

**CERTIFICATION AND PETITION TO MAKE SPECIAL UNDER THE
CANCER MOONSHOT EXPEDITED EXAMINATION PILOT PROGRAM**

First Named
Inventor:

Nonprovisional Application
Number (if known):

Title of
Invention:

APPLICANT HEREBY CERTIFIES THE FOLLOWING AND PETITIONS TO PARTICIPATE IN THE CANCER MOONSHOT EXPEDITED EXAMINATION PILOT PROGRAM (“PROGRAM”) FOR THE ABOVE-IDENTIFIED APPLICATION.

(The **fee** for a petition to make special under 37 CFR 1.102(d) **has been waived** for this program. For information regarding the requirements, conditions, and guidelines of the program, see the 2022 Federal Register notice titled “Cancer Moonshot Expedited Examination Pilot Program” available on the United States Patent and Trademark Office (USPTO) website at <https://www.uspto.gov/patents/laws/patent-related-notices/patent-related-notices-2022>).

1. The above-identified application (the application) is a non-reissue (original), nonprovisional utility application filed under 35 U.S.C. 111(a), or an international application that has entered the national stage under 35 U.S.C. 371.
2. Special status under this program is being sought because the application is limited to the field of oncology or smoking cessation and contains at least one of the following method claims that meet the eligibility requirements of the program (“eligible method claims”):
 - a. A method of treating or reducing the incidence of a cancer using an immunotherapeutic compound or composition (cancer immunotherapy method).

Note: If this box is checked, please complete the following statement:
The applicant has a good faith belief that the following page(s) of the specification contain(s) evidence that the compound or composition used in the method claim to treat or reduce the incidence of a cancer is immunotherapeutic: _____.
 - b. A method of treating a cancer by targeting specific genetic markers or mutations using a specific pharmaceutical composition.

Note: If this box is checked, please complete the following statement:
The applicant has a good faith belief that the following page(s) of the specification contain(s) evidence that the pharmaceutical composition used in the method claim targets the specific genetic markers or mutations to treat the cancer: _____.
 - c. A method of treating a rare or childhood cancer using a specific pharmaceutical composition.
 - d. A method of detecting or treating a cancer using a medical device specifically adapted to detect or treat the cancer.
*The **only use disclosed in the specification** for the medical device is to treat or detect the cancer.*
 - e. A method of treating a cancer by administering a specific pharmaceutical composition wherein the method comprises a step to diagnose the cancer.
 - f. A method of treating a nicotine dependency and promoting smoking cessation by administering a specific pharmaceutical composition.
3. If the application contains eligible product or apparatus claims (that is, claims to the immunotherapeutic compound or composition, the pharmaceutical composition, or the medical device used in eligible method claims), the eligible method claims depend from or are commensurate in scope with the eligible product or apparatus claims (that is, the eligible method claims contain all of the limitations of the eligible product or apparatus claims).
4. The application is being or was filed electronically using Patent Center (at <https://patentcenter.uspto.gov>).

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First Named Inventor:		Nonprovisional Application Number (if known):	
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<p>5. The specification, claim(s), and abstract of the application are being or were submitted in DOCX format at the time of filing or national stage entry.</p> <p>6. The application contains no more than three (3) independent claims and no more than twenty (20) total claims ("the program claim limits") and does not contain any multiple dependent claims.</p> <p>7. This form is being filed electronically using Patent Center prior to the application receiving a first Office action (including an Office action containing only a restriction requirement).</p> <p>8. Any previous nonpublication request for the application has been rescinded on or before the filing date of this form. Form PTO/SB/36 may be used to rescind a nonpublication request.</p> <p>9. The application was not previously granted special status under any program.</p> <p>10. By filing this form, applicant agrees to the following if the application is granted special status under the program:</p> <p>a. If a requirement for restriction or unity of invention is made, applicant will make an election without traverse to an invention that meets the eligibility requirements of this program.</p> <p>b. Throughout the pendency of the application: (i) If applicant elects a product or an apparatus for examination, applicant will present eligible method claims that are commensurate in scope with or depend from the claims to the elected product or apparatus; (ii) applicant will not exceed the program claim limits or add any multiple dependent claims; and (iii) applicant will not cancel all claims to the elected invention or all method claims that meet the eligibility requirements of this program.</p> <p>11. The inventor or any joint inventor has not been named as the inventor or a joint inventor on more than nine other nonprovisional applications in which a petition to make special under this program has been filed.</p>			
Signature		Date	
Name (Printed/Typed)		Practitioner Registration Number	
<p>Note: This form must be signed in accordance with 37 CFR 1.33. See 37 CFR 1.4(d) for signature requirements and certifications. Submit multiple forms if more than one signature is required.*</p>			
<p><input type="checkbox"/> *Total of _____ forms are submitted.</p>			

Privacy Act Statement

The Privacy Act of 1974 (P.L. 93-579) requires that you be given certain information in connection with your submission of the attached form related to a patent application or patent. The United States Patent and Trademark Office (USPTO) collects the information in this record under authority of 35 U.S.C. 2. The USPTO's system of records is used to manage all applicant and owner information including name, citizenship, residence, post office address, and other information with respect to inventors and their legal representatives pertaining to the applicant's/owner's activities in connection with the invention for which a patent is sought or has been granted. The applicable Privacy Act System of Records Notice for the information collected in this form is COMMERCE/PAT-TM-7 Patent Application Files, available in the Federal Register at 78 FR 19243 (March 29, 2013), <https://www.govinfo.gov/content/pkg/FR-2013-03-29/pdf/2013-07341.pdf>.

Routine uses of the information in this record may include disclosure to: 1) law enforcement, in the event that the system of records indicates a violation or potential violation of law; 2) a federal, state, local, or international agency, in response to its request; 3) a contractor of the USPTO having need for the information in order to perform a contract; 4) the Department of Justice for determination of whether the Freedom of Information Act (FOIA) requires disclosure of the record; 5) a Member of Congress submitting a request involving an individual to whom the record pertains, when the individual has requested the Member's assistance with respect to the subject matter of the record; 6) a court, magistrate, or administrative tribunal, in the course of presenting evidence, including disclosures to opposing counsel in the course of settlement negotiations; 7) the Administrator, General Services Administration (GSA), or their designee, during an inspection of records conducted by GSA under authority of 44 U.S.C. 2904 and 2906, in accordance with the GSA regulations and any other relevant (i.e., GSA or Commerce) directive, where such disclosure shall not be used to make determinations about individuals; 8) another federal agency for purposes of National Security review (35 U.S.C. 181) and for review pursuant to the Atomic Energy Act (42 U.S.C. 218(c)); 9) the Office of Personnel Management (OPM) for personnel research purposes; and 10) the Office of Management and Budget (OMB) for legislative coordination and clearance.

If you do not furnish the information requested on this form, the USPTO may not be able to process and/or examine your submission, which may result in termination of proceedings, abandonment of the application, and/or expiration of the patent.