

## IP News Alert

# PATENT OFFICE ESTABLISHES PILOT PROGRAM FOR ACCELERATED REVIEW OF CANCER IMMUNOTHERAPY APPLICATIONS

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- USPTO establishes new pilot program for patent applications pertaining to cancer immunotherapy
- Qualifying applications will be granted special status and undergo accelerated examination

### Overview

In support of the National Cancer Moonshot initiative to eliminate cancer, the U.S. Patent and Trademark Office (USPTO) recently established the “[Patents 4 Patients](#)” program, also known as the “Cancer Immunotherapy Pilot Program” (“the Program”). The Program permits accelerated review of qualifying patent applications claiming a method of cancer immunotherapy.



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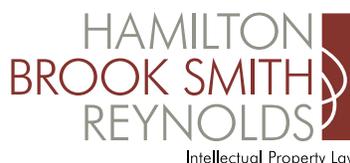
### Highlights of the Program

The goal of the Program is to provide applicants with a “fast-track” review option for patent applications relating to cancer immunotherapy. Upon filing a grantable Petition to Make Special under the Cancer Immunotherapy Program, qualifying applications will be advanced out of turn (i.e., given special status), and the Patent Office will aim to issue a final decision within one year from the date the application is granted special status. There is no fee to participate in the Program. The Program is slated to run for 12 months from its effective date of June 29, 2016.

### Requirements of the Program

Applicants seeking to take advantage of the Program must comply with the following basic requirements:

- the application must be a non-reissue, non-provisional utility application in the field of Oncology;
- the application must include at least one claim to a method of treating a cancer using immunotherapy;
- the application must not contain more than three independent claims or 20 total claims, or any multiple dependent claims;
- the application cannot have been granted special status previously, under the Program or otherwise; and
- the applicant must file a grantable Petition to Make Special under the Cancer Immunotherapy Program using Form: [PTO/SB/443](#) via the Patent Office’s electronic filing system, EFS-Web, before June 29, 2017.



## What Qualifies as Immunotherapy?

Examples of claims qualifying as a method of cancer immunotherapy include claims drawn to:

- 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, including, e.g., the administration of cells, antibodies, proteins, or nucleic acids that invoke an active (or achieve a passive) immune response to destroy cancerous cells;
- 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;
- administering a vaccine that works by activating the immune system to prevent or destroy cancer cell growth; and
- *in vivo*, *ex vivo*, and adoptive immunotherapies, including those using autologous and/or heterologous cells or immortalized cell lines.

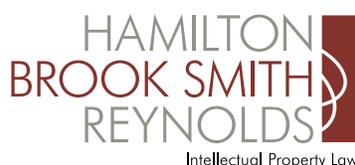
## Other Eligibility Requirements for the Program

Not all applications having a claim to a method of cancer immunotherapy will be eligible for the Program. To qualify for the Program, a patent application must also meet at least one of the following criteria:

- the application has not received a first Office Action (including an Office Action with only a Restriction Requirement);
- the application is eligible for continued examination and a Petition to Make Special under the Cancer Immunotherapy Program is filed concurrently with a Request for Continued Examination (RCE); or
- the application is not under final rejection *and* is the subject of an active Investigational New Drug (IND) application that has entered Phase II or Phase III clinical trials before the FDA.

## Conclusion

The USPTO's free Patents 4 Patients/Cancer Immunotherapy Pilot Program presents an attractive option for applicants seeking to expedite the examination of patent applications with one or more claims to a method of treating cancer using immunotherapy. According to the USPTO, the Office receives approximately 900 cancer immunotherapy applications on an annual basis. Considering the current level of interest surrounding immunotherapy approaches to treating cancer, the number of applications received by the Office in this area is only likely to increase each year. The Cancer Immunotherapy Pilot Program will enable the Office to accelerate the review and examination of many of these applications, lending support to the National Cancer Moonshot initiative.



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