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 AFTER FINAL ACTION UNDER 37 C.F.R. 1.114

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

Dear Sir:

INTRODUCTORY COMMENTS

This response accompanies a Request for Continued Examination. Amendments and remarks presented by this amendment are responsive to the Final Office Action dated December 29, 2010 (Paper No. 20101207), for which a response was due on March 29, 2011. On June 28, 2011, Applicants filed a Notice of Appeal along with a Petition and fee for a three months extension of time. The deadline for filing an appeal brief or a Request for Continued Examination was August 28, 2011. Filed herewith is a Petition and fee for a five months extension of time, thereby extending the deadline for response to January 28, 2012. 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 3 of this paper.

Remarks/Arguments begin on page 7 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 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 (Currently amended): The pharmaceutical formulation of claim [[70]] 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 (Currently amended): The pharmaceutical formulation of claim [[70]] 66, wherein the ~~nanoparticles have a core and the nanoparticle~~ solid core is substantially free of polymeric material.

Claim 75 (Currently amended): The pharmaceutical formulation of claim [[73]] 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 (Currently amended): The pharmaceutical formulation of claim [[70]] 66, wherein at least a portion of the albumin is crosslinked by disulfide bonds.

Claim 77 (Currently amended): The pharmaceutical formulation of claim [[70]] 66, wherein the paclitaxel is substantially amorphous.

Claim 78 (Currently amended): The pharmaceutical formulation of claim [[70]] 66, wherein the paclitaxel is substantially crystalline.

Claim 79 (Withdrawn, currently amended): A method of treatment, comprising administering an effective amount of the composition of claim [[70]] 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, currently amended): A method of treatment, comprising administering an effective amount of the composition of claim [[70]] 66 to a patient to treat ~~rheumatoid arthritis~~ 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 (New): The pharmaceutical formulation of claim 66, wherein the average diameter of the nanoparticles is no greater than about 200 nm.

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

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

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

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