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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
11/383,066	05/12/2006	Amir Shojaei	085199-0034	7083

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EXAMINER	
YOUNG, MICAH PAUL	
ART UNIT	**PAPER NUMBER**
1618	
MAIL DATE	**DELIVERY MODE**
04/30/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	11/383,066	SHOJAEI ET AL.	
	Examiner	Art Unit	
	MICAH-PAUL YOUNG	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-32* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other:

DETAILED ACTION

Acknowledgment of Papers Received: Amendment/Response dated 1/29/10.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-23, 25, and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Burnside et al (USPN 6,605,300 hereafter '300).

The '300 patent teaches an oral pulsed release formulation comprising a combination of immediate release and delayed release amphetamine beads (abstract). The formulation can comprise a coated core comprising an immediate release portion of the amphetamine salts, along with an enterically coated delayed release bead (claim 1). The enteric polymers include pH dependent enteric polymers (col. 8, lin. 43-68). The formulation further comprises a protective coating to the core between the drug layers, or at the enteric layer (col. 8, lin. 10-30). The amphetamine is coated to an inert seed material (Example 1). This coated seed is then coated with various polymers, forming a core with the amphetamine incorporated (Examples 2 and 3). The formulation can comprise multiple coated delayed core comprises different enteric polymers or the same polymers such as Eudragit L or 4110D (Examples 1-4). The formulation comprises a combination of immediate release beads and controlled release beads (Example 4). The formulation can comprise up to 20 mg of a mixture of amphetamine salts including dextroamphetamine saccharate and amphetamine sulfate (claim 1). A single immediate release

bead can be coated with a delayed release bead coating solution and combined with a second delayed release formulation so that the immediate and delayed release portions are present in the same bead and on different beads (Example 4).

Regarding the bioequivalence of the formulation to that of ADDERALL XL, and the other physiological effects of the instant dosage form (food, Tmax, AUC and Cmax values) it is the position of the Examiner that these limitations are merely functional limitations that are the result of the instant compositional components. These functional limitations are inherent properties of the composition and are dependent from the composition components, since a compound and its properties cannot be separated. The same compositions, comprising the same components and compounds must have the same properties. As such, since the formulation of the '300 patent comprises the same immediate release and delayed release beads, comprising the same polymers and arrangement the formulation of the '300 patent must also have the same bioequivalence, and blood plasma concentrations.

Further specifically regarding the potential Tmax, Cmax and AUC of a 37.5 mg dose, it is the position of the Examiner that these limitation merely recite a future intended use for the composition. These values are based on a theoretical future dosage form that has the same fundamental structure and components as the '300 formulation. As such if the same components are applied to the theoretical model they would inherently result in the same in vivo results.

For these reasons the claims are anticipated.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, and 7-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures of Burnside et al (USPN 6,605,300 hereafter '300).

As discussed above the '300 patent discloses a controlled release dosage form comprising immediate release bead sand delayed release beads where the delayed release beads comprise enter polymers and protective coating. The beads comprise a mixture of amphetamine salts and are disclosed at a concentration of at least 20 mg (claims). The reference is silent to a higher dosage, however concentration however increasing the dosage of a well known pharmaceutical dependent on the patient is well within the limits of one of ordinary skill and would be an obvious modification. Since dosing concentrations are based on patient need an increase or decrease in the potency of a dosage form would be an obvious modification to provide the result effective variable to increase or decrease the effectiveness of the dosage form. The general

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