United States Court of Appeals for the Federal Circuit

04-1189, -1347, -1357

PURDUE PHARMA L.P.,
THE PURDUE FREDERICK COMPANY,
THE P.F. LABORATORIES, INC., and THE PURDUE PHARMA COMPANY,

Plaintiffs/Counterclaim Defendants-Appellants,

and

EUROCELTIQUE S.A.,

Counterclaim Defendant,

v.

ENDO PHARMACEUTICALS INC.,

Defendant/Counterclaimant-Cross Appellant,

and

ENDO PHARMACEUTICALS HOLDINGS INC.,

Defendant-Cross Appellant.

Herbert F. Schwartz, Fish & Neave LLP [now known as Fish & Neave IP group of Ropes & Gray LLP], of New York, New York, argued for plaintiffs/counterclaim defendants-appellants. Of counsel were Edward C. DuMont, Jonathan G. Cedarbaum, and Seth P. Waxman, Wilmer Cutler Pickering Hale and Dorr LLP, of Washington, DC; Pablo D. Hendler, Duane-David Hough, Gerald J. Flattmann, Jr., Richard A. Inz, and Denise L. Loring, Ropes & Gray LLP, of New York, New York. Of counsel was Robert J. Goldman, of Palo Alto, California.

Edward V. Filardi, Skadden, Arps, Slate, Meagher & Flom LLP, of New York, New York, argued for defendant-cross appellant defendant/counterclaimant-cross appellant and defendant-cross appellant. With him on the brief were Constance S. Huttner, Douglas R. Nemec, David L. Cohen, and Mark D. Baker. Of counsel on the brief were Nicholas L. Coch and Donald L. Rhoads, Kramer Levin Naftalis & Frankel LLP, of New York, New York.

Nancy J. Linck, Senior Vice President, Chief Legal & Compliance Officer, and Hansjorg Sauer, Patent Counsel, for amicus curiae Guilford Pharmaceuticals Inc., of Baltimore, Maryland. Of counsel on the brief was Scott A.M. Chambers, Patton Boggs LLP, of McLean, Virginia.

Appealed from: United States District Court for the Southern District of New York

Judge Sidney H. Stein

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DECIDED: June 7, 2005

Before GAJARSA, Circuit Judge, PLAGER, Senior Circuit Judge, and LINN, Circuit Judge.

PLAGER, Senior Circuit Judge.

This is a patent infringement case in which the patents were held unenforceable by the trial judge due to inequitable conduct during prosecution before the United States Patent and Trademark Office ("PTO"). Purdue Pharma L.P., The Purdue Frederick

Company, The P.F. Laboratories, Inc., and The Purdue Pharma Company (collectively, "Purdue") filed an infringement suit against Endo Pharmaceuticals Inc. and Endo Pharmaceuticals Holdings Inc. (collectively, "Endo") in the United States District Court for the Southern District of New York. Plaintiffs alleged that Endo's proposed generic versions of OxyContin®, Purdue's controlled release oxycodone product, would infringe three Purdue patents.

After a bench trial, the district court found that Endo would infringe Purdue's patents, but determined the patents were unenforceable due to the inequitable conduct that occurred during prosecution.[1] Purdue appeals the inequitable conduct judgment; Endo cross-appeals the infringement judgment. Because the trial court did not err in its inequitable conduct determination, we affirm the court's judgment on that issue. We do not reach the issues raised in Endo's cross-appeal.

BACKGROUND

The three patents asserted by Purdue against Endo are directed to controlled release oxycodone medications for the treatment of moderate to severe pain. The patents are related: U.S. Patents No. 5,656,295 (the "'295 patent") and No. 5,508,042 (the "'042 patent") are, respectively, a continuation-in-part and a divisional of U.S. Patent No. 5,549,912 (the "'912 patent"). The '912 patent itself is a continuation-in-part of U.S. Patent No. 5,266,331 (the "'331 patent"), which Purdue has not asserted against Endo. The '331 patent is the parent patent, and for ease of reference will be identified as such from time to time.

[1] Purdue Pharma L.P. v. Endo Pharms. Inc., No. 00-CV-8029, 2004 WL 26523 (S.D.N.Y. Jan. 5, 2004).

The written descriptions of the ’912, ’295 and ’042 patents are virtually identical. The asserted claims include composition claims (claims 1-4 of the ’912 patent and claims 1-4 and 6-7 of the ’295 patent) and method claims (claims 8-10 of the ’295 patent and claims 1 and 2 of the ’042 patent). Claim 1 of the ’912 patent is representative of the composition claims and reads:

> A controlled release oxycodone formulation for oral administration to human patients, comprising from about 10 to about 40 mg oxycodone or a salt thereof, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

Claim 1 of the ’042 patent is representative of the method claims and reads:

> A method for reducing the range in daily dosages required to control pain in human patients, comprising administering an oral controlled release dosage formulation comprising from about 10 to about 40 mg oxycodone or a salt thereof which provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

The “Detailed Description” section of the written description in each asserted patent opens with the following statement, which played a prominent role in the trial court’s inequitable conduct determination:

> It has now been *surprisingly discovered* that the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold [range] (10 to 40 mg every 12 hours—around-the-clock dosing) in approximately 90% of patients. This is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general.

'912 patent, col. 3, ll. 34-41 (emphasis added).[2]

The thrust of this language is that the invented oxycodone formulation using a four-fold range of dosages (e.g., between 10 mg and 40 mg) achieves the same clinical results as the prior art opioid formulations using an eight-fold range of dosages (e.g., between 10 mg and 80 mg). The written description later explains that the "clinical significance" of the four-fold dosage range of the oxycodone formulations of the present invention, as compared to other opioid analgesics, such as morphine, requiring twice the dosage range, is a more efficient titration process, which is the process of adjusting a patient's dosage to provide acceptable pain relief without unacceptable side effects. Id., col. 4, ll. 51-63.

In December 1995, after obtaining FDA approval, Purdue introduced its controlled release oxycodone product under the name OxyContin®. In September 2000, pursuant to the procedures of the Hatch-Waxman Act, 21 U.S.C. § 355(j), Endo filed an Abbreviated New Drug Application ("ANDA") with the FDA seeking approval to make and sell a generic version of Purdue's OxyContin® formulation. The patents-in-suit had issued by this time, and Purdue had listed them in the Orange Book[3] as covering OxyContin®. Endo notified Purdue it had filed a paragraph IV certification asserting that Purdue's patents either would not be infringed by Endo's generic drug or were invalid.[4] In October 2000 Purdue initiated a patent infringement suit under 35 U.S.C. § 271(e)(2)

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[2] For sake of brevity, this opinion cites the written description of the '912 patent; the '295 and '042 written descriptions contain the identical text.

[3] Patents covering approved drugs or uses thereof are listed in a book entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book" based on the color of its cover.

[4] See 21 U.S.C. § 355(j)(2)(A)(IV), which provides for what is known as a "paragraph IV certification."

on the basis of Endo's ANDA filing, alleging that Endo's generic drug would infringe the '912, '295, and '042 patents. Endo subsequently twice amended its ANDA to seek approval for additional dosage strengths. Purdue filed two additional infringement suits, which the trial court consolidated with the original action.

Endo filed counterclaims seeking a declaratory judgment that Purdue's patents were invalid, unenforceable, and not infringed. Endo also filed counterclaims under federal antitrust and New York unfair trade practice laws. The trial court bifurcated the patent claims from the antitrust and unfair trade claims and in June 2003 held an 11-day bench trial on the patent issues.

In an extensive and thorough opinion, the trial court found that Purdue had shown by a preponderance of the evidence that Endo's proposed generic drug products would infringe Purdue's patents. Purdue Pharma, 2004 WL 26523, at *27. The trial court also concluded, however, that Endo had shown by clear and convincing evidence that Purdue's patents were "invalid" due to Purdue's inequitable conduct during prosecution of the patents before the PTO. Id. The court based its inequitable conduct determination on underlying findings of materiality and intent. First, the court found that in view of Purdue's repeated statements to the PTO that it had discovered an oxycodone formulation for controlling pain over a four-fold range of dosages for 90% of patients, compared to an eight-fold range for other opioids, Purdue failed to disclose material information because it did not inform the PTO that the "discovery" was based on "insight" without "scientific proof." Id. at *23. Second, the trial court found the record as a whole reflected a "clear pattern of intentional misrepresentation." Id. at *27.

As a result of its inequitable conduct determination, the trial court enjoined Purdue from enforcing the '912, '295, and '042 patents, id., and entered final judgment pursuant to Fed. R. Civ. P. 54(b). Purdue took a timely appeal from the trial court's inequitable conduct judgment; Endo filed a cross-appeal from the trial court's infringement judgment. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

Applicants for patents have a duty to prosecute patents in the PTO with candor and good faith, including a duty to disclose information known to the applicants to be material to patentability. 37 C.F.R. § 1.56(a) (2004); see also Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995). A breach of this duty may constitute inequitable conduct, which can arise from an affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive or mislead the PTO. Molins, 48 F.3d at 1178. A party asserting that a patent is unenforceable due to inequitable conduct must prove materiality and intent by clear and convincing evidence. Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 872 (Fed. Cir. 1988). Once threshold findings of materiality and intent are established, the trial court must weigh them to determine whether the equities warrant a conclusion that inequitable conduct occurred. Molins, 48 F.3d at 1178.

We review the trial court's rulings on inequitable conduct deferentially. The court's factual findings regarding materiality and intent are reviewed for clear error, and thus will not be disturbed on appeal unless this court has a "definite and firm conviction"

that a mistake has been made. Kingsdown, 863 F.2d at 872. The trial court's ultimate conclusion that inequitable conduct has occurred is reviewed for an abuse of discretion. Id.

1. Materiality

In evaluating materiality, this court has consistently referred to the standard set forth in PTO Rule 56. Bruno Indep. Living Aids, Inc. v. Acorn Mobility Servs., Ltd., 394 F.3d 1348, 1352 (Fed. Cir. 2005). Because all of the patent applications at issue in this case were pending on or filed after March 16, 1992, we look to the current version of Rule 56, rather than the pre-1992 version of the rule. See id. at 1352-53. Under the current rule, information is material to patentability when:

> [I]t is not cumulative to information already of record or being made of record in the application, and
>
> (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
>
> (2) It refutes, or is inconsistent with, a position the applicant takes in:
>
> (i) Opposing an argument of unpatentability relied on by the Office, or
>
> (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56(b) (2004).[5] In applying this version of the rule, "we give deference to the PTO's formulation at the time an application is being prosecuted before an examiner of the standard of conduct it expects to be followed in proceedings in the Office." Bruno, 394 F.3d at 1353.

The trial court in this case based its materiality finding on Purdue's repeated and convincing representations to the PTO that it had discovered its controlled release oxycodone formulations controlled pain over a four-fold range of dosages for 90% of

[5] This new standard was not intended to constitute a significant substantive break with the pre-1992 standard. Hoffman-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1368 n.2 (Fed. Cir. 2003).

patients, compared to an eight-fold range for other opioids.[6] Purdue had no clinical evidence supporting its claim at the time it was made or at any time before the patents issued. During prosecution of the patents, the examiner repeatedly rejected the applications on the grounds that the invention was obvious in light of prior art. Eventually, however, in response to the applicants' further explanations, the examiner allowed the claims.

The trial court found that the lack of scientific proof of a four-fold dosage range for oxycodone was a material fact inconsistent with statements made by Purdue to obtain allowance of the patent claims over the examiner's rejections. In the trial court's view, by representing to the PTO that it had "discovered" that oxycodone acceptably controlled pain over a four-fold dosage range, while withholding from the PTO the fact that the discovery was based on insight without scientific proof, Purdue failed to disclose material information.

Purdue does not dispute the absence of clinical evidence during the relevant timeframe to support its claim of a four-fold dosage range for oxycodone. Indeed, Dr. Kaiko testified at trial that it was "insight" that led to discovery of the reduced range. He asserted that, based on his knowledge of the pharmacological properties of opioids and the differences between oxycodone and other opioids such as morphine, he "envisioned" a controlled release oxycodone product that would control pain over a four-fold dosage range in 90% of patients.

[6] Throughout this discussion, we refer to "Purdue" as shorthand for the various applicants—inventors and assignees—involved in the parent application and the later related patents.

Purdue, however, contends it is irrelevant that it lacked scientific proof of the four-fold dosage range for oxycodone because the inventors never stated during prosecution of the patents that the discovery had been clinically tested, and thus did not expressly misrepresent a material fact. But that was not the basis for the trial court's materiality finding. The trial court found Purdue had relied on its discovery of a four-fold dosage range throughout prosecution of the '331 parent patent and the related patents-in-suit as "a prominent, and at times, the only, argument in favor of patentability before the PTO, resulting in allowance of the claims." Purdue Pharma, 2004 WL 26523, at *24. In the trial court's view, by failing to explain to the PTO that Dr. Kaiko's "insight" provided the only support for its "discovery," Purdue failed to disclose material information that was inconsistent with its arguments for patentability.

Purdue first told the PTO it had "surprisingly discovered" the four-fold dosage range for controlled release oxycodone, compared to the eight-fold range for other opioids, during prosecution of the '331 parent patent in October 1992, prior to the filing date of the '912 patent.[7] In response to an obviousness rejection, under headings containing the phrases "Surprisingly Improved Results" and "Results Obtained," Purdue distinguished its oxycodone formulations from other opioids based on the "surprising result" of the four-fold dosage range and its "clinical significance"—a more efficient titration process. Purdue presented this argument even though neither the written description nor the pending claims of the '331 patent application made reference to the

[7] The '331 patent claims controlled release oxycodone formulations, like the patents-in-suit, but expresses them in terms of in vitro dissolution rates, a limitation not present in the claims of the patents-in-suit.

four-fold dosage range. Purdue's response contained language identical to that which was soon to appear in the written description of the '912 patent application.

Purdue continued to rely on oxycodone's four-fold dosage range and more efficient titration process to support its patentability arguments throughout prosecution of the '331 patent. After another obviousness rejection and an interview between the examiner and Purdue's attorney, Purdue submitted a response accompanied by the declaration of Dr. Robert Kaiko (named as an inventor on the '912, '295, and '042 patents, but not on the '331 patent). The Kaiko declaration emphasized the difficulty of predicting the pharmacological characteristics of opioids and cautioned that "the most meaningful therapeutic conclusions" should be based on "the results of the most adequate and well-controlled therapeutic evaluations." This statement referenced an attachment, which appears to be an invention disclosure prepared by Dr. Kaiko. In that attachment, under the heading "INVENTION," Dr. Kaiko asserted that controlled release oxycodone acceptably controls pain over a four-fold dosage range for 90% of patients. The attachment then described clinical studies that compared the resulting in vivo plasma concentrations of controlled release oxycodone with those of immediate release oxycodone. The Kaiko attachment concluded by stating that the "CLINICAL SIGNIFICANCE" of the four-fold dosage range compared to other opioids requiring twice the dosage range was "the most efficient and humane method of managing pain requiring repeated dosing," i.e., an improved titration process.

By the time Purdue submitted the Kaiko declaration to the PTO, the application that resulted in the '912 patent had been filed as a continuation-in-part of the '331 patent. The written description of the '912 patent contains several paragraphs of text

not in the written description of the '331 patent, including the statements that the four-fold dosage range had been "surprisingly discovered" and that the clinical significance of the discovery was a more efficient titration process. During prosecution of the '912 patent, Purdue again found it necessary to distinguish its controlled release oxycodone formulations over prior art directed to a different opioid analgesic by emphasizing its "surprising discovery" of oxycodone's four-fold dosage range and more efficient titration process. Purdue further stated that the in vivo parameters set forth in the claims "are specifically related to the surprising results obtained by the invention," thereby directly linking the features of the claimed invention to the newly discovered four-fold dosage range.

In light of Purdue's consistent representations of the four-fold dosage range for controlled release oxycodone as a "surprising discovery" and the context in which that statement was repeatedly made, we cannot say the trial court's finding that Purdue failed to disclose material information was clearly erroneous. While Purdue never expressly stated that the discovery of the four-fold dosage range was based on the results of clinical studies, that conclusion was clearly to be inferred from the language used by Purdue in both the patents and prosecution history.

For example, Purdue a number of times during prosecution referred to the four-fold dosage range as a "result," implying that clinical results had been obtained. Purdue also frequently noted the "clinical significance" of its discovery, sometimes, as in the Kaiko attachment, in close proximity to a description of the clinical studies performed by Purdue, again suggesting the discovery was supported by experimental results. In addition, Purdue continually compared the dosage range of controlled release

oxycodone to that of other opioid analgesics in concise, quantitative terms (e.g., four-fold vs. eight-fold for approximately 90% of patients). In the absence of any statements indicating the true origin of its "surprising discovery," Purdue's arguments to the PTO provide enough of a suggestion that clinical trials had been performed that failure to tell the PTO the discovery was based on Dr. Kaiko's insight and not scientific proof was a failure to disclose material information.

Purdue contends it did not make material misrepresentations or fail to disclose material information to the PTO because the examiner did not rely on its assertion of a four-fold dosage range for oxycodone. According to Purdue, the examiner could have allowed the claims based on other arguments it made to distinguish the oxycodone claims over the prior art. Even if the examiner did not necessarily rely on Purdue's discovery of a four-fold dosage range, however, that would not be inconsistent with a finding of materiality. See Hoffman-La Roche, 323 F.3d at 1368 (citing Merck & Co. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1421 (Fed. Cir. 1989) (rejecting a "but for" standard of materiality)). A review of the prosecution history of the patents-in-suit and the parent '331 patent leaves no doubt that Purdue disclosed its "surprising discovery" of oxycodone's four-fold dosage range to support one of its central patentability arguments and to oppose the examiner's argument that Purdue's claims were unpatentable in view of the prior art. Information that Purdue's assertion of a four-fold dosage range was based only on Dr. Kaiko's insight and not on experimental results was material because it was inconsistent with Purdue's statements suggesting otherwise.

Purdue also argues that the trial court's materiality finding was unduly influenced by the court's allegedly erroneous conclusion that the claims of the patents-in-suit must be construed to include the four-fold dosage range as a limitation. Purdue's argument is without merit for two reasons. First, the trial court stated it would have reached the same result even if the claims were not so limited. Purdue Pharma, 2004 WL 26523, at *23. Second, materiality "is not limited to matters reflected in the claims of a patent." Hoffman-La Roche, 323 F.3d at 1367. Under the PTO's current materiality standard, information may be material if it refutes or is inconsistent with the applicant's patentability arguments, which may be independent of the claims.

We are also unpersuaded by Purdue's argument that the four-fold dosage range is simply a benefit of the claimed invention and therefore not material because the examiner would have given it little weight. Purdue relies on this court's decision in CFMT, Inc. v. Yieldup International Corp., 349 F.3d 1333 (Fed. Cir. 2003), which reversed the trial court's materiality finding based on a list of advantages of the claimed invention identified by the applicants during prosecution. In that case, however, this court found that the applicants' "advantages advocacy recited only the natural, expected results of a closed system [for cleaning semiconductor wafers]." Id. at 1342. At most the applicants had overemphasized the benefits of the invention. Id. Purdue's assertion of a four-fold dosage range for oxycodone and more efficient titration process compared to other opioids was much more than "advantages advocacy"; it was one of the key arguments Purdue made consistently and repeatedly during prosecution to overcome prior art cited by the examiner in an obviousness rejection. Purdue did not present the four-fold dosage range as a general benefit of the claimed oxycodone

formulations, but instead relied on the four-fold dosage range to distinguish its invention over other opioid analgesics in precise, quantitative terms.

Finally, Purdue and the supporting *amicus curiae* brief of Guilford Pharmaceuticals argue that the trial court erred by requiring a patent application for a pharmaceutical discovery to be supported by clinical results. This argument misconstrues the trial court's ruling. The law recognizes that a discovery can be made by insight or experiment, and that alone does not affect patentability. See 35 U.S.C. § 103(a) ("Patentability shall not be negatived by the manner in which the invention was made.").

Purdue's position presumes that the trial court found materiality only because Purdue described the four-fold dosage range in its patents as a "surprising discovery" without providing any scientific proof. That is not the case. The trial court examined the entire record and found materiality because Purdue repeatedly argued to the PTO that the four-fold dosage range distinguished the invention over prior art and, while using language that implied, if not suggested, experimental results had been obtained, failed to tell the PTO its discovery was based only on Dr. Kaiko's insight.

In this respect the case is similar to Hoffman-La Roche. In that case, the patentees had erroneously stated in the written description that a procedure had been performed and presented "results" of that procedure. Hoffman-La Roche, 323 F.3d at 1363. This court affirmed the trial court's finding of materiality, not on the ground that experimental results were required for patentability, but on the ground that the patentees misrepresented the results and made reference to them during prosecution in responding to a PTO office action. Id. at 1367-68. Similarly, the trial court's finding in

this case was not based on Purdue's failure to provide scientific proof of its "surprising discovery," but on its claim to have made a surprising medical discovery without disclosing the evidentiary basis for it, i.e., that the alleged "discovery" under these circumstances was based on insight and was without an empirical basis.

2. Intent

"Intent [to deceive or mislead the PTO] need not be proven by direct evidence. Indeed, '[d]irect proof of wrongful intent is rarely available but may be inferred from clear and convincing evidence of the surrounding circumstances.'" Baxter Int'l, Inc. v. McGaw, Inc., 149 F.3d 1321, 1329 (Fed. Cir. 1998) (quoting LaBounty Mfg., Inc. v. USITC, 958 F.2d 1066, 1076 (Fed. Cir. 1992)). When balanced against high materiality, the showing of intent can be proportionately less. Brasseler U.S.A. I, L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1381 (Fed. Cir. 1999). When determining whether intent has been shown, a court must weigh all evidence, including evidence of good faith. Baxter, 149 F.3d at 1330. However, "a patentee facing a high level of materiality and clear proof that it knew or should have known of that materiality, can expect to find it difficult to establish 'subjective good faith' sufficient to prevent the drawing of an inference of intent to mislead." Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997).

The trial court began its intent analysis by focusing on Purdue's claim that it believed in good faith that the statements regarding the four-fold dosage range and more efficient titration process were true. After citing trial testimony from Purdue witnesses (Dr. Kaiko and his supervisor Dr. Goldenheim) and quoting a number of internal Purdue memoranda, the trial court concluded that any such good faith belief

was undercut by Purdue's admitted inability to prove scientifically the accuracy of the statements.

The documents and testimony relied on by the trial court relate primarily to Purdue's attempt to gain FDA approval for its proposed labeling claim that OxyContin® was "the most efficiently titratable analgesic" rather than its attempt to obtain allowance of its patent claims. We agree with Purdue that its internal discussions regarding the difficulty in proving the titration claim for FDA approval purposes are not inconsistent with Purdue's asserted belief that it had discovered its oxycodone formulations were effective over a four-fold dosage range, compared to an eight-fold dosage range for other opioids. And we agree that the quantum of proof necessary for FDA approval is significantly higher than that required by the PTO.

The question, however, is not whether Purdue believed the assertions of a four-fold dosage range and more efficient titration process to be true, or even whether in fact they were true. The relevant question is whether Purdue intentionally withheld material information as to the source of its "surprising discovery," information that would be relevant to, and the absence of which might mislead, the examiner in his or her determinations regarding patentability. See Hoffman-La Roche, 323 F.3d at 1367 ("[T]he district court's finding that the inventors had a good faith belief in the novelty of their invention is not incompatible with a finding of deceptive intent.").

In this case, intent to mislead the PTO can be inferred from Purdue's statements and the context in which they were made. Purdue's carefully chosen language suggests that it had obtained clinical results, and that suggestion was left unclarified by any disclosure that discovery of the four-fold dosage range for oxycodone was based on

insight. The trial court's ruling did not hinge on a single statement in the patents, as Purdue suggests, but instead was based on a clear pattern of misdirection throughout prosecution of Purdue's controlled release oxycodone patents. Purdue had several opportunities to inform the PTO it had no scientific proof of a reduced dosage range, yet Purdue continued to describe its discovery in terms of "results," using precise, quantitative, and comparative language. The consistent and repetitive nature of Purdue's communications with the PTO fully supports the trial court's conclusion that Purdue made a deliberate decision to withhold and thus misrepresent the origin of its "discovery" to the PTO. Based on our review of the record, we discern no clear error in the trial court's finding that Purdue acted with intent to mislead the PTO.

Accordingly, we conclude that the trial court's findings on materiality and intent were well-founded, and thus not clearly erroneous. Weighing materiality and intent is a matter of judgment. On the record before us we cannot say that the trial court abused its discretion in weighing these findings to conclude that the patents-in-suit are unenforceable due to Purdue's inequitable conduct.

CONCLUSION

The trial court's judgment that the patents-in–suit are unenforceable due to inequitable conduct is affirmed. Because we affirm the trial court's judgment on inequitable conduct, we do not reach Endo's cross-appeal of the infringement judgment.

AFFIRMED