Docket No.: 638772000301
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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

Application No.: 11/553,339 | Confirmation No.: 3605

Filed: October 26, 2006 | Art Unit: 1656

For: COMPOSITIONS AND METHODS OF DELIVERY OF PHARMACOLOGICAL AGENTS | Examiner: M. Tsay

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 April 28, 2009 (Paper No. 20090415), for which a response was due on July 28, 2009. Filed herewith is a Petition and fee for a three month(s) extension of time, thereby extending the deadline for response to October 28, 2009. 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:

Claim 1 (Cancelled)

Claim 2 (Currently amended): A pharmaceutical composition comprising a pharmaceutical agent and a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises albumin, wherein the albumin and the pharmaceutical agent in the composition are formulated as nanoparticles, and wherein the weight ratio of albumin to pharmaceutical agent in the composition is about 1:1 to about ~~5:1~~ 9:1.

Claim 3 (Previously presented): The pharmaceutical composition of claim 2, wherein the nanoparticles have a mean-diameter of less than about 200 nm.

Claim 4 (Previously presented): The pharmaceutical composition of claim 2, wherein the albumin is human serum albumin.

Claim 5 (Previously presented): The pharmaceutical composition of claim 2, wherein the pharmaceutical agent is selected from the group consisting of anticancer agents, anesthetics, antimicrotubule agents, agents to treat cardiovascular disorders, antihypertensives, anti-inflammatory agents, anti-arthritic agents, antiasthmatics, analgesics, vasoactive agents, immunosuppressive agents, antifungal agents, antiarrhythmic agents, antibiotics, and hormones.

Claim 6 (Previously presented): The pharmaceutical composition of claim 5, wherein the pharmaceutical agent is an anticancer agent.

Claim 7 (Withdrawn): The pharmaceutical composition of claim 5, wherein the pharmaceutical agent is an anti-inflammatory agent.

Claim 8 (Withdrawn): The pharmaceutical composition of claim 5, wherein the pharmaceutical agent is an immunosuppressive agent.

Claim 9 (Withdrawn): The pharmaceutical composition of claim 5, wherein the pharmaceutical agent is an antibiotic.

Claim 10 (Previously presented): The pharmaceutical composition of claim 2, wherein the pharmaceutical agent is selected from the group consisting of paclitaxel, docetaxel, taxanes, camptothecin, propofol, amiodarone, cyclosporine, rapamycin, amphotericin, liothyronine, epothilones, colchicines, thyroid hormones, vasoactive intestinal peptide, corticosteroids, melatonin, tacrolimus, mycophenolic acids.

Claim 11 (Previously presented): The pharmaceutical composition of claim 10, wherein the anticancer agent is a taxane.

Claim 12 (Previously presented): The pharmaceutical composition of claim 11, wherein the pharmaceutical agent is paclitaxel.

Claim 13 (Previously presented): The pharmaceutical composition of claim 12, wherein the pharmaceutical composition is free of Cremophor.

Claim 14 (Withdrawn): A method of treating a disease comprising administering an effective amount of a pharmaceutical composition of claim 2.

Claim 15 (Withdrawn): The method of claim 14, wherein the disease is cancer.

Claim 16 (Withdrawn): The method of claim 14, wherein the disease is arthritis.

Claim 17 (Withdrawn): The method of claim 14, wherein the disease is cardiovascular disease.

Claim 18 (Withdrawn): The method of claim 17, wherein the disease is restenosis.

Claim 19 (Withdrawn): The method of claim 14, wherein the composition is administered intravenously, intraarterially, intrapulmonary, orally, by inhalation, intravasicularly, intramuscularly, intra-tracheally, subcutaneously, intraocularly, intrathecally, or transdermally.

Claim 20 (Withdrawn): The method of claim 19, wherein the pharmaceutical composition is administered intravenously.

Claim 21 (Withdrawn): The method of claim 19, wherein the pharmaceutical composition is administered orally.

Claim 22 (Withdrawn and Currently Amended): A method of preparing a pharmaceutical composition of claim 2, comprising combining a pharmaceutical agent with a pharmaceutically acceptable carrier comprising albumin, wherein the weight ratio of albumin to the pharmaceutical agent in the composition is ~~about 5:1 or less~~ about 1:1 to about 9:1.

Claim 23 (Withdrawn): The method of claim 22, further comprising subjecting the combination of the pharmaceutical agent and the pharmaceutically acceptable carrier to high pressure homogenization.

Claim 24 (New): The pharmaceutical composition of claim 2, wherein the ratio (w/w) of albumin to the pharmaceutical agent in the pharmaceutical composition is about 1:1 to about 5:1.

Claim 25 (New): The pharmaceutical composition of claim 2, wherein the ratio (w/w) of albumin to the pharmaceutical agent in the pharmaceutical composition is 1:1 to 9:1.

REMARKS

Claims 2-23 are pending in the present application. Claims 7-9 and 14-23 are withdrawn from consideration. By this amendment, pending claims 2 and withdrawn claim 22 are amended. New claims 24 and 25 are added. Upon entry of this amendment, claims 2-6, 10-13, and 24-25 are under examination.

Support for the amendment of claim 2 and 22 can be found at page 14, line 21 (Paragraph [0041]) of the specification.

With respect to claim amendments and cancellation, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover have not acquiesced to any rejections and/or objections made by the Patent Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded subject matter or claim embodiments in one or more future continuation and/or divisional application(s).

Summary of interview

Applicants express their gratitude for the telephonic interview between Examiner Marsha M. Tsay and Applicants' representative Jian (Janet) Xiao on May 19, 2009. The time and consideration of the Examiner is greatly appreciated.

During the May 19, 2009 interview, the Examiner and Applicants' representatives briefly discussed the 35 U.S.C. § 103(a) rejection cited in the Office Action. Applicants inquired about the possibility of amending the independent claim to recite a ratio of "about 1:1 to about 9:1." The Examiner indicated that such amended claim will be examined.

Rejection under 35 U.S.C. § 103(a)

Claims 2-6 and 10-13 are rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Damascelli et al. ("Damascelli," 2001 Cancer 92(10): 2592-2602) in view of Ibrahim et al. ("Ibrahim," 2000 Proc Am Soc Clin Onco 19: abstract 609F). Applicants respectfully traverse this rejection. The response addresses claims as amended, and the arguments presented herein apply equally to the claims prior to the amendment.

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