The Future of Patents for Patients: USPTO Temporarily Extends Cancer Immunotherapy Pilot Program (Patents for Patients) and Requests Public Input On Next Steps

On June 29, 2022, the United States Patent & Trademark Office (USPTO) announced that it was temporarily extending its Cancer Immunotherapy Pilot Program ("Patents 4 Patients" or "P4P") to September 30, 2022, and also issued a request for public input on the P4P.

Under the P4P, Applicants can file a petition for expedited examination of a patent application that recites a method of treating cancer using immunotherapy. Petitions to enter the P4P are free, *i.e.*, there is no cost for expediting under this program. This most recently announced extension will allow filing of P4P through September 30, 2022 unless and until the USPTO announces any further extensions.

During the current extension period, the USPTO is also considering whether to further extend and/or modify the P4P. In support of this effort, the USPTO is seeking input from the public. The comment period is open until July 29, 2022.

Once the comment period closes, the USPTO will review and decide whether to: (1) extend the current P4P beyond September 30, 2022; and (2) if so, whether or not to make any modifications, such as by expanding its scope in one or more areas. For example, since the current P4P requires recitation of a method of treatment, one modification could be to allow entry into the P4P based on recitation of compositions of matter, including those which could be used in treating a cancer. Along similar lines, the P4P could be expanded beyond cancer to include other diseases. The official notice can be accessed at the online federal register (**here**) and anyone interested in commenting is able to do so **here**, anytime before midnight July 29, 2022.

Canadian Patent Examination Will Soon Be More Expensive, Less Flexible and Require Additional Care in Prosecution to Avoid Loss of Rights

Canadian Patent Examination

Significant fee increases will be effective at the Canadian Intellectual Property Office ("CIPO") on October 3, 2022 related to excess claims (claims over 20) and the number of examination reports it issues during prosecution. These changes may negatively impact the breadth of patent protection an applicant could pursue in Canada and will likely also require additional care in strategic filing choices during patent examination. Prior to October 3, 2022, applicants should consider requesting examination for pending applications in order to minimize the impact of these fees (the fee increase will not apply to patent applications for which a request for examination is filed prior to October 3, 2022).

Read the client alert **here**.

The Unified Patent Court is (Finally) Coming to Europe and Bringing Some Pretty Fundamental Changes with It

Seven years after the Member States of the EU signed the Agreement on a Unified Patent Court ("UPCA"), the Unitary Patent ("UP") and the Unified Patent Court ("UPC") are likely to commence during the second half of 2022. This promises to bring significant changes to patent protections across Europe, potentially making it easier to both assert *and invalidate* a patent in 24 Member States. Importantly, if current European Patent ("EP") holders wish to opt out of the UP in favor of the existing EP regimen, it will require that they take affirmative steps to do so.

Read the **client alert**.

A Primer on Patenting Ranges

Clinical drug candidates are often claimed in a patent as a pharmaceutical composition or formulation with a specified concentration range of the drug or an excipient; as being purified within certain temperature or pH ranges; or in a method of treating a disease by administering the drug at a certain dosage range. For a claim to be patentable over any prior disclosure, the claim must be novel and nonobvious. But how would a drug developer know that the claimed ranges are patentable over a prior disclosure of overlapping or broader ranges?

Read the **insight**.

Review of FDA's 2021 Drug Approvals – Small Molecules Dominate

The FDA's Center for Drug Evaluation and Research (CDER) approved 50 new drugs and biological products in 2021 (not including the vaccines, cellular and gene therapy products, or other products approved in 2021 by the Center for Biologics Evaluation and Research). As in past years, small molecule drug approvals dominated the list.

Of the 50 approved new drugs and biological products, 33 were small molecule drugs and 17 were monoclonal antibodies and other big molecules drugs. A new ADC (antibody drug conjugate) was approved, Tivdak®, and a bispecific antibody was also approved, Rybrevant®. Notably, a small interfering RNA drug was approved, Leqvio®, for the treatment of atherosclerotic cardiovascular disease.

As small and big molecule drugs enter the clinic, Goodwin's patent attorneys focus on securing not only composition of matter patent protection, but additional patent protection derived from clinical

data. Learn more about additional patent protection secured from the clinic in **Goodwin's Patent Savvy Executive video**.

Each new drug and biological product can be found in the FDA's **Orange Book** or the FDA's **Purple Book**. To learn more about the Orange Book and how to determine patent terms on approved drugs, visit **Goodwin's Patent Savvy Executive video**.

See the full list **here**.

A Joint Research Pitfall – Soon to be Resolved?

Innovators in life sciences at companies and universities often collaborate and conduct research under a joint research agreement (JRA). The Cooperative Research and Technology Enhancement Act of 2004 (the "CREATE Act") was enacted to promote collaboration and cooperative research between different entities. The United States Patent and Trademark Office ("USPTO") recently proposed new rules for filing terminal disclaimers to address a particular issue in the case of JRAs.

Terminal disclaimers can be filed to overcome obviousness-type double patenting rejections. Under the current rules, parties to a JRA can only file a terminal disclaimer if certain circumstances are met. Under the CREATE Act, two patent applications of different ownership are considered commonly owned if an invention at issue was made pursuant to a joint research agreement, the invention is within the scope of the agreement, and the parties to the agreement are the applicants of the application. Even if these requirements are met, a terminal disclaimer can only be filed if the patent or patent application referenced in the double patenting rejection is prior art.

Under current practice, for example, if a company and a university collaborate under a JRA and file two patent applications of different ownership (e.g., one solely owned and the other co-owned) on the same day so that one is not prior art to the other, a terminal disclaimer cannot be filed. In that case, a petition must be filed and granted to waive the requirement.

The USPTO proposed changes to allow an applicant to file a terminal disclaimer even if the referenced patent or application is not prior art without the need to file the petition. These changes, if implemented, will facilitate the management of a patent portfolio subject to a JRA.

Five Tips for Life Sciences Companies to Protect Their AI Technologies

 Given that artificial intelligence (AI) – historically the domain of software companies – is a new frontier for many life sciences companies, we have assembled five helpful tips to consider for protecting AI technologies:

Tip 1: Make sure you have permission to use the data

Familiarize yourself with the data privacy rules applicable to the types of data you are collecting and develop an appropriate consent form with all proper disclosures and terms.

Tip 2: Get IP assignments from everyone contributing to the AI technology

For AI technologies, the universe of contributing individuals may be broader than expected. For example, individuals that: (1) select the data to be acted on by an AI engine, (2) review the outputs of an AI engine, (3) select the algorithms used to train the AI model and tune the modeling parameters, and/or (4) write the source code to implement an AI engine.

Tip 3: Be careful when using open source software

Incorporate good hygiene around your use of open source software and implement policies and procedures to ensure that no source code is used that could jeopardize the secrecy of your proprietary code.

Tip 4: Be thoughtful about the type of legal protection you want for your technology

Consider the following factors when deciding between patent and trade secret protection: (1) likelihood of independent invention, (2) detectability of the invention, and (3) speed of innovation.

Tip 5: If you choose patent protection, employ strategies to maximize chances of success

Describe in your patent applications the AI model's performance and the improvement(s) over conventional techniques. Ideally, use statistical data such as ROC curves, measures of predictive values (PPV or NPV), confusion matrices, F1 scores, and other similar data.

Read the full insight

Got a Broad Chemical Patent? Be Wary.

Idenix's Pharmaceuticals' patent (U.S. Patent No. 7,608,597) was invalidated for having a genus that was "too broad." The trial judge ruled that the patent did not enable a person of skill in the art to select a single compound from the "billions and billions" of compounds encompassed by the genus. On appeal, the Federal Circuit upheld the trial judge's ruling of non-enablement. On January 19, 2021, the Supreme Court of the United States (SCOTUS) declined to review the Federal Circuit's decision to invalidate Idenix's patent.

This decision is likely to have effects across the pharmaceutical and biotech field. The Federal Circuit's ruling may narrow the scope of generic protection granted to pharmaceutical companies for novel drug scaffolds. Chemical genus claims are often used to deter "fast followers" from making small modifications to a drug's design to avoid patent coverage. In their amici briefs, both GlaxoSmithKline and Amgen argued that this narrowing would result in a decrease in innovation across the pharmaceutical space.

Idenix's patent claimed a method of treating Hepatitis C virus (HCV) infection by administering a class of synthetic nucleosides, β-D-2′-methylribofuranosyl nucleosides, also known as a "2'-methyl-up nucleosides". Idenix's patent covered any 2′-methyl-up nucleoside which fell within the claimed chemical genus that was effective in treating HCV. Idenix sued Gilead Sciences, alleging the '597 patent's claimed genus encompassed the compound sofosbuvir, an active ingredient in Gilead's hepatitis C drugs Sovaldi and Harvonis. In 2016, a Delaware jury agreed and awarded Idenix $2.5 billion. However, the district judge set aside the jury's verdict, ruling the patent was invalid on enablement grounds. The judge contended this genus was too broad, and the patent did not enable a person of skill in the art to select a single compound from the "billions and billions" of compounds encompassed by the genus.

On appeal, the Federal Circuit determined the patent did not provide "meaningful guidance" or "useful blaze marks" to direct a person of skill to specific effective hepatitis C therapeutics within the claimed genus. That a person of ordinary skill in the art would not know, without undue experimentation, which 2′- methyl-up nucleosides would be effective for treating HCV. The court concluded that the working examples present in the patent were "very narrow, despite the wide breadth of the claims at issue" and were insufficient to enable such a broad genus.

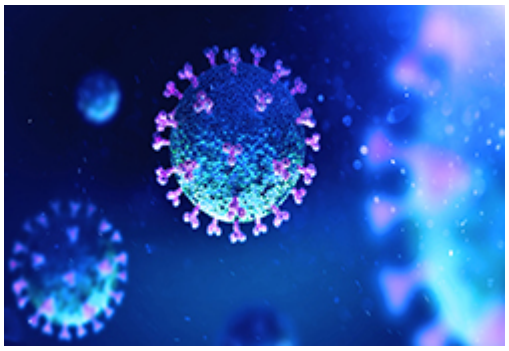
Merck & Co. acquired Idenix Pharmaceuticals for $3.85 billion in 2014.

Congress Enacts Amendments Affecting The Regulation Of Generic Drugs And Biosimilars

 On December 27, 2020, the President signed into law the "Consolidated Appropriations Act, 2021" (the "Act"). Included within this omnibus legislation are several provisions (in Division BB, Title III, Subtitle C) that affect the regulation of generic drugs and biosimilar medicines by the U.S. Food and Drug Administration (FDA).

Read the Alert >>

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.