IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC. and PURDUE PHARMACEUTICALS L.P., Plaintiffs, v. KV PHARMACEUTICAL COMPANY and ACTAVIS TOTOWA LLC, Defendants.	Civil Action No. 07-032-***

ACTAVIS TOTOWA LLC'S MOTION
TO STAY ANTITRUST COUNTERCLAIMS

Actavis Totowa LLC ("Actavis") moves this Court to stay proceedings relating to its antitrust counterclaims, pending the resolution of the patent issues in this case. Pursuant to D. Del. LR 7.1.1, Actavis has conferred with counsel for plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P. (collectively "Purdue"). Taking a position completely at odds with an identical request it recently made in a related case, Purdue does not consent to the stay. For the following reasons, Actavis respectfully requests that this Court grant its Motion to Stay:

1. This is a patent infringement action over, *inter alia*, U.S. Pat. No. 5,508,042 (the "'042 patent").

2. On January 4, 2004, the United States District Court for the Southern District of New York, held the '042 patent unenforceable for inequitable conduct.

Purdue Pharma L.P. v. Endo Pharmaceuticals Inc., No. 00-CIV-8029, 2004 U.S. Dist. LEXIS 10, at *88 (S.D.N.Y. Jan 4, 2004) (Ex. 1).

3. On February 1, 2006, the United States Court of Appeals for the Federal Circuit vacated and remanded the district court's decision. Purdue Pharma L.P. v. Endo Pharmaceuticals Inc., 438 F.3d 1123, 1137 (Fed. Cir. 2006).

4. While the Endo case has settled, other parties sued by Purdue for patent infringement have pursued inequitable conduct claims concerning the '042 patent in the remanded action. Thus, these inequitable conduct claims remain pending in the Southern District of New York. See, e.g., Compl., Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, No. 99-CIV-3658 (SHS), ¶¶ 24-63 (Ex. 2).

5. Based on the cloud of inequitable conduct surrounding the '042 patent, Purdue has been sued for various antitrust violations. All told, Purdue is defending sixty-nine antitrust suits, which have been consolidated into a Multi District Litigation in the Southern District of New York. See Multidistrict Litigation Order No. 2, In re Oxycodone Antitrust Litigation, No. 04-MDL-1603 (SHS), at 1 (Mar. 30, 2006) (Ex. 3). The inequitable conduct and antitrust claims are pending before the same judge.

6. Recognizing that the antitrust claims are predicated on a finding of inequitable conduct, on February 9, 2006, Purdue moved to stay the antitrust suits, pending the outcome of the underlying patent litigations. Mem. in Supp. of Purdue's Mot. for Stay, Feb. 9, 2006, at 2 (Ex. 4). Purdue argued "[i]t would not be a sound use of the Court's resources, or the resources of the parties, to forge ahead with litigation on these antitrust claims before a decision has been reached in the underlying patent litigation on which those claims are based." Id.

7. Thus, the court granted Purdue's motion and stayed the proceedings on all antitrust claims, pending its decision concerning inequitable conduct on remand. Multidistrict Litigation Order No. 2, supra, at 2.

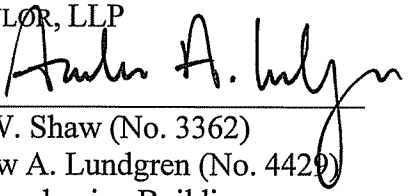
8. The same arguments relied upon by Purdue to justify its request for stay apply with equal force here. Actavis' antitrust counterclaims are dependent on the invalidity or unenforceability of the '042 patent, and resolution of the patent issues prior to discovery on the antitrust claims will promote judicial economy and avoid unnecessary expenditures of the parties' and Court's resources.

9. Indeed, "[i]t is a common practice in federal court to stay antitrust counterclaims until after the trial of the invalidity issue." Chip-Mender, Inc. v. Sherwin-Williams Co., No. 05-3465, 2006 U.S. Dist. LEXIS 2176, at *38 (N.D. Cal. Jan 3, 2006) (Ex. 5) (citing In re Innotron Diagnostics, 800 F.2d 1077, 1084 (Fed. Cir.1986) (discussing the "now-standard practice of separating for trial patent issues and those raised in an antitrust counterclaim")); see also Monsanto Co. v. Syngenta Seeds, Inc., No. 04-305, 2006 U.S. Dist. LEXIS 84963, at *3 (D. Del. Nov. 8, 2006) (Ex. 6) (granting a stay of discovery on antitrust counterclaims pending resolution of patent claims).

For the foregoing reasons, Actavis respectfully requests that the Court grant its Motion to Stay Antitrust Counterclaims.

Respectfully submitted,

YOUNG, CONAWAY, STARGATT & TAYLOR, LLP



John W. Shaw (No. 3362)
Andrew A. Lundgren (No. 4429)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19899-0551
302-571-6600
alundgren@ycst.com

Attorneys for Defendant
Actavis Totowa LLC

OF COUNSEL:

James D. Veltrop
Jonathan A. Harris
Chad A. Landmon
AXINN, VELTROP & HARKRIDER LLP
90 State House Square
Hartford, CT 06103-3702
(860) 275-8100

Dated: April 19, 2007

CERTIFICATE OF SERVICE

I, Andrew A. Lundgren, hereby certify that on April 19, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

Jack B. Blumenfeld, Esquire
Rodger Dallery Smith, II, Esquire
Morris Nichols Arsht & Tunnell
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347

Frederick L. Cottrell, III, Esquire
Chad M. Shandler, Esquire
Jameson A.L. Tweedie, Esquire
Richards Layton & Finger
One Rodney Square
920 North King Street
Wilmington, DE 19801

I further certify that on April 19, 2007, I caused a copy of the foregoing document to be served by hand delivery and e-mail on the above-listed counsel of record and on the following in the manner indicated:

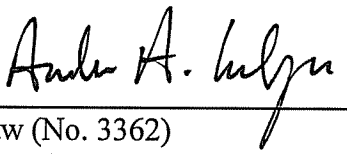
BY E-MAIL AND FEDERAL EXPRESS

Herbert F. Schwartz, Esquire
[herbert.schwartz@ropesgray.com]
Denise L. Loring, Esquire
[denise.loring@ropesgray.com]
Richard A. Inz, Esquire
[richard.inz@ropesgray.com]
Pablo D. Hendler, Esquire
[pablo.hendler@ropesgray.com]
Ropes & Gray LLP
1211 Avenue of the Americas
New York, NY 10020

Robert J. Goldman, Esquire
[robert.goldman@ropesgray.com]
Ropes & Gray LLP
525 University Avenue, Suite 300
Palo Alto, CA 94301-1917

John F. Sweeney, Esquire
[jfsweeney@morganfinnegan.com]
Joseph A. DeGirolamo, Esquire
[jdegirolamo@morganfinnegan.com]
Seth J. Atlas, Esquire
[sjatlas@morganfinnegan.com]
Andrea L. Wayda, Esquire
[alwayda@morganfinnegan.com]
Matthew J. Blackburn, Esquire
[mblackburn@morganfinnegan.com]
Morgan & Finnegan, L.L.P.
3 World Financial Center
New York, NY 10281-2101

YOUNG CONAWAY STARGATT & TAYLOR, LLP



John W. Shaw (No. 3362)
Andrew A. Lundgren (No. 4429)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
alundgren@ycst.com

Attorneys for Defendant Actavis Totowa LLC

EXHIBIT 1

LEXSEE 2004 U.S. DIST. LEXIS 10

PURDUE PHARMA L.P., THE PURDUE FREDERICK COMPANY, THE P.F. LABORATORIES, INC., THE PURDUE PHARMA COMPANY, Plaintiffs and Counterclaim Defendants, -against - ENDO PHARMACEUTICALS INC., Defendant and Counterclaim Plaintiff, ENDO PHARMACEUTICALS HOLDINGS INC., Defendant, v. EUROCELTIQUE S.A., Counterclaim Defendant.

00 Civ. 8029 (SHS), 01 Civ. 2109 (SHS), 01 Civ. 8177 (SHS)

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

2004 U.S. Dist. LEXIS 10; 70 U.S.P.Q.2D (BNA) 1185

January 5, 2004, Decided
January 5, 2004, Filed

SUBSEQUENT HISTORY: Motion denied by Purdue Pharma L.P. v. Endo Pharms., Inc., 2004 U.S. Dist. LEXIS 2276 (S.D.N.Y., Feb. 13, 2004)
Motion granted by, Dismissed by, in part, Motion denied by Purdue Pharma L.P. v. Endo Pharms., Inc., 102 Fed. Appx. 725, 2004 U.S. App. LEXIS 14541 (Fed. Cir., 2004)
Affirmed by Purdue Pharma L.P. v. Endo Pharms., Inc., 410 F.3d 690, 2005 U.S. App. LEXIS 10416 (Fed. Cir., 2005)
Related proceeding at Jolly v. Purdue Pharma L.P., 2005 U.S. Dist. LEXIS 44599 (S.D. Cal., Sept. 27, 2005)
Affirmed in part and vacated in part by, Remanded by, On rehearing at Purdue Pharma L.P. v. Endo Pharms., Inc., 438 F.3d 1123, 2006 U.S. App. LEXIS 2887 (Fed. Cir., 2006)
Vacated by, in part, Reconsideration granted by Purdue Pharma L.P. v. End0 Pharms., 2006 U.S. Dist. LEXIS 15321 (S.D.N.Y., Mar. 29, 2006)

DISPOSITION: [*1] Patent claims against Endo were dismissed, patents 5,549,912, 5,508,042 and 5,656,295 were infringed and declared invalid and Purdue was enjoined from enforcing those patents.

COUNSEL: For Purdue Pharma LP, The Purdue Frederick Company, The PF Laboratories, Inc, The Purdue Pharma Company, PLAINTIFFS (1:00cv8029): Herbert F Schwartz, Richard A. Inz, Robert J. Goldman, Fish & Neave, New York, NY; Kelsey I. Nix, Willkie Farr & Gallagher LLP (NY), New York, NY.

For Endo Pharmaceuticals Inc, Endo Pharmaceuticals Holding Inc, DEFENDANTS (1:00cv8029): Albert B. Chen, Donald Luther Rhoads, Louis H. Weinstein, Michael S. Oberman, Nicholas L. Coch, Robert Alderson, Kramer Levin Naftalis & Frankel, LLP, New York, NY; Edward V Eilardi, Constance S. Huttner, Douglas R. Nemee, Skadden, Arps, Slate, Meagher & Flom, LLP, New York, NY.

For Endo Pharmaceuticals Inc, Endo Pharmaceuticals Holding Inc, COUNTER CLAIMANTS (1:00cv8029): Albert B. Chen, Donald Luther Rhoads, Louis H. Weinstein, Michael S. Oberman, Nicholas L. Coch, Robert Alderson, Kramer Levin Naftalis & Frankel, LLP, New York, NY; Edward V Eilardi, Constance S. Huttner, Douglas R. Nemee, Skadden, Arps, Slate, Meagher & Flom, LLP, New York, NY.

For Purdue Pharma LP, The Purdue Frederick Company, The PF Laboratories, Inc, The Purdue Pharma Company, COUNTER DEFENDANTS (1:00cv8029): Herbert F Schwartz, Richard A. Inz, Robert J. Goldman, Fish & Neave, New York, NY; Kelsey I. Nix, Willkie Farr & Gallagher LLP (NY), New York, NY.

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

OPINION BY: SIDNEY H. STEIN

OPINION:

OPINION AND ORDER

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

Table of Contents

I. Introduction

II. Background

A. The Purdue Patents

1. The Parent Patent: The '331 Patent
2. The [*2] '912 Patent
3. The '042 Patent
4. The '295 Patent

B. Terminology

III. Discussion

A. Infringement

1. Claim Construction
a. C[min]
b. Controlled release
c. OxyContin controls pain relief in approximately 90% of patients over an approximate four-fold dosage range
2. Comparison of Endo's proposed ANDA formulation to Purdue's OxyContin

B. Inequitable Conduct

IV. Conclusion

I. Introduction

Plaintiffs Purdue Pharma, L.P., the Purdue Frederick Company, the P.F. Laboratories, Inc. and the Purdue Pharma Company (collectively, "Purdue") bring this patent action pursuant to 35 U.S.C. § 271(e)(2), alleging that defendants Endo Pharmaceuticals Inc. and Endo Pharmaceuticals Holdings Inc. (collectively, "Endo") infringed Purdue's patents protecting its product OxyContin -- a controlled release oxycodone analgesic designed to treat moderate to severe pain.

Purdue filed suit against Endo pursuant to the procedures set forth in the Hatch-Waxman Act, codified in the Food and Drug Act at 21 U.S.C. § 355 et seq., and incorporated into the patent statute at 35 U.S.C. § 271(e)(2). The [*3] Hatch-Waxman Act permits an applicant to file an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") requesting approval of a bioequivalent ("generic") version of a drug that is already listed by the FDA as approved for safety and effectiveness without having to submit additional safety and efficacy data. See 21 U.S.C. § 355(j)(2)(A). However, the applicant must certify with respect to any relevant patents for the listed drug that it will either not market its drug prior to the relevant patent's expiration, or that the relevant patents "[are] invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the [ANDA] is submitted." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). If the applicant makes the latter certification, it must notify the holder of the patent, who may then timely sue the applicant for infringement pursuant to 35 U.S.C. § 271(e)(2). See 21 U.S.C. § 355 (j)(2)(B)(i), (j)(5)(B)(iii).

In 2000, Endo filed ANDA No. 75-923, subsequently twice amended in 2001, and correspondingly provided Purdue with notices that [*4] it was seeking FDA approval of various dosage strengths of oxycodone hydrochloride extended-release tablets and that it had certified to the FDA that Purdue's relevant patents either (1) would not be infringed or (2) were invalid. Purdue timely filed suit for patent infringement, alleging that Endo's submission of ANDA No. 75-923 violated claims 1-4 of U.S. Patent No. 5,549,912, claims 1 and 2 of U.S. Patent No. 5,508,042 and claims 1-4 and 6-10 of U.S. Patent No. 5,656,295 (each of these patents is assigned to counterclaim defendant Euroceltique S.A.). Purdue also seeks recovery of attorneys fees pursuant to 35 U.S.C. §§ 271(e) and 285. Endo Pharmaceuticals Inc. has filed counterclaims against Purdue and Euroceltique seeking a declaration that the patents in suit are invalid and unenforceable and that Purdue's misuse of these patents violated federal antitrust laws, as well as injunctive relief and damages. On July 31, 2002, the FDA gave tentative approval to Endo's proposed 10 mg, 20 mg, 40 mg and 80 mg products.

Prior to trial, this Court consolidated the above-captioned actions and bifurcated the trial of defendants' antitrust counterclaims from the trial [*5] on the patent issues. See Order dated May 7, 2002; Order dated December 10, 2002. The patent issues were tried to this Court without a jury over the course of several weeks in June 2003. After consideration of all the evidence, this Court finds that Purdue has proven by a preponderance of the evidence that Endo infringed its patents, but Endo has proven by clear and convincing evidence that the patents are invalid due to Purdue's inequitable conduct before the Patent and Trademark Office (the "PTO") during the prosecution of the patents in suit.

II. Background n1

n1 In a prior action, Purdue sued Roxanne Laboratories, Inc. and its related companies for violating the patents in suit in the present action. See Purdue v. Boehringer Ingelheim GMBH, No. 99 Civ. 3658. This Court granted Purdue's motion for a preliminary injunction barring Boehringer from making, using, or offering to sell "Roxicodone SR," a controlled release oxycodone analgesic product, a result that the Federal Circuit affirmed. See Purdue v. Boehringer, 98 F. Supp. 2d 362, 400 (S.D.N.Y. 2000), aff'd 237 F.3d 1359 (Fed. Cir. 2001).

[*6]

A. The Purdue Patents

1. The Parent Patent: The '331 Patent

Purdue filed Patent No. 5,266,331 (the "'331 patent") on November 27, 1991 and it issued on November 30, 1993. Although Purdue is not asserting any of the '331 patent claims against Endo as a basis for finding infringement, this patent is significant to this litigation in that it is the parent application of the patents in suit - all three patents in suit derived as continuations of the '331 patent. n2 The '331 patent lists Benjamin Oshlack, John J. Minogue and Mark Chasin as the inventors.

n2 "In general, a continuing application [either a continuation, divisional or continuation-in-part application] is one filed during the pendency of another application which contains at least part of the disclosure of another application and names at least one inventor in common with that application ... A "continuation" application claims the same invention claimed in an earlier invention, although there may be some variation in the scope of the subject matter claimed ... the divisional application claims only one or more, but not all, of the independent inventions of the earlier application. A [continuation-in-part] application ... contains a portion or all of the disclosure of an earlier application together with added matter not present in that earlier application." Transco Prods. Inc. v. Performance Contracting, Inc., 38 F.3d 551, 555-56 (Fed. Cir. 1994).

[*7]

2. The '912 Patent

Purdue filed Patent No. 5,549,912 (the "'912 patent") - a continuation-in-part of the '331 patent - on November 25, 1992 and it issued on August 27, 1996. The '912 patent, like the other two patents in suit, list Benjamin Oshlack, John J. Minogue, Mark Chasin and Robert F. Kaiko as the inventors. Claims 1 to 4 of the '912 patent state:

1. 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.

2. A controlled release oxycodone formulation for oral administration to human patients, comprising from about 10 mg to about 160 mg oxycodone or a salt thereof, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about [*8] 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

3. A solid controlled release oral dosage form, comprising (a) oxycodone or a salt thereof in an amount from 10 to about 160 mg; (b) an effective amount of a controlled release matrix selected from the group consisting of hydrophilic polymers, hydrophobic polymers, digestible substituted or unsubstituted hydrocarbons having from about 8 to about 50 carbon atoms, polyalkylene glycols, and mixtures of any of the foregoing; and (c) a suitable amount of a suitable pharmaceutical diluent, wherein said composition provides a mean maximum plasma concentration of oxycodone from about 6 to about 240 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 120 ng/ml from a mean of about 10 to about 14 hours after re-

peated administration every 12 hours through steady-state conditions.

4. The controlled release composition of claim 3, wherein said controlled release matrix comprises an acrylic [*9] resin.

3. The '042 Patent

Patent No. 5,508,042 (the "'042 patent") - a divisional of the '912 patent - was filed on June 6, 1995 and issued April 16, 1996. Claims 1 and 2 of the '042 patent mirror claims 1 and 2 of the '912 patent, and read as follows:

1. 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-conditions.

2. A method for reducing the range in daily dosages required to control pain in substantially all human patients, comprising administering an oral solid controlled release dosage formulation comprising from about 10 mg to about 160 mg oxycodone or a salt thereof which provides a mean maximum plasma concentration of oxycodone up to about 240 [*10] ng/ml from a mean of up to about 2 to about 4.5 hours afer administration, and a mean minimum plasma concentration up to about 120 ng/ml from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions.

4. The '295 Patent

Patent No. 5,656,295 (the "'295 patent") - a continuation in part of the '912 patent - was filed on March 19, 1996 and issued August 12, 1997. Claims 1 to 4 and 6 to 10 read as follows:

1. A controlled release oxycodone formulation for oral administration to human patients, comprising from about 10 mg to about 160 mg oxycodone, based on the hydrochloride salt, said formulation providing a mean maximum plasma concentration of oxycodone from about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration and a mean minimum plasma concentration of oxycodone from about 3 to about 120 ng/ml from about 10 to about 14 hours after administration every 12 hours after repeated dosing through steady state conditions, wherein said formulation provides pain relief in said patient for at least 12 hours after administration.

2. The controlled release oxycodone formulation of [*11] claim 1, comprising from about 10 to about 40 mg oxycodone based on the hydrochloride salt, 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.

3. The controlled release oxycodone formulation of claim 1, comprising from about 40 mg to about 160 mg oxycodone based on the hydrochloride salt, said formulation providing a mean maximum plasma concentration of oxycodone from about 60 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration.

4. The solid controlled release oxycodone formulation of claim I, comprising oxycodone hydrochloride dispersed in an effective amount of a controlled release matrix selected from the group consisting of hydrophilic polymers, hydrophobic polymers, digestible substituted or unsubstituted hydrocarbons having from about 8 to about 50 carbon atoms, polyalkylene glycols, and mixtures of any of the foregoing, and a suitable amount of a suitable pharmaceutical diluent.

6. The controlled release oxycodone formulation of claim 1, comprising a tablet wherein said oxycodone is dispersed in a controlled release [*12] matrix.

7. The controlled release oxycodone formulation of claim 1, wherein said oxycodone is in the form of the hydrochloride salt.

8. A method for substantially reducing the range in daily dosages required to control pain in human patients, comprising administering to a human patient an oral controlled release dosage formulation comprising from about 10 to about 160 mg oxycodone or a salt thereof based on the hydrochloride salt which provides a mean maximum plasma concentration of oxycodone form (sic) about 6 to about 240 ng/ml from a mean of about 2 to about 4.5 hours after administration and a mean minimum plasma concentration of oxycodone from about 3 to about 120 ng/ml from about 10 to about 14 hours after administration every 12 hours after repeated dosing through steady state conditions, wherein said formulation provides pain relief in said patient for at least 12 hours after administration.

9. A method for substantially reducing the range in daily dosages required to control pain in substantially all human patients, comprising administering to a human patient an oral solid controlled release dosage formulation comprising from about 10 mg to about 40 mg oxycodone [*13] or a salt thereof based on the hydrochloride salt which provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of up to about 2 to about 4.5 hours after administration and a mean minimum plasma concentration of oxycodone from about 3 to about 30 ng/ml from about 10 to about 14 hours after administration every 12 hours after repeated dosing through steady state conditions, wherein said formulation provides pain relief in said patient for at least 12 hours after administration.

10. A method for substantially reducing the range in daily dosages required to control pain in substantially all human patients, comprising administering to a human patient an oral solid controlled release dosage formulation comprising from about 40 mg to about 160 mg oxycodone or a salt thereof based on the hydrochloride salt which provides a mean maximum plasma concentration of oxycodone from about 60 to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration and a mean minimum plasma concentration of oxycodone from about 30 to about 120 ng/ml from about 10 to about 14 hours after administration after repeated dosing every 12 hours [*14] through steady state conditions, wherein said formulations provides pain relief in said patient for at least 12 hours after administration.

B. Terminology

Drugs known as opioid analgesics include morphine, hydromorphone, and oxycodone - the active ingredient in OxyContin - and are generally used to treat moderate to severe pain. "Pharmacokinetics" refers to the blood plasma concentration of a drug in the body over time. Tr. 86. n3 The pharmacokinetic symbols used in this opinion are as follows: "C" is a shorthand for concentration, "T" for time, "max" for maximum and "min" for minimum. Therefore, "C[max]" is the mean peak blood plasma concentration exhibited by the claimed oxycodone formulations, "T[max]" is the time that C[max] occurs, "C[min]" is the mean minimum blood plasma concentration and "T[min]" is the time that C[min] occurs. A drug formulation is a combination of a biologically active ingredient and excipients - pharmacologically inert ingredients that are not active in the body. Tr. 465-66. Drug formulations are tested through both "in vitro" and "in vivo" testing. In vitro testing examines the rate a drug tablet dissolves in special laboratory apparatuses. [*15] Tr. 470-71. In vivo testing is testing of the drug in humans. Titration is the method by which dosages are adjusted in order to provide acceptable pain control without unacceptable side effects. Tr. 99, 169, 1233. "Steady state" refers to the repeated dosing of a drug until it reaches a stable level of absorption and elimination such that the amount of drug in the body is constant. Tr. 1249. Bioequivalence means that the "rate and extent of absorption of the [generic] drug does not show a significant difference from the rate and extent of absorption" of the reference drug. 21 U.S.C. § 355(j)(8)(B)(i). "Bioavailability" refers to the degree to which a drug is absorbed in the body, for example, "high oral bioavailability" mean that a large portion of an orally administered dosage is absorbed in the bloodstream. Tr. 95-6.

n3 "Tr. _" refers to the relevant page of the transcript of the trial of this action; "PTX " refers to plaintiffs' relevant exhibit; "DX _" refers to defendants' relevant exhibit.

[*16]

III. Discussion

A. Infringement

Determining patent infringement in an ANDA action is no different from determining patent infringement in a non-ANDA action, although the statute requires an infringement inquiry focused on what is likely to be sold following FDA approval, since the allegedly infringing product is not being sold commercially. See Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1568 (Fed. Cir. 1997). Purdue bears the burden of proving infringement by a preponderance of the evidence. See Advanced Cardiovascular Sys. Inc. v. Scimed Life Sys. Inc., 261 F.3d 1329, 1336 (Fed. Cir. 2001). "A two-step process is used in the analysis of patent infringement: first, the scope of the claims are determined as a matter of law, and second, the properly construed claims are compared to the allegedly infringing device to determine, as a matter of fact, whether all of the limitations of at least one claim are present, either literally or by a substantial equivalent, in the accused device." Teleflex, Inc. v. Ficosa North America Corp., 299 F.3d 1313, 1323 (Fed. Cir. 2002) (citations omitted); see also Merck & Co. v. Teva Pharms. USA, Inc., 347 F.3d 1367, 1369 (Fed. Cir. 2003). [*17]

1. Claim Construction

"It is the claims that measure the invention." Amgen Inc. v. Hoechst Marion Roussel, Inc., 314 F.3d 1313, 1325 (Fed. Cir. 2003) (quoting SRI Int'l v. Matsushita Elec. Corp., 775 F.2d 1107, 1121 (Fed. Cir. 1985) (en banc)). The first step in claim construction is to determine the ordinary and customary meaning, if any, that would be attributed to the term by those skilled in the art. See Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp., 320 F.3d 1339, 1347 (Fed. Cir. 2003). Neither party contests that one skilled in the art would be an individual with some education in biology or chemistry, or with a pharmaceutical background, with some experience with controlled-release formulations. Tr. 1207-08, 1469. "In the absence of an express intent to impart a novel meaning to claim terms, an inventor's claim terms take on their ordinary meaning." Teleflex, 299 F.3d at 1325-26 (citation omitted). There is a "heavy presumption" that the terms used in the claim carry their ordinary and customary meaning. CCS Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002). [*18]

The specification is also "highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term." Teleflex, 299 F.3d at 1325 (citing Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "One purpose for examining the specification is to determine if the patentee has limited the scope of the claims." Watts v. XL Sys, 232 F.3d 877, 882 (Fed. Cir. 2000). The prosecution history may also "demonstrate that the patentee intended to deviate from a term's ordinary and accustomed meaning, i.e., if it shows the applicant characterized the invention using words or expressions of manifest exclusion or restriction during the administrative proceedings before the Patent and Trademark Office." Teleflex, 299 F.3d at 1326.

If the meaning of a term is unclear from the claims, specification and prosecution history, a court may rely on extrinsic evidence such as expert or inventor testimony, dictionaries and learned treatises. See Key Pharms. v. Hercon Lab. Corp., 161 F.3d 709, 716 (Fed. Cir. 1998) (citing Markman v. Westview Instruments, Inc., 52 F.3d 967, 980 (Fed. Cir. 1995)). [*19] Extrinsic evidence "cannot change the meaning of a term as used in the claim from the meaning with which it is used in the specification. However, it is not prohibited to provide the opinions and advice of experts to explain the meaning of terms as they are used in patents and as they would be perceived and understood in the field of an invention." Merck, 347 F.3d at 1372 (citing Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1332 (Fed. Cir. 2003); Pitney Bowes, Inc. v. Hewlett-Packard Co., 182 F.3d 1298, 1309 (Fed. Cir. 1999)). Additionally, the testimony of the inventors against their own interest is relevant and persuasive to inform the court's claim construction. See Evans Med. Ltd. v. American Cyamid Co., 11 F. Supp. 2d 338, 350 (S.D.N.Y. 1998), aff'd, 215 F.3d 1347 (Fed. Cir. 1999).

Since the '042 patent is a divisional of, and the '295 patent is a continuation-in-part of, the '912 patent, which is itself a continuation-in-part of the '331 patent, and the patents in suit have identical disclosures, claim limitations may also be derived from the prosecution history of the '331 patent. See Omega, 334 F.3d at 1333; [*20] Advanced Cardiovascular Systems, Inc. v. Medtronic, Inc., 265 F.3d 1294, 1305 (Fed. Cir. 2001) ("the prosecution history of a related patent can be relevant if, for example, it addresses a limitation in common with the patent in suit"); Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999) ("when multiple patents derive from the same initial application, the prosecution history

regarding a claim limitation in any patent that has issued applies with equal force to subsequently issued patents that contain the same claim limitation"); Jonsson v. Stanley Works, 903 F.2d 812, 818 (Fed. Cir. 1990) (prosecution of parent application is relevant to understanding scope of claims issuing in a continuation-in-part application).

a. C[min]

The first claim construction dispute centers around the method for calculating C[min], the mean minimum plasma concentration. Endo contends that C[min] would be calculated by those skilled in the art by taking each patient's minimum concentration, at whatever time it was reached, totaling up those numbers for all patients, and dividing by the number of patients. Purdue, on the other [*21] hand, contends that the claims should not be limited to a particular method for measuring C[min]. It argues that C[min] could be measured as Endo contends, or it could be measured at C,[2], the end of a dosing interval during steady state for a 12-hour formulation, or C[min] could also be properly measured as the average of the plasma levels at T[0] and T[I2].

In resolving this dispute, this Court turns first to the language of the claims themselves. The '912, '042 and '295 patents claim a mean minimum plasma concentration up to 120 ng/ml "from a mean of about 10 to about 14 hours after repeated administration every 12 hours through steady-state conditions." '912 patent, claims 1-3; '042 patent, claims 1-2; '295 patent, claims 1, 8-10. This language does not provide a method for calculating C[min], although it does state in ordinary language that the range for C[min] occurs between 10 and 14 hours after achieving steady-state conditions.

Because the claim language does not provide a method for calculating C[min], we next look to the specifications in the patents in suit. Purdue contends that Example 18 of the '912 patent computed C[min] by taking the average of [*22] the plasma levels at T[0] and T[I2], which, at steady state, represent the end of two dosing intervals for a 12-hour drug formulation. However, no method for calculating C[min] is provided in Example 18 of the '912 patent, or in any other part of the specifications for the '912, '295 or '042 patents. Therefore, the specifications fail to shed light as to how to calculate C[min]. The prosecution histories are similarly devoid of any indication of how to calculate C[min].

Since neither the claim language nor the specifications nor the prosecution histories provide guidance on how to calculate C[min], this Court looks to extrinsic evidence to determine how those of ordinary skill in the art would have calculated C[min] at the time the patents were filed. See Key Pharm., 161 F.3d at 716. Endo's claim construction expert, Dr. Sanford Bolton, testified that the mean minimum plasma concentration is calculated by looking over "a dosing interval at steady state and look at the various concentrations at the blood sampling times, and for each patient or subject in the study obtain a minimum value, and then average those minimum values." Tr. 1469. Dr. Donald Stanski, [*23] Purdue's claim construction expert, and Dr. Paul D. Goldenheim, Purdue's executive vice president of research and development and chief scientific officer, both testified that C[min] could be calculated at C[12], the end of a dosing interval for a 12-hour formulation at steady state, or the average of C[0] and C[12] - both of which occur immediately before dosing at steady state. Tr. 652; Tr. 976-77. Dr. Robert F. Kaiko, a named inventor of all of the patents in suit, testified that he calculated C[min] in the same manner suggested by Dr. Bolton, namely by adding the "lowest oxycodone concentration" of each of the subjects of the study divided by the number of subjects in the study. Tr. 216. However, Dr. Kaiko utilized a different method for calculating C[min] in a 1996 published paper he coauthored which defined C[min] as the "average of the 0- and 12-hour plasma oxycodone concentrations." PTX 563, P645913.

Additionally, the FDA's July 1992 guidelines, applicable in November 1992 when Purdue filed the '912 patent, states that C[min] defined as "the drug concentrations at the end of each dosing interval during steady state." PTX 916. Consequently, pursuant to the FDA [*24] guidelines, C[min] would be C[12] for a 12-hour formulation.

This Court finds Purdue's argument persuasive. A review of the patents' claims, specifications and prosecution histories reveals only that C[min] is measured between 10 and 14 hours after achieving steady state conditions. There is no indication from the intrinsic evidence as to how C[min] should be measured. The extrinsic evidence presented by the parties indicates that one of ordinary skill in the art could use several different methods to calculate C[min] when the patents were filed. Since measurement of C[12] occurs 12 hours after dosing, and the claimed mean minimum plasma concentration is measured between the range of 10 to 14 hours, C[12] (and correspondingly T[12]) falls within the range of 10 to 14 hours - therefore, the claims do not exclude using C[I2] as C[min]. Measuring C[min] as the average of C[0] and C[12] for a 12-hour formulation also falls within the claimed range since C[0] is at the end of a dosing interval during steady state and C[12] is the end of the subsequent dosing interval. Accordingly, this Court will not "import into the claims limitations that were unintended [*25] by the patentee." Amgen, 314 F.3d at 1325; LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc., 275 F.3d 1347, 1353-56 (Fed. Cir. 2001).

One skilled in the art would not limit measurements of C[min] to the sole method proposed by Endo.

b. Controlled release

The second claim construction dispute centers around the meaning of the term "controlled release." Endo contends that "controlled release" should be construed to require reduced dosage range and easier titration. Purdue contends that "controlled release" means that the dosage form is designed so that the active ingredient - oxycodone - releases in a controlled manner over an extended period of time, in contrast to "immediate release" where the release rate of the active ingredient is not controlled.

Looking to the claim language itself, the term "controlled release" oxycodone formulation is used in Claims 1 and 2 of the'912, '042 and '295 patents to describe formulations that result in a mean maximum plasma concentration between 2 and 4.5 hours after administration and a mean minimum plasma concentration from 10 to 14 hours after repeated administration every 12 hours through steady-state [*26] conditions. See also the '295 Patent, Claims 3, 8-10. None of the bodies of the claims disclose a reduced dosage range or easier titration. Accordingly, as inferred from how the term is used in the claims, the ordinary meaning of "controlled release" is consistent with Purdue's interpretation - that is, "controlled release" is the release of oxycodone in a controlled manner over an extended period of time.

The preamble to Claim 8 of the '295 Patent reads, "[a] method for substantially reducing the range in daily dosages required to control pain in human patients, comprising ..." and the preambles to the '042 patent claims both read, "[a] method for reducing the range in daily dosages required to control pain in human patients, comprising ...." However, Endo does not contend that the preambles should be read as imposing limitations on either the claims generally or on the specific term "controlled release." Accordingly, this Court shall not revisit its earlier finding in Purdue v. Boehringer - made in the context of granting a preliminary injunction - that the preambles in the patents in suit do not state independent limitations of the claimed inventions. See Boehringer, 98 F. Supp. 2d at 377. [*27] Some of the claims do set forth a range of dosages, see, e.g., Claim 1 of the '912 patent, which states "[a] controlled release oxycodone formulation for oral administration to human patients, comprising from about 10 to about 40 mg oxycodone or a salt thereof," but this language merely states a dosage range, not a reduced dosage range. Therefore, according to the customary and ordinary language of the claims, "controlled release" does not require reduced dosage ranges or ease of titration limitations.

Turning to the specifications of the patents in suit, the term "controlled release" is used consistent to how it is used in the claims - specifically, "controlled release" is described as the release of oxycodone in a controlled manner over an extended period of time. For example, Examples 1-4 of each of the patents in suit describe "controlled release" tablets in the context of the dissolution rates of oxycodone over an extended period of time. See the '912, '295 and '042 Patents, Tables 2, 4, 6 and 8. Similarly, Figure 5 of the patents in suit charts the plasma concentration over "time from last dose" and is described as a graph "showing the mean plasma concentration for [*28] a 10 mg controlled release oxycodone formulation ...." '912 and '295 Patents, Cols. 3:27-30; '042 Patent, 3:31-34.

However, as this Court previously noted in Boehringer, the specifications also "repeatedly refer to a reduction in the range of daily dosages." 98 F. Supp. 2d at 377. For example, the section of the specifications entitled "Detailed Description" opens with the following passage,"it has now been surprisingly discovered that the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold (10 to 40 mg every 12 hours - around-the-clock-dosing) in approximately 90% of patients for opioid analgesics in general." '912 patent, 3:34-41; '042 Patent, 3:38-45; '295 Patent, 3:34-41. See also '912 Patent, 3:67 to 4:8, 1:10-45; '042 Patent, 2:16-20, 3:5-22; '295 Patent, 2:3-17, 3:1-18. The specifications also state that "the use of from about 10 mg to about 40 mg of 12-hourly doses of controlled-release oxycodone to control pain in approximately 90% of patients ... is an example of the unique characteristics of the present invention." '912 Patent, 3:42-46; '042 Patent, 3:46-51; '295 [*29] Patent, 3:42-47. Further on, the specifications state that,

> 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 sever 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.

'912 Patent, 4:51-57; '042 Patent, 4:53-60; '295 Patent, 4:51-58.

When read in their entirety, the specifications of the patents in suit indicate that the invention itself - the controlled release oxycodone formulation - may be limited to a four-fold dosage range that controls pain for 90% of patients, but it does not indicate that the specific term "controlled release" by itself should be construed to require reduced dosage and ease of titration, especially when the customary and ordinary meaning of the term clearly does not include or even suggest these limitations.

Finally, we turn to the prosecution history of the patents in suit to ascertain whether that history is [*30] consistent with our interpretation of the disputed claim language. Endo contends that Purdue successfully convinced the PTO that the reduced dosage range and easier titration features distinguished the patent claims from the prior art, and therefore cannot now disavow construing the term "controlled release" as requiring reduced dosage range and ease of titration. Purdue contends that the references in the prosecution histories to reduced dosage range and ease of titration relate to benefits of the inventions rather than to claim limitations.

"An inventor may use the specification and prosecution history to define what his invention is and what it is not - particularly when distinguishing the invention over prior art. 'Just as prosecution history estoppel may act to estop an equivalence argument under the doctrine of equivalents, positions taken before the PTO may bar an inconsistent position on claim construction under § 112, P 6.'" See Ballard Med. Prods. v. Allegiance Healthcare Corp., 268 F.3d 1352, 1359 (Fed. Cir. 2001) (quoting Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1457 (Fed. Cir. 1998)). "That explicit arguments made during prosecution [*31] to overcome prior art can lead to narrow claim interpretations makes sense, because 'the public has a right to rely on such definitive statements made during prosecution.'" Spectrum Int'l, Inc. v. Sterilite Corp., 164 F.3d 1372, 1378-79 (Fed. Cir. 1998) (quoting Digital Biometrics v. Identix, Inc., 149 F.3d 1335, 1347 (Fed. Cir. 1998)). "Prosecution history may limit claim scope if the patentee disclaimed or disavowed a particular interpretation of the claims during prosecution. This principle does not, however, mean that any words appearing in the prosecution history but not in the issued claims are forever banished. The prosecution history inquiry asks not what words the patentee discarded, but what subject matter the patentee relinquished or disclaimed." Abbott Labs. v. TorPharm, Inc., 300 F.3d 1367, 1372 (Fed. Cir. 2002); Schumer v. Lab. Computer Sys., Inc., 308 F.3d 1304, 1313 (Fed. Cir. 2002) ("the prosecution history limits even clear claim language so as to exclude any interpretation surrendered during prosecution, but only where the accused infringer can demonstrate that the patentee surrendered that interpretation [*32] with reasonable clarity and deliberateness"). Accordingly, at issue is whether or not Purdue clearly and deliberately disclaimed or surrendered controlled release oxycodone formulations that do not reduce the dosage range and ease titration such that the term "controlled release" must be construed to require reduced dosage range and ease of titration.

In addition, the Federal Circuit has repeatedly emphasized that claim language is to be interpreted in light of the "fundamental purpose and significance" of the invention, Minnesota Mining & Mfg. Co. v. Johnson & Johnson Orthopaedics, Inc., 976 F.2d 1559, 1566-67 (Fed. Cir. 1992) and in a manner "consistent with and further[ing] the purpose of the invention," CVI/Beta Ventures. Inc. v. Tura LP, 112 F.3d 1146, 1160 (Fed. Cir. 1997), cert. denied, 522 U.S. 1109, 118 S. Ct. 1039, 140 L. Ed. 2d 105 (1998). n4 Courts must review the entire prosecution history in construing claims. See Eagle Comtronics, Inc. v. Arrow Commun. Labs., Inc., 305 F.3d 1303, 1315 (Fed. Cir. 2002).

n4 Purdue cites to several Federal Circuit cases for the supposedly contrary proposition that it is error for this Court to consider the disputed issues in a lawsuit based on the differences between the claimed invention and the prior art. See Jones v. Hardy, 727 F.2d 1524, 1528 (Fed. Cir. 1984) ("in determining the obvious/nonobviousness issue, it is improper (even if erroneously suggested by a party) to consider the difference [between the invention and the art] as the invention"); Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1383 (Fed. Cir. 1986); Hodosh v. Block Drug Co., 786 F.2d 1136, 1143 n.5 (Fed. Cir. 1986). See also Para-Ordnance Mfg., Inc. v. SGS Importers Int'l Inc., 73 F.3d 1085, 1087 (Fed. Cir. 1995) (stating, in the context of an obviousness analysis, that "there is no legally recognizable 'heart' of the invention") (citing W.L. Gore & Asoc., Inc. v. Garlock, Inc., 721 F.2d 1540, (Fed. Cir. 1983), cert, denied 469 U.S. 851, 83 L. Ed. 2d 107 (1984)). However, these cases only state that, for purposes of a 35 U.S.C. § 103 obviousness analysis, it is inappropriate for a court to consider the difference between the invention and prior art as the invention itself - here, this Court is construing claims and, accordingly, must consider assertions Purdue made before the PTO to distinguish its invention from prior art. See, e.g., Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc., 222 F.3d 951, 956 (Fed. Cir. 2000).

[*33]

After reviewing the prosecution history of the '331 parent patent and the patents in suit, this Court finds that Purdue surrendered, with deliberateness and clarity, controlled release oxycodone formulations that do not control pain over an approximately four-fold dosage range for approximately 90% of patients; in other words, we conclude that reduced dosage range is a claim limitation. The PTO initially rejected the '331 patent claims pursuant to 35 U.S.C. § 103 because "it would have been obvious to one of ordinary skill in the art to use oxycodone" in place of the hydromorphone in the 4,990,341 patent (the "'341 patent") in view of the 4,861,598 patent (the "'598 patent"). DX 2008, EN205614, EN205615. In Purdue's response to the PTO's rejection, Purdue distinguished the '331 invention by stating that (1) prior art controlled release opioid analgesics had a wide range of dosages that "makes the titration process particularly time consuming and resource consuming," (2) but "it has now been surprisingly discovered" that the oxycodone formulation of the '331 patent "acceptably controls pain over a substantially narrower, approximately four fold (10 to 40 mg every [*34] 12 hours - around-the-clock dosing) in approximately 90% of patients," (3) "the opioid analgesic titration process" of the '331 invention is "substantially reduced through the efficiency of the controlled release oxycodone formulations of the present invention," and (4) that

> it is respectfully submitted that one skilled in the art *having knowledge of the controlled release oxycodone formulations of Goldie, et al.* [the '341 patent] would not be motivated to prepare controlled release oxycodone formulations in a dosage range from about 10 mg to about 40 mg, which formulations thereby acceptably control pain over a substantially narrower, approximately four-fold range in approximately 90% of patients. This is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients utilizing controlled release hydromorphone, or controlled release opioid analgesics in general. One skilled in the art would certainly not arrive at this surprising result without the benefit of hindsight.

DX 2008, EN205621 dated October 22, 1992 - entitled "The Results Obtained by the Present Invention are Not Obvious From the Prior Art" (italics added). [*35]

In other words, Purdue admitted to the PTO that the cited prior art would teach a controlled release oxycodone formulation, but the particular controlled release oxycodone formulation of the '331 invention would, in contrast to other controlled release opioid drugs -and in contrast to the controlled release oxycodone formulations of the cited prior art - control pain over a four-fold dosage range for most patients. Purdue distinguished the claimed '331 invention over the prior art by setting forth what the invention did not cover - specifically, controlled release oxycodone formulations that did not control pain over a four-fold dosage range for most patients.

After the relevant claims of the '331 patent were again rejected for obviousness, the PTO scheduled an interview with Purdue after which the examiner noted that they "discussed nature of dissolution rate with regard to prior art. Applicant will submit proposed declaration supporting unobviousness and unexpected results. Terminal disclaimer will be filed. Favorable consideration will be given for the proposals discussed regarding allowability." PTX 2008, EN205626. Purdue subsequently submitted a proposed declaration prefaced [*36] with a remarks section written by Harold Steinberg, Purdue's outside patent prosecuting attorney for the '331 patent, who wrote that "as was pointed out to the Examiner at the conference, it is totally impossible to predict what dissolution rates for any particular drug will give rise to an extended duration of action." DX 2008, EN205630. In the declaration, Dr. Kaiko stated that one skilled in the art with knowledge of the controlled release hydromorphone formulation as set forth in the '341 patent could not 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." PTX 2008, EN205635. With respect to the '598 patent, Dr. Kaiko stated that one skilled in the art with knowledge of the "teaching of a controlled-release matrix formulation of oxycodone with accompanying in vitro dissolution data" in the '598 patent could not predict "the T[max] and the duration of effect which would be achieved with such a formulation in vivo." Id. Therefore, one skilled in the art could not combine the '341 patent and the '598 patent to make the '331 invention. Id. at EN205637. Dr. Kaiko [*37] also attached an exhibit to the declaration that, under the title "INVENTION," stated that

> [the invention] acceptably controls pain over a substantially narrower, approximately four-fold (10 to 40 mg q 12h 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 ... Regardless of the fact that both con-

> trolled-release oxycodone and control release morphine administered q12h around-the-clock possess qualitatively comparable clinical pharmacokinetic characteristics, [the invention] can be used over approximately 1/2 the dosage range as MS Contin [a morphine-based opioid drug for pain relief also manufactured by Purdue] to control 90% of patients with significant pain.

Id. at EN205639-41.

In sum, Purdue responded to the PTO's initial rejection by distinguishing the '331 invention from prior art by noting its particular analgesic effect over a four-fold dosage range, and after another rejection, subsequently distinguished it again by stating that (1) one skilled in the art could not simply replace hydromorphone with oxycodone, [*38] (2) that in vitro controlled release oxycodone formulation data did not provide a predictable correlation to in vivo data and (3) repeated the distinction raised in response to the earlier rejection, namely that the invention -in contrast to prior art - acceptably controlled pain over a four-fold dosage range for most patients.

With respect to the '912 patent, the PTO rejected certain claims pursuant to 28 U.S.C. § 102(b) as being anticipated by the '341 patent because the '341 patent "teaches opioid analgesics with the claimed rate of release." DX 2033, P 000170. Purdue responded to the rejection with an "Amendment" that stated, in a section titled "The Invention," that

> Applicants have surprisingly found that even in the case of controlled-release opioid formulations having a similar in-vitro release profile, a much wider range of dosage of drug must be administered to the patient in order to achieve a satisfactory analgesic response over the requisite period of time. This is set forth, e.g., in the Specification at page 6, line 30, through page 7, line 3.

DX 2033, P 000177-78 - Amendment, dated February 22, 1995 (the "Amendment").

The referenced [*39] portion of the specification states, in part, that "the oxycodone formulations of the presently claimed invention can be used over approximately 1/2 the dosage range as compared with commercially available controlled release morphine formulations [previously set forth in the specification as an eight-fold range] to control 90% of patients with significant pain." DX 2033, P 000106-107. In the following section of the Amendment, titled "The Rejection under 35 U.S.C. § 102(b)," Purdue continued to respond to the patent examiner's rejection by stating that one of ordinary skill in the art could not have predicted from the disclosure of the '341 patent concerning hydromorphone formulations that oxycodone - a different opioid - would have the particular plasma concentration profile set forth in the '912 patent, and that "in view of the '341 patent's lack of disclosure concerning oxycodone and further in view of the lack of predictability among opioid analgesics, it is respectfully requested that the Examiner reconsider and remove the rejection under 35 U.S.C. § 102(b)." See DX 2033, P 000178, P 000181.

With respect to the '042 patent, [*40] the patent examiner initially rejected the claims pursuant to 35 U.S.C. § 112 due, in part, to deficiencies in the specification. DX 2009, EN205729-30. After an interview between Purdue and the examiner, Purdue deleted the term "substantially" from the claims "to bring into condition for allowance." Id. at EN205733. Subsequently, the PTO issued a Statement of Reasons for Allowance for the '042 patent claims that stated that "none of the references of record singly anticipate or in combination motivate one with ordinary skill in the art to formulate the particular method for reducing the dosage of oxycodone as set forth in the claims." DX 2009, EN 205735. As explicitly and definitively stated by the examiner, the '042 patent claims were allowed because the invention - in contrast to prior art -set forth a method for reducing dosage ranges for oxycodone. n5

> n5 Neither party cites to the patent prosecution history of the '295 in support of their respective claim construction contentions.

[*41]

Reviewing the prosecution history of the '331, '912 and '042 patents, this Court finds that Purdue clearly and deliberately distinguished the claimed invention over the prior art by "indicating what the claims do not cover" - specifically, controlled release oxycodone formulations that do not control pain over a four-fold dosage range for most patients. See Spectrum, 164 F.3d at 1378-79 ("by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover") (quoting Ekchian v. Home Depot, Inc., 104 F.3d 1299,1304 (Fed. Cir. 1997)); Hockerson-Halberstadt, 222 F.3d at 956 ("The inventor then distinguished the prior art by arguing that the claimed invention "provides a much narrower groove for a totally different purpose ... Flowing from this statement is the inventor's clear disavowal of footwear having a groove width greater than

that disclosed in the prior art"); Lemelson v. General Mills, Inc., 968 F.2d 1202, 1206 (Fed. Cir. 1992) ("Prosecution history is especially important when the invention involves a crowded art field, or when there is particular prior art that [*42] the applicant is trying to distinguish.").

During the prosecution history of both the '331 and '912 patents, Purdue distinguished the invention on additional grounds other than just reduced dosage range. However, that Purdue set forth alternative grounds for the PTO to admit the claims does not mean that it disclaimed its earlier explicit distinction of the invention from prior art based on its reduced dosage range, especially given that it continued to assert the reduced dosage range as a reason for allowing the claims. See Hockerson-Halberstadt, 222 F.3d at 957 (citing Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979 (Fed. Cir. 1999) ("it is the totality of the prosecution history that must be assessed, not the individual segments of the presentation made to the Patent and Trademark Office by the applicant"); Ekchian, 104 F.3d at 1303-04 (absent an indication by the examiner to the contrary, an examiner will consider all parts of the prosecution history); Standard Oil Co. v. American Cyanamid Co., 774 F.2d 448, 452 (Fed. Cir. 1985).

As well, that the PTO rejected Purdue's initial attempt to distinguish the '331 [*43] invention on the basis of reduced dosage range does not render the distinction invalid or irrelevant. See Springs Window Fashions LP v. Novo Indus., L.P., 323 F.3d 989, 996 (Fed. Cir. 2003) (citing Laitram Corp. v. Morehouse Indus., Inc., 143 F.3d 1456, 1462 (Fed. Cir. 1998) ("The fact that an examiner placed no reliance on an applicant's statement distinguishing prior art does not mean that the statement is inconsequential for purposes of claim construction."). This Court will not "erase from the prosecution history" Purdue's clear and deliberate disavowal of controlled release oxycodone formulations that do not control pain over an approximately four-fold dosage range for approximately 90% of patients. Hockerson-Halberstadt, 222 F.3d at 957 ("Such an argument is inimical to the public notice function provided by the prosecution history. The prosecution history constitutes a public record of the patentee's representations concerning the scope and meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct.").

Accordingly, this Court finds that Purdue deliberately [*44] and clearly relinquished, disclaimed and surrendered controlled release oxycodone formulations that do not control pain relief in approximately 90% of patients with an approximately four-fold dosage range. See Ballard, 268 F.3d at 1359. However, Purdue's contention to the PTO that the patents eased titration - which, as discussed previously, is the method by which dosages are adjusted in order to provide acceptable pain control without unacceptable side effects - is not a claim limitation. Any ease of titration is due, in part, to the reduced dosage range and is a benefit of the invention rather than a structural feature of the claims.

Moreover, it would be a rather strained claim construction that would result in construing the term "controlled release" with a plain and ordinary meaning - the release of an active ingredient in a controlled manner over an extended period of time - to require reduced dosage range and ease of titration. It is the invention itself, the "controlled release oxycodone formulation," that Purdue claims will control pain relief in approximately 90% of patients with an approximately four-fold dosage range. Accordingly, this Court will construe [*45] the terms "controlled release oxycodone formulation" and "controlled release dosage formulation" to require controlling pain relief in 90% of patients with a four-fold dosage range.

As it is clear from the intrinsic evidence that Purdue deliberately and with clarity limited the scope of its invention, this Court will not address the generally unpersuasive extrinsic evidence both parties have presented in support of their respective claim constructions of the term "controlled release." n6

> n6 In Boehringer, this Court found, in the context of determining whether to grant a motion for a preliminary injunction, that the preambles to the '042 and '295 claims that refer to a reduction in the range of daily dosages were "not structural feature[s] of the administration of the oxycodone formulations set forth but rather simply [] a benefit of the administration of those formulations." Boehringer, 98 F. Supp. 2d at 377. Not only was this conclusion made, as noted, in the context of a preliminary injunction hearing, but also without analysis of the patent prosecution histories. Here, unlike in Boehringer, the Court is able to "construe the asserted claims based upon a final and complete record in the case." CVI/Beta Ventures, Inc. v. Tura LP, 112 F.3d 1146, 1160 (Fed. Cir. 1997).

[*46]

c. OxyContin controls pain relief in approximately 90% of patients over an approximate four-fold dosage range

Purdue contends that, if the Court were to construe the patent claims as requiring proof of a reduction in the range of doses, it has done so, based on (1) the testimony of Dr. Richard Payne, an attending neurologist and chief

of the pain and palliative care practice at Memorial Sloan-Kettering Cancer Center, as well as President of the American Pain Society, an organization dedicated to the research and treatment of pain, and (2) OxyContin usage data as reported by the IMS National Disease and Therapeutic Index ("NDTI") and analyzed by Dr. Stanski. Endo contends that OxyContin does not control pain relief in approximately 90% of patients over an approximate four-fold dosage range, based in part on the opinion of its own expert doctor, Dr. Barbara Coda, a practicing anesthesiologist. Endo also challenges the veracity of the NDTI survey and questions whether Dr. Stanski is an expert in the field of pharmacology such that he can assert an opinion with respect to the NDTI data.

With respect to the battling testifying experts, Dr. Payne and Dr. Coda, this Court finds that [*47] their testimony, and the related expert reports submitted by both parties, do not establish whether or not OxyContin controls pain for most patients over a four-fold dosage range. Dr. Payne testified that, based on his clinical experience, "I and most doctors are able to get the patient to a dose of OxyContin that will control their pain that ends up to be over a much narrower range of doses than would be the case with MS Contin." Tr. 99. In contrast, Dr. Coda, who admitted that she does not have "much of a pain practice" and, in contrast to Dr. Payne, has not prescribed opioids in the past three years since joining a clinical anesthesia practice, Tr. 1268, 1269, testified that a doctor's "clinical impression" is not a substitute for "scientific evidence." Tr. 1239. Dr. Coda also testified that several of 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. Tr. 1252, 1260. However, neither study treated patients with a 10 mg dose, twice daily, which is within the invention's claimed dosage range of 10 - 40 mg, DX 2844, DX 4145; accordingly, it is not clear to the Court [*48] what dosage range conclusions can be drawn from these studies. Each testifying expert also submitted expert reports supporting his or her opinions, as did several other experts from both sides. This Court finds that Dr. Payne's testimony is more persuasive than Dr. Coda's, but the only conclusion that can be reasonably drawn from this finding is that OxyContin controls pain over a narrower dosage range than MS Contin, but not that it controls pain over an approximately four-fold dosage range for 90% of patients.

This Court finds the NDTI data more insightful in supporting the patents' claims. Prior to trial, Endo filed a motion to exclude testimony from Dr. Stanski and Dr. Payne as related to the NDTI data because, among other reasons, the data was allegedly unreliable. This Court denied that motion, noting that Endo's argument was more relevant to a jury case as opposed to a bench trial. Tr. 11; see also Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 596, 113 S. Ct. 2786, 125 L. Ed. 2d 469 (1993) ("vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of [*49] attacking shaky but admissible evidence"). That "vigorous cross-examination" having now taken place, this Court finds the NDTI survey - which Endo admits is itself methodologically and statistically sound n7 - and Dr. Payne's testimony proves by a preponderance of the evidence that OxyContin provides adequate pain relief for approximately 90% of patients over an approximate four-fold dosage range.

n7 See Endo's Memorandum In Support of its Motion In Limine to Exclude the Testimony of Purdue's Experts, Donald R. Stanski, M.D. and Richard Payne, M.D., to the Extent it is Based on NDTI Data, Related Materials and/or the "Meta Study" at 8; see also Tr. 1531 (testimony of Dr. Paul Willis Allen, Endo's expert and a former marketing executive at IMS Health).

As an initial matter, this Court finds that Dr. Stanski, a professor of anesthesia at Stanford University and former chair of the anesthesia department who has published over ninety articles in the area of anesthetic and analgesic drugs, who has been involved [*50] in the development of opioid analgesics for most of his 29 year career in anesthesiology, and who has used NDTI data in his consulting career to understand dosing patterns, is qualified to testify as an expert in the field of pharmacology such that he can assert an opinion with respect to the NDTI data. Tr. 631-33, 804. The NDTI survey "provides statistical information about the patterns and treatment of disease encountered in office-based practice in the continental United States," from a monthly sample of 2200 physicians who specialize in diagnosing and treating disease, which is then extrapolated to reflect approximately 85% of office-based physicians. PTX 842, 28-2. The IMS Health Information Services Manual acknowledges that NDTI survey data does not cover a majority of the physicians in America, but it claims that most of the doctors not covered are specialists that only see patients after they have seen doctors who are covered by the NDTI survey. PTX 842, 28-4. The NDTI survey forms provide space for doctors to record the specific product and exact dosage they issued or recommended to their patients, as well as a separate space to indicate whether the product was actually issued [*51] or whether it was only recommended. PTX 842, 28-12.

Surveying the "uses" of OxyContin reported by NDTI between 1996-2001 - "uses" consisting of 85-90% prescriptions n8 - Dr. Stanski concluded that 84.4% of

the 6,000,000 uses fall with the four-fold range disclosed in the patents in suit (20 mg - 80 mg/day for twice per day usage). See Tr. 814; PTX 578. As Endo does not challenge the methodology of the NDTI survey, and indeed cites cases supporting the use of NDTI data to compute the number of times doctors recommend a particular drug in comparison to other drugs, this Court will utilize the survey for the limited purpose of showing that it is "literally true" that there have been approximately 6,000,000 "uses" of OxyContin between 1996-2001 and, of those 6,000,000 "uses," approximately 84% have fallen within the four-fold range of the claims. See, e.g., Bristol-Myers Co. v. F.T.C., 738 F.2d 554, 563 (2d Cir. 1984) (relying on NDTI survey to conclude that physicians recommended a drug more often than three competing products); McNeilab, Inc. v American Home Products Corp., 501 F. Supp. 517, 524 (S.D.N.Y. 1980) (citing NDTI data showing that it [*52] was "literally true" that one drug was recommended to patients more than another drug).

n8 Dr. Stanski testified that "uses" is a "prescribing event" when a doctor prescribed specific drugs at specific dosage strengths to a patient. Tr. 712, 716. Dr. Allen defined "uses" more broadly to include events where a doctor, in filling out the NDTI survey, recalled the product that was appropriate for a patient's diagnosis. Tr. 1537. Although Dr. Allen testified that NDTI data is not prescription data, Tr. 1524, he never addressed whether or not 85-90% of the data is, in fact, prescription data. Tr. 814.

Given that OxyContin is an analgesic and, as set forth in the testimony of Dr. Payne, an effective analgesic, Tr. 94, 107-09, this Court assumes that "uses," and correspondingly, prescriptions written by doctors, provide an indication that the patient's pain is being adequately relieved by OxyContin, although it notes that both Dr. Coda and Dr. Payne testified that the NDTI data does not, by itself, indicate whether [*53] or not patients were "adequately medicated." See Tr. 145-46; Tr. 1243-46, 1292. Endo has not presented any evidence that OxyContin is not an effective analgesic, and it would appear incongruous for Endo to file an ANDA seeking approval to manufacture and sell a bioequivalent version of an analgesic that failed to adequately control pain. This Court is not using NDTI as evidence to support the conclusion (1) that OxyContin is more easily titratable than other opioid drugs or (2) even that its dosage range for adequate pain relief for most patients is twice as narrow as for MS Contin or other drugs for pain relief.

Dr. Stanski admitted that (1) he had not seen NDTI data used in any "peer-reviewed publications," Tr. 805, even though the IMS Health Information Services Manual asserts that its NDTI data was used in an article in the Journal of the American Medical Association, PTX 842, 28-3, (2) that certain portions of the data were eliminated prior to computation, including 1/2 tablet recommendations and one time per day uses, Tr. 811 - neither of which are uses contemplated anywhere in the claims, specifications or prosecution histories of the patents, (3) that he did not analyze [*54] the data for sampling error, Tr. 814-15, and (4) he, in fact, testified that the NDTI data was "a very important marketing tool," Tr. 804. Dr. Coda also noted a number of drawbacks to using NDTI data. Tr. 1242-43. However, this Court is only utilizing the methodologically sound NDTI data for the limited purpose of quantifying the number of "uses" and corresponding prescribed dosages.

Accordingly, Purdue has proven that the patents in suit adequately control pain for approximately 90% of patients within a four-fold dosage range.

2. Comparison of Endo's proposed ANDA formulation to Purdue's OxyContin

To establish infringement, Purdue must show by a preponderance of the evidence that the accused device contains, either literally or by equivalents, the limitations of the claimed invention. See Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1247 (Fed. Cir. 2000) (citation omitted); Applied Materials, Inc. v. Advanced Semiconductor Materials Am., Inc., 98 F.3d 1563, 1574 (Fed. Cir. 1996). Pursuant to a finding of literal infringement, the patentee must establish that every limitation set forth in the properly construed claim reads on, or in [*55] other words is found in, the accused product, exactly. Allen Engineering Corp. v. Bartell Indus. Inc., 299 F.3d 1336, 1345 (Fed. Cir. 2002). If any claim limitation is absent from the accused product, there is no literal infringement as a matter of law. See Bayer AG, 212 F.3d at 1247.

Endo does not dispute that its proposed drug, filed pursuant to an ANDA, is bioequivalent to OxyContin, for the 10 mg, 20 mg, 40 mg and 80 mg tablets, as it must be in order to secure approval from the FDA. See 21 U.S.C. § 355(j)(2)(A); PTX 845A, 846A, 847A, Endo provided the FDA with one steady state pharmacokinetic study for its 40 mg ANDA formulation that reported C[max], T[max], C[min] and T[min] within the ranges set forth in the patent claims. PTX 845A. Specifically, Endo recorded C[max] as 36.73 ng/ml, C[min] as 17.91 ng/ml, T[max] as 3 hrs and T[min] measured at "just prior to dose administration" which, for steady state testing of 12 hour formulations, occurred at 12 hours. PTX 845A, EN003395, EN003397, EN003412; PTX 845, EN003410. These numbers fall within the ranges set forth in the claims of the patents in suit. [*56] For ex-

ample, claim 1 of the '912 and '042 patent, and Claim 2 of the '295 patent provide for a C[max] of between 6 to 60 ng/ml, a C[min] between 3 to 120 ng/ml, a T[max] of 2-4 hours and a T[min] of 10 to 14 hours. Applying the concept of linear kinetics, where a doubling of the dose results in a doubling of the blood plasma concentration, which experts from both Endo and Purdue accept as a viable method of determining blood plasma concentration, Tr. 1156, Tr. 691-92, Endo's 10 mg, 20 mg and 80 mg proposed drugs also infringe the pharmacokinetic claims of the patents in suit. See PTX 422, EN206132, EN206190; Claim 2 of the '912 and '042 patents; Claim 1 of the '295 patent.

Endo's proposed ANDA formulations also infringe the composition claims as well. Endo does not dispute that the formulations for the 10, 20, 40 and 80 mg proposed ANDA formulations all contain between 10 and 160 mg of oxycodone hydrochloride (an oxycodone salt), Eudragit, a release controlling agent that is an acrylic resin and consists of hydrophilic polymers and Avicel, a diluent that is listed in the ANDA application as a "filler." PTX 845A, EN003903; PTX 846A, EN052849-50; PTX 847A, EN052849; Tr. [*57] 1416. Compare this composition with the composition of Claim 3 of the '912 patent and Claims 4, 6 and 7 of the '295 patent: "oxycodone or a salt thereof in an amount from about 10 to about 160 mg," "a controlled release matrix selected from the group consisting of hydrophilic polymers ...," and " a suitable amount of pharmaceutical diluent." Claim 4 of the '912 patent states that the controlled release matrix of Claim 3 "comprises an acrylic resin." While there are distinctions in the composition of the parties' respective controlled release matrixes -- Dr. Danny Kao, employed at Endo as its principal scientific advisor, testified that Endo's controlled release matrix contains only Eudragit while Purdue's matrix contains Eudragit and stearyl alcohol - among other differences, Tr. 1449-54, the claims are worded broadly enough to encompass these differences, and the specifications and prosecution histories do not otherwise limit the composition claims. Accordingly, Endo's proposed ANDA formulation literally infringes the composition claims of the patents in suit.

Endo contends that since the patients in its 40 mg ANDA formulation steady state pharmacokinetic study took a dose of naltrexone [*58] prior to their morning doses, and naltrexone quantitatively alters the rate and extent of absorption of opioids into humans, the resultant pharmacokinetics will be altered. Since the asserted claims of the patents in suit make no reference to naltrexone, Endo contends there is no reliable evidence that its ANDA formulation falls within the patents' pharmacokinetic claims. Naltrexone is an opioid antagonist that "prevents an opioid from creating any pharmacological effect on the subject" and is used to protect patients "from the narcotic effects" of oxycodone that could occur at high doses. Tr. 702; PTX 845A, EN003397. Subjects in Endo's study - who were "normal, healthy male volunteers," PTX 845A, EN003397, - were given naltrexone "to prevent cardiovascular and gastrointestinal adverse effects associated with the administration of oxycodone to opiate-naive subjects." Id. at EN003413, EN003397. n9

> n9 The excipients listed on Endo's proposed physician inserts for its ANDA formulation do not include naltrexone, PTX 422, EN206125. Naltrexone was also listed as and administered as a separate tablet in Endo's study. Id. at EN003404. The title of the study itself is the "Steady-State Bioequivalence of [Endo's 40 mg proposed ANDA formulation]," not the "Steady-State Bioequivalence of [Endo's 40 mg proposed ANDA formulation and separate 50 mg naltrexone tablet]."

[*59]

Although Endo has asserted that naltrexone would alter the pharmacokinetics of a controlled release oxycodone formulation, Endo does not cite any scientific articles or provide any expert testimony that directly supports this hypothesis and the Court is thus unable to adopt Endo's assertion as fact. On this basis alone, this Court could determine that Endo infringes the pharmacokinetic claims of the patents in suit. In the single published article cited by Endo, the authors reported that in the presence of naltrexone, the C[max] for controlled release *morphine* was 14% higher than the corresponding value without naltrexone and the T[max] was 23% lower, but that the difference for T[max] could not be considered statistically significant because of the large variation in T[max] measurements. DX 2145; Tr. 703-05.

For purposes of analysis, this Court assumes, without deciding, that naltrexone would have the same impact on controlled release oxycodone formulations as it did on the controlled release morphine formulation used in the article. The article does not posit such a replacement, but Dr. Michael Mayersohn, Endo's pharmaceutics expert, testified that, pursuant to an obviousness [*60] analysis, one skilled in the art could replace an opioid with another opioid and yield predictable blood plasma concentration results. Tr. 1128. If the pharmacokinetic properties of Endo's ANDA formulation were adjusted due to the presence of naltrexone pursuant to the percentages set forth in the article, the revised C[max] would be 41.87 ng/ml and T[max] would be 2.31 hours, which are still well within the range of the claims of the patents in suit. See, e.g., Claims 1 of the '042 Patent and

'912 Patent and Claim 2 of the '295 Patent (providing for a range of C[max] values from 6to60 ng/ml and T[max] values from 2 to 4.5 hours); Tr. 705-06.

Accordingly, Endo's ANDA formulation infringes the claims of the patents in suit, including the limitation that the patent claims must control pain relief in approximately 90% of patients over a four-fold range of dosages. Although Purdue failed to perform a clinical analysis of the efficacy of a four-fold dosage range of Endo's proposed ANDA formulation, Endo cannot avoid a finding of infringement. This Court credits the testimony of Dr. Stanski who, after reviewing the proposed package insert Endo submitted to the FDA, testified [*61] that "Endo's [proposed ANDA formulation] will result in a reduced range of dosage because of the bioequivalence that has been demonstrated by Endo." Tr. 718, 834-37; PTX 422. In addition, Dr. Mayersohn - Endo's expert - testified that in vitro release profiles (charts showing the percentage of an active ingredient dissolved in the laboratory over time) are predictive of in vivo profiles (charts showing the blood plasma concentration of an active ingredient in the human body over time), Tr. 1128, 1140-42, and that in vivo profiles of controlled release hydromorphone formulations are predictive of the in vivo profiles of controlled release oxycodone formulations, Tr. 1132-36. See also Dr. Mayersohn's Expert Reports. Accordingly, though not specifically addressed by Endo, this Court can see no reason why these predictive qualities cannot extend to predicting dosage ranges of bioequivalent formulations. That Endo's ANDA formulation is bioequivalent to OxyContin does not by itself result in infringement, see Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc., 288 F. Supp. 2d 562, 2003 U.S. Dist. LEXIS 19105, 2003 WL 22434211 (S.D.N.Y. 2003), but bioequivalence is relevant to infringement [*62] here, where pharmacokinetic properties are included as limitations to the claims at issue in the patents in suit. As Purdue has already proven by a preponderance of the evidence that OxyContin controls pain in most patients over a four-fold dosage range, and OxyContin and Endo's ANDA formulation are bioequivalent, and Endo's ANDA formulation infringes the composition and pharmacokinetic claims of the patents in suit, Purdue has proven by a preponderance of the evidence that Endo infringed its patents in suit.

B. Inequitable Conduct

An otherwise valid patent may be rendered unenforceable by virtue of inequitable conduct committed during the prosecution of the patent application before the Patent Office. Patent applicants are required to prosecute patent applications "with candor, good faith, and honesty." Bristol-Myers Squibb Co. v. Rhone-Poulenc Rorer, Inc., 326 F.3d 1226, 1233 (Fed. Cir. 2003) (quoting Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995)). "A breach of this duty, when coupled with an intent to deceive or mislead the PTO, constitutes inequitable conduct, which, when proven, renders the patent unenforceable." Id. [*63]

"Inequitable conduct entails a two-step analysis: first, a determination of whether the withheld reference meets the threshold level of materiality and intent to mislead, and second, a weighing of the materiality and intent 'in light of all the circumstances' to determine 'whether the applicant's conduct is so culpable that the patent should be held unenforceable.'" Purdue Pharma L.P. v. Boehringer Ingelheim GmbH, 237 F.3d 1359, 1366 (quoting Baxter Int'l, Inc. v. McGraw, Inc., 149 F.3d 1321, 1327 (Fed. Cir. 1998)). "Inequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive." See CFMT, Inc. v. CFM Tech., Inc., 349 F.3d 1333, 1340 (Fed. Cir. 2003) (quoting Molins PLC v. Textron, Inc., 48 F.3d 1172, 1178 (Fed. Cir. 1995)). "When balanced against high materiality, the showing of intent can be proportionally less." Rhone-Poulenc Roher, 326 F.3d at 1233 (citing Brasseler, U.S.A.I., L.P. v. Stryker Sales Corp., 267 F.3d 1370, 1381 (Fed. Cir. 2001)).

Since a patent is presumed valid, [*64] see 35 U.S.C. § 282, Endo must show by "clear and convincing evidence" that Purdue failed to disclose material information with an intent to mislead the PTO. CFMT, 349 F.3d at 1340. "The 'clear and convincing' standard of proof of facts is an intermediate standard which lies somewhere between 'beyond a reasonable doubt' and 'preponderance of the evidence.'" Buildex, Inc. v. Kason Indus., Inc., 849 F.2d 1461, 1463 (Fed. Cir. 1988) (quotation omitted). "Although not susceptible to precise definition, 'clear and convincing' evidence has been described as evidence which produces in the mind of the trier of fact 'an abiding conviction that the truth of [the] factual contentions are 'highly probable.'" Id. (quotation omitted).

There are two interpretations of materiality that courts have relied upon in evaluating a claim of inequitable conduct. Prior to March 16, 1992, the Federal Circuit "held that materiality for purposes of an inequitable conduct determination required a showing that 'a reasonable examiner would have considered such prior art important in deciding whether to allow the parent application.'" Dayco Products, Inc. v. Total Containment, Inc., 329 F.3d 1358, 1363 (Fed. Cir. 2003). [*65] "Information did not need to be prior art in order to be material, but 'instead embrace[d] any information that a reasonable examiner would substantially likely consider important in deciding whether to allow an application to issue as a

patent.'" Id. (quoting Akron Polymer Container Corp. v. Exxel Container, Inc., 148 F.3d 1380, 1382 (Fed. Cir. 1998)). However, in March 1992, the PTO amended its rules to provide for a definition of materiality that was supposedly "clearer and more objective." Duty of Disclosure, 57 Fed. Reg. 2021, 2024 (January 17, 1992). "The new rule reiterated the preexisting 'duty of candor and good faith,' but more narrowly defined materiality, providing for disclosure where the information establishes either 'a prima facie case of unpatentability' or 'refutes, or is inconsistent with a position the applicant takes.'" Dayco Products, 329 F.3d at 1363-64. n10 Since the 1992 amendment, the Federal Circuit has continued to apply the reasonable examiner standard to cases that were prosecuted under the earlier version of 37 C.F.R. § 1.56(b) but has "not decided whether the standard for materiality [*66] in inequitable conduct cases is governed by equitable principles or by the Patent Office's rules." Id. at 1364. However, "the new standard was not intended to constitute a significant substantive break with the previous standard." Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 1368 n.2 (Fed. Cir. 2003). Endo contends that Purdue committed inequitable conduct before the PTO both prior to and subsequent to March 16, 1992, so both standards should apply. Regardless of which standard is applied, Purdue misrepresented material facts to the PTO.

n10 Specifically, the rule provides that:

> 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.
>
> A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.
>
> 37 C.F.R. § 1.56(b) (2003)

[*67]

A finding of intent does not require direct evidence and can be inferred from the facts of the action. See Rhone-Poulenc Roher, 326 F.3d at 1239. "Where withheld information is material and the patentee knew or should have known of that materiality, he or she can expect to have great difficulty in establishing subjective good faith sufficient to overcome an inference of intent to mislead." Id. at 1240. However, "mere gross negligence is insufficient to justify an inference of an intent to deceive" the Patent Office. Baxter Int'l, 149 F.3d at 1329 (citing Kingsdown Med. Consultants, Ltd. v. Hollister, Inc., 863 F.2d 867, 876 (Fed. Cir. 1988) (en banc)). "In determining inequitable conduct, a trial court may look beyond the final claims to their antecedents," including claims of parent patents when such inequitable conduct is material to the claims of the continuation or divisional patents. Baxter Int'l, 149 F.3d at 1332 (quoting Fox Indus., Inc. v. Structural Pres. Sys., Inc., 922 F.2d 801, 803-04 (Fed. Cir. 1990)).

Endo contends that Purdue committed inequitable conduct when it allegedly [*68] misrepresented the material fact that Purdue had "surprisingly discovered" that its invention reduced the dosage range and eased titration in comparison to other opioid formulations. The misrepresentation lay in intentionally failing to disclose material information inconsistent with these assertions. n11

n11 Endo also contends that Purdue misrepresented the material fact that a T[max] of 2 to 4 1/2 hours was surprising for a 12-hour controlled release opioid by failing to disclose that other opioids had the same T[max] range. Because Purdue committed inequitable conduct by misrepresenting its "surprising[] discovery" of a reduced dosage range, thus rendering the patents in suit invalid, this Court need not decide whether or not Purdue committed other acts of inequitable conduct before the PTO.

The specifications of the patents in suit repeatedly note that the inventors "surprisingly discovered" that the controlled release oxycodone formulation "acceptably control[s] pain over a substantially narrower, [*69] 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 opioid analgesics in general." The '912 patent, 3: 34-41. See also '912 Patent, 3:42-47; 3:67 - 4:8; 4:51-57; 1:10-45; 4:51-63. n12 As

discussed previously, the prosecution histories of the patents in suit are replete with examples where Purdue asserted to the PTO that the invention provided pain relief for most patients over a four-fold dosage range, leading to easier titration. See supra pgs. 19 to 23. In fact, after reviewing the claims, specification and prosecution histories of the patents in suit, this Court construed the claim term "controlled release oxycodone formulation" to require adequate pain relief in approximately 90% of patients over an approximately four-fold dosage range, although ease of titration was not construed so as to limit the claims. See also Boehringer, 98 F. Supp. 2d at 375 ("it was a principal purpose of the invention to facilitate the titration process by reducing the range of daily dosages needed to provide effective pain relief [*70] across the spectrum of patients").

n12 As noted supra pg. 11, the specifications of the '912, '042 and '295 patents are identical.

However, during the bench trial, Dr. Kaiko 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. Tr. 407. Instead of scientific proof, Dr. Kaiko testified that he had an "insight ... that the range around the oral bioavailability of oxycodone had to be narrower than the range around the oral bioavailability of morphine." Tr. 172. With this "insight," he "envisioned [a] ... proposed controlled-release oxycodone product ... having an approximate four-fold range." Tr. 176.

To support this insight, he reviewed and "quantitatively analyzed" the "individual patient daily dosages in patients who had been titrated with MS Contin [a morphine-based pain relief drug]" in order to determine that there was an eight-fold range of dosages for morphine, Tr. 173. Dr. Kaiko determined that controlled [*71] release oxycodone had a four-fold range of dosages --in contrast to the eight-fold range of dosages for controlled release morphine -- due to certain factors he knew about oxycodone, including its known oral bioavailability, its effectiveness, its short elimination half-life and "this profile of blood levels that I had in mind." Tr. 176. Dr. Kaiko also provided a demonstrative exhibit that purported to demonstrate his analysis of the morphine data combined with his insights into oxycodone. DX 1061. Purdue failed to provide to the Court any documentary evidence of any actual "individual patient daily dosages" or any other documents that Dr. Kaiko reviewed in coming up with his "insight." Dr. Kaiko in fact testified that no documents exist that show his analysis of data displayed as demonstrative exhibit DX 1061, and that no data at all existed for his insight that a controlled release oxycodone formulation would have 1/2 the dosage range of morphine. Tr. 405-07.

Purdue does not dispute that no clinical studies existed - at either the time of filing or immediately subsequent to the allowance of the claims of the patents in suit - to support the patents' disclosure of a four-fold range [*72] of doses that treat approximately 90% of patients. See Purdue's Opening Brief After Trial at 48. In fact, the evidence Purdue used at trial to prove the patents' reduction in dosage ranges consisted of NDTI data from 1996 to 2001, well after the filing dates of all the '912 and '042 patents, and covering only three months worth of data prior to the March 19, 1996 filing of the '295 patent. See PTX 578; PTX 7-9. Instead, Purdue contends that the word "discovery" can include purely mental acts so Dr. Kaiko had in fact "discovered" a reduction in dosage ranges. Harold Steinberg, Esq., a patent attorney who prosecuted and supervised the prosecution of the '331 patent and a partner in the firm Steinberg, Raskin & Davidson that prosecuted the patents in suit, described such discoveries as "made in the mind, not necessarily in the laboratory. I can give you a good example. Einstein's E = mc<2>. Nothing in the laboratory for it, but the discovery was made in his mind." Tr. 1620. Purdue also cites a dictionary definition of the related term "discover" as meaning "to make known or to obtain knowledge of for the first time." Merriam-Webster New Ninth Collegiate Dictionary 361 (9th [*73] ed. 1989). Accordingly, Purdue contends that it did not need to produce any evidence to the PTO beyond the declaration from Dr. Kaiko stating that he had "surprisingly discovered" this result because the declaration was factual evidence that supported this statement. See also CFMT, 349 F.3d at 1342 (To support an "unexpected result," a patent applicant may, during prosecution of the patent before the PTO, "submit objective factual evidence to the PTO in the form of patents, technical literature, and declarations under 37 C.F.R. § 1.132 (2003).").

In contrast, Endo's expert, Gerald Bjorge, Esq., a former examiner and Administrative Patent Judge at the PTO, testified that, pursuant to the Manual of Patent Examining Procedure, an "insight or theory should be described in the present tense or in language like 'can be done,' 'could be done,' something that imports the notion to the reader, to the scientific community, the public at large and particularly the examiner that something has not yet been actually done or actually reduced to practice." Tr. 1560; see also Manual of Patent Examining Procedure ("MPEP") § 2004.8 (8th ed. 2003) ("Stating [*74] that an experiment 'was run' or 'was conducted' when in fact the experiment was not run or conducted is a misrepresentation of the facts."). n13

n13 In addition, Mr. Steinberg testified that the support given to the PTO for "unexpected results" should be "proof by comparative tests." Tr. 1628. See also DX 2008, EN205626.

This Court finds, by clear and convincing evidence that a reasonable examiner would have considered important the fact that Purdue did not have any "scientific proof" that the claimed invention actually provided adequate pain relief for most people over a four-fold dosage range to be important information: and that the lack of that proof is inconsistent with Purdue's reduced dosage assertion. Although the term "discovery" has a broad dictionary definition that can theoretically cover mere "insights," Purdue repeatedly and convincingly stated to the PTO that it had discovered an oxycodone formulation that did not simply control pain over a reduced dosage range, but controlled pain over a "four-fold" [*75] range of doses for "approximately 90%" of patients. Purdue asserted to the PTO that this "result" n14 was of "extreme clinical importance." DX 2033, P 000177 ("The above result [that the oxycodone formulations claimed can be used over approximately 1/2 the dosage range as morphine] is surprising and of extreme clinical importance"); DX 2008, EN205621 ("One skilled in the art would certainly not arrive at this surprising result without the benefit of hindsight."). Such definitive statements to the PTO would clearly be undercut if the PTO were aware that the statements lacked any support other than Dr. Kaiko's assertions and "insight."

n14 See Webster's Third New International Dictionary 1937 (1993) (defining a "result" as "something obtained, achieved, or brought about by calculation, investigation, or similar activity (as an answer to a problem or knowledge gained by scientific inquiry)"). The Federal Circuit has used Webster's Third New International Dictionary to help construe claims. See Omega, 334 F.3d at 1322.

[*76]

Clearly, the assertion of reduced dosage ranges is itself material - indeed, it is even a claim limitation. Even if this Court did not so limit the claims, these statements would still be material, since as previously discussed, the patent examiner considered these statements decisive in allowing the '042 patent application to issue. See Hoffman-La Rouche, 323 F.3d at 1367 (citing PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc., 225 F.3d 1315, 1322 (Fed. Cir. 2000); see, e.g., DX 2009, EN 205735 - Statement of Reasons for Allowance of the '042 patent ("none of the references of record singly anticipate or in combination motivate one with ordinary skill in the art to formulate the particular method for reducing the dosage of oxycodone as set forth in the claims"). Consequently, information inconsistent with the position that Purdue took before the PTO that the invention controlled pain for most patients over a four-fold dosage range - including information that the position was just an "insight" that was not supported by any "scientific proof" -- is material. See C.F.R. § 1.56(b).

The Federal Circuit recently affirmed a district court's [*77] finding of misrepresentation in similar circumstances. In Hoffmann-La Roche, the Federal Circuit found that a patentee misrepresented the fact that an example - described in the specification in the past tense and including results - had not actually been performed. 323 F.3d at 1364-66. Although here, in contrast to Hoffman-La Roche, neither the patents in suit themselves nor their prosecution histories describe the process by which Purdue discovered that a four-fold dosage range would adequately relieve pain in 90% of patients, the fact that Purdue (1) described the surprising discovery (the "result") in concise, quantified terms, (2) described it as having occurred in the past tense, (3) considered the discovery "absolutely critical to the invention," Tr. 172, and most importantly (4) used this precisely quantified "discovery" throughout the prosecution of the '331, '912 and '042 patents as a prominent, and at times, the only, argument in favor of patentability before the PTO, resulting in allowance of the claims, support this Court's finding that Purdue misrepresented a material fact. Id. at 1368 ("a reasonable examiner would have wanted to [*78] know that the patentability argument ... was unsupported by the experimental results cited by the inventors"); Grefco, Inc., v. Kewanee Indus., Inc., 499 F. Supp. 844, 865-70 (D. Del. 1980). See also CFMT, 349 F.3d at 1341-1342 (asserted "unexpected results" determined not to be material misrepresentations where the statements were in fact accurate and "natural, expected results" that the examiner did not rely on in allowing the application); MPEP § 2004.8.

We now turn to the question of intent. As noted previously, "when balanced against high materiality, the showing of intent can be proportionally less." Rhone-Poulenc Roher, 326 F.3d at 1233. "Proof of high materiality and that the applicant knew or should have known of that materiality makes it difficult to show good faith to overcome an inference of intent to mislead." Semiconductor Energy Lab. Co. v. Samsung Elecs. Co., 204 F.3d 1368, 1375 (Fed Cir. 2000); Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1256 (Fed. Cir. 1997). "Evidence of good faith must be considered in determining whether inequitable conduct has been [*79] shown by clear and convincing evidence." See Baxter Int'l, 149 F.3d at 1330. See also Ulead Systems, Inc. v. Lex Computer & Management Corp., 351

F.3d 1139, 2003 U.S. App. LEXIS 24718, 2003 WL 22889687, at *6 (Fed. Cir. Dec. 9, 2003).

Purdue contends that it believed in good faith that it had "discovered" that OxyContin provided pain relief over a reduced, four-fold dosage range. However, Dr. Kaiko - in addition to his testimony about discovering the reduction in dosage ranges -- testified that at no time prior, during, or subsequent to the prosecution of the patents in suit did there exist at Purdue a "set of procedures and methods" that could "provide definitive conclusions" that OxyContin was "the most easily titratable strong analgesic," and that such a test would require "hundreds of thousands of patients." Tr. 235, 246. Dr. Goldenheim - to whom Dr. Kaiko directly reported since he started working at Purdue, Tr. 969 - testified that as of October 20, 1993, Purdue's researchers "weren't anywhere close" to proving that OxyContin was "the most efficiently titratable long-acting strong analgesic," and these titration claims were "clearly Bob Kaiko's vision." Tr. 984. As discussed earlier [*80] in this Opinion, titration is the method by which dosages are adjusted in order to provide acceptable pain control without unacceptable side effects. Tr. 99, 169, 1233. Thus, a reduction in dosage ranges would directly improve titration, as Purdue itself states in the specifications of the patents in suit:

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

See, e.g., the '295 and '912 patents, Cols. 4:51-63; the '042 Patent, 4:53-65; see also DX 2008, EN 206520.

Dr. Goldenheim also testified [*81] that "I think that being easy to titrate would be one of the components that one would expect in a formulation whose benefit would be associated with a reduced dosage range. So if it were difficult to titrate, if it were not easy to titrate, I wouldn't expect that benefit to accrue." Tr. 990. Accordingly, Purdue's admitted inability to prove titration claims undercuts any good faith belief that the inventions provided pain relief for most patients over a reduced, four-fold dosage range.

Documents created by Purdue contemporaneous to the prosecution of the patents in suit also undercut Purdue's good faith contention. For example, a July 16, 1990 internal memo written by Dr. Kaiko stated that, with respect to any claims of reduced dosage range and resulting ease of titration, "while the theoretical argument may be relatively strong using available data, it may be difficult to demonstrate these claims within the context of efficacy studies. Thus, an acceptance of a priority program for controlled-release oxycodone should not assume that all these claims can be demonstrated." DX 3165. Just four months prior to the filing of the '331 patent, Dr. Goldenheim wrote in a memo to Dr. Kaiko [*82] and other Purdue scientists that "OxyContin *may* have advantages over MS Contin in terms of less variability in dose required." DX 3226 (italics added). In a memo with the subject line "OxyContin Advantages," dated September 28, 1993, nearly one year after Purdue first told the PTO that it had "surprisingly discovered" the inventions' reduced dosage range, Dr. Kaiko wrote that "one would expect that [oxycodone's] characteristics would translate into a number of desirable clinical outcomes such as:... the finding that a narrower range of dosages of oxycodone are required to manage a group of patients than with the utilization of drugs with a lower oral bioavailability," and requested that Purdue researchers focus on these outcomes. DX 3629. Thus, more than a year after representing to the PTO that a four-fold range of dosages was a "surprising discovery," internal memoranda reveal that Dr. Kaiko considered his "surprising discovery" only a non-quantified "expectation" that needed additional studies and supporting data. Id. Shortly thereafter, Dr. Goldenheim noted in response to a memo from Dr. Kaiko where Dr. Kaiko asserted that OxyContin was the "most efficiently titratable [*83] long-acting strong analgesic," that "this is a theory - not yet proven. we will have to see." DX 3156.

Purdue attempts to limit many of these comments as only being made in the context of Purdue's efforts to receive FDA approval for the comparative claim "most efficiently titratable strong analgesic," Tr. 982, and accordingly these comments do not address any assertions Purdue made to the PTO about the reduced dosage ranges of the patents in suit. However, as discussed above, a reduced dosage range is directly related to easier titration; any concerns about proving the latter must affect belief in the former, especially as Purdue's reduced dosage range assertion is - like the titration assertion -

made in a comparative context - i.e., "other opioid analgesics require approximately twice the dosage range." '295 and '912 patents, Cols. 4:51-63; '042 Patent, 4:53-65.

Accordingly, this Court finds 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 case of titration), and cannot "overcome [*84] an inference of intent to mislead." Semiconductor Energy, 204 F.3d at 1375. In any event, good faith does not suffice to negate a finding of intent. In Hoffmann-La Roche v. Promega, the patentees made a similar argument to the Federal Circuit that "'because one cannot intentionally deceive by representing what one honestly believes, the district court's [finding that the intent element of inequitable conduct had been met] judgment cannot stand." Hoffmann-La Roche, 323 F.3d at 1367. In response, the Federal Circuit stated that "the inventors may indeed have believed that they had discovered a novel enzyme, but that belief does not permit them to make misrepresentations in seeking to persuade the examiner to issue a patent for that enzyme." Id. Here, even assuming Purdue believed in good faith that it had discovered a novel result - the four-fold dosage range that relieved pain in most patients -that belief did not entitle it to deceptively withhold from the PTO the fact that it did not have any "scientific proof" to support its discovery, or even a method or procedure in place for proving its discovery. Purdue made a deliberate decision to [*85] misrepresent to the PTO a "theoretical argument" and an "expectation" as a precisely quantified "result" or "discovery." Accordingly, Endo has proven, by clear and convincing evidence, that Purdue intentionally misrepresented its "discovery" to the PTO.

This Court is aware of "the ease of opportunistic challenge to the conduct of experimental science in the patent context," and that inequitable conduct cannot be founded merely on a finding that a patentee included "predicted test results and prophetic examples" in their specification - such "paper examples" are explicitly permitted. See Hoffmann-La Roche, 323 F.3d at 1373, 1377 (dissent, Newman, J.); MPEP § 608.01(p). However, after weighing the materiality and intent "in light of all the circumstances," this Court concludes that Purdue "is so culpable that the patent should be held unenforceable." Boehringer, 237 F.3d at 1366 (quoting Baxter Int'l, 149 F.3d at 1327).

The record as a whole reflects a clear pattern of intentional misrepresentation of a material fact - Purdue knew that it did not have "scientific proof" of its "discovery," yet repeatedly asserted its "discovery" to [*86] the PTO in precise, quantified, past-tense language. And while it is true that "it is not inequitable conduct to omit telling the patent examiner information that the applicant in good faith believes is not material to patentability," see Allied Colloids Inc. v. American Cyanamid Co., 64 F.3d 1570, 1578 (Fed. Cir. 1995), a patent applicant cannot "cultivate ignorance, or disregard numerous warnings that material information or prior art may exist, merely to avoid actual knowledge of that information or prior art." FMC Corp. v. Hennessy Industries. Inc., 836 F.2d 521, 526 n.6 (Fed. Cir. 1987). Here, the "discovery" was so "absolutely critical" to the invention - Tr. 172 (testimony of Dr. Kaiko) - that Purdue initially cited the discovery as the sole reason why the claims of the '331 patent should be allowed, repeatedly cited the "surprising discovery" throughout the prosecution of the patents in suit, highlighted the discovery in numerous parts of the specifications of the patents in suit and, in fact, the patent examiner explicitly allowed the claims of the '042 patent due to Purdue's discovery of the reduced dosage range. As such, Purdue cannot in [*87] good faith contend that it did not know that this "discovery" - and any information that it did not have scientific proof to support this discovery - was material information. Purdue's own scientists and experts testified that Purdue did not have any scientific proof of the "discovery" until analyzing the NDTI data recorded from 1996 to 2001. Clearly, Purdue should have informed the PTO that its discovery - whether termed a "discovery," "insight," a "result," an "expectation," or a "theoretical argument" - had not been proven and was "inherently difficult to demonstrate." DX 3629. These repeated intentional material misrepresentations are so serious as "to warrant the severe sanction of holding the patent[s] unenforceable." Hoffmann-La Roche, 323 F.3d at 1372.

As this Court has found that Purdue committed inequitable conduct before the PTO during the prosecution of the '331, '912, '295 and '042 patents, the patents in suit - the '912, '042 and '295 patents - are rendered unenforceable. See Hoffmann-La Roche, 323 F.3d at 1372; Lummus Indus., Inc. v. D.M. & E. Corp., 862 F.2d 267, 274 (Fed. Cir. 1988) ("The principle is well settled [*88] that if inequitable conduct is established as to any [patent] claim, all claims of the patent are rendered unenforceable."). n15

n15 Since the patents are unenforceable, this Court will not address Endo's other affirmative defenses against Purdue's infringement claims.

IV. Conclusion

For the reasons set forth above, this Court finds that Purdue has proven by a preponderance of the evidence that Endo infringed Purdue's '912, '042 and '295 patents, but Endo has proven by clear and convincing evidence that those patents are invalid due to Purdue's inequitable conduct before the PTO during the prosecution of the patents in suit. The patent claims against Endo are dismissed, patents 5,549,912,5,508,042 and 5,656,295 are declared invalid and Purdue is enjoined from enforcing those patents.

Dated: January 5, 2004

SO ORDERED:

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

EXHIBIT 2

John F. Sweeney (JS5431)
Joseph A. DeGirolamo (JD5830)
Tony V. Pezzano (TP2058)
Bruce D. Radin (BD7353)
Matthew K. Blackburn (MB7408)
MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, New York 10154
(212) 758-4800
(212) 751-6849 (Fax)
Attorneys For Defendants and Counterclaim Plaintiffs

Doc#25

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

PURDUE PHARMA L.P., THE PURDUE FREDERICK COMPANY, THE P.F. LABORATORIES, INC. AND THE PURDUE PHARMA COMPANY, Plaintiffs and Counterclaim Defendants, v. BOEHRINGER INGELHEIM GmbH, Defendant, and ROXANE LABORATORIES, INC. AND BOEHRINGER INGELHEIM CORPORATION, Defendants and Counterclaim Plaintiffs.	C.A. No. 99-CIV-3658 (SHS)

FILED
U.S. DISTRICT COURT
OCT 19 11 03 A 99
S.D. OF N.Y.

ANSWER OF ROXANE LABORATORIES, INC.
AND BOEHRINGER INGELEHIM CORPORATION
TO PLAINTIFFS' AMENDED COMPLAINT
AND DECLARATORY JUDGMENT COUNTERCLAIM

494421_1

Defendants Roxane Laboratories, Inc. ("Roxane") and Boehringer Ingelheim Corporation ("BIC"), for their Answer to the Amended Complaint in the above-captioned matter, state the following:

1. With respect to Paragraph No. 1 of the Amended Complaint, Roxane and BIC admit that plaintiffs have styled their action as one arising under the patent laws of the United States, Title 35, United States Code, but deny the remaining allegations.

2. Roxane and BIC are without sufficient knowledge or information to either admit or deny the allegations of Paragraph No. 2 of the Amended Complaint and therefore deny such allegations, leaving plaintiffs to their proofs.

3. Roxane and BIC are without sufficient knowledge or information to either admit or deny the allegations of Paragraph No. 3 of the Amended Complaint and therefore deny such allegations, leaving plaintiffs to their proofs.

4. Roxane and BIC are without sufficient knowledge or information to either admit or deny the allegations of Paragraph No. 4 of the Amended Complaint and therefore deny such allegations, leaving plaintiffs to their proofs.

5. Roxane and BIC are without sufficient knowledge or information to either admit or deny the allegations of Paragraph No. 5 of the Amended Complaint and therefore deny such allegations, leaving plaintiffs to their proofs.

6. Roxane and BIC are without sufficient knowledge or information to either admit or deny the allegations of Paragraph No. 6 of the Amended Complaint and therefore deny such allegations, leaving plaintiffs to their proofs.

7. Roxane and BIC admit that BIC is a corporation organized and existing under the laws of the [State of Nevada] and that BIC's principal place of business is located at 900 Ridgebury Road, Ridgefield, Connecticut. Roxane and BIC further admit that on or about June 9, 1999, the Arnold & Porter law firm submitted a letter to the United States Food and Drug Administration ("FDA") stating "Arnold & Porter represents Boehringer Ingelheim Corporation and its subsidiary Roxane Laboratories, Inc. with respect to [Purdue's] petitions." Roxane and BIC deny the remaining allegations in Paragraph No. 7 of the Amended Complaint.

8. Roxane and BIC admit that Roxane is a corporation organized and existing under the laws of the State of Delaware and that Roxane's principal place of business is located at 900 Ridgebury Road, Ridgefield, Connecticut, but deny the remaining allegations in Paragraph No. 8 of the Amended Complaint.

9. Roxane and BIC are without sufficient knowledge or information to either admit or deny that plaintiffs are the lawful owners of each of the patents identified in Paragraph No. 9 of the Amended Complaint, and therefore deny such allegations, leaving plaintiffs to their proofs. Furthermore, Roxane and BIC deny that plaintiffs have any right to sue or to recover for past infringement under each such patent or that there has been any past infringement of each such patent or that each such patent contains one or more claims covering the composition and method of use of OxyContin®. Roxane and BIC respond to the allegations concerning each such patent in the same order set forth in the Amended Complaint as follows:

A. Roxane and BIC admit that a copy of United States Patent No. 5,549,912 ("the '912 patent"), is attached to the Amended Complaint as Exhibit A and that such patent is entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS," specifies a

date of patent of August 27, 1996 and names Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko as inventors, but deny that the patent was duly and legally issued.

B. Roxane and BIC admit that a copy of United States Patent No. 5,508,042 ("the '042 patent"), is attached to the Amended Complaint as Exhibit B and that such patent is entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS," specifies a date of patent of April 16, 1996 and names Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko as inventors, but deny that the patent was duly and legally issued.

C. Roxane and BIC admit that a copy of United States Patent No. 5,656,295 ("the '295 patent"), is attached to the Amended Complaint as Exhibit C and that such patent is entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS," specifies a date of patent of August 12, 1997 and names Benjamin Oshlack, Mark Chasin, Joseph Minogue and Robert Francis Kaiko as inventors, but deny that the patent was duly and legally issued.

ANSWER TO COUNT I
FOR DECLARATORY RELIEF

10. Roxane and BIC reallege their responses to Paragraph Nos. 1-9 of the Amended Complaint.

11. Roxane and BIC are without sufficient knowledge or information to admit or deny the allegations of Paragraph No. 11 of the Amended Complaint as to defendant Boehringer Ingelheim GmbH ("Boehringer Germany"), and therefore deny such allegations, leaving plaintiffs to their proofs. As for the allegations in Paragraph No. 11 directed to Roxane and BIC, Roxane and BIC deny each and every allegation.

12. Roxane and BIC are without sufficient knowledge or information to admit or deny the allegations of Paragraph No. 12 of the Amended Complaint as to defendant Boehringer Germany, and therefore deny such allegations, leaving plaintiffs to their proofs. As for the allegations in Paragraph No. 12 directed to Roxane and BIC, Roxane and BIC deny each and every allegation.

13. Roxane and BIC are without sufficient knowledge or information to admit or deny the allegations of Paragraph No. 13 of the Amended Complaint as to defendant Boehringer Germany, and therefore deny such allegations, leaving plaintiffs to their proofs. As for the allegations in Paragraph No. 13 directed to Roxane and BIC, Roxane and BIC deny each and every allegation.

ANSWER TO COUNT II
FOR PATENT INFRINGEMENT

14. Roxane and BIC repeat and reallege their responses to Paragraph Nos. 1-9 of the Amended Complaint.

15. Roxane and BIC are without sufficient knowledge or information to admit or deny the allegations of Paragraph No. 15 of the Amended Complaint as to defendant Boehringer Germany, and therefore deny such allegations, leaving plaintiffs to their proofs. As for the allegations in Paragraph No. 15 directed to Roxane and BIC, Roxane and BIC deny each and every allegation.

16. Roxane and BIC are without sufficient knowledge or information to admit or deny the allegations of Paragraph No. 16 of the Amended Complaint as to defendant Boehringer Germany, and therefore deny such allegations, leaving plaintiffs to their proofs. As for the allegations in Paragraph No. 16 directed to Roxane and BIC, Roxane and BIC deny each and every allegation.

17. Roxane and BIC are without sufficient knowledge or information to admit or deny the allegations of Paragraph No. 17 of the Amended Complaint as to defendant Boehringer Germany, and therefore deny such allegations, leaving plaintiffs to their proofs. As for the allegations in Paragraph No. 17 directed to Roxane and BIC, Roxane and BIC deny each and every allegation.

ANSWER TO PRAYER FOR JUDGMENT AND RELIEF

18. With respect to plaintiffs' prayer for judgment and relief, Roxane and BIC deny that plaintiffs are entitled to the judgment and relief prayed for in Paragraphs A through H of the prayer for judgment, or to any other relief.

DEFENSES

19. Roxane and BIC have not infringed, contributed to the infringement of or induced infringement of the `912, `042 or `295 patents.

FIRST AFFIRMATIVE DEFENSE

20. Each and every claim of the `912, `042 and `295 patents is invalid under 35 U.S.C. § 101.

SECOND AFFIRMATIVE DEFENSE

21. Each and every claim of the `912, `042 and `295 patents is invalid under 35 U.S.C. § 102.

THIRD AFFIRMATIVE DEFENSE

22. Each and every claim of the `912, `042 and `295 patents is invalid under 35 U.S.C. § 103.

FOURTH AFFIRMATIVE DEFENSE

23. Each and every claim of the `912, `042 and `295 patents is invalid under 35 U.S.C. § 112.

FIFTH AFFIRMATIVE DEFENSE

24. Each and every claim of the `912, `042 and `295 patents is unenforceable because they were procured through inequitable conduct in violation of the patent laws and regulations of the United States Patent and Trademark Office.

A. The `331 Patent

25. Euro-Celtique, S.A. filed and prosecuted application Serial No. 800,549 which issued as United States Patent No. 5,266,331 ("the `331 patent") by and through the individuals named therein as inventors, Benjamin Oshlack, Mark Chasin and John J. Minogue, and Euro-Celtique's patent solicitor. Application Serial No. 81,302, which issued as the `912 patent, purports to be a continuation-in-part of Application Serial No. 800,549, which issued as the `331 patent. Application Serial No. 467,584, which issued as the `042 patent, purports to be a division of Application Serial No. 81,302, which in turn is a continuation-in-part of Application Serial No. 800,549, which issued as the `331 patent. Application Serial No.

618,344, which issued as the `295 patent, purports to be a continuation-in-part of Application Serial No. 81,302, which in turn is a continuation-in-part of Serial No. 800,549, which issued as the `331 patent.

26. Pursuant to 37 C.F.R. §1.56, all individuals associated with the filing and prosecution of the `331 patent application, including applicants and their solicitor, had an affirmative duty of candor and good faith in dealing with the PTO, which included a duty to disclose to the PTO all information known to these individuals to be material to the patentability of the claims then under consideration.

27. Upon information and belief, as is more fully set out below, the aforesaid individuals violated their duty of candor and good faith to the PTO by, inter alia: (a) filing an improper terminal disclaimer to overcome the Examiner's rejection; (b) failing to disclose material prior art which rendered the claims that issued in the `331 patent unpatentable; (c) submitting a false and/or misleading declaration to the PTO; and (d) making material false and/or misleading statements and misrepresentations to the PTO during the prosecution of the application.

28. Upon information and belief and based in part upon the factual allegations set forth below, applicants and their solicitor committed the aforesaid acts with intent to deceive and/or mislead the PTO.

1. **The `331 Patent Prosecution**

a. **The Prior Art**

29. In an April 30, 1992 Office Action during prosecution of the `331 patent application, the Examiner rejected the application under 35 U.S.C. §103 as being unpatentable

over Goldie et al. United States Patent No. 4,990,341 ("the Goldie `341 patent") in view of Oshlack United States Patent No. 4,861,598 ("the Oshlack `598 patent"). Both the Goldie `341 and the Oshlack `598 patents, as was the `331 patent, were assigned to Euro-Celtique, S.A. The named inventor of the Oshlack `598 patent is the same named inventor of the `331 patent. The Goldie `341 patent discloses, inter alia, that a hydromorphone-containing composition should have peak plasma levels two to four hours after administration in order to assure at least 12 hours of pain relief. The specification of the Goldie `341 patent is very similar to the specification of the Goldie `331 patent the most notable difference being that the term oxycodone was substituted for hydromorphone throughout the specification. The Oshlack `598 patent discloses, inter alia, a dosage form containing oxycodone, presenting in vitro dissolution data for oxycodone formulations which satisfy the in vitro dissolution parameters of the `331 patent claims.

30. United States Patent No. 4,844,909, also assigned to Euro-Celtique, S.A., issued on July 4, 1989 to Goldie et al. ("the Goldie `909 patent"). The Goldie `909 patent is cross-referenced at col. 9, lines 63-65 of the `331 patent. The Goldie `909 patent contains the same teaching as the later issued Goldie `341 patent, namely peak plasma levels for hydromorphone between two to four hours after administration.

b. Applicants' October 22, 1992 Response And The Examiner's February 3, 1993 Office Action

31. On October 22, 1992, applicants submitted a response to the April 30, 1992 Office Action in which they argued that the originally presented claims were patentable because they were directed to oxycodone formulations in a dosage range from about 10 mg. to about 40 mg. (a four fold range) which controlled pain for approximately 90% of patients. Applicants argued that this was in sharp contrast to the approximately eight-fold range

previously believed required for opioid analgesics to control serious pain in approximately 90% of the patient population.

32. On February 3, 1993, the Examiner issued another Office Action in which he continued to reject the claims of the `331 patent in view of the Goldie `341 patent and Oshlack `598 patent.

c. The Kaiko Declaration

33. On February 25, 1993, applicants' solicitor held an interview with the Examiner. According to the Examiner Interview Summary Record, the solicitor and the Examiner discussed the "nature of dissolution rate with regard to the prior art." The Interview Summary Record noted that applicants would submit a "proposed declaration supporting unobviousness and unexpected results" and that a "[t]erminal disclaimer will be filed."

34. On March 10, 1993, applicants submitted the Declaration of Robert Frances Kaiko, Vice President, clinical researcher for the Purdue Frederick Company, to attempt to overcome the Examiner's rejection dated February 3, 1993. Dr. Kaiko's declaration stated, inter alia, that the teaching in the Goldie `341 patent that the peak plasma level of hydromorphone should occur two to four hours after administration in order to provide a duration of therapeutic effect of at least 12 hours is not predictive of the same relationship for oxycodone. Further, Dr. Kaiko's declaration represents that the in vitro release rates for oxycodone taught in the prior art Oshlack `598 patent would not enable one of ordinary skill in the art to determine that the peak plasma levels of oxycodone should occur in vivo two to four hours after administration, as claimed in the `331 patent application claims.

d. Terminal Disclaimer

35. The February 25, 1993 Examiner Interview Summary Record also states that a terminal disclaimer will be filed.

36. On March 10, 1993, the applicants submitted an Amendment in which they stated that the "Examiner believed applicants were trying to claim the same invention as set forth in the Goldie `341 patent." The applicants further stated "(i)n order to avoid this possibility, a Terminal Disclaimer is submitted herewith ... disclaiming the terminal portion of any patent to be issued in this case beyond the expiration date of the Goldie ['341] patent." Thus, accompanying the March 10, 1993 Amendment, applicants submitted a Terminal Disclaimer disclaiming the terminal part of any patent granted in the application so that the enforceable term of the `331 patent would not extend beyond the expiration date of the Goldie `341 patent.

37. A Notice of Allowability was issued on June 14, 1993, following the submission of the Amendment, Terminal Disclaimer and Kaiko Declaration on March 10, 1993.

2. Filing Of An Improper Terminal Disclaimer

38. The application for the Goldie `341 patent was filed on April 28, 1989, before the filing of the `331 patent application (November 27, 1991), and the Goldie `341 patent issued on February 5, 1991, before the `331 patent (which issued on November 30, 1993). The Goldie `341 patent qualifies as prior art under 35 U.S.C. §§102(a) or (e)/103 and the Examiner's rejection based on the Goldie `341 patent could not have been properly overcome by the filing of a terminal disclaimer.

39. The terminal disclaimer was highly material because the Examiner allowed the `331 patent application claims following the submission of the Terminal Disclaimer.

40. Since a terminal disclaimer could not have removed the Goldie `341 patent as a basis for rejection, and since the Examiner believed that the teachings of the `341 patent rendered the `331 patent application claims unpatentable, it was incumbent upon the applicants and their solicitor to inform the Examiner that a terminal disclaimer would not overcome the substance of the Examiner's rejection. Upon information and belief, applicants and their solicitor filed the terminal disclaimer with intent to deceive and/or mislead the PTO.

3. **Failure To Disclose The `909 Patent With An Intent To Deceive And/Or Mislead The Patent Examiner**

41. The Goldie `909 patent issued on July 4, 1989 and therefore operates as prior art under 35 U.S.C. §102(b) against the `331 patent. The Goldie `909 patent contains the same teachings as in the later issued Goldie `341 patent. The Goldie `909 patent was not merely cumulative to the Goldie `341 patent given that the former qualified as prior art under 35 U.S.C. §102(b) and therefore could not be antedated by a declaration under 37 C.F.R. §1.131.

42. Applicants and their solicitor failed to disclose the Goldie `909 patent to the PTO. The Goldie `909 patent is highly material since the disclosures in the Goldie `341 patent and Goldie `909 patent are nearly identical and the Examiner's rejection was based on the Goldie `341 patent, a rejection that was overcome by an improper terminal disclaimer. The failure of applicants and their solicitor to call the material teachings of the Goldie `909 patent to the Examiner's attention was a highly material omission which had the effect of deceiving the Examiner into allowing the `331 patent claims based upon a terminal disclaimer which had no effect on the prior art status of the Goldie `909 patent or on the Examiner's rejection based upon the Goldie `341 patent.

43. Upon information and belief, the failure of applicants and their solicitor to disclose the `909 Goldie patent was done with an intent to deceive and/or mislead the PTO.

4. **False And Misleading Kaiko Declaration**

44. Dr. Kaiko's Declaration submitted during the prosecution of the `331 patent application states that the Oshlack `598 patent's in vitro dissolution rates would not teach one of ordinary skill in the art that the maximum plasma level of the oxycodone formulation should occur in vivo two to four hours after administration as required by the `331 patent claims. Upon information and belief, Dr. Kaiko's Declaration is false because the in vitro dissolution rates of the `331 patent limitations for the drug oxycodone lead to the required in vivo plasma concentration within two to four hours after administration. As the Oshlack `598 patent at col. 2, lines 48-55 specifically teaches:

> ... a strong correlation has been established between the in vitro dissolution time determined for a dosage form and the in vivo bioavailability. This correlation is so firmly established in the art that dissolution time has become generally descriptive of bioavailability potential for the active component of the particular unit dosage composition.

45. The false statements made in Dr. Kaiko's Declaration set forth in paragraph 44 above were highly material because the Examiner allowed the `331 patent claims following submission of Dr. Kaiko's Declaration.

46. Upon information and belief, Dr. Kaiko submitted the Declaration with intent to deceive and/or mislead the PTO.

5. **Misrepresentations During The `331 Patent Prosecution With Intent To Deceive And/Or Mislead The Patent Examiner**

47. During prosecution of the application for the `331 patent, applicants and their solicitor made the highly material representation that the oxycodone formulations which have peak plasma levels within two to four hours of administration allow pain to be successfully relieved in 90% of patients with a much narrower range of dosages previously believed possible. See October 22, 1992 Response.

48. The representation by applicants and their solicitor has no support in the `331 patent application, the Kaiko Declaration, or any other part of the prosecution history. The pain relief data in the patent was derived from a single dose, not an "around-the-clock" (i.e., steady state) study. See col. 15, lines 23-31. The `331 patent does not state what percentage of patients in this study experienced "acceptable" pain relief, and there is no way to derive this percentage from the data because "acceptable" pain relief is not defined. Nor does the patent compare the level of pain relief provided by the claimed formulations with the level of pain relief provided by any other opioid analgesic. Thus, the representation of applicants and their solicitor is completely unsubstantiated and false.

49. Upon information and belief, the false representation by applicants and their solicitor was made with intent to deceive and/or mislead the PTO.

B. **The `912 Patent**

50. Roxane and BIC reassert and incorporate herein the averments of ¶¶1-49 as if fully set forth herein.

51. The `912 patent is a continuation-in-part of the `331 patent. During prosecution of the `912 patent, applicants and their solicitor filed a terminal disclaimer with

respect to the '912 patent. Both the '912 and '331 patents expire on February 5, 2008, the expiration date of the Goldie '341 patent.

52. Euro-Celtique, S.A. filed and prosecuted the application which matured into the '912 patent by and through the individuals named therein as inventors, Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko and Euro-Celtique's patent solicitors. Pursuant to 37 C.F.R. §1.56, all individuals associated with the filing and prosecution of the '912 patent application, including applicants and their solicitor, had an affirmative duty of candor and good faith in dealing with the PTO, which included a duty to disclose to the PTO all information known to these individuals to be material to the patentability of the claims then under consideration.

53. Upon information and belief, as more fully set forth above, the aforesaid individuals violated their duty of candor and good faith to the PTO by, inter alia: (a) filing an improper terminal disclaimer to overcome the Examiner's rejection; (b) failing to disclose material prior art which rendered the claims that issued in the parent '331 patent unpatentable; (c) submitting a false declaration to the PTO; and (d) making material, false and/or misleading statements and representations to the PTO during prosecution of the application.

54. Upon information and belief, as more fully set forth above, applicants and their solicitor committed the aforesaid acts with intent to deceive and/or mislead the PTO.

C. The '942 Patent

55. Roxane and BIC reassert and incorporate herein the averments of ¶¶1-54 as if fully set forth herein.

56. The '042 patent is a division of the '912 patent, which in turn is a continuation-in-part of the '331 patent. Euro-Celtique, S.A. filed and prosecuted the application

which matured into the `042 patent by and through the individuals named therein as inventors, Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko and Euro-Celtique's patent solicitor. Pursuant to 37 C.F.R. §1.56, all individuals associated with the filing and prosecution of the `042 patent application, including applicants and their solicitor, had an affirmative duty of candor and good faith in dealing with the PTO, which included a duty to disclose to the PTO all information known to these individuals to be material to the patentability of the claims then under consideration.

57. Upon information and belief, as more fully set forth above, the aforesaid individuals violated their duty of candor and good faith to the PTO by, inter alia: (a) filing an improper terminal disclaimer to overcome the Examiner's rejection; (b) failing to disclose material prior art which rendered the claims that issued in the parent `331 patent unpatentable; (c) submitting a false declaration to the PTO; and (d) making material, false and/or misleading statements and representations to the PTO during prosecution of the application.

58. Upon information and belief, as more fully set forth above, applicants and their solicitor committed the aforesaid acts with intent to deceive and/or mislead the PTO.

D. The `295 Patent

59. Roxane and BIC reassert and incorporate herein the averments of ¶¶1-58 as if fully set forth herein.

60. The `295 patent is a continuation of the `912 patent, which in turn is a continuation-in-part of the `331 patent. During prosecution of the `295 patent, applicants and their solicitor filed a terminal disclaimer. Each of the `331, `912 and `295 patents expires on February 5, 2008, the expiration date of the Goldie `341 patent.

61. Euro-Celtique, S.A. filed and prosecuted the application which matured into the '295 patent by and through the individuals named therein as inventors, Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko and Euro-Celtique's patent solicitor. Pursuant to 37 C.F.R. §1.56, all individuals associated with the filing and prosecution of the '295 patent application, including applicants and their solicitor, had an affirmative duty of candor and good faith in dealing with the PTO, which included a duty to disclose to the PTO all information known to these individuals to be material to the patentability of the claims then under consideration.

62. Upon information and belief, as more fully set forth above, the aforesaid individuals violated their duty of candor and good faith to the PTO by, inter alia: (a) filing an improper terminal disclaimer to overcome the Examiner's rejection; (b) failing to disclose material prior art which rendered the claims that issued in the parent '331 patent unpatentable; (c) submitting a false declaration to the PTO; and (d) making material, false and/or misleading statements and representations to the PTO during prosecution of the application.

63. Upon information and belief, as more fully set forth above, applicants and their solicitor committed the aforesaid acts with intent to deceive and/or mislead the PTO.

COUNTERCLAIMS OF ROXANE AND BIC

Counterclaim Plaintiffs Roxane Laboratories, Inc. ("Roxane") and Boehringer Ingelheim Corporation ("BIC") for their Counterclaims against Counterclaim Defendants Purdue Pharma L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc. and The Purdue Pharma company (collectively "Purdue"), allege and aver as follows:

1. This is an action for a declaratory judgment, together with such further relief based thereon as may be necessary or proper, pursuant to the Federal Declaratory

Judgment Act, 28 U.S.C. §§2201, 2202. The basis for the declaratory judgment jurisdiction is, as fully appears below, an actual controversy between Roxane and BIC and Purdue arising under the United States Patent laws, Title 35 of the United States Code. This Court has jurisdiction by virtue of 28 U.S.C. §§1331, 1338(a) and 1367. Venue is proper in this judicial district under 28 U.S.C. §§1391(b) and (c) and is also based on Purdue having brought an action against Roxane and BIC in this District.

2. Roxane is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 1809, Wilson Road, Columbus, Ohio.

3. BIC is a corporation organized and existing under the laws of the State of Nevada, with its principal place of business at 900 Ridgbury Road, Ridgefield, Connecticut.

4. Counterclaim Defendant Purdue Pharma L.P. is a limited partnership organized and existing under the laws of the State of Delaware, having places of business at 100 Connecticut Avenue, Norwalk, Connecticut; and at 444 and 460 Saw Mill River Road, Ardsley, New York. Purdue Pharma is a general partner of The Purdue Pharma Company.

5. Counterclaim Defendant The Purdue Frederick Company is a corporation organized and existing under the laws of the State of New York, having its principal place of business at 100 Connecticut Avenue, Norwalk, Connecticut. Purdue Frederick is a general partner of The Purdue Pharma Company.

6. Counterclaim Defendant The P.F. Laboratories, Inc. is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 700 Union Boulevard, Totowa, New Jersey.

7. Counterclaim Defendant The Purdue Pharma Company is a general partnership organized and existing under the laws of the State of Delaware, having its principal place of business at 100 Connecticut Avenue, Norwalk, Connecticut.

THE PATENTS

8. On November 30, 1993, United States Patent No. 5,266,331 ("the '331 patent") entitled "Controlled Release Oxycodone Compositions," issued to Euro-Celtique, S.A., naming Benjamin Oshlack, Mark Chasin and John J. Minogue as inventors. See Exhibit A, attached hereto. Upon information and belief, Purdue is the owner by assignment of the '331 patent.

9. On August 27, 1996, United States Patent No. 5,549,912 ("the '912 patent") entitled "Controlled Release Oxycodone Compositions" issued to Euro-Celtique, S.A., naming Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko as inventors. See Exhibit B, attached hereto. Purdue has alleged that it is the owner by assignment of the '912 patent.

10. On April 16, 1996, United States Patent No. 5,508,042 ("the '042 patent") entitled "Controlled Release Oxycodone Compositions," issued to Euro-Celtique, S.A., naming Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko as inventors. See Exhibit C, attached hereto. Purdue has alleged that it is the owner by assignment of the '042 patent.

11. On August 12, 1997, United States Patent No. 5,656,295 ("the '295 patent"), entitled "Controlled Release Oxycodone Compositions," issued to Euro-Celtique, S.A. naming Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko as inventors.

See Exhibit D, attached hereto. Purdue has alleged that it is the owner by assignment of the `295 patent.

THE ACTUAL CONTROVERSY

12. On May 18, 1999, Purdue filed an action for alleged patent infringement of the `912, `042 and `295 patents against Roxane, Boehringer Ingelheim GmbH and Boehringer Ingelheim Pharmaceuticals, Inc. On September 28, 1999, Purdue filed an Amended Complaint deleting defendant Boehringer Ingelheim Pharmaceuticals, Inc. and adding BIC as a defendant.

13. An actual and justiciable controversy exists regarding the `912, `042 and `295 patents by virtue of Purdue's Amended Complaint. Furthermore, Roxane and BIC have a reasonable apprehension that they will be sued by Purdue for infringement of the `331 patent because the `331 patent is the parent of the `912, `042 and `295 patents asserted by Purdue in this action, and the `331 patent is directed to claims of comparable scope to those of the `912, `042 and `295 patents. Thus, an actual controversy exists between Purdue and Roxane and BIC as to whether there is any valid and enforceable claim of the `331, `912, `042 and `295 patents that could be infringed by the manufacture, use and/or sale of Roxane's Roxicodone™ SR product and whether Purdue has the legal right to preliminarily and permanently enjoin Roxane from manufacturing, using and selling its Roxicodone™ SR product. Roxane and BIC require an immediate declaration of their rights vis-à-vis Purdue with respect to the `331, `912, `042, and `295 patents.

COUNT I

DECLARATION OF PATENT INVALIDITY

14. This Count is for a declaration that the `331, `912, `042, and `295 patents are invalid.

15. Each and every claim of the `331, `912, `042, and `295 patents is invalid under 35 U.S.C. §101.

16. Each and every claim of the `331, `912, `042, and `295 patents is invalid under 35 U.S.C. §102.

17. Each and every claim of the `331, `912, `042, and `295 patents is invalid under 35 U.S.C. §103.

18. Each and every claim of the `331, `912, `042, and `295 patents is invalid under 35 U.S.C. §112.

COUNT II

DECLARATION OF NONINFRINGEMENT

19. Roxane and BIC reassert and incorporate herein the averments of ¶¶1-18 as if fully set forth here in full.

20. This Count is for a declaration that Roxane's Roxicodone™ SR product does not infringe any claim of the `331, `912, `042, and `295 patents.

21. Roxane and BIC have not infringed, contributed to the infringement of or induced infringement of the `331, `912, `042, and `295 patents.

COUNT III

DECLARATION OF PATENT UNENFORCEABILITY

22. Roxane and BIC reassert and incorporate herein the averments of ¶¶1-21 as if fully set forth here in full.

23. This Count is for a declaration that the `331, `912, `042, and `295 patents are unenforceable because they were procured through inequitable conduct in violation of the patent laws and regulations of the United States Patent and Trademark Office ("PTO").

A. The `331 Patent

24. Euro-Celtique, S.A. filed and prosecuted application Serial No. 800,549 which issued as United States Patent No. 5,266,331 ("the `331 patent") by and through the individuals named therein as inventors, Benjamin Oshlack, Mark Chasin and John J. Minogue, and Euro-Celtique's patent solicitor. Application Serial No. 81,302, which issued as the `912 patent, purports to be a continuation-in-part of Application Serial No. 800,549, which issued as the `331 patent. Application Serial No. 467,584, which issued as the `042 patent, purports to be a division of Application Serial No. 81,302, which in turn is a continuation-in-part of Application Serial No. 800,549, which issued as the `331 patent. Application Serial No. 618,344, which issued as the `295 patent, purports to be a continuation-in-part of Application Serial No. 81,302, which in turn is a continuation-in-part of Serial No. 800,549, which issued as the `331 patent.

25. Pursuant to 37 C.F.R. §1.56, all individuals associated with the filing and prosecution of the `331 patent application, including applicants and their solicitor, had an affirmative duty of candor and good faith in dealing with the PTO, which included a duty to

disclose to the PTO all information known to these individuals to be material to the patentability of the claims then under consideration.

26. Upon information and belief, as is more fully set out below, the aforesaid individuals violated their duty of candor and good faith to the PTO by, inter alia: (a) filing an improper terminal disclaimer to overcome the Examiner's rejection; (b) failing to disclose material prior art which rendered the claims that issued in the `331 patent unpatentable; (c) submitting a false and/or misleading declaration to the PTO; and (d) making material false and/or misleading statements and misrepresentations to the PTO during the prosecution of the application.

27. Upon information and belief and based in part upon the factual allegations set forth below, applicants and their solicitor committed the aforesaid acts with intent to deceive and/or mislead the PTO.

1. **The `331 Patent Prosecution**

a. **The Prior Art**

28. In an April 30, 1992 Office Action during prosecution of the `331 patent application, the Examiner rejected the application under 35 U.S.C. §103 as being unpatentable over Goldie et al. United States Patent No. 4,990,341 ("the Goldie `341 patent") in view of Oshlack United States Patent No. 4,861,598 ("the Oshlack `598 patent"). Both the Goldie `341 and the Oshlack `598 patents, as was the `331 patent, were assigned to Euro-Celtique, S.A. The named inventor of the Oshlack `598 patent is the same named inventor of the `331 patent. The Goldie `341 patent discloses, inter alia, that a hydromorphone-containing composition should have peak plasma levels two to four hours after administration in order to assure at least 12 hours

of pain relief. The specification of the Goldie `341 patent is very similar to the specification of the Goldie `331 patent the most notable difference being that the term oxycodone was substituted for hydromorphone throughout the specification. The Oshlack `598 patent discloses, inter alia, a dosage form containing oxycodone, presenting in vitro dissolution data for oxycodene formulations which satisfy the in vitro dissolution parameters of the `331 patent claims.

29. United States Patent No. 4,844,909, also assigned to Euro-Celtique, S.A., issued on July 4, 1989 to Goldie et al. ("the Goldie `909 patent"). The Goldie `909 patent is cross-referenced at col. 9, lines 63-65 of the `331 patent. The Goldie `909 patent contains the same teaching as the later issued Goldie `341 patent, namely peak plasma levels for hydromorphone between two to four hours after administration.

b. Applicants' October 22, 1992 Response And The Examiner's February 3, 1993 Office Action

30. On October 22, 1992, applicants submitted a response to the April 30, 1992 Office Action in which they argued that the originally presented claims were patentable because they were directed to oxycodone formulations in a dosage range from about 10 mg. to about 40 mg. (a four fold range) which controlled pain for approximately 90% of patients. Applicants argued that this was in sharp contrast to the approximately eight-fold range previously believed required for opioid analgesics to control serious pain in approximately 90% of the patient population.

31. On February 3, 1993, the Examiner issued another Office Action in which he continued to reject the claims of the `331 patent in view of the Goldie `341 patent and Oshlack `598 patent.

c. The Kaiko Declaration

32. On February 25, 1993, applicants' solicitor held an interview with the Examiner. According to the Examiner Interview Summary Record, the solicitor and the Examiner discussed the "nature of dissolution rate with regard to the prior art." The Interview Summary Record noted that applicants would submit a "proposed declaration supporting unobviousness and unexpected results" and that a "[t]erminal disclaimer will be filed."

33. On March 10, 1993, applicants submitted the Declaration of Robert Frances Kaiko, Vice President, clinical researcher for the Purdue Frederick Company, to attempt to overcome the Examiner's rejection dated February 3, 1993. Dr. Kaiko's declaration stated, inter alia, that the teaching in the Goldie `341 patent that the peak plasma level of hydromorphone should occur two to four hours after administration in order to provide a duration of therapeutic effect of at least 12 hours is not predictive of the same relationship for oxycodone. Further, Dr. Kaiko's declaration represents that the in vitro release rates for oxycodone taught in the prior art Oshlack `598 patent would not enable one of ordinary skill in the art to determine that the peak plasma levels of oxycodone should occur in vivo two to four hours after administration, as claimed in the `331 patent application claims.

d. Terminal Disclaimer

34. The February 25, 1993 Examiner Interview Summary Record also states that a terminal disclaimer will be filed.

35. On March 10, 1993, the applicants submitted an Amendment in which they stated that the "Examiner believed applicants were trying to claim the same invention as set forth in the Goldie `341 patent." The applicants further stated "(i)n order to avoid this

possibility, a Terminal Disclaimer is submitted herewith ... disclaiming the terminal portion of any patent to be issued in this case beyond the expiration date of the Goldie ['341] patent." Thus, accompanying the March 10, 1993 Amendment, applicants submitted a Terminal Disclaimer disclaiming the terminal part of any patent granted in the application so that the enforceable term of the '331 patent would not extend beyond the expiration date of the Goldie '341 patent.

36. A Notice of Allowability was issued on June 14, 1993, following the submission of the Amendment, Terminal Disclaimer and Kaiko Declaration on March 10, 1993.

2. **Filing Of An Improper Terminal Disclaimer**

37. The application for the Goldie '341 patent was filed on April 28, 1989, before the filing of the '331 patent application (November 27, 1991), and the Goldie '341 patent issued on February 5, 1991, before the '331 patent (which issued on November 30, 1993). The Goldie '341 patent qualifies as prior art under 35 U.S.C. §§102(a) or (e)/103 and the Examiner's rejection based on the Goldie '341 patent could not have been properly overcome by the filing of a terminal disclaimer.

38. The terminal disclaimer was highly material because the Examiner allowed the '331 patent application claims following the submission of the Terminal Disclaimer.

39. Since a terminal disclaimer could not have removed the Goldie '341 patent as a basis for rejection, and since the Examiner believed that the teachings of the '341 patent rendered the '331 patent application claims unpatentable, it was incumbent upon the applicants and their solicitor to inform the Examiner that a terminal disclaimer would not overcome the substance of the Examiner's rejection. Upon information and belief, applicants and their solicitor filed the terminal disclaimer with intent to deceive and/or mislead the PTO.

3. Failure To Disclose The `909 Patent With An Intent To Deceive And/Or Mislead The Patent Examiner

40. The Goldie `909 patent issued on July 4, 1989 and therefore operates as prior art under 35 U.S.C. §102(b) against the `331 patent. The Goldie `909 patent contains the same teachings as in the later issued Goldie `341 patent. The Goldie `909 patent was not merely cumulative to the Goldie `341 patent given that the former qualified as prior art under 35 U.S.C. §102(b) and therefore could not be antedated by a declaration under 37 C.F.R. §1.131.

41. Applicants and their solicitor failed to disclose the Goldie `909 patent to the PTO. The Goldie `909 patent is highly material since the disclosures in the Goldie `341 patent and Goldie `909 patent are nearly identical and the Examiner's rejection was based on the Goldie `341 patent, a rejection that was overcome by an improper terminal disclaimer. The failure of applicants and their soliciter to call the material teachings of the Goldie `909 patent to the Examiner's attention was a highly material omission which had the effect of deceiving the Examiner into allowing the `331 patent claims based upon a terminal disclaimer which had no effect on the prior art status of the Goldie `909 patent or on the Examiner's rejection based upon the Goldie `341 patent.

42. Upon information and belief, the failure of applicants and their solicitor to disclose the `909 Goldie patent was done with an intent to deceive and/or mislead the PTO.

4. False And Misleading Kaiko Declaration

43. Dr. Kaiko's Declaration submitted during the prosecution of the `331 patent application states that the Oshlack `598 patent's in vitro dissolution rates would not teach one of ordinary skill in the art that the maximum plasma level of the oxycodone formulation should occur in vivo two to four hours after administration as required by the `331 patent claims.

Upon information and belief, Dr. Kaiko's Declaration is false because the in vitro dissolution rates of the `331 patent limitations for the drug oxycodone lead to the required in vivo plasma concentration within two to four hours after administration. As the Oshlack `598 patent at col. 2, lines 48-55 specifically teaches:

> ... a strong correlation has been established between the in vitro dissolution time determined for a dosage form and the in vivo bioavailability. This correlation is so firmly established in the art that dissolution time has become generally descriptive of bioavailability potential for the active component of the particular unit dosage composition.

44. The false statements made in Dr. Kaiko's Declaration set forth in paragraph 44 above were highly material because the Examiner allowed the `331 patent claims following submission of Dr. Kaiko's Declaration.

45. Upon information and belief, Dr. Kaiko submitted the Declaration with intent to deceive and/or mislead the PTO.

5. Misrepresentations During The `331 Patent Prosecution With Intent To Deceive And/Or Mislead The Patent Examiner

46. During prosecution of the application for the `331 patent, applicants and their solicitor made the highly material representation that the oxycodone formulations which have peak plasma levels within two to four hours of administration allow pain to be successfully relieved in 90% of patients with a much narrower range of dosages previously believed possible. See October 22, 1992 Response.

47. The representation by applicants and their solicitor has no support in the `331 patent application, the Kaiko Declaration, or any other part of the prosecution history. The pain relief data in the patent was derived from a single dose, not an "around-the-clock" (i.e.,

steady state) study. See col. 15, lines 23-31. The '331 patent does not state what percentage of patients in this study experienced "acceptable" pain relief, and there is no way to derive this percentage from the data because "acceptable" pain relief is not defined. Nor does the patent compare the level of pain relief provided by the claimed formulations with the level of pain relief provided by any other opioid analgesic. Thus, the representation of applicants and their solicitor is completely unsubstantiated and false.

48. Upon information and belief, the false representation by applicants and their solicitor was made with intent to deceive and/or mislead the PTO.

B. The '912 Patent

49. Roxane and BIC reassert and incorporate herein the averments of ¶¶1-48 as if fully set forth herein.

50. The '912 patent is a continuation-in-part of the '331 patent. During prosecution of the '912 patent, applicants and their solicitor filed a terminal disclaimer with respect to the '912 patent. Both the '912 and '331 patents expire on February 5, 2008, the expiration date of the Goldie '341 patent.

51. Euro-Celtique, S.A. filed and prosecuted the application which matured into the '912 patent by and through the individuals named therein as inventors, Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko and Euro-Celtique's patent solicitors. Pursuant to 37 C.F.R. §1.56, all individuals associated with the filing and prosecution of the '912 patent application, including applicants and their solicitor, had an affirmative duty of candor and good faith in dealing with the PTO, which included a duty to disclose to the PTO all information known to these individuals to be material to the patentability of the claims then under consideration.

52. Upon information and belief, as more fully set forth above, the aforesaid individuals violated their duty of candor and good faith to the PTO by, inter alia; (a) filing an improper terminal disclaimer to overcome the Examiner's rejection; (b) failing to disclose material prior art which rendered the claims that issued in the parent `331 patent unpatentable; (c) submitting a false declaration to the PTO; and (d) making material, false and/or misleading statements and representations to the PTO during prosecution of the application.

53. Upon information and belief, as more fully set forth above, applicants and their solicitor committed the aforesaid acts with intent to deceive and/or mislead the PTO.

C. The `042 Patent

54. Roxane and BIC reassert and incorporate herein the averments of ¶¶1-53 as if fully set forth herein.

55. The `042 patent is a division of the `912 patent, which in turn is a continuation-in-part of the `331 patent. Euro-Celtique, S.A. filed and prosecuted the application which matured into the `042 patent by and through the individuals named therein as inventors, Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko and Euro-Celtique's patent solicitor. Pursuant to 37 C.F.R. §1.56, all individuals associated with the filing and prosecution of the `042 patent application, including applicants and their solicitor, had an affirmative duty of candor and good faith in dealing with the PTO, which included a duty to disclose to the PTO all information known to these individuals to be material to the patentability of the claims then under consideration.

56. Upon information and belief, as more fully set forth above, the aforesaid individuals violated their duty of candor and good faith to the PTO by, inter alia: (a) filing an improper terminal disclaimer to overcome the Examiner's rejection; (b) failing to disclose

material prior art which rendered the claims that issued in the parent `331 patent unpatentable; (c) submitting a false declaration to the PTO; and (d) making material, false and/or misleading statements and representations to the PTO during prosecution of the application.

57. Upon information and belief, as more fully set forth above, applicants and their solicitor committed the aforesaid acts with intent to deceive and/or mislead the PTO.

D. The `295 Patent

58. Roxane and BIC reassert and incorporate herein the averments of ¶¶1-57 as if fully set forth herein.

59. The `295 patent is a continuation of the `912 patent, which in turn is a continuation-in-part of the `331 patent. During prosecution of the `295 patent, applicants and their solicitor filed a terminal disclaimer. Each of the `331, `912 and `295 patents expires on February 5, 2008, the expiration date of the Goldie `341 patent.

60. Euro-Celtique, S.A. filed and prosecuted the application which matured into the `295 patent by and through the individuals named therein as inventors, Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko and Euro-Celtique's patent solicitor. Pursuant to 37 C.F.R. §1.56, all individuals associated with the filing and prosecution of the `295 patent application, including applicants and their solicitor, had an affirmative duty of candor and good faith in dealing with the PTO, which included a duty to disclose to the PTO all information known to these individuals to be material to the patentability of the claims then under consideration.

61. Upon information and belief, as more fully set forth above, the aforesaid individuals violated their duty of candor and good faith to the PTO by, inter alia: (a) filing an improper terminal disclaimer to overcome the Examiner's rejection; (b) failing to disclose

material prior art which rendered the claims that issued in the parent `331 patent unpatentable; (c) submitting a false declaration to the PTO; and (d) making material, false and/or misleading statements and representations to the PTO during prosecution of the application.

62. Upon information and belief, as more fully set forth above, applicants and their solicitor committed the aforesaid acts with intent to deceive and/or mislead the PTO.

RELIEF

WHEREFORE, Roxane and BIC respectfully prays for judgment:

a. that the Amended Complaint against Roxane and BIC be dismissed with prejudice;

b. that the `331, `912, `042 and `295 patents are each invalid, unenforceable and not infringed by Roxane and BIC;

c. that this is an exceptional case and that Roxane and BIC be awarded their reasonable attorney's fees and costs under 35 U.S.C. § 285; and.

d. that the Court grant such other and further relief as it may deem just and proper.

Respectfully submitted,

Dated: October 4, 1999

John F. Sweeney (JS5431)
Joseph A. DeGirolamo (JD5830)
Tony V. Pezzano (TP2058)
Bruce D. Radin (BD7353)
Matthew K. Blackburn (MB7408)
MORGAN & FINNEGAN, L.L.P.
345 Park Avenue
New York, New York 10154-0053
(212) 758-4800
(212) 751-6849 (Fax)

Attorneys For Defendants and Counterclaim Plaintiffs

EXHIBIT 3

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re: OXYCONTIN ANTITRUST LITIGATION	:	04 MDL 1603 (SHS)

MULTIDISTRICT LITIGATION ORDER NO. 2

On Jan. 5, 2004, this Court issued an Opinion and Order holding that Endo Pharmaceuticals Inc. and Endo Pharmaceuticals Holdings Inc. ("Endo") had infringed Oxycontin patents owned by plaintiffs Purdue Pharma, L.P., the Purdue Frederick Company, the P.F. Laboratories, Inc. and the Purdue Pharma Company (collectively, "Purdue"), but that those patents were invalid due to Purdue's inequitable conduct in prosecuting them before the Patent and Trademark Office. Purdue Pharma L.P. v. Endo Pharms. Inc., No 00-Civ.-8029, 01-Civ.-2109, 01-Civ.-8177, 2004 WL 26523 (S.D.N.Y. Jan. 5, 2004). That Order was initially affirmed by the United States Court of Appeals for the Federal Circuit. Purdue Pharma L.P. v. Endo Pharms. Inc., 410 F.3d 690 (Fed. Cir. 2005). Following the affirmance, various plaintiffs filed lawsuits in this Court and around the country alleging that Purdue's conduct in procuring its Oxycontin patents violated federal and state antitrust laws. The Judicial Panel on Multidistrict Litigation established a Multidistrict Litigation ("MDL") in this Court for administration of those actions,[1] and the Court conducted an Initial MDL Conference on January 18, 2006 (the "Initial Conference") to coordinate their progress. Shortly after the Initial Conference,

[1] In addition to the various purchaser actions, actions coordinated in the MDL include Purdue Pharma, L.P., et al. v. Boehringer Ingelheim GmbH, et al., 99-Civ.-3658; Purdue Pharma, L.P., et al. v. Teva Pharmaceuticals USA Inc., et al., 01-Civ.-8507, 01-Civ.-11212, 01-Civ.-2312; Purdue Pharma, L.P., et al. v. Impax Laboratories, Inc., 02-Civ.-2803, 02-Civ.-7659, 02-Civ-8036 (collectively, the "Competitor Litigations").

the Federal Circuit withdrew its earlier affirmance and vacated this Court's holding that Purdue's Oxycontin patents were invalid, remanding the case to this Court for further proceedings consistent with its opinion. Purdue Pharma L.P. v. Endo Pharms. Inc., No. 04-1189, 04-1137, 04-1357, 2006 WL 231480 (Fed. Cir. Feb. 1, 2006). Purdue subsequently moved to stay the MDL proceedings based on the Federal Circuit's decision.

Based on both the Initial Case Management Conference and the Federal Circuit's decision, IT IS HEREBY ORDERED that:

1. Initial Motions for Stay: As determined at the Initial Conference, all motions to stay the actions coordinated under In re Oxycontin Antitrust Litigation, 04-MDL-1603, made by Purdue prior to the Initial Conference are denied.

2. Purdue's Motion for Stay dated February 9, 2006: As a result of the Federal Circuit's decision, Purdue has again moved to stay all activity in this multidistrict litigation pending the Court's determination of the patent claims in Endo on remand from the Federal Circuit. The Court has reviewed Purdue's submissions, as well as the numerous submissions filed in opposition to Purdue's motion, and hereby grants Purdue's Motion for Stay dated Feb. 9, 2006. Because disposition of the antitrust issues will be greatly impacted by the determination on remand of the validity of the underlying patent, the Court declines to entertain the antitrust claims at this time. The Federal Circuit's decision to vacate this Court's patent holding puts the Oxycontin litigation in essentially the same position it was in when the Court initially bifurcated the antitrust and patent claims; for the same reasons that bifurcation was appropriate then, a stay is appropriate now.

3. Direct Purchasers Interim Class Counsel Motion. As determined at the Initial Conference, Plaintiffs Louisiana Wholesale Drug Co. et al.'s Motion for Entry of Case Management Order No. 1 Applicable to Direct Purchaser Plaintiffs is granted only insofar as it seeks consolidation of all direct purchaser actions and appointment of Garwin, Gerstein & Fisher L.L.P., Berger & Montague, P.C. and Boies, Schiller & Flexner L.L.P. as direct purchaser interim co-lead class counsel. The motion is denied in all other respects.

4. Indirect Purchasers Interim Class Counsel Motion. As determined at the Initial Conference, Plaintiffs A.F. of L.-A.G.C. Building Trades Welfare Plan et al.'s Motion to Appoint Interim Class Counsel for End-Payor Plaintiffs and for Consolidation is granted. All end-payor class actions are hereby consolidated, and Lieff, Cabraser, Heimann & Bernstein L.L.LP., Hagens Berman Sobol Shapiro LLP, Miller Faucher and Cafferty, L.L.P., and Labaton Sucharow & Rudoff LLP are appointed indirect purchaser interim co-lead class counsel.

5. Winthrop-University Hospital v. Purdue Pharma L.P., et al., No 04-Civ.-00957. As determined at the Initial Conference, Winthrop shall be a separate case in the MDL. Winthrop's Motion to Appoint Interim Class Counsel dated Dec. 23, 2005 is denied.

6. Balloveras v. The Purdue Pharma Company, et al., No. 04-Civ.-4039. Balloveras's Motion for an Order Appointing the Firm of Harke & Clasby LLP as Interim Class Counsel dated Aug. 11, 2004 is denied.

7. Consolidated Amended Complaints. Direct Purchaser Class Counsel and Indirect Purchaser Class Counsel shall each file a Consolidated Amended Class Action Complaint covering their consolidated actions within 60 days after the stay imposed by this Order is

lifted. All individual direct and indirect purchaser class action complaints filed in the consolidated actions shall be deemed amended by those consolidated amended complaints. All other parties, including those in the Competitor Litigations, submitting amended complaints or counterclaims shall also do so by that date.

8. Purdue Defendants' Motion to Dismiss. Within 30 days after the filing of the consolidated amended complaints and counterclaims, the Purdue defendants shall file their response. If such response is a motion to dismiss, Purdue shall file a memorandum of law in support of no more than 50 pages. All plaintiffs' groups against whom Purdue files a motion to dismiss, including parties in the Competitor Litigations, shall file a joint opposition of no more than 50 pages within 45 days after service of the motion. Any individual plaintiff's group that wishes to file a separate memorandum of law at that time may do so, provided that any separate memoranda of law be no longer than 10 pages. Purdue may file a reply of no more than 20 pages within 14 days after receiving the opposition and memoranda of law.

9. Remand Motions. As determined at the Initial Conference, all pending motions to remand in any of the consolidated actions are hereby dismissed without prejudice. When the stay imposed by this Order is lifted, consolidated briefing on the remand issues shall proceed as follows:

a. *Consolidated Briefing.* Within 10 days of the filing of the indirect purchaser's consolidated amended complaint, all indirect purchaser class plaintiffs that do not join in that complaint and wish to seek a remand to state court shall submit one joint motion for remand of no more than 25 pages. Defendants shall file a response to that motion of no more than 25 pages, within

30 days after service of the motion. Plaintiffs may file one joint reply, with a memorandum of law in support of the reply of no more than 10 pages, within 14 days after receiving Defendants' response.

b. *Case-Specific Remand Issues.* To the extent any plaintiff believes its case presents remand issues not addressed in the consolidated memorandum of law in support of remand, it may file a separate memorandum of law on those issues, no longer than five pages, at the time of the filing of the consolidated motion for remand. Defendants may file a separate response to any such brief of no longer than five pages, within 21 days after service of such case specific memorandum. The individual plaintiffs may file a case-specific reply of no longer than three pages within 13 days after receiving defendants' response.

10. Abbott Laboratories' Motions to Dismiss. At the Initial Conference, the Court determined that it would proceed to a disposition of the various motions to dismiss filed in this litigation by defendants Abbott Laboratories and Abbott Laboratories, Inc. In light of the Federal Circuit's decision vacating this Court's holding as to the validity of Purdue's patent and the stay imposed by this Order, however, it would be imprudent to dispose of those motions at this time. Therefore, the Court hereby dismisses without prejudice Abbott Laboratories and Abbott Laboratories, Inc.'s Motions to Dismiss in Balloveras, et al. v. The Purdue Pharma Company, et al., 04-Civ.-4039; Dennis Deutsch, et al. v. Purdue Pharma Company, et al., 05-Civ.-3827; Carolyn LeMaster, et al. v. Purdue Pharma Company, et al., 04-Civ.-5256; Robert Williams and Clifford Perry v. The Purdue Pharma Company, et al., 04-Civ.-7080; Ashley Kooman, et al. v. The Purdue Pharma Company, et al., 04-Civ.-5450; Roy Charles May, et al. v. The Purdue Pharma

Company, et al., 04-Civ.7119; Archie Pressley, et al. v. The Purdue Pharma Company, et al., 04-Civ.-7115; Danielle Chaballa, et al. v. The Purdue Pharma Co., et al., 05-Civ.-3500; and City of New York v. Purdue Pharma LP, et al., 04-Civ.-3499. The Court also dismisses without prejudice Abbott Laboratories' Consolidated Motion to Dismiss filed dated July 7, 2005 as to Arkansas Carpenters' Health & Welfare Fund, et al. v. Purdue Pharma LP, et al., 04-Civ.-0196; Painters District Council No. 30 Health and Welfare Fund, et al. v. Purdue Pharma LP, et al., 04-Civ.-2078; Paper, Allied-Industrial, Chemical and Energy Workers International Union, AFL-CIO, CLC, et al. v. Purdue Pharma LP, et al., 04-Civ.-0315; The County of Suffolk, New York, et al. v. Purdue Pharma LP, et al., 04-Civ.0651; Louisiana Health Service Indemnity Company d/b/a/ Blue Cross Blue Shield of Louisiana, et al. v. Purdue Pharma LP, et al., 04-Civ.-1212; United Federation of Teachers Welfare Fund, et al. v. Purdue Pharma LP, et al., 04-Civ.-1808; Leanne Whittle, et al. v. Purdue Pharma LP, et al., 04-Civ.-2089; Vista Healthplan, Inc. et al. v. Purdue Pharma LP, et al., 04-Civ.-2179; Local 1199 National Benefit Fund for Health and Human Services Employees, et al. v. Purdue Pharma LP, et al., 04-Civ.-3093. Abbott should refile its motions, if appropriate, when the stay imposed by this Order is lifted.

Dated: New York, New York
March 30, 2006

SO ORDERED:

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

EXIBIT 4

Timothy C. Hester
Mark H. Lynch
Neil K. Roman
Christopher N. Sipes
COVINGTON & BURLING
1201 Pennsylvania Avenue, N.W.
Washington, D.C. 20004-2401
(202) 662-6000

C. William Phillips
Michael C. Nicholson
COVINGTON & BURLING
1330 Avenue of the Americas
New York, New York 10019-5400
(212) 841-1000

Counsel for Purdue Defendants

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In re:	:	
OXYCONTIN ANTITRUST LITIGATION	:	04-MDL-1603 (SHS)
This Document Relates To: All Cases	:	Electronically Filed
PURDUE PHARMA, L.P., *et al.*,	:	
Plaintiffs and Counterclaim Defendants,	:	Civ. No. 00-CV-8029 (SHS)
v.	:	
ENDO PHARMACEUTICALS, INC. and ENDO PHARMACEUTICALS HOLDINGS INC.,	:	
Defendants and Counterclaim Plaintiffs.	:	

MEMORANDUM OF LAW IN SUPPORT OF PURDUE'S MOTION FOR STAY

On February 1, 2006, the Federal Circuit issued a decision granting rehearing in the appeal in *Purdue Pharma L.P. v. Endo Pharms. Inc.*, Nos. 04-1189, 04-1347, 04-1357, which vacated this Court's prior finding of inequitable conduct and directed further consideration of that issue.

In light of the Federal Circuit ruling, Purdue hereby moves for a stay of proceedings in these antitrust cases pending the Court's decision on the inequitable conduct issue. A stay is warranted because the Court's further decision on the issue of inequitable conduct could moot these antitrust cases. It would not be a sound use of the Court's resources, or the resources of the parties, to forge ahead with litigation on these antitrust claims before a decision has been reached in the underlying patent litigation on which those claims are based.

During the initial status conference and organization hearing on January 18, the Court decided to proceed with these antitrust cases because the Federal Circuit had affirmed the *Endo* decision and rehearing had been pending without decision for a half-year. *See* Tr. at 5-6. With the prior inequitable conduct finding now vacated, that reason for proceeding no longer exists -- the Federal Circuit has reconsidered and has now set aside the core factual basis on which the plaintiffs in these many cases have staked their antitrust claims.

Coming out of the January 18 hearing, the first steps to be taken in these antitrust cases were (a) Purdue's production of initial

discovery, (b) the filing of consolidated complaints, (c) consideration of the motion for judgment to be filed by Purdue, and (d) consideration of the pending remand motions through the filing of consolidated briefs.

There is no basis to proceed with the first three of these steps -- initial discovery, consolidated complaints and the filing of Purdue's motion for judgment -- until the underlying patent case has been resolved. Among other factors, the factual premise on which the pending complaints are based has been vacated by the Federal Circuit.

As to the fourth step, the Court may appropriately stay resolution of these remand issues along with the other matters. A decision to stay is not a decision on the merits and thus may be made before a ruling on remand. *See, e.g., Galvan v. Fed. Prison Indus., Inc.*, 199 F.3d 461, 463 (D.C. Cir. 1999) ("There is an array of non-merits questions that we may decide in any order" before deciding subject matter jurisdiction.).[1] Furthermore, these removed complaints are premised on allegations -- based on this Court's prior

---

[1] *See also, e.g., Ruhrgas AG v. Marathon Oil Co.*, 526 U.S. 574, 584 (1999) ("subject-matter jurisdiction necessarily precedes a ruling on the merits" but "the same principle does not dictate a sequencing . . . on non-merits grounds . . . before finding subject matter jurisdiction") (quotation omitted); *Spargo v. N.Y. State Comm'n*, 351 F.3d 65, 74 (2d Cir. 2003) ("while *Steel Co.* may bar the exercise of hypothetical jurisdiction to dismiss on the merits of a claim, *Ruhrgas* reaffirms the inherent flexibility that federal courts exercise 'to choose among threshold grounds' for disposing of a case without reaching the merits.") (footnote and citation omitted); *In re Ivy*, 901 F.2d 7, 9 (2d Cir. 1990) (federal court "has jurisdiction to transfer a case in which a jurisdictional objection is pending").

holding of inequitable conduct -- that are no longer operative given the Federal Circuit's ruling.

In effect, the Federal Circuit's decision has returned matters to the status quo that existed before this Court's decision in January 2004. Pending the Court's decision in the patent case, the Court had stayed the antitrust claims filed by Endo and Teva. The same reasoning that led previously to stays of the antitrust counterclaims pending resolution of the *Endo* patent litigation should now apply to all of these antitrust claims -- both the counterclaims and the original complaints. As to all of these antitrust claims, the patent issues should be finally decided before undertaking the burdens and cost of complex litigation over antitrust claims that could be mooted by the Court's decision on the patent issues.

Accordingly, Purdue submits that the Court should stay any further proceedings in this docket pending a further decision by this Court in the *Endo* patent litigation. The antitrust claims should not proceed until resolution of the underlying patent litigation on which these claims are based.

Respectfully submitted,

/s/Timothy C. Hester

C. William Phillips (CP 3300)
Michael C. Nicholson (MN 3331)
COVINGTON & BURLING
1330 Avenue of the Americas
New York, NY 10019
(212) 841-1000
(646) 441-9031 (facsimile)

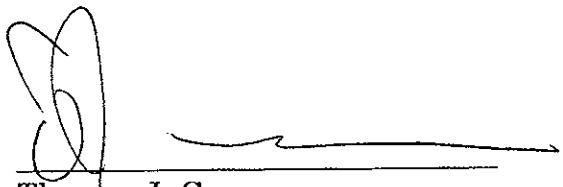
Timothy C. Hester (TH 0676)
Mark H. Lynch (ML 8703)
Christopher N. Sipes (CS 0294)
Neil K. Roman (NR 6012)
COVINGTON & BURLING
1201 Pennsylvania Avenue, NW
Washington, DC 20004-2401
(202) 662-6000
(202) 662-6291 (facsimile)

February 9, 2006

Counsel for Purdue Defendants

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a copy of the foregoing **Purdue's Motion for Stay** was served upon the attorneys of record in this proceeding on February 9, 2006, by filing the same electronically through the Electronic Case Filing ("ECF") system of the U.S. District Court for the Southern District of New York, which system electronically provides notice of the filing and access to the filing to all counsel of record who are admitted to the Court and have registered for notification of filing through the ECF system.



Thomas J. Cosgrove

EXHIBIT 5

LEXSEE 2006 U.S.DIST. LEXIS 2176

CHIP-MENDER, INC. Plaintiff, v. THE SHERWIN-WILLIAMS COMPANY, Defendant. AND RELATED COUNTERCLAIMS.

No. C 05-3465 PJH

UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF CALIFORNIA

2006 U.S. Dist. LEXIS 2176; 2006-1 Trade Cas. (CCH) P75,148

January 3, 2006, Decided
January 3, 2006, Filed

SUBSEQUENT HISTORY: Patent interpreted by *Chip-Mender, Inc. v. Sherwin-Williams Co., 2006 U.S. Dist. LEXIS 77487 (N.D. Cal., Oct. 16, 2006)*

CASE SUMMARY:

PROCEDURAL POSTURE: In a patent infringement action, counterclaimant manufacturer filed claims against counterdefendants, a patent owner and an inventor, alleging, inter alia, violations of *15 U.S.C.S. § 2* of the Sherman Antitrust Act for Walker Process fraud and bad-faith litigation. Counterdefendants filed a motion to dismiss certain counterclaims.

OVERVIEW: The manufacturer launched a touch-up paint pen that was similar to the owner's product. Pursuant to Fed. R. Civ. P. 12(b)(6), the court dismissed the antitrust claims under § 2 of the Sherman Antitrust Act. To state a claim for a violation of § 2, the manufacturer had to show, inter alia, a dangerous probability of success of monopolization and an antitrust injury, which was an injury to the market or competition in general. The potential monopoly would be realized only if the patents were declared valid, at which point the owner would not be liable for restraining competition. The manufacturer's attorneys fees did not constitute an antitrust injury that stifled competition. Thus, the manufacturer failed to show an antitrust violation. Additionally, counterdefendants' failure to disclose details of a reference about the construction of the pen did not constitute knowing and willful fraud to obtain the patents, and no allegation showed that the owner intended to enforce the patents to monopolize the relevant market. Thus the manufacturer failed to allege elements of Walker Process fraud or of bad faith enforcement.

OUTCOME: The court dismissed with prejudice the counterclaims against the inventor and dismissed with leave to amend the antitrust counterclaims against the patent owner. The court granted the motion to bifurcate the counterclaims and to stay discovery.

COUNSEL: [*1] For Chip-Mender Inc., Plaintiff: Esha Bandyopadhyay, Kenneth B. Wilson, Stefani E. Shanberg, Perkins Coie LLP, San Francisco, CA.

For The Sherwin-Williams Company, Defendant: Peter Nels Larson, Jones Day, San Francisco, CA; Anthony Thomas Jacono, Regan Joseph Fay, Jones Day, Cleveland, OH.

For The Sherwin-Williams Company, Counter-claimant: Peter Nels Larson, Jones Day, San Francisco, CA.

JUDGES: PHYLLIS J. HAMILTON, United States District Judge.

OPINION BY: PHYLLIS J. HAMILTON

OPINION:

ORDER GRANTING MOTION TO DISMISS COUNTERCLAIMS

The motion of plaintiff and counterdefendant Chip-Mender, Inc. ("Chip-Mender") and counterdefendant Timothy M. Russo ("Russo") to dismiss the third through seventh counterclaims, and alternative motion to bifurcate the counterclaims and stay discovery, came on for hearing before this court on December 7, 2005. Chip-Mender and Russo appeared by their counsel Kenneth B. Wilson and Stefani E. Shanberg, and defendant and counterclaimant Sherwin-Williams Company ("Sherwin Williams") appeared by its counsel Peter N. Larson and

Regan J. Fay. Having read the parties' papers and carefully considered their arguments and the relevant legal authority, and good cause [*2] appearing, the court hereby GRANTS the motion as follows and for the reasons stated at the hearing.

INTRODUCTION

This is a patent infringement action. Chip-Mender sells automotive paint touch-up pens, and owns two patents for a "Paint Applicator System" -- *U.S. Patent No. 6,254,299*, and *U.S. Patent No. 6,283,663* ("the Chip-Mender patents") -- both issued in 2001. Russo, the founder and president of Chip-Mender, is listed as inventor on both patents.

Sherwin Williams competes with Chip-Mender, and manufactures and sells the "Dupli-Color Scratch Fix 2-in-1 Pen" (the "Dupli-Color Pen"). On May 22, 2003, Chip-Mender wrote to Sherwin Williams, stating that Chip-Mender owned the *299 patent* and the *663 patent*, and offered Sherwin Williams a license for the patented technology. Sherwin Williams did not respond, and launched its Dupli-Color Pen in October 2003.

On April 8, 2005, Chip-Mender wrote Sherwin Williams to inform it of the alleged infringement, and again offered to license the Chip-Mender technology. On September 2, 2005, Sherwin Williams advised Chip-Mender that it was not interested in licensing the technology, claiming that the Chip-Mender patents were invalid in view [*3] of the prior art. Sherwin Williams threatened to seek sanctions pursuant to *Federal Rule of Civil Procedure 11* if Chip-Mender pursued its claim of patent infringement, and also indicated that it would bring antitrust counterclaims against Chip-Mender.

Chip-Mender filed this action on August 26, 2005, alleging that Sherwin-Williams' Dupli-Color Pen infringes Chip-Mender's patents. On September 7, 2005, Chip-Mender effected service of the patent infringement complaint.

On September 27, 2005, Sherwin Williams filed counterclaims against Chip-Mender and Russo, seeking 1) a declaratory judgment for invalidity, non-infringement, and unenforceability of the *299 patent*; and 2) a declaratory judgment for invalidity, non-infringement, and unenforceability of *663 patent*; and alleging 3) violation of *§ 2* of the Sherman Act (Walker-Process fraud); 4) violation of *§ 2* of the Sherman Act (bad faith litigation); 5) violation of *California Business & Professions Code § 17200*; 6) violation of *California Business & Professions Code § 17500*; and 7) violation of *Ohio Revised Code § 4165, et seq.* [*4]

Sherwin Williams alleges, among other things, that Chip-Mender and Russo fraudulently obtained two United States patents for a known paint applicator, by concealing material information that the paint applicator was actually a public domain correction pen (the "Pentel pocket correction pen") readily available to the general public at office supply stores. Sherwin Williams claims that Chip-Mender and Russo concealed critical pieces of information about the prior art during the prosecution of the patents-in-suit.

Chip-Mender and Russo now move for an order dismissing the third through seventh counterclaims, arguing that they fail to state a claim and cannot be amended to state a claim. They also seek an order dismissing the first and second counterclaims for declaratory relief, as against Russo. In the alternative, they seek an order bifurcating and staying the counterclaims pending the resolution of Chip-Mender's claims against Sherwin Williams.

DISCUSSION

A. Legal Standard

A court should dismiss under *Federal Rule of Civil Procedure 12(b)(6)* for failure to state a claim only where it appears beyond doubt that plaintiff can prove [*5] no set of facts in support of the claim which would entitle the plaintiff to relief. *Conley v. Gibson, 355 U.S. 41, 45-46, 78 S. Ct. 99, 2 L. Ed. 2d 80 (1957)*; *Williamson v. Gen'l Dynamics Corp., 208 F.3d 1144, 1149 (9th Cir.)*, cert. denied. *531 U.S. 929, 121 S. Ct. 309, 148 L. Ed. 2d 247 (2000)*. Review is limited to the contents of the complaint. *Allarcom Pay Television, Ltd. v. Gen. Instrument Corp., 69 F.3d 381, 385 (9th Cir. 1995)*. All allegations of material fact are taken as true and construed in the light most favorable to the nonmoving party. *Smith v. Jackson, 84 F.3d 1213, 1217 (9th Cir. 1996)*.

Motions to dismiss for failure to state a claim are disfavored, see *Gilligan v. Jamco Dev. Corp., 108 F.3d 246, 249 (9th Cir. 1997)*, and *12(b)(6)* dismissals are proper only in "extraordinary" cases. See *United States v. City of Redwood City, 640 F.2d 963, 966 (9th Cir. 1981)*. In dismissing for failure to state a claim, "a district court should grant leave to amend even if no request to amend the pleadings was made, unless it determines that the pleading could not possibly be cured by the allegation of other facts." *Doe v. United States, 58 F.3d 494, 497 (9th Cir. 1995)* [*6] (citations omitted).

B. Motion to Dismiss

Chip-Mender and Russo move for an order dismissing the first and second counterclaims for declaratory relief, as against Russo. They also seek an order dismissing the third, fourth, fifth, sixth, and seventh counterclaims, arguing that each fails to state a claim and cannot be amended to state a claim.

1. Declaratory relief counterclaims against Russo

Chip-Mender and Russo seek dismissal of the first and second counterclaims as to Russo, for failure to state a claim. They also argue that there can be no case or controversy as to Russo because he is not the owner of the Chip-Mender patents, and is not a party to the underlying patent infringement suit. Sherwin Williams did not respond to this argument in its opposition brief.

A case must "present a case or controversy under Article III, § 2, of the Constitution" in order to be subject to federal jurisdiction. *Spencer v. Kemna, 523 U.S. 1, 7, 118 S. Ct. 978, 140 L. Ed. 2d 43 (1998)*. The plaintiff has the burden of proving jurisdiction. *Tosco Corp. v. Communities for a Better Environment, 236 F.3d 495, 499 (9th Cir. 2001)*.

Under the Declaratory Judgment Act, "any court of the United [*7] States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought." *28 U.S.C. § 2201*. For a district court to have jurisdiction over a patent declaratory judgment matter, "[t] here must be both (1) an explicit threat or other action by the patentee, which creates a reasonable apprehension on the part of the declaratory plaintiff that it will face an infringement suit, and (2) present activity which could constitute infringement or concrete steps taken with the intent to conduct such activity." *Sierra Applied Sciences. Inc. v. Advanced Energy Indus., Inc., 363 F.3d 1361, 1373 (Fed. Cir. 2004)* (citation and quotation omitted).

Here, Chip-Mender, as the owner of the patents-in-suit, filed the underlying action for patent infringement. Sherwin Williams cannot allege that a case or controversy exists with regard to Russo, in connection with the Chip-Mender patents, because Russo is not the patent owner and lacks standing to sue Sherwin Williams. See *Paradise Creations, Inc. v. UV Sales, Inc., 315 F.3d 1304, 1309 (Fed. Cir. 2003)*. [*8] Accordingly, the court finds that the first and second counterclaims must be DISMISSED as to Russo, for lack of subject matter jurisdiction. n1

n1 The court also finds that the first and second counterclaims fail to state a claim against Russo, as Russo is not the patent owner.

2. Sherman Act counterclaims

In the third and fourth counterclaims, Sherwin Williams alleges attempted monopolization, in violation of *§ 2* of the Sherman Antitrust Act, *15 U.S.C. § 2*. In the third counterclaim, Sherwin Williams alleges "Walker Process fraud," and in the fourth counterclaim, Sherwin Williams alleges "bad faith litigation." Chip-Mender and Russo argue that Sherwin Williams has not stated facts to support the elements necessary for these claims.

a. attempted monopolization

Monopolization and attempted monopolization are prohibited by the Sherman Antitrust Act. *15 U.S.C. § 2*. To state a claim for attempted monopolization, a plaintiff must allege: (1) specific intent to control [*9] prices or destroy competition; (2) predatory or anticompetitive conduct to accomplish the monopolization; (3) a dangerous probability of success; and (4) causal antitrust injury. *Cost Mgmt. Servs. v. Washington Natural Gas Co., 99 F.3d 937, 949-50 (9th Cir. 1996)*: see also *McGlinchy v. Shell Chem. Co., 845 F.2d 802, 811 (9th Cir. 1988)*.

In general, the procurement of a patent does not constitute an antitrust violation. *FMC Corp. v. Manitowoc Co., 835 F.2d 1411, 1418 and n.16 (Fed. Cir. 1987)*. Nor is it a violation of the Sherman Act to bring a patent infringement action in good faith, even if it is ultimately determined in the litigation that the patent-in-suit is invalid. *Atari Games Corp. v. Nintendo of America, Inc., 897 F.2d 1572, 1576 (Fed. Cir. 1990)*.

The two exceptions to these general propositions are that a defendant may assert an antitrust claim where the patent was procured by fraud on the Patent Office, *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp., 382 U.S. 172, 86 S. Ct. 347, 15 L. Ed. 2d 247 (1965)*, and where it is shown by clear and convincing evidence that the patent holder is enforcing the patent in bad [*10] faith, *Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986, 993 (9th Cir. 1979)*. In an action asserting either of these exceptions, all the necessary elements of an antitrust claim must be established, in addition to the alleged fraud and prior knowledge of invalidity. *Prof. Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc., 508 U.S. 49, 60, 113 S. Ct. 1920, 123 L. Ed. 2d 611 (1993)*.

Chip-Mender and Russo argue that Sherwin Williams fails to meet these pleading standards because it has not alleged facts showing two of the four elements required for a claim of attempted monopolization -- dangerous probability of achieving monopoly power, and antitrust injury.

i. dangerous probability of achieving monopoly power

The third element in a claim for attempted monopolization is dangerous probability of achieving monopoly power, which includes allegations regarding the market power held by the antitrust defendant. See *Cost Management Services, 99 F.3d at 950 n. 15*. Monopoly power is "the power to control prices or exclude competition." *United States v. Grinnell Corp., 384 U.S. 563, 571, 86 S.*

Ct. 1698, 16 L. Ed. 2d 778 (1966) (quoting *United States v. E.I. du Pont de Nemours & Co., 351 U.S. 377, 391, 76 S. Ct. 994, 100 L. Ed. 1264 (1956))*. [*11]

Chip-Mender and Russo argue that Sherwin Williams has alleged no facts to support this element. They also contend that Sherwin Williams' allegations of market power are logically flawed, as they depend on the assertion that, on the one hand, Chip-Mender's patents were fraudulently procured (and are invalid), and on the other hand, that the patents are valid and enforceable. They note in particular that Sherwin Williams alleges that Chip-Mender will achieve market power if, and only if, it prevails on its patent infringement claim against Sherwin Williams. However, as Chip-Mender and Russo point out, if Chip-Mender prevails on its infringement claim, that will necessitate a finding that Chip-Mender's patents are valid and enforceable, and its share of the relevant market will then be irrelevant.

Chip-Mender and Russo also contend that the allegation of monopoly power is deficient because Sherwin Williams fails to plead facts showing that Chip-Mender and Russo own a dominant share of the relevant market, that there are significant barriers to entry, and that existing competitors lack the capacity to increase their output in the short run. In support, they cite to the Ninth Circuit's [*12] decision in *Rebel Oil Co. v. Atlantic Richfield Co., 51 F.3d 1421, 1434 (9th Cir. 1995)*.

In opposition, Sherwin Williams contends that it has alleged that there is a dangerous probability that Chip-Mender and Russo will, if successful in their anticompetitive conduct, achieve monopoly power in the relevant market. Sherwin Williams argues, in essence, that it has adequately alleged this element of the attempted monopolization counterclaim because the counterclaims mention the phrase "dangerous probability of success," and allege that "there is a dangerous likelihood that Chip-Mender and Mr. Russo will succeed in their efforts to monopolize the relevant market." Sherwin Williams asserts that the filing of the underlying patent infringement suit constitutes an "attempted monopolization" because it was an "attempt" to assert an invalid patent in bad faith.

Sherwin Williams also argues that the elements of "barriers to entry" and "capacity of competitors" are not elements that must be pled, but rather factors to be considered on summary judgment or at trial, in order to determine whether a party has proved market power. They note that the Ninth Circuit case cited by Chip-Mender-Rebel [*13] Oil -- was a summary judgment case, in which the court was looking at whether the plaintiff had established the monopoly power factor.

The court agrees with Sherwin Williams that the Rebel Oil factors are not "elements" of a claim of attempted monopolization, which are stated as in*Cost Management Services*, cited above. In the court's view, *Rebel Oil* provides an indication of what facts must be established to prove the element of "dangerous probability of achieving monopoly power." The court nonetheless finds that Sherwin Williams has not alleged facts showing a dangerous probability of success because the only potential for monopoly stated in the counterclaim is the potential that will be realized if Chip-Mender prevails in its patent infringement suit. At that point, however, there will be no question of antitrust, because a patent-holder in possession of a valid patent cannot be liable for restraining competition. *FMC Corp., 835 F.2d at 1418 &* n.16.

ii. antitrust injury

Chip-Mender and Russo argue that Sherwin Williams has not attempted to allege antitrust injury. To state a claim under either *section 1* or *section 2* of the Sherman Act, a plaintiff [*14] must allege antitrust injury -- that is, "injury to the market or to competition in general, not merely injury to individuals or individual firms." *McGlinchy, 845 F.2d at 812*.

Antitrust injury is "injury of the type the antitrust laws were intended to prevent and that flows from that which makes the [antitrust] defendants' acts unlawful." *Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489, 97 S. Ct. 690, 50 L. Ed. 2d 701 (1977)*. An antitrust plaintiff must allege more than simply that the defendant's wrongful behavior directly damaged the plaintiff's business-the plaintiff must also allege that the accused behavior stifled competition. *Unitherm Food Sys., Inc. v. Swift Eckrich, Inc., 375 F.3d 1341, 1361 (Fed. Cir. 2004)*.

Sherwin Williams alleges that it has been injured "to the extent of [its] expenses in countering Chip-Mender's and Mr. Russo's assertion of the patents-in-suit against Sherwin Williams, and in such other ways as the proofs may show." In other words, Sherwin Williams' only claimed injury arises from its obligation to compensate its attorneys for defending it against Chip-Mender's patent infringement suit.

A claim of injury in the [*15] form of attorneys' fees in defending against a patent infringement suit is not an injury to "competition" or the type of injury that the antitrust laws were designed to protect against, but is rather a purely individual economic injury to Sherwin Williams that has no effect on competition in the relevant market. Such allegations are insufficient to state a claim under the Sherman Act. See *Les Shockley Racing. Inc. v. Nat'l Hot Rod Ass'n, 884 F.2d 504, 508 (9th Cir. 1989)* (although proof of plaintiffs' allegations of market exclusion and resulting loss of income would establish harm to

their business interests, such proof would not show injury to competition in the market as a whole).

Sherwin Williams maintains that its position is supported by Handgards, where the Ninth Circuit stated that "[i] n a suit alleging antitrust injury based on a bad faith prosecution theory, it is obvious that the costs incurred in defense of the prior patent infringement suit are an injury which flows' from the antitrust wrong." *Handgards, 601 F.2d at 997.*

The court finds, however, that Sherwin Williams has not adequately alleged antitrust injury. An antitrust [*16] plaintiff must allege more than that the defendant's wrongful behavior directly damaged its business -- it must also allege that the accused behavior stifled competition. The only injury alleged here by Sherwin Williams is its own payment of its attorneys' fees in defending against Chip-Mender's patent claims.

The Ninth Circuit's decision in Handgards does not support Sherwin Williams' claim that a litigant's attorneys' fees are sufficient -- standing alone -- to constitute injury. The court did not discuss attorneys' fees in the context of what constitutes an antitrust injury, but rather in connection with the question of the trial judge's charge to the jury regarding the types of damages the plaintiff might obtain. See *Handgards, 601 F.2d at 997.* While attorneys' fees may be recoverable as damages in a bad-faith prosecution suit, the plaintiff still needs to prove an "antitrust injury," as that term has been defined by the Supreme Court.

b. claim of Walker Process fraud

Chip-Mender and Russo also contend that Sherwin Williams fails to plead the facts necessary to support the Walker Process counterclaim. A patentee who brings an infringement action my be [*17] subject to antitrust liability for the anti-competitive effects of that suit if the alleged infringer (the antitrust plaintiff) proves that the asserted patent was obtained through knowing and willful fraud. In Walker Process, the Supreme Court held that in order to strip a patentee of its exemption from the antitrust laws (because a patent is a sort of license for a monopoly), an antitrust plaintiff is first required to prove that the patentee obtained the patent "by knowingly and willfully misrepresenting facts" to the PTO. *Walker Process, 382 U.S. at 177.*

In order to state a counterclaim for*Walker Process* fraud in a patent infringement action, a counterclaimant must allege attempted enforcement of the patent, that the patent was issued because of fraud upon the PTO, that the attempted enforcement threatened to lessen competition in a relevant antitrust market, and that the counterclaimant suffered antitrust damages, as well as all other elements of attempted monopolization. *Unitherm, 375 F.3d at 1355.* Fraud must be alleged in conformance with *Federal Rule of Civil Procedure 9(b). Nobelpharma AB v. Implant Innovations, Inc., 141 F.3d 1059, 1069-70 & n.7 (Fed. Cir. 1998)* [*18] (representation of a material fact, falsity of the representation, intent to deceive, justifiable reliance, and injury to the party deceived). In the context of a patent action, this translates as 1) a false representation, 2) made with intent to deceive the patent examiner, 3) on which the examiner justifiably relied in granting the patent, and 4) but for which misrepresentation or deliberate omission the patent would not have been granted. See *C.R. Bard. Inc. v. M3 Sys., Inc., 157 F.3d 1340, 1364 (Fed. Cir. 1998).*

Chip-Mender and Russo argue that Sherwin Williams' sole basis for its claim of fraud is the assertion that although Russo disclosed the Pentel pocket correction pen as prior art, he failed to disclose the construction of the pen, the viscosity of the liquid in the pen, and the "fact" that the liquid in the pen constituted "paint." Chip-Mender and Russo assert that there is no legal authority supporting the proposition that it is fraudulent to fail to specifically disclose certain details of a reference, when the reference itself has been disclosed to the Patent Office. They also argue that Sherwin Williams has failed to sufficiently plead intent to deceive, [*19] since the allegations suggest simply that Chip-Mender's actions constituted gross negligence.

Sherwin Williams responds that it has properly pled Walker Process fraud, by alleging that Chip-Mender and Russo failed to advise the PTO that the claimed invention was identical to the Pentel pocket correction pen, and that Russo knew that if he disclosed this information, the patent would not issue. Sherwin Williams contends that Russo disclosed the design patent for the Pentel pocket correction pen, but did not disclose its inner "construction," the viscosity of the liquid in the pen, or that the liquid constituted "paint."

The court finds that the motion to dismiss the third counterclaim must be GRANTED. Sherwin Williams has not properly pled the element of intent because it has not alleged that Chip-Mender and Russo are attempting to enforce a patent that has been procured by knowing and willful fraud, and that they have used their fraudulently obtained patent to restrain competition. In order to state facts showing that the alleged fraud was "knowing" and "willful," Sherwin Williams must allege more than inequitable conduct. *Nobelpharma, 141 F.3d at 1069.*

Sherwin [*20] Williams does not allege that Chip-Mender and Russo failed to disclose a specific reference, or that they obtained the patents-in-suit by concealing a reference. n2 Sherwin Williams has provided no support for the proposition that a patent holder who discloses a reference to the PTO can be found liable for Walker

Process fraud solely based on an alleged failure to bring every detail of the disclosed reference to the examiner's attention. In addition, as previously stated, Sherwin Williams fails to allege facts supporting two of the four elements of a claim of attempted monopolization.

n2 As noted above, Sherwin Williams alleges that Chip-Mender and Russo disclosed the Pentel design patent-a patent for the outer case or shape of the product-but failed to disclose "highly material information" regarding the inner "construction" of the Pentel pen. Sherwin Williams does not, however, plead with specificity the particular prior art that was allegedly not disclosed.

c. claim of bad-faith enforcement of patent [*21]

Chip-Mender and Russo contend that Sherwin Williams fails to plead the elements of the claim of bad-faith enforcement of a patent. To state a claim for a § 2 violation based on the bad faith enforcement of a patent Sherwin Williams must allege that (1) Chip-Mender had actual knowledge that certain patents were invalid; (2) Chip-Mender attempted to enforce these patents with the specific intent to monopolize, attempt to monopolize, or combine with others to monopolize, the relevant market; and (3) Chip-Mender has succeeded in gaining monopoly power, or that a dangerous probability of success exists. *Handgards, 601 F.2d at 994-96.*

Chip-Mender and Russo argue that a patentee's infringement suit is presumed to have been brought in good faith, and that to properly plead a claim for bad-faith litigation under *§ 2*, Sherwin Williams must satisfy the two-part criteria for a claim of sham litigation, by alleging that the patent infringement suit is objectively meritless, such that no reasonable litigant could expect success on the merits; and this baseless lawsuit conceals an attempt to interfere directly with the business relationships of a competitor.

Chip-Mender and [*22] Russo note that Sherwin Williams alleges that Chip-Mender will presumably achieve market power if it is successful in enforcing its fraudulently obtained patent-the same allegation as discussed above under "probability of achieving monopoly power." They assert that these allegations show that the sham litigation claim is predicated on the outcome of the infringement claims on the merits. They assert that there is no allegation that Chip-Mender will somehow achieve monopoly power if it is unsuccessful in the underlying litigation. Thus, they argue, because Sherwin Williams has not alleged the use of the litigation process -- as opposed to the outcome -- as a competitive weapon, they cannot state a claim for attempted monopolization through bad-faith or sham litigation. n3

n3 Chip-Mender and Russo also contend that sham litigation claims implicate the right to petition governmental bodies under Noerr-Pennington. See *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 81 S. Ct. 523, 5 L. Ed. 2d 464 (1961)*; *United Mine Workers v. Pennington, 381 U.S. 657, 85 S. Ct. 1585, 14 L. Ed. 2d 626 (1965).* They assert that sham litigation claims are subject to a heightened pleading standard, although they do not seek dismissal of the fourth counterclaim on the basis that the facts were not pled with sufficient specificity. The court notes that the Ninth Circuit recently clarified this issue, ruling in *Empress LLC v. City and County of San Francisco, 419 F.3d 1052 (9th Cir. 2005)*, a case involving the application of the Noerr-Pennington doctrine, that the notice pleading standard applies unless the Federal Rules of Civil Procedure require otherwise. *Id. at 1055-56.*

[*23]

In opposition, Sherwin Williams argues that it has properly pled "sham litigation" because it alleged that Chip-Mender and Russo knew the patent was invalid when Chip-Mender filed the patent infringement suit. In the fourth counterclaim, Sherwin Williams alleges that the illustrations in the patents-in-suit are nothing more than a slight cosmetic variation of the applicator depicted in *U.S. Patent No. 4,812,071*, one of the patents cited as prior art in the application for Chip-Mender's *299 patent.*

The court finds that the motion to dismiss the fourth counterclaim for bad-faith litigation must be GRANTED. Sherwin Williams has not alleged the use of the litigation process as a competitive weapon, and also, as discussed above, has not alleged the necessary elements for an antitrust violation.

d. antitrust claims as to Russo

Finally, Chip-Mender and Russo argue that the antitrust counterclaims must be dismissed as to Russo. They argue that the Supreme Court and the Federal Circuit require the enforcement or assertion of the patent as an element necessary to establish antitrust liability in connection with a patent claim. Here, they contend, Russo is not the owner of the patents-in-suit, [*24] and therefore cannot be liable under the antitrust counterclaims.

Sherwin Williams did not respond to this argument in its opposition brief. At the hearing, counsel for Sherwin Williams stated that its response had inadvertently been omitted from the brief, and asserted that under *Tillamook Cheese & Dairy Ass'n v. Tillamook County*

Creamery Ass'n, 358 F.2d 115 (9th Cir. 1966), Russo can be liable as an individual for antitrust violations because he is an individual through whom Chip-Mender acts.

The court finds that the motion should be GRANTED as to Russo. While it may be true in an ordinary antitrust action that individual corporate officers, directors, or agents who authorize acts constituting violations of the antitrust laws may be individually liable for participating with the corporation in those violations, that rule has no applicability in the present case. As Chip-Mender and Russo point out in the letter brief filed at the court's request following the hearing, Tillamook cannot be construed to support a claim of individual liability in the context of a Walker Process or Handgards antitrust claim because those claims include unique elements relating [*25] to the enforcement of the patent or patents at issue-elements that can be satisfied only by a patent owner. Here, as discussed above in connection with the first and second counterclaims for declaratory relief, Russo is not the owner of the patents. Thus, the rule stated in*Tillamook* has no applicability in the present case.

3. Business & Professions Code *§ 17200* counterclaim

Chip-Mender and Russo argue that the fifth counterclaim for violation of Business & Professions Code *§ 17200* should be dismissed for failure to state a claim. *Section 17200* prohibits acts of unfair competition, including any unlawful, unfair or fraudulent business practice. Unlawful practices are any activities that are forbidden by law. *Samura v. Kaiser Foundation Health Plan, Inc., 17 Cal. App. 4th 1284, 1292, 22 Cal. Rptr. 2d 20 (1993)*. Unfair acts are those that "offend [] an established public policy" or are "immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers." *Podolsky v. First Healthcare Corp., 50 Cal. App. 4th 632, 647, 58 Cal. Rptr. 2d 89 (1996)*.

In the fifth counterclaim, Sherwin Williams alleges that Chip-Mender's silence about the alleged infringement and requested [*26] licensing -- from May 2003 when it wrote the first letter to Sherwin Williams, to April 2005 when it wrote the second letter asserting patent infringement-allowed Sherwin Williams to infer that Chip-Mender did not intend to enforce the patents-in-suit against Sherwin Williams and to rely on this reasonable inference. Sherwin Williams asserts that Chip-Mender waited until Sherwin Williams' Dupli-Color Pen line had achieved commercial success before filing this lawsuit, and claims that that delay constitutes an unlawful, unfair, or fraudulent business practice under *§ 17200*.

Sherwin Williams also alleges that Chip-Mender's patent infringement suit is objectively baseless because no reasonable litigant in Chip-Mender's position -- i.e., with knowledge of the prior art references cited in Sherwin Williams' September 2, 2005, letter to Chip-Mender -- could realistically expect success on a claim of infringement of the patents-in-suit. Sherwin Williams asserts that the filing of this objectively baseless lawsuit also constitutes unlawful, unfair, or fraudulent business acts or practices under *§ 17200*.

Chip-Mender and Russo argue that Sherwin Williams has failed to properly state a claim [*27] for unfair competition under *§ 17200* because Sherwin Williams has not alleged injury in fact, or a loss of money or property as a result of Chip-Mender's alleged delay in filing the underlying suit. They assert that under the recently enacted Proposition 64, a party asserting a claim under *§ 17200* must have suffered injury in fact or have lost money or property as a result of such unfair competition (citing *Cal. Const. Art. II, § 10(a)*; *Huntingdon Life Sci., Inc. v. Stop Huntingdon Animal Cruelty USA, Inc., 129 Cal. App. 4th 1228, 1261, 29 Cal. Rptr. 3d 521 (2005))*.

They argue further that there is no legal authority supporting a theory that undue delay in filing a lawsuit constitutes unfair competition. Indeed, they note, patent holders are generally granted a six-year statute of limitations under *35 U.S.C. § 286*. They note that Sherwin Williams is free to assert defenses of laches or estoppel, but that there is no basis for asserting a counterclaim for violation of *§ 17200* for the asserted delay in filing suit. They also assert that there is no basis for alleging the *§ 17200* claim against Russo, as the underlying suit was brought by Chip-Mender, the owner [*28] of the patents-in-suit.

In opposition, Sherwin Williams argues that it alleged that Chip-Mender and Russo deceived Sherwin Williams into making a substantial investment in commercializing its Dupli-Color product line, believing it was immune from suit under Chip-Mender's patents. Sherwin Williams also argues that Chip-Mender's decision to file an objectively baseless infringement suit supports the unfair competition claim.

The court finds that the motion to dismiss the fifth counterclaim must be GRANTED. There is no legal authority to support the proposition that delay in pursuing licensing discussions or in filing a patent infringement suit constitutes unfair competition. Moreover, in order to have standing under *§ 17200*, Sherwin Williams must plead both that it suffered an injury in fact and that it lost money or property as a result of unfair competition, neither of which allegations appear in the counterclaim.

Sherwin Williams has not identified any act that qualifies as "unlawful" or "fraudulent," and the court therefore assumes that the *§ 17200* claim is intended as a claim of "unfair" business practices. The "unfair" stan-

dard is intentionally broad, allowing courts maximum [*29] discretion to prohibit new schemes to defraud. *Motors, Inc. v. Times Mirror Co., 102 Cal. App. 3d 735, 740, 162 Cal. Rptr. 543 (1980)*. Nevertheless, the California Supreme Court has held that in cases between business competitors, "unfair" means "conduct that threatens an incipient violation of an antitrust law, or violates the policy or spirit of one of those laws because its effects are comparable to or the same as a violation of the law, or otherwise significantly threatens or harms competition." *Cel-Tech Communications, Inc. v. Los Angeles Cellular Tel. Co., 20 Cal. 4th 163, 187, 83 Cal. Rptr. 2d 548, 973 P.2d 527 (1999)*. Sherwin Williams has not alleged any conduct by Chip-Mender or Russo that qualifies as "unfair" business activity under *§ 17200*.

Finally, as Sherwin Williams appears to have conceded the argument with regard to Russo, the motion to dismiss the *§ 17200* claim against him is also GRANTED.

4. Business & Professions Code *§ 17500* counterclaim

Chip-Mender and Russo argue that the sixth counterclaim for violation of Business & Professions Code *§ 17500* should be dismissed for failure to state a claim. *Section 17500* makes it

> unlawful for any person, . . . corporation . . ., or [*30] any employee thereof with intent directly or indirectly to dispose of real or personal property or to perform services . . . or to induce the public to enter into any obligation relating thereto, to make or disseminate . . . before the public in this state, . . . in any newspaper or other publication . . . or in any other manner or means whatever . . . any statement, concerning that real or personal property or those services . . . which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading . . .

Cal. Bus. & Prof. Code § 17500); *Kasky v. Nike, Inc., 27 Cal. 4th 939, 950, 119 Cal. Rptr. 2d 296, 45 P.3d 243 (2003)*. "To state a claim under either the UCL or the false advertising law, based on false advertising or promotional practices, it is necessary only to show that members of the public are likely to be deceived." *Nike, 27 Cal. 4th at 951* (citations and quotations omitted).

In the sixth counterclaim, Sherwin Williams alleges that the attempts by Chip-Mender and Russo to license the patents-in-suit and to sell touch-up paint pens, despite the fact that they knew or reasonably [*31] should have known that the patents are invalid and unenforceable, constitutes "the dissemination and making of untrue and misleading statements, which by the exercise of reasonable care should have been known to be false or misleading," in violation of *§ 17500*.

Chip-Mender and Russo argue that Sherwin Williams has failed to state a counterclaim for false and misleading statements under *§ 17500*, and that no facts exist to support such a claim. They also argue that the *§ 17500* claim against Russo should be dismissed.

In opposition, Sherwin Williams argues that falsely asserting that something was patented when in fact the patent was fraudulently obtained and the alleged invention exists in the public domain is "the essence of unfair competition." Sherwin Williams also contends, in response to the argument that it has not alleged that Chip-Mender and Russo made false statements in an attempt to dispose of personal property, that a patent is personal property, and thus they have stated a claim.

The court finds that the motion to dismiss the sixth counterclaim for violation of *§ 17500* must be GRANTED. In order to state a claim under *§ 17500*, Sherwin Williams must allege facts showing [*32] that Chip-Mender and Russo made untrue or misleading statements, with the intent "to dispose . . . of real or personal property or to perform services . . . or to induce the public to enter into any obligation relating thereto." *Bernardo v. Planned Parenthood Fed. of America, 115 Cal. App. 4th 322, 356, 9 Cal. Rptr. 3d 197 (2004)*, cert. denied, *543 U.S. 942, 125 S. Ct. 373, 160 L. Ed. 2d 254 (2004)*. In addition, Sherwin Williams must allege that members of the public are likely to be deceived. *Committee on Children's Television, Inc. v. Gen'l Foods Corp., 35 Cal. 3d 197, 211, 197 Cal. Rptr. 783, 673 P.2d 660 (1983)*. Sherwin Williams has not alleged facts that meet these elements.

None of the allegedly false statements asserted by Sherwin Williams in the sixth counterclaim constitutes false advertising under *§ 17500*. The licensing proposals do not qualify as "advertisements" regarding the proposed disposition of "real or personal property" or the performance of services. With regard to the sale of the pens, Sherwin Williams has not identified anything untrue or misleading in Chip-Mender's advertisements on its websites. The website simply states that the Chip-Mender products are patented, a true statement. Sherwin Williams [*33] cannot dispute Chip-Mender's statements that its paint pens are patented. Until there is a finding that the patents-in-suit are invalid, any statement made by Chip-Mender to the effect that its products are patented is true.

Finally, as Sherwin Williams appears to have conceded the argument with regard to Russo, the motion to dismiss the *§ 17500* claim against him is GRANTED.

5. Ohio deceptive trade practices counterclaim

Chip-Mender and Russo argue that the seventh counterclaim for violation of the Ohio Deceptive Trade Practices Act should be dismissed for failure to state a claim. The Deceptive Trade Practices Act prohibits a variety of unfair and deceptive trade practices. See *Ohio Rev. Code § 4165.02*.

In the seventh counterclaim, Sherwin Williams alleges that Chip-Mender and Russo violated Ohio's Deceptive Trade Practices Act by attempting to license the patents-in-suit despite knowing that they were invalid and unenforceable, and by using the patents-in-suit to sell Chip-Mender's touch-up paint pens, despite knowing that they were invalid and unenforceable. These allegations are identical to the ones Sherwin Williams made in the sixth counterclaim [*34] for violation of Business § Professions Code *§ 17500*.

Chip-Mender and Russo argue that this claim fails for the same reasons as the *§ 17500* claim. In addition, they contend that Ohio Rev. Coce *§ 4165.02*, which defines the conduct prohibited under the Act, does not list any unlawful activities that resemble Sherwin Williams' licensing allegations. With regard to the claim that Chip-Mender violated the Ohio statute by falsely referring to its products as "patented" or "protected by U.S. patents," Chip-Mender and Russo submit that it is not clear which subsection of *Ohio Rev. Code § 4165.02*, if any, would encompass such charges. They add, however, that the statements were not false, as Chip-Mender's paint pens are covered by U.S. patents.

Finally, Russo argues that the claim under the Ohio law should be dismissed as to him, for the same reasons as the claim under *§ 17500*.

In opposition, Sherwin Williams asserts that it has stated a claim for violation of *Ohio Rev. Code § 4165.02(A)(7)*, which creates liability when a company or employee "[r] epresents that goods or services have . . . characteristics . . . that [they] do [*35] [] not have . . ." Sherwin Williams contends that it alleged that Chip-Mender and Russo, with knowledge that the patents-in-suit were fraudulently obtained, have attempted to license those patents and sell their products as "patented," thus improperly conveying the notion that the patents are valid and enforceable.

The court finds that the motion to dismiss the seventh counterclaim must be GRANTED. As with the *§ 17500* claim, until there is a finding that the patents-in-suit are invalid, any statement made by Chip-Mender to the effect that its products are patented is true.

In addition, as Sherwin Williams appears to have conceded the argument with regard to Russo, the motion to dismiss the claim against him must be GRANTED.

C. Alternative Motion to Bifurcate and Stay

In the alternative, Chip-Mender and Russo argue that the court should bifurcate the counterclaims, and stay discovery related to the third through seventh counterclaims pending resolution of Chip-Mender's patent infringement claims.

Federal Rule of Civil Procedure 42(b) provides that the court may order a separate trial of claims, counterclaims, or issues "in furtherance [*36] of convenience or to avoid prejudice, or when separate trials will be conducive to expedition and economy." *Fed. R. Civ. Proc. 42(b)*; see also *Ellingson Timber Co. v. Great N. Ry. Co., 424 F.2d 497, 499 (9th Cir.1970)* ("One of the purposes of *Rule 42(b)* is to permit deferral of costly and possibly unnecessary discovery proceedings pending resolution of potentially dispositive preliminary issues.")

As the parties seeking bifurcation, Chip-Mender and Russo have the burden of proving that bifurcation is justified given the facts in the case. See *Spectra-Physics Lasers. Inc. v. Uniphase Corp., 144 F.R.D. 99, 101 (N.D. Cal. 1992)*. Chip-Mender and Russo argue that each of the antitrust and related claims depends upon the resolution of the underlying patent claims, and that if the underlying claims are resolved in Chip-Mender's favor, the counterclaims will become moot. Chip-Mender and Russo also argue that granting bifurcation will avoid the prejudice of delay, caused by the need to develop the record on the antitrust and related claims; will avoid confusion of the issues (confusion of the jury caused by mixing antitrust [*37] and patent claims in same trial); will serve judicial economy by resolving certain threshold issues raised by antitrust and related claims; and will not prejudice Sherwin Williams.

In opposition, Sherwin Williams argues that bifurcation would be improper, because Chip-Mender has not established that a consolidated trial would be unduly burdensome. In the alternative, Sherwin Williams contends that the court should at least allow discovery to proceed on all issues, and decide later whether to bifurcate the patent claims and the counterclaims for trial. Sherwin Williams asserts that denying the stay and the bifurcation will further judicial economy because there is substantial overlap between the patent claims and the counterclaims -- e.g., the same issue of fraud will have to be litigated for the inequitable conduct defense, the patent misuse affirmative defense, and the antitrust counterclaims. Sherwin Williams submits that there will be no efficiency to be gained by conducting discovery and adjudicating the fraud issues for inequitable conduct and

patent misuse (along with antitrust violations alleged in the patent misuse defense), and then undertaking separate discovery and adjudication [*38] for the antitrust counterclaims.

It is a common practice in federal court to stay antitrust counterclaims until after the trial of the invalidity issue. See, e.g., *In re Innotron Diagnostics, 800 F.2d 1077, 1084 (Fed. Cir.1986)* (discussing the "now-standard practice of separating for trial patent issues and those raised in an antitrust counterclaim"). On balance, having considered the potential prejudice to Sherwin Williams, along with the other relevant factors, the court finds that the third through seventh counterclaims should be bifurcated, and that discovery on those counterclaims should be stayed, because the benefits to be derived from a stay will outweigh any prejudice. Proceeding on the antitrust claims simultaneously with the patent claims may delay resolution of the case by increasing its complexity, whereas many issues will likely be mooted by addressing the patent claims first. Resolution of the invalidity issue (Sherwin Williams' third affirmative defense, and first and second counterclaims) may dispose of the antitrust counterclaims altogether.

The stay will remain in effect at least until any motions for summary judgment have been decided on the patent [*39] claims. At that point, the court will revisit the question, and will determine whether to maintain the stay through the trial of the patent claims.

CONCLUSION

In accordance with the foregoing, the motion to dismiss the counterclaims asserted against Russo is GRANTED. The dismissal is WITH PREJUDICE.

The motion to dismiss the third through seventh counterclaims against Chip-Mender is GRANTED. The dismissal is WITH LEAVE TO AMEND. Any amended counterclaims shall be filed no later than February 1, 2006.

The motion to bifurcate the third through seventh counterclaims, and to stay discovery as to those counterclaims is GRANTED, as indicated above. Should Sherwin Williams amend the counterclaims, the time for Chip-Mender to file a responsive pleading or motion to dismiss shall not begin to run until after the stay has been lifted.

IT IS SO ORDERED.

Dated: January 3, 2006

PHYLLIS J. HAMILTON

United States District Judge

EXHIBIT 6

LEXSEE 2006 U.S.DIST. LEXIS 84963

MONSANTO COMPANY, et al., Plaintiffs, v. SYNGENTA SEEDS, INC., et al., Defendants.

Civ. No. 04-305-SLR

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF DELAWARE

2006 U.S. Dist. LEXIS 84963

November 8, 2006, Decided

PRIOR HISTORY: *Monsanto Co. v. Syngenta Seeds, Inc., 2006 U.S. Dist. LEXIS 54534 (D. Del., Aug. 4, 2006)*

COUNSEL: [*1] For Monsanto Company, Plaintiff: Richard L. Horwitz, LEAD ATTORNEY, David Ellis Moore, Potter Anderson & Corroon, LLP, Wilmington, DE; John H. Bogart, Pro Hac Vice; John J. Rosenthal, Pro Hac Vice; Sean P. Beaty, Pro Hac Vice.

For Monsanto Technology LLC, Plaintiff: Richard L. Horwitz, LEAD ATTORNEY, David Ellis Moore, Potter Anderson & Corroon, LLP, Wilmington, DE; John J. Rosenthal, Pro Hac Vice.

For DeKalb Genetics Corp, Plaintiff: Richard L. Horwitz, LEAD ATTORNEY, David Ellis Moore, Potter Anderson & Corroon, LLP, Wilmington, DE.

For Syngenta Seeds Inc., Syngenta Biotechnology, Defendants: John W. Shaw, LEAD ATTORNEY, Karen Elizabeth Keller, LEAD ATTORNEY, Young, Conaway, Stargatt & Taylor, Wilmington, DE; Seth Jason Reidenberg, Young, Conaway, Stargatt & Taylor, LLP, Wilmington, DE.

For Garst Seed Company, Defendant: John W. Shaw, LEAD ATTORNEY, Karen Elizabeth Keller, LEAD ATTORNEY, Young, Conaway, Stargatt & Taylor, Wilmington, DE.

For Syngenta Seeds Inc., Syngenta Biotechnology, Counter Claimants: John W. Shaw, LEAD ATTORNEY, Young, Conaway, Stargatt & Taylor, Wilmington, DE.

For Monsanto Company, Monsanto Technology LLC, Counter Defendants: Richard [*2] L. Horwitz, LEAD ATTORNEY, Potter Anderson & Corroon, LLP, Wilmington, DE.

For Golden Harvest Seeds, Inc., Defendant: John W. Shaw, LEAD ATTORNEY, Karen Elizabeth Keller, LEAD ATTORNEY, Young, Conaway, Stargatt & Taylor, Wilmington, DE.

For Garwood Seed Co., Golden Seed Company, LLC, Sommer Bros. Seed Company, Thorp Seed Co., JC Robinson Seeds, Inc., Defendants: John W. Shaw, LEAD ATTORNEY, Young, Conaway, Stargatt & Taylor, Wilmington, DE.

For Advanta USA Inc, Syngenta Corporation, Syngenta Participations AG, Counter Defendants: John W. Shaw, LEAD ATTORNEY, Karen Elizabeth Keller, LEAD ATTORNEY, Young, Conaway, Stargatt & Taylor, Wilmington, DE.

For Garst Seed Company, Syngenta AG, Syngenta Seeds Inc., Syngenta Biotechnology, Golden Harvest Seeds, Inc., Syngenta Corporation, Syngenta Participations AG, Counter Defendants: John W. Shaw, LEAD ATTORNEY, Young, Conaway, Stargatt & Taylor, Wilmington, DE.

JUDGES: Sue L. Robinson, United States District Judge.

OPINION BY: Sue L. Robinson

OPINION:

ORDER

At Wilmington this 8th day of November, 2006, having reviewed various pending motions and the papers submitted in connection therewith;

IT IS ORDERED that:

1. Syngenta's motion [*3] for leave to amend the second amended complaint (D.I. 491), in order to with-

draw the allegations contained in paragraph 133 and count III of said complaint, is granted.

2. Monsanto's motion to dismiss with prejudice the allegations contained in paragraph 133 and count III of Syngenta's second amended complaint (D.I. 486) is denied as moot.

3. Monsanto's motion to stay the trial in the antitrust action pending resolution of Monsanto's patent claims on appeal (D.I. 488) is granted, for the reasons that follow:

a. Monsanto and Syngenta have been arguing about the inter-relatedness of Monsanto's patent claims and Syngenta's antitrust claims since the latter claims were filed. Indeed, the parties have argued both sides of the factual dispute depending upon the legal context at issue (e.g., a motion to stay versus a motion for *Rule 54(b)* certification).

b. The question of whether to stay the antitrust case pending appeal is committed to the discretion of the court and ultimately should be resolved in favor of the "choice most likely to result in a just final disposition of the litigation." *In re Innotron Diagnostics, 800 F.2d 1077, 1085 (Fed. Cir. 1986).*

c. Despite [*4] the contentious nature of this litigation, it is undisputed that there is at least a minimal overlap between the patent case and the antitrust case; therefore, the outcome of the patent appeal necessarily will affect the complexion of the antitrust case to some extent. Having granted Monsanto's *Rule 54(b)* motion, the court concludes that the better course of action is to stay the trial of the antitrust case until the appeal of the patent case has been resolved.

d. The pending motions (D.I. 415, 499, 501, 503) are denied without prejudice to renew. Further, the court will try the patent and antitrust cases during the same period of time, should Monsanto prevail on appeal. n1

n1 This means that trial of the patent issues will await my resolving whatever motions are renewed in the antitrust case.

Sue L. Robinson

United States District Judge

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC. and PURDUE PHARMACEUTICALS L.P., Plaintiffs, v. KV PHARMACEUTICAL COMPANY and ACTAVIS TOTOWA LLC, Defendants.	Civil Action No. 07-032-***

ORDER

AND NOW, this _____ day of _____, 2007, Defendant Actavis Totowa LLC having presented a Motion to Stay Antitrust Counterclaims;

IT IS ORDERED that Defendant Actavis Totowa LLC's Motion to Stay Antitrust Counterclaims is GRANTED.

_____
United States Magistrate Judge