NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

HOFFMANN-LA ROCHE INC. et al., Plaintiffs, 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**
HOFFMANN-LA ROCHE INC. et al., Plaintiffs, 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. et al., Plaintiffs, 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. et al., Plaintiffs, 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. et al., Plaintiffs, v. MYLAN INC., MYLAN PHARMACEUTICALS INC., GENPHARM ULC 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 its own motion for summary judgment, pursuant to Federal Rule of Civil Procedure 56(f). 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

ULC and Genpharm, L.P. (collectively, "Defendants") have asserted, as an affirmative defense to a claim of patent infringement, that claims 1-10 of U.S Patent No. 7,410,957 (the "'957 patent) are invalid based on obviousness. For the reasons stated below, summary judgment will be granted in Defendants' favor.

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, Plaintiff Hoffman-La Roche Inc. ("Roche") owns the '957 patent, which is directed to 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.

APPLICABLE LEGAL STANDARDS

I. Summary Judgment

Summary judgment is appropriate under FED. R. CIV. P. 56(a) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. Celotex Corp. v. Catrett, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all

justifiable inferences are to be drawn in his favor.'" Marino v. Indus. Crating Co., 358 F.3d 241, 247 (3d Cir. 2004) (quoting Anderson, 477 U.S. at 255).

"When the moving party has the burden of proof at trial, that party must show affirmatively the absence of a genuine issue of material fact: it must show that, on all the essential elements of its case on which it bears the burden of proof at trial, no reasonable jury could find for the non-moving party." In re Bressman, 327 F.3d 229, 238 (3d Cir. 2003) (quoting United States v. Four Parcels of Real Property, 941 F.2d 1428, 1438 (11th Cir. 1991)). "[W]ith respect to an issue on which the nonmoving party bears the burden of proof . . . the burden on the moving party may be discharged by 'showing' – that is, pointing out to the district court – that there is an absence of evidence to support the nonmoving party's case." Celotex, 477 U.S. at 325.

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. Jersey Cent. Power & Light Co. v. Lacey Township, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. Anderson, 477 U.S. at 248; Siegel Transfer, Inc. v. Carrier Express, Inc., 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment." Schoch v. First Fid. Bancorporation, 912 F.2d 654, 657 (3d Cir. 1990). "A nonmoving party has created a genuine issue of material fact if it has provided sufficient evidence to allow a jury to find in its favor at trial." Gleason v. Norwest Mortg., Inc., 243 F.3d 130, 138 (3d Cir. 2001).

If the nonmoving party has failed "to make a showing sufficient to establish the existence

of an element essential to that party's case, and on which that party will bear the burden of proof at trial, . . . there can be 'no genuine issue of material fact,' since a complete failure of proof concerning an essential element of the nonmoving party's case necessarily renders all other facts immaterial." Katz v. Aetna Cas. & Sur. Co., 972 F.2d 53, 55 (3d Cir. 1992) (quoting Celotex, 477 U.S. at 322-23).

II. Patent invalidity due to obviousness

"A patent is presumed to be valid, 35 U.S.C. § 282, and this presumption can only be overcome by clear and convincing evidence to the contrary." Bristol-Myers Squibb Co. v. Ben Venue Labs., 246 F.3d 1368, 1374 (Fed. Cir. 2001) (citations omitted). The party asserting invalidity bears the burden of establishing it. 35 U.S.C. § 282. "This burden is especially difficult when . . . the infringer attempts to rely on prior art that was before the patent examiner during prosecution." Glaxo Group Ltd. v. Apotex, Inc., 376 F.3d 1339, 1348 (Fed. Cir. 2004) (quotation omitted).

To patent an invention, the subject matter must be non-obvious:

> A patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103(a).

The Federal Circuit has set forth these basic principles to guide the determination of obviousness:

> Obviousness is ultimately a question of law, based on underlying factual determinations. The factual determinations that form the basis of the legal conclusion of obviousness include (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed

invention and the prior art; and (4) evidence of secondary factors, known as objective indicia of non-obviousness.

Altana Pharma AG v. Teva Pharms. USA, Inc., 566 F.3d 999, 1007 (Fed. Cir. 2009) (citations omitted).

ANALYSIS

I. The Court's motion for summary judgment

The '957 patent contains 20 claims. Only claims 1-10 are at issue in the instant litigation, as they are directed to treatment methods involving the active ingredient in Boniva®.

Claims 1-10 are:

1. A method for treating osteoporosis comprising commencing treatment by orally administering to a subject in need of such treatment, on a single day, a first dose in the form of a tablet, wherein said tablet comprises an amount of a pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid and continuing said treatment by orally administering, once monthly on a single day, a tablet comprising an amount of a pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid.

2. The method of claim 1, wherein the pharmaceutically acceptable salt is a sodium salt of ibandronic acid.

3. The method of claim 2 wherein the pharmaceutically acceptable salt is a monosodium, disodium, or trisodium salt of ibandronic acid.

4. The method of claim 3 wherein the pharmaceutically acceptable salt is a monosodium salt of ibandronic acid.

5. The method of claim 4 wherein the pharmaceutically acceptable monosodium salt of ibandronic acid is a monohydrate.

6. A method for treating osteoporosis consisting of orally administering to a subject in need of such treatment, once monthly on a single day, a tablet comprising an amount of a pharmaceutically acceptable salt of ibandronic acid that is equivalent to about 150 mg of ibandronic acid.

7. The method of claim 6, wherein the pharmaceutically acceptable salt is a sodium salt of ibandronic acid.

8. The method of claim 7 wherein the pharmaceutically acceptable salt is a monosodium, disodium, or trisodium salt of ibandronic acid.

9. The method of claim 8 wherein the pharmaceutically acceptable salt is a monosodium salt of ibandronic acid.

10. The method of claim 9 wherein the pharmaceutically acceptable monosodium salt of ibandronic acid is a monohydrate.

On May 7, 2012, this Court entered an Opinion (the "'634 Opinion") and Order granting Defendants' motion for summary judgment on the affirmative defense to infringement that claims 1-8 of the '634 patent are invalid as obvious. Recognizing the many similarities between the '634 patent and the '957 patent, the Court Ordered the parties to brief the question of "whether the Court's rationale for granting summary judgment of invalidity in the '634 patent actions should be applied to the asserted claims in the '957 patent." (Roche's Opening '957 Br. 4.) Thus, as Roche correctly states, the question presently before this Court is "[w]hether the Court should enter summary judgment of invalidity of claims 1-10 of the '957 patent for obviousnessness under 35 U.S.C. § 103 based on the specific findings of material facts and rationale that the Court entered with respect to the '634 patent." (Id. at 3.)

Roche's brief in response to this Order is largely an argument for reconsideration of the '634 Opinion. Roche's main point is that this Court erred in its conclusions about the issues of anti-fracture efficacy. For Roche's anti-fracture argument to succeed at this juncture, Roche needs to persuade this Court that, because of a difference between the '634 patent and the '957 patent: 1) this Court's analysis and decision regarding anti-fracture efficacy in the context of the '634 patent is inapplicable to the question of invalidity for obviousness of claims 1-10 of the

’957 patent; and 2) factual questions about anti-fracture efficacy have a material impact on the obviousness analysis for the ’957 patent. Roche has not persuaded this Court on either point.

As to the first issue, Roche points only to one difference between the two patents, a difference in claim scope: claim 1 of the ’634 patent claims “a method for treating or inhibiting” osteoporosis, whereas claim 1 of the ’957 patent claims “a method for treating” osteoporosis. Roche contends that the determinations and rationale stated in the ’634 Opinion do not apply to the ’957 patent because of this difference in claim scope. Specifically, Roche argues that this Court erred in finding that anti-fracture efficacy was not material to the obviousness inquiry, but that, because this Court made that finding in regard to preventing osteoporosis, rather than treating osteoporosis, that analysis is inapplicable to the ’957 patent.

Roche’s argument of inapplicability fails because of its false premise: in the ’634 Opinion, this Court did not limit its inquiry to a method of preventing osteoporosis, holding that anti-fracture efficacy was irrelevant to the prevention inquiry. This is a gross misreading of the ’634 Opinion. To the contrary, the ’634 Opinion focused largely on the patented method for treating osteoporosis. The discussion section of the ’634 Opinion contains approximately 68 references to the treatment of osteoporosis. Because the ’634 Opinion focused on the aspects of the claims at issue in the ’634 patent that are directed to the treatment of osteoporosis, and because the claims at issue in the ’957 patent are directed to the treatment of osteoporosis by the same method, this Court rejects Roche’s argument that the findings and rationale stated in the ’634 Opinion should not be applied to the obviousness inquiry for the ’957 patent.

As to the second issue, Roche has failed to persuade this court that factual questions of anti-fracture efficacy have a material impact on the obviousness analysis for the ’957 patent. In

the ’634 Opinion, this Court held that anti-fracture efficacy, required for FDA approval, was irrelevant to the obviousness inquiry. This Court today reaffirms that position, but, even if it were relevant, Roche still has failed to raise a material factual dispute sufficient to defeat the entry of summary judgment.

Roche contends that it has pointed to evidence sufficient to raise a material factual dispute over whether a skilled artisan would have had a reasonable expectation of success in achieving fracture reduction efficacy with the patented method. The standard for the quantum of evidence required to raise a factual dispute is well-known: “The mere existence of a scintilla of evidence in support of the plaintiff's position will be insufficient; there must be evidence on which the jury could reasonably find for the plaintiff.” Anderson, 477 U.S. at 252. The evidence cited by Roche does not amount to a mere scintilla. For the largest part, Roche cites evidence that supports the proposition that bone mineral density is an imperfect predictor of anti-fracture efficacy. Such evidence is not sufficient to persuade a reasonable jury that a skilled artisan would not have had a reasonable expectation of success. Federal Circuit law on this matter is quite clear: “Obviousness does not require absolute predictability of success. . . . For obviousness under § 103, all that is required is a reasonable expectation of success.” In re O'Farrell, 853 F.2d 894, 903-904 (Fed. Cir. 1988). Roche’s evidence could raise a factual dispute over whether there was absolute predictability of success in achieving fracture reduction, but that is not the legal test.

Beyond the evidence regarding the ability of bone mineral density change to predict anti-fracture efficacy, Roche points to only one piece of evidence, the Recker study. In the ’634 Opinion, this Court stated:

> The report of Roche's own expert, Dr. Bilezekian, gives this assessment of the prior art as of May 10, 2002:
>
> > 120. Prior to May 10, 2002, the only antifracture data that was published for ibandronate (Recker) showed that ibandronate failed to reduce incidence of fracture. There was no published data on antifracture efficacy of any oral ibandronate regimen prior to May 10, 2002.
> >
> > 121. Published data for ibandronate prior to May 10, 2002 showed increases in bone mineral density (BMD) for both oral and IV administrations. See Ravn 1996, Thiebaud 1997, Recker 2000, and Riis 2001. However, the failed IV study by Recker taught that ibandronate was not as potent as had previously been thought. As I explained at my deposition, the thinking in the art was that the IV ibandronate study failed because (1) the dose was too low, or (2) the dose-free interval was too long, or (3) the drug ibandronate was not going to work at all.
>
> (Bilezekian Resp. Rpt.) Dr. Daifotis confirms Dr. Bilezekian's view of how the art viewed the results of the Recker study. (Daifotis Supp. Rpt. ¶ 155.) Dr. Daifotis concedes that the Recker study showed that intravenous ibandronate was effective in increasing bone mineral density. (Id.)

('634 Opinion at 15.) Thus, Roche's own expert stated that there was no published data on anti-fracture efficacy of any oral ibandronate regimen prior to the critical date. The only evidence is from the Recker study, which used intravenous administration. The Recker study alone is not sufficient evidence to persuade a reasonable jury that a skilled artisan would not have had a reasonable expectation of success in achieving fracture reduction. The Federal Circuit recently held:

> Evidence that others tried but failed to develop a claimed invention may carry significant weight in an obviousness inquiry. While absolute certainty is not necessary to establish a reasonable expectation of success, there can be little better evidence negating an expectation of success than actual reports of failure.

Eurand, Inc. v. Mylan Pharms., Inc. (In re Cyclobenzaprine Hydrochloride Extended-Release

Capsule Patent Litig.), 676 F.3d 1063, 1081 (Fed. Cir. 2012). The Recker study did not employ the same treatment method as the claimed invention, oral administration of ibandronate. Moreover, as discussed in the '634 Opinion, the evidence of record indicated that Recker found anti-fracture efficacy with intravenous ibandronate, but not at a level sufficient to achieve statistical significance. ('634 Opinion at 16 n.7.) For all these reasons, Recker does not rise to the level of a mere scintilla of evidence. Evidence that a similar, but substantially different, method achieved anti-fracture efficacy, but not at a statistically significant level, does not rise to the level of a mere scintilla of evidence that a skilled artisan would not have had a reasonable expectation of success in achieving anti-fracture efficacy with the patented method.

Furthermore, this Court has already made factual determinations sufficient to support finding claims 1-10 of the '957 patent invalid as obvious. In the '634 Opinion, this Court stated the following factual determination: "Prior to the critical date, May 10, 2002, it was well-known in the field that bisphosphonates, administered orally, were antiresorptive agents effective for the treatment of disorders of bone resorption such as osteoporosis, and that ibandronate was a powerful antiresorptive agent." ('634 Opinion at 43.) Because this Court determined that ibandronate was known to be a powerful antiresorptive agent, and antiresorptive agents were known to be effective for the treatment of osteoporosis, this determines a key factual question in the obviousness analysis for the '957 patent: would the skilled artisan, as of the critical date, had a reasonable expectation of success in using the '957 method to treat osteoporosis? Given the prior factual determination, there is no way this Court could conclude that there is any material factual dispute over this question. The '634 Opinion determined that the skilled artisan, as of the critical date, would have had a reasonable expectation of success in practicing the '957 patent, by

using the method of claim 1, which does not differ in any relevant and material way from the method disclosed in the claims at issue in the '634 patent, to treat osteoporosis.

Second, even if Roche could demonstrate that anti-fracture efficacy was an unexpected result, it would not change the outcome of the obviousness analysis for the '957 patent. It is well-settled that, while the obviousness decision relies on underlying factual determinations, the ultimate determination of obviousness is decided by the Court as a matter of law. In this case, this Court would not find proof of anti-fracture efficacy to be an objective indicator of nonobviousness deserving much weight. There are many reasons for this, but three of the best ones are: 1) the use of ibandronate to treat osteoporosis was known in the prior art; 2) the '957 patent, as a whole, treats anti-fracture efficacy as a characteristic that goes to the superiority of the patented method, rather than as fundamental to it; and 3) there has been no showing in this case that the prior art discouraged monthly oral administration of ibandronate for the treatment of osteoporosis because the art expected that it would not result in anti-fracture efficacy.[1]

Furthermore, surprise is a continuum. Roche has confused the scientific confirmation of a previously unestablished beneficial attribute with a truly surprising result. It may not have been empirically proven at the critical date that oral ibandronate had anti-fracture efficacy, but the quantum of surprise that a drug known to have a powerful effect on bone resorption, and known

[1] To the contrary, it is clear that, following the disclosures in Riis 2001, the skilled artisan would have had a reasonable expectation of success in using monthly administration of ibandronate to treat osteoporosis, as this Court concluded in the '634 Opinion. As discussed in the '634 Opinion, the findings of Riis 2001 changed the art: "Dr. Bauss thus clearly states that Riis 2001 was a breakthrough that led him to reject the idea that dosing must be biweekly or more frequently." ('634 Opinion at 19.) Before Riis 2001, it could conceivably have been surprising that monthly dosing with bisphosphonates would be effective for the treatment of osteoporosis, but not after.

to be effective as a treatment for osteoporosis, should be found to prevent fractures does not seem all that great – it just does not seem very surprising. It is not unexpected at the level of, for example, a finding that monthly oral ibandronate has absolutely zero gastrointestinal side effects, which might more reasonably be viewed as surprising and as an indicator that the 150 mg monthly oral dose was nonobvious. Rather, empirical confirmation that a method for increasing bone mineral density helps increase bone strength enough that bones break less easily would not appear to be all that surprising.

Moreover, Roche appears to be forgetting the place of unexpected results in the obviousness inquiry, as an objective indicator of nonobviousness. A key question is whether it would have been obvious to the skilled artisan to combine two pieces of prior art. As discussed in the '634 Opinion, treatment of osteoporosis via monthly oral administration of ibandronate was known in the prior art. The alleged inventive step was the determination of the 150 mg dose. The mere identification of some unexpected result does not suffice as persuasive objective evidence of the nonobviousness of the invention – there needs to be some logic that supports weighing the unexpected result as evidence of nonobviousness. In the present case, Roche has not articulated a persuasive explanation for how empirical confirmation of anti-fracture efficacy indicates that the choice of the 150 mg dosage was nonobvious. As this Court explained in the '634 Opinion:

> It is the answer to the question of what dosage to use that this Court holds would have been suggested by combining the prior art references of Ravn 1996 (daily oral ibandronate doses of 2.5 mg and 5 mg effectively treat osteoporosis) and Riis 2001 (the total dose concept), supported by Daifotis '932 (recommending weekly oral ibandronate doses of 35, 40, 45, and 50 mg).

('634 Opinion at 44.) Roche has not even attempted to explain how the empirical confirmation

of anti-fracture efficacy has any logical relationship to this analysis, or changes the outcome of it.

As discussed above, this Court also rejects Roche's argument that the difference in claim scope between the '634 patent and '957 patent – "a method for treating" versus "a method for treating or inhibiting" – somehow impacts the applicability of the determinations in the '634 Opinion to the '957 patent. In sum, this Court finds that Roche has failed to persuade that the determinations made in the '634 Opinion do not provide a sufficient basis for this Court to grant summary judgment of invalidity of claims 1-10 of the '957 patent due to obviousness. This Court finds that there are no material factual disputes that preclude the entry of judgment as a matter of law. Federal Rule of Civil Procedure 56(f) states:

> Judgment Independent of the Motion. After giving notice and a reasonable time to respond, the court may:
> (1) grant summary judgment for a nonmovant;
> (2) grant the motion on grounds not raised by a party; or
> (3) consider summary judgment on its own after identifying for the parties material facts that may not be genuinely in dispute.

Pursuant to Rule 56(f), this Court gave the parties notice that it was considering a grant of summary judgment, and the opportunity to respond. This Court has identified for the parties the material facts that are not genuinely in dispute and now grants summary judgment *sua sponte*. Judgment on Defendant's affirmative defense of invalidity due to obviousness to the claim of infringement of the '957 patent will be entered in favor of Defendants. Claims 1-10 of U.S Patent No. 7,410,957 are hereby declared invalid as obvious, pursuant to 35 U.S.C. § 103(a).

CONCLUSION

In summary, the factual determinations and legal reasoning stated in the '634 Opinion are applicable to the obviousness inquiry for claims 1-10 of U.S Patent No. 7,410,957. Thus, the

Court views the obviousness analysis for the ’957 patent as follows. Prior to the critical date, in May of 2002, it was well-known in the field that bisphosphonates, administered orally, were antiresorptive agents effective for the treatment of disorders of bone resorption such as osteoporosis, and that ibandronate was a powerful antiresorptive agent. It was also well-known that oral administration tended to produce adverse gastrointestinal effects, which led to problems with patient compliance, and that a general solution to these problems lay in intermittent dosing regimens. One particular solution, once-monthly oral administration of ibandronate, was placed into the public domain by the Lunar News Spring 1999 reference, as well as the Krause 2001 reference. The skilled artisan, seeking to implement that solution, would only have needed to figure out what dosage to use, and then would have had in possession the subject matter of claims 1-10.

It is the answer to the question of what dosage to use that this Court holds would have been suggested by combining the prior art references of Ravn 1996 (daily oral ibandronate doses of 2.5 mg and 5 mg effectively treat osteoporosis) and Riis 2001 (the total dose concept), supported by Daifotis ’932 (recommending weekly oral ibandronate doses of 35, 40, 45, and 50 mg). The differences between the subject matter which the applicants sought to patent in claims 1-10 of the ’957 patent and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. The differences appear quite small and amenable to being bridged by the application of common sense and ordinary skill.

The evidence of obviousness provided by the prior art analysis is so clear and convincing that the objective considerations evidence, largely the modest commercial success of Boniva®,

cannot overcome it.

For the reasons stated above, this Court finds that Defendants have met the requirements of Federal Rule of Civil Procedure 56(a) and have shown "that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Pursuant to Rule 56(f), this Court *sua sponte* grants summary judgment, and judgment on Defendant's affirmative defense of invalidity due to obviousness to the claim of infringement of the '957 patent is entered in favor of Defendants. Claims 1-10 of U.S Patent No. 7,410,957 are hereby declared invalid due to obviousness, pursuant to 35 U.S.C. § 103(a).

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

Dated: October 1, 2012