

Case IPR2025-00287
U.S. Patent No. 11,446,512

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 IPR2025-00287

U.S. Patent No. 11,446,512

PATENT OWNER'S DISCRETIONARY DENIAL OF INSTITUTION
BRIEFING UNDER 35 U.S.C. §314(a)

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All emphases are added unless otherwise noted.

PATENT OWNER'S EXHIBIT LIST

EX #	DESCRIPTION
2001-2030	RESERVED
2031	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> Investigation No. 337-TA-1411 (Order No. 6 - Setting the Procedural Schedule, dated September 3, 2024)
2032	<i>Sun Pharmaceutical Industries, Inc. v. Biofrontera Inc. et al</i> , Case No. 1:24-cv-11637-IT (D. Mass), dated August 23, 2024 (D.I. 21 Order granting Defendants' Unopposed Motion to Stay Pending Resolution of Proceeding at the International Trade Commission)
2033	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> Investigation No. 337-TA-1411 (Order No. 18 – Construing Certain Claim Terms, dated March 4, 2025 (Public Version))
2034	<i>In Re Certain Photodynamic Therapy Systems, Components Thereof, And Pharmaceutical Products Used In Combination With The Same</i> Investigation No. 337-TA-1411 (Redacted Expert Report of Dr. Robert E. Grove, Ph.D. on behalf of Respondents, dated January 22, 2025)

I. INTRODUCTION¹

The Petition challenges claims 1, 3, 5, 8, 17, 18 and 20 of U.S. Patent No. 11,697,512 (the “’512 patent”) under three grounds of unpatentability. Instituting review in this IPR would cause the parties and the Board to incur significant inefficiencies and wasted efforts of the type warned of in *Fintiv*. On June 25, 2024, Patent Owner Sun Pharma filed a complaint before the International Trade Commission (“ITC”) against Petitioner Biofrontera, asserting infringement of the ’512 patent. That ITC investigation is in advanced stages as the hearing will begin on June 30, 2025, and the final post-hearing briefing will be completed by August 4, 2025. Further, the “target date” for completion of the final determination by the ITC Commission is set for February 2, 2026, which is *six months before* the expected Final Written Decision (“FWD”) of this IPR proceeding. Moreover, the ITC investigation involves the same claim construction standard with overlapping claims, invalidity theories, and prior art as this IPR proceeding. Under the PTAB’s precedential *Fintiv* decision, the Board should exercise its discretion to deny institution under §314(a).

¹ This discretionary denial briefing is filed pursuant to the Interim Processes for PTAB Workload Management Memorandum, issued March 26, 2025, and Paper 6.

II. INSTITUTION SHOULD BE DENIED UNDER 35 U.S.C. §314(a) IN VIEW OF THE CO-PENDING ITC LITIGATION

The Board has identified factors relating to “whether efficiency, fairness, and the merits support the exercise of authority to deny institution” in view of a parallel proceeding—each of which supports denial here. *Apple Inc. v. Fintiv, Inc.*, IPR2020-00019, Paper 11, at 5-6 (Mar. 20, 2020) (precedential) (“*Fintiv*”). The *Fintiv* factors include:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court’s trial date to the Board’s projected statutory deadline for a final written decision;
3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board’s exercise of discretion, including the merits.

Id. As set forth below, a balancing of these factors demonstrates that the efficiency and integrity of the AIA are best served by denying institution. *Fintiv* at 6.

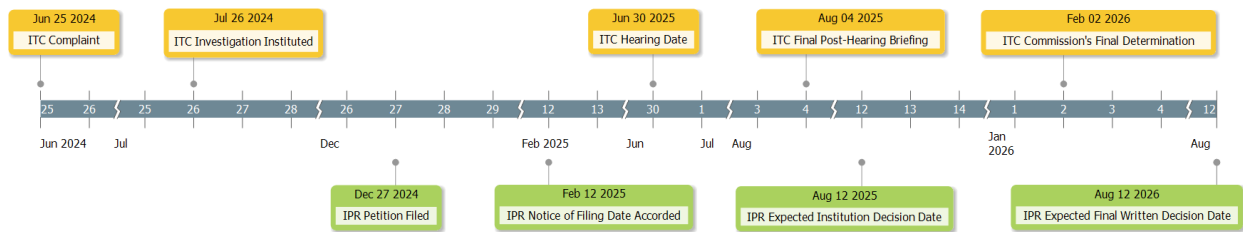
A. Parallel Proceedings

As illustrated below, Sun Pharma filed a complaint in the ITC alleging infringement of the ’512 patent by Petitioner Biofrontera on June 25, 2024. *See In Re Certain Photodynamic Therapy Systems, Components Thereof, And*

Pharmaceutical Products Used In Combination With The Same Investigation No. 337-TA-1411 (before Administrative Law Judge Bryan Moore) (EX1020).

The ITC instituted the investigation on July 26, 2024, as Investigation No. 337-TA-1411 (the “ITC Investigation”).

The ITC Investigation is in advanced stages, with fact and expert discovery completed and pre-hearing activities substantially underway. EX2031, 3-4. The ITC hearing is set to begin on June 30, 2025, with post-hearing briefing to be completed by August 4, 2025. EX2031, 4. And the ITC Commission has set a final determination date of February 2, 2026. EX2031, 5.



In contrast, as shown above, this Petition for *inter partes* review was filed on December 27, 2024, and a notice of filing date accorded was issued on February 12, 2025. As such, assuming an institution date of August 12, 2025, the expected Final Written Decision date is on August 12, 2026—which is more than *six months* after the ITC’s expected final determination date.

In other words, the validity of the ’512 patent will be decided at the ITC long before the expected Final Written Decision date of this proceeding.

Biofrontera correctly notes that under the previously-released “Director’s Interim Guidance Memorandum, “the PTAB will not discretionarily deny petitions based on applying *Fintiv* to a parallel ITC proceeding.” Petition, 86-87. However, on February 28, 2025, the USPTO rescinded that Interim Procedure. On March 24, 2025, the Office further issued a Guidance Memorandum (“Guidance Memo”) explaining that “the Board will apply the *Fintiv* factors where there is a parallel proceeding at the International Trade Commission (‘ITC’).” Guidance Memo, 2. The Guidance Memo explains that “the USPTO rescinded the Interim Procedure to restore policy in this area to the guidance in place before the Interim Procedure,” including the Board’s precedential *Fintiv* and *Sotera* decisions. *Id.*, 1.

“As the *Fintiv* decision explains, although an ITC final invalidity determination does not have preclusive effect, it is difficult as a practical matter to assert patent claims that the ITC has determined are invalid. *See Fintiv* at 8-9. “Additionally, instituting an IPR or a PGR where the ITC has set a target date for completing its investigation (i.e., the full Commission’s final determination) to occur earlier than the Board’s deadline to issue a final written decision in a challenge involving the same patent claims means that multiple tribunals may be adjudicating validity at the same time, which may increase duplication and expenses for the parties and the tribunals.” *Id.*, 2. Thus, the Guidance Memo states that “the Board

is more likely to deny institution where the ITC’s projected final determination date is earlier than the Board’s deadline to issue a final written decision.” *Id.*

Numerous panels have denied institution in view of parallel ITC proceedings, particularly as here, where the ITC is already in advanced stages and the final determination is scheduled to precede the expected FWD. *See, e.g., Google LLC v. Ecolfactor Inc.*, IPR2021-01578, Paper 9 (PTAB Mar. 18, 2022); *Hewlett Packard Enterprise Co. et al. v. Q3 Networking LLC*, IPR2021-00754, Paper 9 (PTAB Oct. 8, 2021); *Kiss Nail Products, Inc. v. Lashify, Inc.*, PGR2021-00046, Paper 12 (PTAB Aug. 9, 2021); *SK Innovation Co., Ltd. et al. v. LG Chem, Ltd. et al.*, IPR2020-01240, Paper 15 (PTAB Jan. 12, 2021) (“*SK Innovation IP*”); *SK Innovation Co., Ltd. et al. v. LG Chem, Ltd. et al.*, IPR2020-00987, Paper 14 (PTAB Nov. 30, 2020) (“*SK Innovation P*”); *Fitbit, Inc. et al. v. Koninklijke Philips N.V.*, IPR2020-00772, Paper 14 (PTAB Oct. 19, 2020).

B. The *Fintiv* Factors Favor Denial Of Institution

As detailed below, a holistic balancing of the *Fintiv* factors favors denial of institution.

1. Factor 1 weighs strongly against institution because the ITC has not granted a stay and no evidence exists that a stay may be granted.

Factor 1 concerns whether the ITC granted a stay or evidence exists that one may be granted if a proceeding is instituted. *Fintiv* at 6.

The ITC has not granted a stay. Further, it is extremely unlikely that an ITC proceeding will be stayed pending IPR. The ITC has a statutory mandate to conclude its investigation at “the earliest practicable time” and has refused requests, in essentially all instances, to stay investigations pending instituted IPRs. *See, e.g., In the Matter of Certain Automated Storage and Retrieval Systems, Robots, and Components Thereof*, Investigation No. 337-TA-1228, Order No. 6 (Mar. 9, 2021); *In the Matter of Certain Laser-Driven Light Sources, Subsystems Containing Laser-Driven Light Sources, and Products Containing Same*, Investigation No. 337-TA-983, Order No. 8 (Mar. 3, 2016); 19 U.S.C. §1337(b)(1).

Petitioner has not requested nor given any indication that they would request a stay of the ITC Investigation. The stay is even more unlikely considering that the ITC Investigation is in advanced stages. For example, final contentions were exchanged in December 2024, expert reports were exchanged in January and February 2025, and expert discovery was completed in March 2025. EX2031, 2-3. The ALJ held a claim construction hearing and issued a Claim Construction Order on March 4, 2025. EX2033. In fact, both the ITC hearing date (June 30, 2025) and the final post-hearing briefing (August 4, 2025) are expected to precede the expected institution decision date of this IPR (August 12, 2025). EX2031, 4.

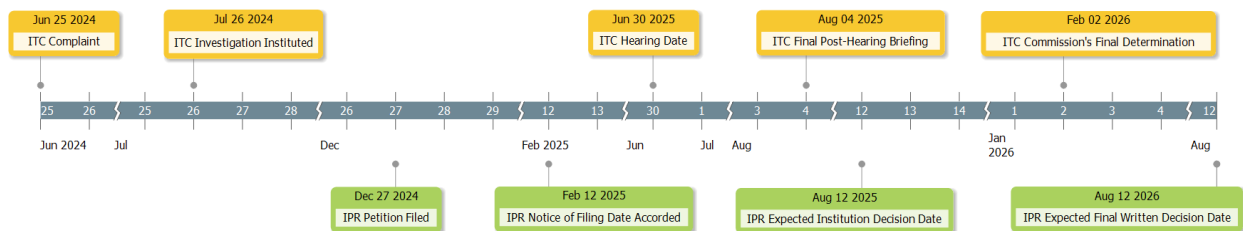
Thus, because the parallel ITC Investigation has not been stayed, and it is unlikely that it will be, factor 1 strongly weighs in favor of discretionary denial. *See*

Google at 8 (weighing factor 1 in favor of not instituting where a stay of the ITC investigation was unlikely given that post-hearing briefing was completed before institution decision).

2. Factor 2 weighs strongly against institution because the ITC’s final determination is scheduled to be completed six months before the Final Written Decision.

Factor 2 asks the Board to evaluate whether parallel proceedings will conclude before the Board’s statutory deadline for a FWD. *Fintiv* at 9.

Here, the ITC hearing will begin on June 30, 2025, and the target date for completion of the ITC Investigation (*i.e.*, ITC Commission’s final determination date) is set for February 2, 2026—all *well before* the expected August 12, 2026 deadline for FWD. EX2031, 4-5.



In other cases where the conclusion of a parallel ITC proceeding pre-dates the FWD by a similar length of time, the Board has found this factor weighs against institution. *See, e.g., Google* at 9 (denying institution where final ITC determination set to pre-date FWD by more than half a year); *Hewlett Packard* at 9-10 (denying institution where final ITC determination set to pre-date FWD by six months); *Kiss*

Nail at 9 (denying institution where final ITC determination set to pre-date FWD by approximately six months); *SK Innovation II* at 16-17 (denying institution where final ITC determination date set to pre-date FWD by at least a six month differential).

Because it is highly likely that the issues bearing on the patentability of the challenged claims will be considered and resolved *six months* before the Board would issue a FWD, factor 2 weighs heavily in favor of discretionary denial.

3. Factor 3 weighs strongly against institution because, by the Institution Decision deadline, the parties and the ITC will have made significant investment in the parallel investigation.

Factor 3 considers “the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision.”

Fintiv at 9.

As already explained above with respect to factor 1, by the time of an institution decision in August 2025, the ITC and the parties will have already invested significant resources in the investigation. Final contentions were exchanged in December 2024, expert reports were exchanged in January and February 2025, and expert discovery was completed in March 2025. EX2031, 2-3. The ALJ held a claim construction hearing and issued a Claim Construction Order on March 4, 2025. EX2033.

Now, the parties are preparing for the hearing, which is set to begin on June 30, 2025. EX2031, 4. The parties are in the process of exchanging hearing exhibits, deposition designations, and witness statements, and will file summary determination motions on May 1, 2025. EX2031, 3. The ITC will then hold a final pre-hearing conference on June 30, 2025 and an evidentiary hearing from June 30 – July 3, 2025. EX2031, 4. The parties will complete post-hearing briefing on August 4, 2025. *Id.* All of this will occur *before* the expected Institution Decision date of August 12, 2025.

Additionally, Petitioner was not diligent in filing this IPR. Petitioner knew of the Lundahl and Larsen references at least as early as April 2024, when Petitioner filed IPR2024-00874. IPR2024-00874, Paper 1, 3 and EX1011. Then, in August 2024, Petitioner told the PTAB it intended to challenge the claims of the '512 patent. *See* IPR2024-01312, Paper 2, 3. Yet, Petitioner waited another four months (for a total of eight months) before filing this IPR. During Petitioner's delay, the parties and the ALJ invested significant resources in the ITC proceeding, including detailed written discovery, fact witness depositions, final contentions, claim construction briefing, and a claim construction hearing. EX2031, 1-2; *see also Roku, Inc. v. Universal Electronics, Inc.*, IPR2021-00264, Paper 11 at 12-13 (PTAB Jul. 12, 2021) (Board found it "cannot credit Petitioner for diligently filing the Petition" where Petitioner delayed eight months before filing IPR).

In sum, by the time of the institution decision, the ITC and parties will have invested a significant amount of time, effort, and resources in the parallel ITC Investigation. The extensive investment by the parties and the ITC strongly favors denial of institution under factor 3. *Google* at 9; *SK Innovation II* at 17-18; *Hewlett* at 10-11; *Kiss Nail* 9-11.

4. Factor 4 weighs strongly against institution because there is substantial overlap between this IPR and the ITC proceeding.

Factor 4 relates to the overlap of issues raised in this petition and the parallel ITC proceeding. *Fintiv* at 12. As the Board found in *Fintiv*, “if the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding, this fact has favored denial.” *Id.* Here, there is ***complete overlap*** of issues bearing on the patentability of the challenged claims of the ’512 patent between this IPR and the claims asserted in the ITC Investigation. The Petition asks the Board to review the same patent claims, based on the same combinations of prior art references as in the ITC. *See, e.g.*, Petition 33-85; EX1015, ¶¶152-262; EX2034, ¶¶436-557.

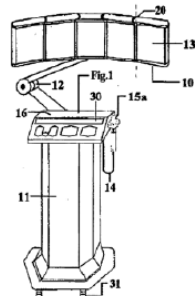
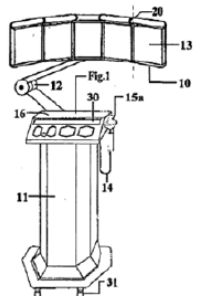
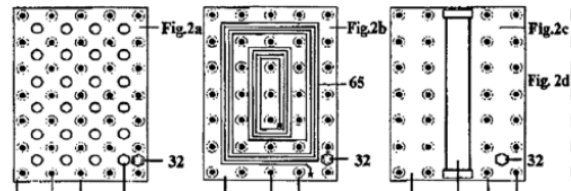
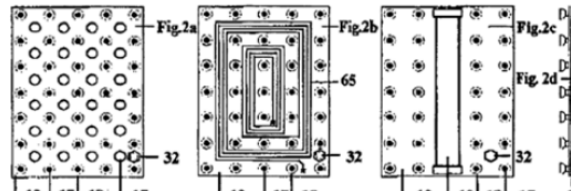
The chart below summarizes the complete overlap between the IPR and ITC.

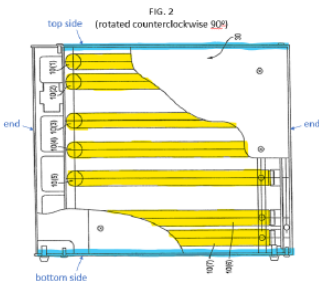
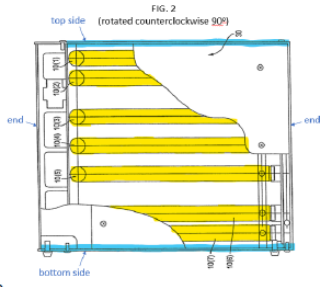
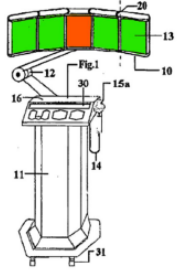
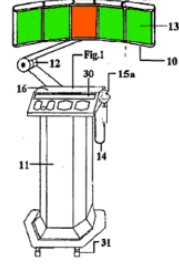
Ground	Challenged Claims	References	35 U.S.C. §	IPR Grove Declaration and Petition	ITC Grove Report
1	1, 3, 5, 8, and 20 ²	Lundahl, Larsen	103	EX1015, ¶¶152-233; Petition 33-65	EX2034, ¶¶436-524
2	1, 3, 5, 8, 17, 18 and 20	Lundahl, Larsen, Hente	103	EX1015, ¶¶234-253; Petition 65-77	EX2034, ¶¶525-548
3	17 and 18	Lundahl, Larsen, Hente, Perutz	103	EX1015, ¶¶254-262; Petition 78-85	EX2034, ¶¶549-557

For example, comparing the paragraphs of the IPR Grove Declaration (EX1015) with the ITC Grove Report (EX2034) shows that Petitioner challenges the same claims based on the same prior art combinations, with nearly identical arguments and evidence presented in the parallel ITC Investigation. In fact, as the following

² The Petition contains inconsistencies on the lists of claims for the Grounds. Compare Petition 24 (“claims 1-3, 5, 8, and 20”) with Petition 33 (“claim 1, 3, 5, 8, and 20”); and Petition 10 (“claims 1-3, 5, 8, 17, 18 and 20”) with Petition 65 (“claims 1, 3, 5, 8, 17, 18 and 20”). The Petition does not challenge claim 2 because there is no analysis of such claim. See Petition, 6-85; EX1015, ¶¶152-262 (providing no claim 2 analysis). Even if claim 2 was challenged, there would still be substantial overlap in the issues. *Roku* at 13-16 (finding sufficient overlap in the issues even though a parallel ITC investigation involved fewer than half the challenged claims).

exemplary screenshots demonstrate, Dr. Grove's IPR Declaration (EX1015) and Dr. Grove's ITC Expert Report (EX2034) are nearly carbon copies of each other.

IPR Grove Declaration (EX1015)	ITC Grove Report (EX2034)
Claim 1[preamble]: "1. A system for photodynamically diagnosing or treating a patient, comprising:" 156. Lundahl discloses an "invention...directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light. In particular, the present invention is directed to an apparatus and method for photodynamic treatment (PDT) or diagnosis (PD) of actinic keratosis of the scalp or facial areas of a patient." Lundahl, 1:9-17.	Claim 1[preamble]: "1. A system for photodynamically diagnosing or treating a patient, comprising:" 439. Lundahl discloses an "invention...directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light. In particular, the present invention is directed to an apparatus and method for photodynamic treatment (PDT) or diagnosis (PD) of actinic keratosis of the scalp or facial areas of a patient." Lundahl, 1:9-17.
Claim 1(a): "an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels," 159. Larsen's illuminator has at least five hinged panels (13):  160. Larsen teaches that "[f]or the treatment of large-area tissues according to Fig. 1, several applicators 13 are flexibly connected to each other through hinges 10, respectively connecting one edge with the other, whereby the applicators are suitable for the treatment of for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators 13 above the skin." Larsen, [0072]. While this passage refers to "hinges 10," it is clear from the disclosure of Larsen that this is a labeling error, and that the "10" illustrated in Figure 1 refers to the device as a whole, while the hinge component is illustrated by the dotted line labeled as "20." Larsen states "[a]s shown in FIG. 1, the invented device 10 for the stimulation of cells with the aid of (PDT) photodynamic light and electromagnetic fields combined with light sensitive substances consists of a stand 11, with which machine applicators 13 (in the following just called applicators 13) are connected through a jointed arm 12." Larsen, [0069] (emphasis added). In view of this express statement from Larsen, it is clear to a POSITA that the "10" designation of Figure 1 is referencing the device as a whole.	Claim 1(a): "an illuminator comprising at least five panels connected by nested hinges on inner side surfaces of adjacent panels," 442. Larsen's illuminator has at least five hinged panels (13):  443. Larsen teaches that "[f]or the treatment of large-area tissues according to Fig. 1, several applicators 13 are flexibly connected to each other through hinges 10, respectively connecting one edge with the other, whereby the applicators are suitable for the treatment of for example, the backs of humans and so become adjustable for an equidistant positioning of the applicators 13 above the skin." Larsen, [0072]. While this passage refers to "hinges 10," it is clear from the disclosure of Larsen that this is a labeling error, and that the "10" illustrated in Figure 1 refers to the device as a whole, while the hinge component is illustrated by the dotted line labeled as "20." Larsen states "[a]s shown in FIG. 1, the invented device 10 for the stimulation of cells with the aid of (PDT) photodynamic light and electromagnetic fields combined with light sensitive substances consists of a stand 11, with which machine applicators 13 (in the following just called applicators 13) are connected through a jointed arm 12." Larsen, [0069] (emphasis added). In view of this express statement from Larsen, it is clear to a POSA that the "10" designation of Figure 1 is referencing the device as a whole.
Claim 1(b): "light sources disposed on surfaces of the at least five panels," 170. Larsen discloses that light sources are disposed on the surfaces of at least five applicators. Figures 2a-2c of Larsen show "plain surfaced printed circuit boards with light sources mounted in the applicators 13." Larsen, [0070]. 	Claim 1(b): "light sources disposed on surfaces of the at least five panels," 453. Larsen discloses that light sources are disposed on the surfaces of at least five applicators. Figures 2a-2c of Larsen show "plain surfaced printed circuit boards with light sources mounted in the applicators 13." Larsen, [0070]. 

IPR Grove Declaration (EX1015)	ITC Grove Report (EX2034)
Claim 1(c): “the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,” 173. Lundahl teaches uniform illumination of the head of a patient via photodynamic therapy. Lundahl states “[t]he present invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light.” Lundahl, 1:9-11. To achieve this uniformity, Lundahl utilizes the light distribution pattern illustrated in Figure 2 (which has been highlighted, annotated, and rotated 90° to better illustrate):  Lundahl, Fig. 2.	Claim 1(c): “the illuminator being configured to uniformly illuminate a treatment surface of the patient via the light sources,” 458. Lundahl teaches uniform illumination of the head of a patient via photodynamic therapy. Lundahl states “[t]he present invention is directed to photodynamic therapy using an illuminator that provides a uniform distribution of visible light.” Lundahl at 1:9-11. To achieve this uniformity, Lundahl utilizes the light distribution pattern illustrated in Fig. 2 (which has been highlighted, annotated, and rotated 90° to better illustrate):  Lundahl, Fig. 2.
Claim 1(d): “one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel,” 180. As shown in Figure 1 of Larsen, one of the at least five panels is positioned as the center panel, with two or more of the remaining panels configured to be angled relative to the center panel.  Larsen, Fig. 1.	Claim 1(d): “one of the at least five panels positioned as a center panel configured to face the treatment surface, and two or more of the at least five panels being configured to be angled relative to the center panel,” 465. As shown in Figure 1 of Larsen, one of the at least five panels is positioned as the center panel, with two or more of the remaining panels configured to be angled relative to the center panel.  Larsen, Fig. 1.

Because the IPR proceeding and the ITC Investigation involve the same claims, prior art combinations, arguments, and evidence, factor 4 weighs strongly in favor of discretionary denial. *See Fintiv* at 12-13; *see also Fitbit* at 18 (weighing

factor 4 in favor of denial of institution based on “concerns of inefficiency and the possibility of conflicting decisions”).³

5. Factor 5 weighs strongly against institution because the parties in this IPR are the same parties in the ITC proceeding.

Factor 5 concerns whether the petitioner and the respondent in the parallel ITC proceeding are the same party. *Fintiv* at 13.

The parties here are the same parties proceeding before the ITC. *See* Petition; EX1020. Where the parties before the PTAB are the same as those in the parallel proceeding, the fifth *Fintiv* factor weighs strongly in favor of discretionarily denying institution. *SK Innovation II* at 21.

6. Factor 6 weighs against institution because the principles of efficiency and economy outweigh the Petition’s merits.

Factor 6 relates to other circumstances that impact the Board’s exercise of discretion, including the merits. *Fintiv* at 14. At the outset, the Guidance Memo

³ The Petitioner has not filed, nor indicated any plan to file, a *Sotera* stipulation. *See Sotera Wireless, Inc. v. Masimo Corporation*, IPR2020-01019, Paper 12 (PTAB Dec. 1, 2020) (precedential). Patent Owner reserves the right to request reply briefing in the event Patent Owner elects to file a *Sotera* stipulation along with its opposition brief.

clarifies that the *Fintiv* factors “are part of a balanced assessment of all the relevant circumstances in the case, including the strength of the merits. However, compelling merits alone is not dispositive of making an assessment.” Guidance Memo, 3.

But even if compelling merits alone were dispositive, there is no reasonable likelihood that the Petitioner would prevail with respect to at least 1 of the claims challenged in the Petition. Patent Owner’s merits briefing and supporting declarations setting forth the reasons why Petitioner’s Petition is deficient will be filed according to 37 C.F.R. §42.107(b). *See also* Guidance Memo, 2 (explaining that “the merits briefing schedule ... remain unchanged”). Patent Owner will demonstrate in its merits briefing that Petitioner has not shown that the challenged claims of the ’512 patent are obvious, including because Petitioner has applied the teachings of the references individually rather than addressing the combinations of references as required for obviousness.

To the extent Petitioner argues that the merits here ought to be viewed in light of the Board’s decision to institute review of the challenged claims of U.S. Patent 11,097,028 in IPR2024-01312, the argument has no merit. The claims of the ’028 patent and ’512 patent challenged here are different, and the challenged grounds are different. For example, challenged claims 1, 5, 20, and 21 of the ’028 patent recite “the five panels being positioned to allow treatment within approximately four inches of the treatment surface,” while the challenged ’512 claims do not; and

challenged claim 20 of the '512 patent recites “the illuminator is configured to output light at a variable irradiance density during treatment” and challenged claims 17-18 recite a “recess,” while the challenged '028 claims do not. In addition, the '028 patent grounds include the Bansal reference and do not include the Hente and Perutz references. Moreover, Patent Owner will present arguments in its merits briefing that differ from those presented in Patent Owner’s Preliminary Response of IPR2024-01312.

But more importantly, factor 6 alone does not outweigh the principles of efficiency and economy that favor avoiding duplication of efforts by the Board, ITC, and parties. Here, the parties and the ITC have already invested an enormous amount of resources in the parallel ITC Investigation. The ITC hearing is just two months away. *See* EX2031, 4. The ITC hearing and post-hearing briefing will conclude before the Board is expected to issue an Institution Decision. *Id.* And the ITC will issue a final determination at least *six months* before the Board is expected to issue a FWD. *Id.* In similar circumstances, the Board has found that “[o]n balance, and even assuming the merits of the Petition are sufficient, we determine that the facts underlying the sixth factor weigh in favor of exercising discretion to deny institution under §314.” *See Regeneron Pharmaceuticals, Inc. v. Novartis Pharma AG, et al.*, IPR2020-01317, Paper 15 at 23-24 (PTAB Jan. 15, 2021) (“Even assuming that the Petition has merit, instituting review in this proceeding will do little to resolve the

disputes between the parties and achieve efficient resolution.”); *see also Roku* at 16 (“We have reviewed Petitioner’s unpatentability arguments and, based on the limited record before us, we do not find that the merits outweigh the other *Fintiv* factors favoring exercising our discretion to deny institution.”); *SK Innovation I* at 15-16 (determining that “the *Fintiv* factors, on balance, weigh in favor of discretionary denial” even where Petitioner argued that “[t]he Board has already considered the grounds asserted in the [present] Petition and found them meritorious”).

Under a balanced assessment of the *Fintiv* factors, with factors 1-5 strongly favoring discretionary denial and factor six nonetheless favoring discretionary denial, the holistic approach articulated in *Fintiv* favors discretionary denial.

C. Summary Regarding *Fintiv* Factors

Factor 1	Weights strongly against institution
Factor 2	Weights strongly against institution
Factor 3	Weights strongly against institution
Factor 4	Weights strongly against institution
Factor 5	Weights strongly against institution
Factor 6	Weights against institution

In summary, a holistic assessment of all six *Fintiv* factors weighs against institution. *See, e.g., SAP America, Inc. v. Cyandia, Inc.*, IPR2024-01496, Paper 13 at 10-11 (PTAB Apr. 7, 2025) (finding that “a holistic weighing of all six *Fintiv* Factors warrants our exercise of discretion under §314(a) to deny institution of review so that the entire dispute between the parties may be resolved in Litigation”).

The ITC hearing involving the same claims, grounds, and arguments will occur before an institution decision and the ITC's final determination will pre-date the expected FWD by more than six months. Further, the level of investment, both in cost and time, in the parallel ITC Investigation has been high. Instituting review under these "facts and circumstances here would be an inefficient use of Board resources." *NHK Spring Co., Ltd. v. Intri-Plex Technologies, Inc.*, IPR2018-00752, Paper 8 at 19–20 (PTAB Sept. 12, 2018) (precedential). Under 35 U.S.C. §314(a), institution should be denied.

III. CONCLUSION

For the foregoing reasons, Patent Owner respectfully requests that the Board deny institution of the Petition.

Dated: April 11, 2025

Respectfully submitted,

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CERTIFICATION UNDER 37 C.F.R. § 42.24(d)

I hereby certify that this paper, excluding the portions exempted under 37 C.F.R. § 42.24(a), has 3,502 words as counted by Microsoft Word 365, the word-processing system used to prepare this paper.

Dated: April 11, 2025

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CERTIFICATE OF SERVICE

Pursuant to 37 C.F.R. § 42.6(e), the undersigned certifies that on April 11, 2025, a complete copy of the foregoing was served on counsel of record for Petitioner by filing this document through P-TACTS and by sending this document via electronic mail to the following addresses:

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