# United States Court of Appeals for the Federal Circuit

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**JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV,**
*Plaintiffs-Appellees*

**v.**

**TEVA PHARMACEUTICALS USA, INC.,**
*Defendant-Appellant*

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2025-1228

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Appeal from the United States District Court for the District of New Jersey in No. 2:18-cv-00734-CCC-LDW, Judge Claire C. Cecchi.

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**JANSSEN PHARMACEUTICALS, INC., JANSSEN PHARMACEUTICA NV,**
*Plaintiffs-Appellees*

**v.**

**MYLAN LABORATORIES LTD.,**
*Defendant-Appellant*

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2025-1252

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Appeal from the United States District Court for the District of New Jersey in No. 2:19-cv-16484-CCC-LDW, Judge Claire C. Cecchi.

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Decided: July 8, 2025

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BARBARA MULLIN, Patterson Belknap Webb & Tyler LLP, New York, NY, argued for plaintiffs-appellees. Also represented by J. JAY CHO, ANDREW D. COHEN, ARON RUSSELL FISCHER, ZHIQIANG LIU.

JOHN C. O'QUINN, Kirkland & Ellis LLP, Washington, DC, argued for all defendants-appellants. Defendant-appellant Teva Pharmaceuticals USA, Inc. also represented by WILLIAM H. BURGESS; NOAH SAMUEL FRANK, Boston, MA; CHRISTOPHER T. JAGOE, JEANNA WACKER, New York, NY.

DEEPRO MUKERJEE, Katten Muchin Rosenman LLP, for defendant-appellant Mylan Laboratories Ltd. Also represented by LANCE SODERSTROM; TIMOTHY H. GRAY, ERIC THOMAS WERLINGER, Washington, DC; JILLIAN SCHURR, Dallas, TX.

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Before PROST, REYNA, and TARANTO, *Circuit Judges*.

TARANTO, *Circuit Judge*.

Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV (collectively, Janssen) sued Teva Pharmaceuticals USA, Inc. (Teva) in 2018, alleging infringement by Teva of Janssen's U.S. Patent No. 9,439,906, which describes and claims dosing regimens of long-acting injectable antipsychotic medications. Teva stipulated to infringement but challenged the patent's validity on several grounds, including that all claims (claims 1–21) were

invalid for obviousness and claims 19–21 were also invalid for indefiniteness. The district court, after a bench trial, held that the challenged claims were not shown to be invalid. *Janssen Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.*, 571 F. Supp. 3d 281, 291 (D.N.J. 2021) (*Initial Decision*). In 2024, on Teva's appeal, we affirmed the district court's rejection of Teva's indefiniteness challenge but vacated the rejection of Teva's obviousness challenge and remanded for further proceedings on that issue. *Janssen Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.*, 97 F.4th 915, 918 (Fed. Cir. 2024) (*Janssen 2024*).

On remand, the district court, following a process not challenged here, reconsidered obviousness based on the existing trial record and the parties' new submissions reflecting our 2024 opinion. *Janssen Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc.*, 760 F. Supp. 3d 184, 190 n.4 (D.N.J. 2024) (*Remand Decision*). The district court held that Teva had not proved any of the asserted claims of the '906 patent invalid for obviousness. *Id.* at 190, 224. Teva timely appealed the decision to us. We now affirm.[1]

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[1] Mylan Laboratories Ltd. (Mylan) is also an appellant here. Janssen sued Mylan in a separate action for infringement of the '906 patent. *Janssen Pharmaceuticals, Inc. v. Mylan Laboratories Ltd.*, Case No. 2:19-cv-16484, ECF No. 1 (D.N.J. Aug. 8, 2019). "In that action, the parties stipulated to be bound by the final judgment in the Teva action with respect to infringement and validity." *Janssen 2024*, at 918 n.1; *see also Remand Decision*, at 189 n.3. Both Mylan and Teva appealed the *Remand Decision*; we consolidated the appeals, and Teva and Mylan joined in a single opening brief and a single reply brief. For simplicity, we refer only to Teva.

# I

## A

Janssen's '906 patent claims and discloses "dosing regimens of paliperidone palmitate" (an ester form of paliperidone), including Janssen's "Invega Sustenna-brand paliperidone palmitate extended-release suspension products," which are "used to treat schizophrenia in adults." *Id.* at 190; '906 patent, col. 1, lines 46–49. In the human body, paliperidone palmitate turns into paliperidone, a prior-art antipsychotic medication that was commercially available in tablet form for oral administration. '906 patent, col. 1, lines 36–41; *Remand Decision*, at 191 n.6. The oral medication, however, had to be taken at frequent intervals, *e.g.*, daily, and patients' noncompliance with the ingestion regimen "often result[ed] in worsening of symptoms, suboptimal treatment response, frequent relapses and rehospitalizations, and an inability to benefit from rehabilitative and psychosocial therapies." '906 patent, col. 1, lines 50–57.

The '906 patent addresses the problem of noncompliance and its adverse effects through a proposed treatment regimen, which uses a long-acting injectable formulation of paliperidone palmitate, administered less frequently than oral medication. *See id.*, col. 1, lines 14–16. This injectable formulation can "provide sustained plasma concentrations of paliperidone when administered once monthly, which may greatly enhance compliance with dosing." *Id.*, col. 1, lines 58–61. The patent claims specific "dosing regimen[s] for administering paliperidone esters to a psychiatric patient in need of treatment." *Id.*, col. 2, line 11, through col. 4, line 42.

The parties agree that claims 2, 10, 13, 20, and 21 are representative. *Remand Decision*, at 191. Claim 2 recites a dosing regimen in which a patient is administered a first dose of about 150 mg-eq. (milligram-equivalents) and, about a week later, a second dose of about 100 mg-eq.—

doses referred to in the case as "loading" doses—followed by monthly maintenance doses of 25–150 mg-eq. (The milligram-equivalent measure is not the "actual weight" of the paliperidone palmitate doses, but "the equivalent amount of paliperidone they contain." *Id.* at 191 n.6.) The loading doses are injected into the patient's deltoid muscle, while maintenance doses may be injected into the deltoid or gluteal muscle. Claims 10 and 13 recite regimens using reduced dosages of the medication for patients with renal impairment. Claims 20 and 21 recite regimens in which injectable paliperidone palmitate formulations' median particle sizes are within a certain range. Those claims—and the claims on which they depend—are recited below:

> 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 $6^{th}$ 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.

2. The dosing regimen of claim 1 wherein after administration of the first maintenance dose, subsequent maintenance doses of from about 25 mg-eq. to 150 mg-eq. are administered in the deltoid or gluteal muscle of the psychiatric patient in need of treatment at monthly (±7 days) intervals.

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

> (a) administering intramuscularly in the deltoid of a renally impaired psychiatric patient in need of treatment a first loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;
>
> (b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the $6^{th}$ to about 10th day of treatment; and
>
> (c) 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 75 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation a month (±7 days) after the second loading dose.

10. The dosing regimen of claim 8 wherein the sustained release formulation is an aqueous nanoparticle suspension.

11. A dosing regimen for administering paliperidone palmitate to a renally impaired psychiatric patient in need of treatment for psychotic disorder comprising

(a) administering intramuscularly in the deltoid of a renally impaired psychiatric patient in need of treatment a first loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the first day of treatment;

(b) administering intramuscularly in the deltoid muscle of the patient in need of treatment a second loading dose of from about 75 mg-eq. of paliperidone as paliperidone palmitate formulated in a sustained release formulation on the eighth day of treatment; and

(c) 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 50 mg-eq. of paliperidone as paliperidone palmitate in a sustained release formulation a month (±7 days) after the second loading dose.

13. The dosing regimen of claim 11 wherein the psychiatric patient is in need of treatment for of a psychotic disorder wherein the psychotic disorder is schizophrenia.

19. The dosing regimen of claims 1, 4, 8 or 11 wherein the sustained release depot formulation is

> an aqueous nanoparticle suspension consists essentially of
>
> > (a) 156 mg/ml of the paliperidone palmitate having an average particle size (d50) of from about 1600 nm to about 900 nm;
> >
> > (b) 12 mg/ml of polysorbate 20;
> >
> > (c) one or more buffering agents sufficient to render the composition neutral to very slightly basic (pH 8.5);
> >
> > (d) 30 mg/ml of a suspending agent wherein the suspending agent is polyethylene glycol 4000; and
> >
> > (f) water q.s. ad 100%.
>
> 20. The dosage regimen of claim 19 wherein in the buffering agents contained in the aqueous nanoparticle suspension are citric acid monohydrate, disodium hydrogen phosphate anhydrous, sodium dihydrogen phosphate monohydrate, sodium hydroxide.
>
> 21. The dosage regimen of claim 19 wherein in the pH of the aqueous nanoparticle suspension is in the range of pH 7 to 7.5.

'906 patent, col. 32, lines 11–36; *id.*, col. 32, line 66, through col. 33, line 20; *id.*, col. 33, lines 26–47, 50–52; *id.*, col. 34, lines 32–51.

B

In December 2017, Teva filed Abbreviated New Drug Application (ANDA) No. 211149, seeking approval from the Food and Drug Administration (FDA) for the manufacture and sale of a generic version of Janssen's Invega Sustenna. *Remand Decision*, at 190; *Initial Decision*, at 291. The next month, Janssen sued Teva in district court under the Hatch-Waxman Act, 35 U.S.C. § 271(e)(2). *Remand*

*Decision*, at 190. Teva stipulated to infringement but challenged all claims of the '906 patent (claims 1–21) for obviousness and lack of adequate written description and claims 19–21 for indefiniteness. *Id.* at 189; *Initial Decision*, at 291, 327; *Janssen 2024*, at 918.

For its obviousness challenge, Teva relied primarily (though not exclusively) on three prior-art references involving Janssen's work. The first is NCT00210548, A Study to Evaluate the Effectiveness and Safety of 3 Doses of Paliperidone Palmitate in Treating Subjects with Schizophrenia ('548 protocol), which details a Janssen Phase III clinical trial for testing the hypothesis that a regimen of three equal-amount doses of paliperidone palmitate would be more effective than a placebo. J.A. 13244–45; *Remand Decision*, at 195. The document is a mere testing protocol—for administering at least three equal doses of 50, 100, or 150 mg-eq. of paliperidone palmitate at specified time intervals, J.A. 13244; it "does not contain clinical results or safety data," *Initial Decision*, at 301; *see Janssen 2024*, at 922. The second prior-art reference is Janssen-owned U.S. Patent No. 6,555,544 ('544 patent), J.A. 13237–43, which discloses a "pharmaceutical composition suitable as a depot formulation for administration by intramuscular or subcutaneous injection, comprising," among other materials, a "therapeutically effective amount" of paliperidone palmitate. '544 patent, col. 9, line 65, through col. 10, line 4. The third prior-art reference is Janssen-owned International Publication No. WO 2006/114384 (WO '384), which describes "a process for preparing aseptic crystalline" paliperidone palmitate. J.A. 13299, Abstract; *see generally* J.A. 13299–13321. The WO '384 reference states that the formulation was "filled aseptically into sterile syringes" in dose volumes "between 0.25 ml and 1.50 ml depending on the dose needed," J.A. 13317, "which corresponds to 25 to 150 mg-eq. of paliperidone," *Janssen 2024*, at 924.

After a bench trial, the district court, on November 16, 2021, held that Teva had not proven invalidity for

obviousness, lack of written description, or indefiniteness. *Initial Decision*, at 291. Regarding obviousness, the district court rejected Teva's theories that a relevant artisan, in considering the prior art, would have had a motivation to combine or modify the references to arrive at the now-claimed dosing regimens with a reasonable expectation of success. *Id.* at 300–13. Teva argued that the representative claims "should be presumed obvious because they merely recite limitations from ranges disclosed in the prior art." *Id.* at 325. The court disagreed, holding that a presumption of obviousness did not apply "where the claimed invention at issue is composed of a unique combination of elements that are not all easily defined with numerical values that can be found in the prior art." *Id.*

In its first appeal, Teva challenged the district court's rejections of its obviousness and indefiniteness challenges. *Janssen 2024*, at 918. We agreed with the district court regarding indefiniteness, but we vacated the rejection of Teva's obviousness challenge. *Id.* We identified a number of problems with the district court's analysis. *Id.* at 925–32. We remanded the case for the district court to reconsider the obviousness issue with the identified analytical flaws corrected. *Id.* at 927–28, 937.

On remand, the district court, based on the existing trial record and the parties' post-remand briefing, again determined that the '906 patent's claims had not been proven invalid for obviousness. *Remand Decision*, at 190 & n.4. Of particular significance to our resolution of the appeal now before us, the district court found against Teva on the factual issues of motivation to combine references and reasonable expectation of success to arrive at the claim 2 regimen. *Id.* at 198–209. The court then rejected Teva's argument that it was entitled to a presumption of obviousness of claim 2, *id.* at 210–11, citing in particular three Teva-acknowledged differences between the claim limitations and prior art ("dosage amounts, claimed dosing sequence and requisite deltoid injections," *id.* at 210), while

adding that such a presumption would in any event be overcome based on "unexpected results and other pertinent secondary considerations," *id.* at 211 (referring ahead to *id.* at 216–24). Regarding claims 10 and 13, the district court found that Teva failed to prove that a relevant artisan would be motivated to combine prior-art references to arrive at the claimed dosing regimens for renally impaired patients. *Id.* at 211–14. The district court then determined that Teva had failed to prove that representative particle-size claims 20 and 21 were invalid for obviousness. *Id.* at 214–16.

Teva timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

II

Obviousness is a question of law based on underlying findings of fact. *Janssen 2024*, at 925. We review the overall determination de novo and the district court's underlying factual findings for clear error. *Id.* Under the clear-error standard, we uphold the district court's findings "in the absence of a definite and firm conviction that a mistake has been made." *Par Pharmaceutical, Inc. v. Eagle Pharmaceuticals, Inc.*, 44 F.4th 1379, 1383 (Fed. Cir. 2022) (quoting *Scanner Technologies Corp. v. ICOS Vision Systems Corp. N.V.*, 528 F.3d 1365, 1374 (Fed. Cir. 2008)).

As the challenger in district court, Teva bore the burden of proving, by clear and convincing evidence, the facts needed to show obviousness. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359–60 (Fed. Cir. 2007). Under the generally applicable framework for showing obviousness, Teva had to show "by clear and convincing evidence that a skilled artisan would have been motivated to combine [or modify] the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so," both parts of which are well-recognized to be factual issues. *Id.* at 1361; *see, e.g.*, *Grunenthal GmbH v. Alkem Laboratories*

*Ltd.*, 919 F.3d 1333, 1341 (Fed. Cir. 2019); *Persion Pharmaceuticals LLC v. Alvogen Malta Operations Ltd.*, 945 F.3d 1184, 1189–90 (Fed. Cir. 2019). Clear and convincing evidence is evidence that "places in the fact finder an abiding conviction" that the factual contentions at issue are "highly probable" to be true. *Procter & Gamble Co. v. Teva Pharmaceuticals USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009) (internal quotation marks omitted); *see Colorado v. New Mexico*, 467 U.S. 310, 316 (1984).

A

We begin with Teva's challenge to the district court's holding that Teva did not prove claim 2 invalid for obviousness. Teva contends that the district court should have applied a presumption of obviousness to claim 2. Teva then contends that even if such a presumption of obviousness does not apply, the district court still erred in finding obviousness not to have been proved. The two contentions are related, as we will indicate, and they could sensibly be discussed in reverse order, but we follow Teva's order of presentation. We reject both contentions.

1

Teva first argues that the district court legally erred in not applying a presumption of obviousness to the claim 2 treatment regimen. Teva Opening Br. at 31–36. We disagree.

a

The cases that Teva invokes for this presumption, usually referred to as overlapping-range cases, are ones in which a challenged claim requires a feature in a numerical amount (specified as, *e.g.*, a single figure or a range) and a prior-art reference teaches that feature in amounts that overlap with the claimed numerical amount. Such facts have in many cases been held sufficient to establish prima facie obviousness and, for the past two decades, to generate a presumption of obviousness. *See*, *e.g.*, *In re Peterson*, 315

F.3d 1325, 1329 (Fed. Cir. 2003) ("A *prima facie* case of obviousness typically exists when the ranges of a claimed composition overlap the ranges disclosed in the prior art."); *Ormco Corp. v. Align Technology, Inc.*, 463 F.3d 1299, 1310–11 (Fed. Cir. 2006); *Galderma Laboratories, L.P. v. Tolmar, Inc.*, 737 F.3d 731, 736–38 (Fed. Cir. 2013); *Allergan, Inc. v. Sandoz Inc.*, 796 F.3d 1293, 1304–05 (Fed. Cir. 2015); *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1006–08 (Fed. Cir. 2018); *Valeant Pharmaceuticals International, Inc. v. Mylan Pharmaceuticals Inc.*, 955 F.3d 25, 31–33 (Fed. Cir. 2020); *Almirall, LLC v. Amneal Pharmaceuticals LLC*, 28 F.4th 265, 272–73 (Fed. Cir. 2022); *Pfizer Inc. v. Sanofi Pasteur Inc.*, 94 F.4th 1341, 1347–48 (Fed. Cir. 2024). When the presumption applies, "'the burden of production falls upon the patentee to come forward with evidence' of teaching away, unexpected results, or other pertinent evidence of nonobviousness," but the burden of persuasion on obviousness remains with the challenger. *E.I. DuPont*, 904 F.3d at 1006–07 (quoting *Galderma*, 737 F.3d at 738); *see also Almirall*, 28 F.4th at 272; *Pfizer v. Apotex*, 480 F.3d at 1360; *In re Kumar*, 418 F.3d 1361, 1366 (Fed. Cir. 2005).

Our cases have addressed, in ways relevant to our decision here, various issues that have arisen regarding the potential scope of the presumption. First: We have ruled that the presumption applies, even where there is no strict overlap with a teaching of a single piece of prior art, if the ranges are "close enough that *one skilled in the art would have expected them to have the same properties*." *Peterson*, 315 F.3d at 1329 (emphasis added) (discussing *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 782–83 (Fed. Cir. 1985)). Second: We have suggested that the presumption might apply to, and we have made clear that it at least supports analogous treatment of, *some* cases in which a plurality of prior-art references together (rather than a single reference alone) may be understood as teaching a range. *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*,

392 F.3d 1317, 1322 (Fed. Cir. 2004) (noting that earlier cases had "a range disclosed within a single [prior-art] patent," whereas in the *Iron Grip* case "the range [was] disclosed in multiple prior art patents," but "under the circumstances of this case, that is a distinction without a difference" because the prior art affirmatively suggests combining the references). Third: We have indicated that the overlapping-range presumption *can* apply even when a claimed compound is structurally similar (rather than identical) to prior-art compounds, stressing that whether the presumption applies in such a situation is a factual question dependent on what properties the relevant artisans would "expect" to follow from the structural similarity. *Valeant*, 955 F.3d at 31–34.

One limitation articulated by the district court we do not find in our cases. Thus, contrary to the district court's statement, when we said in *Kumar* that "[a] *prima facie* case of obviousness may be made when the only difference from the prior art is a difference in the range or value of a particular variable," 418 F.3d at 1366, we did not declare a blanket rule that the presumption "only applies" in that single-difference circumstance, *Remand Decision*, at 210. Nor have we been pointed to other precedents setting a categorical one-difference limit on the presumption at issue here. *See*, *e.g.*, *In re Aller*, 220 F.2d 454, 456 (CCPA 1955) ("[A] change in temperature, or in concentration, *or in both*, would be an unpatentable modification." (emphasis added)). The absence of such a categorical limit, however, does not mean that the number of differences from the prior art or the relationship between those differences is irrelevant to the justification for using the presumption to truncate the usual full case-specific obviousness inquiry in a given context.

More broadly, our cases illustrate that invocation of the presumption is not independent of different inventive contexts. Thus, we have expressly noted certain contextual characteristics that can make the presumption

inapplicable, such as a very wide prior-art range. *See Allergan*, 796 F.3d at 1305; *Genetics Institute, LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1306 (Fed. Cir. 2011) (discussing *Peterson*, 315 F.3d at 1330 & n.1). We have also stressed the role of relevant artisans' expectations (as indicated just above), which may differ for different kinds of inventions, and repeatedly stated the presumption, or explained its bases, in ways that may turn on facts about the invention's context, sometimes stressing the centrality of context-specific factual issues. For example, in *Peterson*, our statement of the basic rule was that "[a] *prima facie* case of obviousness *typically* exists when the ranges of a claimed *composition* overlap the ranges disclosed in the prior art." 315 F.3d at 1329 (second and third emphases added). In *E.I. DuPont*, we relied on *Peterson*'s "typically" statement about compositions and also on the explanation in *Aller*, 220 F.2d at 456, that "*[n]ormally*, it is to be expected that a change in *temperature*, or in *concentration*, or in both, would be an unpatentable modification." 904 F.3d at 1006 (emphases added). In *Genetics Institute,* we recited "our longstanding admonition that 'generalization is to be avoided insofar as specific structures are alleged to be *prima facie* obvious one from the other,'" 655 F.3d at 1306 (quoting *In re Jones*, 958 F.2d 347, 350 (Fed. Cir. 1992)), just before rejecting invocation of the *Peterson* presumption, citing *Peterson*'s "typically" sentence and concluding that the premises of the presumption do "not apply to the facts of this case," *id.* In *Valeant*, which involved claims requiring a pH range for a compound structurally similar (but not identical) to the pertinent compounds of the prior art (teaching overlapping ranges), we explained that "[w]hether [the claimed compound's] structural similarity in an overlapping range of pH in solution is sufficient to yield a prima facie case of obviousness depends on the facts of record. *In re Jones*, 958 F.2d [at 350] ('Every case, particularly those raising the issue of obviousness under section 103, must necessarily be decided upon its own facts.')."

In cases not clearly covered by precedents, the premises on which the presumption rests properly guide whether it should be held to apply in a given setting. The presumption is justified by interrelated premises: "where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation," *E.I. DuPont*, 904 F.3d at 1006 (quoting *Aller*, 220 F.2d at 456); "[t]he normal desire of scientists or artisans to improve upon what is already generally known provides the motivation to determine where in a disclosed set of percentage ranges is the optimum combination of percentages," *Peterson*, 315 F.3d at 1330; "discovery of an optimum value of a result effective variable in a known process is ordinarily within the skill of the art," *id.* (alteration omitted) (quoting *In re Boesch*, 617 F.2d 272, 276 (CCPA 1980)); and numerical amounts can be "close enough such that one skilled in the art would have expected them to have the same properties," *id.* at 1329 (discussing *Titanium Metals*, 778 F.2d at 782–83); *see also, e.g.*, *Pfizer v. Sanofi Pasteur*, 94 F.4th at 1347–48. Those premises are factual ones about relevant artisans' motivations to optimize and expectations from routine experimentation—which, not surprisingly, are materially the same as the basic factual inquiries of the normal full obviousness analysis (motivation to combine or modify and expectation of success) that the presumption, when applicable, replaces.

The facts about the presence of the presumption's premises, like other legally pertinent facts, can be determined in at least two kinds of ways. First, they can be found by the finder of fact after full factfinding proceedings in a particular case. *See In re Applied Materials, Inc.*, 692 F.3d 1289, 1293–95 (Fed. Cir. 2012) (relying on findings by the PTO Board of Patent Appeals and Interferences of a relevant artisan's motivation to optimize by routine experimentation); *Almirall*, 28 F.4th at 272 (applying the presumption based on "factual findings" about overlap and a

relevant artisan's expectations). Most of the presumption cases cited by the parties involve such full factfinding proceedings and our affirmance of an express or implicit determination by the finder of fact (*e.g.*, the PTO or a district court) on the relevant motivation and expectations of the ordinary skilled artisan at issue.[2] Second, sometimes the facts about such motivation and expectation are beyond reasonable dispute, necessitating a particular result on the

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[2] *See Aller*, 220 F.2d at 456, 458–59; *In re Ornitz*, 351 F.2d 1013, 1014–17 (CCPA 1965); *In re Malagari*, 499 F.2d 1297, 1303 (CCPA 1974); *In re Wertheim*, 541 F.2d 257, 267–68 (CCPA 1976) (affirming in relevant part that a prima facie case had been made out regarding certain process claims); *Boesch*, 617 F.2d at 276; *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990); *In re Geisler*, 116 F.3d 1465, 1469–70 (Fed. Cir. 1997); *Peterson*, 315 F.3d at 1329–32; *In re Harris*, 409 F.3d 1339, 1341–44 (Fed. Cir. 2005); *Applied Materials*, 692 F.3d at 1293–97; *Almirall*, 28 F.4th at 272–73; *Pfizer v. Sanofi Pasteur*, 94 F.4th at 1347–49.

In *Genetics Institute*, we affirmed a determination of no prima facie case made after factfinding proceedings. 655 F.3d at 1302–07. In *Allergan*, we affirmed a factfinder's rejection of an obviousness challenge, noting that we did not need to decide whether a prima facie case was made out. 796 F.3d at 1303–07. In *Valeant*, we reversed a grant of summary judgment to the patent owner, holding that "a prima facie case . . . sufficient to survive summary judgment" was present and remanding for more factfinding. 955 F.3d at 33, 34. We also remanded for more factfinding in *Kumar*, 418 F.3d at 1366–69.

record in a case (whether without or after full factfinding) viewed under relevant precedent.[3]

b

In this case, Teva's argument is that because the '548 protocol disclosed *equal* loading doses of 150 mg-eq. or of 100 mg-eq., and WO '384 disclosed a range that contains both these values, the prior art rendered claim 2's loading doses (150, then 100) prima facie obvious. Teva Opening Br. at 33 (citing J.A. 13244; J.A. 13317). But the district court made detailed findings that are counter to finding the premises of the presumption to be present for the treatment regimen of claim 2. *Remand Decision*, at 198–208. We conclude that there is an insufficient basis in the record evidence for us to apply the invoked presumption in the face of the district court's clear findings against Teva on the issues of relevant artisans' motivation and expectations.

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[3] Cases cited by the parties on this issue where we applied the presumption or invoked it at least as analogical support, either by requiring summary judgment or by setting aside the factfinder's ruling reached after full factfinding, include the following: *Iron Grip*, 392 F.3d at 1320–23; *Ormco*, 463 F.3d at 1310–11; *Galderma*, 737 F.3d at 737–38; *E.I. DuPont*, 904 F.3d at 1006–08.

In *Titanium Metals*, we reversed a finding of the district court in a case under 35 U.S.C. § 145, but our decision was in agreement with the PTO's contrary finding (with which the district court had disagreed); and we suggested that the record made clear that certain claimed and prior-art "proportions [components of alloys] were so close that prima facie one skilled in the art would have expected them to have the same properties." 778 F.2d at 782–83.

It is sufficient for us to focus just on the combination of specified dosages at specified times required by the claim, which is different from the prior art. We do not rely on claim 2's requirement of injection in the deltoid (not gluteal) muscle for the two loading doses, though that is also a difference from the prior art. We have already indicated that the district court erred in reading *Kumar* to say that the presumption is unavailable whenever there is more than one difference from the prior art. *Id.* at 210. And the district court found the choice of injection site (one of essentially two choices) to be one a relevant artisan would be motivated to adopt with a reasonable expectation of success. *Id.* at 209.

The treatment regimen at issue is a combination of dosages and times of injection—with decreasing loading doses—where the evidence reasonably characterizes the combination as an integrated unit of steps taken over time for achieving desired medicinal effects (on the brain) in a patient over time. The crucial choice made by Janssen, as the district court properly framed the matter, was the choice to start with a particular high first loading dose and then follow it with a second, lower loading dose. That choice for the *combination* of loading doses is addressed to the relation between two dosage figures in a way that does not *clearly* fit within the presumption's focus on simply selecting a number or range overlapping a prior-art range of a variable or, even, a plurality of variables that overlap with prior-art ranges where the variables are properly considered separately from each other.

To determine whether we nevertheless should deem the choice to be within the presumption, we look to whether the choice made here comes within the underlying rationale of relevant artisans' routine optimization in this particular field. That inquiry is a factual one, as explained above, and on the present record, we will not extend the presumption to this case.

Here, the factual findings by the district court are counter to finding the presumption's premises applicable. Whatever might be shown in a future case, the record in this case does not compel a contrary finding (as we will discuss next, in reviewing the district court's full obviousness analysis). And neither is a contrary finding compelled by case law generally. The cases are overwhelmingly about the makeup of, and/or processes of making, alloys or other compositions, and none involves a choice closely akin to the one made here for the related doses in a (psychosis) treatment regimen.[4] More particularly, none of the cases where we decided the matter based on something other than case-

[4] *See Aller*, 220 F.2d at 458–59 (process for making phenol); *Ornitz*, 351 F.2d at 1014–17 (metal alloys); *Malagari*, 499 F.2d at 1303 (steel-making process); *Wertheim*, 541 F.2d at 267–68 (freeze-drying coffee); *Boesch*, 617 F.2d at 276 (alloys); *Titanium Metals*, 778 F.2d at 782–83 (alloys); *Woodruff*, 919 F.2d at 1578 (refrigeration atmosphere); *Geisler*, 116 F.3d at 1468–69 (protective layered coating); *Peterson*, 315 F.3d at 1329–32 (alloys); *Harris*, 409 F.3d at 1341–44 (alloys); *Kumar*, 418 F.3d at 1366–69 (size and distribution of particles used in polishing compositions); *Genetics Institute*, 655 F.3d at 1302–07 (recombinant blood-clotting proteins); *Applied Materials*, 692 F.3d at 1293–97 (grooves in pads for polishing semiconductor substrates); *Allergan*, 796 F.3d at 1303–07 (composition for ophthalmic use, not deciding prima facie case issue); *Valeant*, 955 F.3d at 31–34 (pharmaceutical preparation, relying on specific record as supporting a prima facie case but remanding for more factfinding); *Almirall*, 28 F.4th at 272–73 (content of dermatological compositions); *Pfizer v. Sanofi Pasteur*, 94 F.4th at 1347–49 (content of conjugates in immunogenic compositions).

specific factfinding supports a similar decision here.[5] In these circumstances, we hold that the proper course at present is to apply the normal full obviousness analysis, rather than a truncated version based on the invoked presumption.

2

Teva argues that even if the invoked presumption does not apply, the district court erred in determining that claim 2 was not invalid for obviousness. Teva Opening Br. at 42–58. Teva asserts that "[t]he *only* patentable difference the district court identified between the claim[] and prior art was the so-called 'unequal, decreasing loading doses.'" *Id.* at 42 (capitalization normalized) (quoting *Remand Decision*, at 199; citing *id.* at 199–209). According to Teva, the district court placed too much emphasis on the "unequal" and "decreasing" characteristics of the claimed dosing regimen and "erred by requiring 'motivation . . . to reach the *specific* dosing regimen of Claim 2.'" *Id.* at 44–45 (citing *Remand Decision*, at 199).

To the extent that Teva alleges an improper focus on the "specific dosing regimen of Claim 2," the criticism is misplaced. It is bedrock law that the inquiry of motivation

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[5] *See Iron Grip*, 392 F.3d at 1320–23 (claim to three elongated holes in barbell weight plates to use as handles; three pieces of prior art disclosed, respectively, one, two, and four such handles); *Ormco*, 463 F.3d at 1310–11 (schedule for switching out teeth aligners—claimed 2–20 days, 14–21 days taught in a prior-art reference); *Galderma*, 737 F.3d at 737–38 (acne medication with 0.3% adapalene claimed, where prior art taught 0.01%–1%); *E.I. DuPont*, 904 F.3d at 1006–11 (method of making a carboxylic acid, with overlap of conditions—particular temperature and partial pressure—between claim requirements and a prior-art reference).

and reasonable expectation of success must focus on arriving at the *claimed* invention, though more than one step may be involved in getting there. *See*, *e.g.*, *Auris Health, Inc. v. Intuitive Surgical Operations, Inc.*, 32 F.4th 1154, 1158 (Fed. Cir. 2022) ("The motivation-to-combine inquiry asks whether a skilled artisan not only could have made but would have been motivated to make the combinations . . . of prior art to arrive at *the claimed invention*." (emphasis added) (internal quotation marks omitted) (quoting *Belden Inc. v. Berk-Tek LLC*, 805 F.3d 1064, 1073 (Fed. Cir. 2015)); *Teva Pharmaceuticals USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1381 (Fed. Cir. 2021) ("The reasonable-expectation-of-success analysis must be tied to the scope of the claimed invention. . . . Teva was required to prove a reasonable expectation of success in achieving the specific invention claimed, a 600 mg dosage."). Contrary to Teva's suggestion, that requirement is wholly consistent with the recognition that a relevant artisan may be motivated to do more than one thing. *Janssen 2024*, at 930.

We conclude that the district court did not commit clear error in its findings that Teva did not prove the key facts needed to establish obviousness of claim 2 by clear and convincing evidence. *Remand Decision*, at 199–208.

a

The district court rejected Teva's contention that WO '384 and the '544 patent would have motivated a relevant artisan to "modify the '548 Protocol to achieve the loading dose regimen of Claim 2," finding, among other things, that "neither reference discloses a loading dose regimen." *Id.* at 200. Teva challenges the district court's determination. It asserts that because WO '384 and the '544 patent teach methods of calibrating doses of paliperidone palmitate for specific patients, these references would have led a relevant artisan to "come up with an optimal dosage regimen," thereby rendering the claimed regimen obvious. Teva Opening Br. at 46–48.

Teva has not shown clear error. As the district court found—and Teva agreed—neither WO '384 nor the '544 patent discloses a loading-dose regimen. *Remand Decision*, at 200 (citing Teva's expert testimony at J.A. 10512, lines 5–8, J.A. 10506, line 24, through 10507, line 1). There was record evidence that the '544 patent would not have "taught or suggested to a skilled artisan to use a loading dose regimen." *Id.* (quoting J.A. 12256, lines 12–14 (Janssen's expert testimony)). The district court, carefully considering Teva's calibration theory, reasonably found that "Teva d[id] not provide sufficient support in the record for this theory." *Id.* at 200 n.11.

b

The district court rejected Teva's theory that a relevant artisan would have been motivated to use a large initial loading dose followed by a reduced second loading dose. *Remand Decision*, at 199–206. Teva challenges that determination, relying on the prior-art references Ereshefsky 1990,[6] Ereshefsky 1993,[7] and Karagianis.[8] Teva Opening Br. at 49–51, 53–55. It argues that those references taught a relevant artisan to "use a larger initial dose to 'load' the patient, so that therapeutic effects are achieved more rapidly" and to administer a reduced second loading dose so as to avoid excessive accumulation of paliperidone palmitate within the patient. *Id.* at 50–51 (citing J.A. 14124 (Ereshefsky 1993); J.A. 14115 (Ereshefsky 1990)); *see also*

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[6] Larry Ereshefsky et al., *Kinetic and Clinical Evaluation of Haloperidol Decanoate Loading Dose Regimen*, 26 Psychopharmacology Bull. 108 (1990). J.A. 14113–20.

[7] Larry Ereshefsky et al., *A Loading-Dose Strategy for Converting from Oral to Depot Haloperidol*, 44 Hosp. & Cmty. Psychiatry 1155 (1993). J.A. 14121–29.

[8] James L. Karagianis et al., *Rapid Tranquilization with Olanzapine in Acute Psychosis: A Case Series*, 62 J. Clinical Psychiatry 12 (2001). J.A. 16199–16203.

*id.* at 53 (asserting that Karagianis teaches a high loading dose of olanzapine, a second-generation long-acting injectable antipsychotic medication).

Teva specifically challenges, in a mix of the district court's and Teva's own words, the district court's finding that a relevant artisan would not have been motivated to administer "sufficiently high [long-acting injectable] loading doses to treat acutely ill patients," as such a treatment would "not [work] fast enough to treat acute conditions." Teva Opening Br. at 49–50 (citing J.A. 12379, lines 4–13 (Teva's expert testimony); J.A. 11212, lines 10–16 (Janssen's expert testimony); *Remand Decision*, at 201). Teva also argues that the district court further erred in finding that Teva's own expert testimony undermined Teva's Karagianis-based proposed motivation for a high first loading dose. *Id.* at 53–54 (citing *Remand Decision*, at 201–02). Teva further challenges the district court's reference to a relevant artisan's motivation to modify the dose's particle sizes (to achieve therapeutic effects more rapidly) as a basis for not finding that a relevant artisan would be motivated to modify the dose amount. *Id.* at 54–55 (citing *Remand Decision*, at 202). Additionally, Teva contends that the district court's understanding that Ereshefsky 1993 "teaches the reduction of *maintenance* doses, not *loading* doses" is too narrow and ignores the application of the Ereshefsky references' teachings to loading doses. *Id.* at 51 (quoting *Remand Decision*, at 203).

Teva has not shown clear error in the foregoing respects. Thus, the district court had an adequate basis for rejecting Teva's theory that a relevant artisan would want to use the maximum safe dose as a first loading dose. *Remand Decision*, at 202–04. With sufficient support from the Ereshefsky references themselves and testimony from Janssen's expert, the court reasonably found that the Ereshefsky references addressed studies of patients who were already stabilized on oral haloperidol (a known and established medication) before starting experimental

regimens with long-acting injectables, so those references would not have taught a relevant artisan to use long-acting injectables to "load" patients. *Id.* at 201 (citing J.A. 14125 (Ereshefsky 1993); J.A. 11568, line 21, through 11569, line 13 (Janssen's expert testimony discussing Ereshefsky 1990)). Likewise, the district court had an adequate evidentiary basis for rejecting Teva's argument about what was taught by Karagianis. For example, while one Teva expert testified that Karagianis taught using a high first loading dose to treat an acutely ill patient, another Teva expert explained that a relevant artisan would not use long-acting injectables to treat an acutely agitated patient. *Id.* at 201–02 (citing J.A. 10313, line 11, through 10314, line 22; J.A. 10090, lines 12–23; J.A. 12383, line 24, through 12384, line 11).

Likewise, we see no clear error in the district court's determination that a relevant artisan would seek to speed up a patient's absorption of the medication by reducing the particle size and not by increasing the dose. The court recognized that a relevant artisan "can be motivated to do more than one thing" and simply found that "the evidence demonstrates a POSA would be motivated to modify the particle size to achieve therapeutic effects more rapidly, and there is insufficient evidence to support that a POSA would be motivated to modify the loading dose size to achieve the same." *Id.* at 202 n.20 (citing *Janssen 2024*, at 930). Although Teva might suggest otherwise, Teva Opening Br. at 54–55, the district court did not find that adjusting the smaller particle size would have precluded adjusting the dose amount or that this was an either/or choice. Rather, the district court evaluated the evidentiary record, credited the testimony of Janssen's expert that administering a larger dose would not help a patient reach the therapeutic threshold more quickly, and found insufficient evidence in support of adjusting the dose amount at all. *Remand Decision*, at 202–03 (citing J.A. 12109, line 22, through 12110, line 4; J.A. 11592, line 22, through 11594,

line 25; J.A. 12111, lines 6–13 (Janssen's expert testimony)).

In addition, the district court had an adequate evidentiary basis for rejecting Teva's theory that Ereshefsky 1993 teaches reducing second loading doses, including testimony from Teva's expert that "loading doses and maintenance doses are distinct concepts," so a relevant artisan "would not infer that Ereshefsky's teachings on maintenance doses would apply equally to loading doses." *Id.* at 203 (citing J.A. 14124 (Ereshefsky 1993); J.A. 10322, line 17, through 10323, line 1; J.A. 10372, lines 15–24; J.A. 10211, lines 8–12; J.A. 10312, lines 12–13 (Teva's expert testimony); J.A. 14115 (Ereshefsky 1990)). The court reasonably found that Teva had not met its evidentiary burden of showing that a relevant artisan "would reasonably infer from the reduction of a *maintenance* dose a motivation to reduce a second *loading* dose." *Id.*

c

Teva next argues that the district court was required to find that the Haldol label prior-art reference,[9] which provides guidance on the injectable administration of another antipsychotic medication (haloperidol decanoate), would have motivated a relevant artisan to reach the claimed dosing regimen. Teva Opening Br. at 51–53. Teva points to two specific teachings in support of this argument: (1) "that an injectable dose should be approximately 10 to 20 times the daily oral dose"; and (2) that because a dose of Haldol should not exceed a certain amount (100 mg), if a patient requires a larger dose, the dose should be administered in two injections: an initial dose of the maximum amount and the remaining (smaller) balance in the second dose. *Id.* at

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[9] *HALDOL® Decanoate 50 (haloperidol) HALDOL® Decanoate 100 (haloperidol) For IM Injection Only* (last modified May 2007). J.A. 16640–53.

51–52 (citing J.A. 16650–52). Teva argues that the district court reversibly erred in "read[ing] the Haldol label's teachings as strictly limited to the particular drug and the specific numbers on the label." *Id.* at 52 (citing *Remand Decision*, at 205).

We disagree. The district court's determination that the Haldol label would not have taught a relevant artisan an unequal, decreasing dosing regimen is not clearly erroneous. The reference itself, as the court identified, instructs a practitioner to "begin with lower initial doses and to adjust the dose upward as needed." *Remand Decision*, at 205 (quoting J.A. 16651 (Haldol label); citing J.A. 12392, line 19, through 12393, line 1 (Teva's expert testimony)). The court also found, reasonably, that the Haldol label's specific instructions actually teach an *increasing* rather than a *decreasing* dosing regimen. *Id.* (citing J.A. 16651). Further, the district court explained—and both parties agreed—that haloperidol decanoate and paliperidone palmitate behave differently in the human body. *Id.* (citing J.A. 10513, lines 17–24, 10515, lines 9–21 (Teva's expert noting that the two drugs have different pharmacokinetic profiles and have different rate processes); J.A. 11566, line 18, through 11567, line 11 (Janssen's expert explaining that studies of drugs with different pharmacokinetics cannot be directly correlated)). Taking into account the inherent differences between the medications, the district court further found that Teva "d[id] not provide sufficient evidence as to *why*" a relevant artisan would be motivated "to apply the specific quantitative amounts recommended based on haloperidol decanoate to paliperidone palmitate." *Id.* at 204.

d

The district court found that a relevant artisan would not have a reasonable expectation of success (of achieving the claimed invention's therapeutic benefits) based on the prior art. *Id.* at 206–08. Teva presents two specific

challenges to that finding, arguing (1) that the court erroneously considered factors not in the claims, *e.g.*, "safety, efficacy, or regulatory approval," and (2) that the district court erred in finding that the multi-dose nature of the claimed regimens added complexity that would have precluded a relevant artisan from expecting success. Teva Opening Br. at 56–58. We discern no reversible error by the district court on this issue.

"The reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the limitations of the claimed invention." *Intelligent Bio-Systems, Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367 (Fed. Cir. 2016). But the district court made its point about reasonable expectation of success in a way that was tied to the motivation to make the needed combination or modification, and it is not legal error or clear error to consider unclaimed factors in the analysis "if a skilled artisan would reasonably consider" these unclaimed factors in the process of "creating a useful claimed invention." *Natera, Inc. v. NeoGenomics Laboratories, Inc.*, 106 F.4th 1369, 1378 (Fed. Cir. 2024); *see also OSI Pharmaceuticals, LLC v. Apotex Inc.*, 939 F.3d 1375, 1385 (Fed. Cir. 2019) (holding that while efficacy data is not always required for a reasonable expectation of success, a lack of efficacy data can be found to affect a relevant artisan's reasonable expectations of success). The district court, relying on testimony from Teva's expert, properly found that a relevant artisan "would be motivated to use a dosing regimen that is safe and effective." *Remand Decision*, at 207 (citing J.A. 10320, lines 5–12; J.A. 10324, line 18, through 10325, line 11, J.A. 10426, lines 6–12). We see no reversible error in the court's consideration of those factors.

The district court next found that a relevant artisan would not reasonably expect the claimed dosing regimen to be a safe and effective treatment. *Id.* at 207–08. That finding was supported by the testimony of Janssen's expert that multi-dose regimens introduce additional complexities

(*e.g.*, excess accumulation of the drug in a patient's body and fluctuation of drug levels between administrations) beyond those of single-dose regimens and may lead to adverse effects. *Id.* (citing J.A. 11597, line 17, through 11599, line 14 (Janssen's expert testimony)). The fact that the only prior-art reference that disclosed multi-dose regimens, the '548 protocol, included no safety or efficacy results further bolstered the court's finding that a relevant artisan would have found multi-dose regimens more unpredictable. *Id.* at 207. Based on the evidentiary record, we see no clear error in the court's determinations that a relevant artisan would not have had reasonable expectation of success.

For all those reasons, we reject Teva's challenge to the district court's upholding of claim 2.

B

Teva also challenges the district court's decision to uphold two groups of other representative claims—claims 10 and 13; and claims 20 and 21. We reject these challenges as well.

1

Teva argues that the subject matter of claims 10 and 13, the representative renal-impairment claims, would have been obvious to a relevant artisan. It contends that the prior art taught how to calibrate paliperidone palmitate doses for renally impaired patients, generally by administering lower doses. Teva Opening Br. at 59–66. Teva relies on the Invega ER label,[10] which it asserts teaches decreasing doses by 50% for mild renal impairment and by 75% for moderate-to-severe renal impairment. *See* J.A. 16233 (teaching doses of 12 mg/day for patients with no renal impairment, 6 mg/day for patients with mild renal

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[10] *INVEGA™ (paliperidone) Extended-Release Tablets*. J.A. 16209–34.

impairment, and 3 mg/day for patients with moderate-to-severe renal impairment). Teva also relies on Cleton 2007,[11] which teaches administering lower doses of paliperidone extended-release tablets to patients with moderate-to-severe renal impairment. J.A. 14112. Teva contends that the district court applied an erroneously narrow test for obviousness in "limiting prior art to express disclosures and disregarding a [relevant artisan]'s motivation to make minor changes." Teva Opening Br. at 60 (discussing *Remand Decision*, at 211, 213, which states that reducing any of the '548 protocol's dosing regimens by 50% or 75%, as suggested by the Invega ER label, would not result in the claimed dosing regimens). Teva argues that the district court mistakenly read "mild renal impairment" into the claim language. *Id.* at 61–64 (citing *Janssen 2024*, at 927). And Teva argues that the district court incorrectly found that Cleton 2007, which is silent on modifying doses for patients with mild renal impairment, teaches away from reducing doses for such patients. *Id.* at 64–66 (citing *Remand Decision*, at 212 & n.26).

We are not persuaded by these arguments. The district court found—without clear error—that Teva failed to prove a motivation to reduce the prior art's dosing regimens in such a way as to arrive at the regimens of claim 10 or 13. The district court reasonably determined, based on Teva's expert testimony that "[p]atients with moderate to severe renal impairment are not to receive [Invega Sustenna]" at all, and that Teva's theory of motivation focused on treating patients with mild renal impairment. *Remand Decision*, at 211 (citing J.A. 10332, lines 10–15); *see also* J.A. 13120 (Invega Sustenna label expressly stating that it is

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[11] A. Cleton et al., *Effects of renal impairment on the pharmacokinetic profile of paliperidone extended-release tablets*, 81 Clinical Pharmacology & Therapeutics S63 (2007). J.A. 14112.

"not recommended in patients with moderate or severe renal impairment"). In other words, the district court's focus on how a relevant artisan would modify a dosing regimen for patients with *mild* renal impairment was not an erroneous reading-in of an extraneous limitation but a fact-driven inquiry in response to the case Teva presented. The court found that Cleton 2007 recommended lowering doses for patients with moderate-to-severe renal impairment but was silent on what to do for patients with mild renal impairment. *Remand Decision*, at 212 (citing J.A. 14112). Contrary to Teva's assertion that the district court wrongly interpreted Cleton 2007 as teaching away, we read the court as having resolved a dispute between experts about what the prior art would have taught a relevant artisan. *Id.* (citing J.A. 11586, lines 14–20 (Janssen's expert testimony)). We see no clear error in the district court's weighing of experts' testimony in determining that Teva's theory of motivation was not supported by the record, so we uphold this factual determination.

2

Representative claims 20 and 21 depend on claim 19, which in turn depends on claims 1, 4, 8, or 11. '906 patent, col. 43, lines 32–51; *Remand Decision*, at 214. Because we affirm the district court's determinations that claims 2 (representative of claims 1 and 4), 10 (representative of claim 8), and 13 (representative of claim 11) have not been proved invalid for obviousness, *see supra* Parts II.A, II.B.1, we hold that claims 20 and 21 have likewise not been proven invalid for obviousness. *See In re Fritch*, 972 F.2d 1260, 1266 (Fed. Cir. 1992) (holding that dependent claims are nonobvious if the independent claims they depend on are nonobvious).

* * *

Because we affirm the district court's rejection of Teva's affirmative case for obviousness on its own terms,

we need not address the district court's consideration of objective indicia invoked by Janssen to show nonobviousness.

III

We have considered Teva's other arguments and find them unpersuasive. For the foregoing reasons, we affirm the district court's determination that the challenged claims have not been proven invalid for obviousness and therefore the court's judgment.

**AFFIRMED**