



INTERNATIONAL TRADE COMMISSION

Certain Laparoscopic Surgical Staplers, Reload Cartridges, and Components Thereof

[Investigation No. 337-TA-1178]

Commission Determination to Review in Part a Final Initial Determination Finding a Violation of Section 337; Schedule for Filing Written Submissions on the Issues Under Review and on Remedy, Public Interest, and Bonding

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 the Administrative Law Judge's ("ALJ") final initial determination ("ID"), issued on June 8, 2021, finding a violation of section 337 in the above-referenced investigation as to two of the four asserted patents. The Commission requests briefing from the parties on certain issues under review, as indicated in this notice.

FOR FURTHER INFORMATION CONTACT: Benjamin S. Richards, Office of the General Counsel, U.S. International Trade Commission, 500 E Street, SW., Washington, D.C. 20436, telephone (202) 708-5453. 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 on (202) 205-1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on July 5, 2019, based on a complaint filed by Ethicon LLC of Guaynabo, PR; Ethicon Endosurgery, Inc. of Cincinnati, OH; and Ethicon US, LLC of Cincinnati, OH (collectively, "Ethicon"). 84 FR 32220 (July 5, 2019); *see also* 84 FR 65174 (Nov. 26, 2019) (amending the caption). The complaint alleged violations of section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, based on the importation into the United States, the sale for

importation, and the sale within the United States after importation of certain laparoscopic surgical staplers, reload cartridges, and components thereof by reason of infringement of one or more claims of U.S. Patent Nos. 9,844,379 (“the ’379 patent”); 9,844,369 (“the ’369 patent”); 7,490,749 (“the ’749 patent”); 8,479,969 (“the ’969 patent”); and 9,113,874 (“the ’874 patent”). 84 FR at 32220. The Commission’s notice of investigation named the following as respondents: Intuitive Surgical Inc., of Sunnyvale, CA; Intuitive Surgical Operations, Inc., of Sunnyvale, CA; Intuitive Surgical Holdings, LLC, of Sunnyvale, CA; and Intuitive Surgical S. De R.L. De C.V. of Mexicali, Mexico (collectively, “Intuitive”). *Id.* The Office of Unfair Import Investigations is not participating in this investigation. *Id.*

On October 23, 2020, the ALJ granted Ethicon’s motion for leave to amend the complaint, case caption, and Notice of Investigation to reinstate the original plain English statement of the category of accused products, as well as the original case caption, and to reincorporate Intuitive’s laparoscopic surgical staplers and components thereof as articles to be excluded. Order No. 14, *unreviewed by Comm’n Notice* (Nov. 21, 2019). As initially instituted, the investigation covered reload cartridges for those staplers, but not the actual staplers themselves. *See id.*

On October 29, 2019, the ALJ conducted a *Markman* hearing. Thereafter, on January 7, 2020, the ALJ issued Order No. 15, which construed various terms in the asserted patents.

On March 5, 2020, the ALJ granted Ethicon’s motion to terminate claim 1 of the ’379 patent and all claims of the ’749 patent from the investigation. *See Order No. 21, unreviewed by Comm’n Notice* (Mar. 25, 2020).

On April 21, 2020, Ethicon moved for leave to file a second amended complaint to include the Certificate of Correction for the ’379 patent. The ALJ granted Ethicon’s motion on May 6, 2020, and Ethicon filed its second amended complaint on May 7, 2020. *See Order No. 36; Doc. ID 709878.*

On June 8, 2021, the ALJ issued the subject ID on violation, which found a violation of section 337 based on infringement of the '369 and '379 patents by Intuitive. The ID found no violation based on the '969 and 874 patents. Also, on June 8, 2021, the ALJ issued his recommended determination on remedy and bonding. The ALJ recommended, upon a finding of violation, that the Commission issue a limited exclusion order, issue a cease and desist order, and impose a bond in the amount of zero percent of the entered value of any covered products imported during the period of Presidential review.

On June 21, 2021, Ethicon and Intuitive submitted petitions seeking review of the subject ID. On June 29, 2021, Ethicon and Intuitive submitted responses to the others' petitions.

Having examined the record of this investigation, including the ID, the petitions for review, and the responses thereto, the Commission has determined to review the ID with respect to (1) the ID's findings on claim construction, infringement, anticipation, obviousness, and enforceability for the '969 patent; and (2) the ID's findings on claim construction, infringement, and obviousness for the '369 patent. The Commission has determined not to review the remainder of the ID.

In connection with its review, Commission requests responses to the following questions. The parties are requested to brief their positions with reference to the applicable law and the existing evidentiary record.

1. Claim 24 of the '969 patent includes the terms "elongated shaft assembly" and "transmission assembly." Concerning these terms, identify where in the record, if anywhere:
 - a. The parties proposed constructions for these terms;
 - b. The parties argued in support of any constructions proposed; and
 - c. The ALJ construed these terms.
2. Concerning the terms "elongated shaft assembly" and "transmission assembly," indicate whether these terms should be construed according to their plain and

ordinary meaning. If these terms should be construed according to their plain and ordinary meaning, what is the plain and ordinary meaning of each term? If these terms should be construed otherwise, identify the correct mode of construction and the corresponding construction for each term. Identify with specificity the evidence of record that supports your contentions with particular emphasis on evidence intrinsic to the '969 patent.

- a. Explain whether the SureForm products meet these limitations under the parties' proposed constructions.
3. Does the evidence of record support the conclusion that persons of ordinary skill in the art with respect to the '969 patent were responsible for the decision to create a joint venture between PMI and Intuitive for the purpose of modifying the PMI i60 stapler to work with the da Vinci Si surgical system? Provide any citations to the record that support your contention.
4. Does the record indicate whether the Si EndoWrist 45 stapler is the subject of one or more patents? Identify any such patents.
5. Claim 22 of the '369 patent includes the term "elongate channel." Concerning that term, identify where in the record, if anywhere:
 - a. The parties proposed constructions for that term;
 - b. The parties argued in support of any constructions proposed; and
 - c. The ALJ construed that term.
6. Concerning the term "elongate channel," indicate whether these terms should be construed according to its plain and ordinary meaning? If this term should be construed according to its plain and ordinary meaning, what is the plain and ordinary meaning of the term? If the term should be construed otherwise, identify the correct mode of construction and the corresponding construction. Identify

with specificity the evidence of record that supports your contentions with particular emphasis on evidence intrinsic to the '369 patent.

- a. Explain whether the SureForm products meet this limitation under the parties' proposed constructions.
7. Claim 22 of the '369 patent includes the limitation: "means for guiding the at least one lower foot on the firing element out of the proximal channel opening into the internal passage upon initial application of a firing motion to the firing element." If the Commission determines that the corresponding structure for that limitation is limited to flat, as opposed to curved, chamfers and slopes, would the accused products practice this limitation?
 8. Concerning claims 22 and 23 of the '369 patent, Intuitive states in its petition for review that its proposed obviousness combination "includes each limitation of the asserted claims under Ethicon's theory of infringement." Identify what aspect of Intuitive's obviousness theory is dependent on Ethicon's theory of infringement and explain how it is dependent.
 9. If the Commission finds that Intuitive does not infringe claims 22 and 23 of the '369 patent, explain whether Intuitive's obviousness theories necessarily fail by virtue of their dependence on Ethicon's infringement theory.

The parties are not to brief other issues on review, which are adequately presented in the parties' existing filings.

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).

If the Commission contemplates some form of remedy, it must consider the effects of that remedy upon the public interest. The factors the Commission will consider include the effect that an exclusion order and/or 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. The Commission is therefore interested in receiving written submissions that address the aforementioned public interest factors in the context of this 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: The parties to the investigation are requested to file written submissions on the issues identified in this notice. 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 recommended determination by the ALJ on remedy and bonding.

In its initial submission, Complainant is also requested to identify the remedy sought and to submit proposed remedial orders for the Commission's consideration. Complainant is

further requested to state the dates that the Asserted Patents expire, 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. The initial written submissions and proposed remedial orders must be filed no later than close of business on **August 23, 2021**. Reply submissions must be filed no later than the close of business on **August 30, 2021**. Opening submissions are limited to 100 pages. Reply submissions are limited to 75 pages. No further submissions on 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 (March 19, 2020). Submissions should refer to the investigation number (Inv. No. 337-TA-1167) 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. A redacted non-confidential version of the document must also be filed simultaneously with 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 Commission vote for this determination took place on August 16, 2021.

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 210).

By order of the Commission.

Issued: August 16, 2021.

Lisa Barton,

Secretary to the Commission.

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