

# What Med Device Companies Need to Know About Litigating in the ITC

Tuesday, July 11<sup>th</sup>

**FISH.**



# Meet the Speakers

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Principal



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# Overview

## Housekeeping

CLE

Questions

Materials

<http://www.fr.com/webinars>

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## WEBINAR

Complimentary CLE

### U.S. and EPO Patent Prosecution Issues

Wednesday, July 19, 2023 | 1:30 - 2:30 p.m. ET

In March, the European Patent Office's Enlarged Board of Appeal issued its G 2/21 decision on plausibility, providing guidance on the circumstances under which post-published evidence may be used when determining inventive step. Then, in May, the U.S. Supreme Court issued its decision on enablement in *Amgen v. Sanofi*, holding that patents that cover an entire class of processes, machines, manufactures, or compositions of matter using broad, functional language must enable a person skilled in the art to make and use the entire class.

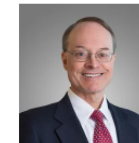
What insights can patent owners and prosecutors glean from these recent developments? On July 19, join Principals [Moritz Ammelburg](#) and [Peter Fasse](#) for a discussion of current patent prosecution issues in the U.S. and Europe.

REGISTER

#### PRESENTED BY:



[Moritz Ammelburg](#)  
Principal



[Peter Fasse](#)  
Principal

#### WHAT YOU'LL LEARN

Moritz and Peter will discuss the following topics and more:

- The Supreme Court's decision in *Amgen v. Sanofi*
- The EPO Enlarged Board of Appeal's plausibility case
- Lessons these cases present for drafting and claiming

# Agenda

**What is the ITC?**

**Can my company sue at the ITC?**

**Will public interest concerns weigh against relief?**

# What is the ITC?

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# Have You Heard of the ITC?

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International Trade Commission

# What is the International Trade Commission?

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- **Independent, nonpartisan, quasi-judicial federal agency:**
  - Provides trade expertise to both the legislative and executive branches of government
  - Determines the impact of imports on U.S. industries
  - Directs actions against certain unfair trade practices, such as patent, trademark, and copyright infringement—“ITC Investigation”

# Section 337 of the Tariff Act

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- **Purpose of Statute:** To stop the importation into the U.S., the sale for importation, or the sale in the U.S. after importation of articles that infringe a valid and enforceable U.S. patent or infringe some other intellectual property right.
- **Remedy:** Prospective relief only, no monetary damages:
  - Exclusion Orders enforced at the borders by U.S. Customs and Border Protection.
  - Cease & Desist Orders enforced in the U.S. by the ITC for illegal U.S. sales activity.



Keep looking forward!



# The ITC is Not Just for Patents

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- Section 337 of the Tariff Act of 1930 (19 U.S.C § 1337(a)(1)) authorizes the ITC to investigate and remedy importation, sale for importation, or sale after importation of articles that:
  - Infringe a valid and enforceable US **patent**;
  - Are made, produced, processed, or mined using a **patented process**;
  - Infringe a valid, enforceable, and registered US **copyright** or **trademark**;
  - Infringe a **registered mask work** (17 U.S.C. § 901 et seq.); or
  - Infringe a **registered boat hull design**.
- **Other prohibited unfair acts** include activities such as **theft of trade secrets, trade dress misappropriation, or false advertising** in the importation and sale of articles that destroy or injure the domestic industry, prevent establishment of such industry, or restrain or monopolize trade.



# Who is the International Trade Commission?



Commissioner  
Amy A. Karpel



Commissioner  
Jason E. Kearns



Commissioner  
Randolph J. Stayin

VACANT

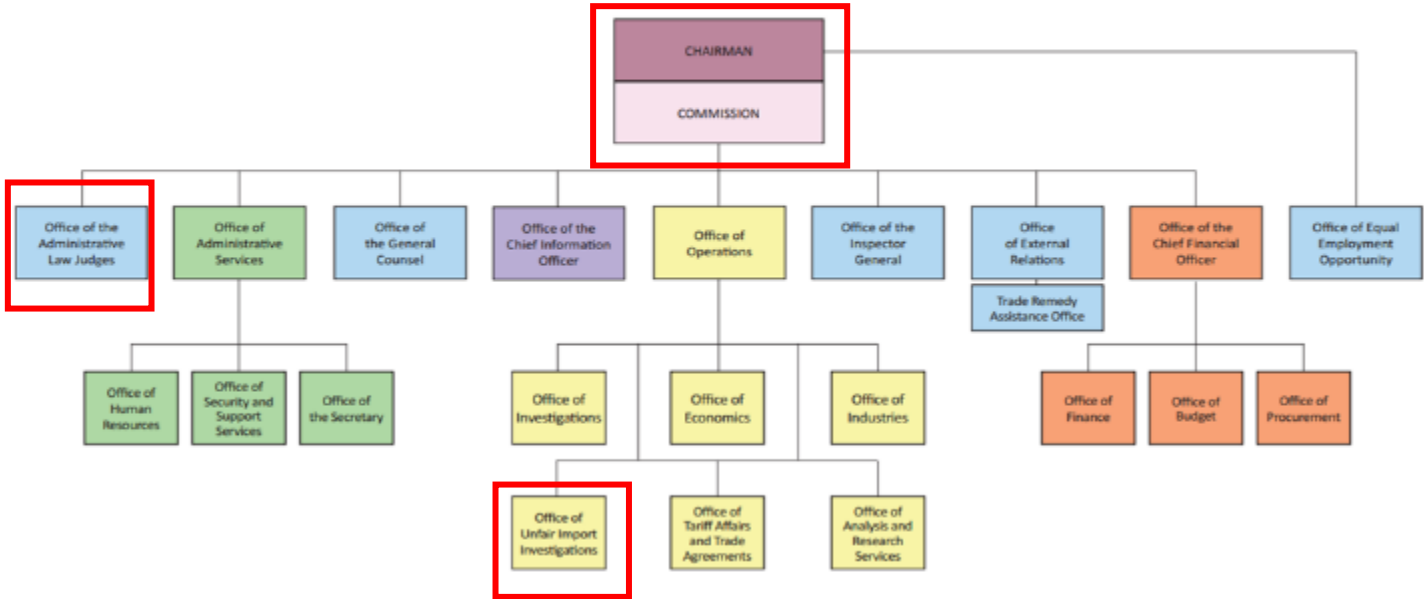


Commissioner  
Rhonda Schmidlein



Commissioner  
David Johanson  
(Chairman)

**UNITED STATES INTERNATIONAL TRADE COMMISSION**  
**Office-Level Organizational Chart**



Revised October 2014

# Role of the Commissioners in Section 337

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- Gatekeepers - Vote to institute investigations
- First Level of Review - Review initial determinations issued by ALJs and make final determinations of the Commission
- Advised by the Office of General Counsel (OGC) and represented by the OGC on appeals at the Federal Circuit



# The Administrative Law Judges (ALJs)

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Clark S. Cheney,  
Chief ALJ  
(sitting since 2018)



Monica  
Bhattacharyya  
(sitting since 2021)



Bryan F. Moore  
(sitting since 2022)



MaryJoan McNamara  
(sitting since 2015)



Doris Johnson Hines  
(sitting since 2023)



Cameron Elliot  
(sitting since 2019)

- Chief Judge assigns cases based on non-transparent factors such as schedules and preferences of ALJs.
- Complainants can no longer time their filings to get a particular ALJ.

# Role of the ALJs

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- Handle *only* Section 337 Investigations
  - They are IP experts!
- Preside over evidentiary hearings.
- Make Initial Determinations (IDs) in Section 337 Investigations (involving unfair practices in import trade).
- Generally, manage litigation.

# Role of OUII Staff Attorneys

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- **OUII investigates the allegations in the complaint and represents the public interest**
- **Begins prior to formal institution of investigation**
  - Reviews draft complaints before they are filed
  - Provides confidential assistance to complainants so that complaint will satisfy Commission rules
  - Advises the Commission on whether to institute an investigation
- **OUII is a full party (sometimes); takes positions on (some or all) merits and procedure**
  - Including petitioning for review and responding to petitions for review of ALJ's decision
- **OUII is often accorded some deference by ALJ due to knowledge of ITC precedent and patent law and lack of economic interest in outcome**
- **Convincing staff attorney of private party's position is valuable**

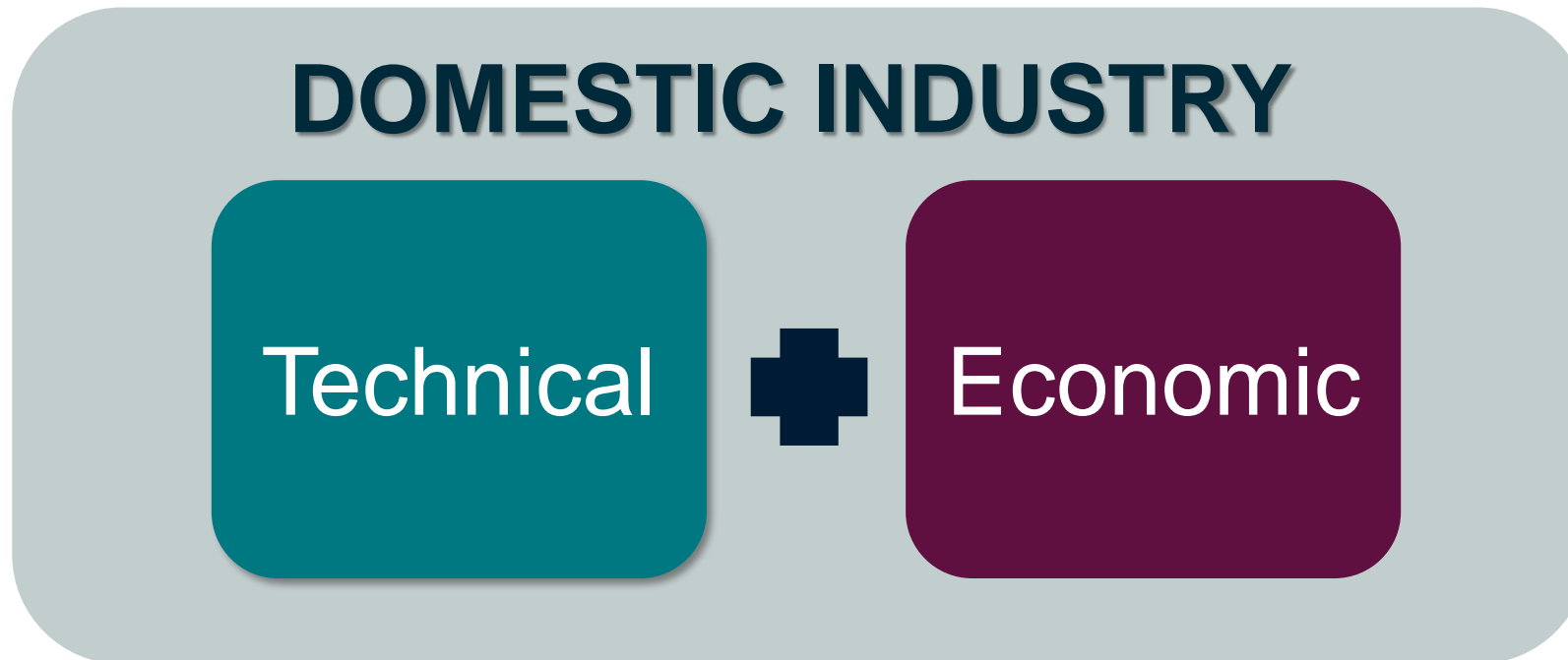
# Unique Aspects of ITC: Importation

- Subject matter jurisdiction in the ITC is established by alleging, e.g., “an unfair act in the importation of articles . . . into the US”
- “Unfair act” is, e.g., infringing a patent, TM or copyright
- **IMPORTATION:** Articles must be **imported** into the United States
- ITC has jurisdiction over those goods (*in rem* jurisdiction) that are imported, sold for importation, or sold after importation
- In *personam* jurisdiction is unnecessary for remedy



# Unique Aspects of ITC: Domestic Industry

- Must exist or be in the process of being established (and must show tangible steps), when complaint is filed
- Test for patent-based domestic industry set out in statute: consists of “**Technical Prong**” and “**Economic Prong**”





# Unique Aspects of ITC: Domestic Industry

## ■ Technical Prong:

- Practice at least one valid, enforceable claim per patent (“**DI Product**”).
- Different patents in investigation can have different domestic industries.
- Note: Must exploit the IP right in patent/copyright/registered TM cases; no technical prong requirement for trade dress/trade secret cases.

## ■ Economic Prong:

- “Significant” investment in plant and equipment.
  - “Significant” employment or capital.
  - “Substantial” investment in R&D or licensing.
- Must be related to “**DI Product**”
- Must also be related to **Asserted Patent (i.e., narrower)**
- 

## DI IS NOT LIMITED TO US COMPANIES

# Unique Aspects of ITC: Remedies

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- **Exclusion Orders** against infringing imports:
  - Enforced by Customs
  - Temporary, General or Limited EOs
  - **General EO against an entire industry, e.g., counterfeits**
- **Cease and Desist Orders** against respondents:
  - Enforced by the Commission
  - Prohibits respondents' sales activity with respect to already-imported infringing products.
  - Penalties of \$100,000/day
- **Consent Orders:**
  - Violation carries same penalties as a cease-and-desist order
- **Duration of orders – usually for life of IP right**
- **No monetary remedy, costs, or fees:**
  - Only sanctions for abuse of process (similar to FRCP 11), abuse of discovery, failure to make or cooperate in discovery, or violation of a protective order



# ITC vs. District Court

## ITC

- **Jurisdictional advantages:**  
(1) name multiple respondents from U.S. and abroad; (2) *in rem* jurisdiction
- **Expedited proceedings** – usually 14-16 months; short deadlines
- Counterclaims by respondents are immediately removed to district court
- **Discovery:** (1) nationwide subpoena power; (2) discovery against foreign respondents; (3) sanctions available against foreign respondents who fail to comply with discovery
- **ALJ expertise;** ALJ handles both discovery disputes and hearing
- Exclusion orders enforced by U.S. Customs and Border Protection

## District Court

- No domestic industry requirement (both (1) technical and (2) economic)
- No importation requirement
- Complaint need not lay out fundamental initial infringement contentions; essentially notice pleading v. fact pleading at ITC
- Jury
- Monetary Damages
- Injunctive relief (?)

# Can My Company Sue at the ITC?

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# Can My Company Sue at the ITC?

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**Two Questions:**

**One About Your Target, One About You**

1. Does **Your Target** import the accused products?
2. Do **You** have (or will you have) a Domestic Industry?

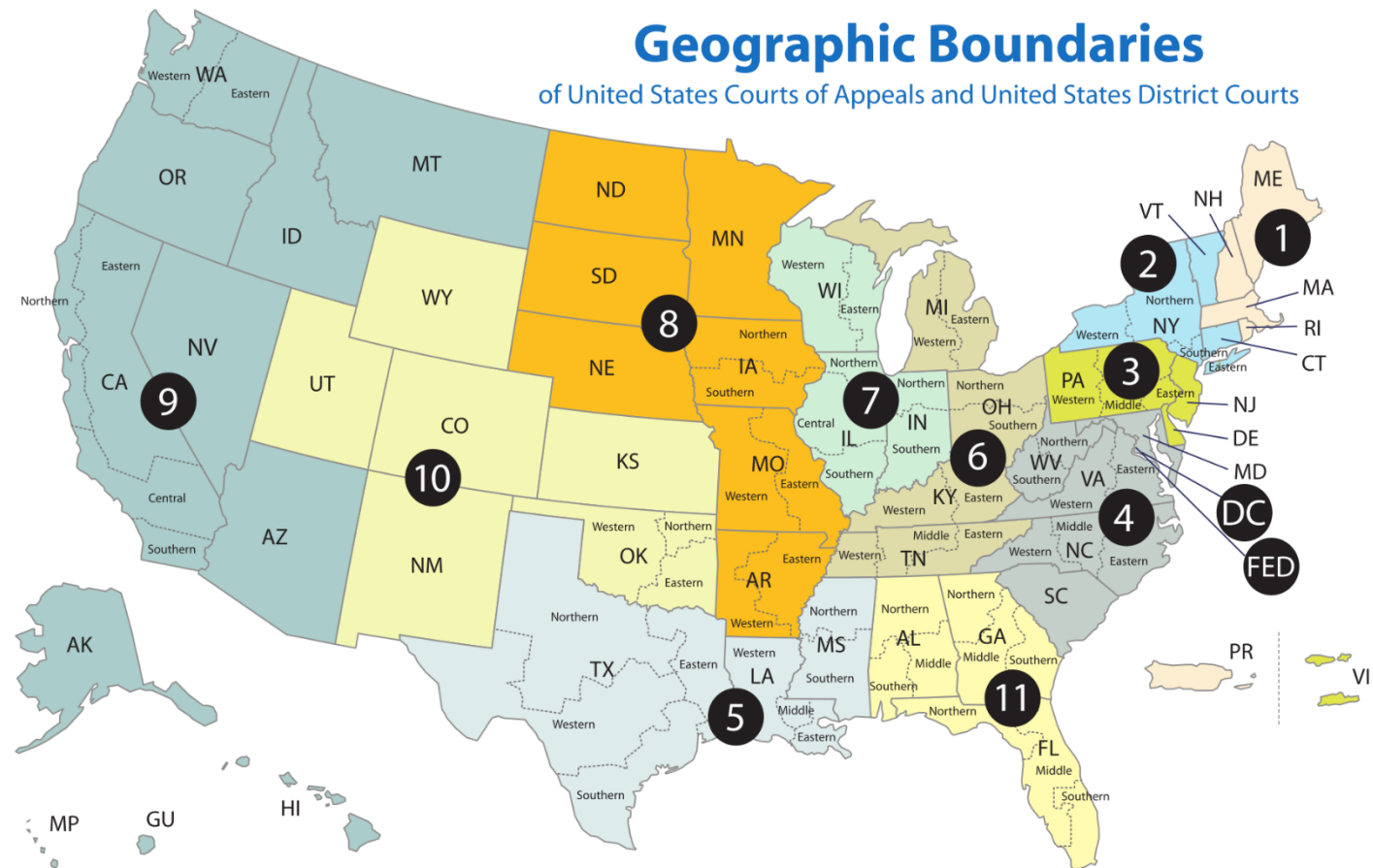
# But Why Should I Sue at the ITC?

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- No Venue Concerns
- Speed
- Unique Remedies

# ITC: No Venue Concerns

- Venue is now a real concern for district court litigation after the *TC Heartland* decision.



# ITC: No Venue Concerns

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- *Exemplary Corporation*

- Incorporated in Wilmington, DE
- Offices in NYC, Dallas, and Los Angeles
- Sells its imported products nationwide

- *Pre-TC Heartland*

- Company A “resides” wherever personal jurisdiction is found:  
**nationwide**

- *Post-TC Heartland*

- Company A “resides” in DE only
- “regular and established place of business”: NYC (SDNY), Dallas (NDTX), Los Angeles (CDCA)

**ONLY 4 VENUES TO CHOOSE FROM**



# ITC: No Venue Concerns

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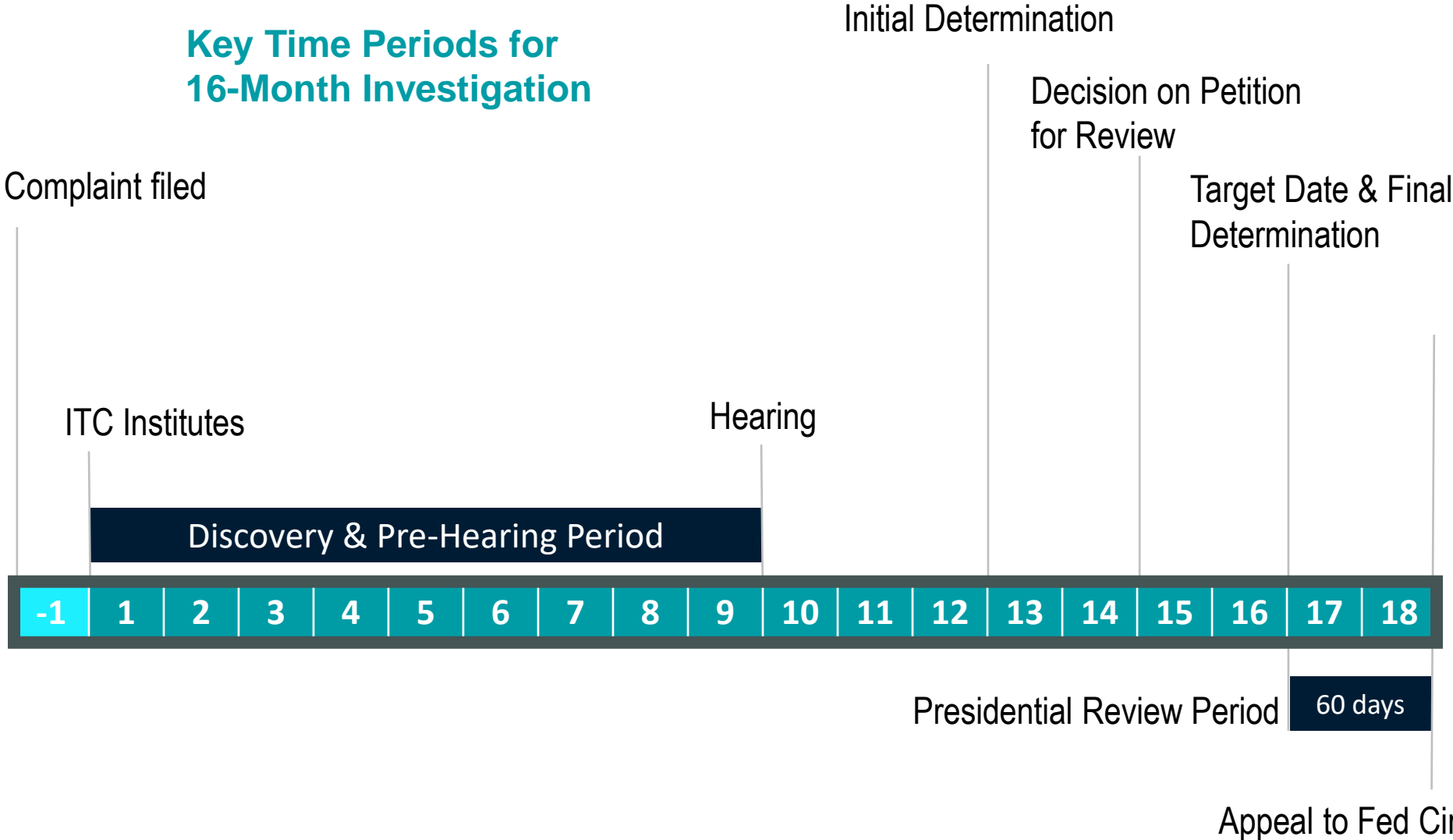
- **Restricted venue options**

- Available venues may not be “plaintiff-friendly”; may be inconvenient for you
- Multiple defendants may be scattered across the country, requiring numerous district court actions

- **ITC as a preferred alternative**

- Patent-savvy judges: patent infringement specialists, neutral & predictable
- Multiple respondents can be named without venue concerns

# ITC: Speed



# ITC: Speed

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- **Only 9 months from institution to hearing / 1 year for initial determination from ALJ**
  - Much faster than district court
  - As complainants, time is on your side
- **IPR unlikely to slow you down**
  - 337-TA-983 (2016):
    - IPRs filed two more than two weeks before filing of the complaint
    - Respondents' motion to stay denied

# ITC: Speed

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**Remember—you need lead time for due diligence**

## **Before filing the complaint:**

- Decide on your domestic industry strategy and gather best evidence
- Develop your infringement theories
- Retain experts

# ITC: Unique Remedies

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- **Exclusion Order / Cease & Desist**
  - Ability for Complainant to eliminate competition from US market
  - Big impact on the future operations of respondents: pressure to negotiate
  - Effective for the life of the patents: better to assert patents with longer life
- **No monetary damages**
  - Cannot recover losses for past sales

# Worried About Domestic Industry? You May Have It Already. If Not, Create One!

Traditional “manufacturing”

**A** Plant & Equipment



**B** Labor & Capital



§ 337(a)(3)

**C** In 1988 Congress added  
Engineering Research & Development & Licensing



# Worried About Domestic Industry? You May Have It Already. If Not, Create One!

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## DI Can Take on Many Forms

**Form 1:** manufacturing key components of the DI products in the U.S.

**Form 2:** Post-importation customization, service, repair

**Form 3:** exploitation of asserted patent (engineering research, development, licensing)

# Form 1: Manufacturing

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- **Expenditure on Plants & Equipment and Labor & Capital to manufacture DI product**
  - Prongs A & B expenditures on traditional manufacturing is the most certain way to establish economic DI
  - Must show a link to the products practicing asserted patent(s)
  - Example: to satisfy economic DI, complainant shifts manufacturing to United States
    - Some DI products (or significant components) manufactured entirely in the US
    - Others assembled in the US
    - Investment in plant and equipment for such manufacturing and assembly almost certainly “significant”



# Form 2: Service, Warranty, Installation

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- **Service/repair/support related to DI product**
  - US subsidiary of a German company imports DI products: manufacturing, servicing, supporting the DI products take place in Germany
  - Alleged Econ DI (\$11.7M over 3.5 yrs)
    - Post-importation customization
    - Service and repair
    - Technical/warranty support
    - Technical training
  - In comparison to activities in Germany, the alleged DI investment was small, yet was “significant”
- All in connection with the DI product**

# Form 3: Exploitation Through Research & Development & Licensing

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- **Prong C, narrowest of the prongs, requires nexus to the patent, not merely products practicing patent**
  - Research & Development: also counts under prongs A and/or B, which only require nexus to DI product
  - Licensing: often utilized by NPEs, requires nexus to
    - i) asserted patents,
    - ii) licensing activities, and
    - iii) United States

# Is My Investment “Significant” or “Substantial” Enough?

an industry in the United States shall be considered to exist if there is in the United States, with respect to the articles protected by the patent, copyright, trademark, mask work, or design concerned—

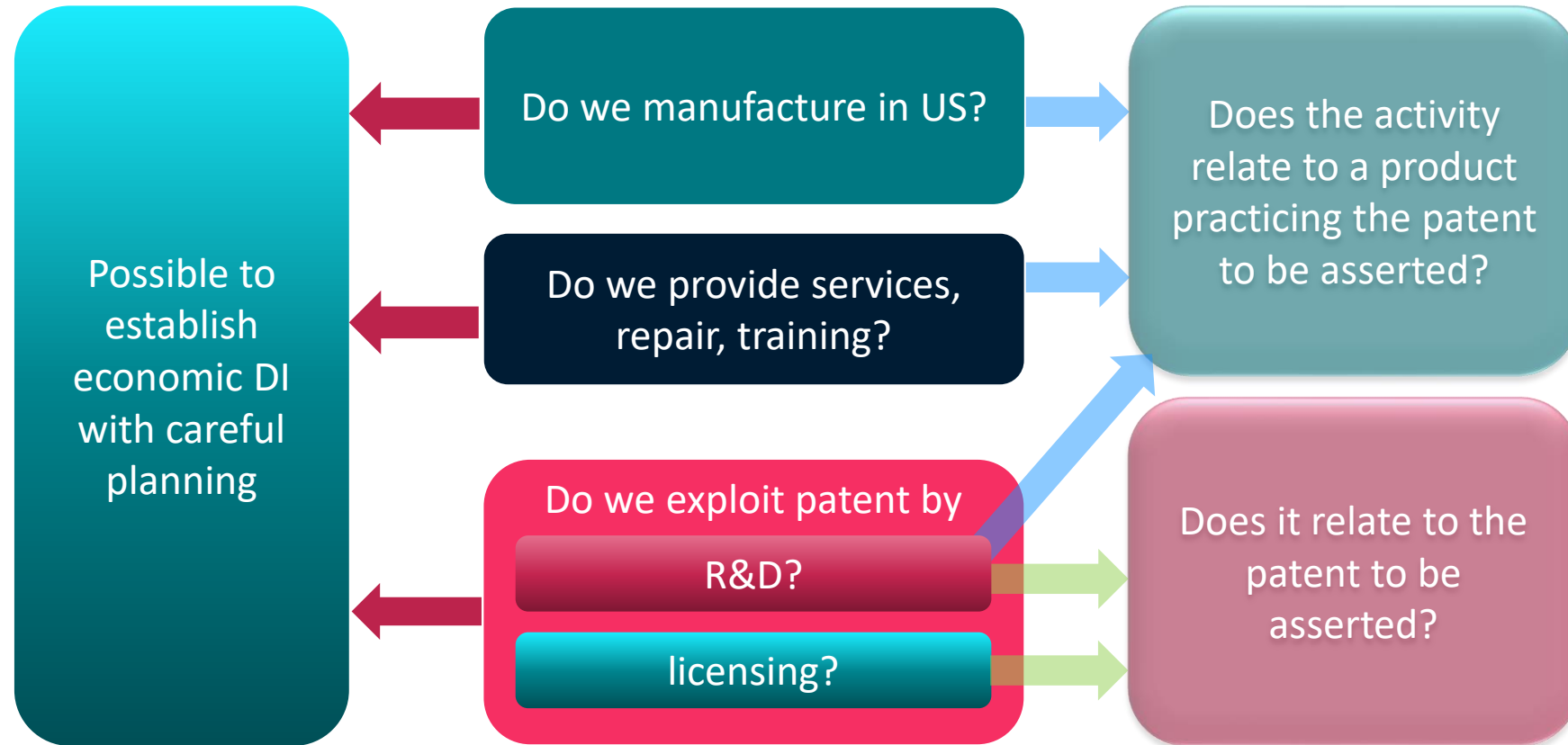
(A) **significant** investment in plant and equipment;

(B) **significant** employment of labor or capital; or

(C) **substantial** investment in its exploitation, including engineering, research and development, or licensing.

- “determining satisfaction of the economic prong is a **flexible exercise**.”
- not measured in the abstract or absolute sense, but with **respect to the nature of activities** and **how they are “significant” to the DI products**.
- The fact that **patent-related investments are small in comparison to overall investments** is **not fatal** to meeting the economic DI.

# Re-cap: Do I Have Economic Domestic Industry?



# Will Public Interest Concerns Weigh Against Relief?

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# What About the Public Interest?

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Section 337 requires issuance of a LEO/CDO “unless after considering the effect of such exclusion upon the public health and welfare...it finds such articles should not be excluded from entry.” 19 U.S.C. § 1337.

1. Public health and welfare
2. Competitive conditions in the U.S.
3. Production of like or directly competitive articles in the U.S.
4. U.S. consumers

# What About the Public Interest?

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- ***Certain Fluidized Supporting Apparatus and Components, Inv. No. 337-TA-182/188 (Oct. 1984) at 23-25 (“Burn Beds”)***
  - “The patented burn bed ***provide benefits unavailable from any other device or method of treatment.***”
  - Complainant could not “supply the new orders of the patented burned beds within a commercially reasonable length of time” in a growing market
  - If Respondent excluded from market, increased price would effectively deny beds to patients with limited means
  - Denied relief

# When Does the Commission Hear Concerns About PI?

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- When the Complaint is filed—Complainant must file a PI statement. 19 CFR §210.8
- Secretary to Commission will publish a notice in the F.R. inviting comments from public on PI within 8 days of publication of notice of filing of the complaint. 19 CFR §210.8
- If Commission orders ALJ to take evidence on PI, respondents must include a PI statement with response to complaint. 19 CFR §210.14.
- Within 30 days of service of the ALJ's ID, parties may submit information relating to PI. 19 CFR §210.50



# What Does the Commission Consider?

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- **Parties, interested members of public, and government agencies may present evidence**
  - Availability of alternative products
  - Comparability of alternatives, i.e., are the alternatives substitutes?
  - Ability to switch to alternatives

# What is a Reasonable Substitute?

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- Non-accused/non-infringing devices sold by respondent
- Devices made by third parties or complainant
- Devices that may be coming on to the market
- Need not be the ***preferred*** device
- Need not have all of the features of the accused product
  - A combination of devices that contain all the features may suffice

# Tailor Request for Relief to Limit Impact on Public Health

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- Propose an exception for service, repair, or replacement of devices imported prior to the effective date of the exclusion order
- Agree to allow importation for targeted uses, e.g. governmental or research use
  - *Certain Microfluidic Devices, Inv. No. 337-TA-1068*
  - Researchers from medical schools and research centers submitted statements saying their research would be compromised if they did not have access to the accused devices
  - Commission tailored LEO and CDO to allow research studies using the infringing articles to continue use. Comm'n Op. at 2 (Dec. 2019).

# One Last Thought on NPEs

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Year	Total	Non-NPE	NPE Category 1	NPE Category 2
2013	42	33	3	6
2014	39	36	0	3
2015	36	34	0	2
2016	54	49	4	1
2017	59	49	7	3
2018	50	43	6	1
2019	47	40	4	3
2020	48	38	7	3
2021	52	42	3	7
2022	59	40	8	11

# Fish ITC Brochure Available at [www.fr.com](http://www.fr.com)

## International Trade Commission



### The Forum of Choice for Expedited Relief

The International Trade Commission (ITC) addresses high-stakes intellectual property (IP) disputes involving imported goods. With its expedited schedule, the ITC can resolve issues quickly and forcefully. It offers a substantive resolution to companies seeking to block imported products that allegedly infringe a U.S. IP right.

To harness the power of an ITC decision on a client's behalf, Fish & Richardson offers the strongest, most experienced team practicing before the ITC today. Fish's lawyers bring a multidisciplinary approach to ITC proceedings, drawing on their expertise in patent law, litigation, and licensing of IP rights.

Together, Fish's lawyers provide an exceptional blend of knowledge and familiarity with the ITC's unique rules and procedures. The Fish team of 170 ITC lawyers includes:

- a former Supervisory Attorney and Investigative Attorney in the Office of Unfair Import Investigations with over 25 years of experience at the ITC,
- a prominent trial attorney who co-teaches, with a former Administrative Law Judge, the first law school class in the U.S. dedicated to IP enforcement rights at the ITC, and
- one of the first lawyers to develop expertise trying patent cases at the ITC, who has handled more than 60 cases in this forum.

Fish was active in the ITC long before the rush to appear in its chambers. Our firm's deep experience and winning track record are why we handle more ITC patent litigation than any other law firm. In 2017 and 2018, Fish was lead counsel in over 20 percent of all new ITC patent investigations and has been involved in more than 130 ITC investigations since 2000.

Fish has handled it all at the ITC: from changing the law regarding "downstream products," to advancing the standards for when non-practicing entities can litigate in the ITC, to confirming the availability of the ITC for emerging industries to conducting unprecedented hearings before the full Commission regarding public interest issues.

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20%

In 2017 and 2018, Fish was lead counsel in over 20 percent of all new ITC patent investigations.

The image features a large teal rectangular area in the center. Inside this area, the word "Questions?" is written in a large, white, sans-serif font. Below it, the word "FISH." is written in a smaller, white, sans-serif font. The background of the entire image is white and contains faint, light blue technical drawings and diagrams, including circles, lines, and symbols, which are partially obscured by the teal rectangle.

**Questions?**

**FISH.**



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# Thank You!

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