IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	C.A. No. 08-627-LPS, C.A. No. 11-81-LPS
WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., Plaintiffs, v. APOTEX, INC. and APOTEX CORP., Defendants.	C.A. No. 09-143-LPS, C.A. No. 10-1111-LPS (consolidated with C.A. No. 08-627-LPS)
WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	C.A. No. 10-285-LPS, C.A. No. 11-286-UNA (consolidated with C.A. No. 08-627-LPS)
THE PROCTER & GAMBLE COMPANY and HOFFMANN-LA ROCHE INC., Plaintiffs, v. SUN PHARMA GLOBAL, INC., Defendant.	C.A. No. 09-61-LPS, C.A. No. 10-1085-LPS (consolidated with C.A. No. 08-627-LPS) **PUBLIC VERSION**

DEFENDANTS' REPLY BRIEF IN SUPPORT OF MOTION FOR SUMMARY JUDGMENT OF INVALIDITY UNDER 35 U.S.C. § 112 FOR INADEQUATE WRITTEN DESCRIPTION AND FAILURE TO ENABLE THE FULL SCOPE OF THE CLAIMS

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Defendants Apotex Inc. and Apotex Corp.; Mylan Pharmaceuticals, Inc.; Sun Pharma Global FZE; and Teva Pharmaceuticals USA, Inc., jointly submit this reply in further support of their motion for summary judgment of invalidity under 35 U.S.C. § 112. All asserted claims of U.S. Patent No. 7,718,634 ("the '634 patent") (D-APP0000017) and U.S. Patent No. 7,192,938 ("the '938 patent") (D-APP0000010) are invalid for failure to include in the application a written description of the subsequently claimed method as excluding the possibility of a loading dose. Also, the asserted claims of the '938 patent are invalid under § 112 for failure to enable the full scope of the claims including use of the method in non-human "subjects."

I. The Patents In Suit Describe Neither A Two-Step Method Nor A Closed Or Partially Closed Method Excluding Other Steps.

It is undisputed that the specification of the '938 and '634 patents provides ***no*** support for a method that excludes the possibility a loading dose. Plaintiffs ***do not contend*** that the specification supports that limitation, but instead now argue that the claims do not have any negative limitation. Plaintiffs, however, ignore Claim 10 of the '634 patent, whose partially closed transitional phrase "consisting essentially of" is ***expressly*** a negative limitation because it ***excludes*** other steps affecting the "basic and novel" properties of the claimed invention — which the plaintiffs say means "without a loading dose," an exclusion the specification never describes. Plaintiffs are also incorrect as a matter of law that affirmative language, such as the "commencing . . . and continuing" claim structure here, cannot express a negative limitation. Moreover, the specification never describes the two-step method plaintiffs later added to the claims in response to a prior art rejection. The claims are therefore invalid for lack of sufficient written description.

A. The Specification Does Not Describe A "Consisting Essentially Of" Method.

Plaintiffs do not dispute that their specification never describes the "consisting essentially of" method recited in Claim 10 of the '634 patent. In fact, they never address that claim at all.

The parties agree that the transitional phrase "consisting essentially of" is a term of art in patent law, as described in the Manual of Patent Examining Procedure ("MPEP").

> The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. . . . If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964). See also *Ex parte Hoffman*, 12 USPQ2d 1061, 1063-64 (Bd. Pat. App. & Inter. 1989) ("Although 'consisting essentially of' is typically used and defined in the context of compositions of matter, we find nothing intrinsically wrong with the use of such language as a modifier of method steps. . . [rendering] the claim open only for the inclusion of steps which do not materially affect the basic and novel characteristics of the claimed method. To determine the steps included versus **excluded** the claim must be read in light of the specification. . . . [I]t is an applicant's burden to establish that a step practiced in a prior art method is excluded from his claims by 'consisting essentially of' language.").

MPEP 2111.03 (boldface added, underlining in original) (D-APP0000286–87).

Thus, it cannot be disputed that the sole purpose of the transitional phrase "consisting essentially of" here is to exclude some other steps from a method. It is also undisputed that here the applicants told the United States Patent and Trademark Office ("USPTO") that the transitional phrase "consisting essentially of" excluded the step of administering a loading dose from the claimed method. That makes Claim 10 of the '634 patent invalid, because the specification does not describe excluding a loading dose. It never describes any other steps as being in any way inconsistent with the method described in the specification. It does not mention a loading dose, much less describe one as being excluded.

Instead, a person of ordinary skill in the art reading the specification would be led to believe that it would not matter whether one did or did not combine additional steps, regimens, or treatments with the monthly dosing described. The specification indicates that the method described can be used equally well either alone or in combination with other bone active drugs:

> The bisphosphonates and pharmaceutically acceptable salts may be administered alone or in combination with other bone active drugs, either in fixed combinations or separately both physically and in time, including hormones, such as a steroid hormone, *e.g.*, an estrogen; a partial estrogen agonist, or estrogen-gestagen combination; a calcitonin or analogue or derivative thereof, *e.g.*, salmon, eel or human calcitonin parathyroid hormone or analogues thereof, *e.g.*, PTH (1-84), PTH (1-34), PTH(1-36), PTH (1-38), PTH (1-31)NH2 or PPTS 893; a SERM (Selective Estrogen Receptor Modulator), *e.g.*, raloxifene, lasofoxifene, TSE-434, FC1271, tibolone, vitamin D or an analog. Such additional bone active drugs may be administered more frequently than the bisphosphonate.

(D-APP0000022, the '634 patent, col.5, ℓℓ.35–48.) Nothing in the patent tells one of ordinary skill in the art that including a loading dose step would materially affect the basic and novel properties of the claimed method (or what those properties are) and that a loading dose is therefore excluded by the "consisting essentially of" language (which is what plaintiffs now argue).

This description stands in contrast to other patent specifications that would support a "consisting essentially of" transitional phrase. For example, the MPEP describes the specification in *AK Steel Corp. v. Sollac*, 344 F.3d 1234, 1240–41 (Fed. Cir. 2003) as follows:

> Applicant's statement in the specification that "silicon contents in the coating metal should not exceed about 0.5% by weight" along with a discussion of the deleterious effects of silicon provided basis to conclude that silicon in excess of 0.5% by weight would materially alter the basic and novel properties of the invention. Thus, "consisting essentially of" as recited in the preamble was interpreted to permit no more than 0.5% by weight of silicon in the aluminum coating.

(MPEP 2111.03, D-APP0000285); *see also*, *AK Steel*, 344 F.3d at 1240–41. Nothing in the specification of these patents similarly describes the exclusion of any other steps or regimens such as a loading dose. Accordingly, if Claim 10 means that a loading dose is excluded (which is what applicants told the USPTO), then it is invalid for lack of written description.

B. Using Affirmative Language Like A Two-Step Method To Impose A Negative Limitation In A Claim Does Not Obviate The Written Description Requirement.

Plaintiffs argue that the two-step method recited with "commencing . . . and continuing" language in Claim 9 of the '634 patent and Claims 1–15 of the '938 patent is not a negative limitation. In so doing, plaintiffs merely assert, without citing any authority, that affirmative language, such as the recital of a two-step method, cannot impose a negative limitation. They ***do not dispute*** that the specification contains ***no*** support for excluding other steps or regimens, and, in particular, contains no support for claims drafted to exclude the possibility of a loading dose — which is what the applicants told the USPTO these claims do. Plaintiffs' argument that affirmative language cannot impose a negative limitation is wrong as a matter of law, and the claims are invalid because the applications did not describe the exclusion of any other step or regimen such as a loading dose as forming any part of what was allegedly invented.

Plaintiffs argue that the claims "do not contain negative limitations" merely because "*no negative or exclusionary language is employed*" (D.I. 316 at 7), but inconsistently argue a few pages later that the claims clearly mean "without a loading dose." (D.I. 316 at 10.) It is well established, however, that one need not employ explicit "negative or exclusionary language" to impose a negative limitation. The law looks to the substance of what is claimed, not "the mere form of language." *See In re Schechter*, 205 F.2d 185, 188 (CCPA 1953). The Court explained:

> Although the italicised portion of claim 47 is affirmative in form, it is clearly a negative limitation in substance. In determining whether part of a claim is a negative limitation of the type which renders a claim fatally indefinite, **we must look to the substance and not the mere form of the language in which the claim is cast**. A limitation though affirmative in form may be negative in substance, and vice versa.

Id. (emphasis added). Although the issue in the case at bar is written description support under § 112 and not indefiniteness, the claim construction point about negative limitations is the same. If these claims ***mean*** "without a loading dose," which is what plaintiffs still contend, then in

order to satisfy § 112 the application as filed had to have ***described*** the invention as being a treatment excluding a loading dose. It did not.

The prior art Schofield reference had disclosed a method of treating postmenopausal osteoporosis that included monthly oral administration of risedronate. It disclosed monthly oral administration of risedronate as a "maintenance dose," along with other maintenance dose regimens that included daily and weekly dosing in amounts known to be safe and effective for treating osteoporosis without a loading dose. (D-APP0000221 ¶ [0037]) Schofield also taught adding a loading dose to maintenance doses to achieve results at "a faster rate" than the maintenance doses alone. (D-APP0000219 ¶ [0007].) If what applicants thought they invented was the elimination of that loading dose (i.e., if they thought they had invented monthly dosing "without a loading dose" as now asserted), then they were required to ***describe*** their invention in the patent application as being monthly dosing ***without a loading dose***. They did not.

The requirement to describe negative limitations such as "without a loading dose" does not force patentees to "describe not just what the invention is, but also what it is not," as plaintiffs argue. (D.I. 316 at 12.) Here, the exclusion of a loading dose is not "what [the invention] is not." It is a requirement from the claims, which ***define*** the alleged invention. Applicants amended the claims specifically in order to exclude the possibility of a loading dose, as disclosed in Schofield. (D-APP0000055–63.) They did so in response to a USPTO rejection over that reference. (D-APP0000047–54.) If it did not matter to applicants when they filed their application whether the disclosed method steps followed a loading dose, if that loading dose concept was irrelevant to what they regarded as their alleged invention, then they were not entitled based on that disclosure to make amendments later that claimed as their invention a method that ***excluded*** that step. If, as the attorney who drafted these claims testified, "the claims by their

terms ***exclude*** the loading dose of Schofield" (D-APP0000195, emphasis added), then § 112 required the application to describe that part of what is now claimed ***when they filed the application***. Because plaintiffs admit that no loading dose was "even contemplated" (D.I. 316 at 13) at the time of filing, their application did not support claims which exclude that possibility.

C. The Specification Does Not Describe Any Two-Step Method.

Plaintiffs admit that the specification does not mention "commencing," does not mention "continuing," and does not describe the invention as being a two-step method. (D.I. 316. at 13-14) They also argue that the claims mean the method is done without a loading dose and that the two steps of commencing and continuing were added "to emphasize the distinction from the prior method of Schofield." That very distinction, however, (i.e., excluding the possibility of a loading dose) was never described in the application.

Plaintiffs' argument is essentially that even though they amended their claims in prosecution, added this new language, and did so in response to a rejection over prior art, the language really does not mean anything. If the language is not limiting, then it would not have been responsive to the rejection over Schofield. Plaintiffs cannot now argue that this claim structure that they adopted in order to obtain allowance of their patent really does not mean anything. *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 –51 (Fed. Cir. 2006) ("Allowing a patentee to argue that physical structures and characteristics specifically described in a claim are merely superfluous would render the scope of the patent ambiguous, leaving examiners and the public to guess about which claim language the drafter deems necessary to his claimed invention and which language is merely superfluous, nonlimiting elaboration. For that reason, claims are interpreted with an eye toward giving effect to all terms in the claim.").

Plaintiffs try to support their argument by pointing to the Court's comment that, with the amendments excluding a loading dose, "the substance of the claimed methods was not changed." (D.I. 289 at 8.) It is unreasonable, however, to construe that comment as indicating that the amendment was meaningless. The Court had just interpreted that language as limiting the method to "[w]ithin the timeframe of a treatment episode, beginning a regimen of taking a particular bisphosphonic acid or a pharmaceutically acceptable salt thereof." (D.I. 289 at 8.) The Court also said this was done "to avoid reading on Schofield." (*Id.*) The comment that "the substance of the claimed methods was not changed" must have meant that the method still related to monthly dosing generally, not that the amendment imposed no additional limitation in response to the rejection over Schofield. That additional limitation (i.e., without a loading dose) is what the specification never described — as the Court also suggested in its claim construction order when it noted that the "remainder of the specification" did nothing to aid the construction of this language that was added later. (D.I. 289 at 8.) The absence of any written description for that additional limitation is the reason the claims are invalid.

All the asserted claims are therefore invalid for failure to comply with § 112 because there is no written description in the specification of their alleged invention as somehow ***excluding*** other steps such as the loading dose of Schofield.

II. The '938 Patent Specification Does Not Enable The Full Scope Of The Claims, Which The Court Has Construed To Include Non-Human Animal Subjects.

Plaintiffs ***do not dispute*** that the '938 patent does not include an enabling disclosure for all the non-human subjects that would fall within the scope of the claims as already construed by the Court. Instead, plaintiffs continue to argue that the claims cannot read on any non-human subject, relying on the declarations of Dr. Bilezikian. The Court already addressed the question of whether "subject" encompasses non-human animals in its Memorandum Opinion on claim

construction and rejected plaintiffs' argument that it applies only to humans and not other animals. The Court based this ruling on the claim language, the specification (which referred to "a mammal"), the prior art of record, expert opinions, and the plain meaning of the word "subject" in a medical dictionary. (D-APP0000210–11.) Plaintiffs' position is nothing more than an effort to reargue claim construction, a question of law that cannot raise a genuine issue of material fact to preclude summary judgment. The fact that the Court has already decided this question is reason enough to reject the argument on that basis alone, but there are also other reasons it fails. Plaintiffs' witness Dr. Bilezikian is not qualified to provide expert opinions about osteoporosis in animals, and even if he were qualified, his conclusory disagreement with express disclosures in the prior art fails to raise a genuine issue of material fact.

Plaintiffs' expert, Dr. Bilezikian, is not qualified to give expert opinions on animal uses of bisphosphonates to treat osteoporosis or lack thereof. He is not a veterinarian. (D-APP0000296.) Although he performed some animal research at NIH in the seventies, that research concerned endocrinology and cell signaling, not osteoporosis. (D-APP0000293.) Dr. Bilezikian was unaware of the published research on osteoporosis in animals and using bisphosphonates to treat animals. He was also unaware of Tildren, a bisphosphonate product for veterinary uses, specifically in horses, that is commercially available in Europe. (D-APP0000302–303.) When asked whether he had considered the literature on animal uses of bisphosphonates, he responded "I'm glad I didn't." (*Id.*)

Only a "witness who is qualified as an expert by knowledge, skill, experience, training, or education" may testify in the form of expert opinions. FED. R. EVID. 702. Regardless of whether Dr. Bilezikian is qualified to testify about the treatment of osteoporosis in humans, he has no basis to testify about veterinary uses. His opinion was not based on his knowledge of

bisphosphonates, but on his lack of knowledge of their veterinary applications. Dr. Bilezikian's lack of relevant experience, and failure to consider the material available renders him unqualified to opine as an expert under FED. R. EVID. 702. His declaration on that point therefore does not raise a genuine issue of material fact.

Dr. Yates, in contrast to Dr. Bilezikian, was very familiar with the use of bisphosphonates in animals. He based his opinions that horses get osteoporosis on his "review of the literature" and his "personal experience in discussing the potential benefit of bisphosphonates in treating horses with veterinary experts from Merck & Company." (D-APP0000310.) Those are proper bases for Dr. Yates to testify in the form of an opinion based on his "knowledge, skill, experience, training, or education," FED. R. EVID. 402. As one example, Dr. Yates is aware that stall immobilization which may occur when treating lameness can lead to immobilization osteoporosis in horses (D-APP0000310–11.), the treatment of which is within the scope of the '938 patent claims (D-APP0000013, the '938 patent, col.3, ℓ.49, listing "immobilization associated osteoporosis"), but which the '938 patent does not enable for horses at the recited doses.

Moreover, even Dr. Bilezikian admits that animals ***can*** have osteoporosis at least in that they can be made osteoporotic. "You can make animals osteoporotic." (D-APP000298.) Immobilization, for example, can induce osteoporosis, and Dr. Bilezikian admits that the dosages recited in the patent do not enable treating osteoporosis such as immobilization osteoporosis in subjects such as horses at the dose range recited.

> A. I think the sense of the, the sense of the patent and certainly when you read the dosing, if there were a horse who had developed immobilization osteoporosis I think **the dose of 100 to 150 milligrams would not be quite enough.**
> Q. Okay. So you would expect that that dosage would not be operable to a horse, would not work for a horse?
> A. For a 1500-pound horse, I don't think so.

(D-APP0000298, objections omitted.)

Dr. Bilezikian argues that osteoporosis in animals does not occur "naturally." That statement is not only beyond the scope of his expertise, but it is also irrelevant here. Nothing in the claims of the '938 patent limits the claims to "naturally occurring" osteoporosis, or any particular form of osteoporosis. The '634 patent claims are limited to "postmenopausal osteoporosis" and "postmenopausal women," but the '938 patent claims are not. Plaintiffs did not argue for a claim construction of osteoporosis that limits it to "naturally occurring." Dr. Bilezikain admits that immobilization osteoporosis is one form of osteoporosis. (D-APP0000292–93.) It occurs in people, and it occurs in animal subjects, too. The claims of the '938 patent are thus not enabled for their full scope.

Moreover, it is well established that "conclusory expert assertions do not give rise to a genuine issue of material fact." *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, 665 F.3d 1269, 1290 (Fed. Cir. 2012); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571 (Fed. Cir. 1997) (affirming summary judgment of obviousness because statements of patentee's expert were conclusory and thus failed to raise a genuine issue of material fact). Even if Dr. Bilezikian were competent to opine on veterinary uses (and he is not), all that he provides is a conclusory assertion. That is not enough to avoid summary judgment. Plaintiffs have failed to raise a genuine issue of material fact, and defendants are entitled to summary judgment that the asserted claims of the '938 patent are invalid under 35 U.S.C. § 112 for failure to enable their full scope.

CONCLUSION

Accordingly, defendants respectfully request entry of summary judgment that all asserted claims of the '938 and '634 patents are invalid under § 112 for lack of sufficient written description, and that the asserted claims of the '938 patent are invalid under § 112 for failure to enable their full scope.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

CERTIFICATE OF SERVICE

I, David E. Moore, hereby certify that on June 14, 2012, the attached document was electronically filed with the Clerk of the Court using CM/ECF which will send notification to the registered attorney(s) of record that the document has been filed and is available for viewing and downloading.

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