TABLE 1—ISSUED PERMITS AND PERMIT AMENDMENTS

| Permit No. | RTID | Applicant | Previous **Federal Register** notice | Issuance date |
|---|---|---|---|---|
| 21585–02 ..... | 0648–XC011 | Oregon State University, Marine Mammal Institute, 2030 Southeast Marine Science Drive, Newport, OR 97365 (Responsible Party: Lisa Ballance, Ph.D.). | 87 FR 27989, May 10, 2022. | November 14, 2022. |
| 25754 ..... | 0648–XC036 | NMFS Pacific Islands Fisheries Science Center, 1845 Wasp Boulevard, Building 176, Honolulu, HI 96818 (Responsible Party: Charles Littnan, Ph.D.). | 87 FR 31210, May 23, 2022. | November 16, 2022. |
| 26226 ..... | 0648–XC363 | Robert DiGiovanni, Jr., Atlantic Marine Conservation Society, P.O. Box 932, Hampton Bays, NY 11946. | 87 FR 56001, September 13, 2022. | November 10, 2022. |
| 26562 ..... | 0648–XC233 | James Hain, Ph.D., Associated Scientists at Woods Hole, Box 721, Woods Hole, MA 02543. | 87 FR 48471, August 9, 2022. | November 9, 2022. |
| 26696 ..... | 0648–XC418 | Dennis Clegg, Ph.D., University of California at Santa Barbara, Neuroscience Research Institute, Mail Code 5060, Santa Barbara, CA 93106. | 87 FR 60126, October 4, 2022. | November 22, 2022. |

In compliance with the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*), a final determination has been made that the activities proposed are categorically excluded from the requirement to prepare an environmental assessment or environmental impact statement.

As required by the ESA, as applicable, issuance of these permit was based on a finding that such permits: (1) were applied for in good faith; (2) will not operate to the disadvantage of such endangered species; and (3) are consistent with the purposes and policies set forth in Section 2 of the ESA.

*Authority:* The requested permits have been issued under the MMPA of 1972, as amended (16 U.S.C. 1361 *et seq.*), the regulations governing the taking and importing of marine mammals (50 CFR part 216), the ESA of 1973, as amended (16 U.S.C. 1531 *et seq.*), and the regulations governing the taking, importing, and exporting of endangered and threatened species (50 CFR parts 222–226), as applicable.

Dated: December 5, 2022.

**Amy C. Sloan,**

*Acting Chief, Permits and Conservation Division, Office of Protected Resources, National Marine Fisheries Service.*

[FR Doc. 2022–26780 Filed 12–8–22; 8:45 am]

**BILLING CODE 3510–22–P**

## DEPARTMENT OF COMMERCE

### Patent and Trademark Office

**[Docket No. PTO–P–2022–0038]**

### Cancer Moonshot Expedited Examination Pilot Program

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

**ACTION:** Notice.

**SUMMARY:** The United States Patent and Trademark Office (USPTO or Office) is implementing the Cancer Moonshot Expedited Examination Pilot Program to replace 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 qualifying technologies. Applications accepted into the new pilot program will be advanced out of turn (accorded special status) for examination until a first Office action. The new pilot program supports the renewed national Cancer Moonshot initiative that aims to reduce the cancer mortality rate by at least 50% within 25 years. This notice outlines the conditions, eligibility requirements, and guidelines of the new pilot program.

**DATES:** *Pilot Duration:* The Cancer Moonshot Expedited Examination Pilot Program will accept petitions to make special beginning on February 1, 2023, until either January 31, 2025, or the date the USPTO accepts a total of 1,000 grantable petitions under the pilot program, whichever is earlier. The USPTO may, at its sole discretion, terminate the pilot program depending on factors such as workload and resources needed to administer the program, feedback from external stakeholders, and the program's effectiveness. If the pilot program is terminated, the USPTO will notify the public. The USPTO will publish on its website an ongoing count of the number of petitions filed and the number of petitions granted under the pilot program.

**ADDRESSES:** Petitions to make special under the Cancer Moonshot Expedited Examination Pilot Program must use form PTO/SB/465 and must be filed electronically using the USPTO's Patent Center (at *https://patentcenter.uspto.gov*). Form PTO/SB/465 is available at *www.uspto.gov/PatentForms.*

**FOR FURTHER INFORMATION CONTACT:** For general questions regarding this pilot program, please contact Susy Tsang-Foster, Senior Legal Advisor, Office of Patent Legal Administration, Office of the Deputy Commissioner for Patent Examination Policy, at 571–272–7711 or *susy.tsang-foster@uspto.gov.* For questions on electronic filing, please contact the Electronic Business Center (EBC) at 866–217–9197 (during its operating hours of 6 a.m. to midnight ET, Monday–Friday) or *ebc@uspto.gov.* For questions related to a particular petition, please contact Gary B. Nickol, Supervisory Patent Examiner, at 571–272–0835 or *gary.nickol@uspto.gov;* or Brandon J. Fetterolf, Supervisory Patent Examiner, at 571–272–2919 or *brandon.fetterolf@uspto.gov,* both of Technology Center 1600.

**SUPPLEMENTARY INFORMATION:**

#### I. Background

New patent applications are normally taken up for examination in the order of their U.S. filing date or national stage entry date. See §§ 708 and 1893.03(b) of the Manual of Patent Examining Procedure (MPEP) (9th ed., rev. 10.2019, June 2020). The USPTO has procedures under which an application will be advanced out of turn (accorded special status) for examination if the applicant files (1) a petition to make special under 37 CFR 1.102(c) or (d) with the appropriate showing, or (2) a request for prioritized examination under 37 CFR 1.102(e). See 37 CFR 1.102(c)–(e) and MPEP §§ 708.02, 708.02(a), and 708.02(b).

In 2016, the USPTO published a notice on the implementation of the Cancer Immunotherapy Pilot Program. *See* Cancer Immunotherapy Pilot Program, 81 FR 42328 (June 29, 2016) (Cancer Immunotherapy Notice). The pilot program was implemented to support the 2016 National Cancer Moonshot initiative to accelerate technological progress to eliminate cancer. The Cancer Immunotherapy Notice indicated that an applicant could have an application advanced out of turn (accorded special status) for examination without meeting all of the current requirements of the accelerated examination program that are set forth in section 708.02(a) of the MPEP if the application contained at least one claim to a method of treating a cancer using immunotherapy and the applicant met other requirements specified in the notice.

The Cancer Immunotherapy Notice established that the pilot program would run for 12 months, beginning on June 29, 2016. Since then, the USPTO has extended the Cancer Immunotherapy Pilot Program multiple times through notices published in the **Federal Register**. The most recent notice (87 FR 58772, September 28, 2022) extended the program until January 31, 2023, to enable the USPTO to continue with its ongoing evaluation of whether to expand the program and to what extent. Recently, the White House renewed the Cancer Moonshot initiative and set a new goal of reducing the cancer death rate by at least 50% over the next 25 years. *See* White House statement at *www.whitehouse.gov/briefing-room/statements-releases/2022/02/02/fact-sheet-president-biden-reignites-cancer-moonshot-to-end-cancer-as-we-know-it/.*

## II. Termination of the Cancer Immunotherapy Pilot Program and Implementation of the New Cancer Moonshot Expedited Examination Pilot Program

In view of the continued interest in and success of the Cancer Immunotherapy Pilot Program and to support the renewed national Cancer Moonshot initiative by providing a broader scope of qualifying technologies, the USPTO is implementing the Cancer Moonshot Expedited Examination Pilot Program, which is an expansion of the Cancer Immunotherapy Pilot Program and replaces that program. Any compliant petition to make special under the Cancer Immunotherapy Pilot Program filed in an application on or before January 31, 2023, will be granted, and the application will be examined in accordance with the provisions of the Cancer Immunotherapy Pilot Program. Any petition to make special under the Cancer Immunotherapy Pilot Program filed in an application after January 31, 2023, will not be accepted.

In contrast to the Cancer Immunotherapy Pilot Program, which required the application to contain a claim to a method of treating a cancer using immunotherapy and the election of that method claim for examination, the Cancer Moonshot Expedited Examination Pilot Program covers a wider range of eligible technologies. Under the new program, applications must be in the field of oncology or smoking cessation and must contain at least one of the following method claims that meet the eligibility requirements of the program as set forth in section V of this notice (''eligible method claims''):

(1) A method of treating or reducing the incidence of a cancer using an immunotherapeutic compound or composition (cancer immunotherapy method);

(2) A method of treating a cancer by targeting specific genetic markers or mutations using a specific pharmaceutical composition;

(3) A method of treating a rare or childhood cancer using a specific pharmaceutical composition;

(4) A method of detecting or treating a cancer using a medical device specifically adapted to detect or treat the cancer;

(5) A method of treating a cancer by administering a specific pharmaceutical composition wherein the method comprises a step to diagnose the cancer; and

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

Furthermore, if the application contains eligible product or apparatus claims as set forth in section V of this notice (that is, claims to the immunotherapeutic compound or composition, the pharmaceutical composition, or the medical device used in an eligible method claim), the eligible method claims must depend from or be commensurate in scope with the eligible product or apparatus claims in the application (that is, the eligible method claims must contain all of the limitations of the eligible product or apparatus claims).

## III. How To Participate in the Cancer Moonshot Expedited Examination Pilot Program

Applicants may participate in the Cancer Moonshot Expedited Examination Pilot Program without meeting all of the requirements of the accelerated examination program set forth in MPEP 708.02(a) (for example, providing an examination support document) by filing a petition to make special, under 37 CFR 1.102(d), in an application that meets all of the requirements set forth in this notice. All other requirements of the accelerated examination program that are not required by this notice, including the 37 CFR 1.17(h) fee for a petition to make special under 37 CFR 1.102(d), are hereby waived based on the special procedure specified in this notice.

If the petition is granted, the application will be treated as special on the examiner's docket and will be accorded special status until a first Office action (which may be an Office action containing only a restriction requirement) is issued. After the first Office action is issued, the application will no longer be treated as special during examination. For example, if an amendment is filed, it will be placed on the examiner's regular amended docket. The USPTO will periodically evaluate the pilot program to determine whether and to what extent its coverage should be expanded or limited.

## IV. Requirements for Petitions To Make Special Under the Cancer Moonshot Expedited Examination Pilot Program

A petition to make special under the Cancer Moonshot Expedited Examination Pilot Program may be granted in an application provided the eligibility requirements set forth in section V of this notice and the following conditions are satisfied:

### *(A) Types of Applications*

The application must be 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.

### *(B) Claim Limits and No Multiple Dependent Claims*

The application must contain no more than 3 independent claims and no more than 20 total claims (''program claim limits'') and must not contain any multiple dependent claims. If an application exceeds 3 independent claims or 20 total claims, or if it contains any multiple dependent claims, the applicant should file a preliminary amendment in compliance with 37 CFR 1.121 to cancel any excess claims or multiple dependent claims no later than the date the petition to make special is filed. Throughout pendency, an application granted special status under the pilot program must meet the

program claim limits and must not contain any multiple dependent claims. The petition must include a statement that the applicant agrees not to exceed the program claim limits or add any multiple dependent claims throughout the pendency of the application. The examiner may refuse entry of any amendment filed in reply to an Office action that, if entered, would result in a set of pending claims that exceeds the program claim limits or adds any multiple dependent claims. *See* section IX of this notice.

*(C) Inclusion of at Least One Method Claim That Meets the Eligibility Requirements of the Pilot Program*

The application must include at least one method claim that meets the eligibility requirements set forth in section V of this notice.

*(D) Statements Regarding a Method Claim and Any Product Claim or Apparatus Claim That Meet the Eligibility Requirements of the Pilot Program*

The petition to make special must include a statement that 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 method claim that meets the eligibility requirements of the pilot program, which are discussed in section V of this notice. The petition must also identify the eligible method claim(s). In addition, the petition must include a statement that the applicant agrees not to cancel all method claims that meet the eligibility requirements of the pilot program throughout the pendency of the application.

Furthermore, the petition must include a statement that if the application contains eligible product or apparatus claims as set forth in section V of this notice (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).

*(E) Statements Regarding Restriction Requirement and Elected Invention*

The petition must include a statement that, if a requirement for restriction or unity of invention is made, the applicant will agree to make an election without traverse to an invention that meets the eligibility requirements of the pilot program. The petition must also include a statement that the applicant agrees not to cancel all claims to the elected invention throughout the pendency of the application.

*(F) Statement That Special Status Was Not Previously Granted Under Any Program*

The petition must include a statement that the application was not previously granted special status under any program. 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 any other program (for example, for reasons of age or health, Patent Prosecution Highway, Accelerated Examination, Prioritized Examination, etc.).

*(G) Time for Filing a Petition*

The petition to make special under the Cancer Moonshot Expedited Examination Pilot Program must be filed prior to a first Office action (which may be an Office action containing only a restriction requirement). A petition under the pilot program may not be filed in any application in which a request for continued examination under 37 CFR 1.114 has been filed.

*(H) Required USPTO Form for Filing a Petition*

Form PTO/SB/465, titled ''CERTIFICATION AND PETITION TO MAKE SPECIAL UNDER THE CANCER MOONSHOT EXPEDITED EXAMINATION PILOT PROGRAM,'' must be used to file the petition to make special under the pilot program. The form is available at *www.uspto.gov/PatentForms.* Form PTO/SB/465 contains the necessary certifications for qualification to participate in the pilot program. Use of the form will enable the USPTO to quickly identify and timely process the petition. In addition, use of the form will help applicants understand and comply with the petition requirements of the pilot program. Under 5 CFR 1320.3(h), form PTO/SB/465 does not collect ''information'' within the meaning of the Paperwork Reduction Act of 1995.

*(I) Required Electronic Filing of an Application and Petition*

The petition to make special may only be made by filing form PTO/SB/465, which must be filed electronically using the USPTO's Patent Center (at *https://patentcenter.uspto.gov*). Applicants must file the petition using the document description (''Petition for Cancer Moonshot Pilot'') indicated on form PTO/SB/465. In addition, the application or national stage entry must be filed electronically using Patent Center.

*(J) Required Use of DOCX Format for Specification, Claim(s), and Abstract on Filing or on National Stage Entry*

The specification, claim(s), and abstract of the application must be submitted in DOCX format at the time of filing or national stage entry. Prior to submitting the application for filing in DOCX format, applicants will receive a feedback document. Applicants may find it beneficial to review the feedback document and make corrections to the application before filing the application. By making the necessary corrections before filing, applicants may avoid delays that can occur in the pre-examination process. For more information on DOCX filing in Patent Center, please *see www.uspto.gov/patents/docx.* Applicants can direct any inquiries concerning electronic filing of the petition and application to the EBC at 866–217–9197 or *ebc@uspto.gov.*

*(K) Publication Requirement for Applications*

If an applicant files the petition to make special on the date of filing of the application, the application may not be filed with a nonpublication request. If the applicant previously filed a nonpublication request in the application, the applicant must file a rescission of the nonpublication request no later than the date the petition to make special is filed. The applicant may use form PTO/SB/36 to rescind the nonpublication request.

*(L) Statement Concerning Filing Limitations*

An applicant may file a petition to participate in the pilot program if the inventor or any joint inventor has not been named as the inventor or a joint inventor on more than nine other nonprovisional patent applications in which a petition to make special under this program has been filed. In other words, the inventor or any joint inventor named on the application can only be named as the inventor or a joint inventor on a maximum of 10 nonprovisional applications in which a petition under the pilot program has been filed. Therefore, if the inventor or any one of the joint inventors of the instant application has been named as the inventor or a joint inventor on more than nine other nonprovisional applications in which petitions under this pilot program have been filed, then the petition for the instant application may not be appropriately filed. Petitions filed under the Cancer Immunotherapy Pilot Program do not count toward the

filing limits in the Cancer Moonshot Expedited Examination Pilot Program.

The petition must include the following statement: ''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.''

**V. Eligibility Requirements**

To be eligible for the Cancer Moonshot Expedited Examination Pilot Program, patent applications must be in the field of oncology or smoking cessation. The applications must claim an invention in at least one of the following technologies:

*(A) Cancer Immunotherapies*

The program will consider the following claims pertaining to cancer immunotherapy:

(i) Method claims to treat or reduce the incidence of a cancer using an immunotherapeutic compound or composition (''cancer immunotherapy method claims'').

These claims encompass a method of ameliorating, treating, or reducing the incidence of a malignancy in a human subject wherein the steps of the method assist or boost the immune system in eradicating cancerous cells. Examples include:

(a) Claims drawn to the administration of cells, antibodies, proteins, or nucleic acids that invoke an active (or achieve a passive) immune response to destroy cancerous cells;

(b) Claims drawn to the co-administration of biological adjuvants (for example, interleukins, cytokines, Bacillus Calmette-Guerin, monophosphoryl lipid A, etc.) in combination with conventional therapies for treating cancer such as chemotherapy, radiation, or surgery;

(c) Claims drawn to the administration of any vaccine that works by activating the immune system to destroy or reduce the incidence of cancer cell growth; and

(d) Claims drawn to *in vivo, ex vivo,* and adoptive immunotherapies for treating a cancer, including those using autologous and/or heterologous cells or immortalized cell lines.

(ii) Product claims to the immunotherapeutic compound or composition used in a cancer immunotherapy method eligible under section V(A)(i) of this notice that is also claimed in the application.

Immunotherapeutic compounds and compositions work by invoking an immune response to destroy or reduce the incidence of cancer cell growth. 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, and the statement must also identify the specific page(s) of the specification containing the evidence.

If product claims to immunotherapeutic compounds or compositions are presented in the application, claims to an eligible method of treating or reducing the incidence of a cancer using these immunotherapeutic compounds or compositions must also be presented in the same application and must depend from or be commensurate in scope with the product claims (that is, the method claims must contain all of the limitations of the product claims) throughout the pendency of the application. The eligible method claims to treating or reducing the incidence of a cancer using an immunotherapeutic compound or composition are required in the application throughout pendency because the immunotherapeutic compound or composition claimed may have an additional use not related to the treatment of cancer. The requirement for the eligible method claims to be commensurate in scope with the eligible product claims in the application facilitates rejoinder of these method claims in the event that there is a restriction requirement between the eligible product claims and eligible method claims and the product claims are elected.

*(B) Personalized Medicine To Treat a Cancer by Targeting Specific Genetic Markers or Mutations Using a Specific Pharmaceutical Composition*

The program will consider method claims to treat a cancer by targeting specific genetic markers or mutations using a specific pharmaceutical composition and any product claims to the pharmaceutical composition used in these method claims. 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, and the statement must also identify the specific page(s) of the specification containing the evidence.

If product claims to the pharmaceutical composition are presented in the application, claims to a method to treat a cancer by targeting specific genetic markers or mutations using the pharmaceutical composition must also be presented in the same application and must depend from or be commensurate in scope with the product claims to the pharmaceutical composition (that is, the method claims must contain all of the limitations of the product claims) throughout the pendency of the application. The method claims to treat a cancer by targeting specific genetic markers or mutations using the pharmaceutical composition are required in the application throughout pendency because the pharmaceutical composition claimed may have an additional use not related to the treatment of cancer. The requirement for all eligible method claims to be commensurate in scope with the eligible product claims presented in the application facilitates rejoinder of these method claims in the event that there is a restriction requirement between the eligible product claims and eligible method claims and the product claims are elected.

*(C) Cancer Treatments for Rare Cancers, Including All Childhood Cancers, Using a Specific Pharmaceutical Composition*

The program will consider method claims to treat rare cancers, including all childhood cancers, using a specific pharmaceutical composition, and any product claims to the pharmaceutical composition used to treat the cancer in these method claims. Rare cancers, which include all childhood cancers, are defined by the National Institutes of Health (*see www.cancer.gov/pediatric-adult-rare-tumor/rare-tumors/about-rare-cancers*). If product claims to the pharmaceutical composition are presented in the application, claims to a method to treat a rare or childhood cancer using this pharmaceutical composition must also be presented in the same application and must depend from or be commensurate in scope with the product claims (that is, the method claims must contain all of the limitations of the product claims) throughout the pendency of the application. The method claims to treat a rare or childhood cancer using the pharmaceutical composition are required in the application throughout pendency because the pharmaceutical composition claimed may have an additional use not related to the treatment of cancer. The requirement for the eligible method claims to be commensurate in scope with the eligible product claims in the application facilitates rejoinder of these method claims in the event that there is a restriction requirement between the eligible product claims and eligible

method claims and the product claims are elected.

*(D) Detecting or Treating a Cancer Using a Medical Device Specifically Adapted To Detect or Treat the Cancer*

The program will consider method claims to detect or treat a cancer using a medical device that is specifically adapted to detect or treat the cancer and any claims to the medical device used to detect or treat the cancer in these method claims if the only use disclosed in the specification for the medical device is to treat or detect a cancer. Applications disclosing any use for the medical device claimed or used in the method to treat or detect a cancer that is not related to the treatment or detection of a cancer are not eligible for the program.

For the purposes of this program, a medical device and a medical device specifically adapted to detect or treat a cancer are defined as follows: A medical device is defined as an instrument, apparatus, machine, or implant used in the diagnosis or treatment of a disease. A medical device specifically adapted to detect or treat a cancer is a medical device that is modified or adapted in some way that enables it to detect or treat a cancer.

If claims to the medical device are presented in the application, claims to a method to detect or treat a cancer using the medical device must also be presented in the same application and must depend from or be commensurate in scope with the claims to the medical device (that is, the method claims must contain all of the limitations of the claims to the medical device) throughout the pendency of the application.

The requirement for the eligible method claims to be commensurate in scope with the claims to the medical device in the application facilitates rejoinder of these method claims in the event that there is a restriction requirement between the claims to the medical device and the eligible method claims and the claims to the medical device are elected. The eligible method claims to detect or treat a cancer using the medical device are required in the application throughout pendency because the medical device claimed may have an additional use (not disclosed in the specification) that is not related to the treatment of a cancer.

*(E) Treating a Cancer by Administering a Specific Pharmaceutical Composition After Diagnosing the Cancer*

The program will consider method claims to treat a cancer by administering a specific pharmaceutical composition wherein the method comprises a step to diagnose the cancer and any product claims to the pharmaceutical composition used to treat the cancer in these method claims. If product claims to the pharmaceutical composition are presented in the application, claims to a method to treat a cancer using this pharmaceutical composition must also be presented in the same application and must depend from or be commensurate in scope with the product claims (that is, the method claims must contain all of the limitations of the product claims) throughout the pendency of the application. The method of treatment claims using the pharmaceutical composition are required in the application throughout pendency because the pharmaceutical composition claimed may have an additional use not related to the treatment of cancer. The requirement for the eligible method claims to be commensurate in scope with the eligible product claims in the application facilitates rejoinder of these method claims in the event that there is a restriction requirement between the eligible product claims and eligible method claims and the product claims are elected.

*(F) Treating a Nicotine Dependency and Promoting Smoking Cessation by Administering a Specific Pharmaceutical Composition*

The program will consider method claims to treat a nicotine dependency and promote smoking cessation by administering a specific pharmaceutical composition and any product claims to the pharmaceutical composition used to treat the nicotine dependency in these method claims. If product claims to the pharmaceutical composition are presented in the application, claims to a method to treat the nicotine dependency using this pharmaceutical composition must also be presented in the same application and must depend from or be commensurate in scope with the product claims (that is, the method claims must contain all of the limitations of the product claims) throughout the pendency of the application. The method of treatment claims using the pharmaceutical composition are required in the application throughout pendency because the pharmaceutical composition claimed may have an additional use not related to the treatment of a nicotine dependency. The requirement for the eligible method claims to be commensurate in scope with the eligible product claims in the application facilitates rejoinder of these method claims in the event that there is a restriction requirement between the eligible product claims and eligible method claims and the product claims are elected.

**VI. Internal Processing of the Petition Under the Pilot Program**

If an applicant files a petition to make special under the pilot program, the USPTO will not render a decision on the petition until the application is in condition for examination. Any inquiries concerning a particular 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 pilot program. The application will then be placed on an examiner's special docket until a first Office action is issued. After the first Office action, the application will no longer be treated as special during examination. For example, if an amendment is filed, it will be placed on the examiner's regular amended docket.

The 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 1.821–1.825 or 1.831–1.835, as applicable, such that the application is not in condition for examination, or if the application and/or petition do not meet all the requirements set forth in this notice, the USPTO may 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 pilot program, the applicant must file a reply via Patent Center that includes appropriate corrections and a properly signed petition form PTO/SB/465 within 1 month or 30 days, whichever is longer, from the mail/notification date of the notice informing the applicant of the deficiency. 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 accepted into the pilot program and will be taken up for examination in regular turn.

In addition, the petition will be dismissed without an opportunity for correction if any of the following deficiencies exist: (1) the petition was not filed prior to the first Office action (including an Office action containing only a restriction requirement); (2) the specification, abstract, and claim(s) of the application were not submitted in DOCX format at the time of filing or

national stage entry; (3) the application or national stage entry was not filed electronically in Patent Center; (4) 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; (5) the application was previously granted special status; (6) the application does not contain at least one method claim that complies with the eligibility requirements set forth in section V of this notice; or (7) 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.

**VII. Requirement for Restriction or Unity of Invention**

If the claims in the application are directed to multiple inventions, the examiner may make a requirement for restriction or unity of invention in accordance with current restriction practice. If such a requirement is made, the applicant must make an election without traverse to an invention that meets the eligibility requirements of this program.

If the applicant elects the product or apparatus, claims to the qualifying method will be withdrawn but must remain pending and depend from or be commensurate in scope with the examined product or apparatus claims (that is, the qualifying method claims must contain all of the limitations of the examined product or apparatus claims). Any reply to an Office action that cancels all of the method claims that meet the eligibility requirements for the pilot program or does not present eligible method claims that are commensurate in scope with or depend from the product or apparatus claims under examination will be treated as not fully responsive. The petition must include a statement that if the applicant elects a product or an apparatus for examination, the applicant agrees to present eligible method claims that are commensurate in scope with or depend from the claims to the elected product or apparatus throughout the pendency of the application.

Where the 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 MPEP. In the event of rejoinder, the requirement for restriction between the product or apparatus claims and the rejoined method claims will be withdrawn, and the rejoined method claims will be fully examined for patentability in accordance with 37 CFR 1.104.

**VIII. Period for Reply by the 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.

**IX. Replies by the Applicant Under the Pilot Program**

Throughout the pendency of an application granted special status under the pilot program, the applicant's replies to Office actions must be fully responsive to the rejections, objections, and requirements made by the examiner. Any amendment filed in reply to an Office action may be treated as not fully responsive if it attempts to: (1) add claims that would result in more than 3 independent claims or more than 20 total claims pending in the application; (2) add any multiple dependent claim(s); (3) cancel all method claims that meet the eligibility requirements of the pilot program; or (4) cancel all claims to the elected invention. The amendment may also be treated as not fully responsive if it does not present eligible method claims that are commensurate in scope with or depend from the claims to the elected product or apparatus. If a reply to a non-final Office action is not fully responsive for the reasons set forth above but is a *bona fide* attempt to advance the application to final action, the examiner may, at their discretion, issue a notice of nonresponsive amendment and provide a shortened statutory period of two months for the 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 be permitted, but in no case can any extension carry the date for reply to this notice beyond the maximum period of *six months* set by statute (35 U.S.C. 133). However, any further nonresponsive amendment typically will not be treated as *bona fide;* therefore, the time period set in the prior notice will continue to run.

**X. After-Final and Appeal Procedures**

Any amendment, affidavit, or other evidence after a final Office action and prior to appeal must comply with 37 CFR 1.116. During the appeal process, the application will be treated in accordance with the normal appeal procedure (*see* MPEP Chapter 1200).

**XI. Withdrawal From the Pilot Program**

There is no provision for withdrawal from the pilot program. The applicant may abandon an application that has been granted special status under the pilot program in favor of a continuing application. However, a continuing application will not automatically be granted special status based on the petition filed in the parent application. Each application (including each continuing application) must, on its own, meet all requirements for special status under the pilot program, and be accompanied by its own petition as detailed in section IV above.

**Katherine K. Vidal,**

*Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.*

[FR Doc. 2022–26776 Filed 12–8–22; 8:45 am]

**BILLING CODE 3510–16–P**

## COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

### Procurement List; Deletions

**AGENCY:** Committee for Purchase From People Who Are Blind or Severely Disabled.

**ACTION:** Deletions from the Procurement List.

**SUMMARY:** This action deletes service(s) from the Procurement List that were furnished by nonprofit agencies employing persons who are blind or have other severe disabilities.

**DATES:** *Date deleted from the Procurement List:* January 8, 2023.

**ADDRESSES:** Committee for Purchase From People Who Are Blind or Severely Disabled, 355 E Street SW, Suite 325, Washington, DC 20024.

**FOR FURTHER INFORMATION CONTACT:** Michael R. Jurkowski, Telephone: (703) 785–6404 or email *CMTEFedReg@AbilityOne.gov*.

**SUPPLEMENTARY INFORMATION:**

**Deletions**

On 8/19/2022 and 9/9/2022, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice of proposed deletions from the Procurement List. This notice is published pursuant to 41 U.S.C. 8503 (a)(2) and 41 CFR 51–2.3.

After consideration of the relevant matter presented, the Committee has determined that the product(s) and service(s) listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 8501–8506 and 41 CFR 51–2.4.