Doc Code: PET.IMMUNO
Document Description: Petition for Cancer Immunotherapy Pilot

PTO/SB/443 (06-16)

CERTIFICATION AND PETITION TO MAKE SPECIAL UNDER THE CANCER IMMUNOTHERAPY PILOT PROGRAM

Application Number (if known):	Filing Date:
First Named Inventor:	Practitioner Docket Number:
Title:	

PATENT APPLICANT HEREBY CERTIFIES THE FOLLOWING AND PETITIONS TO PARTICIPATE IN THE CANCER IMMUNOTHERAPY PILOT PROGRAM ("PILOT PROGRAM") FOR THE ABOVE-IDENTIFIED PATENT APPLICATION. See Instructions starting on page 3.

1. This certification and petition is being electronically filed using the USPTO electronic filing system (EFS-Web).

2. This patent application is a non-reissue, non-provisional 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.

3. Special status under this Pilot Program is sought because this patent application contains a claim to a method of treating a cancer using immunotherapy that meets the eligibility requirements for the Pilot Program that were set forth in the Federal Register notice entitled "Cancer Immunotherapy Pilot Program."

4. Certification that patent applicant or patent applicant's agent has an active Investigational New Drug (IND) application at the U.S. Food and Drug Administration (FDA), currently in Phase II or Phase III of development

(Note: this certification is **only** required if this patent application has received a first Office action or the request for continued examination (RCE) was not filed with this petition):

☐ By checking this box, patent applicant hereby certifies that the claimed method of treating a cancer using immunotherapy (i) meets the eligibility requirements for this Pilot Program, and (ii) is the subject of an active IND application at the FDA filed by patent applicant or their agent (e.g., patent applicant's assignee or licensee) that has entered phase II or phase III clinical trials.

5. Claim Limit and No Multiple Dependent Claims:

a. This patent application contains, or is amended to contain, at least one claim but no more than three (3) independent claims and twenty (20) total claims.

b. This patent application does not contain any multiple dependent claims.

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(continued)

Application Number (if known):	Filing Date:

6. Special status under any program has not been previously granted in this patent application.

7. Any previous nonpublication request for this patent application has been rescinded on or before the filing date of this form.

8. Publication status (check either box a or b below, but **not** both):

☐ a. This patent application is published.

☐ b. This patent application is unpublished. By checking this box, **patent applicant hereby requests early publication** under 37 CFR 1.219.

9. By filing this form, patent applicant agrees to make an election without traverse in a telephonic interview and elect an invention that is directed to a method of treating a cancer using immunotherapy that meets the eligibility requirements for this Pilot Program if the Office determines that the claims are directed to multiple inventions.

10. By filing this form, patent applicant agrees to comply with the following requirements while this patent application is in special status under this Pilot Program:

(a) the patent application will not contain more than three (3) independent claims, more than twenty (20) total claims, or any multiple dependent claims; and

(b) the patent application will contain at least one claim to a method of treating a cancer using immunotherapy that meets the eligibility requirements for this Pilot Program.

NOTE: *This form must be signed in accordance with 37 CFR 1.33. Please see 37 CFR 1.4(d) for the signature requirements. Submit multiple forms if more than one signature is required - see below.**

Signature	Date
Name (Print/Typed)	Registration Number

*Total of ___ forms are submitted.

Instructions for Certification and Petition to Make Special Under the Cancer Immunotherapy Pilot Program

(Not to be Submitted to the USPTO)

The following is a summary of the petition requirements for the Cancer Immunotherapy Pilot Program (for more information regarding these requirements and the Pilot Program guidelines, see the Federal Register Notice entitled "Cancer Immunotherapy Pilot Program" available on the USPTO web site at *http://www.uspto.gov/patent/laws-and-regulations/patent-related-notices/patent-related-notices-2016* ***):***

1. The petition to make special must be filed electronically using the USPTO electronic filing system, EFS-Web, and selecting the document description of "Petition for Cancer Immunotherapy Pilot" on the EFS-Web screen. Patent applicant should use form PTO/SB/443, which will be available as a Portable Document Format (PDF) fillable form in EFS-Web and on the USPTO Web site.

2. The patent application must be a non-reissue, non-provisional 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.

3. The petition to make special must include a statement that special status under the Pilot Program is sought because the patent application contains a claim to a method of treating a cancer using immunotherapy that meets the eligibility requirements for this Pilot Program that were set forth in the Federal Register notice entitled "Cancer Immunotherapy Pilot Program."

4. In general, the petition to make special must be filed (i) at least one day prior to the date that notice of a first Office action (which may be an Office action containing only a restriction requirement) appears in the Patent Application Information Retrieval (PAIR) system (patent applicant may check the status of the application using PAIR), or (ii) with a proper request for continued examination (RCE) in compliance with 37 CFR 1.114.

For patent applicants whose claimed cancer immunotherapy both (i) meets the eligibility requirements for this Pilot Program, and (ii) is the subject of an active Investigational New Drug (IND) application at the U.S. Food and Drug Administration (FDA) that has entered phase II or phrase III clinical trials, the petition may be filed any time prior to an appeal or a final rejection if patent applicant certifies both (i) and (ii) in the petition (i.e., the box for item 4 on this form **is selected**).

Therefore, the petition is **only** required to contain the above patent applicant certification if the patent application has received a first Office action or the request for continued examination (RCE) was not filed with this petition. By default, for patent applications that have been previously examined, if patent applicant makes the above certification in the petition, the above certification would necessarily apply to at least one of the examined claims since patent applicants are not permitted to switch inventions in order to participate in the Pilot Program. See section 821.03 of the Manual of Patent Examining Procedure (9th ed., Rev. 7, November 2015).

Instructions for Certification and Petition to Make Special Under the Cancer Immunotherapy Pilot Program

(continued)

(Not to be Submitted to the USPTO)

5. The patent application must not contain more than three (3) independent claims, more than twenty (20), or any multiple dependent claims. For a patent application that contains more than three independent claims or twenty total claims, or any multiple dependent claim, patent applicant must file a preliminary amendment in compliance with 37 CFR 1.121 to cancel the excess claims and/or the multiple dependent claims at the time the petition to make special is filed.

6. A petition to make special under the Cancer Immunotherapy Pilot Program may not be filed in a patent application in which special status was previously granted under this Pilot Program or in any other program (e.g., age, health, PPH, AE, prioritized examination).

7. If patent applicant previously filed a nonpublication request in the patent application, patent applicant must file a rescission of a nonpublication request on or before the date the petition to make special is filed. Patent applicant may use form PTO/SB/36 to rescind the nonpublication request.

8. For unpublished patent applications, the petition to make special must be accompanied by a request for early publication in compliance with 37 CFR 1.219 (i.e., the box for b in item 8 on this form **is selected**).

9. The petition must state that patent applicant agrees to make an election without traverse in a telephonic interview and elect an invention that is directed to a method of treating a cancer using immunotherapy that meets the eligibility requirements for this Pilot Program if the Office determines that the claims are directed to multiple inventions.

10. The petition must state that patent applicant agrees to comply with the following requirements while the patent application is in special status under this Pilot Program:

(a) the patent application will not contain more than three (3) independent claims, more than twenty (20) total claims, or any multiple dependent claims; and

(b) the patent application will contain at least one claim to a method of treating a cancer using immunotherapy that meets the eligibility requirements for this Pilot Program.

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. Accordingly, pursuant to the requirements of the Act, please be advised that: (1) the general authority for the collection of this information is 35 U.S.C. 2(b)(2); (2) furnishing of the information solicited is voluntary; and (3) the principal purpose for which the information is used by the U.S. Patent and Trademark Office is to process and/or examine your submission related to a patent application or patent. If you do not furnish the requested information, the U.S. Patent and Trademark Office may not be able to process and/or examine your submission, which may result in termination of proceedings or abandonment of the application or expiration of the patent.

The information provided by you in this form will be subject to the following routine uses:

1. The information on this form will be treated confidentially to the extent allowed under the Freedom of Information Act (5 U.S.C. 552) and the Privacy Act (5 U.S.C 552a). Records from this system of records may be disclosed to the Department of Justice to determine whether disclosure of these records is required by the Freedom of Information Act.
2. A record from this system of records may be disclosed, as a routine use, in the course of presenting evidence to a court, magistrate, or administrative tribunal, including disclosures to opposing counsel in the course of settlement negotiations.
3. A record in this system of records may be disclosed, as a routine use, to a Member of Congress submitting a request involving an individual, to whom the record pertains, when the individual has requested assistance from the Member with respect to the subject matter of the record.
4. A record in this system of records may be disclosed, as a routine use, to a contractor of the Agency having need for the information in order to perform a contract. Recipients of information shall be required to comply with the requirements of the Privacy Act of 1974, as amended, pursuant to 5 U.S.C. 552a(m).
5. A record related to an International Application filed under the Patent Cooperation Treaty in this system of records may be disclosed, as a routine use, to the International Bureau of the World Intellectual Property Organization, pursuant to the Patent Cooperation Treaty.
6. A record in this system of records may be disclosed, as a routine use, to 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)).
7. A record from this system of records may be disclosed, as a routine use, to the Administrator, General Services, or his/her designee, during an inspection of records conducted by GSA as part of that agency's responsibility to recommend improvements in records management practices and programs, under authority of 44 U.S.C. 2904 and 2906. Such disclosure shall be made in accordance with the GSA regulations governing inspection of records for this purpose, and any other relevant (*i.e.*, GSA or Commerce) directive. Such disclosure shall not be used to make determinations about individuals.
8. A record from this system of records may be disclosed, as a routine use, to the public after either publication of the application pursuant to 35 U.S.C. 122(b) or issuance of a patent pursuant to 35 U.S.C. 151. Further, a record may be disclosed, subject to the limitations of 37 CFR 1.14, as a routine use, to the public if the record was filed in an application which became abandoned or in which the proceedings were terminated and which application is referenced by either a published application, an application open to public inspection or an issued patent.
9. A record from this system of records may be disclosed, as a routine use, to a Federal, State, or local law enforcement agency, if the USPTO becomes aware of a violation or potential violation of law or regulation.