IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC. and PURDUE PHARMACEUTICALS L.P., Plaintiffs, v. KV PHARMACEUTICAL COMPANY and ACTAVIS TOTOWA LLC, Defendants.	Civil Action No. 07-cv-0032

ANSWER AND COUNTERCLAIMS OF ACTAVIS TOTOWA LLC

Defendant Actavis Totowa LLC ("Actavis") hereby responds to the Complaint of plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc. and Purdue Parmaceuticals L.P. (collectively "Purdue") as follows:

1. Admitted.

2. Admitted.

3. Actavis admits that this Court has personal jurisdiction over it because it resides in this Judicial District. Except as expressly admitted, Actavis is without sufficient information or belief to form an opinion as to the truth of the remaining allegations of Paragraph 3 of the Complaint.

4. Admitted.

5. Admitted upon information and belief.

6. Admitted upon information and belief.

7. Admitted upon information and belief.

8. Actavis lacks sufficient information to respond to this allegation.

9. Admitted.

10. Actavis lacks sufficient information to admit or deny this allegation, and therefore denies the same. Actavis responds to the remaining allegations as follows:

A. Denied, except to admit that U.S. Pat. No. 5,508,042 (the "'042 patent") is entitled "Controlled Release Oxycodone Compositions" and names the listed individuals as inventors;

B. Denied, except to admit that U.S. Pat. No. 5,656,295 is entitled "Controlled Release Oxycodone Compositions" and names the listed individuals as inventors;

C. Denied, except to admit that U.S. Pat. No. 5,549,912 is entitled "Controlled Release Oxycodone Compositions" and names the listed individuals as inventors.

11. - 19. Actavis lacks sufficient information to respond to these allegations.

20. Admitted.

21. Admitted.

22. Admitted.

23. Denied.

24. Admitted.

25. Denied.

26. Admitted.

27. Denied.

28. Denied.

FIRST AFFIRMATIVE DEFENSE
Invalidity

29. The '042 patent is invalid for its failure to satisfy one or more conditions of patentability specified in Title 35, United States Code, including but not limited to Sections 101, 102, 103 and 112.

30. The '042 patent is invalid and void under the judicially created doctrine of obviousness-type double patenting.

SECOND AFFIRMATIVE DEFENSE
Unenforceability Due to Inequitable Conduct

31. Each and every claim of the '042 patent is unenforceable because the '042 patent was procured through inequitable conduct in violation of the patent laws and regulations of the United States Patent and Trademark Office (the "PTO").

I. BACKGROUND

A. The '042 Patent Family

32. Purdue has marketed OxyContin®, whose active ingredient is oxycodone hydrochloride, in the United States since the drug received FDA approval in December 1995.

33. Pursuant to Section 505 of the Hatch-Waxman Act, 21 U.S.C. § 355, Purdue listed six patents in the FDA "Orange Book" (officially known as "Approved Drug Products with Therapeutic Equivalence Evaluation") with respect to oxycodone hydrochloride extended release tablets, 10 mg, 20 mg, 40 mg and 80 mg (collectively "extended release oxycodone" or "ER oxycodone"). Included among the six patents are:

a. United States Patent No. 5,266,331, entitled "Controlled Release Oxycodone Compositions" (the "'331 patent"), filed November 27, 1991 and issued November 30, 1993, naming Benjamin Oshlack ("Oshlack"), John Minogue ("Minogue") and Mark Chasin ("Chasin") as alleged inventors.

b. United States Patent No. 5,549,912, entitled "Controlled Release Oxycodone Compositions" (the "'912 patent"), filed as a Patent Cooperation Treaty application on November 25, 1992, filed in the United States on June 18, 1993, and issued November 30, 1993, naming Oshlack, Minogue, Chasin and Robert F. Kaiko ("Kaiko") as alleged inventors.

c. The '042 patent, entitled "Controlled Release Oxycodone Compositions," filed June 6, 1995 as a division of the '912 patent, which claimed it was a continuation-in-part of the application leading to the '331 patent. The '042 patent issued on April 16, 1996, naming Oshlack, Minogue, Chasin and Kaiko as alleged inventors.

d. United States Patent No. 5,656,295, entitled "Controlled Release Oxycodone Compositions" (the "'295 patent"), filed March 19, 1996, claiming it was a continuation-in-part of the application leading to the '912 patent. The '295 patent issued on August 12, 1997, naming Oshlack, Minogue, Chasin and Kaiko as alleged inventors.

e. The '331, '912, '042 and '295 patents claim nearly identical subject matter and there exists an intimate relation between them.

34. Euro-Celtique S.A. ("Euro-Celtique") filed and prosecuted the application leading to the '331 patent by and through the individuals named therein as inventors, Oshlack, Chasin and Minogue, and Euro-Celtique's patent solicitor.

35. Euro-Celtique filed and prosecuted the application leading to the '912 patent, by and through the individuals named therein as inventors, Oshlack, Chasin, Minogue and Kaiko, and Euro-Celtique's patent solicitor.

36. Euro-Celtique filed and prosecuted the application leading to the '042 patent, by and through the individuals named therein as inventors, Oshlack, Chasin, Minogue and Kaiko, and Euro-Celtique's patent solicitor.

37. Euro-Celtique filed and prosecuted the application leading to the '295 patent, by and through the individuals named therein as inventors, Oshlack, Chasin, Minogue and Kaiko, and Euro-Celtique's patent solicitor.

38. Oshlack, Minogue, Chasin and Kaiko were at all relevant times employees of Purdue, but purported to assign whatever rights they had to the '331, '912, '042 and '295 patents to Euro-Celtique.

B. Relevant Statements In Specifications And Prosecution Histories

1. The '331 Patent

39. 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 Euro-Celtique's U.S. Patent No. 4,990,341 ("Euro-Celtique '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, lines 35-42.)

40. 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 of 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, lines 15-27).

41. During prosecution of the '331 patent application, applicants argued that they surprisingly discovered that extended release oxycodone compositions acceptably control pain over a substantially narrower range (approximately four-fold) 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 pharmacokinetic 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 [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).

42. There was 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 percent of patients for opioid analgesics in general or for ER oxycodone, controlled release morphine or controlled release hydromorphone.

43. During prosecution of the '331 patent application, applicants further 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," and that "in the case of closely related drugs, predictability is impossible . . . ." (Paper #7, received Apr. 8, 1993, p.2). Applicants submitted the affidavit of Kaiko in support of these statements, identifying him as "a person truly skilled in this art . . . ." (Id.)

44. 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.

45. The PTO was not aware of the fact that all of the inventors of the '331 patent were employees of Purdue and that Euro-Celtique had agreed to assign its patent rights to the application leading to the '331 patent to Purdue.

46. Kaiko presented himself to the Patent Examiner reviewing the application leading to the '331 patent as a disinterested, objective and independent person of 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 the 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 "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 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 respect 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 the 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 ['341 and '598 patents]. (Id. ¶ 18.)

47. In order to remove the Euro-Celtique '341 patent as a reference against the '331 patent application, Euro-Celtique ultimately 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 [Euro-Celtique '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.

2. The '912 Patent

48. 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.)

49. The '912 patent specification further states:

> 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.

('912 patent, col. 3, lines 34-40.)

50. The ‘912 patent specification also repeats the representations set forth in Paragraph 40 herein.

51. There was no data set forth in the ‘912 patent specification to support any of the representations respecting the dosage ranges set forth in Paragraphs 40, 48 and 49 herein as suggested, necessary or desirable to control pain for approximately 90 percent of patients for opioid analgesics in general or extended release oxycodone in particular.

52. In its response to rejection of the ‘912 patent application claims, the applicants argued that the claimed ER 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).

53. The applicants argued further that “teaching of controlled-release matrix hydromorphone formulations set forth in the Euro-Celtique ‘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 [Euro-Celtique] ‘341 patent)” (id. p. 5), and that the Euro-Celtique “‘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 unsupported by any data in the specification of the ‘912 patent or by any affidavit or declaration.

54. In further response to rejection of the ‘912 patent application claims, the applicants argued that dissolution rate “such as that found in the [Euro-Celtique ‘341 patent], is . . . often not indicative of in-vivo effect, particularly in the case of opioids” and that “one 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).

3. The '042 patent

55. The '042 patent, as a division of the '912 patent application, contains an identical specification to the '912 patent and contains the same statements set forth in Paragraphs 40, 48 and 49 herein.

4. The '295 patent

56. The '295 patent is a continuation-in-part of the '912 patent application and contains the same statements set forth in Paragraphs 40, 48 and 49 herein.

II. INEQUITABLE CONDUCT

A. Information Known to the Applicants, But Not Disclosed

57. At least one of the inventors of the '331, '912, '042 and '295 patents 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. The Leslie, Oshlack And Contin® Work

58. At no time during the prosecution of the '331, '912, '042 and '295 patent applications was the PTO informed of expired U.S. Patent No. 3,965,256 (the "Leslie patent"), listing Stewart Thomas Leslie ("Leslie") as the sole inventor.

59. The Leslie patent is prior art to the '331, '912, '042 and '295 patents.

60. The Leslie 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.

61. The Leslie patent discloses matrices almost 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 67). The Leslie 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 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.

(Id. col. 4, lines 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, lines 49-53).

62. Opioid analgesics such as morphine, dihydrocodeine, hydromorphone and oxycodone are medicaments requiring frequent repeated dosage administration by the oral route to maintain a therapeutically active blood level.

63. At no time during the prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO 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 tablets in matrices substantially identical to those described in the '331, '912, '042 and '295 patents using the same methods disclosed in such patents, or that Oshlack obtained dissolution rates therefor. (U.S. Pat. No. 4,861,598, Paper #6, Oshlack Decl., Ex. A & B).

64. At no time during the prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO informed that Oshlack predicted, by March 5, 1985, based on dissolution rate studies, that the matrices in the solid, controlled release, oral dosage oxycodone and morphine tablets made in June 1982 and continuing into 1985 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."

65. At no time during the prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO informed that Oshlack, prior to the filing dates of the identified patents, wrote that "it 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."

66. At no time during the prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO informed that Oshlack, prior to the filing dates of the identified patents, 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." (U.S. Pat. No. 4,861,598 Paper #6, Oshlack Decl., Ex. B).

67. At no time during prosecution of the '331, '912, '042 or '295 patent applications was the PTO informed that Purdue had, prior to the filing dates of the identified patents, developed a Contin® controlled-release system, which provides a means of drug delivery that had been previously used successfully with a wide range of drugs, including several opioid analgesics (the "Contin system"). The Contin® system controls 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), leading to 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).

68. 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 43 herein 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 46 herein were affirmative misrepresentations of material facts and led the PTO to improperly issue the '331, '912, '042 and '295 patents.

69. Because such information was contrary to the statements and representations made by the applicants, it would have been important and material to the prosecution of the applications leading to the '331, '912, '042 and '295 patents for the PTO to have known that (i) both Leslie in the Leslie patent and Oshlack in his 1985 work as set forth hereinabove predicted in vivo bioavailability effect from in vitro dissolution rates, (ii) 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® 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.

70. The Leslie patent and the 1985 Oshlack work were material to the patentability of the subject matter claimed in the applications leading to the '331, '912, '042 and '295 patents. If the PTO had known of this information, it would not have accepted the unsupported assertions of the applicants as set forth in Paragraphs 43 and 46 and would have made or maintained its rejections of the claims of the '331, '912, '042 and '295 patents.

71. The Leslie patent and the 1985 Oshlack work were known to at least Oshlack and the attorneys of the '331, '912, '042 and '295 patents during the prosecution of these patents. The Contin® system was known to at least Kaiko during the prosecution of these patents. Both were intentionally withheld by them in order to deceive or mislead the PTO.

2. Kaiko's Bias

72. At no time during the prosecution of the '331 patent application was the PTO 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 Euro-Celtique and was strongly interested in obtaining patent protection for extended release oxycodone.

73. Applicants' failure to inform the PTO of the information set forth in Paragraph 72 herein in connection with prosecution of the application leading to the '331 patent was a violation of applicants' duty of candor and good faith.

74. Failure to inform the PTO of the information set forth in Paragraph 72 herein in connection with prosecution of the application leading to the '331 patent led the PTO to believe that Kaiko, whose declaration the PTO was required to accept in the absence of contrary information, was an independent, objective, and disinterested person.

75. It would have been important and material to prosecution of the application leading to the '331 patent application for the PTO 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.

76. This information was known to at least Oshlack, Chasm, Minogue and their attorneys and was intentionally withheld from the Examiner in order to deceive or mislead the PTO into believing Kaiko was an independent, objective and disinterested person.

77. If the PTO 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, the PTO would not have accepted the unsupported assertions in the declaration of

Kaiko and would have maintained its rejection of the claims of the '331 patent application.

3. Purdue's 1984 Sale Of Controlled Release Morphine

78. At no time during the prosecution of the applications leading to the '331, '912, '042 and '295 patents was the PTO informed of Purdue's sale of solid, controlled release, oral dosage morphine tablets (the "CR morphine tablets") at least as early as 1984 and more than one year prior to the filing of such patent applications.

79. The CR morphine tablets were made by the methods and using the matrices disclosed as useful in the '331, '912, '042 and '295 patents.

80. The CR morphine tablets were made using the Contin® system.

81. The CR morphine tablets have dissolution rates within the scope and coverage of the '331 and '912 patents.

82. The CR morphine tablets have been reported in an article co-authored by Kaiko to have peak plasma levels 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).

83. The CR morphine tablets have been reported in articles co-authored by Kaiko to provide nearly equivalent bioavailability to the formulations disclosed and claimed by the '331, '912, '042 and '295 patents, with the CR morphine tablets providing delayed and attenuated peak plasma levels (id.) and comparable oral potency and efficacy as immediate release morphine ("IR morphine") (CANCER, 1989; 63: 2284-38; 2348-54).

84. The CR morphine tablets 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 ER oxycodone examples set forth in the '042 and '295 patents.

85. It would have been important and material to prosecution of the applications leading to the '331, '912, '042 and '295 patents for the PTO to have known that CR morphine tablets are prior art to each of these applications.

86. CR morphine tablets were known to at least Kaiko during prosecution of the applications leading to the '331, '912, '042 and '295 patents and were intentionally withheld by at least him in order to deceive or mislead the PTO.

4. Purdue's 1986 Disclosure Of CR Codeine

87. At no time during prosecution of the applications leading to the '331, '912, '042 and '295 patents was the PTO informed of Purdue's and Kaiko's disclosures of solid, controlled release, oral dosage codeine tablets (the "CR codeine tablets") at least as early as 1986 and more than one year prior to the filing of such patent applications.

88. The CR codeine tablets were made by the methods and using the matrices disclosed as useful in the '331, '912, '042 and '295 patents.

89. The CR codeine tablets were made using the Contin® system.

90. The CR codeine tablets have pharmacokinetic characteristics within the scope and coverage of the '331, '912 and '042 patents.

91. The CR codeine tablets have been reported in an article co-authored by Kaiko to have peak plasma levels at a t_{max} 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 tablets 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).

92. The CR codeine tablets 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-fold to three-fold range (100 to 300 mg and 200 to 400 mg every 12 hours) in approximately 90 percent of patients (JOURNAL OF PAIN & SYMPTOM MMT., Aug. 1994; 9(6): 363-371; JOURNAL OF PAIN & SYMPTOM MGMT., Nov. 1995; 10(8): 6 12-23; PAIN, 1995; 62: 169-78).

93. The CR codeine tablets 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 ER oxycodone examples set forth in the '042 and '295 patents.

94. It would have been important and material to prosecution of the applications leading to the '331, '912, '042 and '295 patents for the PTO to have known that CR codeine tablets are prior art to each of these applications.

95. The CR codeine tablets were known to at least Kaiko.

96. At least Kaiko intentionally withheld information concerning the CR codeine tablets in order to deceive or mislead the PTO.

5. Euro-Celtique's CR Dihydrocodeine Prior Art

97. At no time during prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO informed that Euro-Celtique was issued U.S. Pat. No. 4,828,836 on May 9, 1989, U.S. Pat. No. 4,834,985 on May 30, 1989, and U.S. Pat. No. 4,834,984 on May 30, 1989.

98. U.S. Pat. No. 4,828,836, U.S. Patent No. 4,834,985, and U.S. Patent No. 4,834,984 (the "'836 patent," the "'985 patent" and the "'984 patent," respectively) are prior art to the '331, '912, '042 and '295 patents.

99. The '836 and '985 patents 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 "agents, such as morphine, codeine, phenazocine, dihydrocodeine, hydroinorphone, meptazinol, phenacetin, pethidine, paracetaniol, oxycodone, diainorphine, nalbuphine, buprenorphine, and inefenamic acid." ('836 patent, col. 3, lines 51-55 & '985 patent, col. 3, lines 39-43.) The '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 '984 patent discloses in words substantially identical to those set forth in Paragraph 40 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 (col. 2, lines 13-27).

100. At no time during prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO informed of the '836 patent and the '985 patent.

101. At no time during the prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO informed that controlled release dihydrocodeine tablets (the "CR dihydrocodeine tablets"), as disclosed in the '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 were made by the methods and using the matrices disclosed as useful in the '331, '912 '042 and '295 patents.

102. At no time during the prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO informed that the CR dihydrocodeine tablets were made using the Contin® system.

103. At no time during the prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO informed that the CR dihydrocodeine tablets have dissolution rates within the scope and coverage of the '331, '912 and '042 patents.

104. At no time during the prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO informed that the CR dihydrocodeine tablets have peak plasma levels between 2-4 hours (t_{max}) and provide a duration of therapeutic effect of at least 12 hours after administration.

105. At no time during the prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO informed that the CR dihydrocodeine tablets have been reported in the '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; 13W: 37-48).

106. At no time during the prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO informed that the CR dihydrocodeine tablets have the concentrations and parameters, when converted to oxycodone on a milligram-by-milligram basis in accordance with known conversion tables, equivalent to the ER oxycodone examples set forth in the '912 patent.

107. At no time during the prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO informed that the CR dihydrocodeine tablets 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 ER oxycodone examples set forth in the '042 and '295 patents.

108. At no time during the prosecution of the applications leading to the '331, '912, '042 or '295 patents was the PTO informed that the CR dihydrocodeine tablets have a range of daily dosage and provide pain relief equivalent to immediate release oral dosage dihydrocodeine tablets.

109. It would have been important and material to prosecution of the applications leading to the '331, '912, '042 and '295 patents for the PTO to have known that the '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 Euro-Celtique believed that such formulations would not be affected by

the particular pharmaceutical agent included therein, including opioid analgesics in general.

110. The information set forth in Paragraph 109 herein was known to at least the inventors and attorneys associated with prosecution of the applications leading to the '331, '912, '042 and '295 patents.

111. The information set forth in Paragraph 109 herein was intentionally withheld by inventors and attorneys associated with prosecution of the applications leading to the '331, '912, '042 and '295 patents to deceive or mislead the Examiners.

112. It would have been important and material to prosecution of the applications leading to the '331, '912, '042 and '295 patents for the PTO to have known that CR dihydrocodeine tablets were patented by Euro-Celtique and had a t_{max} between 2-4 hours and provided 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 99 through 108 are prior art to each of these applications.

113. The information set forth at Paragraph 112 herein was known to at least Oshlack, Kaiko and the attorneys responsible for the prosecution of the applications leading to the '331, '912, '042 and '295 patents.

114. The information set forth at Paragraph 112 herein was intentionally withheld by them to deceive or mislead the PTO in connection with its examination of the applications leading to the '331, '912, '042 and '295 patents.

6. Euro-Celtique's CR Hydromorphone Prior Art

115. Euro-Celtique was issued U.S. Patent No. 4,844,909 on June 4, 1989.

116. U.S. Patent No. 4,844,909 (the "'909 patent") is prior art to the '331, '912, '042 and '295 patents.

117. The '909 patent discloses and claims solid, controlled release, oral dosage hydromorphone tablets (the "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.

118. The '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).

119. At no time during the pendency of the '331 patent application was the PTO informed that Euro-Celtique's '909 patent is prior art under 35 U.S.C. § 102 to the '331 patent application and, though the specification is identical to the Euro-Celtique '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.

120. The oral dosage CR hydromorphone tablets disclosed in the '909 patent were made by the methods and using the matrices disclosed as useful in the '331, '912, '042 and '295 patents.

121. The oral dosage CR hydromorphone tablets disclosed in the ‘909 patent were made using the Contin® system.

122. The oral dosage CR hydromorphone tablets disclosed in the ‘909 patent have dissolution rates within the scope and coverage of the ‘331 and ‘912 patents.

123. The oral dosage CR hydromorphone tablets disclosed in the ‘909 patent 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.

124. The oral dosage CR hydromorphone tablets disclosed in the ‘909 patent 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”).

125. The oral dosage CR hydromorphone tablets disclosed in the ‘909 patent have the concentrations and parameters, when converted to oxycodone on a milligram-by-milligram basis in accordance with known conversion tables, equivalent to the ER oxycodone examples set forth in the ‘912 patent.

126. The oral dosage CR hydromorphone tablets disclosed in the ‘909 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 ER oxycodone examples set forth in the ‘042 and ‘295 patents.

127. The oral dosage CR hydromorphone tablets disclosed in the ‘909 patent have a range of daily dosage and provide pain relief equivalent to immediate release oral dosage hydromorphone tablets.

128. It would have been important and material to prosecution of the applications leading to the ‘331, ‘912, ‘042 and ‘295 patents for the PTO to have known that Euro-Celtique’s ‘909 patent could not be antedated or overcome by a Terminal Disclaimer.

129. It would have been important and material to prosecution of the applications leading to the ‘331, ‘912, ‘042 and ‘295 patents for the PTO to have known of the ‘909 patent.

130. Information concerning the ‘909 patent was known to at least the attorneys prosecuting the ‘331, ‘912, ‘042 and ‘295 patents.

131. Information concerning the ‘909 patent was intentionally withheld by the attorneys prosecuting ‘331, ‘912, ‘042 and ‘295 patents to deceive the PTO and was intentionally withheld by them to deceive or mislead the PTO.

7. The Application Leading To The ‘295 Patent

132. The application that matured into the ‘295 patent, Serial No. 618,334, was filed by Euro-Celtique through its patent solicitors on March 19, 1996.

133. The application that matured into the ‘042 patent, Serial No. 457,644, had not yet issued when the ‘295 patent application was filed.

134. The applications referred to in Paragraphs 132 and 133 contain claims directed to the same purported invention, namely “a method for reducing the range of daily dosages required to control pain in human patients.”

135. After the ‘042 patent issued, the PTO rejected the method claims of the ‘295 patent application based upon obviousness-type double patenting over the ‘042 patent.

136. Euro-Celtique and the named inventors of the ‘295 patent, acting through Euro-Celtique’s patent solicitor, acknowledged the validity of the rejection by terminally disclaiming a portion of the ‘295 patent term to overcome it.

137. At no time during the prosecution of the application leading to the ‘042 patent did the applicants inform the Examiner of the application of the claims directed to the same invention pending in the ‘295 patent application.

138. It would have been important and material to the prosecution of the application leading to the ‘042 patent for the examiner to have known of the copendency of claims directed to the same invention in the ‘295 patent application.

139. The ‘295 patent application was known to at least Euro-Celtique’s patent solicitors during the prosecution of the ‘042 patent and was intentionally withheld by them in order to deceive or mislead the PTO.

B. False And Misleading Information Submitted To The PTO

1. False And Misleading Statements Regarding Beliefs In The Art

140. 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 Euro-Celtique ‘341 patent techniques, as set forth in Paragraph 39, were false and affirmative misrepresentations of material facts important to the prosecution of the ‘331 patent application.

141. The representations set forth at Paragraph 140 herein were intentionally made to deceive the PTO.

142. During prosecution of the application leading to the ‘331 patent, at least the attorneys associated with the ‘331 patent knew that the ‘836 and ‘985 patents

disclosed control release matrix formulations that are virtually identical to the matrices disclosed as useful in the ‘331 patent and that such formulations would not be affected by the particular pharmaceutical agent included therein, including opioid analgesics in general.

143. During prosecution of the application leading to the ‘331 patent, at least Oshlack, Kaiko and the attorneys associated with the ‘331 patent knew that at least four prior art opioid analgesics, namely CR morphine, CR codeine, CR dihydrocodeine and CR hydromorphone, exhibited well known peak plasma levels between 2-4 hours and at least a 12 hour duration of therapeutic activity after administration.

144. Representations 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 were false and affirmative misrepresentations of material facts important to the prosecution of the applications leading to the ‘331, ‘912, ‘042 and ‘295 patents.

145. The representations set forth in Paragraph 144 herein were intentionally made to deceive or mislead the PTO.

146. During prosecution of the application leading to the ‘331, ‘912, ‘042 and ‘295 patents, at least Oshlack, Kaiko and the attorneys associated with the ‘331, ‘912, ‘042 and ‘295 patents knew that the representations set forth in Paragraphs 140 and 144 herein were false.

2. False And Misleading Statements Regarding Obviousness

147. Representations in support of the '331 patent, including that even in the case of closely related drugs predictability of the duration of action is impossible to predict as set forth in Paragraph 43 herein and that one skilled in the art would not arrive at the claims pending before the Examiner as set forth in Paragraph 46, 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.

148. The representations set forth at Paragraph 147 herein were intentionally made to deceive or mislead the PTO.

149. During prosecution of the applications leading to '331, '912, '042 and '295 patents, at least the attorneys associated with these patents knew that the Leslie patent and Oshlack used dissolution data to predict duration of effect.

150. During prosecution of the applications leading to '331, '912, '042 and '295 patents, at least the attorneys associated with these patents knew that the '836 and '985 patents equated all analgesics as operable within the matrices disclosed as useful in the '331, '912, '042 and '295 patents.

151. During prosecution of the applications leading to '331, '912, '042 and '295 patents, at least Oshlack, Kaiko and the attorneys associated with these patents knew that CR morphine, CR dihydrocodeine, as well as CR hydromorphone 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.

152. During prosecution of the applications leading to '331, '912, '042 and '295 patents, at least Kaiko knew that 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.

153. During prosecution of the applications leading to '331, '912, '042 and '295 patents, at least Kaiko knew that certain prior art formulations were "intended to produce a formulation that mimicked the C_{max}, C_{min}, and percent fluctuation in plasma [opioid] concentrations of the IR at steady-state" (CLINICAL THERAPEUTICS, 1996; 18(1): 95-105).

154. Euro-Celtique's and Kaiko's statements and representations set forth in Paragraphs 43 and 46 herein led the PTO 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 extended release oxycodone having peak plasma levels at a 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 extended release oxycodone the t_{max} and duration of effect of such opioid in vivo.

3. Dosage Range Information

155. Representations either during the prosecution or in the specifications of the '331, '912, '042 and '295 patents that ER 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 ER 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.

156. The only support for the statements set forth in Paragraph 155 herein was the Example 17 clinical study set forth in the '912, '042 and '295 patent specifications, summarizing the results of a limited number of patients who received a single dose of ER oxycodone following abdominal or gynecological surgery.

157. Individuals associated with prosecution of the '331, '912, '042 and '295 patents 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 ER oxycodone in approximately 90 percent of patients.

158. Purdue has sponsored and supported numerous clinical studies, of which the applicants were aware during prosecution of the applications leading to the '331, '912, '042 and '295 patents, that contradict the applicants' assertions regarding prior art dosage ranges for opioid analgesics and ER oxycodone, as set forth at Paragraphs 41, 48, 49, 53, 53, 55 and 56. Purdue and Purdue affiliate employees, including the named inventors of the '331, '912, '042 and '295 patents, have co-authored many articles reporting the results of many of these studies, including the following:

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 ER 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 reports the ER 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 reports that, in a comparison of the use of ER oxycodone and CR morphine in cancer related pain, the mean daily dose for ER 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 ER 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 ER oxycodone. This study concluded that when both stable phases were combined, pain control with CR morphine was better than with ER oxycodone (PAIN, 1997; 73: 3745);

d. An article co-authored by Kaiko reporting that dose titration is as easily accomplished and as efficient for ER oxycodone and CR morphine in the treatment of cancer pain. CR morphine is reported to be actually better than ER 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 ER 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 ER oxycodone was 114 mg (range 20 to 400 mg) and for JR 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 ER 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 ER oxycodone group and 140mg (range 60-300 mg) in the CR morphine group, a nine-fold versus a five-fold range, with ER 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 ER 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 ER oxycodone reporting that ER oxycodone has the same daily dosage, pharmacokinetic and pharmacodynamic properties as IR oxycodone except that the duration of effect is extended by ER oxycodone.

159. Most of the articles set forth in Paragraph 158 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.

160. Purdue's sales of CR morphine (MS Contin®) during the 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.

161. It would have been important and material to prosecution of the '912, '042 and '295 patent applications for the PTO to have known of the information set forth in Paragraphs 157, 158, 159 and 160 herein.

162. At no time during the pendency of the '912, '042 and '295 patent applications was the PTO informed of the information and conclusions set forth in Paragraphs 157, 158, 159 and 160 herein, which were intentionally withheld to deceive the PTO.

B. Absence of Sufficient Support for Reported Data

163. In connection with prosecution of the applications leading to the '331, '912, '042 and '295 patents, applicants represented to the PTO that they "surprisingly

discovered" that the extended release oxycodone hydrochloride formulation acceptably controlled pain for approximately 90 percent of patients over a four-fold dosage range, leading to easier titration.

164. The applicants also represented to the PTO during prosecution of at least one of the applications leading to the '331, '912, '042 and '295 patents that the precisely quantified "result" set forth in Paragraph 163 was absolutely critical to the issuance of the patents.

165. The inventors of the applications leading to the '331, '912, '042 and '295 patents had not conducted any tests or experiments, and thus had never obtained the specifically quantified results supporting their data concerning control of pain, which was submitted to the PTO in connection with the applications leading to the '331, '912, '042 and '295 patents.

166. In other words, applicants did not have sufficient support for asserting that the oxycodone hydrochloride product of the '331, '912, '042 and '295 patents was effective for 90 percent of patients within a four-fold dosage range at any time during the prosecution of these patents, since they did not have any scientific proof of this supposed discovery.

167. The applicants' assertions concerning the control of pain for approximately 90 percent of patients over a four-fold dosage range were highly material to subject matter recited by the claims pending in the applications leading to the '331, '912, '042 and '295 patents.

168. A reasonable examiner would have considered material to patentability the fact that the applicants did not have sufficient scientific proof that the invention claimed

by the ‘331, ‘912, ‘042 and ‘295 patents actually provided adequate pain relief for most people over a four-fold range.

169. Kaiko 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. Kaiko knew of the absence of such studies and evidence during prosecution of the applications leading to the ‘331, ‘912, ‘042 and ‘295 patents.

170. Purdue has admitted that the effectiveness of the oxycodone drug effective over a narrow range of dosages for 90 percent of patients was not supported by evidence or clinical studies.

171. 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 Kaiko’s vision.”

172. Individuals associated with prosecution of the applications leading to the ‘331, ‘912, ‘042 and ‘295 patents, including at least Kaiko, intentionally failed to inform, the PTO of the lack of sufficient evidence supporting claims regarding the effectiveness of the claimed compounds over narrow ranges of dosages for 90 percent of patients to deceive the PTO into allowing the applications leading to the ‘331, ‘912, ‘295 and ‘042 patents.

173. This case is exceptional under 35 U.S.C. § 285.

THIRD AFFIRMATIVE DEFENSE
Failure To State A Claim

174. The Complaint fails to state a claim upon which relief can be granted.

COUNTERCLAIMS

The Parties

1. Actavis Totowa LLC ("Actavis") is a company organized and existing under the laws of the State of Delaware, having a place of business at 4 Taft Road, Totowa, New Jersey 07512.

2. Upon information and belief, plaintiff Purdue Pharma L.P. ("Purdue Pharma") is a limited 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.

3. Upon information and belief, plaintiff The P.F. Laboratories, Inc. ("P.F. Labs") is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 700 Union Boulevard, Totowa, New Jersey.

4. Upon information and belief, plaintiff 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.

FIRST COUNTERCLAIM AGAINST PLAINTIFFS
Declaration of Invalidity and Unenforceability

5. Actavis repeats and realleges Paragraphs 1-4 of the Counterclaims.

6. This claim arises under the patent laws of the United States, 35 U.S.C. § 1 et seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c).

7. The ‘042 patent is invalid by reason of failure of the claims of the ‘042 patent to satisfy one or more conditions of patentability specified in Title 35 of the United States Code, including but not limited to Sections 101, 102, 103 and 112.

8. The ‘042 patent is invalid and void under the judicially created doctrine of obviousness-type double patenting.

9. The ‘042 patent is unenforceable for the reasons set forth at Paragraphs 31-172 of Actavis’ Second Affirmative Defense herein. Actavis repeats and realleges Paragraphs 31-172, as if fully set forth herein.

10. Actual and justiciable controversies exists between Actavis and the plaintiffs regarding the validity and enforceability of the ‘042 patent.

11. Actavis is entitled to declarations that the ‘042 patent is invalid and unenforceable.

12. This case is exceptional under 35 U.S.C. § 285.

SECOND COUNTERCLAIM AGAINST PLAINTIFFS
Monopolization in the Relevant Markets

13. Actavis repeats and realleges Paragraphs 1-12 of the Counterclaims, as if fully set forth herein..

14. This claim arises under the antitrust laws of the United States, 15 U.S.C. § 2, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1337(a) and 1367. Venue is proper in this Judicial District under 15 U.S.C. § 22 and 28 U.S.C. §§ 1391(b) and (c).

I. <u>The Regulatory Scheme for the Marketing of Generic Drugs</u>

15. The manufacture and commercial sale of pharmaceutical drugs are regulated by the Food and Drug Administration (“FDA”) pursuant to the Food, Drug and

Cosmetic Act, 21 U.S.C. § 301 et seq. (1994) (the "Act"). Congress passed the "Hatch-Waxman Amendments" to the Act in 1984, after concluding, among other things, that the Act's cumbersome drug-approval process delayed the entry of relatively inexpensive generic drugs into the marketplace.

16. The Hatch-Waxman Amendments permit generic-drug manufacturers to file an Abbreviated New Drug Application ("ANDA") that greatly expedites the drug-approval process, principally because the ANDA may incorporate data that an earlier manufacturer already submitted to the FDA regarding the earlier drug's safety and efficacy in a New Drug Application ("NDA").

17. As protection for NDA drug manufacturers, the ANDA applicant is also required to certify in one of four ways with respect to any purported patent claim that is listed as covering the NDA drug in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book").

18. If an ANDA applicant seeks approval to market before the expiration of any listed patents, it must make a certification for each patent, according to 21 U.S.C. §355(j)(2)(A)(vii)(IV), "that such patent is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted;" a so-called "Paragraph IV certification."

19. The filing of Paragraph IV certifications automatically confers upon the holder of the patents identified in the Orange Book as covering the listed drug standing to assert a cause of action for patent infringement against the ANDA applicant. If such action is brought within forty-five days from receipt of notification of the Paragraph IV certification(s), the FDA cannot finally approve the ANDA until the earlier of thirty

months from the patent-holder's receipt of notification of the Paragraph IV certification(s) or the date on which the court hearing the patent infringement case holds that the patent(s) is (are) invalid, not infringed, or unenforceable.

20. If the holder of the listed patent(s) does not file an infringement action within forty-five days from receipt of the Paragraph IV notification, the FDA can finally approve the ANDA as soon as the FDA'S regulatory requirements are satisfied, and the ANDA applicant can sell the generic product in the United States upon receipt of such final approval from the FDA.

21. If an ANDA has satisfied all FDA requirements, but the thirty-month period has not expired, the FDA will issue a tentative approval of the ANDA. The FDA's issuance of a tentative approval means that the FDA would have issued a final approval in the absence of a stay period that prevents the FDA from doing so.

II. The Relevant Markets

22. The 10, 20, 40 and 80 mg dosage forms of OxyContin® are controlled release pharmaceutical products used for management of severe pain requiring treatment for more than a few days. OxyContin® is part of a class of drugs known as opioid analgesics.

23. The active pharmaceutical ingredient contained in OxyContin® is oxycodone. Generic formulations of oxycodone that are bioequivalent to the 10, 20, 40 and 80 mg dosage forms of OxyContin® are indicated for use in the same circumstances and have the same end use as, respectively, 10, 20, 40 and 80 mg tablets of OxyContin®.

24. The 10, 20, 40 and 80 mg generic formulations of oxycodone that are bioequivalent to 10, 20, 40 and 80 mg tablets of OxyContin®, respectively, will have

sufficient cross-elasticity of demand with, respectively, 10, 20, 40 and 80 mg tablets of OxyContin® to be reasonably interchangeable with the 10, 20, 40 and 80 mg tablets of OxyContin®.

25. The dosage strength of OxyContin® is measured by the quantity of oxycodone in a given dose. One dosage strength of OxyContin® is not reasonably interchangeable with another. A given patient condition warrants a given dosage strength of OxyContin®. For example, 80 mg tablets of OxyContin® are prescribed only for those patients suffering from severe pain who have been previously treated with opioid analgesics. If administered to patients not previously exposed to opioid analgesics, 80 mg tablets of OxyContin® may cause severe, and even fatal, respiratory depression.

26. For reasons set forth in Paragraph 25 of this counterclaim, one dosage strength of a generic formulation of oxycodone bioequivalent to OxyContin® is not reasonably interchangeable with another.

27. A multiple-dose, immediate release formulation of oxycodone is not an economically viable substitute for 10, 20, 40 and 80 mg tablets of OxyContin®, because consumers would not shift from extended release oxycodone to immediate release oxycodone in response to a small but significant price increase in the controlled release product.

28. For reasons set forth in Paragraph 27 of this counterclaim, generic formulations of oxycodone bioequivalent to 10, 20, 40 and 80 mg tablets of OxyContin® are not economically interchangeable with multiple doses of immediate release formulations of oxycodone.

29. Other opioid analgesics, including high dosage, controlled release opioid analgesics, are not economically viable substitutes for OxyContin®. A significant number of physicians and patients specifically prefer OxyContin® because, unlike other opioid analgesics, including high dosage, controlled release morphine, OxyContin® does not carry the stigma of being perceived by the public as an addictive narcotic drug used by the terminally ill as a last resort.

30. For the reasons set forth in the Paragraph 29 of this counterclaim, generic formulations of oxycodone bioequivalent to 10, 20, 40 and 80 mg tablets of OxyContin® are not economically interchangeable with other opioid analgesics, including high-dosage, controlled-release opioid analgesics.

31. The manufacture, marketing and sale of each dosage form of 10, 20, 40 and 80 mg tablets of OxyContin® and their bioequivalent generic formulations constitute four separate relevant product markets (collectively the "OxyContin® and Bioequivalents Markets"). The United States and its possessions and territories constitute the corresponding relevant geographic market for the OxyContin® and Bioequivalents Markets (together, the "Relevant Markets").

III. Purdue's Sham Infringement Action

32. Pursuant to 21 U.S.C. § 355(b), Purdue listed six patents in the FDA's Orange Book applicable to extended release oxycodone. The '042 patent was one of the six patents listed.

33. Purdue's NDA for 10, 20 and 40 mg OxyContin® was approved by the FDA on December 12, 1995. Shortly thereafter, Purdue began to sell 10, 20 and 40 mg OxyContin® in the Relevant Markets. Purdue's NDA for 80 mg OxyContin® was

approved by the FDA on January 6, 1997. Thereafter, Purdue began to sell 10, 20, 40 and 80 mg OxyContin® in the Relevant Markets.

34. From the FDA's approval of Purdue's NDAs until March 2004, Purdue accounted for 100 percent of the sales of in the Relevant Markets. Upon information and belief, Purdue and generics authorized by Purdue continue to account for a dominant percentage and effective monopoly of the sales in the Relevant Markets.

35. On or about September 19, 2006, Actavis filed with the FDA its ANDA under 21 U.S.C. § 355(j), seeking approval to manufacture a generic formulation of oxycodone bioequivalent to 10, 20, 40 and 80 mg OxyContin® in the United States, prior to the expiration of the '042 patent. Actavis' ANDA included, inter alia, Paragraph IV certifications that the '042 patent was invalid and unenforceable.

36. In paragraph 22 of the Complaint, Plaintiffs allege that, between December 6 and 11, 2006, Purdue received Actavis' notice of Paragraph IV certification with respect to Actavis' generic formulations bioequivalent to 10, 20, 40 and 80 mg OxyContin®.

37. On January 16, 2007, within forty-five days of Purdue's receipt of Actavis' notice of Paragraph IV certification, Plaintiffs brought the instant suit against Actavis for infringement of the '042 patent (the "Sham Infringement Action"). Plaintiffs do not assert any other patents in this suit.

38. Upon information and belief, Purdue's own scientists and personnel believed that the '042 paten was and is invalid. The '042 patent is not enforceable because Purdue's own scientists and personnel made material misrepresentations to and withheld material information from the PTO in connection with the prosecution of the

'042 patent and other patents in the '042 patent family, as set forth in Paragraphs 31-172 of Actavis' Second Affirmative Defense, supra.

39. Plaintiffs' claims against Actavis in the Sham Infringement Action are objectively baseless in that no reasonable person could realistically expect success on the merits of those claims knowing, as Plaintiffs did, that the '042 patent was invalid, and knowing, as Plaintiffs did, that the patent was unenforceable due to Purdue's material misrepresentations and failure to disclose material information to the PTO. Plaintiffs had no probable cause to commence the Sham Infringement Action.

40. Purdue commenced and continues to prosecute the Sham Infringement Action with the subjective and wrongful intent through the improper use of the judicial process to interfere directly with the business relationships of Actavis, to maintain a monopoly in the Relevant Markets, and to conceal that unlawful interference and monopoly maintenance. Plaintiffs have not brought the Sham Infringement Action to obtain a favorable outcome on the merits of the claims asserted.

41. By operation of applicable federal law, Plaintiffs' act of bringing the Sham Infringement Action prevents the final approval of Actavis' ANDA until the earlier of thirty months from Plaintiffs' receipt of Actavis' notice of Paragraph IV certification or the entry of a judgment in this case that the '042 patent is invalid and/or unenforceable. Plaintiffs' act of bringing the Sham Infringement Action has foreclosed and will continue to foreclose Actavis from entering the Relevant Markets at least until the FDA finally approves Actavis' ANDA and may continue effectively to foreclose that entry until the Sham Infringement Action is fully concluded or thereafter.

42. Plaintiffs commenced and continues to prosecute this action in violation of the Sherman Act.

IV. The Anticompetitive Effects of Plaintiffs' Sham Infringement Action

43. The commencement and continued prosecution of the Sham Infringement Action had enabled Purdue to maintain effective monopolies in each of the Relevant Markets.

44. As a direct and proximate result of the fraudulent and anticompetitive actions of Purdue, Actavis and consumers in the Relevant Markets have been and will continue to be injured.

A. Injury to Actavis

45. Purdue's commencement of its Sham Infringement Action prevents Actavis from receiving the FDA's final approval of Actavis' ANDA until the earlier of thirty months from Purdue's receipt of Actavis' notice of Paragraph IV certifications or the entry of a judgment that the '042 patent is invalid and/or unenforceable.

46. Actavis' ability to sell its generic equivalents 10, 20, 40 and 80 mg OxyContin® is in danger of being significantly delayed by the FDA's inability to finally approve Actavis' ANDA.

47. If plaintiffs had not commenced and continued to prosecute the Sham Infringement Action, and fraudulently procured and wrongfully enforced the '042 patent, the FDA would grant final approval of Actavis' ANDA in its ordinary and customary timeframe.

48. If Purdue had not commenced and continued to prosecute the Sham Infringement Action, and fraudulently procured and wrongfully enforced the '042 patent,

Actavis would be able to promptly commence selling its generic equivalents of 10, 20, 40 and 80 mg OxyContin® immediately after receiving final FDA approval within the FDA's ordinary and customary timeframe.

49. Purdue's Sham Infringement Action is injuring, and continues to injure, Actavis in at least the following ways:

a. Actavis is losing, and will continue to lose, millions of dollars in profits from lost sales of its generic equivalents of 10, 20, 40 and 80 mg OxyContin® by virtue of its prevented, impeded, and/or delayed entry into the OxyContin and Bioequivalents Markets;

b. Actavis is losing, and will continue to lose, valuable market share and competitive advantage to Purdue and authorized generic competitors in the OxyContin and Bioequivalents Markets by virtue of the additional time that Purdue wrongfully procured in which to market their 10, 20, 40 and 80 mg OxyContin® tablets unimpeded by competition; and

c. Actavis has incurred, and will continue to incur, costs and expenses, including attorneys' fees, in connection with Purdue's Sham Infringement Action.

50. Certain of the actual and threatened harm to Actavis is irreparable and warrants the provision of injunctive relief

B. Injury to Competition

51. When a physician prescribes a pharmaceutical product such as OxyContin®, unless that physician orders otherwise, pharmacies may or must, depending upon applicable law, fill the prescription with either the brand name pharmaceutical product or its generic equivalent, if available.

52. During the period Actavis is foreclosed from the OxyContin® and Bioequivalents Markets, if Actavis were able to enter and compete in the Relevant Markets, Actavis would sell their 10, 20, 40 and 80 mg generic oxycodone products for prices that are materially lower than the prices that Purdue is charging for their 10, 20, 40 and 80 mg OxyContin® tablets.

53. If Actavis were able to enter and compete in the Relevant Markets, Actavis would obtain a substantial share of the sales in each of the Relevant Markets to the benefit of consumers and itself

54. Purdue, through its fraudulent material misrepresentations to the PTO, prosecution of the Sham Infringement Action, and related anticompetitive conduct, is directly and proximately foreclosing Actavis from entering the OxyContin® and Bioequivalents Markets, thereby depriving consumers of a lower cost alternative to 10, 20, 40 and 80 mg OxyContin® tablets and otherwise eliminating competition in the OxyContin® and Bioequivalents Markets, directly injuring competition in those markets and causing consumers millions of dollars in overcharges.

55. The injury to competition constitutes serious and irreparable harm to the public.

56. The injury to competition flows directly from Actavis' injuries (and vice versa), and both Actavis' injuries and the injury to competition result directly from the illegal conduct of Purdue.

V. Summary

57. The acts complained of herein constitute actual and threatened violations of the antitrust laws, including without limitation Section 2 of the Sherman Act, 15

U.S.C. § 2, and warrant relief under Sections 4 and 16 of the Clayton Act, 15 U.S.C. §§ 15 and 26.

58. The injuries that Purdue's conduct has caused to Actavis' business and property are of the type that the antitrust laws were intended to prevent and flow from that which makes Purdue's acts unlawful under the antitrust laws.

59. Actavis is entitled to recover actual damages, including lost profits, the monetary consequences of lost market share and litigation costs, as Actavis is found to have incurred, trebled, plus Actavis' cost of this suit, including reasonable attorneys' fees, pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15.

60. Actavis is entitled to an order enjoining plaintiffs from continuing to enforce the '042 patent in any manner and enjoining Purdue from engaging in the unlawful, anticompetitive conduct described herein, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

THIRD COUNTERCLAIM AGAINST PLAINTIFFS
Attempted Monopolization in the Relevant Markets

61. Actavis repeats and realleges Paragraphs 1-60 of the Counterclaims, as if fully set forth herein.

62. By way of, and as a direct and proximate result of, Purdue's above described acts, and with specific intent, Purdue has unlawfully attempted to achieve and/or maintain monopolies in each of the Relevant Markets in violation of Section 2 of the Sherman Act and threatens to continue such attempts to monopolize.

63. In the absence of relief from this Court, Purdue has a dangerous probability of succeeding in unlawfully obtaining and/or preserving and maintaining monopolies in each of the Relevant Markets by preventing, impeding and/or delaying

Actavis' entry into the Relevant Markets, which success will injure both the business and property of Actavis and consumers in the Relevant Markets.

64. The injuries that Purdue's conduct has caused to Actavis' business and property are of the type that the antitrust laws were intended to prevent and flow from that which makes Purdue's acts unlawful under the antitrust laws.

65. Actavis is entitled to recover actual damages, including lost profits, the monetary consequences of lost market share and litigation costs, as Actavis is found to have incurred, trebled, plus Actavis' cost of this suit, including reasonable attorneys' fees, pursuant to Section 4 of the Clayton Act, 15 U.S.C. § 15.

66. Actavis is entitled to an order enjoining plaintiffs from continuing to enforce the '042 patent in any manner and enjoining Purdue from engaging in the unlawful, anticompetitive conduct described herein, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26.

PRAYER FOR RELIEF

WHEREFORE, Actavis demands judgment in its favor and against plaintiffs, as follows:

(a) Dismissing the Complaint with prejudice and deny each request for relief made by plaintiffs;

(b) Adjudging the claims of the '042 patent invalid;

(c) Adjudging the claims of the '042 patent to be unenforceable;

(d) Declaring that this case is exceptional under 35 U.S.C. § 285;

(e) Awarding Actavis its attorneys' fees pursuant to 35 U.S.C. § 285, other statutes or rules, or the general power of the Court;

(f) Preliminarily and permanently enjoining plaintiffs, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with plaintiffs, from utilizing the '042 patent to block, hamper, hinder or obstruct FDA approval of Actavis' products;

(g) Permanently enjoining plaintiffs, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with plaintiffs, from asserting or otherwise seeking to enforce the '042 patent against Actavis or anyone in privity with Actavis;

(h) Ordering plaintiffs to request FDA to terminate the 30-month statutory stay provided by 21 U.S.C. § 355(j)(5)(B)(iii);

(i) Declaring and adjudging plaintiffs to have violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by monopolizing the Relevant Markets, by attempting to monopolize the Relevant Markets, and by threatening additional violations of that statute;

(j) Awarding Actavis three times the damages it sustained or will sustain as a result of plaintiffs' violations of Section 2 of the Sherman Act, as provided by Section 4 of the Clayton Act, 15 U.S.C. § 15, including damages sustained by Actavis during the pendency of this litigation and to be sustained in the future, all as proven by Actavis at trial;

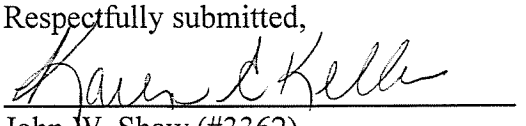
(k) Enjoining plaintiffs from engaging in further unlawful, anticompetitive conduct described herein, pursuant to Section 16 of the Clayton Act, 15 U.S.C. § 26;

(*l*) Awarding Actavis the cost of suit, including reasonable attorneys' fees, as provided in 15 U.S.C. § 15;

(m) Awarding pre-judgment and post-judgment interest as provided by law; and

(n) Awarding Actavis such other and further relief as the Court deems just and proper.

Respectfully submitted,



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March 8, 2007

CERTIFICATE OF SERVICE

I, Karen E. Keller, hereby certify that on March 8, 2007, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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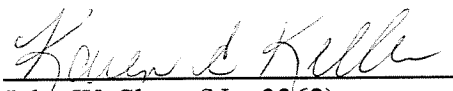
I further certify that on March 8, 2007, I caused a copy of the foregoing document to be served by hand delivery on the above-listed counsel of record and on the following in the manner indicated:

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