

USPTO Announces Cancer Moonshot Expedited Examination Program



The U.S. Patent and Trademark Office (“USPTO”) published a Notice in the Federal Register announcing a new pilot program entitled, “Cancer Moonshot Expedited Examination Pilot Program” (the “Cancer Moonshot Program”) (87 Fed. Reg. 75608 (December 9, 2022)) (the “Notice”) to attempt to further accelerate innovation in the health and medical fields. Beginning on February 1, 2023, this new program will replace the Cancer Immunotherapy Pilot Program and expedite examination for a broader scope of technologies to prevent cancer and advance smoking cessation. The Cancer Moonshot Program is to support President Biden’s recently renewed Cancer Moonshot initiative, which set a new goal of reducing cancer death rate by at least 50% over the next 25 years.

In contrast to the current Cancer Immunotherapy Pilot Program, which required the application to contain a claim to a method of treating a cancer using immunotherapy, the Cancer Moonshot Program covers a wider range of eligible technology areas. Under the new program, applications must be in the field of oncology or smoking cessation and must contain at least one of the following method claims (collectively, the “eligible method claims”):

1. A method of treating or reducing the incidence of a cancer using an immunotherapeutic compound or composition (cancer immunotherapy related technology area);
2. A method of treating a cancer by targeting specific genetic markers or mutations using a specific pharmaceutical composition (personalized medicine related technology area);
3. A method of treating a rare or childhood cancer using a specific pharmaceutical composition (rare cancers related technology area);
4. A method of detecting or treating a cancer using a medical device specifically adapted to detect or treat the cancer (medical device related technology area);
5. A method of treating a cancer by administering a specific pharmaceutical composition wherein the method comprises a step to diagnose the cancer (diagnostic and treatment related technology area); and
6. A method of treating a nicotine dependency and promoting smoking cessation by administering a specific pharmaceutical composition (nicotine dependency and smoking cessation related technology area).

If the application contains “eligible” product or apparatus claims (i.e., claims to the immunotherapeutic compound or composition, the pharmaceutical composition, or the medical device used in an eligible method claim), the eligible method claims must depend from or be commensurate in scope with the eligible product or apparatus claims in the application (i.e., the eligible method claims must contain all of the limitations of the eligible product or apparatus claims).

The Notice details the requirements for petitions to make special under the Cancer Moonshot Program. For example, the application must be a nonprovisional utility patent application and contain no more than 3 independent and 20 total claims, with no multiple dependent claims. The claims must include at least one eligible method claim and a statement to that effect including that the application is limited to the field of oncology or smoking cessation. A statement must be filed indicating that special status was not previously granted for any reason for the application. In addition, a limitation exists on the number of times an inventor can file for special status under this program. Finally, a USPTO form must also be filed with the application, which form contains the necessary certifications for qualification to participate in the program.

Upon granting of the petition, the application will be treated as special on an examiner’s docket and taken up out of turn for examination. The application will be accorded special status until a first Office action, which may be a restriction requirement. After the first Office action, the application will no longer be entitled to special status and will be taken up in a normal course on the examiner’s docket. That is, after the first Office action, the application will undergo regular examination similar to all other applications.

The Notice indicates that the USPTO will periodically evaluate the Cancer Moonshot Program to determine whether and to what extent its coverage should be changed.

Let’s hope that this incentivization program provides a real impact on accelerating innovation in developing new treatments for cancer. And if interested in participating in the program, please contact a Goodwin patent lawyer.