UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

	:	04 md. 1603 (SHS)
	:	
In re:	:	This document relates to:
	:	06 Civ. 13095 (SHS)
OXYCONTIN ANTITRUST LITIGATION	:	07 Civ. 03972 (SHS)
	:	07 Civ. 03973 (SHS)
	:	07 Civ. 04810 (SHS)
	:	
	x	OPINION AND ORDER

SIDNEY H. STEIN, U.S. District Judge.

Plaintiffs Purdue Pharma, L.P., the P.F. Laboratories, Inc., and Purdue Pharmaceuticals, L.P. (collectively, "Purdue") bring this litigation pursuant to 35 U.S.C. § 271(e)(2) against defendant pharmaceutical companies Mallinckrodt, Inc., KV Pharmaceutical Co., and Actavis Totowa L.L.C. for allegedly infringing Purdue's patents protecting a controlled-release oxycodone pain reliever sold under the brand name OxyContin. Due to the procedural posture of this litigation, the Court directed the parties to brief the issue of whether Purdue's conduct before the Patent and Trademark Office ("PTO") warrants the invalidation of the patents-in-suit. Having reviewed the briefs submitted by the parties and considered the arguments made during the December 20, 2007 hearing, the Court now concludes that Purdue did not commit inequitable conduct before the PTO in the prosecution of its OxyContin patents.

I. FACTUAL AND PROCEDURAL BACKGROUND

The Court presumes familiarity with the background of this litigation as detailed in its earlier decision, Purdue Pharma L.P. v. Endo Pharms., Inc., No. 00 Civ. 8029, 01 Civ. 2109, 01 Civ. 8177, 2004 U.S. Dist. LEXIS 10 (S.D.N.Y. Jan. 5, 2004) ("Endo I"), and that of the U.S. Court of Appeals for the Federal Circuit, Purdue Pharma L.P. v. Endo

Pharms., Inc., 438 F.3d 1123 (Fed. Cir. 2006) ("Endo III"). The following summarizes the relevant facts and procedural events described in those decisions, as well as the more recent developments in this litigation.

Beginning in 1999, Purdue filed patent infringement actions against four generic drug companies – Endo Pharmaceuticals, Inc.; Boehringer Ingelheim GmbH; Teva Pharmaceuticals, Inc.; and Impax Laboratories, Inc. – for marketing or attempting to market products that allegedly infringed Purdue's OxyContin patents.[1] The actions against one of those generic drug manufacturers – Endo – proceeded to trial, and on January 5, 2004, this Court issued an Opinion and Order holding that Endo had infringed Purdue's OxyContin patents, but also finding that those patents were invalid due to Purdue's inequitable conduct in prosecuting them before the PTO. See Endo I, 2004 U.S. Dist. LEXIS 10.

The Court then enjoined Purdue from further enforcement of its OxyContin patents and subsequently granted summary judgment in favor of defendants Boehringer, Teva, and Impax in the other pending OxyContin patent infringement suits (the "related cases") based on the collateral estoppel effect of the decision in Endo I, which was subsequently affirmed by the Federal Circuit in an opinion issued on June 7, 2005. See Purdue Pharma L.P. v. Endo Pharms. Inc., 410 F.3d 690 (Fed. Cir. 2005) ("Endo II").

Nearly eight months later – on February 1, 2006 – the Federal Circuit withdrew its affirmance of Endo I and issued Endo III, which vacated this Court's finding of patent

[1] The three patents-in-suit are: U.S. Patents No. 5,656,295 (the "'295 patent"), 5,508,042 (the "'042 patent"), and 5,549,912 (the "'912 patent"). The '295 and '042 patents are, respectively, a continuation-in-part and a divisional of the '912 patent. The '912 patent is, in turn, a continuation-in-part of U.S. Patent No. 5,266,331 (the "'331 patent"), which will be identified as the "parent patent" in this opinion. The prosecution history of the parent patent is relevant to this litigation because "inequitable conduct with respect to one or more patents in a family can infect related applications." Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223, 1230 (Fed. Cir. 2007).

invalidity and remanded that issue to this Court for further proceedings. In light of the Federal Circuit's revised ruling, this Court then vacated both its injunction barring Purdue from enforcing the OxyContin patents and the summary judgment orders in the related cases.

The parties then proceeded to settle the pending infringement actions. In October 2006, Purdue settled its suit against Endo and Teva. Purdue then reached a settlement agreement with Impax in May 2007, and finally, Purdue settled with Boehringer in August 2007.

Meanwhile, other pharmaceutical manufacturers attempted to enter the generic OxyContin market. Specifically, in 2005, Mallinckrodt filed an Abbreviated New Drug Application ("ANDA"), seeking Food and Drug Administration ("FDA") approval to manufacture and sell generic versions of OxyContin.[2] KV and Actavis likewise filed ANDAs for various formulations of generic OxyContin. In response, Purdue brought suit against Mallinckrodt, KV, and Actavis in four separate actions pursuant to the procedures set forth in the Hatch-Waxman Act, which authorizes patent-holders to bring constructive infringement actions against ANDA applicants. See 35 U.S.C. § 271(e)(2).

In light of the unique procedural history of this litigation, the Court determined that judicial economy would be best served by first resolving the issue left open by Endo III – namely, whether Purdue's conduct before the PTO warrants invalidating its OxyContin patents. See Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223, 1230 (Fed. Cir. 2007) ("Trial judges are entitled to arrange the priority of issues in a manner that they

[2] Pursuant to the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), an applicant can file an ANDA with the FDA requesting approval of a bioequivalent (i.e., "generic") version of a drug that is already approved by the FDA (a "listed drug") without having to submit additional safety and efficacy data. See 21 U.S.C. § 355(j)(2)(A).

consider efficient."). Having reviewed the parties' briefs and considered their arguments, the Court now turns to that question.

II. STANDARD

A patent may be ruled unenforceable if the applicant engaged in inequitable conduct during the prosecution of the patent application. Patent applicants are required 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." Endo III, 438 F.3d at 1128 (citing 37 C.F.R. § 1.56(a)). A breach of a patent applicant's duty of candor "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." Endo III, 438 F.3d at 1128 (citing Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995)).

Thus, inequitable conduct comprises two elements: materiality and intent to deceive. Pursuant to the relevant regulations, information is material to patentability when:

> it 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). In addition, "affirmative misrepresentations by the patentee, in contrast to misleading omissions, are more likely to be regarded as material." Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1367 (Fed. Cir. 2003).

With respect to intent, direct evidence "is rarely available but may be inferred from clear and convincing evidence of the surrounding circumstances." Endo III, 438 F.3d at 1133-34 (internal quotation marks and citation omitted). Indeed, if the prosecution of a patent is marked by "an overriding pattern of misconduct," that pattern can be adequate evidence of culpable intent. Paragon Podiatry Lab. v. KLM Lab., 984 F.2d 1182, 1193 (Fed. Cir. 1993). It is improper, however, to infer intent solely from the fact that a material omission or misstatement was made. Endo III, 438 F.3d at 1134. While "'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,'" id. at 1134 (quoting Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1257 (Fed. Cir. 1997)), materiality alone is never sufficient to establish intent because proof of intent "is a separate and essential component of inequitable conduct," id. (internal quotation marks and citation omitted).

Finally, the party asserting inequitable conduct bears the burden of proving materiality and intent to deceive by clear and convincing evidence. Id. at 1128 (citing Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 872 (Fed. Cir. 1988)).

Accordingly, when faced with allegations of inequitable conduct, a court must first determine whether clear and convincing evidence shows: (1) the applicant made a material misrepresentation, failed to make a material disclosure, or submitted false material information to the PTO and (2) the applicant acted with the intent to deceive the PTO. If these "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." Id. (citing Molins, 48 F.3d at 1178). This examination of the equities requires a "careful balancing" – such that misrepresentations of low materiality must be paired with higher intent, and lesser showings of intent must be combined with misrepresentations of high materiality – in order to find a patent unenforceable for inequitable conduct. See id. at 1129.

III. DISCUSSION

Defendants urge this Court to declare Purdue's OxyContin patents unenforceable based on seven alleged misrepresentations and omissions that, defendants contend, paint a disturbing picture of deceit. Each of these allegations is addressed below.

A. Purdue's Lack of Sufficient Empirical Evidence for its Claim of a Reduced Dosage Range

In Endo I, this Court ruled that Purdue had committed inequitable conduct before the PTO by implying that clinical studies demonstrated a reduced dosage range for OxyContin in comparison to other opioids when, in fact, no such studies existed. Specifically, this Court found that "during the bench trial, Dr. [Robert F.] Kaiko" – a named inventor of all of the patents-in-suit – "admitted that he had 'no scientific proof' at the time of filing the '912 patent that the inventions of the patents exhibited a reduced dosage range." Endo I, 2004 U.S. Dist. LEXIS 10, at *70. Instead, the discovery of OxyContin's reduced dosage range was based solely on Dr. Kaiko's "insight," and this fact was never disclosed to the PTO. Id.

1. Materiality

Purdue's failure to disclose that insight rather than evidence supported its discovery of OxyContin's reduced dosage range constituted, in this Court's view, a material omission because Purdue had (1) relied heavily on its discovery of the reduced

dosage range to support its arguments for patentability and (2) the patent examiner considered these statements "decisive" in allowing at least one of the patents-in-suit – the '042 patent – to issue. Id. at *74-76.

On appeal, the Federal Circuit affirmed this Court's determination that Purdue's misrepresentation was material, ruling:

> 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 [i.e., reduced] 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.

Endo III, 438 F.3d at 1132. The Federal Circuit concluded, however, that the materiality of this omission was "not especially high," id. at 1133, and was, in fact, "relatively low," id. at 1134, because it was only an omission rather than an "affirmative misrepresentation," id. at 1133.

2. Intent to Deceive

With respect to intent to deceive, this Court relied on internal documents and trial testimony showing that at the same time Purdue announced to the PTO that it had discovered OxyContin's reduced dosage range, it was unable to prove – and had no process in place designed to prove – that OxyContin was the "most easily titratable strong analgesic," a labeling claim for which Purdue considered seeking FDA approval. Endo I, 2004 U.S. Dist. LEXIS 10, at *79-81. This Court viewed ease of titration and a reduced dosage range as closely related concepts because "titration is the method by which dosages are adjusted in order to provide acceptable pain control without unacceptable

side effects" and therefore, "a reduction in dosage ranges would directly improve titration." Id. at *80.

Based on the apparent inconsistency of informing the PTO of OxyContin's reduced dosage range while at the same time being unable to prove ease of titration to the FDA, this Court determined that "any good faith belief that Purdue had 'discovered' the reduction in dosage range is substantially undercut by its admitted inability to prove, or even to develop, a 'set of procedures and methods' to prove this reduction in dosage range (and related ease of titration), and cannot 'overcome an inference of intent to mislead.'" Id. at *83-84 (quoting Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1375 (Fed. Cir. 2000)).

On appeal, the Federal Circuit concluded that this Court's analysis of the discrepancy between Purdue's discovery of a reduced dosage range and its inability to prove ease of titration was erroneous. The Federal Circuit concluded that "evidence regarding the difficulty in proving the titration claim is 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." Endo III, 438 F.3d at 1134. In support of this conclusion, the Federal Circuit observed that "[w]hile Purdue alleged during prosecution [of the patents-in-suit] that ease of titration would result from a reduced dosage range, the two concepts are different." Id. It further noted that "the quantum of proof necessary for FDA approval [of a labeling claim] is significantly higher than that required by the PTO." The Federal Circuit concluded, therefore, that "evidence that Purdue personnel believed it would be difficult to satisfy FDA requirements is at best marginally related to whether they intended to deceive the

PTO" and that this Court "erred in giving the weight it did to this evidence when determining that Purdue acted with deceptive intent during prosecution of its patents." Id.

In light of the Federal Circuit's analysis in Endo III, defendants in this litigation must come forward with additional evidence in order for this Court to find that Purdue intended to deceive the PTO when it implied that its discovery of a reduced dosage range was based on evidence rather than insight. Defendants have failed to do so. Aside from urging the Court to consider Purdue's alleged pattern of misstatements and omissions as evidence of intent, which the Court addresses below, defendants offer as proof of intent only vague allegations that Purdue had strong business incentives to obtain a patent for OxyContin because of the looming expiration of other patents it held. However, "[s]uch generalized allegations lack the particularity required to meet the threshold level of deceptive intent necessary for a finding of inequitable conduct." Sanofi-Synthelabo v. Apotex, Inc., 470 F.3d 1368, 1381 (Fed. Cir. 2006). If credited, they would show only that Purdue, like any patent applicant, had a strong desire to see its invention patented, and not that it intended to engage in deception in order to accomplish that goal.

Moreover, Purdue's ability to obtain patents for its OxyContin formulations did not turn on whether the discovery of a reduced dosage range was a product of insight or experimentation. As the Federal Circuit explained, "the manner in which an invention is discovered, whether by insight or experiment, does not by itself affect patentability." Id. at 1132 (citing 35 U.S.C. § 103(a)). Therefore, economic pressure to obtain a patent would not, as a matter of logic, prompt an applicant to characterize a discovery obtained

by insight as one derived through experimentation because both types of discoveries are equally patentable.

Accordingly, the record before this Court contains scant evidence that Purdue intended to deceive the PTO when it mischaracterized its discovery as one obtained through experimentation rather than insight.

B. Inadequate Support for Purdue's Claim of an Eight-Fold Dosage Range for Most Opioids

Defendants also question whether Purdue possessed adequate support for its representations to the PTO that unlike OxyContin, other opioid analgesics exhibited an eight-fold dosage range to control pain in ninety percent of patients. This representation was important because Purdue characterized its discovery of OxyContin's reduced four-fold dosage range as an improvement over the eight-fold dosage range of other opioids. As proof of the eight-fold range, Purdue cited "[s]urveys of daily dosages of opioid analgesics required to control pain" in its applications for each of the patents-in-suit.[3] (PTX 4 at '912-7, PTX 6 at '042-8, PTX 5 at '295-8.) Purdue had earlier noted the eight-fold dosage range during the prosecution of the parent patent, but did not indicate that it possessed surveys – or any other type of evidence – that suggested the range.[4] (PTX 7 at '331-43.)

[3] In full, the sentence, which is common to all three patent applications, reads: "Surveys of daily dosages of opioid analgesics required to control pain suggest that an approximately eight-fold range in daily dosages is required to control pain in approximately 90% of patients." (PTX 4 at '912-7, PTX 6 at '042-8, PTX 5 at '295-8.)

[4] Purdue made this statement in an October 22, 1992 submission to the PTO in response to an office action dated April 30, 1992. In its submission, Purdue specified that hydromorphone exhibited an eight-fold range. (PTX 7 at '331-43.) While the basis for this representation is unclear, there is no evidence in the record that hydromorphone does not require an eight-fold dosage range to control pain in ninety percent of patients. Accordingly, this statement cannot be deemed a misrepresentation on the record before this Court.

Defendants contend that at the time it made these representations to the PTO, Purdue had no surveys showing that opioids generally require an eight-fold dosage range to control pain in ninety percent of patients, and at best, Purdue could make that claim with respect to only one opioid, morphine. Purdue's representations, therefore, constituted affirmative misrepresentations of the significance of its discovery, according to defendants.

This Court disagrees. At the time Purdue made these representations to the PTO, it possessed adequate evidence for it to assert that surveys suggested that opioids required an eight-fold dosage range to control pain in ninety percent of patients.

It is undisputed that Purdue had adequate data to claim that the opioid morphine required an eight-fold dosage range for ninety percent of patients. In 1989, two years prior to filing the parent patent application, Dr. Kaiko published an article on morphine reviewing data from multiple studies indicating that an eight-fold dosage range (60 - 480 mg) controlled pain in approximately ninety percent of the subjects of those studies. (Robert F. Kaiko, et al., The United States Experience with Oral Controlled-Release Morphine (MS Contin Tablets), 63 Cancer 2348, 2350 (1989), Ex. 3 to Decl. of Richard A. Inz dated Oct. 12, 2007 ("Inz Decl.").) That article, as defendants concede, provides sufficient support for Purdue's claim that surveys existed with respect to at least one opioid, morphine.

In addition to Dr. Kaiko's study of morphine, a 1992 publication of the American Pain Society provides further support for Purdue's claim that surveys suggested an eight-fold dosage range for opioid analgesics. (American Pain Society, Principals of Analgesic Use in the Treatment of Acute Pain and Cancer Pain (3d ed. 1992), Ex. 4 to Inz Decl.)

This monograph – which Purdue cited in its applications for each of the patents-in-suit (PTX 4 at '912-7, PTX 6 at '042-8, PTX 5 at '295-9) – states in a sub-section entitled "Be aware that the optimal analgesic dose varies widely among patients" that a 1988 study reported a 0.6 to 5.2 mg – or 8.67-fold – dosage range. (Inz Decl., Ex. 4 at P242415 - P242416.) While it is unclear whether this range corresponds to ninety percent of patients surveyed, it is nonetheless consistent with Purdue's representation that surveys generally "suggest" an 8-fold dosage range.

Indeed, Purdue did not state that it possessed surveys that definitively proved the existence of an eight-fold dosage range for ninety percent of patients treated with opioid analgesics; rather it informed the PTO that studies "suggest" such a range. (PTX 4 at '912-7, PTX 6 at '042-8, PTX 5 at '295-8.) And the evidence shows that Purdue was indeed aware of surveys – those cited in Dr. Kaiko's 1989 article and the American Pain Society Monograph – that arguably suggest that opioids generally exhibit an eight-fold dosage range to control pain in approximately ninety percent of patients.

Defendants nevertheless fault Purdue for making statements about the properties of opioids generally when it possessed hard data for morphine only. To the extent that Dr. Kaiko extrapolated from his experience with morphine to draw conclusions about the general properties of opioids, however, that assumption was before the PTO. During the prosecution of the parent patent Dr. Kaiko informed the PTO that he considered morphine to be the "prototypic opioid analgesic." (PTX 7 at '331-59.) It would have been wholly consistent with that view for Dr. Kaiko to draw conclusions about the properties of opioids generally based on what is "suggested" by the surveys of morphine that he considered representative of the entire class of opioids.

Finally, the materiality of this alleged misrepresentation appears vanishingly small to this Court. Under defendants' reasoning, Purdue would have been on safe ground had it stated that: "Surveys of daily dosages of a prototypic opioid analgesic (morphine) required to control pain suggest that an approximately eight-fold range in daily dosages of opioid analgesics is required to control pain in approximately 90% of patients." The difference between this statement and the one that Purdue actually made to the PTO would have been immaterial to the patent examiner.[5]

C. Non-disclosure of Clinical Results that Allegedly Contradict Purdue's Dosage and Titration Claims

Defendants further fault Purdue for failing to disclose clinical results that purportedly contradict Purdue's claim that OxyContin's reduced range of dosage would ease titration. Specifically, defendants point to three studies: (1) the "Reder Survey," which stated that none of ten surveyed physicians found OxyContin easier to titrate than MS Contin ("OxyContin Tablets Investigator Survey Preliminary Report" dated May 3, 1994 at P054893, Ex. 33 to Decl. of Casey B. Howard dated Sept. 21, 2007 ("Howard Decl. I")); (2) the "Kalso Study," which found there were "no significant differences in the time to achieve stable pain control" between controlled-release oxycodone, i.e., OxyContin, and controlled-release morphine and that the two controlled-release opioids had comparable dosage ranges ("Protocol No. OC93-0303 Study Report" dated Oct. 17, 1996 at P275689, P275725, Ex. 57 to Decl. of Casey B. Howard dated Oct. 19, 2007 ("Howard Decl. II"); Ex. 38 to Howard Decl. I at P642973); and (3) the "LoRusso/Berman Study," which concluded that for both controlled-release oxycodone and controlled-release morphine, "[t]he median time to achieve stable pain control was

[5] The hypothetical language added by the Court to Purdue's disclosure is indicated by underscoring.

two days . . . , and the number of dose adjustments required . . . were similar for both drugs" ("Protocol No. OC92-1001 Study Report" dated Sept. 27, 1996 at P187373, Ex. 56 to Howard Decl. II; Ex. 37 to Howard Decl. I at EN000283 - EN000284).

Purdue had access to each of these reports prior to the time when all of the patents-in-suit had been issued, but it never disclosed any of them to the PTO.

Failing to disclose a study that "refutes, or is inconsistent with, a position the [patent] applicant takes in . . . [a]sserting an argument of patentability" can constitute a material omission. 37 C.F.R. § 1.56(b). Indeed, the Federal Circuit has held that "[a] reasonable examiner would certainly want to consider test data that is directly related to an important issue of patentability, along with the applicant's interpretation of that data" even when the applicant believes that the data at issue is "not comparable to the data submitted to the examiner." Cargill, Inc. v. Canbra Foods, Ltd., 476 F.3d 1359, 1366 (Fed. Cir. 2007); see also Merck & Co. v. Danbury Pharmacal, Inc., 873 F.2d 1418, 1420 (Fed. Cir. 1989) (affirming district court determination that Merck, "in prosecuting its four applications, argued over and over that cyclobenzaprine was free of the side effects . . . [but] its own data indicated its awareness of at least one such side effect, i.e., drowsiness").

In light of this standard, the Court now considers whether the nondisclosure of the reports cited by defendants constitutes a material omission.

1. The Reder Survey

Purdue's non-disclosure of the Reder Survey is not material to Purdue's ease of titration claims because the study protocols underlying that survey – OC91-0402A and OC91-0402B – specifically prohibited titration. (See Inz Decl. Ex. 7 at P016197, Ex. 8 at

RK00752, Ex. 9 at P615627.) Because titration was not actually tested in those studies, any opinions the Reder Survey respondents may have expressed concerning the ease of titration could not have been based on any actual experience with titrating OxyContin. Indeed the very language of the Reder Survey suggests that the respondents were invited to speculate about OxyContin's properties: "The investigators were asked several questions about possible benefits of OxyContin." (Howard Decl. I, Ex. 33 at P054893 (emphasis added).) Accordingly, Purdue was under no obligation to disclose this survey to the PTO as the Reder Survey's findings were not grounded in relevant data and therefore immaterial to Purdue's claim that OxyContin's reduced dosage range would ease titration.[6]

2. The Kalso and LoRusso/Berman Studies

Similarly, neither the Kalso Study nor the LoRusso/Berman Study is inconsistent with Purdue's claim that OxyContin's reduced dosage range would have the beneficial effect of facilitating titration.

Purdue made a very specific representation to the PTO regarding OxyContin's reduced dosage range and the corresponding ease of titration. In this regard, the applications for each of the patents-in-suit stated:

> The clinical significance provided by the controlled release oxycodone formulations of the present invention at a dosage range from about 10 to about 40 mg every 12 hours for acceptable pain management in approximately 90% of patients with moderate to severe pain, as compared to other opioid analgesics requiring approximately twice the dosage range provides for the most efficient and humane method of managing pain requiring repeated dosing. The expertise and time of physicians and nurses, as well as the duration of unacceptable pain patients must endure

[6] In addition, the Reder Survey is of limited value on the question of how oxycodone compares to other opioids in terms of ease of titration because the underlying studies compared controlled-release oxycodone to immediate-release oxycodone, and not controlled-release oxycodone to other controlled-release opioids. (Inz Decl. Ex. 7 at P016197, Ex. 8 at RK00748, Ex. 9 at P615623.)

> during the opioid analgesic titration process is substantially reduced through the efficiency of the controlled release oxycodone formulations of the present invention.

(PTX 4 at '912-14, PTX 6 at '042-15, PTX 5 at '295-15 - '295-16.) Accordingly, Purdue indicated that OxyContin's twice daily 10 to 40 mg dosage range would provide relief to ninety percent of patients and this dosage range, because it was narrower than other opioid analgesics, would ease the titration process.

Neither the Kalso Study nor the LoRusso/Berman Study, however, tested the dosage range that Purdue set forth in its applications, i.e., 10 to 40 mg every 12 hours. The Kalso Study tested a daily dosage range that began at the low end with 40 mg (20 mg every 12 hours) and increased at 40 mg (20 mg every 12 hours) increments with no upper limit. (Howard Decl. II, Ex. 57 at P275656, P275725.) The Kalso study, then, tested only two dosages in Purdue's 10 to 40 mg range – 20 mg and 40 mg – and therefore, did not examine the range of dosages that Purdue claimed would facilitate titration. The LoRusso/Berman Study tested a dosage range similar to that in the Kalso Study, 40 mg to 200 mg daily dosages (Howard Decl. II, Ex. 56 at P187442), and correspondingly dissimilar to the one claimed by Purdue.

In addition, neither study actually examined ease of titration, but rather established protocols for first calculating the initial dosage and then adjusting the dosage by large fixed intervals to achieve pain relief. Under the Kalso protocol, after the initial dosage was calculated, the dosage was simply increased by a fixed amount – 40 mg daily – until satisfactory pain relief was obtained. (Howard Decl. II, Ex. 57 at P275656, P275657, P275725.) The LoRusso/Berman Study pursued a similar course – setting the initial dosage by calculation and then adjusting the dosage at 20 mg twice daily

increments. (Howard Decl. II, Ex. 56 at 187387-187388.) Under both regimes, a test subject who entered at the lowest possible dosage – 20 mg every 12 hours – would find himself at the top end of Purdue's range – 40 mg every 12 hours – after an adjustment upward of only one increment. The mechanical nature of these large adjustments cannot be said to provide meaningful insight on the ease of titrating Purdue's invention.

This Court previously considered the Kalso and LoRusso/Berman Studies (DX 2844, DX 4145) in Endo I. They were offered by the defendant in that action to prove that clinical studies contradicted Purdue's claim that a four-fold dosage range of OxyContin controlled pain in most patients. This Court rejected defendant's contention that "Purdue's clinical studies of OxyContin – including the Heiskanen-Kalso study and the Mucci-LoRusso study – show that OxyContin does not have a four-fold dosage range" on the ground that "neither study treated patients with a 10 mg dose, twice daily, which is within the invention's claimed dosage range of 10 - 40 mg; accordingly, it is not clear to the Court what dosage range conclusions can be drawn from these studies." Endo I, 2004 U.S. Dist. LEXIS 10 at *47-48. Defendants have not provided this Court with a sound basis to reconsider its prior determination that these studies do not bear on OxyContin's reduced dosage range and, by implication, the corresponding ease of titration. The Kalso and LoRusso/Berman Studies are not material, therefore, because they neither "refute[]" nor are "inconsistent with, a position" taken by Purdue in "[a]sserting an argument of patentability." 37 C.F.R. § 1.56(b).

Accordingly, the Court finds that the Kalso and LoRusso/Berman Studies, like the Reder Survey, are immaterial to Purdue's representations regarding OxyContin's ease of titration and range of dosages.

D. Purdue's "Surprising" Finding of Peak Plasma Levels and Duration of Pain Relief

Defendants also take issue with Purdue's claim to have been "surprise[ed]" by the discovery that its formulations of controlled-release oxycodone yielded peak plasma levels ("t_{max}") at two to four hours while providing twelve hours of pain relief. This discovery could not have been surprising, according to defendants, because oxycodone was the fifth opioid to exhibit such properties, and therefore anyone familiar with the relevant art would have been unsurprised by that discovery.

In its application for the parent patent, Purdue announced:

> In order to obtain a controlled release drug dosage form having at least a 12 hour therapeutic effect, it is usual in the pharmaceutical art to produce a formulation that gives a peak plasma level of the drug between about 4 - 8 hours after administration (in a single dose study). The present inventors have surprisingly found that, in the case of oxycodone, a peak plasma level at between 2 - 4 hours after administration gives at least 12 hours pain relief.

(PTX 7 at '331-7.) Defendants maintain that prior to developing OxyContin, Purdue had already devised formulations of four other opioids that provided a t_{max} within a two to four hour range and lasted for twelve hours, viz., morphine (specifically, "MS Contin"), dihydrocodeine, hydromorphone, and codeine. (Howard Decl. I, Ex. 10 at P041766-67 (MS Contin), Ex. 13 at 2 (dihydrocodeine), Ex. 14 at 2 (hydromorphone), Ex. 17-18 (codeine).) Against this background, Purdue's claims that it was surprising for its oxycodone formulations to also exhibit a t_{max} between two and four hours while providing twelve hours of relief could not have been sincere, in defendants' estimation.

Purdue responds that indeed it was surprising for OxyContin to exhibit these properties because all opioids are different and one cannot infer that the pharmacokinetic and pharmacodynamic properties – such as t_{max} and duration of activity – exhibited by a

formulation of one opioid will arise in a similar formulation of another opioid. In addition, Purdue maintains that even when similar in vitro results between opioids are obtained, one cannot assume that the in vivo results will also be the same.

In support of these propositions, Purdue refers the Court to Dr. Kaiko's declaration in support of the parent patent. (PTX 7 at '331-51 - '331-77.) There, Dr. Kaiko advanced two relevant observations. First, he stated that "one skilled in the art having information concerning the time to reach peak plasma concentration ["t_{max}"] and duration of effect" for one controlled-release opioid formulation "could not predict whether a controlled-release oxycodone formulation having t_{max} in 2 - 4 hours would also provide duration of therapeutic effect of at least 12 hours." (Id. at '331-54 (emphasis in original).) Second, Dr. Kaiko stated that "[o]ne cannot infer that in vitro release characteristics of a formulation for a particular drug giving rise to certain in vivo peak plasma levels and duration of activity . . . will provide the same duration of activity for another drug." (Id. (emphasis in original).)

In further support of the purported fallacy of extrapolating from one opioid to another and inferring that similar in vitro characteristics of two opioids necessarily implies similar in vivo characteristics, Purdue refers the Court to the 1992 American Pain Society publication noted above, which states in relevant part that "individual patients respond differently to different opioids." (Inz Decl., Ex. 4 at P242416.) Purdue also cites testimony from the Endo I trial that provides additional support for these propositions. At that trial, Dr. Richard Payne of Memorial Sloan-Kettering Cancer Center testified that "a small difference in the structure of an opioid . . . can lead to big differences in properties." (Endo I Tr. at 76; see also id. at 98, 101-07.) This testimony was further

supported by Dr. Joseph Robinson, a professor of pharmacy and ophthalmology at the University of Wisconsin, who explained:

> You simply cannot take a result from one drug and expect performance like that or exactly like that for another drug. The minute you change the drug, the chemical, the formula, you have changed everything about that product. You will need in vivo results to verify that in fact this is an operative system, but there is nothing in here that would tell a formulator which way to proceed.

(Id. at 1691; see also id. at 1681-84, 1691-96.)

In response to Purdue's evidence that similar formulations of different opioids cannot be expected to yield similar pharmacokinetic and pharmacodynamic results, defendants do not offer any contrary scientific evidence, showing, for example that new opioid formulations become more predictable as the number of prior successful formulations increases. Instead, they rely solely on the common sense proposition that by the fifth time the "same" result is achieved, it can no longer be called surprising. This Court, however, is not persuaded by such facile reasoning. Purdue's unchallenged evidence shows that opioids are too dissimilar to permit inferences that the physiological effects resulting from formulations of one opioid can be expected from similar formulations of another opioid. Therefore, when a formulation of one opioid yields similar pharmacokinetic and pharmacodynamic results to that of another opioid, that result can be said to be surprising insofar as it could not be expected in light of the variability of the effects of opioids. Accordingly, defendants have not met their burden of showing that it was a misrepresentation for Purdue to characterize its discovery as "surprising."

E. Purdue's Failure to Disclose Other Controlled-Release Opioids

Defendants further contend that regardless of whether it was fair for Purdue to characterize OxyContin's t_{max} and duration of activity as surprising, it was nevertheless a material omission for Purdue not to disclose the existence of its other controlled-release opioids so that the patent examiner could make his own determination of whether the discovery was indeed surprising. Purdue responds that it did, in fact, disclose controlled-release hydromorphone in the parent patent application and both controlled-release hydromorphone and morphine in the patents-in-suit. Purdue maintains that it did not disclose controlled-release dihydrocodeine and codeine because it considered them to be cumulative to the prior art that was disclosed and, in addition, less relevant.

1. Materiality

Purdue's non-disclosure of all of the other controlled-release opioids exhibiting a t_{max} within a two-to-four-hour range and a twelve-hour duration constitutes a material omission. The existence of four other opioid formulations with the same pharmacokinetic and pharmacodynamic characteristics as those that Purdue considered surprising in OxyContin, "is inconsistent with," 37 C.F.R. § 1.56(b), Purdue's representation that those characteristics were surprising, for the simple reason that those results had been obtained in the past from four opioids and so arguably could be expected in other opioids. While this Court is not persuaded by that argument in light of Purdue's evidence that opioids are too different to infer common physiological characteristics, the issue here is not whether this Court, or the patent examiner, would have been persuaded by the evidence, but rather whether that evidence would have been material to the patent examiner's determination of whether a patent should issue. See Agfa Corp. v. Creo

Prods., 451 F.3d 1366, 1373 (Fed. Cir. 2006); Molins, 48 F.3d at 1179 ("Nor is a reference immaterial simply because the claims are eventually deemed by an examiner to be patentable thereover."). In this case, the information was material, but for the reasons stated in the previous section, its materiality was low in light of the variability of opioids' pharmacokinetic and pharmacodynamic characteristics.

Moreover, Purdue's failure to disclose this information cannot be excused as immaterial on the ground that it was cumulative, see 37 C.F.R. § 1.56(b), because the issue here is not whether the undisclosed "reference teaches no more than what a reasonable examiner would consider to be taught by the prior art already before the PTO," Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1575 (Fed. Cir. 1997). Rather, the materiality of this nondisclosure arises from the sheer number of different opioids – four – that had been crafted into formulations exhibiting the same physiological characteristics as those that Purdue found surprising in OxyContin. Each additional time these results were obtained suggests, in theory, that they became more predictable and hence not unexpected. Thus, information showing the existence of four prior opioid formulations with t_{max} between two and four hours and twelve-hour durations constitutes information material to patentability.

2. Intent to Deceive

No evidence suggests that Purdue failed to disclose the existence of these four controlled-release opioid formulations in an effort to deceive the PTO. Indeed, Purdue offers a reasonable explanation for its nondisclosure, which the Court finds credible. At the Endo I trial, Purdue's attorney, Harold Steinberg, testified that he disclosed only the hydromorphone as relevant prior art in the parent patent application because it "was the

most closely related" and did not disclose dihydrocodeine because he considered it "cumulative" to the art already before the PTO. (Endo I Tr. at 1632.)

Consistent with Steinberg's testimony, Dr. Kaiko explained that he considered controlled-release codeine and dihydrocodeine to be drugs for less than "moderate to severe pain" that were not "in [his] mind as [he] was thinking about this" – i.e., prior art disclosures for the '912 patent application. (Id. at 368-69.) Dr. Kaiko further explained that he did not consider disclosing these formulations because "in the specifications I make it clear that we are talking about drugs for moderate to severe pain" (id. at 368), which in Dr. Kaiko's view did not include codeine and dihydrocodeine. Dr. Kaiko's distinction between codeine and dihydrocodeine – as opioids for mild to moderate pain – and oxycodone, morphine, and hydromorphone – as opioids for moderate to severe pain – while perhaps not undisputed, finds ample support in the literature. (World Health Organization, Cancer Pain Relief (2d ed. 1996) at 13, Ex. 10 to Inz Decl.)

Thus, Steinberg and Dr. Kaiko place Purdue's decision to disclose formulations of morphine and hydromorphone, but not codeine or dihydrocodeine, in the context of determining what prior art would be relevant to the patent examiner. In making this determination, they arrived at what appears to be a good-faith conclusion that prior controlled-release formulations of morphine and hydromorphone would be most relevant to the patent examiner's inquiry, while similar formulations of codeine and dihydrocodeine would be less relevant and, in fact, cumulative. This determination is consistent with a patent applicant's duty to identify and disclose only prior art that is material, which is defined in part as "not cumulative." 37 C.F.R. § 1.56; cf. Molins, 48 F.3d at 1184 ("'[B]urying' a particularly material reference in a prior art statement

containing a multiplicity of other references can be probative of bad faith."). Defendants have come forward with no evidence whatsoever suggesting that Purdue intended to deceive the PTO about the existence of other controlled-release opioid formulations in order to insulate from scrutiny its claim of surprise at OxyContin's properties. Accordingly, this Court has no basis to conclude that Purdue's nondisclosure of all four of the controlled-release opioid formulations arose from an intent to deceive the PTO.

F. Purdue's Failure to Clarify that Dr. Kaiko Is Not an Independent Expert

Defendants also allege that Purdue deceived the PTO while prosecuting the parent patent by falsely presenting Dr. Kaiko as an independent expert. Purdue responds that sufficient evidence of Dr. Kaiko's affiliation was before the patent examiner and, in any event, the examiner never requested the declaration of an independent expert in the first instance.

The background of this allegation is straightforward. Upon the PTO's second rejection of the parent patent application, Mr. Steinberg, Purdue's attorney, met with the patent examiner to discuss the PTO's concerns. At that interview, which was held on February 25, 1993, Steinberg informed the examiner that he would submit a "declaration supporting unobviousness and unexpected results." (PTX 7 at '331-47.) Accordingly, Mr. Steinberg made a submission to the PTO on March 10, 1993 that included a declaration of Dr. Kaiko, who was identified as merely "a person truly skilled in this art," and not as a colleague of the patent applicants nor as an employee of a company affiliated with the invention's assignee, even though he was, in fact, both.[7] (Id. at '331-48 - '331-50.)

[7] The parent patent application listed Benjamin Oshlack, John Minogue, and Mark Chasin as applicants and noted an assignment of the invention to Euroceltique, S.A., a Purdue affiliate. (PTX 7 at '331-2, '331-4.)

In his declaration, Dr. Kaiko explained that a patented formulation of hydromorphone – which the patent examiner had cited as one ground to reject the invention as obvious (id. at '331-35, '331-46) – would not have led one skilled in the art to predict whether "a controlled-release oxycodone formulation having a t_{max} in 2 - 4 hours would also provide a duration of therapeutic effect of at least 12 hours." (Id. at '331-54 (emphasis in original).) Nor could one infer, according to Dr. Kaiko, that the in vivo and in vitro characteristics of one opioid formulation "will provide the same duration of activity for another drug." (Id. at '331-54.) Dr. Kaiko also explained that the matrix composition of oxycodone taught by another patent – also relied on by the patent examiner as proof of obviousness (id. at '331-35, '331-46) – would not permit "[o]ne skilled in the art . . . to accurately predict whether an oxycodone formulation with the in vitro dissolution rates taught in [that] patent would provide the pharmacokinetics (including t_{max}) and the pharmacodynamics (including the duration of effect) set forth in the claims" of the parent patent application. (Id. at '331-55 - '331-56.)

Eight months later, and without further submissions on the patent examiner's obviousness objections, the parent patent issued.

1. Materiality

The question of whether it was a material omission for Purdue not to disclose Dr. Kaiko's relationship to the applicants and assignee of the parent patent application need not detain this Court long. The Federal Circuit has recently ruled that regardless of whether the patent examiner requests the opinion of an impartial expert, a patent applicant must disclose whatever relationship he has with a declarant or affiant testifying in support of patentability. The court explained:

> We conclude that the district court did not abuse its discretion in holding that Nilssen [the patent applicant] engaged in inequitable conduct with respect to the [patents-in-suit] by submitting affidavits by Fiene in support of patentability, including points of distinction over prior art patents, without informing the examiner of the affiant's relationship to Nilssen. Even though the examiner did not raise a question concerning any such relationship, it is material to an examiner's evaluation of the credibility and content of affidavits to know of any significant relationship between an affiant and an applicant; failure to disclose that relationship violated Nilssen's duty of disclosure.

Nilssen v. Osram Sylvania, Inc., 504 F.3d 1223, 1229-30 (Fed. Cir. 2007) (citing Ferring B.V. v. Barr Labs., Inc., 437 F.3d 1181, 1187-88 (Fed. Cir. 2006)).

Purdue's failure to disclose Dr. Kaiko's relationship to the parent patent applicants and his employment by an affiliate of the invention's assignee therefore constitutes a material omission.

2. Intent to Deceive

There is overwhelming evidence, however, that Purdue's omission was made in good faith. First, Purdue listed Dr. Kaiko as one of four applicants – along with the three parent patent applicants – on each of the patents-in-suit, including the '912 patent, which was a continuation in part of the parent patent. (PTX 4 at '912-4, PTX 6 at '042-2, PTX 5 at '295-2.) The '912 patent application began in November 1992 as an international filing under the Patent Cooperation Treaty ("PCT"). (PTX 4 at '912-4.) Therefore, at the time Purdue submitted the Kaiko declaration in support of the parent patent application – March 1993 – it had four months earlier designated Dr. Kaiko as an inventor on a patent application for a related invention. Had Purdue intended to conceal Dr. Kaiko's relationship to the parent patent applicants, it would surely not have listed him on that filing.

Second, the attachment to Dr. Kaiko's declaration strongly suggests that Dr. Kaiko played some role in developing the claimed invention. The attachment refers repeatedly to Dr. Kaiko as "the inventor" and describes the background of the invention, the properties of the invention, and the clinical significance of the invention in a manner that indicates that Dr. Kaiko possessed greater knowledge about the invention than one could expect from an uninvolved third party. (See PTX 7 at '331-57 - '331-60.)

Finally, in stark contrast to the record before the Federal Circuit in Nilssen, the record here does not show any attempt by Purdue to actively conceal Dr. Kaiko's relationships and employment. The district court in Nilssen had found:

> Nilssen [the patent applicant] and Fiene [the affiant] had a significant relationship – personal, professional, and financial – when the affidavits were prepared and submitted. On more than one occasion, Nilssen knowingly failed to inform the PTO of this significant relationship and took active steps to conceal that relationship, i.e., removing his history of employment at Fyrnetics, which could have linked Nilssen and Fiene.

Nilssen v. Osram Sylvania, Inc., 440 F. Supp. 2d 884, 901 (N.D. Ill. 2006). There is no evidence whatsoever that Purdue committed similar acts of affirmative deception.

Accordingly, this Court finds that Purdue's failure to disclose Dr. Kaiko's relationship to the applicants and assignee of the parent patent, while a material omission, was nevertheless made in good faith.

G. Purdue's Failure to Disclose the Oshlack '598 Patent

Defendants charge Purdue with failing to disclose the matrix composition of oxycodone claimed in U.S. Patent No. 4,861,598 ("Oshlack '598") in its application for the parent patent. While Purdue did fail to make this disclosure, the omission is not material because the patent examiner was aware of Oshlack '598, and, in fact, partly based his initial rejection of the application on that prior art. (PTX 7 at '331-35, '331-

46.) Pursuant to the relevant regulations, "[t]he duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office." 37 C.F.R. § 1.56(a). As the Federal Circuit has explained, "[w]hen a reference was before the examiner, whether through the examiner's search or the applicant's disclosure, it can not be deemed to have been withheld from the examiner." Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1582 (Fed. Cir. 1991); see also Young v. Lumenis, Inc., 492 F.3d 1336, 1349-50 (Fed. Cir. 2007) (citing Genentech, 927 F.2d at 1582); Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 98 F. Supp. 2d 362, 396 (S.D.N.Y. 2000) (citing Genentech, 927 F.2d at 1582; 37 C.F.R. § 1.56(a)).[8]

Accordingly, the non-disclosure of Oshlack '598 cannot constitute a material omission on which a finding of inequitable conduct can be based. This omission can be considered, however, for whether it contributes to a pattern of misconduct sufficient for this Court to infer intent to deceive. The Court now turns to that issue.

H. Pattern of Misconduct as Evidence of Intent

Defendants urge this Court to infer Purdue's deceptive intent from the pattern of misconduct allegedly perpetrated by Purdue in the course of prosecuting the parent patent and the patents-in-suit. While defendants are correct that courts are permitted to draw such inferences, see Paragon Podiatry Lab. v. KLM Lab., 984 F.2d 1182, 1193 (Fed. Cir. 1993) ("The prosecution of the patent application in this case, viewed in its entirety,

[8] Defendants' reliance on A.B. Dick Co. v. Burroughs Corp., 798 F.2d 1392 (Fed. Cir. 1986) for the proposition that inequitable conduct can be predicated on the non-disclosure of a document cited by the PTO is misplaced, as that case was decided prior to the promulgation in 1992 of the relevant regulations. See Eli Lilly & Co. v. Zenith Goldline Pharms., Inc., 364 F. Supp. 2d 820, 917 (S.D. Ind. 2005).

demonstrates an overriding pattern of misconduct sufficient to support the district court's finding of culpable intent."), the record in this litigation supports no such finding.

To review, this Court has determined that (1) it was a misrepresentation of low materiality for Purdue to imply that empirical evidence supported its discovery of a four-fold dosage range for ninety percent of patients when, in fact, that discovery was based only on insight; (2) it was an omission of low materiality for Purdue not to disclose its prior controlled-release formulations of codeine and hydrocodeine, but that omission was made in good faith; (3) it was a material omission for Purdue not to disclose Dr. Kaiko's relationship to the parent patent applicants and assignees, but overwhelming evidence of good faith mitigates that oversight; and (4) it was an immaterial omission for Purdue to fail to disclose Oshlack '598 in the parent patent application. Thus, Purdue has, at most, committed a single misrepresentation of low materiality, a single omission that is immaterial, and two omissions that were made in good faith. The picture painted by these few instances – lodged within a voluminous record that was subject to years of scrutiny by a variety of defendants – is hardly damning and does not establish a pattern of misconduct sufficient to infer intent to deceive.

I. Balancing of Materiality and Intent

The Court now turns to the question of whether the conduct defendants have proven justifies a determination that Purdue committed inequitable conduct before the PTO. According to the Federal Circuit, "[o]nce 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." Endo III, 438 F.3d at 1128. Defendants have not, however, established deceptive intent. The record in this action

contains at best "marginal[]" evidence that Purdue intended to deceive the PTO in connection with its misrepresentation that empirical evidence supported its dosage-range discovery. Id. at 1134. There is no evidence of deceptive intent with respect to Purdue's failure to disclose prior controlled-release formulations or its failure to disclose Dr. Kaiko's affiliations, both of which were made in good faith.

Even if this Court were to weigh materiality and intent, it cannot conclude that Purdue, by clear and convincing evidence, committed inequitable conduct before the PTO. Purdue's misrepresentation that empirical evidence supported its dosage-range discovery and its good-faith failure to disclose prior controlled-release formulations are of low materiality, and Purdue's failure to disclose Dr. Kaiko's affiliations, while of greater materiality, was made in good faith. Accordingly, the weight of the equities before this Court does not warrant the extreme sanction of holding the patents-in-suit unenforceable.

IV. CONCLUSION

For the reasons set forth above, defendants have failed to show by clear and convincing evidence that Purdue committed inequitable conduct before the PTO, and therefore the patents-in-suit will not be deemed unenforceable on that basis.

Dated: New York, New York
January 7, 2008

SO ORDERED:

Sidney H. Stein, U.S.D.J.