

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

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

v.

SUN PHARMACEUTICAL INDUSTRIES, INC.
Patent Owner.

Case No. IPR2024-01312
Patent 11,697,028

**ADDITIONAL BRIEFING REGARDING INITIAL DECISION IN ITC INV.
NO. 337-TA-1411**

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I. INTRODUCTION

As the Supreme Court has held, “[a] district court may find a patent claim to be valid, and the [Patent Trial and Appeal Board] may later cancel that claim in its own review.” *Cuozzo Speed Techs. v. Com. for Intell. Prop.*, 579 U.S. 261, 282, 136 S. Ct. 2131, 2146, 195 L. Ed. 2d 423 (2016). “[T]he possibility of inconsistent results is inherent to Congress’ regulatory design.” *Id.* at 283. Here, the International Trade Commission’s Initial Determination (“ID”) concludes that U.S. Patent No. 11,697,028 is not obvious. However, the ID contains numerous findings that are inconsistent with the record developed in this IPR.

However, even if the record were the same, as a matter of law, “the PTAB properly may reach a different conclusion based on the same evidence.” *Novartis AG v. Noven Pharms. Inc.*, 853 F.3d 1289, 1294 (Fed. Cir. 2017) (noting PTAB decides based on preponderance of evidence rather than the clear and convincing evidence standard applicable to district courts and the Commission). Moreover, the ID is not final and Biofrontera will petition for review by the full International Trade Commission (“Commission”). Indeed, an earlier motion for summary determination is already under review by the Commission. Thus, the Commission may ultimately find the claims of the ’028 Patent are obvious.

II. THE ID IGNORED EVIDENCE OF RECORD THAT THE BOARD WILL NEED TO CONSIDER AS IT WAS RAISED IN THE IPR PETITION

The ID overlooks significant record evidence to support its findings of non-obviousness that the Board will need to consider. For instance, the ID concludes that the five-panel illuminator in “Larsen does not disclose ‘a center panel configured to face the treatment surface’ . . . and Biofrontera makes no assertion to the contrary.” Ex. 2090 at 116. This is incorrect, both on substance and the record.¹ It is axiomatic that a series of five objects is going to have one object in the center and the purpose of Larsen’s panels is to face treatment surfaces, as Petitioner and Dr. Grove expressly assert in this IPR. Petition at 42-43 (Larsen’s “center panel (annotated in red) is positioned to illuminate the center of the patient’s back”); Ex. 1015 at ¶¶ 167-68. Patent Owner’s Response in the IPR does not even mention a “center panel” and thus does not even contest this limitation. *See* POR. Thus, the records in the two proceedings are substantially different even though Larsen was considered in both.

Similarly, in its discussion of obviousness, the ID states that Biofrontera waived an argument that Larsen disclosed an illuminator with four wheels because the argument was not addressed in Biofrontera’s post-hearing briefing. Ex. 2090 at 116. Although the ID is incorrect on this point, the record before the Board contains

¹ Petitioner did, in fact, assert that Larsen teaches this limitation in the ITC.

evidence that four wheels are inherent in Figure 1 of the Larsen prior art reference.² Petition at 58-59; Ex. 1015 at ¶¶ 214; Ex. 1002 at 328 (file history for '028 Patent finding that in Figure 1 of Larsen '381, “it is inherent that there are at least two more wheels, for a total of 4, in order for the device to be stable”). Moreover, the record here also explains that using four wheels would be obvious to a POSITA to provide stability of movement and to ensure the device did not topple over. Petition at 58-59; Ex. 1015 at ¶¶ 215-16 (Grove Decl.). Again, Patent Owner’s Response does not even contest this limitation. *See* POR. The difference between the record here and the record in the ITC as well as the ID’s errors—mistakenly stating that it did not have evidence on certain limitations when it did—means that the Board will be considering a substantially different record.

With respect to motivation to combine, the ID reaches a different conclusion than the Board’s institution decision. *See* Paper No. 9 at 19-22. To arrive at this different outcome the ID dismisses motivation to combine Larsen’s flexible panels with Lundahl’s illuminator for, among other reasons, the idea that certain body parts could be treated by jury rigging the inflexible design disclosed in Lundahl instead of combining it with Larsen. *See* Ex. 2090 at 119. Yet, this argument was not raised by Patent Owner in the IPR and thus not part of the record here. This is for good reason,

² Petitioner did not waive this issue in the ITC and intends to contest that finding.

as motivation does not require that the prior art be incapable of operating in order to modify it, as a desire to **improve** technology is all that is required. *DyStar Textilfarben GmbH & Co. Deutschland KG v. C.H. Patrick Co.*, 464 F.3d 1356, 1368 (Fed. Cir. 2006) (“motivation to combine exists . . . [when] the combination of references results in a product or process that is **more desirable**, for example because it is **stronger, cheaper, cleaner, faster, lighter, smaller, more durable, or more efficient**”). In addition, the ID did not have the full record as developed in this IPR, particularly Dr. Grove’s supplemental declaration discussed below.

In addition, the ID does not address all of the arguments raised in the Petition as the Board’s Institution Decision does. For example, Petitioner made two arguments in the ITC as to why a motivation existed to replace the fluorescent tubes of Lundahl with the LEDs of Larsen: (i) fluorescent tubes had known **performance** issues that were solved by LEDs; and (ii) fluorescents were becoming **disfavored** in the industry and by the government. The ID finds against Petitioner on motivation without providing **any** comment, analysis, or rationale related the first argument and dismisses Biofrontera’s second argument in one conclusory sentence, stating “fluorescent tubes did not ‘become obsolete by the 2015 priority date.’” Ex. 2090 at 121. Yet, these two arguments and supporting evidence are expressly raised in the Petition and thus part of the record that the Board will need to address here unlike in the ID. Petition at 31-32 (providing “three reasons” LEDs were superior to

fluorescent tubes and noting that “conversion from fluorescent tubes to LEDs was a routine practice prior to 2015.”); Ex.1015, ¶131.

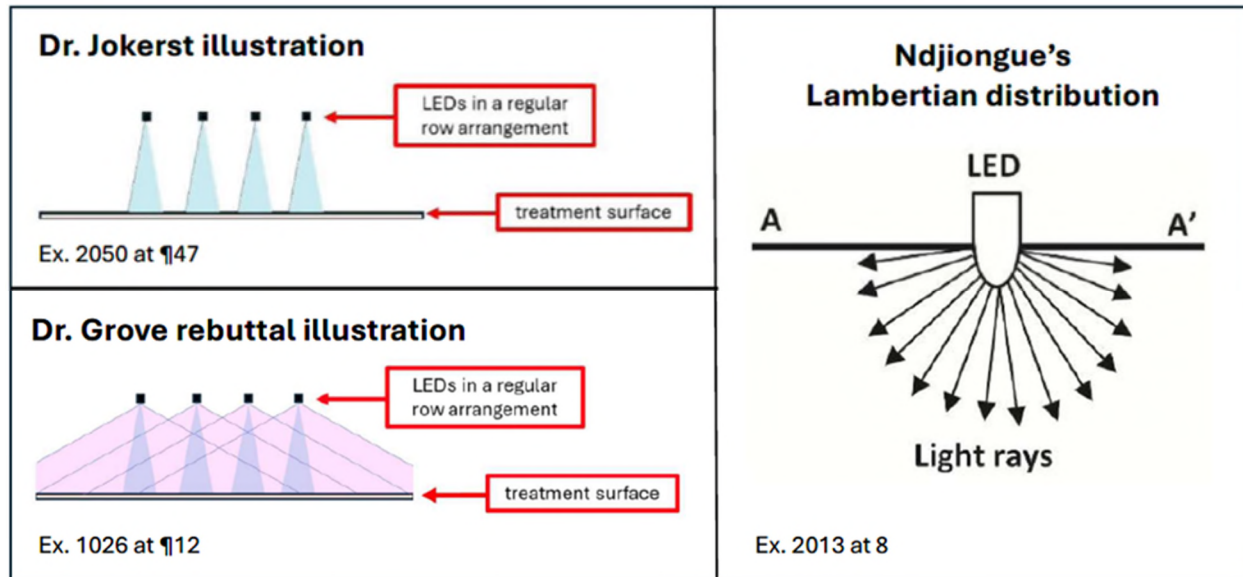
III. IPR CONTAINS ADDITIONAL EVIDENCE IN THE RECORD

The evidentiary record in this proceeding further differs from that at the ITC in a number of key aspects. For instance, (i) Petitioner was able to respond to Dr. Jokerst’s erroneous assertions regarding gaps between LEDs via Dr. Grove’s Supplemental Declaration (Ex. 1026), and (ii) Petitioner was able to question Dr. Jokerst about her assertions regarding the combination of Lundahl’s device with Larsen’s LED panels via the deposition conducted on July 22, 2025 (Ex. 1027).

A. Grove Supplemental Declaration (Ex. 1026)

In Ex. 1026, Dr. Grove responds to Dr. Jokerst’s incorrect assertion that the combination of Larsen and Lundahl would not “uniformly illuminate,” as required by all claims of the ’028 Patent, due to alleged gaps resulting from the use of LEDs. Ex. 2050 at ¶ 121 (“By replacing the continuous, diffuse light of the fluorescent tubes with discrete, directional point source LEDs with Lambertian outputs, Dr. Grove is creating gaps (between the LEDs) that were not in Lundahl’s light distribution.”). Dr. Jokerst’s assertion relied on an erroneous illustration of LED light sources as having a narrow divergence angle which, she argued, would create gaps on an illuminated surface. Ex. 2050 at ¶¶ 46-47. Dr. Grove explained this error

and provided a corrected illustration showing a more accurate Lambertian distribution of light emission. Ex. 1026 at ¶¶ 9-13.



Thus, Dr. Grove explained that, contrary to Dr. Jokerst's flawed analysis, it would be "a very straightforward process," for a POSITA to adapt Lundahl's device to incorporate LED panels, while maintaining Lundahl's disclosed uniformity. Ex. 1026 at ¶¶ 9-13.

Dr. Jokerst presented the same erroneous illustration as a demonstrative at the ITC along with related testimony. Ex. 2090 at 106. However, since this demonstrative and testimony was submitted for the first time along with Dr. Jokerst's rebuttal witness statement, Dr. Grove was not able to respond to this erroneous representation due to procedural differences at the ITC. Indeed, in the ID, the ALJ correctly notes that "LEDs are directional point-source [lights] with

Lambertian outputs,” but then relies on the incorrect illustration of a Lambertian output provided by Dr. Jokerst to erroneously conclude that “LEDs would create gaps” that would impact uniform illumination. Ex. 2090 at 106. The Board has the benefit of this additional evidence that was not available for review by the ALJ.

B. Deposition of Dr. Jokerst (Ex. 1027)

Similarly, in this IPR, Dr. Jokerst offered a number of erroneous and unsupported opinions regarding the difficulties of preserving Lundahl’s uniformity while incorporating LEDs. See Ex. 2050 at ¶¶ 119-140. Here, Petitioner had the opportunity to depose Dr. Jokerst, revealing a number of flaws. For instance, although Dr. Jokerst opined in her declaration that Lundahl’s uniformity requires multiple “carefully selected and engineered components...including (1) the U-shaped tubes, (2) the reflector, (3) the electrical control system, and (4) the cooling system” (Ex. 2050 at ¶ 123), during her deposition, she admitted that the majority of these components are not applicable to LEDs.

In response to questioning about LED output characteristics, Dr. Jokerst admitted that LEDs put out light in only one direction (Ex. 1027 at 59:12-60:9) and therefore would not need a reflector in the same way that fluorescents – which put out light in 360° - do. Similarly, Dr. Jokerst admitted that a POSITA would have been aware that LEDs “do not face the same [electrical] challenges as fluorescent tubes” (Ex. 1027 at 37:17-39:2, 47:12-21) and therefore would not need the same

electrical control systems. Additionally, Dr. Jokerst admitted that LEDs don't have tubes with variable temperature along their length (Ex. 1027 at 47:12-21), resulting in fewer temperature control challenges than fluorescents. With respect to the single remaining component – Lundahl's U-shape – Dr. Jokerst admitted that a paneled device (such as the 5-panel device disclosed in Larsen), could be adjusted to form a U-shape. Ex. 1027 at 31:5-18, 35:3-36:5.

Further, while Dr. Jokerst elaborated in her declaration about the alleged difficulties of modifying Lundahl's device with LEDs to maintain uniform illumination (Ex. 2050 at ¶¶ 138-139), during her deposition, she admitted that, as of the priority date, a POSITA would have known how to construct an electrical system appropriate for operating LEDs. Ex. 1027 at 40:12-42:3, 45:17-48:6. These statements were not part of the evidentiary record before the ALJ.³

³ Petitioner did not have the opportunity to depose Dr. Jokerst on these topics in the ITC investigation because she raised them for the first time after her deposition in the ITC investigation. While Petitioner filed a motion in limine to seeking to exclude these untimely opinions, this motion was denied.

IV. THE ID MADE INCONSISTENT INTERPRETATIONS OF CLAIM SCOPE THAT ARE NOT OF RECORD IN THE IPR

The ID demonstrates inconsistencies in interpreting the scope of the claims. For example, in finding that the RhodoLED® XL infringes the limitations for hinged structures on inner side surfaces of adjacent panels, the ID states that “[t]he claims require only that the ‘panels’ be ‘connected by’ hinges; they do not specify where or how the hinges are connected to the panels.” Ex. 2090 at 19. In contrast, for its validity analysis, the ID finds that Larsen’s disclosure of panels “flexibly **connected to each other through hinges...connecting one edge with the other**” (Ex. 1004 at [0027] (emphasis added)) was not enough, because “even if one reads Larsen as having hinges between the panels, the disclosure is insufficient ...” Ex. 2090 at 94. It is black letter law that “[c]laim terms must be construed the same way for the purpose of determining invalidity and infringement.” *TVIIM, LLC v. McAfee, Inc.*, 851 F.3d 1356, 1362 (Fed. Cir. 2017); *see also Data Engine Techs. LLC v. Google LLC*, 10 F.4th 1375, 1381 (Fed. Cir. 2021) (cannot treat claims like “a nose of wax”). These internally inconsistent constructions are not of record in the IPR and the Board will need to consider the proper claim scope based on the arguments and evidence in the IPR.

For claim 16 and 21’s limitation of “individually configurable to control illumination from each of the five panels” (the “individually configurable”

limitation), the ID once again applies apparently different constructions to reach differing results for infringement and invalidity. Larsen discloses panels that each contain multiple light sources. Ex. 1004 at [0070]-[0072]. Claim 5 of Larsen recites “wherein the ***light sources are individually selected***—switched ***ON*** or ***OFF***.” Ex. 1004 at cl. 5 (emphasis added). Thus, Larsen teaches illuminating or darkening individual light sources within a panel, which necessarily alters or configures the power output and/or light intensity of the panel—by allowing for brightening or dimming of the panel. The ID concludes that Larsen’s disclosure of turning lights on and off did not render the “individually configurable” limitation obvious. Ex. 2090 at 115. However, for purposes of infringement, the ID finds that because the lights on the RhodoLED® XL’s panels can be turned on and off, Biofrontera infringes the “individually configurable” limitation. Ex. 2090 at 69-71. Again, these inconsistencies demonstrate the Board will need to rely on the arguments and evidence of record in this IPR to determine proper claim scope.

V. CONCLUSION

Collectively, these issues in the ID are emblematic of how the ID was decided on a different record that the Board will use to make its decision. In view of these issues, the teachings of *Cuozzo Speed* and *Novartis* that the Board is bound by the determination of the ID are particularly instructive. *See Cuozzo Speed*, 579 U.S. at 282; *Novartis*, 853 F.3d at 1294

Petition for Inter Partes Review of
U.S. Patent No. 11,697,028

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