Docket No.: **241957.000508**
(PATENT) (TRACK 1)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: William H. McKenna et al.	Customer No. 06980
Application No.: 14/515,857	Confirmation No.: 6255
Filed: October 16, 2014	Art Unit: 1613
For: TAMPER RESISTANT DOSAGE FORMS	Examiner: AKHOON, Kauser M.

DECLARATION OF RICHARD O. MANNION UNDER 37 C.F.R. § 1.132

1. I, Richard O. Mannion, am a citizen of the United States and I am more than twenty-one (21) years of age.

2. All statements made herein of my own knowledge are true, and all statements made herein on information and belief are believed to be true.

3. I am an employee and Executive Director of Pharmaceutical & Analytical Development at Purdue Pharma L.P., which is the assignee of this application. I am a co-inventor of this patent application. I receive a salary, bonus and benefits from Purdue Pharma L.P. In my position at Purdue, my goals include initiating and supporting IP filings.

4. I make this declaration in support of the patentability of the above-identified patent application.

5. Each pending claim of this application provides a dosage form (tablets) having at least (1) an opioid or a pharmaceutically acceptable salt thereof (such as hydrocodone bitartrate); (2) at least one low molecular weight polyethylene oxide having, based on rheological measurements,

an approximate molecular weight of less than 1,000,000 (such as a PEO having a molecular weight of 600,000); and (3) at least one high molecular weight polyethylene oxide having, based on rheological measurements, an approximate molecular weight of 7,000,000. Each such tablet is a cured tablet, and is cured at a temperature from about 60 to about 90 °C for about 15 minutes to about 10 hours. Each cured tablet has at least 79 % by weight, based upon the total weight of said composition, of the total combined weight of the high and low molecular weight polyethylene oxides. The experiment described below was conducted using tablets having these features. Consequently, the samples in the experiment are tablets of the invention claimed in this application.

6. The density of uncured and cured hydrocodone tablets was determined under my direction. These tablets contained hydrocodone salt; low molecular weight polyethylene oxide ("PEO") having, based on rheological measurements, an average molecular weight of 600,000; and high molecular weight PEO having, based on rheological measurements, an average molecular weight of 7,000,000. The tablets contained either 20 mg or 120 mg of hydrocodone bitartrate.

7. The 20 mg tablets contained 40% by weight, based upon total weight of the tablet absent cosmetic coating, of the low molecular weight PEO and 56% by weight, based upon total weight of the tablet absent cosmetic coating, of the high molecular weight PEO, which means that the 20 mg tablets contained 96% total combined weight, based upon total weight of the tablet absent cosmetic coating, of high and low molecular weight PEO.

8. The 120 mg tablets contained 27% by weight, based upon total weight of the tablet absent cosmetic coating, of the low molecular weight PEO and 53% by weight, based upon total weight of the tablet absent cosmetic coating, of the high molecular weight PEO, which means that the 120 mg tablets contained 80% total combined weight, based upon total weight of the tablet absent cosmetic coating, of high and low molecular weight PEO.

9. The density of the tablets was determined by Archimedes' principle using hexane, a liquid of known density. The tablet was first weighed in air, and then was immersed in hexane and weighed. From these two weights, the density of the tablet ρ was determined as follows:

$$\rho = \frac{A}{A - B} \cdot \rho_0$$

ρ: Density of the tablet

A: Weight of the tablet in air

B: Weight of the tablet when immersed in the liquid

ρ_0: Density of the liquid at a given temperature.

10. The equipment used was a Top-loading Mettler Toledo balance Model # AE50/M87731 Serial #30000832, a glass beaker, and a thermometer.

11. The materials used were (a) hexane (the density of Hexane at 20°C = 0.660 g/ml); (b) uncured 20 mg hydrocodone bitartrate tablets as described above (Batch No. XWSF90); (c) uncured 120 mg hydrocodone bitartrate tablets as described above (Batch No. XWSG00); and (d) cured and cosmetically coated 20 mg and 120 mg tablets (Lot Nos. 2141-001, 2141-006, 2141-011, 2141-016; 2141-021, 2141-026, 2141-031, 2141-036).

12. The procedure used was as follows:

a. Set up Mettler Toledo balance with Mettler Density Determination Kit No. 33360.

b. Fill an appropriate sized beaker with hexane.

c. Weigh the tablet in air and record the weight as Weight A.

d. Transfer the same tablet onto the lower coil within the beaker filled with hexane.

e. Determine the weight of the tablet in liquid and record the weight as Weight B.

f. Perform the density calculation as above and record the density.

13. Three tablets of each type were measured for density. The average of each set of three tablets is reported in the Tables below.

Table 1. Density of HYD 20mg Tablet Before and After Curing at 70°C/15min

Uncured Tablet Density (g/cm^3)	Cured and Coated Tablet Density (g/cm^3)	% Density Change After Curing
1.158	1.073	-7.4

Table 2. Density of HYD 20mg Tablet Before and After Curing at 70°C/45min

Uncured Tablet Density (g/cm^3)	Cured and Coated Tablet Density (g/cm^3)	% Density Change After Curing
1.158	1.087	-6.2

Table 3. Density of HYD 20mg Tablet Before and After Curing at 78°C/15min

Uncured Tablet Density (g/cm^3)	Cured and Coated Tablet Density (g/cm^3)	% Density Change After Curing
1.158	1.089	-6.0

Table 4. Density of HYD 20mg Tablet Before and After Curing at 78°C/45min

Uncured Tablet Density (g/cm^3)	Cured and Coated Tablet Density (g/cm^3)	% Density Change After Curing
1.158	1.089	-6.0

Table 5. Density of HYD 120mg Tablet Before and After Curing at 70°C/15min

Uncured Tablet Density (g/cm^3)	Cured and Coated Tablet Density (g/cm^3)	% Density Change After Curing
1.177	1.100	-6.5

Table 6. Density of HYD 120mg Tablet Before and After Curing at 70°C/45min

Uncured Tablet Density (g/cm^3)	Cured and Coated Tablet Density (g/cm^3)	% Density Change After Curing
1.177	1.112	-5.5

Table 7. Density of HYD 120mg Tablet Before and After Curing at 78°C/15min

Uncured Tablet Density (g/cm^3)	Cured and Coated Tablet Density (g/cm^3)	% Density Change After Curing
1.177	1.102	-6.4

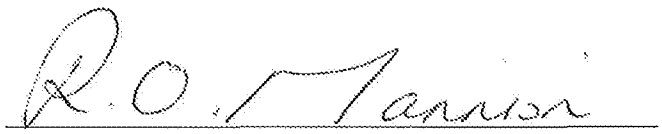
Table 8. Density of HYD 120mg Tablet Before and After Curing at 78°C/45min

Uncured Tablet Density (g/cm^3)	Cured and Coated Tablet Density (g/cm^3)	% Density Change After Curing
1.177	1.113	-5.4

14. The densities of all of the cured tablets were lower than the densities of the corresponding uncured tablets.

I have been warned and acknowledge that willful false statements and the like made by me are punishable by fine or imprisonment, or both (**18 U.S.C. 1001**) and may jeopardize the validity of the above-identified application or any patent issuing thereon.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.



Richard O. Mannion

Executed on March 27, 2015.