

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIOFRONTERA INCORPORATED, BIOFRONTERA BIOSCIENCE
GMBH, BIOFRONTERA PHARMA GMBH, and BIOFRONTERA AG
Petitioner,

v.

DUSA PHARMACEUTICALS, INC.,
Patent Owner.

Case IPR2018-01585
Patent 8,216,289 B2

Before WILLIAM M. FINK, *Vice Chief Administrative Patent Judge*, and
WILLIAM V. SAINDON and STEVEN M. AMUNDSON, *Administrative
Patent Judges*.

SAINDON, *Administrative Patent Judge*.

DECISION
Denying Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Biofrontera Incorporated, et al. (“Petitioner”) filed a petition requesting *inter partes* review of claims 1–19 of U.S. Patent No. 8,216,289 B2 (Ex. 1001, “the ’289 patent”). Paper 1 (“Pet.”). DUSA Pharmaceuticals, Inc. (“Patent Owner”) filed a Preliminary Response. Paper 9 (“Prelim. Resp.”).

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition and the Preliminary Response shows that “there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” 35 U.S.C. § 314; *see also* 37 C.F.R. § 42.4(a) (“The Board institutes the trial on behalf of the Director.”). Taking into account the arguments presented in the Petition and Preliminary Response, we conclude that the information presented in the Petition does not establish a reasonable likelihood that Petitioner would prevail with respect to the challenged claims for a substantial majority of claims and grounds. Based on the particular facts of this case, we exercise our discretion to decline institution.

A. *Related Matters*

The parties identify the following matters related to the ’289 patent (Pet. 2; Paper 4; Ex. 1003):

DUSA Pharmaceuticals, Inc. v. Biofrontera Inc. et al., Civil Action No. 1:18-cv-10568 (D. Mass.).

Related U.S. Patent No. 9,723,991, which claims priority to the same original parent application as the '289 patent, has been challenged in *inter partes* review no. IPR2018-01586.

B. Real Parties-In-Interest

Petitioner identifies Biofrontera Incorporated, Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera AG as real parties-in-interest. Pet. 1. Patent Owner identifies DUSA Pharmaceuticals Inc., Sun Pharmaceuticals Industries, Inc., and Sun Pharmaceutical Industries, Ltd., as real parties-in-interest. Paper 4.

C. The '289 Patent

The '289 patent is directed to an illuminator that produces more uniform visible light over a contoured surface for use in photodynamic therapy (PDT) or photodynamic diagnosis (PD). Ex. 1001, 2:42–51. As explained in the '289 patent, it is desirable to have an illuminator that produces visible light of sufficient uniformity and intensity to activate the photoactivatable agent for optimal therapeutic efficiency. *Id.* at 2:24–39. Addressing this issue, the '289 patent describes an illuminator with light sources that conform to the contoured surface, and a housing that supports the light sources in this configuration. *Id.* at 3:1–6. Specifically, the light sources comprise “U-shaped fluorescent tubes that are driven by electronic ballasts.” *Id.*, Abstract. “The tubes are supported by a sheet-metal or plastic housing,” and there is “[a]n aluminum reflector located behind the tubes [that] increases both the output irradiance and the uniformity of the output distribution.” *Id.* In addition:

The spacing of the U-shaped tubes is varied to increase the output at the edges of the illuminator to make the output more uniform.

Also, different portions of the tubes are cooled at different amounts, to improve uniformity. A light sensor monitors output from the U-shaped tubes to provide a signal for adjusting the output from the tubes.

Id.; see also Figure 1 (showing a cross-section of the illuminator).

D. Challenged Claims

Petitioner challenges claims 1–19 of the '289 patent. Sole independent claim 1 is reproduced below.

1. A method of photodynamically diagnosing or treating a patient, comprising:
illuminating the patient with an illuminator whose measured output over an active emitting area is at least 60% of the measured maximum over all operation distances.

E. Prior Art and Asserted Grounds

Petitioner asserts that claims 1–19 would have been unpatentable on the following grounds.

Reference(s)	35 U.S.C. Basis	Claims Challenged
Rowland ¹	§ 102	1, 2, 10, 12, and 16–19
Rowland and the knowledge of a person of ordinary skill in the art (“POSA”)	§ 103	1, 2, and 4–19
Rowland, Lundahl, ² and knowledge of POSA	§ 103	4–15

¹ International PCT Publication No. WO 90/00420, pub. Jan 25, 1990 (Ex. 1009).

² Stuart L. Marcus, M.D., Ph.D. et al., *Photodynamic Therapy (PDT) and Photodiagnosis (PD) Using Endogenous Photosensitization Induced by 5-Aminolevulinic Acid (ALA): Current Clinical and Development Status*, *Journal of Clinical Laser Medicine & Surgery*, Vol. 14, No. 2, 59–66 (1996) (Ex. 1010).

Reference(s)	35 U.S.C. Basis	Claims Challenged
Levin ³	§ 102	1–3, 12, and 16–19
Levin and knowledge of POSA	§ 103	1–19
Levin, Lundahl, and knowledge of POSA	§ 103	4–15
Bower ⁴ and knowledge of POSA	§ 103	1, 2, and 4–19
Bower, Lundahl, and knowledge of POSA	§ 103	4–15

Pet. 3–4.

II. PATENTABILITY ANALYSIS

A. Claim Construction

The parties filed a motion to request that we apply a district court-type claim construction approach because the '289 patent expired on May 1, 2018. Paper 6; *see In re Rambus, Inc.*, 694 F.3d 42, 46 (Fed. Cir. 2012) (“[T]he Board’s review of the claims of an expired patent is similar to that of a district court’s review.”). Because the patent is expired, we *grant* the parties’ motion.

Petitioner proposes a construction for the term “illuminator,” found in claims 1–6 and 16–19. Pet. 13–15. Patent Owner argues, and we agree, that “construing the term is not necessary to resolve any disputes.” Prelim. Resp. 3. Indeed, we need not resolve any claim construction issues for purposes of determining whether to institute review, and we do not construe any claim terms at this time. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (only those terms that are in controversy need to

³ U.S. Patent No. 4,103,175, iss. July 25, 1978 (Ex. 1011).

⁴ International PCT Publication No. WO 93/21842, pub. November 11, 1993 (Ex. 1012).

be construed, and only to the extent necessary to resolve the controversy); *Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (applying *Vivid Techs.* in the context of an *inter partes* review).

*B. The Rowland Anticipation Ground
(Claims 1, 2, 10, 12, and 16–19)*

Claim 1 of the '289 patent requires an illuminator that produces, at all operation distances, an output of at least 60% of a maximum output.

Petitioner directs our attention to Rowland's Figure 1:

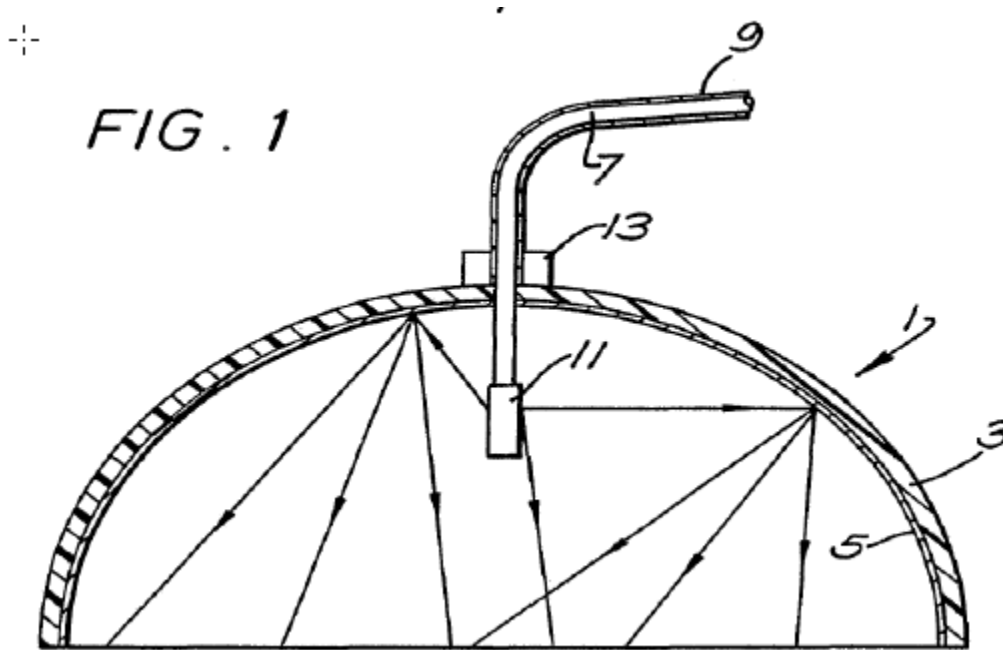


Figure 1 of Rowland discloses a device for uniformly irradiating an area of a surface. Ex. 1009, Abstract. Laser light is received from optical fiber 7 and is dispersed by diffuser 11 within generally hemispherical shell 3, which is coated with reflector 5. *Id.* Because shell 3 is held on the treatment surface, the light from fiber 7 is trapped within and uniform distribution of the light from fiber 7 is achieved under the shell. *Id.*

Petitioner asserts that because Rowland provides substantial uniformity of light, then the measured output of the device is within 60% of the measured maximum “for any distance.” Pet. 24 (citing Ex. 1004 ¶ 88). Patent Owner argues that Petitioner never identifies “all operation distances” or “the measured maximum.” Prelim. Resp. 20. A terse analysis is not fatal per se, however. Claim construction and claim mapping may be apparent when reviewing the contents of the Petition.

It is not apparent to us, however, how Petitioner is reading the claims on Rowland. Petitioner asserts that because Rowland’s output is substantially uniform at *any distance* used, the output would be within 60% of the maximum. This assertion is based on Dr. Bigio’s declaration, Ex. 1004 ¶ 88, which contains neither supporting evidence nor analysis by comparison to a maximum “over an active emitting area” or an explanation of what the recited “operation distance” is. For example, is the relevant distance a length along the treated surface, or a distance from some location on the emitting device? Which location(s) and at what distance(s)? Although it is common that claims may be broad and may read on an array of different prior art structures, the difficulty here is that we do not see any particular path showing how *Petitioner* believes that the claim reads on the prior art. In effect, the ground is an invitation to construe the claim and then to read the claim on the prior art. Petitioner has neither construed the claim nor specified how the claim reads on the art with sufficient clarity to allow us to understand the alleged basis of unpatentability.⁵ See 37 C.F.R.

⁵ In the related district court litigation, Petitioner is asserting that claim 1 of the ’289 patent is indefinite. Ex. 2004. Accordingly, Petitioner’s vague claim mapping may be a result of its good faith belief in its litigation

§ 42.104(b)(4) (“The petition must specify where each element of the claim is found in the prior art patents or printed publications relied upon.”). We decline the invitation to map the art to the claim with sufficient specificity in the first instance here. Accordingly, we decline institution of the Rowland anticipation ground.

*C. The Rowland-POSA Obviousness Ground
(Claims 1, 2, and 4–19)*

Petitioner’s entire discussion of this ground as to claim 1 is reproduced below:

Rowland discloses claim 1(a) for the same reasons as claim 1(a) in Section V.A. Ex. 1004 at ¶ 135-137. To the extent Rowland does not expressly disclose the 60% limitation of claim 1(a), the limitation would have been obvious in view of the knowledge of a POSITA given the design of the shell and Rowland’s teachings about substantial uniformity, including its design to reflect all light from its shell to create “**substantially uniform illumination** of the surface.” *Id.* at 4:5–11; Ex. 1004 at ¶ 138-142.

Pet. 27. Petitioner’s cross-reference to “Section V.A.” is to the anticipation ground just addressed.

In this ground, Petitioner merely concludes that, to the extent the “60% limitation” is not express, it would have been obvious. This assertion does little to address the shortcomings identified above, however. Obviousness grounds cannot be sustained by mere conclusory statements. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). Because Petitioner never explains what the “operation distance” is in Rowland, we cannot determine whether the 60% limitation would have been obvious or not. This

position. Regardless, we decline to make Petitioner’s case for it.

deficiency applies to the remaining claims of the ground. *See* Pet. 27–32. Accordingly, we determine that Petitioner has not established a reasonable likelihood of success in its Rowland-POSA ground.

*D. The Levin-POSA Obviousness Ground
(Claims 1–19)*

As we stated above, claim 1 of the '289 patent requires an illuminator that produces, at all operation distances, an output of at least 60% of a maximum output. Petitioner asserts that if Levin does not disclose “specific operation distances,” a POSA would “use whatever operation distances appropriate for treatment.” Pet. 44. But the claim is not a method requiring a step of operating over various distances. The claim is directed to a method of illuminating with a particular illuminator, one whose output meets certain criteria. As with the Rowland-POSA ground, Petitioner’s assertion here, that it would have been obvious to “use whatever operational distances,” does not explain sufficiently how the prior art is mapped to the claim or the reasoning for why the subject matter of the claim would have been obvious. This deficiency applies to the remainder of the claims in the ground. *See* Pet. 27–32. Accordingly, we determine that Petitioner has not established a reasonable likelihood of success in its Levin-POSA ground.

*E. The Bower-POSA Obviousness Ground
(Claims 1, 2, 4–19)*

In the Bower-POSA ground, Petitioner appears to have two different approaches for how Bower satisfies the limitation in claim 1. First, Petitioner asserts that the contoured array of LEDs in Bower “has uniform power density of approximately 86% at distances of 5 cm and 10 cm in the X and Y plane at any particular distance.” Pet. 55–56 (citing, e.g., Ex. 1012,

Fig. 12). It is not clear how Petitioner is addressing the limitation of claim 1 requiring “at least 60% of the measured maximum over all operation distances.” Petitioner here does not identify what would be the maximum or the operation distances relative to the XY plane (if that is its position), and it is not clear to us how Petitioner is applying the limitations to the art.

Petitioner continues its ground by stating that, “[t]o the extent not disclosed by Bower expressly, a POSITA would have known how to design an illuminator generally conforming to a contoured surface . . . with a uniform power density of approximately 86%.” Pet. 56. Petitioner goes on to state that a POSA:

would have achieved that uniform irradiance at distances of 2 inches, 4 inches, or distances in between 2 and 4 inches in the XY plane or axially, particularly in view of Bower’s teaching that the LED arrays may be any shape or size, and would have been motivated to do so as appropriate and necessary for treatment.

Id. at 56–57.

As with the other obviousness grounds, it is not clear to us why the Petitioner believes that the claimed subject matter would have been obvious in light of Bower and the knowledge of POSA. For example, the claim requires the illuminator to emit an output of 60% of the measured maximum output at all operation distances. This would seemingly involve a comparison of the maximum output as well as values representing outputs measured at relevant operation distances from the illuminator. The Petition, however, focuses on uniform power density in an XY plane, rather than a comparison of outputs to the maximum output at relevant operation distances. This deficiency applies to the remainder of the claims in the

ground. *See* Pet. 57–61. Accordingly, we determine that Petitioner has not established a reasonable likelihood of success on its Bower-POSA ground.

*F. The Rowland-Lundahl-POSA Obviousness Ground,
The Levin-Lundahl-POSA Obviousness Ground, and
The Bower-Lundahl-POSA Obviousness Ground
(Claims 4–15)*

Claims 4–15 depend from claim 1. These grounds do not address the underlying deficiencies noted in the above grounds. Accordingly, we determine that Petitioner has not established a reasonable likelihood of success on these grounds.

*G. The Levin Anticipation Ground
(Claims 1–3, 12, and 16–19)*

Our analysis of this ground is a useful counterpoint to our analysis of the Rowland anticipation ground. Levin describes a hexagonal phototherapy chamber for a patient to stand in. *See, e.g.*, Ex. 1011, Fig. 1, Abstract. Petitioner identifies a teaching in Levin that “there is substantial uniformity [of light] in the chamber and that all measurements are within plus or minus 25% of the average measurement.” Pet. 41 (citing Ex. 1011, 6:1–4). Because the patient is subjected to light within an enclosed chamber, that chamber defines all operation locations, i.e., all locations at which the patient can be subjected to light. *See* Pet. 40 (“As shown in Figure 6 and Table I below, the output at the center (points A, B, C, and D) is at least 85% of the maximum value.” (citing Ex. 1011, Fig. 6, 5:25–36)). Further, Petitioner’s expert explains how plus/minus 25% of the average means that all values are within 60%. Ex. 1004 ¶ 337 (cited at Pet. 41). Thus, because all operative locations in that chamber receive a “substantial uniformity” of light, there is uniformity across all operation distances.

The Rowland ground was deficient because Petitioner did not give us a path to pair claim limitations with features in the art. Here, however, there appears to be only one way to pair the claims and Levin’s features. As such, Patent Owner’s arguments—its only arguments—that Petitioner does not explicitly identify “all operation distances” and “the measured maximum” are not persuasive here. *See* Prelim. Resp. 24–25. Levin specifies that there is uniformity of light throughout the chamber, which is the only place a person would be to receive treatment. Ex. 1011, 6:1–4, 18–21. Reviewing Petitioner’s ground and Patent Owner’s Preliminary Response, we determine that Petitioner has shown a reasonable likelihood that claim 1 is anticipated by Levin.⁶

Dependent claims 2 and 16–19 require output within 70% of the maximum at various distances. Petitioner asserts that Levin discloses 85% uniformity at certain locations in the *middle* of the chamber. Pet. 42 (citing Ex. 1004 ¶¶ 329–338); *id.* at 43 (addressing claims 16–19 by referring back to the claim 2 analysis). Here, we agree with Patent Owner’s prior argument that Petitioner’s failure to provide a claim construction or more explicit claim mapping is fatal. *See* Prelim. Resp. 24–25. Petitioner measures from the center of Levin’s hexagonal chamber. Ex. 1004 ¶¶ 342 (“the irradiance output at the center . . . is at least 85% of the maximum value”), 344 (similarly for “the 8-inch radius of circle EFGH”); *see also* Ex. 1011, 5:14–

⁶ Our finding here does not impact our finding with respect to the Levin-POSA obviousness ground, in which Petitioner and its declarant, Dr. Bigio, assert, without support, that “[t]o the extent Levin does not expressly disclose specific operation distances, a POSITA . . . would have been motivated to use whatever operation distances appropriate for treatment.” Pet. 44; Ex. 1004 ¶ 407.

19 (explaining that points ABCD are in the center and EFGH are measured 8 inches from the center), Fig. 6. Thus, Petitioner implicitly construes “distances of” 2 or 4 inches to be measured out from the centerline of a regular-shaped irradiation chamber. But Petitioner gives no explanation for why that is what the claims require. Further, this construction seems doubtful, as the claims are discussing output from an illuminator, which would imply distance *from* the light source. For example, and although not necessarily limiting, the ’289 patent describes a U-shaped device; it is not clear how one would measure distance from a centerline analogous to Levin’s in that instance. *See* Ex. 1001, Fig. 1. Reviewing the ground, we are not persuaded Petitioner has shown a reasonable likelihood of success with respect to claims 2 and 16–19.⁷

Dependent claims 3 and 12 require fluorescent tubes and treating psoriasis, respectively, both of which Petitioner asserts are explicitly discussed in Levin. Pet. 42–43. Reviewing the cited portions of Levin, we determine that Petitioner has shown a reasonable likelihood of success for claims 3 and 12.

⁷ If we were to institute trial and construe this claim, it is possible that, given Levin’s disclosure of uniformity within the chamber, the claims would read on Levin. However, we do not construe the claims nor institute a trial here, such that there is no reason to evaluate whether Petitioner would meet the reasonable likelihood threshold under a claim construction other than the one implied by Petitioner in this ground.

III. PATENT OWNER’S 35 U.S.C. § 325(d) ARGUMENT

Patent Owner argues that we should deny institution under 35 U.S.C. § 325(d). Prelim. Resp. 8–17. This argument is moot in view of our 35 U.S.C. § 314(a) analysis below.

IV. DISCRETIONARY DENIAL UNDER 35 U.S.C. § 314(a)

We are permitted, but never required, to institute *inter partes* review when a petitioner meets the threshold for institution. *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2140 (2016) (“[T]he agency’s decision to deny a petition is a matter committed to the Patent Office’s discretion.”); *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1367 (Fed. Cir. 2016) (explaining that, under § 314(a), “the PTO is permitted, but never compelled, to institute an IPR proceeding”). A partial institution focusing only on grounds or claims having a reasonable likelihood of success is not an option. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) (“Nothing suggests the Director enjoys a license to depart from the petition and institute a *different* *inter partes* review of his own design.”); *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (“Equal treatment of claims and grounds for institution purposes has pervasive support in *SAS*.”). Although Petitioner has met the statutory threshold for institution under 35 U.S.C. § 314(a), we decline to institute.

As we determined in our analysis of the grounds above, Petitioner has established a reasonable likelihood of success on only 1 of 8 grounds. If we were to institute a trial, Petitioner currently stands reasonably likely to have 3 claims held unpatentable, including the sole independent claim, but does not have a reasonable likelihood for the remaining 16 claims. Although we do not look strictly at precise percentages of institutable grounds and/or

claims, this case presents a clear instance where the benefits of holding a trial to resolve the challenges having a reasonable likelihood would be overwhelmed by the burden of addressing the challenges having no reasonable likelihood. In conclusion, we exercise our discretion not to institute because institution would not serve the just, speedy, and inexpensive resolution of the parties' dispute, or of *inter partes* reviews as a whole. See SAS Q&As, Part D, Effect of SAS on Future Challenges that Could Be Denied for Statutory Reasons (June 5, 2018), available at https://www.uspto.gov/sites/default/files/documents/sas_qas_20180605.pdf (“[T]he panel will evaluate the challenges and determine whether, in the interests of efficient administration of the Office and integrity of the patent system . . . the entire petition should be denied under 35 USC § 314(a).”); 37 C.F.R. § 42.1(b) (“This part shall be construed to secure the just, speedy, and inexpensive resolution of every proceeding.”); see also, e.g., *Deeper, UAB v. Vexilar, Inc.*, Case IPR2018-01310, slip op. at 42 (PTAB Jan. 24, 2019) (Paper 7) (denying institution in a similar situation upon consideration of Rule 42.1(b)).

V. CONCLUSION

We have determined that Petitioner has shown a reasonable likelihood that claims 1, 3, and 12 are anticipated by Levin. But Petitioner has not shown a reasonable likelihood that claims 2 or 16–19 are anticipated by Levin, or that any other of claims 1–19 are reasonably likely unpatentable as anticipated by Rowland or obvious in view of various combinations offered based on Rowland, Levin, or Bower. For the reasons set forth above, we do not institute under 35 U.S.C. § 314(a) because partial institution is not

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available and full institution would not serve the just, speedy, and efficient administration of this proceeding or of the Office.

VI. ORDER

In view of the foregoing, it is hereby:

ORDERED that we exercise our discretion not to institute an *inter partes* review of the '289 patent under 35 U.S.C. § 314(a).

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