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[3510-16-P]

## **DEPARTMENT OF COMMERCE**

### **United States Patent and Trademark Office**

**[Docket No.: PTO-P-2016-0015]**

### **Cancer Immunotherapy Pilot Program**

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Notice.

**SUMMARY:** The United States Patent and Trademark Office (USPTO or Office) is implementing a pilot program to provide for earlier review of patent applications pertaining to cancer immunotherapy (“Cancer Immunotherapy Pilot Program” or “Pilot Program”) in support of the White House national \$1 billion initiative to achieve ten years’ worth of cancer research in the next five years (“National Cancer Moonshot”). The USPTO will advance applications containing a claim(s) to a method of treating a cancer using immunotherapy out of turn for examination if the applicant files a grantable petition to make special under the Pilot Program. The objective of the Pilot Program is to complete the examination of the application within twelve months of special status being granted. Under the Cancer Immunotherapy Pilot Program, an application will be

advanced out of turn for examination without meeting all of the current requirements of the accelerated examination program (e.g., the requirement for an examination support document) or the Prioritized Examination (Track I) program. This notice outlines the conditions, eligibility requirements, and guidelines of the Pilot Program.

**DATES: Effective Date:** [Insert DATE of publication in the FEDERAL REGISTER].

**Duration:** The Cancer Immunotherapy Pilot Program will run for twelve months from its effective date. Therefore, petitions to make special under the Cancer Immunotherapy Pilot Program must be filed before June 29, 2017. The USPTO may extend the Pilot Program (with or without modifications) or terminate it depending on the workload and resources needed to administer the Pilot Program, feedback from the public, and the effectiveness of the Pilot Program. If the Pilot Program is extended or terminated, the USPTO will provide notification to the public.

**FOR FURTHER INFORMATION CONTACT:** Pinchus M. Laufer, Senior Legal Advisor (telephone (571) 272-7726; electronic mail at [pinchus.laufer@uspto.gov](mailto:pinchus.laufer@uspto.gov)) or Susy Tsang-Foster, Senior Legal Advisor (telephone (571) 272-7711; electronic mail at [susy.tsang-foster@uspto.gov](mailto:susy.tsang-foster@uspto.gov)), of the Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy.

For questions relating to a specific petition, please contact Gary B. Nickol, Supervisory Patent Examiner (telephone (571) 272-0835; electronic mail at [gary.nickol@uspto.gov](mailto:gary.nickol@uspto.gov)) or Brandon J. Fetterolf, Supervisory Patent Examiner (telephone (571) 272-2919; electronic mail at [brandon.fetterolf@uspto.gov](mailto:brandon.fetterolf@uspto.gov)), of Technology Center 1600.

**SUPPLEMENTARY INFORMATION:** On February 1, 2016, the White House Office of the Press Secretary announced a new, national \$1 billion initiative to achieve ten years' worth of cancer research in the next five years, with the intent to aid in the global fight against cancer. See the White House Website at <https://www.whitehouse.gov/the-press-office/2016/02/01/fact-sheet-investing-national-cancer-moonshot>. To support this initiative, the USPTO is implementing the Cancer Immunotherapy Pilot Program to advance patent applications pertaining to cancer immunotherapy out of turn for examination to provide for earlier review. The objective of the Pilot Program is to complete the examination of an application containing a claim(s) to a method of treating a cancer using immunotherapy within twelve months of special status being granted. See Part XII below (Twelve-Month Goal) for more information.

New patent applications are normally taken up for examination in the order of their U.S. filing date. See section 708 of the Manual of Patent Examining Procedure (9th ed., 7th Rev., November 2015) (MPEP). The USPTO has procedures under which an application will be advanced out of turn (accorded special status) for examination if the applicant files a petition to make special under 37 CFR 1.102(c) and (d) with the appropriate

showing or a request for prioritized examination under 37 CFR 1.102(e). See 37 CFR 1.102 and MPEP section 708.02. The USPTO revised its accelerated examination procedures effective August 25, 2006, requiring that all petitions to make special comply with the requirements of the revised accelerated examination (AE) program, except those based on an inventor's health or age or the Patent Prosecution Highway (PPH) Pilot Program. See Changes to Practice for Petitions in Patent Applications To Make Special and for Accelerated Examination, 71 FR 36323 (June 26, 2006), 1308 Off. Gaz. Pat. Office 106 (July 18, 2006) (notice); see also MPEP section 708.02(a).

The USPTO is implementing the Cancer Immunotherapy Pilot Program to permit an application containing at least one claim to a method of treating a cancer using immunotherapy to be advanced out of turn (accorded special status) for examination without meeting all of the current requirements of the accelerated examination program set forth in item VIII of MPEP section 708.02(a) (e.g., examination support document) if the applicant files a grantable petition to make special under the Pilot Program.

Applications that have been accorded special status based on any USPTO established procedures (such as PPH, Prioritized Examination, Accelerated Examination, Age, Health, or any other pilot program that takes up an application out of order for examination) are not eligible to be made special under the Cancer Immunotherapy Pilot Program. Applications are accorded special status under the Cancer Immunotherapy Pilot Program after grant of special status until a final disposition (defined in Part XII (Twelve-Month Goal)) is reached in the application. Under special status, an application

that has not been acted on or an application with a proper RCE request will be placed on the examiner's special new docket until a first Office action on the merits. For an application in the Pilot Program where applicant is responding to a first Office action, the application will be placed on the examiner's regular amended docket. Under the Pilot Program, the USPTO is providing examiners with incentives to handle these applicant responses promptly.

The USPTO will accept petitions to make special under the Cancer Immunotherapy Pilot Program provided that the petitions, and applications in which they are filed, meet all of the requirements set forth in this notice. The USPTO will periodically evaluate the Pilot Program to determine whether and to what extent its coverage should be expanded. In addition, the USPTO may extend the Pilot Program (with or without modifications) or terminate it depending on the workload and resources needed to administer the Pilot Program, feedback from the public, and the effectiveness of the Pilot Program. If the Pilot Program is extended or terminated, the USPTO will provide notification to the public.

Applicants may participate in the Cancer Immunotherapy Pilot Program by filing a petition to make special under 37 CFR 1.102(d) meeting all of the requirements set forth in this notice in either a new application or in a pending application. However, continuing applications will not automatically be accorded special status based on papers filed with a petition in a parent application. Each application must, on its own, meet all

requirements for special status. No fee is required. The fee for a petition to make special under 37 CFR 1.102(d) based upon the procedure specified in this notice is hereby waived.

Part I. Requirements for Petitions to Make Special Under the Cancer Immunotherapy

Pilot Program: A petition to make special under the Cancer Immunotherapy Pilot Program may be granted in an application provided the eligibility requirements set forth in Part II and the following conditions are satisfied:

- (1) Types of Applications. The 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.
- (2) Claim Limit and No Multiple Dependent Claims. The application must not contain more than three independent claims and more than twenty total claims. The application must not contain any multiple dependent claims. For an application that contains more than three independent claims or twenty total claims, or any multiple dependent claims, 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. The petition must include a statement that applicant agrees that the application will not have more than three independent claims, more than twenty total claims, and any multiple dependent claims while the application is in special status under the Pilot Program.

- (3) The Application Must Include at Least One Method Claim of Treating a Cancer Using Immunotherapy. The application must include at least one claim to a method of treating a cancer using immunotherapy that meets the eligibility requirements in Part II of this notice. The petition must include a statement that the applicant agrees to include at least one claim to a method of treating a cancer using immunotherapy that meets the Pilot Program eligibility requirements while the application is in special status. For applications that have been previously examined, applicants will not be permitted to switch inventions in order to participate in the Pilot Program. See MPEP section 821.03.
- (4) Statement Regarding Method of Treating a Cancer Using Immunotherapy. The petition to make special must state that special status under the Pilot Program is sought because the application contains a claim to a method of treating a cancer using immunotherapy that meets the eligibility requirements discussed in Part II of this notice.
- (5) Statement Regarding Restriction Requirement. The petition must include a statement that, if the USPTO determines that the claims are directed to multiple inventions, applicant will agree to make an election without traverse in a telephonic interview, and elect an invention directed to a method of treating a cancer using immunotherapy that meets the eligibility requirement discussed in Part II of this notice.
- (6) Statement that Special Status Was Not Previously Granted Under Any Program. The petition must state that the application has not been previously granted special

status. A petition to make special under this Pilot Program may not be filed in an 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) Time for Filing Petition. In general, the petition to make special under the Pilot Program 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 (applicant may check the status of an application using PAIR); or (ii) with a proper request for continued examination (RCE) that is 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 filed by patent applicant or their agent (e.g., a licensee of the patent applicant or the patent applicant's assignee) at the U.S. Food and Drug Administration (FDA) that has entered phase II or phase 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. For an application that has an outstanding Office action, patent applicant must file a complete response together with the petition.



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

- (8) Office Form Available for Filing Petition. Applicant should use form PTO/SB/443 for filing the petition. The form will contain a check-box for the applicant to certify that the claimed cancer immunotherapy both (i) meets the eligibility requirements for this Pilot Program and (ii) is the subject of an active IND application filed by patent applicant or their agent at the FDA that has entered phase II or phase III clinical trials. The form will be available as a Portable Document Format (PDF) fillable form in EFS-Web and on the USPTO Web site at <http://www.uspto.gov/web/forms/index.html>. The Office of Management and Budget (OMB) has determined that, under 5 CFR 1320.3(h), Form PTO/SB/443 does not collect “information” within the meaning of the Paperwork Reduction Act of 1995. Information regarding EFS-Web is available on the USPTO Web site at <http://www.uspto.gov/learning-and-resources/support-centers/patent-electronic-business-center>. Failure to use the form or its equivalent could result in the Office not recognizing the request or delays in processing the request.
- (9) Electronic Filing of Petition Required. The petition to make special must be filed

electronically before June 29, 2017, using the USPTO electronic filing system, EFS-Web, and selecting the document description of “Petition for Cancer Immunotherapy Pilot” on the EFS-Web screen. Any inquiries concerning electronic filing of the petition should be directed to the Electronic Business Center (EBC) at (866) 217–9197.

- (10) Publication Requirement for Applications. For unpublished applications, the petition to make special must be accompanied by a request for early publication in compliance with 37 CFR 1.219. If applicant previously filed a nonpublication request in the application, applicant must file a rescission of a nonpublication request no later than the time the petition to make special is filed. Applicant may use form PTO/SB/36 to rescind the nonpublication request.

Part II. Eligibility Requirements – Applications Pertaining to Cancer Immunotherapy.

To be eligible for the Cancer Immunotherapy Pilot Program, patent applications should be in the field of Oncology. The applications must contain at least one claim encompassing a method of ameliorating, treating, or preventing a malignancy in a human subject wherein the steps of the method assist or boost the immune system in eradicating cancerous cells. For example, this can include the administration of cells, antibodies, proteins, or nucleic acids that invoke an active (or achieve a passive) immune response to destroy cancerous cells. The Pilot Program also will consider claims drawn to the co-administration of biological adjuvants (e.g., interleukins, cytokines, Bacillus Comette-Guerin, monophosphoryl lipid A, etc.) in combination with conventional therapies for treating cancer such as chemotherapy, radiation, or surgery. Claims to administering any

vaccine that works by activating the immune system to prevent or destroy cancer cell growth are included. The Pilot Program also will consider *in vivo*, *ex vivo*, and adoptive immunotherapies, including those using autologous and/or heterologous cells or immortalized cell lines.

As in other programs, eligibility for this pilot is not restricted by (i) the nationality of the patent applicant or its agents, (ii) the location where the underlying research was undertaken or the technology was developed, or (iii) the location where the invention may be produced or manufactured.

Part III. Decision on Petition to Make Special Under the Cancer Immunotherapy Pilot Program. If applicant files a petition to make special under the Cancer Immunotherapy Pilot Program, the USPTO will decide the petition once the application has been docketed for examination. Any inquiries concerning a specific petition to make special should be directed to the appropriate Technology Center handling the petition. If the petition is granted, the application will be accorded special status under the Cancer Immunotherapy Pilot Program until a final disposition (see Part XII (Twelve-Month Goal)). Under special status, an application that has not been acted on or an application with a proper RCE request will be placed on the examiner's special new docket until a first Office action on the merits. For an application in the Pilot Program where applicant is responding to a first Office action, the application will be placed on the examiner's

regular amended docket. Under the Pilot Program, the USPTO is providing examiners with incentives to handle these applicant responses promptly.

Applicant will be notified of the decision on the petition by the deciding official. If the application does not comply with the sequence requirements as set forth in 37 CFR 1.821 through 1.825, such that the application is not in condition for examination, or has an outstanding Office action, or if the application and/or petition does not meet all the formal requirements set forth in this notice, the USPTO will notify the applicant of the deficiency by issuing a notice. The notice will give the applicant only one opportunity to correct the deficiency. If the applicant still wishes to participate in the Cancer Immunotherapy Pilot Program, the applicant must file a proper petition and make appropriate corrections within one month or thirty days, whichever is longer. The time period for reply is not extendable under 37 CFR 1.136(a). If the applicant fails to correct the deficiency indicated in the notice within the time period set forth therein, the application will not be eligible for the Cancer Immunotherapy Pilot Program, and the application will be taken up for examination in accordance with standard examination procedures. If the application does not contain a method claim that complies with the eligibility requirements discussed in Part II of this notice, the petition will be dismissed, and the applicant will not be given an opportunity to correct the deficiency.

Part IV. Requirement for Restriction. If the claims in the application are directed to multiple inventions, the examiner may make a requirement for restriction in accordance

with current restriction practice. The examiner will contact the applicant by telephone and request an oral election of a single invention for prosecution. Applicant must make an election without traverse in a telephonic interview of an invention that is to a method of treating a cancer using immunotherapy that meets the eligibility requirements for this Pilot Program. If the applicant does not respond by telephone to an examiner's request for an election within two working days or refuses to make an election of an invention that is to a method of treating a cancer using immunotherapy, the examiner will treat the first group of claims directed to a method of treating a cancer using immunotherapy that meets the eligibility requirements of this notice as constructively elected without traverse for examination.

Part V. First Action Interview Pilot Program Not Available. Applications accepted into the Cancer Immunotherapy Pilot Program will not be eligible to participate in the First Action Interview Pilot Program. However, standard interview practice and procedures applicable to regular *ex parte* prosecution will still be available See MPEP section 713.02.

Part VI. Period for Reply by Applicant. The time periods set for reply in Office actions for an application granted special status under the Pilot Program will be the same as those set forth in section 710.02(b) of the MPEP. However, if an applicant files a petition for any extension of time under 37 CFR 1.136(a), the special status of the application will be

terminated, and the application will be taken up for examination in accordance with standard examination procedures.

Part VII. Reply By Applicant. A reply to an Office action must be limited to responding to rejections, objections, and requirements made by the examiner. Any amendment to a non-final Office action will be treated as not fully responsive if it attempts to: (A) add claims which would result in more than three independent claims, or more than twenty total claims, pending in the application; (B) add any multiple dependent claim; or (C) cancel all method claims to treating a cancer using immunotherapy. If a reply to a non-final Office action is not fully responsive because it does not comply with the Pilot Program claim requirements, but is a bona fide attempt to advance the application to final action, the examiner may, at his or her discretion, provide one month or thirty days, whichever is longer, for applicant to supply a fully responsive reply. Extensions of this time period under 37 CFR 1.136(a) to the notice of nonresponsive amendment will not be permitted in order for the application to remain in special status. Any further nonresponsive amendment will be treated as non-bona fide and the time period set in the prior notice will continue to run.

Part VIII. After-Final and Appeal Procedures: The mailing of a final Office action or the filing of a Notice of Appeal, whichever is earlier, is a final disposition for purposes of the twelve-month goal for the Cancer Immunotherapy Pilot Program. During the appeal process, the application will be treated in accordance with the normal appeal procedure

(see MPEP Chapter 1200). Any amendment, affidavit, or other evidence after a final Office action and prior to appeal must comply with 37 CFR 1.116. The filing of an RCE is a final disposition for purposes of the twelve-month goal for the Cancer Immunotherapy Pilot Program. The application will not retain its special status after the filing of a proper RCE.

Part IX. Post-Allowance Processing. The mailing of a notice of allowance is a final disposition for the purposes of the twelve-month goal for the Pilot Program. The failure to pay the required issue fee within one (1) month of the mailing date of the Form PTOL-85 or the submission of a non-USPTO required submission under 37 CFR 1.312 will result in the allowance being processed according to the regular allowance process. A submission that includes both USPTO required changes and non-USPTO required changes under the provisions of 37 CFR 1.312 will be considered as a non-USPTO required submission for purposes of the allowance processing.

Part X. Proceedings Outside the Normal Examination Process: If an application becomes involved in proceedings outside the normal examination process (e.g., a secrecy order, national security review, interference, derivation proceeding or petitions under 37 CFR 1.181 through 1.183), the USPTO will place the application in special status under the Cancer Immunology Pilot Program before and after such proceedings. During those proceedings, however, the application will not be under special status. For example, during an interference proceeding, the application will be treated in accordance with the

normal interference procedures and will not be in special status under the Cancer Immunology Pilot Program. Once any one of these proceedings is completed, the application will continue in special status under the Pilot Program until it reaches a final disposition, but that may occur later than twelve months from the grant of special status under the Pilot Program.

Part XI. Withdrawal From Pilot Program. There is no provision for “withdrawal” from special status under the Pilot Program. However, filing a petition for any extension of time under 37 CFR 1.136(a) will result in the application being taken out of the Pilot Program. An applicant may abandon the application that has been granted special status under the Pilot Program in favor of a continuing application, and the continuing application will not be given special status under the Pilot Program unless the continuing application is filed with a petition to make special under the Pilot Program.

Part XII. Twelve-Month Goal. The objective of the Cancer Immunology Pilot Program is to complete the examination of an application within twelve months of special status being granted under the Pilot Program (i.e., within twelve months from the mailing date of the decision granting the petition to make special). The twelve-month goal is successfully achieved when one of the following final dispositions occurs within twelve months from the grant of special status under the Pilot Program: (1) the mailing of a notice of allowance; (2) the mailing of a final Office action; (3) the filing of an RCE; (4) the abandonment of the application; (5) or the filing of a Notice of Appeal. The final



disposition of an application, however, may occur later than the twelve-month time frame in certain situations (e.g., applicant files an amendment that does not comply with the Pilot Program claim requirements or applicant petitions for extension of time under 37 CFR 1.136(a)). See Part X for more information on other events that may cause examination to extend beyond this twelve-month timeframe. In any event, however, this twelve-month time frame is simply a goal. Any failure to meet the twelve-month goal or other issues relating to this twelve-month goal are neither petitionable nor appealable matters.

Dated: \_June 24, 2016.

Michelle K. Lee,  
Under Secretary of Commerce for Intellectual Property and  
Director of the United States Patent and Trademark Office.

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