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/Counterclaim Defendants,	)	
v.	)	C.A. No. 07-032-***
KV PHARMACEUTICAL COMPANY and ACTAVIS TOTOWA LLC,	)	
Defendants/Counterclaim Plaintiffs.	)	

PURDUE'S REPLY TO THE COUNTERCLAIMS SET FORTH IN THE FIRST AMENDED ANSWER AND COUNTERCLAIMS OF ACTAVIS TOTOWA LLC

Plaintiffs and counterclaim defendants Purdue Pharma L.P., The P.F. Laboratories Inc. and Purdue Pharmaceuticals L.P. (collectively "Purdue") reply to the Counterclaims set forth in the First Amended Answer and Counterclaims of Actavis Totowa LLC ("Actavis") as follows:

REPLY

1. Admitted on information and belief.

2. Admitted.

3. Admitted.

4. Admitted.

REPLY TO THE FIRST COUNTERCLAIM

5. Purdue repeats and incorporates its reply to Paragraphs 1-4.

6. Actavis purports to assert claims under the patent laws and the Declaratory Judgment Act. Actavis also purpose to base subject matter jurisdiction on the statutes listed in Paragraph 6. Purdue does not contest that subject matter jurisdiction exists or that venue in this Judicial District is proper, but states that, on information and belief, venue is also proper in the U.S. District Court for the Southern District of New York. Except as expressly admitted, Purdue denies the averments of Paragraph 6.

7. Denied.

8. Denied.

9. Denied.[1]

9.31 Denied.

9.32 Purdue obtained FDA approval for OxyContin®, its innovative controlled-release oxycodone product, in December 1995. Purdue began selling OxyContin® in 1996.

9.33 Under the Food, Drug, and Cosmetic Act ("FDCA"), Purdue identified in the FDA's "Orange Book" (Approved Drug Products With Therapeutic Equivalence Evaluations) six patents, including the '331, '912, '042 and '295 patents. Paragraph 9.33 correctly identifies the title, filing date, issue date and named inventors of the specified patents. Paragraph 9.33 also correctly states the filing history of each of the patents except the '295 patent. The '295 patent is a continuation of the '912 patent, not a continuation in part (*see* '295 patent, col. 1, lines 4-7). Except as expressly admitted, Purdue denies the averments of Paragraph 9.33.

[1] Paragraph 9 of Actavis' Counterclaims "repeats and realleges Paragraphs 31-172" of its second affirmative defense. Thus, Purdue's response to each of those paragraphs is numbered as 9.31 to 9.172.

9.34 Euroceltique S.A. ("Euroceltique"), which is a company associated with the three "Purdue" plaintiffs, was identified as the assignee of the application for the '331 patent. The '331 patent application was prosecuted by attorneys for The Purdue Frederick Company, a Purdue associated company. Paragraph 9.34 correctly identifies the named inventors of the '331 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 9.34.

9.35 Euroceltique was identified as the assignee of the application for the '912 patent. The '912 patent application was prosecuted by attorneys for The Purdue Frederick Company. Paragraph 9.35 correctly identifies the named inventors of the '912 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 9.35.

9.36 Euroceltique was identified as the assignee of the application for the '042 patent. The '042 patent application was prosecuted by attorneys for The Purdue Frederick Company. Paragraph 9.36 correctly identifies the named inventors of the '042 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 9.36.

9.37 Euroceltique was identified as the assignee of the application for the '295 patent. The '295 patent application was prosecuted by attorneys for The Purdue Frederick Company. Paragraph 9.37 correctly identifies the named inventors of the '295 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 9.37.

9.38 The named inventors of the '331, '912, '042 and '295 patents assigned those patents to Euroceltique. At the time they made these assignments, the four inventors were employed by one or more companies associated with the plaintiffs. Except as expressly admitted, Purdue denies the averments of Paragraph 9.38.

9.39 Paragraph 9.39 accurately quotes the cited portion of the specification of the '331 patent. Purdue denies Actavis' characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 9.39.

9.40 Paragraph 9.40 accurately quotes the cited portion of the specification of the '331 patent. Purdue denies Actavis' characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 9.40.

9.41 Paragraph 9.41 accurately quotes the cited portion of the prosecution history of Purdue's '331 patent. Purdue denies Actavis' characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 9.41.

9.42 The '331 patent specification and prosecution history do not contain clinical data specifically directed to the range of dosages that would control pain in 90% of patients. Except as expressly admitted, Purdue denies the averments of Paragraph 9.42.

9.43 Paragraph 9.43 accurately quotes the cited portion of the prosecution history of Purdue's '331 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 9.43.

9.44 In his declaration filed during the prosecution of the '331 patent application, Dr. Kaiko correctly identified himself as Vice President for Clinical Research for The Purdue Frederick Company, Norwalk, Connecticut. The Purdue Frederick Company is not mentioned elsewhere in the '331 file history. Except as expressly admitted, Purdue denies the averments of Paragraph 9.44.

9.45 Denied.

9.46 Paragraph 9.46 accurately quotes the cited portions of the prosecution history of Purdue's '331 patent. Dr. Kaiko never represented that he was "disinterested, objective and independent," as Actavis alleges. Except as expressly admitted, Purdue denies the averments of Paragraph 9.46.

9.47 Paragraph 9.47 accurately quotes the cited portion of the prosecution history of Purdue's '331 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 9.47.

9.48 Paragraph 9.48 accurately quotes the cited portion of the specification of the '912 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 9.48.

9.49 Paragraph 9.49 accurately quotes the cited portion of the specification of the '912 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 9.49.

9.50 Denied.

9.51 Denied.

9.52 Paragraph 9.52 accurately quotes the cited portion of the prosecution history of the '912 patent. Purdue denies Actavis' characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 9.52.

9.53 Paragraph 9.53 accurately quotes the cited portion of the prosecution history of Purdue's '912 patent. Purdue denies Actavis' characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 9.53.

9.54 Paragraph 9.54 inaccurately and incompletely quotes a portion of the prosecution history of Purdue's '912 patent. In its February 22, 1995 Amendment in this

application, Purdue's attorney stated: "The in vitro dissolution data, such as that found in the '341 patent, *is but one of many factors which must be considered when formulating a particular drug composition*. Such data are often not indicative of in-vivo effect, particularly in the case of opioids." The italicized language was omitted from Actavis' quotation. The other portion of the Amendment quoted in Paragraph 9.54 is quoted accurately. Except as expressly admitted, Purdue denies the averments of Paragraph 9.54.

9.55 The '042 patent is a divisional of the '912 application, and as such has a substantially identical specification. Paragraphs 9.48 and 9.49 accurately quote the cited portion of the '042 specification. Except as expressly admitted, Purdue denies the averments of Paragraph 9.55.

9.56 The '295 patent is a continuation of the '912 application. Paragraphs 9.48 and 9.49 accurately quote the cited portion of the '295 specification. Except as expressly admitted, Purdue denies the averments of Paragraph 9.56.

9.57 Denied.

9.58 The prosecution history of each of the '331, '912, '042 and '295 patents do not reflect that the Leslie '256 patent was cited by Purdue or its attorneys during the prosecution of the patents in suit. The Leslie '256 patent is cumulative to, and less pertinent than, art that was cited and considered by the Patent Office ("PTO"). Except as expressly admitted, Purdue denies the averments of Paragraph 9.58.

9.59 Admitted.

9.60 The Leslie patent discloses certain "[s]low release pharmaceutical compositions comprising a combination of a higher aliphatic alcohol and a hydrated

hydroxy-alkyl cellulose" in defined ratios to provide release "during a predetermined period of time of from 5 to 10 hours" for active ingredients not including opioid analgesics. (Leslie patent, Abstract; *Id.* 13:62 – 14:5). Except as expressly admitted, Purdue denies the averments of Paragraph 9.60.

9.61 Paragraph 9.61 accurately quotes the cited portions of Leslie U.S. Patent No. 3,965,256. Purdue denies Actavis' characterization of the Leslie '256 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 9.61.

9.62 Denied.

9.63 Denied.

9.64 Denied.

9.65 Denied.

9.66 Denied.

9.67 The '331, '912, '042 and '295 patents all cite the Goldie '341 patent, which discloses hydromorphone formulations made with hydroxyethylcellulose and cetostearyl alcohol. The specifications of the '912, '042, and '295 patents also discuss the pharmacokinetic characteristics of MS Contin®, which is morphine in a Contin® matrix. Purdue admits that the CANCER, 1989; 63:2275-83 article states "the Contin release system ... has been used successfully with a wide range of drugs." The article further states that "[t]he rate of release of active drug within the gastrointestinal tract [has] the result that the drug is delivered to the body at a specific, planned rate." Purdue admits that Dr. Kaiko co-authored THE HOSPICE JOURNAL, 1990; 6(4):17-29 article. Purdue admits that the JOURNAL OF PAIN & SYMPTOM MGMT., Feb. 1997; 13(2): 75-82 article was authored by Purdue employees. That article states that "[b]ased upon a

comparison of AUC values, the oral bioavailability of oxycodone in the CR tablets was found to be similar to that reported previously for IR oxycodone solution, whereas the C_{max} was approximately 50% less and the T_{max} values observed are consistent with a prolonged release of oxycodone from tablets formulated using the Acrocontin™ delivery system." Except as expressly admitted, Purdue denies the averments of Paragraph 9.67.

9.68 Denied.

9.69 Denied.

9.70 Denied.

9.71 The prosecution histories of the '331, '912, '042, and '295 patents do not reflect that the Leslie patent was cited by Purdue or its attorneys to the PTO. The Leslie patent was less pertinent than and cumulative to other facts that were before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 9.71.

9.72 The PTO was informed of the relationship among Dr. Kaiko and the '331 inventors and the relationship between Dr. Kaiko and Euroceltique in PCT Application No. PCT/US92/10146, filed in the PTO on November 25, 1992. A reasonable examiner would assume that patent applicants and their assignee are interested in obtaining patent protection for the subject matter of the application. Except as expressly admitted, Purdue denies the averments of Paragraph 9.72.

9.73 Denied.

9.74 Denied.

9.75 Denied.

9.76 Messrs. Oshlack and Minogue and Dr. Chasin and their attorneys knew that Dr. Kaiko was their co-worker. Except as expressly admitted, Purdue denies the averments of Paragraph 9.76.

9.77 The PTO did know that Dr. Kaiko was affiliated with the named inventors of the '331 patent application. Except as expressly admitted, Purdue denies the averments of Paragraph 9.77.

9.78 Denied.

9.79 Purdue's MS Contin® controlled-release morphine tablets were made using the Contin® matrix, which included a hydroxy-alkyl cellulose and a higher aliphatic alcohol. Examples 6-11 of the '331 patent and 7-12 of the '912, '042 and '295 patents disclose formulations that include a hydroxyethylcellulose and cetostearyl alcohol. Except as expressly admitted, Purdue denies the averments of Paragraph 9.79.

9.80 Admitted.

9.81 MS Contin® tablets meet the dissolution limitations of certain claims of the '331 and '912 patents. Except as expressly admitted, Purdue denies the averments of Paragraph 9.81.

9.82 The article co-authored by Dr. Kaiko (CLINICAL PHARMACOKINETICS 1986, 11:505-10) reports peak plasma levels for controlled-release morphine in the range of 2-4 hours. The paper quotes other publications for the proposition that CR morphine is dosed every 8 hours in some patients. Except as expressly admitted, Purdue denies the averments of Paragraph 9.82.

9.83 Purdue admits that the CANCER 1989; 63:2284-88 article was co-authored by Dr. Kaiko. The article states that in previous studies, "MSC was

administered every 12 hours to patients with cancer-related pain and found equally as effective as oral immediate-release morphine administered every 4 hours in equivalent daily doses." Except as expressly admitted, Purdue denies the averments of Paragraph 9.83.

9.84 Denied.

9.85 The commercial sale of controlled-release morphine was expressly placed before the PTO in the prosecution of the '912, '042 and '295 patents in suit. To the extent that controlled-release morphine was relevant to the '331 patent, it was disclosed in the Oshlack '598 patent cited during the prosecution of the '331 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 9.85.

9.86 Dr. Kaiko had information about certain controlled-release morphine tablets during prosecution of the '331, '912, '042, and '295 patents. Except as expressly admitted, Purdue denies the averments of Paragraph 9.86.

9.87 The prosecution histories of the '331, '912, '042, and '295 patents do not reflect that information regarding controlled-release codeine was cited by Purdue or its attorneys to the PTO. That information was less pertinent than and cumulative to other facts that were before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 9.87.

9.88 CR codeine tablets were made using the Contin® matrix, which included a hydroxy-alkyl cellulose and a higher aliphatic alcohol. Examples 6-11 of the '331 patent and 7-12 of the '912, '042 and '295 patents disclose formulations that include a hydroxyethylcellulose and cetostearyl alcohol. Except as expressly admitted, Purdue denies the averments of Paragraph 9.88.

9.89 Admitted.

9.90 Purdue's CR codeine tablets have a peak plasma level in the range of 2-4 hours. Except as expressly admitted, Purdue denies the averments of Paragraph 9.90.

9.91 The abstract co-authored by Dr. Kaiko (ASCO PROCEEDINGS March 1986, 5:255) reports peak plasma levels for CR codeine (CRC) in the range of 2-4 hours. The abstract states that the data "indicate comparable overall bioavailability between CRC and immediate-release codeine forms with CRC providing delayed and attenuated peak plasma concentration. The results are generally similar to those obtained in comparisons of controlled- and immediate-release morphine." Except as expressly admitted, Purdue denies the averments of Paragraph 9.91.

9.92 The J. PAIN & SYMPTOM MANAGEMENT 1994; 9:363-71 article was co-authored, *inter alia*, by employees of Purdue Frederick Canada and reports on a study in which patients received 100, 200, or 300 mg of controlled-release codeine every 12 hours. The J. PAIN & SYMPTOM MANAGEMENT 1995; 10:612-23 article was co-authored, *inter alia*, by employees of Purdue Frederick Canada. Except as expressly admitted, Purdue denies the averments of Paragraph 9.92.

9.93 Denied.

9.94 Denied.

9.95 At least in 1986, at the time he co-authored the article referred to in Paragraph 9.91, Dr. Kaiko had information about certain controlled-release codeine tablets. Except as expressly admitted, Purdue denies the averments of Paragraph 9.95.

9.96 Denied.

9.97 The prosecution histories of the ‘331, ‘912, ‘042, and ‘295 patents do not reflect that U.S. Patent Nos. 4,828,836, 4,834,985, or 4,834,984 (which were issued on the dates alleged and at least as of those dates were assigned to Euroceltique) were considered by the PTO during prosecution. Except as expressly admitted, Purdue denies the averments of Paragraph 9.97.

9.98 Admitted.

9.99 Purdue denies Actavis’ characterizations of the ‘836 and ‘985 patents. The ‘836 and ‘985 patents were cumulative to and less pertinent than art that was already before the PTO. Purdue also denies Actavis’ characterizations of the Goldie et al. ‘984 patent. The Goldie et al. ‘984 patent is cumulative to and less pertinent than art that was already before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 9.99.

9.100 The prosecution histories of the ‘331, ‘912, ‘042, and ‘295 patents do not reflect that U.S. Patent Nos. 4,828,836 or 4,834,985 were cited by Purdue or its attorneys during prosecution. The ‘836 and ‘985 patents are cumulative to and less pertinent than art that was cited. Except as expressly admitted, Purdue denies the averments of Paragraph 9.100.

9.101 The prosecution histories of the ‘331, ‘912, ‘042, and ‘295 patents do not reflect that information regarding CR dihydrocodeine tablets as described in the ‘984 patent was cited by Purdue to the PTO. The ‘984 patent specification describes clinical studies on controlled-release dihydrocodeine at 6:34 – 7:58. Information on the CR dihydrocodeine tablets disclosed in the ‘984 patent was cumulative to and less pertinent

than art that was already before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 9.101.

9.102 The prosecution histories of the '331, '912, '042, and '295 patents do not reflect that information regarding CR dihydrocodeine tablets as described in the '984 patent was cited by Purdue to the PTO. The controlled-release dihydrocodeine tablets disclosed in the '984 patent were made with hydroxyethylcellulose and cetostearyl alcohol. Information on the CR dihydrocodeine tablets disclosed in the '984 patent was cumulative to and less pertinent than art that was already before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 9.102.

9.103 The prosecution histories of the '331, '912, '042, and '295 patents do not reflect that information regarding CR dihydrocodeine tablets as described in the '984 patent was cited by Purdue to the PTO. Information on the CR dihydrocodeine tablets disclosed in the '984 patent was cumulative to and less pertinent than art that was already before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 9.103.

9.104 The prosecution histories of the '331, '912, '042, and '295 patents do not reflect that information regarding CR dihydrocodeine tablets as described in the '984 patent was cited by Purdue to the PTO. The controlled-release dihydrocodeine tablets described in the '984 patent have peak plasma levels in the range of 2-4 hours. Information on the CR dihydrocodeine tablets disclosed in the '984 patent was cumulative to and less pertinent than art that was already before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 9.104.

9.105 The prosecution histories of the ‘331, ‘912, ‘042, and ‘295 patents do not reflect that information regarding CR dihydrocodeine tablets as described in the ‘984 patent was cited by Purdue to the PTO. The ‘984 patent reports a peak plasma level of 130 ng/ml at 3 hours for the tablet described in Example 1, and a peak plasma level of 205 ng/ml at 1 hour for immediate-release dihydrocodeine. The clinical study evaluating “the control of moderate to severe pain in osteoarthritis” described at 7:1-58 of the ‘984 patent reports similar pain assessment scores for patients taking controlled-release or immediate-release dihydrocodeine. The CURRENT MEDICAL RESEARCH AND OPINION 1992; 13:37-48 article cites study results “confirm[ing] that the controlled-release formulation [of dihydrocodeine] did have significantly later tmax and lower Cmax values than the normal-release product and that the bioavailability was similar for both formulations at the same total daily dose.” This article also cites study results “confirm[ing] that CR 60 mg dihydrocodeine tablets given twice daily were as efficacious as the normal-release tablet, given 4-times daily to the same total daily dose, in the treatment of moderate to severe pain” in osteoarthritis patients. Information on the CR dihydrocodeine tablets disclosed in the ‘984 patent was cumulative to and less pertinent than art that was already before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 9.105.

9.106 The prosecution histories of the ‘331, ‘912, ‘042, and ‘295 patents do not reflect that information regarding CR dihydrocodeine tablets as described in the ‘984 patent was cited by Purdue to the PTO. Information on the CR dihydrocodeine tablets disclosed in the ‘984 patent was cumulative to and less pertinent than art that was already

before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 9.106.

9.107 The prosecution histories of the '331, '912, '042, and '295 patents do not reflect that information regarding CR dihydrocodeine tablets as described in the '984 patent was cited by Purdue to the PTO. Information on the CR dihydrocodeine tablets disclosed in the '984 patent was cumulative to and less pertinent than art that was already before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 9.107.

9.108 The prosecution histories of the '331, '912, '042, and '295 patents do not reflect that information regarding CR dihydrocodeine tablets as described in the '984 patent was cited by Purdue to the PTO. Information on the CR dihydrocodeine tablets disclosed in the '984 patent was cumulative to and less pertinent than art that was already before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 9.108.

9.109 The '836 and '985 patents are cumulative to and less pertinent than art that was before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 9.109.

9.110 Denied.

9.111 Denied.

9.112 Denied.

9.113 At least at the time Mr. Steinberg prosecuted the applications for the '836, '985, and '984 patents, he had knowledge of the information contained therein. Except

as expressly admitted, Purdue lacks sufficient information to form a belief about the remaining averments of Paragraph 9.113, and therefore denies them.

9.114 Denied.

9.115 Admitted.

9.116 Admitted.

9.117 The ‘909 patent states that the tablets of Examples 1-3 were made using hydroxyethylcellulose and cetostearyl alcohol. Examples 6-11 of the ‘331 patent and 7-12 of the ‘912, ‘042 and ‘295 patents disclose formulations that include a hydroxyethylcellulose and cetostearyl alcohol. Except as expressly admitted, Purdue denies the averments of Paragraph 9.117.

9.118 Paragraph 9.118 accurately quotes the cited portion of the specification of the ‘909 patent. Purdue denies Actavis’ characterization of the quoted language. Except as expressly admitted, Purdue denies the averments of Paragraph 9.118.

9.119 The ‘341 patent is a continuation of the ‘909 patent. Accordingly, the two patents have substantially identical specifications. Both the ‘909 and ‘341 patents were cited by the inventors and their attorneys to the PTO in the specification of the ‘331 patent. Both the ‘341 and ‘909 patents are prior art under 35 U.S.C. § 102. Purdue filed a Terminal Disclaimer in the ‘331 application to obviate a possible rejection of the ‘331 claims for obviousness-type double patenting over the claims of the ‘341 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 9.119.

9.120 Denied.

9.121 The ‘909 patent states that the tablets of Examples 1-3 were made using hydroxyethylcellulose and cetostearyl alcohol. Except as expressly admitted, Purdue denies the averments of Paragraph 9.121.

9.122 Denied.

9.123 The tablets disclosed in ‘909 Examples 1-3 meet the dissolution limitations of claim 1 of the ‘331 patent. The tablets disclosed in ‘909 Example 1 meet the pH independence limitations of claim 1 of the ‘331 patent. The tablets disclosed in ‘909 Example 1 provided a peak plasma level of 2-4 hours in the clinical study reported in the ‘909 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 9.123.

9.124 The CR hydromorphone tablets of Example 1 disclosed in the ‘909 patent have peak plasma levels between 2-4 hours. Except as expressly admitted, Purdue denies the averments of Paragraph 9.124.

9.125 Denied.

9.126 Denied.

9.127 Denied.

9.128 Denied.

9.129 Denied.

9.130 The Goldie et al. ‘909 patent was known to the applicants for Purdue’s ‘331 patent and to Purdue’s attorneys. The proof of this is that they cited it to the PTO in the ‘331 application. But the Goldie et al. ‘909 patent was cumulative to and less pertinent than art that was cited. Except as expressly admitted, Purdue denies the averments of Paragraph 9.130.

9.131 Denied.

9.132 The application for the ‘295 patent (Serial No. 618,334) was filed on March 19, 1996. Except as expressly admitted, Purdue denies the averments of Paragraph 9.132.

9.133 The application for the ‘042 patent (Serial No. 467,584) had not yet issued when the ‘295 patent application was filed.

9.134 The ‘295 and ‘042 applications are related through their parent, the ‘912 application. As such, before amendments, they contained the same claims, directed to the same invention. However, the ‘042 was filed as a divisional application of the ‘912, whereas the ‘295 was filed as a continuation of the ‘912. Except as expressly admitted, Purdue denies the averments of Paragraph 9.134.

9.135 Admitted.

9.136 Denied.

9.137 Although Purdue did not explicitly inform the PTO during prosecution of the ‘042 application that related claims were pending in the ‘295 application, both the ‘042 application and the ‘295 application were examined by the same primary examiner, Edward Webman. Thus, the examiner was aware of the pending claims in the ‘295 patent application. Except as expressly admitted, Purdue denies the averments of Paragraph 9.137.

9.138 Denied.

9.139 Both the attorneys prosecuting the ‘042 patent application and the examiner of that application were aware of the ‘295 patent application. Except as expressly admitted, Purdue denies the averments of Paragraph 9.139.

9.140 Purdue denies Actavis' characterization of the statements that appear in column 1, lines 35-42 of the '331 specification. Those statements were true, and were based on the inventors' own experience. No misstatement of fact was made. Except as expressly admitted, Purdue denies the averments of Paragraph 9.140.

9.141 Denied.

9.142 At least at the time Mr. Steinberg prosecuted the '836 and '985 patents, he had knowledge of the information contained therein. Except as expressly admitted, Purdue denies the averments of Paragraph 9.142.

9.143 Mr. Oshlack, Dr. Kaiko, and one or more of the attorneys knew, at various times, of one or more of controlled-release formulations of morphine, codeine, dihydrocodeine, and hydromorphone. Except as expressly admitted, Purdue denies the averments of Paragraph 9.143.

9.144 Denied.

9.145 Denied.

9.146 Denied.

9.147 Denied.

9.148 Denied.

9.149 Denied.

9.150 Denied.

9.151 Morphine, dihydrocodeine, hydromorphone and oxycodone are all opioid analgesics. Except as expressly admitted, Purdue denies the averments of Paragraph 9.151.

9.152 Denied.

9.153 Paragraph 9.153 inaccurately quotes a portion of the article CLINICAL THERAPEUTICS, 1996; 18(1): 95-105, which was co-authored by Dr. Kaiko. The full quote is: "In developing CR oxycodone, we intended to produce a formulation that, when administered according to the correct dosing guidelines, mimicked the C_{max}, C_{min}, and percent fluctuation in plasma oxycodone concentrations of IR oxycodone at steady state." Except as expressly admitted, Purdue denies the averments of Paragraph 9.153.

9.154 Purdue denies Actavis' speculation about the mental processes of the Patent Examiner and the averments of Paragraph 9.154.

9.155 Denied.

9.156 Purdue admits that the study disclosed in Example 17 provides support for the statements in Purdue's '912, '042 and '295 patents discussed in Paragraph 9.155 of the Counterclaims. Except as expressly admitted, Purdue denies the averments of Paragraph 9.156.

9.157 Denied.

9.158 Purdue has sponsored and supported numerous clinical studies, including the ones cited by Actavis in Paragraph 9.158. Purdue denies Actavis' characterizations of those studies. The studies neither contradict nor disprove what is disclosed or claimed in Purdue's '331, '912, '042 and '295 patents.

9.158.a. Purdue admits that the CANCER 1989; 63:2284-88 article was co-authored by Dr. Kaiko.

9.158.b. Purdue admits that the CANCER 1997; 79:1428-37 article was co-authored by an employee of Purdue Frederick (Canada). That article reports a mean final dose of controlled-release oxycodone of 124 ± 22 mg and a mean final

dose of controlled-release hydromorphone of 30 ± 6 mg. For the patients who completed the study, "[t]he dose of oral oxycodone required to provide optimal analgesia without intolerable side effects ranged from 20-550 mg per day." The authors stated that "[t]his wide variability among patients is consistent with the results of previous studies with controlled-release morphine and controlled-release hydromorphone."

9.158.c. Purdue admits that the PAIN 1997; 73:3745 article was based on a Purdue sponsored study. In that study, "[t]he mean daily dose of CR oxycodone at the end of titration was 123 mg and that of morphine 180 mg" and that "the patient-controlled titration resulted in a total mean daily opioid dose of oxycodone 148 mg compared with morphine 193 mg indicating patient activity in changing the opioid doses from the assumed ratio of 2:3." The article also states that "[d]uring the stable phases, significantly more ($P<0.05$) daily doses of escape analgesics were required during treatment with oxycodone ... compared with morphine."

9.158.d. Purdue admits that the EUROPEAN JOURNAL OF PAIN, 1998; 2:239-49 article was co-authored by Dr. Kaiko. The article states that "CR oxycodone was as easily titrated to the individual's need for pain control as CR morphine."

9.158.e. Purdue admits that the JOURNAL OF CLINICAL ONCOLOGY, Oct. 1998; 16(10): 3222-29 article was co-authored by Purdue Frederick Canada employees. That article reports on a study of 32 enrolled patients, of whom 23 completed the study. The study reports a "mean dose of

controlled-release oxycodone [of] 46.5 ± 57 mg every 12 hours versus 72.6 ± 102 mg every 12 hours for controlled-release morphine." The authors also state that the study results "indicate that the two drugs provide an equivalent level of pain control at morphine equivalent doses up to 592.5 mg." The article states of a different study: "A parallel group study in 101 cancer patients that compared controlled-release oxycodone with controlled-release morphine demonstrated that controlled-release oxycodone and controlled-release morphine can be used with equal facility for around-the-clock therapy in the treatment of cancer pain."

9.158.f. Purdue admits that the JOURNAL OF CLINICAL ONCOLOGY, Oct. 1998; 16(10): 3230-37 article was co-authored by Dr. Kaiko. That study included 156 patients analyzed for efficacy out of the initial enrollment of 180. The mean dose was "114 mg (range, 20 to 400 mg) in the CR and 127 mg (range, 40 to 640 mg) in the IR oxycodone group."

9.158.g. Purdue admits that the CANCER INVESTIGATION, 1998; 16(8): 562-71 article was based on a Purdue sponsored study. 44 patients in that study completed the full 12 weeks. The article states that "patients could have received a wide dose range of prestudy opioid analgesics. One double-blind study enrolled patients previously treated with 6-9 tablets of fixed-combination opioid/nonopioid analgesics (low dose group). The other study included patients treated with a single-entity, strong opioid or a high dose (>9 tablets) of fixed-combination analgesics (high-dose group)." The "final (up to week 12)" value reported for 51 patients was 158.6 ± 20.5 mg.

9.158.h. Purdue admits that the EUROPEAN JOURNAL OF PAIN, 1998; 2:239-49 article was co-authored by Dr. Kaiko. Of the 101 patients enrolled, 79 were analyzed for efficacy. The article states that "[d]ose titration to effect was similar with the two treatments (Table 2). The mean final daily doses of q12h study medication were 101 mg (range: 40-360 mg) in the CR oxycodone group and 140 mg (range: 60-300 mg) in the CR morphine group."

9.158.i. Purdue admits that the JOURNAL OF PAIN & SYMPTOM MGMT., Oct. 1999; 18(4): 271-79 article was co-authored by a Purdue Frederick Canada employee. The article states that "[a]mong cancer patients completing the titration period, the mean daily dose of oxycodone (±SE) was 104 ± 20 mg of CR oxycodone and 113 ± 24 mg of IR oxycodone; among noncancer patients, daily doses were 41 ± 4 mg and 39 ± 4 mg, for those receiving the CR and IR formulations, respectively."

9.158.j. Based on reasonable investigations, and in the absence of a specific identification of a citation by Actavis to a page or even a volume number within the OxyContin® NDA, Purdue is unable to confirm, and therefore denies, that the statement appears in the NDA.

Except as expressly admitted, Purdue denies the averments of Paragraph 9.158.

9.159 To the extent that Dr. Kaiko was a co-author of the articles cited by Actavis, he was aware of what those articles reported at the time the respective articles were published. Except as expressly admitted, Purdue denies the averments of Paragraph 9.159.

9.160 Denied.

9.161 Denied.

9.162 The clinical studies and articles cited by Actavis in Paragraph 9.158 were not cited by Purdue or its attorneys during prosecution of the '912, '042, and '295 patents. The clinical studies and articles cited by Actavis in Paragraph 9.158 were cumulative to and less pertinent than art that was before the PTO. Except as expressly admitted, Purdue denies the averments of Paragraph 9.162.

9.163 In the specification of the patents in suit, the inventors and their attorneys stated that "[i]t has now been surprisingly discovered that the presently claimed controlled release oxycodone formulations acceptably control pain over a substantially narrower, approximately four-fold [range] (10 to 40 mg every 12 hours – around-the-clock dosing) in approximately 90% of patients." '912 patent, 3:33-37. A similar statement was made in the October 28, 1992 response to an office action during the prosecution of the '331 patent. In both the specification of the patents in suit and in the office action response, the inventors and their attorneys stated that an "improv[ement in] the efficiency and quality of pain management" would be one benefit of the formulations disclosed and claimed in the '331 patent and the patents in suit. Except as expressly admitted, Purdue denies the averments of Paragraph 9.163.

9.164 Denied.

9.165 Denied.

9.166 Denied.

9.167 Denied.

9.168 Denied.

9.169 Denied.

9.170 Purdue admits that no clinical studies were conducted to prove Dr. Kaiko's discovery that the claimed formulations would control pain over a narrower, approximately four-fold dosage range in approximately 90% of patients. Except as expressly admitted, Purdue denies the averments of Paragraph 9.170.

9.171 Denied.

9.172 Denied.

10. Admitted.

11. Denied.

12. Purdue denies the allegation that this is an exceptional case under 35 U.S.C. § 285 for Actavis as against Purdue. However, as set forth in Purdue's complaint, Purdue believes that this is an exceptional case for Purdue as against Actavis.

REPLY TO THE SECOND COUNTERCLAIM

13. Purdue repeats and incorporates its reply to Paragraphs 1-12.

14. Actavis purports to assert claims under the antitrust laws and the Declaratory Judgment Act. Actavis also purports to base subject matter jurisdiction on the statutes listed in Paragraph 14. Purdue does not contest subject matter jurisdiction or that venue is proper in this Judicial District, but states that venue is also proper in the U.S. District Court for the Southern District of New York. Except as expressly admitted, Purdue denies the averments of Paragraph 14.

15. The Food and Drug Administration ("FDA") regulates the approval, manufacture, sale, and marketing of pharmaceuticals under the Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et seq. (the "FDCA"). The Drug Price Competition and Patent Term Restoration Act of 1984 ("the Hatch-Waxman Act"), amended certain sections of the FDCA. The Hatch-Waxman

Act was designed to provide a financial incentive for research and development by extending marketing exclusivity to the innovator drug company to offset the time during which the company is seeking FDA approval. That extension is in addition to the exclusivity granted by the issuance of a patent. The Hatch-Waxman Act also legislated a process by which generic drug manufacturers could begin the FDA approval process before an innovator drug patent had expired. Except as expressly admitted, Purdue denies the averments of Paragraph 15.

16. Paragraph 16 states a conclusion of law to which no responsive pleading is necessary. Except as expressly admitted, Purdue denies the averments of Paragraph 16.

17. Paragraph 17 states a conclusion of law to which no responsive pleading is necessary. Except as expressly admitted, Purdue denies the averments of Paragraph 17.

18. Paragraph 18 states a conclusion of law to which no responsive pleading is necessary. Except as expressly admitted, Purdue denies the averments of Paragraph 18.

19. Paragraph 19 states a conclusion of law to which no responsive pleading is necessary. Except as expressly admitted, Purdue denies the averments of Paragraph 19.

20. Paragraph 20 states a conclusion of law to which no responsive pleading is necessary. Except as expressly admitted, Purdue denies the averments of Paragraph 20.

21. Paragraph 21 states a conclusion of law to which no responsive pleading is necessary. Except as expressly admitted, Purdue denies the averments of Paragraph 21.

22. Purdue's OxyContin® has been granted approval by the FDA for the management of moderate to severe pain where use of an opioid analgesic is appropriate for more than a few days. OxyContin® is a controlled-release oxycodone product. Purdue manufactures and sells OxyContin® in 10, 20, 40, and 80 mg dosage strengths. Except as expressly admitted, Purdue denies the averments of Paragraph 22.

23. The active ingredient in OxyContin® is oxycodone. To the extent that ANDAs have been approved for generic copies of OxyContin®, the package inserts for those generics indicate the same uses as does OxyContin®. Except as expressly admitted, Purdue denies the averments of Paragraph 23.

24. To the extent that ANDAs have been approved for generic copies of OxyContin®, each approved dosage strength has been determined by the FDA to be bioequivalent to the corresponding dosage strength of OxyContin®. Except as expressly admitted, Purdue denies the averments of Paragraph 24.

25. Each dosage strength of OxyContin® reflects the amount of the active ingredient, oxycodone, in that dosage strength. To achieve a dose of 80 mg oxycodone, a patient could take one 80 mg tablet, two 40 mg tablets, four 20 mg tablets, eight 10 mg tablets, or any combination of 40 mg, 20 mg, and 10 mg tablets that would add up to 80 mg. Although it is more convenient to take only one tablet, any combination of tablets that added to 80 mg would provide the same effect as a single 80 mg tablet. Doctors titrate each patient individually to a dose that is appropriate for that patient. Except as expressly admitted, Purdue denies the averments of Paragraph 25.

26. Denied.

27. Purdue lacks sufficient information to answer, and therefore denies the averments of Paragraph 27.

28. Purdue lacks sufficient information to answer, and therefore denies the averments of Paragraph 28.

29. OxyContin® has numerous advantages over other opioid analgesics and over other formulations of oxycodone. For example, the active ingredient in OxyContin®, oxycodone, does not suffer from the stigma associated with morphine in the minds of many patients and doctors. Except as expressly admitted, Purdue denies the averments of Paragraph 29.

30. Denied.

31. Denied.

32. Under the FDCA, Purdue submitted the '598, '075, '331, '912, '042 and '295 patents for listing in the FDA's Orange Book with respect to OxyContin®. Except as expressly admitted, Purdue denies the averments of Paragraph 32.

33. Purdue's NDA for 10, 20 and 40 Mg OxyContin® was approved by the FDA on December 12, 1995. Purdue began sales of those dosage strengths in 1996. Purdue's NDA for 80 mg OxyContin® was approved by the FDA on January 6, 1997. Purdue began sales of that dosage strength in February 1997. Except as expressly admitted, Purdue denies the averments of Paragraph 33.

34. From the time Purdue began selling OxyContin® until the first generic sales in March 2004, OxyContin® was the only controlled-release oxycodone product for sale in the United States. Except as expressly admitted, Purdue denies the averments of Paragraph 34.

35. On information and belief, Actavis has sought FDA approval to market 10, 20, 40, and 80 mg dosage strengths of controlled-release oxycodone as a generic version of OxyContin®. Except as expressly admitted, Purdue lacks sufficient information to form a belief about the remaining averments of Paragraph 35, and therefore denies them.

36. In Paragraph 22 of Purdue's Complaint against Actavis, Purdue acknowledged receipt of Actavis' "'notice' with respect to the '042 patent as provided by 21 U.S.C. § 355(j)(2)(B)(ii) ... between December 6 and 11, 2006." Except as expressly admitted, Purdue denies the averments of Paragraph 36.

37. On January 16, 2007, within 45 days of receiving Actavis' notice letter, Purdue filed the Complaint against Actavis for infringement of the '042 patent. Except as expressly admitted, Purdue denies the averments of Paragraph 37.

38. Denied.

39. Denied.

40. Denied.

41. Denied.

42. Denied.

43. Denied.

44. Denied.

45. Denied.

46. Denied.

47. Denied.

48. Denied.

49. Denied.

50. Denied.

51. Admitted.

52. On information and belief, Actavis would sell its generic products at a price lower than Purdue charges for OxyContin®. Except as expressly admitted, Purdue denies the averments of Paragraph 52.

53. Denied.

54. Denied.

55. Denied.

56. Denied.

57. Denied.

58. Denied.

59. Denied.

60. Denied.

REPLY TO THE THIRD COUNTERCLAIM

61. Purdue repeats and incorporates its reply to Paragraphs 1-60.

62. Denied.

63. Denied.

64. Denied.

65. Denied.

66. Denied.

REPLY TO THE FOURTH COUNTERCLAIM

67. Purdue repeats and incorporates its reply to Paragraphs 1-66.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

73. Denied.

74. Denied.

75. Denied.

76. Denied.

77. Denied.

78. Denied.

79. Denied.

80. Denied.

81. Denied.

REPLY TO THE FIFTH COUNTERCLAIM

82. Purdue repeats and incorporates its reply to Paragraphs 1-81.

83. Purdue lacks sufficient information to form a belief about the averments of Paragraph 83, and therefore denies them.

84. Denied.

85. Denied.

86. Denied.

87. Denied.

88. Denied.

89. Denied.

90. Denied.

91. Denied.

DEFENSES

Purdue asserts the following defenses to Actavis' counterclaims:

92. Purdue's '042 patent is valid and is enforceable.

93. Actavis has infringed and will infringe under 35 U.S.C. § 271 the claims of the '042 patent.

94. Purdue has not violated Section One of the Sherman Antitrust Act (15 U.S.C. § 1).

95. Purdue has not violated Section Two of the Sherman Antitrust Act (15 U.S.C. § 2).

96. Purdue has not violated any state antitrust law.

97. Purdue has not interfered with any valid business expectancy that Actavis alleges that it has.

WHEREFORE, Purdue prays for judgment:

A. Dismissing Actavis' Counterclaims;

B. Adjudging that the '042 patent is valid and enforceable;

C. Adjudging that Actavis has infringed the '042 patent and that such infringement has been willful and deliberate;

D. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Actavis' ANDA No. 78-506 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) to be a date which is not earlier than the expiration date of the '042 patent;

E. Preliminary and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., defendant Actavis, its officers, agents, servants,

employees, parents, subsidiaries, affiliate corporations, other related business entities and all other persons acting in concert, participation or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell or sale within the United States, or importation into the United States, of any drug product that infringes the '042 patent;

F. Awarding Purdue damages, together with prejudgment interest and costs, as provided by 35 U.S.C. §§ 271(e)(4)(C) and 284;

G. Trebling the damages awarded, as provided by 35 U.S.C. § 284;

H. Declaring this an exceptional case and awarding Purdue its attorney's fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

I. Awarding Purdue such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Rodger D. Smith II

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April 27, 2007

CERTIFICATE OF SERVICE

I, Rodger D. Smith II, hereby certify that on April 27, 2007, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to the following:

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and that on April 27, 2007, I caused copies to be served upon the following in the manner indicated:

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