No. 2019-2011

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

SUN PHARMACEUTICAL INDUSTRIES, INC., f/d/b/a Concert Pharmaceuticals, Inc.,

Appellant,

v.

INCYTE CORPORATION,

Appellee,

KATHERINE K. VIDAL, Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

Intervenor.

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, No. IPR2017-01256

APPELLANT'S PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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CERTIFICATE OF INTEREST

Counsel for Appellant certifies the following:

1. Represented Entities. Provide the full names of all entities represented by undersigned counsel in this case. Fed. Cir. R. 47.4(a)(1).

Sun Pharmaceutical Industries, Inc.

2. Real Party in Interest. 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. Fed. Cir. R. 47.4(a)(2).

None.

3. Parent Corporations and Stockholders. 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. Fed. Cir. R. 47.4(a)(3).

Sun Pharmaceutical Holdings USA, Inc.
Sun Pharmaceutical Industries Ltd.

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).

Marta E. Delsignore (Goodwin Procter LLP)
Cynthia L. Hardman (formerly of Goodwin Procter LLP)
Sarah J. Fischer (formerly of Goodwin Procter LLP)

5. Related Cases. Other than the originating case(s) for this case, are there related or prior cases that meet the criteria under Fed. Cir. R. 47.5(a)?

No.

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.

October 6, 2023

/s/ *William M. Jay*
William M. Jay

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GLOSSARY

'149 patent	U.S. Patent No. 9,249,149 (Appx1425-1446)
AA	alopecia areata
ADME	absorption, distribution, metabolism, and excretion
Board	Patent Trial and Appeal Board
JAK1	Janus Kinase 1
JAK2	Janus Kinase 2
PTAB	Patent Trial and Appeal Board

RULE 35(b) STATEMENT

Based on my professional judgment, I believe the panel decision is contrary to the following precedents:

1. *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359 (Fed. Cir. 2015)
2. *Dickinson v. Zurko*, 527 U.S. 150 (1999)
3. *INS v. Orlando Ventura*, 537 U.S. 12 (2002) (per curiam)
4. *Nutrinova Nutrition Specialties & Food Ingredients GmbH v. ITC*, 224 F.3d 1356 (Fed. Cir. 2000)
5. *SEC v. Chenery Corp.*, 332 U.S. 194 (1947)

RULE 40(a)(2) STATEMENT

The panel overlooked appellant's argument that there was "a long-felt need for an effective AA treatment with a tolerable long-term side effect profile" (Appx465). That is, the panel failed to recognize that appellant's argument was not limited to a long-felt need for an *already-FDA-approved* AA treatment.

October 6, 2023

/s/ *William M. Jay*
William M. Jay

INTRODUCTION

Concert Pharmaceuticals[1] invented novel chemical compounds that yielded an unexpectedly safe and effective treatment for alopecia areata (AA)—a condition that, until recently, had no FDA-approved therapy. Unlike prior-art compounds, Concert's novel compounds incorporate "deuterium," a rare isotope of hydrogen. Although the effects of deuterium are highly unpredictable, Concert discovered that in this set of compounds the incorporation of deuterium produced superior pharmacokinetic properties that allowed for a viable AA treatment.

But the PTAB held, and a panel of this Court has affirmed, that the patent on Concert's novel compounds was obvious over the prior art. That decision rests on two fundamental legal errors that warrant rehearing. First, the Board never found one of the facts that is essential to any obviousness determination: that a skilled artisan would have had a reasonable expectation of success. Rather than remand, however, a panel of this Court made a finding on that point itself, violating settled precedent governing agency review. Second, the panel held that Concert could not prevail on long-felt need because its product had not yet obtained FDA

[1] Concert later merged into appellant Sun Pharmaceutical Industries.

approval. While the panel acknowledged that the law of long-felt need does not require any such thing, it read Concert to have unilaterally *conceded* that FDA approval was required—even though such a concession would have made the entire argument pointless.

First, with respect to a skilled artisan's reasonable expectations, this Court flouted established precedent by citing "substantial evidence" to sustain a finding the PTAB never made. The PTAB held that skilled artisans would have been motivated to synthesize the claimed compounds to pursue certain desirable properties. But it never found that a skilled artisan would have *expected success* in achieving those properties: instead, it held only that a skilled artisan could have successfully synthesized the compounds—whatever their properties. When Concert pointed out the Board's failure, the panel assumed without deciding that Concert was right about the legal standard. Opinion 9 n.3. Nevertheless, the panel affirmed the Board's decision because, the panel said, "[t]he Board had substantial evidence to conclude that a person of ordinary skill . . . would expect [the claimed compounds] to display 'superior [pharmacokinetic] properties.'" Opinion 12.

But the Board made no such conclusion about the pharmacokinetic properties, and the panel could not permissibly cite "substantial evidence" to affirm a finding the Board never made. It is settled law that this Court "must not [itself] make factual . . . determinations that are for the agency to make." *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015). Because the Board never answered the relevant reasonable-expectation-of-success question, the appropriate course was to remand to the Board for additional factfinding. *See INS v. Orlando Ventura*, 537 U.S. 12, 16-18 (2002) (per curiam).

Second, the panel erred in its treatment of the objective indicia of nonobviousness. Concert invented a compound that addresses the long-felt need for an AA treatment—which is why the FDA granted the compound "Breakthrough Therapy" and "Fast Track" status. Opinion 15. The PTAB refused to consider this evidence of nonobviousness because the relevant compound had not yet received *final* FDA marketing approval by the close of evidence. Appx36-37. But satisfying a long-felt need that others had not solved is objective evidence of nonobviousness *irrespective* of regulatory approval—indeed, regulatory approval will never have been granted at the time of a patent application. Notably, the

panel agreed with Concert and its amicus that the PTAB applied the wrong legal standard, because FDA approval is not a prerequisite to showing that a long-felt need has been met." Opinion 15. But the panel held that this settled law *does not apply to Concert*, because a single line in Concert's PTAB briefing summarized the need as a "long-felt need for an *FDA-approved*, evidence-based alopecia areata treatment." Opinion 15 (quoting Appx465). Treating that reference as a concession is absurd: Concert explicitly argued that it "satisfie[d]" the relevant need, and everyone knew that Concert did not yet have FDA approval. Appx465.

These errors warrant rehearing—either by the panel or the full Court. The Court's improper appellate factfinding disrupts the proper balance between the Court and the agency and creates practical problems for litigants. And the panel's refusal to correct the Board's misapplication of long-felt need will leave future inventors of FDA-regulated products uncertain how to deploy this important objective evidence of nonobviousness.

BACKGROUND

I. Factual Background

A. Deuteration and Its Effects

Whether a drug is clinically useful depends in large part on its pharmacokinetic properties, such as the processes governing its absorption, distribution, metabolism, and excretion (ADME) within the body. *See* Appx1428 (1:23-24) (identifying "[p]oor ADME properties" as "a major reason for the failure of drug candidates in clinical trials"); *see also* Appx7919; Appx8225-8246; Appx9578. Concert's invention focuses on achieving better ADME properties through the use of deuterium. Appx1428 (2:5-10). Because deuterium (whose nucleus consists of one proton and one neutron) forms stronger bonds with carbon than hydrogen (whose nucleus consists of a single proton), substituting deuterium for hydrogen ("deuteration") may affect a drug's pharmacokinetic properties. Appx1428 (2:10-15); Appx1982; Appx2377; Appx9578-9579.

But it is difficult, if not impossible, to predict whether or how deuteration will affect any particular compound's properties. Without experimentation, a skilled artisan generally cannot say whether deuteration will affect a drug's ADME properties at all, let alone whether the deuterated drug will be therapeutically better, worse, or the same. A number

of factors contribute to that unpredictability. First, the catalytic cycle—*i.e.*, the chain of chemical reactions through which the body metabolizes a given drug—is extraordinarily complex. *See generally* Concert Principal Br. 8-10. Second, sometimes deuteration can cause metabolism to "switch" to a different location on the drug molecule. *See generally id.* at 10-11. Third, even if deuteration produces a particular effect in a highly controlled lab environment, skilled artisans cannot predict whether that effect will manifest itself in a living organism because of the complexity of biological processes and the existence of competing effects. *See generally id.* at 11. Finally, "even if expressed *in vivo*, the [effect] that results from deuteration must have an effect on a pharmacokinetic parameter of . . . interest," Appx2395, something a skilled artisan could not predict *ex ante*. *See generally* Concert Principal Br. 12-14.

B. Ruxolitinib and Its Side-Effects

Ruxolitinib is a compound that is FDA-approved to treat life-threatening indications like myelofibrosis, a rare bone marrow/blood cancer. Appx1717; Appx7060; *see* Appx1428-1429(2:66-3:3). Ruxolitinib inhibits signaling proteins known as Janus Kinases 1 and 2 (JAK1 and JAK2),

whose overactivity in the body can lead to certain autoimmune diseases. *See* Appx1428(2:53); Appx1729.

Despite its benefits, ruxolitinib comes with a number of side-effects, including blood-related toxicities such as anemia (low red blood cell count), thrombocytopenia (low blood platelet count), neutropenia (low white blood cell count), and lowered hemoglobin. *See* Appx7794-7795; Appx7827; Appx9472; Appx9479; Appx9484; *see also* Appx9574-9575. These side-effects occur with significant frequency. *See* Appx7794; Appx9478-9479. And they are serious: in one clinical study, more than 40% of patients taking ruxolitinib for myelofibrosis required dose reduction or interruption due to thrombocytopenia and a further 5% required dose reduction or interruption due to anemia. Appx9491-9492; *see also* Appx9483; Appx9491-9492.

The presence of these side-effects limits the medical conditions for which ruxolitinib is an acceptable treatment. While serious adverse reactions like anemia and thrombocytopenia might be acceptable in a treatment for a potentially fatal illness like cancer, they are far less tolerable for patients suffering from non-life-threatening conditions like alopecia. Appx9382; Appx9580. Before Concert's invention, a skilled artisan would

have understood these toxic side-effects to be caused by the same mechanism that causes ruxolitinib's beneficial clinical effects. *See* Concert Principal Br. 17.

C. Alopecia Areata and Concert's Novel Compounds

Alopecia areata is one of the most common autoimmune disorders in the United States. Appx7824. An AA patient's immune system attacks the patient's own hair follicles, leading to unpredictable and sometimes total hair loss. Appx7824; Appx7833; Appx9380-9381. Until June 2022, the FDA had not approved any systemic treatments for AA. *See* U.S. Food & Drug Admin., *FDA Approves First Systemic Treatment for Alopecia Areata* (June 13, 2022), https://bit.ly/3MP8dlS.

Concert recognized the potential for deuterated ruxolitinib to meet the long-felt need for a viable AA treatment. Its '149 patent claims a number of specific deuterated ruxolitinib compounds. *See* Appx1445-1446. Once of these, known as CTP-543 or the "octa-deuterated" compound, differs from ruxolitinib because it substitutes deuterium for hydrogen at eight specific positions.

In clinical trials, Concert found that CTP-543 demonstrated two unexpected qualities that make it particularly promising for treating AA

compared to ruxolitinib. First, CTP-543 possesses a "flatter" pharmacokinetic curve than ruxolitinib, meaning it can effectively treat AA without triggering the same toxic side-effects. *See* Concert Principal Br. 20-21. Second, in a head-to-head comparison with ruxolitinib, the patients who are least likely to benefit from ruxolitinib (because they metabolize it more rapidly) experienced a disproportionately greater benefit with CTP-543. *See id.* at 22-23.

Recognizing the promise of this therapy, the FDA granted CTP-543 "Fast Track" status in 2018 and "Breakthrough Therapy" designation in 2020. Appx10102; Concert Principal Br. 19. In October 2023, the FDA accepted the New Drug Application for an 8 mg twice-daily regimen of CTP-543. Sun Pharma, *Sun Pharma Announces US FDA Filing Acceptance of New Drug Application (NDA) For Deuruxolitinib*, https://sunpharma.com/wp-content/uploads/2023/10/Sun-Pharma-Announces-US-FDA-Filing-Acceptance-for-Deuruxolitnib.pdf (Oct. 6, 2023).

II. Procedural History

A. PTAB Proceedings

Incyte filed a petition for inter partes review of the '149 patent asserting that its claims were obvious over three references. The Board

agreed, holding that a skilled artisan would have chosen ruxolitinib as a lead compound and would have been motivated to modify it as claimed with a reasonable expectation of success.

As relevant here, the Board framed the reasonable-expectations inquiry as "whether a person of ordinary skill in the art would have had a reasonable expectation of *successfully making the claimed invention*"—*i.e.*, successfully synthesizing the claimed compounds "in light of the prior art." Appx31 (emphasis added). Concert had explained to the Board that "a person of ordinary skill in the art would have had no reasonable expectation of achieving either . . . *in vitro* or *in vivo* [effects from deuteration], and would not have been able to predict *a priori* the effect of deuteration on the [drug's] clinical profile." Appx31 (citations omitted). In the Board's view, however, whether a skilled artisan would have reasonably expected any particular pharmacokinetic properties to result from deuteration was irrelevant, because "the challenged claims do not recite any of those features." Appx31. Based on its limited view of reasonable expectations, the Board concluded that "the preponderance of the evidence support[ed] [Incyte]'s assertion that the [prior art] would have provided a person of ordinary skill in the art a reasonable expectation of

successfully deuterating [ruxolitinib at its] metabolic 'hot spots.'" Appx31.

The PTAB also refused to give any weight to Concert's objective indicia of nonobviousness. As relevant here, the Board rejected Concert's argument that its invention fulfilled a long-felt need because CTP-543 showed clinical promise in providing a treatment for AA. The Board did not dispute Concert's proof, but it disregarded that factor as "unsupported" and "premature" for the sole reason that CTP-543 was not yet FDA-approved to treat AA. Appx35-37.

B. Panel Decision

A panel of this Court affirmed the PTAB's judgment.

With respect to reasonable expectations of success, the panel noted the parties' "disagree[ment] as to whether [the Court's] case law limits the reasonable expectation of success inquiry to only those properties that are actually claimed in the patent being challenged," but it "assum[ed] (without deciding) that a skilled artisan would have needed to have reasonably expected success in obtaining the beneficial (though possibly unclaimed) properties [of the] claimed compounds." Opinion 8-9 n.3.

Despite that assumption, the panel held that "[t]he Board had substantial evidence to conclude that a person of ordinary skill would have had a reasonable expectation that she could succeed in modifying ruxolitinib to arrive at its tetra- and octo-deuterated analogs, which she would expect to display 'superior ADME properties.'" Opinion 12 (quoting Appx32).

The panel also concluded that "[n]othing about Sun's objective indicia evidence rebuts Incyte's *prima facie* showing of obviousness." Opinion 13. The panel "[a]ssum[ed], without deciding, that the need for an effective and safe alopecia areata treatment existed." Opinion 15. And it "agree[d] with [Concert and its amicus] that FDA approval is not a prerequisite to showing that a long-felt need has been met, and [that the] FDA's designation of CTP-543 for 'Breakthrough Therapy' and 'Fast-Track' approval are probative of nonobviousness." Opinion 15. Nevertheless, the panel concluded, Concert's PTAB papers had "expressly framed its objective indicia argument as 'CTP-543 satisfies the long-felt need for an *FDA-approved*, evidence-based alopecia areata treatment,' and the Board reasonably found that CTP-543 had not met this need because it lacked FDA approval." *Id.* (citations omitted).

ARGUMENT

I. The panel's decision rested on impermissible appellate fact-finding.

A. This Court may not find new facts in appeals from PTAB decisions.

The PTO is subject to the same principles of judicial review as any other administrative agency. *See, e.g.*, *Dickinson v. Zurko*, 527 U.S. 150, 154 (1999). One of those principles is that an appellate court can review the agency's factual findings for substantial evidence, but "must not [itself] make factual and discretionary determinations that are for the agency to make." *Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015).

This Court has repeatedly upheld that rule. In *Ariosa*, for example, the Court applied the rule in reviewing a PTAB decision that allegedly failed to consider a particular exhibit for legally impermissible reasons. *Id.* at 1365. On appeal, the Court noted that there were certain factual determinations that could provide "a legally proper ground" for the Board to disregard the exhibit. *Id.* at 1366. But the Board had not made those findings, and so this Court vacated and remanded, emphasizing that "[it] cannot do so for the Board where, as here, the matter is not purely legal." *Id.* The *Ariad* decision does not stand alone: the Court has repeated the

same verbatim admonition—"we must not ourselves make factual and discretionary determinations that are for the agency to make"—on numerous occasions in subsequent years. *See In re Warsaw Orthopedic, Inc.*, 832 F.3d 1327, 1335 (Fed. Cir. 2016); *L.A. Biomedical Rsch. Inst. v. Eli Lilly & Co.*, 849 F.3d 1049, 1068 (Fed. Cir. 2017); *Bd. of Trustees of the Leland Stanford Jr. Univ. v. Chinese Univ. of Hong Kong*, 860 F.3d 1367, 1378 (Fed. Cir. 2017); *Google Inc. v. Intellectual Ventures II LLC*, 701 F. Appx. 946, 955 (Fed. Cir. 2017); *Netflix, Inc. v. DivX, LLC*, No. 2022-1083, 2023 WL 2298768, at *5 (Fed. Cir. Mar. 1, 2023).

This is not a new principle: it stems from decades of Supreme Court decisions on administrative law. In *SEC v. Chenery Corp.*, 332 U.S. 194 (1947), the Court made clear that "a reviewing court, in dealing with a determination or judgment which an administrative agency alone is authorized to make, must judge the propriety of such action solely by the grounds invoked by the agency." *Id.* at 196. "If those grounds are inadequate or improper," the Court explained, "the [reviewing] court is powerless to affirm the administrative action by substituting what it considers to be a more adequate or proper basis." *Id.*

From *Chenery*'s starting point, the Supreme Court has refined and

reiterated what it has come to call the "ordinary 'remand' rule." *INS v. Orlando Ventura*, 537 U.S. 12, 18 (2002) (per curiam). Once a court has rejected the stated basis for an agency's decision, the proper course is to return the matter for the agency to resolve any outstanding issues in the first instance. *See Fed. Power Comm'n v. Idaho Power Co.*, 344 U.S. 17, 20 (1952) ("[T]he function of the reviewing court ends when an error of law is laid bare. At that point the matter once more goes to the Commission for reconsideration."); *Fla. Power & Light Co. v. Lorion*, 470 U.S. 729, 744 (1985) ("If the record before the agency does not support the agency action . . . , the proper course, except in rare circumstances, is to remand to the agency for additional investigation or explanation."). This well-established rule applies to all manner of agency determinations—including, as relevant here, contested questions of fact. *Orlando Ventura*, 537 U.S. at 18; *see also, e.g.*, *Gonzales v. Thomas*, 547 U.S. 183, 185 (2006) (per curiam); *Negusie v. Holder*, 555 U.S. 511 (2009).

The rule that an appellate court may not find new facts in reviewing an agency's decision is also inherent in the nature of substantial-evidence review. The Supreme Court held long ago that because "the PTO is an

'agency' subject to the APA's constraints," and because the agency's "finding[s] constitute[] 'agency action,'" this Court "must apply the APA's court/agency review standards"—including the substantial-evidence standard applicable to an agency's findings of fact—in reviewing PTO decisions. *Zurko*, 527 U.S. at 154; *see* 5 U.S.C. §706(2)(E). "Substantial evidence is such relevant evidence as reasonable minds might accept as adequate to support a conclusion *even if it is possible to draw two inconsistent conclusions from the evidence*." *Fleming v. Escort Inc.*, 774 F.3d 1371, 1375 (Fed. Cir. 2014) (emphasis added). In other words, this Court might draw different conclusions from the record than the agency did—but it is the agency's conclusions that should ordinarily control. *See, e.g.*, *Nutrinova Nutrition Specialties & Food Ingredients GmbH v. ITC*, 224 F.3d 1356, 1359 (Fed. Cir. 2000) ("Even if we might have found some of the facts differently, . . . that is not the role of an appellate court.").

In sum, an appellate court violates bedrock administrative-law principles—not to mention decades of precedent—when it bases its review of an agency's decision on facts the agency itself did not find.

B. The panel's reasonable-expectations analysis rested on facts the PTAB never found.

The panel upheld the Board's determination that a skilled artisan would have had a reasonable expectation of success because, the panel said, "[t]he Board had substantial evidence to conclude that a person of ordinary skill . . . would expect [the claimed compounds] to display 'superior [pharmacokinetic] properties.'" Opinion 12. That finding is exactly what the precedent discussed above forbids.

The Board never found what the panel did—*i.e.*, that a skilled artisan would expect the claimed compounds to display superior pharmacokinetic properties. In the proceedings below, the Board found that a skilled artisan would have been able to "deuterat[e] . . . ruxolitinib compounds at their metabolic 'hot spots.'" Appx31. But it concluded that any further inquiry into the compounds' properties was unnecessary, because "the challenged claims do not recite any of those features." Appx31.[2]

[2] The Board did say, in passing, that "a skilled artisan would have had a reasonable expectation that the synthesized ruxolitinib analogs '*may display*' superior ADME properties." Appx32 (quotation marks and citations omitted). But the appellate panel did not rely on that statement, *see* Opinion 12, because it does not meet the relevant standard either: mere "hope" about what *may* happen is "not enough to create a reasonable expectation of success." *OSI Pharm., LLC v. Apotex Inc.*, 939 F.3d 1375, 1385 (Fed. Cir. 2019).

On appeal, the panel "assum[ed] (without deciding) that" the Board applied the wrong legal standard, and that a skilled artisan would have needed to "reasonably expect[] success in obtaining the beneficial . . . properties" of the claimed compounds. Opinion 9 n.3. But if the Board applied the wrong legal standard, the appropriate course was to vacate the Board's decision and remand for further factfinding under the right one. *Chenery*, 332 U.S. at 196; *Ariosa*, 805 F.3d at 1365; *Orlando Ventura*, 537 U.S. at 18; *see also supra*, pp. 13-16 (collecting cases). What the panel could *not* do is "make factual . . . determinations that are for the agency to make." *Ariosa*, 805 F.3d at 1365. But that is just what the panel did.

C. The panel's error warrants the full Court's attention.

The panel's decision not only conflicts with settled precedent—it also raises significant concerns that the full Court should address.

First, the panel's decision raises significant separation-of-powers concerns. Congress (the legislative branch) has entrusted the PTAB (in the executive branch) with the responsibility to adjudicate patent claims in inter partes review proceedings. *See* 35 U.S.C. §§311 *et seq.* If the

Court takes the factfinding role for itself, it "propel[s] [itself] into the domain which Congress has set aside exclusively for the administrative agency." *Chenery*, 332 U.S. at 196; *see also* Christopher J. Walker, *The Ordinary Remand Rule and the Judicial Toolbox for Agency Dialogue*, 82 Geo. Wash. L. Rev. 1553, 1563 & n.32 (2014) (discussing the separation-of-powers principles that animate the *Chenery* doctrine).

Second, the panel's error implicates the uniformity concern that the Supreme Court discussed in *Zurko*. There, the Court "[r]ecogniz[ed] the importance of maintaining a uniform approach to judicial review of administrative action." 527 U.S. at 154. But the panel's decision sows disuniformity by suggesting that appellate panels may engage in factfinding in certain preferred cases.

Finally, the panel's approach creates practical problems for litigants. By affirming on alternative factual grounds that the Board did not reach, the panel's decision suggests that in every PTAB appeal, the appellant should brief every available factual issue—not just those the Board reached, but any issue the Board *could* have reached. Otherwise (the panel's decision suggests), the appellant will run the risk that the Court will affirm the PTAB's decision on factual grounds that the Board

never reached (and that were never briefed on appeal).

II. The panel's decision misconstrues Concert's long-felt-need argument.

Rehearing is also warranted to address the panel's treatment of Concert's long-felt-need argument. The panel acknowledged that the Board got the law of long-felt need wrong: final regulatory approval is no prerequisite, especially where (as here) the regulatory agency itself has awarded "Breakthrough" or similar designations based on clinical results thus far. But the panel essentially concluded that Concert invited the Board's error and therefore refused to correct it. *See* Opinion 15. That characterization does not square with the record and provides no reason not to fix the Board's mistake.

The panel's decision plucks a single stray phrase out of Concert's PTAB briefing while ignoring the totality of Concert's argument. Concert explicitly argued that CTP-543 "satisfie[d]" the long-felt need, Appx465; Appx1085 (heading style omitted), which it could not have done if the need were for an already-FDA-approved drug. In other words, the panel's decision presumes that Concert advanced a patently self-defeating argument. Not surprisingly, it did not. Rather, Concert argued:

> There has been a long-felt need *for an effective AA treatment with a tolerable long-term side effect profile*. Concert's clinical studies have shown that CTP-543 is a promising drug to fill *this* unmet need.

Appx465 (citation and paragraph break omitted) (emphasis added); *see also id.* ("[T]here has been a long-felt need for an evidence-based AA treatment that does not have unacceptable side effects."). Nothing about that description turns on FDA approval.

The panel's mistake is significant: it gives the Board procedural license to disregard powerful objective evidence that the challenged claims are not obvious. The Court should correct that error to maintain the protections against hindsight-driven analysis on which patentees and the public depend.

CONCLUSION

The Court should grant panel rehearing or rehearing en banc.

October 6, 2023

Respectfully submitted.

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ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

SUN PHARMACEUTICAL INDUSTRIES, INC., F/D/B/A CONCERT PHARMACEUTICALS, INC.
Appellant

v.

INCYTE CORPORATION,
Appellee

KATHERINE K. VIDAL, UNDER SECRETARY OF COMMERCE FOR INTELLECTUAL PROPERTY AND DIRECTOR OFTHE UNITED STATES PATENT AND TRADEMARK OFFICE,
Intervenor

2019-2011

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2017-01256.

Decided: August 22, 2023

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, argued for appellant. Also represented by GERARD JUSTIN CEDRONE, EMILY L. RAPALINO, DARYL L. WIESEN,

DAVID ZIMMER, Boston, MA.

MARK J. FELDSTEIN, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, argued for appellee. Also represented by DREW CHRISTIE, C. COLLETTE CORSER, JASON LEE ROMRELL; J. DEREK MCCORQUINDALE, Reston, VA; TRENTON A. WARD, Atlanta, GA.

ROBERT MCBRIDE, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, for intervenor. Also represented by THOMAS W. KRAUSE, FARHEENA YASMEEN RASHEED; SCOTT R. MCINTOSH, MELISSA N. PATTERSON, Civil Division, Appellate Staff, United Department of Justice, Washington, DC.

JOHN C. KAPPOS, O'Melveny & Myers LLP, Dallas, TX, for amicus curiae Bald Girls Do Lunch. Also represented by CAITLIN P. HOGAN, New York, NY.

Before HUGHES, LINN, and STARK, *Circuit Judges*.

STARK, *Circuit Judge*.

Sun Pharmaceutical Industries, Inc. ("Sun")[1] appeals the Final Written Decision of the Patent and Trial Appeal Board ("Board") in an *inter partes* review ("IPR") in which Petitioner, Incyte Corporation ("Incyte"), challenged all claims of Sun's U.S. Patent No. 9,249,149 ("'149 patent"). The Board concluded that the claims were invalid as obvious. Sun sought review by the Director of the Patent and Trademark Office, which was denied, and then timely filed an appeal to this court. We have jurisdiction pursuant to

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[1] The original appellant was Concert Pharmaceuticals, Inc. ("Concert"), which merged with Sun on March 31, 2023. We granted Sun's motion to replace Concert as the appellant on April 26, 2023.

28 U.S.C. § 1295(a)(4) and 35 U.S.C. §§ 141(c) and 319. We affirm.

I

A

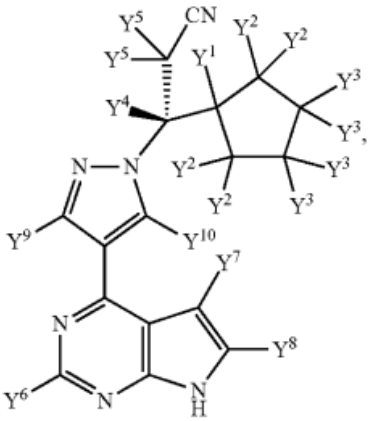
The '149 patent, entitled "Deuterated Derivatives of Ruxolitinib," "relates to novel heteroaryl-substituted pyrrolo[2,3-d]pyrimidines, and pharmaceutically acceptable salts thereof," including the compounds and their use "in methods of treating diseases and conditions that are beneficially treated by administering an inhibitor of Janus-associated kinase with selectivity for subtypes 1 and 2 (JAK1/JAK2)." '149 patent 3:25-32. Ruxolitinib is a known JAK1/JAK2 inhibitor and is "currently approved for the treatment of patients with intermediate or high-risk myelofibrosis." *Id.* at 2:53-67. Common adverse reactions associated with ruxolitinib include thrombocytopenia, anemia, bruising, dizziness, and headache. *Id.* at 3:15-18.

Deuteration involves replacing one or more hydrogen atoms of a drug with deuterium, an isotope of hydrogen, "to slow" the "CYP-mediated metabolism" (i.e., cytochrome P450 enzyme) "of a drug or to reduce the formation of undesirable metabolites." *Id.* at 2:7-10. The bonds formed between deuterium and carbon are stronger than carbon-hydrogen bonds; this stronger bond "can positively impact the ADME [absorption, distribution, metabolism, and/or excretion] properties of a drug, creating the potential for improved drug efficacy, safety, and/or tolerability" without "affect[ing] the biochemical potency and selectivity of the drug as compared to the original chemical entity that contains only hydrogen." *Id.* at 2:12-20. These measures of how a human body processes a drug, ADME, are also referred to as the drug's pharmacokinetic properties. J.A. 8225-46.

The '149 patent has two independent claims, 1 and 9. Claim 1 claims deuterated variations of Formula A and is reproduced below:

1. A compound of Formula A:

Formula A



or a pharmaceutically acceptable salt thereof, wherein:

Y^1 is hydrogen;

each Y^2 is selected from hydrogen and deuterium, and each Y^2 is the same;

each Y^3 is selected from hydrogen and deuterium, and each Y^3 is the same;

Y^4 is selected from hydrogen and deuterium;

each Y^5 is the same and is selected from hydrogen and deuterium; and

Y^6, Y^7, Y^8, Y^9, and Y^{10} are each independently selected from hydrogen and deuterium; provided that:

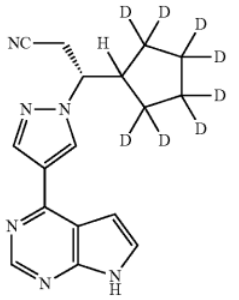
each Y^2 is deuterium; or

each Y^3 is deuterium; or

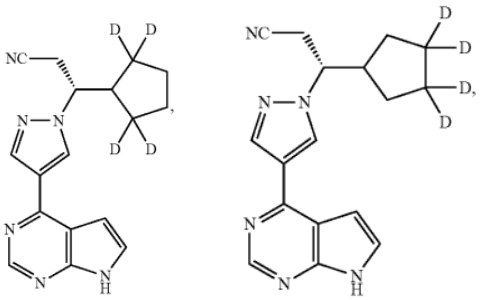
each Y^2 and each Y^3 is deuterium.

Id. at 36:17-53.

The IPR focused primarily on three compounds, pictured below, all of which are within the scope of claim 7, which depends from claim 1: an "octo-deuterated" ruxolitinib analog, in which every Y^2 and Y^3 hydrogen is deuterated,



and two "tetra-deuterated" ruxolitinib analogs,



in which either Y^2 hydrogens or Y^3 hydrogens are deuterated. *Id.* at 36:66-40.

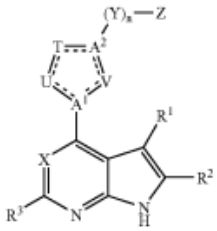
Sun named the octo-deuterated analog with a high isotopic purity CTP-543. Sun contends that CTP-543 has the potential to be a desirable treatment for alopecia areata. The FDA has given "Fast Track" and "Breakthrough Therapy" designations to CTP-543, which means the FDA will

expedite its review of CTP-543 as a new drug. *See, e.g.*, J.A. 10102.

B

In its IPR petition, Incyte presented two obviousness grounds, but the Board only considered one: the combination of Rodgers, Shilling, and the Concert Backgrounder.[2] We summarize these prior art references below.

Rodgers is a U.S. patent directed to "heteroaryl substituted pyrrolo[2,3,-b]pyridines and heteroaryl substituted pyrrolo[2,3-b]pyrmidines that modulate the activity of Janus kinases." J.A. 1747. Rodgers' claimed compounds all depend on "Formula I," reproduced below, and include ruxolitinib. J.A. 1749, 1933.



Shilling discloses a study of the "metabolism, excretion, and pharmacokinetics" of ruxolitinib and teaches that ruxolitinib is a "potent, selective inhibitor" of JAK1/JAK2. J.A. 1729. It adds that ruxolitinib was the "first

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[2] U.S. Patent No. 7,598,257 ("Rodgers") (J.A. 1744-933); Adam D. Shilling et al., *Metabolism, Excretion, and Pharmacokinetics of [^{14}C]INCB018424, a Selective Janus Tyrosine Kinase 1/2 Inhibitor, in Humans*, 38 Drug Metabolism & Disposition 2023 (2010) ("Shilling") (J.A. 1729-37); Concert Pharmaceuticals, Inc., Precision Deuterium Chemistry Backgrounder (2007) ("Concert Backgrounder") (J.A. 1738-43).

investigational drug of its class in phase III studies for the treatment of myelofibrosis." *Id.* Importantly, Shilling also identifies ruxolitinib's metabolic "hotspots," which are the sites on a compound where oxidative metabolism occurs during *in vivo* metabolism. J.A. 154, 1734. The study identifies that the majority of ruxolitinib's metabolism occurs on its cyclopentyl ring at its four methylene carbons (the Y^2 and Y^3 positions in Formulas A and I of the '149 patent and the positions that are deuterated in octo-deuterated and tetra-deuterated ruxolitinib). *See* J.A. 1736.

The Concert Backgrounder is a marketing publication issued by the original owner of the '149 patent, Concert. It teaches that deuteration of compounds provides the potential for improved safety, better tolerability, and enhanced efficacy. J.A. 1739 ("[S]ince deuterium is heavier than hydrogen, it forms significantly stronger bonds with carbon resulting in differentiated ADME (Adsorption, Distribution, Metabolism and Excretion). . . . [Hence,] [d]euterium substitution has the potential to create NCEs [new chemical entities] with improved safety, tolerability and efficacy."). The Concert Backgrounder observes that "the magnitude and nature of the deuterium benefit cannot be predicted *a priori*," so it is necessary to first "test multiple compounds in a range of assays to identify those that are differentiated." J.A. 1740. It further emphasizes, however, that "[d]euteration provides novel agents with the potential for . . . [i]mproved safety[,] . . . [b]etter tolerability[,] . . . [and] [e]nhanced efficacy," adding that Concert "is deploying its product technology platform to rapidly assemble a pipeline of valuable new deuterated drugs." J.A. 1740, 1743 (emphasis omitted).

II

"Obviousness under 35 U.S.C. § 103 is a mixed question of law and fact. We review the Board's ultimate obviousness determination de novo and underlying fact-

findings for substantial evidence." *Hologic, Inc. v. Smith & Nephew, Inc.*, 884 F.3d 1357, 1361 (Fed. Cir. 2018). "A claimed invention is unpatentable if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious to one of ordinary skill in the relevant art." *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1343 (Fed. Cir. 2017) (internal quotation marks omitted). The presence or absence of a motivation to combine prior art references, and a reasonable expectation of success in doing so, are questions of fact. *See Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1366 (Fed. Cir. 2016).

In an IPR, it is the petitioner's burden to prove, by a preponderance of the evidence, that a person of ordinary skill in the art would have been motivated to combine the prior art references the petitioner is relying on in its obviousness grounds. *See* 35 U.S.C. § 316(e) ("In an inter partes review instituted under this chapter, the petitioner shall have the burden of proving a proposition of unpatentability by a preponderance of the evidence.").[3] Motivation

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[3] The parties disagree as to whether our case law limits the reasonable expectation of success inquiry to only those properties that are actually claimed in the patent being challenged. *Compare*, *e.g.*, Appellee Resp. Br. at 51 ("Although an unclaimed property may be relevant to the motivation-to-combine inquiry where it is the reason proffered for the motivation, unclaimed properties are 'of no moment' to the separate 'reasonable expectation of success' inquiry directed to 'success in meeting the claims.'") (internal emphasis omitted; quoting *Intelligent BioSystems*, 821 F.3d at 1367-68), *with* Appellant Reply Br. at 18-19 (responding "that has never been this Court's approach to compound patents" and citing *Takeda Chem. Indus., Ltd.*

to combine "need not be [based on] an explicit teaching that the claimed compound will have a particular utility; it is sufficient to show that the claimed and prior art compounds possess a sufficiently close relationship to create an expectation, in light of the totality of the prior art, that the new compound will have similar properties to the old." *Aventis Pharma Deutschland GmbH v. Lupin, Ltd.*, 499 F.3d 1293, 1301 (Fed. Cir. 2007) (internal quotation marks and alterations omitted). "[T]he greater the structural similarity between the compounds, the greater the motivation to combine and reasonable expectation of success." *Anacor Pharms. Inc. v. Iancu*, 889 F.3d 1372, 1385 (Fed. Cir. 2018).

In evaluating an obviousness claim, we also consider, where present, the objective indicia of nonobviousness. *See Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016). These can include "commercial success enjoyed by devices practicing the patented invention, industry praise for the patented invention, copying by others, and the existence of a long-felt but unsatisfied need for the invention." *Id.* at 1052. A patentee's evidence of objective indicia can rebut a petitioner's *prima facie* showing of obviousness. *See WMS Gaming, Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999).

A

For new chemical compounds, we apply a two-step test for determining obviousness. "First, the court determines

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v. Alphapharm Pty., Ltd., 492 F.3d 1350 (Fed. Cir. 2007)). This case does not call on us to resolve this dispute. Instead, we conclude that the Board had substantial evidence to support its conclusion of obviousness even assuming (without deciding) that a skilled artisan would have needed to have reasonably expected success in obtaining the beneficial (though possibly unclaimed) properties Sun posits for it claimed compounds.

whether a chemist of ordinary skill would have selected the asserted prior art compounds as lead compounds, or starting points, for further development efforts." *Otsuka Pharm. Co. v. Sandoz, Inc.*, 678 F.3d 1280, 1291 (Fed. Cir. 2012). "The second inquiry in the analysis is whether the prior art would have supplied one of ordinary skill in the art with a reason or motivation to modify a lead compound to make the claimed compound with a reasonable expectation of success." *Id.* at 1292.

The parties do not dispute that a person of ordinary skill would have selected ruxolitinib as the lead compound. Rather, Sun argues that the Board erred, in three respects, in connection with the second portion of this test. Specifically, Sun contends the Board failed to (1) ask whether a person of ordinary skill would have been motivated to deuterate ruxolitinib to alter its pharmacokinetic properties, (2) determine whether the skilled artisan would have been motivated to make the specific molecular modifications claimed in the '149 patent, and (3) consider whether the person of ordinary skill would have reasonably expected success in modifying ruxolitinib. We review each of these arguments in turn.

1

Sun asks us to reject the Board's finding of obviousness because the Board purportedly failed to consider whether a person of ordinary skill would have been motivated to deuterate ruxolitinib to modify its pharmacokinetic properties, including its ADME. We conclude that the Board had substantial evidence, including the testimony of Incyte's expert, Dr. Guengerich, to find that the combined teachings of Shilling, Rodgers, and the Concert Backgrounder would have provided a skilled artisan with motivation to deuterate ruxolitinib, at its metabolic hotspots, in order "to achieve the potential benefits that the Concert Backgrounder disclosed, e.g., improved safety, tolerability,

and efficacy." J.A. 23-24; *see also* J.A. 1472-87 (Dr. Guengerich testifying to deuteration's effect on compound's ADME, including improved safety, tolerability, and efficacy), J.A. 1491-92 (Dr. Guengerich stating that Concert Backgrounder teaches deuteration has "substantially reduced R&D risk, time and expense"). The close structural similarity between prior art ruxolitinib and the deuterated ruxolitinib analogs of the '149 patent is undisputed and was reasonably found by the Board to have motivated a skilled artisan to modify ruxolitinib to retain its potency and selectivity, but improve the pharmacokinetic properties identified in the Backgrounder. This conclusion is further supported by Sun's own expert, Dr. Harbeson, J.A. 6016, and Concert's chief executive officer, who added "we've never seen any biologically relevant differences in target selectivity or potency of a drug when we deuterate it," J.A. 2406; *see also* J.A. 2919 ("The attraction of specific deuterium substitution as a parameter in drug design is based on the facts that not only is the replacement of one or a few hydrogens in a drug molecule by deuterium the smallest structural change that can be made but also such a change will have negligible steric consequences or influence on physicochemical properties . . . .").

2

Sun argues that the Board erred in failing to ask whether a person of ordinary skill would have pursued the specific modifications claimed in the '149 patent, particularly those that would have resulted in the tetra- and octodeuterated analogs of ruxolitinib. But the combination of the Concert Backgrounder, Shilling, and Dr. Guengerich's declaration provides substantial evidence for the Board's finding that a person of ordinary skill would have been motivated to modify ruxolitinib at its metabolic hotspots on its cyclopentyl ring. J.A. 23-24; *see also* J.A. 1736 (Shilling identifying ruxolitinib's metabolic hotspots as four methylene carbons on its cyclopentyl ring); J.A. 1739-42

(Concert Backgrounder teaching that "[m]etabolic 'hotspots'" are deuterated to improve compound's efficacy, safety, and tolerability). Dr. Guengerich testified that a skilled artisan "would have deuterated at the site corresponding to Y^2 and/or Y^3 in Formula A or Formula I . . . at every Y^2 and/or every Y^3," meaning that the "most reasonable deuterated analogs" would be the tetra- and octo-deuterated analogs of dependent claim 7. J.A. 1500-02 (emphasis omitted). Hence, there is substantial evidence that an ordinarily skilled artisan would have been motivated to make the specific modifications necessary to modify ruxolitinib to its deuterated analogs.

3

Sun argues that, in finding Incyte had proven a reasonable expectation of success, the Board erred by ignoring the unpredictable effects of deuterating ruxolitinib and by not considering how that unpredictability would have deterred a skilled artisan. "The reasonable expectation of success requirement refers to the likelihood of success in combining references to meet the limitations of the claimed invention. . . . [O]ne must have . . . a reasonable expectation of achieving what is claimed in the patent-at-issue." *Intelligent Bio-Sys.*, 821 F.3d at 1367.

The Board had substantial evidence to conclude that a person of ordinary skill would have had a reasonable expectation that she could succeed in modifying ruxolitinib to arrive at its tetra- and octo-deuterated analogs, which she would expect to display "superior ADME properties." J.A. 32; *see also* J.A. 1491-92, 1495-96 (Dr. Guengerich Decl.). Dr. Guengerich opined that a person of ordinary skill would have viewed the deuteration strategy as predictable, would have been able to synthesize the claimed compounds of the '149 patent, and would also have expected the resulting compounds to demonstrate metabolic stability. J.A. 1503-22. The Board acknowledged that the Concert

Backgrounder discloses that the "magnitude and nature of the deuterium benefit cannot be predicted *a priori*," J.A. 14, 31, 1740, but found, nonetheless, that an ordinarily skilled artisan would have reasonably expected – based on the overall teachings of the Backgrounder and the opinions of Dr. Guengerich – that deuterium modification could "result[] in differentiated ADME," including potential "[r]educed C_{max}-driven side effects" and "[i]mproved efficacy, convenience and compliance," J.A. 1739; *see also* J.A. 1491-92 (Dr. Guengerich explaining that deuteration "substantially reduce[s] R&D risk, time, and expense," notwithstanding lack of *a priori* predictability). "[O]bviousness cannot be avoided simply by a showing of some degree of unpredictability in the art so long as there was a reasonable probability of success." *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007).

Thus, the Board had substantial evidence to support its findings that a person of ordinary skill in the art would have been motivated to modify ruxolitinib to create the '149 patent's deuterated analogs to alter its pharmacokinetic properties and would have reasonably expected that such modifications would lead to the beneficial changes suggested by the Concert Backgrounder.

B

Sun further argues the Board erred in its evaluation of two objective indicia of nonobviousness: unexpected results and long-felt need. We disagree. Nothing about Sun's objective indicia evidence rebuts Incyte's *prima facie* showing of obviousness.[4]

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[4] Incyte argues that none of Sun's objective indicia evidence is probative of nonobviousness because it all relates solely to CTP-543, which is a single embodiment and

Sun argues that CTP-543, the highly pure octo-deuterated embodiment of claim 7 of its '149 patent, displays two unexpected results: (1) a flatter pharmacokinetic curve, which increases the time of the drug in the therapeutic window, and (2) a greater relative increase in half-life for patients who metabolized ruxolitinib most quickly. The record contains substantial evidence to support the Board's contrary finding that CTP-543's results were "an increase in the same clinical activity observed with ruxolitinib, and therefore represent merely a difference in degree and not in kind." J.A. 35; *see Bristol-Myers Squibb Co. v. Teva Pharms. USA Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014) ("While a 'marked superiority' in an expected property may be enough in some circumstances to render a compound patentable, a 'mere difference in degree' is insufficient."). That is, the Board reasonably concluded that CTP-543's increased time in the therapeutic window and increased clinical response at a given dose were differences in degree that did not indicate a marked superiority in these properties. *See* J.A. 6636-37, 6745-55 (Incyte's experts testifying that therapeutic differences between CTP-543 and ruxolitinib were not "clinically meaningful" or "clinically impactful").

"The existence of a long-felt but unsolved need that is met by the claimed invention is further objective evidence of non-obviousness." *Millennium Pharms., Inc. v. Sandoz Inc.*, 862 F.3d 1356, 1369 (Fed. Cir. 2017). "Evidence of a long-felt need is particularly probative of obviousness when it demonstrates both that a demand existed for the

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not commensurate with the scope of any claim of the '149 patent. It is sufficient for our purposes, as it was for the Board, *see* J.A. 35, to assume without deciding that Sun has met its burden to show that CTP-543 is representative of all embodiments within the scope of a challenged claim, as Sun's evidence lacks significant probative value for other reasons that we explain.

patented invention, and that others tried but failed to satisfy that demand." *Id.* (internal quotation marks omitted). Assuming, without deciding, that the need for an effective and safe alopecia areata treatment existed, the Board had substantial evidence for its finding that CTP-543 had not actually satisfied this long-felt need, but only had the "potential" and "likelihood" to do so. J.A. 36-37; *see also* J.A. 9385-86 (Dr. Mackay-Wiggin Decl.). While we agree with Sun (and amicus Bald Girls Do Lunch) that FDA approval is not a prerequisite to showing that a long-felt need has been met, and FDA's designation of CTP-543 for "Breakthrough Therapy" and "Fast-Track" approval are probative of nonobviousness, here Sun expressly framed its objective indicia argument as "CTP-543 satisfies the long-felt need for an *FDA-approved*, evidence-based alopecia areata treatment," J.A. 465 (emphasis added), and the Board reasonably found that CTP-543 had not met this need because it lacked FDA approval, *see* J.A. 1366.[5] Thus, substantial evidence supports the Board's conclusion that Sun did not prove that CTP-543 has satisfied this long-felt need.

III

We have considered Sun's remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm.

AFFIRMED

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[5] Evidence provided by the amicus, Bald Girls Do Lunch, but not otherwise in the record cannot be considered on appeal. *See In re Watts*, 354 F.3d 1362, 1367 (Fed. Cir. 2004).

CERTIFICATE OF SERVICE

I hereby certify that on October 6, 2023, I electronically filed the foregoing document with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit using the Court's CM/ECF system. Counsel for all parties to the case are registered CM/ECF users and will be served by the CM/ECF system.

CERTIFICATE OF COMPLIANCE

I certify that this document complies with the type-volume limitation of Fed. R. App. P. 35(b)(2)(A) because it contains 3,893 words, excluding the parts of the document exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 32(b)(2).

I further certify that this document complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared using Microsoft Word for Office 365 in 14-point Century Schoolbook, a proportionally spaced font.

October 6, 2023

/s/ *William M. Jay*
William M. Jay