NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC., Plaintiff, v. APOTEX INC. and APOTEX CORP., Defendants.	Civil Action No. 07-4417 (SRC) (MAS) Civil Action No. 08-3065 (SRC) (MAS) Civil Action No. 08-4053 (SRC) (MAS) Civil Action No. 10-6241 (SRC) (MAS) (consolidated with 07-4417 for all purposes) **OPINION & ORDER**
HOFFMANN-LA ROCHE INC., Plaintiff, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. 07-4516 (SRC) (MAS) Civil Action No. 08-3607 (SRC) (MAS) Civil Action No. 08-4055 (SRC) (MAS) Civil Action No. 10-5623 (SRC) (MAS) (consolidated with 07-4516 for all purposes)
HOFFMANN-LA ROCHE INC., Plaintiff, v. WATSON LABORATORIES, INC., WATSON PHARMACEUTICALS, INC., WATSON PHARMA, INC., COBALT PHARMACEUTICALS INC., and COBALT LABORATORIES, INC., Defendants.	Civil Action No. 07-4539 (SRC) (MAS) Civil Action No. 07-4540 (SRC) (MAS) Civil Action No. 08-4054 (SRC) (MAS) Civil Action No. 10-6206 (SRC) (MAS) (consolidated with 07-4539 for all purposes)

HOFFMANN-LA ROCHE INC., Plaintiff, v. ORCHID CHEMICALS & PHARMACEUTICALS LTD., ORCHID HEALTHCARE, ORCHID PHARMACEUTICALS INC., and ORGENUS PHARMA INC., Defendants.	Civil Action No. 07-4582 (SRC) (MAS) Civil Action No. 08-4051 (SRC) (MAS) Civil Action No. 10-4050 (SRC) (MAS) (consolidated with 07-4582 for all purposes)
HOFFMANN-LA ROCHE INC., Plaintiff, v. MYLAN INC., MYLAN PHARMACEUTICALS INC., GENPHARM INC. and GENPHARM, L.P., Defendants.	Civil Action No. 07-4661 (SRC) (MAS) Civil Action No. 08-4052 (SRC) (MAS) Civil Action No. 11-0579 (SRC) (MAS) (consolidated with 07-4661 for all purposes)

CHESLER, U.S.D.J.

This matter comes before the Court on the applications by Plaintiff Hoffman-La Roche Inc. ("Roche") and Defendants Watson Pharmaceuticals, Inc., Watson Laboratories, Inc., Watson Pharma, Inc., Cobalt Pharmaceuticals Inc. and Cobalt Laboratories, Inc., Apotex Inc. and Apotex Corp., Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc., Orchid Chemicals & Pharmaceuticals Ltd., Orchid Healthcare, Orchid Pharmaceuticals Inc., Orgenus Pharma Inc., Mylan Inc., Mylan Pharmaceuticals Inc., Genpharm Inc. and Genpharm, L.P. (collectively,

"Defendants"), for claim construction to resolve disputes over the construction of claim terms in U.S. Patent No. 7,718,634 (the "'634 patent"). The Court held oral argument on claim construction on October 24, 2011. For the reasons stated below, the Court agrees with the position advocated by Roche in the one dispute over claim construction that remained after the parties agreed on resolutions to the other issues at oral argument.

BACKGROUND

This matter involves several Hatch-Waxman actions for patent infringement. The cases have been consolidated for pretrial purposes and arise from the following facts. Briefly, Roche owns the '634 patent, which is directed to compounds and treatment methods associated with Roche's osteoporosis drug Boniva®. Defendants are generic pharmaceutical manufacturers who have filed Abbreviated New Drug Applications seeking FDA approval to engage in the manufacture and sale of generic versions of Boniva® prior to the expiration of the Roche patents.

On May 7, 2010, this Court issued a decision (the "2010 Opinion") which resolved certain disputes over the construction of claim terms in U.S. Patent Nos. 4,927,814 (the "'814 patent"), 7,192,938 (the "'938 patent"), and 7,410,957 (the "'957 patent"). The '814, '938, '957, and '634 patents are all listed in the Orange Book entry for Boniva®.

ANALYSIS

I. The law of claim construction

A court's determination "of patent infringement requires a two-step process: first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." Acumed LLC v. Stryker Corp., 483 F.3d 800, 804 (Fed. Cir. 2007). The Court decides claim construction as a matter of law: "the

construction of a patent, including terms of art within its claim, is exclusively within the province of the court." Markman v. Westview Instruments, 517 U.S. 370, 372 (1996).

The focus of claim construction is the claim language itself:

> 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. Attending this principle, a claim construction analysis must begin and remain centered on the claim language itself, for that is the language the patentee has chosen to 'particularly point[] out and distinctly claim[] the subject matter which the patentee regards as his invention.'

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., 381 F.3d 1111, 1115-1116 (Fed. Cir. 2004) (citations omitted).

The Federal Circuit has established this framework for the construction of claim language:

> We have frequently stated that the words of a claim 'are generally given their ordinary and customary meaning.' We have made clear, moreover, that the ordinary and customary meaning of a claim term 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. The inquiry into how a person of ordinary skill in the art understands a claim term provides an objective baseline from which to begin claim interpretation. . .
>
> In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words. In such circumstances, general purpose dictionaries may be helpful. In many cases that give rise to litigation, however, determining the ordinary and customary meaning of the claim requires examination of terms that have a particular meaning in a field of art. Because the meaning of a claim term as understood by persons of skill in the art is often not immediately apparent, and because patentees frequently use terms idiosyncratically, the court looks to those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean. Those sources include the words of the claims themselves, the remainder of the specification, the prosecution history, and extrinsic evidence concerning relevant scientific principles, the meaning of technical terms, and the state of the

art.

Phillips v. AWH Corp., 415 F.3d 1303, 1312-1314 (Fed. Cir. 2005) (citations omitted).

II. Claim construction of the disputed terms in the '634 patent

The parties dispute terms in two claims of the '634 patent:

> 1. A method for treating or inhibiting postmenopausal osteoporosis in a postmenopausal woman in need of treatment or inhibition of postmenopausal osteoporosis by administration of a pharmaceutically acceptable salt of ibandronic acid, comprising: (a) commencing the administration of the pharmaceutically acceptable salt of ibandronic acid by orally administering to the postmenopausal woman, on a single day, a first dose in the form of a tablet, wherein the tablet comprises an amount of the pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid; and (b) continuing the administration by orally administering, once monthly on a single day, a tablet comprising an amount of the pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid.
>
> 5. A method for treating or inhibiting postmenopausal osteoporosis in a postmenopausal woman in need of treatment or inhibition of postmenopausal osteoporosis by administration of a pharmaceutically acceptable salt of ibandronic acid, consisting essentially of orally administering to the postmenopausal woman, once monthly on a single day, a tablet comprising an amount of the pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid.

A. Construction of "treating or inhibiting postmenopausal osteoporosis . . ."

The parties dispute the meaning of the phrase "treating or inhibiting postmenopausal osteoporosis in a postmenopausal woman in need of treatment or inhibition of postmenopausal osteoporosis," which appears in both claims 1 and 5. The parties dispute three issues: 1) whether the applicant disclaimed coverage for prevention of postmenopausal osteoporosis ("PMO") during prosecution; 2) whether "inhibiting" encompasses the prevention of PMO; and 3) whether a prior diagnosis of PMO is required.

Defendants argue that the applicant unequivocally surrendered coverage for prevention of PMO during prosecution, and this surrender occurred during the prosecution of multiple patents from the family of patents that produced the '634 patent. As to this family of patents, Defendants explain:

> The '634 patent, which issued May 18, 2010, originates from a family of patent applications that claim priority to U.S. Application No. 10/430,007 ("the '007 application"). The '007 application produced: (1) U.S. Patent No. 7,410,957 ("the '957 patent"); (2) U.S. Application No. 10/998,849 ("the '849 application"), which issued as U.S. Patent No. 7,192,938 ("the '938 patent"); and (3) U.S. Application No. 12/139,587 ("the '587 application"), which issued as the '634 patent.

(Defs.' Opening Br. 2.) Defendants assert that the prosecution histories of the '957, '938, and '634 patents all show a similar series of events that demonstrate this unequivocal surrender of claim scope.

Claim 1 in the '587 application was directed to "[a] method for treating or preventing disorders characterized by pathologically increased bone resorption. . ." (JA 3207.) The examiner rejected claim 1 for lack of enablement. As Defendants tell the story, the examiner rejected claim 1 because the specification did not enable prevention of the targeted disorder, and so the applicant changed the language of the first claim from "treating or preventing" to the current "treating or inhibiting;" the claim as amended was allowed.

This could be construed as evidence that the applicant surrendered coverage of prevention in order to overcome a rejection, but this is a superficial reading of the prosecution history. The examiner's full explanation of the enablement rejection, set forth in the office action of April 17, 2009, is somewhat lengthy:

> Claim 1 is rejected under 35 U.S.C. 112, first paragraph, because the

specification, while being enabling for treating, suppressing, inhibiting or reducing a disorder characterized by pathologically increased bone resorption, such as osteoporosis, does not reasonably provide enablement for the prevention of the same. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims where a reasonable expectation of success would be enjoyed by the person so skilled.

The concept of "preventing" is not enabled by the present specification because the skilled artisan would not be imbued with a reasonable expectation that this objective could be achieved. The basis of this expectation would be (i) the artisan's appreciation of the term "preventing" to include that instance where the object of prevention is not manifested to any degree, (e.g., preventing bone loss would include an instance where absolutely no bone loss occurs when a compound is administered in anticipation of the occurrence of bone loss), (ii) knowledge readily available in the art where prevention is not shown and (iii) an understanding of the present disclosure in which prevention is also not shown.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary. When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:
The invention provides a method of preventing and suppressing osteoporosis, decreases in bone density, and bone fractures.
(2) The state of the prior art
The prior art methods involve androgen and estrogen therapy for these conditions.
(3) The relative skill of those in the art
The relative skill of the those in the art is that of a medical practitioner or Ph.D.
(4) The predictability or unpredictability of the art
Predictability is very low in that no time frame is given for the "prevention".
(5) The breadth of the claims
The claims are directed the prevention of the various bone-related disorders. The prevention of these disorders, however, would not have

been reasonably expected to be a treatment outcome because the 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, but rather an unexpected result not predictable from a given therapeutic regimen as applied to a given disease/condition/disorder.
(6) The amount of direction or guidance presented
While not required, the specification fails to show any data showing that a bone disorder such as osteoporosis could actually be kept from ever occurring, at any degree.
(7) The presence or absence of working examples
See above at "(6)".
(8) The quantity of experimentation necessary
Long term and definitive studies are indicated to support the term "preventing" as employed in the present claims in the eyes of one skilled in the art.

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.

The Examiner notes that the term "prevent" is not necessarily synonymous with "cure", but such interpretation is proper given that "During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.' *In re Hyatt*, 211 F.3d 1367, 1372,54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretations by the Examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393,1404-05,162 USPQ 541, 550-51 (CCPA 1969)." (MPEP § 2111).

For the above reasons, the claims are deemed properly rejected.

(JA 4277-80.)

The gist of the examiner's objection to the word "prevention" is contained in this statement:

"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."[1] (JA 4279.) It is not incorrect that the examiner found that the specification did not enable prevention, but that is misleading. The examiner raised no objections to the idea that the claim covered a method with the objective of preventing osteoporosis to whatever extent possible; instead, he was rejecting the idea that this was a method for absolute success in preventing osteoporosis.[2]

In response, Roche points to the applicant's October 14, 2009 letter submitting the amended claims after this rejection, which stated:

> Reconsideration and allowance are respectfully requested.
>
> Claim 1 has been canceled. New claims 2 to 11 are submitted by the present amendment. As discussed and agreed to during the interview between the Examiner and applicants' representative (as further detailed below) the amendments to the claims raise no issue of new matter and are fully supported by the specification as originally filed.
>
> . . .
>
> Applicants wish to thank Examiner Henley for extending the courtesy of a personal interview to applicants' representative, David Wildman, on September 3,2009. During the interview, the Examiner and applicants' representative discussed a set of proposed claims that are similar in scope to those in U.S. Patent 7,410,957 but which include the "inhibiting" term recited in the claims of U.S. Patent 7,192,938. This term is found in new independent claims 2, 6, 10, and 11 and is considered to be appropriate as it encompasses prevention of osteoporosis

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[1] The Court is aware that the examiner chose his words somewhat poorly, and that prevention is not by any means synonymous with cure. The point of this quote is that it expresses well the examiner's understanding of "prevention" as meaning "absolutely successful prevention."

[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.

> in women who do not yet suffer from the disorder but are likely candidates to develop it, as well as inhibition of further osteoporosis in women who already suffer from the disorder.
>
> . . .
>
> **The Rejection Under 35 U.S.C. § 112, First Paragraph**
>
> Claim 1 stood rejected by the Examiner for lack of enablement. As claim 1 has been canceled, it is respectfully submitted that this ground of rejection is moot.
>
> New independent claims 2, 6, 10, and 11 open with the recitation "A method for treating or inhibiting postmenopausal osteoporosis ..." As in the '938 patent, and as discussed during the interview, it is respectfully submitted that the claims with this recitation are fully enabled and appropriate as they encompass prevention of osteoporosis in women who do not yet suffer from the disorder but are likely candidates to develop it, as well as inhibition of further osteoporosis in women who already suffer from the disorder.

(JA 4680-81.) This letter makes clear that the applicant considered "inhibiting" in this context to encompass prevention of PMO. The examiner subsequently allowed the claims, as amended, and the patent issued. The parties do not point to any other documents in the file that bear on this issue of claim construction.

The Federal Circuit has held:

> [W]here the patentee has unequivocally disavowed a certain meaning to obtain his patent, the doctrine of prosecution disclaimer attaches and narrows the ordinary meaning of the claim congruent with the scope of the surrender. . . [F]or prosecution disclaimer to attach, our precedent 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, 1324-1326 (Fed. Cir. 2003). Based on the present record, this Court cannot conclude that the applicant unequivocally disavowed coverage for prevention of PMO during prosecution.

There are three problems with Defendants' argument of surrender in the prosecution history. First, as discussed, Defendants' interpretation of the statements in the April 17, 2009 office action does not accurately reflect the examiner's stated reasoning: the examiner appeared only to be rejecting coverage of absolutely successful prevention, and not of partly successful prevention. Second, from the standpoint of ordinary meaning, one would not expect the word "inhibiting" to exclude partly successful prevention.[3] If the examiner truly believed that the specification did not enable partly successful prevention of osteoporosis, he should not have allowed the claim for inhibiting osteoporosis. Lastly, the applicant's October 14, 2009 statements clearly express the understanding that "inhibiting" encompasses prevention. The record does not support finding a clear and unmistakable disavowal of claim scope.

Defendants next argue that the specification only uses "inhibiting" in regard to a condition that already exists – not a condition that might exist in the future. This argument, even if true, gains Defendants little ground. There can be no dispute that the specification refers at numerous points to both the prevention and treatment of disorders. (See, e.g., '634 patent col.1 ll.18-19, col.1 ll.20-21, col.2 ll.43-44, col.2 ll.54-55, col.3 l.8.) Furthermore, the specification generally uses "inhibit" in connection with the Mühlbauer reference. (See, e.g., '634 patent col.2 ll.21-24.) The Mühlbauer article describes a study in which 300 bisphosphonate compounds were screened on rats. (JA 2973-81.) There is no suggestion in the reference that the rats already had osteoporosis, or any disease, at the start of the experiments. This does not support the assertion that the applicant understood "inhibit" to refer only to conditions that already existed.

[3] Consider, for example, that thesaurus.com lists "prevent" as a synonym of "inhibit." (http://thesaurus.com/browse/inhibit).

Moreover, Defendants fail to support their argument about the specification with any citations to any patent law. Defendants appear to argue that the applicant acted as his own lexicographer and gave "inhibit" a special meaning in the specification. On this subject, the Federal Circuit has stated:

> Generally speaking, we indulge a 'heavy presumption' that a claim term carries its ordinary and customary meaning. . . An accused infringer may overcome this 'heavy presumption' and narrow a claim term's ordinary meaning, but he cannot do so simply by pointing to the preferred embodiment or other structures or steps disclosed in the specification or prosecution history. . . Rather, as shown by our precedents, a court may constrict the ordinary meaning of a claim term in at least one of four ways. First, the claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer and clearly set forth a definition of the disputed claim term in either the specification or prosecution history.

Ccs Fitness v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). Defendants have not asserted, no less shown, that the patentee acted as his own lexicographer and clearly set forth a definition of "inhibiting" in either the specification or prosecution history. They have failed, then, to overcome the heavy presumption that "inhibiting" carries its ordinary meaning, which would encompass preventing.

Defendants next argue that Roche's construction of "inhibiting" is "nonsensical given the remainder of the claim language." (Defs.' Opening Br. 15.) Defendants contend that the prevention interpretation is inconsistent with the claim language that refers to women in need of treatment or inhibition of PMO. Defendants then contend that such a construction renders the language of claim 1 redundant. These are two different points.

As to the internal inconsistency argument, Defendants fail to explain what the inconsistency is, and it is not apparent to this Court. As to the redundancy argument, the problem is that Defendants cite no legal authority for the proposition that the wording of a claim

should be void of redundancy. Claim language is designed for precision, not economy of word count. Neither argument has any merit.

Defendants next point to the recognition in the art of the distinction between prevention and treatment – an inconsequential reminder of the obvious. Defendants conclude this section by contending that the specification does not describe the invention now asserted by Roche – again, a surprising point to repeat, given the frequency with which the specification refers to the use of the pharmaceutical compositions for the prevention of certain disorders.

Defendants also contend that the phrase "in need of treatment or inhibition" requires that the postmenopausal woman has been diagnosed with PMO. Defendants do not make any specific arguments on this point, and it appears to be corollary to the prevention question just discussed. This Court has found no basis to exclude prevention from the scope of claim 1.

Roche contends that inhibiting encompasses preventing, and that claim 1 does not require a prior diagnosis of PMO. Roche points to the dictionary definition of "inhibit," which, as already discussed, expressly includes preventing.[4] (See, e.g., Merriam-Webster's Medical Desk Dictionary (2005), Harris Dec. Ex. J at 397.) As explained above, Federal Circuit law accords a heavy presumption that claim terms carry their ordinary and customary meaning. In view of that presumption, and because Defendants have failed to overcome it, this Court construes

[4] Because neither party has persuaded the Court that the intrinsic evidence defines the term "inhibiting," and because neither party has asserted that "inhibiting" has a special technical meaning that differs from its ordinary meaning, it is proper under Phillips to consider a dictionary definition. Atofina v. Great Lakes Chem. Corp., 441 F.3d 991, 996 (Fed. Cir. 2006) ("Because there is no suggestion that the intrinsic evidence defines the term [], one may look to technical dictionaries for assistance in determining that term's meaning to a person of ordinary skill in the art.")

"inhibiting" and "inhibition" in claim 1 as encompassing prevention. For similar reasons, Defendants have failed to persuade this Court that claim 1 requires a prior diagnosis of PMO.[5]

B. Construction of "commencing the administration" and "continuing the administration"

The parties' briefing on the dispute over construction of "commencing the administration" and "continuing the administration" is quite confusing. Roche contends that the primary issue in dispute is whether the frame of reference for these terms is the administration episode, or the patient's lifetime. (Pl.'s Opening Br. 12.) Defendants respond that Roche is wrong, and that this issue is "irrelevant." (Defs.' Resp. Br. 22.)

Defendants contend, instead, that the crux of the dispute is the issue of whether "a patient who commences administration with a first dose of Boniva and later switches to a generic ibandronate product does not infringe the claim, because the patient did not commence administration with a first dose of the generic product." (Defs.' Opening Br. 20.) Roche responds that there is no dispute over that point. (Pl.'s Resp. Br. 8.) With the parties unable to agree on what is at issue, there is no way for this Court to usefully penetrate the confusion.

Furthermore, the Court notes that it finds Defendants' position perplexing, for two reasons. First, the Court asks how this question about infringement is an issue for claim construction. Second, the implied interpretation of the claim is baffling: where does the claim say anything about a generic product or a branded product? Claim construction is about interpreting claim language. Defendants have proposed no theory of interpretation of claim language that would provide a basis for importing into the claim requirements about the generic

[5] This Court agrees with Roche that, with their proposed diagnosis requirement, Defendants seek to add an extraneous limitation to claim 1 for which there is no basis.

or branded nature of the ibandronate.

Equally baffling is the fact that Defendants contend on page 20 of their opening brief that Roche's reliance on the 2010 Opinion is "irrelevant," because of the differences between the '634 patent and the '957 and '938 patents, but then itself relies on the 2010 Opinion on the following page. One cannot argue in one breath that the previous Opinion is irrelevant because the patents are so different, and then make an argument in the next breath that relies on the previous Opinion. Furthermore, Defendants in passing raise the matter of the Schofield reference, but fail to articulate a coherent argument about it – there is no foundation and no explanation about what impact the Schofield reference should have on interpretation of the claim language presently at issue.

At oral argument, the Court questioned the parties to attempt to ascertain the exact claim construction dispute. After much colloquy, the parties stated their agreement on the meaning of the claim language, agreeing that "commencing the administration" and "continuing the administration" have their ordinary meanings within the frame of reference of a course of treatment. (10/24/11 Hrg. Tr. 18:19-19:4.)

Thus, in regard to the interpretation of "commencing the administration" and "continuing the administration," these claim terms carry their ordinary meanings within the frame of reference of a course of treatment.

C. Construction of "once monthly"

Both claims 1 and 5 include the language "administering [], once monthly on a single day, a tablet . . ." There is agreement here that "monthly" refers to a period, an interval of time. This Court is again at a loss, however, to discern in the briefs a specific dispute over the meaning

of "once monthly" that is amenable to resolution through claim construction.

The parties agree on the meaning of "month," which is defined as follows in the specification: "As used herein, the term 'month' is used in accordance with the generally accepted meaning as a measure of time amounting to approximately four (4) weeks, approximately 30 days, or approximately 1/12 of a calendar year." '634 patent col.3 ll.57-61. The question is, given the agreement that "monthly" refers to a period of a month, and that the patent defines what the patentee meant by "month," what exactly is the dispute?

The parties' Joint Claim Construction and Prehearing Statement does not shed light on this question. The Statement says that Defendants take the position that something that occurs once monthly "repeats at an interval of once approximately every 30 days." (Jt. Stmt. 8.) The Statement says that Roche takes the position that "once monthly" means "once during a calendar month." This Court does not discern the material difference between the parties' positions. Nor do the parties' briefs articulate the difference. Defendants' brief even offers a chart in an attempt to illustrate the difference – but the difference is still unclear. Nor does either side explain what the practical implications of this alleged difference in interpretation might be.[6]

In its responsive brief, Roche states:

> At p. 28 of its opening brief, Roche stated that it does not understand what defendants disagree with here. This is particularly evident from the briefing on "once-monthly." If there is still a dispute, Roche cannot tell what it is.

(Pl.'s Resp. Br. 2.) This Court wholeheartedly agrees, and does not discern here a dispute over

[6] The only hint of a practical significance comes in a brief footnote in Defendants' responsive brief. (Defs.' Resp. Br. 26 n.16.) Defendants suggest that what might truly be at issue is whether the claim language covers patients who miss a dose and may take a next dose at an interval that may not be approximately 30 days long. If this is the issue, then both parties need to focus on it and brief it more fully. One short footnote is not sufficient.

the meaning of "once monthly" that is amenable to resolution through claim construction.

At oral argument, the Court questioned the parties to attempt to ascertain the exact claim construction dispute. On this issue, it quickly became clear that there was no dispute over claim construction because the parties agreed that "'once monthly' means approximately at one-month intervals commencing with the first date on which the ibandronate is administered." (10/24/11 Hrg. Tr. 21:5-23.)

CONCLUSION

This Court has examined the disputes over claim construction raised by the parties. In claims 1 and 5, the phrase "treating or inhibiting postmenopausal osteoporosis in a postmenopausal woman in need of treatment or inhibition of postmenopausal osteoporosis" encompasses the prevention of postmenopausal osteoporosis in a woman who does not have that condition. The parties have agreed that the terms "commencing the administration" and "continuing the administration" carry their ordinary meanings within the frame of reference of a course of treatment. The phrase "once monthly" means approximately at one-month intervals commencing with the first date on which the ibandronate is administered.

SO ORDERED.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: November 3, 2011