

Description of the Cancer Immunotherapy Pilot Program and MOU

Description of the Program: The USPTO has determined to implement a Cancer Immunotherapy Pilot program (Pilot), as described herein and in the attached Guidelines. The Pilot will provide for expedited prosecution of applications containing claims directed to a method of treating cancer using immunotherapy. The objective of the Pilot is to complete the examination of the application within twelve months of special status being granted under the Pilot. 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., examination support document) or the Prioritized Examination (Track I) program.

AGREEMENT

Preamble: The USPTO and POPA agree to the following provisions based on the Agency's determination to implement the Cancer Immunotherapy Pilot Program as outlined above and in the attached Guidelines.

- 1. Timing and Duration:** This Pilot will begin on June 29, 2016, and end on June 29, 2017.
- 2. Sharing of Information:** Summary information collected for the evaluation of this pilot will be shared with POPA. Data generated in the Pilot shall be shared promptly so that both parties may analyze the data contemporaneously. Upon request, POPA will be provided with the full data for the Pilot evaluation in electronically sortable format excluding Personally Identifiable Information. Information may include: the number of applications in the Pilot; the distribution of Pilot applications within the office; and the number of Pilot applications on each examiner's docket.
- 3. Evaluation of Pilot:** The parties will begin meeting no later than January 1, 2017, to discuss the results of the Pilot to date. In addition, either party may request meetings during the life of the Pilot to discuss issues relating to the Pilot.
- 4. Dissemination of Information to Examiners:** Management will send information on this Pilot including this agreement and all attachments via e-mail to Examiners in Technology Center 1600. The information will consist of a description of the Pilot and information on how to obtain training for the Pilot.
- 5. Ongoing Discussions:** The parties shall meet at the request of either party to discuss the progress of the Pilot, or any other issues arising from the implementation of the Pilot. The parties agree to work together to jointly address issues raised by either party with a goal of reaching a resolution to the issues that is acceptable to both parties within a reasonable time. Agreed upon changes will be implemented.
- 6. Termination:** The Pilot will terminate on June 29, 2017, as set forth in Paragraph 1, above. Upon notification to POPA, the USPTO may terminate the Pilot earlier at its sole discretion.
- 7. Bargaining Obligation:** POPA acknowledges that the USPTO's obligation to negotiate over the implementation of the Pilot and the attached Guidelines has been fully satisfied. POPA reserves its

right to pre-implementation notice and bargaining, to the extent required by law, should the agency determine to extend the Pilot or make the Pilot a permanent program.

Signatures



Andrew Faile
Deputy Commissioner for Patent Operations
U.S. Patent and Trademark Office



Pamela R. Schwartz
President
Patent Office Professional Association

Date: 7/7/16

Date: July 7, 2016

Attached:

Cancer Immunotherapy Pilot Guidelines

Cancer Immunotherapy Pilot Guidelines

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 81 FR 42328. If the petition is granted, the application will be accorded special status under the Pilot. Under special status, the application will be treated as special on the examiner's docket until a final disposition.

Cancer Immunotherapy Pilot applications will be considered as a special application under the Special New docket management component (Category 2) under the docket management element of the PAP for the purposes of generating a First Office Action on the Merits (FAOM). Any RCE submitted for credit under this pilot, will be considered a management directed RCE and will receive 1.25 counts for the FAOM. An examiner is expected to act on one Special application per qualifying pay period consistent with the rules for the Special New docket management component (Category 2) of the docket management element, (a "qualifying pay period" is one in which the examiner has a number of examining hours equal to or greater than 40 or the examiner's actual goal whichever is greater). An examiner with multiple applications docketed is expected to move at least one Special New application per qualifying pay period, beginning with the oldest application as identified on the examiner's docket management reports.

Applications under the Pilot which have amendments will be placed in the Amendments (56-day) component under the docket management element of the PAP. These applications will be denoted on an examiner's regular amended docket by an identifying mark. For purposes of the docket management element of the examiner PAP:

- Amendments on Cancer Immunotherapy Pilot applications completed within 28 days will count as zero days for purposes of the docket management calculation,

- Amendments on Cancer Immunotherapy Pilot applications completed after 28 days will begin accruing time as a 29 day case for purposes of the docket management calculation.

As the docket management system provides its own incentives for posting applications for credit, other than the additional incentive provided by the availability of a zero day score for posting within 28 days, the normal docket management system will be relied upon for movement of these Amendments. Examiners will not be directed to take an action out of turn because the application is participating in the Pilot.

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. Examiners making oral restrictions pursuant to the Pilot will never-the-less be permitted to take an hour for restriction when they write their office action if, but for the Pilot, the examiner would have written the restriction and been granted an hour of time for doing so under existing practice. 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. If the applicant does not respond 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 that is to a method of treating a cancer using immunotherapy and meets the eligibility requirements of the Pilot as constructively elected without traverse.

Applications accepted into the Pilot 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.

The time periods set for reply in Office actions for an application granted special status under the Pilot 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.

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 that 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, will be treated as not fully responsive. If a reply to a non-final Office action is not fully responsive because it does not comply with the Pilot claim requirements (i.e., the reply contains more than three independent claims, more than twenty total claims, or a multiple dependent claim(s), or the reply does not contain at least one method claim of treating a cancer using immunotherapy), but is a bona fide attempt to advance the application to final action, the examiner may 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 noncompliant amendment will not be permitted in order for the application to remain in special status. Any further noncompliant amendment will be treated as non-bona fide and the time period set in the prior notice will continue to run.

The mailing of a final Office action or notice of allowance, or the filing of a Notice of Appeal, whichever is earlier, is a final disposition for purposes of the twelve-month goal for the Pilot. 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 final 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.