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# **REQUEST FOR CONTINUED EXAMINATION** (RCE) **TRANSMITTAL**

Subsection (b) of 35 U.S.C. § 132, effective on May 29, 2000, provides for continued examination of an utility or plant application filed on or after June 8, 1995. See The American Inventors Protection Act of 1999 (AIPA).

to respond to a collection or information unless it displays a valid OMB control number.				
Application Number	13/034,340			
Filing Date	February 24, 2011			
First Named Inventor	Alan H. Auerbach			
Group Art Unit	1628			
Examiner Name	San Ming R. Hui			
Attorney Docket Number	CGR5001USCNT1			

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application.  NOTE: 37 C.F.R. § 1.114 is effective on May 29, 2000. If the above-identified application was filed prior to May 29, 2000, applicant may wish to consider filing a continued prosecution application (CPA) under 37 C.F.R. § 1.53 (d) (PTO/SB/29) instead of a RCE to be eligible for the patent term adjustment provisions of the AIPA. See Changes to Application Examination and Provisional Application Practice, Final Rule, 65 Fed. Reg. 14865 (Mar. 20, 2000), 1233 Off. Gaz. Pat. Office 47 (Apr. 11, 2000), which established RCE practice.				
1. Submission required under 37 C.F.R. § 1.114				
a. Previously submitted				
i. Consider the amendment(s)/reply under 37 C.F.R. § 1.116 previously filed on				
(any unentered amendment(s) referred to above will be entered).				
ii. Consider the arguments in the Appeal Brief or Reply Brief previously filed on				
iii. ☐ Other				
b. Denclosed				
i. 🛛 Amendment/Reply				
ii. Affidavit(s)/Declaration(s)				
iii. 🔲 Information Disclosure Statement (IDS)				
iv. Other				
2. Miscellaneous				
a. Suspension of action on the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of				
months. (Period of suspension shall not exceed 3 months; Fee under 37 C.F.R. § 1.17(i) required.)				
b. Other				
3. Fees - The RCE fee under 37 C.F.R. § 1.17(e) is required by 37 C.F.R. § 1.114 when the RCE is filed				
a. The Director is hereby authorized to charge the following fees, or credit any overpayments,				
to Deposit Account No. <b>10-0750</b> .				
i. ⊠ RCE fee is required under 37 C.F.R. § 1.17(e) ii. □ Extension of Time (37 C.F.R. §§ 1.136 and 1.17)				
iii.				
b. Check in the amount of \$ enclosed				
c. Payment by credit card (Form PTO-2038 enclosed)				

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT REQUIRED						
Name (print/type)	Andrea Jo Kamage	Registration No.	43,703			
Signature	/Andrea Jo Kamage/	Date	January 11, 2013			
CERTIFICATE OF TRANSMISSION						
I hereby certify that this correspondence is being electronically filed via EFS-Web to the Commissioner for Patents with the U.S. Patent and Trademark Office on: January 11, 2013						
Name (print/type)	Laurie A. Phillips					
Signature	/Laurie A. Phillips/	Date	January 11, 2013			



I hereby certify that this correspondence is being transmitted via The Office Electronic Filing System (EFS) in accordance with 37 CFR 1.6(a)(4).

Date of Electronic (EFS) Transmission: <u>January 11, 2013</u>

Signature: /Laurie A. Phillips/ Name: Laurie A. Phillips

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

### In re Application of:

Applicant(s):	Alan H. Auerbach	Conf. No.:	1597		
Application No.:	13/034,340	Group Art:	1628		
Filing Date:	February 24, 2011	Examiner:	San Ming R. Hui		
Title:	Methods and Compositions for Treating Cancer				

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

#### **RESPONSE**

Dear Sir:

In response to the final Office Action mailed September 11, 2012, Applicants submit the following amendments and remarks.

A list of 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.



**Listing of Claims:** 

1-36. (Canceled).

37. (Previously presented) A method for the treatment of a prostate cancer in a human

comprising administering to said human a therapeutically effective amount of abiraterone

acetate or a pharmaceutically acceptable salt thereof and a therapeutically effective

amount of prednisone.

38. (Previously presented) The method of claim 37, wherein the therapeutically effective

amount of the abiraterone acetate or pharmaceutically acceptable salt thereof is from

about 50 mg/day to about 2000 mg/day.

39. (Previously presented) The method of claim 38, wherein the therapeutically effective

amount of the abiraterone acetate or pharmaceutically acceptable salt thereof is from

about 500 mg/day to about 1500 mg/day.

40. (Previously presented) The method of claim 39, wherein the therapeutically effective

amount of the abiraterone acetate or pharmaceutically acceptable salt thereof is about

1000 mg/day.

41. (Previously presented) The method of claim 37, wherein the therapeutically effective

amount of the abiraterone acetate or a pharmaceutically acceptable salt thereof is

administered in at least one dosage form comprising about 250 mg of abiraterone acetate

or a pharmaceutically acceptable salt thereof.

42. (Previously presented) The method of claim 37, wherein the therapeutically effective

amount of the prednisone is from about 0.01 mg/day to about 500 mg/day.

43. (Previously presented) The method of claim 42, wherein the therapeutically effective

amount of the prednisone is from about 10 mg/day to about 250 mg/day.

44. (Previously presented) The method of claim 44, wherein the therapeutically effective

amount of the prednisone is about 10 mg/day.

45. (Previously presented) The method of claim 37, wherein the therapeutically effective

amount of the prednisone is administered in at least one dosage form comprising about 5

mg of prednisone.

46. (Previously presented) The method of claim 37, comprising administering to said

human about 500 mg/day to about 1500 mg/day of abiraterone acetate or a

pharmaceutically acceptable salt thereof and about 0.01 mg/day to about 500 mg/day of

prednisone.



47. (Previously presented) The method of claim 46, comprising administering to said

human about 1000 mg/day of abiraterone acetate or a pharmaceutically acceptable salt

thereof and about 10 mg/day of prednisone.

48. (Previously presented) The method of claim 37, wherein said prostate cancer is

refractory prostate cancer.

49. (Previously presented) The method of claim 48, wherein the refractory prostate

cancer is not responding to at least one anti-cancer agent.

50. (Previously presented) The method of claim 49, wherein the at least one anti-cancer

agent comprises a hormonal ablation agent, an anti-androgen agent, or an anti-neoplastic

agent.

51. (Previously presented) The method of claim 50, wherein the hormonal ablation agent

comprises deslorelin, leuprolide, goserelin, or triptorelin.

52. (Previously presented) The method of claim 50, wherein the anti-androgen agent

comprises bicalutamide, flutamide, or nilutamide.

53. (Previously presented) The method of claim 50, wherein the anti-neoplastic agent

comprises docetaxel.



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