Biosimilars Webinar: Prosecution and Litigation Trends and Takeaways from BPCIA Litigation

Michael Siekman, **Huiya Wu**, **Allegra Padula**, and **Riley Wyberg** will present their data-driven analyses of trends in BPCIA litigation and relevant takeaways.

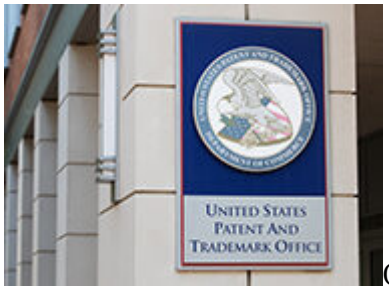
With 10 years of litigation since the first BPCIA complaint on NEUPOGEN (filgrastim) was filed in 2014, trends are becoming apparent that should cause all biopharma companies to reassess how they protect biologics and plan for biosimilar launch.

Webinar Highlights:

- **Patents Being Asserted:** Learn which types of patents are being asserted to block biosimilar competition, how that has changed over time, differences for protein and antibody products, when those patents are being filed during drug development, and differences among Reference Product Sponsors.
- **Trends in BPCIA Litigation:** Learn how often and how much of aBLAs are being produced during the Patent Dance, which Biosimilar Manufacturers are producing them, how much the parties dance and who is engaging in the Patent Dance, when cases are settling, and how many asserted patents are carrying through to a final judgment.
- **Real-World Insights:** We will share practical recommendations for biologics and biosimilars companies based upon on our analysis and our experience with the BPCIA.

Please **RSVP** to confirm your attendance.

The USPTO Proposes a Radical Change to Terminal Disclaimer Practice: You Have an Opportunity to Comment



On May 10, 2024, the United States Patent and Trademark Office (USPTO) issued a **notice of proposed rulemaking** that, if enacted, would tie the enforceability of every claim of a patent subject to a terminal disclaimer to the validity of any claim of the reference patent. In other words, if any claim of the reference patent were found to be invalid for lack of novelty or for obviousness, then the subject patent would be unenforceable **in its entirety**. This proposed rule is a significant departure from current U.S. standards which evaluate the validity of challenged claims on an individual basis.

The USPTO is accepting comments on the proposed rule until July 9, 2024. Comments may be made at **www.regulations.gov/commenton/PTO-P-2024-0003-0001**. As of June 28, 2024, 88 comments have been submitted.

Background

35 U.S.C. § 101 states that:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

This section has been interpreted as meaning that an inventor is only entitled to patent an invention once. If an applicant were to attempt to patent the same invention twice, the claims would be rejected for statutory double patenting under 35 U.S.C. § 101.

U.S. courts created the concept of obviousness-type double patenting (also called non-statutory double patenting). See e.g., In re Longi, 759 F.2d 887, 893 (Fed. Cir. 1985). This judicially-created doctrine holds that an inventor may not obtain a patent on an obvious variant of an issued (or co-pending) claim (the cited patent or co-pending application is known as a reference patent or application) as doing so could result in an unlawful extension of patent protection for an invention.

An obviousness-type double patenting rejection may be overcome by (1) successfully arguing that the pending claims are not obvious variants of the claims of a reference patent/application, or (2) the filing a terminal disclaimer meeting the requirements of 37 C.F.R. 1.321(c). A terminal disclaimer *disclaims* any patent term of the subject patent that extends beyond the term of the reference patent/application. Noteworthy, terminal disclaimers include an agreement by the patentee that the subject patent is only enforceable for and during such period that it is owned by the same party (or parties) that owns the reference patent (with the presence of a Joint Research Agreement impacting this provision).

Current Proposal

The proposed rule released by the USPTO would add an additional requirement to the use of a terminal disclaimer. Under the proposed rule the applicant would need to agree that:

the patent in which the terminal disclaimer is filed, … will be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers

filed to obviate nonstatutory double patenting in which: [a] **any claim** *has been finally held unpatentable or invalid as anticipated or obvious by a Federal court in a civil action or by the USPTO, and all appeal rights have been exhausted; or [b] a statutory disclaimer of a claim is filed after any challenge based on anticipation or obviousness to that claim has been made.* (emphasis added)

Per the USPTO,

[t]his action is being taken to prevent multiple patents directed to obvious variants of an invention from potentially deterring competition and to promote innovation and competition by allowing a competitor to avoid enforcement of patents tied by one or more terminal disclaimers to another patent having a claim finally held unpatentable or invalid over prior art.

The USPTO states that the proposed rule is designed to "further the objectives of Executive Order 14036 on "Promoting Competition in the American Economy," 86 FR 36987 (July 14, 2021)." In that Executive Order, President Biden noted that "patent and other laws have been misused to inhibit or delay—for years and even decades—competition from generic drugs and biosimilars, denying Americans access to lower-cost drugs." The proposed rule on terminal disclaimers specifically notes that "multiple patents tied by terminal disclaimers that are directed to obvious variants of an invention could deter competition due to the prohibitive cost of challenging each patent separately in litigation or administrative proceedings."

The Appeals Review Panel's In Re Xencor Decision: The USPTO Provides Its Position on Written Description and Means-Plus-Function Claims

 On May 17, 2024, an Appeals Review Panel (ARP) of the United States Patent and Trademark Office ("USPTO") released its decision in ***Ex parte Chamberlain*** (referred to in Federal Circuit proceedings as *In re Xencor*; "**Chamberlain**"). The ***Chamberlain*** decision provides some clarity on the USPTO's position on written description requirements for Jepson and means-plus-function claims in the life sciences space. Importantly, it suggests that carefully drafted means-plus-function claims are a potential path for Applicants to claim antibodies broadly by use of functional language (i.e., by their targets) once again.

The two claims considered in ***Chamberlain*** are functional claims to an antibody styled as (a) a Jepson claim (claim 8) and (b) a means-plus-function claim (claim 9). In the ***Chamberlain*** decision,

officially dated May 21, 2024, the ARP maintains the Patent Trial and Appeal Board's ("PTAB") rejection of both claims for lack of written description, reverses the rejection of claim 9 for indefiniteness, and reverses the Examiner's obviousness-type double patenting rejections of claims 8 and 9 (not addressed in this publication).

Read the full alert **here**.

Janssen v. Teva: Not an April Fool's Day Joke for Life Sciences Companies

On April 1, 2024 the Federal Circuit released its **opinion** in *Janssen Pharmaceuticals, Inc. et al v. Teva Pharmaceuticals USA, Inc. et al.*, affirming the district court's finding that certain claims were not indefinite and remanding to the district court to reevaluate its obviousness decision. The Federal Circuit's analysis provides important considerations for life sciences companies litigating method of treatment patents.

Janssen sued Teva for patent infringement, asserting U.S. Patent No. 9,439,906 ("the '906 patent"). Teva stipulated to infringement but challenged validity, arguing that all representative claims were invalid as obvious and that claims 19-21 were invalid as indefinite. After a bench trial, the district court found that Teva had not proven invalidity on either basis.

Claim 1 of the '906 patent claims:

1. A dosing regimen for administering paliperidone palmitate to a psychiatric patient in need of treatment for schizophrenia, schizoaffective disorder, or schizophreniform disorder comprising

(1) administering intramuscularly in the deltoid of a patient in need of treatment a first loading dose of about 150 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

(2) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of about 100 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the 6th to about 10th day of treatment; and

(3) administering intramuscularly in the deltoid or gluteal muscle of the patient in need of treatment a first maintenance dose of about 25 mg-eq. to about 150 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation a month (±7 days) after the second loading dose.

To demonstrate obviousness of the claimed paliperidone palmitate dosing regimen at issue, Teva

relied on three primary prior-art references at trial: (1) clinical study protocol NCT00210548 ("the "'548 protocol") describing 3 fixed doses of paliperidone; (2) US 6,555,544 (the "'544 patent") describing the composition used in the claim of the '906 patent; and (3) International Publication No. WO 2006/114384 ("WO '384") describing preparation of aseptic crystalline paliperidone palmitate.

Erroneous Claim Scope

The district court had "found that the prior art did not demonstrate *population-wide* safety and efficacy and thus did not teach a generalized dosing regimen." (emphasis added) Teva argued at the Federal Circuit that the claims did not pertain to a generalized population but instead to an individual patient: "A dosing regimen for administering paliperidone palmitate to ***a*** psychiatric patient in need of treatment for schizophrenia" (emphasis added) The Federal Circuit agreed with Teva's argument, writing that "[n]othing in the claims requires that the regimen be used for—let alone be ideal for—the patient population generally or a certain percentage of the patient population. On their face, the claims only recite a dosing regimen for a psychiatric patient. Because '[w]hat matters is the objective reach of the claim,' KSR, 550 U.S. at 419, the district court erred to the extent it effectively defined its obviousness inquiry as one concerning the "generalized" suitability of the dosing regimens."

Rigid Obviousness Analysis

Teva also argued that the district court was overly rigid in its obviousness analysis. The Federal Circuit agreed. Specifically, the Federal Circuit identified the district court's analysis of the clinical trial results as overly rigid: "[T]he district court analyzed the ['548 protocol and the corresponding PSY-3003 trial] without giving the needed weight to the perspective of a POSA capable of deducing what references fairly suggest or employing ordinary creativity."

Per the Federal Circuit, the district court's obviousness analysis erred in "concluding that (1) there were issues with starting from the '548 protocol because "it contains no information about the safety of the dosing regimen or its efficacy"; and (2) without knowledge of the results of the trial that Janssen considered a failure, a POSA would not be motivated to modify the protocol." The Federal Circuit wrote that while the '548 protocol and the resulting clinical trial may not have published results or been considered a success, the POSA could still assign "significance … to the Phase III status of the protocol" and the fact that paliperidone was already marketed for schizophrenia.

Unexpected Results

In assessing secondary considerations, the district court had noted that "'the conventional wisdom,' related to antipsychotics generally, that dosing should 'start low and go slow" and that Janssen had discovered that "[t]he claimed dosing regimens run contrary to these prior art teachings because they use depot injections of high, rather than low, loading doses to initiate treatment." The district court looked to dosing of other anti-psychotics, including risperidone, haloperidol decanoate, and risperdal consta.

The Federal Circuit found that the district court's comparators were incorrectly selected, writing that "to the extent this analysis related to results (unexpected or otherwise), it clearly does not involve a comparison of the closest prior art. All the testimony cited for the "start low and go slow" proposition relates to medications with active ingredients other than paliperidone. Risperidone was used as a reference, and it does not have the active ingredient of paliperidone, and is not an injectable medication." The Federal Circuit also wrote that "evaluating unexpectedness via a comparison of the 'start low and go slow' paradigm for other medications was improper. There is simply nothing unexpected about starting with a dose of the paliperidone palmitate LAI that was

already disclosed simply because other medications were dosed differently."

Janssen also argued that long-felt need and commercial success supported the non-obviousness of the claims. Teva challenged this analysis arguing that the presence of blocking patents was not properly considered when evaluating commercial success. The Federal Circuit noted that the effect of blocking patents is a fact specific inquiry but that "if all other variables are held constant, a blocking patent diminishes possible rewards from a non-owner's or non-licensee's investment activity aimed at an invention whose commercial exploitation would be infringing, therefore reducing incentives for innovations in the blocked space by non-owners and non-licensees of the blocking patent. … In turn, this decrease in incentives 'can discount the significance of evidence' of commercial success and long-felt need."

Holding regarding Obviousness

The Federal Circuit vacated the district court's judgment and remanded its non-obviousness determination, holding that (1) the district court required a showing of obviousness that was incongruent with the scope of the claims by requiring obviousness be shown with respect to generalized or population-wide dosing; (2) the district court analyzed the prior art with a degree of rigidity foreclosed by *KSR*; and (3) the district court did not properly analyze the secondary considerations.

Indefiniteness

The Federal Circuit also affirmed the district court's finding of indefiniteness. The claims at issue recited a range of average particle sizes. Teva had argued that the claims were indefinite because the claims do not specify the measurement technique, and the that results may vary depending on which technique was used. The district court had found that the discrepancy in particle-size measurement results was due to "an outlier measurement taken with a defective device," and not due to a discrepancy that was typical of the measurement techniques. The Federal Circuit concluded that, based on the district court's factual findings, that Teva had not presented evidence that "different measurement techniques would yield different particle-size measurements of paliperidone palmitate," and therefore affirmed the district court's conclusion that the claims were not shown to be indefinite.

USPTO Emphasizes Searches of FDA Databases for Pharmaceutical Patent Applications

 In response to Biden Administration goals regarding increasing pharmaceutical competition and lowering drug prices, the USPTO recently released training provided to the USPTO examining corps on utilizing publicly available FDA and NIH databases for prior art searches. The goal of the training is to ensure that all relevant prior art is considered by examiners when assessing patentability. As with disclosures on **clinicaltrials.gov**, drug labels and drug approval information are publicly available and thus may qualify as prior art.

This training is related to initiatives outlined in President Biden's **Executive Order (EO) 14036** entitled "Promoting Competition in the American Economy," signed on July 9, 2021. In this EO, President Biden stated his administration's goal of increasing competition in the pharmaceutical space and lowering prescription drugs prices. As part of this goal, President Biden instructed the Commissioner of Food and Drugs to write a **letter** to the Director of the USPTO describing any relevant concerns of the Food and Drug Administration (FDA) with respect to USPTO procedures. In its **response** to the FDA letter, the PTO outlines several initiatives, including working with the FDA to develop training materials for the patent examining corps on searching publicly available FDA resources (e.g., FDA and NIH databases) for prior art and to assess the state of the art in the pharmaceutical and biopharma areas.

On March 20, 2024, the USPTO released new training materials ("**March 2024 Training Materials**") it developed in conjunction with the FDA for the examining corps regarding use of FDA and National Institutes of Health (NIH) databases to search for prior art. The March 2024 Training Materials outlines search strategies for use with various FDA and NIH public databases, including:

- **FDALabel** – FDALabel (current drug labels) contains "over 140,000 human prescription, biological, over-the-counter and animal drug label documents." This database allows for complex queries, including with structures, and "[m]ay be used to find information on indications, dosage and administration, contraindications (including warnings, adverse reactions, drug interactions, or information about use in particular populations of patients)."
- **Drugs@FDA** – Drugs@FDA gives examiners access to current and retired drug labels, along with non-label content such as FDA reviews, regulatory history, and approval letters. This database covers prescription brand-name drug products, generic drug products, therapeutic biological products, and OTC brand-name and generic drugs.
- **DailyMed** – DailyMed (current drug labels; operated by the NIH) contains labeling information on prescription drug and biological products for human use, OTC drugs and biological products, medical devices, medical gases, and prescription and nonprescription drugs for animal use. This database doesn't permit structure searches but does provide "publicly available" dates that can be used to establish the effective date of the disclosure. Information available in this database includes usages/indication, dosage/administration and forms/strengths.
- **DailyMed Archive** – DailyMed Archive provides retired drug labels for prescription drug and biological products for human use, OTC drugs and biological products, medical devices, medical gases, and prescription and nonprescription drugs for animal use.

USPTO’s New Guidance on AI-Assisted Inventions: The Impact on the Use of AI in the Life Sciences

 On February 12, 2024, the US Patent Office and Trademark Office (USPTO) released the Inventorship Guidance for AI-assisted Inventions (**the Guidance**). We previously discussed the Guidance **here**.

Following up on the Guidance, the USPTO released two examples illustrating what the USPTO considers proper inventorship analyses for AI-assisted inventions. Each example sets forth different fact patterns and walks through an analysis of whether one or more human individuals qualify as inventors. Acknowledging that life sciences companies are increasingly employing AI systems to help identify molecular targets and/or design therapeutic molecules, one of the two examples focuses on the use of AI to develop therapeutic molecules: Developing a Therapeutic Compound for Treating Cancer (**Example 2**).

Life sciences companies using AI-assisted systems should carefully consider whether their current R&D efforts allow for natural persons to provide a significant contribution such that the resulting efforts may properly identify a human inventor.

Read the full alert **here**.

Recent Bayh-Dole Act News: Comments on the Draft Framework; HHS Refuses to March-In on Xtandi; and Delayed Contracting Doesn’t Avoid Bayh-Dole

 U.S. universities and academic institutions rely heavily on federal grants to fund their research and generate innovations in life sciences. Universities often out-license patents protecting inventions created using federal funding to private companies including many startups. Hundreds of drugs have been developed by collaboration between universities and private industry. The Bayh-Dole Act of 1980 governs the use of federal grants and ownership of inventions and intellectual property generated from the sponsored research. In exchange for federal support, recipients agree to grant the federal government a non-exclusive license to resulting patents covering any inventions supported by the grant. Further, the government retains the right to "march-in" and grant third parties licenses under certain circumstances.

Proposed Updates to Exercise of March-In Rights

On December 7, 2023, the National Institute of Standards and Technology (NIST) released a **draft framework** attempting to clarify the circumstances under which the U.S. federal government can "march-in" and grant licenses to third parties for inventions supported by federal grants. We originally wrote about the proposed guidance on "march-in" rights and provided Q & A **here**. To date, the government has never exercised such "march-in" rights.

Public comments to the draft framework were due by February 6, 2024. Evidencing the potential impact on the dynamics in the U.S. life sciences startup ecosystem, 51,873 public comments were submitted by the deadline. As of February 12, 2024, there were **672 posted comments**. Of these, those in opposition of the proposed framework expressed concerns that it would disincentivize entrepreneurship and innovations, countering the original purpose of the Bayh-dole Act.

- Howard Dean, former governor of Vermont, stated that "the framework put forward on December 8 will have little – if any – impact on the prices consumers pay for medicines, but will negatively impact the private sector's willingness to commercialize federally supported technologies, across all industries. … even if marching in on the basis of price were authorized by the law, which is not, the NIH's long-held contention that prices would not be impacted is correct. The truth is that most medicines are protected by a number of different patents, very few of which are Bayh-Dole subject inventions."

- Biotechnology Industry Organization (BIO) commented that "[t]he suggestions in the draft framework that agencies use the march-in authority to regulate the pricing of successfully commercialized products, particularly complex products like biopharmaceutical products, is not only inconsistent with the statute, it is unrealistic. In the biopharmaceutical sector, for example, patents on inventions supported by federal funding only infrequently have a connection to a finished, marketed biopharmaceutical product, and when they do, that connection is usually attenuated. … One study estimates that 'biotechnology companies invest $100 in development for every $1 the government invests in research that leads to an innovation.'"

- The National Venture Capital Association (NVCA) commented that "NIST's guidance would unavoidably deter VCs from investing in inventions arising from federally funded

research—directly contrary to the innovation environment the Act meant to foster. The increased risk directly disrupts existing investors' reliance interests. And it further makes any future technologies backed by federal funds potentially toxic for VC investment. This outcome 'frustrate[s] the policy that Congress sought to implement' through the Bayh-Dole Act—that is, to encourage private investment in government-funded inventions."

- Multiple universities submitted comments, some noting that Bayh-Dole works well in its current form. The **University of North Carolina – Chapel Hill** commented that "[t]he Bayh-Dole Act is legislation that works extremely well, and no changes to the Act are necessary. In fact, the use of march-in rights as described in the Draft Guidelines would represent a huge step backwards and threaten to undermine the positive effects of the Act." **Ann Arbor SPARK** commented that "[t]he framework changes you are proposing are unnecessary. They increase uncertainty and undermine a proven policy framework. They will have a detrimental and destabilizing effect on university research commercialization and startup company formation." Several universities raised concerns regarding negative effects on their ability to commercialize university research. **Cornell University** noted that "[t]he risk of price-based march-in rights will discourage potential licensees, disincentivize the commercialization of federally funded inventions, and decrease the likelihood of university technology adoption. This will likely lead to the scenario where new products, particularly new drugs, will no longer be based on the technologies of federally funded intellectual property to the detriment of the U.S. economy, consumers, and U.S. global competitiveness. This would have a negative impact on Cornell's technology transfer enterprise, …" **Yale University** likewise commented that "[t]he shift of final control of licensing away from universities would have significant adverse effects on universities' efforts in knowledge transfer. Exercising march-in rights to issue a non-exclusive license is tantamount to breaking a patent, and the knowledge that an agency could take such action would erode investors' confidence in the value of the intellectual property embodied in the patent. Entrepreneurs and investors would be reluctant to make the considerable investment required to bring university inventions to market if they knew that federal agencies could issue non-exclusive licenses to competitors at any time. No private entity would expect to attract investors on such terms, and it is unrealistic to expect that the proposed march-in framework could be adopted without undermining the efficacy of the Bayh-Dole Act." The **University of Texas System** commented on the potential effects on faculty: "[i]f this proposal is enacted, there is substantial concern that faculty will become less interested in the commercial process overall, adversely impacting businesses and start-ups across the state that seek to partner with their local institutions. … Faculty who want to see their research developed and translated into public benefit will be incentivized to leave our universities for industry, depriving our students of important learning and research opportunities."

Many of the comments were from individuals in support of the proposed framework. The Federal Trade Commission also submitted comments in support, arguing amongst other things that "price may be an appropriate basis for marching in." Knowledge Ecology International (a filer of multiple petitions for march-in) was likewise pleased to see price as a basis for march-in, but commented that "on the issue of standards for unreasonable pricing, the draft guidance gets a failing grade."

Xtandi® Decision

On February 5, 2024, the U.S. Department of Health and Human Services (HHS) **affirmed** the National Health Institute's (NIH) decision not to exercise march-in rights with respect to Xtandi® (enzalutamide). The NIH's original decision was issued in **March 2023** in response to a petition by several cancer patients. NIH stated that Xtandi was widely available to the public. Further, NIH

noted that the remaining patent life and the lengthy administrative process involved for a march-in proceeding weighed against any attempt to exercise its march-in rights.

University of South Florida Board of Trustees v. U.S.

The Federal Circuit recently upheld the government's royalty-free license to a patent resulting from government sponsored research. The ***University of South Florida Board of Trustees v. United States***, decided on February 9, 2024, involved the issue of whether the government held a royalty-free patent license over certain Alzheimer's disease research funded by a NIH grant if the inventions were created prior to a sub-contractor funding agreement. In this case, the grant covered experiments to reduce the claimed invention to practice (i.e., production of transgenic mice and recognition that the mice worked for their intended purpose). Mayo, the grantee, agreed to cover the cost of certain research conducted at UCSF (the subcontractor). The Mayo/UCSF contract was actually executed after UCSF's work was begun. The Federal Circuit ruled that the license to the government can be retroactively applied because the statutory language broadly covers work done before the contract if the work was eventually paid for by the federal funding. Per the Federal Circuit, "what occurred here is not an uncommon fact pattern in government funding of research conducted in part by non-grantee members of a consortium called for in a government grant. Specifically, the record makes clear that subcontracts are commonly not executed until sometime after the grant is awarded, yet the grant-covered work proceeds without waiting for the inking of a subcontract."

This case is a good reminder that (1) Bayh-Dole kicks in even when the funds are only supporting reducing a prior-made invention to practice, and (2) it does not matter when the contract is executed; if federal monies are used, Bayh-Dole kicks in.

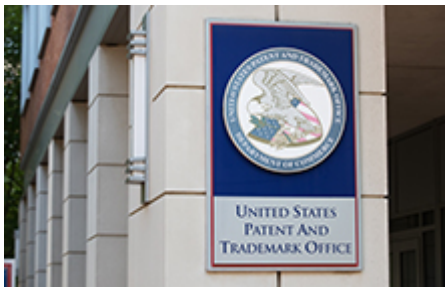
Life Sciences Companies Make Up a Small Portion of the Companies Opting-In to the Unitary Patent; Ireland Announces Referendum Date

Life sciences companies continue to make up a small portion of the companies registering for Unitary Patents. Per the European Patent Office's **statistics** portal, as of January 30, 2024 there have been 18,721 registered Unitary Patents. The Uptake Rate is 17.5%. Of this, Medical Technology companies account for 2,266 (or, 11.8%) of the registrations. This is the largest of the 35 technology fields that the portal is tracking. Pharmaceuticals account for 717 (or, 3.7%) of the registrations. Biotechnology accounts for 444 (or, 2.3%) of the registrations.

Notably, Johnson & Johnson has the largest share of registrations at 267. This is followed by Siemens, with 261 registrations. Other life sciences companies cracking the top 25 include: Hoffman-La Roche (82 registrations), Align Technology (46 registrations) and Becton, Dickinson & Company (105 registrations).

In related news, Ireland has also **announced** that its referendum on whether to ratify the Agreement on a Unified Patent Court (UPCA) will occur in June 2024. If Ireland votes yes, it will become the 18th country to actively join the UPC. All 27 members of the EU are eligible to join the UPC, though only 24 have signed the UPCA. Non-EU countries, such as England, cannot join the UPC. Notably, Poland and Spain have not signed the UPCA.

USPTO Publishes Enablement Guidelines in view of Amgen v. Sanofi



On January 10, 2024, the USPTO **published** guidelines for assessing enablement in view of *Amgen v. Sanofi* and other recent court cases ("the Guidelines"). The Guidelines state that they are not intended to "announce any major changes to USPTO practice or procedure" but instead "incorporat[e] guidance from the *Amgen* decision and several post-*Amgen* enablement court decisions that are consistent with current USPTO policy."

"The enablement requirement refers to the requirement of 35 U.S.C. § 112(a) that the specification must describe the invention in such terms that one skilled in the art can make and use the claimed invention." The Guidelines emphasize that an enablement assessment during prosecution still requires use of the *Wands* factors, including "(A) the breadth of the claims, (B) the nature of the invention, (C) the state of the prior art, (D) the level of one of ordinary skill, (E) the level of predictability in the art, (F) the amount of direction provided by the inventor, (G) the existence of working examples, and (H) the quantity of experimentation needed to make and use the invention based on the content of the disclosure." Per the Guidelines, use of the *Wands* factors is consistent with *Amgen* and several of the Federal Circuit's post-*Amgen* decisions, including *Baxalta*. The Guidelines state "[t]he *Wands* analysis should provide adequate explanation and reasoning for a lack of enablement finding in order to facilitate the USPTO's clarity of the record goals, as well as the USPTO's goals of providing consistency between examination and post-grant challenges."

Federal Circuit Remands to USPTO to Clarify Analysis of Jepson-Format and Means-Plus-Function Claims in the Field of Biotechnology

 On January 23, 2024, the U.S. Court of Appeals for the Federal Circuit ("Federal Circuit") issued its **decision** granting the USPTO's request to remand Xencor's appeal of the rejection of U.S. Patent App. No 16/803,690 ("'690 patent application") back to the USPTO. The USPTO requested remand so that the USPTO's Appeals Review Panel can "clarify the USPTO's position on the proper analysis of Jepson-format and means-plus function claims in the field of biotechnology, and particularly in the antibody art," and issue "a revised decision."

The claims at issue in the '690 patent application cover use of anti-C5 antibodies with an Fc domain. The claims were drafted in both the "Jepson" and means-plus-function format (claims 8 and 9, respectively):

8. **In a method** of treating a patient by administering an anti-C5 antibody with an Fc domain, **the improvement** comprising said Fc domain comprising amino acid substitution M428L/N434S as compared to a human Fc polypeptide, wherein numbering is according to the EU index of Kabat, wherein said anti-C5 antibody with said amino acid substitution has increased in vivo half-life as compared to said antibody without said substitutions.
9. A method of treating a patient by administering an anti-C5 antibody comprising: a) **means for** binding human C5 protein; and b) an Fc domain comprising amino acid substitution M428L/N434S as compared to a human Fc polypeptide, wherein numbering is according to the EU index of Kabat, wherein said anti-C5 antibody with said amino acid substitution has increased in vivo half-life as compared to said antibody without said substitutions.

The examiner had rejected the claims as unpatentable (a) for failing to comply with the written description requirement, and (b) under the obviousness-type double patenting doctrine. Xencor appealed the rejection to the Patent Trial and Appeal Board ("PTAB"), after which the examiner withdrew the written description rejection.

In its **decision**, the PTAB reinstated the written description rejection. Xencor **appealed** to the Federal Circuit. Following the filing of Xencor's appeal brief, the Director of the USPTO filed a **motion** for remand back to the USPTO "to permit further consideration and issuance of a revised decision by the Appeals Review Panel." The Director's motion for remand stated that:

> Xencor's pending claims present novel questions involving the application of the Supreme Court's and this Court's precedent for both Jepson-format and means-plus-function claims in the field of biotechnology, and in particular the antibody art. The use of Jepson format and means-plus-function claims in the life sciences is exceedingly rare.

> Therefore, the USPTO seeks remand in order to issue a revised decision that clearly and thoroughly expresses the Agency's view on application of the case law to this important area of technology.

While Xencor **opposed** the USPTO's request as arising too late, the Federal Circuit ultimately sided with the USPTO. In its decision, the Federal Circuit wrote that the Director raised legitimate concerns and that it was "confident that proceedings will be conducted expeditiously."