



PROGRAM MATERIALS

Program #36192

September 9, 2026

Not for the Faint of Heart! Navigating Fast-Paced Section 337 Investigations at the ITC

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5301 North Federal Highway, Suite 150, Boca Raton, FL 33487
Phone 561-241-1919

Not for the Faint of Heart! Navigating Fast -Paced Section 337 Investigations at the ITC

Gary Hnath
Partner

202-263-3040

ghnath@mayerbrown.com

Nan Zhang
Associate

212-506-2141

nzhang@mayerbrown.com



Presenters



Gary Hnath
Mayer Brown LLP



Nan Zhang
Mayer Brown LLP

Have you heard
of Section 337
before today's
program?

A. Yes

B. No

Have you been
involved in a
Section 337
case before
today's
program?

A. Yes

B. No

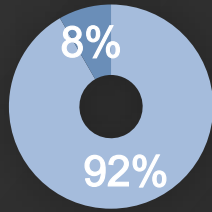
What is the U.S. International Trade Commission ("ITC")?

- Independent non-partisan, quasi-judicial federal agency
- Administers U.S. Trade remedy laws
- Provides U.S. Trade Representative and Congress with independent advice and information on matters of international trade and competitiveness
- Administers import injury investigations
- Oversees intellectual property-based import investigations under §337 of Tariff Act of 1930



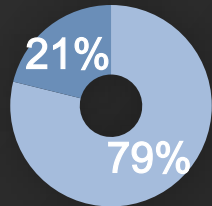
UNITED STATES INTERNATIONAL TRADE COMMISSION

2025 ITC Investigations



■ Patent

2026 ITC Investigations*



■ Patent

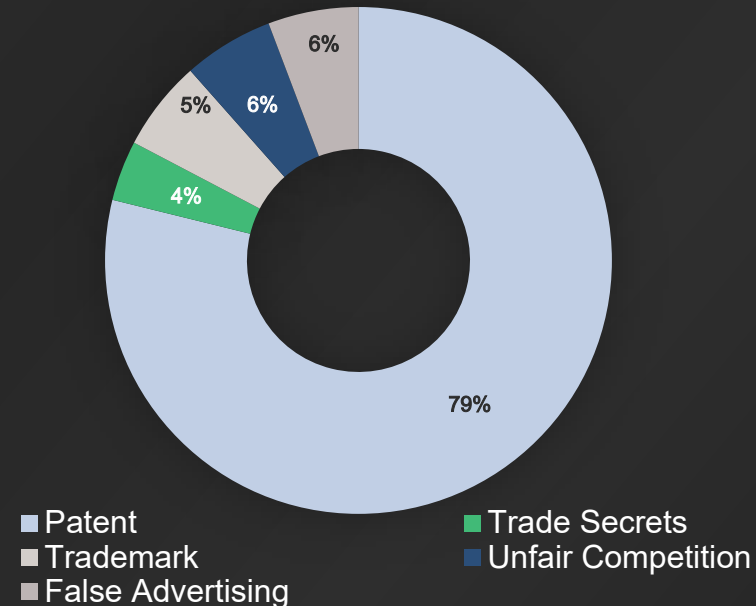
Section 337 Investigations

- May be based on any unfair act in the importation of articles into the United States
- Are most frequently used in patent cases involving imports that are alleged to infringe a U.S. patent

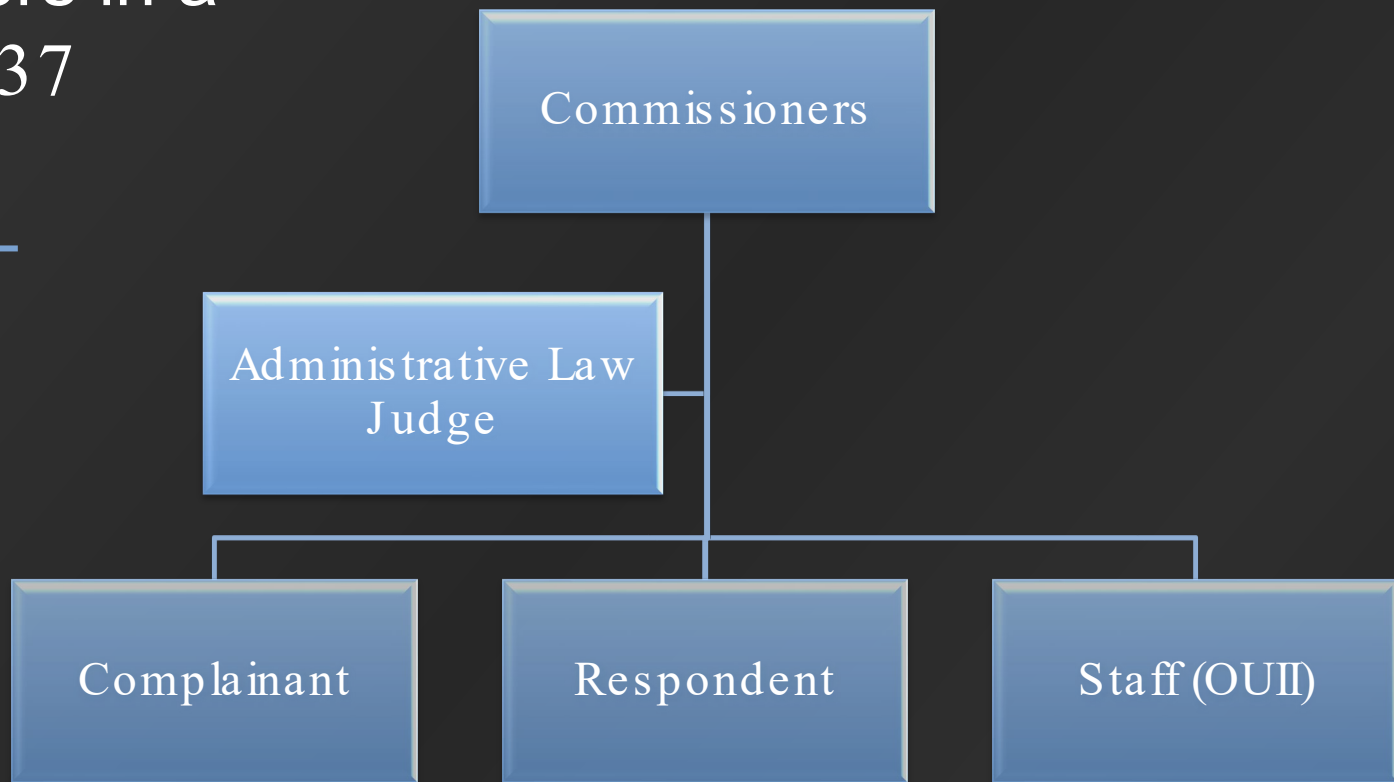
- Have also been based on Trademarks, Copyrights, Trade Secrets, Gray Market Goods, Unfair Competition, and Antitrust Violations, among others

Type of Inv.	Number
Trade Secrets	2
Trademarks	3
False Advertising	3
Unfair Competition	3

2026 ITC Investigations *



Key Players in a Section 337 Case



Key Players in a Section 337 Case

President / Office of
the U.S. Trade
Representative

Court of Appeals for
the Federal Circuit

U.S. Customs &
Border Protection

Elements of a Section 337 Case

To succeed, a complainant
must establish:

Existence of a
domestic industry

Importation of
products by a
respondent

Unfair act (such as
infringement of a
U.S. patent)

Remedy, bond
during Presidential
review, and public
interest

For non-statutory IP
(*e.g.*, trade secret
misappropriation),
Injury to a domestic
industry

Domestic Industry Requirements

- Requirements for existence of a domestic industry
 - Activities must relate to the patent at issue or articles protected by the patent
- A domestic industry exists in the U.S. if, with respect to the articles protected by the patent, there is in U.S. either
 - Significant investment in plant and equipment
 - Significant employment of labor or capital, or with respect to the asserted patent or
 - Substantial investment in its exploitation, including engineering, research and development, or licensing
 - Manufacturing in U.S. not required.
 - Sales and marketing alone not enough

Domestic Industry Requirements (*con't.*)

- What is “significant” investment and/or employment?
 - “[N]ot measured in the abstract or in absolute terms”
 - “[E]valuated in the context of the activities and how they are ‘significant’ to the articles protected by the intellectual property right.”
- “Technical prong” and “economic prong”
- “Technical prong”: complainant (or licensee) must practice at least one valid claim of asserted patent
- Complainants relying on licensing activities must demonstrate existence of articles practicing asserted patents. *Computers and Computer Peripheral Devices*(337-TA-841) (Jan. 2014)
 - Although covered product can be manufactured abroad.

Domestic Industry Requirements (*con't.*)

Even if “in the process of being established” the ITC generally looks at investments/activities at time complaint filed.

Thermoplastic Encapsulated Electric Motors, 337-TA-1073, Comm’n Op. (Aug. 12, 2019)

In one case, R&D expenditures 5 years before complaint filed were considered sufficient based on ongoing field service that would be otherwise insufficient.

Automated Teller Machines, 337-TA-972, Comm’n Op. (Nov. 30, 2016, *aff’d* Fed. Cir. 2019)

Domestic Industry Requirements (*con't.*)

Integrated Circuit Chips , Inv. No. 337-TA-859

Commission held domestic industry based on research and development must show both that:

- 1) it or its licensee produces an article that practices the asserted patent(s)
- 2) its U.S.-based R&D investments have a nexus to the asserted patent(s). R&D on unpatented features of article is insufficient.

Kinesiotherapy Devices (Fed. Cir. May 2015)

Reversed a finding of DI where value added in U.S. was relatively low but U.S.-sourced materials were critical to patented product

A Complainant cannot rely on amounts paid to contractors for materials or components sourced in U.S. to make patented article, but must prove actual expenditures in plant and equipment or labor by contractors

Commission cannot rely on qualitative factors alone in assessing whether investments and employment are “significant” or “substantial”

Domestic Industry Requirements (*con't.*)

Wuhan Healthgen Biotechnology Corp. (Fed. Cir. Feb. 2025)

Affirmed the Commission's finding that even small domestic industry investments can be significant and substantial.

The investment-to-revenue ratio can indicate whether an investment is significant and substantial.

Further support is whether all of the investments and other activities, like marketing, happen in the U.S.

Lashify, Inc. v. Int'l Trade Comm'n (Fed. Cir. 2025)

Reversed the Commission's decision on domestic industry. Federal Circuit held that expenses related to "labor and capital even when they are used in sales, marketing, warehousing, quality control, or distribution," may be included, since they qualify as "labor or capital" under Section 337.

Lashify builds on *Wuhan Healthgen Biotech* in expanding what a complainant can include as qualifying expenses to meet threshold for significant domestic investments in a domestic industry.

Lashify's Immediate Effects

- *Lashify* had an immediate effect on complainants successfully supplementing their domestic industry allegations with investments that previously would have only been seen as those of a mere importer.
 - *Oil Vaporizing Devices*, 337-TA-1392, Remand Initial Determination (July 18, 2025) (on remand of ID issued one day before *Lashify*, expanding scope of activities complainant may use to establish a domestic industry); Comm'n Op. (Feb. 3, 2026) (affirming the domestic industry showing, including pre-patent-issuance investments directed to the patented products, and finding a violation).

Lashify did not give complainants carte blanche for domestic industry

- Complainant's domestic industry must still practice the asserted patent claims.¹
- Investments must have a nexus to "the articles protected by the patent." Therefore, a complainant cannot pool spending across different products that do not all practice the same asserted patent(s).²
- Whether an investment is significant is still an evidentiary question.

Soft Projectile Launching Devices, 337-TA-1325 (Comm'n Op. Jan. 5, 2026)

- No violation: U.S. design, development, and labor investments were not "significant" under 337(a)(3)(B).
- The Commission applied a holistic significance inquiry under *Wuhan Healthgen*, required quantitative support, and rejected treating licensing expenditures as "capital."

¹ *Lashify*, 130 F.4th at 952–55.

² See *Zircon Corp. v. ITC*, Appeal No. 2022-1649, slip op. at 6–9 (Fed. Cir. May 8, 2024)

Practicing Different Patents Requires Separate Domestic Industry Analysis

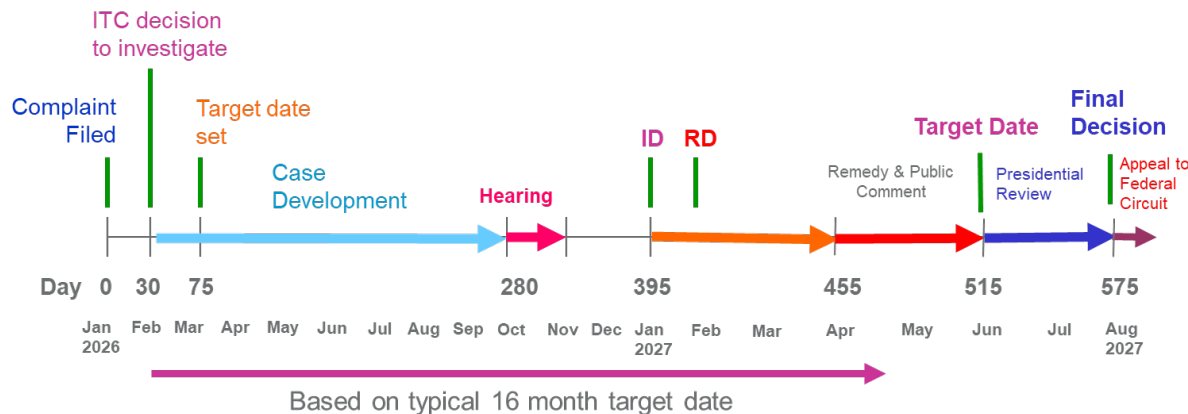
Replacement Automotive Lamps I & II, Inv. No. 337-TA-1291 & 1292 (3/7/2024 & 3/24/2024)

- Significance analysis must be conducted as to each product that is covered by a different patent.
- Significance must be calculated based on per-patent sales and cannot be fulfilled by looking at combined investments and sales revenue
- Complainant cannot not rely on the Chief ALJ's independent finding to fulfill its burden of proof

Zircon Corp. v. ITC , Appeal No. 2022 -1649 (Fed. Cir. May 8, 2024)

- When the complainant's products all practice different patents, economic prong cannot be fulfilled by aggregating all domestic expenditures.

Timeline of an ITC 337 Investigation



Case Development Process

- Fact Discovery
- Expert Discovery
- Motions
- Settlement Conferences/Mediation (2-3)
- Summary Determination
- Hearing preparation

Notes

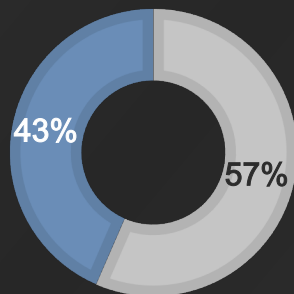
- Target Date = date for final ruling by ITC
- ID = Initial Determination on liability
- RD = Recommended Determination on remedy

Remedies Under Section 337

- No monetary damages
- Types of Remedies:
 - Exclusion Orders (General vs. Limited)
 - Cease-and-Desist Orders

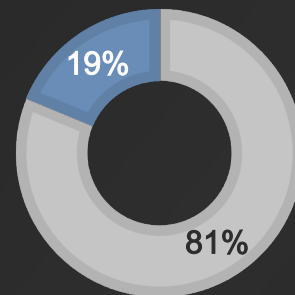
CASES DECIDED ON MERITS (2025)

- Violation Found, Remedy Issued
- No Violation



CASES DECIDED ON MERITS (2026)*

- Violation Found, Remedy Issued
- No Violation



Remedies Under Section 337



Exclusion Orders

- Directed to U.S. Customs to exclude goods from entering U.S.
- A *limited exclusion order* prevents entry of a particular company's goods; not limited to specific models found to infringe
- A general *exclusion order* prohibits importation of all infringing goods, including those of third-parties
- Commission recognizes "potential of a general exclusion order to disrupt legitimate trade";

Complainant by statute must show:

- General exclusion necessary to prevent circumvention of an exclusion order limited to products of named persons; or
- Pattern of violation and difficult to identify source of infringing products

Remedies Under Section 337 (*con't*)



Cease & Desist Orders

- Only against named U.S. respondents, in theory to prevent “stockpiling”
- Prevents sale, advertising, marketing, distribution, use, etc. of imported covered products
- Complainant typically must show “commercially significant” U.S. inventory or “significant domestic operations that could undercut the remedy provided by an exclusion order”
- Civil penalties available for violations

Seizure & Forfeiture Orders

- Allows for seizure and permanent forfeiture of goods imported into the U.S.
- Issued after importer had same goods denied entry pursuant to an Exclusion Order and had already been notified by Customs that seizure and forfeiture could result from future importations

Provisional Remedies Under Section 337

Temporary Exclusion Orders and/or Cease -and-Desist Orders

- Similar to a preliminary injunction in federal court and issued by the ITC prior to completion of an investigation.
- Neither frequently pursued nor commonly granted, likely because of already expedited nature of ITC proceedings and analogous heightened standard used by federal courts and adopted by the Commission in granting preliminary injunctions.
- Last granted in 1996 (*Hardware Logic Emulation Systems*, 337-TA-383)
- Since January 1, 2015, only four motions for temporary relief filed by complainants.

Will Downstream Products Be Covered?

- ITC considers:
 - Relationship of infringing article to downstream product
 - Need of complainant to include downstream products to obtain meaningful relief
 - Harm to respondent if downstream products are included
 - Burden on Customs to include downstream products

Kyocera v. ITC(2008): Federal Circuit held Commission cannot include third party downstream products in its exclusion orders. 545 F.3d 1340

ITC has rejected request for a “limited scope general exclusion order” based on a circumvention theory (*Semiconductor Chips with Minimized Package Design*, 337-TA-605, Comm’n Op. (June 3, 2009))

District Court Case vs. Investigation Under Section 337

District Court	ITC
Damages and injunctive relief	Exclusion and Cease & Desist orders
Private lawsuit	Public investigation
Plaintiff responsible for service; complaint may require translation under Hague Convention	ITC serves complaint; nothing is translated
Show jurisdiction for each party	In rem – name all parties at once
Jury trials available	No jury trials
Counterclaims available	Counterclaims can be asserted but removed to district court
No time limits	Target dates typically 16 months
Results are binding on parties	No binding (“res judicata”) effect
Full discovery available	Full discovery available
Appeal to Federal Circuit	Appeal to Federal Circuit

Article III Standing Not Needed at the ITC

- District court requirements of (i) Article III standing, and (ii) “statutory standing” under 35 U.S.C. § 281 do not apply to ITC proceedings.
- The ITC is not an “Article III court,” so the “case or controversy” requirement for standing does not apply.
- “35 U.S.C. § 281 does not apply directly to the Commission,” but the Commission’s interpretation of § 281 requires *at least one* complainant to be analogous to a “patentee.”
- “Subject matter jurisdiction” and “personal jurisdiction” also do not apply at the ITC

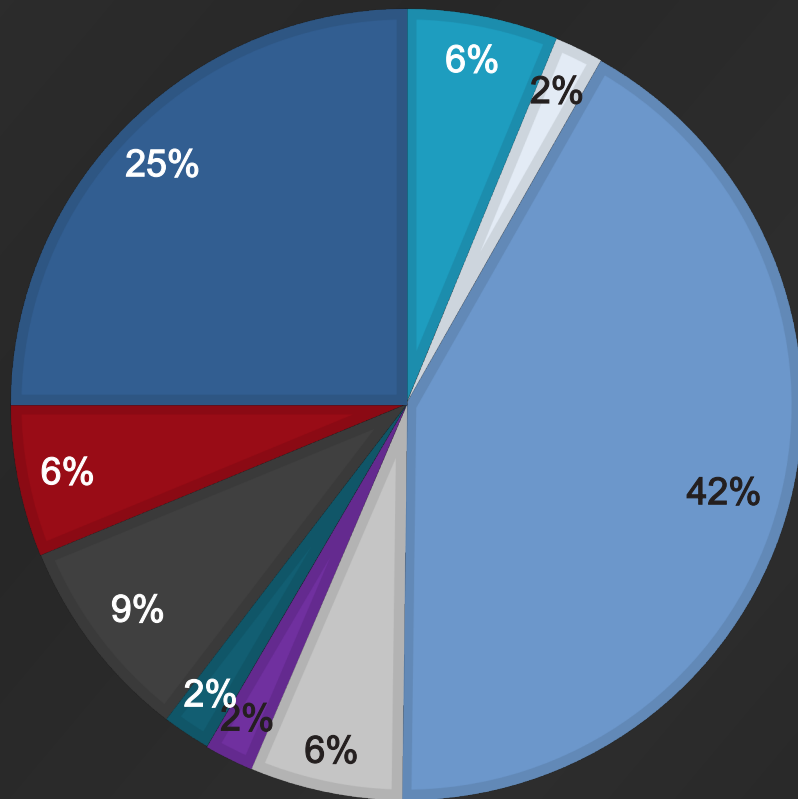
Do ITC Decisions Have Preclusive Effect in a Parallel District Court Action?

- In patent cases the answer is clearly no – based on legislative history, patent decisions of the ITC have no preclusive effect in district court cases, *Texas Instruments v. Cypress Semiconductor* (Fed. Cir. 1996)
- Supreme Court has “long favored application of the common-law doctrines of collateral estoppel (as to issues) and res judicata (as to claims) to those determinations of administrative bodies that have achieved finality” (*Astoria*, S. Ct. 1991)
- ITC decisions may have preclusive effect in copyright and antitrust cases; also trade secret cases (*Mahindra & Mahindra Ltd. v. FCA US LLC*, 503 F. Supp. 3d 542, 551 (E.D. Mich. 2020)).

Filing Trends at the ITC (2024)

Types of Accused Products in New Filings by Fiscal Year (Percent of Total Cases Filed)

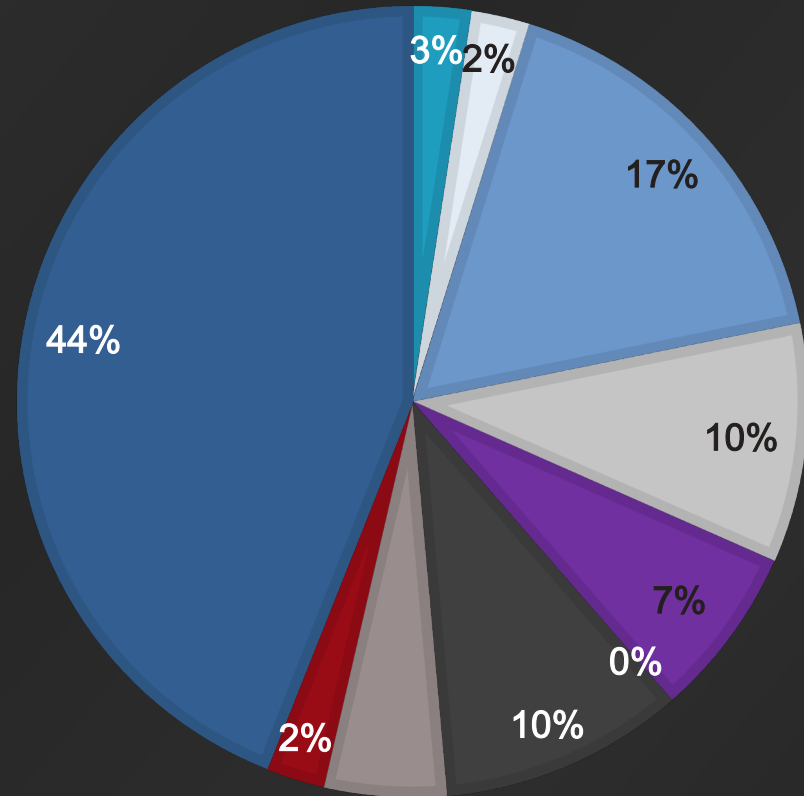
- Automotive/Manufacturing/Transportation
- Chemical Compositions
- Computer and Telecommunications Products
- Consumer Electronics Products
- Integrated Circuits
- LCD/TV
- Lighting Products
- Memory Products
- Pharmaceuticals and Medical Devices
- Printing Products
- Small Consumer Items
- Other



Filing Trends at the ITC (2025)

Types of Accused Products in New Filings by Fiscal Year (Percent of Total Cases Filed)

- Automotive/Manufacturing/Transportation
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- Computer and Telecommunications Products
- Consumer Electronics Products
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- Lighting Products
- Memory Products
- Pharmaceuticals and Medical Devices
- Printing Products
- Small Consumer Items
- Other



New Developments at the ITC: AI-Related Investigations

- The ITC has historically been a forum for litigation over new technologies, and AI is now at the forefront of tech innovation.
- In 2025, 5 notable AI-related investigations were instituted:

Certain Integrated Circuits (337-TA-1450) (AI chips).

Certain Active Electrical Cables (337-TA-1446) (data connectivity wiring for AI networks).

Certain Foreign-Fabricated Semiconductor Devices (337-TA-1443) (AI chips).

Certain Wi-Fi Routers (337-TA-1454) (devices using AI monitoring).

Certain Wearable Electroencephalogram Devices and Systems (337-TA-1458)
(devices using AI algorithms).

Enforcement of ITC Exclusion Orders



- Exclusion orders are enforced by Customs (U.S. Customs & Border Protection)
- All products infringing the patent are excluded, not just the specific products in the investigation
- Often, a losing respondent will try to “design around” the patent – Customs will decide if a new product infringes
- Complainants can also seek enforcement by the Commission
 - Civil penalties are available for violation of cease and desist or consent orders – up to \$100,000 or twice the value of goods for each day on which violation occurred.
- Respondents can also seek an advisory opinion from Commission; pilot program announced in 2015 to streamline process

- Previously, contacts with Customs regarding redesigned products were *ex parte*
- Recently, Customs has introduced new rules for *inter partes* proceedings to make the decision-making process more transparent and get full input from both sides
- Respondent submits a “**Rule 177 Request**” to Customs, which conducts a proceeding including pretrial briefs, a hearing at Customs, posthearing briefs and a decision by Customs; may also include expert reports, depositions
- Process usually moves quickly; around 11-12 weeks from request for ruling letter to decision is the typical target, but it can take longer

Customs’ *Inter Partes* Procedures for Determining Status of Redesigned Products



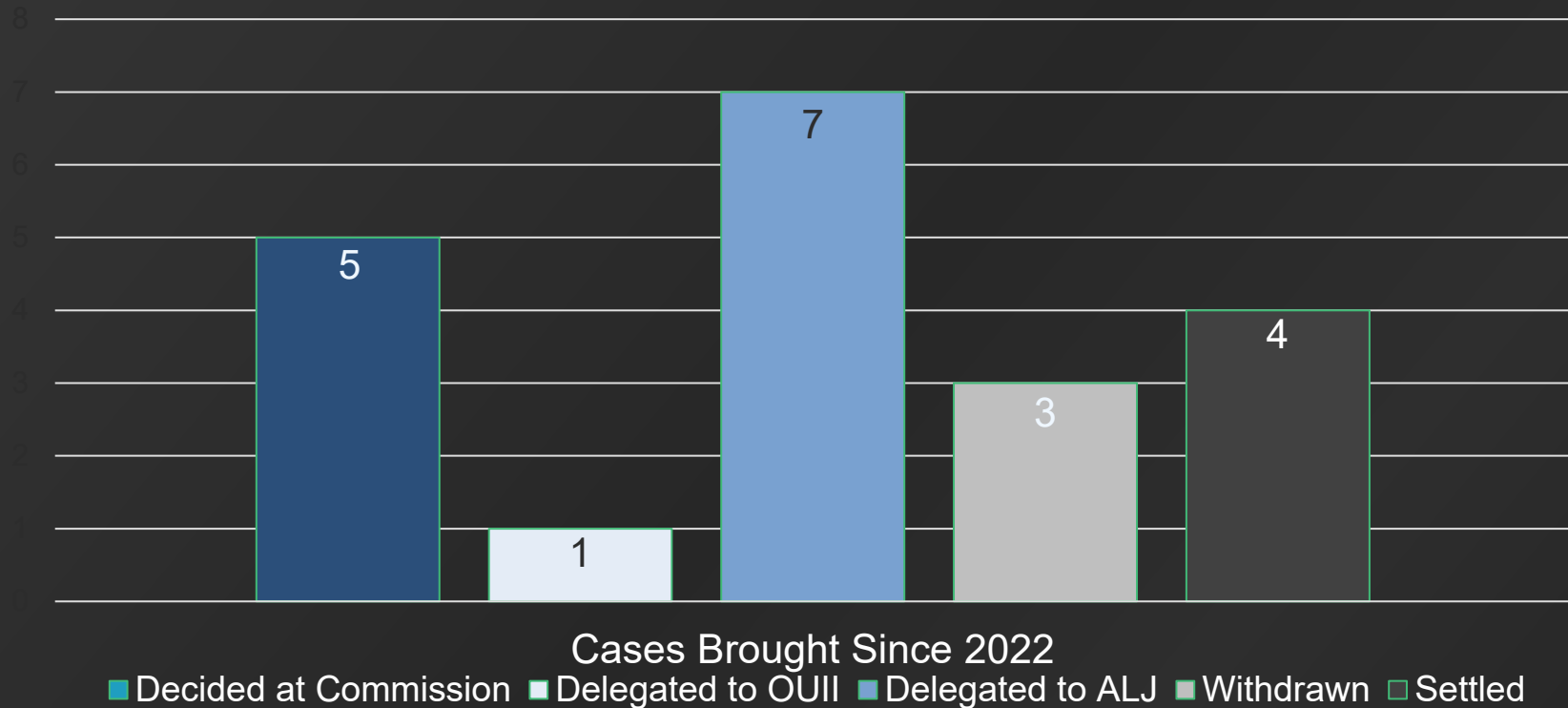
ITC's Program for Faster Resolution of Ancillary Actions

- On Feb. 23, 2015, ITC announced new pilot program to evaluate and rule on new and redesigned products in modification and advisory opinion proceedings (codified in Rule 210.79 in 2018)
- Any person can request modification of an existing exclusion, consent or cease & desist order to determine whether a redesigned product is covered and whether the order should provide a “carve -out” for the product
- Any person can also request an advisory opinion that a redesigned product is not covered by an existing order

ITC's Program for Faster Resolution of Ancillary Actions (*cont'd*)

- If a *pure question of law*, Commission's Office of General Counsel will conduct the proceeding, with the Commission's final decision normally issued within *60-90 days*
- If case involves *minimal factfinding*, Commission's Office of Unfair Import Investigations will conduct proceeding, Commission's final decision normally within *90-180 days*
- If case requires *extensive factfinding*, Commission will refer the matter to an ALJ for appropriate proceedings and issuance of an initial ruling, with Commission's final decision to issue within *6-9 months*

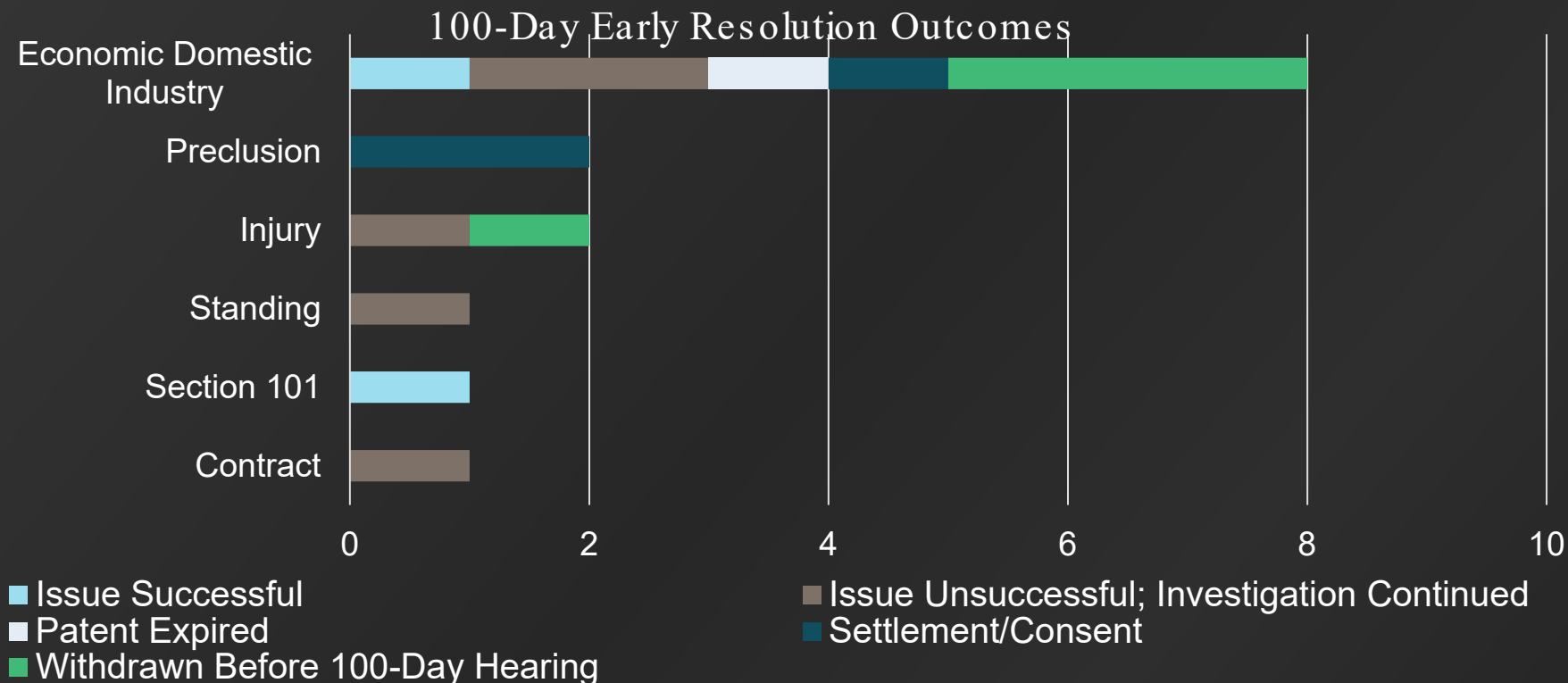
Of the 13 cases decided on their merits, 10 were completed on time, while the other 3 were very close.



ITC's 100-Day Program for Early Disposition

- Commission in *Laminated Packaging* (2013, TA-874) ordered ALJ to issue, within 100 days, ID on whether complainant met domestic industry requirement. ITC later made this part of new “pilot program” designed to make ITC cases more streamlined and efficient; decision made pre-institution.
- The 100-day program was subsequently codified at 19 C.F.R. § 210.10(b)(3).
- Issues that are too complex will not be included in the 100-day program.

15 investigations have gone through the ITC's 100-day program since its inception.



ITC's Interim Pilot Program for Early Disposition

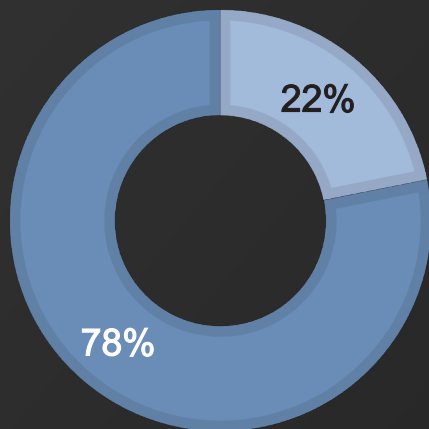
- May 19, 2021: ITC established pilot program to allow ALJs to issue interim IDs on fewer than all issues in investigation. ALJ can receive briefing and hold evidentiary hearing on one or more discrete issues before main evidentiary hearing; discretion to suspend procedural schedule during Commission review.
- First used by Chief Judge Cheney in a pair of related cases in 2022 in *Replacement Automotive Lamps* (337-TA-1291) and *Replacement Automotive Lamps II* (337-TA-1292) to determine the economic prong of the domestic industry requirement.
- Since 2021, five ALJs, including Chief Judge Cheney, have denied motions for entry into the pilot program for five different investigations. Granting entry is rare as implementation is based heavily on the ALJ's discretion.

- The ITC by statute must always consider the public interest in assessing potential remedies
- Parties (typically respondents) can request through pre-institution submissions that the Commission delegate public interest to be decided by the ALJ (including discovery and evidence presented at the evidentiary hearing)
- While Commission has declined to issue relief in only three cases based on public interest, the chances are greater that it could be used to modify or delay any remedy

Public Interest Considerations

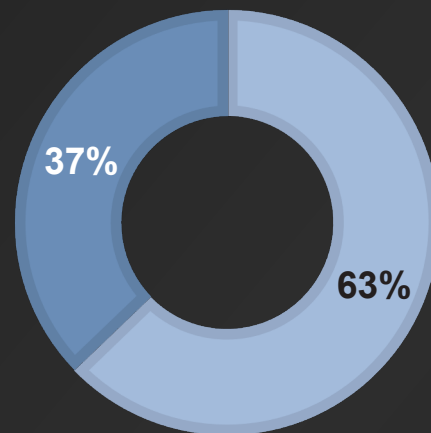
INVESTIGATIONS DELEGATING PUBLIC INTEREST, 2010 -2025

■ Delegation to ALJ ■ No Delegation



INVESTIGATIONS DELEGATING PUBLIC INTEREST IN 2025

■ Delegation to ALJ ■ No Delegation



Proposed Rule: Disclosure of Ownership and Financial Interests

- April 30, 2026: the Commission published a notice of proposed rulemaking amending its Rules of Practice and Procedure governing Section 337 adjudication and enforcement. 91 Fed. Reg. 23190 (Apr. 30, 2026).
 - Driven by “concerns that have arisen in Commission practice.” Many federal courts already require real-party-in-interest and litigation-funding disclosure, while the Commission currently has no such rule.

- Proposed new Rule 210.14(a) would require each nongovernment party — and any nongovernment party seeking to intervene — to file a disclosure statement with the Secretary identifying:
 - Any parent corporation and any entity owning the party's stock (excluding natural persons);
 - Any person or entity, other than the complainant, with the legal right to bring a Section 337 investigation based on the unfair acts asserted in the complaint; and
 - Any person or entity (excluding counsel) that provides funding specifically for the investigation, or whose approval is necessary for litigation or settlement decisions, including the nature of settlement terms.
- Excluded from disclosure: contingency fee arrangements between the party and its counsel, personal loans, bank loans, and insurance.

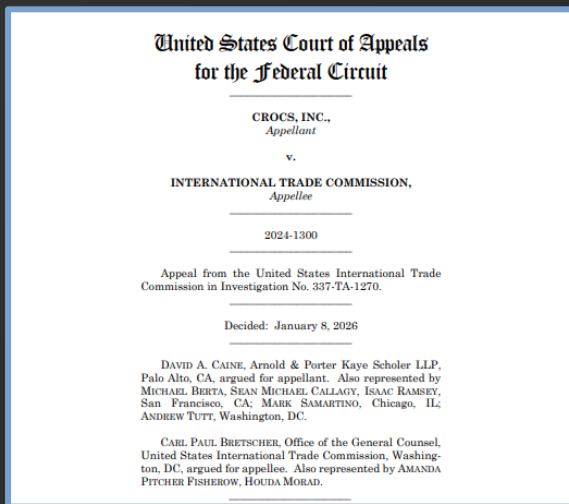
Proposed Rule: Disclosure of Ownership and Financial Interests (*cont'd*)

Deadlines to Appeal at the CAFC



- Crocs filed ITC complaint against multiple respondents for trademark infringement and requested relief either as a GEO, or, in the alternative, an LEO. Three respondents participated in an evidentiary hearing in Sept. 2022, while four respondents defaulted.
- Sept. 14, 2023: Commission found no violation by the active respondents and issued LEO against the defaulting respondents based on public interest factors.
- Dec. 22, 2023: Crocs appealed to the Federal Circuit, challenging the Commission's finding of no violation.

Deadlines to Appeal at the CAFC (*cont'd*)



- Commission argued that under 337(c), 60-day deadline to file appeal began on September 14, 2023, the day the Commission found no violation and issued the LEO. Crocs' appeal on December 22, 2023 was untimely.
 - Crocs therefore should have filed its appeal by November 13, 2023, more than a month earlier.
- January 8, 2026: Federal Circuit dismissed Crocs' appeal against the active respondents as untimely.
 - Fed. Cir., agreeing with Commission, ruled Crocs missed deadline to appeal because Commission's findings became final when issued and not subject to Presidential review.
 - Court rejected Crocs' argument that embodying both rulings in a single writing made the determination one indivisible final determination subject to the Presidential review period, holding that position "merely elevates form over substance."

- ITC ruled that Respondents (Suprema) induced infringement of method claim by importing a product that, only when combined with domestically developed software, would directly infringe asserted patent.
- Issue: is the product an “article that infringes” even though infringement does not take place until after importation?
- Federal Circuit panel: ITC may not predicate an exclusion order “on a theory of induced infringement under 35 U.S.C. §271(b) where direct infringement does not occur until after importation of the articles the exclusion order would bar.”
- Aug. 10, 2015: Federal Circuit *en banc* upheld ITC’s authority to interpret statute to mean “articles that infringe” includes goods used by an importer to infringe post-importation as a result of the seller’s inducement.

Does Section 337 Apply to Induced Infringement of Method Patents?

- Section 337 of the Tariff Act of 1930 prohibits unfair acts and unfair methods of competition in the “importation of articles.”
- On May 6, 2013, the ALJ rendered a final ID in *Certain Digital Models, Digital Data, and Treatment Plans for Use, in Making Incremental Dental Positioning Adjustment Appliances* (Inv. No. 337-TA-833), finding a violation by the Respondents for importing infringing digital data into the US.
- Upon review, on January 17, 2014, the ITC extended the target date for the investigation and sought public comment for the question: “Are electronic transmissions ‘articles’ within the meaning of Section 337?”

What is an
Imported
“Article”?



FOR PATIENTS | FOR DOCTORS



UNITED STATES



HOW INVISALIGN WORKS

WHY INVISALIGN

INVISALIGN FOR ADULT & TEENS

COST

HOW DO I GET IT

Find a Doctor

ZIP Code

A background image showing a series of clear, custom-made Invisalign aligners arranged in a curved path, receding into the distance. The aligners are set against a solid blue background.

1 Talk to an Invisalign Provider

2 A customized treatment plan is created for you

3 Receive your custom aligners

4 Wear a new aligner every two weeks

5 Reveal your new smile & keep it looking great

Show off your smile

ClearCorrect clear aligners straighten teeth invisibly, without metal braces.



HOW IT WORKS



1 Find a provider

As a dental lab, ClearCorrect makes aligners based on a doctor's prescription. You'll need an orthodontist or dentist to manage your treatment.

If your primary dentist doesn't offer ClearCorrect, another doctor near you probably does.

2 Get evaluated

If you're a good candidate for clear aligners, your doctor will take photos and x-rays, use a scanner or impressions to capture the shape of your teeth, and submit your prescription to ClearCorrect.

3 Wear your aligners

We'll make a series of aligners customized to apply pressure to the teeth that you want to move.

Your doctor will check your progress periodically and give you new sets of aligners. You'll wear the aligners for at least 22 hours per day, progressing through each step until your treatment is done.

Digital Models, Inv. No. 337-TA-833

Electronic Transmissions

Facts: asserted patents related to a system and methods for repositioning teeth using a series of successively placed dental appliances (Align's product is "Invisalign").

- ClearCorrect US used ceramic models to create digital data sets that were electronically transmitted to Pakistan, where they were manipulated by ClearCorrect Pakistan, and then electronically transmitted back to U.S.
- ClearCorrect US then used 3-D printers to create 3-D models of the patient's teeth, which were, in turn, used to make aligners for the patient.

- ClearCorrect argued: digital data sets are not "articles" within the meaning of Section 337 and the uploading of data abroad to a server in the U.S. does not constitute a mode of "importation" encompassed by the statute.

How do you think the issue of jurisdiction over electronic transmissions was ultimately resolved?

A. The ITC has jurisdiction over electronic transmissions under Section 337.

B. The ITC does not have jurisdiction over electronic transmissions under Section 337.

Commission Determination in *Digital Models*, Inv. No. 337-TA-833

- Commission held that “having reviewed the plain language of the statute, its legislative history and purpose, pertinent case law, and the arguments of the parties and public commenters”:
 - “[T]he statutory phrase ‘importation . . . of articles’ should be construed to include electronic transmission of digital data because the digital data sets at issue in this investigation are true articles of international commerce that are imported into the United States and their inclusion within the purview of section 337 would effectuate the central purpose of the statute.”

Commission Determination in *Digital Models*, Inv. No. 337-TA-833 *(cont'd.)*

- Vigorous dissent by Commissioner Johansen:
 - “In sum, the plain language of the statute, its interplay with other trade statutes, the lack of guidance in the statute’s legislative history, and the statute’s prior judicial interpretation all lead to the same place: Congress did not delegate to the Commission the authority to remedy importation of ‘articles’ based only on electronic data transmitted into the United States.”
- Nov. 10, 2015: the Federal Circuit held that electronic transmissions are not importations of articles and therefore outside the Commission’s jurisdiction; ITC’s motion for rehearing *en banc* was denied

- Non-practicing entities or “trolls” can bring cases at the ITC by arguing that they are involved in “substantial investment” in exploitation of a patent through licensing (their own investments and/or investments of licensees)
- Why would an NPE/troll come to the ITC when their primary objective is to seek money for licensing their patent? Because the threat of an exclusion order gives them greater bargaining leverage
- Under the Supreme Court’s decision in *eBay*, permanent injunctions are not automatic; patent owner needs to show irreparable harm, etc. A Section 337 complainant need not show injury to get an exclusion order

Use of Section 337 by Non-Practicing Entities (“NPE”) or “Trolls”



IPRs and Section 337 Investigations



- ITC Does Not Stay Investigations for Pending IPRs
 - The ITC consistently declines to stay investigations for pending IPRs, even when IPR decisions are expected before the ITC target date.
- USPTO Denies IPR Institution Based on Parallel ITC Proceedings
 - Under *Fintiv*, the PTAB discretionarily denies institution in most cases involving parallel ITC investigations because ITC proceedings will almost always conclude first and the ITC will not stay for a pending IPR.
- Estoppel Rules Apply—But Not to OUII
 - The ITC applies IPR estoppel to respondents who petitioned for IPR, even where unsuccessful. However, estoppel does not bind OUII.
- Strategic Timing Consideration
 - Optimal timing for an IPR decision may be after the ITC hearing but before the final Commission decision.

Putting It All Together - the Apple Watch Saga



- Oct. 13, 2023: ITC issued a limited exclusion order and cease and desist order against Apple smart watches incorporating pulse oximetry technology found to infringe patents owned by Masimo Corporation
- ITC issued remedial orders despite arguments from Apple that such orders would be contrary to public interest
- Dec. 26, 2023: Apple lobbied USTR to overturn ITC's decision during Presidential review, to no avail
- Apple appealed to Federal Circuit, which granted Apple's temporary emergency stay motion on Dec. 27, 2023, pending further decision on a motion to stay, which was ultimately denied on Jan. 17, 2024
- But Apple had already initiated a Rule 177 proceeding before CBP, which cleared smart watches without the blood oxygen-measuring features on Jan. 12, 2024, allowing Apple to continue marketing and selling smart watches

- Aug. 20, 2025: Masimo filed a lawsuit for temporary restraining order against U.S. Customs and Border Protection (“CBP”) in D.C. District Court, claiming CBP failed to comply with Administrative Procedure Act, among other claims, and CBP’s *ex parte* ruling had issued without Masimo’s knowledge.
- Nov. 14, 2025: ITC issued order instituting expedited review of whether the *new* version of Apple Watch without oxygen-measuring features still infringes Masimo patents.
- March 19, 2026: ALJ Bhattacharyya ultimately concluded that the new Apple Watch did not infringe Masimo's patents.
- April 17, 2026: The Commission determined not to review ALJ Bhattacharyya's determination and terminated the proceeding.

Putting It All Together - the Apple Watch Saga (*cont'd.*)

The conclusion? The new Apple Watch is not subject to the LEO.

- March 19, 2026: In *Apple Inc. v. Int'l Trade Comm'n*, No. 2024-1285 (Fed. Cir.) (appeal from Inv. No. 337-TA-1276), the Federal Circuit affirmed the Commission's violation finding, upholding and its domestic industry, claim construction, infringement, and validity determinations and rejecting Apple's prosecution laches defense for the Apple Watch with oxygen monitoring.
 - Technical prong: Masimo could rely on the final "Masimo Watch" together with prior designs and physical prototypes as "successive embodiments" of the same domestic industry product.
 - Economic prong: investments in predecessor prototypes made as part of the same iterative design process qualify.
- On September 3, 2026, Apple filed a petition for certiorari before the Supreme Court challenging the Federal Circuit's decision to confirm the Commission's findings.

What about the original Apple Watch?



Image from <https://dukaan.b-cdn.net/>

The LEO remains in place...but only for the original watch.

Another Bite At Apple?

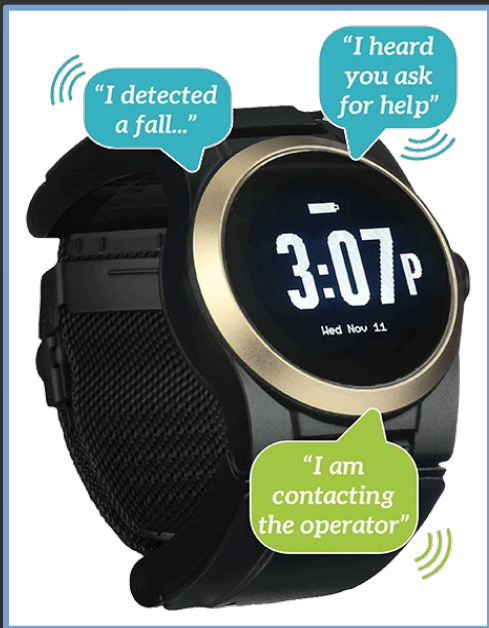


Image from <https://www.unaliwear.com/why-kanega-watch>

- On January 8, 2026, the ITC instituted an investigation against several companies, including Apple for its Apple Watch, for infringing the patents of UnaliWear, a Texas-based firm (*Wearable Devices With Fall Detection* -1477).
- Unaliwear, which is known for the Kanega Watch, a medical alert device for seniors, is seeking an LEO against Apple, Garmin, Google, and Samsung.
- Current status: on August 17, 2026, the ALJ denied a Motion for Summary Determination filed by the Respondents, including Apple.
- The parties are going to trial, and -1477 might once again result in a ban on Apple Watches.

Key Takeaways



01

Speed and Power: The ITC offers fast, border-blocking remedies without requiring proof of damages or irreparable harm.

02

Domestic Industry Flexibility: Recent case law has lowered the bar for proving a qualifying domestic industry.

03

No Preclusive Effect: ITC patent rulings can be relitigated in federal court.

04

Emerging Tech Hub: The ITC is a go-to forum for cutting-edge technology disputes.

05

Strong Enforcement: Customs and ITC programs ensure exclusion orders are enforceable, with significant penalties for violations.

MAYER | BROWN

Thank you!

