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 EXTEND THE DATE FOR DETERMINING WHETHER TO REVIEW A FINAL INITIAL DETERMINATION

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to extend to September 14, 2026, the date for the Commission's decision on whether to review a final initial determination ("FID") issued by the presiding administrative law judge ("ALJ").

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.

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. On July 17, 2026, Complainants filed a response to Fiagon's petition.

The Commission has determined to extend the deadline for determining whether to review the subject FID to September 14, 2026.

The Commission's vote on this determination took place on September 9, 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 9, 2026