USPTO Doubles Down Calling Out Pharmaceutical Industry

 The new Director of the U.S. Patent and Trademark Office (USPTO), Katherine Vidal, published a stern reminder regarding the duties of disclosure and reasonable inquiry during examination of a patent application, including reexamination, reissue, and proceedings before the Patent Trial and Appeal Board (PTAB) (87 FR 45764 (July 29, 2022)). The justification was to provide examiners and judges with all the material information needed to decide on patentability of a claimed invention. According to the USPTO, more robust and reliable patents should result, which is better for the public. **See** *USPTO Publishes Notice Calling Out Pharmaceutical Industry*, Goodwin Life Sciences Perspective blog, August 1, 2022.

The USPTO now published a Request for Comments (RFC) (87 FR 60130 (October 4, 2022)) on USPTO initiatives to ensure "robustness and reliability" of patent rights, the new buzz words for increased patent quality. Again, the pharmaceutical industry appears to be the main target of the new initiatives. In the background section is President Biden's Competition Executive Order (EO) that calls for action "to help ensure that the patent system, while incentivizing innovation, does not unjustifiably delay generic drug or biosimilar competition beyond that reasonably contemplated by applicable law." The RFC also references the Food and Drug Administration and USPTO interactions and communications to help promote the EO.

In particular, the new initiatives for "robust and reliable" patents are primarily directed to preventing what's been termed, "patent thickets," which has been defined by Senators Leahy, Blumenthal, Klobuchar, Cornyn, Collins and Braun as a "large number of patents that cover a single product or minor variations on a single product." According to the Senators, patent thickets impede the generic drug industry to the detriment of the U.S. public.

Included in the new USPTO initiatives to execute the EO are more time and resources to examine patent applications, enhanced processes for information disclosure statements and the identification of key prior art, consideration of applying greater scrutiny to continuation patent applications and use of declaratory evidence during patent prosecution, revisiting terminal disclaimer practice and procedures for third party input during prosecution, and a comparative analysis of the prosecution and grant of "pharmaceutical and biological patents" in the United States versus other countries.

The stated primary purpose of this RFC is to solicit comments from the public on these initiatives, the latter of which is specific to the pharmaceutical industry. Of note, though, the specific topics and initiatives currently being addressed in the RFC are prior art searching, e.g., databases of non-patent literature, support for patent claims in continuation patent applications including priority dates, request for continued examination (RCE) practice, and restriction, divisional, and terminal disclaimer practices.

The RFC includes a list of eleven questions. The first five, some with many subparts, address the USPTO topics and initiatives discussed immediately above. The final six questions are directly from

a letter from the Senators to the USPTO. These latter questions are quite enlightening as to what's in the minds of the Senators and their possible solutions to their perceived problems with the U.S. patent system.

More specifically, the Senators question terminal disclaimer practice, suggesting eliminating it to prohibit patents that are obvious variants. Another question suggests that patents terminally disclaimed over each other should stand or fall together with respect to their validity because they are all obvious variants of each other. Other questions lean towards higher scrutiny and examination of continuation patent applications including limiting the time frame when such applications can be filed and increasing the fees for such filings.

Although the specific questions posed do not single out patents of the pharmaceutical industry nor include a comparison of such patents to non-U.S. counterpart patents, the incentive for the RFC, which typically precedes a notice of proposed rulemaking, seems to signal an attempt to change the current patent practices of the pharmaceutical industry.

In sum, similar to the USPTO Notice on disclosure requirements, although all technologies are included, the RFC appears to be directed most specifically to brand name pharmaceutical companies. Is the RFC another a shot over the bow of the brand name pharmaceutical companies' patent filing and prosecution strategies? Is this more signaling of the beginning of higher scrutiny for their patent applications and the "patent thickets" they create? If so, will such scrutiny permit generics to enter the marketplace earlier, to meet the Administration's objectives? Again, only time will tell.

USPTO Publishes Notice Calling Out Pharmaceutical Industry

President Biden's *Executive Order on Promoting Competition in the American Economy*, 86 FR 36987 (2021), expressed concerns about the patent system being misused to unnecessarily inhibit or delay entry of generic drugs or biologics to the marketplace for years, denying Americans access to lower cost drugs. The President called for action "to help ensure that the patent system, while incentivizing innovation, does not unjustifiably delay generic drug or biosimilar competition beyond that reasonably contemplated by applicable law."

The Food and Drug Administration (FDA) was charged with the task of identifying any concerns with the patent system being used in such an unjustified way. To this end, the FDA reached out to the U.S. Patent and Trademark Office (USPTO) in a cooperative spirit to promote further interactions to

better understand their overlap in work and information, particularly where inconsistent statements might be made to each agency.

In response to the President and the FDA's outreach, the new Director of the USPTO, Katherine Vidal, published in the Federal Register (87 FR 45764 (July 29, 2022)) a stern reminder regarding the duties of disclosure and reasonable inquiry during examination of a patent application, including reexamination, reissue, and proceedings before the Patent Trial and Appeal Board (PTAB). The justification is to provide examiners and judges with all the material information needed to decide on patentability of a claimed invention. Consequently, more robust and reliable patents should result, which is better for the public.

The Notice reminds us of who has duty to disclose material information and what material information needs to be disclosed. In essence, anyone associated with the prosecution of a patent application or involved in the examination of a patent before the USPTO or PTAB is required to disclose to the patent examiner or administrative law judge information that would be material to the patentability of the claimed invention. Material information could include communications from other government agencies, for example, from the FDA.

The Notice also details what is the duty of reasonable inquiry. For example, a party filing a paper with the USPTO has a duty to perform an inquiry as reasonable under the circumstances, which may include reviewing documents received from another government agency, for example, the FDA. If the document is material to patentability, then the document must be appropriately submitted to the USPTO.

The final section of the Notice is under the heading, "When the Duties of Disclosure and Reasonable Inquiry Arise in Dealings With Other Government Agencies," which section emphasizes the consistency of statements made to different agencies and the need to correct statements later learned to be incorrect at the time they were made. Activities and publications associated with testing, marketing, and commercialization by a patentee or patent applicant can also be material to patentability and must be disclosed. Examples also include information learned from a generic company filing an Abbreviated New Drug Application (ANDA) and namely, a paragraph IV certification alleging that the patent(s) covering the brand name drug product are invalid. The prior art cited in the ANDA certification must be cited to the USPTO unless cumulative to publications already cited.

Of particular note is the discussion of inequitable conduct when inconsistent positions were taken before the USPTO and the FDA. The Notice details a number of examples of where inconsistent statements led to detrimental effects for the malfeasance. The Notice further warns that attempts to wall off patent practitioners from the FDA lawyers to prevent learning of possible material information are inappropriate and likely will have dire consequences. "By following the guidance in this notice, it is expected that patent applicants can obtain more reliable patent protection and avoid the findings of inequitable conduct and sanctions noted [herein]."

In sum, although all technologies are included, the Notice appears to be directed most specifically to brand name pharmaceutical companies and their dealings with the USPTO and FDA. Is the Notice a shot over the bow of the brand name pharmaceutical companies' patent filing and prosecution strategies? Is this signaling the beginning of higher scrutiny for their patent applications and the "patent thickets" they create? If so, will such scrutiny permit generics to enter the marketplace earlier, which ultimately could mean cheaper medicines sooner, meeting the Administration's objectives? Only time will tell.

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**.

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.

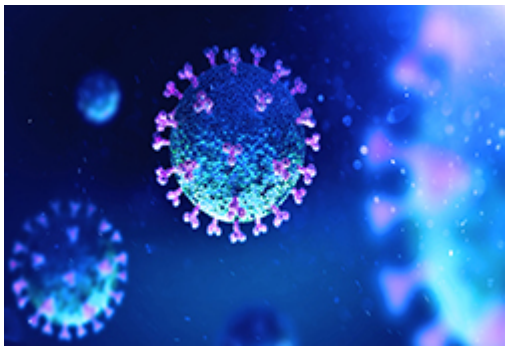
Idenix's patent claimed a method of treating Hepatitis C virus (HCV) infection by administering a class of synthetic nucleosides, β-D-2′-methylribofuranosyl nucleosides, also known as a "2'-methyl-up nucleosides". Idenix's patent covered any 2′-methyl-up nucleoside which fell within the claimed chemical 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.

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.