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Practical cross-border insights into drug and medical device litigation

Drug & Medical Device Litigation 2022

Third Edition

Contributing Editors:
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Sidley Austin LLP

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Expert Analysis Chapters

Q&A Chapters

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

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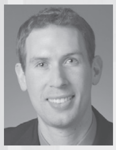
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Introduction

Plaintiffs often file product liability and class action lawsuits in the United States (hereinafter: U.S.) 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 U.S. (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 U.S. for entities within the distributive chain of prescription drugs and medical devices. However, the pitfalls and challenges are particularly acute for ex-U.S. entities unfamiliar with the U.S. 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 U.S.

This chapter 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 U.S. 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 chapter is to facilitate a basic understanding of the U.S. legal system and regulatory regime. U.S. 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 U.S. should consider communicating with knowledgeable attorneys who can conduct risk assessments tailored to their circumstances and needs. Likewise, 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.

1 Personal Jurisdiction Over Ex-U.S. Entities

The determination of whether a court has personal jurisdiction over defendants is usually one of the first major issues presented in a given case. For ex-U.S. entity defendants, 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 U.S. 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 (and preserving any other defences).

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 the law of the state in which they are located to determine the bounds of their personal jurisdiction, but state law cannot extend beyond the limits of due process.

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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 a 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 U.S. For example, it would be challenging to argue that a pharmaceutical company headquartered in Europe – even one that operates through an independent U.S. subsidiary – is essentially "at home" in the U.S. Generally, registration to do business is insufficient to confer general jurisdiction for all purposes. *See, e.g.*, *Brown v. Lockheed Martin Corp.*, 814 F.3d 619, 627–30, 640 (2d Cir. 2016) ("to confer general jurisdiction by implicit consent, every corporation would be subject to general jurisdiction in every state in which it registered, and *Daimler's* ruling would be robbed of meaning by a back-door thief"). Note, however, that a few jurisdictions have upheld general jurisdiction under state laws expressly providing that registration to do business in a particular forum is "consent" to general jurisdiction in that forum. Recently, Pennsylvania's highest court addressed a split in authority relating to the state registration statute. In *Mallory v. Norfolk S. Railway Co.*, the Pennsylvania Supreme Court held that Pennsylvania's statutory scheme violated due process to the extent that it allowed for general jurisdiction over foreign corporations, absent continuous and systemic affiliations that render a corporation essentially "at home" in Pennsylvania. *See Mallory v. Norfolk S. Ry. Co.*, No. 3 EAP 2021, 2021 WL 6067172, at *1 (Pa. Dec. 22, 2021). The court in *Mallory* further held that compliance with Pennsylvania's statute mandating registration to do business in the state did not subject the entity to general jurisdiction in Pennsylvania in light of the constitutional constraints on general jurisdiction expressed by *Daimler* and its progeny. *Id.* Prior to this decision, courts within Pennsylvania (including federal courts) were split as to the constitutionality of this statute, and it remains to be seen how courts within the Third Circuit (embodying Pennsylvania) and beyond will now analyse these issues, post-*Mallory*. Courts in other states continue to allow general personal jurisdiction based on consent. *See Cooper Tire & Rubber Co. v. McCall*, 863 S.E.2d 81 (Ga. 2021) (out-of-state tire manufacturer's consent to general personal jurisdiction in Georgia by virtue of its registration to do business in Georgia did not violate due process).

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). In other words, specific jurisdiction requires 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 a non-resident pharmaceutical company in a mass-tort case as to non-resident Plaintiffs 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 the 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. Courts have generally held, however, that merely placing products into the stream of commerce, alone, is not sufficient to establish jurisdiction, even if that product ultimately caused an alleged injury in the jurisdiction at issue. *See, e.g.*, *Asahi*, 480 U.S. at 112 (plurality opinion holding that in order to establish personal jurisdiction under a "stream of commerce plus" theory, the defendant must engage in some "additional conduct" to establish its "intent or purpose to serve the market in the forum State").

In *Ford Motor v. Montana Eighth Judicial District Court, et al.*, the Supreme Court recently held that a court sitting in a state where a car accident occurred could exercise specific jurisdiction over the defendant car manufacturer, even though the manufacturer did not design, manufacture, or sell the particular vehicle at issue in the lawsuit in that state. 141 S. Ct. 1017 (2021) (finding personal jurisdiction over Ford). The Court recognised that for a specific jurisdiction, the Plaintiff's claims must "'arise out of or relate to the defendant's contacts' with the forum", *id.* at 1026, but held that this does not require a direct *causal chain* between the defendant's contacts with the forum and the Plaintiff's claim. *Id.* (specific jurisdiction does not require that "the plaintiff's claim came about because of the defendant's in-state conduct"). Rather, to show that the Plaintiff's claim "relates to" Ford's conduct in the forum, it is sufficient that Ford "serves a market for a product in the forum State and the product malfunctions there". *Id.* at 1027. In the drug and device context, Plaintiffs' counsel will likely now similarly argue that specific personal jurisdiction exists against a manufacturer whose products are knowingly and deliberately sold nationwide, so long as the alleged injury at issue occurs in the forum where a suit is filed. It is worth noting, however, that the *Ford* decision does not mean "anything goes" in the world of specific jurisdiction, and the Court stressed that the phrase "relates to" incorporating "real limits" – although it remains unclear where these limits lie. *Id.* at n.1026. Significantly, *Ford* involved in-state Plaintiffs, yet reaffirmed the Court's holding in *Bristol-Myers Squibb* as to non-resident Plaintiffs whose claims lacked the requisite connection with the forum state. *Id.* at 1031.

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The question of Internet transactions remains an open issue – the Supreme Court in *Ford* declined to address the impact of virtual transactions on specific personal jurisdiction, and lower courts have subsequently reached varying conclusions. *Compare Ayla, LLC v. Alya Skin Pty. Ltd.*, 11 F.4th 972, 981 (9th Cir. 2021) (holding that specific jurisdiction could be exercised because Alya Skin had done more than merely place its products into the stream of commerce where, *inter alia*, it offered its products directly for sale on its website, operated social media accounts for sales through third-party websites, and determined how and where its orders were fulfilled), *with Chouinard v. Marigot Beach Club & Dive Resort*, No. CV 20-10863-MPK, 2021 WL 2256318, at *10 (D. Mass. June 3, 2021) ("[t]he Supreme Court has not yet provided clear guidance on defendants' 'virtual' contacts with a forum state…Absent such clear guidance, the First Circuit has been reluctant to announce broadly-applicable rules, but has identified a baseline principle: defendants do not necessarily purposefully avail themselves of the benefits and protections of every state in which their website is accessible") (internal quotations and citations omitted); *see also Ford Motor Co.*, 141 S. Ct. 1017, 1028 n.4 ("and we do not here consider internet transactions, which may raise doctrinal questions of their own").

Even prior to *Ford*, Plaintiffs' counsel were 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.*, n.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 for the medication at issue occurred "throughout the State of California". *Id.* at *4. Since *Ford*, federal district courts have identified several cases that fall within the ambiguity of the Supreme Court's ruling, but have found specific personal jurisdiction where there is a strong relationship among the defendant, the forum, and the litigation. *See, e.g.*, *In re: Zantac (Ranitidine) Prod. Liab. Litig.*, No. 20-MD-2924, 2021 WL 2682602, at *14 (S.D. Fla. June 30, 2021) (in an innovator-liability claim, the "real limits for the purposes of specific personal jurisdiction [involved] only those activities that related to the brand-name manufacturers' labeling decisions regarding their own product"). 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, and a U.S. federal court's determination of the limits to specific jurisdiction may vary with the forum and the nature of the particular claim.

In the context of class actions, some courts have held that the Supreme Court's decision in *Bristol-Myers Squibb v. Superior Court*, 137 S. Ct. 1773 (2017) (*BMS*) requires the dismissal of non-resident putative class members' claims that have no connection to the forum. *See, e.g., Chavira v. OS Restaurant Services, LLC*, No. 18-cv-10029-ADB, 2019 WL 4769101, at *6 (D. Mass. Sept. 30, 2019) (granting motion to strike non-resident class action allegations, noting that *BMS* applies to all cases, including class actions); *see also Molock v. Whole Foods Mkt. Grp., Inc.*, 952 F.3d 293, 306 (D.C. Cir. 2020) (Silberman, J., dissenting) ("[A]lthough the Supreme Court avoided opining on whether its reasoning in the mass action context would apply also to class actions, it seems to me that logic dictates that it does"). Other courts, including a growing number of Courts of Appeals, have maintained that *BMS* is inapplicable to proposed class members' claims, resulting in a split of authority. *See, e.g.*, *Lyngaas v. Ag*, 992 F.3d 412, 433 (6th Cir. 2021) ("[w]e decline to extend *Bristol-Myers Squibb* in this manner. Long-standing precedent shows that courts have routinely exercised personal jurisdiction over out-of-state defendants in nationwide class actions, and the personal-jurisdiction analysis has focused on the defendant, the forum, and the named Plaintiff, who is the putative class representative"); *Mussat v. IQVIA, Inc.*, 953 F.3d 441, 443 (7th Cir. 2020) ("[w]e hold that the principles announced in [*BMS*] do not apply to the case of a nationwide class action filed in federal court under a federal statute"), *cert. denied*, n.20-510, 2021 WL 78484 (2021); *Molock*, 952 F.3d at 298 (putative class members are not "parties" and thus not subject to personal jurisdiction challenge; "[o]nly after the putative class members are added to the action—that is, when the action is certified as a class under Rule 23—should the district court entertain [defendant's] motion to dismiss the nonnamed class members") (internal quotations omitted); *see also*, *e.g.*, *Carranza v. Terminix Int'l Co. Ltd. P'ship*, n.20-CV-1819-DMS-WVG, 2021 WL 1174732, at *4 (S.D. Cal. Mar. 29, 2021) ("[t]he Court is not convinced that the holding in *Bristol-Myers* reaches unnamed Plaintiffs in a class action brought in federal court alleging claims under federal law"); *Cruson v. Jackson Nat'l Life Ins. Co.*, 954 F.3d 240, 247 n.4 (5th Cir. 2020) (outlining the split in authority regarding how *BMS* applies to class actions brought in federal court).

Finally, ex-U.S. entities should be aware of the possibility that a U.S. court will order jurisdictional discovery in order to address a dispute regarding personal jurisdiction. Jurisdictional discovery has been permitted in various product liability cases, often in order to determine facts pertaining to a defendant's contacts in the forum state, including the nature of a defendant's relationship with an in-state entity. *See, e.g.*, *Garner Rickman, et al., Plaintiffs, v. BMW of North America LLC, et al.,* n.CV-1804363-KMJ-BC, 2021 WL 1904740, at *10 (D.N.J. May 11, 2021) (concluding that jurisdictional discovery was warranted to develop facts regarding minimum contacts). Although jurisdictional discovery is not proper where Plaintiffs have not identified plausible jurisdictional facts to be uncovered, this remains an important consideration for ex-U.S. entities challenging personal jurisdiction in U.S. courts. *See California Capital Insurance Co. v. Broan-Nutone, LLC*, n.121-CV-00388-NONESKO, 2021 WL 5494892, at *5 (E.D. Cal. Nov. 23, 2021) (declining to permit the "speculative discovery Plaintiff seeks"); *Scheaffer v. Albertson's LLC*, n.CV H-21-2326, 2021 WL 4822159, at *6 (S.D. Tex. Oct. 15, 2021) (denying jurisdictional discovery where the Plaintiff did "not state what facts he expects to obtain thereby or how such information will support a proper exercise of personal jurisdiction").

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 a U.S. 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 U.S. subsidiaries to help them navigate the FDA's regulatory processes and, ultimately, market and sell their

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products in the U.S. 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 U.S. 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 a U.S. subsidiary company – particularly if the litigation arises out of the work done pursuant to that agency relationship.

In relation to the above, Plaintiffs may also attempt to establish personal jurisdiction over an ex-U.S. entity by alleging that its U.S. 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 U.S.

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 the 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 a 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 a 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 U.S.* 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 U.S. 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 or Commercial Matters (Hague Service Convention). The U.S. 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. In a number of instances (and in the wake of the COVID-19 pandemic), Plaintiffs have sought leave of court to serve ex-U.S. entities' U.S. counsel (in the same or other litigations) and bypass the requirements of the Hague Service Convention, with mixed results. *Compare Tevra Brands LLC v. Bayer HealthCare LLC*, n.19-cv-04312, 2020 WL 3432700, at *4–5 (N.D. Cal. June 23, 2020) (denying a Plaintiff's

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request for alternative service through ex-U.S. entity's U.S. counsel where there was no evidence that entities were "evading service or cannot be located" or that foreign authority had had "adequate time" to process service; prior delay in service was due to Plaintiff's "missteps", and "simply citing COVID-19 as an obstacle is not sufficient to bypass the requirements of the Hague Convention"); *with Crockett v. Luitpold Pharm., Inc.*, No. 19-276, 2020 WL 4039046, at *3 (E.D. Pa. July 17, 2020) (allowing alternative service on U.S. counsel where ex-U.S. entities were "on notice of the case brought against them: they are closely affiliated with one another and with a served Defendant which has been litigating this and many other substantially similar cases before this Court for over a year now, they are represented by the same U.S. based counsel and U.S. based counsel is in close contact with them").

In some instances, there may be benefits to waiving the formal service requirements for U.S. and ex-U.S. entities alike. For instance, the federal rules provide that a defendant "who, before being served with process, timely returns a waiver", receives additional time to file an answer to the Plaintiff's complaint. Fed. R. Civ. P. 4(d)(3) ("[a] defendant who, before being served with process, timely returns a waiver need not serve an answer to the complaint until 60 days after the request was sent—or until 90 days after it was sent to the defendant outside any judicial district of the United States"); *compare* Fed. R. Civ. P. 12(a)(1)(A)(i) (otherwise providing only 21 days after service to answer a complaint).

Removing a case to federal court

"Removal" refers to the transfer of an action from state to federal court. When sued in a U.S. 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). In addition, the Class Action Fairness Act of 2005 established the original jurisdiction of federal courts in certain class action suits. Pub. L. No. 109-2, 119 Stat. 4. Specifically, federal courts "have original jurisdiction of any civil action in which the matter in controversy exceeds $5,000,000 . . . and is a class action in which—(A) any member of a class of Plaintiffs is a citizen of a State different from any defendant; (B) any member of a class of Plaintiffs is a foreign state or a citizen or subject of a foreign state and any defendant is a citizen of a State; or (C) any member of a class of Plaintiffs is a citizen of a State and any defendant is a foreign state or a citizen or subject of a foreign state". 28 U.S.C. § 1332(d)(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. If a Plaintiff whose case has been removed to federal court disagrees with the bases asserted for federal jurisdiction, it can move to remand the case to state court. 28 U.S.C. § 1447(c). The federal court judge must then decide whether federal jurisdiction exists, or whether it is instead appropriate to remand the case to state court.

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 if, for instance, they have substantial experience managing mass tort and class action litigation, or there is favourable precedent from courts in that jurisdiction on key issues.

3 Discovery Outside of the United States

In the U.S., 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 U.S. – 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 it can be ordered to disclose data or materials as a third party during another party's litigation. Expansive U.S. 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 the company is 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 U.S. discovery laws. U.S. 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 its obligations in U.S. 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.

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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 its home jurisdiction and seek a confidentiality agreement or protective order if necessary. These protective orders will often permit parties to designate certain materials as "confidential" and/or "highly confidential", thereby limiting the public disclosure of sensitive, proprietary or private information.

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 and in pre-trial or dispositive motions. Counsel should evaluate early in 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, a U.S. court may order a person outside of the U.S. to attend a deposition in the U.S. – provided that person is subject to the personal jurisdiction of the court.

As the Federal Rules of Civil Procedure only apply in the U.S., a U.S. 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 U.S. courts, the Hague Evidence Convention may govern (assuming the foreign country is a signatory to the Convention) because the U.S. 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 U.S. 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 U.S. 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 written transcript recorded by the court reporter.

Courts have also addressed the expanded use of remote depositions since the start of the COVID-19 pandemic. Specifically, courts have acknowledged that "a 'new normal' has taken hold throughout the country in the wake of the COVID-19 pandemic that may necessitate the taking of remote depositions unless litigation is going to come to an indefinite halt until there is a cure or a vaccine for COVID-19". *In re Broiler Chicken Antitrust Litig.*, n.1:16-CV-08637, 2020 WL 3469166, at *5 (N.D. Ill. June 25, 2020) (collecting cases). In granting remote depositions under Federal Rule of Procedure 30(b)(4), courts have balanced the interests of the party seeking the remote deposition with the prejudicial impact on the opposing party. *Rouviere v. DePuy Orthopaedics, Inc.*, 471 F. Supp. 3d 571, 574 (S.D.N.Y. 2020). Courts have also engaged in a more explicit two-step analysis: first, the proponent advances a legitimate reason for seeking a remote deposition; and second, the burden shifts to the opposing party to make a particularised showing that a remote deposition would be prejudicial. *Swenson v. GEICO Cas. Co.*, 336 F.R.D. 206, 209 (D. Nev. 2020); *In re Broiler Chicken Antitrust Litig.*, 2020 WL 3469166, at *7. Although these are fact-intensive analyses, courts have held that legitimate reasons for a remote deposition "plainly exist" under pandemic conditions, such as physical distancing orders. *Swenson*, 336 F.R.D. at 211; *see also Broiler Chicken*, 2020 WL 3469166, at *7 (legitimate reasons for remote depositions existed because of health and safety concerns, and in the interest of moving the case through the pretrial process at an acceptable pace); *Rouviere*, 471 F. Supp. 3d at 574–75 ("[t]here is a significant health risk to Howmedica's representatives (and to Plaintiffs' counsel as well) if the deposition were to proceed in person"). Parties have therefore increasingly agreed to the use of remote depositions during the pandemic, and have stipulated to remote deposition protocols that govern the manner in which such depositions will occur in a given litigation. As a practical matter, with the passage of time, these remote deposition protocols have become a part of case management orders, embraced by the parties and courts. It remains to be seen whether remote depositions will become a fixture of U.S. litigation in the coming years, whether or not the pandemic remains.

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 U.S. 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 U.S. 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 U.S., an in-house attorney should consider ensuring that their title indicates that they are 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 U.S.

Foreign data privacy laws and blocking statutes may provide obstacles to discovery when the material to be produced is housed

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outside of the U.S. 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 U.S. law, the Hague Evidence Convention procedures are not mandatory and are only permissive; to apply the Hague Evidence Convention, a U.S. 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 (*e.g.*, the United States) than the original jurisdiction. 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 U.S. 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 U.S.

4 Critical and Dispositive Motions, Trial, and Appeal

Critical and dispositive motions

In the U.S., 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 the 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 U.S., 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". Fed. R. Civ. P. 23(a) (emphasis added). Plaintiffs seeking class certification must also establish that at least one of the prongs set forth in Rule 23(b) is satisfied. Where money damages are sought, that typically involves establishing that "questions of law or fact common to class members *predominate* over any questions affecting only individual members...". Fed. R. Civ. P. 23(b)(3) (emphasis added). 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 a U.S. trial, the foreign witness's testimony typically can only make its way into evidence through video clips from depositions. Accordingly, a foreign company should choose its witnesses at the discovery stage with an eye towards trial. In recent years, Plaintiffs in consolidated litigation, including product liability matters, have increasingly sought to compel company witnesses to appear at trial remotely, to testify via contemporaneous transmission from a different location. Pursuant to Federal Rule of Civil Procedure 43(a), courts can only order a witness to do so "[f]or good cause in

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compelling circumstances and with appropriate safeguards". Under this rule, most "justifications for remote transmission must be approached cautiously", and "[t]ransmission cannot be justified merely by showing that it is inconvenient for the witness to attend the trial". Fed. R. Civ. P. 43, advisory committee's note to 1996 amendment; *see also, e.g., In re Epipen (Epinephrine Injection, USP) Mktg., Sales Practices & Antitrust Litig.*, 17-md-2785, 2021 WL 2822535, at *5 (D. Kan. July 7, 2021) ("a party's inability to elicit live testimony from a witness outside of the court's subpoena power occurs all the time and does not present a compelling circumstance when the party can introduce deposition testimony instead") (internal quotation marks omitted).

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 cognisant 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 U.S. litigation process may not be complete. If a party is dissatisfied with a judgment, it can usually appeal the judgment to a higher court. 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 a U.S. 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 of the U.S. Constitution, 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 a U.S. judgment against it and does not have sufficient U.S.-based assets for the judgment to be wholly enforced within the U.S., a Plaintiff may initiate proceedings abroad to enforce the judgment. Many foreign countries have treaties in place with the U.S. 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 to gain traction. Within each jurisdiction, the requirements for enforcing a judgment vary. Other nations may be hostile to certain types of U.S. judgments; judgments that include punitive damages, for example, are often viewed as excessive. A U.S. 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, 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 "pre-empted" 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 pre-emption 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 consider when doing business in the U.S. 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 it 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 U.S. and the European Union (hereinafter: E.U.) 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 cognisant 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.

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Conclusion

As demonstrated throughout this chapter, 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 U.S. Although the issues discussed herein are complex and fact-specific, the key takeaway is that ex-U.S. entities cannot proceed under the mistaken assumption that they will never be dragged into U.S. courts. To the contrary, Plaintiffs have become increasingly creative in litigating against companies located outside of the U.S. 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 a U.S. newspaper, ex-U.S. entities should be strategic about structuring their activities in the U.S. 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 a U.S. 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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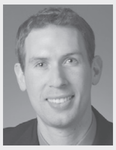

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