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Cancer Moonshot Expedited Examination Pilot Program

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Cancer Moonshot Expedited Examination Pilot Program

- In February 2022, the White House renewed the national Cancer Moonshot initiative that aims to reduce the cancer mortality rate by at least 50% within 25 years and improve the experiences of people living with and surviving cancer.
- To support the renewed initiative, the USPTO launched the Cancer Moonshot Expedited Examination Pilot Program on February 1, 2023.
  - See Federal Register notice published on December 9, 2022 (87 FR 75608).

Cancer Moonshot Expedited Examination Pilot Program

- The new pilot program is an expansion of and replaces the Cancer Immunotherapy Pilot Program, which expedited examination for eligible patent applications pertaining to methods of treating a cancer using immunotherapy.
- The new pilot program broadens the scope of technologies eligible for fast-track review.
- The USPTO will accept up to 1,000 qualifying applications until January 31, 2025, subject to its discretion to terminate sooner.
- The total number of petitions filed and the number of applications accepted into the pilot program are tracked on the pilot program webpage at www.uspto.gov/patents/initiatives/patent-application-initiatives/cancer-moonshot-expedited-examination

Special status until first office action

- Qualifying applications accepted into the pilot program will be advanced out of turn for examination until a first office action.
  - Petition grant
  - "Special New" docket= 28 days or less, typically
- The application is afforded special status without applicant incurring the petition to make special fee, or satisfying the requirements of the accelerated examination program.

Overview of requirements to participate

- Incentivizing new innovations in a desired space
  - Inventions must be specific cancer-related technologies that support the renewed national Cancer Moonshot initiative.
  - The application must be subject to 18-month publication.
- Promoting efficiency
  - Conditions on the number and the format of claims
  - Required use of USPTO petition form
  - Electronic filing requirements for petition and application
- Promoting diversity of applicants and inventors
  - Petition filing limitations

Eligible applications

- This pilot program is open to:
  - Non-reissue (original), nonprovisional utility applications filed under 35 U.S.C. 111(a), or international applications that have entered the national stage under 35 U.S.C. 371.
    - Limited to the field of oncology or smoking cessation
    - Must not be previously granted special status under any program

Nonpublication request impermissible

- Applicant may not opt out of 18 month publication.
  - If applicant files the petition (form PTO/SB/465) on the date of filing of an application, the application may not be filed with a nonpublication request.
  - If applicant previously filed a nonpublication request, applicant must rescind the nonpublication request no later than the time that the petition is filed.
- Form PTO/SB/36 may be used to rescind a prior nonpublication request.

Overview of claim eligibility requirements

- The application must contain at least one method claim that meets the eligibility requirements of the pilot program ("eligible method claim").
- Details of the eligibility requirements are in Section V of the Federal Register notice announcing the pilot 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)

- The petition under the program must include a statement that the applicant has a good faith belief that the specification contains evidence that the compound or composition used in the method claim to treat or reduce the incidence of a cancer is immunotherapeutic. The statement must also identify the specific page(s) of the specification containing the evidence.

B. A method of treating a cancer by targeting specific genetic markers or mutations using a specific pharmaceutical composition

- The petition under the program must include a statement that the applicant has a good faith belief that the specification contains evidence that the pharmaceutical composition used in the method claim targets the specific genetic markers or mutations to treat the cancer. The statement must also identify the specific page(s) of the specification containing the evidence.

Eligible method claims (cont.)

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.
- Applications are not eligible for the pilot program if they disclose any use for the medical device claimed or used in the method that is not related to the treatment or detection of a cancer.

Eligible method claims (cont.)

E. A method of treating a cancer by administering a specific pharmaceutical composition wherein the method comprises a step to diagnose the cancer

- The method claim **must** have a specific step to diagnose the cancer such as steps in a specific diagnostic method.
- It is insufficient for the method claim to either nominally recite a step to diagnose the cancer (for example, "diagnosing the individual with cancer") or to have a single step of "administering a pharmaceutical composition X to an individual diagnosed with cancer."

F. A method of treating a nicotine dependency and promoting smoking cessation by administering a specific pharmaceutical composition

Eligible product and apparatus claims

- Eligible product or apparatus claims are claims to:
  - the immunotherapeutic compound or composition used in an eligible method claim;
  - the pharmaceutical composition used in an eligible method claim; or
  - the medical device used in an eligible method claim.

Eligible product and apparatus claims (cont.)

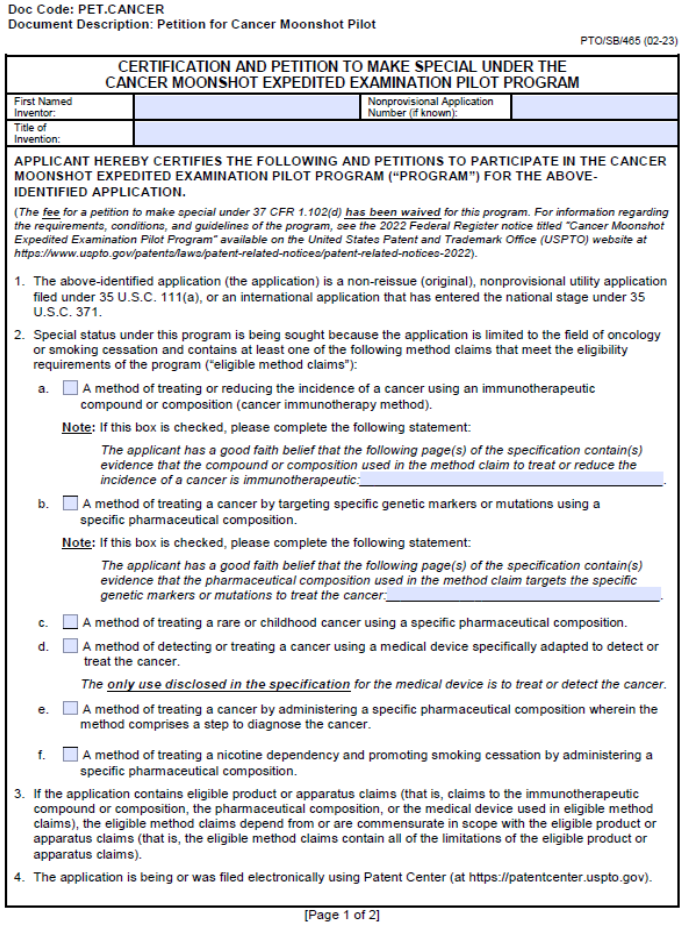
- The applicant may claim an eligible product or apparatus in the application only if:
  - Claims to eligible methods using the product or apparatus are presented in the same application, and
  - These method claims depend from or are commensurate in scope with the eligible product or apparatus claims (that is, the eligible method claims must contain all of the limitations of the eligible product or apparatus claims).
- Eligible method claims are required in the application because the eligible product or apparatus claimed may have an additional use not related to the treatment of cancer.
- Requiring the method claims to be commensurate in scope with the claims to the product or apparatus facilitates rejoinder of the method claims if the claims are subject to a restriction requirement and the claims to the product or apparatus are elected.

Claim requirements for grantable petition and for remaining pendency of applications granted special status

- The application must contain three or fewer independent claims and twenty or fewer total claims.
- The application must not contain any multiple dependent claim.
- The application must contain at least one eligible method claim.
- If the application contains eligible product or apparatus claims, the eligible method claims must depend from or are commensurate in scope with the eligible product or apparatus claims.

Petition to make special

- Applicant must file a grantable petition to make special to participate in the pilot program.
- Petition form PTO/SB/465
  - is required to be used to request participation in the pilot program.
  - contains the required certifications and statements.
  - must be filed electronically using Patent Center.
  - must be filed prior to a first office action (which may be an office action containing only a restriction requirement).
  - may not be filed in any application in which a request for continued examination under 37 CFR 1.114 has been filed.



Doc Code: PET.CANCER
Document Description: Petition for Cancer Moonshot Pilot

PTO/SB/465 (02-23)

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).

[Page 1 of 2]

Electronic filing requirements for application

- Application or national stage entry must be filed electronically using Patent Center.
- Specification, claims, and abstract must be submitted in DOCX format at the time of filing or national stage entry.

Petition filing limitations

- Applicant may not file a petition to participate in the pilot program if the inventor or any joint inventor of the application has been named as an inventor or a joint inventor on more than nine other nonprovisional applications in which a petition to make special under this pilot program has been filed.
  - In other words, the inventor or a joint inventor is limited to no more than 10 nonprovisional applications in which a petition to make special under the pilot program was filed.
- Petition filing limitations prevents overuse by bulk filers and promotes diversity of applicants and inventors.
- Petitions filed under the Cancer Immunotherapy Pilot Program do not count toward the filing limits in this pilot program.

Petition decision dismissal

- A petition decision dismissing the petition to make special will indicate whether a deficiency can be corrected.
- Some defects allow for correction but others are fatal.

Deficiencies identified as correctable in petition decision

- Applicant **will be given one opportunity** in the petition decision to correct the following deficiencies:
  - Petition form PTO/SB/465 was not used.
  - The petition was not filed electronically using Patent Center.
  - The petition was not properly signed.
  - The application contains or has been amended to contain more than three independent claims, more than twenty total claims, and/or one or more multiple dependent claims.
  - The application contains eligible product or apparatus claims but the eligible method claims do not depend from or are not commensurate in scope with the eligible product or apparatus claims.
  - The application does not comply with the sequence requirements as set forth in 37 CFR 1.821-1.825 or 37 CFR 1.831-1.835, as applicable, such that the application is not in condition for examination.
  - The application contains a nonpublication request that has not been rescinded.

Deficiencies identified as non-correctable in petition decision

- Applicant **will not be given any opportunity** in the petition decision to correct the following deficiencies:
  - The petition was not filed prior to the first office action (including an office action containing only a restriction requirement).
  - The application or national stage entry was not filed electronically using Patent Center.
  - The specification, claim(s), and abstract of the application at the time of filing or national stage entry were not submitted in DOCX format.
  - The application is not an original (non-reissue), 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.
  - The application was previously granted special status.
  - The application pertains to a medical device adapted to detect or treat a cancer and discloses a use for the medical device that is not related to the treatment or detection of a cancer.
  - The application does not contain at least one method claim that complies with the eligibility requirements of the pilot program.

Prosecution of applications accepted into pilot program – Restriction requirement

Requirement for restriction or unity of invention:

- If multiple inventions are found in the application, the examiner may make a requirement for restriction or unity of invention.
  - Applicants must make an election without traverse to an invention that meets the eligibility requirements of the pilot program.

Prosecution of applications accepted into pilot program — Rejoinder

When rejoinder should be considered:

- Where applicant elects claims directed to an eligible product or apparatus, and all product or apparatus claims are subsequently found allowable:
  - Withdrawn eligible method claims that include all the limitations of the allowable product or apparatus claims will be considered for rejoinder in accordance with sections 806.05 et seq. and 821.04 et seq. of the Manual of Patent Examining Procedure (MPEP).
- **In the event of rejoinder, the requirement for restriction** between the product or apparatus claims and the rejoined method claims **will be withdrawn by the examiner**, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104.

Prosecution of applications accepted into pilot program — Amendments

Amendments:

- Any amendment to a non-final office action will be considered non-responsive if it attempts to:
  - Add claims which would result in more than three independent claims or more than 20 total claims.
  - Add any multiple dependent claim.
  - Cancel all claims to the elected invention.
  - Cancel all eligible method claims.
  - Present eligible method claims that are not commensurate in scope with elected claims to an eligible product or apparatus.

Questions?

- For questions about Patent Center, please contact the Patent Electronic Business Center at ebc@uspto.gov or 866-217-9197.
- For questions regarding a Cancer Moonshot Expedited Examination Pilot Program petition, please contact:
  - Gary B. Nickol, Supervisory Patent Examiner, Technology Center 1600, at 571-272-0835 or gary.nickol@uspto.gov; or
  - Brandon J. Fetterolf, Supervisory Patent Examiner, Technology Center 1600, at 571-272-2919 or brandon.fetterolf@uspto.gov
- For questions regarding the Cancer Moonshot Expedited Examination Pilot Program Federal Register Notice, please contact the Office of Patent Legal Administration at 571-272-7704 or email PatentPractice@uspto.gov.

Thank you!

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