No. 2024-1181

United States Court of Appeals for the Federal Circuit

SHILPA PHARMA, INC.,

Appellant

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Appellee

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Case No. IPR2022-00886 for U.S. Patent No. 9,266,816 B2

APPELLANT SHILPA PHARMA, INC.'S CORRECTED COMBINED PETITION FOR PANEL REHEARING AND REHEARING *EN BANC*

Mark Boland
Michael R. Dzwonczyk
Raja N. Saliba
SUGHRUE MION, PLLC
2000 Pennsylvania Avenue, NW
Suite 9000
Washington, DC 20006
Tel: (202) 293-7060
Fax: (202) 293-7860

Attorneys for Appellant Shilpa Pharma, Inc.

August 7, 2024

CERTIFICATE OF INTEREST

Counsel for Patent Owner-Appellant certifies the following:

1. The full name of every party represented by me is:

   SHILPA PHARMA, INC.

2. The name of the real party in interest (Please only include any real party in interest NOT identified in Question 3 below) represented by me is:

   SHILPA PHARMA, INC.

3. All parent corporations and publicly held companies that own 10 percent or more of the stock of the party represented by me are:

   SHILPA MEDICARE LIMITED.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this court are:

   SUGHRUE MION, PLLC: Mark Boland, Michael R. Dzwonczyk, Raja N. Saliba, Brett S. Sylvester and L. Roman Rachuba.

5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this Court's decision in the pending appeal:

   N/A – see Form 9A, Notice of Related Case Information filed Dec 6, 2023.

6. Information required under Fed. R. App. P. 26.1(b) and 26.1(c) and Fed. Cir. R. 47.4(a)(6).

   None/Not Applicable.

August 7, 2024

/s/ Mark Boland
Mark Boland
Counsel for Appellant
Shilpa Pharma, Inc.

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FEDERAL CIRCUIT RULE 40(c) STATEMENT OF COUNSEL

Based on my professional judgment, I believe the Panel decision is contrary to at least the following decision of the Supreme Court of the United States or the precedents of this court: *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 29 (1997) ("Each element contained in a patent claim is deemed material to defining the scope of the patented invention"); *Eli Lilly & Co. v. L.A. Biomedical Research Inst. at Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074 (Fed. Cir. 2017) (to anticipate a claim, a prior art reference must disclose every limitation of the claimed invention); *Perkin-Elmer Corp. v. Westinghouse Electric Corp*., 822 F.2d 1528, 1533 & n.8 (Fed. Cir. 1987) (all claim limitations are material and essential): *Intervet Am., Inc. v. Kee-Vet Labs., Inc*., 887 F.2d 1050, 1053 (Fed. Cir. 1989) (courts cannot alter what the patentee has chosen to claim as his invention); and *Autogiro Co. of America v. United States*, 384 F.2d 391, 395-96 (Ct. Cl. 1967) ("[c]ourts can neither broaden nor narrow the claims …courts do not rework claims. They only interpret them.").

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

1. May the Court find a patent claim anticipated when one of the claim limitations is admittedly absent from the anticipatory reference?
2. May the Court redraft a patent claim by reading out and dismissing a claim limitation as immaterial in order to find anticipation?

August 7, 2024

/s/ Mark Boland
Mark Boland
Counsel for Appellant
Shilpa Pharma, Inc.

INTRODUCTION

In summarily affirming the judgment of the PTAB that claims 2 and 4 of U.S. Patent No. 9,266,816 ("the '816 patent") were invalid for anticipation, two legal errors by the PTAB were approved by this Court. *First*, anticipation requires that each limitation of a recited claim be found in a single prior art reference, expressly or inherently, and as arranged in the claim. Although the PTAB *conceded* that one claim element was missing from the allegedly anticipatory reference, it nonetheless held the '816 invalid for anticipation. That was legal error.

Second, despite clear precedent that each claim limitation is material and essential and that a court cannot rewrite what a patentee chooses to claim as his or her invention, the PTAB here did just that in stating that a "characteristic" peak claimed by the inventors could not, as a matter of science, be characteristic at all. Both errors disregard well-established precedent of this Court and Petitioner requests rehearing or rehearing *en banc* to correct those errors.

STATEMENT OF RELEVANT FACTS

Fingolimod hydrochloride is a drug marketed commercially by Novartis under the tradename Gilenya®. Fingolimod hydrochloride is a polymorphic compound, which means that in the solid-state, it is known to exist in different three-dimensional configurations. Petitioner Shilpa is the owner of the '816 Patent directed to crystalline fingolimod hydrochloride Form-β, which is a particular polymorphic form discovered by the '816 patent inventors. Appx138-149. Claim

1 recites Form-β, characterized by seven peaks of an x-ray powder diffraction (XRPD) pattern. Appx149. Claim 2 depends from Claim 1 and further characterizes Form-β by reciting four specific endothermic peaks obtained by differential scanning calorimetry (DSC). *Id.* Claim 4 depends from claim 3 and recites DSC peaks more narrowly. *Id.* The DSC peaks are defined by the range of temperatures over which the peak is observed.

Shilpa sued Novartis for patent infringement in April, 2021 in the District of Delaware. Novartis sought *inter partes review* in April, 2022, challenging the '816 Patent claims as anticipated by PCT Patent Publication No. W02010/055028 A2 (the "Mutz" reference). Appx182-183; Appx1980-2006. The PTAB instituted review. In a September, 2023 final written decision, the PTAB ruled that claims 2 and 4 were anticipated by Mutz even though it *conceded* that Mutz did not disclose the fourth claimed DSC peak. Appx117-118. According to the PTAB, whether Mutz failed to disclose the fourth claimed DSC peak was largely "*immaterial* to [its] anticipation analysis." Appx118 (emphasis added).

Even though claim 2 specifically recites that Form-β is "further characterized by" endothermic "Peak-4 Between 265 to 270°C" (Appx149), the PTAB disagreed as a matter of science with the language of the claim and the '816 patent disclosure, stating that "Peak 4 cannot be characteristic of the crystalline form of fingolimod hydrochloride crystalline Form-β." Appx118. In so stating, the PTAB effectively rewrote Peak 4 out of claims 2 and 4 because it disagreed

with the scientific premise of the claim. This Court summarily affirmed under Rule 36 in a Judgment of July 10, 2025.

POINTS OF LAW OVERLOOKED OR MISAPPREHENDED

The summary affirmance overlooked or misapprehended that the PTAB found anticipation of claims 2 and 4 of the '816 patent despite the PTAB's concession that a claim limitation, DSC Peak-4, was missing from the Mutz reference at issue.

The summary affirmance overlooked or misapprehended that the PTAB found anticipation of claims 2 and 4 of the '816 patent despite the PTAB's having redrafted claims 2 and 4 by reading out and dismissing the DSC Peak-4 claim limitation in order to find anticipation.

ARGUMENT

A. A Reference That Does Not Disclose Every Claimed Element Cannot Be Anticipatory

The Rule 36 judgment affirmed a PTAB decision that a prior art reference may anticipate a challenged patent claim under 35 U.S.C. §102(b), even though it does not contain each and every limitation of that claim. Both the PTAB's decision and this Court's affirmance defy decades of jurisprudence holding to the contrary. It is a bedrock principle of law that anticipation requires the presence of each and every element of a claim to be present in a single prior reference. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1370 (Fed. Cir. 2008) ("an

anticipatory reference [must] show all of the limitations of the claims"). That did not happen here.

Claim 1 of the '816 patent recites Fingolimod hydrochloride crystalline Form-β characterized by seven x-ray powder diffraction (XRPD) peaks. Dependent Claim 2 further characterizes crystalline Form-β of Claim 1 by reciting four endothermic peaks obtained by differential scanning calorimetry (DSC), recited as:

a. Peak-1—Between 40 to 45°C.

b. Peak-2—Between 65 to 70°C.

c. Peak-3—Between 107 to 115°C.

d. Peak-4—Between 265 to 270°C.

Appx149. The sole prior art reference on appeal is the "Mutz" reference which discloses fingolimod hydrochloride, Forms I, II and III. Novartis argued, and the PTAB held, that Form I of Mutz was the same as Form-β of the '816 Patent. Shilpa disagreed, and offered evidence showing why Form I was not Form-β and why the '816 claims were not anticipated as a result. Before the PTAB, Shilpa demonstrated that DSC Peak-4 was not disclosed in Mutz. Shilpa Opening Brief filed March 18, 2024 ("Blue Br.") at 16-18. Indeed, the PTAB *conceded* that **"Mutz does not disclose Peak-4…"** Appx117-118 (emphasis added), but it expressly sidestepped the question of inherent anticipation as "largely immaterial" to its analysis. *Id*; *see* pp. 8-10 below. This should have ended the anticipation analysis as to claims 2 and 4 in Shilpa's favor. Blue Br. at 17-18.

Anticipation requires that every claim element be present in a single prior art reference and every member of this Court has applied that rule faithfully. *See e.g., Eli Lilly & Co. v. L.A. Biomedical Research Inst. at Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074 (Fed. Cir. 2017) (Bryson) ("To anticipate a claim, a prior art reference must disclose every limitation of the claimed invention, either expressly or inherently"); *accord ATEN Int'l Co. v. Uniclass Tech. Co.*, 932 F.3d 1364, 1368 (Fed. Cir. 2019) (Moore); *Enplas Display Device Corp. v. Seoul Semiconductor Co.*, 909 F.3d 398, 405 (Fed. Cir. 2018) (Stoll); *In re Smith Int'l, Inc.*, 871 F.3d 1375, 1381 (Fed. Cir. 2017) (Lourie); *Acoustic Tech., Inc. v. Itron Networked Sols., Inc.*, 949 F.3d 1366, 1373 (Fed. Cir. 2020) (Reyna); *ABS Glob., Inc. v. Cytonome/St, LLC*, 84 F.4th 1034, 1042-43 (Fed. Cir. 2023) (Taranto); *Genentech, Inc. v. Hospira, Inc.*, 946 F.3d 1333, 1340 (Fed. Cir. 2020) (Chen); *VirnetX, Inc. v. Cisco Sys.*, 767 F.3d 1308, 1323 (Fed. Cir. 2014) (Prost); *Sage Prods., LLC v. Stewart*, 133 F.4th 1376, 1380 (Fed. Cir. 2025) (Stark); *Target Corp. v. Proxicom Wireless, LLC*, Nos. 2022-1282, 2022-1283, 2022-1338, 2022-1339, 2023 U.S. App. LEXIS 24861 at *7 (Fed. Cir. Sep. 20, 2023) (Hughes); *Monsanto Tech. LLC v. E.I. DuPont De Nemours & Co.*, 878 F.3d 1336, 1342-43 (Fed. Cir. 2018) (Wallach); *In re Montgomery*, 677 F.3d 1375, 1379-80 (Fed. Cir. 2012) (Dyk); *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008) (Linn); *Zenith Elecs. Corp. v. PDI Commun. Sys.*, 522 F.3d 1348, 1363 (Fed. Cir. 2008) (Schall); *Monterey Rsch., LLC v. Vidal*, No. 2022-1577, 2023 U.S. App. LEXIS

32712 at *6 (Fed. Cir. Dec. 12, 2023) (Clevenger); *Yukiyo, Ltd. v. Watanabe*, 97-1115, 1997 U.S. App. LEXIS 13777 at *1 (Fed. Cir. June 11, 1997) (Plager); *Power Integrations, Inc. v. Lee*, 797 F.3d 1318, 1323 (Fed. Cir. 2015) (Mayer); *In re Starrett*, No. 2023-1425, 2023 U.S. App. LEXIS 33170 (Fed. Cir. Dec. 15, 2023) (Lourie, Stoll, Cunningham).

Here, the PTAB failed to apply that principle correctly, and its ruling to the contrary was error. The Panel's affirmance requires correction.

B. Courts Cannot Rewrite Claims

The PTAB compounded its error by rationalizing that the absence of Peak-4 in the Mutz reference was *immaterial* to its finding of anticipation, stating:

> ***We find the question of whether Mutz inherently discloses an endothermic Peak-4 at 265-270°C to be largely immaterial to our anticipation analysis*** . . .
>
> Peak-4 cannot be characteristic of the crystalline form of fingolimod hydrochloride crystalline Form-β, which exits [sic] only at temperatures of less than 40°C.[1] See Ex. 1004, 15. Indeed, Peak-4 cannot be said to be characteristic of any crystalline from of fingolimod HCl at all . . .

Appx118 (emphasis added). In stating that the absence of Peak-4 in the Mutz reference was *immaterial* to its anticipation analysis, the PTAB effectively struck Peak-4 and eliminated a limitation from the claims. That was improper. It is

[1] This finding by the PTAB is astounding given the clear disclosures of the '816 patent showing the presence of Form-β at temperatures well above 40°C.

axiomatic that claims are construed the same for infringement and validity. *Polaroid Corp. v. Eastman Kodak Co.*, 789 F.2d 1556, 1573 (Fed. Cir. 1986). In both contexts, all claim limitations are "*material* and *essential*," and cannot be ignored. *Perkin-Elmer Corp. v. Westinghouse Electric Corp*., 822 F.2d 1528, 1533 & n.8 (Fed. Cir. 1987); *Microsoft Corp. v. IQ Techs., Inc*., 1993 U.S. App. LEXIS 16128, *6-7 (Fed. Cir. 1993) (defendant's contention that the claimed "connector means" structure should be deemed "immaterial" in determining infringement was rejected as an "extreme position" because*:* "[t]he place to delete a claim limitation believed to be immaterial to patentability is in the Patent and Trademark Office during prosecution"). Indeed, nothing in the '816 patent or its prosecution history places DSC Peak-4 on any different footing than DSC Peaks 1-3, much less suggests it must be or can be ignored.

The PTAB's decision that Peak-4 was not characteristic of Form-β effectively rewrote claims 2 and 4, against this Court's precedent, which "has consistently adhered to the proposition that courts cannot alter what the patentee has chosen to claim as his invention." *Intervet Am., Inc. v. Kee-Vet Labs., Inc*., 887 F.2d 1050, 1053 (Fed. Cir. 1989), citing *E. I. Du Pont De Nemours & Co. v. Phillips Petroleum Co.*, 849 F.2d 1430, 1433 (Fed. Cir. 1988); *see also SSIH Equipment S.A. v. U.S. Int'l Trade Comm.*, 718 F.2d 365, 378 (Fed. Cir. 1983). All three cases quoted with approval *Autogiro Co. of America v. United States*, 384 F.2d 391, 395-96 (Ct. Cl. 1967), which held that "[c]ourts can neither broaden nor

narrow the claims …courts do not rework claims. They only interpret them." *Id.* The PTAB's conclusion that Peak-4 was not "characteristic" of Form-β is a repudiation of the '816 patent disclosure, wherein the inventors said Peak-4 *was* characteristic of Form-β. In effect, the PTAB found anticipation in the absence of the prior art disclosure of Peak-4 by ruling that the '816 patent inventors wrongly characterized the DSC peaks as "characteristic" of Form-β.

The PTAB cited no authority permitting a claimed DSC peak to be disregarded as "immaterial," nor is Shilpa aware of any. The '816 patent defines Form-β by its characteristic peaks, which the inventors had the right to select and claim. Appx145, Col. 2, ll. 29-43. *See Astellas Pharma Inc. v. Actavis Elizabeth LLC*, 2018 U.S. Dist. LEXIS 106117, *35 (D. Del. June 18, 2018) (discussing inventors' right to select "[c]haracteristic peaks"). In *Zenith Laboratories, Inc. v. Bristol-Myers Squibb Co.*, 19 F.3d 1418, 1423-24 (Fed. Cir. 1994), this Court held that an accused product exhibiting only 22 peaks did not prove infringement of a new crystalline form of cefadroxil 'characterized by' a 37-peak XRPD pattern, making clear that every claimed peak is a material limitation. This is precisely the case here. Mutz does not disclose an endothermic DSC peak at 265-270°C and does not expressly anticipate (Appx117); and multiple grounds of evidence, including undisputed evidence from Novartis, disproved any alleged inherent disclosure (Blue Br. at 37-41). Yet, not a shred of that undisputed evidence was mentioned by the PTAB or this Court.

Having found that claimed DSC Peak-4 and whether Mutz inherently disclosed it were immaterial, the PTAB rationalized that Peak-4 was only "a hitherto undisclosed property of an already-disclosed compound" in the context of applying *In re Wilder*, 429 F.2d 447 (C.C.P.A. 1970), *Titanium Metals Corp. of Am. v. Banner*, 778 F.2d 775 (Fed. Cir. 1985) and *In re Spada*, 911 F.2d 705 (Fed. Cir. 1990). Appx119. If that were true, Mutz's Form I would have that "property" because it was an "already-disclosed compound." But the only DSC evidence of record – *completely disregarded by the PTAB and the summary affirmance* – is that Mutz's Form I did ***not*** have that Peak-4 "property." Blue Br. at 39-41. *First*, Dr. Mutz testified at his deposition that he *did* conduct a DSC experiment on his Form I polymorph and to his recollection, the peak at about 260ºC was not an *endothermic* peak as claimed, but a different type.[2] *Id.* at 39, citing Appx9468-9470 (pp.166-168); Appx9391-9392 (¶¶ 9-10). *Second*, not a single internal (Novartis) DSC scan of Mutz's Form I polymorph shows an endothermic peak between 265-270°C. To the contrary, every DSC scan of Mutz Form I shows a different peak, not an endothermic peak as claimed, and all are at temperature

[2] Novartis disregarded Dr. Mutz's own testimony showing that a DSC on Form I *was* performed at high temperatures. At the oral argument, Novartis's counsel stated that there were factual reasons "why you might well expect that the Mutz experiment just didn't do DSC up to Peak 4." *See* https://www.cafc.uscourts.gov/home/oral-argument/listen-to-oral-arguments/ at 25:30 - 25:46.

ranges *other* than 265-270°C.[3] Blue Br. at 39-41, citing Appx9579; Appx9496; Appx9421-9429 (50:14-58:11-23); Appx9513; Appx9390 (¶ 6); Appx9442-9446 (92:22- 96:11). *Finally*, Novartis's expert Dr. McClurg testified "[w]ould I have known that [Peak-4 in claims 2 and 4] would be an *endotherm* by knowing what I see in Mutz? No." Shilpa's Reply Brief filed June 24, 2024 ("Gray Br.") at 13, citing Appx9962 (emphasis added).

None of this evidence was disputed, and all of it demonstrates that the PTAB clearly erred in concluding that Peak-4 was an "undisclosed property" of an already-disclosed compound. Importantly, the evidence proves the '816 patent inventors' assertion that Peak-4 is indeed characteristic of Form-β. The PTAB's misapprehension of these facts led it to incorrectly apply *Wilder, Titanium Metals*, and *Spada* to its resolution of this dispute. Appx119. But all of those cases are based on the starting premise that the claimed subject matter was disclosed identically in the prior art. Here, the existence of endothermic Peak-4 at 265-270°C is nowhere found in the prior art anywhere in the record, making clear that Form-β is not Form I. Moreover, *Wilder, Titanium Metals*, and *Spada* simply do not apply because in none of those cases was a claim limitation read out of and

[3] As Judge Stark aptly stated in *Bristol-Myers Squibb Co. v. Mylan Pharms., Inc.*, 2012 U.S. Dist. LEXIS 68802, *6 (D. Del. May 16, 2012), "If two thermograms of a given compound have a peak in the same position, but one peak is exothermic and the other peak is endothermic, one of ordinary skill in the art would conclude that the thermograms are of two different polymorphs."

dismissed from the claims as immaterial, as the PTAB did here. The summary affirmance erroneously endorsed that this case is in any way governed by the holdings of those cases.

C. The Rule 36 Summary Affirmance

This Court has said that summary affirmance is appropriate "when the position of one party is so clearly correct as a matter of law that no substantial question regarding the outcome of the appeal exists." *Joshua v. United States*, 17 F.3d 378, 380 (Fed. Cir. 1994). For the reasons set forth above, Shilpa disagrees that the PTAB decision was legally correct, that its judgment was based on findings that were not clearly erroneous, or that affirmance is warranted under the appropriate standard of review.

The Panel's Rule 36 affirmance of this decision authorizes the PTAB and courts to improperly disregard claim limitations.

CONCLUSION

The PTAB committed at least two reversible legal errors that the Panel's affirmance failed to address. Accordingly, Petitioner respectfully requests that the Court grant its petition for Panel rehearing or rehearing *en banc* to reconsider the important precedent-altering questions raised by these errors.

August 7, 2024

Respectfully submitted,

/s/ Mark Boland

Mark Boland
Michael R. Dzwonczyk
Raja N. Saliba
SUGHRUE MION, PLLC
2000 Pennsylvania Ave., NW
Washington, D.C. 20006
Tel: (202) 293-7060
Fax: (202) 293-7860
mboland@sughrue.com
rsaliba@sughreu.com

Counsel for Appellant
Shilpa Pharma, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on August 7, 2024, I electronically filed the foregoing Combined Petition for Panel Rehearing/ Rehearing En Banc with the Clerk of the United States Court of Appeals for the Federal Circuit using the CM/ECF system, which will send notice of such filing to all registered CM/ECF users.

/s/ Soo Jin Hur
Soo Jin Hur

CERTIFICATE OF COMPLIANCE

This brief complies with type-volume limits because, excluding the parts of the document exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b), this brief contains 2,916 words.

This brief complies with the typeface and type style requirements because it was prepared in a proportionally spaced typeface using Microsoft Word 2016 in 14 pt Times New Roman.

August 7, 2024

/s/ Mark Boland
Mark Boland
Counsel for Appellant Shilpa Pharma, Inc.

ADDENDUM

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

SHILPA PHARMA, INC.,
Appellant

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
Appellee

2024-1181

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2022-00886.

JUDGMENT

MARK BOLAND, Sughrue Mion, PLLC, Washington, DC, argued for appellant. Also represented by MICHAEL R. DZWONCZYK, RAJA SALIBA.

WILLIAM M. JAY, Goodwin Procter LLP, Washington, DC, argued for appellee. Also represented by ELIZABETH A. KIERNAN, Gibson, Dunn & Crutcher LLP, Dallas, TX; JANE M. LOVE, ROBERT TRENCHARD, New York, NY.

THIS CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

PER CURIAM (MOORE, *Chief Judge*, STOLL, *Circuit Judge,* and BUMB, *Chief District Judge*[1]).

AFFIRMED. *See* Fed. Cir. R. 36.

ENTERED BY ORDER OF THE COURT

July 10, 2025
Date

Jarrett B. Perlow
Clerk of Court

[1] Honorable Renée Marie Bumb, Chief Judge, United States District Court for the District of New Jersey, sitting by designation.