

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.).

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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).

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