

Navigating Risks for Foreign Manufacturers Whose Products are Distributed in The United States

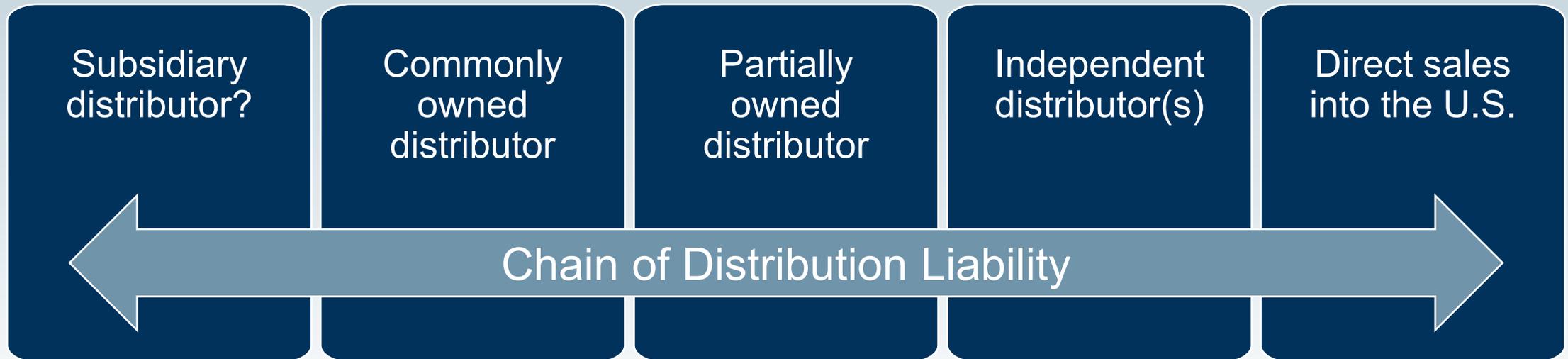
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Presentation Overview

- Exposure of foreign importers/manufacturers to jurisdiction in the U.S., generally
- Alternative means to secure jurisdiction through “alter ego” and agency arguments
- The Regulatory Interaction (with FDA)
- Addressing contractual obligations between Foreign Manufacturers and U.S. Distributors
- Discovery efforts over Foreign Manufacturers
- Domestication of Foreign Judgments

How is the Foreign Manufacturer Getting Its Products to U.S. Market?



Jurisdiction and Liability Exposure in U.S. Courts

- First defense is typically based on a challenge to jurisdiction
- States get jurisdiction through their “long arm” statutes
- Courts in the U.S. are limited in their ability to hear disputes involving companies that do not “purposefully avail themselves” of jurisdiction in the forum
- Foreign suppliers of products that do not knowingly distribute products into a jurisdiction may take advantage of this defense



Stream of Commerce Theory

- For product liability in particular many courts interpret Supreme Court precedent under a “stream of commerce” theory
- If a foreign importer or manufacturer does not direct (in some cases) or know about (in some cases) distribution of the product into the jurisdiction, they cannot be sued in that jurisdiction
- Active vs. Passive distribution into jurisdiction
- Marketing into the jurisdiction
- *Asahi Metal Indus. Co. v. Superior Court of Cal.* (1987) and more recent cases out of the SCOTUS

Recent SCOTUS Decisions on Personal Jurisdiction

Ford Motor Co. v. Montana Eight Judicial District (2021)

- Allows a court to exercise specific jurisdiction over defendant with nationwide presence when a corporation serves a market for a product in the forum state
- Affirmed “related enough” standard for corporate defendant’s contacts with forum
- Defendant must take active steps to serve a market for a product before it is subject to personal jurisdiction because the stream of commerce swept the product there

Mallory v. Norfolk Southern Railway (2023)

- Allows a court to exercise general jurisdiction over a corporation registered to do business in a state
 - If the state law is explicit that registration is a basis for general jurisdiction
 - Company has substantial in-state presence
- Because every U.S. state requires foreign corporations to register, must check state law on scope of general jurisdiction

SCOTUS has not addressed e-commerce/internet sales

Does The Interaction With the U.S. Regulators Establish Jurisdiction Over Foreign Manufacturers?



FDA

- Premarket approval
- 510(k) clearance
- Quality Systems Regulation



Import requirements

- FDA registration
- U.S. Agent Requirement
- Customs and Border Protection considerations

Who is Interacting With the FDA?

Before selling a medical device in the United States it must be approved or cleared with the FDA.

- Who is getting that approval?
- Who is responsible for recalls?
- Who is responsible for vigilance?
- Who is communicating with the FDA?

Any of these activities could confer U.S. jurisdiction over the party engaged in these activities.

Jurisdiction Through “Alter Ego” Arguments

- A court may take jurisdiction over a foreign manufacturer if its distributor is simply an “alter ego” of the same company – whether they are in fact “separate entities”
- Key is the recognition and maintenance of the corporate formalities between the two entities

The Key Considerations are:

- Whether there is such unity of interest and ownership that the separate personalities of the two entities no longer exists
- The failure to disregard their separate identities would result in fraud or injustice



Jurisdiction Through Agency Arguments

- Courts will extend jurisdiction over foreign parent or principal company's where they are using a subsidiary as their “agent” in the U.S.
- Generally, an agency relationship is formed where one party (the foreign manufacturer in this case) has the right to control the performance of another party (the U.S. distributor in this case).
- Ownership is generally not sufficient by itself (assuming no alter ego) – there must be other elements of control to establish agency.
- This is a fact intensive inquiry and it involves the existence of the agency relationship as well as the scope of that relationship.

Strategies to Avoid Being Subject to Widespread Jurisdiction in U.S. Courts

- Reducing active, widespread involvement in the distribution and marketing of products in the U.S.
 - Use U.S. subsidiaries (but not wholly owned)
 - Limit direct involvement in U.S. to specific jurisdictions
- Limited Footprint in the U.S.
- Make foreign entity an additional insured on U.S. subsidiary's insurance
- Carefully craft distribution agreements

Distribution Agreements (Key Components)



Plaintiffs may use distribution agreements to confer jurisdiction, establish agency or pierce the corporate veil



Agreements must be written to avoid these risks



Agreements must clearly delineate who has responsibility for what (such as who is interacting with the FDA)



Agreements may limit liability, require insurance and indemnification of foreign manufacturer



You can build in all the protections in the world—this is no substitute for insurance

U.S. Discovery of Foreign Manufacturers

- Even if the foreign manufacturer is not sued—a plaintiff may still seek discovery from the foreign manufacturer
- U.S. discovery can be quite onerous

The Key Considerations are:

- Force the use of the Hague or other service mechanisms
- Use home laws to protect information/documents
- Use home discovery laws to thwart the discovery process
- How data/documents are shared between foreign manufacturers and U.S. distributor
- Measure risk of non-compliance with a U.S. court order of discovery



Practical Considerations to Resisting Discovery of Foreign Manufacturers

- May pose significant practical challenges for defense of manufacturer's product in the U.S. in product liability suit against others in distribution chain
- Evaluation of risk of resisting manufacturer discovery must consider how litigation will proceed
 - Who has design or manufacturing records?
 - Who has product testing information?
 - What personnel can serve as witnesses on behalf of the defense?
- Will the product liability litigation impact reputation, sales, regulatory requirements of the manufacturer's product such that participation is necessary?

The Plaintiff Has a U.S. Judgment Against You: Now What?

- Plaintiff's lawyers want to follow the easiest path to collect on a judgment
- Going to a foreign jurisdiction to try to collect a judgment can be daunting
 - Concerns about a lack of comity in a foreign jurisdiction
 - Concerns about risk of bankruptcy in a foreign jurisdiction
- When resolving cases for foreign manufacturers, leverage these concerns



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