

UNITED STATES INTERNATIONAL TRADE COMMISSION
Washington, D.C.

In the Matter of

**CERTAIN BALLOON DILATION
DEVICES, SYSTEMS, AND COMPONENTS
THEREOF**

Investigation No. 337-TA-1449

**NOTICE OF A COMMISSION DETERMINATION TO REVIEW IN PART A FINAL
INITIAL DETERMINATION FINDING A VIOLATION OF SECTION 337;
REQUEST FOR WRITTEN SUBMISSIONS ON THE ISSUES UNDER REVIEW
AND REMEDY, THE PUBLIC INTEREST, AND BONDING;
EXTENSION OF TARGET DATE**

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to review, in part, a final initial determination (“FID”) of the presiding administrative law judge (“ALJ”) finding a violation of section 337 of the Tariff Act of 1930, as amended. The Commission requests written submissions from the parties on the issues under review and submissions from the parties, interested government agencies, and other interested persons on the issues of remedy, the public interest, and bonding, under the schedule set forth below. The Commission has also determined to extend the target date for completion of the above-captioned investigation to November 13, 2026.

FOR FURTHER INFORMATION CONTACT: Paul Lall, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, S.W., Washington, D.C. 20436, telephone (202) 205-2043. Copies of non-confidential documents filed in connection with this investigation may be viewed on the Commission’s electronic docket (EDIS) at <https://edis.usitc.gov>. For help accessing EDIS, please email EDIS3Help@usitc.gov. General information concerning the Commission may also be obtained by accessing its Internet server at <https://www.usitc.gov>. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission’s TDD terminal, telephone (202) 205-1810.

SUPPLEMENTARY INFORMATION: On May 23, 2025, the Commission instituted this investigation based on a complaint filed by Entellus Medical, Inc. of Plymouth, Minnesota; Stryker Corporation of Portage, Michigan; and Stryker Sales, LLC of Portage, Michigan (collectively, “Complainants”). 90 FR 22,116-17 (May 23, 2025). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337 (“section 337”) based on the importation into the United States, the sale for importation, or the sale within the United States after importation of certain balloon dilation devices, systems, and components thereof by reason of infringement of one or more of claims 1-11, 14, 15, and 19-30 of U.S.

Patent No. 11,083,878 (“the ’878 patent”); claims 1-16, 18-22, 24, 25, 27, 29, and 30 of U.S. Patent No. 11,090,472 (“the ’472 patent”); and claims 1-4, 6-12, 15-20, and 22 of U.S. Patent No. 12,274,847 (“the ’847 patent”). *Id.* The Commission’s notice of investigation named the following respondents: Fiagon GmbH of Hennigsdorf, Germany; Fiagon AG Medical Technologies of Hennigsdorf, Germany; Fiagon NA Corporation of Austin, Texas; Fiagon NA, LLC of Austin, Texas; and Hemostasis, LLC of White Bear Lake, Minnesota (collectively, “Fiagon”). The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

On September 8, 2025, the ALJ held a *Markman* hearing on claim construction, and on December 8, 2025, the ALJ issued Order No. 15 construing certain claim terms. *See* Order No.15 (Dec. 8, 2025).

On January 29, 2026, the Commission terminated the investigation as to claims 2-11, 15, 19, 21, and 24-30 of the ’878 patent; claims 2-16, 18-22, 24, 25, 27, 29, and 30 of the ’472 patent; and claims 2-4, 6-10, 12, 15-20, and 22 of the ’847 patent. *See* Order No. 17 (Jan. 6, 2026), *unreviewed by* Comm’n Notice (Jan. 29, 2026).

The ALJ held an evidentiary hearing on January 14-16 and 20-21, 2026. As of the evidentiary hearing, the following claims remained in the investigation: claims 1, 14, 20, 22, and 23 of the ’878 patent; claim 1 of the ’472 patent; and claims 1 and 11 of the ’847 patent (collectively, “the Asserted Claims”).

On June 26, 2026, the presiding ALJ issued the FID, finding a violation of section 337 in the importation into the United States, the sale for importation, and/or the sale in the United States after importation of certain balloon dilation devices, systems, and components thereof with respect to certain claims of the asserted patents. Specifically, the FID finds that: 1) Complainants have satisfied the importation requirement for the accused products; 2) Complainants have shown infringement as to claims 1, 14, 20, 22, and 23 of the ’878 patent, claim 1 of the ’472 patent, and claims 1 and 11 of the ’847 patent; 3) Fiagon has not shown invalidity as to claims 1, 14, 20, 22, and 23 of the ’878 patent, claim 1 of the ’472 patent, or claims 1 and 11 of the ’847 patent; 4) Fiagon has not shown that the ’878, ’472 are unenforceable; and 5) Complainants have satisfied the technical and economic prongs of the domestic industry requirement for the ’878, ’472, and ’847 patents.

The FID also includes a Recommended Determination on Remedy and Bonding (“RD”). *Id.* at 168-74. The RD recommends that the Commission issue a limited exclusion order and cease and desist orders against all respondents in the event the Commission finds a violation of section 337. *Id.* at 168-72. The RD also recommends that the Commission impose a of 61% for certain accused products, but no bond for other accused products during the period of Presidential Review. *Id.* at 174.

On July 27, 2026, Complainants submitted a public interest statement pursuant to Commission Rule 210.50(a)(4), 19 C.F.R. § 210.50(a)(4). On the same day, Fiagon also submitted a public interest statement pursuant to Commission Rule 210.50(a)(4). On July 28, 2026, Congressman Bill Huizenga from Michigan submitted a letter responding to the

Commission's July 2, 2026 notice in the *Federal Register*. See 91 FR 40,588-89 (July 2, 2026). In addition, on July 29 and 30, 2026, Fiagon submitted separate letters from six doctors related to the public interest.

On July 10, 2026, Fiagon filed a petition for review of several of the FID's findings concerning claim construction, whether the accused articles are "articles that infringe," induced infringement, validity under the written description requirement, and obviousness. On July 17, 2026, Complainants filed a response to Fiagon's petition.

Having reviewed the record of the investigation, including the parties' petitions for review and related submissions, the Commission has determined to review the FID in part. Specifically, the Commission has determined to review the FID's findings that: 1) Complainants have satisfied the importation requirement for the accused products; 2) Complainants have established induced infringement of the Asserted Claims; 3) Fiagon failed to establish by clear and convincing evidence that any asserted claim is invalid for lack of written description under 35 U.S.C. § 112; 4) Fiagon failed to establish by clear and convincing evidence that any asserted claim is invalid as obvious under 35 U.S.C. § 103; and 5) Complainants have satisfied the economic prong of the domestic industry requirement for the '878, '472, and '847 patents.

In connection with the final disposition of this investigation, the statute authorizes issuance of, *inter alia*, (1) an exclusion order that could result in the exclusion of the subject articles from entry into the United States; and/or (2) cease and desist orders that could result in the respondents being required to cease and desist from engaging in unfair acts in the importation and sale of such articles. Accordingly, the Commission is interested in receiving written submissions that address the form of remedy, if any, that should be ordered. If a party seeks exclusion of an article from entry into the United States for purposes other than entry for consumption, the party should so indicate and provide information establishing that activities involving other types of entry either are adversely affecting it or likely to do so. For background, see *Certain Devices for Connecting Computers via Telephone Lines*, Inv. No. 337-TA-360, USITC Pub. No. 2843, Comm'n Op. at 7-10 (Dec. 1994). In connection with these findings, the Commission requests responses from the parties to the following questions:

- (1) Please explain whether and how the FID finds a violation of Section 337 based on Fiagon's own direct infringement of any Asserted Claim. Please discuss whether, including under the framework articulated by Commissioner Kearns in his Additional Views in *Certain High-Density Fiber Optic Equipment and Components Thereof*, Inv. No. 337-TA-1194, the imported components (namely those combined with U.S.-sourced components and assembled into complete VenSure devices/systems at Fiagon's site in Minnesota) should be considered articles that directly infringe the asserted claims of the '878 and '472 patents and therefore are "articles that infringe" under section 337. See FID at 17-18; *Certain High-Density Fiber Optic Equipment and Components Thereof*, Inv. No. 337-TA-1194, Comm'n Op. at 98-104, Additional Views of Chair Kearns Regarding "Articles that Infringe" (Aug. 23, 2021).
- (2) Complainants argued before the ALJ that Fiagon takes actions to instruct or encourage physicians and healthcare facilities to use the Accused Products in a

manner that constitutes direct infringement. The FID finds that the complaint, with its allegations of direct, induced, and contributory infringement, put Fiagon on notice of its infringement. Please identify evidence in the record showing that Fiagon took such actions after receipt of the complaint in this investigation.

The parties are invited to brief only the discrete issues requested above, with reference to the applicable law and limited to arguments and evidence in the existing evidentiary record. The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

The statute requires the Commission to consider the effects of that remedy upon the public interest. The public interest factors the Commission will consider include the effect that an exclusion order and cease and desist orders would have on: (1) the public health and welfare, (2) competitive conditions in the U.S. economy, (3) U.S. production of articles that are like or directly competitive with those that are subject to investigation, and (4) U.S. consumers. To the extent that any party in this investigation asserts that the proposed remedy would adversely impact the public interest, please identify and describe specific evidence supporting this assertion and where in the record such evidence was first submitted to the ALJ. If such evidence was not submitted to the ALJ, please explain why the Commission should give such evidence any weight at this stage in the investigation.

If the Commission orders some form of remedy, the U.S. Trade Representative, as delegated by the President, has 60 days to approve, disapprove, or take no action on the Commission's determination. *See* Presidential Memorandum of July 21, 2005, 70 FR 43251 (July 26, 2005). During this period, the subject articles would be entitled to enter the United States under bond, in an amount determined by the Commission and prescribed by the Secretary of the Treasury. The Commission is therefore interested in receiving submissions concerning the amount of the bond that should be imposed if a remedy is ordered.

WRITTEN SUBMISSIONS: Parties to the investigation, interested government agencies, and any other interested parties are encouraged to file written submissions on the issues of remedy, the public interest, and bonding. Such submissions should address the RD by the ALJ on remedy and bonding.

In its initial submission, Complainants are also requested to identify the remedy sought, and Complainants are requested to submit proposed drafts of remedial orders for the Commission's consideration. Complainants are further requested to provide the HTSUS subheadings under which the accused products are imported and to supply the identification information for all known importers of the products at issue in this investigation. All initial written submissions, from the parties and/or third parties/interested government agencies, and proposed remedial orders from the parties must be filed no later than close of business on **September 28, 2026**. All reply submissions must be filed no later than the close of business on **October 5, 2026**. Opening submissions from the parties are limited to **50** pages. Reply submissions from the parties are limited to **25** pages. All submission from third parties and/or

interested government agencies are limited to **10** pages. No further submissions on any of these issues will be permitted unless otherwise ordered by the Commission.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above. The Commission's paper filing requirements in 19 CFR 210.4(f) are currently waived. 85 FR 15798 (Mar. 19, 2020). Submissions should refer to the investigation number ("Inv. No. 337-TA-1449") in a prominent place on the cover page and/or the first page. (See Handbook for Electronic Filing Procedures, https://www.usitc.gov/documents/handbook_on_filing_procedures.pdf). Persons with questions regarding filing should contact the Secretary, (202) 205-2000.

Any person desiring to submit a document to the Commission in confidence must request confidential treatment by marking each document with a header indicating that the document contains confidential information. This marking will be deemed to satisfy the request procedure set forth in Rules 201.6(b) and 210.5(e)(2) (19 CFR 201.6(b) & 210.5(e)(2)). Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. Any non-party wishing to submit comments containing confidential information must serve those comments on the parties to the investigation pursuant to the applicable Administrative Protective Order. A redacted non-confidential version of the document must also be filed with the Commission and served on any parties to the investigation within two business days of any confidential filing. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this investigation may be disclosed to and used: (i) by the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel, solely for cybersecurity purposes. All contract personnel will sign appropriate nondisclosure agreements. All nonconfidential written submissions will be available for public inspection on EDIS.

The target date for completion of the investigation is extended to November 13, 2026.

The Commission's vote on this determination took place on September 14, 2026.

The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR Part 210).

By order of the Commission.



Lisa R. Barton
Secretary to the Commission

Issued: September 14, 2026