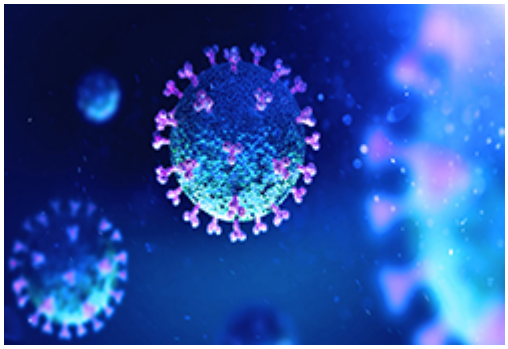
USPTO Deferred-Fee Provisional Application Pilot Program for COVID-19 Related Inventions



In an effort to lend further support to the expedited development of COVID-19-related vaccines and therapeutics (*see* **Covid-19 Prioritized Examination Pilot Program**), the United States Patent and Trademark Office (USPTO) has implemented a deferred-fee provisional patent application pilot program whereby applicants filing under 35 U.S.C. 111(b) can elect to defer the $300.00 USD provisional filing fee ($150 for small entities; $75 for micro-entities) until the filing of a corresponding non-provisional application.

In order to be eligible for the deferred-fee pilot program:

1. the subject matter disclosed in the provisional application must be directed to a product or process related to COVID-19;
2. the product or process must have obtained, be pending, or will seek prior to marketing, Food and Drug Administration (FDA) approval for COVID-19 use;
3. the applicant must submit a technical disclosure, a provisional application coversheet, and a completed PTO/SB/452 form ("Certification and Request for COVID-19 Provisional patent Application Program"); and
4. the applicant must agree that the technical subject matter disclosed in the provisional application will be published on the USPTO website.

While insulated from being cited against an inventor's own later-filed corresponding non-provisional application in the United States, the USPTO warns that special consideration should be taken by applicants seeking international patent protection since "[m]any foreign jurisdictions treat an inventor's public disclosure made within one year of filing as prior art against the inventor's own application unless that earlier disclosure is the subject of a proper priority claim in that jurisdiction."

The USPTO will accept certifications and requests to participate in the deferred-fee program until September 17, 2021, after which the program may be extended beyond that date and may be expanded to other technological areas beyond COVID-19 requiring rapid innovation.

Orange Book Listable?

 When submitting a new drug application ("NDA") with the FDA, an applicant (or branded company) is required to file a list of patents that cover the drug product. These patents will be listed in the FDA's Orange Book upon approval of the drug for commercial sale. Patents that are eligible to be listed in the Orange Book are patents that have claims that cover the drug substance (active ingredient), the drug product (formulation and composition), or the approved method of use.

What patents can't be listed in the Orange Book?

Patents that have claims directed to the process or manufacture of the drug substance, to the packaging of the drug product, or to metabolites or intermediates of the drug substance are not eligible to be listed in the Orange Book.

Why pursue patents that are Orange Book listable?

Competitors seeking to market a generic version of the drug must certify for each patent claiming the drug or the approved use of the drug that (i) such patent information has not been filed; (ii) the patent has expired; (iii) the date the patent will expire; or *(iv) the patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.* Filing a paragraph IV certification can constitute an act of patent infringement and the generic company can be sued before even selling the generic version of the drug. If the branded company files the suit within 45 days of the notice of filing the certification, the FDA will postpone the generic drug approval for 30 months. During this 30 month period, the branded company and the generic competitor can litigate the patent dispute while the generic drug is barred from entering the market. If all patents are held invalid or not infringed, the FDA can proceed to approve the generic drug even if the 30 month period has not yet concluded.

The Purple Book and The Orange Book – When do Patents Expire and Regulatory Exclusivities end for FDA Approved Products?

The Food and Drug Administration (FDA) maintains two searchable online databases for approved products: the **Purple Book** (approved licensed biological products) and the **Orange Book** (approved drug products). The Orange Book provides details about an approved drug product, including the patents covering the approved drug product and the expiration dates of the patents and regulatory exclusivities, leaving investors, competitors, and the public in the dark as to when an approved biological product falls into the public domain.

For example, Sunosi® (solriamfetol hydrochloride) is a small molecule drug developed by Jazz Pharmaceuticals and was approved by the FDA on June 17, 2019 for the treatment of excessive sleepiness in adult patients with narcolepsy or obstructive sleep apnea. The NDA (new drug application) number, patents covering the product, the expiration dates of the patents, and regulatory exclusivity data are provided in the Orange Book.

Contrast this with Evenity® (romosozumab-aqqg), Amgen's monoclonal antibody approved for the treatment of osteoporosis in postmenopausal women at high risk for fracture. The Purple Book provides the approval date, proprietary name and generic name, BLA (biologics license application) number and type, date of first licensure, and a link to the product label. However, the Purple Book does not list the patents covering the product or regulatory exclusivity information. Thus, unlike patent litigation involving generic approvals for small molecule drugs, where the patents that will be involved are predictable based on the Orange Book listings, the patents that will be involved in litigation over a biosimilar approval are typically revealed for the first time during the litigation itself.

China Closer to Granting Patent Term Extensions?

A new draft amendment to Chinese Patent Law was submitted to the National People's Congress

Standing Committee on June 28, 2020. Key provisions include the establishment of patent term adjustment (PTA) caused by delays in the patent office and patent term extension (PTE). Under the new draft amendment, a Patentee could receive up to 5 years of PTE, as long as the overall patent term does not extend beyond 14 years after approval of the drug, similar to PTE available in the United States

The proposed amendments in the draft also address many other weaknesses in biopharma IP protection in China. For example, these changes include litigation reform, including stronger and more efficient patent enforcement, an increase in the statutory limit on damages (up to CNY 5,000,000), and a 6-month grace period for public disclosures made for the benefit of the public during a national emergency.

Notably, the draft also provides for a delay of marketing approval of a new drug, if that new drug is subject to patent dispute. If a lawsuit is filed by an owner of a patent listed in China's "drug patent information registration platform" within 30 days of publication of a marketing approval application, the application is stayed for up to 9 months.

If implemented, these changes would make China a more attractive jurisdiction for life science innovators and biopharmaceutical investment opportunities from around the world.

This new draft is currently available for public comment until August 16, 2020.

USPTO Announces COVID-19 Prioritized Examination Pilot Program for Small or Micro Entities

The United States Patent and Trademark Office (USPTO) is accepting requests for prioritized examination or "fast track" of patent applications that claim a product or process subject to FDA approval for COVID-19 use, without the payment of additional fees. The USPTO will advance accepted patent applications out of turn, aiming to reach a final disposition within one year of granting prioritized status. Up to 500 patent applications will be accepted under the pilot program. As of July 9, 2020, 66 requests had been granted, with 434 acceptances still available.

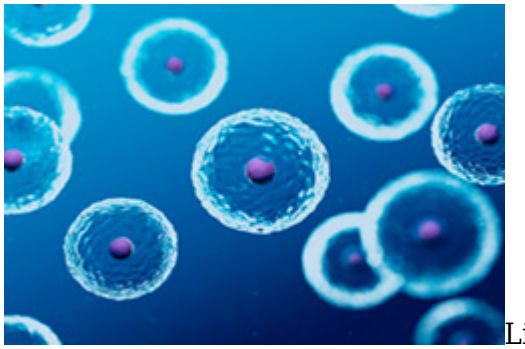
Details regarding the pilot program were published in the Federal Register (**85 Fed. Reg. 28932**). The Federal Register Notice indicates that FDA approvals may include, but are not limited to, an Investigational New Drug (IND) application, an Investigational Device Exemption (IDE), a New Drug Application (NDA), a Biologics License Application (BLA), a Premarket Approval (PMA), or an

Emergency Use Authorization (EUA).

To qualify for consideration under the pilot program, a **request** for prioritized examination must be made with the filing of a new utility or plant nonprovisional application or with the filing of a utility or plant nonprovisional application claiming priority to only one prior nonprovisional or international patent application. In addition, a request for prioritized examination may be filed with or after filing a Request for Continued Examination (RCE) of an existing utility or plant nonprovisional application, but only one such request may be granted in an application. The Applicant also must certify that they qualify for small or micro entity status. Other requirements include the submission of an Application Data Sheet with the application, and limiting the number of claims to 4 independent claims and 30 total claims.

The USPTO has announced that it will periodically evaluate whether the program should be expanded.

Strategic Considerations for Seeking Patent Term Extension (PTE) and Its Scope for Drug Products



Life science companies developing new therapeutics – both small molecule and biologic – know that obtaining long patent term for their products is a key driver of valuation and revenue. A particular challenge in this respect is minimizing the loss of patent term during drug development. Fierce competition in the marketplace often requires that innovators patent their drug products as early as possible in the development process, but because the clock on a United States (patent's lifespan starts running the moment it is filed, years of valuable patent term are often lost as a product navigates the regulatory approval process. An important method to mitigate these losses can be found in the Patent Term Extension ("PTE") provisions of 35 U.S.C § 156, which provide statutory compensation for the substantial time and resources expended by an innovator to bring a new drug to market. In a nutshell, PTE restores a portion of the patent term, up to five years, that is lost during the period a new drug or medicinal product is awaiting pre-market regulatory approval in the U.S.. When a new chemical entity ("NCE") – either a small molecule or a biologic – is approved by FDA as a therapeutic, a patent claiming either the NCE or its method of use may be entitled to PTE.

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When does my patent expire?

To determine when your (or your competitor's) patent expires, first identify the correct filing date of the patent application. A U.S. utility patent (filed on or after June 8, 1995) expires 20 years from the earliest filing date of the patent. If the patent claims priority to an earlier patent application, then the 20 year term starts from the filing date of the earlier patent application. (Note, some earlier patent applications are excluded from this consideration and do not impact the patent term). You can determine if your patent claims priority to an earlier patent application by looking at the first page of the patent for a subsection titled "Related U.S. Application Data." Sometimes this information is also found in the first paragraph of the specification of the patent. If your patent claims priority to one or more earlier-filed patent applications, those patent applications will be listed by their application number and filing date in this subsection. Application numbers can be in the format of an international patent application (having the application serial number format of PCT/XXYEAR/######) or in the format of a U.S. patent application (having the application number format of 01/###,### through 16/###,###). Identify the earliest filing date from these patent applications, and the patent term expires 20 years from this date.

However, if the "Related U.S. Application Data" lists one or more provisional U.S. patent applications (having the application serial number format of 60/###,### through 63/###,###), then these filing dates are not used to calculate patent term. If only provisional U.S. patent applications are listed in the "Related U.S. Application Data" subsection, or if this subsection is missing from the front of the patent, then the filing date for purposes of calculating patent term is the filing date listed on the left front page of the patent, indicated as "Filed:" In this case, the patent term expires 20 years from the filing date on the front page of the patent.

In some cases, a patent may be extended beyond its 20 year term. For example, some patents are awarded a patent term adjustment (PTA) by the United States Patent Office. If a patent is awarded PTA, this is typically listed on the front page of the patent. For example, the front of the patent may state, "Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 246 days." If the patent has this award, add the number of days of PTA to the patent term. Additionally, some patents are awarded a patent term extension (PTE) by the United States Patent Office. If a patent is awarded a PTE, a Patent Term Extension Certificate is filed in the file history of the patent. The file history of the patent can be found at **https://portal.uspto.gov/pair/PublicPair**. If the patent has been awarded a PTE, add the number of days of PTE to the term of the patent in addition to any PTA award.

Finally, a patent term may be shortened. In these cases, the front of a patent may (or may not) state that "This patent is subject to a disclaimer." In this case, the patentee has surrendered any patent term (including any PTA) beyond the expiration date of another patent. Identifying this patent or application can be found by reviewing the file history of the patent at

https://portal.uspto.gov/pair/PublicPair. We recommend you contact your Goodwin life sciences or patent lawyer for a determination of how this disclaimer impacts patent term.