

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE OFFICE OF THE UNDER SECRETARY OF COMMERCE
FOR INTELLECTUAL PROPERTY AND DIRECTOR OF THE
UNITED STATES PATENT AND TRADEMARK OFFICE

BIOFRONTERA INC., BIOFRONTERA BIOSCIENCE GMBH,
BIOFRONTERA PHARMA GMBH, and BIOFRONTERA AG,
Petitioner,

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.,
Patent Owner.

IPR2024-01312
Patent 11,697,028 B2

Before JOHN A. SQUIRES, *Under Secretary of Commerce for Intellectual
Property and Director of the United States Patent and Trademark Office.*

ORDER
Granting Director Review, Vacating the Final Written Decision, and
Dismissing the Petition

Sun Pharmaceutical Industries, Inc. (“Patent Owner”) filed a request for Director Review of the Final Written Decision (Paper 53) in this *inter partes* review (“IPR”), and Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera AG (“Petitioners”) filed an authorized response. *See* Paper 54 (“DR Request”); Paper 55 (“DR Response”).

Patent Owner argues that the Final Written Decision should be vacated, and this proceeding terminated, in view of a parallel proceeding between the same parties at the U.S. International Trade Commission (“ITC”), in which the ITC already has decided the patentability of the challenged claims over the same prior art and substantially the same evidence. DR Request 9–13, 15. According to Patent Owner, the Board’s Final Written Decision is inconsistent with the ITC’s determination on patentability—the ITC concluded the claims had *not* been shown invalid as obvious, yet the Board subsequently concluded those claims would have been obvious. *Id.* That inconsistent result, Patent Owner contends, is unjustified based on any alleged new “critical” arguments or evidence, or due to different burdens of proof in the two forums. *Id.*

I have reviewed the parties’ arguments in the request and authorized response, as well as the Final Written Decision and the ITC’s determination on the patentability of the challenged patent. I conclude, on the record before me, that there was no justifiable reason for the Board to have reached a different patentability determination than the ITC.

The Board must consider prior findings of fact and conclusions of law when patent claims being challenged before the Board have already been adjudicated at the Office or in another forum, including the ITC. *See*

Memorandum, “PTAB Consideration of Prior Findings of Fact and Conclusions of Law” (Sept. 16, 2025).¹ As instructed in that Memorandum, a “more detailed explanation is required from the Board when the same or substantially the same evidence and/or arguments that were previously presented to the Office, the district court, or the ITC are being relied upon in the subsequent AIA trial proceeding.” *Id.* Whether the Board has provided such an explanation or whether an explanation is sufficient is a matter committed to the Director’s discretion and will determine whether a proceeding should be instituted and/or maintained or otherwise dismissed and terminated. *Cf. Verizon Connect Inc. v. Omega Patents, LLC*, IPR2023-01162, Paper 40, 2 (Acting Director June 3, 2025) (vacating the Final Written Decision and dismissing the petition in view of, *inter alia*, a prior jury verdict finding the relevant claims infringed and not invalid).

It is undisputed that the same claims, prior art, and obviousness grounds at issue in this IPR were at issue before the ITC. *See, e.g.*, Paper 53, 4 (explaining “the ITC determined that the asserted claims—also challenged in this IPR—were not invalid over the same prior art references and combinations that Petitioner asserts in this IPR”). Although the Board ostensibly considered the ITC’s prior determination in the course of reaching its Final Written Decision, the Board sought to justify the different results because the ITC’s determination was “not final,” because new evidence (i.e., certain expert testimony) was allegedly not before the ITC, and due to differences in the applicable burdens of proof. *See, e.g., id.* at 4, 25 n.9, 27 n.10 (“In contrast with the ITC’s finding that Larsen does not disclose

¹ https://www.uspto.gov/sites/default/files/documents/Memo_re_prior_findings_of_fact_and_conclusions_of_law_9_16_25.pdf.

‘uniform illumination’ under a clear and convincing standard, we find Larsen, by a preponderance of the evidence, discloses this element.”). None of those explanations adequately supports the different outcome here.

Petitioners and the Board both emphasize that the ITC Administrative Law Judge’s (“ALJ”) initial determination (“ID”) was “under review” by the full ITC and, thus, was “not final” when the Board issued its Final Written Decision. DR Response 1–2, 9–10, 12; Paper 53, 4. But an initial determination at the ITC may still favor terminating a co-pending IPR proceeding. In *Hydrafacial*, for example, I concluded that the ITC’s ID involving the same claims and prior art grounds supported terminating the IPR. *Sinclair Pharma Ltd. v. Hydrafacial LLC*, IPR2025-00145, Paper 41 (Director Feb. 12, 2026) (de-instituting and terminating IPR after a petitioner’s reply brief was filed). Although this case has progressed further than *Hydrafacial*, the concerns I raised in *Hydrafacial* are manifest here—avoiding inconsistent results and additional expenses for the parties as they move toward resolution (through appeal) of an overlapping patentability dispute. As I also have explained, the purpose of AIA reviews is “to provide a quick and cost-effective *alternative*” to litigating validity in other forums, not to provide a party with another forum for simultaneously litigating the identical dispute. *Magnolia Med. Tech., Inc. v. Kurin, Inc.*, IPR2026-00097, Paper 17 at 2–3 (Director May 14, 2026) (precedential).

Further, the ITC’s patentability determination is not “initial” anymore. In a Commission Opinion dated May 6, 2026, the ITC upheld the ALJ’s initial determination that Petitioners had not shown that the claims of the challenged patent are invalid as obvious. *See* Ex. 2103, 23–24, 44 (“[T]he Commission affirms the [I]D’s overall finding that none of the asserted

claims . . . are invalid as obvious under 35 U.S.C. § 103”). And the Commission upheld that determination notwithstanding its review of the Board’s Final Written Decision to the contrary. *See, e.g., id.* at 23, 40–41.

The Board’s and the ITC’s determinations are also at odds on several technical findings, with inadequate explanation from the Board for the inconsistencies. For example, as part of a detailed analysis, the ITC determined that Petitioners had failed to show that the combination of Lundahl² and Larsen³ teaches the “uniformly illuminate” limitation of the claims, finding further that Petitioners’ “analysis fails to sufficiently show that it is free of improper hindsight.” *See* Ex. 2090, 112–17 (crediting evidence about the “difficulty in achieving uniform illumination” and citing testimony from Petitioners’ expert Dr. Grove “that the claimed uniformity requires ‘undue experimentation’”). The Board, however, found that Larsen itself discloses “uniform illumination” under a “preponderance of the evidence” standard.⁴ *See* Paper 53, 27 n.10. The difference in the ITC’s and Board’s standards of proof does not, without more, explain this discrepancy in the findings between the two forums.

² US 6,223,071 B1, issued Apr. 24, 2001 (Ex. 1014).

³ US 2005/0075703 A1, published Apr. 7, 2005 (Ex. 1004).

⁴ Patent Owner also argues that the Board’s finding that Larsen meets this limitation is premised on an implicit claim construction that neither party proposed and that is contrary to the parties’ agreed-to construction of the “uniformly illuminate” limitation that the ITC adopted. DR Request 1–7; Paper 14, 18–19. This argument highlights why proceeding in two forums is inefficient and undermines the integrity of the patent system. Further, although I question whether the Board’s Final Written Decision departed from the parties’ agreed-to claim construction without adequate notice or explanation, it is not necessary to resolve this issue to decide Patent Owner’s request for Director Review.

Moreover, insofar as further explanation for such discrepancies are alleged to be found in “critical” testimony in the Supplemental Declaration of Dr. Grove that purports to show how the light in the combination of Lundahl and Larsen would meet the “uniformly illuminate” limitation, this evidence was not presented until Petitioners’ Reply. *See* Paper 53, 4 (citing Ex. 1026), 25–29 (citing Ex. 1026 ¶¶ 16–20). If the evidence was “critical,” Petitioners should have included it in the Petition. Instead, the record suggests that Petitioners used the Reply declaration to backfill gaps in the Petition and indirectly address the shortcomings that came to light, and that the ALJ eventually pointed out, in Petitioners’ same theory of obviousness before the ITC.

Here, the Board failed to adequately explain why it was reaching a different outcome than the ITC. Under these circumstances and in view of the ITC’s decision, which is now final, the appropriate course is to grant Director Review, vacate the Board’s Final Written Decision, and dismiss the Petition.

Accordingly, based on the foregoing, it is

ORDERED that Director Review of the Board’s Final Written Decision is granted;

FURTHER ORDERED that the Board’s Final Written Decision (Paper 53) is vacated; and

FURTHER ORDERED that the Petition is dismissed and the proceeding is terminated.

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