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 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."