IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 08-627-LPS C.A. No. 11-81-LPS
TEVA PHARMACEUTICALS USA, INC.,	:	
Defendant.	:	

WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 09-143-LPS (consolidated with C.A. No. 08-627-LPS)
APOTEX, INC. and APOTEX CORP.,	:	
Defendants.	:	

WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC.,	:	
Plaintiffs,	:	
v.	:	C.A. No. 10-285-LPS (consolidated with C.A. No. 08-627-LPS)
MYLAN PHARMACEUTICALS, INC.,	:	
Defendant.	:	

WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC.,	:	
Plaintiffs,	:	

	:	C.A. No. 09-61-LPS
v.	:	(consolidated with C.A. No. 08-627-LPS)
	:	
SUN PHARMA GLOBAL FZE,	:	
	:	
Defendant.	:	

Frederick L. Cottrell, III, Steven J. Fineman, Jaclyn C. Levy, RICHARDS, LAYTON & FINGER, P.A., Wilmington, DE. David B. Bassett, WILMER CUTLER PICKERING HALE AND DORR LLP, New York, NY. Vinita Ferrera, Allen C. Nunnally, WILMER CUTLER PICKERING HALE AND DORR LLP, Boston, MA. Mark E. Waddell, LOEB & LOEB LLP, New York, NY.

Attorneys for Plaintiffs.

Karen L. Pascale, Pilar G. Kraman, YOUNG, CONWAY, STARGATT & TAYLOR LLP, Wilmington, DE. James Galbraith, Maria Luisa Palmese, Antony Pfeffer, Peter L. Giunta, KENYON & KENYON LLP, New York, NY.

Attorneys for Defendant Teva Pharmaceuticals USA, Inc.

Richard K. Herrmann, Mary B. Matterer, MORRIS JAMES LLP, Wilmington, DE. Edgar H. Haug, Robert E. Colletti, Richard E. Parke, FROMMER LAWRENCE & HAUG, LLP, New York, NY.

Attorneys for Defendant Mylan Pharmaceuticals, Inc.

Richard L. Horwitz, David E. Moore, POTTER ANDERSON & CORROON LLP, Wilmington, DE. Steven E. Feldman, Louise T. Walsh, Philip D. Segrest, Jr., Sherry L. Rollo, HUSCH BLACKWELL, LLP, Chicago IL.

Attorneys for Defendants Apotex, Inc. and Apotex Corp.

John C. Phillips, Jr., Megan C. Haney, PHILLIPS, GOLDMAN & SPENCE, P.A., Wilmington, DE. Eric C. Cohen, Jeremy C. Daniel, KATTEN MUCHIN ROSENMAN LLP, Chicago, IL.

Attorneys for Defendant Sun Pharma Global FZE.

MEMORANDUM OPINION

March 28, 2014
Wilmington, Delaware

STARK, U.S. District Judge:

Presently before the Court are the Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 103 for Obviousness (D.I. 330) and 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 (D.I. 303), both filed by Defendants Apotex Corp., Apotex, Inc., Teva Pharmaceuticals USA, Inc., Mylan Pharmaceuticals, Inc., and Sun Pharma Global FZE's (collectively, "Defendants"). Also pending is the Motion for Summary Judgment of Infringement (D.I. 333) filed by Plaintiffs Warner Chilcott Company, LLC and Hoffmann-La Roche Inc. (collectively, "Plaintiffs").

For the reasons discussed below, the Court will grant Defendants' Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 103 and deny as moot the remaining motions.

I. BACKGROUND

On September 26, 2008, Plaintiffs brought suit (D.I. 1) alleging that Defendant Teva's abbreviated new drug application ("ANDA") infringed U.S. Patent No. 7,192,938 (the "'938 patent") (D.I. 336 Ex. 2). On January 24, 2011, Plaintiffs filed another action against Teva (C.A. No. 11-81-LPS), which is now consolidated with the earlier action,[1] asserting infringement of U.S. Patent No. 7,718,634 (the "'634 patent"). The '938 and '634 patents ("patents-in-suit") are continuations from the same parent application, U.S. Application No. 10/430,007, and relate to methods for treating or preventing osteoporosis or postmenopausal osteoporosis using a monthly

[1]Plaintiffs' case against Apotex Corp. and Apotex, Inc. was consolidated with the action against Teva in September 2009. (D.I. 34) The case against Mylan Pharmaceuticals Inc. was consolidated with the instant action in July 2010. (D.I. 88) The case against Sun Pharma Global, Inc. was consolidated in November 2010 (D.I. 104) and, in July 2011, the parties stipulated to substitute Sun Pharma Global FZE for Sun Pharma Global, Inc. (D.I. 219).

dose of a pharmaceutically acceptable salt of risedronic acid, a nitrogen-containing bisphosphonate ("NCBP"). It is undisputed that osteoporosis is a disorder of abnormal bone resorption and bone loss. (*Id.* at col.1, ll.34-43)

The Court construed the disputed claim terms. (D.I. 290) Trial was set to begin on July 23, 2012, but, at the request of most of the parties (D.I. 319), the Court cancelled trial after a decision was issued by the Honorable Stanley R. Chesler of the District of New Jersey invalidating claims 1-8 of the '634 patent[2] (D.I. 322). Subsequently, the parties requested the opportunity to file the pending motions (D.I. 323), on which the Court heard oral argument on December 14, 2012 (D.I. 392) ("Tr.").

II. LEGAL STANDARDS

A grant of summary judgment is appropriate only where "the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c)(2). The moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *See Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.10 (1986). If the moving party has carried its burden, the nonmovant must then "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Id.* at 587 (quoting Fed. R. Civ. P. 56(e)). The Court will "draw all reasonable inferences in favor of the nonmoving party, and it may not make credibility determinations or weigh the evidence." *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000). If the Court is able to determine that "there is

[2]Claims 1-8 of the '634 patent are not asserted in this case. They cover once monthly dosing of ibandronate for treatment of osteoporosis, whereas the asserted claims in the instant action cover dosing of risedronate.

no genuine issue as to any material fact" and that the movant is entitled to judgment as a matter of law, summary judgment is appropriate. *See Hill v. City of Scranton*, 411 F.3d 118, 125 (3d Cir. 2005); *see also* Fed. R. Civ. P. 56(c).

To defeat a motion for summary judgment, the nonmoving party must "do more than simply show that there is some metaphysical doubt as to the material facts." *Matsushita*, 475 U.S. at 586; *see also Podobnik v. U.S. Postal Serv.*, 409 F.3d 584, 594 (3d Cir. 2005) (stating party opposing summary judgment "must present more than just bare assertions, conclusory allegations or suspicions to show the existence of a genuine issue") (internal quotation marks omitted). Moreover, the "mere existence of some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment;" a factual dispute is genuine only where "the evidence is such that a reasonable jury could return a verdict for the nonmoving party." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 247-48 (1986).

III. DISCUSSION

A. Defendants' Motion for Summary Judgment Under 35 U.S.C. § 103

A patent is invalid if the differences between the invention and the prior art are such that the invention would have been obvious to one of ordinary skill in the art at the time of the invention. *See* 35 U.S.C. § 103; *see also In re O'Farrell*, 853 F.2d 894, 904 (Fed. Cir. 1988). Obviousness is a question of law based on factual determinations, including: "(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).

In May 2012, Judge Chesler of the District of New Jersey reviewed the '634 patent and granted summary judgment of invalidity under 35 U.S.C. § 103. *See Hoffmann-La Roche Inc. v. Apotex Inc.*, 2012 WL 1637736, at *1 (D.N.J. May 7, 2012) ("*Hoffman*"). Claims 1-8 of the '634 patent were asserted in *Hoffmann* and claimed a once monthly dosage of ibandronate for the treatment of osteoporosis. *See id.* at *3. The prior art before the *Hoffman* Court included: Lunar News Spring 1999,[3] Ravn 1996,[4] U.S. Patent Nos. 6,432,932 ("Daifotis"), 6,468,559 ("Chen"), 5,616,560 ("Geddes"), Riis,[5] U.S. Patent Application No. 2003/0118634 ("Schofield"), and Krause 2001.[6] *See id.* at *4.

Judge Chesler concluded that the asserted claims consisted of three elements: (1) oral administration of ibandronate, (2) once monthly dosing for the treatment of osteoporosis, and (3) a 150 mg dose. *See id.* The Court found that the Lunar News article disclosed the first two elements of the claims, while the remaining prior art established that a person of ordinary skill in the art would have found the 150 mg dose obvious. *See id.* at *10.

In terms of dosage, Ravn 1996 disclosed that daily 2.5 mg and 5 mg doses of ibandronate were effective in women with postmenopausal osteoporosis. *See id.* at *4. Daifotis claimed the

---

[3] *Update: Bisphosphonates*, Lunar News (Spring 1999).

[4] P. Ravn et al., *The effect on bone mass and bone markers of different doses of ibandronate: A new bisphosphonate for prevention and treatment of postmenopausal osteoporosis: A 1-year, randomized, double-blind, placebo-controlled dose-finding study*, 19 Bone 527 (1996).

[5] B.J. Riis et al., *Ibandronate: A Comparison of Oral Daily Dosing Versus Intermittent Dosing in Postmenopausal Osteoporosis*, 16 J. of Bone and Mineral Research 1871 (2001).

[6] Krause et al., *Roche, GlaxoSmithKline in Drug Pact*, 260 Chemical Market Reporter 10 (2001).

use of bisphosphonates dosed weekly or biweekly to inhibit bone resorption. *See id.* at *5. Daifotis further taught that a weekly dose of ibandronate could be effective in doses between 35 mg and 50 mg. *See id.* at *6. Moreover, Daifotis revealed that "'the administration of a bisphosphonate at a high relative dosing frequency causes less adverse gastrointestinal effects, particularly esophageal effects, compared to the administration of a low relative dosage at a high relative dosing frequency,'" and highlighted this finding as "'surprising in view of the teachings suggesting that adverse gastrointestinal effects would be expected to increase as a function of increasing bisphosphonate dosage.'" *Id.* at *5 (quoting Daifotis at col. 3 l.58- col. 4 l.6). The Court found that a person of ordinary skill in the art would observe that the 35 mg weekly dose disclosed in Daifotis corresponded to the 5 mg daily dose disclosed in Ravn 1996. *See id.* at *6.

Riis disclosed that "preclinical data with ibandronate provided evidence that a total dose administered over a defined period provides equivalent results irrespective of the dosing schedule, providing that the dose used is efficacious." *See id.* at *5. That is, Riis taught the "total dose concept." *See id.* Hence, the *Hoffman* Court held that the combination of the daily 5 mg dose disclosed in Ravn 1996, the weekly 35 mg dose disclosed in Daifotis, and the Riis total dose concept rendered a once monthly dose of 150 mg obvious. *See id.* at *6 n.6.

Schofield stated that bisphosphonates administered at longer intervals, including weekly, biweekly, and monthly dosages, could treat osteoporosis. *See id.* at *6. Like Riis, then, Schofield disclosed the total dose concept. Judge Chesler recognized the parties before him presented a battle of experts over whether Schofield's daily dose of between 5 and 10 mg extrapolated to a 150 mg monthly dose, but determined that this battle was irrelevant because even without the Schofield reference, Ravn 1996, Daifotis, and Riis were sufficient to render

obvious the choice of a 150 mg monthly dose. *See id.*

Still more prior art supported Judge Chesler's conclusions. He explained that Chen claimed a preferred embodiment of a once monthly dosage form of bisphosphonates useful in the treatment of osteoporosis. *See id.* at *7. Likewise, Krause 2001 and Geddes discussed a once monthly dosage of bisphosphonates to treat osteoporosis. Thus, the *Hoffman* Court found that, based on the prior art, there was a reasonable expectation of success with respect to the treatment of osteoporosis with a once monthly dose of ibandronate at 150 mg. *See id.*

In an attempt to demonstrate that genuine issues of material fact remained to be adjudicated in connection with obviousness, plaintiffs in the *Hoffman* action argued that Schnitzer 2001[7] taught away from the claimed invention. *See id.* at *9. Schnitzer 2001 stated that "there is evidence that the desired reductions in bone turnover are not maintained if dosing intervals are longer than 1 or 2 weeks." *Id.* at *10 n.13. This is known as the "osteoclast life cycle theory." *Id.* Judge Chesler rejected plaintiffs' reliance on the osteoclast life cycle theory because "a skilled artisan would have understood Riis 2001 to have superceded the views about intermittent dosing with ibandronate expressed in Schnitzer." *Id.* at *10 (citing *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 36 (1966)).

In the end, the *Hoffman* Court found a "mere . . . scintilla" of evidence in support of plaintiff's position. *Id.* at *20 (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 266 (1986)). Given this minimal showing by plaintiffs, and moreover, the lack of material dispute as to the content of the prior art, the scope of the patent claims, and the level of ordinary skill in the

---

[7]Thomas J Schnitzer, *Update on alendronate for osteoporosis: once-weekly dosing*, 2 Expert Opin. Pharmacother. 1461 (2001).

art, the Court concluded that defendants had met the high burden of proving by clear and convincing evidence that claims 1-8 of the '634 patent were obvious and, thus, invalid. *See id.* at *21-22.

Here, Defendants, like the defendants in the New Jersey *Hoffman* action, contend that the patents-in-suit are obvious because the prior art discloses the three elements of the asserted claims: (1) oral administration of risedronate for the treatment of osteoporosis, (2) once monthly, (3) at a dose of 150 mg. (D.I. 331 at 13-16) Plaintiffs oppose summary judgment of obviousness by arguing that the once monthly dosing regime was not well accepted at the time of invention and, at that time, the 150 mg dose amount was unknown to persons of ordinary skill in the art. (D.I. 353 at 3; Tr. at 36) Having reviewed the record provided by the parties and considered the parties' arguments, the Court concludes that Defendants have met their burden of proving, by clear and convincing evidence, that the prior art discloses that a once monthly 150 mg dosage of risedronate effectively and safely treats osteoporosis, rendering the '938 and '634 patents obvious (even after considering evidence of secondary considerations of nonobviousness). No reasonable finder of fact could conclude otherwise.

Dr. Mazess' 2000 Lunar News article discloses the first element of the claimed invention: the use of risedronate as an effective treatment of osteoporosis. (D.I. 336 Ex. 12, *Update: Bisphosphonates*, Lunar News (Winter 2000) (stating that "risedronate has met all standards for efficacy . . . for prevention and treatment of osteoporosis . . .")) Plaintiffs observe that at the time Mazess' Lunar News article was published, risedronate was not yet approved by the FDA for the prevention or treatment of osteoporosis (D.I. 353 at 8) – but such approval is not an element of the claims at issue and is not relevant here. *Cf. Hoffmann-La Roche*, 2012 WL 1637736, at *9,

n.9. Schofield similarly states that risedronate may be effective to treat and prevent bone loss. (D.I. 336 Ex. 18 at [0037])

Lunar News and Schofield also disclose the second element: once monthly administration. Lunar News states that "[w]eekly, or even monthly, dosing if done properly could foster long-term compliance as well as minimiz[e] side effects." (D.I. 336 Ex. 12) Likewise, Schofield discloses daily, weekly, or monthly dosages. (D.I. 336 Ex. 18 at [0037]) Undesirable side effects associated with more frequent dosing – such as requiring patients to take the drug without food and then to stand or be seated upright for half an hour – would have motivated those skilled in the art to pursue a dosing regimen that required taking the drug as infrequently as possible. (*See, e.g.*, D.I. 357 at ¶ 17) (stating that undesirable side effects motivated those skilled in art to move away from daily dosing treatments to weekly dosages)[8]

Plaintiffs attempt, but fail, to create a genuine issue of material fact with evidence suggesting that one of ordinary skill in the art would reject monthly dosing because it was believed that the two-week osteoclast life cycle required dosing at least once every two weeks for effective osteoclast inhibition. (D.I. 353 at 3-4; D.I. 357 at ¶ 65) However, the prior art discloses that bisphosphonates were effective treatments for osteoporosis, even when dosed in intervals exceeding two weeks. For example, Riis presented evidence that dosing bisphosphonates at intervals of up to nine weeks was as effective as daily administration. (D.I. 336 Ex. 9) Indeed, Riis stated that "a total dose administered over a defined period provides equivalent results irrespective of the dosing schedule." (*Id.*) *Cf. Hoffmann-La Roche*, 2012 WL

[8]The level of ordinary skill in the art is not disputed. (D.I. 331 at 17; D.I. 353 at 18)

1637736, at *13 (stating that there is no dispute that Riis teaches this, as "it is a direct quote").[9] Provisional Application 60/370501 further supports the conclusion that monthly dosages of other NCBPs are effective even when given in longer intervals. (D.I. 332 Ex. 3 (claiming monthly dose of 280 mg alendronate to treat osteoporosis))

Prior art studies confirmed that risedronate, an NCBP, is effective in preventing bone loss even when given at long intervals. For example, the 1997 Delmas study "determine[d] the effectiveness and safety of the bisphosphonate risedronate in preventing bone loss." (D.I. 336 Ex. 23, PD Delmas et al., *Bisphosphonate risedronate prevents bone loss in women with artificial menopause due to chemotherapy of breast cancer: a double-blind, placebo-controlled study*, 15 J. of Clinical Oncology 955, 955 (1997)) Delmas concluded that "[r]isedronate appears to be a safe treatment that prevents both trabecular and cortical bone loss in women," even with dosing intervals longer than one month. (*Id.*)

A 2001 study further supports the conclusion that high intermittent doses of risedronate are effective. (D.I. 366 Ex. 22, R. Zegels et al., *Effect of High Doses of Oral Risedronate (20 mg/day) on Serum Parathyroid Hormone Levels and Urinary Collagen Cross-link Excretion in Postmenopausal Women With Spinal Osteoporosis*, 28 Bone 108 (2001)) Zegels administered 20 mg of risedronate each day for 14 days and observed that bone resorption markers decreased for up to 50 days. (*Id.* at 110) The Zegels authors hypothesized that the total amount of risedronate,

---

[9]In affirming Judge Chesler's denial of plaintiffs' motion for a preliminary injunction, the Federal Circuit stated: "[i]t was not clear error for the district court to find that the cited references disclose every claim limitation and that while uncertainties remained, the field was trending towards intermittent dosing based on the [Riis] total dosing concept, including a one-monthly dose of 150 mg." *Hoffmann-La Roche v. Apotex*, 2012 WL 4829204, at *4 (Fed. Cir. Oct. 11, 2012).

280 mg, rather than the 20 mg daily dosing, was the driving factor in reduced bone resorption. The authors supported this expectation by citing two other studies stating that bisphosphonates are similarly effective whether administered intermittently or taken daily. (*Id.* at 111) (citing M. Dooley et al., *Ibandronate*, 57 Drugs 101 (1999) and J-Y L Reginster et al., *Bisphosphonates for the treatment of osteoporosis*, in Osteoporosis: Diagnosis and Management 123 (1998))

Turning to the third element of the claims, the prior art also renders the choice of a 150 mg dose of risedronate obvious. Schofield discloses a daily risedronate dose of from about 5 to 10 mg. (D.I. 336 Ex. 18 at [0037]) Schofield also states that "[e]quivalent doses can be given every other day, twice a week, weekly, biweekly or monthly" and provides a weekly equivalent dose of 35 mg, seven times the daily dose. (D.I. 336 Ex. 18 at [0042])[10] Daifotis similarly disclosed a 5 mg daily dose of bisphosphonate, extrapolated to 35 mg per week. (D.I. 336 Ex. 20) Plaintiffs' own expert recognizes that one of ordinary skill in the art might expect risedronate dosing to scale linearly, so that the daily 5 mg dosage could be extrapolated to a monthly dosage of 150 mg. (D.I. 372 Ex. 4 at 78 (stating that linear scaling of risedronate is not unreasonable, merely unknown); D.I. 359 at ¶ 20 (stating that some bisphosphonates scale linearly)) Moreover, Plaintiffs' expert recognizes that "[a]s of May 2002, it was known that risedronate pharmacokinetics after a single-dose oral administration of 2.5 mg to 30 mg were linear." (D.I. 359 ¶ 24) The disclosure in Riis that long term intermittent dosing provides equivalent results as compared to daily dosing, and the linear scaling disclosed in Schofield and Daifotis, render the specific dose of 150 mg obvious.

---

[10]While Plaintiffs point out, correctly, that during prosecution the patentees overcame rejections based on Schofield, it nonetheless is true that Schofield teaches that the subsequent maintenance doses are effective in treating and preventing osteoporosis.

Defendants have presented clear and convincing evidence that the prior art demonstrates that high doses of risedronate are safe and effective. (D.I. 336 at ¶¶ 83-84 (discussing studies demonstrating that high dosages of bisphosphonates are safe and effective)) For example, Dr. Yates cites to Patent Application WO 01/15703, which states that "bisphosphonate at a high relative dosage at a low relative dosing frequency causes ***less*** adverse gastrointestinal effects." (*Id.* at ¶ 82 (emphasis added)) Additionally, a 2001 study stated that 160 mg of another bisphosphonate, alendronate, given weekly was "safe and well tolerated." (*Id.* Ex. 30) Notwithstanding Plaintiffs' expert's conclusory statements that one of ordinary skill in the art would be concerned that high doses might be ineffective or unsafe (D.I. 359 at ¶ 25), the prior art would lead a finder of fact to conclude that such a person would have reasonably expected a high dose to be effective and safe.[11]

Plaintiffs urge the Court to deny summary judgment because there is a battle of experts over whether the prior art was generally accepted. (Tr. at 45-48) Plaintiffs rely on expert testimony from Drs. John P. Bilezikian, David Y. Mitchell, and Anastasia G. Daifotois to support the contention that a person of ordinary skill in the art would not believe a once-monthly risedronate dose would effectively treat osteoporosis. (D.I. 353 at 4) All three experts rely on Schnitzer 2001 to support the assertion that a person of ordinary skill in the art would not have believed that a dosing interval longer than the two-week osteoclast life cycle would be effective. (D.I. 357 ¶ 66; D.I. 358 ¶ 17; D.I. 359 ¶¶ 34-36; D.I. 354 Ex. 9, Thomas J Schnitzer, *Update on alendronate for osteoporosis: once-weekly dosing*, 2 Expert Opin. Pharmacother. 1461 (2001))

[11] *Hoffmann* concluded that the prior art, including Schofield, was "sufficient to give the skilled artisan a reasonable expectation of safety with a 150 mg dose." 2012 WL 1637736, at *17.

However, Dr. Bilezikian, citing Riis, stops short of stating that longer dosing beyond the two-week osteoclast life cycle would not be effective and opines, instead, that it is "less effective" than daily dosing. (D.I. 357 ¶¶ 53, 68) Dr. Daifotis states in conclusory fashion that the Riis total dose concept was not accepted by those of ordinary skill in the art. (D.I. 358 ¶ 12) *See generally Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1001 (Fed. Cir. 2008) ("Conclusory expert assertions cannot raise triable issues of material fact on summary judgment."). Similarly, Dr. Mitchell states that a person of ordinary skill in the art would not have a reasonable basis to expect monthly dosing of all bisphosphonates to be safe and effective, but he provides no support. (D.I. 359 ¶ 16) Notably, none of the experts cites to a study dated after Riis discrediting the total dose concept. *See Graham*, 383 U.S. at 36 (stating that after appearance of relevant prior art, "unsuccessful attempts to reach a solution to the problems . . . before that time [become] wholly irrelevant"). Even Plaintiffs admit that "Riis would have been understood by a [person of ordinary skill in the art] in May 2002 as a reference that showed ***some*** antiresorptive effect over longer dose-free intervals." (D.I. 353 at 15) (emphasis in original)

Riis, Delmas, and Zegels provided one of ordinary skill in the art with a reasonable expectation of success with respect to longer dosing periods of bisphosphonates to treat osteoporosis. "For obviousness under § 103, all that is required is a reasonable expectation of success." *In re O'Farrell*, 853 F.2d 894, 903-04 (Fed. Cir. 1988) ("Obviousness does not require absolute predictability of success. Indeed, for many inventions that seem quite obvious, there is no absolute predictability of success until the invention is reduced to practice. There is always at least a possibility of unexpected results, that would then provide an objective basis for showing that the invention, although apparently obvious, was in law nonobvious."); *see also Merck & Co.,*

Inc. v. Teva Pharms., USA, Inc., 395 F.3d 1364, 1375 (Fed. Cir. 2005) (invalidating patent claiming weekly dose of alendronate, stating "to the extent the district court finds [patentee's] weekly-dosing idea non-obvious because it went against prevailing wisdom, the court must still explain why [patentee] and not Dr. Mazess [of Lunar News] should get credit for the idea . . . . [Patentee's] idea added nothing to what came before . . . .").

Secondary considerations support the Court's conclusion that the patents-in-suit are invalid as obvious. Simultaneous invention is evidence that one of ordinary skill in the art would have considered it obvious to combine elements of the prior art. *See Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1338 (Fed. Cir. 2004). Here, there is evidence of simultaneous invention. (*See* D.I. 331 at 18; D.I. 332 Exs. 2 & 3)

Plaintiffs' evidence of the commercial success of once-a-month Actonel® fails to raise a genuine issue of material fact. Judge Chesler rejected a similar argument in *Hoffman*, stating that "this Court does not find this commercial success to have much value as an indicator of nonobviousness . . . because others were legally barred from commercially testing the Lunar News ideas." *Hoffmann-La Roche Inc.*, 2012 WL 1637736, at *18. P&G's U.S. Patent No. 5,583,122, claiming the risedronate compound, would have discouraged development of risedronate products. *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005) (stating that commercial success was weak evidence of nonobviousness because market entry was barred by others due to patent claiming alendronate); *see also* Tr. at 29; *Galderma Labs., L.P. v. Tolmar, Inc.*, 737 F.3d 731, 740 (Fed. Cir. 2013) ("Where 'market entry by others was precluded [due to blocking patents], the inference of non-obviousness of [the asserted claims], from evidence of commercial success, is weak.' This principle applies

forcefully to the present case.") (quoting *Merck*, 395 F.3d at 1376).

Nor does Plaintiffs' evidence of long-felt need create a genuine issue of material fact. Long-felt need is evaluated from the date of the closest prior art. *See Graham*, 383 U.S. at 36. Lunar News proposed a monthly dose of risedronate to treat osteoporosis in 2000, only two years before the May 2002 priority date of the patents. Any long-felt need prior to 2000 is not relevant.

The Court finds that Defendants have met their burden of presenting clear and convincing evidence that allows this Court to conclude that one of ordinary skill in the art would consider the patents-in-suit obvious. In particular, Lunar News, Schofield, Riis, Delmas, Zegels, and Daifotis disclose the three elements of the patents-in-suit: oral administration of risedronate for the treatment of osteoporosis, administered monthly, at a dose of 150 mg. As a whole, the prior art discloses the efficacy and safety of high doses of risedronate, rendering the patents-in-suit obvious. Plaintiffs have failed to rebut this conclusion and have not presented evidence that raises a genuine issue of material fact. Thus, the Court will grant Defendants' motion.[12]

B. Defendants' Motion for Summary Judgment Under 35 U.S.C. § 112

In light of the Court's decision to grant Defendants summary judgment of invalidity due to obviousness, the Court will deny as moot their motion for summary judgment of invalidity under Section 112.

---

[12]In another related case, the District of New Jersey found claims 1-10 of U.S. Patent No. 7,410,957 (the "'957 patent") invalid as obvious, relying on essentially the same analysis and prior art. *See Hoffmann-La Roche Inc. v. Apotex Inc.*, 2012 WL 4661588, at *9 (D.N.J. Oct. 1, 2012). The '957 patent arises from the same patent family as the '938 and '634 patents and claims a method for treating osteoporosis with 150 mg of ibandronate. The Federal Circuit also found a similar patent invalid as obvious, based in part on Lunar News. *See Merck & Co., Inc. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1377 (Fed. Cir. 2005). The *Merck* patent, U.S. Patent No. 5,994,329, claimed a "less-than-daily administration" of a bisphosphonate compound, alendronate, for the treatment of osteoporosis.

C. Plaintiffs' Motion for Summary Judgment of Infringement

In light of the Court's decision to grant Defendants summary judgment of invalidity, the Court will deny as moot Plaintiffs' motion for summary judgment of infringement.

IV. CONCLUSION

An appropriate Order follows.

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 (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 (consolidated with C.A. No. 08-627-LPS)

WARNER CHILCOTT COMPANY, LLC and HOFFMANN-LA ROCHE INC.,	:	
Plaintiffs,	:	
	:	C.A. No. 09-61-LPS
v.	:	(consolidated with C.A. No. 08-627-LPS)
SUN PHARMA GLOBAL FZE,	:	
Defendant.	:	

ORDER

At Wilmington this 28th day of March, 2014, consistent with the Memorandum Opinion issued this date, IT IS HEREBY ORDERED that:

1. Defendants' Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 103 (D.I. 330) is GRANTED.

2. Defendants' Motion for Summary Judgment of Invalidity Under 35 U.S.C. § 112 (D.I. 303) is DENIED AS MOOT.

3. Plaintiffs' Motion for Summary Judgment of Infringement (D.I. 333) is DENIED AS MOOT.

4. The Clerk of Court is directed to enter judgment AGAINST Plaintiffs and FOR Defendants and to CLOSE these consolidated cases.

UNITED STATES DISTRICT JUDGE