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USPTO Cancer Drug Pilot Program Not Likely To Be Used Much

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The U.S. Patent and Trademark Office announced a pilot program to fast-track examination of patent applications directed to cancer immunotherapy inventions as part of the Obama administration's "Cancer Moonshot" initiative. However, the fast-tracking of drug applications is often not in the best interest of biopharma companies as it eliminates patent term adjustment. The end of a patent term is the most lucrative for drug patents. Thus, the drug industry will likely eschew the pilot program.

On June 28, 2016, Vice President Joe Biden announced new administrative actions to further President Obama's Cancer Moonshot initiative to make a decade of advances in cancer prevention, diagnosis, treatment, and care within five years. Included among the 12 actions announced were programs through the National Cancer Institute (NCI) to expedite access by researchers to cancer compounds and to make clinical trials more accessible to cancer patients, a new program through the U.S. Food and Drug Administration to accelerate cancer product regulatory review, and the establishment by the U.S. Patent and Trademark Office of a fast-track review for cancer treatment-related patents.[1]

This announcement was followed up by a notice in the Federal Register by the U.S. Patent and Trademark Office providing requirements for participation in the Cancer Immunotherapy Pilot Program.[2] Among the requirements is that the application contain at least one claim to a method of treating cancer using immunotherapy. According to the Federal Register, the method of treating cancer using immunotherapy should encompass 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 the eradication of cancerous cells. The stated objective of the pilot program is to complete examination of an application within 12 months of special status being granted. The pilot program will accept petitions filed before June 29, 2017.

NCI administrative actions include forging a public-private partnership with pharmaceutical and biotechnology companies to expedite access through a preapproved formulary list of investigational agents and approved drugs that can be tested for new purposes and in new combinations and making cancer clinical trial data available through an application programming interface.[3]

Administrative action through the FDA includes the creation of the Oncology Center for Excellence to expedite the development of new cancer products by working with directors in other agencies to

enhance coordination of clinical review across oncology-related drugs, biologics and medical devices.[4] Once implemented, this action should help to speed new cancer drug approvals. According to statistics compiled by the FDA, the median approval time in 2015 after receiving a new drug application was 12 months under standard processing and eight months under priority processing.[5]

The creation of programs to make clinical trials more accessible and to accelerate cancer product regulatory review are likely to be widely welcomed; however, the proposal to accelerate the examination of immunotherapy patent applications is not likely to be widely adopted — because a patent that grants quickly is not entitled to patent term adjustment.

Why Pharma Will Likely Not Use the Pilot Program Much

The patent office already has programs for advancing the examination of an application out of turn including the "Track I" program.[6] Under Track I, an applicant need not provide any justification for expediting the examination of an application and need only pay a fee to obtain Track I status.[7] Under the Cancer Immunotherapy Pilot Program, no fee is required for patent applications pertaining to immunotherapeutic drugs. And, similar to the Track I program, a request can be filed in an application under examination if the petition is filed prior to notice of a first office action or is filed with a request for continued examination.

The PTA statutes provide a patent owner with one day of PTA for each day after 14 months from the filing date that the patent office does not mail an action or issue a notice of allowance ("A delay"). The statutes also provide for one day of PTA for each day after three years that the patent office does not issue a patent ("B" delay). And, the statutes provide for one day for each day of delay caused by interference or derivation proceedings ("C" delay). The statutes also require deductions due to failure of the patent applicant to engage in reasonable efforts to conclude prosecution.[8]

According to a study of patents issued between 2008 and 2014, patents in the 1618 (organic compounds) and 1619 (biotechnology and organic chemistry) art units received an average of almost 1.5 years of PTA.[9] If one avails themselves of the pilot program and obtains a quick issuance of their patent, they will not be entitled to any PTA. Pharmaceutical and biotechnological patents often reach their maximum value toward the end of their patent terms — after the inventions have matured through product development, clinical trials, regulatory approval, marketing, and sales growth — thus, companies should be aware of opportunities for extending the term of their patent beyond the standard 20 years.

To emphasize the importance of PTA, consider Celgene's immunotherapeutic drug Revlimid. Celgene's last to expire patent pertaining to Revlimid is U.S. Pat. No. 7,465,800.[10] This patent received 569 days of patent term adjustment. In 2015, Celgene enjoyed $5.8 billion in sales for Revlimid.[11] At that rate of sales and without PTA, Celgene would lose protection against generic competition of $10 million in sales for each of those 569 days — a total projected sales of $9 billion over the entire period of PTA.

For patents pertaining to valuable drugs, it makes economic sense to avoid obtaining a quick patent and instead to drag out the prosecution, appeal the patent office rejections, and engage in additional strategies to obtain the longest possible PTA.

When Does Use of the Pilot Program Make Sense?

For startups and other small companies, its patent estate is usually its biggest asset. When trying to raise

money and pass due diligence analyses by potential purchasers and licensors, issued patents are much more valuable than pending applications that may never be granted. These companies will benefit by using the pilot program to firmly establish their patent estate and limit the costs of patent prosecution.

For large pharmaceutical and biotechnology companies that may be facing generic competition, multiple patents help to stave off generic competition. To win an abbreviated new drug application challenge, the generic company must be successful in defeating every asserted claim of the patents. The more patents there are, the less likely the generic challenge will be successful. Thus, large pharma companies with immunotherapeutic drugs may take advantage of the pilot program to create a patent thicket around their drugs. But the pharma companies should not use the program for its most important patents and last to expire patents.

Conclusion

While welcome, the patent office's Cancer Immunotherapy Pilot Program is likely not to be used very much. The initiatives to make clinical trails more accessible and to accelerate regulatory review will be much more effective to get life saving drugs on the market. The authors hope that the NCI and FDA work quickly to finalize these initiatives.

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[1] https://www.whitehouse.gov/the-press-office/2016/06/28/fact-sheet-cancer-moonshot-summit-vice-president-biden-announces-new.

[2] https://www.federalregister.gov/articles/2016/06/29/2016-15533/cancer-immunotherapy-pilot-program.

[3] http://www.cancer.gov/research/key-initiatives/moonshot-cancer-initiative/milestones/nci-activities.

[4] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm509063.htm.

[5] http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/NDAandBLAApprovalReports/UCM491533.pdf

[6] 37 C.F.R. § 1.102.

[7] The fee is $4000 for a large entity with more than 500 employees and $2000 for a small entity.

[8] 35 U.S.C. § 154 and 37 C.F.R. §§ 1.703.

[9] K. Gaudry and D. Cummings, "Low Examiner Allowance Rates, High Patent Term Adjustments," Law360, April 17, 2014.

[10] See the Patent Data for Revlimid® in the U.S. Federal Drug Administration Orange Book.

[11] "Celgene Reports Fourth Quarter And Full Year Operating And Financial Results," Celgene Corporation, Summit, NJ, January 28, 2016.