

RESEARCH ARTICLE**Cancer Immunotherapy Pilot Program- extended to June 30, 2022 – Launch your patent application under the Cancer Moon Shot Program before it is too late!****Authors**

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Abstract

Patent protection for cancer treatments is critical to safeguard the considerable time, effort and expenses involved in such endeavors. The United States Patent Office has a special program that enables cancer researchers to obtain patent protection for their inventions with unprecedented speed (less than one year!) and without any additional fees required. The Cancer Immunotherapy Pilot Program has been extended to June 30, 2022. This program has proven to be exceptionally useful in advancing the protection and commercialization of cancer treatments and should be employed by everyone in the cancer research field.

Andre Gide once said, “One doesn't discover new lands without consenting to lose sight of the shore for a very long time.” The journey every single inventor makes through the patenting process is admittedly uncertain, with no assurances that it will result in an issued patent. But a terrific program implemented by the United States Patent and Trademark Office (USPTO) makes such a journey far shorter than it would otherwise be. The “Patents 4 Patients” program, also known as the “Cancer Moon Shot” program, was introduced in 2016 and has now been extended until **June 30, 2022**, now entitled “Cancer Immunotherapy Pilot Program.” This program permits patent applications pertaining to cancer immunotherapy to be advanced out of turn for examination and reviewed earlier (accorded special status). It provides for the extremely prompt examination of qualifying patent applications – without any additional fees – and has resulted in the issuance of over 400 patents in the last few years – which otherwise would not have issued for years to come.

The number of Americans who contract cancer each year is about 1.7 million, with almost 590,000 dying annually from the disease. With the issuance of patents, entities financially backing inventors of cancer therapies are provided with the certainty they desire, permitting them to focus their resources on implementing such new, lifesaving technologies, as well as giving them an

incentive to take further risks in attempting to secure patent rights for the latest cancer related innovations.

The patent process is uncertain and variable due to a variety of factors, including the art unit assigned the case, the examiner, the prior art at issue, how the claims are drafted, etc. The time it takes to get to a No or Yes as to patent allowance is also uncertain – putting pressure on those responsible for deciding whether they should continue to spend precious resources to attempt to protect inventions that are believed to be promising but that have not yet proven themselves. Hence, the critical question: Is it worth the time and expense of attempting to patent an invention in view of such uncertainties? At least for cancer related inventions – the answer is an unequivocal “yes.”

The Patents 4 Patients program puts a patent application on a “fast track” at the USPTO, accelerating patent prosecution to cut in half the time it takes for the patent examiner to arrive at either a Notice of Allowance or a final rejection of the presented claims. Petitions to enter the program are granted with unprecedented speed, typically within about 30 days, and complete prosecution of a case is performed in less than 12 months after the petition is granted.

In the cancer field, the cost of drug development has been estimated to be as high as \$1.3 billion per drug. To fend off generic competition, companies desire some confidence that they will be afforded patent protection. The Patents 4 Patients program, while in no way eliminating the risks inherent in the patenting process, provides a far more timely assurance that embarking on the patent journey will be more akin to a direct jet flight rather than a slow boat cruise.

In practice, the Patents 4 Patients program is truly simple. The petition must be filed either at least one day before a first Office Action is issued or with a proper request for continued examination (RCE). Moreover, if a cancer immunotherapy method has entered phase II or III clinical trials, then a petition may be filed even after a first office action (but before a final office action) from the USPTO. Such petitions are acted upon within about a month and the vast majority (over 90%) are promptly granted. While only 20 total claims (3 independent) can be pursued, with at least one directed to a cancer treatment, and despite there being no option to seek extensions of time to respond beyond the 3 months afforded after an office action, the program is extremely efficient in moving the case forward.

One of the best aspects of the program is that it is entirely FREE. Normally, requesting a “fast track” examination costs a large entity (one that has over 500 employees) \$4000, with a small entity being charged \$2000. Moreover, it has been the author’s experience that the patent examiner’s focus and attention is increased under the expedited examination, as he/she does not suffer the significant delays encountered in the typical patent prosecution process, which requires the examiner to revisit and re-learn the case and the prior art at issue. Thus, both the speed and quality of the patent examination are enhanced.

From updated statistics generated by the USPTO on January 5, 2021, there have been a total of 661 submissions under the Program. Of those, 608 were granted and only 21 dismissed (the remainder undecided). That means that the chances of having a patent application accepted under the Program is 97%. The average number of days from the grant of a petition to a first office action on the merits is a mere 29 days. The number of “closed” cases totals 527 (“closed” meaning that the case was either allowed, a final office action issued or it was abandoned), with another 81 pending. As of January 5, 2021 – 420 unique patents have issued under the program.

During his tenure as the director of the USPTO, Andrei Iancu has improved the functioning of the patent examining corps and his directives have increased the quality of patent examination, as well as reduced the variability and uncertainty observed across art units. One of the best programs ever implemented by the USPTO- and that Director Iancu continues to administer - is the Patents 4 Patents program – and for all the reasons set forth above, all cancer researchers should avail themselves of this special opportunity to obtain patent protections for their inventions, thus hastening the day when we can all celebrate effective treatments for the scourge that is cancer.