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Drug & Medical Device Litigation 2020

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Challenges for ex-U.S. Entities Confronting the U.S. Regulatory and Tort Labyrinth


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Introduction

Plaintiffs often file product liability and class action lawsuits in the United States against corporations and other entities that are located *outside* of the United States. These "ex-U.S. entities", particularly in the life sciences sector, may also be subject to extensive regulations that are enforced by administrative agencies within the United States (such as the U.S. Food and Drug Administration (FDA) or Federal Trade Commission (FTC)). Increasingly, protracted litigation and pervasive regulation are considered costs of doing business in the United States for entities within the distributive chain of prescription drugs and medical devices. But the pitfalls and challenges are particularly acute for ex-U.S. entities unfamiliar with the American judicial system and administrative framework. Indeed, given the recent spate of high-profile, billion-dollar verdicts in product liability cases, ex-U.S. entities should make every effort to understand the litigation risks and opportunities associated with marketing and selling their products in the United States.

This article offers an introduction to the legal and regulatory obstacles that ex-U.S. entities must navigate when facing lawsuits related to manufacturing, distributing, and selling prescription drugs and medical devices in the United States. Among other key issues, we provide an overview of the following topics: (1) personal jurisdiction; (2) venue, service of process, and other forum-related considerations; (3) written and oral discovery; (4) dispositive motions, jury trial, and appeals; (5) enforcement of judgments; and (6) regulations administered by the FDA and other relevant agencies. Along the way, we provide some general observations on strategy and risk management for ex-U.S. entities to consider during the regulatory process and once litigation has commenced.

The goal of this article is to facilitate a basic understanding of the U.S. legal system and regulatory regime. American litigation is often costly and protracted, involving fact-specific and high-stakes disputes over both procedural and substantive matters. For example, in the early stages of litigation, ex-U.S. entities may be subject to intrusive discovery into commercially sensitive internal documents. And at the culmination of litigation, ex-U.S. entities may be subject to potential liability for exorbitant compensatory and punitive damages awards. Moreover, the U.S. system of federalism – under which only certain cases may proceed in federal court, while others must proceed in the courts of individual states with potential local biases – can lead to great disparity in verdicts and rulings on dispositive motions. For these reasons, ex-U.S. entities that are conducting (or planning to conduct) business in the United States should consider communicating with knowledgeable attorneys who can conduct risk assessments tailored to their circumstances and needs. Likewise, on the regulatory side, ex-U.S. entities should consider working with attorneys who are knowledgeable about the relevant regulatory framework – from product formulation and marketing authorisation, to post-marketing compliance, lifecycle management, and enforcement matters. This article is not a substitute for legal advice with regard to any specific scenario faced by any particular entity.

1. Personal Jurisdiction over ex-U.S. Entities

The determination of whether a court has personal jurisdiction over the defendants is usually one of the first major issues presented in a given case. For ex-U.S. entities, personal jurisdiction is an important "gatekeeping" issue because it can provide an opportunity for swift dismissal at the outset of a case. This section provides a brief overview of "general" and "specific" personal jurisdiction, explains how ex-U.S. companies may become subject to personal jurisdiction through their U.S.-based subsidiaries, and provides some general strategies for mitigating the risk that an ex-U.S. entity will be haled into American courts.

Personal jurisdiction

At a fundamental level, personal jurisdiction refers to a court's power over a defendant's personal rights. When this power exists, a court can bring the defendant into its adjudicative process – for example, compelling discovery and entering monetary judgment. There are two types of personal jurisdiction – general and specific. If a court cannot exercise one of these forms of personal jurisdiction over a given defendant, then outright dismissal is appropriate. Note, however, that personal jurisdiction is considered a "waivable" defence. A defendant can forfeit its objection to personal jurisdiction by litigating the case on the merits. Thus, at the outset of a case, ex-U.S. entities should promptly assess and consider raising the defence of personal jurisdiction by making a "special appearance" only for that purpose.

Personal jurisdiction is rooted in the U.S. Constitution. Historically, under the Due Process Clause of the Fourteenth Amendment, a state court may not exercise personal jurisdiction over a defendant that lacks minimum contacts with the forum. Otherwise, the exercise of such power would offend "traditional notions of fair play and substantial justice". *Int'l Shoe Co. v. Wash.*, 326 U.S. 310, 316 (1945). Each state has a law (typically called a "long-arm statute") that sets the outer jurisdictional reach of its courts. Federal courts follow state law in determining the bounds of their personal jurisdiction, but state law cannot extend beyond the limits of due process.

General jurisdiction

In some cases, a court may exercise personal jurisdiction over a defendant *without* regard to any connection between the defendant's specific conduct at issue in the litigation and the forum. This is called "general" jurisdiction, and it arises when the defendant's affiliations with the forum are so "continuous and systematic" as to render it essentially "at home" there. *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 919 (2011). For a corporation, the "place of incorporation" and "principal place of business" are the paradigmatic bases for general jurisdiction. *Daimler AG v. Bauman*, 571 U.S. 117, 137 (2014). Only in an "exceptional case" will "a corporation's operations in a forum other than its formal place of incorporation or principal place of business . . . be so substantial and of such a nature as to render the corporation at home in that State". *Id.* at 761 n.19; *see also Perkins v. Benguet Consol. Min. Co.*, 342 U.S. 437, 448 (1952) (finding general jurisdiction over non-resident defendant where "he carried on in Ohio a continuous and systematic supervision of . . . limited wartime activities of the company").

Ordinarily, courts will have great difficulty establishing general jurisdiction over ex-U.S. entities. These entities, by definition, are not incorporated in and do not maintain a principal place of business in the United States. For example, it would be challenging to argue that a pharmaceutical company headquartered in Europe – even one that operates through an independent American subsidiary – is essentially "at home" in the United States. Note, however, that a few jurisdictions enforce state laws providing that registration to do business in a particular forum is "consent" to general jurisdiction in that forum. *Compare Webb-Benjamin, LLC v. Int'l Rug Grp., LLC*, 192 A.3d 1133, 1139 (Pa. Super. Ct. 2018) (finding general jurisdiction where state registration statute expressly provided that registration to do business constitutes "consent"), *with In re Asbestos Prod. Liab. Litig. (No. VI)*, 384 F. Supp. 3d 532, 545 (E.D. Pa. 2019) (rejecting argument that, "by registering to do business in Pennsylvania, a foreign corporation consents to general personal jurisdiction" as "irretrievably irreconcilable with the teachings of *Daimler*"). This issue may be addressed by the U.S. Supreme Court in the near future. *See Ford Motor Co. v. Bandemer*, No. 19-369 (U.S.) (cert. granted Jan. 17, 2020).

Specific jurisdiction

In most cases, personal jurisdiction stems from the defendant's particular activity *vis-à-vis* the forum state, when that particular activity is at issue in the litigation. This is called "specific" jurisdiction, and it "aris[es] out of or relate[s] to the defendant's contacts with the forum". *Helicopteros Nacionales de Colombia, S.A. v. Hall*, 466 U.S. 408, 414 n.8 (1984). Moreover, there must be a connection between the forum and the specific claims at issue. *See Bristol-Myers Squibb Co. v. Superior Court*, 137 S. Ct. 1773, 1781 (2017) (declining to exercise specific jurisdiction over non-resident pharmaceutical company in mass-tort case because there was no "connection between the forum and the [non-resident plaintiffs'] specific claims").

Whether a court has power to exercise specific jurisdiction over an ex-U.S. entity will often be a fact-intensive inquiry that considers specific conduct, and largely turns on the subsidiary question of whether the defendant has "minimum contacts" with the forum sufficient to satisfy due process. Minimum contacts can take countless forms, but generally "come about by an action of the defendant purposefully directed toward the forum State", so long as the litigation arises out of or relates to that action. *Asahi Metal Indus. Co. v. Superior Court*, 480 U.S. 102, 112 (1987). For example, minimum contacts may exist in a product liability case where an ex-U.S. entity places the product at issue into the "stream of commerce" and also "design[s] the product for the market in the forum State, advertis[es] in the forum State, establish[es] channels for providing regular advice to customers in the forum State, or market[s] the product through a distributor who has agreed to serve as the sales agent in the forum State". *Id.* In modern times, courts increasingly consider whether defendants targeted the state through online activities.

Given the importance of this threshold issue, plaintiffs' counsel are ever more creative in conjuring up new ways to establish specific jurisdiction. Indeed, in product liability cases, plaintiffs may attempt to establish minimum contacts over pharmaceutical companies by focusing on key developmental and regulatory events that occur in the United States. For example, in *Dubose v. Bristol-Myers Squibb Co.*, No. 17-CV-00244-JST, 2017 WL 2775034, at *2–4 (N.D. Cal. June 27, 2017), a federal district court exercised specific jurisdiction over a defendant that conducted clinical trials in California. The court credited the plaintiff's allegation that "nearly every pivotal clinical trial" necessary for the FDA's approval of the New Drug Application (NDA) for the medication at issue occurred "throughout the State of California". *Id.* at *4. The upshot is that ex-U.S. entities should be aware that plaintiffs may aggressively argue for specific jurisdiction based on the location of manufacture, development, study, and other key events in the FDA regulatory process.

Jurisdiction over parent companies

Generally, when a parent company and its subsidiary are "separate and distinct" entities, the presence of one in a forum state may not be imputed to the other for purposes of establishing personal jurisdiction. *See Holland Am. Line Inc. v. Wartsila N. Am., Inc.*, 485 F.3d 450, 459 (9th Cir. 2007). Nonetheless, the Supreme Court has recognised that "[a]gency relationships . . . may be relevant to the existence of specific jurisdiction". *Daimler AG*, 571 U.S. at 135 n.13. For example, "a corporation can purposefully avail itself of a forum by directing its agents or distributors to take action there". *Id.* This "agency theory" of specific jurisdiction should only apply where an American subsidiary's activities are directed and controlled by an ex-U.S. parent company.

The agency theory is especially salient in the world of prescription drugs and medical devices. Often, ex-U.S. entities will establish American subsidiaries to help them navigate the FDA's regulatory processes and, ultimately, market and sell their products in the United States. In such cases, the ex-U.S. parent company may not be able to entirely surrender control over (and may actually work hand-in-hand with) its American subsidiary for purposes of research and development, pre-clinical and clinical trials, manufacturing, marketing, distribution, or post-marketing obligations. Enterprising plaintiffs may seek to establish specific jurisdiction over an ex-U.S. parent company on such facts in order to increase potential liability. In all events, ex-U.S. entities should remain aware that plaintiffs' counsel may seek to establish specific jurisdiction through an agency relationship with an American subsidiary company – particularly if the litigation arises out of the work done pursuant to that agency relationship.

Relatedly, plaintiffs may also attempt to establish personal jurisdiction over an ex-U.S. entity by alleging that its American subsidiary is merely an "*alter ego*". In such cases, plaintiffs must show "(1) that there is such unity of interest and ownership that the separate personalities of the two entities no longer exist and (2) that failure to disregard their separate identities would result in fraud

or injustice". *Williams v. Yamaha Motor Co.*, 851 F.3d 1015, 1021 (9th Cir. 2017). When justified by economic realities, courts may be willing to exercise personal jurisdiction over ex-U.S. parent entities through their "*alter ego*" subsidiaries in the United States.

2. Other Preliminary Forum-Related Considerations

Although personal jurisdiction is usually the most important dispute that can arise at the outset of a case, there are several other preliminary forum-related issues worth exploring. For example, ex-U.S. entities should consider whether it is possible to avoid litigating in an inconvenient location or unfavourable forum by objecting to an improper venue, seeking dismissal based on *forum non conveniens*, objecting to improper service of process, or seeking to remove a case from state court to federal court. This section provides a brief overview of those preliminary issues.

Choice of venue

The concept of "venue" refers to the proper location – or one of several possible locations – for a lawsuit to proceed. Venue is often defined by statute. Generally, an appropriate venue will bear some connection to the events underlying the lawsuit (*e.g.*, a forum where a substantial part of the events giving rise to the claim occurred) or to the parties (*e.g.*, a forum where the defendant resides). *See* 28 U.S.C. § 1392(b). If a given forum lacks this logical connection to the parties or to the subject matter of their dispute, then it is likely that venue is improper – even if the Court has personal jurisdiction over the defendants. This can be a significant issue with so-called "litigation tourism", where tort plaintiffs attempt to concentrate cases in plaintiff-friendly jurisdictions. Note, however, that – like personal jurisdiction – an objection to venue can be waived if not timely asserted by the defendant.

If an ex-U.S. entity is sued in the wrong venue, it is worth considering whether to seek dismissal or transfer to a forum in which the case could have originally been brought. *See* 28 U.S.C. § 1406(a). Transfer of venue has some potential strategic implications (*e.g.*, the location of documents and evidence, a different jury pool, and different judicial officers). Even when venue is technically proper, the parties can still seek to transfer venue "[f]or the convenience of parties and witnesses" and "in the interest of justice". *See* 28 U.S.C. § 1404(a). In such cases, courts have the power to "transfer any civil action to any other district or division where it might have been brought or to any district or division to which all parties have consented". *Id.*

Forum non conveniens

In addition to filing a motion for transfer of venue, ex-U.S. entities may seek to invoke the doctrine of "*forum non conveniens*". The doctrine provides that an appropriate forum – even though technically correct under the law – may withdraw jurisdiction if, for the convenience of the litigants and the witnesses, it appears that the action should proceed in another forum in which the action might also have been originally brought. For example, this may occur when a court determines that a forum *outside of the United States* is the more appropriate and convenient forum for adjudicating the dispute. *See Piper Aircraft Co. v. Reyno*, 454 U.S. 235, 241 (1981).

There are several limiting factors to this doctrine. First, dismissal for *forum non conveniens* is only possible where there exists an adequate alternative forum. Courts are not inclined to dismiss on *forum non conveniens* grounds if the parties cannot adjudicate their dispute in another forum. Second, after balancing various factors, the relevant public and private interests must weigh heavily in favour of dismissal on *forum non conveniens* grounds. *See Gulf Oil Corp. v. Gilbert*, 330 U.S. 501, 508–09 (1947) (providing a list of non-exclusive "public interest" and "private interest" factors). Among other things, courts consider the relative access to sources of proof, availability of compulsory process, and administrative difficulties in hearing the case and enforcing a judgment. Third, the court may be inclined to provide a degree of deference to the plaintiff's original choice of forum. Finally, it is worth noting that *forum non conveniens* can also be waived if not timely asserted by the defendant.

Service of process

After deciding where to file suit against an ex-U.S. entity, plaintiffs must follow certain procedures to correctly commence the action. Among other things, most jurisdictions require plaintiffs to "serve" the defendant with a summons and copy of the complaint. This is called "service of process", *i.e.*, the formal delivery of a writ, summons, or other legal process, pleading, or notice to a litigant or other party interested in litigation. If plaintiffs fail to properly effectuate service, the defendant may be able to move to dismiss based on that defect.

Generally, the appropriate method of service depends on the defendant's location and legal status. Relevant factors include whether the defendant is an individual, a corporation, or a sovereign entity and whether the defendant is located within the United States or abroad. Importantly, service of an ex-U.S. entity may implicate a multilateral treaty called the Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil and Commercial Matters (Hague Service Convention). The United States is a signatory to the Hague Service Convention, which was intended to simplify, standardise, and generally improve the process of serving documents abroad. The "primary innovation" of the Hague Service Convention is that it "requires each state to establish a central authority to receive requests for service of documents from other countries". *Volkswagenwerk Aktiengesellschaft v. Schlunk*, 486 U.S. 694, 698 (1988). Due to the time and expense, plaintiffs often fail to meet the Hague Service Convention requirements – perhaps hoping that defendants will waive the defence.

Removing a case to federal court

"Removal" refers to the transfer of an action from state to federal court. When sued in an American state court (*e.g.*, the Los Angeles County Superior Court), ex-U.S. entities may have the option of removing the lawsuit to a parallel federal court (*e.g.*, the U.S. District Court for the Central District of California).

Federal courts have *limited* subject matter jurisdiction defined by the U.S. Constitution and congressional statutes. Among other types of cases, federal courts have "original jurisdiction" over (1) disputes involving federal law, and (2) disputes between citizens of different states. The latter category is called "diversity jurisdiction", which also extends to disputes involving citizens of a state and foreign citizens. Specifically, federal courts have diversity jurisdiction over "all civil actions where the matter in controversy exceeds the sum or value of $75,000, exclusive of interest and costs, and is between . . . citizens of a State and citizens or subjects of a foreign state". 28 U.S.C. § 1332(a)(2).

Under 28 U.S.C. § 1441(a), a defendant may remove "any civil action brought in a State court of which the district courts of

the United States have original jurisdiction". To remove a case from state court, an ex-U.S. entity files a notice in the federal forum "containing a short and plain statement of the grounds for removal". 28 U.S.C. § 1446(a); *see also Dart Cherokee Basin Operating Co., LLC v. Owens*, 574 U.S. 81, 87 (2014). A notice of removal "shall be filed within 30 days after the receipt by the defendant, through service or otherwise, of a copy of the initial pleading". 28 U.S.C. § 1446(b)(1). This choice of forum is given to "foreign" defendants in order to counteract potential bias from which local plaintiffs may benefit in their home states' courts.

When a case is removed from state to federal court, the plaintiff's allegations and claims for relief remain the same. It is the forum, the judicial officers, and the applicable procedures that change. Common wisdom holds that defendants prefer to litigate in federal court as opposed to state court. As a general matter, federal courts have greater resources and federal judges have more experience with matters of national and international concern. Federal judges also have life tenure and are not subject to political elections, as is the case for many state court judges. Moreover, it is presumed that federal courts generally conduct proceedings in a more orderly and consistent manner, apply more stringent procedural rules, and more quickly see matters through to resolution. Nonetheless, some state courts may be worth considering because they have substantial experience managing mass tort and class action litigation, and to the extent there is favourable precedent from courts in that jurisdiction on key issues.

3. Discovery Outside of the United States

In the United States, the discovery phase of litigation refers to the exchange of facts and evidence that occurs before trial. When litigation is reasonably anticipated – which may be before any lawsuit is ever filed – a party has an obligation to preserve potentially relevant documents for the litigation. Ex-U.S. entities can be surprised by the breadth of material subject to discovery in the United States – a party may be required to produce any material that is relevant to a claim or defence in the litigation or, in some jurisdictions, relevant to the subject matter of the litigation (even if it would not be admissible at a trial). Beyond the broad subject matter that may be requested, discovery can take many different forms, including paper documents, computer files, emails, text messages, voicemails, and other electronic communications. Even non-documentary materials (physical evidence, such as product samples or packaging) must be preserved and can be requested in discovery. Counsel for an ex-U.S. entity should also be aware that they can be ordered to disclose data or materials as a third party during another party's litigation. Expansive American discovery laws permit courts to compel the cooperation of any company that is subject to their jurisdiction to comply with a discovery request, regardless of whether they are a party to the litigation.

Even if an entity is not subject to jurisdiction in the United States, there are other methods to compel a foreign company to provide evidence during litigation. A foreign company located in a country that is a party to the Hague Evidence Convention, an international treaty on cross-border discovery, may be required to provide evidence under the Convention procedures. However, requests under the Convention are also subject to the home country's laws; ex-U.S. entities must therefore be aware of their local laws, which can create conflicts with broad American discovery laws. American courts differ as to how much deference they give to foreign, local laws related to discovery.

Given the large amount of data and material involved in discovery and the many pitfalls facing foreign entities, an ex-U.S. entity should develop a comprehensive discovery strategy with counsel to manoeuvre these obstacles and ensure compliance with their obligations in American courts. Counsel's discovery strategy can depend on many factors including the client, its home country's foreign data privacy laws or blocking statutes, and the client's goals as a company.

Written and oral discovery

Like many other discovery issues, the production of documents in the cross-border context turns on whether the custodian of the documents is subject to the court's personal jurisdiction. In preparing for a potential document production, an ex-U.S. party to a litigation should identify custodians with relevant information, review foreign regulations and company policy on cross-border data transfers, consider proportionality arguments on the scope of material to be produced, and raise cross-border issues with opposing counsel early in the discovery process. Prior to producing documents, a foreign entity should review the data privacy laws in their home jurisdiction and seek a confidentiality agreement or protective order if necessary.

In litigation involving an ex-U.S. entity, there may also be a need to take depositions of witnesses located abroad. At a deposition, a party questions a witness before trial to gather sworn oral testimony which may be used at trial. Counsel should evaluate early in a litigation whether overseas depositions will be necessary, as it can take months to arrange a foreign deposition, particularly if the jurisdiction has restrictions on depositions or the witness is not cooperative. This often occurs with third-party foreign witnesses, who are not affiliated with a party to the litigation. If the witness is unwilling to testify, an American court may order a person outside of the United States to attend a deposition in the United States – provided that person is subject to the personal jurisdiction of the court.

As the Federal Rules of Civil Procedure only apply in the United States, an American litigant has no power to directly compel a foreign witness to testify in a foreign country. If the person or entity is located abroad and is not subject to the jurisdiction of American courts, the Hague Evidence Convention may govern (assuming the foreign country is a signatory to the Convention) because the United States has ratified the Convention. A party may also pursue an order from a foreign jurisdiction to compel an uncooperative witness's testimony within that foreign jurisdiction. However, the party seeking the testimony should check if the foreign jurisdiction has any blocking statutes that would prevent the deposition from taking place in that jurisdiction. The United States does not have any blocking statutes that would prevent a deposition from being conducted abroad, but if a foreign deposition is going to be taken and utilised in American litigation, counsel must comply with one of the four different deposition methods in Federal Rule of Civil Procedure 28(b).

When arranging a deposition, in-house counsel should also consider strategic and logistical concerns. If witnesses are located in foreign countries, counsel must determine where the depositions should take place. The party seeking the deposition generally covers the witness's travel costs, therefore it is worth investigating whether conducting the deposition abroad will be less costly and more efficient. Counsel may wish to consider a translator for the witness. Counsel can also arrange to preserve witness testimony on video to use at trial in addition to the transcript recorded by the court reporter.

Limitations on discovery: privilege, blocking statutes, and confidentiality

Attorney-client privilege is a complicated issue in cross-border and international legal disputes. The law on this privilege varies greatly depending on the jurisdiction; information that is privileged in one country may not receive the same protection in another. Moreover, it is not always clear which jurisdiction's law will govern – *i.e.*, the law of the forum in which the privileged communication occurred or the law of the forum in which the litigation is filed. Due to this uncertainty, in-house counsel for ex-U.S. entities cannot assume that their communications are privileged simply because the communications occurred outside of the United States or across borders.

If American law applies, ex-U.S. entities should be aware of the strong privilege protections in place that serve as a counterweight to the broad scope of discovery in the United States. Attorney-client privilege is designed to protect the relationship between the lawyer and her client. Therefore, when in-house counsel provides legal advice to the corporation, those communications are generally protected. Further, when working outside of the United States, an in-house attorney should consider ensuring that her title indicates that she is a lawyer to improve the likelihood of receiving privilege protection for communications.

When the client is a corporation, as is the case in litigation involving pharmaceutical companies, the corporation holds the privilege as opposed to company employees. A company employee's communication with the company's counsel (in-house or external) is generally privileged if information was supplied for counsel to provide legal advice, the communication was made within the employee's scope of employment, the employee was aware she was being questioned in order for the corporation to obtain legal advice, and the communication was intended to be confidential. *Upjohn Co. v. United States*, 449 U.S. 383 (1981). These basic principles form the foundation of privilege law in the United States.

Foreign data privacy laws and blocking statutes may provide obstacles to discovery when the material to be produced is housed outside of the United States and that foreign country's laws limit access to the requested material. The Hague Evidence Convention provides procedures for obtaining evidence in foreign countries, but it is not a solution to all of the issues that arise in cross-border discovery. Under American law, the Hague Evidence Convention procedures are not mandatory and are only permissive; to apply the Hague Evidence Convention, an American court must conduct a comity analysis under *Société Nationale Industrielle Aérospatiale v. U.S. Dist. Ct. for S. Dist. of Iowa*, 482 U.S. 522 (1987). The *Aérospatiale* analysis weighs several factors in deciding whether discovery should proceed under the Hague Evidence Convention rather than the Federal Rules of Civil Procedure, which favour ordering foreign discovery.

In the event that the Hague Evidence Convention is applied to govern cross-border discovery, two types of laws may still prevent information from legally leaving a foreign jurisdiction: privacy laws and blocking statutes. Privacy laws function to prevent the transfer of data containing private personal information to a country with less stringent privacy protections than the original jurisdiction (the United States often falls into this category). Generally, information that could be used to identify an individual is considered private personal information and is protected against disclosure. Blocking statutes are laws enacted with the specific purpose of impeding cross-border discovery by making it illegal (and even criminal) to produce some electronic discovery for litigation in foreign countries. While foreign privacy laws and blocking statutes may appear to be significant hurdles to discovery, U.S. courts applying *Aérospatiale* frequently order foreign parties to comply with U.S. discovery orders, notwithstanding the laws of the company's home country. *See* M.J. Hoda, *The Aérospatiale Dilemma: Why U.S. Courts Ignore Blocking Statutes and What Foreign States Can Do About It*, 106 Calif. Law Rev. 233 (2018). In such situations, ex-U.S. companies must navigate a quandary: face sanctions for failing to comply with a U.S. discovery order, or violate foreign law and confront other penalties within that jurisdiction. *Id.* Parties should consult with experienced counsel to determine how to proceed when encountering this dilemma.

Ex-U.S. companies can also consider negotiating protocols and protective orders with opposing counsel to help manage the scope of discovery. An electronically stored information (ESI) protocol can establish parameters for electronic discovery by confining the scope of data collection, dictating the format in which data will be produced, and prescribing how the data can be used. An ESI protocol can be particularly helpful in curbing the costs of complying with discovery requests, especially for a party with a large volume of electronic data.

Protective orders govern how data produced in a litigation may be used and can prohibit public disclosure of confidential or proprietary business information produced in litigation. An order requiring confidential treatment of information may help a foreign company comply with privacy laws in its home country without flouting a discovery request from within the United States. Such orders may provide limitations on the parties that can access the data, set confidentiality designations that comply with the foreign jurisdiction's privacy laws, dictate procedures for using the protected information in court, and establish a plan for destroying or returning the data at the conclusion of the litigation in the United States.

4. Critical and Dispositive Motions, Trial, and Appeal

Critical and dispositive motions

In the United States, very few legal disputes proceed to trial – the vast majority of cases are resolved by either motions before trial or settlement, though mass tort litigation is more likely than others to see a trial go forward. Dispositive motions, such as a motion to dismiss or a motion for summary judgment, are motions seeking a court order disposing of all or part of the claims in favour of the moving party before the case proceeds to trial. At the beginning of a lawsuit, a defendant may file a motion to dismiss, which argues that the plaintiff has not alleged enough facts to support his claim and thus the claim should be dismissed.

If a motion to dismiss is denied, and after parties have had a chance to gather and analyse information from their adversaries through discovery, a party may have sufficient evidence to support another dispositive motion: a motion for summary judgment. A motion for summary judgment is ordinarily brought after the close of discovery and asks the court to determine that, based on all the information gathered throughout discovery, one party is entitled to a judgment as a matter of law. That is, the moving party asks the judge to rule that there are no facts from which a jury could find in the opposing party's favour at trial. These motions may be used to dispose of a litigation entirely or whittle down the number of claims.

Another motion that can greatly affect the trajectory of a trial is a motion for class certification. In the United States, a class action is a procedural device that allows a small number of representatives to file legal claims on behalf of an entire group of similarly situated individuals (*i.e.*, the class). To bring a class

action, plaintiffs must certify the class of individuals to be represented under Federal Rule of Civil Procedure 23 by meeting four requirements: the class is "so *numerous* that joinder of all the members is impracticable"; there are "questions of law or fact that are *common* to the class"; the representative parties' claims or defences are "*typical* of those of the claims or defenses of the class"; and the class representatives will "*fairly and adequately protect* the interests of the class". These requirements help ensure that judicial economy is achieved by evaluating whether the issues in the case are alike enough to merit adjudicating all of the claims in one trial. In the product liability arena, class actions are typically brought based on marketing, false advertising, and consumer protection theories.

Trial issues

In a civil trial, the burden is generally on the plaintiff to present adequate evidence to prove that it is more likely than not that the defendant is liable. Evidence gathered throughout discovery will then come to bear on the final outcome at trial. Ex-U.S. entities should be aware that early strategic decisions, especially those during discovery, are likely to have an impact at trial. For example, one critical decision for a foreign company is deciding who to designate as a corporate representative for depositions because it could be the first and only opportunity for the company to testify. If it is unlikely that a foreign witness will come to testify during an American trial, the foreign witness's testimony can only make its way into trial through video clips from the depositions. Accordingly, a foreign company should choose its witnesses at the discovery stage with an eye towards trial.

Litigation involving foreign parties also raises the problem of language barriers. If a foreign witness cannot testify in English, an ex-U.S. party must choose a strong translator to assist with questioning. Even if the opposing party is providing the primary translator, the foreign party can bring a "check" translator to challenge any ambiguous translations and advocate for the witness or party. Peter J. Stern and Lucia E. Ballard, *"Lost in Translation": Dealing with Interpretation Issues in International Litigation* (Feb. 22, 2013), https://www.acc.com/resource-library/lost-translation-dealing-interpretation-issues-international-litigation-united#. Alternatively, to avoid conflicts in translation, parties may enter into a stipulation establishing a protocol on the procedure for translations and settling translation disputes before they arise. Lee F. Berger and Sophie J. Sung, *Translation Protocols In Cross-Border Antitrust Litigation* (Aug. 22, 2013), https://www.law360.com/articles/466666/translation-protocols-in-cross-border-antitrust-litigation.

Another issue of which ex-U.S. entities must be particularly cognizant is potential juror bias. A company presenting a case with mostly foreign witnesses should consider the possibility of implicit bias against foreign individuals. To help address potential bias, foreign parties with cases involving foreign witnesses should consider retaining a jury consultant to guide the party strategically through *voir dire*, which is the process in which the parties question and select jurors before trial.

Appeals

Even after a trial verdict has been rendered, the lengthy American litigation process may not be complete. If a party is dissatisfied with a judgment, it can usually appeal the judgment to a higher court. Appeals can often take multiple years to be resolved. Although appeals can take several months, or even years, the execution of any judgment typically can be stayed pending appeal as long as the appealing party posts an "appeal bond". Further, during the pending of the appeal, a judgment debtor may be required to post a bond to secure payment of the judgment if it is affirmed on appeal.

5. Enforcement of Judgments

In the event that litigation results in an adverse monetary judgment, ex-U.S. entities will have to grapple with the ways that decision (if unfavourable) may be enforced against them. Generally, after an American court enters a judgment for money damages against a party, that party must satisfy the judgment by paying it. Under the Full Faith and Credit Clause, the judgment of a court in one U.S. state can be enforced in courts of all other states. Judgments are usually executed according to the law of the forum state from which the judgment originates.

If a foreign company is not willing to comply with an American judgment against it and does not have sufficient U.S.-based assets for the judgment to be wholly enforced within the United States, a plaintiff may initiate proceedings abroad to enforce the judgment. Many foreign countries have treaties in place with the United States regarding enforcement of arbitral awards and mediation agreements, but foreign court judgments are generally harder to enforce. The 2019 Hague Convention on the Recognition and Enforcement of Foreign Judgments in Civil and Commercial Matters aims to resolve this issue, but thus far has failed gain traction. Within each jurisdiction, the requirements for enforcing a judgment vary. Other nations may be hostile to certain types of American judgments; judgments that include punitive damages, for example, are often viewed as excessive. An American judgment creditor can run into difficulties in enforcing these types of awards abroad.

6. Regulatory Implications for Litigation

As alluded to above, ex-U.S. entities in the life sciences sector can also face litigation and pre-litigation regulatory challenges. Pharmaceuticals, medical devices, supplements, and over-the-counter products are mainly regulated by federal agencies, including: the FDA, which approves the products for safety; the FTC, which regulates advertisements and certain labels; and the Drug Enforcement Agency (DEA), which regulates specific drugs that are susceptible to abuse. In addition to the rules and procedures promulgated by these agencies, ex-U.S. entities should know that states may set more demanding legal standards with respect to the safety and marketing of products – so long as the state's laws are not "preempted" by federal law. Under the Supremacy Clause of the U.S. Constitution, federal law is "the supreme Law of the Land" notwithstanding any contrary state law. Accordingly, the doctrine of federal preemption generally provides that federal law supersedes conflicting state laws.

Overall, with regard to regulatory obligations, the FDA is the primary federal agency that ex-U.S. entities should think about when doing business in the United States. FDA infractions can be addressed in a variety of ways. On the less serious end, the FDA may send warning letters to a manufacturer to notify them that a rule has been violated with the goal of prompting the manufacturer's voluntary compliance. Alternatively, if the violation remains, enforcement actions can be brought by U.S. government attorneys to remove a product from the market. FDA regulatory judgments, however, may also give rise to an important defence – namely that the FDA's determination is within the primary jurisdiction of the FDA, not a court. Regulatory compliance can also provide a defence under state tort law, or otherwise mitigate exposure to bankruptcy.

Through their regulatory compliance efforts, companies producing life sciences products may become involved in tort or consumer fraud litigation stemming from the FDA regulatory process. Plaintiffs often bring claims challenging the FDA's determination on the safety of a product or whether the product was properly labelled in light of still-developing data. Further, an ex-U.S. company's actions to comply with FDA regulations, such as product recalls, warning letters, black box warnings, inspections, and investigations into off-label promotion, can have significant implications for such tort litigation. When litigating a "design defect" or "failure-to-warn" claim, for example, regulatory documents related to pharmacovigilance, correspondence with the FDA, labelling changes, promotional materials, and brand plans may all be relevant and potentially discoverable. In addition, comparisons between FDA-approved labels in the United States and the European Union can provide key evidence on failure-to-warn claims. It is important to note that E.U. regulations may impose different obligations than U.S. regulations. Plaintiffs will often seek to exploit those differences and conduct significant discovery into such issues (while defendants fight to keep such issues out of court). Ex-U.S. entities should be cognizant that these materials prepared for regulatory compliance are not confined to the grip of a federal agency and may influence the outcome in a later litigation.

Conclusion

As demonstrated throughout this article, ex-U.S. entities face numerous obstacles – but also opportunities – when faced with litigation concerning manufacturing, distributing, and selling prescription drugs and medical devices in the United States. Although the issues discussed herein are complex and fact-specific, the upshot is that ex-U.S. entities cannot proceed under the mistaken assumption that they will never be dragged into American courts. To the contrary, plaintiffs have become increasingly creative in litigating against companies located outside of the United States. And once litigation begins in earnest, ex-U.S. entities are often surprised by the amount of sensitive material that they must disclose during discovery (including draft documents and internal emails). To mitigate the risk of winding up on the front page of an American newspaper, ex-U.S. entities should be strategic about structuring their activities in the United States and how they comply with their regulatory obligations long before an actual lawsuit is on the horizon. Even activities that are necessary to obtain FDA approval of prescription drugs – *e.g.*, conducting clinical trials – can become a hook for haling an ex-U.S. entity into an American court. Ultimately, the key to managing risk is communicating with knowledgeable counsel who can conduct an assessment tailored to the client's particular circumstances.

Note

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