UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

RITE AID CORPORATION, Plaintiff, v. PURDUE PHARMA, L.P., THE PURDUE FREDERICK COMPANY, PURDUE PHARMACEUTICALS, L.P. P.F. LABORATORIES INC., THE PURDUE PHARMA COMPANY, and EUROCELTIQUE, SA Defendants.	:	06 CV 15304 Case No._____ COMPLAINT

COMPLAINT FOR DECLARATORY JUDGMENT OF INVALIDITY AND UNENFORCEABILITY

Plaintiff Rite Aid Corporation, with its principal place of business at 30 Hunter Lane, Camp Hill, Pennsylvania 17011, brings this civil action against Defendants Purdue Pharma L.P., The Purdue Frederick Company, The Purdue Pharma Company, Purdue Pharmaceuticals L.P., and P.F. Laboratories Inc., and Euroceltique, SA ("collectively "Purdue") under the laws of the United States and allege as follows:

NATURE OF ACTION

1. This is an action (a) pursuant to 28 U.S.C. § 2201 and 2202 for declaratory relief that each of U.S. Patent Nos. 5,549,912 (the "'912 Patent"), 5,508,042 (the "'042 Patent"), and 5,656,295 (the "'295 Patent") (collectively referred to as the "Patents"), is invalid and unenforceable within the meaning of 35 U.S.C. § 271, and (b) for injunctive and other relief.

PARTIES

2. Plaintiff Rite Aid Corporation ("Rite Aid") is a corporation organized and existing under the laws of the State of Delaware and having its principal place of business in Camp Hill, Pennsylvania. Rite Aid purchases substantial quantities of pharmaceutical products and other goods for resale to the public through more than 3,300 drugstores operated by its affiliates. During the relevant period of time, Rite Aid has purchased and resold generic oxycodone hydrochloride manufactured by Endo Pharmaceuticals, Inc. ("Endo"), Teva Pharmaceuticals, USA, Inc. ("Teva"), and Impax Laboratories ("Impax").

3. Defendant Purdue Pharma L.P. ("Purdue Pharma") is a Delaware Limited Partnership with its principal place of business in Stamford, Connecticut. Purdue is a general partner of The Purdue Pharma Company. Purdue is an owner by assignment of the Patents and markets and sells prescriptions drugs including OxyContin®, throughout the United States.

4. Defendant The Purdue Frederick Company is a New York corporation with its principal place of business in Stamford, Connecticut. The Purdue Frederick Company is a general partner of The Purdue Pharma Company. The Purdue Frederick Company is an owner by assignment of the Patents and markets and sells prescription drugs, including OxyContin®, throughout the United States.

5. Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals"), is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, North Carolina 27893.

6. Defendant P. F. Laboratories, Inc., is a New Jersey corporation, with its principal place of business at 700 Union Boulevard, Totowa, New Jersey 07512. P. F. Laboratories, Inc. is an owner by assignment of the Patents and manufactures prescription drugs, including OxyContin®, in the United States.

7. Defendant The Purdue Pharma Company is a Delaware general partnership. The Purdue Pharma Company is an owner by assignment of the Patents and is engaged in the business of research, development, manufacture and sale of pharmaceutical products, including OxyContin®, throughout the United States. The Defendants in paragraphs 3 to 6 are referred to collectively as "Purdue."

8. Defendant Euroceltique 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 prosecuted and was or is the owner by assignment of the patents-in-suit, described in more detail, *infra* Operative Facts, Section I.A .

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction over this civil action based on an actual controversy between Plaintiff and Defendants arising under the United States Patent Laws, Title 35 of the United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, pursuant to 28 U.S.C. 1331, 1338(a) and 1367.

10. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c), because each Defendant is an inhabitant of this District or is found or transacts business in this District, and the interstate trade and commerce, hereinafter described, is carried out, in substantial part, in this District. Venue as to Euroceltique is further proper pursuant to 28 U.S.C. § 1391(d).

OPERATIVE FACTS

I. The Patent Applicants Committed Inequitable Conduct Before the Patent and Trademark Office (PTO) During the Prosecution of the OxyContin® Patents, Rendering Those Patents Invalid and Unenforceable.

11. The PTO is unable in many instances to conduct adequate searches to locate the most pertinent prior art and does not have access to experts readily available to evaluate the prior art that the PTO finds. Moreover, the PTO has no laboratory and no ability to replicate or assess

scientific data cited or supplied by patent applicants. The PTO, therefore, relies on the patent applicant to disclose the material prior art known to the applicant.

12. For this and other reasons, rules governing patent prosecution impose a duty of candor and good faith on those dealing with the PTO, "which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. § 1.56.

13. Between July 1986 and August 1997, patent applicants applied for and obtained the patents in dispute (*see infra*, Operative Facts, Section I.A). In each application, the PTO assigned an Examiner who evaluated the proposed claims for patentability under applicable rules.

14. As explained in more detail below, the applicants knowingly made false statements of material fact to the PTO in seeking issuance of the Patents. The applicants also failed to provide the PTO with the material information that the applicants did not have any scientific proof to support arguments made to the PTO or even a method or procedure in place to obtain that proof. If the applicants had not knowingly violated their duty of candor and good faith in dealing with the PTO, the Patents would not have issued.

A. The Relevant Patents

15. Purdue has marketed OxyContin®, whose active ingredient is oxycodone hydrochloride, in a controlled release format, in the United States and elsewhere since the drug received FDA approval in December, 1995.

16. Pursuant to Section 505 of the Hatch-Waxman Act, Purdue listed six patents in the FDA "Orange Book" (Approved Drug Products with Therapeutic Equivalence Evaluation) applicable to CR oxycodone (the "Six Patents"). The Six Patents are:

a. U.S. Patent No. 4,861,598 entitled "CONTROLLED RELEASE BASES FOR PHARMACEUTICALS," (the "'598 Patent"), filed July 18, 1986, issued August 29, 1989, assigned to Euroceltique, naming Benjamin Oshlack ("Oshlack") as the 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 '598 Patent application, issued November 13,1990, assigned to Euroceltique, also naming Oshlack as the 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 U.S. on June 18, 1993, claiming 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, as a division of the '912 Patent, which claimed it was a continuation-in-part application of the '331 Patent application, 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, claiming it was a continuation-in-part application of the '912 Patent application, which claimed it was a continuation-in-part of the '331 Patent application, issued August 12, 1997, assigned to Euroceltique, naming as the alleged inventors the same three individuals named in the '331 Patent plus Kaiko.

17. Oshlack, Minogue, Chasin and Kaiko were at all relevant times employees of Purdue yet assigned whatever rights they had to the '598, '075, '331, '912, '042 and '295 Patents to Euroceltique.

B. Relevant Statements In The Specifications And Prosecution Histories Of The Six Patents

18. Between July 1986 and August 1997, the applicants applied for and obtained the Six Patents. In each application, the PTO assigned an Examiner who evaluated the proposed claims for patentability under applicable rules. The PTO is unable in many instances to conduct adequate searches to locate the most pertinent prior art and does not have access to experts readily available to evaluate the prior art that the PTO finds. Therefore, the PTO relies on the applicant for the patent to disclose the material prior art that is known to the applicant. As explained in more detail, infra, the applicants were able to overcome the rejection issues raised in each instance by the Examiner, but only by withholding material information or by submitting false and misleading misrepresentations. If all material information been disclosed to the Examiner, and if no misrepresentations had been made, at least the '331, '912, '042 and '295 Patents would not have been allowed.

1. *The '598 & '075 Patents*

19. The '598 and '075 Patent specifications represent 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 controlled release 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.

('598 Patent, Col. 2, ll. 47-59; '075 Patent, Col. 2, ll. 50-61.)

20. The claims in the '598 and '075 Patents are directed to compositions for *in vivo* use of controlled release pharmaceutically active agents and, in the '598 Patent, are directed specifically to such oxycodone compositions. Neither the '598 Patent nor the '075 Patent specifications, however, 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 a reduction to practice of the claimed compositions neither contain nor refer to clinical studies but rely solely on *in vitro* dissolution rates as proof of a reduction to practice of such *in vivo* claims.

21. In response to a requirement to elect a particular species, the applicant elected "oxycodone, in the event that no generic claim is finally held allowable" (Paper #5 Received February 6, 1989, p. 3), although he objected to this requirement "because it is clear that the

invention in this case is the extended action controlled release composition, and this is not affected by the particular pharmaceutical agent." (*Id.*, 3.)

2. *The '331 Patent*

22. The '331 Patent specification represents that it was not believed that other analgesics structurally related to hydromorphone could be obtained as controlled release compositions using techniques similar to those set forth in Euroceltique's U.S. Patent No. 4,990,341 ("Euroceltique '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 U.S. Patent No. 4,990,341.

('331 Patent Col. 1, ll. 35-42.)

23. The '331 Patent specification further represents that those in the pharmaceutical art believed that to obtain a controlled release 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.

(*Id.* Col. 2, ll. 15-27).

24. In support of the '331 Patent application, the applicants argued that they had surprisingly discovered that CR oxycodone compositions acceptably control pain over a substantially narrower approximately four-fold range than the approximately eight-fold range required by opioid analgesics in general and controlled release morphine and controlled release hydromorphone in particular, 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 (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.
>
> * * *
>
> Despite the fact that both controlled-release oxycodone and controlled release morphine administered every 12 hours around-the-clock possess qualitatively comparable clinical pharmaco-kinetic characteristics, the oxycodone formulations of the presently claimed invention can be used over approximately 1/2 the dosage range as compared to seemingly similar controlled release morphine formulations to control 90% of patients with significant pain.
>
> 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.

(Paper #4, (Oct. 28, 1992), pp. 3, 4, 5),

There were no data set forth in the '331 Patent specification nor any affidavit submitted to support any of the representations 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, controlled release morphine or controlled release hydromorphone.

25. In support of the '331 Patent application, the applicants argued that "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," that " in the case of closely related drugs, predictability is impossible..." (Paper #7, received Apr. 8, 1993, p. 2) and submitted the affidavit of Kaiko in support of these statements. Kaiko was identified as "a person truly skilled in this art . . . ." (*Id.*)

26. In his declaration filed in support of the '331 Patent application claims, Kaiko 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. Kaiko withheld from the PTO the fact that all of the patent applicants were employees of Purdue and that Purdue had agreed to assign its patent rights to Euroceltique. Kaiko falsely presented himself to the Patent Examiner as a disinterested, objective and independent person of true skill in the art. 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 2 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, Received Apr. 8, 1993, Kaiko Decl., p. 4, ¶ b).

Kaiko further stated:

> 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. (*Id.* ¶ 11.)

Kaiko further stated:

> 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*. (*Id.* ¶ 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). (*Id.* ¶ 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 t_{max}) and the pharmacodynamics (including the duration of effect) set forth in the claims of the presently considered patent application identified above. (*Id.* ¶ 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 [Euroceltique '341 Patent and the '598 Patent]. (*Id.* ¶ 18.)

27. In order to remove the Euroceltique '341 Patent as a reference against the '331 Patent application, Euroceltique filed a Terminal Disclaimer, stating:

> 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 [the Euroceltique '341 Patent]. In order 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.

3. *The '912 Patent*

28. The '912 Patent specification represents:

> 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, ll. 10-13.)

The '912 Patent specification further represents:

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

(*Id.* Col. 3, ll. 34-40.)

The '912 specification also repeats the representations set forth in paragraph 23.

29. There were no data set forth in the '912 Patent specification to support any of the representations respecting the dosage ranges set forth in paragraph 28 as suggested, necessary, or desirable to control pain for approximately 90% of patients for opioid analgesics in general or CR oxycodone in particular.

30. In its response to the Examiner's rejection of the '912 Patent application claims, the applicants 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." (Paper #8, Received Mar. 14, 1995, p. 3). The applicants argued further that "[t]he teaching of controlled-release matrix hydromorphone formulations set forth in the '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 [Prior Art] '341 patent)" (*id.* p. 5) and that the Prior Art "'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 or by any affidavit or declaration.

31. In further response to the PTO Examiner's rejection of the '912 Patent application claims, the applicants argued that dissolution rate "such as that found in the '341 patent, is . . . 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 '341 patent would provide the pharmacokinetics (including the mean peak and mean minimum 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." (Paper #8, Received March, 14, 1995, p. 6).

4. *The '042 Patent*

32. The '042 Patent specification, as a division of the '912 Patent application, is identical to the '912 Patent specification and contains the same statements set forth in paragraph 28.

5. *The '295 Patent*

33. The '295 Patent specification contains the same statements as set forth in paragraph 28.

C. Information Known to the Applicants

34. Pursuant to 37 C.F.R. § 1.56, each "individual associated with the filing and prosecution of a patent application" has an affirmative duty of candor and good faith in dealing with the PTO and this duty includes the obligation to disclose to the PTO all material information known to that individual. The above-mentioned individuals violated their duty of candor and good faith to the PTO by committing the acts set forth herein with the intent to deceive or mislead the PTO.

1. *Kaiko Was Not An Independent Expert*

35. At no time during the prosecution of the '331 Patent application was the Examiner informed that Kaiko was a co-worker of the named inventors of the '331 Patent application, all of whom were employed by Purdue, that Purdue was affiliated with Euroceltique and was strongly interested in obtaining patent protection for CR oxycodone, or that Purdue was seeking FDA approval for sale of the products sought to be patented by the applicants.

36. Statements and representations by the applicants to the PTO that Kaiko was a person truly skilled in the art as set forth in paragraph 25 and the failure to inform the Examiner of the information set forth in paragraph 35 were violations of the applicants' duty of candor and good faith and led the Examiner to believe that Kaiko, whose declaration the Examiner was required to accept in the absence of contrary information, was an independent, objective, and disinterested person.

37. It would have been important and material to prosecution of the '331 Patent application for the 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 their attorneys and was intentionally withheld from the Examiner in order to

deceive or mislead the Examiner into believing Kaiko was an independent, objective, and disinterested person.

38. If the PTO Examiner had known that Kaiko was not an independent, objective, and disinterested person, but rather 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, he would not have accepted the unsupported assertions in the declaration of Kaiko and would have maintained his rejection of claims of the '331 Patent application.

2. *The Leslie, Oshlack And Contin® Work As To The Predictability Of Opioid Dissolution Rates On In Vivo Effects*

39. At no time during the prosecution of the '331, '912, '042 and '295 Patent applications were the respective Examiners informed of expired 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 the Contin® controlled release system (defined *infra*, paragraph 41). The Leslie Expired Patent states 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.

(Leslie Expired Patent, Col. 3, ll. 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.

(*Id.* Col. 4, ll. 4-29)

> [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.

(*Id.* Col. 8, ll. 49-53).

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

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

a. at least as early as June 1982, and continuing at least into 1985, made solid, controlled release, oral dosage oxycodone and morphine tablets 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 therefor. (File History '598 Patent, Paper #6, Oshlack Decl., Ex. A & B); and

b. 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 that "[I]t was unexpectedly found when using [his suggested matrix], that there was a potentiation of the control of the drug release properties ... [his suggested matrix] will show optimum control of the drug release ... and a delay in retardation of usually 5 to 12 hours, and 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." (*Id.* Paper #6, Oshlack Decl., Ex. B).

41. At no time during the prosecution of the '331, '912, '042 or '295 Patent applications were the respective Examiners informed that Purdue had developed the Contin® controlled-release system that provides a means of drug delivery that had been previously used successfully with a wide range of drugs, including several opioid analgesics, that controlled the rate of release of active opioids within the gastrointestinal tract, with the result that the opioid is delivered to the body at a specific, planned rate (CANCER, 1989, 63 2275-83) (THE HOSPICE JOURNAL, 1990; 6(4): 17-29), and that delayed and attenuated peak plasma levels in comparison with the corresponding immediate release opioid (JOURNAL OF PAIN & SYMPTOM MGMT., Feb. 1997; 13(2): 75-82).

42. Statements and representations made by the applicants 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 paragraph 25 and Kaiko's representations that those skilled in the art could not predict peak plasma levels and duration of effect as set forth in paragraph 26 were

affirmative misrepresentations of material facts and led the PTO Examiner during the prosecution of the '331, '912, '042 and '295 Patents to believe that:

a. persons skilled in the art believed that *in vitro* dissolution rates are not indicative of *in vivo* effect; and

b. 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*.

43. 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 Leslie in the Leslie Expired Patent and Oshlack in his 1985 work as set forth in paragraphs 39 and 40 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, and (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 paragraph 41 because such information was contrary to the statements and representations made by the applicants. The Leslie and Oshlack information was known to at least Oshlack and the attorneys of the '331, '912, '042 and '295 Patents during the prosecution of these patents and the Contin® information was known to at least Kaiko and was intentionally withheld by them in order to deceive or mislead the Examiner into believing that dissolution rates were not predictive.

44. If the respective PTO Examiners had known the information about the views of Leslie and Oshlack as set forth in paragraphs 39 and 40 and the Contin® information as set forth in paragraph 41, they would not have accepted the unsupported assertions of the applicants as set

forth in paragraphs 25 and 26 and would have made or maintained their rejections of the claims of the '331, '912, '042 and '295 Patents.

3. *Purdue's 1984 Sale Of CR Morphine Made By The Methods And Using The Matrices Disclosed As Useful In The '331, '912, '042 and '295 Patents*

45. At no time during the prosecution of the '598, '075, '331, '912, '042 and '295 Patent applications were the respective Examiners informed of Purdue's sale of solid, controlled release, oral dosage morphine ("CR morphine") tablets 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 Purdue:

a. were made by the methods and using the matrices disclosed as useful in the '331, '912, '042 and '295 Patents;

b. were made using the Contin® controlled release system;

c. have dissolution rates within the scope and coverage of the '331 and '912 Patents;

d. have been reported in an article co-authored by Kaiko to have peak plasma levels (t_{max}) of between 2-4 hours and to provide a duration of therapeutic effect of at least 12 hours after administration (CLINICAL PHARMACOKINETICS, 1986; 11: 505-10);

e. have been reported in articles co-authored by Kaiko to provide nearly equivalent bioavailability, with the CR morphine providing delayed and attenuated peak plasma levels (*Id.*), and comparable oral potency and efficacy as immediate release morphine ("IR morphine") (CANCER, 1989; 63: 2284-88; 2348-54); and

f. 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.

46. It would have been important and material to prosecution of the '598, '075, '331, '912, '042 and '295 Patent applications for the respective Examiners to have known that CR morphine tablets having the characteristics set forth in paragraph 45 are prior art to each of these applications. This information was known to at least Kaiko and was intentionally withheld by him in order to deceive or mislead the Examiners.

47. If the respective Examiners had known of the information set forth in paragraph 45, they would have made and maintained rejections of claims of the '331, '912, '042 and '295 Patent applications.

4. *Purdue's 1986 Disclosure Of CR Codeine*

48. At no time during the prosecution of the '331, '912, '042 and '295 Patent applications were the respective Examiners informed of Purdue's and Kaiko's disclosures of solid, controlled release, oral dosage codeine ("CR codeine") tablets 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 Purdue and Kaiko:

a. were made by the methods and using the matrices disclosed as useful in the '331, '912, '042 and '295 Patents;

b. were made using the Contin® controlled release system;

c. have dissolution rates within the scope and coverage of the '331 and '912 Patents;

d. 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 delayed and attenuated peak plasma concentrations, which results were generally similar to those obtained in comparisons of CR and IR morphine (ASCO PROCEEDINGS, March 1986; 5: 255);

e. have been reported in articles co-authored by employees of Purdue's Canadian affiliate 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 (JOURNAL OF PAIN & SYMPTOM MGMT., Aug. 1994; 9(6): 363-371; JOURNAL OF PAIN & SYMPTOM MGMT., Nov. 1995; 10(8): 612-23; PAIN, 1995; 62: 169-78); and

f. 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 tables, equivalent to the CR oxycodone examples set forth in the '042 and '295 Patents.

49. 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 paragraph 48 are prior art to each of these applications. This information was known to at least Kaiko and was intentionally withheld by him in order to deceive or mislead the Examiners.

50. If the respective Examiners had known of the information set forth in paragraph 48, they would have made and maintained rejections of claims of the '331, '912, '042 and '295 Patent applications.

5. *Euroceltique's CR Dihydrocodeine Prior Art*

51. At no time during the prosecution of the '331, '912, '042 or '295 Patent applications were the respective PTO Examiners informed that Euroceltique was issued U.S. Patent No. 4,828,836 on May 9, 1989 and U.S. Patent No. 4,834,985 on May 30, 1989. U.S. Patent No. 4,828,836 and U.S. Patent No. 4,834,985 are prior art to the '331, '912, '042 and '295 Patents (the "Prior Art '836 Patent" and the "Prior Art '985 Patent," respectively). The Prior Art

'836 Patent and the Prior Art '985 Patent disclose preferred controlled release 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 mefenarnic acid." (Prior Art '836 Patent, Col. 3, ll. 51-55 & Prior Art '985 Patent, Col. 3, ll. 39-43.)

52. At no time during the prosecution of the '331, '912, '042 or '295 Patent applications were the respective Examiners informed that Euroceltique filed on May 19, 1987 and was issued U.S. Patent No. 4,834,984 on May 30, 1989. U.S. Patent No. 4,834,984 is prior art to the '331, '912, '042 and '295 Patents (the "Prior Art '984 Patent"). 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 paragraph 23 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 levels (of dihydrocodeine) in the normal period of 1-2 hours after administration. (Col. 2, ll. 13-27).

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

a. were made by the methods and using the matrices disclosed as useful in the '331, '912, '042 and '295 Patents,

b. were made using the Contin® controlled release system;

c. have dissolution rates within the scope and coverage of the '331 and '912 Patents;

d. 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;

e. 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 to 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 3 5-67 to Col. 7, lines 1-60; *see also* CURRENT MEDICAL RESEARCH & OPINION, 1992; 13(l): 37-48);

f. 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;

g. 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

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

54. 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 formulations that are virtually identical to the matrices disclosed as useful in the '331, '912, '042 and '295 Patents and that Euroceltique 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 responsible for the prosecution of the '331, '912, '042 and '295 Patent applications and was intentionally withheld by them to deceive or mislead the Examiners.

55. It would have been important and material to prosecution of the '331, '912, '042 and '295 Patent applications for the respective Examiners to have known that CR dihydrocodeine tablets were patented by Euroceltique and had 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 paragraphs 52 and 53 are prior art to each of these applications. This information was known to at least Oshlack, Kaiko and the attorneys responsible for the prosecution of the '331, '912, '042 and '295 Patent applications and was intentionally withheld by them to deceive or mislead the Examiners.

56. If the respective PTO Examiners had known of the information set forth in paragraphs 51-53, they would have made and maintained rejections of the claims of the '331, '912, '042 and '295 Patent applications.

6. *Euroceltique's CR Hydromorphone Prior Art*

57. Euroceltique was issued U.S. Patent No. 4,844,909 on June 4, 1989. U.S. Patent No. 4,844,909 is prior art to the '331, '912, '042 and '295 Patents (the "Prior Art '909 Patent"). The Prior Art '909 Patent discloses and claims solid, controlled release, oral dosage hydromorphone ("CR hydromorphone") tablets that were made by methods and using 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, '042 and '295 Patents that the CR hydromorphone tablets have a peak plasma level of between 2-4 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).

58. At no time during the pendency of the '331 Patent application was the Examiner informed that Euroceltique's Prior Art '909 Patent is prior art under 35 U.S.C. § 102(b) to the '331 Patent application and, though the specification is identical to the Euroceltique '341 Patent, differs from that patent because it could not be antedated under 37 C.F.R. § 1.131 nor overcome by a Terminal Disclaimer.

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

a. were made by the methods and using the matrices disclosed as useful in the '331, '912, '042 and '295 Patents;

b. were made using the Contin® controlled release system;

c. have dissolution rates within the scope and coverage of the '331 and '912 Patents;

d. 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;

e. 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");

f. 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;

g. 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; and

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

60. It would have been important and material to prosecution of the '331, '912, '042 and '295 Patent applications for the respective Examiners to have known that Euroceltique's

Prior Art '909 Patent was a statutory bar and could not be antedated or overcome by a Terminal Disclaimer as set forth in paragraph 58 as was done by the Euroceltique attorneys. This information was known to at least the attorneys of the '331, '912, '042 and '295 Patents and intentionally withheld by them to deceive the Examiners.

61. 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 paragraph 58. This information was known to the attorneys responsible for the prosecution of the '331, '912, '042 and '295 Patent applications and was intentionally withheld by them to deceive or mislead the Examiners.

62. If the respective Examiners had known of the information set forth in paragraph 58, they would have made and maintained rejections of claims of the '331, '912, '042 and '295 Patent applications.

D. Defendants Submitted False And Misleading Information To The PTO Examiner

1. *False And Misleading Statements Regarding Beliefs In The Art*

63. The applicants' representations in the '331 Patent that it was not believed that other therapeutically active agents having the same medicinal use and structurally related to hydromorphone could be obtained using the Euroceltique '341 Patent techniques as set forth in paragraph 22, 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 Prior Art '985 disclosed control release matrix formulations 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

paragraph 51 and at least Oshlack, Kaiko and the attorneys knew that at least for prior art opioid analgesics, namely CR morphine, CR codeine, CR dihydrocodeine and CR hydromorphone, well known to have peak plasma levels of between 2-4 hours and at least a 12 hour duration of therapeutic activity after administration as set forth in paragraphs 45, 48, 52, 53, 57, and 59

64. If the Examiner had known that the statements set forth in paragraph 22 were false and had known of the prior art referred to in paragraph 63, the Examiner would have made and maintained rejections of the claims of the '331 Patent application.

The applicants' statements in the '331 Patent that it was usual in the pharmaceutical art to produce a formulation that gives a peak plasma level between 4-8 hours to obtain a controlled release 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 2-4 hours and that the pain relief obtained is greater than immediate release formulation as set forth in paragraph 23 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 or mislead 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 and were known to have peak plasma levels of 2-4 hours, to provide 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 paragraphs 45, 48, 52, 53, 57, and 59.

65. If the respective PTO Examiners had known that the statements set forth in paragraph 23 were false and had known of the prior art referred to in paragraph 0, they would have made and maintained rejections of the claims of the '331, '912, '042 and '295 Patent applications.

2. *False And Misleading Statements Regarding Obviousness*

66. The applicants' representations in support of the '331 Patent that even in the case of closely related drugs predictability of the duration of action is impossible as set forth in paragraph 25, 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 Examiner as set forth in paragraph 26 and Euroceltique's argument that one skilled in the art would not be able to accurately predict as set forth in paragraph 31 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 or mislead the PTO. At least the attorneys knew that Leslie and Oshlack used dissolution data to predict duration of effect as set forth in paragraphs 40 and 41, 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 paragraph 51, 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 2-4 hours and give at least 12 hours pain relief after administration, 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 paragraphs 45, 48, 52, 53, 57, and 59 and

at least Kaiko knew that the such formulations were "intended to produce a formulation that mimicked the C_{max} ,C_{min}, and percent fluctuation in plasma [opioid] concentrations of the IR [opioid] at steady-state" (CLINICAL THERAPEUTICS, 1996; 18(1): 95-105).

67. Euroceltique's and Kaiko's statements and representations set forth in paragraphs 25 and 26 led the PTO Examiners to believe that:

a. persons skilled in the art would have concluded that for any controlled release 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 4-8 hours;

b. persons skilled in the art could not predict that controlled release oxycodone having peak plasma levels (t_{max}) of 2 to 4 hours would also provide a duration of therapeutic effect of at least 12 hours;

c. persons skilled in the art believed that *in vitro* dissolution rates are not indicative of *in vivo* effect; and

d. persons skilled in the art could not predict from *in vitro* dissolution rates for controlled release oxycodone the t_{max} and duration of effect of such opioid *in vivo*.

68. At no time during the prosecution of the '912, '042 and '295 Patent applications were the respective PTO Examiners informed that the results of the clinical tests set forth in these patent applications reveal predictable relationships between oxycodone dosage and plasma oxycodone concentrations, as well as between concentration and certain expected opioid effects.

69. If the respective PTO Examiners had known that the statements set forth *supra*, paragraphs 25 and 26, were false and had known of the prior art referred to in paragraph 66 and the information as to predictability submitted to the FDA as set forth in paragraph 68, they would

have made and maintained rejections of the claims of the '331, '912, '042 and '295 Patent applications.

3. *False And Misleading Statements And Omissions Regarding Dosage Range Information*

70. The applicants' representations either during the prosecution or in the specifications of the '331, '912, '042, and '295 Patents that CR oxycodone unexpectedly controls pain over a four-fold 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% of patients as set forth in paragraphs 24, 28, 30, 32, and 33 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.

71. The applicants' only support for the statements set forth in paragraph 70 was the Example 17 clinical study set forth in the '912, '042, and '295 Patent specifications that summarizes the results of a limited number of patients who received a single dose of CR Oxycodone following abdominal or gynecological surgery.

72. The applicants knew during the prosecution of those applications that such a limited study did not provide an adequate basis to support assertions regarding the adequate control of pain within narrow dosage ranges for CR oxycodone in approximately 90% of patients.

73. Purdue has sponsored and supported numerous clinical studies, of which the applicants were aware, that clearly and overwhelmingly contradict the applicants' assertions regarding the dosage ranges for opioid analgesics and CR oxycodone as set forth in paragraphs 24, 28, 30, 32, and 33. 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:

a. An article co-authored by Kaiko reporting that some surveys indicate that most patients with pain due to advanced cancer can be controlled on doses of oral morphine between 10 and 30 mg every 4 hours, a three fold range (CANCER, 1989; 63: 2284-88);

b. 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 efficacy of treatments are equal and are comparable to the mean dosages for CR morphine in previous cancer studies. The article further reports the CR oxycodone dose required to provide optimal analgesia without intolerable side effects ranges from 20-550 mg/day. 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 studies with CR morphine and CR hydromorphone and well within the range of oxycodone doses used in the management of cancer pain (CANCER, 1997; 79: 1428-37);

c. 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 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 (PAIN, 1997; 73: 37-45);

d. An article co-authored by Kaiko reporting that dose titration is as easily accomplished and as efficient for CR oxycodone and CR morphine in the treatment of cancer pain. CR morphine is reported to be actually better than CR oxycodone with respect to time to stable analgesia, need for rescue analgesics, number of dose adjustments, and patients requiring no dose adjustments (EUROPEAN JOURNAL OF PAIN, 1998; 2: 239-49);

e. 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, were substantially equal and the two drugs provide an equivalent level of pain control at morphine equivalent doses over a wide range (JOURNAL OF CLINICAL ONCOLOGY, Oct. 1998; 16(10): 3222-29);

f. 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 127 mg (range 40 to 640 mg) (JOURNAL OF CLINICAL ONCOLOGY, Oct. 1998; 16(10): 3230-37);

g. A Purdue-sponsored 12-week study reporting that for a group of 87 cancer patients, a "high dose" patient group required a mean daily dose of CR oxycodone of 158.6 mg by the end of the study (CANCER INVESTIGATION, 1998; 16(8): 562-71);

h. An article co-authored by Kaiko reporting that for 101 patients who required around-the-clock treatment for chronic, cancer related pain, the mean final daily doses were 101 mg (range 40-360 mg) in the CR oxycodone group and 140 mg (range 60-300

mg) in the CR morphine group, a 9 fold versus a 5 fold range, with CR oxycodone being as easily titrated as CR morphine (EUROPEAN JOURNAL OF PAIN, 1998; 2: 239-49);

i. An article co-authored by a Purdue Canada employee reporting that for cancer and non-cancer patients the mean daily dosage for CR oxycodone and IR was essentially the same with a minimum of dose titration (JOURNAL OF PAIN & SYMPTOM MGMT., Oct. 1999; 18(4): 271-79); and

j. The FDA's summary basis of approval of Purdue's new drug application for CR oxycodone reporting that CR oxycodone has the same daily dosage, pharmacokinetic and pharmacodynamic properties as IR oxycodone except that the duration of effect is extended by CR oxycodone.

74. Most of the articles set forth in paragraph 73 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 the pendency of the '912, '042 and '295 Patent applications showed that approximately 90% 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 Examiners informed of the information and conclusions set forth in paragraphs 72, 73, and 74.

75. 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 paragraphs 72, 73, and 74.

76. If the respective PTO Examiners had known of the information set forth in paragraphs 72, 73, and 74., they would have made and maintained rejections of claims of the '912, '042 and '295 Patent applications.

II. The Court Should Find Defendants' Patents Unenforceable Based on the Applicants' Repeated Intentional, Material Misrepresentations and Omissions to the PTO

A. Defendants' Omissions and Misrepresentations Were Material

77. The applicants misrepresented and failed to disclose material information to the PTO with an intent to mislead the PTO into issuing the Patents.

78. Specifically, the applicants repeatedly represented to the PTO that they "surprisingly discovered" that the controlled release oxycodone hydrochloride formulation acceptably controlled pain for approximately 90% of patients over a four-fold dosage range, leading to easier titration. The applicants also represented to the PTO that this precisely quantified "result" was absolutely critical to the issuance of the Patents.

79. The applicants' representations to the PTO were demonstrably false and misleading because they had not "discovered" any precisely quantified "results" of any tests or experiments that were "of extensive clinical importance" that supported its claims of patentability as represented to the PTO. Contrary to their representations to the PTO, the applicants had not conducted any such tests or experiments, and thus had never obtained the specifically quantified "results" they cited to the PTO as the basis for their applications for the Patents.

80. In other words, the applicants had not "discovered" that the oxycodone hydrochloride product was effective for 90% of patients within a four-fold dosage range at any time during the prosecution of the Patents, since they did not have any scientific proof of this supposed "discovery." Nevertheless, the applicants affirmatively represented to the PTO that

they had made this precisely quantified scientific discovery, when, in fact, their discovery was nothing more than the vision or theoretical insight of a co-inventor that was not supported by any scientific proof. The applicants' misrepresentations and omissions were highly material to the issuance of the Patents. Indeed, the applicants' misrepresentations were often the only arguments proffered to the PTO in support of patentability.

81. A reasonable examiner would have considered important the fact that the applicants did not have any scientific proof that the claimed invention actually provided adequate pain relief for most people over a four-fold range. The applicants repeatedly and convincingly stated to the PTO that they had discovered an oxycodone formulation that did not simply control pain over a reduced range, but controlled pain over a "four-fold" range of doses for "approximately 90%" of patients.

82. Representations such as the applicants' assertion to the PTO that this "result" was of "extreme clinical importance" would clearly be undercut if the PTO were aware that the representations lacked any support other than Dr. Kaiko's assertions and "insight." Consequently, information inconsistent with the position that the applicants took before the PTO that the invention controlled pain for most patients over a four-fold dosage range -- including information that the position was just an "insight" that was not supported by any scientific proof -- was highly material.

83. The fact that the applicants (1) described the surprising discovery (the "result") in concise, quantified terms, (2) described it has having occurred in the past tense, (3) considered the discovery "absolutely critical to the invention," and most importantly (4) used this precisely quantified "discovery" throughout the prosecution of the '331, '912 and '042 patent applications as a prominent, and at times, the only, argument in favor of patentability before the PTO,

resulting in allowance of the claims, support a finding that the applicants misrepresented a material fact.

B. The Applicants Misrepresentations and Omissions Of Material Information Were Deliberate and Intentional

84. Dr. Robert F. Kaiko, OxyContin®'s inventor, has acknowledged that he had done no clinical studies and had no evidence to support the applicants' claim that the drug was effective over a narrow range of dosages for 90 percent of patients.

85. Purdue admitted that Dr. Kaiko's "discovery" was not supported by evidence or clinical studies but insisted it was true even though it was unable to prove it. Internal company documents show that Purdue executives concluded in 1993 that the applicants' representations to the PTO "weren't anywhere close" to being proved and were "clearly Bob Kaiko's vision."

86. Even assuming the applicants believed in good faith that they had discovered a novel result — the four-fold dosage range that relieved pain in most patients — that belief did not entitle them to deceptively withhold from the PTO the fact that they did not have any "scientific proof" to support their discovery, or even a method or procedure in place for obtaining such proof. The applicants made a deliberate decision to misrepresent to the PTO a "theoretical argument" and an "expectation" as a precisely quantified "result" or "discovery."

87. In summary, because of the serious, repeated, intentional, and highly material misrepresentations made to the PTO during the prosecution of the '331, '912, '295 and '042 patents, the Patents are unenforceable.

III. The Applicants Inequitable Conduct Has Permitted Them to Successfully Enforce Their Patents and Obtain the Withdrawal of Endo and Teva Generic OxyContin® From the Market

A. OxyContin® ANDA Filings and Subsequent Patent Litigation

1. *Defendants' Litigation Against Endo*

88. In 2000, Endo filed ANDA No. 75-923, subsequently twice amended in 2001, seeking FDA approval of various dosage strengths of oxycodone hydrochloride extended-release tablets.

89. Endo gave written notice to Purdue that Endo had filed its ANDA with the FDA and the accompanying certification under paragraph IV that the Patents were not infringed and/or were invalid. In accordance with 21 U.S.C. § 355(j)(2)(B)(ii), the notices set forth the legal and factual bases for their claims that the Patents are invalid and/or unenforceable.

90. Within forty-five days of receipt of the notice of certification, in October 2000, Purdue sued Endo for patent infringement in the United States District Court for the Southern District of New York (C.A. No. 00-8029, S.D.N.Y, complaint filed Oct. 20, 2000). The filing resulted in an automatic 30-month stay of the FDA's authority to grant final marketing approval to Endo under its ANDA for its 40 mg extended release oxycodone hydrochloride.

91. Endo obtained tentative FDA approval for its 10 mg, 20 mg, 40 mg and 80 mg versions of extended release oxycodone hydrochloride on July31, 2002.

92. On January 5, 2004, Judge Stein issued an opinion finding, *inter alia*, that Defendants committed inequitable conduct before the PTO during the prosecution of the OxyContin patents, thus rendering those patents unenforceable. *See* Order in *Purdue Pharma L.P. v. Endo Pharms., Inc.*, Civil Action Nos. O0-CV-8029 (SHS), 01-CV-2109 (SHS), and 01-CV-8177 (SHS)(S.D.N.Y.), holding, *inter alia*, the '912, '042, and '295 Patents unenforceable due to inequitable conduct ("Endo Unenforceability Order").

93. On January 12, 2004, Purdue filed a Notice of Appeal in the United States District Court for the Southern District of New York, petitioning the United States Court of Appeals for the Federal Circuit to overturn the District Court's January 5, 2004 ruling. Purdue requested that the District Court stay its injunction against enforcement of the patents until its appeal was resolved, but such request was denied by the District Court on February 13, 2004. Purdue had also petitioned the Federal Circuit to stay the District Court's injunction during the pendency of its appeal and to expedite the appeal. The Federal Circuit denied both requests on March 19, 2004, noting that "we are not persuaded that Purdue has shown a strong likelihood that it will succeed in establishing that the district court's findings concerning materiality and intent are clearly erroneous."

94. On January 13, 2004, the Purdue Plaintiffs moved the District Court to suspend the Endo Injunction. On February 17, 2004, the District Court denied that motion.

95. Endo obtained final FDA approval of Endo's abbreviated new drug application (ANDA) for oxycodone extended-release tablets, 10mg, 20mg and 40mg on or about March 24, 2004.

96. On June 7, 2005, the Federal Circuit issued an opinion affirming Judge Stein's decision that the patents are unenforceable. *Purdue Pharma L.P. v. Endo Pharms. Inc.*, 410 F.3d 690 (Fed. Cir. 2005).

97. Endo Pharmaceuticals promptly entered the market with a generic version of OxyContin®.

2. *Defendants' Litigation Against Other ANDA Filers*

(a) Impax Laboratories

98. In February 2002, Impax Laboratories, Inc. ("Impax") filed ANDA 76-318 with the FDA for an 80 mg generic extended release oxycodone hydrochloride.

99. Impax gave written notice to Purdue that it had filed with the FDA its ANDA and the accompanying certification under paragraph IV that the Patents were not infringed and/or were invalid. In accordance with 21 U.S.C. § 355(j)(2)(B)(ii), the notices set forth the legal and factual bases for their claims that the Patents are invalid and/or unenforceable.

100. Within forty-five days of receipt of the notice of certification, in April 2002, Purdue sued Impax for patent infringement in the United States District Court for the Southern District of New York (C.A. No. 02-2803, S.D.N.Y, complaint filed Apr. 11, 2002). The filing resulted in an automatic 30-month stay of the FDA's authority to grant final marketing approval to Impax under its ANDA for its 80 mg extended release oxycodone hydrochloride.

101. Impax obtained tentative FDA approval for its 80 mg version of extended release oxycodone hydrochloride on September 4, 2003.

102. In August 2002, Impax Laboratories filed ANDA 76-446 with the FDA for a 40 mg generic extended release oxycodone hydrochloride, and subsequently amended the ANDA to include a 10 mg and a 20 mg extended release oxycodone hydrochloride.

103. Impax gave written notice to Purdue that it had filed with the FDA its ANDA and the accompanying certification under paragraph IV that the Patents were not infringed and/or were invalid. In accordance with 21 U.S.C. § 355(j)(2)(B)(ii), the notices set forth the legal and factual bases for their claims that the Patents are invalid and/or unenforceable.

104. Within forty-five days of receipt of the notice of certification, in September 2002, Purdue sued Impax for patent infringement in the United States District Court for the Southern District of New York (C.A. No. 02-7569, S.D.N.Y, complaint filed Sept. 19, 2002). The filing resulted in an automatic 30-month stay of the FDA's authority to grant final marketing approval

to Impax under its ANDA for its 10 mg, 20 mg, and 40 mg extended release oxycodone hydrochloride.

105. Impax obtained tentative FDA approval for its 10 mg, 20 mg, and 40 mg versions of extended release oxycodone hydrochloride on December 23, 2003.

106. On January 5, 2005, the District Court issued an Order in *Purdue Pharma L.P. v. Impax Labs., Inc.*, Civil Action No. 02-C V-2803 (SHS) (S.D.N.Y.), granting Impax's motion for summary judgment of unenforceability of the '912, '042, and '295 Patents based on the collateral estoppel effect of the Endo Unenforceability Order ("Impax Collateral Estoppel Order").

107. On November 7, 2005, Impax announced a ten year Exclusive Supply and Distribution agreement with DAVA Pharmaceuticals, Inc. ("DAVA") pursuant to which DAVA would market generic OxyContin manufactured by Impax.

108. On or about December 7, 2005, Endo's 180-day exclusivity expired, and DAVA subsequently entered the market.

(b) Teva Pharmaceuticals USA, Inc.

109. In February 2003, Teva Pharmaceuticals USA, Inc. ("Teva") filed ANDA 76-610 with the FDA for a 10 mg, a 20 mg and a 40 mg generic extended release oxycodone hydrochloride.

110. Teva gave written notice to Purdue that it had filed with the FDA its ANDA and the accompanying certification under paragraph IV that the Patents were not infringed and/or were invalid. In accordance with 21 U.S.C. § 355(j)(2)(B)(ii), the notices set forth the legal and factual bases for Teva's claims that the Patents are invalid and/or unenforceable.

111. Within forty-five days of receipt of the notice of certification, in April 2003, Purdue sued Teva for patent infringement in the United States District Court for the Southern District of New York (C.A. No. 03-2312, S.D.N.Y, complaint filed Apr. 3, 2003). The filing

resulted in an automatic 30-month stay of the FDA's authority to grant final marketing approval to Teva under its ANDA for its extended release oxycodone hydrochloride.

112. On June 28, 2004, the District Court issued a Memorandum Order in *Purdue Pharma L.P. v. Teva Pharms. USA, Inc.*, Civil Action Nos. 01-CV-8507 (SHS), 0l-CV 11212 (SHS), and 03-CV-2312 (SHS)(S.D.N.Y.), granting a motion by for summary judgment of unenforceability of the '912, '042, and '295 Patents based on the collateral estoppel effect of the Endo Unenforceability Order ("Teva Collateral Estoppel Order").

113. On or about December 7, 2005, Endo's 180-day exclusivity expired, and Teva subsequently entered the market.

(c) Mallinckrodt

114. Upon information and belief, Mallinckrodt, Inc. ("Mallinckrodt") filed ANDA 77-822 with the FDA for a 10 mg, a 20 mg, 40 mg, and an 80 mg generic extended release oxycodone hydrochloride.

115. On or about October 4, 2005, Mallinckrodt gave written notice to Purdue that it had filed with the FDA its ANDA and the accompanying certification under paragraph IV that the Patents were not infringed and/or were invalid. In accordance with 21 U.S.C. § 355(j)(2)(B)(ii), upon information and belief, the notices set forth the legal and factual bases for Mallinckrodt's claims that the Patents are invalid and/or unenforceable. Upon information and belief, Mallinckrodt's Notice of Certification pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) ("Notice Letter") explained that the sole basis for its Paragraph IV Certification with respect to the '912, '042, and '295 Patents is the collateral estoppel effect of the Endo Unenforceability Order and the Federal Circuit's June 7, 2005 Opinion affirming the Endo Unenforceability Order.

116. On November 9, 2006, Purdue filed a patent infringement complaint against Mallinckrodt, alleging, *inter alia*, that Mallinckrodt's commercial manufacture, use, and sale of

its oxycodone hydrochloride extended-release tablets, 10 mg, 20 mg, 40 mg, and 80 mg, will constitute infringement of the '912, '042, and '295 Patents. Purdue Pharma, LP v. Mallinckrodt, Inc., Civil Action No. 06-CV-13095 (S.D.N.Y.).

117. Purdue's complaint seeks, *inter alia*, the following: (1) An Order finding hat the '912, '042, and '295 Patents are valid and enforceable; (2) An Order finding that Mallinckrodt has willfully and deliberately infringed the '912, '042, and '295 Patents; (3) Ordering Mallinckrodt to amend its Paragraph IV Certification to a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III") as provided in 21 C.F.R. § 3 14.94(a)(12)(viii)(A); (4) Ordering, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and 35 U.S.C. § 271 (e)(4)(A), the effective date of any approval of Mallinckrodt's ANDA No. 77-822 to be a date that is not earlier than 30 months from the date of receipt by Purdue of the Notice Letter; (5) Ordering, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mallinckrodt's ANDA No. 77-822 to be a date that is not earlier than the last date of expiration of the '912, '042, or '295 Patents; and (6) Enjoining Mallinckrodt from the commercial manufacture, use, offer to sell, or sale within, or importation into, the United States, of any drug product or active pharmaceutical ingredient that infringes the '912, '042, and '295 Patents.

B. Purdue's Settlements With Endo and Teva

118. In response to Purdue's Petition for Rehearing or Rehearing En Banc, the Federal Circuit on February 1, 2006 vacated its prior opinion affirming Judge Stein's conclusion of invalidity. *Purdue Pharma L.P. v. Endo Pharm. Inc.*, 438 F.3d 1123 (Fed. Cir. 2006). The panel vacated Judge Stein's decision and remanded for further proceedings. *Id.*

119. On remand, Purdue and Endo submitted updated briefing to Judge Stein on the question of inequitable conduct under the standards set forth by the Federal Circuit.

120. Neither of the sides in the litigation supplemented the record with any additional testimony.

121. Briefing on the issue was completed on or about June 26, 2006, and the parties were expecting a decision from Judge Stein imminently.

122. On August 29, 2006, the press reported that Purdue had settled the patent claims against both Endo and Teva.

123. Pursuant to the settlement agreement, Endo has agreed to stop selling generic oxycodone by December 31, 2006, and in exchange, Purdue will not pursue damages for past infringement.

124. Pursuant to the settlement agreement, Teva has agreed to stop selling generic oxycodone by March 31, 2007, and in exchange, Purdue will not pursue damages for past infringement.

IV. Plaintiff Is Entitled to a Declaration of Unenforceability and Invalidity

125. There is a justiciable controversy between Plaintiff and Defendants with respect to the enforceability and validity of the Patents. Plaintiff is entitled to a declaration of the rights and other legal relations as between Plaintiff and Defendants because Defendants have enforced the Patents to the financial detriment of Plaintiff and because Defendants have directly threatened to sue Plaintiff for patent infringement.

A. Defendants Have Enforced the Patents to Plaintiff's Harm

126. The price that Plaintiff and other retailers pay for oxycodone is determined in substantial part by the number of manufacturers of that product. The greater the number of suppliers, the lower the price that Plaintiff and other retailers must pay.

127. Defendants have successfully enforced the Patents against Endo and Teva. As a result of Defendants' enforcement of the Patents, Endo has agreed to stop selling oxycodone by December 31, 2006, and Teva has agreed to stop selling oxycodone by March 31, 2007.

128. Defendants currently are actively attempting to enforce the Patents against another supplier of generic OxyContin, Impax, and against another potential supplier of generic OxyContin, Mallinckrodt.

129. Defendants have adopted a strategy of settling their enforcement actions against the generic manufacturers rather than permitting Judge Stein to rule on the enforceability and validity of the Patents. The generic manufacturers are willing to enter into these settlements because the settlements permit the generic manufacturers to retain all of the profits that they made when they were on the market. Those profits represent the vast majority of the total profits that the generic manufacturers could make even if Judge Stein were to find the Patents unenforceable or invalid. A ruling of unenforceability or invalidity would permit multiple additional generic manufacturers to enter the market, and the profit margins and total profits earned by each generic manufacturer would plummet. In short, the generic manufacturers are willing to settle because Defendants' agreement to permit the generic manufacturers to retain the profits that they earned while they were in the market gives to the generic manufacturers a very substantial portion of the profits that they would earn even if Judge Stein were to find the Patents unenforceable or invalid.

130. Consequently, the economic evidence indicates that Defendants are very likely to reach a settlement agreement with Impax that will require Impax to stop selling generic OxyContin at some defined date. Defendants will thereby again prevent Judge Stein from issuing a decision as to the unenforceability or invalidity of the Patents.

131. The same will be true of Mallinckrodt if it enters the market before obtaining a ruling on invalidity or unenforceability. If Mallinckrodt does not enter the market before such a finding, Mallinckrodt (and any additional ANDA filers) may fall prey to one or more of the numerous "evergreening" techniques used by brand-name pharmaceutical manufacturers to delay or prevent the onset of generic competition. These techniques include making cash payments to the generic manufacturer to withdraw the challenge to the patent (*see, e.g., In re Schering-Plough,* FTC Docket No. 9297, 2003 WL 2298651 (FTC Dec. 8, 2003)), and switching the market to a successor product before the generic manufacturer wins the patent litigation and enters the market (*see, e.g., Abbott Laboratories v. Teva Pharmaceuticals USA Inc.*, 432 F. Supp. 2d 408 (D. Del. 2006)).

132. The financial incentives confronting Mallinckrodt, and the Defendants' potential use of evergreening techniques to delay or prevent Mallinckrodt from obtaining a finding of invalidity or unenforceability, make Mallinckrodt an uncertain champion of interests of purchasers in obtaining such a finding.

133. Defendants' settlement agreements with Endo, and presumably also with Teva, provide that if the Patents are found to be unenforceable or invalid in another legal proceeding, Endo and Teva may re-enter the market. These provisions ensure that Plaintiff will receive a substantial benefit from a declaration that the Patents are unenforceable and invalid. Such a declaration would open the way to market (re-) entry for all interested generic manufacturers, including Endo, Teva, and Impax.

B. Defendants Have Threatened to Sue Plaintiffs

134. After the Federal Circuit's decision remanding the Endo and Teva actions to Judge Stein, Purdue sent letters to Plaintiff and other major purchasers asserting that the generic versions of OxyContin® infringed Purdue's patents.

135. Purdue's letter dated May 15, 2006, makes clear its intention to "vigorously pursue" its rights against Rite Aid for damages that allegedly resulted from the introduction of generic forms of OxyContin® to the market. Purdue's letter asserts:

> Purdue intends to vigorously pursue its previously filed patent infringement actions and to seek equitable relief and monetary damages for all infringing activity that has occurred since March 2004. In addition to the named defendants in these actions, Purdue intends, to the extent necessary, to pursue infringement claims against other entities that have been, or continue to be, involved in the manufacture, sale, distribution or importation of infringing generic OxyContin® Tablets. While the harm to Purdue has been and continues to be irreparable, we believe that the monetary component of that harm will be very substantial.

Letter from Howard R. Udell Executive Vice President, Chief Legal Officer, Purdue Pharma, L.P., to Robert Sari, Esq., EVP, General Counsel, and Secretary, Rite Aid Corporation (May 15, 2006).

136. By letter dated September 5, 2006, Purdue sent letters to Plaintiff and other major purchasers advising that Purdue had entered into separate settlement agreements with Teva and Endo relating to their sales of generic forms of OxyContin®, and noting that "[s]ubsequent to regulatory review and entry of a stipulated Consent Judgment in the Teva action, the only remaining infringing products on the market will be those manufactured by Impax." Letter from Howard R. Udell Executive Vice President, Chief Legal Officer, Purdue Pharma, L.P., to Robert Sari, Esq., EVP, General Counsel, and Secretary, Rite Aid Corporation (Sept. 5, 2006).

137. Purdue's letter dated September 5, 2006, reiterates Purdue's intention to "vigorously pursue" its rights against Rite Aid for the continuing damages allegedly resulting from the introduction of generic forms of OxyContin® manufactured by Impax to the market.

COUNT I

DECLARATORY JUDGMENT OF UNENFORCEABILITY BASED ON DEFENDANTS' INEQUITABLE CONDUCT

138. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 137 above, as if fully set forth herein.

139. As explained in detail above (1) the applicants withheld multiple material references and information from the PTO; (2) the applicants made false and misleading statements and misrepresentations to the PTO as a result of the non-disclosure; and (3) the applicants' inequitable conduct formed the basis for the issuance of the Patents.

140. Plaintiff is entitled to a declaratory judgment that the Patents are unenforceable by virtue of the applicants' inequitable conduct committed during the prosecution of the Patent applications before the PTO.

141. There is an actual, substantial and continuing justiciable controversy between Plaintiff and Defendants.

COUNT II

DECLARATORY JUDGMENT OF INVALIDITY FOR FAILURE TO COMPLY WITH 35 U.S.C. §§ 101, 102, 103, 112 AND FOR DOUBLE PATENTING

142. Plaintiff incorporates by reference the allegations contained in paragraphs 1 through 141 above, as if fully set forth herein.

143. Each of the Patents is invalid under 35 U.S.C. § 103(a).

144. Plaintiff is entitled to a declaratory judgment that each of the Patents is invalid under 35 U.S.C. § 103(a).

145. There is an actual, substantial and continuing justifiable controversy between Plaintiff and Defendants.

WHEREFORE, Plaintiff prays for judgment against Defendants and for the following relief:

a. Entry of judgment in Plaintiff's favor;

b. A declaration that U.S. Patent No. 5,549,912, U.S. Patent No. 5,508,042 and U.S. Patent No. 5,656,295 are invalid and unenforceable;

c. An injunction prohibiting Purdue from enforcing U.S. Patent No. 5,549,912, U.S. Patent No. 5,508,042 and U.S. Patent No. 5,656,295;

d. An award of Plaintiff's costs, expenses, attorneys' fees and post-judgment and pre-judgment interest pursuant to the provisions of 35 U.S.C. Sections 284 and 285; and

e. Such other relief as this Court deems just and equitable.

Dated: December 18, 2006

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