Cancer Moonshot: USPTO Extends Cancer Immunotherapy Pilot Program Initiative

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Client Alert

The United States Patent and Trademark Office (PTO) issued a Notice today extending the Cancer Immunotherapy Pilot Program (Pilot Program), also known as “Patents 4 Patients.” The Pilot Program, which accelerates the examination of patent applications directed to cancer immunotherapy methods, will now expire on December 31, 2018, absent further extension.

The PTO implemented the Pilot Program a year ago as part of the National Cancer Moonshot initiative. That initiative seeks to transform cancer research and care by substantially accelerating efforts to combat cancer over the next five years. Because the patent system is a driver of innovation, the program aims to advance cancer treatments so that they may reach patients faster. Specifically, the Pilot Program seeks to achieve allowance of meritorious patents within 12 months from filing a petition under the program.

There were more than 900 immunotherapy patent applications pending when the Pilot Program was first implemented. That number likely has grown substantially due to the innovations in the immuno-oncology field. In its Notice, the PTO indicated that 80 petitions have been requested, to date, and nine eligible patents have been granted under the Pilot Program.

To be eligible for fast-track review under the Pilot Program, a patent application must contain at least one claim to a method of treating a cancer using immunotherapy that meets the PTO’s requirements. The applicant may submit a petition before a first Office Action (which may be a Restriction Requirement) or when filing a request for continued examination. After an Office Action has issued, only a patent application that is the subject of an active Investigational New Drug application that has entered phase II or phase III (FDA) clinical trials is eligible for fast-track review. At the time the petition is filed, the patent application may contain only three independent claims and not more than 20 claims total. There is no fee to apply for the program.

The Pilot Program’s extension is encouraging for life science companies, as it confirms the PTO’s commitment to supporting innovation as part of the National Cancer Moonshot initiative. For clients in the immuno-oncology space, the Pilot Program may provide strategic advantages. For example, obtaining a quick patent allowance may maximize patent term extension (PTE) in connection with regulatory approval of a drug therapy. Other PTO programs, such as the PTO’s Track One Prioritized Examination Program, also allows for accelerated patent examination. For this reason, before submitting a petition under the Pilot Program, interested applicants should work closely with patent counsel to confirm which program is the best fit for the company’s overall objectives.