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.	**C.A. No. 07-032-***** **JURY TRIAL DEMANDED**
KV PHARMACEUTICAL COMPANY, Counterclaim-Plaintiff, v. PURDUE PHARMA, L.P., THE PURDUE FREDERICK COMPANY, THE P.F. LABORATORIES, INC., THE PURDUE PHARMA COMPANY, PURDUE PHARMACEUTICALS, L.P., AND EUROCELTIQUE S.A., Counterclaim-Defendants.	**DEFENDANT KV PHARMACEUTICAL COMPANY'S ANSWER AND COUNTERCLAIMS**

DEFENDANT KV PHARMACEUTICAL COMPANY'S ANSWER AND COUNTERCLAIMS

Defendant KV Pharmaceutical Company ("KV"), by their attorneys Morgan & Finnegan L.L.P., answers the Complaint of Plaintiffs Purdue Pharma, L.P., The P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P. (collectively "Purdue") in the above-captioned matter, and, based upon personal knowledge as to its own actions and intent, and upon information and belief as to the actions and intent of others, specifically avers as follows:

ANSWER

I. NATURE OF THE ACTION

1. KV admits that Purdue has styled this action as one arising under the Patent Laws of Title 35, United States Code, but specifically denies that there have, in fact, been any acts of infringement by KV given that an invalid and/or unenforceable patent cannot be infringed, and denies all other allegations contained in Paragraph 1 of the Complaint.

II. JURISDICTION AND VENUE

2. KV admits the allegations contained in Paragraph 2 of the Complaint.

3. KV admits the allegations contained in Paragraph 3 of the Complaint as they relate to KV, and lacks sufficient information to admit or deny the allegations as they relate to Actavis Totowa LLC ("Actavis"), and on that basis denies all other allegations contained in Paragraph 3.

4. KV admits the allegations contained in Paragraph 4 of the Complaint only for the purposes of this action.

III. THE PARTIES

5. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 5 of the Complaint.

6. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 6 of the Complaint.

7. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 7 of the Complaint.

8. KV admits the allegations contained in Paragraph 8 of the Complaint.

9. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 9 of the Complaint.

IV. THE PATENTS IN SUIT

10. KV denies that U.S. Patent Nos. 5,549,912 ("the '912 patent"), 5,508,042 ("the '042 patent") and 5,656,295 ("the '295 patent") were duly and legally issued; admits that copies of the three referenced patents were attached to the Complaint that purport on their face to have the specified titles, issue dates and named inventors, but lacks sufficient information to admit or deny, and on that basis denies all other allegations contained in Paragraph 10 of the Complaint.

V. KV'S ANDA

11. KV admits the allegations contained in Paragraph 11 of the Complaint.

12. KV admits the allegations contained in Paragraph 12 of the Complaint.

13. KV admits the allegations contained in Paragraph 13 of the Complaint, except KV lacks sufficient information to admit or deny, and on that basis denies the allegation that "plaintiffs received KV's Notice on or about December 11, 2006."

14. KV denies each and every allegation contained in Paragraph 14 of the Complaint.

15. KV denies each and every allegation contained in Paragraph 15 of the Complaint.

16. KV admits that it has submitted an Abbreviated New Drug Application ("ANDA") as alleged in Paragraph 16 of the Complaint, but specifically denies that there has been an infringement of a valid, enforceable U.S. Patent.

17. KV denies each and every allegation contained in Paragraph 17 of the Complaint.

18. KV denies each and every allegation contained in Paragraph 18 of the Complaint, except KV admits "KV has been aware of the existence of the '912, '042 and '295 patents."

19. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 19 of the Complaint, and further denies that it has or is committing any acts of infringement against Purdue.

VI. ACTAVIS' ANDA

20. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 20 of the Complaint.

21. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 21 of the Complaint.

22. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 22 of the Complaint.

23. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 23 of the Complaint.

24. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 24 of the Complaint.

25. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 25 of the Complaint.

26. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 26 of the Complaint.

27. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 27 of the Complaint.

28. KV lacks sufficient information to admit or deny, and on that basis denies the allegations contained in Paragraph 28 of the Complaint.

PRAYER FOR RELIEF

29. KV states that the enumerated paragraphs A-H, following Purdue's prayer for relief, contain a request for relief as to which no response is required. To the extent a response is required, KV denies that Purdue is entitled to the requested relief or to any relief.

GENERAL DENIAL

30. KV denies each and every allegation of the Complaint that is not specifically admitted herein.

VII. AFFIRMATIVE DEFENSES

FIRST AFFIRMATIVE DEFENSE
(Invalidity)

31. Each and every claim of the '912, '042 and '295 patents is invalid and void for failure to meet one or more of the conditions for patentability set forth in the patent laws of the United States, 35 U.S.C. § 101 *et seq.*, including but not limited to the requirements set forth in 35 U.S.C. §§ 101, 102, 103, 112, 132, 282 and/or for double patenting.

SECOND AFFIRMATIVE DEFENSE
(Non-infringement)

32. KV did not infringe, contribute to the infringement of, or actively induce others to infringe any claim of the '912, '042 and '295 patents through its activities relating to ANDA number 78-506.

THIRD AFFIRMATIVE DEFENSE
(Inequitable Conduct)

33. Each and every claim of the '912, '042 and '295 patents is unenforceable because these claims were procured through inequitable conduct in violation of the patent laws and regulations of the United States Patent and Trademark Office ("PTO"). The '912, '042 and '295 patent applicants and their solicitors and the parent U.S. Patent No. 5,266,331 ("the '331 patent") applicants and their solicitors breached their duty of candor and good faith to the PTO by making affirmative

misrepresentations of material facts, failing to disclose material information and submitting false information to the PTO with the intent to deceive the PTO as more fully set forth below and explained in Counterclaim paragraphs 1-180 and 226-238.

34. The misrepresentations and/or withheld information were material to the issuance of the '331, '912, '042 and '295 patents.

35. The '912, '042 and '295 patents were each procured by fraud, and are therefore unenforceable. The '331 patent also was procured by fraud, the fraud tainting all related patents issuing therefrom (i.e., the '912, '042 and '295 patents), and therefore providing a further basis for unenforceability of these patents.

FOURTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

36. The Complaint fails to state a claim against KV upon which relief can be granted.

FIFTH AFFIRMATIVE DEFENSE
(Patent Misuse)

37. Purdue has misused the '912, '042 and '295 patents, and has so used those patents in violation of the antitrust laws as to render them unenforceable.

SIXTH AFFIRMATIVE DEFENSE
(Sham Litigation)

38. Purdue has asserted and continues to assert rights in the '912, '042 and '295 patents despite the fact that it knows that those patents are unenforceable, in an attempt to interfere directly with KV's business relationships. Therefore, this action brought by Purdue for infringement is a mere sham.

COUNTERCLAIMS

Counterclaim Plaintiff KV Pharmaceutical Company ("KV"), for its Counterclaims against Counterclaim-Defendants Purdue Pharma, L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., The Purdue Pharma Company, Purdue Pharmaceuticals, L.P., and Euroceltique S.A. (collectively "Counterclaim Defendants"), alleges on personal information as to itself and on information and belief as to the conduct of Counterclaim Defendants and third parties as follows:

I. NATURE OF THE COUNTERCLAIMS

1. Purdue[1] is a monopolist that has engaged in an overall scheme to protect its monopoly, injure competition and subject consumers to supra-competitive prices for controlled-release ("CR") oxycodone.

2. KV brings these counterclaims for declaratory judgment, injunctive relief and damages based on Counterclaim Defendants' repeated frauds on the United States Patent and Trademark Office ("PTO") that resulted in the issuance of the '331,'912, '042, and '295 patents (defined below) and in Counterclaim Defendants' filing and maintenance of multiple sham litigations to enforce the patents that Counterclaim Defendants knew were unenforceable because they were procured by fraud and inequitable conduct.

3. Counterclaim Defendants have engaged in, and continue to engage in, an improper, exclusionary and anticompetitive pattern and practice of conduct and overall scheme to preserve their monopoly by thwarting entry of competitive CR oxycodone products, as spelled out more fully below. Counterclaim Defendants have taken and continue to take improper actions to maintain their monopoly in CR oxycodone sales.

[1] In these Counterclaims, "Purdue" collectively refers to the Counterclaim Defendants other than Euroceltique S.A.

4. Counterclaim Defendants knowingly, intentionally, and repeatedly made affirmative misrepresentations of material facts to, withheld material information from and provided false, material information to the PTO, without which the '331, '912, '042 and '295 patents would not have issued. The misrepresentations and omissions of material facts are summarized as follows:

a. In response to rejections of their patent applications for obviousness, Counterclaim Defendants repeatedly asserted that "results" – implying empirical evidence -- indicated a "surprising discovery" that the claimed CR oxycodone formulation controls pain over a narrow four-fold dosage range in about 90 percent of patients, in "sharp contrast" to the purported prior art's broader eight-fold dosage range;

b. Counterclaim Defendants repeatedly represented to the PTO that the claimed CR oxycodone controlled pain over a narrow four-fold dosage range knowing their statements were false;

c. Counterclaim Defendants submitted to the PTO a sworn declaration to overcome a pending rejection of the claims that purportedly substantiated their "surprising results," but failed to disclose the affiliation of the declarant (Dr. Kaiko) with the assignee, thereby concealing the declarant's bias;

d. Counterclaim Defendants failed to disclose to the PTO clinical studies that directly contradicted their assertions to the PTO regarding the narrowness of the dosage range of their CR oxycodone in comparison to other analgesics, because disclosing those studies would have prevented Counterclaim Defendants from distinguishing their claims from the prior art;

e. Counterclaim Defendants repeatedly asserted "surprise" that their CR oxycodone formulation, which dissolved in the test tube (*in vitro*) within known parameters, produced an early peak level of oxycodone in the bloodstream (*in vivo*) and afforded 12 hours of pain relief for most patients, when they actually had a "reasonable expectation" it would achieve those results;

f. Counterclaim Defendants failed to disclose that they had succeeded in obtaining the same purportedly "surprising" dissolution results with four prior pain relief formulations;

g. Counterclaim Defendants failed to disclose two prior art formulations that matched the purportedly "surprising" dissolution profile; and

h. Counterclaim Defendants misrepresented and withheld additional material facts that would have caused the PTO to deny issuance of Counterclaim Defendants' patent applications had the true facts been known.

i. Counterclaim Defendants caused the fraudulently obtained patents to be listed in the Orange Book and maintained their listing in the FDA's "Orange Book" (*Approved Drug Products With Therapeutic Equivalence)* despite Counterclaim Defendants' knowledge that the patents were unenforceable.

5. Moreover, since the '331, '912, '042 and '295 patents issued, Counterclaim Defendants have known that the bases for issuance of the patents were false, but nevertheless repeatedly have sought to enforce these patents in sham litigations against multiple competitors.

6. As each of several potential rivals (including Roxane Laboratories, Inc. ("Roxane"), Endo Pharmaceuticals ("Endo"), Teva Pharmaceuticals USA ("Teva") and Impax Laboratories ("Impax"), Mallinckrodt, Inc. ("Mallinckrodt"), Actavis Totowa LLC ("Actavis") and now KV) either received U.S. Food & Drug Administration ("FDA") approval, or filed an abbreviated new drug application ("ANDA") seeking FDA approval, to manufacture and sell a competing CR oxycodone product, Purdue has sued the potential competitors for patent infringement knowing that Counterclaim Defendants' own fraud and inequitable conduct rendered their patents unenforceable.

7. Purdue brought the pattern of lawsuits as part of Counterclaim Defendants' overall scheme to maintain monopoly power. Their lawsuits were objectively baseless and were brought with the subjective intent to injure competition.

8. Endo filed counterclaims alleging inequitable conduct and, after a bench trial on the infringement and inequitable conduct claims, the district court found that Endo proved by clear and convincing evidence that the patents were unenforceable as a result of Counterclaim Defendants' inequitable conduct in prosecuting the patents before the PTO.

9. Upon appeal, the Federal Circuit agreed with the district court that Counterclaim Defendants had failed to disclose material information and had made material misstatements to the PTO with the intent to deceive, but remanded to the district court for further evaluation of the level of Counterclaim Defendants' intent to deceive, and for weighing of the evidence of intent and the materiality of the omission to determine whether the '912, '042 and '295 patents should be held unenforceable.

10. Rather than await a ruling on remand that would confirm the patents were unenforceable, Purdue settled with Endo to avoid a judgment of inequitable conduct that would have brought an end to Purdue's monopoly. Since then, Counterclaim Defendants also settled with Teva. The Roxane, Impax, Mallinckrodt, Actavis and current litigations continue, and Counterclaim Defendants' monopoly remains intact.

11. Despite the rulings on intentional misrepresentations of material fact by both the district court and the Federal Circuit, Purdue sued KV, Actavis and Mallinckrodt for patent infringement to maintain Counterclaim Defendants' monopoly.

12. Counterclaim Defendants' conduct has had and continues to have the following anticompetitive effects:

a. Because of the issuance of the invalid and unenforceable patents and maintenance of sham litigation, competitors, including KV, have been delayed in entering the market, prevented from entering the market, or forced to exit the market;

b. Because of the issuance of the invalid and unenforceable patents and maintenance of sham litigation, KV's manufacture and sale of its competing 10 mg, 20 mg, 40 mg and 80 mg oxycodone hydrochloride extended-release tablets to consumers will be delayed.

13. Counterclaim Defendants' overall scheme may contain other elements of improper conduct which will come to light during discovery.

14. Counterclaim Defendants' improper and exclusionary conduct constitutes an unreasonable restraint of trade.

15. KV was, and still is being, injured as a proximate result of Counterclaim Defendants' conduct.

16. Consumers and health care payors have been, and will continue to be, injured by Counterclaim Defendants' conduct. These consumers have paid, and will pay, higher prices than they would have paid in the absence of Counterclaim Defendants' wrongful conduct. These consumers also had fewer choices.

17. KV is entitled to damages and injunctive relief because KV has suffered, and will continue to suffer, monetary loss and irreparable harm as a direct and proximate result of Counterclaim Defendants' improper and exclusionary conduct in filing and maintaining the above-described patent infringement lawsuits.

18. By its Counterclaims, KV seeks an Order invalidating and/or rendering unenforceable these fraudulently procured patents, to open the market to competition in the sale of CR oxycodone, and to recover the damages that KV has suffered and is suffering, due to Counterclaim Defendants' unlawful conduct.

II. THE PARTIES

19. Counterclaim Plaintiff KV is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business located at 2503 South Hanley Road, St. Louis, Missouri 63144. KV is a specialty pharmaceutical company and a leader in developing innovative products using its advanced drug delivery technologies. KV has developed numerous innovative branded prescription products in women's healthcare, including anti-infective products such as Gynazole-1® (the only one-dose prescription treatment for vaginal yeast infections) and Clindesse® (the first and only one-dose prescription treatments for bacterial

vaginosis), both of which leverage KV's proprietary SITE RELEASE™ bioadhesive technology; advanced prescription nutritional products, including PrimaCare® and PrimaCare® One (the first prescription prenatal/post natal product with omega-3 essential fatty acids, including its once-a-day dosage form), and oral hematinic products, such as the novel Repliva 21/7™ (a new prescription product providing iron supplementation). KV also manufactures various generic and non-branded products in the cardiovascular, women's health, pain management and respiratory care therapeutic areas, including a range of pain management products such as morphine sulfate concentrated oral solution and Eth-Oxydose (oxycodone HCl) oral solution in InveAmp™ unit dose ampoules (which provide a more precise way to dispense these concentrated narcotic solutions). KV is also the first and only company to manufacture United States Food and Drug Administration ("FDA") approved immediate release Oxycodone HCl 5 mg Tablets and Hydromorphone HCl 2 and 4 mg Tablets.

20. Counterclaim Defendant Purdue Pharma L.P. alleged in paragraph 5 of the Complaint that it is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business located at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431, and that it is an owner of the '912, '042 and '295 patents.

21. Counterclaim Defendant The Purdue Frederick Company is a corporation organized and existing under the laws of the State of New York, and having its principal place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue Frederick has purported to be an owner of the '912, '042 and '295 patents during at least part of the relevant time period.

22. Counterclaim Defendant P.F. Laboratories, Inc. alleged in paragraph 6 of the Complaint that it is a corporation organized and existing under the laws of the State of New

Jersey, having a place of business located at 700 Union Boulevard, Totowa, New Jersey, and that it is an owner of the '912, '042 and '295 patents.

23. Counterclaim Defendant The Purdue Pharma Company is a general partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431, and has purported to be an owner of the '912, '042 and '295 patents during at least part of the relevant time period.

24. Counterclaim Defendant Purdue Pharmaceuticals L.P. alleged in paragraph 7 of the Complaint that it is a limited partnership organized and existing under the laws of the State of Delaware, having its principal place of business located at 4701 Purdue Drive, Wilson, North Carolina 27893, and that it is an owner of the '912, '042 and '295 patents.

25. Counterclaim Defendant Euroceltique S.A. is a corporation organized and existing under the laws of Luxembourg, having its principal place of business at 122 Boulevard de la Petrusse, Luxembourg. Euroceltique is an affiliate of Purdue that was or is the owner by assignment of the '598, '075, '331, '912, '042 and '295 patents (each defined in Counterclaim paragraph 49 below).

III. JURISDICTION, VENUE AND INTERSTATE COMMERCE

26. On January 16, 2007 (07 CV 032) and again on February 12, 2007 (07 CV 077), Purdue sued KV for allegedly infringing the '912, '042 and '295 patents. At the time this cause of action arose, there was an actual case or controversy between Purdue and KV as to KV's infringement of any valid or enforceable claim of the '912, '042 and '295 patents.

27. At the time this cause of action arose, this Court had subject matter jurisdiction over the counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 2201 *et seq.*, 1331, 1337(a), 1338(a) and 1367, and also had subject matter jurisdiction separately under 28 U.S.C. §§ 1331 and 1337 based on actual controversies between KV and Purdue arising under the patent

laws of the United States, 35 U.S.C. § 1 *et seq.* The Court continues to have subject matter jurisdiction under 28 U.S.C. § 1331 and the antitrust laws of the United States, including Section 2 of the Sherman Act, 15 U.S.C. § 2; Section 4 of the Clayton Act, 15 U.S.C. §§ 15 and 26; and Section 16 of the Clayton Act, 15 U.S.C. § 16.

28. Venue is proper in this judicial district pursuant to 15 U.S.C. §§ 15 and 22, and 28 U.S.C. § 1391, and also is based on Purdue having brought an action against KV in this district.

29. Counterclaim Defendants have monopolized and restrained trade in sales of CR oxycodone products in this judicial district and in interstate commerce throughout the United States.

30. Counterclaim Defendants are engaged in the sale of CR oxycodone products in interstate commerce and in this judicial district. As a direct and proximate result of its anticompetitive conduct, Counterclaim Defendants have threatened to block KV's participation in interstate commerce in the manufacture, distribution and/or sale of KV's CR oxycodone products.

IV. RELEVANT MARKET AND COUNTERCLAIM DEFENDANTS' MARKET POSITION

31. Oxycodone is an opioid analgesic. On December 12, 1995, Counterclaim Defendants received approval from the FDA for a CR oxycodone branded drug, OxyContin® Controlled-Release Tablets, in 10, 20, and 40 mg strengths. Counterclaim Defendants subsequently received FDA approval for 80 and 160 mg[2] dosage strengths. Counterclaim Defendants' OxyContin® product has been granted approval for the management of moderate to severe pain when a continuous, around-the-clock analgesic is needed for an extended period of time.

[2] Purdue suspended sales of this dosage alleged because of its abuse potential in 2001.

32. As a "single entity" (i.e., single ingredient) analgesic, CR oxycodone can be administered more safely for long-term consumption than combination products; some doctors and patients specifically prefer CR oxycodone.

33. OxyContin® contains more oxycodone than any drug previously marketed.

34. While there are immediate release ("IR") opioid analgesic products on the market, many doctors prefer to reduce the number of times a patient must be given the drug, and thus prefer a CR product. In that regard, Counterclaim Defendants' OxyContin® is intended to provide relief for a full 12 hours while other, immediate release analgesics are often effective for only four to six hours.

35. To date, the only other companies to receive either tentative or final approval from the FDA to market competitive CR oxycodone products are Roxane, Endo, Teva, and Impax. Counterclaim Defendants prevented or delayed their entry into the market by filing and maintaining sham patent infringement litigation. Counterclaim Defendants have also successfully forced the exit of Endo and Teva by settling the litigation against them. But for the exclusionary conduct of Counterclaim Defendants, OxyContin® would compete with these CR oxycodone products.

36. The relevant product market in which to assess the anticompetitive effects of Counterclaim Defendants' conduct is the market for CR oxycodone ("Relevant Market").

37. The relevant geographic market is the United States and its territories. The FDA regulatory process for approving drugs for sale in the United States, and the fact that marketing, sales and distribution of drugs occurs on a nationwide basis, establish the boundaries of the geographic market.

38. Counterclaim Defendants presently possess monopoly power in the Relevant Market. They have the ability to control price and exclude competitors. Physicians, patients and other health care decision-makers do not view other products as a reasonable substitute for OxyContin® or CR oxycodone.

39. Counterclaim Defendants' market share has always exceeded 50 percent in the Relevant Market, during the entire relevant period, through their virtual exclusivity in the sale of its OxyContin®.

40. Counterclaim Defendants' specific intent was and continues to be to exclude and restrict competition in the Relevant Market, and with the specific intent that the threat of large infringement damages and injunctive relief against Roxane, Endo, Teva and Impax and their customers would serve as a significant barrier to market entry by Roxane, Endo, Teva and Impax and others, thereby injuring competition and enabling Counterclaim Defendants to maintain their monopoly power in the Relevant Market.

41. Barriers to entry in the Relevant Market are substantial. By virtue of Counterclaim Defendants' '912, '042 and '295 patents, large market share percentage in the Relevant Market, and enforcement of these patents (which carries the threat of an injunction and large infringement damages and imposes a significant barrier to market entry), Counterclaim Defendants have the ability and have achieved and/or dangerously threaten to achieve monopoly power in the Relevant Market, including without limitation the power to raise prices, restrict output, eliminate choice for consumers and/or exclude competition.

42. Counterclaim Defendants' monopoly power in the Relevant Market has been achieved entirely by the wrongful acquisition and enforcement of the '912, '042 and '295 patents.

V. BACKGROUND FOR PATENT UNENFORCEABILITY AND ANTITRUST COUNTERCLAIMS

KV's ANDA for CR oxycodone and the Current Patent Litigation Against KV

43. Through its research and development, KV developed 10, 20, 40 and 80 mg strength oxycodone hydrochloride extended-release tablets ("KV's CR oxycodone products") and submitted to the FDA an ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

44. KV's ANDA includes a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) stating that Counterclaim Defendants' patents are invalid, unenforceable or will not be infringed by KV's manufacture, use or sale of KV's CR oxycodone products.

45. As required by statute, KV provided Counterclaim Defendants written notice of its Paragraph IV certification.

46. KV's ANDA seeks FDA approval to manufacture, market and sell CR oxycodone products as bioequivalent to Counterclaim Defendants' CR oxycodone products that are sold under the trade name OxyContin®.

47. Counterclaim Defendants sued KV on January 16, 2007, within 45 days of receiving KV's Paragraph IV notice and, as provided by statute, final FDA approval of KV's ANDA is stayed pending a final judgment on the infringement claims, or the passing of 30 months, whichever occurs first.

48. Should the FDA find KV's ANDA approvable during the 30-month stay, it will grant KV tentative approval. As of date of the FDA's grant of tentative approval of KV's ANDA, the only barrier to KV's manufacture and sale of a competing CR oxycodone product will be the 30-month stay prompted by Counterclaim Defendants' patent infringement claims. KV anticipates receiving tentative approval prior to expiration of the 30-month stay.

The Patents at Issue

49. Pursuant to Section 505 of the Hatch-Waxman Act, six patents are listed in the FDA's "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) applicable to Purdue's OxyContin®. These patents are:

a. U.S. Patent No. 4,861,598 entitled "CONTROLLED RELEASE BASES FOR PHARMACEUTICALS," ("the '598 patent" or "the Oshlack '598 patent"), filed July 18, 1986, issued August 29, 1989, assigned to Euroceltique, naming Benjamin Oshlack ("Oshlack") as the sole alleged inventor.

b. U.S. Patent No. 4,970,075 entitled "CONTROLLED RELEASE BASES FOR PHARMACEUTICALS," ("the '075 patent"), filed April 5, 1989, as a divisional application of the Oshlack '598 patent application, issued November 13, 1990, assigned to Euroceltique, also naming Oshlack as the sole alleged inventor.

c. U.S. Patent No. 5,266,331 entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS," ("the '331 patent"), filed November 27, 1991, issued November 30, 1993, assigned to Euroceltique, naming Oshlack, John Minogue ("Minogue") and Mark A. Chasin ("Chasin") as the alleged inventors.

d. U.S. Patent No. 5,549,912 entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS," ("the '912 patent") originally filed November 25, 1992 as a Patent Cooperation Treaty ("PCT") application, filed in the United States on June 18, 1993, claimed it was a continuation-in-part application of the '331 patent application, issued August 27, 1996, assigned to Euroceltique, naming as the alleged inventors the same three individuals named in the '331 patent plus Robert F. Kaiko ("Kaiko").

e. U.S. Patent No. 5,508,042 entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS," ("the '042 patent"), filed June 6, 1995, claimed it was a division of the '912 patent, which claimed it was a continuation in part application of the '331 patent, issued April 16, 1996, assigned to Euroceltique, naming as the alleged inventors the same three individuals named in the '331 patent plus Kaiko.

f. U.S. Patent No. 5,656,295 entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS," ("the '295 patent"), filed March 19, 1996, claimed it was a continuation in part application of the '912 patent, which claimed it was a continuation in part of the '331 patent, issued August 12, 1997, assigned to Euroceltique, naming as the alleged inventors the same three individuals named in the '331 patent plus Kaiko.

50. It was wrongful and illegal for Counterclaim Defendants to list the patents in the Orange Book, because, as Counterclaim Defendants knew, there was no reasonable basis to believe that the patents were valid or a claim of patent infringement could reasonably be asserted because the patents were obtained by fraud.

51. The named inventors Oshlack, Minogue, Chasin and Kaiko were at all relevant times employees of Purdue, and assigned whatever rights they had to the '598, '075, '331, '912, '042 and '295 patents to Euroceltique.

52. Euroceltique assigned the '912, '042 and '295 patents to Purdue Pharma, L.P., The Purdue Frederick Company, The P.F. Laboratories, Inc., and The Purdue Pharma Company for the purpose of commencing patent infringement litigation against Roxane Laboratories. More recently, a further assignment of the '912, '042 and '295 patents was made to Purdue Pharma, L.P., The P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P., who have brought the present action against KV.

53. The '912, '042 and '295 patents are not entitled to the benefit of the filing date of the '331 patent provided by 35 U.S.C. § 120 because the '912, '042 and '295 patent claims are not supported by the '331 patent application in terms of Section 112 of the Patent Statute.

54. The persons named as inventors of the '331 patent are a different entity within the meaning of the United States Patent Laws from the persons named as inventors of the '912, '042, and '295 patents.

Wrongful Conduct in the Prosecution of
the '331, '912, '042 and '295 Patents Before the PTO

55. Between July 1986 and August 1997, Counterclaim Defendants applied for and obtained the '598, '075, '331,'912, '042 and '295 patents.

56. In each application, the PTO assigned an Examiner who evaluated the proposed claims for patentability under applicable rules. The PTO is unable in most instances to conduct adequate searches to locate the most pertinent prior art and does not have access to experts readily available to evaluate art that the PTO finds. Therefore, the PTO relies on the patent applicant to disclose the prior art that the applicant knows is pertinent to the examination. Applicants have a duty of candor before the PTO.

57. In its patent infringement claims against KV, Purdue asserts only the '912, '042 and '295 patents. All three patents in suit claim priority to the filing date of the '331 patent.

58. As explained in detail in Counterclaim paragraphs 72-180, on several occasions as to each of the '331, '912, '042 and '295 patents, Counterclaim Defendants were able to overcome rejections raised by the PTO Examiner, but only by representing highly material information that was false or misleading, or by withholding material facts inconsistent with that information. Counterclaim Defendants' misrepresentations and omissions were knowing and willful, and made with the intent to deceive the PTO and to cause invalid patents to issue. As to the omission of material facts, Counterclaim Defendants made repeated affirmative statements that contradicted the omitted facts.

59. As to each of the '331, '912, '042 and '295 patents, Counterclaim Defendants repeatedly made the same highly material assertion in response to the PTO Examiners' rejections, to paraphrase:

> "[i]t now has been surprisingly discovered" that Counterclaim Defendants' CR oxycodone formulations are distinguishable from other prior art opioid analgesics (CR morphine and CR hydromorphone), because Counterclaim Defendants' CR oxycodone product controls pain in 90 percent of patients over a substantially narrower four-fold dosage range than the broader eight-fold

range required for prior art opioid analgesics generally.

60. Counterclaim Defendants repeatedly described this highly material distinction as "Surprisingly Improved Results," "Clinical Advantages" and "Results obtained," implying that the distinction was a discovery made after clinical tests and based on empirical evidence. The misrepresentation was highly material because the purported narrower dosage range was the sole basis for Counterclaim Defendants' distinction of its patent claims from prior art, and without empirical support for the alleged discovery, the PTO would not have approved Counterclaim Defendants' patents.

61. In response to the PTO Examiners' rejection of the patents for obviousness, Counterclaim Defendants made misrepresentations in addition to those summarized above. These misrepresentations also are highly material in as much as the PTO Examiner relied on them to allow Counterclaim Defendants' patent claims.

62. During the prosecution of each patent, after the PTO Examiner had rejected Counterclaim Defendants' application for obviousness, the PTO Examiner relied on Counterclaim Defendants' assertions to traverse the rejection and approve Counterclaim Defendants' application. These misrepresentations also are highly material, as the PTO Examiner relied on them to allow Counterclaim Defendants' patent claims.

63. Not only did Counterclaim Defendants repeatedly misrepresent that the "surprising discovery" of the narrower dosage range was based on empirical evidence and the result of clinical studies, they did so omitting the highly material fact that clinical studies contradicted Counterclaim Defendants' assertions. As set forth in more detail in Counterclaim paragraphs 167-171, a study that concluded during the pendency of the '912, '042, and '295 patents showed that, contrary to Counterclaim Defendants' assertions in response to the PTO

Examiners' rejection of its patents for obviousness, CR oxycodone did not exhibit a reduced dosage range in comparison to CR morphine.

64. The test results were summarized in a final report before the '295 patent issued, but Counterclaim Defendants failed to bring the study or the results to the attention of the PTO, in violation of its obligation of candor before the PTO. The omission was highly material because the purported narrower dosage range, now contradicted by a clinical study, was the sole basis for Counterclaim Defendants' distinction of their patent claims from prior art.

65. Later studies also contradicted Counterclaim Defendants' representations, but Counterclaim Defendants never brought the contrary information to the PTO's attention.

66. Counterclaim Defendants made the repeated misrepresentations and omissions of material facts in furtherance of their improper, exclusionary and anticompetitive pattern and practice of conduct and overall scheme to preserve their monopoly by thwarting generic entry of CR oxycodone products.

67. Counterclaim Defendants have monopoly power in the Relevant Market, and their improper and exclusionary conduct before the PTO successfully prevented or delayed rivals from entering the market or forced rivals to exit the market, and constitutes an unreasonable restraint of trade.

68. As a direct and proximate result of Counterclaim Defendants' improper and exclusionary conduct, KV, other rivals and consumers were, and continue to be, injured. As a direct and proximate result of Counterclaim Defendants' conduct, competition has been thwarted and consumers pay supra-competitive prices for OxyContin® that would not exist but for Counterclaim Defendants' improper and exclusionary conduct.

Prosecution of the '598 and '075 Patents

69. The '598 and '075 patent specifications allege that those skilled in the art rely on the strong correlation established between *in vitro* dissolution rates and *in vivo* bioavailability as descriptive of the bioavailability potential for the active therapeutic drug incorporated in the CR matrix, stating:

> Notwithstanding the diverse factors influencing both dissolution and absorption of a drug substance 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. In view of this relationship, it is clear that the dissolution time determined for a composition is one of the important fundamental characteristics for consideration, when evaluating slow release compositions. (Col. 2, lines 47-59; col. 2, lines 50-61, respectively).

Example II of the '598 patent sets forth in vitro dissolution rates for CR oxycodone, as follows:

Time (hours)	**Release of Oxycodone by Percentage Weight**
1	16
2	51
4	70
6	78

('598 patent, col. 6, lines 40-50).

70. The claims of the '598 patent and '075 patents are directed to compositions for *in vivo* use of CR pharmaceutically active agents and, in the '598 patent, are directed specifically to such oxycodone compositions. However, neither the '598 nor the '075 patent specifications contain any data as to clinical studies and rely entirely on *in vitro* dissolution rates in their examples to support such *in vivo* claims. Oshlack's declarations filed during the pendency of the '598 and '075 patent applications as proof of reduction to practice of the claimed compositions neither contain nor refer to clinical studies but solely rely on *in vitro* dissolution rates as proof of a reduction to practice of such *in vivo* claims.

71. In response to a requirement to elect a particular species, Counterclaim Defendants elected "oxycodone, in the event that no generic claim is finally held allowable" ('598 patent file history, Paper #5, Rec'd Feb. 6, 1989, p. 3), although it objected to this requirement "because it is clear that the invention in this case is the extended action CR composition, and this is not affected by the particular pharmaceutical agent." (*Id.*, p. 3).

Prosecution of the '331 patent

72. Counterclaim Defendants filed and prosecuted Application Serial No. 800,549, which issued as the '331 patent, by and through the individuals named therein as "inventors," Oshlack, Chasin and Minogue, and Counterclaim Defendants' patent solicitors.

73. The '331 patent specification alleges that it had not been believed that other analgesics structurally related to hydromorphone could be obtained as CR compositions using techniques similar to those set forth in Counterclaim Defendants' U.S. Patent No. 4,990,341 ("the '341 patent" or "the Goldie '341 patent"), stating:

> While controlled release compositions utilizing hydromorphone as the therapeutically active ingredient were obtained, controlled release compositions containing other therapeutically active agents having the same medicinal use (analgesia) and structurally related to hydromorphone, such as oxycodone, were not believed to be obtained when using similar techniques as those set forth in US Pat. No. 4,990,341. (Col. 1, lines 35-42).

The *in vitro* dissolution profile of the '341 patent was the following:

Time (hours)	Release of Active Ingredient by Percentage Weight
1	12.5-42.5
2	25-55
4	45-75
6	55-85

('341 patent, col. 1, lines 10-26).

74. The '331 patent specification further alleges that those in the pharmaceutical art believed that to obtain a CR drug dosage form having at least a 12-hour therapeutic effect, a peak plasma level must be achieved between 4-8 hours after administration and that it had been surprisingly discovered that, in the case of oxycodone, a peak plasma level at 2-4 hours after administration gives at least 12 hours pain relief, stating:

> In order to obtain a controlled release drug dosage form having at least a 12 hour therapeutic effect, it is usual in the pharmaceutical art to produce a formulation that gives a peak plasma level of the drug between about 4-8 hours after administration (in a single dose study). The present inventors have surprisingly found that, in the case of oxycodone, a peak plasma level at between 2-4 hours after administration gives at least 12 hours pain relief and, most surprisingly, that the pain relief obtained with such a formulation is greater than that achieved with formulations giving peak plasma levels (of oxycodone) in the normal period of 1-2 hours after administration. (Col. 2, lines 15-27).

Counterclaim Defendants asserted that a peak plasma level between 4-8 hours after administration was "usual in the pharmaceutical art" to obtain 12-hour therapeutic effect.

75. During prosecution of the '331 patent application, the PTO Examiner rejected all pending claims for obviousness under 35 U.S.C. § 103 in an April 30, 1992 Office Action, using the Goldie '341 patent as a primary reference and the Oshlack U.S. Patent No. 4,861,598 ("the Oshlack '598 patent") as a secondary reference. ('331 file history, Paper #2, Apr. 30, 1992, p. 2).

76. The Goldie '341 patent, which issued on February 5, 1991, is prior art to the '331 patent under 35 U.S.C. §§ 102(a) and/or 102(e), and is prior art to the later '912, '042 and '295 patents under 35 U.S.C. § 102(b). The Goldie '341 patent discloses, *inter alia*, a CR oral dosage form containing hydromorphone, and teaches that the formulation should be chosen so that the peak plasma level occurs *in vivo* between two and four hours after administration to assure at least 12 hours of pain relief, just as taught in the '331 patent and in the subsequent '912, '042 and '295 patents with respect to CR oxycodone formulations. The specification of the

Goldie '341 patent is virtually identical to the specification of the '331 patent, the most notable difference being that the term "hydromorphone" throughout the specification of the Goldie '341 patent is changed to the term "oxycodone" in the specification of the '331 patent.

77. The Oshlack '598 patent issued on August 29, 1989 and is prior art under 35 U.S.C. § 102(b) to the '331, '912, '042 and '295 patents. As discussed above, the Oshlack '598 patent discloses, *inter alia*, a dosage form containing oxycodone and presents *in vitro* dissolution data for oxycodone formulations, which satisfy the *in vitro* dissolution parameters of the oxycodone formulations of the '331, '912, '042 and '295 patent specifications.

78. In their October 22, 1992, Response to the obviousness rejection, under headings containing the phrases "Surprisingly Improved Results," "Clinical Advantages," and "Results Obtained," Counterclaim Defendants purported to distinguish their claimed CR oxycodone formulations from other opioids by making a representation, highly material to the alleged non-obviousness of applicants' "invention" of the "surprising result" of a four-fold dosage range for 90 percent of patients rather than the approximately eight-fold dosage range required by opioid analgesics in general and CR morphine and CR hydromorphone in particular, under the heading "The Oxycodone Formulations of the Present Inventions Provide Surprisingly Improved Results," stating:

> It has now been surprisingly discovered that the presently claimed controlled release oxycodone formulations acceptably control pain over a *substantially narrower, approximately four-fold* [range] (10 to 40 mg every 12 hours - around-the-clock dosing) in approximately 90% of patients. This is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general. ('331 file history, Paper #4, Rec'd Oct. 28, 1992, pp. 2-3) (emphasis original).

There was neither data set forth in the '331 patent specification, nor any affidavit submitted to support any of the statements respecting the dosage ranges set forth in the file history of the

'331 patent as suggested, necessary or desirable to control pain for approximately 90% of patients for opioid analgesics in general or for CR oxycodone, CR morphine or CR hydromorphone.

79. Also in their October 22, 1992, Response, Counterclaim Defendants and their solicitors made a representation, again highly material to the alleged non-obviousness of applicants' "invention," regarding the comparative dosage range of CR oxycodone to that of CR morphine:

> Despite the fact that both controlled-release oxycodone and controlled-release morphine administered every 12 hours around-the-clock possess qualitatively comparable clinical pharmacokinetic characteristics, the oxycodone formulations of the presently claimed invention can be used over *approximately 1/2 the dosage range* as compared to seemingly similarly controlled release morphine formulations to control 90% of patients with significant pain. ('331 file history, Paper #4, Rec'd Oct. 28, 1992, pp. 3-4) (emphasis original).

80. Further, in their October 22, 1992, Response, Counterclaim Defendants and their solicitors made additional representations, highly material to the alleged non-obviousness of applicants' "invention," regarding the comparative ease of titratability with CR oxycodone versus opioid analgesics requiring approximately twice the dosage range of oxycodone, in a section titled "The Present Invention Provides Important Clinical Advantages":

> 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. ('331 file history, Paper #4, Rec'd Oct. 28, 1992, p. 4).

81. Counterclaim Defendants then concluded in their October 22, 1992 Response:

> It is respectfully submitted that one skilled in the art having knowledge of the controlled release oxycodone [sic, hydromorphone] formulations of Goldie, et al. 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. ('331 file history, Paper #4, Rec'd Oct. 28, 1992, p. 5) (emphasis original).

82. On February 3, 1993, the PTO Examiner maintained the Section 103 rejection over the Goldie '341 and Oshlack '598 patents with respect to pending claims 14-17. ('331 file history, Paper #5, Feb. 3, 1993, p. 3).

83. On or about February 25, 1993, Counterclaim Defendants' solicitors held an interview with the PTO Examiner. The Interview Summary Record noted that Counterclaim Defendants could overcome the Section 103 obviousness rejection by submitting a "proposed declaration supporting unobviousness and unexpected results" (i.e., reduced dosage range) and that a "[t]erminal disclaimer will be filed." ('331 file history, Paper #6, Feb. 25, 1993, p. 1).

84. On or about March 10, 1993, Counterclaim Defendants submitted an Amendment in support of the '331 patent application. In an attempt to overcome, *inter alia*, the PTO Examiner's Section 103 obviousness rejection over the Goldie '341 and Oshlack '598 patents, that paper argued "it is totally impossible to predict what dissolution rates for any particular drug will give rise to an extended duration of action, e.g., a 12 hour duration of action as set forth in this case," and that "[e]ven in the case of closely related drugs, predictability is impossible ...." ('331 file history, Paper #7, Rec'd Apr. 8, 1993, p. 2), and submitted the affidavit of Kaiko in support of these statements.

85. In his declaration filed in support of the '331 application claims, Kaiko was identified as "a person truly skilled in this art....," stated that he was an officer and employee of Purdue (a company never previously or thereafter mentioned in the file history of the

'331 patent). The '331 patent was filed by Euroceltique and did not name Kaiko as an inventor. Thus, Kaiko was presented to the PTO Examiner as a disinterested, objective and independent person of true skill in the art, who had no connection to the assignee of the '331 patent (i.e., Euroceltique) or to the named inventors of the '331 patent. ('331 file history, Paper #7, Rec'd Apr. 8, 1993, p. 2). In his declaration, Kaiko stated:

> The claims of the present patent application are all related in part to the fact that in order to have at least a 12 hour duration of therapeutic activity, the time to reach peak plasma level (t_{max}) of oxycodone in an oral controlled-release formulation should be from 2 to 4 hours after administration. The inventors have further characterized the invention in the claims by way of *in vitro* release rate, pH and other characteristics. (Paper #8, Rev'd Apr. 8, 1993, Decl. of Kaiko, p. 4, ¶10b).

Kaiko further stated that:

> It is my opinion that one skilled in the art having information concerning the time to reach peak plasma concentration (hereinafter referred to as "the t_{max}") and duration of effect for a controlled-release *hydromorphone* formulation as set forth in the Goldie, et al. '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. ('331 file history, Paper #8, Rec'd Apr. 8, 1993, p. 4, ¶11).

Kaiko further stated that:

> It is my further opinion that the teaching of a controlled-release matrix formulation of oxycodone with accompanying *in vitro* dissolution data is not predictive of the t_{max} and the duration of effect which would be achieved with such a formulation *in vivo*. ('331 file history, Paper #8, Rec'd Apr. 8, 1993, p. 4, ¶11a).

Kaiko further stated:

> One cannot infer that *in vitro* release characteristics of a formulation for a particular drug giving rise to certain *in vivo* peak plasma levels and duration of activity (in this case, hydromorphone as taught in the Goldie, et al. '341 patent) will provide the same duration of activity for another drug (i.e., oxycodone). ('331 file history, Paper #8, Rec'd Apr. 8, 1993, p. 4, ¶12).

Kaiko also stated:

> With regard to the Oshlack '598 patent, *in vitro* dissolution data are but one of many factors which must be considered when formulating a particular drug composition, and are often not indicative of *in vivo* effect. One skilled in the art would not be able to accurately predict whether an oxycodone formulation with the *in vitro* dissolution taught in the Oshlack '598 patent would provide the pharmacokinetics (including the tmax) and the pharmacodynamics (including the duration of effect) set forth in the claims of the presently considered patent application identified above. ('331 file history, Paper #8, Rec'd Apr. 8, 1993, p. 5, ¶17).

Finally, Kaiko concluded:

> It is therefore my opinion that one skilled in the art would not arrive at the presently claimed invention by combining the teachings of the [Goldie '341 patent and the Oshlack '598 patent]. ('331 file history, Paper #8, Rec'd Apr. 8, 1993, p. 6, ¶18).

86. An attachment to the Kaiko declaration stated as follows under the title "INVENTION":

> [The invention] acceptably controls pain over a substantially narrower, approximately four-fold [range] (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 controlled-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. ('331 file history, Paper #8, Mar. 9, 1993, attachment p. 3).

The attachment concluded by stating that the "CLINICAL SIGNIFICANCE" of the four-fold dosage range compared to other opioids requiring twice the dosage range was "the most efficient and humane method of managing pain requiring repeated dosing," i.e., an improved titration process, because "the duration of unacceptable pain patients must endure during the opioid

analgesic titration process is substantially reduced. . . ." ('331 file history, Paper #8, Mar. 9, 1993, attachment p. 4).

87. In the Declaration of Dr. Kaiko submitted on March 10, 1993, representations were made 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 claims of the '331 patent application.

88. The Oshlack '598 patent teaches, *inter alia*, a dosage form containing oxycodone and presents *in vitro* dissolution data for oxycodone formulations which satisfy the *in vitro* dissolution parameters of the oxycodone formulations of the '331, '912, '042 and '295 patent specifications.

89. The Oshlack '598 patent also teaches that *in vitro* data is predictive of *in vivo* results:

> Notwithstanding the diverse factors influencing both dissolution and absorption of a drub [sic, drug] substance 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. In view of this relationship, it is clear that the dissolution time determined for a composition is one of the important fundamental characteristics for consideration when evaluating slow release compositions. ('598 patent, col. 2, lines 47-59).

90. In fact, the *in vitro* release rates for oxycodone taught in the Oshlack '598 patent *would* have enabled 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.

91. Counterclaim Defendants and their solicitors were intimately familiar with the teachings of the Oshlack '598 patent. Benjamin Oshlack, a co-"inventor" of the '331 patent, was

the sole inventor of the Oshlack '598 patent. The '598 and '331 patent applications were prosecuted by at least one of the same patent solicitors. Furthermore, both the '331 patent and the Oshlack '598 patent were assigned to a Purdue affiliate (Euroceltique).

92. Also on March 10, 1993, along with the Kaiko declaration and the Amendment, Counterclaim Defendants submitted a Terminal Disclaimer disclaiming the terminal part of any patent granted on the pending application, which would extend beyond the expiration date of the Goldie '341 patent. ('331 file history, Paper #9, Rec'd Apr. 8, 1993). This was done to remove the Goldie '341 patent as a reference against the '331 patent application, as explained in the Amendment papers:

> At the conference, Examiner Spear indicated that it seemed that the Applicants herein were nevertheless trying to claim the same invention as that set forth in the cited Goldie, et al. patent. In other to avoid this possibility, a Terminal Disclaimer is submitted herewith, along with the appropriate fee, disclaiming the terminal portion of any patent to be issued in this case beyond the expiration date of the Goldie, et al. patent. ('331 file history, Paper #7, Rec'd Apr. 8, 1993, p. 3).

93. Counterclaim Defendants concluded their March 10, 1993, Amendment by stating:

> In view of the submission herewith of the Declaration of Dr. Kaiko and of the Terminal Disclaimer, it is believed that Applicants have established the allowability of all of the claims in this case as presently set forth. ('331 file history, Paper #7, Rec'd Apr. 8, 1993, p. 3).

94. Following the submission of the Declaration of Dr. Kaiko and the terminal disclaimer as described above, all pending claims were allowed. ('331 file history, Paper #12, Jun. 14, 1993, p. 1).

95. Thus, the Declaration of Dr. Kaiko and the filing of the terminal disclaimer were highly material to allowance of the '331 patent.

Prosecution of the '912 Patent

96. During prosecution of the '912 patent application, Counterclaim Defendants and their solicitors claimed benefit pursuant to U.S.C. § 120 of the earlier filing date of the '331 patent by amending the '912 patent specification. ('912 file history, Paper #10, Sept. 12, 1995, p. 1). However, all of the pending claims were directed to new matter when Counterclaim Defendants and their solicitors made this amendment, and the pending claims were not entitled to the benefit of the earlier filing date of the '331 patent. In fact, the '331 patent is prior art to the '912 patent under 35 U.S.C. § 102(e).

97. The '912 patent specification states:

> Surveys of daily dosages of opioid analgesics required to control pain suggest that an approximately eight-fold range in daily dosages is required to control pain in approximately 90% of patients. ('912 patent, col. 1, lines 10-13).

The section of the '912 patent specification entitled "Detailed Description" opens with the following past-tense recitation of the "surprising discovery":

> It has now been surprisingly discovered that the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold [range] (10 to 40 mg every 12 hours--around-the-clock dosing) in approximately 90% of patients. This is in sharp contrast to the approximately eight-fold range required for approximately 90% of patients for opioid analgesics in general. ('912 patent, col. 3, lines 33-41).

The '912 patent specification also states:

> 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 relative to a wider dosage range of other mμ-agonist analgesics, indicated for moderate to severe pain, is an example of the unique characteristics of the present invention. ('912 patent, col. 3, lines 42-46).

The '912 patent specification also states:

> Despite the fact that both controlled-release oxycodone and controlled release morphine administered every 12 hours around-the-clock possess qualitatively comparable clinical pharmacokinetic characteristics, the oxycodone formulations of the presently claimed invention can be used over approximately 1/2 the dosage range as compared to commercially available controlled release morphine formulations (such as MS Contin™) to control 90% of patients with significant pain. ('912 patent, col. 3, line 67 - col. 4, line 8)

The '912 patent specification further states:

> 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. ('912 patent, col. 4, lines 51-57).

The '912 patent specification also states:

> 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. ('912 patent, col. 4, lines 58-63).

The '912 patent specification also states:

> In order to obtain a controlled release drug dosage form having at least a 12 hour therapeutic effect, it is usual in the pharmaceutical art to produce a formulation that gives a peak plasma level of the drug between about 4-8 hours after administration (in a single dose study). The present inventors have surprisingly found that, in the case of oxycodone, a peak plasma level at between 2-4.5 hours after administration gives at least 12 hours pain relief and, most surprisingly, that the pain relief obtained with such a formulation is greater than that achieved with formulations giving peak plasma levels (of oxycodone) in the normal period of up to 2 hours after administration. ('912 patent, col. 5, lines 5-15).

Counterclaim Defendants again asserted that a peak plasma level between 4-8 hours after administration was "usual in the pharmaceutical art" to obtain 12-hour therapeutic effect. The '912 patent specification also repeats the statements set forth in Counterclaim paragraph 73.

98. The '912 patent specification did not contain data to support any statements set forth in Counterclaim paragraph 97 regarding dosage ranges as being suggested, necessary or desirable to control pain for approximately 90 percent of patients for opioid analgesics generally or for CR oxycodone in particular.

99. On August 22, 1994, during prosecution of the '912 patent application, the PTO Examiner rejected all pending claims under 35 U.S.C. § 102(b) as being anticipated by the Goldie '341 patent, because the Goldie '341 patent "teaches opioid analgesics with the claimed rate of release." ('912 file history, Paper #6, Aug. 22, 1994, p. 2).

100. In response, Counterclaim Defendants and their solicitors again argued that the claimed CR oxycodone "can be used over approximately 1/2 the dosage range as compared to commercially available controlled-release morphine formulations." ('912 file history, Paper #8, Rec'd Mar. 14, 1995, p. 3). Counterclaim Defendants argued further that "[t]he teaching of controlled-release matrix hydromorphone formulations as set forth in the [Goldie] '341 patent does not provide one with the information necessary to design the claimed controlled-release *oxycodone* formulations which would provide surprising benefits (which would not be obtained via the hydromorphone formulations of the [Goldie] '341 patent)" (*Id.*, p. 5) and that the Goldie "'341 patent is completely silent concerning the particular claimed *in-vivo* parameters claimed herein, which are specifically related to the surprising results obtained by the invention." (*Id.*) These arguments were totally unsupported by any data in the specification of the '912 patent, and were not supported by any affidavit.

101. Counterclaim Defendants further made past-tense representations concerning the surprising finding of narrowing of dosage ranges in the February 22, 1995, Response in a section titled "The Invention":

> The present invention is directed in part to the surprising discovery that by choosing the above-identified parameters in the controlled-release formulation [of the claims], it is possible to acceptably control pain over a substantially narrower dosage range than through the use of other opioid analgesics of similar chemical structure. Thus, Applicants have surprising[ly] 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. ('912 file history, Paper #8, Rec'd Mar. 14, 1995, p. 3).

These arguments were neither supported by any data in the specification of the '912 patent, nor supported by any affidavit. The referenced portion of the specification is set forth above at Counterclaim paragraph 97 and states, in part, that:

> [T]he 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. ('912 patent, col. 4, lines 4-8).

102. Additionally, in the February 22, 1995, Response submitted during the prosecution of the '912 patent application, Counterclaim Defendants and their solicitors argued that *in-vitro* dissolution rates "such as that found in the [Goldie] '341 patent ... are often not indicative of *in-vivo* effect, particularly in the case of opioids" and that "[o]ne skilled in the art would not be able to accurately predict whether a *hydromorphone* formulation with the *in-vitro* dissolution profile taught in the [Goldie] '341 patent would provide the pharmacokinetics (including the mean peak and mean minimum peak plasma concentrations) and the pharmacodynamics (including the duration of effect to allow administrations every 12 hours) set

forth in the claims of the presently considered patent application directed to *oxycodone*." ('912 file history, Paper #8, Rec'd Mar. 14, 1995, p. 6).

103. Additionally, in the February 22, 1995, Response submitted during the prosecution of the '912 patent application, Counterclaim Defendants and their solicitors made representations concerning the comparative ease of titration due to the narrower dosage range:

> The above result is surprising and of extreme clinical importance in that the clinician is able to identify the dose of oxycodone which will control pain in a wide variety of patient populations while reducing the duration of unacceptable pain that individual patients must endure during the opioid analgesic titration process. ('912 file history, Paper #8, Rec'd Mar. 14, 1995, pp. 3-4).

104. In the Office Action following the February 22, 1995 Response, the PTO Examiner withdrew the Section 102(b) rejection. ('912 file history, Paper #9, Jun. 12, 1995, p. 2). Counterclaim Defendants and their solicitors' arguments were thus material to the allowance of the '912 patent claims.

105. The June 12, 1995, Office Action, however, rejected all pending claims of the '912 patent application for obviousness-type double patenting over claim 1 of the '331 patent. ('912 file history, Paper #9, June 12, 1995, p. 2). In addition to making this rejection, the PTO Examiner stated: "Should applicant[s] desire to obtain the benefit of the filing date of the prior ['331 patent] application, attention is directed to 35 U.S.C. § 120 and 37 C.F.R. § 1.78." ('912 file history, Paper #9, June 12, 1995, p. 2).

106. In their responsive Amendment dated September 12, 1995, Counterclaim Defendants and their solicitors amended the specification to claim the benefit of the filing date of the '331 patent. ('912 file history, Paper #10, dated Sept. 12, 1995, p. 1). Counterclaim Defendants and their solicitors also submitted an accompanying Terminal Disclaimer to overcome the PTO Examiner's double patenting rejection over claim 1 of the '331 patent.

107. Counterclaim Defendants have since admitted in its August 8, 2000, Federal Circuit brief that the claims prosecuted and issued in the '912 patent were directed to new matter, and thus were not entitled to the benefit of the earlier filing date of the '331 patent:

> There is no dispute that the ['912] claims that were ultimately prosecuted and issued all relied on new matter first disclosed in '912. These claims were not entitled to the benefit of the '331 filing date. (Brief of Plaintiffs-Appellees by Purdue Pharma L.P., et al., *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, No. 00-1398 (Fed. Cir., Aug. 8, 2000), p. 55).

108. Counterclaim Defendants and their solicitors had a duty to call to the PTO Examiner's attention the fact that none of the pending claims of the '912 patent application were entitled to the benefit of the filing date of the '331 patent, and that the '331 patent was prior art under 35 U.S.C. § 102(e). Instead, Counterclaim Defendants and their solicitors improperly amended the '912 patent specification to claim the benefit of the filing date of the '331 patent, deceptively removing the '331 patent from the prior art.

109. The failure of Counterclaim Defendants and their solicitors to inform the PTO Examiner that the '331 patent was prior art under 35 U.S.C. § 102(e) and that none of the claims of the '912 patent were entitled to the benefit of the filing date of the '331 patent, was done with an intent to deceive and/or mislead the PTO and avoid a rejection which Counterclaim Defendants and their solicitors could not traverse.

Prosecution of the '042 Patent

110. The '042 patent specification is identical to the '912 patent specification, and contains the same statements set forth in Counterclaim paragraph 97.

111. The "Examiner's Statement of Reasons for Allowance" for the '042 patent demonstrates that the PTO Examiner was misled by Counterclaim Defendants about the scope

and coverage of the prior art. In allowing the '042 patent claims, the PTO Examiner, in his December 24, 1995 Statement of Reasons for Allowance, reasoned:

> 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. ('042 file history, Paper #6, Dec. 24, 1995, p. 2).

The PTO Examiner invited Counterclaim Defendants to correct any misstatements in the Examiner's Statement of Reason's for Allowance ("Any comments considered necessary by applicants ..."), but Counterclaim Defendants remained silent, never correcting the PTO Examiner's statement regarding the prior art and never informing the PTO Examiner that in Counterclaim Defendants' view the claims are not directed to a "method for reducing the dosage of oxycodone."

Prosecution of the '295 Patent Using Information Counterclaim Defendants Knew Was False

112. The '295 patent specification contains the same statements set forth in Counterclaim paragraph 97.

113. As explained below, it is now evident that that Counterclaim Defendants and their solicitors' representations regarding the reduction in daily dosage ranges and the comparative ease of titratability were false, that Counterclaim Defendants had knowledge of the falsity of these representations and that Counterclaim Defendants intended to deceive and/or mislead the PTO.

114. Pursuant to 37 C.F.R. § 1.56, all individuals associated with the filing and prosecution of the '331, '912, '042 and '295 patent applications, including Counterclaim Defendants and their solicitors, have an affirmative duty of candor and good faith in dealing with the PTO, which includes 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. This duty is a

continuing obligation which persists throughout the course of prosecution of all of the patent applications.

115. As set out below, one or more of the aforesaid individuals violated their duty of candor and good faith to the PTO by, *inter alia*: (a) submitting a false and/or misleading declaration to the PTO during the prosecution of the '331 patent; (b) failing to apprise the PTO Examiner that the '331 patent could not be removed as prior art with respect to the pending claims of the '912 patent application because none of the claims of the '912 patent application were entitled to the benefit of the filing date of the '331 patent; and (c) making material false and/or misleading statements and representations to the PTO during the prosecution of the '331, '912, '042 and '295 patents and failing to disclose information contradictory to these statements and representations.

116. One or more of the aforesaid individuals committed the aforesaid acts with the intent to deceive and/or mislead the PTO.

Kaiko Was Not An Independent Expert

117. Kaiko was not a named inventor of the '331 patent, and instead was falsely presented during prosecution of the '331 patent (through a declaration submitted to the PTO) as an unbiased, disinterested person of ordinary skill in the art. The '331 patent application was assigned to Euroceltique – not to Purdue itself. Kaiko's declaration identified him as an employee of Purdue. At no time during the prosecution of the '331 patent application was the PTO Examiner informed that (i) Kaiko was in fact a co-worker of the named inventors of the '331 patent application, (ii) Kaiko's employer (i.e., Purdue) was affiliated with the assignee of the '331 patent (i.e., Euroceltique) and was strongly interested in obtaining patent protection for OxyContin®, and (iii) Kaiko's employer (i.e., Purdue) was seeking FDA approval for sale of the

products sought to be patented by the applicants and Euroceltique. By omitting these facts from the Declaration and Amendment, Counterclaim Defendants were able to create the false impression that Kaiko was an unbiased expert.

118. Counterclaim Defendants' statements and representations to the PTO that Kaiko was a person truly skilled in the art as set forth in Counterclaim paragraph 85 and the failure to inform the PTO Examiner of the information set forth in Counterclaim paragraph 117 were affirmative misrepresentations of material facts and led the PTO Examiner to believe that Kaiko, whose declaration the PTO Examiner was required to accept in the absence of contrary information, was an independent, objective and disinterested person.

119. It would have been important and material to the prosecution of the '331 patent application for the PTO Examiner to have known that Kaiko was a co-worker of the named inventors of the '331 patent application, and an employee of a company that had an interest in the issuance of the '331 patent application. This information was known to at least Oshlack, Chasin, Minogue and the attorneys of the '331 patent application, and was intentionally withheld from the PTO Examiner to deceive the Examiner into believing Kaiko was an independent, objective and disinterested person.

120. If the PTO Examiner had known that Kaiko was not an independent, objective, and disinterested person, but rather was a co-worker of the named inventors of the '331 patent application and an employee of a company with an interest in the issuance of the '331 patent, the PTO Examiner would not have accepted the unsupported assertions in the declaration of Kaiko and, instead, would have maintained his rejection of the claims of the '331 patent application.

Withholding of the Contradictory Leslie Information

121. At no time during the prosecution of the '331, '912, '042 and '295 patent applications were the respective PTO Examiners informed of expired[3] U.S. Patent No. 3,965,256 ("Leslie Expired Patent") listing Stewart Thomas Leslie ("Leslie") as the sole inventor. The Leslie Expired Patent discloses methods of making and using solid, controlled release, oral dosage pharmaceutical compositions providing controlled release of therapeutically active compounds incorporated therein over a predetermined period of time after oral ingestion. The Leslie Expired Patent discloses matrices virtually identical to those set forth in the '331, '912, '042, and '295 patents, and is the basis of Counterclaim Defendants' Contin® release system (further described in Counterclaim paragraphs 123-124). The Leslie Expired Patent alleges that such matrices have been unexpectedly found to provide critical control that permits an accurate prediction of the rate of release of the pharmaceutical agents incorporated therein, such as those requiring frequent oral repeated dosage administration, stating:

> It was unexpectedly found ... that the amount of aforesaid hydrated compound present in such formulation ... provides a new and unexpected critical control of the rate of release of a medicament incorporated in said hydrated sustained release composition ... which permits an accurate prediction of the rate of release of a therapeutically active compound per unit time from a unit dosage-form. ('256 patent, col. 3, lines 23-36).
>
> It was further found that the ratio of the amount of the combined higher aliphatic alcohol and hydrated hydroxy-alkyl cellulose to the weight of the formulation had added special effect in controlling the time periods during which the release of the active ingredient from a unit dosage form will occur.... In this manner, sustained release pharmaceutical tablets and capsules may be prepared to provide a release of the active ingredient over a period of five to ten hours. ('256 patent, col. 4, lines 4-29).

[3] This patent expired in 1993.

> The slow release properties of the tablets were evaluated with the disintegration time test and the dissolution rate test. These tests were well known and well accepted methods for evaluating suitability of tablets for human and animal administration. By determining the rate of release of active medicament from a tablet (dissolution rate test), the slow release characteristics of a tablet is demonstrated. ('256 patent, col. 5, lines 29-36).
>
> This test is described in the U.S. Pharmacopeia, XVIII Edition, at pp. 934-935, and is considered to be an objective means of determining the dissolution availability of a solid dosage form. ('256 patent, col. 5, lines 44-47).
>
> [M]edicaments requiring frequent repeated dosage administration by the oral route to maintain a therapeutically active blood level are particularly suitable for inclusion into the present slow release composition. ('256 patent, col. 8, lines 49-53).

Opioid analgesics such as morphine, dihydrocodeine, hydromorphone and oxycodone are such pharmaceutical medicaments.

122. At no time during the prosecution of the '331, '912, '042 or '295 patent applications were the respective PTO Examiners informed that Oshlack:

- At least as early as June 1982, and continuing at least into 1985, made solid, controlled release, oral dosage oxycodone and morphine tables in matrices substantially identical to those described in the '331, '912, '042 and '295 patents using the same methods disclosed in such patents and obtained dissolution rates therefore. ('598 patent file history, Paper #6, Oshlack Decl., Exhs. A, B); and

- Predicted, by March 5, 1985, based on dissolution rate studies, that these matrices would "provide a sustained release of a therapeutically active compound (or compounds) over a period of time from five hours up and to twenty-four hours, after administration (usually oral) in humans or animals." Moreover, Oshlack wrote, "it was unexpectedly found when using [his suggested matrix], that there was a potentiation of the control of the drug release ... and a delay in retardation of usually 5 to 12 hours, even up to 24 hours, can be achieved." Oshlack further wrote that "as the % weight of the retarding agents increases, so does the extension time of the drug release, until the critical point is reached." Finally, Oshlack predicted a controlled release morphine tablet "would thus make this tablet even suitable for a once a day administration." ('598 patent file history, Paper #6, Oshlack Decl., Exh. B)

123. The Contin® or Continus® CR system ("the Contin® release system") developed by Counterclaim Defendants and their affiliates in the 1970s and provides a matrix for slowing the release of a drug in the body that had previously been used successfully with a wide range of drugs, including several opioid analgesics (e.g., morphine), to (i) control the rate of release of opioids and other drugs within the gastrointestinal tract with the result that the opioid or other drug is delivered into the body at a specific, planned rate, and (ii) delay and attenuate the peak plasma levels in comparison with the corresponding immediate release opioid. Michael P. Thirlwell et al., *Pharmacokinetics and Clinical Efficacy of Oral Morphine Solution and Controlled-Release Morphine Tablets in Cancer Patients*, 63 CANCER 2275-2283 (1989); Robert F. Kaiko et al., *Controlled-Release Morphine Bioavailability (MS Contin® Tablets) in the Presence and Absence of Food*, 6 HOSP J. 17-30 (1990) (reporting t_{max} of 2.4 and 2.5 hours for fasted and fed subjects).

124. Counterclaim Defendants knew, at least as early as 1981, that by varying the ingredients of the Contin® release system, they were capable of controlling the diffusion and dissolution of the drug and, therefore, its therapeutic activity *in vivo*, to obtain 12 hours of pain relief in comparison with conventional dosage forms that obtain three hours of pain relief. *E.g.*, Stuart T. Leslie, *Continus Controlled Release Preparations,* 10 BR. J. CLIN. PRACTICE 5-8 (1981). Counterclaim Defendants also knew, at least as early as 1981, that the characteristic drug plasma concentrations for immediate release and CR dosage forms show a peak plasma level at about two hours for immediate release and just less than four hours for controlled release. *Id.*

125. By July 1985, Counterclaim Defendants had concluded two clinical trials showing that MS Contin® provided 12 hours of pain relief in patients with chronic pain. In August 1985,

Counterclaim Defendants published several articles describing the clinical study results including t_{max} values between 2-4.5 hours after administration. John H. Savarese et al., *Steady-State Pharmacokinetics of Controlled Release Oral Morphine Sulphate in Healthy Subjects*, 11 CLIN. PHARMACOKINETICS 505-510 (1986)[4] (DTX 2766) (t_{max}=2.27 hours and provides 12 hours pain relief), and Paul D. Goldenheim, *Current Research on MS Contin*, HOSP. THER. (June 1986) (DTX 3278). Counterclaim Defendants received final FDA approval for MS Contin on May 29, 1987.

126. At no time during prosecution of the '331, '912, '042 or '295 patent applications were the respective PTO Examiners informed of the information contained in Counterclaim paragraphs 123-125.

127. Counterclaim Defendants and their attorney's statements and representations with respect to the impossibility of predicting duration of action from dissolution rates even in the case of closely related drugs as set forth in Counterclaim paragraph 85, and Kaiko's representations that those skilled in the art could not predict peak plasma levels and duration of effect as set forth in Counterclaim paragraph 84 were affirmative misrepresentations of material facts. These misrepresentations led the PTO Examiner during the prosecution of the '331, '912, '042 and '295 patents to believe that:

- Persons skilled in the art believed that *in vitro* dissolution rates are not indicative of *in vivo* effect; and
- Persons skilled in the art could not predict from *in vitro* CR oxycodone dissolution rates the t_{max} and duration of effect of such opioid *in vivo*.

128. It would have been important and material to the prosecution of the '331, '912, '042 and '295 patent applications for the respective PTO Examiners to have known that (i) both

[4] "DTX" refers to an Endo trial exhibit that was offered into evidence during the District Court proceedings in the Southern District of New York with Purdue.

Leslie in the Leslie Expired Patent and Oshlack in his 1985 work as set forth in Counterclaim paragraphs 121-122 predicted from *in vitro* dissolution rates *in vivo* bioavailability effect, (ii) that Leslie and Oshlack had diametrically opposed views from Kaiko's as to the predictability of opioid dissolution rates on *in vivo* effect, (iii) that the Contin® release system had been previously used successfully on a wide range of drugs, including several opioid analgesics that delivered the opioid to the body at a specific and planned rate as set forth in Counterclaim paragraph 123-124 because such information was contrary to the statements and representations made by Counterclaim Defendants, the attorneys and Kaiko, and (iv) that the Contin® release system would be capable, by varying ingredients of the system, of controlling the diffusion and dissolution of drug and therefore its therapeutic activity *in vivo* to obtain 12 hours of pain relief in comparison with conventional dosage forms that obtain 3 hours of pain relief, and that the characteristic drug plasma concentrations for immediate release and CR dosage forms show a peak plasma level at about two hours for immediate release and just under four hours for controlled release. The Leslie and Oshlack information was known to at least Oshlack and the attorneys for the '331, '912, '042 and '295 patents during the prosecution of these patents and the Contin® release system information was known to at least Kaiko, and was intentionally withheld by them in order to deceive the PTO Examiner into believing that dissolution rates were not predictive.

129. If the respective PTO Examiners had known the information about the views of Leslie and Oshlack and the Contin® release system information as set forth in Counterclaim paragraphs 121-128, they would not have accepted the unsupported assertions of Counterclaim Defendants and Kaiko as set forth in Counterclaim paragraphs 85-87, and would have made or maintained their rejections of the claims of the '331, '912, '042 and '295 patent applications.

Oshlack's Earlier CR Oxycodone Product

130. At no time during the prosecution of the '331, '912, '042 or '295 patent applications were the respective PTO Examiners informed that during the period from 1982 to 1985 Oshlack and his team at Purdue made CR oxycodone tablets of at least 10 and 20 milligrams ('598 file history, Paper #6, Oshlack Decl., Exhs. A12, A13), each of which actually or inherently:

- Was made by the methods and using the matrices disclosed as useful in the '331, '912, '042 and '295 patents;
- Meets identically every limitation of claim 1 and substantially all of the remaining claims of the '331 patent, including the dissolution rates, the independence of pH and the peak plasma levels;
- Has a range of daily dosage and provide pain relief equivalent to the examples in the '042 and '295 patents; and
- Has a range of daily dosage, provide pain relief and has a C_{max} and C_{min} equivalent to immediate release oxycodone, with the CR oxycodone providing, as expected, delayed and attenuated peak plasma levels.

131. Development of the CR oxycodone tablets involved matching the initial portion of the dissolution curve for MS Contin to duplicate MS Contin's early rise in blood levels (i.e., t_{max} between 2-4 hours). Tr. 178-179, 504, 570-71.[5]

132. It would have been important and material to the prosecution of the '331, '912, '042 and '295 patent applications for the respective PTO Examiners to have known about the oral dosage CR oxycodone tablets made in 1985 by Oshlack. This information was known to at least Oshlack and the attorneys of the '331, '912, '042 and '295 patents, was intentionally withheld by them in order to deceive the PTO Examiners.

[5] "Tr." refers to a page from the trial transcript of the District Court proceedings in the Southern District of New York between Purdue and Endo.

133. If the respective PTO Examiners had known of the information set forth in Counterclaim paragraphs 130-131, they would have made and maintained their rejections of the claims of the '331, '912, '042 and '295 patent applications.

Counterclaim Defendants' Sale of Prior Art CR Morphine

134. At no time during the prosecution of the '598, '075, '331, '912, '042 and '295 patent applications were the respective PTO Examiners informed of Counterclaim Defendants' sale of solid, controlled release, oral dosage morphine ("CR morphine") tablets that occurred at least as early as 1984 and more than one year prior to the filing of such patent applications. The CR morphine tablets sold by Counterclaim Defendants:

- Were made by the methods and using the matrices disclosed as useful in the '331, '912, '042 and '295 patents;
- Were made using the Contin® release system;
- Have dissolution rates within the scope and coverage of the '331 and '912 patents;
- Have been reported in an article authored by Leslie to have steady state peak plasma levels between 2-4 hours and not between 4-8 hours (Stuart T. Leslie et al., *Controlled Release Morphine Sulphate Tablets – A Study in Normal Volunteers*, 9 BR. J. PHARMACOLOGY 531-34 (1980));
- Have been reported in articles co-authored by Kaiko to have peak plasma levels (t_{max}) of between 2-4 hours, to provide a duration of a therapeutic effect of at least 12 hours after administration and to provide nearly equivalent bioavailability, with the CR morphine providing delayed and attenuated peak plasma levels (John H. Savarese et al., *Steady-State Pharmacokinetics of Controlled Release Oral Morphine Sulphate in Healthy Subjects*, 11 CLIN. PHARMACOKINETICS 505-510 (1986) (DTX 2766)), and to have comparable oral potency and efficacy as immediate release morphine ("IR morphine") (Russell K. Portenoy, M.D., et al., *Oral Controlled-Release Morphine Sulfate*, 63 CANCER 2284-2288 (1989); Robert F. Kaiko et al., *The United States Experience with Oral Controlled-Release Morphine (MS Contin Tablets)*, 63 CANCER 2348-2354 (1989)); and
- Have a range of daily dosage and provide pain relief for cancer patients, when converted to oxycodone on a milligram-by-milligram basis in accordance with

known conversion tables, equivalent to the CR oxycodone examples set forth in the '042 and '295 patents.

135. It would have been important and material to prosecution of the '598, '075, '331, '912, '042 and '295 patent applications for the respective PTO Examiners to have known that CR morphine tablets having the characteristics set forth in Counterclaim paragraph 134 are prior art to each of these applications. This information was known to at least Kaiko and was intentionally withheld by at least him, and in order to deceive the PTO Examiners.

136. If the respective PTO Examiners had known of the information set forth in Counterclaim paragraph 134, they would have made and maintained rejections of the claims of the '331, '912, '042 and '295 patent applications.

Withholding of Counterclaim Defendants' CR Codeine Prior Art

137. At no time during the prosecution of the '331, '912, '042 and '295 patent applications were the respective PTO Examiners informed of Counterclaim Defendants and Kaiko's disclosures of solid, controlled release, oral dosage codeine ("CR codeine") tablets that occurred at least as early as 1986 and more than one year prior to the filing of such patent applications. The CR codeine tablets disclosed by Counterclaim Defendants and Kaiko:

- Were made by the methods and using the matrices disclosed as useful in the '331, '912, '042 and '295 patents;
- Were made using the Contin® release system;
- Have dissolution rates within the scope and coverage of the '331 and '912 patents;
- Have been reported in an article to have a higher oral potency along with oxycodone than the structurally similar morphine and oxymorphine because of the "first pass" effect, which also reports that codeine is structurally similar to oxycodone (William T. Beaver et al., *Analgesic Studies of Codeine and Oxycodone in Patients with Cancer. I. Comparisons of Oral with Intramuscular Codeine and of Oral with Intramuscular Oxycodone,* 207 J. PHARMACOLOGY & EXP. THER. 92-100 (1978));

- Have been reported in an article co-authored by Kaiko to have peak plasma levels (t_{max}) of between 2-4 hours, to provide a duration of therapeutic effect of at least 12 hours after administration and to have comparable overall bioavailability with immediate release codeine ("IR codeine"), with CR codeine providing, as expected, delayed and attenuated peak plasma concentrations, which result were generally similar to those obtained in comparisons of CR and IP morphine (Robert F. Kaiko, et al., *Pharmacokinetic Characterization of Controlled-Release Oral Codeine For Chronic Cancer Pain,* 5 Proceedings of Am. Soc'y of Clin. Oncology 255 (1986));

- Have been reported in articles co-authored by Purdue's Canadian affiliate employees to provide a range of daily dosage and provide pain relief for patients with mild to moderate pain over an approximately two to three fold range (100 to 300 mg and 200 to 400 mg every 12 hours-around-the-clock) in approximately 90% of patients (Srini Chary et al., *The Dose-Response Relationship of Controlled-Release Codeine (Codeine Contin) In Chronic Cancer Pain,* 9 J. PAIN & SYMPTOM MANAGE. 363-71 (Aug. 1994); H.S. Dhaliwal et al., *Randomized Evaluation of Controlled-Release Codeine and Placebo in Chronic Cancer Pain,* 10 J. PAIN & SYMPTOM MANAGE. 612-23 (Nov. 1995)); and

- Have a range of daily dosage and provide pain relief for patients with mild to moderate pain, when converted to oxycodone on a milligram-by-milligram basis in accordance with known conversion tablets, equivalent to the CR oxycodone examples set forth in the '042 and '295 patents.

138. It would have been important and material to prosecution of the '331, '912, '042 and '295 patent applications for the respective PTO Examiners to have known that CR codeine tablets having the characteristics set forth in Counterclaim paragraph 137 are prior art to each of these applications. This information was known to at least Kaiko and was intentionally withheld by at least him, and in order to deceive the PTO Examiners.

139. If the respective PTO Examiners had known of the information set forth in Counterclaim paragraph 137, they would have made and maintained rejections of the claims of the '331, '912, '042 and '295 patent applications.

Withholding of Counterclaim Defendants' CR Dihydrocodeine Prior Art

140. At no time during the prosecution of the '331, '912, '042 or '295 patent applications were the respective PTO Examiners informed that Purdue was issued U.S. Pat. No.

4,828,836 on May 9, 1989 ("the Prior Art '836 patent"), and U.S. Pat. No. 4,834,985 on May 30, 1989 ("the Prior Art '985 patent"). These patents are prior art to the '331, '912, '042 and '295 patents. The Prior Art '836 and '985 patents disclose preferred CR matrices that are virtually identical to the matrices disclosed as useful in the '331, '912, '042 and '295 patents, and teach a variety of therapeutic agents or drugs that may be incorporated into such matrices including "[a]nalgesic agents, such as *morphine*, *codeine*, phenazocine, *dihydrocodeine*, *hydromorphone*, meptazinol, phenacetin, pethidine, paracetamol, *oxycodone*, diamorphine, nalbuphine, buprenorphine, and mefenamic acid." (Col. 3, lines 51-55 and col. 3, lines 39-43, respectively) (emphasis added).

141. At no time during prosecution of the '331, '912, '042 or '295 patent applications were the respective PTO Examiners informed that Counterclaim Defendants filed on May 19, 1987 and was issued U.S. Pat. No. 4,834,984 on May 30, 1989 ("the Prior Art '984 patent"). That patent is prior art to the '331, '912, '042, '295 patents. The Prior Art '984 patent discloses and claims solid, controlled release, oral dosage dihydrocodeine ("CR dihydrocodeine") tablets that were made by the methods and using the matrices disclosed as useful in the '331, '912, '042 and '295 patents. The prior art '984 patent discloses, in words substantially identical to those set forth in Counterclaim paragraph 74 and in the '331, '912, '042 and '295 patents, that CR dihydrocodeine has a peak plasma level of between 2-4 hours and gives at least 12 hours of relief, stating:

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

> Most surprisingly, the present inventors have also found that the pain relief obtained with the present formulation is greater than that achieved with normal release formulations giving peak plasma level (of dihydrocodeine) in the normal period of 1-2 hours after administration. (Col. 2, lines 13-27).

Counterclaim Defendants again asserted that a peak plasma level between 4-8 hours after administration was "usual in the pharmaceutical art" to obtain 12-hour therapeutic effect.

142. At no time during the prosecution of the '331, '912, '042 or '295 patent applications were the respective PTO Examiners informed that the CR dihydrocodeine tablets disclosed in the Prior Art '984 patent were used in clinical studies by Counterclaim Defendants' affiliates more than one year prior to the filing of the '331, '912, '042 and '295 patent applications and, actually or inherently:

- Were made by the methods and using the matrices disclosed as useful in the '331, '912, '042 and '295 patents;
- Were made using the Contin® release system;
- Have dissolution rates within the scope and coverage of the '331 and '912 patents;
- Have peak plasma levels (t_{max}) of between 2-4 hours and provide a duration of therapeutic effect of at least 12 hours after administration;
- Have been reported in the Prior Art '984 patent to have a peak plasma level for 60 mg tablets of 130 ng/ml (C_{max}) at 3.0 hours (t_{max}) as compared with 205 ng/ml (C_{max}) at 1.0 hours (t_{max}) for 30 mg tablets of immediate release dihydrocodeine ("IR dihydrocodeine"), to provide a duration of therapeutic effect of at least 12 hours after administration and to have comparable overall bioavailability and pain relief with IR dihydrocodeine, with CR dihydrocodeine providing delayed and attenuated peak plasma concentrations, in the control of moderate to severe pain for osteoarthritis patients. (Col., 6, lines 35-67; see also R.S. Lloyd, et al., *The Efficacy and Tolerability of Controlled-Release Dihydrocodeine Tablets and Combination Dextropropoxyphene/paracetamol Tablets in Patients with Severe Osteoarthritis of the Hips,* 13 CURR. MED. RES. AND OPIN. 37-48 (1992));

- Have the concentrations and parameters, when converted to oxycodone on a milligram-by-milligram basis in accordance with known conversion tables, equivalent to the CR oxycodone examples set forth in the '912 patent;

- Have a range of daily dosage and pain relief of moderate pain, when converted to oxycodone on a milligram-by-milligram basis in accordance with known conversion tables, equivalent to the CR oxycodone examples set forth in the '042 and '295 patents; and

- Have a range of daily dosage and provide pain relief equivalent to immediate release oral dosage dihydrocodeine tablets.

143. It would have been important and material to prosecution of the '331, '912, '042 and '295 patent applications for the respective PTO Examiners to have known that the Prior Art '836 and '985 patents disclosed control release matrix formulation that are virtually identical to the matrices disclosed as useful in the '331, '912, '042, and '295 patents, and that Counterclaim Defendants believed that such formulations would not be affected by the particular pharmaceutical agent included therein, including opioid analgesics in general. This information was known to at least the attorneys of the '331, '912, '042 and '295 patents and was intentionally withheld by them to deceive the PTO Examiners.

144. It would have been important and material to prosecution of the '331, '912, '042 and '295 patent applications for the respective PTO Examiners to have known that CR dihydrocodeine tablets were patented by Counterclaim Defendants and have a t_{max} at between 2-4 hours and provide a duration of therapeutic effect of at least 12 hours after administration and that such CR dihydrocodeine tablets having the characteristics set forth in Counterclaim paragraphs 141-142 are prior art to each of these applications. This information was known to at least the attorneys of the '331, '912, '042 and '295 patents and was intentionally withheld by them to deceive the PTO Examiners.

145. If the respective PTO Examiners had known of the information set forth in Counterclaim paragraphs 140-142, they would have made and maintained rejections of the claims of the '331, '912, '042, and '295 patent applications.

Withholding of Counterclaim Defendants' CR Hydromorphone Prior Art

146. Counterclaim Defendants were issued U.S. Pat. No. 4,844,909 ("the Prior Art '909 patent") on June 4, 1989. The Prior Art '909 patent is prior art to the '331, '912, '042, and '295 patents. The prior art dihydrocodeine '984 patent and the prior art hydromorphone '909 patent shared common inventors and the same prosecuting attorney. The Prior Art '909 patent discloses and claims solid, controlled release, oral dosage hydromorphone ("CR hydromorphone") tablets that were made by the methods and using the matrices that are identical to those disclosed as useful in the '331, '912, '042, and '295 patents. The Prior Art '909 patent discloses, in words substantially identical to those set forth in the '331, '912, '042, and '295 patents, that the CR hydromorphone tablets have a peak plasma level of between two to four hours and give at least 12 hours of relief, stating:

> In order to obtain a controlled release drug dosage form having at least a 12 hour therapeutic effect, it is usual in the pharmaceutical art to produce a formulation that gives a peak plasma level of the drug between about 4-8 hours after administration (in a single dose study). The present inventors have surprisingly found that, in the case of hydromorphone, a peak plasma level at between 2-4 hours after administration gives at least 12 hours pain relief and, most surprisingly, that the pain relief obtained with such a formulation is greater than that achieved with formulations giving peak plasma levels (of hydromorphone) in the normal period of 1-2 hours after administration. (Col. 2, lines 11-23).

Counterclaim Defendants again asserted that a peak plasma level between 4-8 hours after administration was "usual in the pharmaceutical art" to obtain 12-hour therapeutic effect. In the '341 patent, which is a continuation of the Prior Art '909 patent with the same specification, Counterclaim Defendants stated:

> Even if a person skilled in the art had progressed so far as to consider experimenting with the in vitro release rate, the general teaching in the pharmaceutical art with respect to controlled release formulations would lead such person to expect that in order to obtain a 12 hour therapeutic effect, it would be necessary to aim for a peak plasma level of hydromorphone of between 4-8 hours after administration. It would not be expected that peak plasma levels of between 2 and 4 hours after administration, as called for in the instant disclosure and the claims of this case would give the therapeutic levels of hydromorphone in vivo over a 12 hour period such that the dosage form could be used for twice daily administration. Consequently, the persons skilled in the art could not have predicated the advantages associated with choosing the presently claimed in vitro and in vivo release rates. (Paper #4, Rec'd Jun. 25, 1990, p. 5).

Thus, when the '331 patent was filed, Counterclaim Defendants and those working in the art already knew that preparations with peak plasma levels of between 2 and 4 hours after administration obtained 12 hours of therapeutic effect. Similarly, Counterclaim Defendants and those working in the art knew that *in vitro* dissolution rates determine the therapeutic effect, as demonstrated by arguments made by Counterclaim Defendants to the PTO in the '341 patent prosecution history:

> The limitations of the claims with respect to the specific release times are not merely desired results. The desired result is the obtention [sic] of the analgesic response to hydromorphone with minimum side effects and over the desired prolonged period of time. The specific release rate as set forth in the claims are [sic] applicants' discovery of how to achieve this desired result. (Paper #4, Rec'd Jun. 25, 1990, p. 2).

> [A]pplicants set forth in the claims specific limited release rates which applicants have found to give the best results upon administration of hydromorphone for analgesic purposes. (Paper #4, Rec'd Jun. 25, 1990, p. 2).

> Applicants set forth specific release rates which are essential to achieve the desired results of the present invention. Without the teaching of these specific release rates, there can be no teaching of the present invention. (Paper #4, Rec'd Jun. 25, 1990, p. 3).

147. At no time during the pendency of the '331 patent application was the PTO Examiner informed that Counterclaim Defendants' Prior Art '909 patent is prior art under 35 U.S.C. § 102(b) to the '331 patent application. Though the Prior Art '909 patent specification is identical to the '341 patent (cited by the PTO Examiner), it differs from that patent because the Prior Art '909 patent could neither be antedated under 37 C.F.R. § 1.131 nor overcome by a Terminal Disclaimer.

148. The oral dosage CR hydromorphone tablets disclosed in the Prior Art '909 patent, actually or inherently:

- Were made by the methods and using the matrices disclosed as useful in the '331, '912, '042 and '295 patents;
- Were made using the Contin® release system;
- Have dissolution rates within the scope and coverage of the '331 and '912 patents;
- Meet identically every limitation in claim 1 of the '331 patent, including the dissolution rate schedule, pH independence and the peak plasma level, except for the substitution of the opioid analgesic hydromorphone for oxycodone;
- Have peak plasma levels of between 2-4 hours and provide a duration of effect of at least 12 hours, with CR hydromorphone providing delayed and attenuated peak plasma concentrations as compared to immediate release hydromorphone ("IR hydromorphone");
- Have the concentrations and parameters, when converted to oxycodone on a milligram-by-milligram basis in accordance with known conversion tables, equivalent to the CR oxycodone examples set forth in the '912 patent;
- Have a range of daily dosage and provide pain relief for cancer patients, when converted to oxycodone on a milligram-by-milligram basis in accordance with known conversion tables, equivalent to the CR oxycodone examples set forth in the '042 and '912 patents;
- Are similar to CR morphine and CR oxycodone tablets, these "slow-release opioids have no significant clinical advantage with regard to analgesic efficacy or side-effect profile" and "[t]he main advantage of all these agents is increased patient comfort, particularly when patients require long-term

therapy at home" (Eduardo Bruera, Correspondence, J. OF CLIN. ONCOL., 738 (1998)); and

- Have a range of daily dosage and provide pain relief equivalent to immediate release oral dosage hydromorphone tablets.

149. It would have been important and material to prosecution of the '331, '912, '042 and '295 patent application for the respective PTO Examiners to have known that Counterclaim Defendants' Prior Art '909 patent was a statutory bar and could not be antedated or overcome by a Terminal Disclaimer as set forth in Counterclaim paragraph 147 as was done by the Counterclaim Defendants' attorneys with respect to the '341 patent as set forth in Counterclaim paragraph 92. This information was known to at least the attorneys of the '331, '912, '042, and '295 patents and intentionally withheld by at least them, and in order to deceive the PTO Examiners.

150. It would have been important and material to prosecution of the '331, '912, '042, and '295 patent applications for the PTO Examiner to have known that the Prior Art '909 patent could not be overcome as set forth in Counterclaim paragraphs 146-148. This information was known to the attorneys of the '331, '912, '042, and '295 patents and was intentionally withheld by them to deceive the PTO Examiners.

151. If the respective PTO Examiners had known of the information set forth in Counterclaim paragraph 146-148, they would have made and maintained rejections of claims of the '331, '912, '042 and '295 patent applications.

False and Misleading Statements Regarding the Belief in the Art

152. Counterclaim Defendants and the inventors' statements made during prosecution of the '331 patent regarding therapeutically active agents structurally related to hydromorphone. Although these therapeutically active agents have the same medicinal use as hydromorphone, Counterclaim Defendants and their inventors stated that these agents were not believed

obtainable using the '341 patent techniques as set forth in Counterclaim paragraph 73. These statements were false and affirmative misrepresentations of material facts important to the prosecution of the '331 patent application and were intentionally made to deceive the PTO. At least the attorneys knew that the Prior Art '836 and '985 patents disclosed CR matrices that are virtually identical to the matrices disclosed as useful in the '331, '912, '042, and '295 patents and that such formulations would not be affected by the particular pharmaceutical agent included therein, including opioid analgesics in general, as set forth in Counterclaim paragraph 140 and at least Oshlack, Kaiko and the attorneys knew that at least four prior art opioid analgesics, namely CR morphine, CR codeine, CR dihydrocodeine and CR hydromorphone, were known to have both similar *in vitro* dissolution rates and peak plasma levels of between 2-4 hours with at least a 12 hour duration of therapeutic activity after administration as set forth in Counterclaim paragraphs 134 (CR morphine), 137 (CR codeine), 140-142 (CR dihydrocodeine), and 146-148 (CR hydromorphone).

153. If the PTO Examiner had known that the statements set forth in Counterclaim paragraph 73 were false and had known of the prior art referred to in Counterclaim paragraph 152, he would have made and maintained rejections of the claims of the '331 patent application.

154. Counterclaim Defendants and the inventors' statements made during prosecution of the '331 patent that it was usual in the pharmaceutical art to produce a formulation that gives a peak plasma level between four to eight hours to obtain a CR drug dosage form having at least a 12 hour therapeutic effect, and that the inventors had surprisingly found that, in the case of oxycodone, that such therapeutic effect is obtained with a peak plasma level at between two to four hours and that the pain relief obtained is greater than immediate release formulation as set forth in Counterclaim paragraph 74 were false and affirmative misrepresentations of material

facts important to prosecution of the '331, '912, '042 and '295 patent applications, and were intentionally made to deceive the PTO. At least Oshlack, Kaiko and the attorneys knew that at least four prior art opioid analgesics, namely CR morphine, CR codeine, CR dihydrocodeine and CR hydromorphone, were structurally and chemically similar to oxycodone, had similar *in vitro* dissolution rates, were known to have peak plasma levels of two to four hours that provided at least a 12 hour duration of therapeutic activity after administration and were reported in articles and the Prior Art '984 and '909 patents to provide pain relief greater than their counterpart immediate release formulations as set forth in Counterclaim paragraphs 134 (CR morphine), 137 (CR codeine), 140-142 (CR dihydrocodeine), and 146-148 (CR hydromorphone). None of Counterclaim Defendants' prior CR opioid formulations had a t_{max} of 4-8 hours, and Dr. Kaiko was unable to identify any 12-hour drug with a 4-8 hour t_{max}. Tr. 365-66.

155. If the respective PTO Examiners had known that the statements set forth in Counterclaim paragraph 74 were false and had known of the prior art referred to in Counterclaim paragraph 154, they would have made and maintained rejections of the claims of the '331, '912, '042 and '295 patent applications.

False and Misleading Statements Regarding Obviousness

156. Counterclaim Defendants and the inventors' statements in support of the '331 patent including (i) the statement that even in the case of closely related drugs, predictability of the duration of action is impossible, as set forth in Counterclaim paragraph 84, (ii) Kaiko's statements and opinions that prediction was impossible and that one skilled in the art would not arrive at the claims pending before the PTO Examiner, as set forth in Counterclaim paragraph 85, and (iii) Counterclaim Defendants' argument that one skilled in the art would not be able to accurately predict *in-vivo* effect based on *in vitro* dissolution rates, as set forth in

Counterclaim paragraph 103, were false and affirmative misrepresentations of material facts important to the prosecution of the '331 patent application, as well as the later '912, '042, and '295 patent applications, and were intentionally made to deceive the PTO. At least the attorneys knew that Leslie and Oshlack used dissolution data to predict duration of effect as set forth in Counterclaim paragraphs 121-126. At least the attorneys knew that the Prior Art '836 and '985 patents equated all analgesics as operable within the matrices disclosed as useful in the '331, '912, '042 and '295 patents as set forth in Counterclaim paragraph 140. At least Oshlack, Kaiko and the attorneys knew that CR morphine, CR dihydrocodeine, as well as CR hydromorphone all are chemically, structurally and therapeutically related to oxycodone and have peak plasma levels at between two to four hours and give at least 12 hours pain relief after administration, and at least Kaiko knew that such opioid analgesics have daily dosage levels (consistent with recognized conversion factors between opioids) within the scope and coverage of the '331, '912, '042 and '295 patents as set forth in Counterclaim paragraphs 134 (CR morphine), 137 (CR codeine), 140-142 (CR dihydrocodeine), and 146-148 (CR hydromorphone). At least Kaiko knew that such formulations were "intended to produce a formulation that ... mimicked the C_{max}, C_{min} and percent fluctuation in plasma [opioid] concentration of the IR [opioid] at steady-state." (Robert F. Reder, *Steady State Biovailability of Controlled Release Oxycodone in Normal Subjects*, 18 Clinical Therapeutics 95-105 (1996)).

157. Counterclaim Defendants and Kaiko's statements and representations set forth in Counterclaim paragraphs 85 and 86 led the PTO Examiners to believe that:

- Persons skilled in the art would have concluded that for any CR opioid to have at least a 12 hour duration of therapeutic activity, the time to reach the peak plasma level (t_{max}) should be from four to eight hours;

- Persons skilled in the art could not predict that CR oxycodone having peak plasma levels (t_{max}) of two to four hours would also provide a duration of therapeutic effect of at least 12 hours;

- Persons skilled in the art believed that *in vitro* dissolution rates are not indicative of *in vivo* effect; and

- Persons skills in the art could not predict from *in vitro* dissolution rates for CR oxycodone the t_{max} and duration of effect of such opioid in *in vivo*.

158. At no time during prosecution of the '912, '042, and '295 patent applications were the respective PTO Examiners informed that the results of the clinical tests set forth and claimed in these patent applications "reveal predictable relationships between oxycodone dosage and plasma oxycodone concentrations, as well as between concentration and certain expected opioid effects" as set forth in Purdue Pharma L.P.'s new drug application for its CR oxycodone product.

159. If the respective PTO Examiners (i) had known that the statements set forth in Counterclaim paragraphs 85-86 were false, (ii) had known of the prior art referred to in Counterclaim paragraph 156, and (iii) had known of the information as to predictability submitted to the FDA as set forth in Counterclaim paragraph 158, the PTO Examiners would have made and maintained rejections of the claims of the '331, '912, '042 and '295 patent applications.

False and Misleading Statements and Omissions Regarding Dosage Range Information

160. Counterclaim Defendants' statements made during prosecution and/or in the specifications of the '331, '912, '042 and '295 patents that the "inventors" had "surprisingly discovered" that CR oxycodone unexpectedly controls pain over a four-fold dosage range, while other opioids, in particular CR morphine and CR hydromorphone, require an eight-fold range, allowing for more efficient titration using CR oxycodone and that the specific range of 10-40 mg every 12 hours is sufficient to control pain in approximately 90 percent of patients, were false

and affirmative misrepresentations of material facts important to the prosecution of the '331, '912, '042 and '295 patent applications, and were intentionally made to deceive the PTO.

161. The statements set forth in Counterclaim paragraph 160 do not find support in the Example 17 clinical study set forth in the '912, '042 and '295 patent specifications. This clinical study only summarizes the results of a limited number of patients who received CR oxycodone following abdominal or gynecological surgery. This study is not sufficient to support the statements set forth in Counterclaim paragraph 160, which, at a minimum, would have required a head-to-head comparison with the other CR drugs.

162. Counterclaim Defendants and Kaiko knew during the prosecution of those applications that such a limited study does not provide an adequate basis to support assertions regarding the adequate control of pain within narrow dosage ranges for CR oxycodone in approximately 90 percent of patients.

163. A July 16, 1990 internal Purdue memorandum written by Dr. Kaiko recounted "recent meetings" about "controlled-release oxycodone." The very first sentence under the heading "Rationale for Another Controlled-Release Opioid Analgesic" explained the motivation for pursuing this development activity: "MS Contin may eventually face such serious generic competition that other controlled-release opioids must be considered." DTX 3165 at P664252. Dr. Kaiko contended "it would be unwise to 'put all of our eggs into the MS Contin basket' in the face of the prospect of generic MS Contin competition that would 'crush all of the analgesic eggs.'" *Id.* Under the next heading, "Rationale for Controlled-Release Oxycodone In Particular," Dr. Kaiko further explained that "[w]hile we have reason to believe that other pharmaceutical firms are formulating controlled-release morphine and controlled-release hydromorphone, there is no evidence to date that this is being done with oxycodone. A

controlled-release oxycodone is, thus, less likely to initially have generic competition." *Id.* at P664253. Dr. Kaiko also explained the anticipated "positioning" of this new drug: "Controlled-release oxycodone will be indicated primarily as the opioid analgesic of choice for the management of chronic, moderate to severe cancer-related pain due to its theoretical and, possibly, demonstrable advantages over morphine, given that there will be substantial generic MS Contin competition." *Id.* Dr. Kaiko also explained that oxycodone's known properties gave it theoretical advantages over morphine as a controlled-release formulation:

> Theoretically, oxycodone has an ideal combination of short elimination half-life and high oral-to-parenteral bioavailablity for a controlled-release opioid analgesic. This combination of characteristics is not shared by any other morphine-like agonist analgesic. The shorter elimination half-life, the sooner parenteral bioavailability the less intra- and interindividual variation in bioavailability and, thus, the more efficient the titration process and the stabler the stablization process. (*Id.* at P664252-53).

Referring to claims of a narrower dosage range and improved ease of titration, Dr. Kaiko conceded that:

> 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. (*See Purdue/Endo I*, 2004 U.S. Dist. Lexis 10, *81 (citing DTX 3165)).

164. An internal Purdue memorandum authored by Dr. Kaiko, as well as statements made by Dr. Kaiko at trial indicates that despite Counterclaim Defendants' representations to the PTO that these unexpected results and consequential benefits have been demonstrated, there existed no clinical support for these representations, and Dr. Kaiko knew it. In an internal memorandum, dated September 28, 1993, almost one full year after the filing of the application

for the '912 patent, Dr. Kaiko wrote that the "surprising result" (reduction in dosage range) was merely the expected consequences of the known properties of morphine and oxycodone:

> 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 that with the utilization of drugs with a lower oral bioavailability. (DTX 3629 at P037082-83).

Kaiko requested that the memorandum recipients focus on such an outcome, and also that they examine each of their ongoing planned studies as potential candidates for supporting a "claim" that the primary advantage of OxyContin® over MS Contin® (CR morphine) and other strong opioids is that OxyContin® is "the most efficiently titratable strong analgesic." (*Id.* at P037083).

165. Dr. Kaiko indicated in the memorandum that Counterclaim Defendants have been unable to demonstrate whether CR oxycodone provides a more efficient titration than, for example, CR morphine:

> You should know that the "claim" is theoretically rational but practicably and inherently difficult to demonstrate, in part, because of the extraordinary degree of "noise" typically associated with analgesic studies and, in part, because of the fact that none of our ongoing and planned studies have been specifically designed to address such issues. We should not be discouraged or even surprised in finding "no apparent differences" between the use of OxyContin and other therapies in respect to the "claim." (*Id.*).

166. The following month, Dr. Kaiko reiterated that oxycodone's greater bioavailability meant that it should, as a theoretical matter and thus be easier to titrate to the right dose. DTX 3735. Dr. Kaiko's memorandum summarized the known pharmacological parameters of oxycodone and the expected properties of CR oxycodone as follows:

Property/Expected Behavior	**Basis**
"Short half-life of elimination"	"well established in the literature"
"rapidly attains steady-state plasma oxycodone levels"	"[a]ccording to basic pharmacokinetic principles, a short half-life provides for rapid attainment of steady state."

Property/Expected Behavior	Basis
"rapidly attains stable pain control"	"a drug with a short half-life invariably achieves steady state rapidly and concurrently achieves stable pharmacodynamics."
"rapidly titratable to the 'right dose'	"any drug with a short half-life can be safely and appropriately titrated on a daily basis."
"high oral bioavailability"	"[n]umerous published studies have established that morphine has a low oral bioavailablity (20-40%) while several other studies have established that oxycodone has high oral bioavailablity (50-90%)."
"less variation in bioavailablity"	"any drug with a high oral bioavailability will inherently have less variation associated with its bioavailability than a drug with low oral bioavailability."
"less variations in plasma oxycodone concentrations"	"see the preceding section."
"less variation in pain control"	"any drug with less variation in bioavailability and in plasma concentration will, according to basic pharmacokinetic/pharmacodynamic principles, have less variation associated with its pharmacodynamics."

167. Counterclaim Defendants have sponsored and supported numerous clinical studies that clearly and overwhelmingly contradict its assertions regarding the "surprising discovery" of a four-fold dosage range for the claimed CR oxycodone as compared to an eight-fold dosage range for prior art opioid analgesics. For example, a Purdue-funded study (known as the "Kalso study") conducted at the Helsinki University Hospital in Finland beginning February 22, 1994, was a single site study (i.e., a single investigator) which examined the pharmacokinetic and pharmacodynamic differences between controlled-release oxycodone and controlled-release morphine in patients with cancer pain. (*See* PTX 475).[6]

168. The Kalso study ("Protocol No. OC93-0303") was concluded on May 16, 1995, prior to the issuance of any of the '912, '042 or '295 patents. The results of the Kalso study,

[6] "PTX" refers to a Purdue trial exhibit that was offered into evidence during the District Court proceedings in the Southern District of New York with Endo.

which were submitted by Purdue to the FDA as part of its OxyContin® NDA, were summarized in a final Study Report dated October 17, 1996 (PTX 475). Dr. Kaiko reviewed and approved the Study Report for OC93-0303 as of October 25, 1996, while the '295 patent was still pending. *Id.* at P275624; Tr. 424.

169. The OC93-0303 Study Report stated, under the heading "Conclusions" (p. 26), that CR oxycodone and CR morphine had "comparable efficacy" and further stated:

> The median number of days to stable pain control during titration was not significantly different between treatments. . . . [T]here were no significant differences in time to stable dosing for patients titrated with oxycodone or morphine. (PTX 475 at P275647).

170. The Kalso study data showed that CR oxycodone did *not* exhibit a reduced dosage range in comparison to CR morphine; rather, they were comparable in dosage range and both wider than four-fold. Tr. 1251-52.

171. The data and the stated conclusions of the Kalso study contradict the representations made to the PTO by the Counterclaim Defendants and solicitors during prosecution of the '331, '912, '042 and '295 patents that CR oxycodone has a narrower (four-fold vs. eight-fold) dosage range than CR morphine, and is therefore much more easily titrated. The Kalso study shows that (as Dr. Kaiko clearly knew) Counterclaim Defendants and the inventors and solicitors still did not have clinical support for these representations even by this late date. Although the Kalso study was completed while the '912, '042 and '295 patents were pending before the PTO, it was never brought to the attention of the PTO during the prosecution. The '295 patent was still pending when the final Kalso study report issued. Dr. Kaiko was aware of the conclusions in the final report as of August 16, 1996.

172. Another such Purdue-funded study was a multicenter study (i.e., multiple investigators) conducted between June 1, 1994, and December 27, 1995 (the "Berman study,"

named for one of the investigators, also referred to in the *Endo* trial record as the "Mucci-LoRusso study"). *See* PTX 717. Like the Kalso study, the Berman study was concluded prior to the issuance of any of the '912, '042 or '295 patents, and before the application that led to the '295 patent was filed. Also like the Kalso study, the Berman study examined the pharmacokinetic and pharmacodynamic differences between CR oxycodone and CR morphine in patients with chronic cancer pain.

173. The results of the Berman study ("Protocol No. OC92-1001"), which were submitted by Purdue to the FDA as part of its OxyContin® NDA, were summarized in a final Study Report dated September 27, 1996, which was also reviewed by Kaiko. PTX 717 at P187348. Kaiko was involved with and aware of the study during the pendency of the '912, '042 or '295 patent applications, and testified that at the time he reviewed the final report he was aware that the '295 patent application was pending. Tr. 421-422. Like the Kalso study, the Berman study was never disclosed to the PTO. Dr. Kaiko received a draft of the final study report and on August 22, 1996 provided detailed comments on the draft, including a draft of the conclusions. DTX 4358.

174. In the "Conclusions" section, the OC92-1001 Study Report states (p. 27):

> CR oxycodone was as effective as CR morphine in relieving pain in cancer patients. The median time to achieve stable pain control was two days with both treatments, and the number of dose adjustments required and rescue medication use were similar for both drugs. (PTX 717 at P187373).

175. The results of the Berman study were published in a 1998 article co-authored by Kaiko: P. Mucci-LoRusso et al., *Controlled-release Oxycodone Compared With Controlled-release Morphine in the Treatment of Cancer Pain: a Randomized, Double-blind, Parallel-group Study*, 2 EUR. J. PAIN 239-49 (1998) (DTX 2844). According to the authors, there were no

statistically significant differences between treatment with CR oxycodone and CR morphine with regard to time to stable analgesia (i.e. length of titration) and number of dose adjustments:

> Dose titration to effect was similar with the two treatments.... [There were] no statistically significant differences between treatments.
>
> * * *
>
> The results of the present study show that CR oxycodone was as effective as CR morphine in relieving chronic cancer-related pain. CR oxycodone was as easily titrated to the individual's need for pain control as CR morphine. (*Id.* at 243, 248].

176. The authors of the European Journal of Pain article also compared the daily dosage range of controlled-release oxycodone with that of controlled-release morphine:

> The mean final daily doses of q12h study medication were 101 mg (range: 40-360 mg) in the CR oxycodone group and 140 mg (range: 60-300 mg) in the CR morphine group. (*Id.* at 243).

The daily dosage range reported for controlled-release oxycodone in the Berman study as reported in the European Journal of Pain article was thus *wider* than that reported for controlled-release morphine (nine-fold (40-360 mg) vs. five-fold (60-300 mg), respectively), not the reversed and narrower range comparison (four-fold vs. eight-fold) relied on in the PTO.

177. Purdue and Purdue affiliate employees, including the named inventors of the '912, '042 and '295 patents, have co-authored many articles reporting the results of many of these studies, including the following articles:

- An article co-authored by Kaiko reporting that some surveys indicate that most patients with pain due to advanced cancer can be controlled on dosages of oral morphine between 10 and 30 mg every four hours, a three fold range (Russell K. Portenoy, M.D., et al., *Oral Controlled-Release Morphine Sulfate*, 63 CANCER 2284-2288 (1989));

- An article co-authored by a Purdue Canada employee reporting that mean daily dosages of CR oxycodone and CR hydromorphone for patients with chronic severe cancer pain are equivalent when dosages are compared with known conversion tables and that the efficiency of treatments are equal and

comparable to the mean dosages for CR morphine in previous cancer studies. The article further reports that CR oxycodone doses required to provide optimal analgesia without intolerable side effects range from 20-550 mg/day [a 27-fold range]. This dosage range is degrees of magnitude greater than four-fold and this wide variability among patients is stated to be consistent with the results of previous CR morphine and CR hydromorphone and well within the range of oxycodone doses used in the management of cancer pain (N.A. Hagen and N. Babul, *Comparative Clinical Efficacy and Safety of a Novel Controlled-Release Oxycodone Formulation and Controlled-Release Hydromorphone in the Treatment of Cancer Pain*, 79 CANCER 1428-37 (1997));

- An article based on a Purdue sponsored study reporting that in a comparison of the use of CR oxycodone and CR morphine in cancer related pain, the mean daily dose for CR oxycodone at the end of titration was 123 mg and for CR morphine was 180 mg. Adding rescue doses to these mean daily doses increases the mean daily opioid consumption for CR oxycodone to 148 mg and for CR morphine to 193 mg. During the stable phases, significantly more daily doses of rescue analgesics were required during treatment with CR oxycodone. This study concluded that when both stable phases were combined, pain control with CR morphine was better than with CR oxycodone (T. Heiskanen and E. Kalso, *Controlled-Release Oxycodone and Morphine in Cancer Related Pain*, 73 PAIN 37-45 (1997) (DTX 4145));

- An article co-authored by Purdue Canada employees reporting that a group study of 101 cancer patients demonstrated that CR oxycodone and CR morphine can be used with equal facility for around the clock therapy, the mean daily doses, taking into account the normal conversion tables (oxycodone has a twofold greater oral potency than oral morphine), were substantially equal and the two drugs provide an equivalent level of pain control at morphine equivalent doses over a wide range (Eduardo Bruera et al., *Randomized, Double-Blind, Cross-Over Trial Comparing Safety and Efficacy of Oral Controlled-Release Oxycodone with Controlled-Release Morphine in Patients with Cancer Pain*, 16 J. CLIN. ONCOL. 3222-29 (1998) (DTX 2847));

- A Purdue sponsored study co-authored by Kaiko reporting that for a group of 180 patients, the mean daily dose for CR oxycodone was 114 mg (range 20 to 400 mg) and for IR oxycodone was 127 mg (range 40 to 640 mg). (Ronald Kaplan et al., *Comparison of Controlled Release and Immediate Release Oxycodone Tablets in Patients with Cancer Pain*, 16 J. CLIN. ONCOL. 3230-37 (1998));

- A Purdue sponsored 12-week study involving 87 cancer patients reporting that a "high dose" patient group required a mean daily dose of CR oxycodone of 158.6 mg by the end of the study (Marc L. Citron, *Long-Term Administration*

of Controlled Release Oxycodone Tablets for the Treatment of Cancer Pain, 16 CANCER INVEST. 562-71 (1998));

- An article co-authored by two Purdue Canada employees reporting that for cancer and non-cancer patients the mean daily dosage for CR oxycodone and IR oxycodone was essentially the same with a minimum of dose titration (Robert Salzman et al, *Can a Controlled-Release Oral Dose Form of Oxycodone Be Used as Readily as an Immediate-Release Form for the Purpose of Titrating to Stable Pain Control*, 18 J. PAIN & SYMPTOM MANAGE. 271-79 (Oct. 1999)); and

- Articles reporting that in a study of 10 cancer patients with metastasized cancer and suffering from chronic severe pain, the daily dosage of oral IR morphine and oxycodone required to provide adequate pain relief was approximately the same and the mean daily dosage, taking into account the relative potencies, was comparable (Eija Kalso et al., *Morphine and Oxycodone in the Management of Cancer Pain: Plasma Levels Determined by Chemical and Radioreceptor Assays*, 67 PHARMACOLOGY & TOXICOLOGY 322-28 (1990); Eija Kalso et al., *Morphine and Oxycodone Hydrochloride in the Management of Cancer Pains*, 67 CLIN. PHARMACOLOGY AND THER. 639-46 (1990)).

178. Most of the articles set forth in Counterclaim paragraph 177 were based on studies that Purdue had completed prior to the issuance of the '912, '042 and '295 patents and the information and conclusions set forth therein were known to at least Kaiko during the pendency of the '912, '042 and '295 patent applications. Furthermore, Purdue's sales of CR morphine (MS Contin®) during pendency of the '912, '042 and '295 patent applications showed that approximately 90 percent of such sales were in the range of 15-60 mg, a four-fold range. At no time during the pendency of the '912, '042, and '295 patent applications were the respective PTO Examiners informed of the information and conclusions set forth in Counterclaim paragraphs 162-177, which contradicted Counterclaim Defendants' critical representation that the claimed invention provides a narrower range of dosages for 90 percent of patients.

179. It would have been important and material to prosecution of the '912, '042 and '295 patent applications for the respective PTO Examiners to have known the information set forth in Counterclaim paragraphs 162-178, because if the PTO Examiners had know that

information they would have made and maintained rejections of claims of the '912, '042, and '295 patent applications.

180. At the time that Purdue filed this action, it knew that the claims of the '042 and '295 patents as well as the arguments and statements made to support the '331 and '912 patents were based on unsupported and unscientific data, and the claims of such patents directed to such arguments and statements were invalid. *See Purdue/Endo I*, 2004 U.S. Dist. Lexis 10, *70 (Kaiko had "no scientific proof" for reduction in dosage range representation to PTO Examiners). Therefore, Counterclaim Defendants' listing of the '331, '912, '042 and '295 patents for each of the different OxyContin® strengths in the FDA's Orange Book, including Purdue's amendment to list the '331 and '912 patents with other patents for the 80 mg strength, were deceptive and fraudulent acts done in furtherance of Counterclaim Defendants' improper, exclusionary and anticompetitive pattern and practice of conduct and overall scheme to preserve Counterclaim Defendants' monopoly and to create additional barriers for ANDA applicants which, because of Purdue's wrongful enforcement of invalid patents, are required to submit certifications in their ANDAs regarding the '331, '912, '042 and '295 patents.

Counterclaim Defendants' Sham Litigation

181. Purdue repeatedly filed and prosecuted patent infringement litigation in furtherance of its improper, exclusionary pattern and practice of conduct and overall scheme to monopolize. Purdue brought these suits knowing that clinical studies conducted in 1995 and later contradicted the highly material facts repeatedly misrepresented to the PTO that provided the basis for the issuance of the patents. The filing and maintenance of those lawsuits is wrongful and actionable, both as steps in the overall scheme and standing alone.

182. In addition to the lawsuits against KV and Actavis (1:07-cv00032-*** and 1:07-cv00077-*** (D. Del., Jan. 16, 2007 and Feb. 12, 2007)), Purdue asserted the '912, '042 and '295 patents against Roxane (99 Civ. 3658 (SHS) (S.D.N.Y. May 18, 1999)), Endo (00 Civ. 8029 (SHS) (S.D.N.Y. Oct. 20, 2000), 01 Civ. 2109 (SHS) (S.D.N.Y. Mar. 13, 2001), 01 Civ. 8177 (SHS) (S.D.N.Y. Aug. 30, 2001)), Teva (01 Civ. 8507 (SHS) (S.D.N.Y. Sept. 14, 2001), 01 Civ. 11212 (SHS) (S.D.N.Y. Dec. 6, 2001), 03 Civ. 2312 (SHS) (S.D.N.Y. Apr. 3, 2003)), Impax (02 Civ. 2803 (SHS) (S.D.N.Y. Apr. 11, 2002)), and Mallinckrodt Inc. (06 Civ. 13095 (SHS) (S.D.N.Y. Nov. 9, 2006)).

183. The FDA approved Roxane's NDA for CR oxycodone in October 1998. Purdue filed a "Citizen's Petition" with the FDA on May 18, 1999, to declare the approval null and void. On February 3, 2000, the FDA "stayed" its approval pending the submission of additional test data. Purdue then filed a motion for a preliminary injunction with the United States District Court for the Southern District of New York on or about October 1, 1999. That motion was subsequently granted on May 16, 2000, and the District Court issued a preliminary injunction on May 25, 2000, which enjoined Roxane from infringing, actively inducing infringement of, or contributing to the infringement of various claims of the '912, '042 and '295 patents.

184. The suits by Purdue against Endo, Teva, Impax and Mallinckrodt automatically put in place a stay of any approval until the earliest of the expiration of the patents, the expiration of 30 months from the patent holder's receipt of notice of the Paragraph IV Certification, or a final judicial determination of non-infringement, delaying the sale of CR oxycodone by Endo, Teva, Impax and Mallinckrodt.

185. On or about January 6, 2004, Purdue, through its attorneys, wrote to the FDA and petitioned for stay of action against final approval of any ANDAs for CR oxycodone (i.e., the

ANDAs of Endo, Teva and Impax). That petition was denied by the FDA as being moot on or about March 23, 2004.

186. In the litigation between Purdue and Endo involving the '912, '042 and '295 patents, Endo contended that Purdue committed inequitable conduct when it 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, and that Purdue intentionally failed to disclose material information that contradicted these assertions.

187. On January 5, 2004, the United States District Court for the Southern District of New York issued an Opinion and Order in *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 2004 U.S. Dist. LEXIS 10, *67-68 (S.D.N.Y. Jan. 5, 2004) ("Purdue/Endo I") holding, *inter alia*, the '912, '042, and '295 patents unenforceable due to inequitable conduct during their prosecution and that of their parent the '331 patent. The district court also enjoined Purdue Pharma L.P., Purdue Frederick Company, P.F. Laboratories, Inc., and Purdue Pharma Company from further enforcement on the '912, '042 and '295 patents. The district court found to be material the repeated assertions that the inventors "surprisingly discovered" a narrower dosage range that are made in the specifications of the '912, '042 and '295 patents, as well as the repeated assertions during prosecution that the invention provided pain relief in approximately 90 percent of patients over a four-fold dosage range, leading to easier titration. *Purdue/Endo I,* 2004 U.S. Dist. LEXIS *68-78.

188. The district court also considered Dr. Kaiko's trial testimony (i) admitting 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, (ii) admitting that no data at all existed for his "insight" that a CR oxycodone formulation would have 1/2 the dosage range of morphine, and (iii) stating that

instead these representations were based on an "insight ... that the range around the oral bioavailability of oxycodone had to be narrower than the range around the oral bioavailability of morphine" which led him to "envision[] ... [a] proposed controlled-release oxycodone product ... having an approximate four-fold range." *Id.* at *70.

189. The district court then "[found], 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." *Id.* at *74. "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' range of doses for 'approximately 90%' of patients." *Id.* at *74-75. "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.'" *Id.* at *75. The district court then summarized the bases for its finding of materiality:

> 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 *77).

The district court continued, "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' .... 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." *Id.* at *79, *81. The district court added, "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.'" *See id.* at *83. Accordingly, the district court concluded:

> "Accordingly, any good faith belief that Purdue had 'discovered' the reduction in dosage range is substantially undercut by its admitted inability to prove, or even to develop, a 'set of procedures and methods' to prove this reduction in dosage range (and related ease of titration), and cannot 'overcome an inference of intent to mislead.'" *See id.* at *83-84.

190. The district court found that Counterclaim Defendants misrepresented these material facts with the intent to deceive the PTO.

191. The Federal Circuit affirmed the district court's ruling. *Purdue Pharma L.P. v. Endo Pharms., Inc.*, 410 F.3d 690 (Fed. Cir. 2005). On petition for rehearing, the Federal Circuit reaffirmed the district court's determination that during the prosecution of the patents-in-suit, Counterclaim Defendants failed to disclose material information relating to the alleged four-fold dosage range benefit for controlled-release oxycodone with the intent to deceive the PTO:

> In light of Purdue's consistent representations of the four-fold dosage range for controlled release oxycodone as a 'surprising discovery' and the context in which that statement was repeatedly made, we cannot say the trial court's finding that Purdue failed to disclose material information was clearly erroneous. While Purdue never expressly stated that the discovery of the four-fold dosage range was based on the results of clinical studies, that conclusion was clearly to be inferred from the language used by Purdue in both the patents and prosecution history. (*Purdue Pharma L.P. v. Endo Pharms., Inc.*, 438 F.3d 1123, 1131 (Fed. Cir. 2006)).

The Federal Circuit pointed out that Counterclaim Defendants' repeated reference to the four-fold dosage range as a "result" falsely implied that actual clinical results supporting Counterclaim Defendants' comparative dosage range claim had been obtained, as did

Counterclaim Defendants' frequent emphasis of the "clinical significance" of their alleged discovery and their repeated quantitative comparison of the dosage range of CR oxycodone to that of other opioids (i.e. four-fold vs. eight-fold for approximately 90 percent of patients). *Id.* The Federal Circuit further stated that: "[i]nformation that Purdue's assertion of a four-fold dosage range was based only on Dr. Kaiko's insight and not on experimental results was material because it was inconsistent with Purdue's statement suggesting otherwise," but vacated the district court's judgment of inequitable conduct and remanded the action for further proceedings. *Id.* at 1132. The Federal Circuit explained its affirmance of this Court's finding that Counterclaim Defendants withheld material information during the procurement of the patents-in-suit as follows:

> We emphasize that this case is an unusual one. A failure to inform the PTO whether a "surprising discovery" was based on insight or experimental data does not in itself amount to a material omission. In this case, however, Purdue did *much more* than characterize the four-fold dosage range of the claimed oxycodone formulation as a surprising discovery. *Purdue repeatedly relied on that discovery to distinguish its invention from other prior art opioids while using language that suggested the existence of clinical results supporting the reduced dosage range.* Presented with these unique facts, we cannot say the trial court erred in finding that Purdue failed to disclose material information to the PTO.

Id. at 1133 (emphasis added).

192. On or about June 7, 2005, after expiration of the 30-month stay, Endo began selling CR oxycodone in the United States. Teva began selling CR oxycodone in the United States on or about December 7, 2005. In 2006, both Endo and Teva settled the patent infringement suits brought by Purdue asserting the '912, '042 and '295 patents. The settement agreements provided that Endo and Teva agreed to stop selling CR oxycodone in the United States after December 1, 2006 and after about March 31, 2007, respectively.

193. The patent infringement claims against Impax and Impax's counterclaims against Counterclaim Defendants continue to be litigated. The case was remanded to the district court for findings consistent with the Federal Circuit's opinion that Counterclaim Defendants intentionally made material misstatements to the PTO. The district court was asked to make a finding regarding the level of materiality and then weigh the materiality of the statements against Counterclaim Defendants' intent to reach a decision whether the patents were unenforceable.

194. Purdue sued KV in this district for infringement of the '912, '042, and '295 patents on January 16, 2007 (07 CV 032) and again on February 12, 2007 (07 CV 077).

195. At the time it sued, Purdue knew that the bases for issuance of the '912, '042 and '295 patents were false, but nevertheless filed the objectively baseless suit at the time it filed, Purdue knew:

- that it had procured the patents through fraud to the PTO;
- that clinical studies both during and after the prosecution of the patents clearly contradicted Purdue's sole basis for the patents;
- the two courts agreed that Purdue had intentionally made material misrepresentations to the PTO.

196. By filing the lawsuits against KV, Purdue triggered 30-month stay periods that prohibit the FDA from granting final approval of KV's ANDA.

197. Purdue filed the lawsuits against KV even though, as a result of Counterclaim Defendants' fraudulent procurement of the patents, it had no factual basis – and knew it had no factual basis – for alleging infringement.

198. Purdue was aware when it filed suit against KV that the mere filing of the complaint would impose a 30-month stay during which time the FDA is prevented from granting final approval of KV's ANDA, regardless of the lack of merit of Purdue's allegations. Purdue

sued with the intention of gaining well over 30 additional months of continued monopoly of the Relevant Market.

199. Purdue filed, prosecuted, maintained and/or settled all of the infringement suits with the improper and exclusionary intent to interfere directly with the various relationships of KV and maintain an illegal monopoly in the Relevant Market through the improper use of the judicial process. Purdue filed, prosecuted and maintained all of the infringement suits, not to obtain a favorable outcome on the merits, but in furtherance of its overall scheme to thwart competition and monopolize the Relevant Market.

VI. ANTICOMPETITIVE EFFECTS OF COUNTERCLAIM DEFENDANTS' CONDUCT

200. Counterclaim Defendants' overall scheme to maintain its monopoly through, among other things, engaging in a pattern and practice of (a) omitting and misrepresenting material facts with the intent to deceive the PTO and (b) filing multiple patent infringement suits when Counterclaim Defendants knew the '912, '042 and '295 patents were unenforceable because they were procured by fraud is exclusionary and unreasonably restrains competition. The conduct is reasonably capable of creating, enlarging or maintaining Counterclaim Defendants' monopoly power by impairing the opportunities of rivals, including KV.

201. Counterclaim Defendants' procurement of '912, '042 and '295 patents (as well as the '331 patent) through intentional, material omissions and misrepresentations was done solely to permit Purdue to create and maintain a monopoly. Counterclaim Defendants knew they were not entitled to the legitimate temporary monopoly created by patent protection because they knew the only reason the patents issued was their convincing the PTO that these patents were distinguishable from prior art. Counterclaim Defendants repeated this fraud and inequitable

conduct on the PTO as to the '331, '912, '042 and '295 patents. That conduct was exclusionary and an unreasonable restraint of trade.

202. Counterclaim Defendants' wrongful filing and wrongful maintenance of multiple infringement suits was exclusionary and unreasonably restrained, and unreasonably continues to restrain, competition. Purdue knew when it sued Roxane, Endo, Teva, Impax and Mallinckrodt that Counterclaim Defendants had procured the relevant patents through fraud on the PTO. When it sued KV and Actavis, Purdue knew that clinical studies contradicted the bases offered for the patents and that two federal courts had found that Counterclaim Defendants had intentionally misrepresented material facts to the PTO, intending to deceive it. Counterclaim Defendants abused and manipulated the Hatch Waxman regime through the wrongful filing and maintenance of all of these suits for exclusionary and anticompetitive purposes, with the direct and intended effect of blocking competition from KV and other rivals and harming consumers. Consequently, Purdue engaged in a pattern of sham litigation with the intent to injure competition.

203. Counterclaim Defendants' overall scheme allowed it wrongfully to obtain and maintain monopoly power.

204. But for Counterclaim Defendants' anticompetitive conduct and overall scheme, doctors, patients and health care providers would have the option to prescribe or purchase less expensive generic CR oxycodone, and patients in the United States would be able to receive the benefits of CR oxycodone at competitive prices. As a direct and proximate result of Counterclaim Defendants' anticompetitive conduct and overall scheme, patients in the United States currently must pay, and in the future likely will be required to pay, supra-competitive prices for CR oxycodone.

VII. INJURY TO COMPETITION, ANTITRUST INJURY AND DAMAGES

205. When a physician prescribes a pharmaceutical product, such as OxyContin®, unless the physician directs otherwise, pharmacies automatically fill the prescription with a generic substitute if one is available, because generic substitutes are priced substantially below branded pharmaceuticals.

206. As a result of Counterclaim Defendants' improper and exclusionary conduct in securing patents through fraud on the PTO, generic rivals were, and continue to be, precluded from the Relevant Market with the result that overall prices for CR oxycodone to patients and healthcare providers are higher than they otherwise would be, and healthcare providers and patients are deprived of choices that would otherwise exist.

207. Counterclaim Defendants' anticompetitive conduct and overall scheme injured KV when Purdue sued KV for patent infringement in January 2007 and in February 2007. The 30-month statutory stays will delay KV's entry into the Relevant Market. Until either the litigations are resolved or the 30-month stays expire, the FDA will be prevented from granting KV final approval of its ANDA.

208. KV would receive FDA final approval prior to the end of the relevant Hatch-Waxman stay but for Counterclaim Defendants' improper and exclusionary conduct. Upon approval, KV would begin commercial manufacture and sale of CR oxycodone products.

209. Because KV's competing CR oxycodone products would be priced competitively and automatically would be substitutable for Purdue's OxyContin®, KV would capture significant sales immediately upon entry into the Relevant Market.

210. Counterclaim Defendants' conduct in furtherance of its overall scheme to monopolize has prevented and will continue to delay the entry of a court order discontinuing, dismissing or otherwise terminating Counterclaim Defendants' patent infringement actions,

thereby maintaining in place the statutory stay period and preventing KV from obtaining final FDA approval of its CR oxycodone products.

211. Counterclaim Defendants' conduct their furtherance of its their scheme to monopolize and prevent competition directly and proximately is foreclosing KV from the Relevant Market and is causing injury to KV in at least the following ways:

a. KV has been forced to expend, and is continuing to expend, substantial sums to study and defend against the '912, '042 and '295 patents, and the expenses of this litigation.

b. KV will lose millions of dollars in profits from lost sales of its generic CR oxycodone products by virtue of its foreclosure from the Relevant Market and the destruction of generic competition in the Relevant Market in which Counterclaim Defendants are illegally maintaining their monopoly power;

c. KV will be prevented from developing new customer relationships and competitive advantage with respect to generic versions of OxyContin® in the Relevant Market by virtue of Counterclaim Defendants' improper conduct that is allowing them to market and sell OxyContin® unimpeded by competition; and

d. KV is losing valuable goodwill due to the competitive disadvantage resulting from its foreclosure from the Relevant Market.

212. Counterclaim Defendants' conduct is continuing, and without the intervention of the Court, KV faces continuing and irreparable damage and injury from Counterclaim Defendants' '912, '042 and '295 patents and from being restricted from entering the Relevant Market. In addition, KV has suffered and continues to suffer monetary damages in an amount to be determined at trial.

213. KV does not currently know the full extent of its damages, but it is believed that the total of the actual damages for the causes alleged herein above will be substantial. KV reserves the right to amend the present Counterclaims at such time as KV has ascertained more precisely the full extent of its damages.

214. The injury to competition flows directly from KV's injuries, and both KV's injuries and the injury to competition result directly from Counterclaim Defendants' anticompetitive conduct.

215. The injury to KV resulting from Purdue's wrongful conduct constitutes antitrust injury.

VIII. NEED FOR INJUNCTIVE RELIEF

216. Counterclaim Defendants' anticompetitive conduct has foreclosed competition in the Relevant Market that otherwise would have existed.

217. But for Counterclaim Defendants' anticompetitive conduct, entry of rivals' CR oxycodone products would have established competition in sales of CR oxycodone. Instead, Counterclaim Defendants' anticompetitive conduct had the purpose and effect of both impeding past competition and preventing future competition.

218. Counterclaim Defendants obtained the '912, '042 and '295 patents through fraud on the PTO in furtherance of their overall scheme to prevent past and future competition.

219. Counterclaim Defendants filed, and are maintaining, sham lawsuits in furtherance of their overall scheme to prevent past and future competition.

220. But for Counterclaim Defendants' wrongful conduct alleged herein, no current or future patents would block KV or other rivals from selling CR oxycodone products in the United States and establishing competition in the Relevant Market.

221. KV has suffered, and will continue to suffer, irreparable harm as a direct and proximate result of Counterclaim Defendants' improper and exclusionary conduct in procuring their patents through fraud and, knowing the patents are invalid, filing and maintaining suits to enforce those patents. That harm cannot be redressed fully by money damages.

222. The irreparable harm to KV constitutes antitrust injury.

223. To allow for competition and to afford consumers the benefits of competition they should have been receiving for several years, the Court should order Counterclaim Defendants to withdraw the '331, '912, '042 and '295 patents from the Orange Book, which immediately would permit unfettered competition by KV and others, and/or should enjoin Counterclaim Defendants from enforcing the patents against KV.

224. This remedy is necessary to establish competition and prevent Counterclaim Defendants from continuing their scheme to block generic competition in the future.

225. Other injunctive relief may be needed to prevent future harm and restore the status quo.

IX. COUNT I—DECLARATION OF INVALIDITY

226. KV repeats and re-alleges the allegations of Counterclaim paragraphs 1-225 as though alleged herein.

227. The '912, '042, and '295 patents are each invalid and void for failure to meet one or more of the conditions for patentability set forth in the patent laws of the United States, 35 U.S.C. § 101 *et seq.*, including but not limited to the requirements set forth in 35 U.S.C. §§ 101, 102, 103, 112, 132, 282 and/or double patenting, and KV is entitled to a declaration to that effect.

228. There is an actual controversy between KV and Purdue as to the invalidity of the '912, '042 and '295 patents.

X. COUNT II— DECLARATION OF NON-INFRINGEMENT

229. KV repeats and re-alleges the allegations of Counterclaim paragraphs 1-225 as though alleged herein.

230. KV has not infringed any claim of the '912 patent, either directly or indirectly, literally or under the doctrine of equivalents, willfully, or otherwise, and KV is entitled to a declaration to that effect.

231. KV has not infringed any claim of the '042 patent, either directly or indirectly, literally or under the doctrine of equivalents, willfully, or otherwise, and KV is entitled to a declaration to that effect.

232. KV has not infringed any claim of the '295 patent, either directly or indirectly, literally or under the doctrine of equivalents, willfully, or otherwise, and KV is entitled to a declaration to that effect.

233. There is an actual controversy between KV and Purdue as to the noninfringement of the '912, '042 and '295 patents.

XI. COUNT III— DECLARATION OF UNENFORCEABILITY

234. KV repeats and re-alleges the allegations of Counterclaim paragraphs 1-225 as though alleged herein.

235. At least the inventors and attorneys of the '912, '042 and '295 patents breached their duty of candor to the PTO by making affirmative misrepresentations of material facts, failing to disclose material information and submitting false information to the PTO with an intent to deceive the PTO.

236. The misrepresentations and withheld information were material to the issuance of the '912, '042, and '295 patents.

237. The '912, '042, and '295 patents were procured by inequitable conduct in violation of applicable laws and regulations and by common law fraud, and therefore the '912, '042, and '295 patents are unenforceable.

238. There is an actual controversy between KV and Counterclaim Defendants as to the unenforceabilty of the '912, '042 and '295 patents in view of Counterclaim Defendants' inequitable conduct during the prosecution of the applications for the '912, '042 and '295 patents as set forth above.

XII. COUNT IV—MONOPOLIZATION (SHERMAN ACT § 2) THROUGH *WALKER PROCESS* FRAUD

239. KV repeats and re-alleges the allegations of Counterclaim paragraphs 1-225 as though alleged herein.

240. Counterclaim Defendants have monopoly power in the Relevant Market.

241. By obtaining and enforcing the fraudulently obtained '912, '042 and '295 patents, Counterclaim Defendants have willfully acquired a monopoly over the manufacture, use and/or sale of CR oxycodone in the Relevant Market possesses the power to exclude others from producing, and is the exclusive producer of, OxyContin® in the United States. The existence of the '912, '042 and '295 patents raises significant barriers to entry into the Relevant Market.

242. Counterclaim Defendants knowingly and willfully misrepresented highly material facts to the PTO in connection with their prosecution of the '331, '912, '042 and '295 patents.

243. Counterclaim Defendants made the misrepresentations to the PTO with the intent to deceive the PTO Examiners and cause the PTO to issue invalid patents.

244. Counterclaim Defendants knowingly and willfully omitted highly material facts from the PTO in connection with their prosecution of the '331, '912, '042 and '295 patents. Counterclaim Defendants' intent to deceive is evident from separate affirmative statements Counterclaim Defendants made to contradict the information omitted and from collateral evidence, including their own internal documents.

245. The PTO relied on Counterclaim Defendants' misrepresentations in granting the '331, '912, '042 and '295 patents, and but for the misrepresentations of material fact, Counterclaim Defendants' claims would not have issued.

246. Counterclaim Defendants caused the patents to be listed, and remain listed, in the Orange Book despite their knowledge that the patents were obtained by fraud and, as a result, unenforceable. Maintaining the patents in the Orange Book allowed Counterclaim Defendants to maintain their monopoly.

247. Counterclaim Defendants' conduct occurred in, and is having a substantial effect on, interstate commerce.

248. Counterclaim Defendants' conduct has injured and will continue to injure competition in the form of, among other things, higher prices for and reduced customer choices among CR oxycodone products.

249. As an intended, direct, foreseeable and proximate result of Counterclaim Defendants' wrongful, anticompetitive conduct, there has been cognizable injury to both KV and to competition. Counterclaim Defendants' monopolistic conduct has also caused and/or will cause harm to other actual and/or prospective competitors in the Relevant Market and to purchasers and prospective purchasers in the Relevant Market.

250. As a direct and proximate cause of Counterclaim Defendants' exclusionary and anticompetitive conduct, KV has been injured and has sustained damages.

251. As a direct and proximate cause of Counterclaim Defendants' exclusionary and anticompetitive conduct, KV will continue to sustain damages in the future.

252. The injury to KV constitutes antitrust injury.

253. KV is entitled to recovery for its damages under Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15.

XIII. COUNT V—MONOPOLIZATION (SHERMAN ACT § 2) THROUGH SHAM LITIGATION

254. KV repeats and re-alleges the allegations of Counterclaim paragraphs 1-225 as though alleged herein.

255. Counterclaim Defendants have monopoly power in the Relevant Market.

256. Counterclaim Defendants have taken exclusionary acts to improperly acquire or maintain monopoly power in the Relevant Market, including through the filing and maintenance of objectively baseless patent infringement suits against KV and other rivals without any good-faith belief that Purdue could prevail in the litigation and with the subjective intent of preventing, impeding or delaying KV and other rivals' entry into the Relevant Market through the use and abuse of judicial processes.

257. Counterclaim Defendants' actions have unreasonably restrained trade in the Relevant Market.

258. Counterclaim Defendants' conduct occurred in, and is having a substantial effect on, interstate commerce.

259. Counterclaim Defendants' conduct has injured and will continue to injure competition in the form of, among other things, higher prices for and reduced customer choices among CR oxycodone products.

260. As an intended, direct, foreseeable and proximate result of Counterclaim Defendants' wrongful, anticompetitive conduct, there has been cognizable injury to both KV and to competition. Counterclaim Defendants' monopolistic conduct has also caused and/or will

cause harm to other actual and/or prospective competitors in the Relevant Market and to purchasers and prospective purchasers in the Relevant Market.

261. As a direct and proximate cause of Counterclaim Defendants' exclusionary and anticompetitive conduct, KV has been injured and has sustained damages.

262. As a direct and proximate cause of Counterclaim Defendants' exclusionary and anticompetitive conduct, KV will continue to sustain damages in the future.

263. The injury to KV constitutes antitrust injury.

264. KV is entitled to recovery for its damages under Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15.

XIV. COUNT VI—OVERALL SCHEME TO MONOPOLIZE (SHERMAN ACT § 2)

265. KV repeats and re-alleges the allegations of Counterclaim paragraphs 1-225 as though alleged herein.

266. Counterclaim Defendants have monopoly power in the Relevant Market.

267. Counterclaim Defendants have engaged in an overall scheme with specific intent to wrongfully monopolize the Relevant Market.

268. Counterclaim Defendants have engaged in a pattern and practice of exclusionary conduct in furtherance of their overall scheme to monopolize, including:

a. Obtaining the '331, '912, '042 and '295 patents through fraud on the PTO;

b. Filing and maintaining patent infringement actions against KV and other rivals under the Hatch-Waxman Act, even though the '331, '912, '042 and '295 patents are unenforceable; and

c. Taking other actions in support of their overall scheme.

269. Counterclaim Defendants' actions have unreasonably restrained trade in the Relevant Market.

270. Counterclaim Defendants' conduct occurred in, and is having a substantial effect on, interstate commerce.

271. Counterclaim Defendants' conduct has injured and will continue to injure competition in the form of, among other things, higher prices for and reduced customer choices among CR oxycodone products.

272. As an intended, direct, foreseeable and proximate result of Counterclaim Defendants' wrongful, anticompetitive conduct, there has been cognizable injury to both KV and to competition. Counterclaim Defendants' monopolistic conduct has also caused and/or will cause harm to other actual and/or prospective competitors in the Relevant Market and to purchasers and prospective purchasers in the Relevant Market.

273. As a direct and proximate cause of Counterclaim Defendants' exclusionary and anticompetitive conduct, KV has been injured and has sustained damages.

274. As a direct and proximate cause of Counterclaim Defendants' exclusionary and anticompetitive conduct, KV will continue to sustain damages in the future.

275. The injury to KV constitutes antitrust injury.

276. KV is entitled to recovery for its damages under Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15.

XV. COUNT VI – ATTEMPTED MONOPOLIZATION (SHERMAN ACT § 2)

277. KV repeats and re-alleges the allegations of Counterclaim paragraphs 1-225 as though alleged herein.

278. Counterclaim Defendants have attempted to monopolize the Relevant Market.

279. Counterclaim Defendants have a specific intent to monopolize, and have taken affirmative exclusionary acts in furtherance of their attempt to monopolize.

280. There is a dangerous probability that Counterclaim Defendants will succeed in their attempt to acquire or maintain monopoly power in the Relevant Market.

281. Counterclaim Defendants' conduct occurred in, and is having a substantial effect on, interstate commerce.

282. As a direct and proximate cause of Counterclaim Defendants' exclusionary and anticompetitive conduct, KV has been injured and has sustained damages.

283. The injury to KV constitutes antitrust injury.

284. KV is entitled to recover for its damages under Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15.

XVI. COUNT VII – CONSPIRACY TO MONOPOLIZE (15 U.S.C. § 2)

285. KV repeats and re-alleges the allegations of Counterclaim paragraphs 1-225 as though alleged herein.

286. Counterclaim Defendants have monopoly power in the Relevant Market.

287. Counterclaim Defendants entered into a contract, combination or conspiracy to monopolize the Relevant Market and have engaged in an overall scheme to wrongfully monopolize the Relevant Market.

288. Counterclaim Defendants have engaged in an overall scheme to wrongfully monopolize the Relevant Market.

289. Counterclaim Defendants have engaged in a pattern and practice of exclusionary conduct in furtherance of their overall scheme and conspiracy to monopolize, including:

a. Obtaining the '331, '912, '042 and '295 patents through fraud on the PTO;

b. Filing and maintaining patent infringement actions against KV and other rivals under the Hatch-Waxman Act, even though the '331, '912, '042 and '295 patents are unenforceable; and

c. Taking other actions in support of their conspiracy.

290. Counterclaim Defendants acted with specific intent to monopolize.

291. Counterclaim Defendants' actions have unreasonably restrained trade in the Relevant Market.

292. Counterclaim Defendants' conduct occurred in, and is having a substantial effect on, interstate commerce.

293. As a direct and proximate cause of Counterclaim Defendants' exclusionary and anticompetitive conduct, KV has been injured and has sustained damages.

294. The injury to KV constitutes antitrust injury.

295. KV is entitled to recover for its damages under Section 2 of the Sherman Act, 15 U.S.C. § 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15.

XVII. COUNT VIII – UNREASONABLE RESTRAINT OF TRADE (15 U.S.C. § 1)

296. KV repeats and re-alleges the allegations of Counterclaim paragraphs 1-225 as though alleged herein.

297. Counterclaim Defendants entered into a contract, combination or conspiracy in restraint of trade.

298. Counterclaim Defendants have taken affirmative acts in furtherance of their contract, combination or conspiracy, including:

a. Obtaining the '331, '912, '042 and '295 patents through fraud on the PTO;

b. Filing and maintaining patent infringement actions against KV and other rivals under the Hatch-Waxman Act, even though the '331, '912, '042 and '295 patents are unenforceable; and

299. Taking other actions in support of their conspiracy.

300. Counterclaim Defendants' actions have caused injury to and unreasonably restrained trade in the Relevant Market.

301. Counterclaim Defendants' conduct occurred in, and is having a substantial effect on, interstate commerce.

302. As a direct and proximate cause of Counterclaim Defendants' exclusionary and anticompetitive conduct, KV has been injured and has sustained damages.

303. As a direct and proximate cause of Counterclaim Defendants' exclusionary and anticompetitive conduct, KV will continue to sustain predictable damages in the future.

304. The injury to KV constitutes antitrust injury.

305. KV is entitled to recover for its damages under Section 1 of the Sherman Act, 15 U.S.C. § 2, and Section 4 of the Clayton Act, 15 U.S.C. § 15.

XVIII. COUNT VII -- INJUNCTIVE RELIEF (CLAYTON ACT § 16)

306. KV repeats and re-alleges the allegations of Counterclaim paragraphs 1-225 as though alleged herein.

307. Counterclaim Defendants have violated Section 2 of the Sherman Act, as alleged above.

308. KV has suffered and will continue to suffer irreparable harm as a direct and proximate result of this continuing wrongful exclusion from the Relevant Market by Counterclaim Defendants' illegal conduct. That harm cannot be fully redressed by money damages. KV repeats and re-alleges the allegations of Counterclaim paragraphs 1-225 as though alleged herein.

309. The irreparable harm constitutes antitrust injury.

310. KV is entitled to injunctive relief under Section 16 of the Clayton Act, 15 U.S.C. § 26, in the form of compulsory delisting of the '331, '912, '042 and '295 patents from the Orange Book as well as an injunction preventing Purdue from suing KV to enforce claims of patent infringement related to CR oxycodone.

XIX. INTENTIONAL INTERFERENCE WITH VALID BUSINESS EXPECTANCY

311. KV repeats and re-alleges the allegations of Counterclaim paragraphs 1-225 as though alleged herein.

312. KV is an established manufacturer and seller of pharmaceutical products. KV has established relationships with customers and strong distribution channels for its products. But for Counterclaim Defendants' wrongful and exclusionary conduct, KV would enter the market for CR oxycodone and achieve substantial sales and make significant profits from selling its CR oxycodone products.

313. KV has valid business expectancies concerning the sale of its CR oxycodone products to various purchasers upon KV's receipt of FDA final approval of its ANDA.

314. Counterclaim Defendants know that KV has valid business expectancies with various entities relating to the purchase of KV's CR oxycodone products upon receipt of FDA final approval.

315. Counterclaim Defendants, through the conduct alleged above, have intentionally interfered with KV's valid business expectancies, and their interference is a significant factor in preventing KV from being able to sell, and in preventing KV's customers from purchasing, KV's CR oxycodone products.

316. Counterclaim Defendants' conduct lacks justification.

317. Counterclaim Defendants' conduct is outrageous, because of Counterclaim Defendants' ill motive and/or reckless indifference to the rights of others.

318. As a direct and proximate cause of Counterclaim Defendants' conduct, KV has been injured and sustained damages.

319. KV is entitled to actual and punitive damages.

XX. PRAYER FOR RELIEF

WHEREFORE, KV respectfully requests that the Court enter a judgment in its favor and against Counterclaim Defendants, and grant the following relief:

A. Entering an Order dismissing plaintiffs/counter-defendant Purdue's complaint in its entirety with prejudice.

B. Declaring that each of the claims of U.S. Patent Nos. 5,549,912, 5,508,042, and 5,656,295 is invalid;

C. Declaring that KV has not infringed any valid claim of U.S. Patent Nos. 5,549,912, 5,508,042, and 5,656,295;

D. Declaring that each of the claims of U.S. Patent Nos. 5,549,912, 5,508,042, and 5,656,295 is unenforceable;

E. Enjoining plaintiffs/counter-defendant Purdue, their officers, agents, attorneys, employees and those in active concert with them from enforcing U.S. Patent Nos. 5,549,912, 5,508,042, and 5,656,295 against KV;

F. Declaring this case exceptional under 35 U.S.C. § 285 and awarding KV its attorney fees and costs;

G. Entering a judgment that Counterclaim Defendants have violated Sections 1 and 2 of the Sherman Antirust Act (15 U.S.C. §§ 1-2);

H. Entering an Order, pursuant to the Sherman Antitrust Act (15 U.S.C. § 1 et seq.) and the Clayton Act (15 U.S.C. § 15), awarding damages, costs of suit, interest and attorneys' fees to KV and that KV's damages be trebled;

I. Entering an Order, pursuant to the Sherman Antitrust Act (15 U.S.C. § 1 et seq.) and the Clayton Act (15 U.S.C. § 26), requiring Counterclaim Defendants to delist the '331, '912, '042 and '295 patents from the Orange Book, permanently enjoining Counterclaim

Defendants from suing KV to enforce claims of patent infringement related to CR oxycodone and awarding KV its costs of suit and reasonable attorneys' fees;

J. Awarding KV actual and punitive damages as a result of Counterclaim Defendants' intentional interference with KV's valid business expectations; and

K. Awarding KV such further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, KV demands a trial by jury as to all issues triable of right to a jury.



Frederick L. Cottrell, III (#2555)
(cottrell@rlf.com)
Chad M. Shandler (#3796)
(shandler@rlf.com)
Richards, Layton & Finger, P.A.
One Rodney Square, P.O. Box 551
Wilmington, DE 19899
(302) 651-7700
Attorneys for Defendant
KV Pharmaceutical Company

OF COUNSEL
John F. Sweeney
Joseph A. DeGirolamo
Seth J. Atlas
Andrea L. Wayda
Matthew K. Blackburn
MORGAN & FINNEGAN, L.L.P.
3 World Financial Center
New York, NY 10281-2101
(212) 415-8700

Dated: March 8, 2007

CERTIFICATE OF SERVICE

I hereby certify that on March 8, 2007, I hand delivered the foregoing document to the following persons and electronically filed the foregoing document with the Clerk of Court using CM/ECF which will send notification of such filing to the following:

Jack B. Blumenfeld
Rodger Dallery Smith, II
Morris, Nichols, Arsht & Tunnell, LLP
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-9200

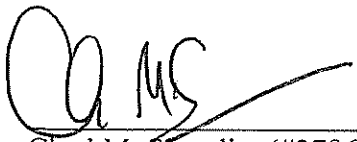
John W. Shaw
Andrew A. Lundgren
Young Conaway Stargatt & Taylor, LLP
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19899-6600

I hereby certify that on March 8, 2007, I have sent by Federal Express the foregoing document to the following non-registered participants:

Herbert F. Schwartz
Denise L. Loring
Richard A. Inz
Pablo D. Hendler
Ropes & Gray, LLP
1211 Avenue of the Americas
New York, NY 10036

Robert J. Goldman
Ropes & Gray, LLP
525 University Avenue
Suite 300
Palo Alto, CA 94301-1917

Chad A. Landmon
Axinn Veltrop & Harkrider, LLP
90 State House Square
Hartford, CT 06103-3702



Chad M. Shandler (#3796)
Shandler@rlf.com