

UNITED STATES INTERNATIONAL TRADE COMMISSION

Washington, D.C.

In the Matter of

**CERTAIN PHOTODYNAMIC THERAPY
SYSTEMS, COMPONENTS THEREOF,
AND PHARMACEUTICAL PRODUCTS
USED IN COMBINATION WITH THE
SAME**

Inv. No. 337-TA-1411

**ORDER NO. 23: INITIAL DETERMINATION GRANTING MOTION FOR
SUMMARY DETERMINATION ON THE SATISFACTION OF
ECONOMIC PRONG OF DOMESTIC INDUSTRY**

(June 25, 2025)

On May 2, 2025, complainant Sun Pharmaceutical Industries, Inc. (“Sun Pharma”) moved for summary determination on the satisfaction of economic prong of domestic industry (Motion No. 1411-13). Respondents Biofrontera Inc., Biofrontera Pharma GmbH, Biofrontera AG, and Biofrontera Bioscience GmbH (collectively, “respondents”) oppose.

I. LEGAL PRINCIPLES

Summary determination is appropriate when there is no genuine issue as to any material fact and the moving party is entitled to a determination as a matter of law. *See* 19 C.F.R. § 210.18. “The determination sought by the moving party shall be rendered if pleadings and any depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a summary determination as a matter of law.” *Id.* at § 210.18(b). In determining whether there is a genuine issue of material fact, “the evidence must be viewed in the light most favorable to the party opposing the motion with doubts resolved in favor of the nonmovant.” *Crown Operations Int’l, Ltd. v. Solutia, Inc.*, 289 F.3d 1367, 1374 (Fed. Cir. 2002) (citations omitted). The Commission

has analogized summary determination to summary judgment, wherein “the evidence of the nonmovant is to be believed, and all justifiable inferences are to be drawn in his favor.” *Certain Carburetors and Products Containing Such Carburetors*, Inv. No. 337-TA-1123, Comm’n Op. at 5-6 (Oct. 28, 2019) (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 481 F.3d 1371, 1377 (Fed. Cir. 2007) (citing *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986))). Where the moving party bears the burden of proof on a particular issue, the moving party must show that there is no genuine issue of material fact as to every element. *See Meyers v. Asics Corp.*, 974 F.2d 1304, 1307 (Fed. Cir. 1992).

Section 337(a)(3) sets forth the following economic criteria for determining the existence of a domestic industry in such investigations:

(3) For purposes of paragraph (2), an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned –

- (A) significant investment in plant and equipment;
- (B) significant employment of labor or capital; or
- (C) substantial investment in its exploitation, including engineering, research and development, or licensing.

19 U.S.C. § 1337(a)(3). Because the statutory criteria are listed in the disjunctive, satisfaction of any one of them will be sufficient to meet the economic prong of the domestic industry requirement. *See InterDigital Commc’ns*, 707 F.3d at 1303 n.4; *Certain Variable Speed Wind Turbines and Components Thereof*, Inv. No. 337-TA-376, Comm’n Op. at 15, USITC Pub. No. 3003 (Nov. 1996).

II. ANALYSIS

Sun Pharma relies on internal investments as well as payments made to contractors for

satisfaction of the economic prong of the domestic industry requirement under Sections 337(a)(3)(B) and (C). For the reasons discussed below, Sun Pharma has satisfied the economic prong of the domestic industry requirement under Sections 337(a)(3)(B) and (C).

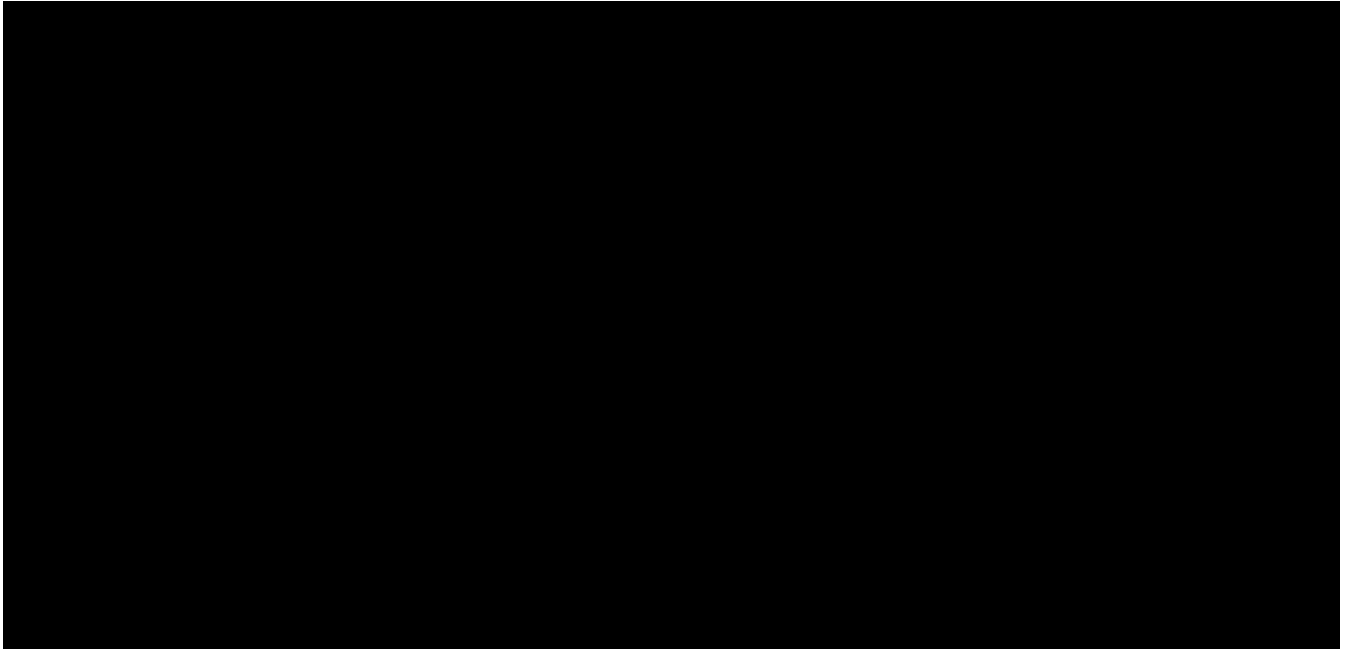
A. Sun Pharma's Internal Investments Under Section 337(a)(3)(B)

Sun Pharma spent approximately [REDACTED] on internal labor expenditures, including regulatory [REDACTED] and research and development [REDACTED] labor, from 2021 through June 25, 2024. Mot. at 8, Table 1; *see also* Mot. at 8-13. Sun Pharma's R&D employees perform product engineering, electronics technician work, medical science liaison, medical information and medical affairs work, and publications work, and Sun Pharma's regulatory employees perform FDA compliance work, including preparation and submission of documentation to the FDA and facilitating FDA approval for product release. Mot. at 11. Sun Pharma's three PDT products include the BLU-U® 4170D device, the BLU-U® 4710E device, and Levulan® Kerastick®. Only the BLU-U® 4710E device is relied on for domestic industry. No Sun Pharma employee that works on the BLU-U® 4170E is located outside of the United States. Mot. Ex. 5 (Albert Decl.) at ¶ 13.

Sun Pharma maintains accounting records in an SAP system, from which it produced data in the form of Excel spreadsheets in this Investigation. Mot. Ex. 6 (Albert Dep. Tr.) at 23:2–10, 43:20–44:11; Mot. Ex. 5 (Albert Decl.) at ¶ 19. Sun Pharma produced four spreadsheets relating to annual employee compensation for United States-based Sun Pharma personnel working on PDT products—*i.e.*, the BLU-U® 4170D device, the BLU-U® 4710E device, and Levulan® Kerastick®. Mot. Ex. 20 (FY 2022 Sun Pharma Salary spreadsheet); Mot. Ex. 21 (FY 2023 Sun Pharma Salary spreadsheet); Mot. Ex. 22 (FY 2024 Sun Pharma Salary spreadsheet); Mot. Ex. 23 (FY 2025 Sun Pharma Salary spreadsheet). [REDACTED]

[REDACTED] Mot. Ex. 6 (Albert Dep. Tr.) at 46:1–22. The data is presented on a fiscal year basis,

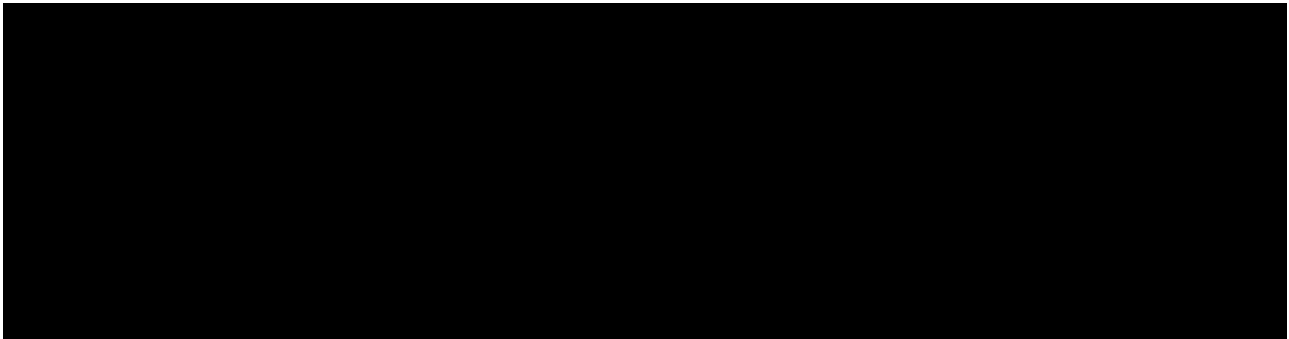
which for Sun Pharma runs from April 1st through March 31st. Mot. Ex. 6 (Albert Dep. Tr.) at 20:13–15. All of the employees listed in these records work in the United States. Mot. Ex. 6 (Albert Dep. Tr.) at 45:20–22. As shown in the table below, each salary spreadsheet categorizes Sun Pharma employees by their job function, *e.g.*, R&D, regulatory, customer service, and marketing.



Mot. at 10, Fig. 3.

As Mr. Zvi Albert, Sun Pharma’s Chief Financial Officer, explained, Sun Pharma allocated each employee’s time to the PDT business, which includes work related to the BLU-U® 4170, BLU-U® 4170E, and Levulan®. Mot. Ex. 6 (Albert Dep. Tr.) at 48:3–19. Each employee’s time, and corresponding compensation, was then further allocated to Sun Pharma’s specific PDT products. The specific percentage of each employee’s time allocated to a product was determined by Mr. Scott Lundahl, the technical lead on the product, for the technical activities, and Mr. Ron Groff, the head of product support, for product support and customer service activities. Mot. Ex. 6 (Albert Dep. Tr.) at 24:12–25:15; 46:1–52:4. Because the compensation data was provided on a fiscal year basis (April 1 – March 31), Dr. Vander Veen adjusted the totals to coincide with

calendar years. Those adjusted amounts are shown in Table 1, the relevant portion reproduced below.



Mot. at 8, Table 1. As the table above shows, Sun Pharma spent approximately [REDACTED] on internal labor expenditures, including regulatory [REDACTED] and research and development [REDACTED] labor, from 2021 through June 25, 2024.

Respondents do not raise any genuine factual issues concerning Sun Pharma's internal labor expenditures related to BLU-U® 4170E. *See generally* Opp. at 8-22 (not disputing the facts discussed above). However, respondents argue that Sun Pharma's BLU-U® 4170E investments compared to Sun Pharma's overall R&D expenses are not substantial or significant. Opp. at 14–21. However, such a comparison is not appropriate where a company has a diversified product portfolio such as Sun Pharma. See Ex. 19 (Vander Veen Opening Rpt.) at Tab 9 (showing different products offered by Sun Pharma); *Certain Mobile Electronic Devices*, Inv. No. 337-TA-794, Initial Determination at 604–05 (Oct. 3, 2012) (rejecting a comparison of claimed investments to overall operations because “such an analysis is not a requirement” and “such a comparison would hurt large, diversified companies that produce a wide range of products”).

Respondents similarly argue that Sun Pharma's R&D investments in the BLU-U® 4170E compared to Levulan® R&D investments or revenue are not substantial or significant. Opp. at 15–16. Again, this comparison is misguided. While Levulan® can be used with the BLU-U® lamps, they are different types of products—one is a pharmaceutical while the other is a medical

device. Thus, Levulan® and the BLU-U® lamps have different revenue structures (recurring versus one-time cost) and development costs. The relevant comparison to determine whether the market for PDT illuminators is significant to Sun Pharma is to determine how much of the revenue from the older lamp Sun Pharma is reinvesting in its next generation lamp. Here, as Dr. Vander Veen explained, Sun Pharma's purely domestic investments in R&D related to the BLU-4170E have a high investment-to-revenue ratio when compared to the revenues being generated by its current PDT illuminator—the BLU-U® 4170. Because the BLU-U® 4170E is not currently being sold, Dr. Vander Veen determined what percentage of the revenues generated by the current BLU-U® 4170 illuminator is being reinvested by Sun Pharma into the research and development of its next generation BLU-U® 4170E device. He determined that Sun Pharma spent ████████ of its revenues from the BLU-U® 4170 on R&D for the BLU-U® 4170E,¹ representing a substantial reinvestment of revenues in its next-generation device. Mot. at 30, Table 8.

There is no genuine dispute with respect to the significance of Sun Pharma's investments in research and development, testing, manufacturing services, and regulatory work for the BLU-U® 4170E. All of Sun Pharma's investments related to the BLU-U® 4170E are made in the United States. All of Sun Pharma's employees working on R&D and regulatory functions related to the BLU-U® 4170E device are located in the United States. Mot. Ex. 6 (Albert Dep. Tr.) at 43:9–45:8. All of the R&D, testing, and regulatory activities undertaken by third party contractors (discussed in detail below) that Sun Pharma paid for occurs in the United States. Mot. Ex. 5 (Albert Decl.) ¶ 10; Mot. Ex. 25 (Bacon Decl.) ¶ 7–8. All of the manufacturing services Sun Pharma paid for (discussed in detail below), occurs in the United States. Mot. Ex. 56 (Albert Decl. (May 1, 2025)) ¶ 3; Mot. Ex. 13 (Lundahl Decl.) ¶ 19; Mot. Ex. 40 (Briggs Decl.) ¶ 7–9. Thus, 100% of

¹ He determined the percentage by dividing Sun Pharma's R&D investments in the BLU-U® 4170E from FY2020-2024 by BLU-U® 4170 revenues for the same period.

the value added to the BLU-U® 4170E is created by Sun Pharma's domestic investments. I find that Sun Pharma's value-added analysis suggests its domestic investments related to the patented articles are significant. *See Male Prophylactic Devices*, Comm'n Op. at 43. Additionally, as discussed above, Sun Pharma's R&D investments in labor and capital represent [REDACTED] reinvestment of revenues from the current BLU-U® 4170 device into R&D for the next generation BLU-U® 4170E device.

Sun Pharma has satisfied the economic prong of the domestic industry requirement under Section 337(a)(3)(B).

B. Sun Pharma's Contractor Investments Under Section 337(a)(3)(B)

[REDACTED]

Sun Pharma argues that approximately [REDACTED] in payments to [REDACTED] [REDACTED] which were later acquired by [REDACTED] [REDACTED] should be included as domestic industry investments. Mot. at 8, Table 1; Mot. at 13–15. [REDACTED] assisted in the design and development of BLU-U® 4170E including sizing, spacing, electronic feedback, and the mechanical design of the BLU-U® 4170E prototype to achieve the desired wavelength with the LED light sources. Mot. Ex. 25 ([REDACTED] Decl.) ¶ 4; Mot. Ex. 26 ([REDACTED] Dep. Tr.) at 24:1–8, 29:12–30:13, 77:8–79:19; Mot. Ex. 27 (Lundahl Dep. Tr.) at 73:5–22; Mot. Ex. 14 (Carota Dep. Tr.) at 38:18–39:10, 55:1–11.

Respondents do not raise any genuine factual issues but makes a legal argument that “Sun Pharma cannot claim stale investments which dwindled years ago to establish a domestic industry.” Opp. at 10. Respondents are misguided. As the Federal Circuit has stated, “[t]here is nothing in the statutory language that supports [a] bright line rule for rejecting research expenditures that are made more than five years earlier.” *Hyosung TNS Inc. v. ITC*, 926 F.3d 1353, 1362 (Fed. Cir. 2019). Past expenditures can be counted so long as those investments pertain to

articles protected by the asserted patents and “the complainant is continuing to make qualifying investments at the time the complaint is filed.” *Id.* at 1361 (quoting *Certain Television Sets, Television Receivers, Television Tuners, and Components Thereof*, Inv. No. 337-TA-910, 2015 WL 6755093, at *36 (Oct. 30, 2015)). Here, all of Sun Pharma’s investments dating back to 2016 were made in order to develop the BLU-U® 4170E that as of February 2025 merely needs regulatory approval to be commercialized. Indeed, in the six months leading up to the complaint, Sun Pharma invested over [REDACTED] to get the BLU-U® 4170E to this final stage before commercial release.

But even if payments to [REDACTED] are excluded, the evidence supports that Sun Pharma’s internal labor expenditures related to BLU-U® 4170E alone satisfy the economic prong of the domestic industry requirement under Section 337(a)(3)(B).

[REDACTED]

Sun Pharma argues that approximately [REDACTED] in payments and future payments to [REDACTED] should be included as domestic industry investments. Mot. at 8, Table 1; Mot. at 17–19, 35. In 2021, in preparation for the commercial release of the BLU-U® 4170E, Sun Pharma entered into a Development and Contract Manufacturing Agreement with [REDACTED] for the manufacture of BLU-U® 4170E devices. Mot. Ex. 38 ([REDACTED] [REDACTED]). [REDACTED] is a manufacturer based in [REDACTED], and provides labor, engineering services, and equipment for manufacturing the BLU-U® 4170E. Mot. Ex. 13 (Lundahl Decl.) ¶ 19. To support its commercial launch, Sun Pharma also entered into a purchase order with [REDACTED] for an additional [REDACTED] [REDACTED] to manufacture [REDACTED] of the BLU- U® 4170E. Mot. Ex. 40 [REDACTED] Decl. ¶ 6).

Respondents argue that “despite Sun Pharma’s planned [REDACTED] launch date for the

BLU-U® 4170E, the product has yet to be commercially launched. Sun Pharma has paid none of the [REDACTED] from the purchase order to [REDACTED], and has received none of the units in the order,” and that “Sun Pharma cites no precedent for its argument that it can claim amounts that it has not invested (*i.e.*, paid) for products which have not been delivered.” Opp. at 10.

In determining whether there is a genuine issue of material fact, “the evidence must be viewed in the light most favorable to the party opposing the motion with doubts resolved in favor of the nonmovant.” *Crown Operations Int’l*, 289 F.3d at 1374. Given the lack of information concerning how much work has been completed, there are genuine issues of material fact with respect to the [REDACTED] purchase order that has not been paid. Thus, it is appropriate to subtract the purchase order amount at this time. However, even if this amount is subtracted, approximately [REDACTED] is cognizable [REDACTED] domestic industry investment. And even if [REDACTED] is excluded, the evidence supports that Sun Pharma’s internal labor expenditures related to BLU-U® 4170E alone satisfy the economic prong of the domestic industry requirement under Section 337(a)(3)(B).

[REDACTED]; and Other Contractors

Sun Pharma argues that approximately [REDACTED] in payments to [REDACTED] [REDACTED] should be included as domestic industry investments. Mot. at 8, Table 1; Mot. at 15–16. [REDACTED] is a certification company which performed product safety evaluations on the BLU-U® 4170E, including electrical & mechanical construction review and testing, as well as evaluating the device for compliance with recognized industry standards and safety requirements. Mot. Ex. 5 (Albert Decl.) ¶ 22; Mot. Ex. 36 ([REDACTED] Quote for Compliance Testing of BLU- U, Model 4170E). This work was carried out at [REDACTED] [REDACTED] location. Mot. Ex. 13 (Lundahl Decl.) ¶ 20.

Sun Pharma argues that approximately [REDACTED] in payments to [REDACTED]

██████████ should be included as domestic industry investments. Mot. at 8, Table 1; Mot. at 16–17. ██████████ is an Assurance, Testing, Inspection and Certification company based in ██████████ ██████████ provided safety compliance services with various industry standards for the BLU-U® 4170E device at Sun Pharma’s direction. Mot. Ex. 13 (Lundahl Decl.) ¶ 21; Mot. Ex. 5 (Albert Decl.) ¶ 23; Mot. Ex. 10 (Boyajian Dep. Tr.) at 163:4–15.

Sun Pharma argues that approximately ██████████ in payments to ██████████ should be included as domestic industry investments. Mot. at 8, Table 1; Mot. at 21–22. Sun Pharma contracted with ██████████, a custom plastic injection molding company based in ██████████, to manufacture certain parts for the BLU-U® 4170E device.

Sun Pharma argues that approximately ██████████ in payments to three additional contractors ██████████ should be included as domestic industry investments. Mot. at 8, Table 1; Mot. at 19–21. Sun Pharma contracted with these individuals for regulatory consulting and pre-launch compliance activities for the BLU-U® 4170E. Sun Pharma paid ██████████ to provide Quality Assurance consulting for the BLU-U® 4170E device in the U.S. Mot. Ex. 56 (Albert Decl. (May 1, 2025)) ¶ 4; Mot. Ex. 43 (Contract with ██████████); Mot. Ex. 44 (Vander Veen Dep. Tr.) at 109:18–110:4; Mot. Ex. 19 (Vander Veen Rpt.) at ¶ 69 (citing conversation with Mr. Albert and Mr. Lundahl). ██████████ does business as ██████████, and provided Sun Pharma with expert opinion on regulatory consulting services for the BLU-U® 4170E. Mot. Ex. 45 (Consulting Agreement between Sun Pharma and ██████████ ██████████ ██████████ ██████████ Sun-ITC-0163993); Mot. Ex. 44 (Vander Veen Dep. Tr.) at 110:5–11; Mot. Ex. 19 (Vander Veen Rpt.) at ¶ 69 (citing conversation with Mr. Albert and Mr. Lundahl). Sun Pharma also retained ██████████, who does business as ██████████ ██████████ to provide regulatory support for preparation and submission of

the 510(k) application to the FDA as well as the Premarket Approval Application, including review of the applications for submission. Mot. Ex. 56 (Albert Decl. (May 1, 2025)) ¶ 5; Mot. Ex. 46 (██████████ Proposal for Regulatory Support); Mot. Ex. 44 (Vander Veen Dep. Tr.) at 110:12–17; Mot. Ex. 19 (Vander Veen Rpt.) at ¶ 69 (citing conversation with Mr. Albert and Mr. Lundahl).

I find that if these contractor expenses are excluded, the evidence supports that Sun Pharma’s internal labor expenditures related to BLU-U® 4170E alone satisfy the economic prong of the domestic industry requirement under Section 337(a)(3)(B).²

C. Domestic Industry in the Process of Being Established

Sun Pharma argues that “to the extent there is any doubt that Sun Pharma’s domestic industry exists because the BLU-U® 4170E is not yet available, Sun Pharma’s investments alternatively establish a domestic industry in the process of being established.” Mot. at 32. Respondents argue that “Sun Pharma relies on the same investments to show a domestic industry

² In addition to calculating Sun Pharma’s labor and capital expenditures related to the BLU-U® 4170E under prong (B), Dr. Vander Veen allocated approximately ██████████ in R&D investments under prong (C). Mot. at 22, Table 6. To calculate investments under prong (C), Dr. Vander Veen excluded the manufacturing expenses to ██████████ from his labor and capital investments. These remaining expenditures relate to the design, development, engineering, and regulatory activities necessary for the launch of the BLU-U® 4170E. As Sun Pharma’s technical expert Dr. Nan Jokerst has shown, the BLU-U® practices and embodies the claims of the asserted patents. Mot. Ex. 49 (Jokerst Opening Rpt.) at ¶¶ 140–207; 368–422.

Respondents argue that “Sun Pharma has not shown a nexus between its claimed investments in the BLU-U® 4170E and the Asserted Patents, which is required under subsection (C).” Opp. at 12. I note respondents’ arguments appear to be related to technical prong rather than economic prong, which may be addressed ultimately in an initial determination or in a determination by the Commission.. *See, e.g., Certain Pouch-Type Battery Cells, Battery Modules, and Battery Packs, Components Thereof, and Products Containing the Same*, 337-TA-1179, Initial Determination at 6 (Dec. 14, 2020) (administrative law judges “routinely consider[s] these prongs separately and ha[ve], in fact, issued determinations finding that the economic prong is met, even if the technical prong is not”). Nevertheless, I need not reach prong (C) because I have found that Sun Pharma has satisfied the economic prong of the domestic industry requirement under Section 337(a)(3)(B).

at the time of filing of the Complaint that it relies on to argue that there is a domestic industry in the process of being established,” and “[t]herefore, Sun Pharma fails to show a domestic industry in the process for the same reasons it failed to show a domestic industry at the time of the Complaint.” Opp. at 21. As noted above, Sun Pharma has satisfied the economic prong of the domestic industry requirement under Section 337(a)(3)(B) without regard to expenditures alleged to be tied to an industry in the process of being established. Therefore, I do not reach whether Sun Pharma has shown a domestic industry in the process of being established.

* * *

Accordingly, it is my initial determination that Sun Pharma’s motion for summary determination be granted.

Pursuant to 19 C.F.R. § 210.42(h), this Initial Determination shall be the determination of the Commission unless a party files a petition for review of the initial determination pursuant to 19 C.F.R. § 210.43(a), or the Commission, pursuant to 19 C.F.R. § 210.44, orders, on its own motion, a review of the initial determination on certain issues herein.

Within seven days of the date of this document, the parties shall jointly submit a single proposed public version of this document with any proposed redactions indicated in red. If the parties submit excessive redactions, they may be required to provide declarations from individuals with personal knowledge, justifying each proposed redaction and specifically explaining why the information sought to be redacted meets the definition for confidential business information set forth in 19 C.F.R. § 201.6(a). To the extent possible, the proposed redactions should be made electronically, in a single PDF file using the “Redact Tool” within Adobe Acrobat. The proposed redactions should be submitted as “marked” but not yet “applied.” The proposed redactions should be submitted via email to Moore1411@usitc.gov and not filed on EDIS.

SO ORDERED.


Bryan F. Moore
Administrative Law Judge

CERTIFICATE OF SERVICE

I, Lisa R. Barton, hereby certify that the parties listed have entered an appearance in the above captioned investigation, and a copy of the PUBLIC CERTIFICATE OF SERVICE was served upon the following parties via first class mail and air mail where necessary.

Document	Security	Document Type	Official Rec'd	Title
856425	Public	ID/RD - Other Than Final on Violation	07/10/2025 08:45 AM	Initial Determination Granting Motion for Summary Determination on the Satisfaction of Economic P...

Service Date: July 10, 2025

/s

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