FDA Issues Final Rule on Regulation of Laboratory Developed Tests

 On April 29, 2024, the U.S Food and Drug Administration (FDA) announced its **final rule** on Laboratory Developed Tests (LDTs). This final ruling amends the FDA's regulations to make explicit that *in vitro* diagnostic products (IVDs), including those manufactured by laboratories, are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act). Alongside the amendment, FDA issued its policy to phase in regulatory requirements for certain LDTs over the course of four years.

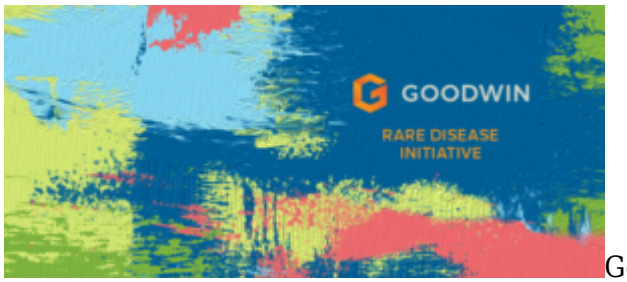
The FDA will host a webinar to provide an overview of the final rule on May 14, 2024. A link to register can be found **here**. The final rule is expected to have profound effects on many LDT developers. Goodwin's **Life Sciences Regulatory & Compliance Team** are ready to work with clients to navigate the challenges that the final rule may pose. Our breakdown and analysis of the rule will be upcoming on **Goodwin's LDT Resource page**.

The European Parliament Adopts Position on the European Commission's Proposal for the First Major Overhaul of the EU Medicines Regulatory Framework in 20 Years

 In April 2023, we published an **alert** in relation to two European Commission legislative proposals: new **Regulation 2023/0131** and new **Directive 2023/0132**, to replace the current EU regulatory framework for all medicines (including those for rare diseases and children). On April 10, 2024, the European Parliament adopted its position on the European Commission's legislative proposals with respect to (i) Regulation 2023/0131 that can be found **here** and (ii) Directive 2023/0132 that can be found **here**. For certain key areas covered in the

proposed EU legislation, we have set out a brief summary of (i) the European Commission's original proposals and (ii) the European Parliament's proposed amendments. You can read more **here**.

Recap: Goodwin Rare Disease Symposium 2024



Goodwin's **Rare Disease Initiative** hosted its Annual Rare Disease Symposium in Boston on March 13, 2024. Participants were invited to join for an afternoon of engaging and inspirational conversations led by **Julie Tibbets**, **Matt Wetzel**, and **Danielle Lauzon**, in addition to networking with peers in the rare disease community. The program included speakers covering the patient, advocacy, policy, research, and CEO perspectives.

For more event highlights and key takeaways from our speakers, please visit the **Goodwin Rare Disease Symposium 2024** page.

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."

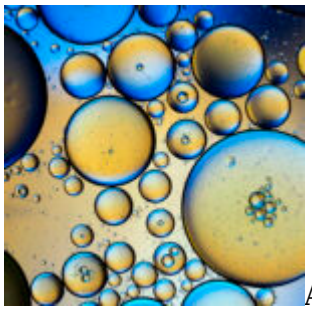
Holding regarding Obviousness

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.

A Look Ahead in Life Sciences: What We Are Tracking in Q2 2024 and Beyond

 As the life sciences, medtech, and diagnostic industries continue to expand and grow increasingly complex, so does the legal, regulatory, and compliance landscape. To help companies and investors navigate the many evolving and emerging laws and regulations across pharmaceuticals, biologics, medical devices, diagnostics, and laboratory testing, our Life Sciences Regulatory & Compliance team has provided an overview of key developments. We update and publish a quarterly tracker detailing these developments. You can read about the Q2 2024 updates **here**.