No.

In the Supreme Court of the United States

MERCK & CO., INC.,

Petitioner,

v.

TEVA PHARMACEUTICALS USA, INC.,

Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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PETITION FOR A WRIT OF CERTIORARI

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QUESTIONS PRESENTED

1. Whether the Federal Circuit is correct in holding that, because the *ultimate* issue of patent claim construction is one of law for the court under *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370 (1996), even the factual aspects of a district court's claim construction may be reviewed *de novo* on appeal.

2. Whether the Federal Circuit violated Fed. R. Civ. P. 52 and contravened precedents such as *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 574 (1985), by rejecting admittedly plausible factual findings and credibility determinations supporting the district court's ultimate legal conclusion that the invention disclosed by petitioner's patent was not obvious.

3. Whether a patentee's strong showing of commercial success with a demonstrated nexus to an improvement invention covered by a patent can be disregarded as an indicator of the non-obviousness of the improvement because the patentee had exclusivity under earlier related patents.

RULE 14.1(b) AND 29.6 STATEMENT

Pursuant to Supreme Court Rule 14.1(b), petitioner Merck & Co., Inc. (Merck) states that all parties to the proceedings below appear in the caption of the case on the cover page. For clarity and to avoid any possible confusion, petitioner also notes that it is a completely separate legal entity from the unrelated German corporation that was the petitioner in this Court's recent decision in *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, No. 03-1237 (June 13, 2005).

Pursuant to Supreme Court Rule 29.6, petitioner states that it has no parent company and that there is no publicly held company that owns 10% or more of petitioner's corporate stock.

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OPINIONS BELOW

The majority and dissenting opinions of the court of appeals (App., *infra*, 1a-34a) are reported at 395 F.3d 1364. The opinion of the district court (App., *infra*, 43a-99a) is reported at 288 F. Supp. 2d 601. The order denying rehearing en banc and the dissenting opinion of three judges (App., *infra*, 35a-39a) are reported at 405 F.3d 1338.

JURISDICTION

The jurisdiction of the district court was invoked under 28 U.S.C. § 1338(a). The jurisdiction of the court of appeals was invoked under 28 U.S.C. § 1292(a)(1) and § 1295(a)(1). The court of appeals issued its judgment on January 28, 2005, and denied Merck's timely petition for rehearing on April 21, 2005. App., *infra*, 1a, 35a-39a. On June 23, 2005, Chief Justice Rehnquist extended the time within which to petition for a writ of certiorari to and including August 19, 2005. This Court has jurisdiction under 28 U.S.C. § 1254(1).

STATUTORY PROVISION AND RULE INVOLVED

The statutory provision at issue is 35 U.S.C. § 103(a), entitled "Conditions for patentability; non-obvious subject matter," which provides:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, 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.

The rule at issue is Federal Rule of Civil Procedure 52(a), which provides:

> In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon, and judgment shall be entered pursuant to Rule 58; and in granting or refusing interlocutory injunctions the court shall similarly set forth the findings of fact and conclusions of law which constitute the grounds of its action. Requests for findings are not necessary for purposes of review. Findings of fact, whether based on oral or documentary evidence, shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge of the credibility of the witnesses. * * *

STATEMENT

The FOSAMAX® medication developed by Merck was the first effective drug treatment for osteoporosis. Osteoporosis is a potentially debilitating disease afflicting millions, primarily post-menopausal women. It is caused by an imbalance in the body's natural process of destroying (or "resorbing") old bone and laying down new bone in its place. As people age, bone is resorbed faster than it is replaced. When the imbalance is too great, it can result in bones that are porous, brittle, and prone to fracture, leading to chronic pain, disability, and even death. Before the FDA approved Merck's daily FOSAMAX® products, post-menopausal women had only diet, exercise, and less satisfactory hormonal treatments to use against that serious disease.

This is the second patent infringement case related to FOSAMAX® between Merck and respondent Teva Pharmaceuticals USA, Inc. (Teva), a manufacturer of generic drugs.[1] The first case involved Merck's earlier '077 patent, which pioneered using the particular bisphosphonate in FOSAMAX®

[1] Both cases were brought under the provisions of the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585 (also known as the "Hatch-Waxman Act").

(called "alendronate"), to treat osteoporosis, administered by "daily" dosing with 10-mg tablets (and then 5-mg tablets for prevention). See *Merck & Co., Inc.* v. *Teva Pharm. USA, Inc.*, 347 F.3d 1367 (Fed. Cir. 2003). In that case, the district court found infringement and upheld the validity and the patent term restoration of the '077 patent, and the Federal Circuit affirmed. *Id.* at 1369-74. Because Teva's challenge to Merck's '077 patent failed in the "daily" case, Teva is foreclosed from introducing generic alendronate tablets until after expiration of that patent and the related marketing exclusivity periods in February 2008. See 21 U.S.C. § 355(c)(2)(b).

The present patent infringement case involves Merck's '329 patent entitled "Method for Inhibiting Bone Resorption," in which the two claims at issue are directed to methods for treating or preventing osteoporosis through "once-weekly" administration of high alendronate doses. The parties have agreed that, when rewritten in independent form, the asserted claims read as follows (emphasis added):

> 23. A method for treating osteoporosis in a human comprising orally administering *about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis,* as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.
>
> 37. A method for preventing osteoporosis in a human comprising orally administering *about 35 mg of alendronate monosodium trihydrate, on an alendronic acid basis*, as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.

The first question presented to this Court is squarely framed by the Federal Circuit's use of *de novo* review to disagree with the district court's construction of the highlighted phrases in claims 23 and 37 above.[2] The second and third questions chal-

[2] As it did below, Merck refers to the "about 70 mg" and the "about 35 mg" phrases as shorthand for the entire disputed phrases, which appear in italics above.

lenge the Federal Circuit's increasing practice – in direct contradiction to this Court's cases – of reweighing a district court's detailed, plausible, and supported factual findings (in this case, as required by *Graham* v. *John Deere Co*., 383 U.S. 1 (1966)), en route to reversing the district court's ultimate legal conclusion reached after a bench trial.

The FDA approved Merck's once-weekly FOSAMAX® dosing regimen in late 2000, and Merck began selling once-weekly tablets in November 2000. C.A. App. 718-19. Although Merck's 10- and 5-mg "daily" products were successful and enjoyed sales increases averaging more than $150 million each year before the once-weekly FOSAMAX® products were commercialized, the annual sales increases more than doubled after the improved once-weekly FOSAMAX® dosing regimen was introduced. C.A. App. 812-14, 817, 4007, 4006, 4340, 4344. That dramatic increase in physician and patient acceptance demonstrates that the invention created significant additional sales for the FOSAMAX® franchise.

A. State Of The Art in 1997: Widespread Belief That Alendronate Caused Dose-Related Side Effects

FDA approval for marketing FOSAMAX® as a high-dose, once-weekly tablet, as disclosed in the '329 patent, required Merck to undertake extensive clinical testing in support of a supplemental New Drug Application. 21 U.S.C. § 355(b); C.A. App. 527-28. The motivation for a weekly tablet was to avoid the inconvenient daily dosing regimen.[3] However, the '329 patent specification and the clinical studies it cited reflected the true state of the art at that time: strong apprehension over poten-

[3] The dosing regimen for ingesting alendronate tablets required osteoporotic patients to take the tablets on an empty stomach with a full glass of water and to remain upright without eating for up to an hour after ingestion so as to avoid a broad spectrum of food substances that could destroy effectiveness and to avoid any prolonged contact of alendronate with the esophagus. C.A. App. 220-22, 600, 3786, 3832, 3951-52.

tial adverse side effects from oral administration of bisphosphonates at high doses.

After Merck's 10-mg daily FOSAMAX® tablets became publicly available, reports began surfacing of severe upper gastrointestinal injuries among osteoporotic patients. See, *e.g.*, C.A. App. 341-52, 3825-36. Ten articles detailing case reports of severe upper gastrointestinal injuries were published in peer-reviewed medical journals. C.A. App. 344-50, 354-56, 525-26, 3825-36, 3840-43, 3855-56, 3870-71. The report in the October 1996 *New England Journal of Medicine* was perhaps the most compelling for physicians. *Id*. at 348-51, 550-51, 3828-33, 4323. The lead author concluded that "alendronate can cause chemical esophagitis, including severe ulcerations in some patients." *Id*. at 3828-29, 3832, 348-52. In response, Merck notified the FDA and warned physicians of the potential for upper gastrointestinal injury from daily FOSAMAX® tablets, urging strict adherence to the dosing instructions. *Id*. at 615-16, 631-32, 664, 3782-84. Because such side effects were reported as dose-related, any suggestion to increase the dose would have directly contradicted accepted clinical experience. Among those who adopted and publicly advocated avoiding gastric injury by administering the bisphosphonates in smaller doses more often each day was Teva's bone and bisphosphonate expert in this case, Dr. Russell. C.A. App. 580.

The concern in the art about alendronate deterred any escalation to higher unit doses. C.A. App. 348-49. Merck itself submitted a report based on its clinical trials to the FDA explaining the clinical history that had led Merck initially to limit experimental doses for osteoporosis to 20 mg or less. C.A. App. 4060, 635-36, 639-40.

After the "side effect" incidents, Merck launched introspective studies to investigate the gastrointestinal side effects of alendronate and improve the treatment methods. Based on animal studies, Merck's inventors postulated that increasing dose size while decreasing frequency to weekly dosing might be as well or even better tolerated than the existing daily dosing regi-

men. The inventors first formulated this idea in May 1996. C.A. App. 610-611, 621. Because weekly dosing was one of many alternatives being advanced at Merck in 1996, the idea – which the Federal Circuit would later insist had been "obvious" – faced substantial skepticism within the company and was laid aside. *Id.* at 617-22. Only in mid-1997, after additional animal studies confirmed their thesis, did the inventors apply for a patent directed to administering sevenfold the daily dose on a weekly basis. *Id.* at 620-23, 713-14.

Until Merck's once-weekly studies, undertaken after the invention resulting in the '329 patent, no clinical investigator reported exposing osteoporotic women to unit doses over 20 mg of alendronate. Even statements by Teva before this lawsuit confirm the widespread perception and understanding of those skilled in the art about the potential for gastrointestinal injuries from high doses. C. A. App. 4414 (c.3, l.12-25, 34-43). The suggestion that a sevenfold dose would not increase gastrointestinal side effects seemed as surprising – at the time – as a suggestion that eating a whole pizza on Sunday night would cause no more heartburn than eating one slice of pizza a day.

The PTO issued Merck's '329 patent in 1999. Even though Teva could not enter the market until 2008, Teva recognized the superiority of Merck's "once-weekly" product, and filed an Abbreviated New Drug Application (ANDA) seeking FDA approval to copy Merck's once-weekly 70-mg and 35-mg FOSAMAX® tablets before the expiration of the patent. In response, Merck filed this infringement suit under 35 U.S.C. § 271(e)(2).

B. The District Court Proceedings

Following a four-day bench trial, the district court ruled for Merck in an exhaustive opinion citing evidentiary support for the court's factual findings and making credibility determinations. App., *infra*, 43a-99a. Judge Farnan found that Merck provided an express definition in the specification of the disputed phrases in the claims (*id.* at 58a-62a) and rejected Teva's expert's contrary construction as unpersuasive (*id*. at 62a-64a). Teva sought to prove that a July 1996 article in a publication

called the *Lunar News* anticipated Merck's invention. Judge Farnan, however, rejected that contention as a matter of fact. *Id*. at 65a-73a. He also concluded that that *Lunar News* article and another similar article could not render the claims obvious. *Id*. at 73a-91a He further found that Merck's secondary considerations strongly weighed in favor of his ultimate legal conclusion that the invention was not obvious. *Id*. at 91a-94a.

1. The Claim Construction Issue

The district court held that the '329 patent expressly defines the "about 70 mg" and "about 35 mg" phrases by explaining that the terms account for the variability in active ingredient weight that would result from the use of alendronic acid derivatives. App., *infra*, 61a-62a. The specification says:

> Because of the mixed nomenclature currently in use by those of ordinary skill in the art, reference to specific weight * * * of a bisphosphonate compound in the present invention is on an acid active weight basis * * *. For example, *the phrase* "about 70 mg of a bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof, and mixtures thereof, on an alendronic acid active weight basis" *means that the amount of the bisphosphonate compound selected is calculated based on 70 mg of alendronic acid*.

C.A. App. 3594-95 (c10, l.65, to c.11, l.8) (emphasis added). The patent specification was exceptionally clear as to the meaning of the "about" phrase: any mention of a "specific weight" was to be standardized by reference to its acid form.

As defined by the specification, the "about 70 mg" and "about 35 mg" phrases adjust the weight of the active ingredient by taking into account variances in molecular weight for alendronic acid derivatives. As construed by the district court, the claim language requires that the amount of the alendronic acid derivative in the tablet be adjusted so that the tablet contains the same number of alendronate core molecules as 70 or 35 mg of alendronic acid. App., *infra*, 62a.

Attempting to parse the individual words from the defined phrase, Teva argued that "about" simply meant "approximately" – as if the patent had made no attempt to define the phrases that contain the word "about." The district court recognized that Teva's proposition that "about" means "approximately" was utterly implausible given that the patent's examples carefully denote the resulting quantity of alendronate derivative for its formulations to one-hundredth of a milligram. See App., *infra*, 62a-64a.[4]

The word "about" was placed within the quotation marks circumscribing the phrase being defined. See page 7, *supra*. The specification defines the phrase within the quotation marks as being calculated "based on 70 mg" and not "based on about 70 mg." Teva's construction required casting aside the patent's precise definition and moving the term "about" outside the quotation marks of the defined phrase or inserting the term "about" into the "based on 70 mg" definition.

Even Teva's expert, Dr. Russell, reluctantly but unambiguously accepted the '329 patent's explicit definition:

> Q. But they gave you that exact definition; correct?
>
> A. It's a curious use of the English language.
>
> Q. I understand, but it is what it says, and perhaps the person wanted to say if it's a certain salt one, you might use 71, and if it's a certain salt 2, you might use 73. Isn't that what's indicated in this?
>
> A. Possibly.

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[4] By accounting for the differences in the weights of alendronate derivatives, such usage is precise, not approximate. Examples 7 and 8 in the '329 patent provide for "about 35 mg of alendronate, on an alendronic acid active basis" and "about 70 mg of alendronate monosodium trihydrate, on an alendronic acid active basis." C.A. App. 3599 (c19, l.13-15, 44-45). Those examples show that the adjusted weight for the alendronate derivative used is 45.68 mg and 91.35 mg respectively. *Id.* (c.19, l.20, 51).

Q. But that's what the definition says; right?

A. *That is the definition as it's described in the patent*.

C.A. App. 432-35 (emphasis added). Relying on both intrinsic and extrinsic evidence, the district court rejected Teva's construction based on the term "about." App., *infra*, 61a-64a.

2. Teva's Invalidity Defenses

Teva's invalidity defenses centered around two articles in the *Lunar News*. C.A. App. 3655-90. As the district court found, the *Lunar News* was not a scientific publication, but a quarterly newsletter of short, unattributed articles about multiple topics, published as a marketing tool by Lunar, a bone densitometer manufacturer. App., *infra*, 70a & n.1; C.A. App. 222-23, 321-22, 4957, 4959-60. Dr. Richard Mazess, Lunar's CEO, wrote most of the articles. C.A. App. 4954-56.

Dr. Mazess's one-page article entitled "Update: Bisphosphonate" in the July 1996 *Lunar News* observed that "[s]ome United States physicians are reluctant to treat because of: a) side effects; b) difficulty of dosing; and c) high costs ($700/year)." A3677. Near the end, without any supporting citation, that article suggests that "[e]ven alendronate potentially could be given in a 40 or 80 mg dose once/week to avoid dosing problems and reduce costs." *Id*.

The district court expressly found that "the prior art cited * * * demonstrates that the suggestion to give 40 or 80 mg of alendronate sodium to treat or prevent osteoporosis was not clinically useful or obvious in July 1997 because of the known dose-related gastrointestinal side effects." App., *infra*, 89a-90a. Moreover, even looking only at the two *Lunar News* articles,[5] the district court found that, "in light of the [clinical] case re-

[5] Teva relied on a *Lunar News* article from April 1996, as well as the July 1986 article, in its obviousness defense. C.A. App. 3641. Suffering from even more defects than the July 1996 issue, the April 1996 *Lunar News* did not disclose any doses at all and failed to address the well-known expectation of gastrointestinal side effects with higher doses. *Id*.

ports, and the Chestnut study, in conjunction with observations written about alendronate by Dr. Fleis[c]h,[6] * * * the *Lunar News* references did not render the seven-fold daily dose of alendronate * * * obvious given the clearly documented and known dose related gastrointestinal side effects associated with high doses (over 20 mg) of oral alendronate." App., *infra*, 91a.

Those factual issues were disputed at trial, and were the subject of much evidence and expert testimony. The district court found that the evidence established that persons skilled in the art at the time of Merck's invention would have been skeptical of the *Lunar News* suggestion to try 40- and 80-mg doses in light of the dose-related gastrointestinal problems. App., *infra*, 90a. The support for that finding came from the trial evidence from the acknowledged experts in the art, including Drs. Papapoulos, Chestnut, Fleisch, and Fennerty, and even Teva's Dr. Russell. The district court expressly noted that Dr. Fennerty was "very credible" when explaining why any physician would have been "extraordinarily concerned" to suggest a 40- or 80-mg dose for osteoporotic patients. *Id.*

In contrast, the district court recognized that Dr. Mazess, the author of the *Lunar News* articles, "[did] not possess an MD, has no formal training in pharmacology, and obtained his bachelors degree and Ph.D in anthropology." App., *infra*, 70a n.1. Given that Judge Farnan also found for purposes of the *Graham* factors that a person of ordinary skill in the art was "an individual who would have an M.D. and/or Ph.D. and was working in the field of and doing research on osteoporosis" (App., *infra*, 84a), Dr. Mazess's expertise fell short of the osteoporosis treatment experts that were the source of the other evidence at trial. To rule in Merck's favor, the district court did not have to go so far as to deem Dr. Mazess not an expert at all; rather, it sufficed to find Dr. Mazess *less credible* than other experts – just what finders of fact do in all types of complex cases.

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[6] As the district court recognized, Dr. Fleisch is known as the "father of bisphosphonates" due to his extensive work and authorship of the leading treatise in the field. App., *infra*, 85a.

Finally, the district court found that "the significant secondary considerations offered by Merck undermine any claim of obviousness." App., *infra*, 94a. The court found Merck's expert testimony "persuasive" in explaining the increased sales after the launch of the once-weekly FOSAMAX® product, without any corresponding increase in expenditures, and noted a sharp increase in physician adoption of FOSAMAX® after introduction of the weekly regimen. App., *infra*, 91a-92a. In contrast, the district court found Teva's expert to be "unpersuasive." App., *infra*, 93a.

C. Proceedings In The Federal Circuit

In a 2-1 decision, the Federal Circuit reversed the district court's judgment, disagreeing with its claim construction and holding the asserted claims invalid for obviousness as a matter of law. See App., *infra*, 2a.

1. The Reversal On Claim Construction

In reversing the district court's claim construction, the court first redefined the parties' dispute as being over the meaning of the word "about" rather than the entirety of the phrases in the claims where that term appears. Declaring the definition of those phrases in the specification "ambiguous," the Federal Circuit believed itself free to give "about" its ordinary meaning of "approximately" because the specification had not redefined that term. App., *infra*, 2a, 10a & n.7, 15a.

But the meaning of the term "about" was never in issue at the trial and was never litigated. The entirety of the phrase was the issue. To sidestep Merck's irrefutable position about what the words of the patent specification actually say, the majority simply declared that the drafters made a mistake: "While Merck's grammatical savvy is noted, we believe that the omission of a second 'about' is likely an inadvertent error rather than the product of meticulous claim drafting." App., *infra*, 13a n.8. Not even Teva had asserted such an inadvertent drafting error, and there was *no* evidence to suggest one.

2. The Reversal Of The Nonobviousness Holding, Including The Nullification Of Merck's Demonstrated Commercial Success Evidence

Separately, the Federal Circuit held that Merck's two claims were invalid as a matter of law in light of the two *Lunar News* articles by reaching its own conclusion of obviousness, and then globally reweighing the evidence, making new findings on appeal, and – with unusual candor – universally rejecting contrary findings as "clearly erroneous." See, *e.g.*, App., *infra*, 22a (emphasis added) ("*to the extent* that the district court interpreted the scope of the prior art *otherwise*, that was clear error"). That inverted approach to reviewing the district court's strict and careful adherence to this Court's *Graham* factors accorded no deference to the district court's detailed findings on several pivotal and clearly disputed factual issues.

In addition, the Federal Circuit took a surprising approach to the law of secondary considerations – law emanating from *this* Court's *Graham* v. *John Deere* decision and numerous even earlier decisions of this Court. The court declared that Merck's dramatic "commercial success" evidence had "no force" on the ground that Merck's prior existing patent had "legally barred" anyone else from pursuing or testing any improvements to Merck's prior "daily" invention. App., *infra*, 23a-24a. Under that approach, an existing patent owner could ever prove commercial success of an improvement patent, in the pharmaceutical field or any other field.

3. The Dissenting Opinions

a. Judge Rader's Dissent

Judge Rader dissented from the panel decision, asserting that "[t]his case shows the consequences of paying only lip service to the often-cited, but rarely-followed lexicographer rule and the basic jurisprudential principle of according trial courts proper deference." App., *infra*, 26a. He observed that the Federal Circuit's claim construction rules are used as either "a subtle way for judges to impose their own semantic subjectivity

on claim terms" or "a way for judges to import limitations not included in the claims." *Id*.

Judge Rader explained why the word "about" was inseparable from the entire phrase defined in the specification, and pointed out that the specification set off the entire phrase in quotation marks, including the term "about," and expressly stated what that phrase "means" for purposes of the patent. App., *infra*, 28a-29a. Judge Rader understood that the specification explained why the phrase was being defined – "[b]ecause of the mixed nomenclature currently in use by those o[f] ordinary skill in the art" – and revealed the scientific reason for including "about" in its definition – "[a] salt or a mixture may require a different weight to achieve the same number of bisphosphonate molecules present in 70 mg of alendronate." *Id*. at 29a-30a.

Judge Rader concluded by decrying his own court's inability or refusal to give deference to the efforts and conclusions of district courts in matters of claim construction. "This was the classic 'close case,' so close in fact that ultimately two federal judges (one of whom conducted an entire bench trial on this issue) and the United States Patent and Trademark Office agreed with [Merck] and two federal judges agreed with [Teva]." App., *infra*, 32a. Despite the district court's "superior tools and time" to evaluate the record, the witnesses, and the evidence, he noted that the Federal Circuit often "becomes enamored with its own analysis of a very close issue and reverses the district court." *Id*. As he put it, the court has a double-edged "'truth in advertising' problem" when it comes to giving deference to district courts. *Id*. at 33a-34a.

b. The Dissent Of Three Additional Judges

Judge Lourie, joined by Chief Judge Michel and Judge Newman, dissented from the denial of rehearing en banc. App., *infra*, 38a-39a. In their view, the panel majority erroneously concluded that commercial success is not probative because "others were legally barred" from commercially testing certain ideas and because the majority erred in linking commercial success to the failure of others. App., *infra*, 38a.

Judge Lourie explained that "[c]ommercial success is a question of fact, and, once it is established, as found here by the trial court, the only other question is whether the success is attributable to the claimed invention ('nexus')." App., *infra*, 38a. In the view of those dissenting judges, "[t]he panel's rule is especially unsound in the context of an improvement patent, as here, because it holds in effect that commercial success for an improvement is irrelevant when a prior patent dominates the basic invention." *Id.* at 38a-39a. "[T]he full court should have reheard the appeal to eliminate the confusion in the law that the panel opinion creates." *Id.* at 39a.

REASONS FOR GRANTING THE PETITION

When Congress created the United States Court of Appeals for the Federal Circuit in 1982, it centralized the *appellate* function in patent cases. The *trial* function remains with district courts around the country, following normal trial procedures. Nothing gives the Federal Circuit more reason than any other appellate court to substitute its judgment on *factual* issues for that of a district court that has held a trial. Yet the Federal Circuit is doing just that – by allocating to itself the power of *de novo* review, by giving lip service to the "clearly erroneous" rule but then transparently failing to apply it, and most recently by robbing of all substance an important criterion established by this Court for determining obviousness.

All of this has provoked howls of outrage from some of the Federal Circuit's own judges. See App., *infra*, 26a (Rader), 38a-39a (Lourie); *Phillips* v. *AWH Corp.*, 376 F.3d 1382, 1384 (Fed. Cir. 2004) (Mayer, C.J., dissenting from en banc order) ("Until the court is willing to reconsider its holdings * * * that claim construction is a pure question of law subject to *de novo* review in this court, any attempt to refine the process is futile. * * * [S]huffling our current precedent merely continues a charade * * *."); *Phillips* v. *AWH Corp.*, No. 03-1269, 2005 WL 1620331, at *22-*26 (Fed. Cir. July 12, 2005) (en banc) (Mayer, J., dissenting). There is a war on within the Federal Circuit, and only this Court can stop the fighting and bring the Federal

Circuit's approach to factual issues in line with the approach of other appellate courts.

The open disagreement among judges of the Federal Circuit suggests that now is a particularly appropriate occasion for this Court to oversee how that court is handling its exclusive appellate docket. In 1986 this Court felt constrained to remind the Federal Circuit of the proper role of appellate courts in reviewing findings of fact. *Dennison Mfg. Co.* v. *Panduit Corp.*, 475 U.S. 809, 811 (1986). The Federal Circuit has not been alone in needing such supervision from this Court for failing to defer on factual issues.[7] Moreover, this is a case in which the standard of review mattered – the district court's exhaustive opinion, heavily dependent on factual findings including credibility determinations after a trial, could not have been reversed on either claim construction or obviousness by a court truly engaged in deferential review of the facts. And one of the most important patents in the pharmaceutical field has been invalidated because the Federal Circuit overstepped its bounds.

Furthermore, this case usefully complements *Markman* v. *Westview Instruments, Inc.*, 517 U.S. 370 (1996). In that case this Court almost a decade ago held that patent claim construction is an issue exclusively for "the court" but said nothing to indicate whether "the court's" findings following a trial should be reviewed deferentially – as factual findings underlying an issue reserved for judicial determination usually are. See, *e.g.*, *Ornelas* v. *United States*, 517 U.S. 690, 699 (1996); *Cooter & Gell* v. *Hartmarx Corp.*, 496 U.S. 384, 402 (1990); *Pierce* v.

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[7] See, *e.g.*, *Amadeo* v. *Zant*, 486 U.S. 214, 223 (1988); *Icicle Seafoods, Inc.* v. *Worthington*, 475 U.S. 709 (1986); *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 574 (1985); *Inwood Labs., Inc.* v. *Ives Labs., Inc.*, 456 U.S. 844 (1982); see also *Ornelas* v. *United States*, 517 U.S. 690, 699 (1996) (after holding that the standard of appellate review of ultimate determinations of probable cause or reasonable suspicion is *de novo*, "hasten[ing] to point out that a reviewing court should take care * * * to review [underlying] findings of historical fact only for clear error"). See generally 1 CHILDRESS & DAVIS, FEDERAL STANDARDS OF REVIEW § 2.08 (3d ed. 1999).

Underwood, 487 U.S. 552, 560 (1988); *Miller* v. *Fenton*, 474 U.S. 104, 114-115 (1985).

The court compounded its lack of deference by announcing an erroneous, new, and far-reaching principle of law that the commercial success criterion announced in this Court's cases can be disregarded whenever a patentee obtains an improvement patent. On all three questions presented, the Federal Circuit has decided important issues contrary to this Court's precedents, and this case presents an excellent vehicle for addressing Federal Circuit practices that have become problematic as the court regularly reverses district courts' proper, fact-dependent holdings on both claim construction and obviousness.

I. This Court Should Review The Federal Circuit's Strident But Erroneous View That There Is No Evidentiary Factfinding In Patent Claim Construction

The Federal Circuit's *de novo* standard of review as applied indiscriminately to facts underlying claim construction has afforded that court the extraordinary license to reverse district court findings that could not have been reversed under any other standard. The *de novo* standard, adopted by the Federal Circuit in two en banc decisions and recently reaffirmed en banc, is ripe for this Court's review. The standard is plainly wrong, and this case presents an excellent vehicle for reviewing it.

A decade ago, the Federal Circuit held in *Markman* v. *Westview Instruments, Inc*., 52 F.3d 897 (Fed. Cir. 1995) (*Markman I*), aff'd in part, 517 U.S. 370 (1996) (*Markman II*), that "the interpretation and construction of patent claims, which define the scope of the patentee's rights under the patent, is a matter of law exclusively for the court." 52 F.3d at 970. The en banc also declared that there were no findings of fact to be made by a court (*id*. at 981 (emphasis added)):

> Through this process of construing claims by, among other things, using certain extrinsic evidence that the court finds helpful and rejecting other evidence as unhelpful, and resolving disputes en route to pronouncing the meaning of

> claim language as a matter of law based on the patent documents themselves, *the court is not crediting certain evidence over other evidence or making factual evidentiary findings*. * * * The district court's claim construction, enlightened by such extrinsic evidence as may be helpful, is still based upon the patent and prosecution history. *It is therefore still construction, and is a matter of law subject to de novo review*.

In *Markman II*, this Court held that "the construction of a patent * * * is exclusively within the province of the court," 517 U.S. at 372, but did not call the question one of law or address the standard of appellate review. Instead, this Court focused on allocating claim construction as between court or jury, and concluded that "judges, not juries, are the better suited to find the acquired meaning of patent terms." *Id*. at 388. The Court unmistakably focused, however, on the claim construction task as performed by *trial* judges (*id*. at 389-90 (emphasis added)):

> [I]n these cases a jury's capabilities * * * are much less significant than a trained ability to ***evaluate the testimony*** in relation to the overall structure of the patent. The decisionmaker vested with the task of construing the patent is in the better position to ascertain whether an expert's proposed definition fully comports with the specification and claims and so will preserve the patent's internal coherence. We accordingly think there is sufficient reason to treat construction of terms of art like *many other responsibilities that we cede to* ***a*** *judge in the normal* ***course of trial***, ***notwithstanding its evidentiary underpinnings***.

Nonetheless, again sitting en banc in *Cybor Corp.* v. *FAS Techs., Inc*., 138 F.3d 1448, 1456 (Fed. Cir. 1998), the Federal Circuit announced that under *Markman II* it was permitted to "review claim construction *de novo* on appeal including any allegedly fact-based questions."

The Federal Circuit insists that claim construction is a question of law for the court, and that it follows that the appellate court is entitled to give all aspects of claim construction *de novo*

review without deference to factual findings. Those concepts are not the same, however, and not all questions reserved for the court are reviewed *de novo*. Indeed, there is no reason why claim construction should be different in this regard from patent validity, as to which this Court has emphasized that "the ultimate question * * * is one of law," but pointed out in the same sentence that a subsidiary question "lends itself to several basic *factual* inquiries." *Graham*, 383 U.S. at 17 (emphasis added). Just as *Graham* acknowledged factual inquiries underlying obviousness, *Markman II* acknowledged "evidentiary underpinnings" of claim construction, 517 U.S. at 390. The two issues should receive parallel treatment.

Last month, the Federal Circuit issued its eagerly awaited en banc decision in *Phillips* v. *AWH Corp.*, No. 03-1269, 2005 WL 1620331 (Fed. Cir. July 12, 2005). Despite numerous amicus briefs urging it to abandon the holdings of *Markman I* and *Cybor*, the court without substantive comment, and over vehement dissent, "decided not to address that issue at this time * * * [and] therefore le[ft] undisturbed [its] prior en banc decision in *Cybor*." 2005 WL 1620331, at *20. The three en banc holdings that there is no deference-worthy factual component to claim construction are the source of the Federal Circuit's current and internally recognized quagmire.

The fiction that district courts never weigh evidence or find facts when deciding the meaning of patent claims has – in little more than a decade – proved itself to be unworkable and increasingly arbitrary.[8] The most recent and comprehensive study

[8] See *Phillips* v. *AWH Corp.*, 376 F.3d at 1384 (Mayer, C.J., dissenting from en banc order) ("Nearly a decade of confusion has resulted from the fiction that claim construction is a matter of law, when it is obvious that it depends on underlying factual determinations which, * * * if disputed, are * * * reviewable on appeal for clear error."); *Phillips*, 2005 WL 1620331, at *22 (Mayer, J., dissenting) ("Now more than ever I am convinced of the futility, indeed the absurdity, of this court's persistence in adhering to the falsehood that claim construction is a matter of law devoid of any factual component. * * * [A]ny attempt to fashion a coherent

of all Federal Circuit decisions since *Markman II* through 2003 calculated that the reversal rate for appealed claim terms is 34.5%. Moore, *Markman Eight Years Later: Is Claim Construction More Predictable?*, 9 LEWIS & CLARK L. REV. 231, 233 (2005) (citing other empirical studies). That extremely high reversal rate is well over three times the average for all circuits combined, which has been below 10% each year between 2001 and 2004.[9] Professor Moore concluded that "[t]he problem is getting worse, not better," noting that, since *Markman II*, there should be more predictability in claim construction, not less, and the reversal rate should be going down, not up, but the opposite is true in both respects. *Id*. at 245-47.

Not only has the Federal Circuit's flawed premise that there is no fact finding in claim construction directly caused increased unpredictability, uncertainty, litigation costs, and reversal rates, but also it has damaged the court's credibility and legitimacy in the eyes of both litigants and district courts. *Phillips*, 2005 WL 1620331, at *24 (Mayer, J., dissenting) ("that claim construction is dependent on underlying factual determinations has been verified by our experience, which shows that reviewing these questions de novo has not clarified the law, but has instead distort[ed] the appellate process, causing confusion among the district courts and bar") (internal quotation marks omitted). Any hope that the Federal Circuit's *en banc* decision in *Phillips* might confront the real problem ended when the court declined to disturb its prior decision in *Cybor*. See 2005 WL 1620331, at *20. Hence, the Federal Circuit's unjustifiable fiction authorizing its form of "*de novo* review" should not escape this Court's oversight any longer.

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standard under this regime is pointless, as illustrated by our many failed attempts to do so * * *.").

[9] See http://www.uscourts.gov/caseload2004/tables/B05Mar04.pdf; http://www.uscourts.gov/caseload2003/tables/B05Mar03.pdf; http://www.uscourts.gov/caseload2002/tables/B05Mar02.pdf; http://www.uscourts.gov/caseload2001/tables/B05Mar01.pdf.

To be sure, construing patent claims involves construing a written instrument, a task better allocated to judges than to juries. But that does not mean claim construction has no factual component. As a matter of substantive patent law, the issue is not what the claims *mean to judges*, but what they mean to "those skilled in the art to which the invention pertains or with which it is most nearly connected." *Phillips*, 2005 WL 1620331, at *5 (opinion of the court) (quoting *In re Nelson*, 280 F.2d 172, 181 (CCPA 1960)). That is a matter most frequently resolved by weighing evidence, not by parsing legal principles. Factual, not legal, inquiry is necessary to educate a court about the views of those skilled in the art, especially because "patentees frequently use terms idiosyncratically" (*Phillips*, 2005 WL 1620331, at *6), as was done in this case. It follows that the standard of appellate review is that usually applied to factual findings underlying a question for the court. See note 7, *supra*; pages 15-16, *supra*; *Phillips*, 2005 WL 1620331, at *23 (Mayer, J., dissenting). For the Federal Circuit to hold otherwise, simply because it believes the *ultimate* issue is one of law, is nothing but a power grab away from district judges.[10]

Even with proper deference accorded to district courts under Rule 52(a), some claim construction issues may be decided as a matter of law, when, for example, the patent itself and other evidence show that there is only one *reasonable* way to construe the affected term.[11] In other instances, however, a pat-

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[10] See App., *infra*, 32a-34a (Rader, J.., dissenting); *Phillips*, 2005 WL 1620331, at *22 (Mayer, J., dissenting) ("This court was created for the purpose of bringing consistency to the patent field. * * * Instead, we have taken this noble mandate, to reinvigorate the patent and introduce predictability to the field, and focused inappropriate power in this court. * * * [T]he resulting mayhem has seriously undermined the legitimacy of the process, if not the integrity of the institution.").

[11] Ironically, this was such a case. Yet the majority dismissed the only reasonable reading of the patent's explicit definition as mere "grammatical savvy," and insisted on substituting its judgment that there was an "inadvertent error" for the judgment of the district court, the words of the patent, and the expert testimony. App., *infra*, 13a n.8. By disregard-

ent's intrinsic evidence will be obscure or inconclusive. Shortly after *Markman I*, the Federal Circuit in *Hoechst Celanese Corp.* v. *BP Chems. Ltd.*, 78 F.3d 1575, 1578 (Fed. Cir. 1996), reviewed the intrinsic evidence, experimental data, expert testimony, and dictionaries to determine the meaning of the disputed term in the specification's definition, while being careful to say that it did not accord any deference to the district court's findings or credibility determinations. Nevertheless, the Federal Circuit conceded it was "necessary to rely on the evidence presented at the trial and credit certain evidence over other evidence" when construing claims. *Id*. at 1579. That is what all courts do in such situations, even if the Federal Circuit's en banc decisions in *Cybor* and *Markman I* insisted they do not.[12]

A court's determination of the meaning of a disputed claim phrase, in an environment that requires consideration of what the claim terms meant to a person of skill in the art at the time, inevitably involves weighing conflicting evidence. Here, for example, Judge Farnan explicitly found Teva's expert "unpersuasive." App., *infra*, 64a. Resolving such conflicts requires factfinding, the prototypical task for which district courts are best suited and entitled to deference. See *Zenith Radio Corp.* v.

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ing the patent's definition in its entirety, the Federal Circuit gutted a patentee's ability to act as its own lexicographer to avoid the uncertainties of a future contested claim construction. See App., *infra*, 26a-32a (Rader, J., dissenting).

[12] See App., *infra*, 32a (Rader, J., dissenting) ("Despite the district court's superior tools and time to evaluate the complete record, to hear and inquire from expert and fact witnesses, to delve into countless related details, to probe the scientific and semantic context, and to entertain argument as long as necessary for clarity, this court with its reading three briefs before its half-hour hearing becomes enamored with its own analysis of a very close issue and reverses the district court."); *Phillips*, 2005 WL 1620331, at *22 (Mayer, J., dissenting) ("[A]fter * * * whipping the bar into a frenzy of expectation, we say nothing new, but merely restate * * * that we will decide cases according to whatever mode or method results in the outcome we desire * * *. [T]here can be no workable standards by which this court will interpret claims so long as we are blind to the factual component of the task.").

Hazeltine Research, Inc., 395 U.S. 100, 123 (1969). What this Court said last Term about tax cases is no less true of patent cases: "The officer who hears witnesses and sifts through evidence in the first instance will have a comprehensive view of the case that cannot be conveyed full strength by a paper record." *Ballard* v. *Comm'r*, 125 S. Ct. 1270, 1283 (2005). "It is, of course, true that credibility judgments have to be made about the experts who testify in patent cases" (*Markman II*, 517 U.S. at 389), and that fact – although no reason to assign factfinding to juries – is very much a reason to review deferentially on appeal the factual component of claim construction. One month after *Markman II*, this Court announced a *de novo* standard of review for probable-cause determinations in search-and-seizure cases but insisted on "clear error" review for "findings of historical fact." *Ornelas*, 517 U.S. at 699. This Court's opinions thus disprove the Federal Circuit's inference that, because claim construction is for the court, *de novo* review applies to all aspects of the issue.

This "standard of review" controversy generated by the Federal Circuit's en banc precedent extends well beyond the enormous dollars at issue in this case. This case provides an excellent vehicle to resolve the dispute within the Federal Circuit and rampant within the affected legal community over whether district courts engage in factfinding subject to Rule 52(a) when construing the meaning of patent claims.[13] When the judicial

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[13] In addition to the strong disagreement within the Federal Circuit reflected by the dissenting opinions in the en banc cases, see, *e.g.*, *Lucas Aerospace, Ltd.* v. *Unison Indus., L.P.*, 890 F. Supp. 329, 333-34 (D. Del. 1995) ("when the Federal Circuit Court of Appeals states that the trial court does not do something that the trial court does and must do to perform the judicial function, that court knowingly enters a land of sophistry and fiction"); Burgess, Comment, *Simplicity At The Cost Of Clarity: Appellate Review Of Claim Construction And The Failed Promise of Cybor*, 153 U. PA. L. REV. 763 (2004); Zura, *Looking For Fire Amidst The Smoke – Is The Federal Circuit Really Exceeding Its Appellate Authority In Patent Infringement Cases?*, 12 U. BALT. INTELL. PROP. L.J. 1 (2003); Staheli, Comment, *Deserved Deference: Reconsidering*

process for claim construction allows the Federal Circuit to invent a factual premise advanced by no party and supported by no evidence – that an inadvertent drafting error took place (App., *infra*, 13a n.8) – it becomes clear that factfinding is occurring in the wrong court. And when the Federal Circuit supplants the trial court's plausible choice between two reasonable interpretations of Merck's "ambiguous" definition for the disputed phrase in claims 23 and 37 (App., *infra*, 13a), it is apparent that the deferential review provisions of Rule 52(a) are being ignored.[14] As Judge Rader noted, "In this case, this court eschews all deference, a particularly striking choice in the face of a very close case and a district court whose diligent and intelligent process and resolution earned more respect than it received." App., *infra*, 33a (dissenting opinion).

The Federal Circuit will never voluntarily relinquish its self-granted power of unrestricted review. See App., *infra*, 10a n.7; *Phillips*, 2005 WL 1620331, at *20. The Federal Circuit has begun expanding its flawed "*de novo*" rationale into other areas of patent law "related to" claim construction. See, *e.g.*, *Exxon Research & Eng'g Co.* v. *United States*, 265 F.3d 1371, 1376 (Fed. Cir. 2001) (holding the invalidity defense of indefiniteness was sufficiently tied to claim construction that it did

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The De Novo Standard Of Review For Claim Construction, 3 MARQ. INTELL. PROP. L. REV. 181 (1999).

[14] In a footnote, the majority defensively asserted that "[i]t makes no difference to this conclusion [of invalidity] whether the court begins with the claim construction set forth by the panel or the dissent." App., *infra*, 16a n.10. Clearly, however, the parties' claim constructions were different, both could not have been right, and there is no question that obviousness can be properly determined only in view of the correct claim construction. The Federal Circuit, indeed, contradicted its own footnote by beginning its obviousness discussion by saying, "*In light of* the corrected claim construction we find reversible error in the district court's obviousness analysis." App., *infra*, 15a (emphasis added). If claim construction truly did not matter, the issue would not have been hotly litigated throughout this case and the Federal Circuit would not have addressed that issue at length on appeal.

not involve underlying issues of fact) (citing *Cybor*). Thus, as further evidenced by its obviousness ruling in this case, the Federal Circuit's basic misunderstanding of "*de novo* review" is not confined to claim construction issues, but infects that court's approach to anything that it perceives as a "legal issue." This Court should not wait to correct that entrenched and erroneous practice.

II. The Court Should Review The Federal Circuit's Practice Of Using Its *De Novo* Review Of Legal Issues To Reweigh Evidence And Substitute Its Views For A District Court's Factual Findings

In *Dennison Mfg. Co.* v. *Panduit Corp.*, 475 U.S. at 811, this Court summarily vacated a Federal Circuit decision that had reversed a district court's holding of obviousness, noting that the determinations on the *Graham* factors and secondary considerations (including commercial success), "at the least, ought to be subject to [Rule 52(a)]." Now, almost 20 years later, the Federal Circuit needs a refresher course.

Of course, since 1986, the Federal Circuit's decisions on obviousness have routinely cited Rule 52(a) and the *Graham* factors. See App., *infra*, 8a, 16a. Just as routinely, however, the Federal Circuit pays lip service to Rule 52(a) but then reweighs the conflicting evidence to conform to its own conclusion on the ultimate legal issue. See App., *infra*, 26a (Rader, J., dissenting).

This case is the latest and most striking example of a bench trial nullified by the Federal Circuit's self-granted license to review findings of fact without any real deference.[15] As its own opinion in this case illustrates, the Federal Circuit arrives at its outcome, and then globally mows down any contrary finding with a declaration of clear error. That result-oriented approach

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[15] See Rooklidge & Weil, *Judicial Hyperactivity: The Federal Circuit's Discomfort With Its Appellate Role*, 15 BERKELEY TECH. L.J. 725 (2000) (explaining the Federal Circuit's increasing tendencies toward appellate factfinding, creating new records on appeal, and raising new arguments on its own, citing illustrative cases).

of first deciding the legal issue *de novo* and then going back to review the underlying factual determinations cannot possibly accord the proper Rule 52(a) deference to a district court's findings on disputed factual issues. See App., *infra*, 32a-34a (Rader, J., dissenting).

"If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently." *Anderson* v. *City of Bessemer City*, 470 U.S. 564, 573-74 (1985). "Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous." *Id*. at 574. Here, the district court's exhaustive findings on disputed factual issues reached after a fully litigated bench trial could not have been legitimately cast aside.

For present purposes, this Court need only recognize that the district court's factual findings are both plausible and fully supported by the cited evidence and expert testimony. See App., *infra*, 90a (finding Merck's expert "very credible"); *id*. at 93a (finding Teva's expert "unpersuasive"). "When findings are based on determinations regarding the credibility of witnesses, Rule 52(a) demands even greater deference to the trial court's findings." *Bessemer City*, 470 U.S. at 565.

But the Federal Circuit did more than substitute one plausible set of findings for the district court's different findings. The district court found that persons skilled in the art at the time of Merck's invention would have been skeptical of the *Lunar News* suggestion to try 40- and 80-mg doses in light of the dose-related health problems. App., *infra*, 90a. The Federal Circuit accepted that finding (App., *infra*, 19a), but then proceeded to elevate Dr. Mazess's alleged expertise over all others, holding that "the district court failed to give proper credit to the fact that Dr. Mazess was an expert in osteoporosis." App., *infra*, 22a. Any such issue of "proper credit" is a disagreement on weight, which should not have been revisited on appeal or circumvented simply by declaring Mazess an "expert."

The Federal Circuit's post-trial revision of Dr. Mazess's skill level is disingenuous. Even if Dr. Mazess qualified as an expert, the trier of fact was entitled to find him *less credible* than other experts, and did so. App., *infra*, 90a-91a. The testimony the district court accepted was that the *Lunar News* suggestion would have been incredible to anyone skilled in the relevant art. Hence, only someone unskilled in the relevant art would even have suggested investigating 80-mg doses when everyone with actual skill in the art was unwilling to give osteoporosis patients more than 20 mg.

In making its *Graham* findings on the scope and content of the prior art and the differences between that art and the claimed inventions, the district court properly looked at what a number of individuals skilled in the art knew and examined all of the art before finding that the serious side effect concerns would have rendered the naked suggestion in the *Lunar News* articles to try higher doses "not clinically useful." App., *infra*, 90a. That treatment of those two articles was entirely proper. Even if they had been "published in peer-reviewed journals or authored by one skilled in the art," there could be no clear error in finding that they would not have overcome what one skilled in the art would have understood from the body of prior art as a whole.

Confining its analysis to the two *Lunar News* articles, the Federal Circuit improperly circumscribed the prior art and disregarded everything that taught away from the article's invitation to try. See *United States* v. *Adams*, 383 U.S. 39, 51-52 (1966) (known disadvantages in the prior art which would naturally discourage the search for new inventions may be considered in determining obviousness). Here, because those skilled in the art in 1997 would not have followed the unsupported July 1996 *Lunar News* suggestion, the finding that the *Lunar News* articles could not have overcome the teachings of the prior art as a whole again could not have been clearly erroneous.[16]

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[16] The prior art and the acknowledged skepticism in the art instead created a clear expectation that the *Lunar News* suggestion would fail. Such a demonstrated expectation of failure is the antithesis of a reason-

On appeal the Federal Circuit found that a motivation would have existed to reduce the 80/40-mg dose suggestions in *Lunar News* to the claimed 70/35-mg doses. App., *infra*, 16a-17a. As the district court realized, however, that was not even the correct inquiry. Instead, the relevant analysis was whether there would have been any motivation in the art to increase the dosage beyond the 20-mg level believed to cause unacceptable side effects. App., *infra*, 91a. Not even the Federal Circuit could find that anyone in 1997 would have been motivated to do that, which reveals that any necessary teaching or motivation could have been found only in hindsight.

If there was ever a case in which Rule 52(a) should have compelled accepting a district court's findings, it is this one. This case is therefore an excellent vehicle by which to correct the Federal Circuit's clear misapprehension of the concept and scope of its appellate "*de novo*" review while sparing this Court from becoming bogged down in the underlying factual disputes already plausibly resolved by the district court.

III. This Court Should Review The Federal Circuit's Ruling Nullifying The Probative Value Of A Patentee's "Commercial Success" Evidence Related To Its Improvement Patent

The Federal Circuit also held that the district court "erred in its weighing of secondary considerations of non-obviousness." App., *infra*, 22a. That, too, was not the Federal Circuit's prerogative to reassess. See *Inwood Labs., Inc.* v. *Ives Labs., Inc*., 456 U.S. 844, 856 (1982) ("Determining the weight and credibility of the evidence is the special province of the trier of fact."). This issue shares with the first two issues the characteristic that the Federal Circuit has unjustifiably substituted its judgment for that of the trier of fact, but it also involves separate *legal* considerations as to which the Federal Circuit departed from this Court's cases.

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able expectation of success. See, *e.g., Boehringer Ingelheim Vetmedica, Inc.* v. *Schering-Plough Corp*., 320 F.3d 1339, 1354 (Fed. Cir. 2003).

The commercial success criterion strongly supported the non-obviousness of Merck's "once-weekly" patent. As noted above, sales of FOSAMAX® skyrocketed following the insight that once-weekly doses could be effective without increased potential for gastrointestinal distress. Judge Farnan appropriately placed "importance" on this factor. App., *infra*, 93a.

In so doing, he followed this Court's cases faithfully. In *Smith* v. *Goodyear Dental Vulcanite Co.*, 93 U.S. 486, 495 (1876), the Court recognized commercial success as something that could "justify the inference" that an innovation "was, in truth, invention." The Court phrased it more strongly in *Minerals Separation, Ltd.* v. *Hyde*, 242 U.S. 261, 271 (1916): commercial success, "of itself, is persuasive evidence of * * * invention." In *Graham* v. *John Deere Co.*, 383 U.S. at 17-18, the Court reiterated (following a change in statutory law) that "[s]uch secondary considerations as commercial success" are important, and noted that "failure of others" is a *separate* "secondary consideration[]." See also *Goodyear Tire & Rubber Co.* v. *Ray-O-Vac Co.*, 321 U.S. 275, 279 (1944); *Krementz* v. *The S. Cottle Co.*, 148 U.S. 556, 560 (1893).

This Court, not the Federal Circuit, originated the commercial success criterion, and the Federal Circuit was not at liberty to reduce it essentially to a nullity whenever a patentee obtains an improvement patent. Yet the Federal Circuit declared that Merck's "commercial success" evidence "has *no force* in this case" because "others were legally barred from commercially testing the Lunar News ideas" due to Merck's other patent rights. App., *infra*, 23a (emphasis added). That ignores not only the decisions of this Court's cited above, but also the Constitution. See U.S. CONST. Art. I, § 8, cl. 8. Given that Congress is to "secure[e] for limited times to * * * Inventors the exclusive right to their * * * Discoveries" in exchange for full disclosure so that the public may benefit from and build on the patent's teachings, the Federal Circuit's misplaced reliance on others' having no incentive to improve patented inventions before patent expiration directly undermines

the fundamental purposes of the patent system. See 35 U.S.C. § 101 (patentable inventions include "any new and useful improvement"); *Gen. Elec. Co.* v. *Wabash Appliance Corp.*, 304 U.S. 364, 368 (1938) ("most inventions represent improvements on some existing article, process or machine"); see also *Graham*, 383 U.S. at 7 (Thomas Jefferson's "improvements on plows, to mention but one line of his inventions, won acclaim and recognition on both sides of the Atlantic").

The Federal Circuit's rule nullifying a prior patentee's commercial success evidence will also unjustly discriminate against patentees who continue to enrich the public by improving their inventions. If the rule is allowed to stand, a third party that develops and patents an improvement to an earlier patented invention can support its non-obviousness case by proving commercial success and nexus but the earlier patentee would be foreclosed from doing so. That distinction makes no sense, and threatens to undermine the patent system's basic goals of encouraging innovation and full disclosure to the public.

On that basis alone, the Federal Circuit's far-reaching new rule should be reviewed and reversed. See App., *infra*, 38a-39a (Lourie, J., dissenting). But the Federal Circuit's other justifications for nullifying Merck's strong commercial success evidence for its improved dosing regimen in the '329 patent are equally meritless. For example, the Federal Circuit ignored 35 U.S.C. § 271(e)(1), which provides certain "safe harbors" from infringement for testing of a new drug product. See *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 125 S. Ct. 2372, 2381 (2005); *Eli Lilly & Co.* v. *Medtronic Inc.*, 496 U.S. 661 (1990). Indeed, Teva was in fact doing research and seeking patents on other alendronate inventions, and had a strong incentive to develop Merck's present invention, both for purposes of licensing Merck and for obtaining its own exclusivities extending beyond the expiration of Merck's '077 patent. The fact that Teva filed an ANDA and challenged the '329 patent rather than waiting to market generic versions of Merck's "once-daily" products is a compelling admission of both the value of Merck's

improved "once-weekly" invention and the evidentiary significance of Merck's commercial success as support for the validity of the '329 patent.

Because the Federal Circuit's rule is based on such clearly flawed premises, it should be reviewed immediately. Because of that court's exclusive jurisdiction, no percolation is needed or likely. The Federal Circuit has already invoked that rule when vacating another commercial success finding supporting a non-obviousness ruling reached after a bench trial. See *Syntex (U.S.A.) LLC* v. *Apotex, Inc*., 407 F.3d 1371 (Fed. Cir. 2005). Citing this case, the Federal Circuit expanded its new rule by stripping commercial success of its longstanding status – based on decisions of this Court – as a unique secondary consideration, declaring that a high degree of commercial success permits merely an inference that others have tried and failed to reach a solution. *Id*. at 1383. No more patentees, cases, or improvements in any field should be subjected to the Federal Circuit's flawed new "commercial success" rule.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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AUGUST 2005

APPENDIX

APPENDIX A

United States Court of Appeals for the Federal Circuit

04-1005

MERCK & CO., INC.,

Plaintiff-Appellee,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellant.

DECIDED: January 28, 2005

Before RADER, GAJARSA, and PROST, Circuit Judges.

Opinion for the court filed by Circuit Judge GAJARSA.
Dissenting opinion filed by Circuit Judge RADER.

GAJARSA, Circuit Judge.

Teva Pharmaceuticals USA, Inc. ("Teva") appeals the final judgment of the United States District Court of Delaware, which, after a bench trial, found Merck & Co.'s ("Merck") U.S. Patent No. 5,994,329 (issued Nov. 30, 1999) ("the '329 patent") not invalid as anticipated or obvious. The district court further found the '329 patent to be enforceable, and the '329 patent claims 23 and 37 constructively infringed by Teva's Abbreviated New Drug Application ("ANDA") under 35 U.S.C. § 271 (e)(2)(A) of the Hatch-Waxman Act. Merck & Co., Inc. v. Teva Pharms. USA, Inc., 288 F. Supp.

2d 601 (D. Del. 2003) ("Merck"); Merck & Co., Inc. v. Teva Pharms. USA, Inc., No. 01-CV-0048, Order (D. Del. Sept. 24, 2003) (Final Judgment Order Pursuant to Fed. R. Civ. P. 54(b)) ("Final Judgment Order").[1]

We disagree with the district court's construction of the claim term "about" in claims 23 and 37 of the '329 patent. Because we further hold claims 23 and 37 obvious in light of the prior art, we vacate the judgment of the district court and hold the claims invalid and not infringed.

I. BACKGROUND

A. '329 Patent

Merck owns the '329 patent. The '329 patent, entitled "Method for Inhibiting Bone Resorption," teaches a method of treating and preventing osteoporosis through less-than-daily administration of bisphosphonate compounds. '329 patent, col. 1, II. 15-25. The patent was filed on August 14, 1998, and Merck stipulated at trial that it would not allege an invention date prior to July 22, 1997 for the claims at issue. Merck, 288 F. Supp. 2d at 606.

Bisphosphonates are a family of chemical compounds that are known to selectively inhibit the bone destruction process that contributes to osteoporosis and other bone diseases. '329 patent, col. 1, II. 45-50. Bisphosphonates include, among other compounds, alendronate, risedronate, tiludronate, pamidronate, ibandronate, zolendronate, and etidronate. Id. at col. 1, II. 54-65; col. 2, II. 28-31. At issue in

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[1] On appeal, Teva does not challenge the district court's determination that the '329 patent is enforceable or that it would be infringed by Teva's proposed drug product.

this case are once-weekly dosages of alendronate monosodium trihydrate.

Bisphosphonates are not readily absorbed by the gastrointestinal ("GI") tract. The medications thus require rigorous dosing instructions: a patient must take the medicine on an empty stomach and remain upright and fasting for thirty minutes after ingestion. '329 patent, col. 2, II. 3-24. In addition, the compounds are known to have adverse GI side effects that physicians believed to be related, in part, to (a) irritation to the patient's esophagus, or (b) the size of the dose. Id. at col. 2, II. 23-46.

Before the '329 patent issued, standard osteoporosis treatments consisted of small daily doses of bisphosphonates to avoid GI complications. Id. at col. 1, II. 54-61; col. 2, II. 34-35, 44-46. According to the patent, however, the adverse GI side-effects resulting from repetitive irritation to the GI tract were the primary concern in the field. Id. at col. 2, II. 65-67; col. 3, I. 57 - col. 4, I. 13. The inventors trumpeted the reduced-frequency dosing schedule disclosed in the '329 patent as decreasing the irritating effect of the compounds, as well as increasing patient compliance with the rigorous dosing instructions. Id. at col. 3, II. 57-64; col. 4, II. 14-23.

This case involves dependent claims 23 and 37 of the '329 patent. At trial, the parties agreed to cast the text of these claims in independent form, incorporating all the dependent limitations:

> 23. A method for treating osteoporosis in human comprising orally administering about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis, as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.

> 37. A method for preventing osteoporosis in human comprising orally administering about 35 mg of alendronate monosodium trihydrate, on an alendronic acid basis, as a unit dosage according to a continuous schedule having a dosing interval of once-weekly.

'329 patent, col. 21, II. 24-27 (claim 23) (emphasis added); col. 22, II. 24-26 (claim 37) (emphasis added). We note that the only differences between claim 23 and claim 37 are (1) the dosage amount of alendronate monosodium trihydrate (70 mg or 35 mg) and (2) whether the method is directed to treating or preventing osteoporosis.

Merck has Food and Drug Administration ("FDA") approval to market both a once-weekly and a relatively diminished daily dose of alendronate monosodium trihydrate, which it does under the trade name Fosamax. Merck, 288 F. Supp. 2d at 605.

B. Litigation

In late 2000, Teva amended an existing ANDA and sought FDA approval to market generic versions of Merck's once-weekly Fosamax supplement in 35 mg and 70 mg quantities.[2] Merck, 288 F. Supp. 2d at 605-06; Teva Br. at 4. Merck subsequently filed suit against Teva under 35 U.S.C. §

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[2] Teva filed one amendment for the once-weekly 70 mg dosage, and later filed another for the once-weekly 35 mg dosage. Merck, 288 F. Supp. 2d at 605-06. Merck separately sued Teva for infringement, under 35 U.S.C. § 271 (e)(2)(A), based on each ANDA amendment. Id. The district court consolidated those suits in the present action.

271 (e)(2)(A), alleging Teva's ANDA filing was an act of infringement.[3]

According to the trial court, Merck acted as its own lexicographer and through the specification redefined the ordinary meaning of "about" in claims 23 and 37 - which both parties agree has the ordinary meaning "approximately" - to something quite different. Merck, 288 F. Supp. 2d at 612-16. Thus, the district court concluded the terms "about 35 mg" in claim 37 and "about 70 mg" in claim 23 mean exactly 35 (or 70) mg of alendronic acid.[4]

Relying on this construction of "about," the district court dismissed Teva's allegations that the claims at issue were (1) anticipated by a July 1996 Lunar News article or (2) rendered obvious by an April 1996 Lunar News article combined with the July 1996 article.[5] The trial court found

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[3] The present case relates to another action between the two parties involving Merck's daily formulation of Fosamax. The district court found Teva's proposed generic daily alendronate compound would infringe Merck's patent on that drug, and this court affirmed that decision. Merck & Co. v. Teva Pharms. USA Inc., 347 F.3d 1367 (Fed. Cir. 2003). In this action the parties agreed to be bound by the judgment from this court on issues relating to the daily formulation. As a result, the only issues before the district court in this case related to the '329 patent. Merck, 288 F. Supp. 2d at 606.

[4] That is, the trial court construed "the disputed claim terms 'about 70/35 mg' to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories," Merck, 288 F. Supp. 2d at 616.

[5] Lunar News is a quarterly newsletter distributed to approximately 15,000 to 20,000 physicians and others in the medical art by Lunar Corporation, a manufacturer of bone densitometry equipment used to diagnose osteoporosis. Merck, 288 F. Supp. 2d at 618-19; Teva Br. at 11-12. The author of each article is Dr. Mazess, who has a doctorate degree in anthropology, but does not have formal training in pharmacology. Id.

both articles qualified as prior art publications under 35 U.S.C. § 102(a). Merck, 288 F. Supp. 2d at 618-19. The April 1996 article in Lunar News recommends weekly dosages of alendronate to improve patient compliance:

> [O]ne of the difficulties with alendronate is its low oral bioavailability. When taken with water in a fasting state, only about 0.8% of the oral dose is bioavailable. Even coffee or juice reduces this by 60%, and a meal reduces it by >85%. Alendronate must be taken, after an overnight fast, 30-60 minutes before breakfast. Subjects should remain seated or standing; a very small group of patients have reported some upper gastrointestinal distress if this is not done. This regime may be difficult for the elderly [to] maintain chronically. An intermittent treatment program (for example, once per week, or one week every three months), with higher oral dosing, needs to be tested.

Update: Bisphosphonate, Lunar News, Apr. 1996, at 31 (emphasis added).

The July 1996 Lunar News article further emphasizes the need for a once-weekly dose of Fosamax because "[s]ome United States physicians are reluctant to treat [patients with Fosamax] because of: a) side effects; b) difficulty of dosing; and c) high costs ($700/year)." The author suggests:

Teva points out, however, that Dr. Mazess directed the Bone Mineral Laboratory at the University of Wisconsin, established bone densitometry as a diagnostic tool, founded the first manufacturer of bone densitometry measuring equipment (Lunar), was Lunar's first president, has participated in and designed clinical trials for osteoporosis treatment, and is widely published in the bone disease field.

> The difficulties with oral bisphosphonates may favor their episodic (once/week) or cyclical (one week each month) administration. Even oral alendronate potentially could be given in a 40 or 80 mg dose once/week to avoid dosing problems and reduce costs.[6]

Update: Bisphosphonate, Lunar News, July 1996, at 23 (emphasis added).

Regarding anticipation, the trial court held the July 1996 article does not "expressly or inherently disclose the dosage amounts for alendronate in claims 23 and 37" because there was no evidence that 40 mg and 80 mg of alendronate contains "the same number of alendronate core molecules" as found in 35 mg and 70 mg, respectively, of alendronic acid. Merck, 288 F. Supp. 2d at 618-20.

As for obviousness, the district court concluded the suggestion of weekly treatment was not "clinically useful or obvious in July 1997 because of the known dose-related gastrointestinal side effects" associated with the daily formulation of Fosamax. Merck, 288 F. Supp. 2d at 628. Although it is undisputed that a once-weekly dosage was known to be efficacious, the court determined that the Lunar

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[6] Teva argues that the 40 mg and 80 mg amounts were recommended because 40 mg tablets of alendronate monosodium trihydrate were commercially available for those who suffer from Paget's disease, a bone disorder that also responds to bisphosphonate treatment. The standard daily dose of Fosamax is 5 mg or 10 mg. Exact multiples of the standard daily dose corresponding to the amount of Fosamax administered in a week, i.e., 35 mg or 70 mg, were not commercially available at the time of the 1996 Lunar News articles. Thus, Teva argues, the 40 mg and 80 mg dosages should be viewed as teaching the '329 patent's seven-fold increase in daily dosages (5 and 10 mg), in terms of the 40 mg doses then-available on the market.

News articles could not overcome doctors' concerns associated with higher dosages because the Lunar News articles were not published in peer-reviewed journals or authored by one skilled in the art. Merck, 288 F. Supp. 2d at 628-29.

Finding the '329 patent not invalid as anticipated or obvious, the district court delayed the effective date of the FDA approval of Teva's ANDA until the '329 patent expires and enjoined commercial sale of Teva's generic treatment. Final Judgment Order at 1. This appeal followed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II. DISCUSSION

A. Standard of Review

On appeal from a bench trial, this court reviews the district court's conclusions of law de novo and findings of fact for clear error. Golden Blount, Inc. v. Robert H. Peterson Co., 365 F.3d 1054, 1058 (Fed. Cir. 2004); Brown & Williamson Tobacco Corp. v. Philip Morris Inc., 229 F.3d 1120, 1123 (Fed. Cir. 2000). A finding is clearly erroneous when, despite some supporting evidence, "the reviewing court on the entire evidence is left with the definite and firm conviction that a mistake has been committed." United States v. United States Gypsum Co., 333 U.S. 364, 395 (1948).

The court reviews claim construction, a question of law, de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc). Obviousness is a question of law based on underlying factual determinations. Richardson-Vicks, Inc. v. Upjohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997). The court reviews an obviousness ruling de novo, but reviews the underlying factual findings for clear error. Graham v. John Deere Co., 383 U.S. 1, 17 (1966); Golden Blount, 365 F.3d at 1058. The underlying factual

determinations 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) objective indicia of nonobviousness. Graham, 383 U.S. at 17-18.

B. Claim Construction

In finding that Merck acted as its own lexicographer, the district court relied on the following passage from the specification:

> Because of the mixed nomenclature currently in use by those or [sic] ordinary skill in the art, reference to a specific weight or percentage of bisphosphonate compound in the present invention is on an active weight basis unless otherwise indicated herein. For example the phrase "about 70 mg of bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof and mixtures thereof, on an alendronic acid weight basis" means that the amount of bisphosphonate compound selected is calculated based on 70 mg of alendronic acid.

'329 patent, col. 10, I. 65 - col. 11, I. 8 (emphasis added). According to the district court's opinion, the patentee uses the phrase "about 35 [or 70] mg" to account for variations in the molecular weight of the different derivatives of alendronic acid and to deliver exactly 35 (or 70) mg of alendronic acid. Merck, 288 F. Supp. 2d at 613. For example, the court noted that alendronate monosodium trihydrate, which is used in Fosamax, requires an atom of sodium for each molecule. Id. at 613-14. If a heavier metal were chosen, such as potassium, the weight of the derivative compound would have to increase to deliver exactly the same number of molecules of

the active alendronate compound found in 35 [or 70] mg of alendronic acid. Id. at 614. The district court thus construed the term "about 35 [or 70] mg" to mean the amount of the derivative compound that gives exactly 35 [or 70] mg of the active compound.

We reverse the district court's construction of "about" and hold that such term should be given its ordinary meaning of "approximately."[7] To properly construe a claim term, a court first considers the intrinsic evidence, starting with the

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[7] The dissent frames the dispute in terms of the entire phrase "about 70 [35] mg of alendronate monosodium trihydrate, on an alendronic acid basis." Post at 2:22-3:2. Notwithstanding this contention, the district court identified the "disputed claim terms" as "about 70 / 35 mg." Merck, 288 F. Supp. 2d at 616. In its brief to this court, Merck likewise stated the issue as whether the district court properly construed the aforementioned limitation (not disputed term) on grounds that the '329 patent expressly defined "about 70 mg" as calculated "based on 70 mg of alendronic acid." See Appellee Br. at 3 (statement of issues). We agree with Merck, and the district court, that the dispute concerns the proper meaning of "about." We thus understand the dissent to argue that meaning is fixed by the context of the claim and the language of the written description.

It is correct to look first to those sources for the meaning at issue. See Vitronics, 90 F.3d at 1582. However, as is noted above when the intrinsic evidence does not clearly establish its own lexicography, it is proper to determine the ordinary meaning of the term. For that reason we ascribe "about" its ordinary meaning here.

Moreover, the dissent pursues a philosophical argument as to the deference which should be given to the trial court. Claim construction being a legal matter it is reviewed de novo and this is still the law notwithstanding the desire of some members of this court to consider creating an exception to that rule. See Cybor, 138 F.3d at 1462-63 (Plager, J., concurring); id. at 1463-66 (Mayer, C.J., concurring in judgment); id. at 1473-75 (Rader, J., dissenting). Therefore, if we apply proper legal precedent as the majority has done in this case, the result is clear and obvious.

language of the claims. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). Generally claim terms should be construed consistently with their ordinary and customary meanings, as determined by those of ordinary skill in the art. Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1298 (Fed. Cir. 2003). While in some cases there is a presumption that favors the ordinary meaning of a term, Tex. Digital Sys. v. Telegenix Inc., 308 F.3d 1193, 1202 (Fed. Cir. 2002), the court must first examine the specification to determine whether the patentee acted as his own lexicographer of a term that already has an ordinary meaning to a person of skill in the art. See, e.g., Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1988); Brookhill v. Wilk, 334 F.3d at 1299.

When a patentee acts as his own lexicographer in redefining the meaning of particular claim terms away from their ordinary meaning, he must clearly express that intent in the written description. See, e.g., Bell Atl. Network Servs. v. Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001). We have repeatedly emphasized that the statement in the specification must have sufficient clarity to put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term. Id.; see also Elekta Instrument S.A. v. O.U.R. Sci. Int'l, Inc., 214 F.3d 1302, 1307 (Fed. Cir. 2000) ("Absent an express intent to impart a novel meaning, claim terms take on their ordinary meaning."); Renishaw, 158 F.3d at 1249 ("The patentee's lexicography must, of course, appear 'with reasonable clarity, deliberateness, and precision' before it can affect the claim.") (quoting In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994)); Union Carbide Chems. & Plastics Tech. Corp. v. Shell Oil Co., 308 F.3d 1167, 1177-78 (Fed. Cir. 2002) (stating that the "presumption in favor of the claim term's ordinary meaning is overcome, however, if a different meaning is clearly and deliberately set forth in the intrinsic evidence"). In the

present case, the passage cited by the district court from the specification for Merck's definition of "about" is ambiguous. It fails to redefine "about" to mean "exactly" in clear enough terms to justify such a counterintuitive definition of "about."

The phrase's ambiguity arises from the fact that it can easily be read as Teva does - as a way of explaining what is meant by the use of the phrase "alendronate acid active basis" rather than as a way of radically redefining what is meant by "about." The district court construed the phrase "about 70 [or 35] mg" to mean that one should administer approximately 70 (or 35) mg of the derivative compound, such that the end result is that the patient is administered exactly 70 (or 35) mg of alendronic acid. In other words, the district court determined that the quantity specified in the claims (35 or 70 mg) modifies the amount of the derivative compound rather than the active compound. Under such a construction, the term "about" informs one of ordinary skill in the art to select whatever quantity of the derivative compound necessary to give exactly 35 (or 70) mg of alendronic acid; for alendronate monosodium trihydrate, the word "about" thus meant that 45.68 mg (or 91.35 mg) of that compound should be delivered - the amount necessary to give exactly 35 (or 70) mg of alendronic acid.

Unlike the limiting definition of "about" adopted by the district court, Teva's interpretation of the paragraph in question would mean that "70 [or 35] mg" refers to the amount of the active compound to be administered rather than the amount of the derivative compound. The term "about" in the claims would then serve to modify the quantity of the active compound in a way consistent with its normal definition of "approximately." Under this construction, the

modifying phrase "about 70 [or 35] mg" would refer to approximately 70 (or 35) mg of alendronic acid.[8]

The claim construction urged by Merck and adopted by the district court reads the sentence of the passage underlined above out of context. In the sentence before the highlighted sentence, the patentee informs those of ordinary skill in the art that, when the patent refers to a certain amount of a bisphosphonate compound, it is actually instructing them to administer a certain amount of the active component of the compound rather than the compound itself, i.e., that one should calculate the amount dispensed on an "active weight basis." This preceding sentence thus acts to specify a common denominator to be used for all derivatives of alendronic acid. The underlined sentence merely gives a specific example - that of an alendronate derivative - to show what is meant by using the phrase "active weight basis."

Given that the passage that Merck relies on is amenable to a second (and more reasonable) interpretation, we hold Merck did not clearly set out its own definition of "about" with "reasonable clarity, deliberateness, and precision," and thus failed to act as its own lexicographer. In re Paulsen, 30 F.3d at 1480.

As further support for this conclusion, we note that other parts of the specification also suggest that "about" should be given its ordinary meaning of "approximately." The specification repeatedly describes a range of acceptable

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[8] Merck argues that the district court's construction is supported by the fact that "about" was not used twice in the underlined sentence cited by Merck, i.e., that the specification does not state that "the amount of bisphosphonate compound selected is calculated based on about 70 mg of alendronic acid." (emphasis added). While Merck's grammatical savvy is noted, we believe that the omission of a second "about" is likely an inadvertent error rather than the product of meticulous drafting.

dosage amounts, with the patentee emphasizing that unit dosages will vary. For example, the specification suggests that a once-weekly dosage amount could contain anywhere from about 17.5 mg to about 70 mg of any alendronate compound on an alendronate acid active basis, with about 35 mg and about 70 mg being only two examples of a unit dosage:

> For once-weekly dosing, an oral unit dosage comprises from about 17.5 mg to about 70 mg of the alendronate compound, on an alendronic acid active weight basis. Examples of weekly oral dosages include a unit dosage which is useful for osteoporosis prevention comprising about 35 mg of the alendronate compound, and a unit dosage which is useful for treating osteoporosis comprising about 70 mg of the alendronate compound.

'329 patent, col. 12, II. 56-63 (emphasis added). In addition to the above passage, at another point in the specification the range for the normal unit dosage is further widened to "about 8.75 to about 140 mg." '329 patent, col. 12, II. 52-55 (stating that "a unit dosage typically comprises from about 8.75 mg to about 140 mg of an alendronate compound on an alendronic acid active weight basis"). The specification thus suggests the patentee contemplated a range of dosages, further compromising Merck's proposition that it acted as its own lexicographer in defining "about" to mean "exactly."[9]

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[9] We also note that Examples 7 and 8 in the '329 patent do not contradict the construction we adopt on appeal because they are only examples of the tablets that could be prepared according to the patent. Neither example clearly states that the only embodiment of the claims would be the exact formulations described therein.

Finally, our construction of "about" eliminates the problem pointed out by Teva that the district court's construction of the term "about" renders other parts of the claim superfluous. As Teva notes, the specification uses both the term "about" and "on an alendronic acid basis" at least 15 times to describe a dosage strength. If, as Merck urges, "about 35 [or 70] mg" means exactly 35 (or 70) mg of alendronic acid, then the oft-repeated phrase "on an alendronic acid active basis" would be unnecessary since such an understanding would be clear simply by using the term "about." A claim construction that gives meaning to all the terms of the claim is preferred over one that does not do so. Elekta, 214 F.3d at 1307 (construing claim to avoid rendering the 30 degree claim limitation superfluous); Gen. Am. Transp. Corp. v. Cryo-Trans, Inc., 93 F.3d 766, 770 (Fed. Cir. 1996) (rejecting the district court's claim construction because it rendered superfluous the claim requirement for openings adjacent to the end walls). By construing "about" to mean its accepted and ordinary meaning of "approximately," the phrase "alendronic acid basis" is no longer excess verbiage, but is instead necessary because it is the noun that "about 35 [or 70] mg" modifies.

Because the patentee did not clearly redefine "about" in the specification, and because the district court construed the claim term in a manner inconsistent with the specification, we reverse the district court's claim construction. We thus hold that the term "about" should be given its ordinary and accepted meaning of "approximately."

C. Invalidity

In light of the corrected claim construction we find reversible error in the district court's obviousness analysis. A patent claim is invalid "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." 35 U.S.C. § 103(a) (2000). The ultimate issue of obviousness turns on four factual determinations: (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) objective indicia of nonobviousness. Graham v. John Deere Co., 383 U.S. 1, 17-18 (1966). As explained below, we find clear error in the trial court's findings on these underlying facts.[10] On reviewing these factual bases, we conclude the district court also erred in refusing to invalidate claims 23 and 37 for obviousness in view of the 1996 Lunar News articles.

The central issue concerns the differences between the aspects of the invention claimed at claims 23 and 37, and the teachings of the Lunar News articles. As the district court necessarily recognized, there are more similarities than differences. These claims, and the July 1996 article, both teach administering alendronate once a week instead of once a day. These claims read in light of the specification, and the July 1996 article, both indicate - and it has been conceded as known in the art at the time[11] - that for treating or preventing osteoporosis a once-weekly dosage at seven times the daily dose would be as effective as seven daily doses. The '329 patent, and both the April and July 1996 articles, explain the motivation for a once-weekly dose as increasing patient compliance, by making it easier to take the drug (and incur

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[10] It makes no difference to this conclusion whether the court begins with the claim construction set forth by the panel or the dissent. In either case, the district court erred in finding the '329 patent was not invalid as obvious in view of the Lunar News articles.

[11] See Merck, 288 F. Supp. 2d at 624.

the inconvenience of the rigorous dosing regimen less frequently). Although the claims teach 70 or 35 mg doses rather than the 80 or 40 mg doses disclosed in the July 1996 article, Dr. Arthur C. Santora - one of the co-inventors on the '329 patent - admitted against Merck's interest that a once-weekly 40 mg dose would be as effective as seven daily 5 mg doses, and a once-weekly 80 mg dose would be as effective as seven daily 10 mg doses, in preventing or treating osteoporosis. There was no great leap required of those skilled in the art to go from 40 or 80 mg once a week, the pills available at the time to treat patients with Paget's disease, to a 35 or 70 mg pill once a week. The district court's conclusion that the claims are not obvious cannot rest on any of these similarities between the claimed invention and the two Lunar News articles.

The district court distinguished the two Lunar News articles on grounds that they failed to explain how the once-weekly dosing overcame concerns in the art with adverse GI side effects. Merck, 288 F. Supp. 2d at 628-29. We are left with the firm conviction that this distinction is misplaced. As noted, the district court found those in the art had identified two types of adverse GI problems with alendronate. The first, and most significant, involved esophageal injury or repetitive irritation of the esophagus. The district court, reviewing the October 1996 article by DeGroen in the New England Journal of Medicine, expressly recognized the literature taught that complications related to alendronate were due to "prolonged contact of the drug with the esophagus." Merck, 288 F. Supp. 2d at 627. Confronted with this problem, Merck revised its dosing instructions and sent the clarifying materials to prescribing physicians in a March 1996 "Dear Doctor" letter. After Merck sent this letter, the reported incidence of GI distress fell to almost nothing even as the number of patients being prescribed Fosamax doubled by October 1996. Although the '329 patent focuses on this

adverse GI side-effect, it provides no additional motivation to overcome this problem beyond the motivation described in the two articles. The '329 patent, both articles, and the prevailing knowledge of those skilled in the art, recognized that to the extent "dosing problems" were related to repetitive irritation of the esophagus (from patients getting pills stuck in their throats), taking fewer pills each week could reduce the attending GI problems.[12] Thus, the district court clearly erred in finding any significant difference between the claimed invention and the two articles as to this type of GI problem.

The district court found a second adverse GI side-effect related to the size of the dose, which Merck argued gave rise to "the expectation by physicians in the field during 1996-1997 that alendronate sodium at doses over 20 mg would not be well-tolerated in the prevention and treatment of osteoporosis." Merck, 288 F. Supp. 2d at 624; see also id. at 622-23, 627-30 (discussing Chesnut study). Neither the '329 patent nor the Lunar News articles explain how a higher

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[12] As the '329 patent states:

> [I]t is found that the administration of a biphosphonate at a high relative dosage at a low 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.
> ... Such administration methods of the present invention would be especially beneficial in treating patients that have been identified as suffering from or are susceptible to upper gastrointestinal disorders, e.g., gastrointestinal reflux disease (i.e. "GERD"), esophagitis, dyspepsia (i.e. heartburn), ulcers, and other related disorders. In such patients conventional bisphosphonate therapy could potentially exacerbate or induce such upper gastrointestinal disorders.

'329 patent, col. 3, l. 57 - col. 4, l. 13 (emphasis added).

once-weekly dosing regimen would avoid this set of dose-related adverse side effects. The '329 patent sets forth no human clinical or laboratory data showing the safety and tolerability of the treatment methods claimed by the patent. The only data provided in the '329 patent was generated in beagles, an experiment discredited at trial and disregarded by the district court in its decision. So while the district court may be correct in finding the Lunar News articles may have invited skepticism based on concerns for 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.

The district court's only remaining distinction between the claimed invention and the two Lunar News articles goes to the probative value of the articles. The trial court wrote that it "[was] not persuaded that the two Lunar News articles, not published in peer-reviewed journals or authored by one skilled in the art, either alone or in combination, overcame the serious side effect concerns associated with higher dosage units of alendronate sodium." Merck, 288 F. Supp. 2d at 629. Although these indicia of reliability - whether a study is peer-reviewed, and the credentials of the author - properly go to weight when the trial court has not excluded evidence as unreliable and irrelevant, the district court's reliance on these factors to distinguish Merck's claimed invention is, again, misplaced. First, as noted above, these factors provide no relevant distinction between the articles and the claimed invention because the '329 patent also fails to explain how its higher dosing would overcome these dose-related side-effects. Second, as explained below the district court's finding the author of the Lunar News articles not skilled in the relevant art is inconsistent with the court's own definition of the relevant art. Thus, the extent to which the district court

discounts the probative value of the two articles based on the credentials of the author calls for closer scrutiny and casts doubt on the findings that depend on this reasoning.

In short, the district court clearly erred in distinguishing the claimed invention from the two Lunar News articles offered as section 103 prior art. Contrary to the district court's findings, these articles support the conclusion that Merck's claims 23 and 37 are invalid as obvious.

For similar reasons we find the district court's characterization of the scope and content of the prior art favors invalidating claims 23 and 37 as obvious. The district court described its larger task as identifying "a showing of the teaching or motivation to combine prior art references." Merck, 288 F. Supp. 2d at 625 (quoting In re Gartside, 203 F.3d 1305, 1319 (Fed. Cir. 2000)). But as shown above, in this case the Lunar News articles contain the relevant teaching of the weekly dosing claimed in the '329 patent. The "specific combination" of elements in claims 23 and 37 differs from the disclosure in the Lunar News articles only in terms of a minor difference in the dosage; without this difference, the Lunar News articles would anticipate claims 23 and 37 under section 102. For the Lunar News articles to render claims 23 and 37 obvious, the district court need only have found a suggestion or motivation to modify the dosages from those in the articles to those in the claims. See, e.g., Sibia Neurosciences, Inc. v. Cadus Pharm. Corp., 225 F.3d 1349, 1356 (Fed. Cir. 2000). But as noted above, Merck's own inventors admit the difference in dosing amount is obvious. If anything, concern over dosing amount suggests lowering the weekly dosage - from 80 to 70 mg, and from 40 to 35 mg, just as Merck did. The district court thus clearly erred to the extent it found lacking any motivation to combine existing knowledge with the Lunar News articles to reach the claimed invention.

The district court failed to ascertain the required motivation to combine references to achieve the claimed invention, and it ignored the plain teachings of the Lunar News articles. As the court stated, "the issue is when viewing the mosaic of prior art, whether those of ordinary skill in the art would have had the motivation to formulate a once-weekly seven-fold daily dose of alendronate, despite safety concerns." Merck, 288 F. Supp. 2d at 626.

The Lunar News articles had clearly suggested the once-weekly dosing. They did so, as noted above, and as described in the '329 patent, to avoid or minimize problems related to dosing frequency. And as shown above, the district court itself found this particular set of problems were of greatest concern in the art. Indeed, to the extent the district court finds Merck's weekly-dosing idea non-obvious because it went against prevailing wisdom, the court must still explain why Merck and not Dr. Mazess should get credit for the idea. Because Merck's idea added nothing to what came before, the district court's answer comes down to nothing more than the credentials of the authors. In this case that difference is not enough to avoid invalidating the claims.[13]

The district court answered its own question incorrectly, because its analysis of the prior art fails to credit its own distinction between the "safety concerns" from dosing frequency and dosing amount. As noted above, the claimed invention does not address the problems with the dosing amount, but only the more widespread problems of

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[13] Although the court is unsure whether an obviousness ruling can ever turn solely on the credentials of the inventors and prior art authors, where the prior art has been admitted, it need not decide that question here. As noted below, by the district court's own functional definition (if not its actual finding) Dr. Mazess was one of skill in the art, and the Lunar News was widely circulated in the field.

the dosing frequency. The court's review of the scope and content of the prior art itself focuses on this concern with "prolonged contact of the drug with the esophagus." Merck, 288 F. Supp. 2d at 627. This understanding of the prior art does not support a conclusion that the claimed invention as a whole was non-obvious in view of the prior art. See Para-Ordnance Mfg. v. SGS Imports Int'l Inc., 73 F.3d 1085, 1087; In re Kaslow, 707 F.2d 1366, 1374 (Fed. Cir. 1983). Insofar as the district court relied on safety concerns related to dosing frequency, the prior art favors the conclusion that taking pills once a week was obvious.

Thus, the scope and content of the prior art confirms that the invention claimed in claims 23 and 37 would have been obvious in view of the Lunar News articles. To the extent the district court interpreted the scope of the prior art otherwise, that was clear error.

We likewise find clear error in the district court's conclusion that Dr. Mazess was not skilled in the relevant art. The district court failed to credit the evidence showing Mazess's Lunar News was widely distributed among those working in the field of osteoporosis. Moreover, while we recognize the importance academic or professional training plays in establishing expert qualifications or the probative value of a section 103 reference, we think the district court failed to give proper credit to the fact that Dr. Mazess was an expert in osteoporosis. In focusing on Dr. Mazess's academic training, the district court ignored its own finding that one of skill in the art would be someone "working in the field of, or doing research on, osteoporosis." Thus, the district court erred in dismissing or minimizing the probative value of the Lunar News articles.

Finally, the district court erred in its weighing of secondary considerations of non-obviousness. Although the

district court correctly found Merck's once-weekly dosing of Fosamax was commercially successful, in this context that fact has minimal probative value on the issue of obviousness. Merck, 288 F. Supp. 2d at 629-30. Commercial success is relevant because the law presumes an idea would successfully have been brought to market sooner, in response to market forces, had the idea been obvious to persons skilled in the art. Thus, the law deems evidence of (1) commercial success, and (2) some causal relation or "nexus" between an invention and commercial success of a product embodying that invention, probative of whether an invention was non-obvious. See Graham, 383 U.S. at 17-18 ("Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquiries may have relevancy."); McNeil-PPC. Inc. v. L. Perrigo Co., 337 F.3d 1362, 1370 (Fed. Cir. 2003).

That rationale has no force in this case. In Graham the Supreme Court relied on the reasoning from a law review note discussing commercial success. See Graham, 383 U.S. at 17-18, citing Note, Subtests of Nonobviousness": A Nontechnical Approach to Patent Validity. 112 U. Pa. L. Rev. 1169, 1175 (1964). The article suggested "[t]he possibility of market success attendant upon the solution of an existing problem may induce innovators to attempt a solution. If in fact a product attains a high degree of commercial success, there is a basis for inferring that such attempts have been made and have failed." As our predecessor court explained in In re Fielder, 471 F.2d 640, 644 (C.C.P.A. 1973), "[t]hese rationales, presumably approved by the [Supreme] Court, tie commercial success and the like directly to the practical, financial source of impetus for research and development." But that chain of inferences fails on these facts. Although

commercial success might generally support a conclusion that Merck's claimed invention was non-obvious in relation to what came before in the marketplace, the question at bar is narrower. It is whether the claimed invention is non-obvious in relation to the ideas set forth in the Lunar News articles. Financial success is not significantly probative of that question in this case because others were legally barred from commercially testing the Lunar News ideas. Dr. Mazess, for example, could not put his ideas to practice in 1996 - he could only exhort Merck to try it. They did.

In this case Merck had a right to exclude others from practicing the weekly-dosing of alendronate specified in claims 23 and 37, given (1) another patent covering the administration of alendronate sodium to treat osteoporosis, U.S. Pat. No. 4,621,077 (issued Nov. 4, 1986); and (2) its exclusive statutory right, in conjunction with FDA marketing approvals, to offer Fosamax at any dosage for the next five years. 21 U.S.C. § 355(c)(3)(D)(ii) (2000). Because market entry by others was precluded on those bases, the inference of non-obviousness of weekly-dosing, from evidence of commercial success, is weak. Although commercial success may have probative value for finding non-obviousness of Merck's weekly-dosing regimen in some context, it is not enough to show the claims at bar are patentably distinct from the weekly-dosing ideas in the Lunar News articles. Thus, we conclude the district court misjudged this factor as confirming its conclusion of non-obviousness.

In short, we find the relevant Graham factors establish claims 23 and 37 of the '329 patent are obvious in view of the April 1996 and July 1996 Lunar News articles. Thus, we reverse the district court and hold claims 23 and 37 invalid.

III. CONCLUSION

We reverse the district court's claim construction and hold that "about" should be construed consistently with its ordinary meaning of "approximately." In addition, we vacate the district court's determination that the '329 patent was not invalid as obvious. We hold claims 23 and 37 invalid as obvious and not infringed. The district court's judgment of infringement is therefore

REVERSED

COSTS

A. No costs.

United States Court of Appeals for the Federal Circuit

04-1005

MERCK & CO., INC.,

Plaintiff-Appellee,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellant.

RADER, Circuit Judge, dissenting,

This case shows the consequences of paying only lip service to the often-cited, but rarely-followed lexicographer rule and the basic jurisprudential principle of according trial courts proper deference.

Elect the Lexicographer Option at Your Own Risk

With this court's claim constructions wavering between the plain meaning rule (often a subtle way for judges to impose their own semantic subjectivity on claim terms, see, e.g., K-2 v. Salomon, 191 F.3d 1356 (Fed. Cir. 1999) ("permanent" affixation of the wheels to the skate boot in the context of in-line skates did not include a bolt that could only be reached by tearing apart the shoe)) and the "specification über alles" rule (often a way for judges to import limitations not included in the claim, see, e.g., Phillips v. AWH Corp., 363 F.3d 1207, 1213-14 (Fed. Cir. 2004), vacated, reh'g en banc granted, 376 F.3d 1382 (Fed. Cir. July 21, 2004)), a patent applicant might suppose that the best option to define the scope of the claim language might be the lexicographer rule. Under the lexicographer rule, an inventor acts as an

independent lexicographer and can even give claim terms a meaning "inconsistent with its ordinary meaning." Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1347 (Fed. Cir. 2003) (citing Teleflex, Inc. v. Ficosa N. Am. Corp., 299 F.3d 1313, 1325-26 (Fed. Cir. 2002)); see also Teleflex, 299 F.3d at 1325 ("[A]n inventor may choose to be his own lexicographer if he defines the specific terms used to describe the invention 'with reasonable clarity, deliberateness, and precision.'" (quoting In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994))). Indeed, this court often acknowledges that an applicant, acting as a lexicographer, may define "black" as "white." See Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558, 1563 (Fed. Cir. 1990) ("It is a well-established axiom in patent law that a patentee is free to be his or her own lexicographer and thus may use terms in a manner contrary to or inconsistent with one or more of their ordinary meanings."); see also, e.g., Int'l Rectifier Corp. v. IXYS Corp., 361 F.3d 1363, 1373 (Fed. Cir. 2004) (patentee defining "annular," which ordinarily means in the shape of a ring, to describe structures that are not circular or curved, but polygonal). In this case, the patentee used the lexicographer rule to define a lengthy phrase. In its definition, the patentee defined the phrase with precise values. The patentee's definition, however, fell five letters short of success because the phrase included the word "about." This court seized on that word, gave it an ordinary meaning, and cast aside the lexicographer rule without a convincing explanation. Moreover, this court overturned the result of a lengthy district court trial for the sole reason that the trial court applied this court's lexicographer rule. I find it hard to explain to the district court how it erred by following this court's rules.

The disputed term in claim 23 of the '329 patent is the phrase "about 70 mg of alendronate monosodium trihydrate,

on an alendronic acid basis." Similarly, the disputed term in claim 37 is the phrase "about 35 mg of alendronate monosodium trihydrate, on an alendronic acid basis." Teva contends that this court should parse out one word in that phrase, "about," and accord that single word its ordinary meaning of "approximately." Merck, on the other hand, contends that the term "about" is inseparable from the entire phrase, which it defines under the lexicographer rule to account for the variability in the active ingredient weight that would result from the use of a salt of alendronic acid.

The specification shows the proper interpretation of the disputed phrase. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("The specification acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication."). In the specification of the '329 patent, the patentee exercised the lexicographer option and defined the disputed phrase as follows:

> Because of the mixed nomenclature currently in use by those o[f] ordinary skill in the art, reference to a specific weight or percentage of a bisphosphonate compound in the present invention is on an acid active weight basis, unless otherwise indicated herein. For example, the phrase "about 70 mg of a bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof, and mixtures thereof, on an alendronic acid active weight basis" means that the amount of the bisphosphonate compound selected is calculated based on 70 mg of alendronic acid.

'329 patent, col. 10, I. 65 - col. 11, I. 8.

In a passage that classically invokes this court's lexicographer doctrine, the patentee clearly, deliberately, and precisely defined the phrase "about 70 mg of a bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof, and mixtures thereof, on an alendronic acid active weight basis." The patentee set forth that entire term with quotations, including the word "about" and then stated unambiguously that the "phrase . . . means that the amount of the bisphosphonate compound selected is calculated based on 70 mg of alendronic acid." '329 patent, col. 11, II. 2 - 8 (emphases added). The choice of the words "phrase" and "means," combined with the use of quotation marks to set the phrase off from the rest of the sentence, unmistakably notify a reader of the patent that the patentee exercised the option to define the entire phrase without respect to its ordinary meaning as understood by one of ordinary skill in the art at the time of the invention. See Multiform Dessicants Inc. v. Medzam Ltd., 133 F.3d 1473, 1477 (Fed. Cir. 1998).

To underscore the choice to define the phrase as a lexicographer, the patentee explains the reason that this phrase needs definition - "[b]ecause of the mixed nomenclature currently in use by those o[f] ordinary skill in the art." '329 patent, col. 10, II. 65-66. Therefore, even a casual reader, let alone one with skill in this art, would immediately recognize that the patentee intended to avoid any ambiguity inherent in "mixed nomenclature" by explicitly defining the entire phrase. See Paulsen, 30 F.3d at 1480 ("'Where an inventor chooses to be his own lexicographer and to give terms uncommon meanings, he must set out his uncommon definition in some manner within the patent disclosure' so as to give one of ordinary skill in the art notice of the change." (quoting Intellicall, Inc. v. Phonometrics, Inc., 952 F.2d 1384, 1388 (Fed. Cir. 1992))).

The language of this definition explains further the scientific reason that an express definition is necessary. Alendronate monosodium trihydrate is a bisphosphonate selected from the group consisting of alendronic acid, pharmaceutically acceptable salts thereof, and mixtures thereof. A salt or a mixture may require a different weight to achieve the same number of bisphosphonate molecules present in 70 mg of alendronate.

The patentee did not leave this difference vague, however, but instructed that the precise dose in claim 23 - "about 70 mg of alendronate monosodium trihydrate, on an alendronic acid basis" - means that the amount of alendronate monosodium trihydrate is calculated based on 70 mg of alendronic acid. Similarly, the disputed language of claim 37 - "about 35 mg of alendronate monosodium trihydrate, on an alendronic acid basis" - means that the amount of alendronate monosodium trihydrate is calculated based on 35 mg of alendronic acid. The word "about" in the defined phrase takes into account the variability of the weight of the active ingredient that would result from using different salts of alendronic acid in the tablets, instead of the acid itself. In other words, a heavier salt would require more by weight to achieve the same number of alendronate molecules. For example, about 70 mg of alendronate sodium, on an alendronic acid active basis, contains the same number of molecules of alendronate as 70 mg of alendronic acid, regardless of the actual weight of the alendronate sodium in the tablet.

With respect to the word "about," the patentee included that word in the entire phrase expressly defined in the specification and set off by quotation marks. Therefore, this court cannot, without disturbing the patentee's express definition of the entire phrase, abstract that term out of its context and supply an ordinary meaning. Thus, by abstracting

"about" out of the patentee's express definition, this court's opinion defeats the patentee's choice of words, punctuation, and phraseology and instead extracts a single word from its context in the phrase. Accordingly, the majority rewrites the express definition either by moving the word "about" outside of the quotation marks of the defined phrase or by inserting the word "about" into the definitional portion of the sentence so that it would read "the amount of the bisphosphonate compound is calculated based on about 70 mg of alendronic acid." If the patentee had chosen either of those two phraseologies, the majority opinion might be correct in its analysis. But because the patentee did not, this court cannot give any principled reason that the district court erred in applying the lexicographer rule. Contrary to this court's rules, this opinion rewrites the specification and substitutes language not chosen by the patentee. See, e.g., Chef Am., Inc. v. Lamb Weston, Inc., 358 F.3d 1371, 1374 (Fed. Cir. 2004) (repeating the well-established rule that "courts may not redraft claims").

Throughout the patent, the applicant remained faithful to the disputed phrases in claims 23 and 37 consistent with the specified lexicography, thus completely dispelling any notion of ambiguity in the term "about." In particular, Examples 7 and 8 corroborate the express definition. Example 7 states that "[t]ablets containing about 35 mg of alendronate, on an alendronic acid active basis, are prepared using the following weights of ingredients" and lists alendronate monosodium trihydrate requiring a mass of 45.68 mg. See '329 patent, col. 19, II. 14 - 21. Similarly, example 8 states that "[a] liquid formulation containing about 70 mg of alendronate monosodium trihydrate, on an alendronic acid active basis, per about 75 mL of liquid is prepared using the following weights of ingredients" and lists alendronate monosodium trihydrate having a mass of 91.35 mg. Id. at col. 19, II. 44 - 52. In these examples, the applicant supplied an

exact weight that equates with "about 70 mg of alendronate . . . on an alendronic acid active basis." Accordingly, the district court did not err in construing "the disputed claim terms 'about 70/35 mg' to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories." Merck, 288 F. Supp. 2d at 616. The district court followed this court's rules.

Deference to Trial Courts:
Time for "Truth in Advertising?"

This is the classic "close case," so close in fact that ultimately two federal judges (one of whom conducted an entire bench trial on this issue) and the United States Patent and Trademark Office agreed with Merck & Co., and two federal judges agreed with Teva Pharmaceuticals. The United States District Court of Delaware tried this case from March 4 - 7, 2003, then issued a 75-page opinion analyzing the claims and arguments in consummate and accurate detail. Merck & Co. v. Teva Pharms. USA, Inc., 288 F. Supp. 2d 601 (D. Del. 2003). This court received the typical briefs from the parties, an appendix containing selected portions of the record, and heard a total of approximately thirty minutes of argument by the parties on the issues before this court. Despite the district court's superior tools and time to evaluate the complete record, to hear and inquire from expert and fact witnesses, to delve into countless related details, to probe the scientific and semantic context, and to entertain argument as long as necessary for clarity, this court with its reading three briefs before its half-hour hearing becomes enamored with its own analysis of a very close issue and reverses the district court.

This court often hears criticism from district court judges that its reversal rate on claim construction issues far

exceeds that of other circuit courts. See. e.g., Symposium, The Law, Technology and the Future of the Federal Circuit: A Panel Discussion: Claim Construction from the Perspective of the District Judge, 54 Case W. Res. L. Rev. 671 (2003) (Symposium I) (district judges discussing problems with this court's high reversal rate on claim construction issues); see Gregory J. Wallace, Note, Toward Certainty and Uniformity in Patent Infringement Cases after Festo and Markman: A Proposal for a Specialized Patent Trial Court with a Rule of Greater Deference, 77 S. Cal. L. Rev. 1383, 1391 (2004) (discussing various studies regarding this court's reversal rate on claim construction issues). In response, nearly every judge on this court has publicly professed to accord some level of deference to district courts regardless of this court's de novo review of claim construction issues. See, e.g., Symposium I at 680 (a district court judge stating "I have certainly heard a number of federal circuit judges agree, that the CAFC gives some deference to a well-reasoned opinion, as a practical matter"); Symposium, The Past, Present and Future of the Federal Circuit: Judicial Constellations: Guiding Principles as Navigational Aids, 54 Case W. Res. L. Rev. 757, 761 (2004)(judge of the Federal Circuit stating: "Review is really not de novo after all. It is unfortunate that there is no label in between de novo and clear error review. Functionally, claim construction falls in this middle ground."). Either the Federal Circuit accords deference in accordance with its public protestations or it does not in accordance with its legal standard barring any deference. If the former, this court has a "truth in advertising" problem. Its actual practice clashes with its professed legal duty. If the latter, this court has a different kind of "truth in advertising" problem.

In this case, this court eschews all deference, a particularly striking choice in the face of a very close case and a district court whose diligent and intelligent process and resolution earned more respect than it received. I am not

entirely sure which aspect of the "truth in advertising" problem this case illustrates, but it certainly makes any protestations of deference in fact sound rather hollow.

APPENDIX B

United States Court of Appeals for the Federal Circuit

04-1005

MERCK & CO., INC.,

Plaintiff-Appellee,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellant.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before MICHEL, Chief Judge, NEWMAN, MAYER, LOURIE, CLEVENGER, RADER, BRYSON, GAJARSA, LINN, DYK, and PROST, Circuit Judges.

O R D E R

A combined petition for panel rehearing and rehearing en banc was filed by the Appellee, and a response thereto was invited by the court and filed by the Appellant.[1]

[1] An amicus curiae brief was filed by the Pharmaceutical Research and Manufacturers of America.

The petition for rehearing was referred first to the merits panel that heard the appeal. Thereafter, the petition for rehearing en banc, response, and the amicus curiae brief were referred to the circuit judges who are authorized to request a poll whether to rehear the appeal en banc. A poll was requested, taken, and failed.

Upon consideration thereof,

IT IS ORDERED THAT:

(1) The petition for panel rehearing is denied.

(2) The petition for rehearing en banc is denied.

(3) The mandate of the court will issue on April 28, 2005.

NEWMAN and LOURIE, Circuit Judges, would rehear the appeal en banc.

LOURIE, Circuit Judge, with whom MICHEL, Chief Judge, and NEWMAN, Circuit Judge, join, dissents in a separate opinion.

SCHALL, Circuit Judge, did not participate in the vote.

FOR THE COURT

APR 21 2005
Date

Jan Horbaly
Clerk

cc: John F. Lynch, Esq.
James Galbraith, Esq.
William F. Lee, Esq.

FILED
U.S. COURT OF APPEALS FOR
THE FEDERAL CIRCUIT

Apr 21, 2005

JAN HORBALY
CLERK

United States Court of Appeals for the Federal Circuit

04-1005

MERCK & CO., INC.,

Plaintiff-Appellee,

v.

TEVA PHARMACEUTICALS USA, INC.,

Defendant-Appellant.

LOURIE, Circuit Judge, with whom MICHEL, Chief Judge, and NEWMAN, Circuit Judge, join, dissenting from order denying rehearing en banc.

I respectfully dissent from the court's declining to hear this case en banc. In my opinion, the panel erroneously concludes that commercial success is not probative because "others were legally barred" from commercially testing certain ideas in the prior art. Moreover, I believe the panel erred in linking commercial success to the failure of others.

Commercial success is a fact question, and, once it is established, as found here by the trial court, the only other question is whether the success is attributable to the claimed invention ("nexus"), rather than to other factors such as market power, advertising, demand for all products of a given type, a rising economy that "lifts all boats," etc. It is not negatived by any inability of others to test various formulations because of the existence of another patent. Success is success. The panel's rule is especially unsound in the context of an improvement patent, as here, because it

holds in effect that commercial success for an improvement is irrelevant when a prior patent dominates the basic invention.

Commercial success is also independent of any "failure of others," as that is another, separate secondary consideration.

Respectfully, the full court should have reheard the appeal to eliminate the confusion in the law that the panel opinion creates.

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	C.A. No. 01-0048 (JJP) (CONSOLIDATED)

FINAL JUDGEMENT ORDER
PURSUANT TO FED. R. CIV. P. 54(b)

For the reasons set forth in this Court's Memorandum Opinion of August 28, 2003;

IT IS HEREBY ORDERED that:

1. Claims 23 and 37 of US. Patent No. 5,994,329 ("the '329 Patent") are not invalid;

2. The '329 Patent is not unenforceable;

3. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any Food and Drug Administration approval of Defendant's Abbreviated New Drug Application No. 75-710 with respect to tablets containing 70 mg or 35 mg of alendronate sodium (on an alendronic acid basis) for

treatment or prevention of osteoporosis, respectively, will be a date not earlier than July 17, 2018, the expiration date of the '329 Patent;

4. Pursuant to 35 U.S.C. § 271(e)(4)(B), Defendant, its officers, agents, attorneys and employees, and those persons in active concert or participation with any of them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from engaging in the commercial use, offer to sell, or sale within the United States, or importation into the United States, of tablets containing 70 mg or 35 mg of alendronate sodium (on an alendronic acid basis) for the treatment or prevention of osteoporosis, respectively, on or before July 17, 2018, the expiration date of the '329 Patent;

5. Judgment is entered in favor of Plaintiff and against Defendant on Plaintiff's claims of infringement of claims 23 and 37 of the '329 Patent and on Defendant's defenses to those claims, and in favor of Plaintiff and against Defendant on Defendant's counterclaim relating to the unenforceability of the '329 Patent; and

6. On December 2, 2002, the Court entered a Final Judgment Order in Consolidated Actions C.A. No. 00-035-JJF and C.A. No. 00-052-JJF regarding U.S. Patent No. 4,621,077 (the "'077 patent"). The Court entered Judgment that Teva's filing of its Abbreviated New Drug Application No. 75-710 infringed claim 1 of the '077 patent, that the '077 patent is not invalid, and that the patent term extension of the '077 patent is valid. Teva appealed the Court's Final Judgment Order to the United States Court of Appeals for the Federal Circuit, and the appeal is pending. Per the parties' agreement, and Court's Order of March 7, 2003, the outcome of the appeal (and any subsequent proceedings) will be dispositive of all issues regarding Merck's infringement

claims and Teva's counterclaims brought in this action regarding the '077 patent.

Accordingly, in accordance with Fed. R. Civ. P. 54(b), there is no just reason for delay in entering this Judgment and the Court directs that it be entered.

SO ORDERED this 23 day of September, 2003.

_____

United States District Judge

APPENDIX D

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK & CO., INC., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	Civil Action No. 01-048 (JJF) (Consolidated)

Mary B. Graham and Maryellen Noreika, Esquires of MORRIS,
NICHOLS, ARSHT & TUNNELL, Wilmington, Delaware.
Of Counsel: John F. Lynch, Nicolas G. Barzoukas, and Stephen E. Edwards, Esquires of HOWREY SIMON ARNOLD & WHITE, LLP, Houston, Texas.
Paul D. Matukaitis, Edward W. Murray, and Gerald M. Devlin, Jr. Esquires of MERCK & CO., Whitehouse Station, New Jersey.
Attorneys for the Plaintiff.

Josy W. Ingersoll, and Adam W. Poff Esquires of YOUNG, CONAWAY STARGATT & TAYLOR, LLP, Wilmington, Delaware.
Of Counsel: James Galbraith, Maria Luisa Palmese and William G. James, II, Esquires of KENYON & KENYON, New York, New York.
Attorneys for Defendant Teva Pharmaceuticals, USA, Inc.

OPINION

August 28, 2003
Wilmington, Delaware.

Farnan, District Judge.

I. Procedural Background

Plaintiff, Merck & Co., Inc. (“Merck”) is a Delaware corporation with its principal place of business in New Jersey. Defendant, Teva Pharmaceuticals USA, Inc. (“Teva”) is a Delaware corporation with its principal place of business in Pennsylvania. Merck is the owner of the entire right, title and interest in United States Patent No. 5,994,329, entitled “Method for Inhibiting Bone Resorption” (the “'329 Patent”), which issued November 30, 1999, naming as inventors Anastasia G. Daifotis, Arthur C. Santora I, and John Yates. Merck filed the application for the '329 Patent on July 22, 1997. The '329 Patent is set to expire on August 14, 2018. (PTX 1).

Merck listed the '329 Patent in the Federal Drug Administration's (“FDA”) publication “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”) in connection with its 70 mg and 35 mg dosage for alendronate sodium, which Merck markets under the name “Fosamax.” On October 3, 2000, Teva filed a supplement to an existing Abbreviated New Drug Application (“ANDA”) seeking FDA approval to market generic versions of Merck's 70 mg alendronate sodium product for weekly administration. Included with Teva's ANDA filing were “paragraph IV” certifications (21 U.S.C. § 355 (j) (2) (A) (vii) (IV)) asserting that the Patents listed in the Orange Book, including the '329 Patent, are invalid, unenforceable or would not be infringed by the commercial marketing of Teva's proposed product. Merck filed this action on January 21, 2001, alleging that Teva's filing of its supplement was an act of infringement under 35 U.S.C. § 271 (e) (2) (A). Thereafter, Merck listed U.S. Patent No. 6,225,294 (the “'294 Patent”) in the Orange book and Teva

filed a paragraph IV certification asserting that the '294 Patent is invalid, unenforceable or would not be infringed by the commercial marketing of Teva's proposed 70 mg alendronate sodium product. On October 4, 2001, Merck filed Civil Action No. 01-675-JJF, alleging that Teva's filing of its supplemental ANDA was an act of infringement of the '294 Patent under 35 U.S.C. § 271 (e) (2) (A).

Subsequently, Teva filed another supplement to its ANDA, seeking approval to market a generic version of Merck's 35 mg Fosamax product. The supplement also included a paragraph IV certification asserting that all the listed patents were invalid, unenforceable or would not be infringed by Teva's commercial marketing of its proposed product. On November 6, 2001, Merck filed Civil Action No. 01-728, alleging that the filing of Teva's supplement to the ANDA was an act of infringement under 35 U.S.C. § 271 (e) (2) (A). On January 14, 2002, the Court consolidated all three cases under Civil Action No. 01-048.

One of the listed patents against which Teva certified was U.S. Patent No. 4,621,077 (“the '077 Patent”), which had already been the subject of litigation between the parties in this Court (Civil Action No. 00-035-JJF) in connection with Teva's application to market alendronate sodium for daily administration. The Court entered judgment in favor of Merck in that case on December 2, 2002, and an appeal from that judgment is now pending in the United States Court of Appeals for the Federal Circuit. (D.I. 123-1). The parties agreed that they will be bound in this case, with regard to issues concerning the '077 Patent, by a final decision in the prior litigation. (D.I. 128). Prior to trial Merck stipulated that the only claims at issue in this litigation are claims 23 and 37 of the '329 Patent and further stipulated that it would not allege an invention date for those claims prior to July 22, 1997. (D.I. 128).

Teva stipulated that if found valid and enforceable, claims 23 and 37 of the '329 Patent would be infringed by the commercial marketing of Teva's proposed 70 mg and 35 mg alendronate sodium products for weekly administration. (D.I. 109, Pretrial Order, Tab 1, ¶¶ 8-9). The issues of validity and enforceability of the '329 Patent were tried before the Court from March 4-7, 2003.

The Court has jurisdiction over the parties and the subject matter pursuant to 28 U.S.C. § 1338(a). Additionally, venue is appropriate under 28 U.S.C. § 1391(c) and § 1400(b). Neither jurisdiction nor venue are contested by the parties. This Opinion constitutes the Court's Findings of Fact and Conclusions of Law with respect to the issues tried before the Court.

II. The '329 Patent and Bone Biology In General

The '329 Patent discloses less-frequent-than daily administration of bisphosphonates (e.g., alendronate) to inhibit bone resorption. (D.I. 143 at 8). Claims 23 and 37, the only asserted claims, relate specifically to the treatment and prevention of osteoporosis by once-weekly administration of alendronate. Osteoporosis is related to processes that are imbalanced in bone, and therefore, the Court will discuss the background of bone biology as it relates to osteoporosis and the use of alendronate for treatment of the disease.

Bone is the tissue that provides mechanical support to the body. It is made up of a protein matrix, which is overlaid with mineral to give it hardness. (Russell[1] at 108-109; DTX 523 at 2). Two principal types of cells maintain bone: 1) osteoclasts, which break down bone, and 2) osteoblasts,

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[1] The bench trial transcript is cited throughout the Opinion by a notation to the witness and the page number of the transcript.

which build new bone. Id. The process of bone destruction and rebuilding is known as "remodeling." In the bone remodeling process, osteoclasts attach to the bone surface, become activated, and erode away the bone material beneath them, leaving defects in the bone structure. The destruction of bone by osteoclasts is called bone "resorption." Osteoblasts then attach to the eroded surface of these defects, lay down new bone, and then become inactive. In the normal healthy adult the remodeling process is balanced. In other words, bone is destroyed and built at the same rate. (Russell at 109-110; DTX 523 at 3-4).

In osteoporosis, bone destruction and formation are no longer balanced and bone is destroyed faster than it is replaced. Therefore, osteoporosis can lead to bone that is thinner, weaker, more fragile and porous. (Russell at 110-115; DTX 523 at 7, 8). Osteoporosis is treated primarily by inhibiting bone resorption - thus restoring the balance between bone destruction and formation. Alendronate inhibits bone resorption by blocking the bone destroying effects of osteoclasts. (Russell at 116-117). A small portion of the ingested drug makes its way to and adheres to the bone surface, where it resides until it is taken up by osteoclasts. The alendronate then inhibits the osteoclasts from resorbing bone. (Russell at 121-122; DTX 523 at 10).

Paget's disease is also a common bone disease characterized by increased bone resorption. In Paget's disease, increased bone remodeling occurs in localized areas of the skeleton. If Paget's disease is not detected and treated early it can lead to an increase in bone size, fractures, and deformity. (Russell at 97). Like osteoporosis, Paget's disease is treated by inhibiting bone resorption with alendronate. (Russell at 125-126).

III. Teva's Motion in Limine to Preclude Merck From Relitigating the Factual Findings Underlying the Decision in Teva Pharmaceuticals Ltd. et al. v. Instituto Gentili Spa et al. (D.I. 113).

Teva filed a Motion in Limine to Preclude Merck from Relitigating the Factual Findings Underlying the Decision in Teva Pharmaceuticals Ltd et al. Istituto Gentili Spa et al., (High Court of Justice, Chancery Division, Patents Court, January 21, 2003)). (D.I. 113). Accordingly, the Court will discuss the motion in limine before it delves into the issues of validity and enforceability of the '329 Patent.

Teva's principal defense in this case is that claims 23 and 37 are invalid because the claimed invention is anticipated or would have been obvious in view of the prior art. At the same time that the parties were litigating the validity of the '329 Patent in this Court, they were also involved in a case in the British High Court of Justice (the "High Court"). That case was a challenge by Teva and others to the validity of the European Patent No. 998,292 (the "'292 Patent"), which corresponds to the '329 Patent, and is based on the same provisional applications filed in July 1997. Teva, by its motion, contends that the '292 Patent covers the identical concept as the '329 Patent: the once-weekly dosing of alendronate sodium to treat osteoporosis, using seven times the normal daily dose.[2]

The High Court conducted a full trial on the merits from November 5-8, 2002, and heard further arguments from counsel on November 12-13, 2002. The trial involved live testimony from Merck's expert Dr. Socrates Papapoulos, who

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[2] This claim is in the form of a "Swiss claim." Such claims are used in attempts to avoid restrictions on claiming methods of treatment, which are unpatentable in many countries.

is Merck's expert in this case. In addition, Merck offered the testimony of Dr. Yates, the principal inventor of the '329 Patent, who also testified in this case. On January 22, 2003, Justice Jacob of the High Court found that the claimed invention was invalid because it would have been obvious to a person skilled in the art, it claims a method of treatment, and is incapable of industrial application.

A. Applicable Legal Principles

Teva contends that the Court should adopt the High Court's factual findings concerning obviousness pursuant to the doctrine of collateral estoppel. Collateral estoppel is appropriate if: (1) the issue is identical to one decided in the first action; (2) the issue was actually litigated in the first action; (3) resolution of the issue was essential to a final judgment in the first action; and (4) plaintiff had a full and fair opportunity to litigate the issue in the first action. Micron Technology, Inc. v. Rambus, Inc., 189 F. Supp. 2d 201, 209 (D. Del. 2002) (citations omitted). Additionally, the doctrine of collateral estoppel applies in patent cases. See Blonder-Tongue Laboratories. Inc. v. University of Illinois Foundation, 402 U.S. 313 (1971).

B. Parties' Contentions

1. Teva's Contentions

By its motion, Teva contends that Merck had the identical motivation in litigating the British case as it does in the instant case: to discredit the Lunar News (a prior art reference) and Teva’s reliance on its teachings. Moreover, Teva contends that Merck's barristers were afforded a full and fair opportunity to cross-examine all of Teva's witnesses and did so at length. Teva contends that the evidence was heard by Justice Jacob of the High Court, who is experienced in patents.

On January 22, 2003, Justice Jacob found the '292 Patent invalid and entered judgment against Merck. In its motion, Teva concedes that the legal standard may vary between Britain and the United States; nevertheless, Teva contends that regardless of the differences, if any, between the legal standards for determining validity, collateral estoppel should still apply to the resolution of the underlying factual issues. Specifically, Teva contends that all of the elements of collateral estoppel are met in this case with regard to the High Court's factual findings on obviousness.

First, Teva contends that collateral estoppel applies to fact findings of foreign courts. Teva argues that courts have recently recognized that parties who litigate in a foreign court should be bound by the results of that litigation to the extent that the requirements of the collateral estoppel doctrine are met. For example, Teva points to Vas-Cath, Inc. v. Mahurkar, 745 F. Supp. 517 (N.D. Ill. 1990), rev'd on other grounds, 935 F.3d 1555 (Fed. Cir. 1991), where the parties extensively litigated the issue of obviousness in Canada, and the district court held that the parties were bound by the fact-finding of the Canadian Court. Additionally, Teva points to Northlake Marketing & Supply, Inc. v. Glaverbel, S.A., 958 F. Supp. 373, 379 (N.D. Ill. 1997) (“Northlake I”) and Northlake Marketing & Supply, Inc. v. Glaverbel, S.A., 986 F. Supp. 471, 475-76 (N.D. Ill. 1997) (“Northlake II”), where the parties had previously litigated the validity of a Belgian patent that corresponded to the United States patent in suit. The district court in those cases held that the Belgian Court's conclusions about the scope and content of prior art were binding on the parties in the United States litigation.

Further, Teva directs the Court to Oneac Corp. v. Raychem Corp., 20 F. Supp. 2d 1233, 1242-1243 (N.D. Ill. 1998), where a corresponding European patent was litigated in the High Court and the district court held that with respect

to the United States patent, it would not give preclusive effect to questions of law or mixed questions of law and fact, but it would adopt the British Court's factual findings. Additionally, Teva points to Federal Circuit decisions that have declined to afford collateral estoppel effects to judgments in foreign cases, but distinguishes them on the basis that those decisions were predicated on what the Federal Circuit views as different standards of patentability in other countries. See, e.g., Meditronic Inc. v. Daig Corp., 789 F.2d 903 (Fed. Cir. 1996) (declining to adopt German tribunal's determination that corresponding German patent was invalid in view of different legal standards); In re Duhlberg, 472 F.2d 1394 (C.C.P.A. 1973) (same).

Second, Teva contends that the issues were the same in the British litigation; the obviousness of administering alendronate sodium once a week at a dose of about seven times the daily dose. Further, Teva argues that the issue of the scope and content of the prior art are the same in both cases; whether the Lunar News publications taught the administration of alendronate sodium once a week, and whether the prior art taught that the dose should approximate seven times the daily dose. In addition, Teva argues that Merck's fear defense is an issue in both cases. Merck claims that persons skilled in the art would have rejected the Lunar News teachings because of the fear that patients would not tolerate the larger dose. Merck raised the issue in Britain, and after considering the evidence, the High Court concluded that the “fear defense fails”. For example, the High Court found that the rare instances of esophageal side effects were attributed primarily to failure to follow the dosing instructions (D.I. 114, Ex. A, ¶ 65).

Third, Teva argues that the same issues were actually litigated in the High Court. For instance, Teva contends, the parties fully aired all factual evidence, where both sides had

qualified expert witnesses to explain the evidence to the Court. Further, Teva argues that all witnesses appeared live and were extensively cross-examined and after the trial both parties provided written submissions and appeared for extensive argument before Justice Jacob. As a result, Teva argues, Merck cannot contend that these issues were not litigated.

Fourth, Teva argues that the issues were determined by a valid and final judgment. Teva points out that the judgment of the High Court was the "Approved Judgement of that Court." It was issued on January 21, 2003 and reissued in corrected form January 22, 2003. Teva notes that Merck has appealed the judgment, but that fact does not imply that the judgment is not final for purposes of collateral estoppel. In fact, Teva argues that it is well settled that the pendency of an appeal does not diminish the preclusive effect of an appealed judgment. (D.I. 114 at 13) (quoting Rice v. Department of Treasury, 998 F.2d 997, 999 (3d Cir. 1993)).

Lastly, Teva contends that the resolution of obviousness was essential to the judgment in the High Court. Specifically, it contends that Justice Jacobs was required to and did evaluate and interpret the prior art provided by Merck's witnesses, and that, all findings on these issues were necessary to his final judgment that the patent was invalid for obviousness. Based on this, Teva argues that the High Court's factual findings should be given preclusive effect.

2. Merck's Contentions

In response, Merck argues that there is no transnational collateral estoppel as to the validity of a United States Patent. First, Merck contends that Teva fails to point to a single Federal Circuit case where, a foreign court's judgment that the patent was invalid, or the factual underpinnings of such a judgment, was given collateral

estoppel effect in a case litigating the validity of a United States Patent. In fact, Merck argues that the Federal Circuit and its predecessor court have rejected such attempts. For example in Meditronic Inc. v. Daig Corp., 789 F.2d 903 (Fed Cir. 1986), cert. denied, 107 S. Ct. 402 (1986), the Federal Circuit rejected the argument that it should adopt the conclusion of a German tribunal that a German counterpart was obvious and stated, "[t]his argument is specious. The patent laws of the United States are the laws governing a determination of obviousness/nonobviousness of a United States patent in a federal court." Id. at 907-908.

Additionally, Merck contends that the predecessor to the Federal Circuit came to the same conclusion in In re Duhlberg 472 F.2d 1394, 1398 (C.C.P.A. 1973) and In re Larsen, 292 F.2d 531, 533 (C.C.P.A. 1961), where in both cases, the court refused to consider the actions of a foreign country's patent office with respect to the patentability of the subject matter before the court.

Further, Merck argues that district courts have refused to give collateral estoppel effect to a foreign court's judgment. For example, Merck points to Cuno, Inc. v. Pall Corp., 729 F. Supp. 234 (E.D.N.Y. 1989), where the High Court found the European counterpart of the United States patent at issue to be valid and infringed, and when the plaintiff sought to have the United States district court give collateral estoppel effect to certain factual findings, the court denied the request and stated. that:

> Even if the court were to apply collateral estoppel to certain factual findings made by the British Court - as opposed to importing its legal conclusions wholesale-it is not clear that the trial time would be significantly shortened. Furthermore, the Federal Circuit's reluctance to give collateral estoppel effect

> to foreign judgments would seem to apply here to foreign findings of facts insofar as those findings involve mixed questions of fact and foreign law.

Id. at 238-239.

Moreover, Merck distinguishes the cases cited by Teva. First, in regard to the Oneac case, Merck points out that the court refused to give preclusive effect to questions of law or mixed questions of law and fact, and to the extent that certain factual findings were given collateral estoppel effect, it was because both parties to the suit agreed to be bound by those factual determinations. Oneac Corp., 20 F. Supp. 2d at 1242-1243. Additionally, Merck points to the Vas-Cath case where the Northern District of Illinois adopted certain factual findings of a Canadian Court in regard to the validity of a patent, after parsing out the Canadian judgment, comparing the relative Canadian and United States' laws and making its own conclusions regarding the applicability of the factual determinations in the context of the United States' legal framework. Additionally, in the Northlake cases, Merck points out that the district court adopted only certain factual findings from a previous Belgian proceeding after careful review of those findings and contends that most importantly, the issues that were precluded limited the evidence that the patent challenger could rely on. See Northlake II, 986 F. Supp. 475-476; Northlake I, 958 F. Supp. at 379.

Next, Merck argues that the requirements for collateral estoppel have not been met. First, Merck contends that the High Court's factual findings regarding obviousness were not essential to the final judgment because the High Court found that the '292 was invalid based on three grounds: 1) invalid as a method of treatment; 2) incapable of industrial application; and 3) invalid as obvious- not obviousness alone.

Lastly, Merck argues that the facts and applicable legal standard is different. Specifically, Merck contends that in the United States obviousness is ultimately a question of law which rests on the following factual inquiries: 1) the scope and content of prior art; 2) the level of ordinary skill in the art; 3) the differences between the claimed invention and the prior art; and 4) objective considerations of nonobviousness. See Advanced Display Systems, Inc. v. Kent State Univ., 212 F.3d 1272, 1284-85 (Fed. Cir. 2000), On the other hand, Merck argues, in Britain, the determination of obviousness is based on the following factual inquiries: 1) identifying the inventive concept embodied in the patent in suit; 2) assuming the mantle of the normally skilled but unimaginative addressee in the art at the priority date and impute to him what was, at that date, common general knowledge in the art; 3) identifying what, if any, differences exist between the matter cited as being made available to the public and the alleged invention; 4) determining whether, viewed without any knowledge of the alleged invention, those differences constitute steps which would have been obvious to the skilled man or whether they required any degree of invention. (D.I. 126 at 17) (citing Windsurfing International, Inc. v. Tabur Marine (Great Britain) Ltd., 1985 R.P.C. 59, 60-61 (1985 Ct. Of Appeal)). Merck contends that although these standards are similar, the United States Court is required to consider objective considerations of obviousness, while in Britain they are not. Accordingly, Merck contends that collateral estoppel is improper.

C. **Discussion**

As outlined above, the standards for determining obviousness in the United States and Britain are different. In fact, for purposes of this motion, Teva concedes that there may be differences in the legal standards for validity between

the United States and Britain. Additionally, after reviewing the "factual findings" of the High Court, the Court finds that many of the principles are mixed questions of law and fact. The cases cited demonstrate that mixed questions of law and fact should not be adopted if there are two different legal standards, as in this case. See, e.g., Oneac Corp., 20 F. Supp. 2d at 1242-1243 (declining to adopt mixed questions of law and fact). Additionally, in Oneac the court only adopted factual findings from a foreign tribunal where the parties agreed to be bound by such factual findings. Id. at 1242-43. This is not the situation in the instant case because Merck opposes any adoption of the High Court's factual findings. Also, the Court finds that Merck has successfully distinguished the Northlake cases from the instant case, where in the Northlake cases the issues that were precluded limited the evidence that the patent challenger could rely on and the adopted factual findings did not go to the validity of the patent in suit.

The Court also concludes that all of the elements necessary for a finding of collateral estoppel are not present in this case. Specifically, the High Court's factual findings relating to obviousness were not essential to the High Court's decision because that decision was based on three separate grounds as detailed above. The Third Circuit has stated that "if a judgment of a court of first instance is based on determinations of two issues, either of which standing independently would be sufficient to support the result, the judgment is not conclusive with respect to either issue standing alone." Arab African Int'l Bank v. Epstein, 958 F.2d 532, 535, (3d Cir. 1992) (quoting Restatement (Second) of Judgments § 27, cmt. i), rev'd in part on other grounds, 10 F.3d 168 (3d Cir. 1996). The Court concludes that based on this standard, the High Court's finding of obviousness cannot be said to be essential to the final determination.

There may be cases where "the balance tips in favor of preclusion because of the fullness with which the issue was litigated and decided in the first action." Masco Corp v. United States, 303 F.3d 1329-1330 (Fed. Cir. 2002). However, the Court concludes that this is not such a case, especially in light of the fact that the Federal Circuit has cautioned courts against giving too much weight to foreign tribunals who are confronted with the same prior art. See Heidelberger Druckmaschinen AG v. Hantscho Comm. Prods., Inc., 21 F.3d 1068, 1072 (Fed. Cir. 1994) (recognizing that theories and laws of patentability differ from country to country and stating that "[c]aution is required when applying the action of a foreign patent examiner to deciding whether the requirements of 35 U.S.C. § 103 are met under United States law, for international uniformity in theory and practice has not been achieved."). While the Court has reviewed Justice Jacob's factual findings in regard to obviousness, based on the aforementioned reasons, the Court declines to adopt them and will make independent findings of fact on the issue of validity. Accordingly, Teva's motion will be denied.

IV. **Invalidity**

Once issued a patent is presumed to be valid. See 35 U.S.C. § 282. The party challenging the patent bears the burden of proving by clear and convincing evidence that the patent is invalid. See Helifix Ltd. v. Blok-Lok Ltd., 208 F.3d 1339, 1346 (Fed. Cir. 2000). Clear and convincing evidence is evidence that places in the fact finder "an abiding conviction that the truth of [the] factual contentions are 'highly probable.'" Colorado v. New Mexico, 467 U.S. 310, 316 (1984).

Defendants contend that the '329 Patent is invalid and therefore cannot be infringed. Defendants argue invalidity on

two grounds: anticipation by the July 1996 Lunar News reference under 35 U.S.C. § 102(e), and obviousness under 35 U.S.C. § 103. For the reasons set forth below, the Court concludes that the '329 Patent is valid.

A. **Claim Construction**

The first step in any invalidity analysis is claim construction which is an issue of law. SIBIA Neurosciences, Inc. v. Cadus Pharmaceutical Corp., 225 F.3d 1349, 1355 (Fed. Cir. 2000); Markman v. Westview Instruments, Inc., 52 F.3d 967, 970-71 (Fed. Cir. 1995) (en banc), aff'd, 517 U.S. 370 (1996). A claim term should be construed to mean "what one of ordinary skill in the art at the time of the invention would have understood the term to mean." E.g., Markman, 52 F.3d at 986. Further, when conducting a claim construction analysis, a district court should be cognizant of the fact that claims should be construed, if possible, to uphold their validity. In re Yamamoto, 740 F.2d 1569, 1571 & n.* (Fed. cir. 1984) (citations omitted).

The starting point for a claim construction analysis is the claims themselves. Vitronics Corp. v. Conceptronic, Inc., 90 F.3d at 1582; see also Pitney Bowes, Inc. v. Hewlett Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999) (stating that "[t]he starting point for any claim construction must be the claims themselves."). Thereafter, the remainder of the intrinsic evidence should be examined beginning with the specification and concluding with the prosecution history. Vitronics, 90 F.3d at 1582 (outlining this order for examination in claim construction).

Generally, there is a strong presumption in favor of the ordinary meaning of claim language as understood by those of ordinary skill in the art. Bell Atl. Network Servs., Inc. v, Covad Communications Group, Inc., 262 F.3d 1258, 1268 (Fed. Cir. 2001). However, it is well-settled that a

patentee may act as his own lexicographer and use the specification to supply implicit or explicit meanings for claim terms. Bell Atl. Network Servs., 262 F.3d at 1268 (Fed. Cir. 2001); Vitronics Corp., 90 F.3d at 1582; Markman, 52 F.3d at 980 (noting that patentee is free to be his own lexicographer, but emphasizing that any special definitions given to words must be clearly set forth in patent). "[T]he patentee's lexicography must, appear 'with reasonable clarity, deliberateness, and precision' before it can affect the claim." Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1249 (Fed. Cir. 1998) (quoting In re Paulsen, 30 F.3d 1475, 1480 (Fed. Cir. 1994)).

If the meaning of a claim term is clear from the totality of the intrinsic evidence, than the claim may be construed. If, however, the meaning of a claim term is "genuinely ambiguous" after examining the intrinsic evidence, than a court may consult extrinsic evidence. Bell & Howell Document Mgmt. Prods. Co. v. Altek Sys., 132 F.3d 701, 706 (Fed. Cir. 1997).

Claim terms in claims 23 and 37 of the '329 Patent are disputed in this case. Accordingly, the Court will focus its discussion on these claims

In full, claim 23 of the '329 Patent provides, "[a] method according to claim 22 wherein said unit dosage of said bisphosphonate comprises about 70 mg of alendronate monosodium trihydrate on an alendronic acid active basis." (PTX 1, '329 Patent at col. 21, lines 24-27) (emphasis added).

In full, claim 37 of the '329 Patent provides, "[a] method according to claim 36 wherein said bisphosphonate unit dosage comprises about 35 mg of alendronate monosodium trihydrate, on an alendronic acid active basis." (PTX 1, '329 Patent at col. 22, lines 24-26) (emphasis added).

Teva contends that the term "about" in claims 23 and 37 should be construed according to its ordinary meaning of "approximately." (D.I. 147 at 3). Merck contends that the patentee in this case acted as his own lexicographer and set out the meaning of "about" in the specification where the specification explains that the term "about" accounts for the variability of weight of the active ingredient that would result from the use of different salts of alendronic acids. (D.I. 141 at 42). Thus, Merck contends that the phrase "about 70 mg" as used in claim 23 and "about 35 mg" as used in claim 37 means 70 and 35 mg respectively of the active ingredient on an alendronic acid active basis. Id. at 43. In other words, Merck contends that, regardless of the final weight of the actual active ingredient in the tablet, it contains the same number of alendronate core molecules as 70/35 mg of alendronic acid.

In rebuttal, Teva contends that Merck's proffered construction makes no sense. Teva points out that according to Merck, the word "about" is used to account for the fact that different alendronate salts have different molecular weights, and that to deliver the same amount of physiologically active compound to the bone they must be delivered at slightly different dosage strengths. (D.I. 147 at 4). Teva contends that Merck's interpretation is nonsensical because the claim itself accounts for this phenomenon by directing that the compound be administered on the basis of a common denominator, i.e., "on an alendronic active basis." Id. In other words, Teva contends that the claims require that the amount "alendronate sodium trihydrate" be sufficient to deliver the same amount of active material as "about 70/35 mg" of alendronic acid. Id. As a result, Teva contends, the term "about" does not perform the function which Merck assigns to it, and must be in the claim for another purpose, that is, to have its ordinary meaning of "approximately."

After reviewing the claim terms and the specification, the Court concludes that the patentee explicitly and with reasonable clarity and precision defined the term "about 70 mg" in claim 23 and "about 35 mg" to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories. Simply put, no matter what the final weight of the actual active ingredient in the tablet is, it contains the same number of alendronate core molecules as 70/35 mg of alendronic acid.

The relevant portion of the '329 Patent specification provides:

> Because of the mixed nomenclature currently in use by those or [sic] ordinary skill in the art, reference to a specific weight or percentage of bisphosphonate compound in the present invention is on an active weight basis unless otherwise indicated herein. For example the phrase "about 70 mg of bone resorption inhibiting bisphosphonate selected from the group consisting of alendronate, pharmaceutically acceptable salts thereof and mixtures thereof, on an alendronic acid weight basis" means that the amount of bisphosphonate compound selected is calculated based on 70 mg of alendronic acid.

PTX 1, the '329 Patent, col. 10, 65-col. 11, line 8. (emphasis added). The Court concludes that the specification clearly indicates that the terms "about 70 mg" and "about 35 mg" refer to the fact that depending on the derivative of the alendronic acid that could be used in the oral formulation, different weights will be needed in order to get the same effect as 70 or 35 mg of the seminal compound, alendronic acid. As Merck points out, the alendronate sodium in

Fosamax includes an atom of sodium metal for each molecule of alendronate sodium. (D.I. 138 at 24). If a formulator was to select a different salt which includes a metal atom that is heavier than salt, e.g., a potassium or barium atom, the total amount of material in each tablet would have to increase if the amount of alendronic acid were to remain the same. By conforming the weight of the alendronate derivative in the claim of the '329 Patent to the equivalent weight of the alendronic acid, a formulator can consistently know how many basic units (alendronic acid units) are to be used, even though the final total weight may be different. Examples 7 and 8 of the '329 Patent reinforce this conclusion. They provide for oral formulations "containing about 35 mg" and "about 70 mg" of alendronate "on an alendronic acid active basis." The claims at issue use the same phraseology and the ingredient tables in the examples are consistent with the premise that "about" accounts for the fact that alendronate derivatives have accessories that add to the weight of the molecules. Thus, in the examples "about 35 mg" turns out to be 45.68 mg of alendronate monosodium trihydrate and the "about 70 mg" turns out to be 91.35 mg of alendronate monosodium trihydrate. See PTX 1, the '329 Patent col. 19 lines 13-15, col. 19, lines 44-46, col. 19 lines 20-21, col. 19 lines 51-52.

Although the Court finds that Dr. Russell, is competent in the area of bisphosphonates, it does not find his opinion as to the definition of the phrases "about 70/35 mg" in the '329 Patent persuasive. During cross examination on this issue, Dr. Russell testified as follows:

> Q. Now is it true that when you deal with the claims in this case, the claims recite 70 and 35; correct? That is 70 mg a week and 35?
> A. The claims say about 70 and about ....
> Q. And what does "about" mean to you?

A. Well about to me depends how precise a definition we want. But for purposes of how close the 40 and 80 are to about 35 and 70, I've given you my opinion on that, that for practical purposes, those would be the same, they would be indistinguishable in their effects, given everything else we know about the properties of these drugs.
Q. But the claim itself, what the claim really means, is 70, not 80; correct?
A. It says about 70 and about 35.
Q. Did you read the patent, Dr. Russell, the entire body of the patent?
A. Yes, I have.
Q. So in the patent, does it tell you what about 70 means?
A. There is a reference somewhere to about in the patent as I recall, but I'd need to be directed to where it was.
Q. Why don't you go to the first, in the patent, which is Defendant's Exhibit 1 and Plaintiff's Exhibit 1, at column 11, lines-about 1 through 9. It says here in the definitional context exactly what about 70 milligrams means; correct?
A. It- well, there's almost an intrinsic contradiction in this, because the definition here is talking about 70, and then referring to whatever salt form is used being referenced to the alendronic acid itself, yes.
Q. But in the patent it gives you a precise reference and says when we say about 70 milligrams of a bone resorption inhibiting bisphosphonate, what we mean is that amount of a bisphosphonate that will deliver an equivalent amount, the equivalent of 70 milligrams of alendronic acid; correct?
A. Yes. I have difficulty with this statement because the reason if it's that precise at 70, why does it use the phrase about?

> Q. But they gave you that exact definition; correct?
> A. It's a curious use of the English language.
> Q. I understand, but it is what it says, and perhaps the person wanted to say if it's a certain salt one, you might use 71, and if it's a certain salt 2, you might use 73. Isn't that what's indicated in this?
> A. Possibly.
> Q. But that's what the definition says; right?
> A. That is the definition as it's described in the patent.

Russell at 337-339. (emphasis added). Although Dr. Russell opined that the explicit definition of the disputed claim terms in the specification was "a curious use of the English Language," he testified that Merck's proffered construction is the definition as it is described in the patent. The Court finds Dr. Russell's interpretation unpersuasive, especially in light of the fact that patentees may give special meanings to claim terms either explicitly or implicitly in patent specifications. Further, with regard to Teva's claim that there is no function to Merck's proffered construction, the Court finds this argument unpersuasive given the clear directive in the specification to construe the term "about 70/35 mg" to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives and the fact that depending on the derivative of alendronic acid used in the oral formulation, different weights will be needed in order to get the same effect as 70 or 35 mg of alendronic acid. See Bell Atl. Network Servs., 262 F.3d at 1268 (noting that the specification must express a clear intent to redefine a claim term). Accordingly, the Court will accept Merck's proffered construction and construe the disputed claim terms "about 70/35 mg" to mean the equivalent of 70/35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories.

B. **Anticipation**

Anticipation is determined through a comparison of the claim language with a single prior art reference. See Wesley Jessen Corp. v. Bausch & Lomb, Inc., 209 F. Supp. 2d 348, 391 (D. Del 2002). In pertinent part, 35 U.S.C.§ 102(e) (2) provides:

> A person shall be entitled to a patent unless ...
> (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351 (a).

35 U.S.C. § 102 (e) (2). Anticipation under 35 U.S.C. § 102 (e) requires that every element of the claim be found either expressly or inherently "in a single prior art reference." In re Robertson, 169 F.3d 743, 745 (Fed. Cir. 1999). Thus, if the prior art reference does not expressly state an element of the claim, "that reference may still anticipate if that element is 'inherent' in its disclosure." Id. Inherency is established if the evidence makes "clear that the missing descriptive matter is necessarily present in the thing described in the reference and, and that it would be so recognized by persons of ordinary skill." Continental Can Co. v. Monsanto Co., 948 F.2d 1264, 1268 (Fed. Cir. 1991). Although inherency cannot be established through probabilities, recognition by a person of ordinary skill in the art before the critical date of the patent is not required to show inherent anticipation. Schering Corp. v. Geneva Pharms., Inc., 2003 U.S. App. Lexis 15496 at *9-10 (Fed. Cir. August 1, 2003) (rejecting the contention that inherent anticipation

requires recognition in the prior art before the critical date); In re Robertson, 169 F.3d at 745 (noting that inherent anticipation cannot be demonstrated through probabilities).

1. The Parties' Contentions

Teva contends that a July 1996 Lunar News article expressly anticipates claims 23 and 37 of the '329 Patent. Teva points out that since Merck has stipulated that it does not assert an invention date before July, 22, 1997, the July 1996 Lunar News is prior art under 35 U.S.C. § 102(a). (D.I. 143 at 19). Further, Teva points out that although it has the burden of proving invalidity by clear and convincing evidence, that burden is more easily met in this situation because Merck failed to provide the PTO with the July 1996 Lunar News.

Teva contends that the July 1996 Lunar News discloses every element of claims 23 and 37 of the '329 Patent. Teva points out that claim 23 defines a method of treating osteoporosis which comprises of oral administration of "about 70 mg" alendronate monosodium trihydrate, on an active alendronic acid basis, once-weekly. Similarly, Teva argues the July 1996 Lunar News discloses the same elements where it discusses the use of bisphosphonates, including alendronate, "in dealing with osteoporosis," which means the treatment and prevention of osteoporosis. (D.I. 143 at 21; Russell at 137). Further, Teva contends that the July 1996 Lunar News also specifies that the alendronate therapy it is discussing includes "oral" alendronate therapy, and that the term "alendronate" refers to "Fosamax by Merck." Teva also contends that the active ingredient of Fosamax was well known to be alendronate monosodium trihydrate, and the dosage strength of Fosamax was known to be reported on an alendronic acid basis. (D.I. 143 at 21; DTX

394; Russell at 138-39). Teva also points out that the article specifies that the drug can be administered on a weekly basis at a dose of 80 mg where it states that, " ... oral alendronate potentially could be given in a 40 or 80 mg dose once/week." (D.I. 143 at 21) (quoting DTX 418 at 23). Teva directs the Court to Dr. Russell's testimony where he opines that to a person skilled in the art, 80 mg of alendronate once per week is clinically indistinguishable from 70 mg once a week, and is therefore "about 70 mg." (D.I. 143 at 21; Russell at 138). Teva also contends that Merck itself viewed 80 mg and 70 mg as the same weekly dose. (D.I. 143 at 21; DTX 147 at MK0158265). Thus, Teva contends the July 1996 Lunar News Article discloses every element of claim 23: treatment of osteoporosis by the administration of about 70 mg monosodium trihydrate on an alendronic acid basis once-weekly. (D.I. 143 at 22).

Teva further contends that the July 1996 Lunar News anticipates claim 37 of the '329 Patent. Claim 37 claims a method for preventing osteoporosis in a human being comprising of orally administering about 35 mg of alendronate sodium on an alendronic acid basis as a unit dosage according to a continuous schedule having a dosage interval of once-weekly. (D.I. 143 at 22; DTX 1). Teva points out that the only difference between the two claims is that claim 23 is directed to "treatment" of osteoporosis with a 70 mg weekly dose, and claim 37 is directed to "prevention" with a 35 mg weekly dose. Teva reiterates the contention that the July 1996 Lunar News deals with both the treatment and prevention of osteoporosis and discloses the use of a 40 mg once-weekly oral dose. (D.I. 143 at 22). Teva again directs the Court to Dr. Russell's testimony where he testified that to a person skilled in the art, a 40 mg dose of alendronate once per week is clinically indistinguishable from 35 mg once per week and is therefore "about 35 mg." (D.I. 143 at 22; Russell at 140; DTX 147 at MK0158265). As a result, Teva contends

that the July 1996 Lunar News discloses every element of claim 37: prevention of osteoporosis by oral administration of about 35 mg alendronate monosodium trihydrate on an alendronic acid basis once weekly. (D. I. 143 at 22).

Teva contends that Merck's "fear defense" is irrelevant to anticipation. First, Teva points out that claims 23 and 37 do not require that once-weekly administration of alendronate meet any standard of safety or tolerability. (D. I. 143 at 23). Even if they did, Teva argues, such a requirement would not avoid anticipation because the property of tolerability is inherent in the method disclosed in prior art. Further, Teva argues that the concept of "teaching away" from an invention is inapplicable in an anticipation analysis, and therefore, the Court should not consider it. (D.I. 143 at 24). Based on this, Teva contends that claims 23 and 37 are anticipated by the July 1996 Lunar News, and are therefore, invalid.

In reply, Merck contends that the July 1996 Lunar News fails to anticipate claims 23 and 37 of the '329 Patent. Merck points out that the claims require the use of 70 or 35 mg of alendronate sodium on an alendronic acid active basis and even if one were to read the July 1996 Lunar News suggestion that "[e]ven alendronate potentially could be given in a 40 or 80 mg dose once/week" as referring to the amount on an alendronic acid active basis, 80 mg is not the same as 70 mg and 40 mg is not the same as 35 mg. Merck argues that the unambiguous weight requirement for alendronate in claims 23 and 37 is not met by the Lunar News' suggestion of 80 or 40 mg, and therefore, it fails to anticipate claims 23 and 37. (D.I. 138 at 27). Further, Merck argues that the July 1996 Lunar News is not enabling, and therefore, cannot anticipate. Specifically, Merck contends that in order for a disclosure to be enabling it must allow one of skill in the art to practice the invention, and the July 1996

Lunar News falls short of this standard because it fails to address the expectation by physicians in the field during 1996-1997 that alendronate sodium at doses over 20 mg would not be well-tolerated in the prevention and treatment of osteoporosis. Merck points to Dr. Fennerty's testimony to establish that a knowledgeable gastroenterologist during the applicable period would have been "extraordinarily concerned" about suggesting 40 or 80 mg of alendronate to treat osteoporosis. (D.I. 138 at 28; Fennerty at 270-271).

Further, Merck argues that Dr. Papapoulos, Merck's expert with extensive bisphosphonate and clinical osteoporosis experience, corroborates this sentiment. (D.I. 138 at 28). Merck argues that given the state of the medical knowledge at the time, a physician would not administer those high dosages when managing osteoporosis, and as a result, the July 1996 Lunar News fails to anticipate claims 23 and 37 of the '329 Patent.

2. Whether the July 1996 Lunar News Anticipates the '329 Patent

After a review of the record evidence, the Court concludes that claims 23 and 37 of the '329 Patent are not anticipated under 35 U.S.C. § 102(e) (2). Specifically, the Court concludes that Teva has failed to prove by clear and convincing evidence that the July 1996 Lunar News expressly or inherently discloses the dosage amounts for alendronate in claims 23 and 37. As a threshold matter and contrary to Teva's contentions, it has to prove invalidity by clear and convincing evidence. See American Hoist & Derrick Co. v. Sowa & Sons, Inc., 725 F.2d 1350, 1360 (Fed. Cir. 1984) (citations omitted) (stating that when a challenger produces prior art not before the PTO "the standard of proof does not change; it must be by clear and convincing evidence

or its equivalent.") With this standard in mind, the Court will consider the parties' contentions with regard to anticipation.

The Lunar corporation was a manufacturer of bone densitometry equipment, which is a diagnostic tool for osteoporosis. (Russell at 129). The Lunar News was a quarterly newsletter distributed by the Lunar Corporation to its customers. (Mazess Dep. at 55-56; Russell at 129). It was authored by Dr. Richard Mazess[1], the former President of the Lunar Corporation. The July 1996 edition[2] contained a section entitled, "Update Bisphosphonate," (PTX 29 at 23). The section discusses bisphosphonates as a treatment for osteoporosis. Id. Specifically, in reference to the use of alendronate for treatment of osteoporosis, it states that "[s]ome United States physicians are reluctant to treat because of: a) side effects; b) difficulty of dosing; and (c) high costs ($700/year). (PTX 19 at 23). To address the difficulty of dosing and high costs the article suggests:

> The difficulties with oral bisphosphonates may favor their episodic (once/week) or cyclical (one week each month) administration. Even oral alendronate potentially could be given in a 40 or 80

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[1] Dr. Mazess does not possess an MD, has no formal training in pharmacology, and obtained his bachelors degree and Ph.D. in anthropology. (Mazess Dep at 30-32).

[2] The Court understands that Teva is not contending that the April 1997 edition of the Lunar News anticipates the '329 Patent. See D.I. 143; Opening Brief at 19-24 (failing to assert that the April 1997 Lunar News anticipates claims 23 and 37 of the '329 Patent). However, even if Teva made this assertion, the Court concludes that the April 1997 Lunar News did not anticipate claims 23 and 37 because it does not suggest any dosage amounts in connection with its discussion of once-weekly dosing of alendronate. (DTX 417). Thus, it does not disclose all of the elements of claims 23 and 37, namely "about 35/70 mg" of alendronate, and therefore, cannot anticipate the claims either expressly or inherently.

> mg dose once/week to avoid dosing problems and reduce costs.

PTX 29 at 23. Teva contends that the July 1996 Lunar News article discloses all of the elements in claim 23 of the '329 Patent. Specifically, Teva argues that the July 1996 Lunar News discloses the following elements: 1) A method of treating osteoporosis in a human; 2) orally administering; 3) about 70 mg; 4) of alendronate monosodium trihydrate; 5) on an alendronic acid active basis; 6) as a unit dosage; and 7) according to a continuous schedule having a dosing interval once-weekly. (D.I. 143 at 23). Merck asserts that the July 1996 Lunar News article does not anticipate claim 23 because it fails to reference 70 mg of alendronate sodium on an alendronic acid active basis as required by claim 23. (D.I. 141 at 44).

After reviewing the July 1996 Lunar News in light of the '329 Patent, and the Court's construction of the claim terms, the Court is not persuaded that Teva has demonstrated by clear and convincing evidence that claims 23 and 37 of the '329 Patent are anticipated by the July 1996 Lunar News. The July 1996 Lunar News fails to reference 70 mg of alendronate sodium on an alendronic acid basis as required by the claim. Instead it references an 80 mg dose of oral alendronate. Thus, it does not expressly disclose “about 70 mg” of alendronate sodium “on an alendronic acid basis.” Likewise, the Court is not persuaded that Teva has demonstrated inherency. Although Dr. Russell testified that 80 mg and “about 70 mg” are the same for all practical purposes because they have the same effect on patients, he did not testify that this element was “necessarily present” in the July 1996 Lunar News reference or that its disclosure was sufficient to show that this element was the natural result flowing from the operation as taught. In fact, in the Court's view, Dr. Russell's testimony was insufficient on this issue,

and was, at best, conclusory. For example, although Dr. Russell testified that 80 mg and 70 mg are the same for all practical purposes because they would have the same effect, the Court recognizes that in rendering his opinion Dr. Russell did not take into account the Court's construction of the term "about 70 mg". (Russell at 137-139). Further, the Court notes that Dr. Russell provided no evidence to support his conclusion that 70 and 80 mg were equivalent. In fact, Dr. Papapoulos testified on cross-examination that one would need to test the 80 and 70 mg doses before concluding with any certainty that they are the same and the regulations regarding the filing of an ANDA recognize that any change in the dosage of a drug would require additional data. (Papapoulos at 676-678; 21 U.S.C. § 355 (j)(2); 21 C.F.R. § 314.93). Dr. Russell, provided no such data. Based on this, the Court concludes that Teva has failed to demonstrate that the July 1996 Lunar News inherently or expressly disclosed the element of "about 70 mg" of alendronate sodium "on an alendronic acid active basis" as required by claim 23 of the '329 Patent.

Similarly, the Court concludes that the July 1996 Lunar News fails to disclose "about 35 mg" as required by claim 37 of the '329 Patent. Specifically, the July 1996 Lunar News fails to reference "35 mg" of alendronate sodium "on an alendronic acid active basis" as required by the claim. Although it references "40 mg", in light of the Court's claim construction of "about 35 mg" to mean the equivalent of 35 mg of alendronic acid when taking into account molecular weight variances for its derivatives that carry accessories, the Court concludes that the July 1996 Lunar News reference does not expressly disclose "about 35 mg" as required by claim 37. Likewise, the Court concludes that Teva's inherency argument as to claim 37 must also fail. Dr. Russell testified that a 40 mg dose is about the same as a 35 mg for all practical purposes. (Russell art 140-141). However, the

Court finds Dr. Russell's opinion on this issue to be conclusory because he provides no evidence, statistical tests or data to support this assertion. Further, Dr. Russell did not testify that this element was "necessarily present" in the July 1996 Lunar News reference or that its disclosure was sufficient to show that this element was the natural result flowing from the operation as taught. Based on this, the Court finds that the evidence is insufficient to show that each element of claims 23 and 37 of the '329 Patent were present in the prior art reference expressly or inherently. Accordingly, the Court concludes that Teva has failed to establish by clear and convincing evidence that the '329 Patent was anticipated by the July 1996 Lunar News. Because the Court concludes that claims 23 and 37 of the '329 Patent were not anticipated by the July 1996 Lunar News, the Court will not address the parties' contentions concerning enablement of the prior art.

C. **Obviousness**

Teva contends that the '329 Patent is invalid, under 35 U.S.C. § 103, as obvious. In pertinent part, 35 U.S.C. § 103 provides that a patent may not be obtained "if the differences between the subject matter sought to be patented and prior art are such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art ..." 35 U.S.C. § 103. The obviousness determination is a question of law which is based on several underlying factual inquiries. See Richardson-Vicks Inc. v. UpJohn Co., 122 F.3d 1476, 1479 (Fed. Cir. 1997). The underlying factual inquiries require consideration of the four "Graham" factors which are: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) any secondary considerations of nonobviousness such as commercial success, long felt but unsolved need, failure of others, and acquiescence of others in the industry that the patent is valid.

See Graham v. John Deere Co. of Kansas City, 383 U.S. 1, 17-18 (Fed. Cir. 1996). Additionally, as with anticipation, the burden of demonstrating obviousness is with the challenger and invalidity must be proven by clear and convincing evidence. C.R. Bard, Inc. v. M3 Systems, 157 F.3d 1340, 1351 (Fed. Cir. 1998).

1. The Parties' Contentions

Teva contends that the '329 Patent is invalid as obvious because both the April 1997 and July 1996 editions of Lunar News explicitly disclose the weekly administration of alendronate for osteoporosis and a person skilled in the art would have understood in July 1997 that the weekly dose for treatment and prevention of osteoporosis should be "about 70 mg" and "about 35 mg" respectively, and that these doses are explicitly set out in the July 1996 Lunar News. Teva argues that not only did the Lunar News disclose the concept of once-weekly dosing and provide the appropriate dose, a person of ordinary skill would have predicted the Lunar News teaching to be effective. (D. I. 143 at 26).

Further, Teva contends that there was a motivation to employ once-weekly dosing because of the inconvenience of the dosing regimen which consisted of taking the tablet before eating, remaining upright for a half an hour and taking the tablet with a full glass of water. Id. at 27. Teva points out that the April 1997 and July 1996 editions of Lunar News explicitly stated the motivation to administer alendronate weekly; to improve patient convenience and compliance with the dosing instructions. Id. Thus, Teva argues that the prior art that claimed the invention also disclosed the motivation to make it. Id.

Teva contends that a person of skill in the art would not have been deterred from once-weekly dosing because of the fear of increased gastrointestinal side effects. Id. As to

this point Teva argues that the early reports of esophagitis would not have deterred a person of skill in the art from once-weekly dosing because the early reports showed that these events were rare, occurring in one out of every ten thousand patients taking 10 mg of alendronate daily, and that these effects were for the most part reversible with proper treatment. Id. at 28; Markowitz at 436-37; 451. Teva also points out that in March 1996, five months after the launch of 10 mg daily alendronate tablet, ten million patients had been prescribed the tablet and fifty cases of severe esophagitis had been reported to Merck, and Merck took no action until it learned that a letter written by a well-known bone-specialist discussing two such cases was circulating within the Mayo Clinic Health System. D.I. 143 at 29; Hirsch Dep. at 54-56). When it finally took action, Teva argues, Merck's investigation concluded that the pill esophagitis cases were caused primarily by the failure of patients to adhere to the dosing instructions. (D.I. 143 at 29; Markowitz at 442; Hirsch Dep. at 66; 82-84).

Teva also points out that in March 1996, Merck disseminated a "Dear Doctor" letter, informing physicians about the infrequent cases of esophagitis, stating that in a "large majority" of cases patients appeared to have not complied with the dosing instructions, and advocating "strict compliance" with those instructions. (D.I. 143 at 30; DTX 34). Merck later reported on the severe esophagitis cases in the October 1996 De Groen et al.[3] article in the New England Journal of Medicine. (PTX 91). The De Groen paper reported that 51 patients experienced adverse effects classified as "serious" or "severe" out of the 470,000 patients worldwide who had received prescriptions for alendronate to treat osteoporosis up to that time. (D. I. 143 at 30). Teva

[3] De Groen et al., The New England Journal of Medicine, 1996 (PTX 91).

directs the Court to its gastroenterology expert, Dr. David Markowitz, who testified that the extremely low incidence of these effects, and the description of the cases, led gastroenterologists to conclude at the time that the likely cause of the problem was "pill esophagitis."(D.I. 143 at 30; Markowitz 435, 438). Teva argues that the evidence presented at trial leads to the conclusion that once-weekly administration would have been expected to decrease the incidence of severe esophagitis cases because it would: 1) improve patient compliance with the dosing instructions (Russell at 195-96; Markowitz at 485-86; Fennerty at 311); and 2) decrease the frequency of administration, thereby decreasing the chances of the tablet "sticking" in the esophagus (Russell at 196-197; Markowitz at 443).

Teva also asserts that the evidence presented at trial does not support a dose-response relationship between alendronate and gastrointestinal effects that would have deterred a person of ordinary skill in the art from once-weekly dosing. (D.I. 143 at 32). For example, Teva argues that the results of the Chestnut[4] study related to daily and not weekly dosing and demonstrated that 90% of postmenopausal women with osteoporosis tolerated the 40 mg daily dose. Id. at 34. Also, Teva contends that Dr. Fennerty's testimony regarding a dose-related relationship was discredited by Merck's pre-litigation behavior and directs the Court to the testimony of Dr. Markowitz who testified that his contemporaneous investigations indicated that severe events were extremely rare with alendronate and that overall the drug was well tolerated. Id. at 35.

In addition, Teva contends that before this litigation, Merck admitted that prior art data available in July 1997 from Paget's patients showed that once weekly dosing would

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[4] Chestnut et al., The American Journal of Medicine, 1995, (PTX 69).

be well-tolerated. For example, Teva directs the Court to a May 1997 "Tactical PAC" review seeking management approval to go forward with the once-weekly dosing program where it stated that "the 40 and 80 mg doses were well-tolerated even when given on a daily basis." (D.I. 143 at 39, DTX 147 at MK0158265). Further, Teva points out that Merck, in a formal submission to the FDA maintained that data from Paget's disease provided an expectation that once-weekly doses would be well tolerated. (D.I. 143 at 39; DTX 192 at 17).

Teva also argues that a person of skill in the art would not have been deterred from once-weekly dosing because of the alleged dose-related effects of prior art bisphosphonates, because the magnitude of data available on alendronate in treating osteoporosis and Paget's disease made reference to other bisphosphonates unnecessary. (D.I. 143 at 41). Teva also points out that Merck's Physician Survey conducted in 1997 indicated that physicians perceived that larger less-frequent doses would result in "less-GI upset." (D.I. 143 at 43; DTX 244 at MK0174861).

Teva also contends that the '329 invention did not provide unexpected results because the prior art disclosed its principal advantage; convenience and compliance. (D.I. 143 at 44). Additionally, Teva contends that Merck did not carry its burden of demonstrating commercial success because it was required to show that the once-weekly product contributed to the incremental success beyond the daily product and that Merck's expert, Dr. Vellturo failed to demonstrate any connection between the patented invention and Merck's sales of once-weekly Fosamax. Specifically, Teva contends that Dr. Vellturo did not opine that the two were connected but merely asserted that "commercial success could be at least in part, significant part, attributable to the Daifotis patients." D.I. 143 at 48; Vellturo at 715. Further,

Teva suggests that Dr. Vellturo's analysis is flawed because of his emphasis on sales and prescriptions as the only indicia of success without considering any other market factors such as the increased awareness about osteoporosis and the effect of the increasing number of Americans over the age of sixty, like its own expert, economist, Dr. Richard Rozek took into account. (D.I. 143 at 48). Additionally, with regard to commercial success, Teva contends that Merck ignored its own successful marketing efforts such as its heavy promotional expenditures during the applicable period when examining the commercial success of the once-weekly dose of alendronate. (D.I. 143 at 51). Finally, Teva argues that Dr. Vellturo's diffusion model is flawed because a diffusion model in not particularly useful as a forecasting devise, and therefore, its use in this context is inappropriate and alternatively argues that Dr. Vellturo's use of the model is incorrect. (D.I. 143 at 54).

In response, Merck contends that the once-weekly high dose regimen of the '329 Patent was not obvious to a skilled practitioner in 1997 because without hindsight, the overwhelming knowledge in the field was that high oral unit doses would not be safe and tolerable for osteoporotic women. Merck points out that Dr. Russell, Teva's expert, acknowledged that a person of ordinary skill "would be familiar with publications in the field and the technical background in this field of bisphosphonates and osteoporosis." (Russell at 144). Thus, according to Dr. Russell's interpretation of one of ordinary skill, Merck argues, a skilled practitioner would know that: 1) etidronate and clodronate caused gastrointestinal side effects at high doses; 2) pamidronate caused dose-related gastrointestinal side effects that even led to the discontinuation of its development as an oral medication; 3) alendronate caused dose-related gastrointestinal side-effects; and 4) alendronate sodium, even though proven to be safe and tolerable at 10

and 5 mg doses, could still potentially cause severe upper gastrointestinal injuries. (D.I. 145 at 10-11) (citations omitted). Merck contends that the overwhelming knowledge, laid out by contemporaneous publications in respected peer-reviewed medical journals establishes that the pre-invention expectation by those skilled in the art was that one could not use alendronate sodium at unit doses higher than 20 mg for the management of osteoporosis. Id. at 11.

Further, Merck asserts that Teva's "spin" on the Chestnut study is flawed. Specifically, Merck points out that in the Chestnut study only one out of sixty two women (1.6%) withdrew from the 10 and 5 mg doses, but seven out of sixty three women (11.1 %) withdrew from the 40 mg alendronate treatment. Id.; PTX 69 at 150; Markowitz at 479-482; Fennerty at 266. Moreover, contrary to Teva's assertion, Merck points out that it informed the FDA that the Chestnut Study had led it to "limit the maximum dose to 20 mg in subsequent osteoporosis treatment studies." (D.I. 145 at 15; PTX 202 at MK250180; PFF 66). Additionally, Merck asserts that as Dr. Papapoulos testified, a skilled practitioner at the time knew that in actual clinical practice 10 to 12 percent of patients discontinued 10 mg Fosamax treatment because of gastrointestinal side effects. (D.I. 145 at 12; Papapoulos at 651-652). Thus, Merck argues that any reasonable clinician, viewing this data could compare these ratios and would expect the discontinuation rate for osteoporotic women in actual practice, outside the confines of a controlled clinical environment, to have been unacceptably high at a 40 mg dose. Merck asserts that Teva failed to consider that clinical studies are different than daily practice and that discontinuations are far less common in the context of a clinical study. (D.I. 145 at 12; PFF 60; Fennerty at 262-64).

In reference to Teva's reliance on internal and FDA submitted documents, Merck contends that these publications as presented by Teva were taken out of context, and therefore, do not bolster Teva's argument with regard to obviousness. Merck argues that Teva improperly relied on these documents because these documents reflect the inventors' rationales to overcome the skepticism about high unit doses and the inventors' insights about their own invention. In regard to extrapolating results from the Paget's disease experience to doses for osteoporosis, Merck points out that Professor Fleish's book, which Dr. Russell later edited, reflected the thinking in the art that the tolerability for alendronate sodium appeared to be higher for the pagetic disease population than the osteoporosis population. (D.I. 145 at 15).

Merck also contends that it has never disputed that it was known that once-weekly dosing would be efficacious in providing the alendronate sodium needed to inhibit bone resorption, but notes that it was the safety concern about high oral doses (higher than 20 mg) that obscured the advantageous once-weekly invention for the management of osteoporosis. (D.I. 145 at 15). Further, Merck points out that it did not rely on the case reports such as De Groen as evidence of a dose-response, rather, Merck claims, the case reports simply raised the awareness of physicians that alendronate sodium was a potentially dangerous agent and that Teva's expert, Dr. Markowitz admitted that the case reports were clinically significant. (D.I. 145 at 18; Markowitz at 468). Merck also rebuts the contention that it took no action in response to the case reports and points out that it promptly obtained data about each case, constructed a data base and organized a meeting with Dr. De Groen and other consultants by March 1996. Then, on March 15, 1996 Merck sent out a “Dear Doctor” letter informing physicians about the potential upper gastrointestinal injuries and emphasizing

the importance of following directions in order to minimize them. Merck also undertook internal studies to understand the problem, including dog studies. (D.I. 145 at 19; PTX 67; PFF 88).

In reference to Dr. Fennerty's testimony, Merck contends that Teva mischaracterized his testimony regarding the Blank[5] article. Merck asserts that the Blank study provided a glimpse as to what happens when the use of aminobisphosphonates is combined with Non-Steroidal Anti-Flammatory Drugs ("NSAIDs") such as aspirin and ibubrofen. This study was published during February of 1997 in the peer reviewed Digestive Diseases and Sciences, and it showed clear dose-related upper gastrointestinal injuries from alendronate sodium when it was combined with the NSAID indomethacin in a rat model. (D.I. 145 at 20; PTX 104 at 284 fig. 3). Merck contends that Dr. Fennerty observed that when placed in the mosaic of prior art showing the dose dependent injuries from bisphosphonates, the Blank study was important to gastroenterologists, and he never retreated from this position. (Fennerty at 270, 292-94). Additionally, Merck points out that Teva itself stated to the PTO in 2000, in an attempt to gain the issuance of claims for a delayed gastric release alendronate formulation, that bisphosphonates as a class exhibit side effects that "consist of irritation of the upper gastrointestinal mucosa ... with the potential for this irritation leading to more serious conditions." (PTX 301, U.S. Patent No. 6,476,006 ("the '006 Patent") at col. 3, lines 25-25). Merck contends that Teva also told the PTO that the "larger" once weekly doses have "the potential of exacerbating the upper GI side effects of the drug." D.I. 145 at 21 (quoting the '006 Patent at col. 3, lines 12-14).

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[5] Blank et al., Digestive Diseases and Sciences, 1997 (PTX 106).

Merck argues that Teva's reliance on the 1997 Physicians Survey is misplaced because it did not address the use of higher doses. Specifically, Merck points out that at issue is the invention of administering seven-fold the daily dose of alendronate sodium once a week, and in the survey, a twice-weekly dosing schedule was inquired about along with other choices that included placing alendronate sodium in diet colas and cranberry juice. (D.I. 145 at 22; DTX 244 at 174866). Merck points out that the invention of the '329 Patent does not lie solely in the less frequent dosing, but in the fact that an entire weekly complement of daily doses could be administered as a single unit dose and that the marketing survey inquired about twice weekly dosing without any mention of increasing the dose. Therefore, Merck argues that it does not bear any relevance to the invention of once-weekly dosing at sevenfold the daily dose. (D.I. 145 at 22).

In regard to secondary considerations, Merck contends that contrary to Teva's assertion that commercial success is irrelevant in the obviousness inquiry because Merck was the only entity allowed to market alendronate sodium tablets, its direct competitors, including Procter & Gamble, had an incentive to develop an improved dosage form. (D.I. 145 at 23). Further, in reference to commercial success, Merck contends that the increased sales for the Fosamax franchise upon the launch of the once-weekly dosing regimen is dramatic regardless of which way it is viewed. (D.I. 145 at 25). Specifically, Merck points out that the Fosamax franchise sales followed a constant increase trend from 1996 until the introduction of once-weekly Fosamax in 2000, where if the trend established before the once-weekly dose was introduced had continued, an increase of 18.9% over the prior year would have resulted. However, after the once-weekly dosing was introduced, a dramatic increase of 42.5% was realized. (D.I. 145 at 26; PTX 166;

Vellturo at 718-720). Additionally, Merck contends that Teva's attempt to discredit Dr. Vellturo's diffusion model was unsuccessful. Merck argues that, in any event, Dr. Vellturo testified that his opinion regarding the commercial success of the '329 Patent was not based on model, but on a fundamental shift in the constant trends he observed regarding the Fosamax franchise's sales increases, market share, prescription volume and on an evaluation of the market share and prescription volume data for the osteoporosis market as a whole, and that the diffusion model only confirmed the opinion he formed based on the aforementioned factors. (D.I. 145 at 26; Vellturo at 718-728, 735; 755-757). Finally, Merck notes that Dr. Rozek, Teva's expert on obviousness, provided no ultimate conclusion about the commercial success of the once-weekly dosing of Fosamax or any of the factors he believed Dr. Vellturo should have considered. (D. I. 145 at 26).

2. Whether the '329 Patent Was Obvious in View of the Prior Art

After reviewing the relevant prior art in light of the evidence and the factors related to the obviousness inquiry, the Court concludes that Teva has failed to establish by clear and convincing evidence that the '329 Patent was obvious in light of the prior art references. The Court in its obviousness analysis must be cognizant of "hindsight syndrome." In re Warner Kotzab, 217 F.3d 1365, 1369-1370 (Fed. Cir. 2000). The Federal Circuit has instructed that, "the best defense against the subtle but powerful attraction of a hindsight-based obviousness analysis is rigorous application of the requirement for a showing of the teaching or motivation to combine prior art references." In re Gartside, 203 F.3d 1305; 1329 (Fed. Cir. 2000). Therefore, in order to establish obviousness from a combination of elements disclosed in prior art, "there must be some motivation, suggestion or

teaching of the desirability of making the specific combination that was made by the applicant." Kotzab, 217 F.3d at 1370. With this standard in mind, the Court will discuss the relevant factors of the obviousness inquiry as they relate to the '329 Patent.

i. Level of One Skilled in the Art

For the purposes of the obviousness inquiry, the Court finds that at the time of the filing of the '329 Patent, a person of ordinary skill in the art was an individual who would have an M.D. and/or Ph.D. and was working in the field of and doing research on osteoporosis. Such a person would be familiar with the publications and technical literature and background in the field of bisphosphonates and osteoporosis. (D.I. 142 at 17-18; D.I. 141 at 41). The Court bases this finding on a combination of Merck and Teva's proffered interpretation of one skilled in the art and finds that there are no significant differences between the two proffered definitions.

ii. Scope and Content of Prior Art

At the outset, the Court notes that Merck has never disputed that it was known that once-weekly dosing would be efficacious in providing the alendronate sodium needed to inhibit bone resorption. (D.I. 145 at 15). However, Merck contends that it is the safety concern about high oral doses, specifically unit doses higher than 20 mg, that obscured the advantageous once-weekly invention for the management of osteoporosis. Id. Thus, the issue is when viewing the mosaic of the prior art, whether those of ordinary skill in the art would have had the motivation to formulate a once-weekly seven-fold daily dose of alendronate sodium, despite safety concerns.

The Court concludes that the history of bisphosphonates as a class is minimally relevant to the instant discussion because although alendronate is a bisphosphonate and general knowledge of bisphosphonates is certainly within the knowledge of one of ordinary skill in the art during the relevant time period, it was also well known that each bisphosphonate had its own unique characteristics. (See DTX 547 at 543) (Dr. Papapoulos, Merck's expert, noting that because of differences in mechanisms of action and pharmacological and toxicological profiles, it is "important that specific properties of every individual bisphosphonate be determined and that results obtained with one bisphosphonate not be extrapolated readily to the whole class."). As a result, although the earlier bisphosphonates etidronate, clodronate and pamidronate had dose related gastrointestinal side effects, the Court concludes that this fact holds little weight in its obviousness analysis given the unique characteristics of each bisphosphonate, particularly with side effects. (Papapoulos at 653-654; Russell at 384-385; PTX 110 at 127, 129, 130; PTX 111 at 148, 149, 152; PTX 112 at 154, 15, 1585; PTX 113 at 170, 171, 175; PTX at 289, E91, C278, C279).

Therefore, the Court will focus its discussion on the prior art dealing with alendronate. The 1995, 1997, and 2000 editions of "Bisphosphonates in Bone Disease" written by Professor Herbert Fleish, who is described as the "father of bisphosphonates", reported that oral alendronate sodium can cause gastrointestinal disturbances at doses of 40 mg. (PTX 111 at 148; PTX 112 at 153; PTX 113 at 169; see also PTX 300 at 26). Further, in the 1997 and 2000 editions, Dr. Fleish reported that a 40 mg dose may cause gastrointestinal disturbances in patients with osteoporosis, but that the same dose was well tolerated in patients with Paget's disease. (PTX 112 at 153; PTX 113 at 169).

Additionally, the Court finds that case reports are probative in its obviousness inquiry because, as Dr. Fennerty testified, they often contain information that would alter the way a physician would treat patients. (Fennerty at 247-248). Case reports are publications usually involving one or a few patients that have an outcome of clinical relevance or importance. (Fennerty at 246-247). In October 1995, Maconi[6] published a case report in the American Journal of Gastroenterology, which reported that an osteoporosis patient after taking 5 mg of alendronate, had an endoscopy which revealed severe damage to the esophagus. (Fennerty at 249-250). Dr. Fennerty testified that this case report was significant because the particular journal it was published in was "clinically relevant" and because this "severity of injury had never been reported in a patient taking a bisphosphonate prior to this, especially a bisphosphonate that was being used now very commonly in clinical practice as it had just been released at about the time the case report was published." (Fennerty at 250). In October 1996, De Groen published an article in The New England Journal of Medicine which set out three case reports describing the side effects of alendronate sodium. (PTX 91). The first case report reported that a 73-year-old woman developed chest pain and dysphagia after her first dose of 10 mg of alendronate sodium. (PTX 91 at 1016-1017). After two more doses she was transferred to the Mayo Clinic where an endoscopy revealed severe ulcerative esophagitis. (PTX 91 at 1017; Fennerty at 254-56). The other two case reports revealed that two additional women developed severe esophageal injury as a result of taking 10 mg oral dose of alendronate sodium. (PTX 91 at 1017; Fennerty 254-256). The article also revealed that Merck revised dosing instructions in the Fosamax product circular based on the results noted in the

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[6] Maconi, The American Journal of Gastroenterology, (1995) (PTX 90).

paper so as to further minimize potential for prolonged contact of the drug with the esophagus and thus, to reduce the risk of injury. (PTX 91 at 1020). Additional case reports published by Abdelmalek (PTX 96), Sorrentino (PTX 98), Naylor (PTX 101), Rimmer (PTX 102), Pizzanni (PTX 109) and Girelli (PTX 106) also suggested evidence that alendronate sodium may be associated with severe side effects not recognized in clinical trials. (Fennerty at 259).

The Court also finds that several studies dealing with alendronate are significant. In 1993, Harris[7] published an early Phase II study, which is a dose-ranging study used to determine the dose and the preliminary data on both the safety and efficacy of a drug, sponsored by Merck in the Journal of Clinical Endocrinology and Metabolism investigating the effects of oral alendronate sodium treatment. (PTX 116; Russell at 159, 364-65). The women in this study were between the ages of 40 and 60 and did not have osteoporosis. The women were treated with alendronate sodium doses from 5 to 40 mg for six weeks and the dosages were well-tolerated. (PTX 116 at 1399).

Merck then sponsored a study investigating the effects of a range of different oral doses of alendronate for the treatment of osteoporosis. (PTX 69). The results of this study were published by Chestnut in 1995 in the American Journal of Medicine. The Chestnut study lasted for two years and involved 188 women with osteoporosis. (PTX 69; Yates at 502-504). Of these women, 31 were exposed to placebo, 32 to 5 mg, 30 to 10 mg, 32 to 20 mg and 63 to 40 mg of alendronate sodium. (PTX 69 at Table 1). As of 1996, the Chestnut study was the only study that administered alendronate sodium to osteoporosis patients. (PTX 69;

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[7] Harris, Journal of Clinical Endocrinology and Metabolism, (1993) (PTX 116).

Markowitz at 478-479). Chestnut reported that nine women discontinued alendronate sodium therapy due to gastrointestinal side effects that included nausea, dyspepsia, mild esophagitis/gastritis and abdominal pain. (PTX 69 at 150; Markowitz at 479-482; Fennerty at 265-66). Nine women withdrew from treatment because of these side effects: seven women withdrew from the 40 mg dose, one woman withdrew from the 20 mg dose and one women withdrew from the group taking between 5 and 10 mg doses. (PTX 69 at 150; Markowitz at 479-482; Fennerty at 266; Yates at 539-540). Chestnut also reported that the gastrointestinal side effects "occurred primarily in the first year during treatment with 40 mg alendronate." (PTX 69 at 150, col. 1). Dr. Fennerty testified that the fact that 11.1% (7 out of 63) withdrew from the 40 mg alendronate dose was noteworthy within the context of a clinical trial.[8]

Teva contends that the April and July 1996 editions of the Lunar News render claims 29 and 37 of the '329 Patent obvious. The July 1996 Lunar News issue contained a section entitled, "Update Bisphosphonate." (PTX 29 at 23). The section discusses bisphosphonates as a treatment for osteoporosis. Id. In reference to the use of alendronate for treatment of osteoporosis, it states that "[s]ome United States physicians are reluctant to treat because of: a) side effects; b) difficulty of dosing; and (c) high costs ($700/year)." (PTX 19

[8] The Court concludes that studies dealing with Paget's disease are not relevant to its analysis because it was well-known to those of ordinary skill in the art that patients with Paget's disease tolerate higher doses of alendronate than patients with osteoporosis. (Papapoulos at 710-711; PTX 112 at 153; PTX 113 at 169; see also PTX 300 at 26). Thus, the Court finds that tolerability of alendronate sodium from studies involving Paget's patients should not be extrapolated to a discussion of osteoporosis about the tolerability of alendronate. For this reason, the Court will not address studies dealing with Paget's disease and the tolerability of higher doses of alendronate sodium.

at 23). To address the difficulty of dosing and high costs the article suggested:

> The difficulties with oral bisphosphonates may favor their episodic (once/week) or cyclical (one week each month) administration. Even oral alendronate potentially could be given in a 40 or 80 mg dose once/week to avoid dosing problems and reduce costs.

PTX 29 at 23. In a section entitled "Update: Bisphosphonates," the April 1996 edition of the Lunar News discusses difficulties of the dosing regimen associated with alendronate and states:

> one of the difficulties with alendronate is its low oral bioavailability. When taken with water in a fasting state, only about 0.8% of the oral dose is bioavailable. Even coffee or juice reduces this by 60%, and a meal reduces it by > 85%. Alendronate must be taken, after an overnight fast, 30-60 minutes before breakfast. Subjects should remain seated or standing; a very small group of patients have reported some upper gastrointestinal distress if this is not done. This regime may be difficult for the elderly maintain chronically. An intermittent treatment program (for example, once per week, or one week every three months), with higher oral dosing, needs to be tested.

DTX 417 at 31. (citations omitted).

iii. Differences Between the Prior Art and the Claims at Issue

The Court concludes that the prior art cited above demonstrates that the suggestion to give 40 or 80 mg of

alendronate sodium to treat or prevent osteoporosis was not clinically useful or obvious in July 1997 because of the known dose-related gastrointestinal side effects. Further, the Court is not persuaded that the two Lunar News articles, not published in peer-reviewed journals or authored by one skilled in the art, either alone or in combination, overcame the serious side effect concerns associated with higher dosage units of alendronate sodium. For example, Dr. Fennerty, whom the Court finds very credible, testified that in light of the prior art, any physician would have been "extraordinarily concerned" to suggest a 40 or 80 mg dose because alendronate sodium was a new compound that had been associated with dose-related injury and severe injuries in case reports. (Fennerty at 270-271; see also PTX 69, 91, PTX 300 at 14). In this regard Dr. Fennerty testified:

> Q: Now in July of '97 or any period preceding that, what would your opinion be about a suggestion that you give 40 or 80 milligrams of alendronate to an osteoporotic woman?
> A. Given what I just described, a new compound, a Dear [D]octor letter, publications in the New England Journal of severe caustic injury, smattering case reports around that, the Chestnut [sic] paper before talking about as you go up on a dose, that you may be seeing more adverse effects, the smattering of papers, and now animal data showing that types of patients that use NSAIDS use some higher dose of these compounds, shows evidence of gastric injury in the model, I would have been extraordinarily concerned about anybody suggesting that this was a useful clinical approach at that point and time.

(Fennerty at 270-21). Additionally, Dr. Papapoulous testified about the concerns of side effects associated with the

suggestion in the July 1996 Lunar News where he stated, "[Lunar News] is using 40 and 80 not on any scientific rationale, but because it is available. Secondly, he doesn't tell us how he's going to address the issue of side effects, which is one of the main points in this particular article." Papapoulos at 665-666. Thus, in light of the case reports, and the Chestnut study, in conjunction with observations written about alendronate by Dr. Fleish, the Court concludes that the Lunar News references did not render the seven-fold daily dose of alendronate for the treatment and prevention of osteoporosis obvious given the clearly documented and known dose related gastrointestinal side effects associated with high doses (over 20 mg) of oral alendronate.

First, the April 1997 Lunar News did not deal with the specific dosages of 70 or 35 mg in relation to its discussion of once-weekly dosing of alendronate. Second, the July 1996 Lunar News listed 40 and 80 as compared to 70 and 35 mg dosages as suggested by the '329 Patent and did not deal with the problem of known gastrointestinal side effects. Additionally, in reaching its conclusion, the Court gives more weight to the prior art references written and reviewed by those skilled in the art such as the Chestnut study and the De Groen case report as opposed to the Lunar News, a quarterly newsletter written by someone without a Ph.D. or MD. in the applicable field.

iv. Secondary Indicia of Non-Obviousness

As for the secondary considerations of non-obviousness, the Court finds that Merck has presented sufficient evidence to show that the 35 mg and 70 mg once-weekly dosing of Fosamax was commercially successful. On this issue, the Court finds Dr. Vellturo's testimony persuasive.

Dr. Vellturo testified regarding the evidence of increased sales after the launch of once-weekly Fosamax.

Originally, Merck's Fosamax osteoporosis product line consisted of once-daily 10 and 5 mg Fosamax tablets. (D.I. 138 at 32). Dr. Vellturo testified that daily Fosamax was a successful product that enjoyed an average increase in sales of 152 million dollars per year for each of the four years preceding the introduction of the once-weekly Fosamax. (Vellturo at 718-720; PTX 166; PTX 300 at 37). In 2001, the first full year following the launch of the once-weekly dosing regimen, the sales increase was 343 million dollars, more than double the expected increase, without any corresponding relative increase in expenditures. (Vellturo at 719-720; PTX 166; PTX 300 at 37).

The Court finds that further evidence of the success of the once-weekly dosing regimen is present in the prescription data for the Fosamax tablets. A sharp increase in physician adoption of Fosamax upon the introduction of the once-weekly dosing regimen is manifested in the number of total prescriptions reported each month for Fosamax. (Vellturo at 723; PTX 164; PTX 300 at 32, 33, 36). The marked increase in prescription volume of once weekly dosages of Fosamax tablets is more compelling in light of its effects on the osteoporosis market in general. FAME is an acronym for the four prescription drug products whose primary indication is for the treatment of osteoporosis, (i.e., Fosamax, Actonel, Miacalcin, and Evista). (Vellturo at 722, 753-754). IMS is a data collection firm specializing in data reflecting the prescribing patterns of physicians and in prescription volume data. (Vellturo at 716-717). Within six months of its launch, once-weekly Fosamax tablets became the most prescribed drug in the FAME market. (PTX 164; PTX 165; PTX 300 at 33). Based on the IMS data points present in the plot of monthly total prescriptions, it can be

calculated that the Fosamax franchise share of the FAME market grew from 45 % to 55 % in the first six months after the introduction of the once-weekly dosing regimen. (PTX 164; PTX 300 at 33).

Teva's expert Dr. Rozek testified that the increase in Fosamax sales could be due to other factors such as the increasing number of Americans over the age of sixty, the increasing awareness of osteoporosis, an increase in the number of people seeking treatment for osteoporosis and Merck's marketing efforts. However, the Court finds Dr. Rozek's explanation unpersuasive because he offered no affirmative opinion as to what affect these factors would have on the analysis of the FAME market as a whole or with Fosamax individually. (Rozek at 871-72; 869; 878). In fact, Dr. Rozek testified the he was "not instructed to do anything affirmative with regard to the measuring of any relationship that might exist between the ['329 Patent] and sales, or success of Fosamax." (Rozek at 869). In the Court's view, Dr. Rozek's suggestion that there are factors that Dr. Vellturo should have considered, is not sufficient to rebut the affirmative evidence of the commercial success of the once-weekly dosing regimen. (Rozek at 878-79). Also, the Court concludes that Merck has shown a sufficient nexus between the claimed secondary considerations and the patented method given the testimony of Dr. Vellturo and the timing of the launch of the once-weekly dosing regimen for Fosamax. Accordingly, the Court has given the above discussed secondary considerations the importance they deserve in reaching its conclusion of nonobviousness. See Minnesota Mining & Manufacturing Co. v. Johnson & Johnson Orthopedics, Inc. 976 F.2d 1559, 1573 (Fed. Cir. 1992) (noting the importance of secondary considerations in the obviousness analysis).

v. Summary

In sum, the Court concludes that Teva has not proven by clear and convincing evidence that it was obvious to combine the Lunar News suggestions in light of the knowledge of one of ordinary skill in the art of the gastrointestinal side effects accompanying large doses of oral alendronate. In addition, the Court finds that the significant secondary considerations offered by Merck undermine any claim of obviousness, and accordingly, the Court concludes that Teva has not proven by clear and convincing evidence that the '329 Patent was obvious in light of prior art.

V. Unenforceability Due To Inequitable Conduct

A. The Inequitable Conduct Standard

As a general matter, patent applicants and their patent attorneys have a duty of candor, good faith and honesty in their dealings with the PTO. 37 C.F.R. § 1.56(a). The duty of candor, good faith and honesty includes the duty to submit truthful information and the duty to disclose to the PTO information known to the patent applicants or their attorneys which is material to the examination of the patent application. Elk Corp. of Dallas v. GAF Bldg. Materials Corp., 168 F. 3d 28, 30 (Fed. Cir. 1999). Breach of the duty of candor, good faith and honesty may constitute inequitable conduct. Id. If it is established that a patent applicant engaged in inequitable conduct before the PTO, the entire patent application so procured is rendered unenforceable. Kingsdown Medical Consultants v. Hollister Incorporated, 863 F.2d 867, 877 (Fed. Cir. 1988).

A patent applicant engages in inequitable conduct before the PTO when he withholds or misrepresents information material to the patentability of his invention, with an intent to deceive.

See Nobelpharma AB v. Implant Innovations. Inc., 141 F.3d 1059, 1064 (Fed. Cir. 1998); (citing Molins PLC v. Textron. Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995)). Inequitable conduct encompasses affirmative misrepresentations of material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive. Baxter Int'l, Inc. v. McGaw Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998) (citing Nobelpharma, 141 F.3d at 1068-71). In order to establish unenforceability based on inequitable conduct, Teva must prove, by clear and convincing evidence, that material information was intentionally withheld for the purpose of misleading or deceiving the patent examiner. See Allied Colloids, Inc. v. American Cyanamid Co., 64 F.3d 1570, 1578 (Fed. Cir. 1995) (citation omitted).

A determination of inequitable conduct entails a two step analysis. First, the court must determine whether the withheld information meets a threshold level of materiality. A reference is considered material if there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent. See id. This determination is not the end of the inquiry with respect to intent. The Federal Circuit has stated that, "materiality does not presume intent, which is a separate and essential component of inequitable conduct." See Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 552 (Fed. Cir. 1990) (internal citation omitted).

After determining if the applicant withheld information that is material, the court must then determine whether the evidence demonstrates a threshold level of intent to mislead the PTO. See Baxter, 149 F.3d at 1327. "Intent to deceive cannot be inferred solely from the fact that information was not disclosed; there must be a factual basis for a finding of deceptive intent." Hebert v. Lisle Corp., 99

F.3d 1109, 1116 (Fed. Cir. 1996). Therefore, in order to satisfy the intent to deceive element of inequitable conduct, the conduct when viewed in light of all of the evidence, including evidence of good faith, must demonstrate sufficient culpability to require a finding of intent to deceive. See Paragon Podiatry Lab., Inc. v. KLM Lab, Inc., 984 F.2d 1182, 1189 (Fed. Cir. 1993).

The initial determinations of materiality and intent to deceive are questions of fact. See Monon Corp. v. Stoughton Trailers, Inc., 239 F.3d 1253, 1261 (Fed. Cir. 2001) (citation omitted). Once these facts are established, the court should then weigh the findings and their premises and determine, in its discretion, whether to hold the patent unenforceable. See ATD Corp. v. Lydall. Inc., 159 F.3d 534, 547 (Fed. Cir. 1998).

B. **Whether Dr. Yates Engaged In Inequitable Conduct Before the PTO Rendering The '329 Patent Unenforceable**

Teva contends that Dr. Yates engaged in inequitable conduct before the PTO rendering the '329 Patent unenforceable. Specifically, Teva contends that Dr. Yates intentionally withheld the July 1996 edition of the Lunar News from the Patent Examiner.

In response, Merck contends that the July 1996 Lunar News was not considered material because it was cumulative to the cited prior art. Merck further contends that Dr. Yates did not make any material misrepresentations to the PTO, and that Teva cannot establish an intent to deceive the PTO by clear and convincing evidence.

1. The Allegedly Withheld Prior Art

In the Court's view, the July 1996 Lunar News has some degree of materiality because it has relevance to the claimed invention, specifically, the recommended once-weekly dosage level of alendronate for osteoporosis patients. Additionally, the Court finds that it is not cumulative to the cited prior art, specifically the April 1997 Lunar News because, although the April edition mentions a 40 mg dose of alendronate it does not suggest a 40 or 80 mg dose in the context of once-weekly dosing as the July 1996 edition of the Lunar News does. However, as previously discussed, the Court finds that the July 1996 Lunar News does not reflect the claimed invention directly and does not render the claimed invention invalid as either obvious or anticipated. See, e.g., Life Technologies, Inc. v. Clontech Labs. Inc., 224 F.3d 1320, 1325 (Fed. Cir. 2000) (citing 35 U.S.C. § 103(a) and stating that "the path that leads an inventor to the invention is expressly made irrelevant to patentability by statute").

2. Intent to Deceive

The Court concludes that Teva has failed to meet its burden of demonstrating a prima facie showing of intent to deceive the PTO. As to this issue, Teva contends that Dr. Yates' testimony indicating that he did not read the July 1996 Lunar News was not credible in light of the fact that in September 1996, Dr. Yates received a memorandum discussing Lunar News' comments about alendronate, with the relevant portions of the July issue attached. Further, Teva argues that Dr. Yates' testimony that he did not focus on the July 1996 issue again on May 21, 1997 at a meeting with Lunar Corp., where the July 1997 issue was attached as an agenda item, is not credible.

The Court finds that this evidence of intent to deceive falls short of the applicable standard. Dr. Yates testified unequivocally that he had never seen the statements regarding once-weekly dosing of alendronate in the July 1996 Lunar News prior to this litigation. (Yates at 533-34; 572-573; 575). Additionally, in reference to the September 1996 memo that was circulated with the July 1996 Lunar News as an attachment, the Court recognizes that there were twelve pages attached to the original memo and the relevant article in the July 1996 Lunar News was the last page. Based on this, the Court finds Dr. Yates' testimony that he did not read the July 1996 Lunar News article in September 1996, credible. Likewise, the Court does not find Teva's assertion that Dr. Yates should have read the article that was attached to the agenda at the May 1997 meeting, probative of Dr. Yates' intent to deceive because attendees, including Dr. Mazess, did not recall whether the once-weekly dosing concept was specifically addressed at the meeting. (Mazess Dep. at 180:19-181:7; Beckman Dep. at 131:1-23; Magri Dep. at 105:7-25; Sherwood Dep. at 146:17-23, 147:11-148:3). Further, the Court finds that even if once-weekly dosing was discussed at the meeting, the focus of the discussion was more likely than not centered on the April 1997 edition of the Lunar News, which was disclosed to the examiner, rather than the July 1996 edition because the April 1997 edition came out in the month preceding the meeting.

"In a case involving an omission of a material reference to the PTO, there must be clear and convincing evidence that the applicant made a deliberate decision to withhold a known reference." Baxter Int'l, Inc. v. McGaw. Inc., 149 F.3d 1321, 1329 (Fed. Cir. 1998). The Court concludes that Teva has proffered insufficient evidence of an intent to deceive on the part of Dr. Yates. Accordingly, the Court cannot conclude that Dr. Yates engaged in inequitable

conduct before the PTO by failing to disclose material prior art.

Conclusion

For the reasons discussed, the Court concludes that Teva has not proven that the patent-in-suit is invalid or that Merck engaged in inequitable conduct before the PTO.

An appropriate Order will be entered.