



INTERNATIONAL TRADE COMMISSION

Certain Laparoscopic Surgical Staplers, Reload Cartridges, and Components Thereof

[Investigation No. 337-TA-1167]

Final Determination Finding a Violation of Section 337 and Issuance of Remedial Orders; Suspension of Enforcement of the Remedial Orders Pending Final Resolution of a Final Written Decision by the Patent Trial and Appeal Board; and Termination of the Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission (the “Commission”) has determined that: (i) the respondents have violated section 337 of the Tariff Act of 1930, as amended, by importing, selling for importation, or selling in the United States after importation certain laparoscopic surgical staplers, reload cartridges, and components thereof that infringe complainants’ U.S. Patent No. 9,844,379 (“the ’379 patent”); (2) the appropriate remedies are a limited exclusion order and cease and desist orders; and (3) enforcement of said remedial orders will be suspended pending final resolution of a Final Written Decision by the Patent Trial and Appeal Board (“PTAB”) that the asserted claims of the ’379 patent are unpatentable. This investigation is terminated.

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; 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 Chief Administrative Law Judge (“CALJ”) 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 staplers themselves. *See id.*

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

On March 5, 2020, the CALJ 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 CALJ 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 CALJ issued the subject ID on violation, which found a violation of section 337 based on infringement of the asserted claims 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 CALJ issued his recommended determination on remedy and bonding. The CALJ recommended, upon a finding of violation, that the Commission issue a limited exclusion order, issue cease and desist orders, and impose a bond in the amount of zero percent (0%) 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. Intuitive's petition included a request for suspension of enforcement of any remedial orders directed to the '379 patent based on a Final Written Decision by the PTAB, in which the PTAB found all claims of the '379 patent unpatentable. *See Intuitive Surgical, Inc. v. Ethicon LLC*, IPR2020-00050, IPR2020-00051, Patent 9,844,379, Final Written Decision Determining All Challenged Claims Unpatentable (Mar. 26, 2021). On June 29, 2021, Ethicon and Intuitive submitted responses to the other's petitions.

On June 9, 2021, the Commission issued a notice soliciting public comments on the public interest factors, if any, that may be implicated if a remedy were to be issued in this investigation. 85 FR 30735 (May 20, 2020). The Commission received twelve submissions from the public in response to its notice.

On August 16, 2021, issued notice of its determination to review the ID in part 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 determined not to review the remainder of the ID, including the ID's determination that a violation of section 337 had occurred with respect to the '379 patent and that no violation occurred with respect to the '874 patent. In connection with its review of the ID, the Commission sought briefing from the parties on several questions germane to the issues on review and on remedy, bonding, and the public interest.

The parties filed their initial response to the Commission's review questions on August 23, 2021, and their respective reply briefs on August 30, 2021.

Having considered the parties' submissions, the ID, and the record in this investigation, the Commission has determined that Intuitive has violated section 337 by importing into the United States, selling for importation, or selling in the United States after importation certain laparoscopic surgical staplers, reload cartridges, and components thereof that infringe claims 2 and 3 of the '379 patent. The Commission has further determined to affirm, reverse, and take no position on certain portions of the ID, as explained in the Commission's opinion issued concurrently herewith.

The Commission has determined that the appropriate remedy is: (a) a limited exclusion order prohibiting the importation of certain laparoscopic surgical staplers, reload cartridges, and components thereof that infringe claims 2 and 3 of the '379 patent; and (b) cease and desist orders against Intuitive. The Commission has determined that the public interest factors enumerated in section 337(d)(1) and (f)(1) do not preclude issuance of the limited exclusion order or cease and desist orders. The Commission has also determined to set a bond in the amount of zero percent (0%) (*i.e.*, no bond) of the entered value of the excluded products imported during the period of Presidential review (19 U.S.C. 1337(j)).

The Commission has also determined to suspend enforcement of its remedial orders, including the bond provision, pending final resolution of a Final Written Decision issued by the PTAB on March 26, 2021, finding all claims of the '379 patent to be unpatentable. *See* 35 U.S.C. § 318(b); *Intuitive Surgical, Inc. v. Ethicon LLC*, IPR2020-00050, IPR2020-00051, Patent 9,844,379, Final Written Decision Determining All Challenged Claims Unpatentable (Mar. 26, 2021).

The Commission's orders and opinion were delivered to the President and United States Trade Representative on the day of their issuance.

The Commission vote for this determination took place on October 14, 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: October 14, 2021.

Lisa Barton,

Secretary to the Commission.

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