Risks "OUS"

What to Do When Your U.S. Mass Tort Goes International

By David L. Ferrera and Dawn M. Curry

Being open to the perspectives of foreign counsel and witnesses, and increasing one's understanding of nuanced differences in foreign jurisdictions, will help create a cost-effective approach to international mass tort litigation.

In a global economy, drug and medical device companies that face mass tort litigation that starts in the United States can see it quickly "spread" to international markets. While many lawyers are familiar with the nuances of navigating the differences between U.S. federal and state litigation, the scope of coordinating with international counsel and their local court rules adds a whole new layer of complexity.

Consider the typical life cycle of a U.S. mass tort litigation. Your client designs, manufactures, and markets a drug or a medical device. Something happens that captures the attention of the plaintiffs' bar as potentially affecting a large number of patients—for example, an FDA action such as non-approval or recall, poor clinical results published or presented at a physician meeting, or an adverse newspaper article or television feature in the national press. Lawsuits are filed, discovery takes place, fact and expert witnesses are selected, and bellwether cases are chosen and tried to verdicts. In the meantime, similar events may occur on either a parallel or an overlapping timeline "outside the United States," which we will refer to as "OUS."

The challenges are many when working with a client's worldwide legal team to ensure consistency of factual and expert testimony and defense themes across multinational borders. Lengthy treatises that discuss the substance of international laws are beyond the scope of this article. Instead, based on our recent experiences, we focus on the following topics to offer some insight and practical advice on what to do when your U.S. mass tort goes international. Specifically, we focus on the following:

- Managing the effect of different legal systems on multinational litigation;
- Using pre-trial fact discovery in multinational litigation;
- Preparing and presenting expert witnesses;
- Understanding developments in the OUS legal landscape;
- Practical tips for effective coordination between U.S. and OUS counsel; and

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- Cultivating awareness of cultural differences.

Managing the Effect of Different Legal Systems on Multinational Litigation

When a U.S. legal team coordinates foreign litigation, it is inevitable that the strategy and the direction of the litigation will be influenced by the U.S. attorneys' experiences with the American legal system. It is natural for U.S. counsel to default to our familiar American legal principles and concepts while working on a case in a foreign jurisdiction. However, resisting that temptation and making a concerted effort to understand the structure, organization, and nuances of the applicable foreign law is important to ensure a robust defense.

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Most U.S. lawyers operate comfortably in the common law system. Developed by the English, the American common law tradition has made U.S. attorneys reliant on case law for legal interpretation and analysis. Although statutes are important sources of law, U.S. lawyers depend on judicial decisions to state the rule of law. Former English colonies that adopted the common law system include Australia, India, Canada, and of course, the United States. In total, there are an estimated 80 countries that operate under the common law system. CIA, Legal System, The World Factbook, https://www.cia.gov/library/publications/the-world-factbook/fields/2100.html (last visited July 28, 2014).

On the other hand, almost twice as many countries—approximately 150—operate under a completely different legal framework, the civil law system. In these countries, codes and statutes are designed to cover all possible contingencies, and judges have a more limited role in deciding the law. Litigation Section, State Bar of Texas, *Cross-Border Litigation: Preparing for Cultural Nuances*, 63 The Advocate 38 (Summer 2013). Civil law judges act in an investigatory capacity, as opposed to common law judges, who act as arbiters between adversarial parties who present their own arguments. Common law systems shape their laws by adhering to the precedent of higher courts, creating consistency in the development of the law. Civil law systems are more flexible, and past judgments are typically guidelines rather than binding law.

Some jurisdictions mix the two systems. The most well-known example in the United States is Louisiana. While Louisiana has the unique status as the only American state with a civil code, it has also incorporated aspects of the American common law system. David Gruning, *Bayou State Bijuralism: Common Law and Civil Law in Louisiana*, 81 U. Det. Mercy L. Rev. 437 (Summer 2004). Examples of OUS mixed systems include Quebec, Scotland, and Puerto Rico. Vernon Valentine Palmer, *Mixed Legal Systems… and the Myth of Pure Laws*, 67 Louisiana Law Review 1205 (Summer 2007). These jurisdictions are unique because they operate within larger legal frameworks that are very different from their internal structure. It is important to learn whether the foreign jurisdiction adjudicating your case blends legal frameworks or is part of a country that contains more than one legal system within its borders.

For example, in China, a civil law country, compensation for drug and device-related injuries is a relatively new establishment. Sara Gourley, Yang Chen, & Scott Bass, *China—Compensation for Drug and Device-Related Injuries*, *in* PLC Cross-Border Life Sciences Handbook 2008–09 (Practical Law Company). China has developed into one of the leading manufacturers of pharmaceutical drugs and medical device products in the world. However, the nation is still adapting its legal system to compensate patients when they suffer injuries that may be related to these products. Although China restricts compensating patients as a result of its fault-based liability doctrine, a court can still order a manufacturer or a distributor that has not committed fault to assume contributory liability for damages that a consumer suffered. These judicial orders have lacked consistency and have played a minor role in how compensation decisions are made. Patients, manufacturers, and distributors cannot look to judicial precedent as a solid basis for predicting the outcomes of future compensation decisions.

In Japan, another civil law country, the nation's domestic law is codified in its Code of Civil Procedure, which prohibits parallel litigation. Minji Soshoho [Code of Civil Procedure], Law No. 29 of 1890; Yoshimasa Furuta, *International Parallel Litigation*, 5 Pacific Rim Law & Policy Journal 1 (Nov. 1995). However, the statute prohibiting parallel litigation has been interpreted as being inapplicable to *foreign* parallel litigation. This interpretation allows litigants to file suit in another country and then file suit in Japan. But Japanese courts have attempted to restrict international parallel litigation through different frameworks. They have reasoned that it is possible for the courts to infer the prohibition of parallel litigation to foreign cases and regulate later litigation to avoid conflicting judgments, ensure equity among parties, and promote fair and speedy litigation. This statutory interpretation prohibiting parallel litigation is favorable to defendants and presents another tool for international legal teams to consider, but be wary of its inconsistent application.

Using Pre-trial Fact Discovery in Multinational Litigation

Pre-trial discovery rules vary greatly in common law countries from the rules in civil law legal systems. Common law countries such as the United States encourage the free flow of information, truth-finding, and informational equity between parties. In contrast, civil law countries view evidence gathering as a task for a sovereign or judge, and greatly restrict the ability of private litigants to discover information outside the direct supervision of the tribunal. Some countries, such as France, vehemently oppose the U.S. discovery system and have enacted statutes to block the application of U.S. discovery rules to their citizens. Carla L. Reyes, *The U.S. Discovery-EU Privacy Directive Conflict: Constructing a Three-Tiered Compliance Strategy*, 19 Duke Journal of Comparative and International Law 357 (2009).

These differences can present challenges to clients and their outside counsel trying to coordinate evidence gathering within countries with conflicting discovery rules. In a mass tort scenario, co-counsel must coordinate creatively to ensure that these differences do not derail development of the company defense. For example, while evidence discovered in a U.S. case may not be admissible in a trial in a European Union civil law country, it can certainly be shared with foreign counsel to guide and to shape strategy and negotiation. In the other direction, foreign tribunals and individuals may use U.S. federal courts to obtain testimony and documents to use in foreign litigation. *See* 28 U.S.C.A. §1782; *Intel Corp. v. Advanced Micro Devices, Inc.*, 542 U.S. 241 (2004) (holding that 28 U.S.C.A. §1782 does not contain a foreign-discoverability requirement and rejecting that a §1782(a) applicant must show that U.S. law would allow discovery in domestic litigation analogous to the foreign proceeding); *In re Gemeinschcaftspraxis Dr. Med. Schottdorf*, 2006 WL 3844464, at *5 (S.D.N.Y. Dec. 29, 2006) (determining that §1782(a) applies to documents located abroad so long as the party from whom discovery is sought is found in the U.S. district). *In re Order for Labor Court of Brazil*, 466 F. Supp. 2d 1020, 1034 (N.D. Ill. 2006) (holding that §1782(a) does not impose a foreign-admissibility rule); Kristine L. Roberts, *U.S. Discovery Procedures Increasingly Available for Use in Foreign Proceedings: Rulings Expand the Reach of 28 U.S.C.A. §1782*, Litigation News (ABA) (July 2007).

One of the biggest challenges facing U.S. lawyers working in cross-border litigation involving countries in the European Union (EU) is data protection. The U.S. rules permitting full-scale discovery of documents conflict with European data protection laws, specifically European Directive 95/46/EC (Privacy Directive). The EU position is that the United States lacks adequate data protection, and thus, EU countries will not readily release personal information to U.S. parties. There are procedures for dealing with the conflict between the Privacy Directive and the U.S. discovery rules, such as submitting a formal letter of request, engaging diplomatic or consular offices, and appointing commissioners. But none of these are likely to seem adequate when faced with the information demands of fast-moving mass tort litigation.

The Hague Convention on Taking of Evidence Abroad in Civil and Commercial Matters, to which the United States is a signatory, also provides methods for discovering information in a foreign country that might otherwise be prohibited by the laws of the country holding the information. Laura W. Smalley, *How to Conduct International Discovery*, 71 Am. Jur. Trials 1 (1999). This treaty provides that "discovery should follow as closely as possible the practice and procedures of the requesting state" so that the evidence obtained will be usable in the requesting state. However, the *Hague Convention* is only enforceable in its approximately 30 signatory countries. Outside of this group, the domestic laws of the foreign country would dictate the scope and the methods of discovery. Of course, anyone who has suffered the delays inherent in using the *Hague Convention* procedures will agree that discovery by agreement under U.S. rules is greatly preferred.

For all these reasons, we recommend early coordination of U.S. and OUS fact discovery. Talk with co-counsel about the information that a company needs to obtain to mount a defense, and then seek it multiple times in multiple jurisdictions in accordance with the local rules. Use what you obtain lawfully in one jurisdiction to inform requests in another, obtaining the information separately for use in different jurisdictions. For instance, if an affidavit presented in South Africa cannot be used in U.S. litigation to cross-examine a witness here due to South African court rules, serve requests for admission in the United States that mirror the sworn statements in the affidavit. Taking these rules into account and working around them will allow international co-counsel to develop the company defense while avoiding conflicting pre-trial discovery rules.

Preparing and Presenting Expert Witnesses

Identifying, preparing, and examining expert witnesses can be drastically different processes depending on the jurisdiction of the case. U.S. attorneys are well familiar with the guidelines of Fed. R. Civ. P. 26 and the *Daubert/Frye* limits on the scope of expert testimony. Even more fundamental is our adversarial system, in which each party "retains" the named experts who advise the retaining party on strategy, and in a defendant's case, may testify during a deposition or a trial in support of a particular defense strategy or defense narrative.

In contrast, in many OUS jurisdictions, experts play either an advocacy role as an advisor or a neutral role as an independent expert. Ethical rules in these jurisdictions may dictate the formation of the attorney-expert witness relationship, the process for reviewing expert reports, and even the conduct of the experts themselves. *See, e.g.*, *Ethical Considerations in Dealing with Experts*, Hearsay.org: The Electronic Journal of the Bar Association of Queensland, Australia (Dec. 1, 2010). In such jurisdictions, while it is possible for an expert to serve as both an advisor and independent expert, *Evans Deakin Pty Ltd v. Sebel Furniture Ltd* (2003) FCA 171, Allsop J (Australia), there may be strategic reasons for not asking a witness to do so. For example, there could be difficulty admitting a report written by an advisor turned independent expert because the ability of the newly appointed independent expert to review that evidence neutrally would be called into question.

It is important to learn whether the foreign jurisdiction adjudicating your case blends legal frameworks or is part of a country that contains more than one legal system within its borders.

Consider the preparation and the presentation of expert witnesses in Australia. There, expert examination occurs through a process known as "hot-tubbing"—legal slang for concurrent evidence. Justin L. Heather, Ryan A. Horning, Frances P.

Kao, & Martin V. Sinclair, Jr., *Into the Hot Tub… a Practical Guide to Alternative Expert Witness Procedures in International Arbitration*, 44 International Lawyer 1035 (Fall 2010). In this method of presenting evidence, the parties still choose their own expert witnesses, but they all testify together during the same hearing. The Australian method tends to be less adversarial than the American process, and some believe that it is more useful to the trier of fact.

One of the biggest challenges facing U.S. lawyers working in cross-border litigation involving countries in the European Union (EU) is data protection.

In a "hot tub," experts discuss the case, respond to questions from the judge and the lawyers, and even question each other. Essentially, direct examination and cross-examinations occur simultaneously, making it even more critical for defense attorneys to have great knowledge of a plaintiff's experts and be prepared to ask questions and respond to the free flow of ideas between experts or among the experts and the trier of fact. One way to help your Australian counterparts find experts to fill these roles, while still complying with Australian ethical rules, is to ask your U.S. experts to recommend colleagues from conferences and professional organizations. Often, experts are interconnected and know others in foreign countries who can lend their expertise to an OUS case.

Finally, in a global economy, the same persons may be asked to serve as expert witnesses in multiple countries in the same mass tort. In this scenario, U.S. discovery rules can have both positive and negative consequences. One potential benefit would be taking advantage of the liberal discovery process in the United States to depose an expert here who has been disclosed as an expert in an OUS jurisdiction that prohibits such discovery. One potential disadvantage would be inconsistently executed attorney agreements about the use of the draft expert witness reports. U.S. counsel may agree to exclude expert witness draft documents from discovery only to find that no such agreement exists between foreign counsel so an expert's draft work product becomes a matter of public record in the foreign jurisdiction. Again, closely coordinating with international co-counsel can help ensure that your attorney work product remains both timely and confidential.

Understanding Developments in the OUS Legal Landscape

Assisting a client and a foreign legal team in litigation outside the United States requires understanding the procedural differences between the U.S. and foreign legal systems. Some procedural differences may have a significant effect on a case yet not be obvious topics of initial strategy conversations between legal teams. Two such examples most relevant to large-scale drug and medical device cases include class action certification and payment of attorneys' fees.

In drug and medical device litigation, U.S. plaintiffs attempting to bring a class action face a rigorous certification process. During this process, defense counsel has meaningful opportunities to challenge the formation of a class and to prevent a lawsuit from ever gaining momentum. Fed. R. Civ. P. 23(c)(1). This is why in the United States most medical device or pharmaceutical cases are brought in federal multidistrict litigation. In contrast, in other countries, plaintiffs face much lower standards for class formation, which has resulted in a growing number of drug and medical device cases that start elsewhere before making their way to a U.S. forum.

For example, class action laws have traditionally been much more favorable for plaintiffs in Canada than in the United States. The main difference is that in Canada, specifically in Ontario, class certification will not be denied on grounds that a member of a class has individual damages, whereas in the United States a class action is more likely to fail if the class members are faced with the task of evaluating damages on an individual basis. *Class Proceedings Act, 1992*, S.O. 1992, c. 6 (Ontario 1993); Gary R. Will & Paul S. Miller, *Participation of US Counsel in Canadian Class Actions and Mass Torts*, Association of Trial Lawyers of America (2006). For this reason alone, it may be futile to attempt to defeat a class in a country such as Canada, and filing lengthy affidavits during the class certification stage may do little more than disclose your best defenses prematurely for use against your client in other countries.

Another procedural difference relevant to OUS strategy includes the rules related to payment of attorneys' fees and contingent-fee agreements. The American rule, under which each party pays its own legal fees, is in stark contrast to the British rule, under which the loser generally pays the legal fees for both parties. The potential for the losing party to pay all legal fees may make both sides think twice before making pricey discovery requests or driving up other costs. Although contingency-fee arrangements are commonplace in the United States, especially in class actions, for which plaintiffs' attorneys typically receive 30–40 percent of an award, these types of arrangements have traditionally been prohibited in most civil law countries. However that may be changing. Some European countries that have historically prohibited contingency-fee arrangements, such as Sweden, Germany, and England, recently have modified their litigation rules to allow attorneys to be paid out of their clients' damage awards. For example, in Sweden, "risk-assessment" agreements can now be negotiated in collective litigation between attorneys and their clients. These agreements allow clients to pay their attorneys a reasonable fee, rather than a percentage of the award, based on the value of a dispute to the extent that an action is successful. Gregory L. Fowler, Marc Shelley, & Silvia Kim, *Emerging Trends in International Litigation*, 3 Disp. Resol. Int'l 101 (Oct. 2009). In Germany, the country's Federal Constitutional Court repealed the nation's bar on contingent-fee arrangements in 2006, holding that the ban prevented many citizens from bringing claims. Bundesverfassungsgericht [BVerfGE] [Federal Constitutional Court] Dec. 12, 2006, 1 BVR 2576/04 (F.R.G.). In England, a new form of contingency-fee agreement—damages-based agreements—became effective in

April 2013. Under these arrangements, a lawyer's agreed fee is contingent upon the success of the case and is determined as a percentage of the compensation received by the client. Before these regulations, such damages-based agreements in England were only enforceable in employment matters. Note that agreements do not affect the British rule, which provides that the unsuccessful party normally bears the reasonable costs of the successful party's legal fees and disbursements. According to the Legal Aid, Sentencing and Punishment of Offenders (LASPO) Act, if the contingency fee payable to an English solicitor exceeds what would be chargeable under a normal fee arrangement, the successful party must bear that cost. *Legal Aid, Sentencing and Punishment of Offenders (LASPO) Act 2012*, c. 2, §45 (2012) (Eng.); *The Damages Based Agreements Regulations 2013,* No. 609 (Eng.).

It is possible that these new laws may increase drug and medical device litigation in OUS countries for the same reasons that contingent-fee litigation blossomed in the United States. Under this scenario, OUS litigation "hot spots" may soon change, along with the need in such countries for more sophisticated legal counsel or greater support from U.S. counsel.

Practical Tips for Effective Coordination Between U.S. and OUS Counsel

Of all the considerations that an in-house attorney makes when dealing with multinational litigation, one unusual challenge is ensuring that the international legal teams are communicating properly and efficiently with the U.S. teams. We suggest some simple, practical tips that might seem intuitive but are often forgotten in the urgency of the moment. We suggest mastering your time zones, keeping attuned to "the time float," shrinking the planet, living in the cloud, and managing the message. We take each in turn.

Master your time zones. Handheld devices such as iPhones offer screens with "world clocks" for any jurisdiction. It is not as simple as Eastern versus Pacific Time. India Standard Time (IST), for example, is on the half hour. Some countries do not recognize Daylight Savings Time, or what the Europeans call "Summer Time." Those that do may not follow the same dates as the United States. If you have repeat business with a particular location, try using an analog solution: keep a second clock on your desk set to the local time in the active international jurisdiction.

Keep attuned to "the time float." Coordinating between U.S.-based and OUS-based offices creates narrow windows in which to work. If you reside in Boston and need to talk to a company witness in Amsterdam, remember to call before 11 a.m. Eastern Time or you may find your witness has left for the day. Keep lists of international filing deadlines and think through how this may affect work schedules in the United States. For example, Malaysia is 12 hours ahead of New York, and court filings must be in the local dialect. If, for example, a company's lawyers in Kuala Lumpur need U.S. counsel to opine on a draft answer due Friday, in practice, the U.S. counsel may need to have comments completed by close of business Wednesday to ensure sufficient time for transmission, translation, and filing.

Shrink the planet. Liberally use technology such as online meeting, Web conferencing, and videoconferencing applications. Even if co-counsel speak English as a second language, accents can be difficult to understand over traditional phone calls. Developing a personal rapport with those whom you may never meet in person is enhanced when you can see them. Technology has improved dramatically from the days when a videoconference was like a badly dubbed movie for which the speakers' lips move but the audible words follow after a two-second delay, and no doubt they will only continue to improve. Keep checking the latest offerings and their availability.

Live in the cloud. Similarly, early on in a litigation, consider setting up extranets and other cloud-based document sharing systems. E-mail is fine for basic communication, but to operate a true virtual international law firm, you must share large documents and electronic files that are often so big that you cannot prevent them from becoming trapped in spam filters. Sharing data in the cloud allows all of the attorneys on a team to have immediate access to all documents without the time delay (and cost) of copying and mailing such items. Plaintiffs' lawyers abroad frequently collaborate with plaintiffs' lawyers in the United States, sharing document productions, briefs, and legal arguments. The technology exists for defense lawyers to seamlessly do the same; insist that it happen and that all lawyers take advantage of it.

Manage the message. It is inevitable that international mass tort litigation for drugs or medical devices will occur at different times across the globe and proceed on different tracks. The internet and social media foster instant publicity of trial or settlement events in one country that can easily be misinterpreted by the popular press in another country and manipulated by plaintiffs' attorneys to their local advantage. If a company enters into a global settlement program in the United States, plaintiffs in other countries may cry "why not me" with little regard to the competing legal systems. Similarly, a trial verdict in one jurisdiction will surely be cited in another, again with little regard to the competing legal systems. While these scenarios are unavoidable, regular information sharing between international co-counsel will help ensure that the worldwide message consistently puts these events into proper context.

A Final Word—Cultivating Awareness of Cultural Differences

Even when U.S. and OUS lawyers use all of these best practices, an unintended intercultural miscue can derail a high-functioning international litigation team. "Cultural competence" is a term used to describe the ability to interact effectively with people of different cultures, and it requires individuals to confront stereotypes and bias and acknowledge the value of differences. Many large U.S. law firms have embraced the term when developing internal diversity and inclusion initiatives, but surprisingly, these same lawyers often fail to take the time to factor in the effect of significant cultural differences between U.S. and OUS personnel, even in the largely English-speaking Western business world.

Cultural differences can be easy to miss, especially for lawyers. Susan Sample, *Intercultural Competence as a Professional Skill*, 1 Pacific McGeorge Global Business & Development Law Journal 117 (2013). But recognition and awareness of that fact is the first step for cross-cultural legal teams to avoid needless conflict arising from cul-

tural misunderstandings. Communication is the fundamental tool by which attorneys interact with others. This includes gestures and other nonverbal communication that tend to vary from culture to culture. There are familiar examples of differences in business etiquette for greeting someone or for presenting your business card. You should also understand the importance of timeliness, dress, tone of voice, class background, and assumed understanding of pop culture references. There is great wisdom in the time-honored expression that the United States and so-called Commonwealth countries are "divided by a common language."

Ethical rules in these jurisdictions may dictate the formation of the attorney-expert witness relationship, the process for reviewing expert reports, and even the conduct of the experts themselves.

Consider a U.S. attorney conducting work product interviews of Indian chemists at a U.S. subsidiary in Bangalore. If the U.S. attorney is male, or upper-middle class, or European American, or any combination of these, local cultural norms may create a real or perceived elevated social status of the U.S. attorney that inhibits open dialog with the Indian witnesses. A more subtle example is a U.S. attorney conducting the same interview of British research and development engineers of a U.S. subsidiary in London.

Overlooking these seemingly obvious differences by launching immediately into a substantive dialog about the mass tort litigation can lead to uncomfortable working relationships and less effective communication. Obviously, one of the immediate costs of not communicating well is lost information. For this reason, we suggest holding a detailed "pre-session" with OUS witnesses and attorneys designed to provide background information on the litigation generally, but also to convey a more detailed introduction of the U.S. lawyers than normally would happen if the litigation did not involve OUS witnesses or attorneys, including their background, previous roles representing the company in U.S. litigation, and any shared cultural experiences that may strengthen personal bonds.

Everyone expects differences in legal procedures, courtroom etiquette, and standard business practices, but we often forget to take the time to understand basic cultural differences about the people themselves that may impede effective working relationships. Foreign outside counsel—particularly those trained in U.S. law schools or specializing in U.S. business relationships—can serve as a vital resource to facilitate this understanding and early recognition of cultural misunderstandings within the courts and a company client.

Conclusion

U.S. drug and medical device manufacturers that offer their products worldwide open themselves to global risks of litigation. To tell "a company story" properly and mount a vigorous defense, OUS attorneys defending litigation around the world need to do so on a coordinated and cooperative basis with U.S. counsel. Not only does this coordination entail developing the requisite knowledge about litigating in a foreign jurisdiction, it also requires U.S. lawyers to refocus their cultural lenses. Approaching foreign litigation solely from an American legal and cultural perspective will hinder the potential for full cooperation with OUS counsel. Being open to the perspectives of foreign counsel and witnesses, and increasing one's understanding of nuanced differences in foreign jurisdictions, will help create a cost-effective approach to international mass tort litigation. FD