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<b>Request for Continued Examination (RCE) Transmittal</b>  Address to: <b>Mail Stop RCE Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450</b>	Application Number	11/553,339
	Filing Date	October 26, 2006
	First Named Inventor	Neil P. DESAI
	Art Unit	1656
	Examiner Name	M. Tsay
	Attorney Docket Number	638772000301

**This is a Request for Continued Examination (RCE) under 37 CFR 1.114 of the above-identified application.**

Request for Continued Examination (RCE) practice under 37 CFR 1.114 does not apply to any utility or plant application filed prior to June 8, 1995, or to any design application. See Instruction Sheet for RCEs (not to be submitted to the USPTO) on page 2.

1.  **Submission required under 37 CFR 1.114** Note: If the RCE is proper, any previously filed unentered amendments and amendments enclosed with the RCE will be entered in the order in which they were filed unless applicant instructs otherwise. If applicant does not wish to have any previously filed unentered amendment(s) entered, applicant must request non-entry of such amendment(s).
- a.  Previously submitted. If a final Office action is outstanding, any amendments filed after the final Office action may be considered as a submission even if this box is not checked.
- i.  Consider the arguments in the Appeal Brief or Reply Brief previously filed on \_\_\_\_\_
- ii.  Other \_\_\_\_\_
- b.  Enclosed
- i.  Amendment/Reply (14 pages)      iii.  Information Disclosure Statement (IDS) (3 pages)
- ii.  Affidavit(s)/Declaration(s)      iv.  Declaration (61 pages), PTO/SB/08A/B (1 page), References (3)
2.  **Miscellaneous**
- a.  Suspension of action on the above-identified application is requested under 37 CFR 1.103(c) for a period of \_\_\_\_\_ months. (Period of suspension shall not exceed 3 months; Fee under 37 CFR 1.17(i) required)
- b.  Other \_\_\_\_\_
3.  **Fees** The RCE fee under 37 CFR 1.17(e) is required by 37 CFR 1.114 when the RCE is filed.
- a.  The Director is hereby authorized to charge the following fees, any underpayment of fees, or credit any Overpayments, to Deposit Account No. 03-1952.
- i.  RCE fee required under 37 CFR 1.17(e)
- ii.  Extension of time fee (37 CFR 1.136 and 1.17)
- iii.  Other \_\_\_\_\_
- b.  Check in the amount of \$ \_\_\_\_\_ enclosed
- c.  Payment by credit card (Form PTO-2038 enclosed)

**WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.****SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED**

Signature	/Jian Xiao/	Date	April 14, 2010
Name (Print/Type)	Jian Xiao	Registration No.	55,748

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

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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

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Examiner: M. Tsay

**AMENDMENT AFTER FINAL ACTION UNDER 37 C.F.R. 1.116**

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 31, 2009 (Paper No. 20091228), for which a response is due on March 31, 2010. A Petition and fee for a one month extension of time was filed on April 12, 2010, thereby extending the deadline for filing the response to April 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 4 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 for injection comprising paclitaxel ~~a pharmaceutical agent~~ and a pharmaceutically acceptable carrier, wherein the pharmaceutically acceptable carrier comprises albumin, wherein the albumin and the ~~pharmaceutical agent~~ paclitaxel in the composition are formulated as nanoparticles, wherein the nanoparticles have a particle size of less than about 200 nm, and wherein the weight ratio of albumin to ~~pharmaceutical agent~~ paclitaxel in the composition is about 1:1 to about 9:1.

Claim 3 (cancelled).

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

Claims 5-12 (cancelled).

Claim 13 (currently amended): The pharmaceutical composition of claim ~~[[12]]~~ 2, 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, intravascularly, intramuscularly, intra-tracheally, subcutaneously, intraocularly, intrathecally, or transdermally.

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

Claims 21-23 (cancelled).

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

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

Claim 26 (new): The pharmaceutical composition of claim 2, wherein the ratio (w/w) of albumin to the paclitaxel in the pharmaceutical composition is about 9:1.

**REMARKS**

Claims 2-25 were pending in the present application. Claims 7-9 and 14-23 were withdrawn from consideration. By virtue of this response, claims 3, 5-12, and 21-23 have been cancelled, claims 2, 13, 24, and 25 have been amended, and new claim 26 has been added. Accordingly, claims 2, 4, 13, and 24-26 are currently under consideration.

Support for the amendment of claim 2 can be found at paragraphs [0016]-[0017], [0028], and [0033] of the specification, as well as previously pending claim 12 of the specification. Support for new claim 26 can be found at paragraph [0041] of the specification. Claims 13, 24, and 25 are amended to correct claim dependencies and/or antecedent bases. No new matter is added.

With respect to the cancellation and amendment of claims, Applicants have not dedicated or abandoned any unclaimed subject matter and moreover, have not acquiesced to any rejections and/or objections made by the Office. Applicants expressly reserve the right to pursue prosecution of any presently excluded claim embodiments in future continuation, continuation-in-part, and/or divisional applications.

***Interview Summary***

Applicants thank Examiners Marsha Tsay and Maryam Monshipouri for the courtesy in conducting the in-person interview with inventor Dr. Neil Desai and Applicants' representatives Catherine Polizzi and Jian Xiao on January 14, 2010. The guidance provided by the Examiners during the interview is greatly appreciated.

During the interview, Dr. Desai discussed the invention. The Examiners suggested that previously pending claims be amended to a narrower scope. The present claim amendment has narrowed the scope of the claims as the Examiner has suggested.

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