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:

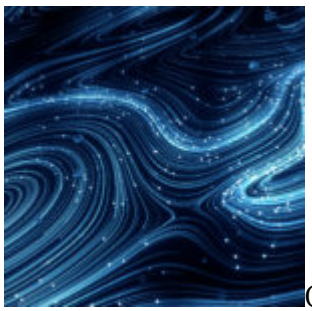
the patent in which the terminal disclaimer is filed, … will be enforceable only if the patent is not tied and has never been tied directly or indirectly to a patent by one or more terminal disclaimers filed to obviate nonstatutory double patenting in which: [a] **any claim** *has been finally held unpatentable 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**.

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

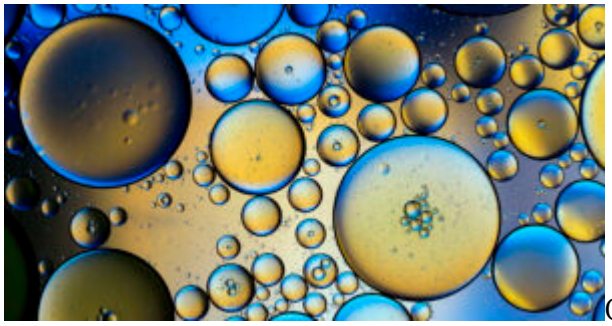
description requirement, and (b) under the obviousness-type double patenting doctrine. Xencor appealed the rejection to the Patent Trial and Appeal Board ("PTAB"), after which the examiner withdrew the written description rejection.

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."

K-Fee Provides a Warning to Life Sciences Companies – What You Say in Foreign Prosecution May Affect Your U.S. Claim Scope



On December 26, 2023, the United States Court of Appeals for the Federal Circuit issued its **decision** in K-Fee System GMBH v. Nespresso USA, Inc. While nominally a case related to coffee makers, its teachings are highly applicable to life science companies as they tend to file large numbers of ex-U.S. patent cases. The lesson: under certain circumstances, a court may consider statements made in patent prosecution proceedings outside of the U.S. when construing the scope of related U.S. claims, and as such those statements should be carefully weighed against implications in your U.S. patent portfolio.

K-fee System GmbH ("K-fee") owns U.S. Patent Nos. 10,858,176, 10,858,177, and 10,870,531. K-fee filed suit against Nespresso USA ("Nespresso") in the Central District of California ("District Court") alleging that Nespresso's coffee system infringed claims in each of the three patents. Nespresso filed a motion for summary judgment of non-infringement, arguing that its products did not infringe

the asserted patent claims. The District Court agreed and granted Nespresso's motion for summary judgment. K-fee appealed to the Federal Circuit, which agreed with K-fee that the District Court erred in construing certain terms in the K-fee claims. The Federal Circuit remanded the case back to the District Court for further proceedings.

Previously, Nespresso had filed an opposition against a European patent related to the three U.S. patents K-fee asserted in its U.S. case. K-fee filed a motion asking the EPO to deny the opposition. K-fee argued that its claims were patentable over certain prior art cited by Nespresso based on the plain meaning of the term "barcode." In its motion, K-fee provided what it alleged to be the plain meaning of that term. K-fee provided the opposition filings to the USPTO, including the motion containing this claim construction argument. The District Court and the Federal Circuit would both treat K-fee's motion as intrinsic evidence as it had been made part of the U.S. file history by K-fee.

In deciding the motion for summary judgment in favor of Nespresso, the District Court referred to K-fee's definition of barcode provided in the opposition filings. Accordingly, the District Court accepted Nespresso's argument that its products fell outside of the asserted claims as interpreted according to the K-fee's proffered definition. K-fee appealed to the Federal Circuit, arguing that the District Court's narrowing of the term "barcode" was effectively a holding of disclaimer based on its prior arguments to the EPO, which, K-fee argued, did not meet the standard for disclaimer. In finding in favor of K-fee, the Federal Circuit held that the District Court's conclusion regarding the definition of barcode based on K-fee's EPO statements "was too confining," agreeing with K-fee that its arguments to the EPO did not rise to the level of disclaimer. The case was again remanded to the District Court for further proceedings.

The Federal Circuit concluded its opinion by writing "we note that K-fee makes the legal argument that a conclusion of disclaimer cannot be premised on statements made when defending a related but distinct patent against a different legal standard—here the European standard for novelty. We do not address that contention because we have concluded that K-fee's statements were too unclear to constitute disclaimer."

Some Much-Needed (Applicant-Friendly) Clarification on Priority Claims at the European Patent Office

 On October 10, 2023, the Enlarged Board of Appeal of the European Patent Office (EPO) issued a **consolidated decision in cases G1/22 and G2/22** clarifying a common issue regarding the validity of a priority claim made at the EPO. **Per the Board of Appeal, there is a rebuttable presumption that an Applicant claiming priority is entitled to claim that priority**.

Read the full client alert **here**.