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Developments in US product liability law and the issues relevant to foreign manufacturers

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Product-liability exposure is a key consideration that every foreign product manufacturer must analyse and consider when doing business in the US market. To prepare for and minimise this exposure, manufacturers must be familiar with the relevant substantive law and the tactics used by claimants to exert pressure on corporate defendants.

This article examines US product liability law and its impact on foreign product manufacturers, in particular:

- The framework for US product liability law, including:
  - causes of action;
  - available defences.
- Developments in pre-emption.
- Developments in state tort reform.
- Tactics used by claimants and potential defence countermeasures, including:
  - state court litigation;
  - mass advertising and case collection;
  - multi-district litigation.
- Litigation issues specific to foreign manufacturers, including:
  - personal jurisdiction;
  - service of process;
  - discovery abroad;
  - enforcement of judgments.

THE FRAMEWORK FOR US PRODUCT LIABILITY LAW

Causes of action

There is no federal product liability law. Therefore, the laws of each state determine the liability of product manufacturers. While several states have passed comprehensive statutes, most state product liability law is based on common law. Although state law varies, there are many similarities among the jurisdictions. This section focuses on these similarities. Manufacturers, however, should be aware of the intricacies of product liability law in the states in which they do business.

Parties subject to product liability laws. Parties involved in selling or distributing a product are subject to liability for harm caused by a defect in that product (*Restatement (Third) of Torts: Products Liability § 1*). This includes all parties in the chain of manufacture and distribution, such as the component manufacturer, assembling manufacturer, wholesaler and retailer. However, some jurisdictions have enacted innocent seller statutes, which provide that a seller is not liable in a product liability action if it:

- Did not manufacture the product.
- Was unaware of the defect.
- Could not have reasonably discovered the defect.
- Did not change the product but merely passed it on in the chain of commerce.

Types of claim. Product liability claims may be based on breach of warranty, negligence or strict liability.

Claims based on the breach of an express or implied warranty are generally governed by Article 2 of the Uniform Commercial Code (UCC), which has been adopted in similar form in every state other than Louisiana. The UCC provides remedies when a product fails to satisfy express representations, is not merchantable, or is unfit for its particular purpose.

In a negligence claim, the defendant can be held liable for failing to use due care. Strict liability claims, however, do not depend on the degree of care exercised by the defendant. Strict liability focuses on product defect rather than a manufacturer's conduct. In every claim based on strict liability, the claimant must establish that the product was defective. There are three types of product defects (*Restatement (Third) of Torts: Products Liability § 2*):

- **Design defects.** A product is defectively designed when both the:
  - foreseeable risks presented by the product could have been reduced or avoided by employing an alternative design; and
  - failure to use an alternative design renders the product unreasonably dangerous.

  The alternative design must be reasonable. In determining reasonableness, the court may consider, among other things, the effect on production costs, durability, maintenance and aesthetics. Additionally, the overall safety of the product must be considered. For example, an alternative design would not be reasonable if it created or increased other risks of equivalent danger simply to minimise a particular risk. Generally, the claimant has the burden of proving that a reasonable alternative design was available at the time of distribution.

- **Manufacturing defects.** Unlike a design defect, a manufacturing defect does not depend on the design specifications of a product. Instead, a product has a manufacturing defect when it fails to meet its intended design specifications, despite the exercise of due care. The claimant must usually prove that the product was defective when it left the manufacturer's hands. If a defect arises during shipment or storage, a distributor in the chain of commerce can be held liable, just as if the product were defectively manufactured.
- **Warning defects.** A product contains a warning defect when both the:
  - foreseeable risks of the product could have been reduced or avoided by providing reasonable warnings or instructions; and
  - due to the absence of such information, the product is unreasonably dangerous.

  While most warnings are generated by manufacturers, sellers and distributors must provide warnings when doing so is reasonable. Claimants must prove that adequate warnings or instructions were not provided. The court must weigh a number of factors to determine the adequacy of a warning, including the targeted consumers. For example, a product intended for children may require more information than a product intended for adults. Additionally, a product can have an adequate warning without providing information on every possible risk. In fact, a warning with too much information can make it difficult for a consumer to focus on the most important details.

Analysis

Available defences

Defences, like the product liability claims themselves, are a matter of state law. Therefore, defences can vary from jurisdiction to jurisdiction.

Statutes of limitation. A claimant must file a lawsuit within a certain statutory period of time following injury. The period depends on the jurisdiction and the type of liability (*see above, Causes of Action: Types of claim*). For personal injury claims, the limitation period can range from one year to six years. Many states employ the "discovery rule" to determine when the limitation period begins to run. Generally, the discovery rule provides that the period does not begin to run until the claimant knows, or should know, that he has been injured by the product in issue.

Statutes of repose. Unlike statutes of limitation, statutes of repose do not depend on when the claimant is injured. Instead, they require a claimant to bring a claim within a certain period of time after the product is manufactured or sold. While repose periods are usually longer than limitation periods, they are not subject to the discovery rule and represent an absolute bar to a product liability claim.

The learned intermediary doctrine. The learned intermediary doctrine provides that a prescription drug or device manufacturer discharges its duty to warn by adequately warning the claimant's prescribing physician. The manufacturer has no duty to warn the claimant directly because, under federal law, prescription drugs are only available through a licensed physician, who acts as the learned intermediary between the patient and the manufacturer.

There are recognised exceptions to the learned intermediary doctrine. Some courts have held that the doctrine does not apply to mass immunisation programmes, due to the lack of physician-patient contact (*Petty v US, 740 F.2d 1428, 1440 (8th Cir. 1984)*). Certain contraceptives have also been excluded from the doctrine because patients actively participate in contraceptive decision-making (*Odgers v Ortho Pharm. Corp., 609 F.Supp. 867, 878 (E.D. Mich. 1985)*). Finally, at least two courts have held that the doctrine does not apply under certain circumstances to products that have been advertised directly to consumers (*Centocor, Inc. v Hamilton, 310 S.W.3d 476, 506-08 (Tex. App. 2010); Perez v Wyeth Labs., Inc., 734 A.2d 1245 (N.J. 1999)*). The learned intermediary doctrine has been adopted by more than 40 states. Only one state, West Virginia, has expressly rejected the learned intermediary doctrine (*State ex rel. Johnson & Johnson Corp. v Karl, 647 S.E.2d 899 (W.Va. 2007)*). However, the United States District Court for the District of New Mexico recently held that the New Mexico Supreme Court would not adopt the learned intermediary doctrine despite the fact that there were three New Mexico Court of Appeals' decisions adopting or applying the doctrine (*Rimbert v Eli Lilly and Co., 577 F.Supp.2d 1174 (D.N.M. 2008)*). On 8 February 2011, members of the US House of Representatives introduced a bill entitled the Consumer Protection Act of 2011 that attempts to strike the learned intermediary defence altogether in tort claims based on products' liability. (*See Jessica Dye, House Bill Targets Learned Intermediary Defense, Law 360, 9 February 2011, www.law360.com/productliability/articles/224683?utm_source=newsletter&utm_medium=email&utm_campaign=productliability.*) The bill is still pending before the House Committee on the Judiciary (Consumer Protection Act of 2011, H.R. 542, 111th Cong. (2011), *www.govtrack.us/congress/bill.xpd?bill=h112-542*).

Intervening/superseding cause. If a claimant's injury was caused by the intervening conduct of another and that conduct is also a superseding cause, a defendant may avoid liability in most jurisdictions. An intervening act is a superseding cause when a manufacturer could not reasonably be expected to protect against things such as:

- Criminal acts.
- Use of a product in an unforeseeable manner.
- Alteration of the product.
- Negligent use.
- Failure to properly maintain a product.

Contributory negligence/comparative fault. Under contributory negligence, a claimant is barred from recovery if his own negligence caused or contributed to his injury. However, most jurisdictions have abandoned contributory negligence in favour of comparative fault. Under comparative fault, a claimant's recovery is reduced if his own negligence (or fault) contributed to his injury. There are two types of comparative fault:

- **Pure comparative fault.** The jurisdictions that apply pure comparative fault reduce a claimant's recovery by the percentage of fault attributed to the claimant.
- **Modified comparative fault.** Jurisdictions using modified comparative fault also reduce a claimant's recovery by the percentage of his fault, but completely bar recovery if the claimant's fault exceeds a specified percentage. For example, in some jurisdictions a claimant is barred from recovery if the percentage of his fault is greater than that of the defendant.

Assumption of the risk. In some jurisdictions, a claimant may also be barred from recovery if he is aware of a product defect and the accompanying dangers, but uses the product anyway. The assumption of the risk defence is based on what the claimant actually knew, not what a reasonable person would have known.

State of the art. If a manufacturer can establish that a product was manufactured according to the current state of scientific and technical knowledge in the relevant field (that is, the product is "state of the art"), that evidence can be used to show the manufacturer acted with due care. State of the art evidence is also relevant to warning issues. Claimants must show that the defendant failed to provide reasonable and adequate warnings in accordance with the current state of medical or scientific knowledge (*see above, Causes of action: Warning defects*). This evidence may also be key to design defect claims in jurisdictions where the claimant must demonstrate the existence of a safer alternative (*see above, Causes of action: Design defects*). However, state of the art evidence is not admissible in every jurisdiction.

DEVELOPMENTS IN PRE-EMPTION

Federal statutes, rules and regulations control certain aspects of product safety. However, in some instances, compliance with federal standards may require a manufacturer to deviate from conflicting state requirements, and in turn, subject it to liability. The pre-emption doctrine attempts to prevent manufacturers from being subjected to inconsistent federal and state standards by pre-empting state tort claims to the extent they impose different or additional requirements on manufacturers. The pre-emptive effect of a statute or regulation can be expressly stated or implied from the comprehensive nature of the enactment.

Pre-emption is a particularly current issue in the area of prescription drugs and medical devices, which are both regulated by the US Food and Drug Administration (FDA). In fact, whether a claimant's claims under state law will survive pre-emption depends substantially on whether the relevant product is a prescription drug or a medical device. The US Supreme Court (Supreme Court) addressed pre-emption doctrine in relation to medical devices in *Riegel v Medtronic, Inc., 552 US 312 (2008)*. In *Riegel*, the court held that state law tort claims against Class III medical device manufacturers are pre-empted to the extent they are "different from, or in addition to" the requirements imposed by federal law. In so holding, the court left open the possibility of a so-called "parallel claim" exception that would allow state tort claims to survive pre-emption if both:

- They are "premised on a violation of FDA regulations".
- The claimant's alleged injuries are causally related to such violation.

Defining which causes of action constitute viable parallel claims under *Riegel* continues to be a fiercely debated issue. While many courts across the country have applied *Riegel* broadly, pre-empting all manner of claims from strict product liability and negligence, to breach of warranty, to failure to warn and manufacturing-and-design-defect, to negligence per se (*In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig., 592 F.Supp. 2d 1147, 1152 (D. Minn. 2009), aff'd, 623 F.3d 1200 (8th Cir. 2010); Wolikci-Gables v Arrow Intl. Inc. 634F.3d1296, 1301-02 (11th Cir. 2011); Walker v Medtronic, Inc., 2012 WL 208036 (4th Cir. 2012)*), others have sought to expand the parallel claim boundaries (*see Hughes v Boston Scientific Corp., 631 F.3d 762 (5th Cir. 2011); Bausch v Stryker Corp., 630 F.3d 546 (7th Cir. 2010), cert. denied. 132 S.Ct. 498 (2011)*).

A year after deciding *Riegel*, the Supreme Court addressed pre-emption in the context of prescription drugs in *Wyeth v Levine, 555 US 555 (2009)*. In *Levine*, the Court was asked to decide whether FDA approval of a prescription drug's label pre-empted the claimant's product liability claims under state law alleging that the label contained inadequate warnings. In a 6-3 decision, the Court held that federal law did not pre-empt the claimant's claims, finding that "it is not impossible for [the manufacturer] to comply with its state and federal law obligations". The Court emphasised that the "central premise of federal drug regulation is that the manufacturer bears responsibility for the content of its label at all times".

Essential to *Levine's* holding is the fact that a manufacturer may make unilateral changes to a drug's label without prior FDA approval. As a result, a manufacturer can supplement the label with different or additional warnings as required by state law without simultaneously violating federal law. The court explained that while "the FDA retains authority to reject [such] labelling changes...absent *clear evidence* that the FDA would not have approved the change to [the drug's] label, we will not conclude that it was impossible for [the manufacturer] to comply with both federal and state requirements" (emphasis added).

Application of *Levine's* "clear evidence" standard is becoming an increasingly debated issue. Already, federal Courts of Appeals have grappled with defining what type of evidence constitutes "clear evidence" sufficient to pre-empt a claimant's state law claims (*see Mason v Smithkline Beecham Corp., 596 F.3d 387 (7th Cir. 2010); Miller v Smithkline Beecham Corp., 381 Fed. Appx. 776 (10th Cir. 2010)*).

The Supreme Court recently limited *Levine's* holding, however, to apply only to brand name prescription drug manufacturers. In *Pliva. Inc. v Mensing, 131 S.Ct. 2567 (2011)*, the Court held that federal law pre-empts state law failure to warn claims when asserted against generic prescription drug manufacturers because, unlike their brand name counterparts, generic manufacturers are not permitted to make unilateral changes to their drugs' labels. Due to their "ongoing federal duty of 'sameness'", generic manufacturers are responsible for ensuring that their warning labels are, at all times, identical to those set forth on the corresponding brand name drugs' labels. As a result, generic manufacturers are not permitted to change their drugs' labelling unless and until such changes are made to the brand name versions of the corresponding drugs.

UPDATE ON THE RECENT DEVELOPMENTS IN TORT REFORM

Claimants' trial lawyers take in more than US$40 billion (as at 1 March 2012, US$1 was about EUR0.74) annually (*see James R. Copeland, "Trial Lawyers, Inc., Message from the Director", at www.triallawyersinc.com*). Not surprisingly, these numbers have fuelled the impetus for tort reform. Some of the more important reform initiatives are summarised below.

Punitive damages

Large punitive damage awards have seriously distorted settlement and litigation processes and have led to wildly inconsistent outcomes in similar cases (*see www.atra.org*). The Supreme Court recently held that punitive damages could not be imposed on a defendant for harm allegedly done to non-parties (*Philip Morris USA v Williams, 127 S.Ct. 1057, 549 US 346 (2007)*). The American Tort Reform Association (ATRA) has pushed for:

- The establishment of an appropriate punitive damages trigger, such as actual malice.
- Application of the "clear and convincing evidence" standard to establish liability.
- Proportionality between the punitive damages award and the offence.
- Federal legislation to deal with multiple punitive damages awards.

32 states have enacted some type of punitive damages reform, while one state had reforms held unconstitutional and has not enacted further reforms (*see Tort Reform Record: December 2011 at www.atra.org*).

Joint and several liability

Under joint and several liability, a claimant can recover from multiple defendants collectively or just one of those defendants individually. This rule encourages the inclusion of wealthy corporations as defendants, even if the relevant corporation had only a remote role in the alleged harm. 39 states have modified joint and several liability rules, making it more difficult to recover fully against all of the defendants (*see Tort Reform Record: December 2011 at www.atra.org*).

Non-economic damages

Non-economic damages include losses for intangible injuries such as pain and suffering, and emotional distress. The trend has been towards excessive non-economic damage awards. ATRA believes that "the broad and basically unguided discretion given to juries awarding damages for non-economic loss is the single greatest contributor to the inequalities and inefficiencies of the tort liability system". 23 states have modified the rules for awarding non-economic damages, for example by placing caps on the amount that can be awarded. In four states, reforms were held unconstitutional and they have not passed further reform legislation (*see Tort Reform Record: December 2011 at www.atra.org*).

Product liability reform

By imposing liability for the sale and/or distribution of defective products, the law attempts to compensate injured individuals and, simultaneously, deter manufacturers from marketing such products. But the law does not serve these functions when manufacturers and distributors are both:

- Uncertain as to how to avoid liability.
- Subjected to liability for risks they could not have anticipated.

20 states have passed legislation directed specifically at product liability. Three states have had reforms held unconstitutional and have not passed further reform legislation (*see Tort Reform Record: December 2011 at www.atra.org*).

Collateral source rule

Under the collateral source rule, evidence may not be admitted to establish that a claimant's losses have been reimbursed by other sources, such as insurance. Therefore, a significant percentage of the payments made to claimants are to compensate for losses that have already been covered. 24 states have either modified or abolished the collateral source rule. Two states have had reforms held unconstitutional and have not passed further reforms (*see Tort Reform Record: December 2011 at www.atra.org*).

Appeal bond reform

While large damages awards are often overturned on appeal, defendants in many states must post an appeal bond up to 150% of the damages awarded. This type of bond can force a company or industry into bankruptcy. 39 states have adopted some form of appeal bond reform (*see Tort Reform Record: December 2011 at www.atra.org*).

Jury service reform

According to ATRA, up to 20% of those summoned for jury duty do not respond (some jurisdictions have an even higher rate). "Occupational exemptions, flimsy hardship excuses, lack of meaningful compensation, long terms of service and inflexible scheduling results in a jury pool that makes it difficult for working Americans to serve on a jury and disproportionately excludes the perspectives of many people who understand the complexity of issues at play during trial" (*see Tort Reform Record: December 2011 at www.atra.org*). ATRA supports the following reforms to improve the jury system:

- Elimination of occupational exemptions.
- Strict adherence to the "true hardship" standard for excuse from jury service.
- Greater flexibility in scheduling.
- Protecting employees from retaliatory employers.
- Establishment of a trial fund to compensate jurors who serve on long civil trials.

14 states have enacted reform legislation in this area.

Class action reform

Designed as a mechanism to promote judicial economy by aggregating potentially hundreds of thousands of "common" claims into a single action, class actions today are viewed by many as a means of defendant extortion. While class members often receive little or no benefit from a class action, typically compensation in the form of coupons or other awards of little value, claimants' counsel walk away with millions in legal fees. 11 states have enacted class action reforms (*see Tort Reform Record: December 2011 at www.atra.org*).

TACTICS USED BY CLAIMANTS TO PRESSURE DOMESTIC AND FOREIGN MANUFACTURERS, AND POTENTIAL DEFENCE COUNTERMEASURES

State court litigation

Why claimants want to be in state court. Claimants want to be in state courts because they are generally more "claimant friendly" and there is a greater potential for large awards. ATRA has issued a report identifying jurisdictions that have attracted lawsuits from

across the country due to their claimant-friendly reputation. Not surprisingly, all the forums identified as "judicial hellholes" are state courts known for granting huge awards and ignoring established procedure. The "judicial hellholes" identified by ATRA in 2011/2012 were (*www.atra.org*):

- Philadelphia, Pennsylvania.
- California.
- West Virginia.
- South Florida.
- Madison and St. Clair Counties, Illinois.
- New York City and Albany, New York.
- Clark County, Nevada.
- McLean County, Illinois.

ATRA additionally identified the following for the "Watch List" in 2011/2012:

- Eastern District of Texas.
- Cook County, Illinois.
- Southern New Jersey.
- Atlantic County, New Jersey.
- Franklin County, Alabama.
- Smith County, Mississippi.
- Louisiana.

Federal courts are less political and the judges are generally more likely to consider dispositive motions (that is, motions that, if granted, conclude all or part of the cause of action), including motions to exclude expert testimony under the *Daubert* standard.

How claimants keep cases in state court. A case filed in state court can only be removed (transferred) to federal court if either:

- There is a federal question involved (federal question jurisdiction).
- There is complete diversity of citizenship between the parties and more than US$75,000 is in dispute (diversity jurisdiction).

Federal questions are rare in the context of product liability claims. Under the well-pleaded complaint rule, a federal claim must appear on the face of the claimant's complaint. Potential defences available to defendants, including pre-emption, are "ignored" by the court for purposes of federal question jurisdiction. Therefore, corporate defendants are forced to rely on diversity jurisdiction as the basis for removal. However, because so many large awards of damages are awarded in state courts, claimants have developed numerous strategies for destroying diversity.

Joinder of non-diverse parties. To establish complete diversity, no defendant can be a citizen of a state where any claimant is also a citizen. To destroy complete diversity, claimants join a defendant that is a citizen in a state where the claimants are located (non-diverse defendants). For example, if a corporate defendant is a citizen of Delaware and the claimants are citizens of Missouri, the claimants will add a Missouri defendant to the lawsuit. In the product liability context, this additional defendant usually has had little or no role in the product defect or injury at issue. Non-diverse defendants include parties such as:

- Sales representatives.
- Local distributors.
- Local employees.

In pharmaceutical product liability cases, claimants often join a local pharmacy or a local prescribing or treating doctor to destroy diversity of citizenship and thus prevent removals to federal court.

Claimants may also attempt to join non-diverse claimants. For example, if the defendant corporation is a citizen of Delaware and the claimants are citizens of Missouri, the claimants will add an additional, unrelated claimant from Delaware.

A defendant may remove a case to federal court if it can establish that the non-diverse party was fraudulently joined. To meet the fraudulent-joinder standard, the defendant must show that there is either:

- No reasonable basis for recovery against the non-diverse defendant.
- No reasonable basis for the joinder of the non-diverse claimant.

Some courts in product liability cases have recently recognised claimants' ongoing joinder of non-diverse parties as a charade. For example, in *In re Diet Drugs*, the multi-district litigation (MDL) court held that such joinder of physicians, pharmacies and sales representatives "can only be characterised as a sham, at the unfair expense not only of [the manufacturer] but of many individuals and small enterprises that are being unfairly dragged into court simply to prevent the adjudication of lawsuits against [the manufacturer], the real target, in a federal forum" (*220 F.Supp. 2d 414, 425 (E.D. Pa. 2002); see also In re Rezulin, 133 F.Supp. 2d 272 (S.D.N.Y. 2001)*).

Impact on foreign manufacturers. Foreign manufacturers may be forced to litigate in state court jurisdictions that are less sympathetic (or even hostile) to a foreign defendant. The juries in the courts of "judicial hellholes" appear to be biased against foreign corporate defendants. Likewise, judges in the "judicial hellhole" jurisdictions are likely to be less experienced with issues specific to foreign manufacturers.

Potential countermeasures. To counter (or at least help minimise) the threat of state court litigation, a foreign manufacturer must be aware of the US jurisdictions in which it maintains related entities that could be joined in the lawsuit. There is little a manufacturer can do in relation to the other, non-related entities that are often joined. However, it is important to have US counsel knowledgeable and experienced in removal and fraudulent joinder issues.

Advertising and mass case collection

Claimants' counsel attempt to create pressure on manufacturers in product liability litigation by collecting a large number of potential cases (often through internet advertising). These cases inevitably include a few potential high exposure cases and numerous cases of little or no value. Strategically, claimants' counsel leverage their high value cases to boost the value of their low (or no) damage cases.

How claimants' counsel collect cases. The internet has revolutionised lawyers' ability to solicit potential claimants. A simple search on the internet for any one of the major products currently the subject of litigation returns numerous websites hosted by claimants' counsel. These websites provide a method for a "free case review" and an avenue for that counsel, regardless of location, to collect cases. Television, radio and billboard advertisements are still also regularly used.

Impact on foreign manufacturers. The ability of claimants' counsel to advertise and solicit cases not only allows for the easy collection of cases, but can also influence public opinion. Any consumer who searches the internet regarding a targeted product is inundated with biased information generated by claimants' counsel.

Potential countermeasures. There is little a manufacturer can do to avoid the advertising onslaught. Having a publicly available website to provide accurate information can help provide consumers with a more balanced presentation of the facts. A manufacturer can also purchase potential website addresses before claimants' counsel has an opportunity to do so. Finally, simply knowing the technique claimants' counsel will employ helps a manufacturer appreciate the weaknesses and pressure-points that claimants' counsel likewise face.

MDL

MDL is a vehicle to consolidate cases in federal courts for co-ordinated pre-trial discovery, therefore avoiding conflicting schedules in multiple cases and duplication of discovery. Claimants can attempt to put pressure on a manufacturer by initiating an MDL proceeding, but an MDL can also be very helpful for the defendant. Under relevant legislation, litigation pending in multiple federal districts can be transferred to one district court for consolidated pre-trial proceedings (*28 USC. § 1407*). The decision to transfer cases to an MDL is made by the Judicial Panel on Multi-district Litigation (JPML), a panel of seven federal judges appointed by the Chief Justice of the Supreme Court. Once consolidated and co-ordinated pre-trial proceedings have been completed, individual cases are sent back to the district court from which it was transferred for trial. However, MDL courts often encourage both sides to agree to bellwether trials before the MDL judge as a way to establish values and encourage resolution.

Advantages. An MDL provides potential benefits for product liability defendants. Specifically, it allows a defendant to streamline discovery. For example, instead of responding to many requests for production of documents, in an MDL, a defendant produces documents once to a central depository. In addition, it allows depositions of company witnesses and experts to be taken only once, saving resources.

Importantly, an MDL provides defendants with consistency on legal rulings. When large numbers of cases relating to the same product are pending in various federal districts, a defendant will face inconsistent and contradictory pre-trial rulings. With an MDL, pre-trial rulings affecting all cases are made by one judge with comprehensive knowledge of both the history of the litigation and the relevant facts.

Disadvantages. While an MDL allows corporate and expert depositions to be taken only once, if those depositions go poorly, defendants are stuck with that result in all of the MDL cases (and in the state court cases). Additionally, while the MDL judge will provide consistent rulings, those rulings may go against the manufacturer. This could be more damaging than rulings that cut both ways across a number of jurisdictions. Finally, claimants tend to file large numbers of their less serious injury cases in the MDL while pursuing parallel litigation in state courts for more seriously injured claimants who used the same product. They try to use the large number of cases in the MDL as leverage to settle all their cases, including those with claimants who may not have suffered any injury.

Impact on foreign manufacturers. For a foreign manufacturer, it is desirable to obtain consistent rulings regarding complicated issues involving discovery. Additionally, in an MDL, a foreign manufacturer is more likely to get a judge who is experienced in legal issues unique to foreign defendants.

LITIGATION ISSUES SPECIFIC TO FOREIGN MANUFACTURERS

Product liability law has an enormous effect on foreign product manufacturers who sell products in the US. Product liability claims raise issues unique to foreign manufacturers, including personal jurisdiction, service of process, discovery and enforcement of judgments.

Personal jurisdiction

Under current law, a foreign manufacturer could be sued in any state where its products are distributed and therefore subjected to the product liability laws of that state. The elements of personal jurisdiction must, therefore, be understood.

The Due Process Clause of the 14th Amendment to the US Constitution places boundaries on a court's ability to exercise jurisdiction over foreign defendants. While many states have adopted a "long-arm statute" governing personal jurisdiction for their own courts, in no case may the exercise of jurisdiction violate due process. The Supreme Court has developed a two-part test to determine if the requirements of due process are met:

- The defendant must have sufficient contacts with the forum (minimum contacts requirement).
- The exercise of personal jurisdiction must be reasonable.

Minimum contacts. To satisfy the minimum contacts requirement, the defendant must have "purposefully availed itself of the privilege of conducting activities within the forum state, thus invoking the benefits and protections of its laws" (*Hanson v Denckla, 357 US 235, 253 (1958) (citing International Shoe Co. v State of Washington, 326 US 310 (1945)*).

Whether a defendant purposefully availed itself of the forum state depends on the facts of each case. First, minimum contacts must be based on the defendant's acts, not on the unilateral conduct of a consumer (*World-Wide Volkswagen Corp., 444 US 286, 298 (1980)*). Second, in the context of a product liability case, the court will look to see if the defendant specifically intended to serve the forum market (*World-Wide Volkswagen Corp., 444 US at 297*). Relevant facts include whether the defendant:

- Designed a product specifically for the forum market.
- Advertised in the forum.
- Established direct lines of communication with customers in the forum.

- Marketed the product through a sales agent located in the forum.
- Expected consumers in the forum to buy products placed in the stream of commerce (*Asahi Metal Indus. Co., Ltd. v Super Ct. of California, 480 US 102, 112 (1987)*).

Simply placing a product in the stream of commerce alone is not likely to be enough to establish personal jurisdiction.

When a defendant's contacts with the forum are not systematic and continuous, the contacts must be related to the claim at issue. However, when a defendant's contacts with the forum are systematic and continuous, the contacts need not relate to the claim. Systematic and continuous contacts arise when a defendant does such things as:

- Maintain an office in the forum.
- Keep company files in the forum.
- Carry on correspondence in the forum.
- Tacitly solicit business in the forum.

Reasonableness. The reasonableness test can be either a shield or a sword. When the defendant's contacts with the forum state are marginal, a heightened sense of fairness can validate personal jurisdiction. Conversely, even when contacts with the forum state are significant, an unjust burden on the defendant can nullify the exercise of jurisdiction (*Burger King Corp. v Rudzewicz, 471 US 462, 476-77 (1985)*). The court considers:

- The burden on the defendant.
- The forum state's interest in adjudicating the dispute.
- The claimant's interest in obtaining convenient and effective relief.
- The interstate judicial system's interest in obtaining the most efficient resolution of controversies.
- The shared interest of the several states in furthering fundamental substantive social policies (*World-Wide Volkswagen Corp., 444 US at 292*).

The reasonableness test is particularly important when a foreign manufacturer is involved:

> "The unique burdens placed upon one who must defend oneself in a foreign legal system should have significant weight in assessing the reasonableness of stretching the long arm of personal jurisdiction over national borders." (*Asahi Metal Indus. Co., Ltd., 480 US at 114.*)

In addition, asserting personal jurisdiction over a foreign manufacturer requires the court to consider the procedural and substantive policies of other nations whose interests are affected by the assertion of jurisdiction.

Cases involving foreign manufacturers. A review of case law reveals that courts tend to focus on two questions when examining personal jurisdiction over foreign product manufacturers:

- Was the product designed or marketed for the US market?
- Did the foreign manufacturer distribute or control distribution of the product such that it knew the product would reach the state at issue?

When a foreign product manufacturer markets a product specifically for the US and knows that, through the chain of distribution, the product will reach a particular state, the manufacturer almost certainly is subject to personal jurisdiction in that state. For example, *Tungate v Bridgestone Corp.* involved an allegedly defective automotive tyre. Despite the fact that the defendant, Bridgestone, was a Japanese corporation, the Southern District of Indiana held that "Bridgestone foresaw and intended that the model of tire would be distributed across the US to American consumers, including those in Indiana, for the benefit of Bridgestone. That intended activity is sufficient to support jurisdiction in Indiana" (*2002 WL 31741484, at *4 (S.D. Ind. 2002); see also Hein v Cuprum, S.A. DE CV., 136 F.Supp. 2d 63, 69 (N.D.N.Y. 2001)*).

Conversely, when a foreign manufacturer does not design a product for the US and does not control distribution, the courts are much less likely to exercise jurisdiction. In *Irizarry v East Longitude Trading Co., Ltd.*, an individual was injured by an allegedly defective woodworking tool. The US District Court for the Northern District of Ohio did not exercise jurisdiction, and stated that "there is no evidence in this case that [the manufacture] designed its products expressly for the US or Ohio markets...Here, there is no evidence that [the manufacturer] retained any control over how, when, or where [the US distributor] distributed the products" (*296 F.Supp.2d 862, 868 (N.D. Ohio 2003); see also Four B Corp. v Ueno Fine Chemicals Indus., Ltd., 241 F.Supp. 2d 1258 (D. Kan. 2003)*).

In November 2009, Maryland's highest court dismissed a case against an Australian corporation brought by the estates of two former Maryland port workers (*CSR, Ltd. v Taylor, No. 129, 2009 WL 3806075 (Md. Nov. 16, 2009)*). They alleged that the port workers had contracted mesothelioma from unloading raw asbestos products shipped by the corporation to its customers in other states. The court held that the corporation's use of the port as a conduit in shipping raw asbestos to non-Maryland users did not satisfy the purposeful availment test (that is, the defendant's use of the port was not sufficient to permit the Maryland courts to assert jurisdiction over the corporation).

In August 2010, the Fifth Circuit considered whether specific jurisdiction existed in Louisiana over an Italian firearm manufacturer, which itself had no contacts with the forum, under a theory of imputed contacts or alter egos (*Jackson v Tanfoglio Giuseppe, S.R.L., 615 F.3d 579, 586 (5th Cir. 2010)*). Under this theory, where two or more corporations are, in essence, the same entity, the jurisdictional contacts of one become the jurisdictional contacts of the other. In acknowledging the court's ability to assert specific jurisdiction under this theory, the *Jackson* court held that, under Louisiana state law, the defendant manufacturer was not the alter ego of another foreign corporation, which had sufficient contacts with the forum.

Service on foreign manufacturers

Service of process must be accomplished by following explicit rules when foreign manufacturers are named as defendants.

The applicability of the Hague Service Convention. The applicability of the HCCH Convention on the Service Abroad of Judicial and Extrajudicial Documents in Civil and Commercial Matters 1965 (Hague Service Convention) (*20 UST. 1361; 658 U.N.T.S. 163; T.I.A.S. No. 6638*) is particularly important. Whether the Hague Service Convention applies depends on the law of the forum state.