

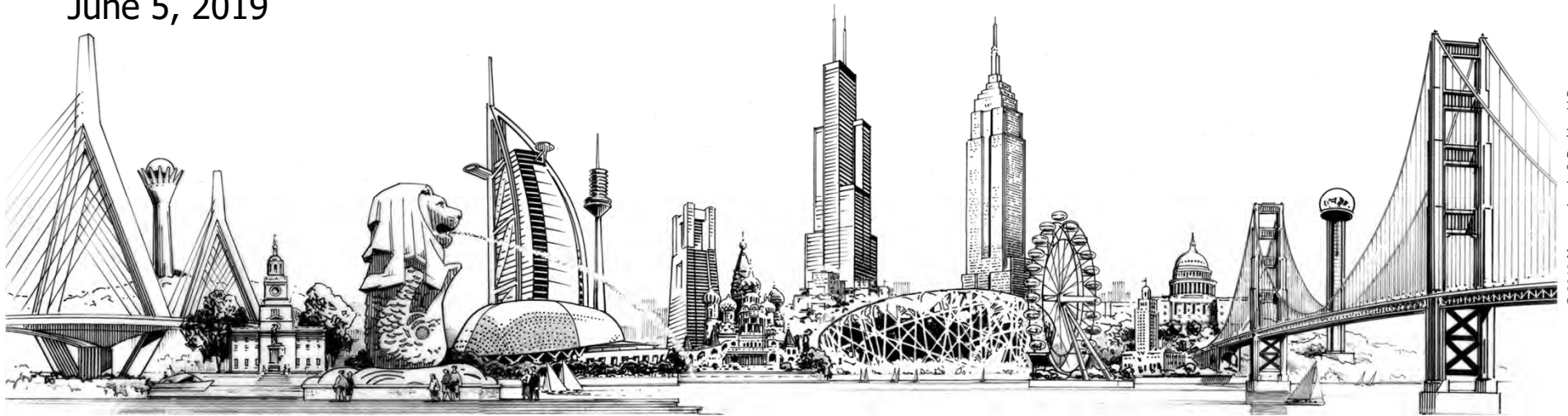
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EXCLUDED:

STRATEGIES FOR MAXIMIZING THE EFFECTIVENESS OF AN ITC EXCLUSION ORDER – OR REDESIGNING YOUR WAY AROUND IT

Ric Macchiaroli, Nick Restauri, and Andrew Gray

June 5, 2019



Overview

- ITC provides a venue to remedy unfair acts and competition in the importation of goods into the United States
- Section 337 Investigations may result in exclusion orders (limited or general), cease & desist orders, and/or seizure and forfeiture orders
- US Customs & Border Protection is charged with enforcing exclusion orders
- US Court of International Trade has jurisdiction to review certain actions and decision by Customs
- ITC also has mechanisms for enforcing, modifying, and interpreting exclusion orders
- Understanding the available procedures each venue provides is critical to the effective enforcement of an exclusion order or, for the prospective importer, avoiding disruptions in legitimate trade

Agenda

- General ITC Background
- Overview of the Enforcement Regime
- Enforcing an exclusion order at the ITC
- Enforcing an exclusion order at Customs
- Responding to an exclusion order at the ITC
- Responding to an exclusion order at Customs
- Review of Customs' decisions by the Court of International Trade
- Interplay of the ITC, Customs & CIT

SECTION 01

GENERAL ITC BACKGROUND

The U.S. International Trade Commission

- The ITC is an independent, quasi-judicial Federal agency with broad investigative responsibilities on matters of trade.
- One of the ITC's primary functions is to adjudicate cases involving imports that allegedly infringe intellectual property rights, known as section 337 investigations.
- 19 U.S.C. § 1337 declares unlawful "unfair methods of competition and unfair acts" in the importation of articles into the U.S.
- Section 337 investigations most often involve claims of patent infringement, but can also include trademark and copyright infringement, trade secret misappropriation, and others.

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The U.S. International Trade Commission

Four offices within the ITC play a role in investigations:

- **The Commissioners.** There are five Commissioners, with a sixth awaiting confirmation by Congress. Each serves overlapping terms of nine years and no more than three from one political party. The Commissioners issue the Final Determination as to the merits of the case.
- **The Office of the General Counsel.** The OGC is staffed by approximately 30 lawyers who provide legal advice and support to the Commissioners.
- **The Administrative Law Judges.** There are six ALJs. Following a hearing on the merits, an ALJ will issue an Initial Determination setting out his or her rulings. The Initial Determination will then go up to the Commissioners for review and issuance of the Final Determination, much like an appeal.
- **The Office of Unfair Import Investigations.** The OUII is comprised of 20 lawyers who are responsible for representing the public interest. The Staff, when assigned, is a full party to the investigation.

Unique Elements of a Section 337 Investigation

There are several unique elements in an ITC investigation:

- **Speed.** By statute, investigations must conclude at the “earliest practicable time.” This has practical effects, such as the Commission’s refusal to stay an investigation pending a successful, but non-final, *inter partes* review.
- **Broad Discovery.** Discovery at the ITC is extremely broad and incredibly expedited. Parties typically have ten days to respond to discovery requests, and there are few limits to the number of requests.
- **The Domestic Industry Requirement.** The complainant must show that it has made sufficient investments in the U.S. related to its own products which practice the asserted IP. For federally registered IP rights, injury to the domestic industry is assumed.
- **Prospective Remedies.** The ITC does not award money damages. Rather, it offers powerful injunctive relief:
 - Limited Exclusion Order (LEO)
 - General Exclusion Order (GEO)
 - Cease and Desist Order (CDO)

Remedies for a Violation - LEO

Limited Exclusion Order. The LEO is the default remedy for a violation of Section 337. Excludes covered products of the named respondent.

“The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting the unlicensed entry into the United States of covered [infringing products] manufactured by or on behalf of the Respondents or any of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns.”

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UNITED STATES INTERNATIONAL TRADE COMMISSION Washington, D.C.	
In the Matter of CERTAIN L-TRYPTOPHAN, L-TRYPTOPHAN PRODUCTS, AND THEIR METHODS OF PRODUCTION	Investigation No. 337-TA-1005
LIMITED EXCLUSION ORDER	
The United States International Trade Commission ("Commission") has determined that there is a violation of Section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the unlawful importation, sale for importation, or sale within the United States after importation by Respondents CJ CheilJedang Corp., CJ America, Inc., and PT CheilJedang Indonesia (collectively, "Respondents") of certain L-tryptophan and L-tryptophan products covered by claim 20 of U.S. Patent No. 7,666,655 or claim 10 of U.S. Patent No. 6,180,373.	
Having reviewed the record of this investigation, including the written submissions of the parties, the Commission has made its determination on the issues of remedy, public interest, and bonding. The Commission has determined that the appropriate form of relief is a limited exclusion order prohibiting the unlicensed entry into the United States of covered L-tryptophan and L-tryptophan products manufactured by or on behalf of the Respondents or any of their affiliated companies, parents, subsidiaries, or other related business entities, or their successors or assigns.	
The Commission has also determined that the public interest factors enumerated in 19 U.S.C. 1337(d) do not preclude the issuance of the limited exclusion order, and that the bond	

Remedies for a Violation - GEO

General Exclusion Order. The GEO excludes all covered products regardless of source.

“The Commission has determined that a general exclusion order from entry for consumption is necessary to **prevent the circumvention of an exclusion order limited to products of named persons** and because there is a **pattern of violation of section 337 and it is difficult to identify the source of infringing products.** Accordingly, the Commission has determined to issue a general exclusion order prohibiting the unlicensed importation of [infringing products].”

To obtain a GEO, a complainant must demonstrate that:

- the GEO is necessary to prevent circumvention of an LEO, or
- there is a pattern of violation and it is difficult to identify the source of infringing products.

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UNITED STATES INTERNATIONAL TRADE COMMISSION Washington, D.C.	
In the Matter of CERTAIN PUMPING BRAS	Investigation No. 337-TA-988
GENERAL EXCLUSION ORDER	
The Commission has determined that there is a violation of Section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. § 1337, in the unlawful importation, sale for importation, or sale within the United States after importation of certain pumping bras that infringe claims 10, 12, 14, or 27-37 of United States Patent No. 8,323,070 ("the '070 patent").	
Having reviewed the record in this investigation, including the written submissions of the parties, the Commission has made its determinations on the issues of remedy, the public interest, and bonding. The Commission has determined that a general exclusion from entry for consumption is necessary to prevent circumvention of an exclusion order limited to products of named persons and because there is a pattern of violation of section 337 and it is difficult to identify the source of infringing products. Accordingly, the Commission has determined to issue a general exclusion order prohibiting the unlicensed importation of infringing pumping bras ("covered products").	
The Commission has also determined that the public interest factors enumerated in 19 U.S.C. § 1337(d) do not preclude issuance of the general exclusion order, and that the bond during the Presidential review period shall be in the amount of one hundred (100) percent of entered value for all covered products in question.	

Preparing for the Remedy

Focus on achieving a positive outcome, but prepare for a negative outcome.

- Meet with your customers if they are not part of the Investigation
 - ✓ Explain the situation and address their concerns
- Consider alternative suppliers of accused products or components
- Stockpiling product in the US is not a viable option

Determine whether a design-around is possible.

- Work with outside counsel, experts, and engineers to assess feasibility
- Begin work as early as case will allow
- Obtaining a ruling on the redesign during the investigation is far preferable to waiting until after an exclusion order has issued

Preparing for the Remedy

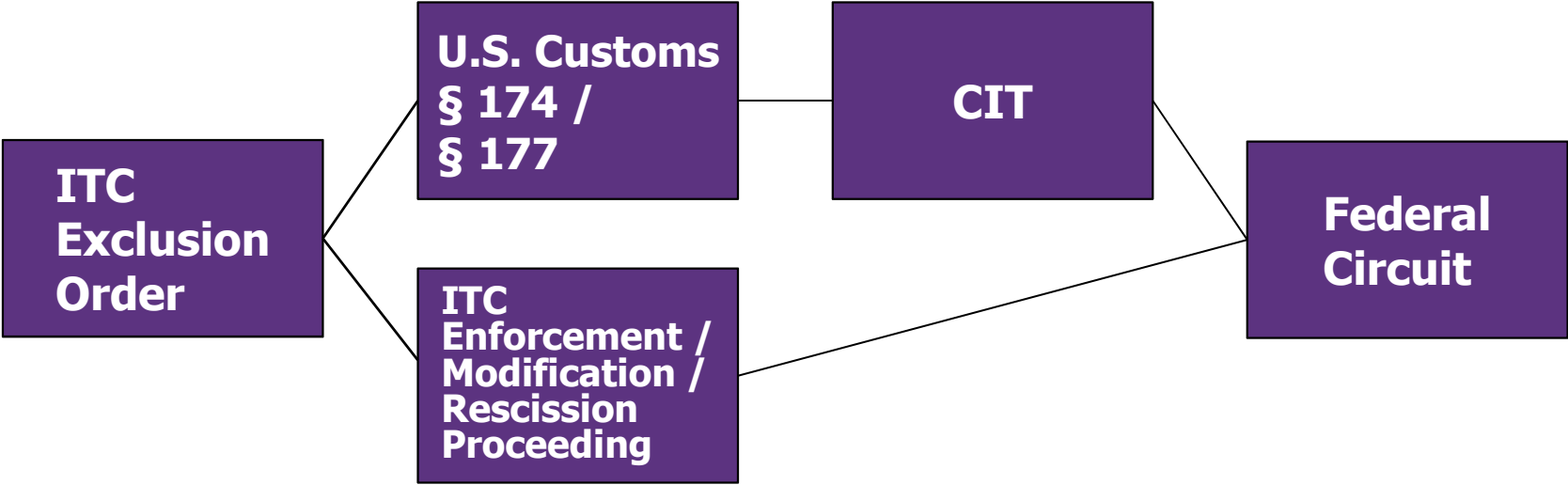
Ask for a Certification Provision.

- Exclusion Orders can include a “certification provision” by which an importer may certify to Customs that a given entry of articles is not covered by an exclusion order.
- Generally require the importing party to certify, in writing and under oath, that based upon a reasonable inquiry, the goods the importer is seeking to import are outside the scope of the exclusion order.
- While the standard certification provision language is broadly worded, Customs’ historical application of such provisions has been limited.

SECTION 02

OVERVIEW OF THE ENFORCEMENT REGIME

Overview of the Enforcement Regime



International Trade Commission

- Exclusive jurisdiction to issue, rescind, or modify Exclusion Orders
- Successful complainant can request enforcement actions
- Importers can request modification / rescission actions
 - Based on changed circumstances of fact or law
 - May determine whether a new or redesigned product is covered or order should be modified to include “carve-out” for new or redesigned product
 - Appealable to Federal Circuit
- Importers can request advisory opinion
 - Not appealable to Federal Circuit

U.S. Customs & Border Protection

- Charged with enforcing Exclusion Orders
- Intellectual Property Rights Branch in Washington DC
 - Provides instructions to over 300 Ports of Entry (not public)
 - Occasionally meets with parties, receives briefing, and/or holds hearings
 - Patentees may provide industry intelligence and other info to assist with enforcement
 - Importers may provide information to avoid disruption in legitimate trade
- Statutory mechanisms for obtaining Customs' official position
 - 19 CFR Part 177 – Administrative Rulings
 - 19 CFC Part 174 – Protests

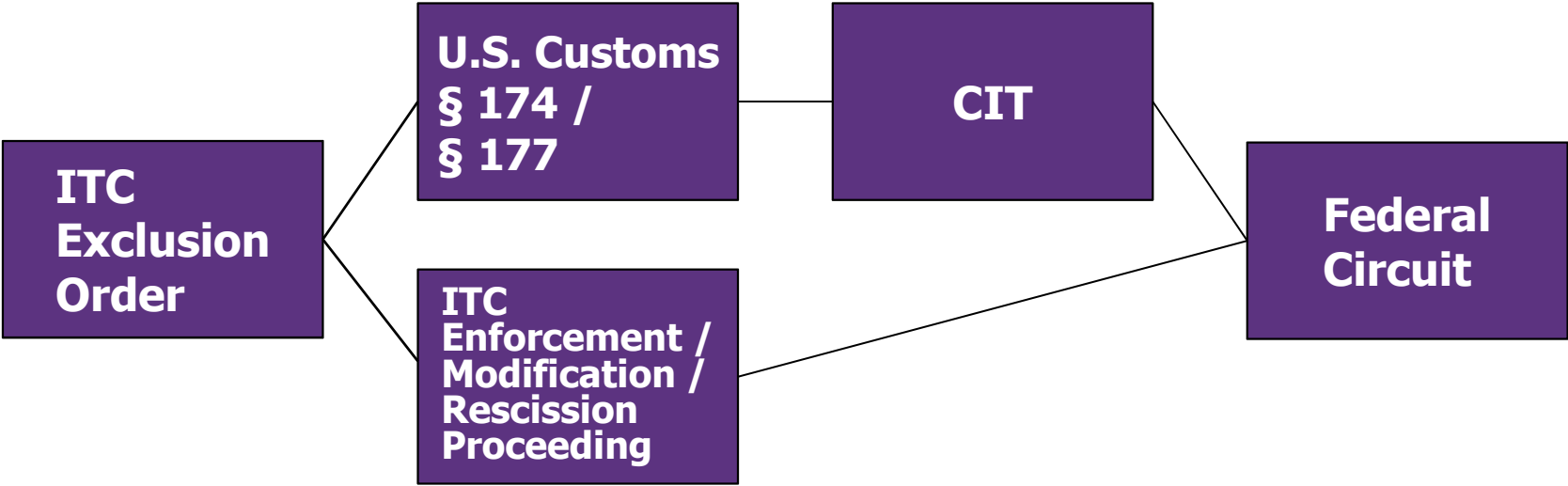
U.S. Court of International Trade

- Customs Courts Act of 1980 converted the US Customs Court into the Court of International Trade
 - Expanded the power of the CIT
 - Article III court with full powers in law and equity as any District Court
- CIT has nationwide jurisdiction over civil actions rising out of the customs and international trade laws – 28 USC Chapter 169
- Court of special jurisdiction – 28 USC Chapter 95
- Many of the cases involve challenges to appraised values of goods; goods classification and rates for duties; liquidation of entries; etc.

SECTION 03

ENFORCING AN EXCLUSION ORDER AT THE ITC

Overview of the Enforcement Regime



Enforcing an Exclusion Order: ITC Enforcement Proceedings

- **A complainant can enforce an exclusion order through an ITC Enforcement Action.**
- **Two types of Enforcement Actions: Informal and Formal.**
- **Informal Enforcement Actions** are governed by Commission Rule 210.75(a).
 - They are conducted by the Commission through the Office of Unfair Import Investigations, and are generally handled through correspondence and conference with the accused party.
 - The Commission may issue such orders as it deems appropriate to implement and insure compliance with the exclusion order.
 - Any issues not resolved by informal action may be made the subject of a formal action.
 - There is no set time for the Commission to conduct an informal enforcement action.

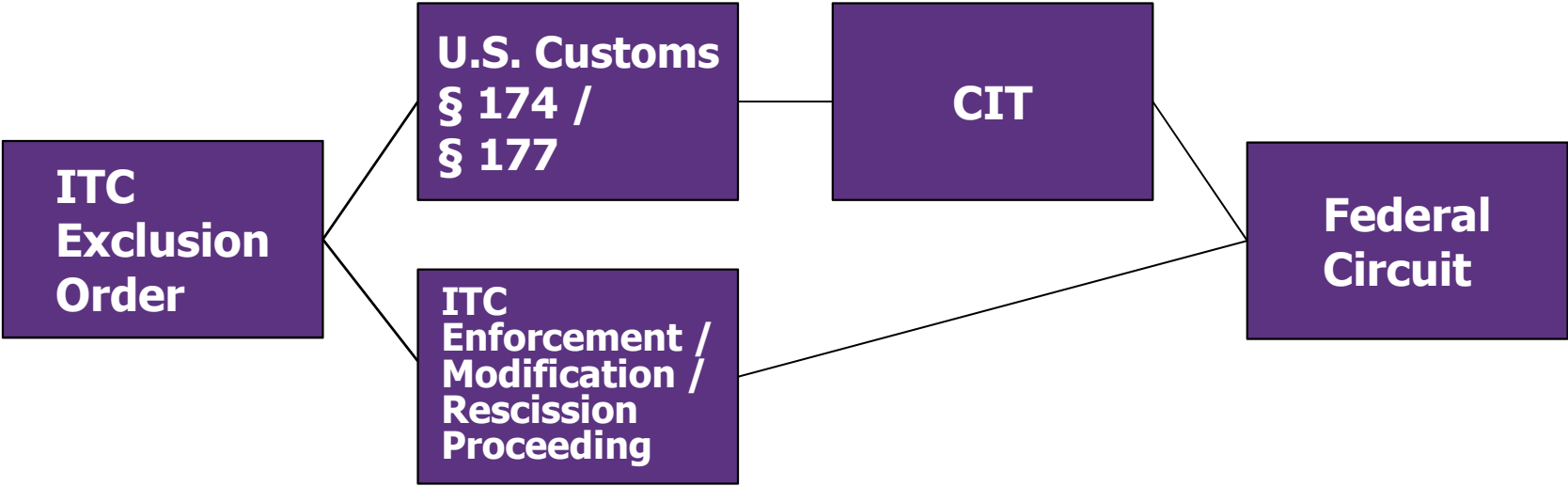
Enforcing an Exclusion Order: ITC Enforcement Proceedings

- **Formal Enforcement Actions** are governed by Commission Rule 210.75(b).
 - Formal enforcement proceedings are delegated to an ALJ, and proceed in much the same manner as a violation phase investigation.
 - If an importer is found to have violated the exclusion order, the Commission may modify the order in any manner necessary to prevent the continuing unfair practices.
 - Commission Rule 210.51(a)(2) requires that the target date for a formal enforcement proceeding be no more than twelve months from institution without Commission approval.
 - Enforcement actions are *inter partes*, and may also include the Staff.
 - An enforcement respondent may assert any defense not barred by claim preclusion. Specifically, the Federal Circuit has found that enforcement actions fall within the scope of 19 U.S.C. § 1337(c), which provides that “all legal and equitable defenses may be presented in all cases,” including invalidity.

SECTION 04

ENFORCING AN EXCLUSION ORDER AT CUSTOMS

Overview of the Enforcement Regime



Customs' Enforcement of Exclusion Orders

- Typical import process
 - Shipments of goods arrive at a port
 - If suspected of violating an Exclusion Order, Customs requests that merchandise be delivered to a container examination station ("CES") for inspection
 - Unloaded by private contractor and "presented for examination"
 - Customs has 5 days to issue a Notice of Detention
 - Customs has 30 days to release the goods or issue a Notice of Exclusion
 - If Customs excludes goods, it provides notice to the ITC
 - ITC may issue a seizure order

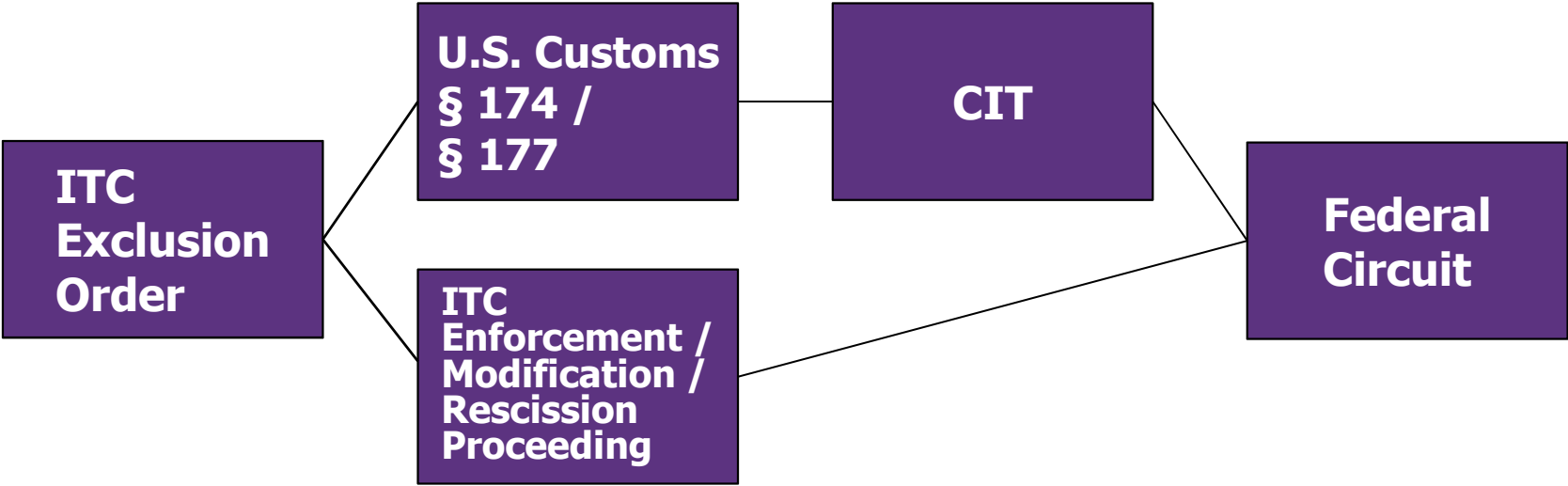
Ways for the Complainant to Assist Customs

- Meet with Customs' IPR Branch shortly after issuance of Exclusion Order
- Complainant can give presentation to assist Customs in drafting instructions to Ports
 - Any interested party may meet with CBP to present its interpretation of the scope of a limited or general exclusion order and position regarding implementation
 - Customs' final instructions not publicly available; not subject to FOIA
- Complainant can provide information on suspected violations of an Exclusion Order
 - Identify potential importers and offending goods
 - E.g., ports of entry, importers, packaging to look for, markings or labels, etc.

SECTION 05

**RESPONDING TO AN
EXCLUSION ORDER AT THE
ITC**

Overview of the Enforcement Regime



Responding to an Exclusion Order: ITC Modification Proceeding

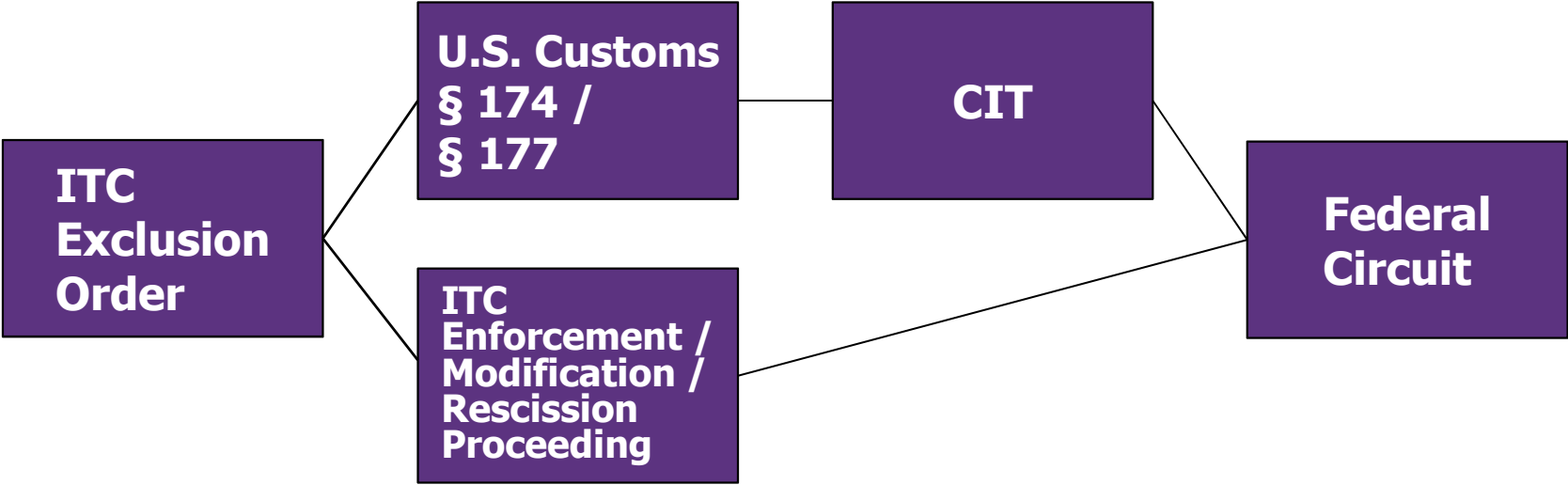
Importer may ask ITC whether a redesign product is covered by an exclusion order

- **Modification Proceedings under 19 C.F.R. § 210.76**
 - ✓ Prospective in nature; Requested *before* importation
 - ✓ Redesign must not have been available during the violation phase
 - ✓ Depending on the complexity, proceeding could last between 60 days and 9 months
 - 60-90 days: pure legal questions; office of general counsel conducts proceeding
 - 90-180 days: minimal factfinding; office of unfair import investigations conducts proceeding
 - 6-9 months: extensive factfinding; ALJ conducts proceeding
 - ✓ Unlike a Customs Ruling Letter, ITC modification determination is binding on Customs
 - ✓ Appealable to the Federal Circuit
- **Advisory Opinions under 19 C.F.R. § 210.79**
 - ✓ Similar in scope and timing, but neither appealable nor precedential

SECTION 06

**RESPONDING TO AN
EXCLUSION ORDER AT
CUSTOMS**

Overview of the Enforcement Regime



Responding to an Exclusion Order: U.S. Customs

An importer may ask Customs whether a product is covered by an exclusion order.

- **Administrative Ruling Request under 19 C.F.R. § 177**
 - ✓ Prospective in nature; applies to future entries
 - ✓ Intellectual Property Rights Branch (IPRB) conducts proceeding
 - ✓ Ruling in 30-90 days, but typically takes longer
 - ✓ Customs' ruling not binding on ITC
 - ✓ Appealable to the CIT under 28 U.S.C. § 1581
- **Protest Against Exclusion under 19 C.F.R. § 174**
 - ✓ Retrospective in nature; only applies to the excluded entry
 - ✓ No proceedings; briefing only
 - ✓ Ruling in 30 days (if expedited treatment requested)
 - ✓ Customs' ruling not binding on ITC
 - ✓ Appealable to the CIT under 28 U.S.C. § 1581(a)

19 CFR Part 177 Administrative Rulings

- Intended to provide Customs' official position on treatment of *prospective* transactions
 - E.g., how Customs will treat application of an Exclusion Order to new or redesigned goods
- Often referred to as a "Ruling Letter"
 - Importer submits written information and request for ruling to IPR Branch
 - IPR Branch issues a "Ruling Letter" representing "the official position of Customs" and that is "binding on all Customs Service personnel" – 19 CFR 177.9
- Generally, an *ex parte* process, but IPR Branch may convert to *inter partes*
- Timing varies
 - 30-90 days, but may include a request to expedite

19 CFR Part 174 Protest Decisions

- Mechanism to challenge Customs' official actions
- 19 CFR 174.11 – Matters subject to protest
 - Includes protest of “exclusion of merchandise from entry”
- Recall typical import process
 - Goods arrive at port and are unloaded and “presented for examination”
 - Customs has 5 days to make initial decision or issue a Notice of Detention (§ 151.16(b))
 - Customs has 30 days to release goods or issue a Notice of Exclusion (§ 151.16(f))
- Importer has 180 days to file protest (§ 151.14)
- May include a request to expedite (§ 151.15)
- Customs has 30 days to decide protest or deemed denied (§ 151.16(g))

Other Informal Actions

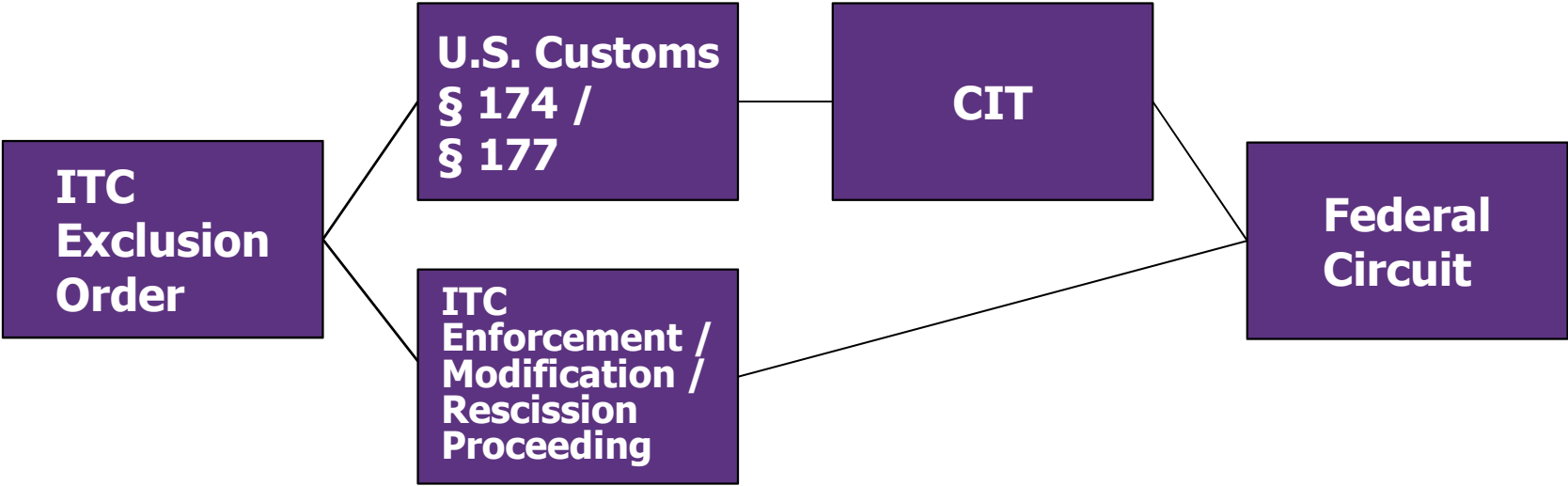
Take action to guard against disruption in the supply chain

- Assist Customs by providing information regarding incoming shipments of non-infringing products
- Maintain close contact with IPRB and the relevant ports of entry regarding incoming shipments of non-infringing products
- Expect and anticipate that the complainant will also be speaking with Customs to urge the broadest possible interpretation of the exclusion order
- Expect the complainant to monitor the marketplace closely

SECTION 07

**REVIEW BY THE COURT OF
INTERNATIONAL TRADE**

Overview of the Enforcement Regime



CIT Jurisdiction

- The CIT has exclusive jurisdiction over Customs' protest decisions and Ruling Letter decisions. *See* 28 U.S.C. § 1581
- USC 1581 - Exclusive jurisdiction over civil actions against the US and agencies and officers thereof, including:
 - 1581(a) over protest denials
 - 1581(h) over actions with respect to future shipments BUT ONLY if irreparable harm if not permitted pre-importation judicial review (injunctive relief not available)
 - 1581(i) residual jurisdiction
 - Actions commenced against US and arising out of laws providing for (1) import revenue; (2) tariffs; (3) embargoes; or (4) administration and enforcement of matters identified in (1)-(3) AND described in (a)-(h)

1581(a) - Protest Denials

- Importation Process
 - Import goods
 - Customs issues Notice of Exclusion or takes longer than 30 days after “presentment for examination”
- Importer has 180 days to file a protest pursuant to 19 CFR Part 174
 - CBP Form 19
 - Format is flexible, can be a memorandum or letter in support of protest
 - § 174.13 specifies content required for protest – e.g., importer information, number and date of entry, description of goods, and “nature of, and justification for the objection”
- Customs has 30 days to decide protest or deemed denied (§ 151.16(g))
- After 30 days or denial, importer may file a complaint at Court of International Trade

1581(h) – Rulings with respect to Prospective Imports

- Importer can file CIT complaint seeking declaratory judgment with respect to specific contemplated future shipments of goods
 - E.g., that a new or redesign product does not infringe a patent
- Must show irreparable harm if not permitted to obtain pre-import review
- Catch-22
 - Have to show that the delay in importing goods and proceeding through a protest would cause irreparable harm
 - But injunctive relief not available - 28 U.S.C. § 2643(c)
 - Shipping only takes 5 weeks, and obtaining a DJ at the CIT could take several months or more

1581(i) – Residual jurisdiction

- 28 USC 1581(i) – CIT has exclusive jurisdiction over actions commenced against US and arising out of laws providing for
 - (1) import revenue;
 - (2) tariffs;
 - (3) embargoes; or
 - (4) administration and enforcement of matters identified in (1)-(3) AND described in 1581(a)-(h)
- Recall 1581(a) describes the protest process and 1581(h) describes pre-importation reviews

1581(i) – Residual jurisdiction

- Why is this section often called “residual jurisdiction” –
 - “§ 1581(i) is the residual jurisdiction provision, and may only be invoked when another subsection of § 1581 is unavailable **or** the remedy provided by another subsection is ‘manifestly inadequate.’” *Am. Frozen Food Inst., Inc. v. United States*, 855 F. Supp. 388, 392 (Ct. Int'l Trade 1994).
 - If a party has “meaningful opportunities for protest” of a Customs action, it must exhaust those opportunities *before* § 1581(i) becomes available as a basis for CIT jurisdiction. *CDCOM (U.S.A.) Int'l, Inc. v. United States*, 963 F. Supp. 1214, 1218 (Ct. Int'l Trade 1997).
 - *See also R.J.F. Fabrics*, 651 F. Supp. at 1434 (“A party must exhaust meaningful opportunities for protest instead of resorting to § 1581(i) as a jurisdictional basis.”)

1581(h) & (i) – Review of Customs’ Ruling Letters

- Customs’ Ruling Letters issued under 29 CFR Part 177 are also reviewable by the CIT
- How?
 - Catch-22 that § 1581(h) is only available if can show irreparable harm if forced to protest
 - Can § 1581(i) be invoked because “another subsection of § 1581 is unavailable”?
- Very few importers have utilized this option, but case law recognizes it:
 - *Am. Air Parcel Forwarding Co. v. United States*, 718 F.2d 1546, 1549 (Fed. Cir. 1983) (“It does appear that § 1581(h) was intended to provide an importer with review of a ruling contained in a ‘ruling letter’ issued to him [19 CFR § 177.9(b)]. . . . However, we do not need to rule on this issue but merely note that the importers failed to utilize this procedure ”)
 - “Section 1581(i) is the proper basis to challenge CBP’s failure to comply with § 1625’s requirements. No other subsection of § 1581 allows for such a challenge.” *Best Key Textiles Co. Ltd. v. U.S.*, 942 F. Supp. 2d 1367,1373 (Ct. Int’l Trade 2013).
 - § 1625(c) involves Customs procedures when issuing interpretive rulings

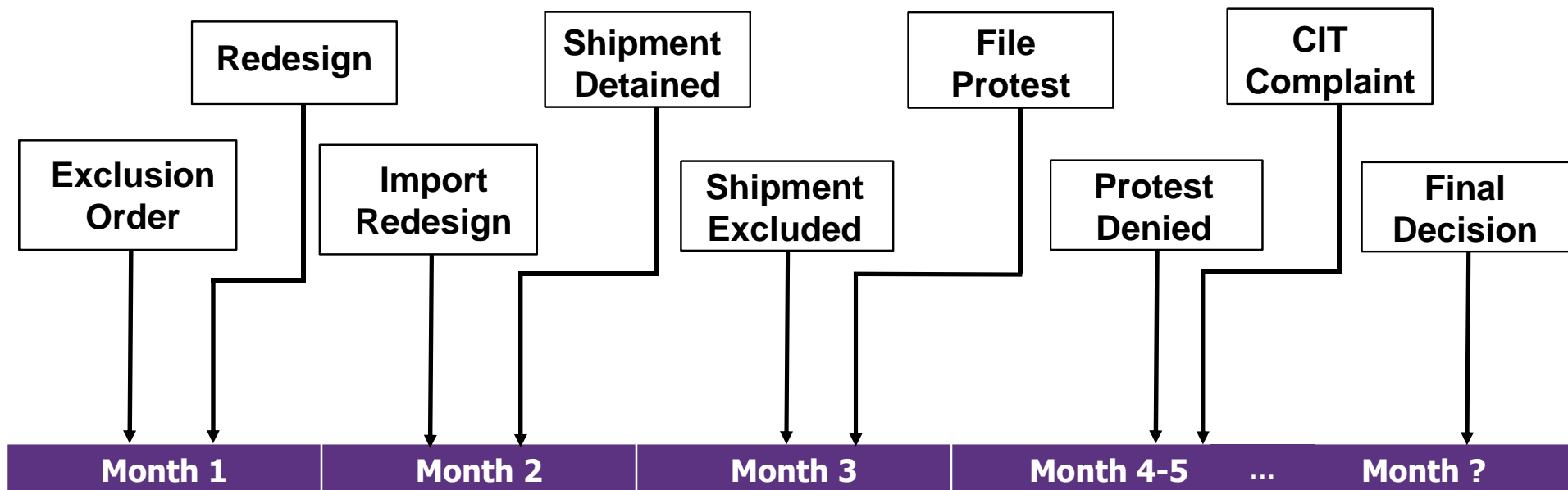
SECTION 08

**INTERPLAY OF THE ITC,
CUSTOMS, & CIT**

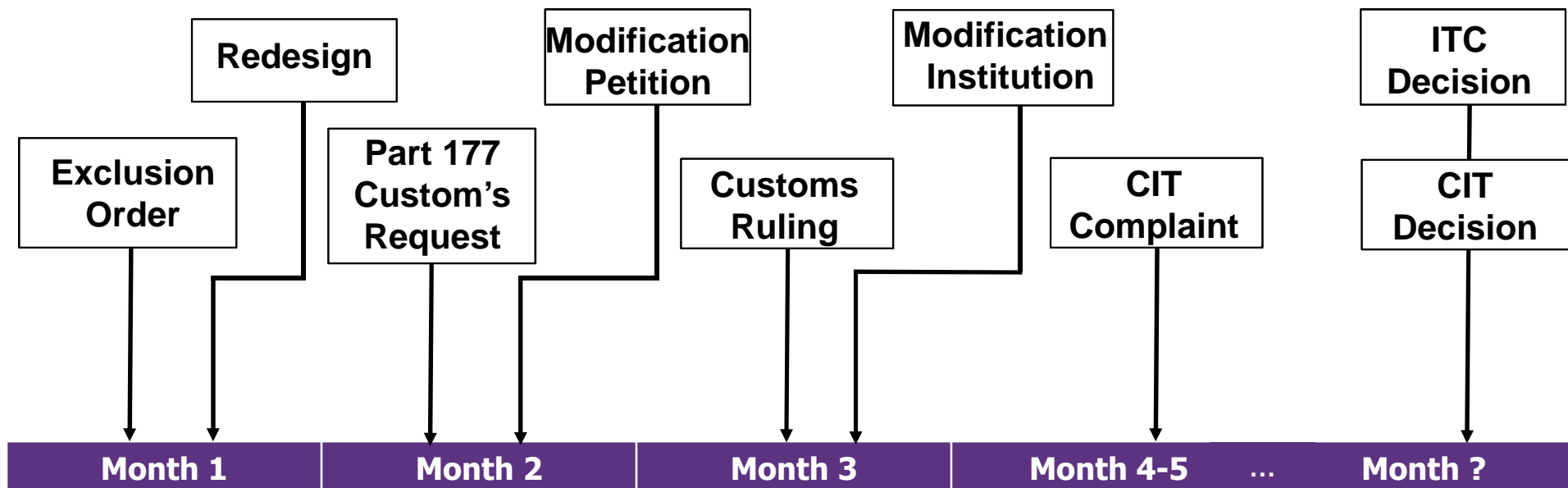
Possible Tension in Enforcement Scheme

- ITC issues Exclusion Orders, CDOs, and Seizure Orders
- Customs enforces and may have to interpret issues not directly reached by the ITC
- Customs' opinions reflecting its official position are reviewable by the CIT
- CIT can vacate or reverse Customs' decisions
- Possible for tension with the ITC's exclusive or primary jurisdiction to modify or rescind Exclusion Orders
- CIT only reviews Customs' position, not the ITC's

Example Timeline 1



Example Timeline 2



Biography



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Riccardo (Ric) Macchiaroli's practice focuses on intellectual property litigation and international trade, with a particular focus on Section 337 investigations before the US International Trade Commission (ITC). Ric has represented complainants, respondents, and third parties in more than 30 investigations, involving a wide array of technologies and industries.

Biography



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Biography



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Serving as the leader of Morgan Lewis’s semiconductor practice, Andrew J. Gray IV concentrates his practice on intellectual property (IP) litigation and prosecution and on strategic IP counseling. Andrew advises both established companies and startups on computer and Internet law issues, financing and transactional matters that involve technology firms, and the sale and licensing of technology. He represents clients in patent, trademark, copyright, and trade secret cases before state and federal trial and appellate courts throughout the United States, and before the US International Trade Commission.

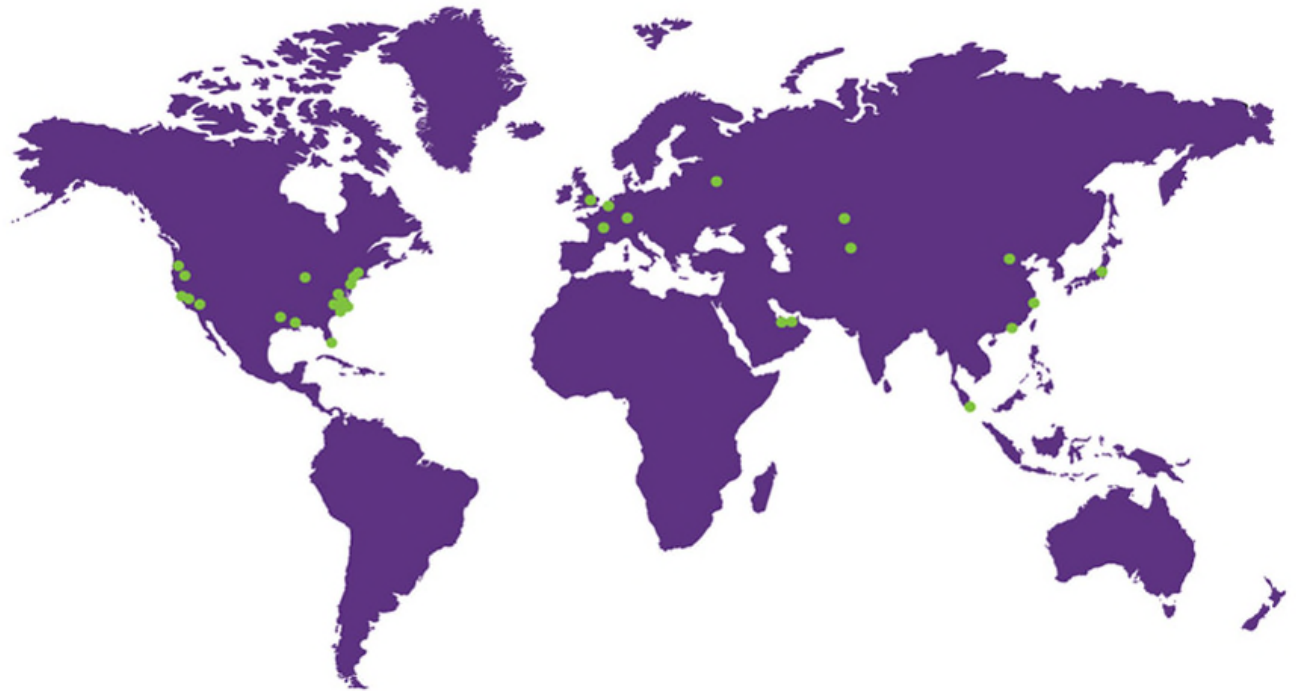
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Our Global Reach

Africa
Asia Pacific
Europe
Latin America
Middle East
North America

Our Locations

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Almaty
Beijing*
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Dallas
Dubai
Frankfurt
Hartford
Hong Kong*
Houston
London
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