determining the meaning of a term to those of skill in the relevant art because such dictionaries "endeavor to collect the accepted meanings of terms used in various fields of science and technology." *Phillips*, 415 F.3d at 1318. In addition, expert testimony can be useful "to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of ordinary skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id.* Nonetheless, courts must not lose sight of the fact that "expert reports and testimony [are] generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence." *Id.* Overall, while extrinsic evidence "may be useful" to the court, it is "less reliable" than intrinsic evidence, and its consideration "is unlikely to result in a reliable interpretation of patent claim scope unless considered in the context of the intrinsic evidence." *Id.* at 1318-19.

Finally, "[t]he 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." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998). It follows that "a claim interpretation that would exclude the inventor's device is rarely the correct interpretation." *Osram GmbH v. Int'l Trade Comm'n*, 505 F.3d 1351, 1358 (Fed. Cir. 2007). Thus, if possible, claims should be construed to uphold validity. *See In re Yamamoto*, 740 F.2d 1569, 1571 (Fed. Cir. 1984).

III. CONSTRUCTION OF DISPUTED TERMS

A. "treating or inhibiting" ('938 patent Claim 1, 6, 8-9, 13-16, 21, 23-24, 28-30; '634, patent Claim 9-10)

1. Plaintiffs' Construction: Taking measures to counteract, prevent, retard, or interfere with the progression of a disease or disorder.

2. Defendants' Construction: The phrase "treating or inhibiting" indicates that the steps of the recited method affect or are intended to affect the progress of a disease already having been diagnosed, and does not include preventing a disease that has not yet been diagnosed.

3. Court's Construction: Taking measures to counteract, prevent, retard, or interfere with the progression of a disease or disorder.

B. "a subject in need of such treatment" ('938 patent Claim 1, 6, 8-9, 13-16, 21, 23-24, 28-30)

1. Plaintiffs' Construction: Denotes patients who have osteoporosis or have experienced bone loss or are otherwise at risk of developing osteoporosis.

2. Defendants' Construction: The phrase "in need of such treatment" indicates that the subject already has been diagnosed with osteoporosis.

3. Court's Construction: A patient who has osteoporosis or has experienced bone loss or is otherwise at risk of developing osteoporosis.

C. "a postmenopausal woman in need of treatment or inhibition of postmenopausal osteoporosis" ('634 patent Claim 9-10)

1. Plaintiffs' Construction: Patients who have postmenopausal osteoporosis or have experienced bones loss or are otherwise at risk of developing postmenopausal osteoporosis.

2. Defendants' Construction: The phrase "in need of such treatment" indicates that the subject already has been diagnosed with osteoporosis.

3. Court's Construction: A patient who has postmenopausal osteoporosis or has experienced bones loss or is otherwise at risk of developing postmenopausal osteoporosis.

There appears to be no meaningful dispute among the parties that the plain and ordinary meaning of "inhibit" encompasses prevention. *See Merriam-Webster's Medical Desk Dictionary* 394 (2d ed. 2002) (defining "inhibit" as "to retard, interfere with, or prevent (a process or reaction)"); *see also* '938 patent, col.1 ll.45-51 (referring to "treatment and prevention" of diseases). Defendants dedicate no portion of their briefing to this issue. (*See* D.I. 178 at 16-22;

D.I. 173 at 2-6)

Instead, the parties' dispute is whether there is a prosecution history disclaimer. Specifically, the question is whether Plaintiffs forfeited preventing, and prevention of, osteoporosis during the prosecution of this family of patents.[2] To limit the scope of a claim term based on prosecution disclaimer, the case law "requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable." *Omega Eng'g, Inc., v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003). The prosecution proceedings here fall short of this standard. In response to three separate enablement rejections (one during prosecution of the patents-in-suit's parent patent, and one for each of the '938 and '634 patents-in-suit),[3] Plaintiffs changed the claim term "treating and preventing" to "treating and inhibiting."[4] With respect to the '938 and '634 patents, however, the applicants included in their responsive filings a statement that "inhibiting" "is considered appropriate as it encompasses prevention of osteoporosis in subjects who do not yet suffer from the disorder but are likely candidates to develop it, as well as inhibition of further osteoporosis in subjects who already suffer from the disorder." (D.I. 177 Ex. E at AP-RISE0004477; *see also id.* Ex. F at AP-RISE0006359) Thus, the Court does not find a clear and unmistakable disavowal of "prevention;" the examiner voiced

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[2]This same disagreement is reflected in the proposed constructions of "a subject in need of such treatment" and "a postmenopausal woman in need of treatment or inhibition of postmenopausal osteoporosis." If the claims do not cover prevention of osteoporosis in patients who do not yet have osteoporosis, people without osteoporosis are not within the scope of these terms.

[3]*See* D.I. 177 Ex. D at AP-RISE0006865-66, AP-RISE000690; *id.* Ex. E at AP-RISE 0004419-23; *id.* Ex. F at AP-RISE0005955-57.

[4]*See* D.I. 177 Ex. D at AP-RISE0006905-07; *id.* Ex. E at AP-RISE0004472, AP-RISE0004276-77, AP-RISE0004279; *id.* Ex. F at AP-RISE0006355-57, AP-RISE0006359.

no objection to the quoted statement. (*See id.* Ex. E at AP-RISE0004516) Instead, as Plaintiffs concede (*see* D.I. 168 at 10; *see also* Tr. at 28-29), the claim scope they forfeited was with respect to "complete" prevention of osteoporosis (i.e., ensuring a patient will never develop the disease as a result of the patented method), which was a matter with which the examiner explicitly voiced concern when rejecting the application which led to the '634 patent.[5] The Court will hold Plaintiffs to this concession and exclude "complete prevention" from the scope of this term.[6]

D. "commencing treatment . . . and continuing said treatment" ('938 patent Claim 6, 8-9, 13-15)

1. Plaintiffs' Construction: Within the timeframe of the treatment episode, beginning a regimen of taking a particular bisphosphonic acid or a pharmaceutically acceptable salt thereof . . . and proceeding with that regimen thereafter.

2. Defendants' Construction: To begin treatment for (or inhibiting the progression of) the disease osteoporosis, for the first time . . . and to go on

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[5]*See* D.I. 177 Ex. F at AP-RISE0005957 ("[T]he term 'prevention' is broad enough to encompass an outcome of absolute absence of such disorders. In the medical arts, however, therapeutic outcomes of absolute success is not the norm . . . . Further regarding the concept of prevention, as noted above, this term may be reasonably interpreted as being synonymous with the term 'curing' and both circumscribe objectives of absolute success. Because absolute success is not reasonably possible with most diseases/disorders, especially those having an etiology and pathophysiological manifestations as complex/poorly understood as bone-remodeling conditions, the specification, which lacks an objective showing that such conditions may actually be prevented, is viewed as lacking an enabling disclosure of the same.").

[6]The Court's constructions addressed in this section are consistent with those recently issued by U.S. District Judge Stanley R. Chesler of the U.S. District Court for the District of New Jersey, who was called on to construe terms of the '634 patent. *See Hoffman-La Roche Inc. v. Apotex Inc.*, 2011 WL 5325565 (D.N.J. Nov. 3, 2011); *see also id.* at 2 n.2 ("One could reasonably conclude from the prosecution history that the applicant did surrender coverage of a method for absolutely successful prevention of osteoporosis, but this has little meaning in this dispute, since there do not appear to be at issue any methods for the absolutely successful prevention of osteoporosis.").

with treating (or inhibiting the progression of) the disease osteoporosis, by any means, after the first "commencing treatment" step.

3. Court's Construction: Within the timeframe of the treatment episode, beginning a regimen of taking a particular bisphosphonic acid or a pharmaceutically acceptable salt thereof . . . and proceeding with that regimen thereafter.

The Court's construction is supported by the intrinsic evidence. The claim language itself indicates what is meant by "commencing treatment:" "What is claimed is . . . A method for treating or inhibiting osteoporosis comprising ***commencing treatment by*** . . . ." ('938 patent col.7 ll.23-24) (emphasis added) "Treatment" refers to the "treating and inhibiting" of the claimed methods, and the claims teach how to begin these methods (i.e., with what follows "commencing treatment by"). (*See, e.g.,* '938 patent col.7 ll.24-35) The remainder of the specification adds little with respect to this dispute because the claims were redrafted as two-step methods to overcome an obviousness rejection over Schofield et al., U.S. Pub. No. 2003/0118634 ("Schofield") (*see* D.I. 168 Ex. E at AP-RISE0004551-53), although the substance of the claimed methods was not changed (*see id.* at AP-RISE0004657-58). There is no clear intent to limit the meaning of "treatment" to only the approved indication of risidronate present in the specification. *See Liebel-Flarsheim*, 358 F.3d at 906. A person of ordinary skill in the art would understand that the claims are drawn to a specific regimen and would appreciate that anything occurring before the claimed regimen is outside the scope of the claims. (*See* D.I. 157 at ¶ 44)

The Court's construction is also supported by the prosecution history. As noted, the claims were redrafted as two-step methods to avoid reading on Schofield; the first step of the claimed method is different from that of the method disclosed in Schofield. (*See* D.I. 168 Ex. E

at AP-RISE000457-58) A new "treatment episode" is not started with every dose of bisphosphonate. A "treatment episode" is the time frame which a person of skill in the art would understand as a regimen. (*See* D.I. 157 at ¶ 44; *see also Hoffmann-La Roche Inc. v. Apotex Inc.*, 2010 WL 1875569, at *12 (D.N.J. May 10, 2010) In any event, the second step of the Schofield method cannot begin the claimed regimen; it is improper to construe claims as covering prior art distinguished in prosecution. *See Kinik Co. v. Int'l Trade Comm'n*, 362 F.3d 1359, 1365 (Fed. Cir. 2004); *SciMed Life Sys. v. Advanced Cardiovascular*, 242 F.3d 1337, 1343 (Fed. Cir. 2001); *see also Hoffmann-La Roche Inc.*, 2010 WL 1875569, at *14.

E. "subject" ('938 patent Claim 1, 6, 8-9, 13-16, 21, 23-24, 28-30)

1. Plaintiffs' Construction: A human patient.

2. Defendants' Construction: Encompasses not only human subject, but also any other animal subjects that can have or be diagnosed with osteoporosis.

3. Court's Construction: A human subject or any other animal subject that can have or be diagnosed with osteoporosis.

The dispute here is whether osteoporosis afflicts only humans and not animals. The Court's construction is consistent with the claim language, which does not indicate any exclusion of animals from being subjects, and the specification, which refers to administering bisphosphonic acids or salts thereof "to a mammal." (*See, e.g.*, '938 patent col.7 ll.24-25; *see also id.* col.6 ll.9-13) Additionally, prior art cited in the patents-in-suit supports the Court's construction. (*See id.* col.3 ll.28, 38; D.I. 177 Ex. M, U.S. Patent No. 4,761,406, col.2 ll.67-68; D.I. 177 Ex. N, U.S. Patent No. 3,962,432 at [57], col.1 ll.6-7) Both sides present expert opinion in their favor (*see* D.I. 157 at ¶¶ 20, 51; D.I. 154 at ¶¶ 17-20; D.I. 166 at ¶¶ 26-32), but Defendants' position is consistent with the plain meaning of "subject" in a medical dictionary,

see Dorland's Illustrated Medical Dictionary 1559 (27th ed. 1988) (defining "subject" as "a person or animal subjected to treatment, observation, or experiment").

F. "a pharmaceutical composition comprising from about 100 mg to about 150 mg of bisphosphonic acid" ('938 patent Claim 1, 6, 8-9, 13-15)

1. Plaintiffs' Construction: A composition of matter that is a medicament, with the two references to "a pharmaceutical composition" in claim 1 referring to the same pharmaceutical composition, not two distinct compositions.

2. Defendants' Construction: A composition of matter that is a medicament; the claim recites two distinct "pharmaceutical compositions" which could include different bisphosphonates or the same bisphosphonate; a pharmaceutical composition may include a single dose or as multiple sub-doses.

3. Court's Construction: A composition of matter that is a medicament, which may include a single dose or multiple sub-doses, with the two references to "a pharmaceutical composition" in claim 1 referring to the same thing.

G. "the pharmaceutical composition" ('938 patent Claim 3, 5, 6, 8-9)

1. Plaintiffs' Construction: The composition of matter that is a medicament referenced in independent claim 1.

2. Defendants' Construction: Has no proper construction.

3. Court's Construction: The composition of matter that is a medicament referenced in independent Claim 1.

H. "said bisphosphonic acid" ('938 patent Claim 6, 8-9, 13-15)

1. Plaintiffs' Construction: The single bisphosphonic acid recited in the independent claim

2. Defendants' Construction: Has no proper construction

3. Court's Construction: The bisphosphonic acid recited in the independent claim.

It is evident from the claim language, specification, and prosecution history that the "a" preceding the second occurrence of "pharmaceutical composition comprising about 100 mg to about 150 mg of bisphosphonic acid" was a drafting error. By referring to "the pharmaceutical composition" (*see, e.g.*, '938 patent col.7 ll.41-45, 50-53), the dependent claims imply that both references are to the same thing. The specification describes the claimed treatment method as involving the monthly administration of bisphosphonate, making no mention of a process in which two different compositions are administered. As discussed above, the claimed method is a one-step method which was redrafted as a two-step process explicitly to distinguish the prior art. (*See* D.I. 168 at AP-RISE0004657-58) In this way, the prosecution history also supports the Court's construction. Given this, the required correction is not subject to reasonable debate (that is, the second "a" should read "said"). Accordingly, the Court can correct the drafting error. *See Novo Indus., L.P. v. Micro Molds Corp.*, 350 F.3d 1348, 1357 (Fed. Cir. 2003) ("A district court can correct a patent only if (1) the correction is not subject to reasonable debate based on consideration of the claim language and the specification and (2) the prosecution history does not suggest a different interpretation of the claims."). The terms in the dependent claims, thus, have distinguishable antecedent bases, ascertainable meaning, and are amenable to construction.[7] *See Energizer Holdings, Inc. V. Int'l Trade Comm'n*, 435 F.3d 1366, 1370-71 (Fed. Cir. 2006).

Additionally, no limitation requiring a single dose is warranted. The claim language supports this conclusion – "a" is typically construed to mean "one or more." *See Baldwin*

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[7]The term "risedronic acid or a pharmaceutically acceptable salt thereof" in Claims 8-9, 21, and 23-24 of the '938 patent is likewise amenable to construction. "Risedronic acid or a pharmaceutically acceptable salt thereof" replaces "bisphosphonic acid or an amount of pharmaceutically acceptable salt thereof" in the independent claim, since the latter is the antecedent basis for "said bisphosphonic acid."

Graphics Sys., Inc., v. Siebert, Inc., 512 F.3d 1338, 1342 (Fed. Cir. 2008); *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1356 (Fed. Cir. 2000). Thus, "a pharmaceutical composition" is best interpreted as "one or more pharmaceutical compositions," which encompasses sub-doses. The remainder of the specification confirms this construction. (*See, e.g.*, '938 patent col.3 ll.51-54, 59-61, 63-67; *id.* col.4 ll.6-19; *id.* col.6 ll.21-24, 29-31) The statement that the "medicament comprises about 50 to 250 mg" ('938 patent col.2 ll.54-55) is no clear disavowal of multiple sub-doses.

Likewise, there is no basis for excluding multiple-day administrations from the scope of Claims 16-30 of the '938 patent, which do not include the limitation "on a single day" present in other claims. *See Phillips*, 415 F.3d at 1314-15; *Liebel-Flarsheim*, 358 F.3d at 906. The specification amply supports this conclusion. (*See, e.g.,* '938 patent col.2 ll.56-58; *id.* col.3 ll.11-12, 20-21, 64-67; *id.* col.4 ll.10-19; *id.* col.6 ll.18-21, 25-28, 31-39)

I. "once monthly" ('938 patent Claim 16-30)

1. Plaintiffs' Construction: Once in a period or interval of approximately 30 days.

2. Defendants' Construction: Repeated with a repeating period of approximately four (4) weeks, approximately 30 days, or something approaching 1/12 of a calendar year. Something occurring "once monthly" may have a duration of more than one minute, hour, or day, provided that it repeats at an interval of once a month.

3. Court's Construction: Receiving a dose, in either a single dose or multiple subdoses on one or more days, once in a period or interval of approximately 30 days.

The parties do not meaningfully disagree as to the "monthly" portion of this term, which for simplicity the Court construes as "a period or interval of approximately 30 days," which is

Plaintiffs' proposal. Defendants' proposal for monthly, while in some ways more precise than Plaintiffs' (and having support in the specification, *see* '938 patent col. 3 ll.54-58), risks confusing the jury on a point not reasonably subject to dispute.

More important is the parties' disagreement as to whether the "once" that occurs on a monthly basis during treatment must consist of receiving a single dose on a single day or may, instead, consist of multiple subdoses (either on a single day or multiple days). For the reasons already given in connection with the very similar dispute in the previous section of this Memorandum Opinion, the Court agrees with Defendants that multiple subdoses (on one or more days) are within the scope of the patent claims.

IV. CONCLUSION

A separate Order, consistent with this Memorandum Opinion, will be entered.

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SUN PHARMA GLOBAL, INC.,	:	
Defendant.	:	

ORDER

At Wilmington, this 29th day of December 2011:

For the reasons set forth in the Memorandum Opinion issued this date,

IT IS HEREBY ORDERED that the disputed claim language of U.S. Patent Nos. 7,192,938 ("the '938 patent") and 7,718,634 ("the '634 patent") shall be construed as follows:

1. "**Treating of inhibiting**," as is appears in Claim 1, 6, 8-9, 13-16, 21, 23-24, and 28-30 of the '938 patent and Claims 9-10 of the '634 patent, is construed as "taking measures to counteract, prevent, retard, or interfere with the progression of a disease or disorder."

2. "**A subject in need of such treatment**," as it appears in Claim 1, 6, 8-9, 13-16, 21, 23-24, and 28-30 of the '938 patent, is construed as "a patient who has osteoporosis or has experienced bone loss or is otherwise at risk of developing osteoporosis."

3. "**A postmenopausal woman in need of treatment or inhibition of postmenopausal osteoporosis**," as it appears in Claims 9-10 of the '634 patent, is construed as "a patient who has postmenopausal osteoporosis or has experienced bones loss or is otherwise at risk of developing postmenopausal osteoporosis."

4. "**Commencing treatment . . . and continuing said treatment**," as it appears in Claim 6, 8-9, and 13-15 of the '938 patent, is construed as "within the timeframe of the treatment

episode, beginning a regimen of taking a particular bisphosphonic acid or a pharmaceutically acceptable salt thereof . . . and proceeding with that regimen thereafter."

5. "**Subject**," as it appears in Claim 1, 6, 8-9, 13-16, 21, 23-24, and 28-30 of the '938 patent, is construed as "a human subject or any other animal subject that can have or be diagnosed with osteoporosis."

6. "**A pharmaceutical composition comprising from about 100 mg to about 150 mg of bisphosphonic acid**," as it appears in Claim 1, 6, 8-9, and 13-15 of the '938 patent, is construed as "a composition of matter that is a medicament, which may include a single dose or multiple sub-doses, with the two references to 'a pharmaceutical composition' in claim 1 referring to the same thing."

7. "**The pharmaceutical composition**," as it appears in Claim 3, 5, 6, and 8-9 of the '938 patent, is construed as "the composition of matter that is a medicament referenced in independent Claim 1."

8. "**Said bisphosphonic acid**," as it appears in Claim 6, 8-9, and 13-15 of the '938 patent, is construed as "the bisphosphonic acid recited in the independent claim."

9. "**Once monthly**," as it appears in Claims 16-30 of the '938 patent, is construed as "receiving a dose, in either a single dose or multiple subdoses on one or more days, once in a period or interval of approximately 30 days."

Delaware counsel are reminded of their obligation to inform out-of-state counsel of this Order. To avoid the imposition of sanctions, counsel should advise the Court immediately of any problems regarding compliance with this Order.

UNITED STATES DISTRICT JUDGE