

Insights: Alerts

“Patents 4 Patients”: A New Cancer Immunotherapy “Fast Track” for U.S. Patent Applicants

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Written by Yifan Mao, Charles W. Calkins,

In connection with the White House Cancer Moonshot Initiative, the United States Patent and Trademark Office (“USPTO”) announced on June 29 that it is “Teaming Up to Cure Cancer” by establishing a new accelerated process for protecting (and making publicly available) innovations in treating cancers by immunotherapy. This Cancer Immunotherapy Pilot Program or “Patents 4 Patients” program (“P4P Program”) began on June 2 and, unless extended, ends on June 29, 2017. The P4P Program is one piece of a concerted drive that includes other programs, such as the new FDA “Oncology Center for Excellence” (“OCE”), to accelerate protection, publication, and regulatory review of cancer-related therapies, with the overriding goal of getting new life-saving therapies to patients as quickly as possible.

The USPTO currently receives about 900 applications a year directed to immunotherapies for cancer – a number that is expected to increase. Under the P4P program, an application that includes a claim to a method for treating a cancer using immunotherapy will, upon filing a grantable petition, be taken up out of turn (*i.e.*, first) for examination and will receive final decisions within twelve months.

A patent application is eligible for the P4P Program if it:

- is a non-reissue, nonprovisional utility application, or an international application that has entered the national phase;
- contains at least one claim to a method of treating a cancer using immunotherapy, *i.e.*, a method of ameliorating, treating, or preventing a malignancy in a human subject wherein at least one step of the method assists or boosts the immune system in eradicating cancerous cells;
- contains no more than three independent claims, no more than 20 total claims, and no multiple dependent claims; and
- has not previously been granted special status under this or any other USPTO program.

To participate in the P4P Program, an applicant must file a petition requesting the application be made part of the Program. The P4P Program is open to any applicant, from bio-tech startups, to universities, to big pharma – even entities with products already in FDA-approved clinical trials may be able to opt in. Special status under the P4P Program is contingent on early publication of the patent application, consistent with the program’s goal of removing extended prosecution as a barrier to research and development.

Patent applicants in the field of cancer immunotherapy must act quickly to take advantage of this program. Applicants should evaluate pending applications to determine whether they can be recast or refocused to be eligible for special status, and may want to accelerate national phase application in the U.S. Inventors should consider focusing pre-filing efforts on gathering data sufficient to support claims for treatment methods that include enhancing or stimulating the human immune system to attack cancerous cells.

For more information on the Patents 4 Patients Program and other intellectual property issues relating to cancer immunotherapy and other drugs and biologics, please see sources² or contact the authors of this Legal Alert.

To view a printer-friendly version of this alert, [click here](#).

¹ <https://www.federalregister.gov/articles/2016/06/29/2016-15533/cancer-immunotherapy-pilot-program>

Related People



Yifan Mao

t 650.324.6311

ymao@ktslaw.com



Charles W. Calkins

t 336.607.7315

ccalkins@ktslaw.com