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STATUTE

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I. THE PRIOR ART DISCLOSES MONTHLY DOSING OF RISEDRONATE FOR THE TREATMENT OF OSTEOPOROSIS.

A. *Lunar News* Disclosed Once-Monthly Risedronate for Osteoporosis.

Plaintiffs do not dispute that *Lunar News* states both that risedronate can be administered once monthly to treat osteoporosis, and the motivation for doing so: to “foster long-term compliance as well as minimizing side effects.” (D.I. 336, Yates Decl. Ex. 12 at 32.) While plaintiffs argue that *Lunar News* is not peer reviewed and that the author is not a person of ordinary skill in the art (“a skilled person”), the Federal Circuit has rejected exactly those criticisms about this same publication in declaring invalid the patent on weekly bisphosphonate dosing. *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1374 (Fed. Cir. 2005) (holding that the district court’s reliance on factors including whether *Lunar News* “is peer reviewed” and “the credentials of the author” was “again, misplaced”). As in *Merck*, where the “*Lunar News* articles had clearly suggested the once-weekly dosing,” here *Lunar News* clearly suggested once-monthly dosing of risedronate. The patents in suit, as in *Merck*, “sets forth no human clinical or laboratory data showing the safety and tolerability of the treatment methods claimed by the patent.” *Merck*, 395 F.3d at 1374. In assessing why the named inventors “and not Dr. Mazess should get credit for the idea,” arguments about the comparative “credentials of the authors” are “not enough to avoid invalidating the claims” because the patentees’ “idea added nothing to what came before.” *Id.* at 1375.¹

Plaintiffs’ argument that skilled persons would have been “skeptical” of the prior art is legally insufficient. *Merck*, 395 F.3d at 1374 (Fed. Cir. 2005) (“So while the district court may be correct in finding the *Lunar News* articles may have invited skepticism based on concerns for

¹ Also, plaintiffs improperly focus on what *Lunar News* taught when published, asserting that FDA had not yet approved risedronate. The relevant date for assessing obviousness is the date of the alleged invention (here, the date Roche filed its patent application), 35 U.S.C. § 103, not the date the prior art was published—and FDA approved risedronate before then.

dose-related GI problems, the claimed invention adds nothing beyond the teachings of those articles. Thus, the district court clearly erred in finding any difference between the claimed invention and the articles on this point.”). Plaintiffs added nothing to Lunar News, and they are not entitled to a patent merely for repackaging Dr. Mazess’s disclosure.

B. Plaintiffs Have Not Raised a Genuine Issue of Material Fact About Schofield.

The New Jersey court squarely rejected the same attack on Schofield that plaintiffs offer here (that one “would not have divorced the essential loading step from the maintenance component” because it “requires as a critical first step a loading dose”). *Hoffmann-La Roche Inc. v. Apotex Inc.*, 2012 WL 869572, *6 (D.N.J. Mar. 14, 2012) (“*Roche I*”) (holding Roche’s contention “that it would have taught little of relevance because Schofield requires a loading dose” to be “unpersuasive.”); *Hoffmann-La Roche Inc. v. Apotex Inc.*, 2012 WL 1637736, *13 (D.N.J. May 7, 2012) (holding plaintiffs’ conclusory assertions about “whether a skilled artisan would believe that the loading dose was optional” had “failed to show any genuine and material factual dispute over Schofield.”) (“*Roche II*”).² As that court noted, “Schofield’s treatment method for the maintenance period is very, very close to the treatment method at issue.” *Roche II* at *6; *Roche I* at *6. Just as it does for ibandronate, Schofield also discloses that one can maintain osteoporosis treatment by administering once monthly doses of risedronate which are equivalent to 5 mg per day and the equivalent dose is 150 mg per month. (Yates Decl. ¶ 55); *see Roche II* at *6; *Roche I* at *6.

Indeed, Schofield (a published P&G patent application) is an even stronger reference for risedronate than for ibandronate. P&G owned the patent on the risedronate compound.

² Plaintiffs’ failure to distinguish or even cite the New Jersey court’s analysis is telling, especially because this Court vacated the trial date in favor of this additional summary judgment briefing “primarily as a result of” the summary judgment grant in that case. (D.I. 327, May 23, 2012 Tel. Conf. Tr. at 11:23–24.)

Schofield's Example 1 discloses a maintenance dose of 35 mg per week to treat osteoporosis (D.I. 336, Ex. 18 at [0042]), which a skilled person knew was the weekly dosage P&G developed to treat osteoporosis without a loading dose. Plaintiffs' argument, which did not raise a genuine issue in *Roche II*, is even weaker here.

Statements about "long term efficacy" are also immaterial, as that is not a limitation in the asserted claims and the patent applications disclosed no data or studies about long term efficacy. Dr. Bilezikian's conclusory assertion about "serious doubts" concerning the "long term efficacy" of Schofield's monthly regimen (D.I. 357, Bilez. Decl. ¶ 43) does not change the indisputable fact that Schofield discloses a monthly regimen. Moreover, as with *Lunar News*, Dr. Bilezikian never explains what the patents in suit add to Schofield. Plaintiffs provide no reason for the skilled person to have been more receptive to the disclosure in the patents than to that in Schofield. Again, plaintiffs cannot explain why their inventors rather than Dr. Schofield should get credit for the idea.

II. THERE IS NO GENUINE DISPUTE ABOUT THE "TOTAL DOSE" CONCEPT.

A. It Is Undisputed That Riis Established The Total Dose Concept With A Dose Free Interval Of More Than A Month.

It is undisputed that Riis 2001 taught "that a total dose administered over a defined period provides equivalent results irrespective of the dosing schedule," that intermittent dosing "is as effective as the continuous treatment," and that a daily regimen and an intermittent regimen with a nine-week rest period were equally effective in increasing bone mineral density. (D.I. 336, Ex. 9); *Roche II* at *5, *13 ("There can no dispute that Riis 2001 teaches this: it is a direct quote."); *Roche I* at *5. Plaintiffs cite Schnitzer 2001's discussion of an earlier study that preceded Riis 2001, but the New Jersey court rejected that same argument, noting that Riis published new results in October 2001 that made Schnitzer's earlier discussion obsolete. *Roche II*, 2012 WL

1637736 at *9 (“Thus, to whatever extent the skilled artisan might have read Schnitzer 2001 as teaching away from the invention at issue, on October 1, 2001, with the publication of Riis 2001, the game changed.”). The New Jersey court also observed that principal inventor Dr. Bauss “makes absolutely clear that Riis 2001 persuasively refuted the osteoclast life cycle theory.” *Id.* at *10 (“The skilled artisan would have understood Riis 2001 to have superseded the views about intermittent dosing with ibandronate expressed in Schnitzer 2001.”).

Unable to dispute what Riis 2001 unequivocally teaches, and without any response to the New Jersey court’s analysis, plaintiffs resort instead to their expert’s conclusory assertion that a skilled person would not have believed Riis 2001 because he would have been “more skeptical” than Dr. Bauss. Nothing supports this assertion. Nor does anything support Dr. Bilezikian’s conclusory claim that a skilled person would arbitrarily disregard clinical trial results Roche published in a peer-reviewed journal; his assertion does not raise a material issue. *Roche II*, 2012 WL 1637736, *13 (“Conclusory expert assertions cannot raise triable issues of material fact on summary judgment.”) (quoting *Sitrick v. Dreamworks, LLC*, 516 F.3d 993, 1001 (Fed. Cir. 2008)).

B. Schofield And Other References Also Taught The Total Dose Concept.

Other references also taught the total dose concept, including Schofield, Delmas, and Zegels. Plaintiffs do not dispute the New Jersey court’s observation that Schofield “expresses the total dose concept: one may treat osteoporosis by administering a particular amount of a bisphosphonate as a daily dose, or one may administer the proportionately equivalent amount intermittently (monthly, for instance).” *Roche I* at *6. This, alone, suffices for purposes of summary judgment. Two additional references, Delmas and Zegels, further show application of the total dose concept in the risedronate context. Plaintiffs’ attempts to distinguish these are inconsistent with their texts. As to Delmas, plaintiffs state there is “no evidence that a POSITA

would believe bone loss in chemotherapy-induced menopause is similar to that in natural menopause.” (D.I. 351, Pl. Br. at 7; Bilez. Decl. ¶ 61.) Delmas, however, compares his study design and results to studies of postmenopausal osteoporosis in both his discussion and conclusion. (D.I. 336, Ex. 23 at 958–59, 961.) Similarly, plaintiffs argue that “a POSITA would have drawn no conclusions from Zegels regarding efficacy (Pl. Br. at 7) because Zegels cautions that “no definite conclusions about the degree of suppression can be reached from such a short-term study.” (Bilez. Decl. ¶ 57.) But that same sentence from Zegels notes that the suppression of bone turnover he observed was similar to that from a larger study with a similar dose. (*See* Yates Decl. ¶ 76.) Plaintiffs’ selective quotations from those references do not change what is disclosed and does not create an issue of fact.

That the osteoclast life cycle theory was dead letter is further demonstrated by the actions of Dr. Daifotis, another of plaintiffs’ experts. In April 2002, before plaintiffs’ priority date, she filed a patent application, in which Example 5 described both a monthly tablet and a monthly oral liquid formulation for treating osteoporosis, each comprising 280 mg of alendronate (four times the weekly dose). (D.I. 332, Ex. 3 at 37–38.) If Dr. Daifotis, a physician, had believed that the formulations would not be effective because the interval was longer than the two-week osteoclast life cycle, she would not have included it. Her subsequent non-provisional application deleted the tablet from that example, but continued to disclose a 280 mg tablet in Example 4, and continued to disclose a monthly oral dosage (as a buffered oral solution) in Example 5. Whether an oral dose is a solution or a tablet only affects how the drug is delivered to the stomach; it has nothing to do with the existence of the two-week osteoclast life cycle.

C. Dr. Mitchell’s Declaration Does Not Create A Genuine Issue Of Fact.

Dr. Mitchell asserts that the 150 mg monthly dose would not have been obvious because a skilled person could not have been certain beforehand that the dose would scale up from the

daily dose in a linear fashion. (D.I. 359, Mitchell Decl. ¶¶ 17–28.) Linearity or nonlinearity of absorption (sometimes called bioavailability) is immaterial to obviousness. Nothing in the patent describes nonlinear bioavailability, and the patent contains no absorption data.

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Dose finding is routine, regardless of whether doses scale linearly. *See Merck & Co., Inc. v. Biocraft Labs., Inc.*, 874 F.2d 804, 809 (Fed. Cir. 1989).

Thus, anyone concerned about the issue could have found the answer and would have concluded that risedronate dosing was linear.

Moreover, absolute certainty is not required. *In re O'Farrell*, 853 F.2d 894, 903–04 (Fed. Cir. 1988) (“Obviousness does not require absolute predictability of success . . . [A]ll that is required is a reasonable expectation of success.”). A skilled person would have believed it reasonable that risedronate could scale linearly, as it in fact did.

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He likewise admitted that

the only available data for risedronate showed linear absorption. (Mitchell Decl. ¶ 20.) The only “non-linear” data Dr. Mitchell cites are for bisphosphonates other than risedronate, and only at enormous doses: e.g., tiludronate, 400 mg/day for 12 days; and alendronate, 20 mg/kg, which extrapolates to 1400 mg for a 70 kg patient—140 times the daily dose. Far from being dissuaded by possible nonlinearity, a skilled person would have reasonably expected linear absorption for risedronate.

Dr. Mitchell misrepresents the record to support his contention that “cyclical” dosing studies would have discouraged the skilled person. Figure 1 in Dr. Mitchell’s declaration

purports to compare bone resorption rates for daily oral, weekly oral, and monthly oral dosing regimens. He claims that figure is “adapted from Cremers et al., 2005” and shows higher variability in resorption for the monthly regimen. (*Id.* ¶ 42.) To “adapt” the figure, however, Dr. Mitchell merely changed the labels from “3-monthly IV” to “1 month oral” and the time axis from “0, 3, 6” to “0, 1, 2.” (Giunta Decl. Ex. 7 at 561 (fig. 3).) Cremer’s 2005 is not prior art.

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But Dr. Mitchell’s Figure 1 does far worse than just make up data—it misrepresents the existing data. By accelerating the time scale threefold, Dr. Mitchell shows daily and weekly dosing doing in one month what Cremers says takes three months.³ Plaintiffs cannot create a genuine issue of material fact by misrepresenting the record.

D. Plaintiffs’ “Safety” Issue Is A Red Herring.

The New Jersey court also considered and rejected plaintiffs’ conclusory arguments about alleged safety concerns, noting several references that disclosed ibandronate doses well above 150 mg. *Roche II*, 2012 WL 1637736, at *17 (“These are sufficient to give the skilled artisan a reasonable expectation of safety with a 150 mg dose.”). Plaintiffs offer nothing to rebut that judicial analysis. Many of the same references contain the same disclosure for risedronate. For example, “Schofield teaches that a loading dose of any of a group of bisphosphonates, which includes ibandronate [and risedronate], may be as much as 20 times the maintenance dose, which may be as high as 15 mg per day, yielding a maximum loading dose of 300 mg per day.” *See id.*; (D.I. 336, Ex. 18.) And “Daifotis ’932 teaches that, for ‘human oral compositions,’ the range of

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a typical unit dosage goes up to 200 mg.” *Id.* Similarly, unit doses of risedronate up to 200 mg were disclosed in WO ’703, with the stated purpose of “minimizing the occurrence of or potential for adverse gastrointestinal effects.” (Yates Decl. ¶ 82.) Alendronate was “safe and well tolerated” for osteoporosis patients at an oral tablet dose of 160 mg taken once-weekly for a year. (Yates Decl. ¶ 83.) Every study at every oral dosing regimen of risedronate showed that the drug was safe and well tolerated. (*Id.* ¶ 84.) Here, as in *Roche II*, these and other references would have given a skilled person a reasonable expectation that 150 mg risedronate in a single dose would be safe.

The art plaintiffs identify for safety issues concerned repeated exposure at continuous doses. (Pl. Br. at 8–10.) The prior art development of weekly dosage forms had already shown that less frequent exposure to higher doses did not produce the same effects, as evidenced by the success of once-weekly alendronate and the available information about once-weekly risedronate.

Plaintiffs also contend that a skilled person would have been deterred by the prospect of “systemic” toxic effects. (Pl. Br. at 10; Bilez. Decl. ¶ 24.)

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Plaintiffs only support for these alleged safety concerns is Dr.

Bilezikian’s conclusory assertion, which (as the New Jersey court observed) does not raise a genuine issue. *Roche II*, 2012 WL 1637736, at *17 (“Dr. Bilezekian’s qualms appear to be

⁴ Dr. Bilezikian also mentions the Suri paper as suggesting a concern for higher doses (Bilezikian Decl. ¶ 20),

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unsupported by evidence of record and, because they are purely conclusory and unsupported, they do not suffice to raise a factual dispute over whether a skilled person would have had a reasonable expectation that the 150 mg dose would be safe for humans.”). Plaintiffs cannot ignore the prior art teachings of doses up to and higher than 150 mg, when their patents provide no greater disclosure. The asserted patents disclose no safety data.

Plaintiffs are not entitled to remove information from the public domain on the grounds that a skilled person would have been concerned, particularly when the patents in suit add nothing to dispel any such alleged concern. Like the patent held invalid in *Merck*, nothing in the patents in suit explains how to overcome alleged concerns about higher doses. *Merck*, 395 F.3d at 1374 (“Neither the ’329 patent nor the *Lunar News* articles explain how a higher once-weekly dosing regimen would avoid this set of dose-related adverse side effects.”).

III. PLAINTIFFS DO NOT RAISE A GENUINE ISSUE OF MATERIAL FACT CONCERNING ANY SECONDARY CONSIDERATIONS.

A. Alleged Commercial Success Does Not Raise A Genuine Issue.

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Merck, 395 F.3d at 1377 (“Financial success is not significantly probative of that question in this case because others were legally barred from commercially testing the *Lunar News* ideas.”); *Roche II*, 2012 WL 1637736, *17–18 (“As in *Merck*, Roche’s commercial success with monthly dosing of ibandronate is not enough to show that the claims at bar are patentably distinct from the monthly dosing ideas in the prior art references.”); (see D.I. 331, Def. Br. at 19–20.) By ignoring this argument, plaintiffs essentially concede that they cannot challenge it.⁵

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B. Alleged Long Felt Need Does Not Raise A Genuine Issue.

Plaintiffs' assertion that there was a long-felt unmet need for a less frequent dosing regimen from the introduction of daily Fosamax in 1995 (Bilez. Decl. ¶ 71) fails on the facts and the law. A less frequent dosing regimen of weekly had already been introduced in 2000, and completely supplanted sales of the daily product. Alleged long-felt need must be evaluated from the date of closest prior art, such as the introduction of weekly alendronate in 2000 and the *Lunar News* suggestion of monthly dosing of risedronate, also in 2000. *Graham v. John Deere Co.*, 383 U.S. 1, 36 (1966) (stating that evidence of long-felt need and unsuccessful efforts, before the pertinent prior art became available, are "wholly irrelevant"); *Carter-Wallace, Inc. v. Otte*, 474 F.2d 542, 546 (2d Cir. 1972) (long-felt need was "all but completely forestalled" where relevant prior art appeared less than two years before the invention). These undisputed circumstances fail to raise a genuine issue of material fact as to any alleged long felt need.

C. Near Simultaneous Development Is Evidence Of Obviousness.

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Geo. M. Martin Co. v. Alliance Mach. Sys. Int'l LLC, 618 F.3d 1294, 1305 (Fed. Cir. 2010); *Ecolochem, Inc. v. S. Cal. Edison Co.*, 227 F.3d 1361, 1376 (Fed. Cir. 2000). Plaintiffs' case citation is not to the contrary, and involved a delay of many years between two alleged inventions. *Lindemann Maschinenfabrik GMBH v. American Hoist and Derrick Co.*, 730 F.2d 1452, 1460-61 (Fed. Cir. 1984).

CONCLUSION

Wherefore, defendants respectfully request that the Court enter summary judgment that the asserted patent claims are invalid for obviousness under 35 U.S.C. § 103.

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