No. 2023-1247

United States Court of Appeals
for the
Federal Circuit

VANDA PHARMACEUTICALS INC.,

Plaintiff-Appellant,

– v. –

TEVA PHARMACEUTICALS USA, INC., APOTEX INC., APOTEX CORP.,

Defendants-Appellees.

On appeal from a final judgment of the
United States District Court for the District of Delaware,
Case Nos. 1:18-cv-00651, 1:18-cv-00689, 1:19-cv-00560, 1:19-cv-00685, 1:19-cv-02202, 1:19-cv-02375, 1:20-cv-00083, 1:20-cv-00093, 1:20-cv-01104, 1:20-cv-01333, 1:21-cv-00121, 1:21-cv-00282
Chief Judge Colm F. Connolly

CORRECTED PETITION FOR REHEARING OR REHEARING EN BANC

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CERTIFICATE OF INTEREST

1. The full names of all entities represented by the undersigned counsel in this case: *Vanda Pharmaceuticals Inc.*

2. All real parties in interest for the entities: *None*.

3. All parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities: *Appellant has no parent corporation. Blackrock Fund Advisors owns more than 10% of Appellant's stock.*

4. All law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this Court for the entities: *Paul, Weiss, Rifkind, Wharton & Garrison LLP (Jacob Berman, Kira Davis)*; *Morris, Nichols, Arsht & Tunnell LLP (Karen Jacobs; Derek Fahnestock)*.

5. Related or prior cases meeting the criteria of Fed. Cir. R. 47.5(a): *None*.

6. Any information required under Fed. R. App. P. 26.1(b): *None*.

I certify the above information is accurate and complete to the best of my knowledge.

Dated: June 9, 2023

/s/ Paul W. Hughes
Paul W. Hughes

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RULE 35(b) STATEMENT

Based on my professional judgment, I believe the panel's decision is contrary to the following decision(s) of the Supreme Court of the United States or the precedent(s) of this Court:

- *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375 (Fed. Cir. 2019)
- *Sanofi v. Watson Lab'ys Inc.*, 875 F.3d 636 (Fed. Cir. 2017)

Based on my professional judgment, I believe this appeal requires an answer to one or more precedent-setting questions of exceptional importance:

- Whether method-of-treatment patents directed to the effect of food on a particular drug are per se obvious because of FDA Guidance acknowledging that food may affect the bioavailability of drugs and should be studied.
- Whether the disclosure of the existence of an ongoing clinical trial is evidence of a reasonable expectation of success as to the result of the trial.
- Whether a drug-drug interaction patent is obvious when a POSA could not "rule out" the interaction because another compound in the same general category has shown such an interaction.

Dated: June 9, 2023

/s/ Paul W. Hughes
Paul W. Hughes

INTRODUCTION

The panel's decision adopts broad legal pronouncements regarding obviousness that would categorically render entire classes of pharmaceutical subject matter unpatentable.

Under the panel's reasoning, expensive and time-consuming clinical studies to determine the relationship between drug treatments and food—relationships that often result in meaningful, novel changes to therapeutic courses—are no longer protectable because the Food and Drug Administration (FDA) promulgated a guidance 20 years ago. The undermining of drug patents then continues, with the government-mandated disclosure of ongoing clinical studies—no matter how innovative the study or how unexpected the conclusion—rendering a result unpatentable if the study takes more than a year to conduct (as they almost always do). And finally, by refusing to recognize the unpredictability associated with individual compounds—and, in particular, the unpredictability of drug-drug interactions—the panel fell victim to the "insidious attraction of the siren hindsight" (*W.L. Gore Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 1553 (Fed. Cir. 1983)) by crediting prior art about a different compound, ramelteon, over that about the claimed compound, tasimelteon, which taught away from the claimed inventions.

In the face of the Supreme Court's recent decision in *Amgen Inc. v. Sanofi*, 143 S. Ct. 1243 (2023), the panel's rules *must* be error. Under *Amgen*, a drug innovator cannot patent its novel methods without possessing sufficient detail to explain to another the scope of the invention. *See id.* at 1256-1257. That often requires clinical results. But, by using the mere existence of ongoing clinical studies or FDA suggestions about possible studies as indicia of obviousness, the panel's holding forecloses a drug manufacturer's attempts to reach the very results that *Amgen* requires. Thus, the effect of the panel's decision is that drug innovators are always either too early—or too late. That cannot be the law.

Rehearing or rehearing en banc is imperative to unwind the panel's adoption of "rigid rule[s] that limit[] the obviousness inquiry" (*KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007)) and threaten the patentability of pharmaceutical inventions achieved through performing a clinical trial.

BACKGROUND

Vanda Pharmaceuticals Inc. (Vanda) is a small drug development company with only two marketed products. Vanda acquires molecules that other pharma innovators have shelved and, through painstaking, significant, and costly clinical testing, finds a use for them. Appx19024-19025. Such is the story of Hetlioz® (tasimelteon), the first drug that FDA

approved to treat two different orphan conditions. The condition at issue here, Non-24-Hour Sleep-Wake Disorder, is a debilitating circadian-rhythm disorder that disproportionately afflicts individuals who are totally blind. Slip op. 2. Non-24 sufferers cannot synchronize their internal circadian clock to the 24-hour day and, thus, experience a circadian rhythm that shifts further back each day. Slip op. 2.

The patents at issue reflect Vanda's clinical work; they cover:

- tasimelteon's unpredicted need to be administered without food (the '487 patent (Appx195-198)),
- tasimelteon's unexpected efficacy in entraining a Non-24 patient's circadian rhythm when administering a certain dose on a specific schedule (the RE604 patent (Appx77-118)), and
- tasimelteon's previously unknown interaction with a certain class of drugs (the '910 and '829 patents (Appx119-159, Appx160-194)).

The district court found claims from each of these patents obvious, and a panel of this Court affirmed.

First, the panel concluded that claim 5 of the '487 patent was obvious because FDA guidance from 2002 recognized that food can affect the bioavailability of drugs. Slip op. 10-12. According to the panel, because "it [was] clear that food-effect studies were expected to be performed on

new drugs" and "there [are] only two permutations for the food variable: … with food or without food," the results of such an investigation—however novel or unexpected—are always obvious. *Id.*

Second, the panel concluded that claim 3 of the RE604 patent was obvious based on a combination of references that included a disclosure of Vanda's ongoing phase III clinical trial in Non-24, concluding that an "ongoing clinical trial" "contribute[s] to a skilled artisan's expectation of success" "to support an obviousness determination." Slip op. 4-5, 8.

Third, the panel concluded that, because a POSA "could not have ruled out an interaction between tasimelteon and a CYP3A4 inducer" based on a reference concerning a separate drug (ramelteon), claim 4 of the '910 patent was obvious. Slip op. 15.

REASONS FOR GRANTING THE PETITION

The panel's obviousness rules are deeply flawed and, left to stand, threaten invalidation of many novel drug patents because of government action. Because FDA issues general guidance and requires clinical trial disclosure, pharmaceutical innovators run the risk of being unable to patent their inventions, a result fully at odds with Congress's long-held concerns about regulatory processes stripping away patent rights. *See, e.g.*, *Unimed, Inc. v. Quigg*, 888 F.2d 826, 829 (Fed. Cir. 1989). Rehearing or rehearing en

banc is imperative to ensure the continued viability of pharmaceutical patents by unwinding the rigid rules that would invalidate vast swaths of them.

A. Rehearing is warranted to prevent wholesale eviscer-ation of patent claims concerning pharmaceutical food effects.

Based on nothing more than a general 2002 FDA guidance, the panel determined that it would be obvious to conduct a food-effects study with tasimelteon and that any treatment method encapsulating the *results* of such a study would be unpatentable. Such a "rigid rule" has no basis in this Court's or the Supreme Court's obviousness law. *KSR*, 550 U.S. at 419.

Multiple decisions of this Court have previously concluded that food-effect pharmaceutical inventions are patentable. *E.g.*, *Endo Pharms. Inc. v. Teva Pharms. USA, Inc.*, 731 F. App'x 962, 970-972 (Fed. Cir. 2018), *vacated in part on other grounds*, 729 F. App'x 936 (Fed. Cir. 2018) (mem.); *Par Pharm., Inc. v. TWI Pharms., Inc.*, 773 F.3d 1186, 1194-1197 (Fed. Cir. 2014). In *Par Pharmaceutical*, the Court recognized that claims relating to a food effect were not invariably obvious and specifically rejected an inherency argument on this score. *PAR Pharm.*, 773 F.3d at 1194-1196. And in *Endo Pharmaceuticals*, the Court upheld the validity

of a patent claim requiring certain release in "fed versus fasted conditions." *Endo Pharms.*, 731 F. App'x at 965-966.

The panel's decision here conflicts with these holdings and establishes a categorical rule that food-effect patents are invalid simply because the FDA issued guidance in 2002 that suggests studying food effects because food can change a drug's bioavailability. That is, the panel rested on a blanket conclusion that "it would have been obvious to try administering tasimelteon without food" (Slip op. 10) simply because of existing FDA suggestions (*id.* at 11 & nn. 9-10). The effect of this holding is profound: It ipso facto invalidates all food-effects patents—even ones based on completely unexpected results.

The panel's new rule is wrong for two reasons. *First*, the panel's conclusion is based on the premise that suggested or required regulatory testing cannot lead to a patentable result. The panel concluded that the FDA guidance qualified as "market pressure" under *KSR*, meaning that "food-effect studies were expected to be performed on new drugs." Slip op. 10-11. But this gets *KSR* wrong: The "market pressure" must be tied to "solv[ing] a problem." *KSR*, 550 U.S. at 402; *Abbott Lab'ys v. Sandoz, Inc.*, 544 F.3d 1341, 1351 (Fed. Cir. 2008) (explaining that under *KSR*, an "obvious to try" analysis requires that "the problem is known"); *In re Brimonidine Pat. Litig.*, 643 F.3d 1366, 1375 (Fed. Cir. 2011), *as corrected*

(Aug. 8, 2011) (same). This case fails that basic threshold of having a known problem; that is, no public knowledge about any potential food interaction with tasimelteon existed.

And indeed, this Court has before explained that *KSR*'s obvious-to-try analysis is an ill-fit for situations like the one presented here. "To the extent an art is unpredictable, as the chemical arts often are, *KSR*'s focus on … 'identified, predictable solutions' may present a difficult hurdle [for a patent challenger] because potential solutions are less likely to be genuinely predictable." *Eisai Co. v. Dr. Reddy's Lab'ys, Ltd.*, 533 F.3d 1353, 1359 (Fed. Cir. 2008); *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1090 (Fed. Cir. 2008). This holds true even where the *process to reach* the claimed invention is known in the art, but the results are unpredictable, and no other evidence creates a reasonable expectation of success. *E.g.*, *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1378-1380 (Fed. Cir. 2006). That exactly describes the prior art here. The uncontroverted evidence established that for tasimelteon to be effective in treatment of Non-24, a "short pulse" of the drug is required in order to reset the circadian clock. Appx19031. There was simply no way of predicting whether and how ingestion of food might affect the bioavailability of the drug, and thus the mere suggestion that tests should be conducted in no way renders the answer obvious.

Moreover, a significant scientific discovery can occur in connection with testing recommended or required by FDA. Indeed, this Court has rejected the contrary reasoning embraced by the panel—i.e., the idea that results of mandatory regulatory testing are unpatentable—in other types of pharmaceutical technologies, like required polymorph screening. *See Grunenthal GMBH v. Alkem Lab'ys Ltd.*, 919 F.3d 1333, 1337 (Fed. Cir. 2019). And it has rejected this same analysis in the context of a drug-drug interaction patent where FDA had issued guidance. *See Teva Pharms. USA, Inc. v. Corcept Therapeutics, Inc.*, 18 F.4th 1377, 1379, 1381-1383 (Fed. Cir. 2021) ("At best, the prior art directed a skilled artisan to try combining the Korlym Label, Lee, and the FDA guidance. But without showing a reasonable expectation of success, Teva did not prove obviousness.").

Second, the panel disregarded the facts before it. In applying the 2002 FDA Guidance, the panel claimed that the specification recognized, as the district court held, "there were only two permutations for the food variable: tasimelteon could have been administered with food or without food. In other words, there were two identifiable and predictable options." Slip op. 12. Not true, for multiple reasons. To start, food effects are not themselves predictable. While the general idea that food may affect bioavailability is well known, the specific effect that food—or a subset of type

of food—will have on the administration of a particular substance is not known until tested.

Nor is this a binary examination of "with or without" food. As the very FDA Guidance makes clear, there are all sorts of possible permutations of food options and conditions: with food, without food, food agnostic, avoid certain foods, or within a certain amount of time of food/timed with meals, etc. *See generally* U.S. Food & Drug Admin., Guidance for Industry: Food-Effect Bioavailability and Fed Bioequivalence Studies (2002). The FDA Guidance is rife with suggestions of various clinical trial methods that may impact food effect bioavailability, including outlines of specific fasting conditions, examples of test meals, dosage strength, and more—all of which are *un*predictable. *See, e.g.*, *id.* at 4-6. And still further, this unpredictability is particularly acute with respect to tasimelteon, which has a strict bioavailability requirement: it must be high enough to act on the patient's circadian rhythm but low enough to facilitate metabolism in the right window to avoid continuing effects of the drug that would *de*regulate the circadian rhythm. Appx19034. The patented method of treatment strikes the delicate balance of bioavailability for this treatment to be effective.

B. Rehearing is warranted to preclude the mere existence of clinical trials from foreclosing patentability.

In finding obvious an asserted claim of the RE604 patent covering a specific method of administering tasimelteon to Non-24 sufferers, the panel blessed the district court's reliance on the mere *existence* of—not the reporting of results from—an ongoing clinical trial (as described in a publication called Lankford) to find that a skilled artisan would reasonably expect success in achieving the trial's hypothesis. *See* Slip op. 8 (finding Lankford's disclosure of a clinical trial would have "contributed to a skilled artisan's reasonable expectation of success"). But clinical trials are by their nature unpredictable. By establishing a presumption of success from the conduct of a Phase III clinical trial, the panel relieved defendants of their burden and deviated from this Court's precedent in a manner likely to invalidate even the most novel of drug discoveries. The panel's reasoning affects nearly every pharmaceutical patent that issues. It warrants the full court's scrutiny.

1. The panel's decision conflicts with this Court's precedent.

This Court has affirmed that evidence that a drug developer is conducting a clinical trial does not support finding that an ordinarily skilled artisan would reasonably expect success. *E.g.*, *OSI Pharms., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385 (Fed. Cir. 2019) (explaining that "in a highly

unpredictable art" like cancer treatment, disclosure of a clinical trial "provide[s] no more than hope," which "is not enough to create a reasonable expectation of success"); *Sanofi v. Glenmark Pharms. Inc., USA*, 204 F. Supp. 3d 665, 696 (D. Del. 2016) (finding it "not credible that a POSA would simply read the outline of a future clinical trial and the results of a single post-hoc analysis" to reach a reasonable expectation of success), *aff'd sub nom. Sanofi v. Watson Lab'ys Inc.*, 875 F.3d 636 (Fed. Cir. 2017); *see also Novartis Pharms. Corp. v. West-Ward Pharms. Int'l Ltd.*, 923 F.3d 1051, 1061 (Fed. Cir. 2019) (affirming district court's finding of no reasonable expectation of success from positive Phase I study results and entry into Phase II clinical trials).

And Vanda has located no case of this Court holding that mere knowledge of a clinical trial, without any results showing efficacy, is evidence that a POSA would have a reasonable expectation of success. In fact, this Court has said the opposite. In *OSI Pharmaceuticals*, the Court used evidence of the high failure rate for drugs entering Phase II clinical studies as evidence that a POSA would *not* have had a reasonable expectation of success. *OSI Pharms.,* 939 F.3d at 1383. The panel's decision throws this uniformity into doubt.

And not for good reason. Clinical trials—tests of unproven hypotheses in the highly unpredictable field of the chemical arts—will rarely be

enough to provide a POSA with a reasonable expectation of success. *Cf. Eisai*, 533 F.3d at 1359 (describing the chemical arts as "often" unpredictable). After all, about half of phase III clinical trials are unsuccessful, and there are many reasons why a clinical trial might fail.

Nor could the panel be said to seriously rely on other record evidence to provide the missing reasonable expectation of success that the claimed dose of tasimelteon could entrain a Non-24 patient's circadian rhythm. *See* Slip op. 4-8; Opening Br. 31-40. The decision itself makes this clear: The reference to 20mg dosing is necessarily tied to the clinical trial. Slip op. 4-8. The Hack publication, for example, concerns only melatonin and discusses the results of a clinical trial of certain doses of melatonin and its effects in entraining some, but not all, totally blind individuals with Non-24. It does not mention tasimelteon or claim that tasimelteon should be able to do the same, and it does not even speculate whether other molecules that bind to melatonin receptors would have a similar or different activity than melatonin. And the other combination references—Hardeland and the '244 patent—merely parrot the clinical trial materials. These too cannot be a basis to invalidate a patent.

2. The panel's decision involves an issue of critical importance.

Under federal law, a drug study sponsor like Vanda must submit clinical study information to the National Institutes of Health's National Library of Medicine for review, which is then "made publicly available through the internet." 42 U.S.C. § 282(j)(2)(A)(i) (2011). Such information includes "the study design; … the study phase; study type; the primary disease or condition being studied, or the focus of the study; the intervention name and intervention type; ... outcomes, including primary and secondary outcome measures;" and "recruitment information." 42 U.S.C. § 282(j)(2)(A)(ii)(I)&(II) (2011); *see also* 21 C.F.R. § 50.25(c) (2011); *see generally* 42 U.S.C. § 282(j)(2)(A)(ii) (listing required information). Lankford—the focal prior art reference—merely identified what was already required to be disclosed publicly: that Vanda was studying tasimelteon in Non-24 patients.

That Vanda was conducting a study of tasimelteon in Non-24 and that the study was posted on clinicaltrials.gov, as is required by FDA regulation for all clinical trials, cannot significantly weigh in support of a finding of obviousness. In holding otherwise (Slip op. 8), the panel has effectively created new law that for every drug developer complying with the government's requirement to announce an ongoing clinical study, the

scales are tipped towards finding a reasonable expectation of success in achieving their results.

Taken to its conclusion, the panel's logic combined with the Supreme Court's recent *Amgen* decision puts drug developers in a no-protection scenario. Filing a patent application before obtaining the results of a clinical trial and claiming an expected functionality may risk invalidation for failing to satisfy the enablement and written description requirements, given that the inventors may not even yet have possession of the effectiveness of a claimed treatment method. *Cf. Amgen*, 143 S. Ct. at 1256-1257; *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1375 & n.20 (Fed. Cir. 2017) (explaining that invention is not ready for patenting where patentee could not satisfy § 112 written description requirement), *aff'd*, 139 S. Ct. 628 (2019); *In re Omeprazole Pat. Litig.*, 536 F.3d 1361, 1373-1375 (Fed. Cir. 2008) (holding that even where the formulation to be studied in Phase III trials had been shown to treat gastrointestinal disease, the inventors did not know whether the formulation could achieve the claimed long term, *in vivo* stability absent in the Phase III study, and thus the claimed invention had not been reduced to practice).

But waiting until after a clinical trial concludes—a process that often takes more than a year—now creates a risk that the government-

mandated disclosure of the mere *existence* of a clinical trial furnishes a potential invalidator with firepower to claim *any* positive result is an expected success. Regardless of how otherwise astoundingly unexpected the results may be, the panel's opinion all but assumes them as preordained. Patent law is supposed to encourage innovation, not punish innovators awaiting the concrete results of their costly and time-intensive experimental endeavors.

C. Rehearing is warranted to reaffirm the burden of proof applicable to drug-drug interaction claims.

The panel also found obvious claims of the '910 patent that disclose certain drug-drug interactions and instruct to discontinue the use of rifampicin (a specific antibiotic) before administering tasimelteon. According to the panel, a POSA "could not have ruled out an interaction between tasimelteon and a CYP3A4 inducer, like rifampicin" based on a reference concerning a separate drug, ramelteon. Slip op. 15. Yet there is a world of distance between being unable to exclude the possibility of an interaction and reasonably expecting one to occur. This Court has many times held that the patent challenger must prove the latter. In ruling to the contrary, the panel never explained how a skilled artisan would reasonably expect success based on the *ramelteon* prior art as of the time of the priority date.

A party seeking to invalidate a patent must demonstrate with clear and convincing evidence that "a skilled artisan would have been motivated to combine 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." *Novartis Pharms.*, 923 F.3d at 1059 (quoting *Procter & Gamble Co. v. Teva Pharms. USA, Inc.*, 566 F.3d 989, 994 (Fed. Cir. 2009)). Yet the panel's opinion places the burden on *Vanda* to have disproven defendants' theory. The panel acknowledged that the prior art reported no interaction between tasimelteon and CYP3A4 (the enzyme that rifampicin induces, which causes the unwanted drug interaction). Nonetheless, relying solely on art related to this different molecule, the panel's decision reasoned it was "*possible* for CYP3A4 to metabolize a drug after being induced even" though tasimelteon had not done so without induction. Slip op. 14 (emphasis added). That something is *possible* does not mean a POSA would reasonably expect it to occur. Indeed, mere possibility sets the bar even lower than this Court's precedent, which holds that even references that provide "hope … [are] not enough to create a reasonable expectation of success in a highly unpredictable art." *OSI Pharms.,* 939 F.3d at 1385; *see also Teva Pharms. USA*, 18 F.4th at 1383 ("At best, the prior art directed a skilled artisan to try combining the Korlym Label, Lee, and the FDA

guidance. But without showing a reasonable expectation of success, Teva did not prove obviousness."). By refusing to give proper weight to prior art concerning the molecule at issue (tasimelteon) over that concerning another molecule (ramelteon), the panel fell victim to the "insidious attraction of the siren hindsight." *W.L. Gore*, 721 F.2d at 1553. The Court should reaffirm that patentees need not disprove every hypothesis conjurable from prior art to prevail, and that it is the infringer who must show that a POSA would have expected success.

As with the other identified errors, here too, the panel substituted a categorical rule—that in the unpredictable field of drug development, POSAs would credit art about other molecules—even though teachings about the actual molecule at issue point in the other direction. By the panel's logic, drug-drug interaction patents are rendered obvious so long as any other compound in the same general category has shown such an interaction because a POSA could not "rule out" such an interaction. Under this Court's law, that cannot be the standard.

CONCLUSION

The Court should grant rehearing or rehearing en banc.

Dated: June 9, 2023

Respectfully submitted,

/s/ *Paul W. Hughes*

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), I hereby certify that this petition:

(i) complies with the type-volume limitation of Rules 35(b) and 40(b) because it contains 3,603 words, excluding the parts of the petition exempted by Rule 32(f) and Circuit Rule 32(b)(2); and

(ii) complies with the typeface requirements of Rule 32(a)(5) and the type style requirements of Rule 32(a)(6) because it has been prepared using Microsoft Office Word 2016 and is set in New Century Schoolbook LT Std in 14 point font.

Dated: June 9, 2023 /s/ *Paul W. Hughes*

ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

VANDA PHARMACEUTICALS INC.,
Plaintiff-Appellant

v.

TEVA PHARMACEUTICALS USA, INC., APOTEX INC., APOTEX CORP.,
Defendants-Appellees

2023-1247

Appeal from the United States District Court for the District of Delaware in Nos. 1:18-cv-00651-CFC, 1:18-cv-00689-CFC, 1:19-cv-00560-CFC, 1:19-cv-00685-CFC, 1:19-cv-02202-CFC, 1:19-cv-02375-CFC, 1:20-cv-00083-CFC, 1:20-cv-00093-CFC, 1:20-cv-01104-CFC, 1:20-cv-01333-CFC, 1:21-cv-00121-CFC, 1:21-cv-00282-CFC, Chief Judge Colm F. Connolly.

Decided: May 10, 2023

NICHOLAS P. GROOMBRIDGE, Groombridge, Wu, Baughman & Stone LLP, New York, NY, argued for plaintiff-appellant. Also represented by ERIC ALAN STONE, JOSEPHINE YOUNG; JENNIFER REA DENEAULT, DANIEL KLEIN, MICHAEL F. MILEA, Cold Spring, NY.

JOHN CHRISTOPHER ROZENDAAL, Sterne Kessler Goldstein & Fox, PLLC, Washington, DC, argued for defendant-appellee Teva Pharmaceuticals USA, Inc. Also represented by WILLIAM MILLIKEN, BYRON LEROY PICKARD, SASHA RAO, DEIRDRE M. WELLS.

AARON S. LUKAS, Cozen O'Connor P.C., Washington, DC, argued for defendants-appellees Apotex Inc., Apotex Corp. Also represented by WILLIAM BLAKE COBLENTZ; KERI SCHAUBERT, New York, NY.

Before DYK, BRYSON, and PROST, *Circuit Judges*.

DYK, *Circuit Judge*.

Vanda Pharmaceuticals Inc. sued Apotex Inc. and Apotex Corp. (collectively, "Apotex") and Teva Pharmaceuticals USA, Inc. alleging that their abbreviated new drug applications ("ANDAs") infringed claims in four patents owned by Vanda. Those claims relate to a method of treating Non-24-Hour Sleep-Wake Disorder ("Non-24") with tasimelteon. The district court held that all of the asserted claims were invalid as obvious. We *affirm*.

BACKGROUND

Non-24 is a circadian rhythm disorder that occurs in individuals whose biological clocks are not synchronized, that is, entrained, to the 24-hour day. Non-24 causes too little nighttime sleep and too much daytime sleep. It can be treated by causing entrainment, i.e., synchronizing a person's circadian rhythm to the 24-hour day. "Approximately 55 to 70 percent of totally blind individuals . . . suffer from Non-24." J.A. 11.

Vanda sells a tasimelteon drug product (Hetlioz®) that is approved by the Food and Drug Administration (FDA)

and indicated for the treatment of Non-24. Vanda owns patents related to using tasimelteon to treat Non-24.

Appellees Teva and Apotex both filed ANDAs with the FDA "seeking approval for the commercial manufacture, use, and sale of tasimelteon." J.A. 15. At issue in this case are four claims from four different unexpired Vanda-owned patents, U.S. Patent No. RE46,604 (the RE604 patent); U.S. Patent No. 10,149,829 (the '829 patent); U.S. Patent No. 9,730,910 (the '910 patent); and U.S. Patent No. 10,376,487 (the '487 patent), all of which are listed in the FDA's Orange Book (Approved Drug Products with Therapeutic Equivalence Evaluations) for Hetlioz®. Teva's and Apotex's ANDAs both included certifications pursuant to 21 U.S.C. § 355(j)(2)(a)(vii)(IV) ("Paragraph IV Certifications") alleging that the asserted claims are invalid and that all or most of the claims will not be infringed by the ANDA products.[1]

Vanda sued Teva and Apotex in the District of Delaware alleging that their ANDA submissions constituted infringement of claim 3 of the RE604 patent; claim 14 of the '829 patent; claim 4 of the '910 patent; and claim 5 of the '487 patent. Teva and Apotex stipulated to infringement of claim 5 of the '487 patent, denied infringement as to the other claims, and alleged that all asserted patent claims were invalid.

In a thorough opinion, the district court held that all four claims were invalid for obviousness. The court also held that Teva and Apotex did not infringe claim 3 of the RE604 patent, but did not make infringement findings for the asserted claims in the '829 patent or '910 patent.

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[1] Teva's certification alleged that no asserted claims would be infringed, and Apotex's alleged that three of the four asserted claims would not be infringed.

Vanda appealed the district court's obviousness and infringement determinations.

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

DISCUSSION

"[W]e review a district court's conclusions of law *de novo* and its findings of fact for clear error." *Merck Sharp & Dohme Corp. v. Hospira, Inc.*, 874 F.3d 724, 728 (Fed. Cir. 2017). "Obviousness is a question of law, based on underlying factual findings . . . ." *Id.*

I. RE604 Patent

Vanda alleged that Teva and Apotex infringed claim 3 of the RE604 patent, which depends from claims 1 and 2:

> 1. A method of entraining a patient suffering from Non-24 to a 24 hour sleep-wake cycle in which the patient awakens at or near a target wake time following a daily sleep period of approximately 7 to 9 hours, and maintaining said 24 hour sleep-wake cycle said method comprising: treating the patient by orally administering to the patient 20 mg of tasimelteon once daily before a target bedtime.
>
> 2. The method of claim 1 wherein the patient is totally blind.
>
> 3. The method of claim 2 wherein the tasimelteon is administered 0.5 to 1.5 hours before the target bedtime.

J.A. 117 (RE604 patent, col. 38, ll. 25–36). The district court held that claim 3 would have been obvious over two combinations of prior art references: Hack,[2] the

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[2] Lisa M. Hack et al., *The Effects of Low-Dose 0.5-mg Melatonin on the Free-Running Circadian Rhythms of Blind Subjects*, 18 J. Biological Rhythms 420 (2003).

'244 Publication,[3] and Lankford;[4] and, alternatively, Hack, the '244 Publication, and Hardeland.[5]

Vanda claims that the district court made several errors in determining that claim 3 was obvious. Vanda first argues that the district court erred in stating that a skilled artisan would look to Hack, a prior art reference that explains that melatonin can be used to entrain blind patients with Non-24, when considering whether there would have been a reasonable expectation that tasimelteon would entrain. The district court did not err.

Of course, tasimelteon and melatonin are not identical. *See* J.A. 19,299–300 (Emens 858:21–859:9) (testimony that melatonin and tasimelteon have different binding affinities for melatonin receptors); J.A. 20,525–26 (Hardeland) (noting that melatonin and tasimelteon have some structural differences). However, as Lankford explains, "tasimelteon has high affinity for both the [melatonin] receptors, both in ranges similar to that of melatonin." J.A. 20,539. The district court noted that prior art references concluded that tasimelteon and melatonin are similar, and, because of their similarities, "tasimelteon could . . . potentially entrain patients suffering from circadian rhythm sleep disorders." J.A. 25 (citing J.A. 20,523 (Hardeland); J.A. 20,539 (Lankford)). There was no error in the district court's choice to credit statements in the prior art explaining the similarities between tasimelteon and melatonin and why

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[3] Int'l Pat. Application No. WO 2007/137244.

[4] D. Alan Lankford, *Tasimelteon for Insomnia*, 20 Expert Op. Investigational Drugs 987 (2011).

[5] Rüdiger Hardeland, *Tasimelteon, a Melatonin Agonist for the Treatment of Insomnia and Circadian Rhythm Sleep Disorders*, 10 Current Op. Investigational Drugs 691 (2009).

those similarities would have made data for melatonin relevant to tasimelteon.

Vanda's second argument is that, contrary to the district court's conclusion, none of the prior art references "would give a skilled artisan a reasonable expectation of success in using 20mg of tasimelteon . . . to entrain." Appellant's Br. 36. Vanda is incorrect.

The district court found that the claim element "orally administering to the patient 20 mg of tasimelteon" was disclosed in Hardeland, the '244 Publication, and Lankford.

Hardeland summarizes a phase II clinical trial by Rajaratnam et al.[6] that looked at the effect of tasimelteon on phase shifting, which is necessary for and related to entrainment. In that study, trial participants were given either a placebo or 10mg, 20mg, 50mg, or 100mg of tasimelteon after having their bedtimes shifted by five hours. Only the 100mg dose produced a statistically significant phase shift compared to the placebo. However, the 20mg dose produced a phase shift of over one hour, which was greater than the shift of about thirty minutes observed with the placebo (although the difference was not statistically significant). Based on this and other data, Hardeland concluded that the prior art showed that tasimelteon "may be useful in the treatment of sleep disturbances related to circadian rhythm sleep disorders, such as . . . entrainment difficulties" and stated that "[t]he most effective doses of

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[6] Shantha M. W. Rajaratnam et al., *Melatonin Agonist Tasimelteon (VEC-162) for Transient Insomnia After Sleep-Time Shift: Two Randomised Controlled Multicentre Trials*, Lancet (Dec. 2, 2008).

tasimelteon were in the range of 20 to 50 mg/day."[7] J.A. 20,529.

Relying on the Rajaratnam study, Dr. Jonathan Emens, one of Teva and Apotex's expert witnesses, testified: "You would never really need a shift of more than an hour, and so [a phase shift of over an hour caused by a 20mg dose of tasimelteon] would be a sufficient shift to treat any individual with Non-24. " J.A. 19,267 (Emens 729:16–18). While Dr. Emens recognized that a 20mg dose of tasimelteon did not have a statistically significant effect on phase shifting, J.A. 19,302–03 (Emens 870:4–871:23); J.A. 19,304 (Emens 877:11–16); J.A. 19,306 (Emens 884:17–21), he still concluded that Rajaratnam suggested that 20mg of tasimelteon can cause entrainment, *see* J.A. 19,267 (Emens 729:9–18). The district court found Dr. Emens to be "very credible" and "found his testimony to be compelling." J.A. 10 (citation omitted).

The '244 Publication, an international patent application filed by Vanda, also summarized the Rajaratnam study. Based largely on that study, the '244 Publication stated that "[a]n oral dose of about 20 to about 50 mg is effective in treating sleep disorders when administered about 1/2 hour before sleep time." J.A. 20,629. The '244 Publication also claimed using 20mg of tasimelteon to treat

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[7] Vanda is incorrect in saying that "Hardeland was flat-out wrong" in its interpretation of Rajaratnam. Appellant's Reply Br. 10. Vanda argues that "Hardeland wrote that Rajaratnam had *not tested* doses below 100mg." Appellant's Reply Br. 10. While the sentence in Hardeland that Vanda relies on for that assertion is admittedly poorly worded, *see* J.A. 20,529, Vanda has not shown that "Hardeland was flat-out wrong" in its interpretation of Rajaratnam. It is clear reading Hardeland that Rajaratnam tested a 20mg dose of tasimelteon. *See* J.A. 20,527–28.

a circadian rhythm disorder. J.A. 20,630. Dr. Emens stated that the '244 Publication "says [tasimelteon] . . . can . . . cause entrainment . . . specifically at doses of about . . . 20 to 50 milligrams." J.A. 19,267 (Emens 727:17–21). Thus, Vanda's own patent application found significance in the 20mg result from the Rajaratnam study.

Lankford, another prior art reference, stated that a then-ongoing phase III trial of tasimelteon in blind people with Non-24 was "designed to assess the effectiveness of 20 mg of tasimelteon, compared with placebo, in improving nighttime sleep." J.A. 20,539. Vanda argues that "the court erred in finding that Vanda's ongoing clinical trial [mentioned in Lankford] would give an ordinary artisan an expectation of success." Appellant's Br. 40 (capitalization changed). Contrary to Vanda's characterization, the district court did not find that Vanda's ongoing clinical trial would have given a POSA an expectation of success in using tasimelteon to treat Non-24 in and of itself. Instead, the district court found "Lankford's disclosure of Vanda's Phase III trial would also have contributed to a skilled artisan's expectation of success." J.A. 43. There is no error in the district court's use of the then-ongoing clinical trial as one piece of evidence, combined with other prior art references, to support an obviousness determination.

Taken together, the evidence is sufficient to support the district court's finding that the tasimelteon prior art would have given a skilled artisan a reasonable expectation of success of entrainment with 20mg.[8]

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[8] Vanda also argued that the district court erred in concluding, as part of its analysis of objective indicia of non-obviousness, that success in entrainment with 20mg of tasimelteon would not have been unexpected. For the reasons explained above, we find no error.

Vanda's final argument is that the district court erred in its assessment of the objective indicia of non-obviousness. First, Vanda argues that the district court "disregarded the contrary evidence" of long-felt need, Appellant's Reply Br. 14, namely "the Reexamination Specialists' finding [in reexamination] that Vanda had 'provided evidence that the invention satisfies a long felt need,'" Appellant's Br. 43 (quoting J.A. 22,842). Vanda argues that the district court was required to weigh such evidence as part of secondary considerations concerning obviousness. However, "[t]he fact that the district court did not in its opinion recite every piece of evidence does not mean that the evidence was not considered." *Plant Genetic Sys., N.V. v. DeKalb Genetics Corp.*, 315 F.3d 1335, 1343 (Fed. Cir. 2003) (citation omitted).

Vanda also argues that the district court disregarded evidence from Non-24 sufferers that "until tasimelteon nothing worked for them." Appellant's Reply Br. 14; *see also* Appellant's Br. 43. The district court did not disregard this evidence. It explained that Vanda cited one article that "recounts the successful treatment of one adolescent Non-24 patient who had previously been treated unsuccessfully with melatonin" and that the remaining evidence cited by Vanda was "cursory at best." J.A. 57. We find no error in the district court's determination that evidence of the successful treatment of one person does not constitute evidence of long-felt need and that the remaining evidence was cursory. The district court correctly found that long-felt need was not established.

Vanda finally argues that the district court erred by "dismiss[ing] the praise that Vanda has received because it was not 'praise specifically directed at the treatment method claimed in the RE604 patent.'" Appellant's Br. 43 (quoting J.A. 57). This was not an error. "[O]bjective evidence of non-obviousness fails [when] it is not 'commensurate in scope with the claims which the evidence is offered

to support.'" *Therasense, Inc. v. Becton, Dickinson & Co.*, 593 F.3d 1325, 1336 (Fed. Cir. 2010) (quoting *In re Grasselli*, 713 F.2d 731, 743 (Fed. Cir. 1983)).

In sum, we find no error in the district court's determination that claim 3 of the RE604 patent is invalid for obviousness.

II. '487 Patent

Vanda alleged that Teva and Apotex infringed claim 5 of the '487 patent, which depends from claims 1 and 4:

> 1. A method of treating a human patient suffering from a circadian rhythm disorder or a sleep disorder that comprises orally administering to the patient an effective dose of tasimelteon without food, wherein the effective dose is 20 mg/d.
>
> . . .
>
> 4. The method of claim 1, wherein the patient is suffering from a circadian rhythm disorder.
>
> 5. The method of claim 4, wherein the circadian rhythm disorder is Non-24 Disorder.

J.A. 198 ('487 patent, col. 4, ll. 2–16).

The district court held that claim 5 would have been obvious. At issue is the claim element that tasimelteon is administered "without food." We agree with the district court because it would have been obvious to try administering tasimelteon without food.

"When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 421 (2007). "If one of these predictable solutions leads to the anticipated success, the combination was obvious to

try." *Valeant Pharms. Int'l, Inc. v. Mylan Pharms. Inc.*, 955 F.3d 25, 34 (Fed. Cir. 2020).

In this case, there was market pressure (regulatory advice) to determine if food would have an effect on the efficacy of a drug, such as tasimelteon. At the time Vanda's tasimelteon product was being developed, the FDA recognized that "[f]ood can change the [bioavailability] of a drug . . . [and f]ood effects on [bioavailability] can have clinically significant consequences." U.S. Food & Drug Admin., Guidance for Industry: Food-Effect Bioavailability and Fed Bioequivalence Studies 2 (2002).[9] Therefore, a POSA would have understood that administering a drug with or without food could make it more or less effective. The guidance document also states that "[f]ood effect [bioavailability] studies are usually conducted for new drugs," *id.* at 1, and that "[f]ood-effect [bioavailability] information should be available to design clinical safety and efficacy studies and to provide information for the CLINICAL PHARMACOLOGY and/or DOSAGE AND ADMINISTRATION sections of product labels." *Id.* at 3.[10] Based on this language, it is clear that food-effect studies were expected to be performed on new drugs, meaning clinicians and others who purchased or prescribed the drug would have expected food effect information about the drug to have been developed.

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[9] Vanda cited this guidance document in its clinical study report on tasimelteon. J.A. 23,145.

[10] In a later publication, the FDA clarified its position. *See* U.S. Food & Drug Admin., Bioavailability Studies Submitted in NDAs or INDs – General Considerations: Guidance for Industry 8 (2022) (noting that "[t]he effect of food on the [bioavailability] of the test product should also be assessed" when describing study design considerations for bioavailability studies for new drug applications).

Here, as the specification appears to recognize, *see* J.A. 197 ('487 patent, col. 2, ll. 18–19), there were only two permutations for the food variable: tasimelteon could have been administered with food or without food. In other words, there were two identifiable and predictable options. As the district court recognized, "[w]hether to administer tasimelteon with food is a binary choice." J.A. 72. Under these circumstances, given the FDA guidance, it would have been obvious to try administering tasimelteon without food. Therefore, we agree with the district court that claim 5 of the '487 patent is invalid for obviousness.

III. '910 Patent

Vanda alleged that Teva and Apotex infringed claim 4 of the '910 patent, which depends from claims 1, 2, and 3:

> 1. A method of treating a patient for a circadian rhythm disorder wherein the patient is being treated with rifampicin, the method comprising:
>
> (A) discontinuing the rifampicin treatment and then
>
> (B) treating the patient with tasimelteon,
>
> thereby avoiding the use of tasimelteon in combination with rifampicin and also thereby avoiding reduced exposure to tasimelteon caused by induction of CYP3A4 by rifampicin.
>
> 2. The method of claim 1 that comprises treating the patient for Non-24-Hour Sleep-Wake Disorder.
>
> 3. The method of claim 2 wherein the patient is light perception impaired (LPI).
>
> 4. The method of claim 3 wherein treating the patient with tasimelteon comprises orally

> administering to the patient 20 mg of tasimelteon once daily before a target bedtime.

J.A. 159 ('910 patent, col. 40, ll. 7–22).

The district court found claim 4 would have been obvious. With respect to obviousness, the only additional limitation at issue here with respect to claim 4 is the limitation in claim 1 of: "(A) discontinuing the rifampicin treatment and then (B) treating the patient with tasimelteon." J.A. 159 ('910 patent, col 40, ll. 10–11). The focus of claim 1 is avoiding the coadministration of rifampicin (an antibiotic drug) and tasimelteon. Rifampicin, also known as rifampin, is a strong inducer of CYP3A4. CYP3A4 is an enzyme that is often involved in drug metabolism. A CYP3A4 inducer induces the expression of CYP3A4, which causes CYP3A4 to increase its drug metabolism thereby decreasing the amount of the metabolized drug in blood plasma.

As of January 2012, the priority date of the patent, it was known that ramelteon (a drug similar to tasimelteon) "undergoes an 80 percent decrease in blood plasma levels when it is co-administered with the CYP3A4 inducer rifampin" because it is metabolized by CYP3A4. J.A. 29.

The district court found that a POSA "would have looked to ramelteon to predict tasimelteon drug-drug interactions because of the many known similarities between ramelteon and tasimelteon." J.A. 47. Based on the ramelteon studies, the district court held that if "a skilled artisan wanted to administer tasimelteon to a patient who was already taking . . . rifampin, then the artisan would have expected that tasimelteon should not be co-administered with rifampin and would have thought it necessary and obvious to stop treating the patient with rifampin before treating the patient with tasimelteon." J.A. 48 (citations omitted).

We see no error in the district court's finding that a skilled artisan would have looked to the ramelteon art because ramelteon and tasimelteon bind to the same receptors, have similar half lives in the body, and are structurally similar. The district court's finding that a POSA "would have looked to ramelteon" is not clearly erroneous.

Vanda also argues that the prior art taught away from there being any problems with administering tasilemteon with a CYP3A4 inducer. It is true that the only cited prior art that studied the metabolism of tasimelteon by CYP3A4, the Vachharajani reference,[11] found that "[n]o metabolism of [tasimelteon] was observed following incubation with [CYP3A4]." J.A. 23,857. This conclusion was echoed in Hardeland, which did not include CYP3A4 in its list of enzymes that metabolize tasimelteon. However, these studies did not look into CYP3A4's metabolism of tasimelteon after CYP3A4 had been induced by rifampicin, a requirement of the claims.

The evidence in Vachharajani and Hardeland does not refute the conclusion that a skilled artisan would recognize that tasimelteon and ramelteon have similar properties, nor does it suggest that the metabolism of tasimelteon by CYP3A4 in its induced and uninduced (natural) states would be the same. Induction of CYP3A4 by rifampicin causes a large increase in CYP3A4 activity. So, it is possible for CYP3A4 to metabolize a drug after being induced even if CYP3A4 does not metabolize that drug in its uninduced state. *See* J.A. 19,412 (Greenblatt 1,116:17–20). A credible Teva/Apotex expert testified that, for this reason, a skilled artisan who knew about the Vachharajani

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[11] Nimish N. Vachharajani et al., *Preclinical Pharmacokinetics and Metabolism of BMS-214778, a Novel Melatonin Receptor Agonist*, 92 J. Pharm. Scis. 760 (2003).

reference could not have ruled out an interaction between tasimelteon and a CYP3A4 inducer, like rifampicin—i.e., could not have ruled out that coadministration of tasimelteon and a CYP3A4 inducer such as rifampin would cause tasimelteon to be metabolized too quickly. J.A. 54; *see also* J.A. 19,412 (Greenblatt 1,116:17–20) ("[I]nduction causes a massive increase in the amount of enzymes, and you cannot exclude a major role of CYP3A4 [in metabolizing tasimelteon] in the induced state even if you can't detect it in the uninduced state."). We therefore find no error in the district court's finding that it was obvious to avoid coadministration of rifampicin and tasimelteon, and that claim 4 would have been obvious.

IV. '829 Patent

Vanda alleged that Teva and Apotex infringed claim 14 of the '829 patent, which depends from claim 13:

> 13. A method of treating a patient for a circadian rhythm disorder or for a sleep disorder wherein the patient is being treated with a strong CYP1A2 inhibitor selected from a group consisting of fluvoxamine, ciprofloxacin, and verapamil, the method comprising:
>
> > (A) discontinuing treatment with the strong CYP1A2 inhibitor and then
> >
> > (B) treating the patient with 20 mg of tasimelteon once daily.
>
> 14. The method of claim 13, that comprises treating the patient for Non-24-Hour Sleep-Wake Disorder.

J.A. 194 ('829 patent, col. 38, ll. 52–62). The claim elements at issue here are "(A) discontinuing treatment with the strong CYP1A2 inhibitor and then (B) treating the

patient with . . . tasimelteon." J.A. 194 ('829 patent, col. 38, ll. 57–59).

The district court relied on Hardeland and, as with claim 4 of the '910 patent, a ramelteon study in finding that claim 14 of the '829 patent would have been obvious. CYP1A2 is another enzyme that is often involved in drug metabolism. A CYP1A2 inhibitor decreases CYP1A2's ability to metabolize drugs, leading to a higher concentration of drugs metabolized by CYP1A2 in blood plasma. The Hardeland reference states that "[a]s tasimelteon is metabolized by [CYP1A2] . . . , coadministration of any drug that inhibits [this enzyme] should be regarded with caution." J.A. 20,528. The ramelteon study showed that "ramelteon underwent a 100-fold increase in blood plasma levels when it was co-administered with the CYP1A2 inhibitor fluvoxamine." J.A. 29 (citations omitted). The district court explained that, as with claim 4 of the '910 patent, the ramelteon study is relevant to tasimelteon and "[a] skilled artisan would have known that any drug-drug interaction resulting in a five-fold change in blood plasma levels is considered 'large' by FDA standards, and therefore a skilled artisan would have viewed the ramelteon-fluvoxamine drug-drug interaction as a 'huge interaction' and clearly significant." J.A. 29 (citation omitted).

Vanda argues that the prior art does not tell a skilled artisan not to prescribe tasimelteon with a CYP1A2 inhibitor and notes that the testing that explicitly showed that coadministration of tasimelteon and a CYP1A2 inhibitor renders tasimelteon ineffective was done after the priority date. This argument misunderstands the standard for obviousness.

Obviousness does not require certainty—it requires a reasonable expectation of success. *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007). Taken together, Hardeland's warning and the ramelteon study supported

the district court's finding that a skilled artisan would have expected that taking a CYP1A2 inhibitor with tasimelteon would have negatively impacted the efficacy of tasimelteon and so the two should not be given together. Appellees did not need to show that coadministration would have negatively impacted tasimelteon's efficacy, just that it would have been reasonable to expect it to do so. The district court did not err in finding that claim 14 would have been obvious.

CONCLUSION

The district court did not err in finding all of the challenged claims obvious. In light of our invalidity conclusion, we do not reach the question of infringement.

AFFIRMED

CERTIFICATE OF SERVICE

I hereby certify that on June 20, 2023, I electronically filed the foregoing petition with the Clerk of this Court using the CM/ECF system, and counsel for all parties will be served by the CM/ECF system.

Dated: June 20, 2023 /s/ *Paul W. Hughes*