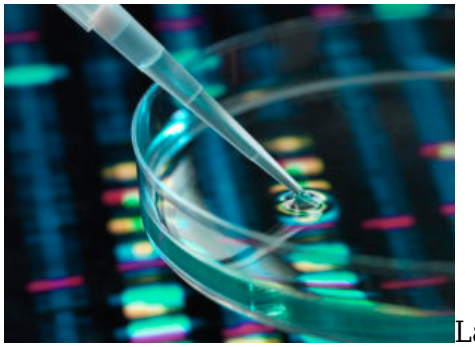
Is it Biosimilar or Interchangeable? It Won't Be Easy to Tell Under FDA's Latest Draft Labeling Guidance



Last week, **FDA released** a draft guidance, "**Labeling for Biosimilar and Interchangeable Biosimilar Products**" that—when finalized—will revise and replace its July 2018 final guidance, "**Labeling for Biosimilar Products**." FDA noted that this 2023 Draft Guidance reflects recommendations based on the "valuable experience about labeling considerations" that FDA has gained through its approval of 42 biosimilar products, including four interchangeable biosimilar products.

Notably, the 2023 Draft Guidance provides further recommendations regarding when to use a biosimilar or interchangeable biosimilar product name, and when to use the reference product name in labeling:

- The biosimilar or interchangeable biosimilar product's proprietary name[1] (or if the product does not have a proprietary name, its proper name[2]) should be used when –
  - Information in the labeling is *specific to the biosimilar (or interchangeable biosimilar) product*, including such references to the product in the INDICATIONS AND USAGE, DOSAGE AND ADMINISTRATION, DESCRIPTION, and HOW SUPPLIED/STORAGE AND HANDLING sections, and/or
  - For "directive statements and recommendations for preventing, monitoring, managing, or mitigating risk," including such references to the product in the BOXED WARNING, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, and DRUG INTERACTIONS sections.

- When referring to the *drug substance* in the labeling, the biosimilar or interchangeable biosimilar product's proper name should be used.

- When information *specific to the reference product* is described in the biosimilar or interchangeable biosimilar product's labeling (for example, data from clinical trials of the reference product in the ADVERSE REACTIONS and CLINICAL STUDIES sections), the reference product's proper name should be used.

- In sections of the labeling containing *information that applies to both the biosimilar (or interchangeable biosimilar) product and the reference product*—such as BOXED WARNING, CONTRAINDICATIONS, WARNINGS AND PRECAUTIONS, ADVERSE REACTIONS—the labeling should use the core name of the reference product followed by the word "products."[3]

FDA acknowledges that the application of these recommendations is highly context-dependent and

may not always be clear, but recommends that biosimilar and interchangeable biosimilar product sponsors evaluate all statements in product labeling carefully to determine the most appropriate product identification approach in each instance.

Another noteworthy aspect of the 2023 Draft Guidance is the Agency's recommendation regarding the biosimilarity statement and footnote in the HIGHLIGHTS section of a biosimilar or interchangeable biosimilar product's labeling.[4] Previously, FDA recommended a biosimilarity statement for a biosimilar product and an interchangeability statement for an interchangeable biosimilar product. The 2023 Draft Guidance now recommends a statement and footnote in the HIGHLIGHTS section that the product is biosimilar to the reference product, *regardless of* whether the product is a biosimilar or an interchangeable biosimilar to the reference product. In the **Federal Register notice** announcing the 2023 Draft Guidance, FDA acknowledges that this marks an "evolution in our thinking" and explains that "a labeling statement noting that certain products within a 351(k) [Biologics License Application] have been approved as interchangeable, and explaining the interchangeability standard, is not likely to be useful to prescribers, who can prescribe both biosimilar and interchangeable biosimilar products in place of the reference product with equal confidence that they are as safe and effective as their reference products." FDA further states that "information about interchangeability is more appropriately located in the Purple Book rather than labeling."

Other notable elements of the 2023 Draft Guidance include recommendations regarding how to describe pediatric use data in a range of scenarios and how to incorporate immunogenicity data. With respect to immunogenicity data, the 2023 Draft Guidance suggests that a contextual paragraph[5] generally be included in the relevant CLINICAL PHARMACOLOGY subsection before describing the available immunogenicity data for the reference product and the biosimilar or interchangeable biosimilar product. The 2023 Draft Guidance also outlines the Agency's expectations for patient labeling—such as a Medication Guide, Patient Information, or Instructions for Use—for a biosimilar or interchangeable biosimilar product, if the reference product has such patient labeling.

Information on how to submit comments on the 2023 Draft Guidance can be found at **https://www.regulations.gov/docket/FDA-2016-D-0643.**

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[1] The proprietary name of a biosimilar product is a brand name determined by the sponsor. The fictitious example provided in the 2023 Draft Guidance is "NEXSYMEO."

[2] The proper name of a biosimilar product is the nonproprietary name designated by FDA that consists of a biological product's core name plus a unique four-letter suffix. The fictitious example provided in the 2023 Draft Guidance is "replicamab-cznm."

[3] The fictitious example provided by FDA in the 2023 Draft Guidance is "replicamab products".

[4] The fictitious example provided by FDA in the 2023 Draft Guidance is "NEXSYMEO (replicamab-cznm) is biosimilar* to JUNEXANT (replicamab-hjxf)" and the accompanying footnote is "Biosimilar means that the biological product is approved based on data demonstrating that it is highly similar to an FDA-approved biological product, known as a reference product, and that there are no clinically meaningful differences between the biosimilar product and the reference product. Biosimilarity of *[BIOSIMILAR OR INTERCHANGEABLE BIOSIMILAR PRODUCT'S PROPRIETARY NAME]* has been demonstrated for the condition(s) of use (e.g., indication(s), dosing regimen(s)), strength(s), dosage form(s), and route(s) of administration) described in its Full Prescribing Information."

[5] The Agency's suggested paragraph is, "The observed incidence of anti-drug antibodies is highly dependent on the sensitivity and specificity of the assay. Differences in assay methods preclude meaningful comparisons of the incidence of anti-drug antibodies in the studies described below with the incidence of anti-drug antibodies in other studies, including those of [*proper name of reference product*] or of other [*core name*] products."

Supreme Court Affirms Amgen Patents' Invalidity in Closely Watched Enablement Case

The U.S. Supreme Court has decided a closely watched case regarding patent law's enablement requirement, *Amgen Inc. v. Sanofi*. The Supreme Court affirmed the Federal Circuit's decision that Amgen's patent claims were invalid, holding that the patents' disclosures "offer[ed] persons skilled in the art little more than advice to engage in 'trial and error.'"

The Court's decision was unanimous. Although Amgen and various amici had urged the Court to adjust the standard for enablement in ways that would favor patent validity, the Court's decision announced no major changes to the doctrine.

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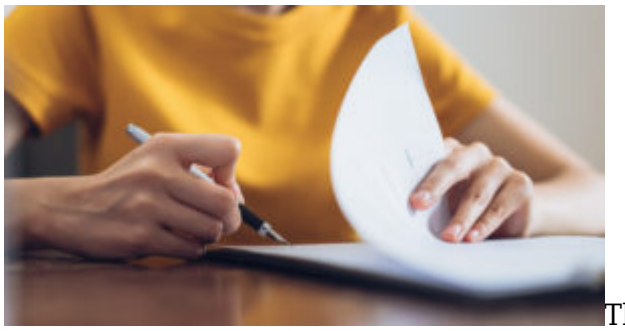
Proposed USPTO Fee Changes Will Make It Much More Expensive to Patent and to Challenge Patents on Therapeutics. You Have an Opportunity to Comment...

 The United States Patent & Trademark Office (USPTO or PTO) recently announced **proposed changes** to certain fees it charges with respect to patent applications, design patents, and America Invents Act (AIA) trials. These changes may significantly increase costs associated with building a robust patent portfolio for New Chemical Entities (NCEs) and Biologics, and to challenge patents at the PTAB. An oral hearing on the proposed changes will

be held on **May 18, 2023**, and the USPTO is accepting written comments until **May 25, 2023**.

Read the client alert **here**.

NIH Again Refuses to Exercise March-In Rights to Control Drug Price

In a letter dated March 21, 2023, the National Institutes of Health ("NIH") again refused the request of petitioners to exercise march-in rights under the Bayh-Dole Act to control the price of a drug. Here, as before, the NIH found that the statutory criteria for the use of march-in rights were not satisfied by the petitioners.

March-in rights can permit the government to require a patent owner to grant additional licenses to the invention to avoid situations such as a company licensing the technology but then not commercializing it. The Bayh-Dole Act enumerates the circumstances under which march-in rights and the grant of additional licenses are warranted, for example, to achieve practical application of the invention or to alleviate health and safety needs that are not being reasonably satisfied.

In November 2021, the Secretary of the Department of Health and Human Services ("HHS") received a petition from individuals Robert Sachs and Clare Love requesting the exercise of march-in rights under the Bayh-Dole Act to lower the price of the prostate cancer drug, Xtandi (enzalutamide). The patented drug product was invented at the University of California, Los Angeles, with funding from the NIH and U.S. Army. Xtandi, which is marketed in the United States by Astellas and Pfizer, costs more in the U.S. than it does elsewhere including other high-income countries. Petitioners argued that drug price can forbid access, specifically at prices that are allegedly unreasonable, contrary to the Bayh-Dole Act.

While the NIH's response letter expressed its concern about the high cost of drugs and the burden it places on patients, the letter explained the purpose of the Bayh-Dole Act is to promote the commercialization and public availability of government funded inventions. The overarching proposition of the Act is to permit recipients of federal government funding to retain ownership of patent rights and thereby commercialize the inventions by partnering with the private sector. Prior to the Bayh-Dole Act, most government funded inventions were not licensed or commercialized, including not one drug product.

The letter indicated that the NIH's analysis found that Xtandi is widely available to the public. The NIH stated that consistent with past march-in determinations in response to petitions for controlling drug prices, practical application of the invention is evidenced by practice of the invention and the invention's availability to the public. Astellas, the maker of Xtandi, estimated that more than

200,000 patients since 2012 were treated with the drug. Accordingly, the NIH concluded that the patent owner, the University of California, which licenses the patents to Astellas, meets the requirement for bringing Xtandi to practical application.

In addition, the NIH also stated that given the remaining patent life of the drug and the lengthy administrative procedure for the exercise of march-in rights, the NIH does not believe that the use of march-in rights would be an effective way at lowering the cost of the drug. Therefore, for these reasons, the NIH determined that march-in rights were not warranted in this situation.

The letter ends stating that the NIH and HHS would pursue a "whole of government approach," informed by public input, to ensure the use of march-in rights is consistent with the Bayh-Dole Act, promotes commercialization of federally funded research, maximizes the potential for federally funded technologies to become products, and is in the interests of the American public. To that end, on the same day as the NIH letter, HHS and the Department of Commerce ("DOC") announced a plan to review march-in authority as found in the Bayh-Dole Act with these same goals.

The NIH decision is in line with the several other petitions that have been filed for other drugs over the last few decades as well as previous petitions involving Xtandi. The exercise of march-in rights by a federal agency likely would have a negative impact on companies developing products invented using federal funding if investors believe that the price of such products could be controlled by the federal government based on public input. We will continue to monitor developments in this area, including for any recommendations from the HHS and DOC inter-agency working group on this important topic.

USPTO Director Issues Precedential Review Decision Regarding Multiple Dependent Claims

Director Katherine Vidal of the U.S. Patent and Trademark Office ("USPTO") issued a precedential review decision with respect to the interpretation of multiple dependent claims, in a case of first impression before the Patent and Trial Appeal Board ("PTAB"). In the review of the PTAB's final written Decision and Order, the Director modified it consistent with her determination of the treatment of multiple dependent claims, which are claims that refer to and incorporate by reference more than one other claim.

More specifically, at issue in the *inter partes* review captioned, Nested Bean, Inc. v. Big Beings Pty Ltd., was the interpretation of 35 U.S.C. § 112, fifth paragraph, which is the controlling statute for multiple dependent claims. The Patent Owner contended that the statute requires the PTAB to

consider the patentability of each claim referenced separately. In contrast, the Petitioner argued that if any claim of a multiple dependent claim is unpatentable, then the entire claim is unpatentable. For the reasons that follow, the Director agreed with the Patent Owner.

35 U.S.C. § 112, fifth paragraph, states in relevant part, "[a] multiple dependent claim shall be construed to incorporate by reference all the limitations of the particular claim in relation to which it is being considered." The related Codified Rule, 37 C.F.R. § 1.75(c) states, in relevant part, "[a] multiple dependent claim shall be construed to incorporate by reference all the limitations of each of the particular claims in relation to which it is being considered." With other statutes and Rules considered, the Director reasoned that the plain language of 35 U.S.C. § 112, fifth paragraph, conveys that a multiple dependent claim is the equivalent of several single dependent claims.

In addition to relying upon the applicable statute and Rules, the Director also considered Federal Circuit case law, legislative history, and USPTO procedure.

More specifically, with respect to precedent, neither party identified a judicial or administrative decision addressing the issue at hand. However, the Director found that Federal Circuit cases identified were supportive of the Patent Owner's position.

The Director found that USPTO guidance and procedures further supported the Patent Owner's interpretation. For example, the Manual for Patent Examining Practice (M.P.E.P.) advises examiners that "a multiple dependent claim must be considered in the same manner as a plurality of single dependent claims." M.P.E.P. § 608.01(n)(I)(B)(4).**[1]** Further, as the Director found, the USPTO claim fee structure is such that applicants must pay separately for each multiple dependent combination, e.g., for a multiple dependent claim that refers to three independent claims, the USPTO charges for three dependent claims.

Thus, after reviewing the PTAB's Decision and the relevant information, Director Vidal acknowledged that it was an issue of first impression before the Board. And based on the plain meaning of the statute, 35 U.S.C. § 112, fifth paragraph, requires that the patentability of a multiple dependent claim be considered separately with respect to each claim to which it refers. Accordingly, the Director's Review Decision modifies the PTAB's final written Decision and Order consistent with her interpretation of determining the patentability of multiple dependent claims, each separately as if multiple single dependent claims.

The Director's Review Decision clarifies the interpretation of U.S. patents containing multiple dependent claims and determining the patentability thereof. In particular, a patentee now knows that each claim of a multiple dependent claim should stand or fall by itself, independent of the invalidity of other dependent claims of the same multiple dependent claim.

[1] Eighth Ed., Rev. 7 (July 2008), which was the version in effect as of the earliest priority date of the relevant patent.

Decision Time: The Unified Patent Court Begins in 2023

The Unified Patent Court ("UPC") is set to begin on June 1, 2023. Under the UPC framework, a single court proceeding could result in simultaneous revocation of European Patents across multiple European Union ("EU") countries, including France and Germany.

A three-month "Sunrise Period" is set to begin March 1, 2023. If a request is filed during the Sunrise Period, patent owners can "opt-out" specific patents from the UPC, such that they never become subject to the UPC unless the patent owner decides to withdraw the opt-out. However, the opt-out procedure is not necessarily straightforward. Importantly, if not done correctly ***and*** completed within the Sunrise Period, any patent challenged by a third party within the UPC will irrevocably be confined to the UPC's jurisdiction. Given the high stakes, patent owners should begin assessing which patents they would like to opt-out of the UPC and ensure that the necessary parties are involved in the opt-out procedure. Parties to license agreements, collaboration agreements, and the like should evaluate their existing agreements to see if they are UPC ready. Further, parties to future agreements should take the UPC into account when drafting those agreements.

Read the client alert **here**.

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.

USPTO and FDA Continue to Focus on Patent Quality in the Pharmaceutical Industry

After a recent reminder from the U.S. Patent and Trademark Office (USPTO) regarding the duties of disclosure and reasonable inquiry during examination of a patent application and a Request for Comments (RFC) on the USPTO initiatives to ensure "robustness and reliability" of patent rights,[1] the Director of the U.S. Patent and Trademark Office published a third notice in less than four months. The latest notice is in conjunction with the Food and Drug Administration (FDA) to further the discussion surrounding the patent practices of the pharmaceutical industry (**87 Fed. Reg. 67019** (November 7, 2022)). Specifically, the notice is of a public listening session and request for comments (PLS/RFC).

Against the backdrop of 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," as well as Congressional and public interest in this goal, the stated purpose of the present notice of the PLS/RFC is to obtain public input for areas of joint USPTO-FDA collaboration and engagement with respect to the pharmaceutical industry to promote greater access to medicines for American families.

In particular, the USPTO and FDA are seeking feedback from a broad group of stakeholders, most notably, patients and their caregivers, patient advocates, representatives from regulated industry, including companies that sell branded medicines, generic drugs and biosimilars, healthcare organizations, payers and insurers, academic institutions, public interest groups, and the general public.

The background of the notice of the PLS/RFC describes the response to the EO and details certain communications between the USPTO and the FDA in furtherance of its objectives. More specifically, in a letter from the USPTO to the FDA, initiatives for collaboration were outlined including exploring joint USPTO-FDA public engagements, providing examiners with training on publicly available FDA resources, exploring consistency in representations made to the USPTO and the FDA, revisiting patent term extension (PTE) practice, exploring the policies surrounding the use of "skinny labels," and being open to discussing "patent thickets," "evergreening," and "product hopping."

Further, in the current notice, the USPTO states in a footnote that this collaborative PLS/RFC is in parallel with the USPTO's initial RFC. The initial RFC included new USPTO initiatives to advance the EO; such initiatives include seeking input on enhancing processes for information disclosure statements and the identification of key prior art, considering 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 conducting a comparative analysis of the prosecution and grant of "pharmaceutical and biological patents" in the United States versus other countries.

Although the USPTO notice on disclosure requirements and the initial RFC include all technologies, it is clear that the focus of the USPTO/FDA's inquiries are related to the pharmaceutical and biologics industries.

More specifically, with respect to the PLS/RFC, its inquiries include considering what FDA resources may be available to USPTO examiners to assess patentability, e.g., determining whether inconsistent statements were made to the USPTO and the FDA, using AIA proceedings to address the patentability of claims in pharmaceutical and biotechnological patents, revisiting PTE practices, understanding "skinny label" practice, and generally promoting greater availability of generic products. The PLS/RFC also seeks input on the questions posed in the USPTO letter to the FDA mentioned above.

The in-person PLS at the USPTO is scheduled for January 19, 2023, from 10 am to 5 pm (ET), for which preregistration is needed to speak. Written comments to the PLS/RFC will be accepted until February 6, 2023, with the comments to the initial RFC of the USPTO extended until February 1, 2023.

Stakeholders are encouraged to participate and we will monitor how the USPTO and the FDA respond to these hotly debated topics that impact almost every American.

[1] See **87 FR 45764** (July 29, 2022) and **87 FR 60130** (October 4, 2022), respectively. See also ***USPTO Publishes Notice Calling Out Pharmaceutical Industry***, Goodwin Life Sciences Perspective blog, July 29, 2022; and ***USPTO Doubles Down Calling Out Pharmaceutical Industry***, Goodwin Life Sciences Perspective blog, October 19, 2022, respectively.

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.