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Dated: November 1, 2013 Signature: /Krista Chaffin-Penny/
(Krista Chaffin-Penny)

Docket No.: 638772000109
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Neil P. DESAI et al.

Application No.: 11/520,479 Confirmation No.: 8972

Filed: September 12, 2006 Art Unit: 1611

For: NOVEL FORMULATIONS OF PHARMACOLOGICAL AGENTS, METHODS FOR THE PREPARATION THEREOF AND METHODS FOR THE USE THEREOF

Examiner: T. Love

AMENDMENT IN RESPONSE TO NON-FINAL OFFICE ACTION

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Madam:

INTRODUCTORY COMMENTS

This is in response to the non-final Office Action dated May 2, 2013 (Paper No. 20130429), for which a response was due on August 2, 2013. Filed herewith is a Petition and fee for a three months extension of time, thereby extending the deadline for response to November 2, 2013. Accordingly, this response is timely filed. Reconsideration and allowance of the pending claims, as amended, in light of the remarks presented herein are respectfully requested.

Claims are reflected in the listing of claims which begins on page 2 of this paper.

Remarks/Arguments begin on page 6 of this paper.

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings of claims in the application:

Claims 1-65 (Cancelled).

Claim 66 (Currently amended): A pharmaceutical formulation comprising:
paclitaxel at a concentration between 5 mg/ml and 15 mg/ml,
wherein the pharmaceutical formulation is an aqueous suspension that is stable for at least 3 days under at least one of room temperature or refrigerated conditions, wherein the pharmaceutical formulation comprises nanoparticles comprising a solid core of paclitaxel and an albumin coating, and wherein the size of the nanoparticles in the ~~composition~~ formulation is less than 400 nm.

Claim 67 (Previously presented): The pharmaceutical formulation of claim 66, wherein the pharmaceutical formulation is a stable aqueous suspension reconstituted from a sterile lyophilized powder.

Claim 68 (Previously presented): The pharmaceutical formulation of claim 67, wherein the pharmaceutical formulation comprises paclitaxel at a concentration of 5 mg/ml.

Claim 69 (Cancelled).

Claim 70 (Previously presented): The pharmaceutical formulation of claim 67, wherein the average diameter of the nanoparticles is no greater than 220 nm.

Claim 71 (Previously presented): The pharmaceutical formulation of claim 67, wherein there is substantially no precipitation of paclitaxel for at least 3 days under at least one of room temperature or refrigerated conditions.

Claim 72 (Previously presented): The pharmaceutical formulation of claim 66, wherein the average nanoparticle size does not substantially change for at least 3 days under at least one of room temperature or refrigerated conditions.

Claim 73 (Cancelled).

Claim 74 (Previously presented): The pharmaceutical formulation of claim 66, wherein the solid core is substantially free of polymeric material.

Claim 75 (Previously presented): The pharmaceutical formulation of claim 66, wherein the albumin coating has free albumin associated therewith, and wherein a portion of the paclitaxel is contained within the albumin coating and a portion of the paclitaxel is associated with the free albumin.

Claim 76 (Previously presented): The pharmaceutical formulation of claim 66, wherein at least a portion of the albumin is crosslinked by disulfide bonds.

Claim 77 (Previously presented): The pharmaceutical formulation of claim 66, wherein the paclitaxel is substantially amorphous.

Claim 78 (Previously presented): The pharmaceutical formulation of claim 66, wherein the paclitaxel is substantially crystalline.

Claim 79 (Withdrawn): A method of treatment, comprising administering an effective amount of the composition of claim 66 to a patient to treat a tumor.

Claim 80 (Withdrawn): The method of claim 79, wherein the composition is administered parenterally, orally, intravenously, subcutaneously, intraperitoneally, intrathecally, intramuscularly, by inhalation, topically, transdermally, rectally, or vaginally.

Claim 81 (Withdrawn): The method of claim 80, wherein the composition is administered intravenously.

Claim 82 (Withdrawn): The method of claim 81, wherein the pharmaceutical formulation is infused, and the infusion volume is no greater than 200 ml.

Claim 83 (Withdrawn): A method of treatment, comprising administering an effective amount of the composition of claim 66 to a patient to treat breast cancer.

Claim 84 (Withdrawn): The method of claim 83, wherein the composition is administered parenterally, orally, intravenously, subcutaneously, intraperitoneally, intrathecally, intramuscularly, by inhalation, topically, transdermally, rectally, or vaginally.

Claim 85 (Previously presented): The pharmaceutical formulation of claim 66, wherein the average diameter of the nanoparticles is no greater than about 200 nm.

Claim 86 (Previously presented): The pharmaceutical formulation of claim 67, wherein the average diameter of the nanoparticles is no greater than about 200 nm.

Claim 87 (Previously presented): The pharmaceutical formulation of claim 68, wherein the average diameter of the nanoparticles is no greater than about 200 nm.

Claim 88 (Previously presented): The pharmaceutical formulation of claim 74, wherein the average diameter of the nanoparticles is no greater than about 200 nm.

Claim 89 (Previously presented): The pharmaceutical formulation of claim 77, wherein the average diameter of the nanoparticles is no greater than about 200 nm.

Claim 90 (Previously presented): The pharmaceutical formulation of claim 66, wherein the albumin is human albumin.

Claim 91 (Previously presented): The pharmaceutical formulation of claim 67, wherein the albumin is human albumin.

Claim 92 (Previously presented): The pharmaceutical formulation of claim 68, wherein the albumin is human albumin.

Claim 93 (Previously presented): The pharmaceutical formulation of claim 74, wherein the albumin is human albumin.

Claim 94 (Previously presented): The pharmaceutical formulation of claim 77, wherein the albumin is human albumin.

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