United States Court of Appeals for the Federal Circuit

BAYER PHARMA AKTIENGESELLSCHAFT,
Appellant

v.

MYLAN PHARMACEUTICALS INC., TEVA PHARMACEUTICALS USA, INC., INVAGEN PHARMACEUTICALS INC.,
Appellees

2023-2434

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. IPR2022-00517, IPR2022-01513, IPR2022-01515.

Decided: September 23, 2025

DOV PHILIP GROSSMAN, Williams & Connolly LLP, Washington, DC, argued for appellant. Also represented by BEN PICOZZI, ALEXANDER STEINWAY ZOLAN.

WENDY L. DEVINE, Wilson, Sonsini, Goodrich & Rosati, PC, San Francisco, CA, argued for all appellees. Appellee Mylan Pharmaceuticals Inc. also represented by KELSEY CATINA, Seattle, WA; TASHA THOMAS, RICHARD TORCZON, Washington, DC; MATTHEW GREINERT, Mylan, Canonsburg, PA.

JOHN CHRISTOPHER ROZENDAAL, Sterne Kessler Goldstein & Fox PLLC, Washington, DC, for appellee Teva Pharmaceuticals USA, Inc. Also represented by CHANDRIKA VIRA.

A. NEAL SETH, Wiley Rein, LLP, Washington, DC, for appellee InvaGen Pharmaceuticals Inc. Also represented by TERESA MARIE SUMMERS.

Before MOORE, *Chief Judge*, CUNNINGHAM, *Circuit Judge*, and SCARSI, *District Judge*.[1]

MOORE, *Chief Judge*.

Bayer Pharma Aktiengesellschaft (Bayer) appeals a final written decision (FWD) of the Patent Trial and Appeal Board (Board) holding claims 1–2 of U.S. Patent No. 10,828,310 unpatentable as anticipated and claims 1–8 unpatentable as obvious. For the following reasons, we affirm-in-part, vacate-in-part, and remand for further proceedings.

BACKGROUND

Bayer owns the '310 patent, which describes the results of a phase III clinical trial called "COMPASS" that evaluated the efficacy and safety of administering rivaroxaban with and without aspirin for the prevention of major adverse cardiac events. '310 patent at 3:27–34, 13:38–18:51. The claims are directed to methods for reducing the risk of cardiovascular events in patients with coronary artery disease (CAD) and/or peripheral artery disease (PAD) by

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[1] Honorable Mark C. Scarsi, District Judge, United States District Court for the Central District of California, sitting by designation.

administering rivaroxaban and aspirin. *Id.* at 1:16–19, 2:1–3, 3:47–55. Claim 1 is illustrative:

> 1. A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, comprising administering to the human patient rivaroxaban and aspirin in amounts that are *clinically proven effective* in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial disease, wherein *rivaroxaban is administered in an amount of 2.5 mg twice daily* and *aspirin is administered in an amount of 75-100 mg daily*.

Id. at 18:56–65 (emphases added).

Claim 5 of the '310 patent is similar to claim 1 but specifically recites a once daily administration of "a first product comprising rivaroxaban and aspirin" and "a second product comprising rivaroxaban":

> 5. A method of reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral artery disease, the method comprising administering to the human patient rivaroxaban and aspirin in amounts that are *clinically proven effective* in reducing the risk of myocardial infarction, stroke or cardiovascular death in a human patient with coronary artery disease and/or peripheral arterial disease, wherein the method comprises once daily administration of a *first product comprising rivaroxaban and aspirin* and a *second product comprising rivaroxaban*, and further wherein *the first product comprises 2.5 mg rivaroxaban and 75-100 mg aspirin* and *the second product comprises 2.5 mg rivaroxaban*.

Id. at 19:5–17 (emphases added).

Mylan Pharmaceuticals Inc., Teva Pharmaceuticals USA, Inc., and Invagen Pharmaceuticals, Inc. (collectively, Appellees) filed substantively identical petitions for *inter partes* review (IPR) challenging the claims of the '310 patent, and the Board joined those proceedings. J.A. 2. Among other grounds, Appellees argued claims 1–2 are anticipated by Foley[2] and claims 1–8 are obvious over Foley alone or in combination with Plosker.[3] J.A. 8. The Board held the challenged claims unpatentable based on these grounds and did not reach Appellees' other grounds. J.A. 1–40. Bayer appeals. We have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

DISCUSSION

Bayer argues the Board erred in (1) construing "clinically proven effective" as non-limiting and finding, in the alternative, that it is inherently anticipated; (2) construing "first product comprising rivaroxaban and aspirin" to encompass administration of rivaroxaban and aspirin as separate dosage forms; (3) failing to articulate why a skilled

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[2] T. Raymond Foley, Stephen W. Waldo & Ehrin J. Armstrong, 21 VASCULAR MED. 156, 156–69 (2016). J.A. 2341–54. Foley is a 2016 journal article that summarizes the then-ongoing COMPASS trial (including its dosing regimen of 2.5 mg rivaroxaban twice daily and 100 mg aspirin once daily) without disclosing the trial results. J.A. 2352; *see also* J.A. 22–23.

[3] Greg L. Plosker, *Rivaroxaban: A Review of Its Use in Acute Coronary Syndromes*, 74 DRUGS 451, 451–64 (2014). J.A. 2355–68. Plosker is a 2014 journal article that describes a phase III trial called "ATLAS ACS 2-TIMI 51," which discloses a dosing regimen of 2.5 mg rivaroxaban twice daily, co-administered with 75–100 mg aspirin. J.A. 2355, 2364; *see also* J.A. 27.

artisan would have combined Foley and Plosker with a reasonable expectation of success; and (4) failing to analyze whether clinical proof of efficacy was an unexpected result. Appellant's Br. 7–8, 25–48, 55–62.

I. "clinically proven effective"

We review the Board's claim construction de novo except for subsidiary fact findings based on extrinsic evidence, which we review for substantial evidence. *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 801, 808 (Fed. Cir. 2021). Anticipation, including whether a claim limitation is inherent in a prior art reference, is a question of fact we review for substantial evidence. *Monsanto Tech. LLC v. E.I. DuPont de Nemours & Co.*, 878 F.3d 1336, 1342 (Fed. Cir. 2018).

The Board concluded "clinically proven effective" is non-limiting and found, in the alternative, that it is inherently anticipated. J.A. 13–19, 25–27. Bayer argues "clinically proven effective" is limiting and requires clinical proof of efficacy as shown, for example, by results from a clinical trial. Appellant's Br. 27–40. Bayer also argues "clinically proven effective," if construed as limiting, is not inherently anticipated by Appellees' prior art. *Id.* at 40–45.

We do not decide whether "clinically proven effective" is limiting in relation to claims 1–8 because we conclude that, even if the phrase were limiting, "clinically proven effective" would still be a functionally unrelated limitation that fails to make the challenged claims patentable. In *King Pharmaceuticals, Inc. v. Eon Labs, Inc.*, 616 F.3d 1267, 1277–79 (Fed. Cir. 2010), we held that an otherwise anticipated method of treatment was not made patentable simply by adding a limitation of "informing the patient" about the benefits of the anticipated method. "[T]he relevant inquiry . . . [was] whether the additional instructional limitation . . . [had] a 'new and unobvious functional relationship' with the known method of [treatment]." *Id.* at 1279 (quoting *In re Ngai*, 367 F.3d 1336, 1338 (Fed. Cir.

2004)). As we explained in *King*, the rationale underlying this inquiry is "preventing the indefinite patenting of known products [and methods] by the simple inclusion of novel, yet functionally unrelated limitations." *Id.*

The rationale underlying *King* applies to the present case. Just as it would be troubling if one could patent a long-practiced method of treatment simply by adding an instructional limitation or a limitation referencing a subsequent accolade (*e.g.*, "Best Drug of 2026"), *see* Oral Arg. at 5:47–6:55, we find it equally troubling that one could claw back from the public domain an anticipated method of treatment merely by adding a limitation that the method subsequently performed well in a clinical trial. Like the instructional limitation in *King*, "clinically proven effective" has no "functional relationship" with the claimed method. 616 F.3d at 1279. Even if the term required clinical proof of efficacy, such proof "in no way transforms the process of taking the drug[s]" at the amounts and frequencies expressly recited in the claims. *Id.* "Irrespective of whether the [anticipated treatment regime is proven to be clinically effective], the actual method . . . is the same." *Id.* In other words, even if the phrase were limiting, "clinically proven effective" cannot make the challenged claims patentable because it would still lack a "new and unobvious functional relationship" with the remainder of the claimed methods, which the Board determined to be unpatentable.

Bayer argues *Allergan Sales, LLC v. Sandoz, Inc.*, 935 F.3d 1370 (Fed. Cir. 2019) controls and requires us to treat "clinically proven effective" as material to patentability. Appellant's Br. 36–38; Oral Arg. at 6:55–7:34. We do not agree. In *Allergan*, we held certain "wherein" clauses that specified minimum safety and efficacy requirements were material to the patentability of a claimed method of treatment involving "topically administering twice daily to an affected eye a single composition comprising 0.2% w/v brimonidine tartrate and 0.68% w/v timolol maleate." 935 F.3d at 1372–76. *Allergan* is distinguishable from the

present case, however, because the claims at issue were "written in open format" with the "wherein" clauses modifying the overall composition rather than any specifically recited ingredients within the composition. *Id.* at 1378–79 (Prost, C.J., concurring). As such, the "wherein" clauses were functional limitations that limited the open-ended universe of potential compositions that included 0.2% w/v brimonidine and 0.68% w/v timolol maleate by specifying safety and efficacy benchmarks the overall composition must meet. *See Allergan*, 935 F.3d at 1379; *see also* Appellees' Br. 35. "Clinically proven effective," serves no analogous function in the claims at issue here. Because the claims of the '310 patent already specify the exact dosages of rivaroxaban and aspirin to be administered to a patient, the additional limitation that the amounts be "clinically proven effective" does not further define the dosages that are administered.

For the foregoing reasons, we conclude "clinically proven effective"—even if limiting—cannot breathe patentability into the challenged claims as a functionally unrelated limitation. Accordingly, we do not reach whether "clinically proven effective" is inherently anticipated. *See King*, 616 F.3d at 1278–79 (concluding the functionally unrelated "informing" limitation did not make an otherwise anticipated method of treatment patentable despite the district court never expressly finding the "informing" limitation disclosed in the prior art).

II. "first product"

The Board concluded "first product comprising rivaroxaban and aspirin," in relation to claims 5–8, is not limited to a single dosage form, and if administered separately, the dosage forms can be administered simultaneously or sequentially. J.A. 20–21. Bayer argues the Board erred because the "first product" must be "a single dosage form" that "include[s] or contain[s] both rivaroxaban and aspirin." Appellant's Br. 46–47. We agree.

The plain language of the claims requires a single dosage form that includes both rivaroxaban and aspirin. The claims recite "administration of *a first product* comprising rivaroxaban *and* aspirin," not simply "administration of rivaroxaban and aspirin." '310 patent at 19:13–14 (emphases added). "Claims must be interpreted with an eye toward giving effect to all terms in the claim." *Becton, Dickinson & Co. v. Tyco Healthcare Grp., LP*, 616 F.3d 1249, 1257 (Fed. Cir. 2010) (internal quotation omitted). The Board's interpretation of "first product" as encompassing separate dosage forms violates this basic claim construction principle by rendering "a first product comprising" meaningless. Moreover, while Appellees argue a product can include "a kit or a blister pack" containing "multiple, separate components," Appellees' Br. 44, this would result in an unnatural reading of claim 5, which recites "administration of a first product," not administration of *components within* a first product, '310 patent at 19:13–14.

The remainder of the specification of the '310 patent is also consistent with "first product" requiring a single dosage. For example, the specification states that "combination therapy may be administered using separate dosage forms for rivaroxaban and aspirin, or using *a combination dosage form containing both rivaroxaban and aspirin*." *Id.* at 8:65–9:1 (emphasis added). The Board reached a different construction by equating "first product" to the broader term "combination therapy," which includes separate dosage forms *and* a combination dosage form. J.A. 20–21; *see also* Appellees' Br. 44–45. We see no indication, however, that "first product comprising rivaroxaban and aspirin" is used synonymously with "combination therapy" rather than "a combination dosage form containing both rivaroxaban and aspirin." On the contrary, we agree with Bayer that "first product comprising rivaroxaban and aspirin" more closely mirrors the latter, narrower term. *See* Appellant's Br. 47–48. While not every "product" must be a

combination dosage form, the claim language here is more limiting because it recites "first product *comprising rivaroxaban and aspirin*," which directly tracks with the specification's recitation of "a combination dosage form *containing both rivaroxaban and aspirin*." '310 patent at 8:65–9:1, 19:13–14 (emphases added).

Appellees argue this claim construction is moot because Bayer "forfeited any resulting benefit by failing to show why its construction overcomes [Appellees'] obviousness arguments." Appellees' Br. 47. We do not agree. Appellees bear the burden of proving the challenged claims are unpatentable under the correct construction. *Fanduel, Inc. v. Interactive Games LLC*, 966 F.3d 1334, 1341 (Fed. Cir. 2020) ("the burden of proving invalidity in an IPR remains on the petitioner throughout the proceeding") (citing 35 U.S.C. § 316(e)). Whether or not Appellees met this burden is an issue the Board should decide in the first instance. Accordingly, we remand for further consideration of Appellees' obviousness arguments under the correct construction of the "first product" term.

III. Combination of Foley and Plosker

Next, Bayer argues the Board failed to articulate why a skilled artisan would have combined Foley and Plosker with a reasonable expectation of success in concluding dependent claims 3–4 and 6–7 are obvious. Appellant's Br. 55–58. We do not agree.

"[T]he [Board] must articulate a *reason why* a [skilled artisan] would combine the prior art references." *In re Nuvasive, Inc.*, 842 F.3d 1376, 1382 (Fed. Cir. 2016). However, "[w]hether a skilled artisan would have been motivated to combine references or would have had a reasonable expectation of success in combining references are questions of fact reviewed for substantial evidence." *Elekta Ltd. v. ZAP Surgical Sys., Inc.*, 81 F.4th 1368, 1374 (Fed. Cir. 2023).

Claims 3 and 7 depend from independent claims 1 and 5, respectively, and recite administering 81 mg aspirin daily. '310 patent at 19:1–2 (claim 3), 19:20–21 (claim 7). Claims 4 and 6 depend from independent claims 1 and 5, respectively, and recite administering 75 mg aspirin daily. *Id.* at 19:3–4 (claim 4), 19:18–19 (claim 6). The Board expressly found a skilled artisan "would have had a reason to use 75 mg and 81 mg aspirin daily instead of 100 mg aspirin taught by Foley with a reasonable expectation of success, because those dosages simply represent the dosage amounts of aspirin available throughout the world" and are "consistent with the dosage range taught by Plosker." J.A. 33–34 (citing J.A. 1396–97 (Zusman Decl.); J.A. 2364 (Plosker); '310 patent at 9:21–22). Thus, we see no failure by the Board to articulate an adequately supported rationale for why a skilled artisan would have combined Foley and Plosker with a reasonable expectation of success, especially where the record indicates that both references taught a dosage regimen for "reducing the risk of myocardial infarction, stroke, or cardiovascular death." J.A. 1396 ¶ 354, 1398 ¶ 360 (Zusman Decl.); *see also* J.A. 33 (citing Zusman Decl.).

IV. Unexpected Results

Finally, Bayer argues the Board erred by failing to analyze its secondary evidence that "the fact that COMPASS provided clinical proof of efficacy was itself an unexpected property." Appellant's Br. 58; *see also id.* at 58–62. We do not agree.

Secondary considerations of nonobviousness, including unexpected results, "must be taken into account" when present. *Bristol-Myers Squibb Co. v. Teva Pharms. USA, Inc.*, 752 F.3d 967, 977 (Fed. Cir. 2014). However, "[f]or objective evidence of secondary considerations to be relevant, there must be a nexus between the merits of the claimed invention and the objective evidence." *Volvo Penta of the Ams., LLC v. Brunswick Corp.*, 81 F.4th 1202, 1210 (Fed.

Cir. 2023). "Where the offered secondary consideration actually results from something other than what is both claimed and *novel* in the claim, there is no nexus to the merits of the claimed invention." *In re Huai-Hung Kao*, 639 F.3d 1057, 1068 (Fed. Cir. 2011).

As the Board noted in its FWD, Bayer's "arguments and evidence of unexpected results rely solely on the term 'clinically proven effective,' as recited in the claims." J.A. 35–36. Because we conclude that "clinically proven effective" is a functionally unrelated limitation that fails to breathe patentability into the challenged claims, Bayer's evidence that clinical proof of efficacy was unexpected has no connection to the "merits of the claimed invention." *Volvo*, 81 F.4th at 1210. Absent such nexus, we conclude Bayer's evidence of secondary considerations "do[es] not compel a holding of nonobviousness." *In re Huai-Hung Kao*, 639 F.3d at 1074.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. For the foregoing reasons, we affirm the Board's judgment holding claims 1–4 unpatentable, vacate the judgment of unpatentability with respect to claims 5–8, and remand for further proceedings consistent with this opinion.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED

COSTS

No costs.