

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

Inter Partes Review Case No. 2024-00874
Patent No. 11,697,028

PETITIONER’S UPDATED MANDATORY NOTICES

Pursuant to 37 C.F.R. § 42.8(b)(2), Petitioners Biofrontera Inc., Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, and Biofrontera AG (collectively, “Petitioner”) hereby files its updated mandatory notices.¹

¹ Sun Pharmaceutical Industries, Inc. filed its mandatory notices indicating that it is the Patent Owner. Paper 4.

I. Real Party-In-Interest (37 C.F.R. § 42.8(b)(1))

No change.

II. Related Matters (37 C.F.R. § 42.8(b)(2))

Patent No. 11,697,028 is involved in three matters that may affect or be affected by this proceeding:

a. PTAB IPR Parallel Petition

Biofrontera Inc., Biofrontera Bioscience GMBH, Biofrontera Pharma GMBH, and Biofrontera AG v. DUSA Pharmaceuticals, Inc., IPR2024-01312 (petition filed on August 21, 2024) (hereinafter, the '1312 IPR). Petitioner has filed a notice regarding parallel petitions in the '1312 IPR that compares the petition in this proceeding with the petition filed in the '1312 IPR, which is attached herein as Exhibit A.

b. ITC Complaint

In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same, Investigation No. 337-TA-1411 (complaint filed on June 25, 2024).

c. District Court Litigation

Sun Pharmaceutical Industries, Inc. v. Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera AG, and Biofrontera Inc., Civil Action No. 1:24-cv-11637 (D. Mass) (complaint filed on June 25, 2024).

III. Lead and Backup Counsel (37 C.F.R. § 42.8(b)(3))

No change.

IV. Service Information (37 C.F.R. § 42.8(b)(4))

No change.

Dated: September 5, 2024

Respectfully submitted,

By: /s/ Tyler T. VanHoutan

Tyler T. VanHoutan

Reg. No. 54,506

MCGUIREWOODS LLP

845 Texas Avenue, Suite 2400

Houston, TX 77002

Telephone: (713) 571-9191

Facsimile: (713) 571-9652

Email:

tvanhoutan@mcguirewoods.com

Attorney for Petitioner

CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. §§ 42.6(e), the undersigned certifies that on September 5, 2024, a complete and entire copy of Petitioner's Updated Mandatory Notices along with Exhibit A was served on the following counsel of record for Patent Owner via electronic mail:

Gabrielle E. Higgins, Reg. No. 38,916
DESMARAIS LLP
101 California Street, Suite 3000
San Francisco, CA 94111
ghiggins@desmaraisllp.com

Yung-Hoon Ha (Reg. No. 56,368)
DESMARAIS LLP
230 Park Avenue
New York, NY 10169
yha@desmaraisllp.com

By: /s/ Tyler T. VanHoutan
Tyler T. VanHoutan
Reg. No. 54,506
tvanhoutan@mcguirewoods.com

EXHIBIT A

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 IPR2024-01312
PATENT 11,697,028

**PETITIONER’S NOTICE
REGARDING PARALLEL PETITIONS¹**

¹ This paper is authorized by the Patent Trial and Appeal Board Consolidated Trial Practice Guide, November 2019 (“PTAB Trial Practice Guide”) at pgs. 59-60, FN4 (“After the publication of this guide, it will be expected that petitioners will justify multiple petitions in the first instance in their petitions or in a separate paper with the petitions...”)

I. Introduction

Petitioner concurrent with this paper is filing a second *inter partes* review petition against U.S. Patent No. 11,697,028 (“the ’028 Patent”). The first petition is associated with IPR2024-00874 (“874 IPR”) and the second is associated with IPR2024-01312 (“1312 IPR”). The 1312 IPR petition is a parallel petition because it is filed before a preliminary response was filed or due in the 874 IPR. *See* PTAB Consolidated Trial Practice Guide at 59 (parallel petitions are “[t]wo or more petitions filed against the same patent at or about the same time (e.g., before the first preliminary response by the patent owner)...”); *see also* USPTO Proposed Rules, Fed. Reg. Vol. 89, No. 77 at 28694 (parallel petitions includes those filed “up until the filing of the preliminary response in the first filed proceeding” after which time they are treated as serial petitions); *id.* at 28696.

As the PTAB recognizes, there are circumstances in which more than one IPR petition may be necessary. PTAB Consolidated Trial Practice Guide at 59. Here, Petitioner has filed a parallel petition in order to align the PTAB proceedings with newly filed ITC and District Court complaints and reduce the overall burden on the Board and parties. After the 874 IPR was filed, Patent Owner filed District Court and ITC complaints against Petitioner asserting the ’028 Patent. *See* Ex.1018 and Ex.1020. Patent Owner has identified in its District Court and ITC Complaints a subset of claims of the ’028 Patent it alleges are infringed. Ex.1019 and Ex.1020. In

addition, Petitioner also now believes a modified POSITA definition more directly encompass medical treatment education and experience reflected in independent Claim 5 as well as engineering experience. As such Petitioner files 1312 IPR petition against the '028 Patent to narrow the challenge before the Board to only those claims asserted by Patent Owner in the ITC and to address medical treatment background in the level of skill in the art.

Furthermore, Petitioner intends to file an IPR petition against U.S. Patent 11,446,512 (which is the parent of the '028 Patent and also asserted in the District Court and ITC) based on similar level of skill in the art and similar prior art argument as set forth in the 1312 IPR petition. This IPR petition against the '512 Patent is expected to be filed before the Board makes its decision to institute either of Petitioner's IPRs on the '028 Patent. As such, the Board would ultimately need to consider substantially the same issues raised in the 1312 IPR even if the 1312 IPR petition were to be discretionarily denied. Thus, instituting the 1312 IPR petition will not substantially increase the overall burden on the Board or the parties.

To further help the Board decide on the parallel petitions, Petitioner provides the following information requested in the PTAB Consolidated Trial Practice guide showing why Petitioner has good cause for filing parallel IPR petitions.

II. Ranking of the Petitions

Petitioner asserts both the 874 and 1312 IPR petitions demonstrate the unpatentability of their challenged claims. However, if the Board were to institute only one petition, then Petitioner requests the Board institute the 1312 IPR petition.

The 1312 IPR focuses only on the claims asserted in the ITC and raised in Patent Owner's District Court infringement contentions. Ex.1019 and Ex.1020. This allows the parties and Board to focus their resources on the most relevant claims. In addition, the 1312 IPR petition contains arguments that will substantially overlap the arguments Petitioner intends to present to challenge the claims of the parent '512 Patent. Indeed, the claims of the '512 Patent recite many identical or substantially similar limitations as recited in the challenged claims of the '028 Patent. Finally, the 1312 IPR petition provides a modified level of ordinary skill that adds in the possibility of being on member of a multi-disciplinary team as well as providing for medical treatment experience.

Therefore, the overall burden on the Board and the parties would be reduced if the Board instituted the 1312 IPR petition compared to the 874 IPR petition.

III. Relevant Differences in Petitions

There are three primary distinctions between the 1312 IPR and 874 IPR petitions: 1) claims challenged, 2) proposed level of ordinary skill in the art, and 3) proposed grounds of rejection. All are discussed below.

A. Claims Challenged

While both petitions challenge asserted claims 1, 2, 4-6, 16, 17, and 19-21, the earlier filed 874 IPR includes non-asserted claims 3, 7, 8, 10, 11, 13, 14, and 18. Thus the 1312 IPR focuses the Board and parties' resources on the most relevant claims relative to Patent Owner's infringement allegations.

B. Level of Ordinary Skill in the Art

Upon review of Patent Owner's ITC and District complaints as well as the '028 Patent as a whole, Petitioner believes a modified POSITA definition requiring medical treatment education and experience, either individually or as a member of a multi-disciplinary team, including engineering experience. As such, the 1312 IPR petition modifies the level of skill in the art proposed in the 874 IPR to more clearly account for the medical treatment aspects of the '028 Patent. In particular, the 1312 IPR level of skill in the art adds that a POSITA "would have been an individual or member of a multi-disciplinary team" having "a medical degree in fields relating to the diagnosis and treatment of skin conditions and related disease states" and "at least four years of experience in one or more fields of medical treatment of skin conditions and related disease states." *See* 1312 Petition.

C. Proposed Grounds of Rejection

While both petitions rely on Larsen and Bansal, the 1312 IPR adds in Lundahl for all proposed grounds. Lundahl is related to WO 99/56827 referenced as Ex.1011

in the 874 Petition but not used in a proposed ground therein. Despite the foregoing, the 1312 IPR petition still has fewer proposed grounds and references to consider since it does not rely on rejections under Jones, Anderson, or Mackinnon relied on in the 874 IPR. Lundahl is also a patent filed and prosecuted by the Patent Owner's predecessor, so the Patent Owner is very familiar with the teachings of Lundahl. A table comparing the different grounds is provided below.

1312 IPR Proposed Grounds	874 IPR Proposed Grounds
Claims 1, 2, 4-6, 16, 17, and 19-21 are obvious over Lundahl in view of Larsen.	Claims 1, 2, 4-8, and 16-21 are obvious over Larsen, in view of Bansal, further in view of Jones.
Claims 1, 2, 4-6, 16, 17, and 19-21 are obvious over Lundahl in view of Larsen and further in view of Bansal.	Claims 2-4 are obvious over Larsen in view of Bansal, further in view of Jones, further in view of Anderson.
	Claims 10, 11, 13, and 14 are obvious over Larsen in view of Bansal, further in view of Jones, further in view of Mackinnon

IV. Board should Institute Both Petitions

Due to the ITC and District Court complaints filed by Patent Owner, the parties will potentially have to address the same or similar grounds of invalidity raised in both the 874 and 1312 petitions in the ITC proceeding. Accordingly, any perceived added burden to the parties to address the grounds in both IPRs before the PTAB is minimal since many of these same issues and briefing may also need to be provided in the course of the ITC and District Court proceedings.

Dated: August 21, 2024,

Respectfully submitted,

By: /James P. Murphy/

James P. Murphy

Reg. No. 55,474

Polsinelli PC

1000 Louisiana Street

Suite 6400

Houston, Texas 77002

Tel: (713) 374-1600

Corey Casey

Reg. No. 66,950

Polsinelli PC

900 West 48th Place

Suite 900

Kansas City, Missouri 64112

Tel: (816) 572-4439

Megan Hart

Reg. No. 79,202

Polsinelli PC

7676 Forsyth Blvd.

Suite 800

St. Louis, Missouri 63105

Tel: (314) 622-6107