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

Appeals 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

APPELLEES' RESPONSE TO APPELLANT'S COMBINED PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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Dated: July 31, 2023

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 23-1247

Short Case Caption Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.

Filing Party/Entity Apotex Inc. and Apotex Corp.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 07/31/2023

Signature: /s/ William Blake Coblentz

Name: William Blake Coblentz

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Apotex Inc.		Apotex Pharmaceuticals Holdings Inc.
Apotex Corp.		Aposherm Delaware Holdings Corporation

☐ Additional pages attached

4. Legal Representatives. List 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. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

Kaan Ekiner (Cozen O'Connor)	Thomas J. Francella, Jr. (Cozen O'Connor)	Gregory F. Fischer (Cozen O'Connor)
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5. Related Cases. Provide the case titles and numbers of any case known to be pending in this court or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. Do not include the originating case number(s) for this case. Fed. Cir. R. 47.4(a)(5). See also Fed. Cir. R. 47.5(b).

☑ None/Not Applicable ☐ Additional pages attached

6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

☑ None/Not Applicable ☐ Additional pages attached

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Date: 07/31/2023

Signature: /s/ John Christopher Rozendaal

Name: John Christopher Rozendaal

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Teva Pharmaceuticals USA, Inc.		See Attachment A.

☐ Additional pages attached

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☐ None/Not Applicable ☐ Additional pages attached

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☑ None/Not Applicable ☐ Additional pages attached

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

Vanda Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc., No. 23-1247

Certificate of Interest

Attachment A

3. Parent Corporations and Stockholders Teva Pharmaceuticals USA, Inc. is an indirect wholly owned subsidiary of Teva Pharmaceutical Industries Ltd., which is publicly traded. Teva Pharmaceutical Industries Ltd. is the only publicly traded company that owns 10% or more of Teva Pharmaceuticals USA, Inc.

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INTRODUCTION

The panel in this case issued a non-precedential decision affirming the district court's application of black-letter obviousness law to case-specific disputed questions of fact. It is hard to imagine a more inappropriate candidate for rehearing en banc.

En banc consideration is a "rare intervention" that "should be reserved for real conflicts as well as cases of exceptional importance." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1311 (Fed. Cir. 2006) (Michel, C.J., and Mayer, J., concurring). The panel's decision fits neither of these criteria. It breaks no new legal ground and creates no circuit precedent. There are no "broad legal pronouncements regarding obviousness" here, *contra* Pet. 1; Vanda's arguments otherwise flatly mischaracterize the panel's analysis.

When not erecting and dismantling straw men, Vanda spends its time making arguments that—while dressed up in legal garb—are in reality thinly veiled disagreements with the factual findings underlying the district court's obviousness conclusion. Those are the same disagreements that Vanda unsuccessfully advanced in its merits briefing. As the panel correctly concluded, the district court's findings were not clearly erroneous—on the contrary, they were entirely correct—and, in all events, such factbound disputes are not the stuff of meritorious rehearing petitions.

That Vanda's petition merely seeks to relitigate its merits appeal is particularly evident from Vanda's inability to meaningfully narrow its arguments for the rehearing stage. Vanda asks for rehearing on not one, not two, but *three* separate issues. The consequence of that scattershot approach is underdeveloped arguments—essentially, a Readers' Digest version of Vanda's opening brief. Vanda's arguments have now been heard and rejected twice—once by the district court and once by a panel of this Court. Vanda supplies no reason why they should be heard yet again. Rehearing should be denied.[1]

ARGUMENT

I. Rehearing en banc is inappropriate because the panel's decision creates no precedent.

The first and most fundamental problem with Vanda's petition is that the panel's decision creates no precedent. This Court's rules recognize that "[a] petition for rehearing en banc is rarely appropriate if the appeal was the subject of a nonprecedential opinion by the panel of judges that heard it." Fed. Cir. R. 35 Practice Note. That makes good sense; rehearing en banc is reserved for cases in

[1] Although Vanda's petition is styled in the alternative as a petition for panel rehearing, the petition focuses exclusively on Vanda's arguments for rehearing en banc. Vanda does not contend that the panel "overlooked or misapprehended" any "point of fact or law," as would be required for panel rehearing. Fed. Cir. R. 40(a). In any event, panel rehearing is unwarranted for the same reasons that rehearing en banc is unwarranted: Vanda's petition simply rehashes the arguments it made unsuccessfully in its merits briefs.

which the panel's decision presents an issue of "exceptional importance" or creates disuniformity of circuit precedent. Fed. R. App. P. 35(b)(1); *see Grimsrud v. Dep't of Transp.*, 902 F.3d 1364 (Fed. Cir. 2019) (Lourie, J., concurring in the denial of rehearing en banc). Nonprecedential decisions, by definition, do not do that.

Vanda's contention (at 1) that the panel "adopt[ed] broad legal pronouncements regarding obviousness that would categorically render entire classes of pharmaceutical subject matter unpatentable"—in addition to mischaracterizing the panel's analysis, *see infra* Section II—is thus factually wrong. The panel's decision does nothing more than affirm that Vanda's patents are obvious. It has no application beyond this specific case and these specific facts.

II. Vanda's criticisms of the panel's analysis are meritless.

Even if the panel's decision here were precedential, there would still be no reason for rehearing en banc, because the district court's analysis—and the panel's endorsement of it—are unassailable. Vanda's criticisms of that analysis lack merit.

A. The panel correctly found Vanda's "take it without food" patent obvious.

The first patent addressed in Vanda's petition—the '487 patent—claims a method of treating Non-24 by administering 20 mg tasimelteon without food. The panel agreed with the district court that administering tasimelteon without food would have been obvious to try because "there was market pressure (regulatory advice)" from the FDA "to determine if food would have an effect on the efficacy"

of new drugs. *Vanda Pharm. Inc. v. Teva Pharm. USA, Inc.*, 2023 WL 3335538, at *5 (Fed. Cir. May 10, 2023). As the patent specification itself "recognize[s], there were only two permutations for the food variable: tasimelteon could have been administered with food or without food"—that is, "there were two identifiable and predictable options." *Id.* "Under these circumstances, given the FDA guidance, it would have been obvious to try administering tasimelteon without food." *Id.*

Vanda contends (at 6) that the panel's decision "establishes a categorical rule that food-effect patents are invalid" and "ipso facto invalidates all food-effects patents." As an initial matter, a non-precedential decision cannot "establish[]" anything. But, in any event, the panel did no such thing.

An innovator that discovers *and claims* a novel or surprising food effect may be entitled to a patent. *Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, 731 F. App'x 962 (Fed. Cir. 2018) (cited at Pet. 5–6), illustrates the point: the claim there "describe[d] blood concentration level of oxymorphone … upon dosing of controlled release oxymorphone in fed versus fasting conditions," and it was found non-obvious because the prior art did not disclose that effect. *Id.* at 965, 970. So, too, with *Par Pharmaceutical, Inc. v. TWI Pharmaceuticals, Inc.*, 773 F.3d 1186 (Fed. Cir. 2014) (cited at Pet. 5): The patent claimed a method of administering a specific formulation of megestrol (namely, an oral suspension of a specified volume with a specified particle size) that resulted in the same

pharmacokinetic profile when administered with or without food. *Id.* at 1189. This Court vacated the district court's obviousness conclusion because (i) the prior art did not expressly disclose the claimed food effect and (ii) the district court had failed to conduct a proper inherency analysis. *Id.* at 1194–96.[2]

But Vanda did not do that here. The '487 patent does not claim a pharmacokinetic result (or any result, for that matter). The claim just requires administration of tasimelteon without food—full stop. That was obvious, or at least obvious to try, long before 2012.

Vanda implies (at 7) that its claims cover a beneficial food effect because "[t]he 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." Setting aside that the claim says nothing about this (nor does the specification, for that matter), this purportedly "uncontroverted" fact is not even true, much less uncontroverted. The only evidence Vanda introduced to support it was the self-serving testimony of Vanda's CEO Dr. Polymeropoulos, whom the district court found not credible. Appx14 (¶ 33). Vanda's suggestion that it

[2] Vanda's petition—like its merits briefing—omits that, on remand, the district court again found the claims obvious and this Court summarily affirmed. *See Par Pharm., Inc. v. TWI Pharm., Inc.*, 624 F. App'x 756 (Fed. Cir. 2015); Appellee Br. 47.

invented a better method of administering tasimelteon is thus both irrelevant and unsupported by the record.

Vanda also contends (at 8–9) that food effects generally are unpredictable and could depend on the precise composition of the food given to the patient. As an initial matter, Vanda cites no record evidence (or anything else) for these assertions—a notable omission, given that Vanda accuses (at 8) the panel of "disregard[ing] the facts before it." In any event, even if Vanda's premise is assumed true, it does not help Vanda here because, again, the '487 patent *does not claim a food effect*, unpredictable or otherwise.

B. The panel did not hold that "the mere existence of clinical trials" forecloses patentability.

Vanda's RE604 patent claims administration of 20 mg tasimelteon shortly before bedtime to entrain Non-24 patients to a 24-hour sleep-wake cycle. The district court found that Defendants' prior-art combinations disclosed each limitation of claim 3—dose, timing of administration, patient population, and result of entrainment. Appx40–41 (¶¶ 150–155); Appx69. The district court further found that, as of the priority date, skilled artisans would have been motivated to combine those references with a reasonable expectation of success because (i) the Hack reference discloses entrainment of Non-24 patients with melatonin via phase-shifting and (ii) the Lankford, '244 publication, and Hardeland references observe that tasimelteon has similar phase-shifting properties to melatonin and so is

expected to have similar effects. Appx42–45 (¶¶ 156–160); Appx69. Crediting Defendants' expert Dr. Emens, the district court also found that "Lankford's disclosure of Vanda's Phase III trial"—which used the precise dosing regimen recited in the asserted claims—"would also have contributed to a skilled artisan's expectation of success." Appx43 (¶ 159).

The panel affirmed the district court's obviousness conclusion, finding "no error in the district court's choice to credit statements in the prior art explaining the similarities between tasimelteon and melatonin and why those similarities would have made data for melatonin relevant for tasimelteon." *Vanda*, 2023 WL 3335538, at *2. The panel also agreed with the district court that the 20 mg dose would have been obvious, noting that both Hardeland and Vanda's own '244 publication concluded that 20 mg was an effective dose to treat circadian rhythm disorders like Non-24. *See id.* at *3. "Taken together," the panel concluded, the extensive evidence reviewed by the district court was "sufficient to support [its] finding that the tasimelteon prior art would have given a skilled artisan a reasonable expectation of success of entrainment with 20 mg." *Id.* at *4.

Continuing its parade of straw men, Vanda contends (at 10) that the panel's obviousness analysis of the RE604 patent "establish[ed] a presumption of success from the conduct of a Phase III clinical trial." Wrong again. Neither the panel nor the district court held that the mere fact of Vanda's Phase III trial would have

given a skilled artisan a reasonable expectation that the trial would succeed. Instead, after cataloguing numerous prior-art disclosures that collectively disclose each limitation of the RE604 patent claims and hypothesized that tasimelteon would be successful at treating Non-24 at the claimed doses, the district court observed that the disclosure of the Phase III trial would further "contribute[] to" the expectation of success. Appx43–44 (¶ 159). And the panel found that conclusion supported by the evidence. *See Vanda*, 2023 WL 3335538, at *4.

Vanda's mischaracterization on this score is particularly notable given that Vanda's merits briefing misstated the district court's analysis in the exact same way—a fact not lost on the panel. "Contrary to Vanda's characterization," the panel noted, "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." *Id.* "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.'" *Id.* (quoting Appx43). And the panel found "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." *Id.*

Vanda protests (at 12) that the panel *must* have relied solely on the existence of the Phase III clinical trial because none of the other prior art would have

supplied a reasonable expectation of success. But Vanda simply lost this argument on the facts—and for good reason. To take just one example, as the district court found, Vanda's own prior-art '244 patent application concluded that tasimelteon is effective in treating sleep disorders when administered at doses of 20–50 mg a half hour before bedtime. Appx38 (¶ 144) (quoting Appx20629). That prior-art application even included claims—claims closely mirroring those asserted here—covering a method of treating circadian-rhythm disorders by administering 20–50 mg tasimelteon a half-hour before bedtime, Appx39 (¶¶ 146–147) (quoting Appx20630–20631). Those disclosures on their own would be sufficient to supply a reasonable expectation of success.[3]

Vanda's odd detour into enablement law (at 2, 14–15) is likewise unpersuasive. Method-of-treatment patents need not include Phase III clinical trial results to satisfy § 112. *See In re Montgomery*, 677 F.3d 1375, 1382 (Fed. Cir. 2012) ("It is well established that a patent may be secured, and typically is secured, before the conclusion of clinical trials.").[4] The Supreme Court's decision in *Amgen*

[3] Vanda's contention (at 12) that the '244 publication and the prior-art Hardeland reference "merely parrot the clinical trial materials" makes no sense. The '244 publication (from 2007) and Hardeland (from 2009) both *predate* the disclosure of Vanda's Phase III clinical trial (2010).

[4] Nor can Vanda credibly claim that it was laboring under that misimpression; as evidenced by the '244 publication, Vanda filed for patent protection on methods closing mirroring the methods claimed here in 2006, four years before the Phase III trial even started.

did not hold otherwise. *Contra* Pet. 14. *Amgen* did not involve questions about clinical trial results at all; the question there was whether functionally defined claims to a genus of antibodies potentially spanning millions of species were supported by a specification that disclosed 26 example antibodies and invited skilled artisans to find others through "random trial-and-error discovery." *Amgen Inc. v. Sanofi*, 143 S. Ct. 1243, 1257 (2023).

In short, Vanda's problem is not that it had to publish its Phase III protocol. *Contra* Pet. 13. Vanda's problem is that it waited until January 2012—after the protocol and a wealth of other prior art rendering its purported invention obvious had accumulated—to apply for the RE604 patent. The panel correctly found that patent invalid.

C. The panel correctly deferred to the district court's factual finding that a skilled artisan would have reasonably expected a drug-drug interaction between tasimelteon and strong CYP3A inducers.

The final patent at issue in Vanda's petition claims a method of discontinuing the strong CYP3A inducer rifampicin before administering tasimelteon. Expressly crediting Defendants' expert over Vanda's, the district court concluded that, in light of the art's warnings regarding coadministration of ramelteon and the strong CYP3A4 inducer rifampicin and the similarities between ramelteon and tasimelteon, it would have been obvious to avoid co-administration of rifampicin and tasimelteon. Appx46–48 (¶¶ 166–170); Appx70–72. The panel—

appropriately deferring to the district court's credibility findings—found "no error" in the conclusion 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." *Vanda*, 2023 WL 3335538, at *6; *cf. Anderson v. City of Bessemer*, 470 U.S. 564, 575 (1985) (credibility determinations by a trial court "can virtually never be clear error"). Vanda's assertion (at 15) that "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" is thus demonstrably false. The panel explained exactly why there was a reasonable expectation of success; Vanda just disagrees with the conclusion.

Vanda's further contention (at 16) that the panel found this patent obvious based on the "mere possibility" of a drug-drug interaction likewise misstates the opinion. The panel quoted and endorsed the district court's finding that, based on the ramelteon art, "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 coadministered with rifampin and *would have thought it necessary and obvious* to stop treating the patient with rifampin" before administering tasimelteon. *Vanda*, 2023 WL 3335538, at *6 (quoting Appx48) (emphases added). That is the applicable standard, as Vanda agrees, *see* Pet. 16 (quoting *Novartis Pharms. Co. v. West-Ward Pharms. Int'l Ltd.*, 923 F.3d 1051,

1059 (Fed. Cir. 2019)). The "possibility" language Vanda quotes comes from the section of the panel opinion rejecting Vanda's argument that the prior art taught away from the invention because one reference (Vachharajani) found no metabolism of tasimelteon by CYP3A4. *See Vanda*, 2023 WL 3335538, at *6–7. Vanda's attempt to twist that rejection of its teaching-away argument into a misstatement of the obviousness standard thus fails.

At bottom, Vanda is simply trying to relitigate the facts (its assertion (at 17) that the panel "refus[ed] to give proper weight to" Vachharajani is a rather large tell on this score). The panel applied no "categorical rule[s]." *Contra* Pet. 17. It deferred to the district court's detailed and case-specific factual determinations and therefore affirmed the court's conclusion that Vanda's patents are obvious. The district court got it right; the panel properly deferred to the factfinder; and—more to the point—this factbound dispute certainly does not warrant en banc consideration.

CONCLUSION AND RELIEF SOUGHT

Vanda's petition should be denied.

Dated: July 31, 2023

Respectfully submitted,

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FORM 19. Certificate of Compliance with Type-Volume Limitations **Form 19**
July 2020

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS

Case Number: 2023-1247

Short Case Caption: Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.

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Date: 07/31/2023

Signature: /s/ John Christopher Rozendaal

Name: John Christopher Rozendaal