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.

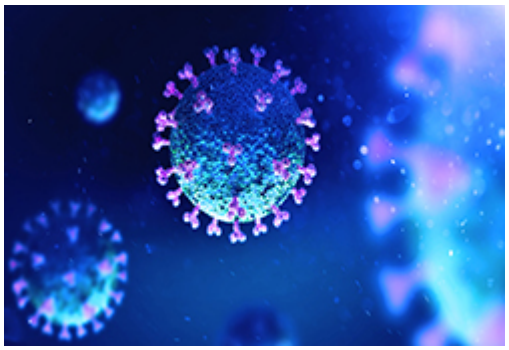
Merck & Co. acquired Idenix Pharmaceuticals for $3.85 billion in 2014.

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.

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

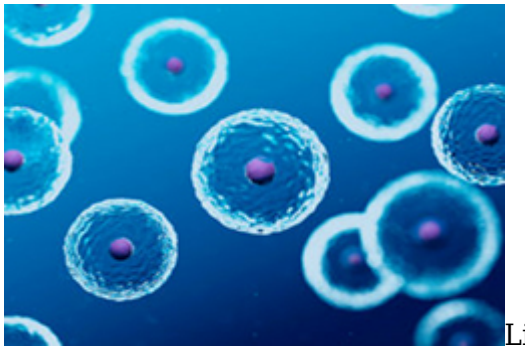
 The United States Patent and Trademark Office (USPTO) is accepting requests for prioritized examination or "fast track" of patent applications that claim a product or process subject to FDA approval for COVID-19 use, without the payment of additional fees. The USPTO will advance accepted patent applications 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.

Read the Insight >>