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 Sir:

INTRODUCTORY COMMENTS

This is in response to the non-final Office Action dated March 30, 2010 (Paper No. 20100324), for which a response is due on June 30, 2010. Filed herewith is a Petition and fee for a three months extension of time, thereby extending the deadline for response to September 30, 2010. 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.

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

Remarks/Arguments begin on page 5 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 (Previously presented): 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 paclitaxel and albumin.

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 70, 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 (Previously presented): The pharmaceutical formulation of claim 70, wherein the nanoparticles comprise paclitaxel and have an albumin coating.

Claim 74 (Previously presented): The pharmaceutical formulation of claim 70, wherein the nanoparticles have a core and the nanoparticle core is substantially free of polymeric material.

Claim 75 (Previously presented): The pharmaceutical formulation of claim 73, 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 70, wherein at least a portion of the albumin is crosslinked by disulfide bonds.

Claim 77 (Previously presented): The pharmaceutical formulation of claim 70, wherein the paclitaxel is substantially amorphous.

Claim 78 (Previously presented): The pharmaceutical formulation of claim 70, wherein the paclitaxel is substantially crystalline.

Claim 79 (Withdrawn): A method, comprising administering an effective amount of the composition of claim 70 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 70 to a patient to treat rheumatoid arthritis.

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.

REMARKS

Claims 66-68 and 70-84 were pending in the present application. Claims 79-84 are withdrawn. No amendment is made to the claims. Accordingly, claims 66-68 and 70-78 are currently under examination.

Withdrawn Rejections

Applicants acknowledge with appreciation that the rejection of claims 66-68 and 70-76 under 35 U.S.C. § 103(a) over Trissel (US Pat. No. 5,681,846) in view of Yen (U.S. Pat. No. 5,725,804) is withdrawn. Applicants acknowledge with appreciation that the rejection of claims 77-78 under 35 U.S.C. § 103(a) over Trissel and Yen, further in view of Ueda (U.S. Pat. No. 5,272,171) is withdrawn.

Applicants acknowledge with appreciation that the rejection of claims 66-68 and 70-78 on the ground of nonstatutory obviousness-type double patenting over claims 1-14, 17-19, and 34 of Pat. No. 6,096,331 in view of Trissel and further in view of Yen is withdrawn. Applicants further acknowledge with appreciation that the rejection of claims 77-78 on the ground of nonstatutory obviousness-type double patenting over claim 34 of U.S. Pat. No. 6,096,331 in view of Trissel further in view of Yen and Ueda is withdrawn.

Claim Rejections – 35 USC § 103

Desai in view of Shively

Claims 66-68 and 70-77 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Desai et al. ("Desai," U.S. Pat. No. 5,439,686) in view of Shively ("Shively," U.S. Pat. No. 5,407,683). Applicants respectfully traverse this rejection.

The Examiner states that Desai teaches 2 mg/ml paclitaxel and that "a higher loading of taxol can be achieved by utilizing an additional solvent…." While acknowledging that "Desai fails to directly teach that the concentration of taxol (paclitaxel) is 5 mg/ml," the Examiner relies on Shively as allegedly teaching that "[f]or therapeutic use, emulsion containing between about 0.5 and

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