IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Curtis Wright et al.

Application No.: 13/726,324 **Confirmation No.:** TBA

Filed: December 24, 2012 **Art Unit**: TBA

For: PHARMACEUTICAL FORMULATION CONTAINING GELLING AGENT **Examiner:** TBA

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P.O. Box 1450
Alexandria, VA 22313-1450

Supplemental Amendment

Sir:

Prior to examination of the above-referenced application, Applicants submit the following:

Amendments to the Claims begin on page 2 of this paper.

Remarks begin on page 3 of this paper.

I. Amendments to the Claims

1-70. Canceled.

71. (New) An extended release abuse deterrent dosage form comprising:

a. a core matrix comprising a blended mixture of:

(a) PEO having a molecular weight of from about 300,000 to about 5,000,000;

(b) magnesium stearate; and

(c) oxycodone or a pharmaceutically acceptable salt thereof;

wherein the matrix is heated to melt at least a portion of the PEO included in the matrix; and

b. PEG applied onto the core matrix;

wherein the dosage form provides extended release of the drug.

II. Remarks

A. Status of the Claims

Claims 1-70 are hereby canceled. New claim 71 is added.

B. Remarks

Pursuant to 37 C.F.R. § 41.202 and MPEP § 2304.02, Applicants declare that new claim 71 as introduced herein is copied from US Patent No. 8,101,630 B2, which issued January 24, 2012 to Kumar et al. ("Kumar") from U.S. Application No. 12/383,906.

New claim 71 is identical to sole claim 1 of Kumar. Applicants urge that, as the instant claim 71 is copied from Kumar, the claims interfere; and further that the instant claim 71 (and Kumar claim 1) should constitute the count. As claim 71 is identical to issued claim 1 of Kumar, Applicants have identified a patentable claim as the count.

As claim 1 is the only claim issued in Kumar, and as claim 71 is now the sole claim pending in the instant application, Applicants submit that the sole claim of the instant application interferes with the sole claim of Kumar, *i.e.*, all claims pending in the instant application interfere with the sole issued claim of the patent.

Applicants' support for new claim 71 (and claim 1 of Kumar, and the proposed count) is shown in the claim chart below.

Claim 71 [Claim 1 of Kumar]	**Supporting Disclosure USSN 10/214,412**
An extended release	At page 6, lines 4-9: "The term "sustained release" is defined for purposes of the present invention as the release of the opioid analgesic from the oral dosage form at such a rate that blood (e.g., plasma) concentrations (levels) are maintained within the therapeutic range but below toxic levels over an extended period of time, e.g., from about 12 to about 24 hours as compared to an immediate release product. Preferably the sustained release is sufficient to provide a twice-a-day or a once-a-day formulation." and at page 6, line 29 to page 7, line 4:

Claim 71 [Claim 1 of Kumar]	Supporting Disclosure USSN 10/214,412
	"The aversive agents of the present invention are preferably for use in connection with oral dosage forms including opioid analgesics, which provide valuable analgesia but which may be abused. This is particularly true for controlled release opioid analgesic products which have a large dose of opioid analgesic intended to be released over a period of time in each dosage unit. Drug abusers typically may take a controlled-release product and crush, shear, grind, chew, dissolve and/or heat, extract or otherwise damage the product so that the full contents of the dosage form become available for immediate absorption by injection, inhalation, and/or oral consumption."
abuse deterrent dosage form comprising:	At page 6, line 29 to page 7, line 4: "The aversive agents of the present invention are preferably for use in connection with oral dosage forms including opioid analgesics, which provide valuable analgesia but which may be abused. This is particularly true for controlled release opioid analgesic products which have a large dose of opioid analgesic intended to be released over a period of time in each dosage unit. Drug abusers typically may take a controlled-release product and crush, shear, grind, chew, dissolve and/or heat, extract or otherwise damage the product so that the full contents of the dosage form become available for immediate absorption by injection, inhalation, and/or oral consumption."
a. a core matrix	At page 16, lines 15-20: "The opioid analgesic formulation in combination with one or more aversive agents can be formulated as an immediate release formulation or controlled release oral formulation in any suitable tablet, coated tablet or multiparticulate formulation known to those skilled in the art. The controlled release dosage form may include a controlled release material which is incorporated into a matrix along with the opioid analgesic. In addition, the aversive agent may be separate from the matrix, or incorporated into the matrix."
comprising a blended mixture of:	At page 24, line 32 to page 25, line 6: "In other embodiments of the invention, melt-extruded formulations are prepared without the inclusion of the opioid analgesic; one or more aversive agents; or mixtures thereof; which is added thereafter to the extrudate. Such formulations typically will have the opioid analgesic; one or more aversive agents; or mixtures thereof blended together with the extruded matrix material, and then the mixture would be tableted in order

Claim 71 [Claim 1 of Kumar]	Supporting Disclosure USSN 10/214,412
	to provide a slow release formulation. Such formulations may be advantageous, for example, when the opioid analgesic; one or more aversive agents; or mixtures thereof included in the formulation is sensitive to temperatures needed for softening the hydrophobic material and/or the retardant material."
(a) PEO	At page 8, lines 23 to 33: "In certain embodiments of the present invention wherein the dosage form includes an aversive agent comprising a gelling agent, various gelling agents can be employed including, for example and without limitation, sugars or sugar derived alcohols, such as mannitol, sorbitol, and the like, starch and starch derivatives, cellulose derivatives, such as microcrystalline cellulose, sodium caboxymethyl cellulose, methylcellulose, ethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and hydroxypropyl methylcellulose, attapulgites, bentonites, dextrins, alginates, carrageenan, gum tragacanth, gum acacia, guar gum, xanthan gum, pectin, gelatin, kaolin, lecithin, magnesium aluminum silicate, the carbomers and carbopols, polyvinylpyrrolidone, polyethylene glycol, polyethylene oxide, polyvinyl alcohol, silicon dioxide, surfactants, mixed surfactant/wetting agent systems, emulsifiers, other polymeric materials, and mixtures thereof, etc."
having a molecular weight of from about 300,000 to about 5,000,000;	At page 31, line 10 to page 32, line 10: "In certain embodiments, the bilayer core comprises a drug layer with opioid analgesic and a displacement or push layer optionally containing the one or more aversive agents. The one or more aversive agents may optionally be included in the drug layer instead of or in addition to being included in the push layer. In certain embodiments the drug layer may also comprise at least one polymer hydrogel. The polymer hydrogel may have an average molecular weight of between about 500 and about 6,000,000. Examples of polymer hydrogels include but are not limited to a maltodextrin polymer comprising the formula $(C_6H_{12}O_5)_n.H_2O$, wherein n is 3 to 7,500, and the maltodextrin polymer comprises a 500 to 1,250,000 number-average molecular weight; a poly(alkylene oxide) represented by, e.g., a poly(ethylene oxide) and a poly(propylene oxide) having a 50,000 to 750,000 weight-average molecular weight, and more specifically represented by a poly(ethylene oxide) of at least one of 100,000, 200,000, 300,000 or 400,000 weight-average molecular weights; an alkali carboxyalkylcellulose, wherein the alkali is sodium or potassium, the alkyl is methyl, ethyl, propyl,

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