KLUWER LAW INTERNATIONAL

International Product Law Manual

Edited by

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AUSTIN BOSTON CHICAGO NEW YORK THE NETHERLANDS

Published by:
Kluwer Law International
PO Box 316
2400 AH Alphen aan den Rijn
The Netherlands
Website: www.kluwerlaw.com

Sold and distributed in North, Central and South America by:
Aspen Publishers, Inc.
7201 McKinney Circle
Frederick, MD 21704
United States of America
Email: customer.service@aspenpublishers.com

Sold and distributed in all other countries by:
Turpin Distribution Services Ltd.
Stratton Business Park
Pegasus Drive, Biggleswade
Bedfordshire SG18 8TQ
United Kingdom
Email: kluwerlaw@turpin-distribution.com

Printed on acid-free paper.

ISBN 978-90-411-2638-2

Printed in Great Britain.

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Chapter 16
Product Liability Litigation: United States of America – The Procedural Law

Joseph K. Hetrick, Elisa T. Wiygul & Alison V. Hawley

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1. INTRODUCTION

It is a particularly daunting task to try to summarize litigation procedures for product liability claims in the United States. This is so for several reasons. First, because of certain fundamental characteristics of the United States legal system – such as contingent fee agreements, the lack of any form of ''loser pays'' rule, juries, and the availability of punitive damages – there have been many, many more product liability suits brought, developed, and tried to verdict in the United States than in the rest of the world combined. Thus, the discussions that follow will necessarily be simplified in light of the large amount of trial and appellate law existing in the United States.

Secondly, unlike virtually every other country, the United States has two parallel sets of laws in place: federal law which is national in scope; and individual state laws which are restricted to that particular state. Thus, a product liability claim could be asserted in any one of fifty-one different court systems, but, more importantly, will be subject to both federal and state law governing its ultimate outcome. While a federal court is required to follow the substantive law of the state in which it sits, the procedural law often differs markedly between the two systems. Thus, in the sections below, commentary is based on the United States Federal Rules of Civil Procedure. Many states follow analogous rules, and where there is a significant divergence, it will be noted in the text.

Finally, disclosure requirements (or ''discovery requests'' as they are called in the United States) have expanded to the point where most product liability litigation is now driven and dominated by discovery procedures, request

disputes and ultimate compromises involving literally millions of documents. Because of this, the presentations below may appear rather simplistic to seasoned American litigators, but hopefully will be able to provide enough guidance to the "comparative lawyer" seeking an informed overview of the American system of product liability litigation.

2. HOW A CLAIM IS COMMENCED

A plaintiff (claimant) begins his suit by filing a complaint.[1,2] In the federal courts, as well as in most states, the complaint is a document with numbered paragraphs that describe, in broad strokes, the basis of the plaintiff's claim and the facts that he believes support that claim. The complaint need not spell out each factual element of the claim in exact detail.[3] The plaintiff must serve the complaint upon the defendant or defendants.[4]

The complaint is the first of multiple documents filed with the court that set forth claims and defences, called pleadings. In United States federal courts, the complaint only needs to provide enough detail to put the other side on notice that a claim is being brought and what the broad contours of that claim are. This is referred to as *notice pleading*. Specifically, the complaint must state why the court has jurisdiction over the subject matter of the suit, a short and plain statement of the claim, a showing of why the claimant is entitled to relief, and a claim for damages against the manufacturer or retailer.[5]

The plaintiff often has a choice of whether to file a claim in state court or federal court. Generally, this is a strategic choice, with plaintiffs preferring state courts, which historically have more sympathetic and generous juries due to the methods used to select potential jurors – usually "local people" from smaller communities. Even if there is subject matter jurisdiction to support a federal case,[6] plaintiffs strongly prefer a state court for the juror-related reasons just noted, as well as the fact that many state courts have much more relaxed procedures, broader discovery allowances, and more lenient interpretations of the requirements for causes of actions. Defendants would, if at all possible, prefer to be in a federal court with stricter procedural and substantive rules and more conservative juries. Federal juries are drawn from a much larger geographic area and tend to be more conservative than state court juries. As mentioned earlier, this chapter will assume that a claim has been filed in federal, not state, court. While federal courts are governed by the Federal Rules of Civil

1. A few states have additional methods by which a claimant may commence his lawsuit.
2. Federal Rule of Civil Procedure ("Fed. R. Civ. P.") 3.
3. Fed. R. Civ. P. 8, 10.
4. Fed. R. Civ. P. 4, 5.
5. Fed. R. Civ. P. 7, 8.
6. See *infra* 2.5.

Procedure, individual federal districts and judges also usually have their own local rules and policies, which need to be consulted as well.

The plaintiff must file suit in a court that has personal jurisdiction over the defendant. Personal jurisdiction encompasses the notion that it is only fair to sue a person in a jurisdiction where that person has acted or toward which that person has directed activity.[7] For larger products liability defendants with operations throughout the United States, this requirement is usually easily met virtually anywhere. For a defendant with smaller operations being sued in a state where it does not ordinarily do business, however, personal jurisdiction may become an issue. The plaintiff must also ensure that he files in a district where *venue* is proper. Venue refers to which district or districts within a state may hear a case, based on the location of the alleged injury and the location of the defendants.[8]

In addition, a federal court may hear a case only if it has subject matter jurisdiction.[9] To show subject matter jurisdiction, either the plaintiff must be raising a claim under federal law (*federal question jurisdiction*),[10] or the parties must be from different states or countries and the amount in controversy must exceed USD 75,000 (diversity jurisdiction).[11] Most often, products liability claims are based on state, not federal, law, and therefore a federal court may hear the claim only if diversity jurisdiction exists.

In any case in which there is no "federal question" raised, unless the suit is a class action,[12] *complete diversity* of citizenship must exist between all plaintiffs on one hand and all defendants on the other. If any one plaintiff is a citizen of the same state as any one defendant, then diversity jurisdiction is defeated, and a federal court may not hear the claim. A corporate defendant is considered to be a citizen of both the state of its incorporation and the state in which its principal place of business is located.[13] An LLC or partnership has the citizenship of each of its individual members.[14]

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7. In order for a court to have personal jurisdiction over a particular defendant, both federal constitutional and state statutory requirements must be satisfied. For the constitutional principles, see, e.g., the U.S. Supreme Court cases of *Asahi Metal Indus. Co. v. Superior Court*, 480 United States Reporter ("U.S.") 102 (1987); *Burger King Corp. v. Rudzewicz*, 471 U.S. 462 (1985); and *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286 (1980). Each of the 50 states has its own so-called "long-arm statute" providing for when that state's courts, and federal courts within that state, may exercise personal jurisdiction. Finally, see Fed. R. Civ. P. 12(b)(2) (authorizing dismissal of case if personal jurisdiction is lacking).
8. 28 United States Code ("U.S.C.") §§ 1391, 1404, 1406.
9. See generally Fed. R. Civ. P. 8(a)(1) (requiring complaint to include "short and plain statement of the grounds for the court's jurisdiction"), 12(b)(1) (authorizing dismissal of case if subject matter jurisdiction is lacking).
10. 28 U.S.C. § 1331.
11. 28 U.S.C. § 1332.
12. See *infra* ¶ 2.7.
13. 28 U.S.C. § 1332(c)(1).
14. See *Carden v. Arkoma Associates*, 495 U.S. 185 (1990); *Navarro Savings Ass'n v. Lee*, 446 U.S. 458 (1980); *Great Southern Fire Proof Hotel Co. v. Jones*, 177 U.S. 449 (1900).

The Class Action Fairness Act of 2005 (“CAFA”)[15] provides an exception to the general rule that diversity jurisdiction is absent if any plaintiff has the same state citizenship as any defendant. Under CAFA, subject to certain exceptions, a federal court may hear a class action if the amount in controversy exceeds USD 5 million, there are more than 100 members of the prospective class of plaintiffs, and the citizenship of any plaintiff is different from the citizenship of any defendant (*minimal diversity*).[16]

Sometimes, the plaintiff may file in state court, but, as noted earlier, the defendant would prefer that the case be heard in federal court. In that case, if the plaintiff could have brought the case in federal court, then the defendant may remove the case to the federal court that sits in the same location as the state court in which the plaintiff brought suit.[17] If the plaintiff believes the federal court does not have jurisdiction, then the plaintiff may file a motion to remand the case back to state court.[18] The federal judge, not the state judge, decides that motion. A party may file a motion to remand only if the suit was originally brought in state court. CAFA eases several of the usual requirements for removal and also makes it easier to obtain appellate review of a trial court’s decision on whether or not to remand the case to state court.

When a defendant receives a complaint, it must file either an answer or a motion to dismiss.[19] An answer is a pleading that responds, paragraph by paragraph, to the complaint, admitting or denying each of the complaint’s factual allegations.[20] The answer frames the issues to be resolved by the court at trial. The answer must address each allegation made by the plaintiff in the complaint, but can be amended later as new facts emerge during disclosure. Court permission is needed to amend an answer, but is very freely given upon a showing of new facts.[21]

A motion to dismiss is a formal request to the court to dismiss the claim because it is insufficient even if all of the plaintiff’s allegations were true, that is, the complaint fails to state any recognized or viable cause of action or the claim is time barred under the applicable statute of limitation.[22] If the defendant believes the federal court lacks personal or subject matter jurisdiction, it may also raise these arguments in a motion under Rule 12.[23] The defendant may also raise improper venue and move either to dismiss or to transfer the case to a different venue.[24] Some but not all grounds for

15. Public Law No. 109-2, 119 Stat. 4 (2005), *codified at* 28 U.S.C. §§ 1332(d), 1453, 1711–1715.
16. 28 U.S.C. § 1332(d).
17. 28 U.S.C. §§ 1441–1453; see also Fed. R. Civ. P. 81(c) (procedure after removal).
18. 28 U.S.C. § 1447(c)–(d).
19. Fed. R. Civ. P. 12; see also Fed. R. Civ. P. 7(a) (listing types of pleadings).
20. Fed. R. Civ. P. 8(b).
21. Fed. R. Civ. P. 15.
22. Fed. R. Civ. P. 12(b)(6).
23. Fed. R. Civ. P. 12(b)(1) (subject matter jurisdiction), 12(b)(2) (personal jurisdiction).
24. Fed. R. Civ. P. 12(b)(3; 28 U.S.C. §§ 1404, 1406.

dismissal are considered waived if the defendant does not raise them in its first filing with the court. Specifically, lack of personal jurisdiction, improper venue, and insufficient service of process are waived if not asserted in a motion to dismiss prior to the filing of the answer.[25] If the court grants a motion to dismiss in full, then the case is generally over, although the court sometimes gives the plaintiff permission to amend the complaint to attempt to revive the claim.

Once the defendant has been formally served with the complaint, it has twenty-one days from the date of service to answer or otherwise respond to the complaint.[26] If the plaintiff has requested a waiver of service in writing and the defendant has consented to that waiver, also in writing, then the defendant has sixty days from the date of the request (or ninety days if the defendant is outside the United States) in which to answer or otherwise respond to the complaint, rather than the usual twenty-one days from the date of proper service of the complaint.[27]

3. HOW CLAIMS ARE MANAGED

Once a claim has been filed, it is assigned to an individual judge, called a district judge. Within weeks after the plaintiff files the complaint and the defendant files the answer, the parties must hold an initial conference in an attempt to agree on a discovery (disclosure) plan.[28] Shortly thereafter, the judge holds an initial scheduling conference, known as a Rule 16 conference.[29] During the Rule 16 conference, the judge and attorneys for both sides discuss the overall scheduling of the case and other logistical matters. Following the conference, the judge issues a scheduling order, often called a case management order, designating deadlines for completing all disclosures, exchanging expert reports, and filing any motions which could end the case prior to trial, such as a Motion for Summary Judgment. The scheduling order also sometimes sets a tentative trial date.

When several claims have been filed in different federal courts concerning the same subject matter, or indeed the very same product, those claims will sometimes be assigned to one judge for all pretrial proceedings. The section on group and class action procedures describes this process, called Multi-District Litigation (“MDL”), in more depth.[30]

25. Fed. R. Civ. P. 12(h).
26. Fed. R. Civ. P. 12(a)(1)(A).
27. Fed. R. Civ. P. 4(d)(3).
28. Fed. R. Civ. P. 26(f).
29. Fed. R. Civ. P. 16.
30. See *infra* ¶¶ 5.12–5.14.

If disputes arise during discovery, either the district judge or a magistrate judge assigned to assist that district judge will resolve them. The parties ordinarily attempt to resolve disputes without involving the judge.[31]

At the end of discovery, each side has the opportunity to file dispositive motions, most often a motion for summary judgment.[32] The district judge assigned to the case hears such motions. The moving party, usually the defendant, must prove that, given all of the evidence gathered in discovery, there is no disputed issue of material fact, and no reasonable factfinder could find for the opposing party. While either party may file a motion for summary judgment, such motions by plaintiffs are very rare in the United States, as there are always some factual issues, usually in the area of proximate causation, to preclude the entry of such judgment.[33] Defence motions, on the other hand, rest on purely legal argument that even if all of plaintiffs alleged facts are true, still recovery is precluded as a matter of law. Thus, defendants' motions are more common. If the judge grants full summary judgment, then the case is dismissed. The judge may also include in that order costs and attorneys fees, but the granting of such costs and fees in this setting is extremely rare in the United States.

If the judge does not grant summary judgment, then the case goes to trial. Most civil (as opposed to criminal) claims, including all product liability claims, are tried before a jury of six to twelve members.[34] The attorneys for both sides select the jury from among a pool of citizens in the jurisdiction where the case is brought.[35] Certain types of claims are heard by a trial judge instead of a jury, but this is very rare in product liability cases.[36]

The plaintiff has the burden of proving each and every required element of his claim. He must prove each element by a *preponderance of the evidence* (more likely than not) standard.

At trial, the judge must decide which evidence to allow the parties to present to the jury. This question is called the admissibility of evidence and is governed by the Federal Rules of Evidence. Among other considerations, the judge must evaluate whether the probative value of the proposed evidence outweighs the possibility that it will cause undue prejudice to one side or the other.[37] If the judge decides that a piece of evidence or testimony is inadmissible, then the jury will not hear that evidence at all. Counsel must therefore be alert during discovery to the need to build a case based only on evidence that will be admissible at trial.

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31. For more on discovery, see *infra* § 6.
32. Fed. R. Civ. P. 56.
33. See *infra* ¶ 8.7.
34. Fed. R. Civ. P. 48.
35. See Fed. R. Civ. P. 47.
36. Fed. R. Civ. P. 38, 39.
37. Federal Rules of Evidence ("Fed. R. Evid.") 403.

In practice, suits rarely go to trial. If the judge does not dispose of them by granting a motion to dismiss or for summary judgment, then the great majority of cases settle. This is particularly true if a class is certified, since the risk to the defendant of a potential adverse verdict is magnified and, indeed, potentially catastrophic.

4. FUNDING FOR CLAIMS

In the United States, parties to a products liability lawsuit are responsible for hiring and compensating their own legal counsel. Publicly-funded legal aid is not available for such claims.

Since products liability cases can be very expensive, the plaintiffs typically reach a contingent fee arrangement with their legal counsel. A contingent fee arrangement is one in which the lawyer receives his fee only if the case is favourably resolved for his client. The attorney's fee is usually a percentage of the recovery. This percentage is usually 33%-1/3% of the recovery, though it may be upwards to 40% or even more for riskier cases.

The Rules of Professional Conduct require that the fee be reasonable in amount.[38] The fee arrangement must be in writing and signed by the client, and specifically explain how the fee is to be calculated, what expenses will be deducted from the recovery, whether these deductions will be made before or after the fee is calculated, and what expenses the client must pay.[39]

Some cases are so large and expensive that plaintiff's counsel cannot afford to advance all of the costs involved. Thus, in some of the larger cases, plaintiff attorneys have tried to create alternative means of financing the suits, such as investment or syndication arrangements. In investment agreements, attorneys invest money in the lawsuit and stand to earn a considerable return on this investment if there is a large verdict. Courts, however, have found such arrangements to violate ethical rules.[40] Syndication agreements involve selling *shares* of a lawsuit to public investors, who then have a right to a percentage of any recovery. There is considerable controversy regarding whether these arrangements are ethical, and they are very rare in any event.[41]

The defendant pays for his legal defence by employing counsel and paying an agreed upon fee, usually based on a set hourly rate. The attorney and client must make a clear fee agreement, and the fees charged must be reasonable in

38. Each state has its own rules of professional conduct, but many are similar to the American Bar Association's Model Rules of Professional Conduct.
39. See generally American Bar Association Model Rule of Professional Conduct ("Model R. Prof. Conduct") 1.5.
40. See, e.g., *Rancman v. Interim Settlement Funding Corp.*, 789 N.E.2d 217 (Ohio 2003).
41. See generally Douglas R. Richmond, *Other People's Money: The Ethics of Litigation Funding*, 56 Mercer L. Rev. 649 (2005).

light of the difficulty of the case, the skill and time required, the amount at stake, what other lawyers charge for similar work, and the experience, reputation, and ability of the attorney.[42]

5. GROUP AND CLASS ACTION PROCEDURES

This section is broken into two subsections: class actions and multi-district litigation ("MDL"). There are certain other methods for multiple claims to be aggregated or coordinated, but the two discussed here are the main mechanisms for large-scale coordination.

5.1. Class Actions

Provided certain requirements are met, plaintiffs may bring a suit on behalf of numerous other plaintiffs in a single proceeding known as a *class action.*[43] The class is the group of plaintiffs. The federal rules also provide procedural mechanisms for aggregating, or *joining*, small numbers of actively-participating plaintiffs or defendants in a single suit,[44] but such a process is fundamentally different from a class action and is limited to a truly small number of claimants.

A true class action is a proceeding in which one or more named plaintiffs sue as representatives of a large number of similarly situated claimants, whose claims are thus adjudicated all at once. The non-named parties generally do not participate in the proceeding, although they are legally bound by its result. The class action is unusual in that members of a class generally have an opportunity to opt out of the class, but if they do not, then they are bound by the result of the case even if they neither knew about nor participated in it. As a result, the court must approve any proposed settlement of class claims[45] and may exercise greater than usual oversight to ensure that the interests of the absent class members are protected. The actual members of a class are never all named, but rather are described in the initial pleadings in such a way that the judge can determine if a class is feasible and manageable, and in such a way that proposed class members can be contacted at least indirectly by means such as publication of notices.

For a suit to proceed as a class action, the court must certify the class. Class certification should occur early in the proceedings if possible.[46] The plaintiff

42. See generally Model R. Prof. Conduct 1.5.
43. Fed. R. Civ. P. 23.
44. Fed. R. Civ. P. 19–21.
45. Fed. R. Civ. P. 23(e).
46. Fed. R. Civ. P. 23(c)(1)(A).

files a motion to certify the proposed class and sometimes one or more subclasses.[47] The plaintiff bears the burden of showing that he has met all of the requirements described below.[48] The court will usually permit discovery before the motion for class certification, focused on evidence relevant to whether the class should be certified.[49]

Class certification is a hotly contested stage of litigation. As a threshold matter, a class action requires one or more named plaintiffs who are members of a definable class. Federal Rule of Civil Procedure 23, which governs class actions, sets forth four basic requirements that all class actions must satisfy: (1) numerosity; (2) commonality; (3) typicality; and (4) adequacy of representation.

The members of the putative or prospective class must be so numerous that joinder or consolidation via ordinary means is impracticable.[50] There is no specific numerical cut-off to satisfy this requirement, but some courts have used 25 as a rough figure.[51] In addition to sheer numbers, courts often consider other factors that would make joinder impracticable, such as whether the potential plaintiffs are geographically dispersed and whether the individual claims are so small that individual plaintiffs might not bring suit at all if not for the availability of a class action.[52]

The claims of the putative class members must involve common questions of law or fact.[53] Courts have disagreed about whether even a single common issue is sufficient, or whether several issues must be common to the claims of the class members.[54] The central inquiry under this requirement is whether trying the case as a class action will increase efficiency without sacrificing fairness.

The claims of the representative class member or members must be typical of those of the other class members.[55] A court may find a lack of typicality, for instance, if the proposed representative plaintiff is subject to defences to which other proposed class members are not.

Both the proposed class representatives and the proposed class counsel must be able to adequately represent the interests of the class.[56] This decision is usually based on experience in the case of counsel and based on

47. Fed. R. Civ. P. 23(c)(1), (5).
48. See, e.g., *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 320 (3d Cir. 2008); *Unger v. Amediasys Inc.*, 401 F.3d 316, 320 (5th Cir. 2005).
49. Manual For Complex Litigation § 21.133.
50. Fed. R. Civ. P. 23(a)(1).
51. See, e.g., *Talbott v. GC Servs. Ltd. P'ship*, 191 F.R.D. 99, 102 (W.D. Va. 2000).
52. See, e.g., *Anderson v. Dep't of Pub. Welfare*, 1 F. Supp. 2d 456, 461 (E.D. Pa. 1998).
53. Fed. R. Civ. P. 23(a)(2).
54. See, e.g., *In re Schering Plough Corp. ERISA Litig.*, 589 F.3d 585, 597 (3d Cir. 2009) (one common issue is sufficient); *Applewhite v. Reichhold Chemicals, Inc.*, 67 F.3d 571, 573 (5th Cir. 1995) (requiring plaintiffs to identify more than one common issue).
55. Fed. R. Civ. P. 23(a)(3).
56. Fed. R. Civ. P. 23(a)(4).

commitment in the case of the named plaintiff.[57] This is an important requirement because, as mentioned above, the legal rights of the class members will be decided by the outcome of the class action.

In addition to the above requirements, a class action must fall under one of three additional categories. The most important category for product liability litigation is the one specified in Rule 23(b)(3), in which the court must find that issues common to the putative class members *predominate* over individual issues, and the class action is the *superior* way to adjudicate the claim fairly and efficiently.[58]

Courts have disagreed about what it means for common issues to predominate. Some focus on the number of issues, while others address more holistically whether the case is mainly about the common issues. Even if it certifies the class, the court has the option of separately dealing with any common issues (for instance, liability) before having separate proceedings for individual issues (for instance, damages). Among the most important factors that a court considers in assessing superiority is whether the suit will be manageable and fair as a class action.

An order certifying a class must define the class, as well as setting out the class claims, issues, and defences, and must appoint class counsel.[59] A court may also certify subclasses, each of which must satisfy each of the requirements discussed above.[60] Additionally, a court may, in its discretion, certify for class treatment some issues in a case but not others (this process is called *bifurcation*).[61] The court also retains the power to decertify a class later,[62] but this is rare. Classes are decertified only if, during discovery, new facts come to light that prove that the original proposed and certified class can no longer meet all of the requirements for certification.

For class actions proceeding under Rule 23(b)(3), the court must order that class members be given the best practicable form of notice of the suit. This notice must spell out in plain language the nature of the suit, the right to hire one's own attorney, the right to opt out of the class altogether, and the fact that the judgment will bind the class member if he does not opt out. The court may periodically require that additional notice be sent at later points in the proceedings and must order that notice be provided before the court approves any settlement.[63]

As mentioned above, the court must approve any class settlement, whereas a court ordinarily need not approve a settlement among individual named

57. *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 625–26 (1997).
58. Fed. R. Civ. P. 23(b)(3).
59. Fed. R. Civ. P. 23(c)(1)(B).
60. Fed. R. Civ. P. 23(c)(5).
61. Fed. R. Civ. P. 23(c)(4).
62. Fed. R. Civ. P. 23(c)(1)(C).
63. Fed. R. Civ. P. 23(c)(2).

parties absent certain circumstances such as the claimant being a minor or legally incompetent. The court may give class members a second opportunity to opt out before it approves a class settlement. Class members also have the opportunity to object to a settlement.[64]

Most state courts also allow class actions, but their requirements may sometimes differ, often markedly, from those of federal courts. The conventional wisdom is that it is easier to get a class certified in state court than in federal court, as the rules, whatever they may be, are more liberally interpreted. The certified class, however, will, of necessity, be a much smaller class. Multiple state classes are not unusual.

5.2. MULTIDISTRICT LITIGATION

When suits filed in several federal courts involve one or more common facts (usually the same product), the Judicial Panel on Multidistrict Litigation (MDL Panel)[65] may transfer all of the suits to one court for all pretrial proceedings if doing so would promote convenience, fairness, and efficiency. The MDL Panel may transfer the cases on its own initiative (*sua sponte*), or any party may apply to the Panel for a transfer. The Panel must notify all parties in the relevant actions and hold a hearing about whether to transfer all the cases to a single judge. The Panel may transfer cases even if some or all of the parties object.[66]

Once the cases are transferred, the transferee judge will typically hold a scheduling conference and issue a case management order for all cases that are part of the MDL. An MDL may include a combination of class actions and individual suits. The transferee judge has the power to rule on all pretrial motions and to manage pretrial proceedings.[67] If any case in the MDL reaches the trial stage, then that case will be sent back to the court in which it was originally filed, to be tried in that court, not the MDL court.[68]

It is not possible to use an MDL to aggregate claims that are brought in the courts of different states, since the state court systems are each separate and cannot transfer cases to one another. If appropriate, however, a defendant sued in state court could remove the case to federal court and then apply for a transfer under the MDL statute or another provision. In addition, the judges or

64. Fed. R. Civ. P. 23(e).
65. See 28 U.S.C. §§ 1407, 2112 (statutes governing MDL Panel); 199 F.R.D. 425 (2001) (MDL Panel Rules). The Panel is composed of seven circuit (appeals court) and district (trial court) judges, no two of whom may be from the same circuit, appointed from time to time by the Chief Justice of the United States Supreme Court. 28 U.S.C. § 1407(d). For more on circuit and district courts in general, see *infra* ¶ 11.1.
66. 28 U.S.C. § 1407(c).
67. 28 U.S.C. § 1407(b).
68. 28 U.S.C. § 1407(a).

parties in related cases pending in state and federal court may sometimes informally or even formally coordinate the cases.

6. DISCOVERY

The scope of both required and permitted disclosure in the United States is extremely broad. In the United States, pretrial disclosure between the parties is called discovery. During pretrial discovery, a party can request or disclose not only anything actually relevant to a claim or defence, but in fact anything "reasonably calculated to lead to the discovery of admissible evidence", unless the information is privileged.[69] The information does not necessarily have to be admissible at trial, as the scope of discovery is much broader than the scope of actual admissibility under the evidentiary rules governing trial.

The *attorney-client privilege* protects from discovery all communications between an attorney and a client, unless the client waives the privilege.[70] The *work product* of an attorney prepared in anticipation of litigation, is also generally protected from discovery. Some of an attorney's investigations and notes may be discoverable if the party seeking those notes can demonstrate a substantial need for the materials and that the materials are not available elsewhere; however, an attorney's mental impressions, opinions, conclusions, legal theories, and strategies are not discoverable under any circumstances.[71]

After the Rule 26(f) conference (the initial scheduling conference with the court), the parties have both written and oral means of obtaining information. Interrogatories are written questions given to another party that must be answered in writing, under oath. After receiving the interrogatories, a party has thirty days to respond. The responses may either be answers or objections. The party may also state that he does not know the answer to the question, but only after *reasonable investigation.* A party cannot use his own answers to questions at trial, but the opposing party can. In addition, the inquiring party may not serve more than twenty-five questions or subparts to questions without court order or stipulation.[72] Courts are, however, very liberal in allowing more interrogatories, especially in complex product cases. The parties rarely complain, as they will be entitled to the same expanded discovery granted to the other party.

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69. Fed. R. Civ. P. 26(b)(1).
70. Fed. R. Evid. 501; Fed. R. Civ. P. 26(b)(5)(A), 26(c)(1), 45(d)(2)(A), 45(c)(3)(A)(iii). In diversity jurisdiction cases, the substantive law of attorney-client privilege is provided by state law.
71. Fed. R. Civ. P. 26(b)(3); *Hickman v. Taylor*, 329 U.S. 495 (1947). The substantive law of the work product protection is provided by federal law, even in diversity jurisdiction cases.
72. Fed. R. Civ. P. 33.

Requests to produce documents may be served on a party or a nonparty. The requesting party typically seeks copies of numerous documents, including information stored electronically.[73]

Additionally a party may also request entry upon property for inspection or physical measuring of the property itself.[74] Viewing or measuring of the property may be necessary for a proper understanding of the claims made, or, more often, for the assertion of certain defences, such as the accident could not have happened as the plaintiff claims, given the size of the machinery involved or the size of the room in which the accident occurred. A party can oppose such a request, and the same criteria apply to that objection as to any other objection to a discovery request.

In a deposition, which is typically oral, a person gives sworn testimony in response to questions by counsel. This testimony is recorded and made into a written transcript.[75] It is possible to depose both parties and nonparty witnesses. If the party does not know the name of the specific witness he needs to depose, a party may name an organization as the deponent. The organization must then designate an individual with the type of knowledge the opposing party seeks to testify on behalf of the organization.[76]

In some cases, a party may request a *physical or mental examination* of another party by an appropriate expert. This requires a court order, and is only permitted when the examined party's health is in controversy and there is good cause shown for the examination.[77]

Finally, in a procedure called a *request for admission*, a party asks another party to admit the truth of a particular fact.[78] Litigants commonly use this tool to authenticate documents and to establish truly undisputed facts for use at the trial, as well as to set up issues for dispositive motions.

Parties have a duty to supplement their responses to all discovery requests if they learn that a prior response was incomplete or incorrect.[79]

While most discovery involves the parties requesting information from each other, some disclosures are required by the court rules themselves.

For example, within fourteen days of the initial Rule 26(f) conference, the parties must disclose to each other the identity of persons and documents likely to have discoverable information that the disclosing party may use to support his claims or defences or support his computation of damages. Additionally, the parties must disclose the existence of insurance for any of

73. Fed. R. Civ. P. 34(a)(1), 34(b).
74. Fed. R. Civ. P. 34(a)(2), 34(b).
75. Fed. R. Civ. P. 30.
76. Fed. R. Civ. P. 30(b)(6).
77. Fed. R. Civ. P. 35.
78. Fed. R. Civ. P. 36.
79. Fed. R. Civ. P. 26(e).

the judgment which might ultimately be entitled.[80] Discovery is ideally managed between the parties, with court involvement available only in the case of a true dispute. Thus, these required disclosures are only required insofar as the parties require them of each other. Particularly in extremely large cases, such as mass tort cases, it is possible that these early required disclosures are superseded by an agreed upon or court-ordered case management order.

In addition, the parties must identify experts who may be used at trial and must provide the expert's written report containing his opinions, data, qualifications, compensation, etc.[81] Lastly, thirty days before trial, the parties must provide information about all evidence to be proffered at trial, all documents to be used, and all witnesses who will testify.[82] The opposing party may challenge the admissibility of the evidence or the competence of the witnesses before the trial begins.[83] The court cannot order the use of experts, either by a single party or jointly, or even by the court itself. The court can and will, however, determine whether the parties' proposed expert witnesses are competent and able to testify, as well as the scope of the expert testimony that will be received.[84]

7. STATUTES OF LIMITATIONS

Various laws in the United States impose a limit on the amount of time a plaintiff has to bring a product liability suit after the harm occurs. A law creating these limits is called a statute of limitations.[85] Typically the statute of limitations for tort cases, at least those based on negligence or strict liability, is two years. Actions brought under the Uniform Commercial Code, which governs contracts for the sale of goods, have a statute of limitations of four years.[86] The statute of limitations is typically six years for actions brought under common law contract theories, such as breach of express or implied warranties for the product. The statute of limitations is *tolled*, meaning the time does not run, while class action certification is pending.[87] The tolling does not depend on the type of product involved, only on the existence of a certified or pending class.

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80. Fed. R. Civ. P. 26(a)(1).
81. Fed. R. Civ. P. 26(a)(2).
82. Fed. R. Civ. P. 26(a)(3).
83. Fed. R. Civ. P. 26(a)(3)(B).
84. See *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993); *Kumho Tire Co. v. Carmichael*, U.S. 137 (1999): 137; Fed. R. Evid. 702–706.
85. Each jurisdiction has its own statute of limitations. For statutes of limitations for product liability cases, see generally Morton Daller, *Product Liability Desk Reference: A Fifty-State Compendium* (2006).
86. U.C.C. § 2–725.
87. *Am. Pipe & Constr. Co.*, 414 U.S. 538, 550–51 (1974).

Sometimes statutes provide a *discovery rule* modification to the statute of limitations, which is particularly relevant in *toxic tort cases*, including chemical exposure, as well as cases in the drug and medical device fields.[88] When there is a discovery rule, the statute of limitations begins to run only when the plaintiff discovers or should have discovered the harm, rather than when the harm actually occurred.

Statutes of repose are an additional limitation on product liability suits. Under a statute of repose, all product liability claims are put to rest, even if the harm is still undiscovered, usually about 10–12 years from the date the product was sold.[89]

8. STANDARD MINIMUM REQUIREMENTS

There are several different possible claims or theories of recovery in product liability suits, including negligence, tortious misrepresentation, breach of warranty, and strict liability. Regardless of which theory of liability a plaintiff uses, they all have some common issues in the products liability context.[90]

In general, manufacturers may be *strictly liable* for harm caused by their defective products, even if they were not negligent.[91] The plaintiff generally must prove only that the defendant sold the defective product, that the defect was present at the time of the sale, and that the defect proximately caused harm.[92] Defects include errors in manufacturing, defects in design, lack of adequate warning or instruction, and failure of the product to conform to a representation made by the manufacturer or seller.[93] The product must be defective at the time of sale, and remain so through the time of use.[94]

To show that a product is defective, the plaintiff must show that there is some risk associated with the product that consumers would not expect or that the manufacturer can avoid without excessive cost and effort.[95] There are limits, however, on the dangers that render a product defective and give rise to liability. Open and obvious risks are one exception.[96] Things that people generally know are dangerous and that must be dangerous to be

88. See, e.g., 42 Pa. Cons. Stat. Ann. § 5524(2); *Debiec v. Cabot Corp.*, 352 F.3d 117 (3d Cir. 2003).
89. See *Prosser & Keeton on Torts* § 30 (5th edn 1984). See generally Daller, *supra* n. 85.
90. For a more detailed discussion of possible theories of recovery and available defences, please refer to the *CCH Products Liability Reporter*; Marshall Shapo, *CCH Law of Product Liability*; and Lewis Bass, *Product Liability, Design and Manufacturing Defects* (West 2001).
91. Restatement (Third) of Torts: Products Liability § 1 cmt. a (1997).
92. *Ibid.*, §§ 2, 15.
93. *Ibid.*
94. *Ibid.*
95. *Ibid.*, § 2 cmt. d.
96. *Ibid.* § 2 cmt. l.

functional, such as sharp knives, are not defective simply because they are dangerous.[97] In addition, there is an exception for *state of the art* products.[98] These are products that, based on current scientific or technical knowledge, are designed to eliminate all known foreseeable risks. Since, based on all current knowledge, the risks of these products cannot be foreseen, there will not be liability if a danger is later discovered.

There is also usually some requirement that the product be used in a foreseeable manner.[99] The manufacturer may be liable if the plaintiff used the product improperly, or not for its intended purpose, if it should have been foreseeable that the product would be used, that is, misused, in that way.[100] If a plaintiff, however, uses a product in some way that is, completely unforeseeable, there will usually not be liability for harm caused.

When the plaintiff brings a products liability suit under a negligence theory, he must prove that the manufacturer or seller had a duty to do something that he did not do, and that the fact that he did not perform this duty caused the plaintiff's injury.[101] Manufacturers and sellers have a duty to exercise *reasonable care* not to sell products that bear an unreasonable risk of harm. They do not have to exercise perfect care; instead, the analysis focuses only on foreseeable risks and foreseeable plaintiffs. Moreover, they do not always have to go to all possible lengths to eliminate all possible risks. The standard requires reasonableness, and reasonableness involves balancing costs and benefits. Reasonableness is the touchstone of any case based on negligence.

In all cases, the plaintiff must also prove causation. Causation involves two components: cause-in-fact or *general causation*, and proximate or *specific causation.* General causation requires that the plaintiff show a link between the harm and the defect, such that "but for" the defect, the harm would not have happened.[102] This also requires the plaintiff to show that the defendant manufactured or distributed the actual product that caused the harm.

Proximate causation (sometimes called "specific causation") requires that the plaintiff show a close connection between the defect and the actual harm suffered by the plaintiff.[103] This analysis involves whether the plaintiff was a foreseeable victim, whether the harm was foreseeable, and whether there were intervening or superseding causes.[104] Thus, it is not enough that the defendant started some long chain of events that ultimately resulted in harm to the

97. *Ibid.*, § 2 cmt. d.
98. *Ibid.*
99. *Ibid.*, § 2 cmt. m.
100. *Ibid.*, § 2 cmt. p.
101. See *Prosser & Keeton on Torts* § 96.
102. See *ibid.*, § 41.
103. See *ibid.*, § 42.
104. See *ibid.*, §§ 42–45.

plaintiff. The defective product and the harm must be close in the causal chain to give rise to liability. Lastly, plaintiffs in all products liability cases must show that they suffered actual damage.[105] This harm may be physical injury or disfigurement, death, property damage, emotional distress, lost consortium, that is, the loss of spousal or parental services and support, or economic loss.[106] If the plaintiff is successful in the case, he can recover compensatory damages to compensate for the harm suffered. In addition to compensatory damages that compensate for physical or economic harm, all United States jurisdictions permit recovery of damages for pain and suffering. Pain and suffering damages compensate plaintiffs for their loss of ability to enjoy life as fully as they did before their injury. This type of damages is taken very seriously, and pain and suffering awards can be quite large. In negligence and strict liability cases, the plaintiff usually cannot recover for purely economic loss if there is no other accompanying physical injury or harm.[107]

The United States also allows the award of punitive damages.[108] If the fact-finder (judge or jury) decides that the defendant's conduct was ''outrageous'' and worthy of punishment, the defendant may be punished with a punitive damage award over and above all other damages for which it may be found liable. These awards can be quite large, although the United States Supreme Court has suggested that the punitive damage award should not exceed ten times the amount of all other damages awarded combined.[109] In a jury case, it is the jury that determines both the applicability and the size of the punitive awards. Examples of factual circumstances where such punitive awards are made are perhaps best exemplified by the famous Ford Pinto litigation when company employees advised Ford management that it was cheaper to settle product liability claims involving fire deaths when its Pinto automobile was involved in crashes, than it would be to redesign and change production methods of the product line.[110] Courts found this decision reprehensible and awarded large punitive damage awards. Generally, any conduct that the jury finds ''shocking'' or ''outrageous'' will support such an award and enable the plaintiff to defend that award on appeal.

A suit for misrepresentation requires that the plaintiff prove that the manufacturer or seller communicated false or misleading information about the product, and that the plaintiff suffered harm because he reasonably relied on that communication.[111] Misrepresentation suits arise as three different types of claims: fraud, negligent misrepresentation, and strict liability for

105. See *ibid.* §§ 30, 95.
106. See Restatement (Third) of Torts: Products Liability § 21.
107. David Owen, *Products Liability In a Nutshell* 40 (8th edn 2008).
108. See *Prosser & Keeton on Torts* § 2.
109. *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003).
110. *Grimshaw v. Ford Motor Co.*, 119 Cal. App. 3d 757 (1981).
111. Restatement (Third) of Torts: Products Liability § 9.

misrepresentations.[112] Fraud involves an intentional misrepresentation, whereas *negligent misrepresentation* involves a defendant's failure to exercise due care in providing information.[113] Some statutes allow for tort liability even when the manufacturer or seller innocently makes a false statement about product quality, similar to the breach of express warranty cause of action available under a contract theory.[114]

Lastly, a manufacturer or seller may be liable for breach of warranty. Breach of warranty claims are based on contract law, rather than tort law. A defendant may be liable for breach of an express warranty when he makes an affirmative assertion about the product that is, false, even though the product itself may not be defective.[115]

By law, all products sold also include an *implied warranty of merchantability.* This is an assurance that the product is suitable for the general purposes for which it is purchased.[116] Thus, if a product is not fit for ordinary purposes, the seller may be liable for breach of this warranty.

Sometimes a seller can also be liable for breach of the *implied warranty of fitness for a particular purpose.* This warranty arises when the seller has reason to know that the buyer has a specific purpose for the product and knows that the buyer is relying on the seller to select a product suitable for this need.[117] The seller may be liable if the goods are not fit for this particular purpose. These warranties may be disclaimed (and thus avoided) in certain circumstances, but the disclaimers must be clear, precise, and agreed upon in the sales contract.[118]

9. DEFENCES

In addition to arguing that the plaintiff simply did not prove his case, defendants in products liability claims may avoid liability by arguing that the plaintiff misused the product. Historically, the most basic defence was *contributory negligence*, whereby even minor plaintiff misconduct or misuse could bar the entire claim.[119] In most jurisdictions, however, this defence has changed to *comparative negligence* or comparative fault, which does not bar plaintiff's claim completely if there is misuse of the product, but will reduce plaintiff's recovery by the percentage of the negligence assigned

112. *Ibid.*, cmts. a, b.
113. Restatement (Second) of Torts §§ 310–311 (1977).
114. Restatement (Third) of Torts: Products Liability § 9 cmts. b, e; Restatement (Second) of Torts § 402B.
115. U.C.C. § 2–313.
116. U.C.C. § 2–314.
117. U.C.C. § 2–315.
118. U.C.C. § 2–316.
119. See *Prosser & Keeton on Torts* § 65.

to the plaintiff by the jury.[120] In addition, the defendant may avoid liability by arguing that the plaintiff assumed the risk of injury, by knowingly disregarding the warned about risks associated with the product.[121]

10. ATTORNEY ADVERTISING

Lawyers in the United States may advertise, subject to certain restrictions. Individual states often have laws regulating lawyer advertising, though the United States Constitution, as part of its protection of "free speech", limits the laws that states may pass in this regard.[122] In addition, the Rules of Professional Conduct, adopted in some form in every state, limit some forms of lawyer advertising as an ethical matter.[123]

Lawyer advertising is commercial speech, which is protected by the First and Fourteenth Amendments of the United States Constitution. States may adopt reasonable regulations that ensure that the advertising is not false or misleading, but they may not completely prohibit all attorney advertising. The Constitution provides even more protection for truthful, nondeceptive advertising. States may only regulate this type of advertising if the government has a substantial interest in doing so, the restriction directly and materially advances that interest, and the regulation is narrowly drawn. One permissible restriction under the Constitution is that states may prohibit in-person solicitation of clients for profit.[124]

Ethically, a lawyer may be subject to discipline for any advertising that is, false or misleading. This includes omitting material information, creating unjustified expectations, or making unsubstantiated comparisons. In addition, every advertisement must include the name and office address of a lawyer or law firm responsible for its content. While lawyers may not ethically solicit clients for profit in person (or via phone or real-time electronic contact), they may offer free initial legal service or solicit individuals with whom the lawyer has a familial, personal, or prior professional connection. Direct-mail solicitation is permitted, though solicitations must be labelled as advertising.[125]

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120. See *ibid.*, § 67.
121. See *ibid.*, § 68.
122. See generally *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977).
123. See generally Model R. Prof. Conduct 7.1–7.3.
124. For major First Amendment case law regarding attorney advertising, see *Florida Bar v. Went For It, Inc.*, 515 U.S. 618 (1995); *Peel v. Attorney Disc. Comm'n*, 496 U.S. 91 (1990); *Shapero v. Kentucky Bar Ass'n*, 486 U.S. 466 (1988); *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985); *In re R.M.J.*, 455 U.S. 191 (1982); *Ohralik v. Ohio State Bar Ass'n*, 436 U.S. 447 (1978); *Bates v. State Bar of Arizona*, 433 U.S. 350 (1977).
125. See generally Model R. Prof. Conduct 7.1–7.3.

In fact, lawyer advertising is quite common in the United States. Roadside billboards and TV and radio ads abound, and this is especially true in high stakes class action and mass tort cases where attracting a large number of plaintiffs raises the litigation stakes enormously and puts the defendant at great risk. Indeed, a plaintiff seeking representation may now search the product on-line, find counsel and sign up for a lawsuit without leaving his home computer.

11. MODES OF APPEAL

A party has the right to appeal a decision of a federal district court to a federal circuit court of appeals.[126] The United States is divided into thirteen circuit courts, twelve allocated according to geography and a thirteenth devoted to specialized subject matter. With a few exceptions, a party may appeal only a final order – that is, an order that disposes of the case. One such exception is the grant or denial of class certification, which the losing party may appeal immediately. The court of appeals has discretion over whether to hear such an appeal of a class certification decision.[127]

The circuit court sits as a panel of three judges. The court reviews the district court's factual conclusions deferentially and its legal conclusions *de novo*, or without deference. The circuit court will sometimes decide to hear the case *en banc*, which usually means all active members of the court, not just the usual three-judge panel, will hear the case.

A party unhappy with the appeals court's ruling may petition the United States Supreme Court for a Writ of Certiorari, or permission to appeal to that court.[128] The Supreme Court grants certiorari to fewer than one hundred cases per year, so the chances of obtaining Supreme Court review are very slim. Generally, a party's best chance of Supreme Court review is if the circuit courts have split on a particular difficult issue of law.

Most state courts have a similar three-tiered system of appellate courts, but appeal usually exists as of right at all levels of appeal. A party may appeal a decision of the highest state court to the United States Supreme Court if the appeal concerns a question of federal, not state, law.[129]

12. LITIGATION STRATEGIES

A party's litigation strategy in a product liability case in the United States depends on whether that party ultimately intends to settle the case or take it

126. 28 U.S.C. § 1291.
127. Fed. R. Civ. P. 23(f).
128. 28 U.S.C. § 1254.
129. 28 U.S.C. § 1257.

to trial. Cases involving only a small number of incidents, where the harm is unlikely to repeat, are more likely to settle. However, in cases involving thousands or millions of plaintiffs, such as pharmaceutical or medical device liability cases, the initial cases are more likely to proceed to trial. This is because it is necessary for the parties to establish settlement values, based on the different types and severity of injuries, who is liable, causation, and damages. These issues are explored through a trial or series of "bellwether" trials, and the results of the trials are then used for later settlement negotiations. Because there are so many plaintiffs in these cases, the cases cannot possibly all proceed to trial, but most plaintiffs will reach a settlement with the defendant following the initial round of bellwether trials.

Each party conducts the early parts of the case, particularly the discovery process, with this goal of settlement or trial in mind. The early pleading phases involving the initial complaint and answer help to create the basic framework for the case, and the early motions further define the issues.

Plaintiffs most commonly prefer to bring cases based on a strict liability theory, rather than negligence, because it is easier to prove. Under a strict liability theory, the plaintiff must establish only a defect and causation, not that the defendant engaged in any carelessness or wrongdoing. However, since negligence theories involve an inquiry into the defendant's conduct, cases based on negligence have more latitude during the discovery process to look into the defendant's alleged wrongdoing. A plaintiff may therefore want to make such a claim because it sets the stage for obtaining evidence that may bear on punitive damages.

The first round of discovery is typically written. This involves written interrogatories and document requests.[130] The plaintiff begins this process and usually makes very broad and burdensome requests. This is usually an intentional tactic to get the defendant's attention. Particularly with the advent of electronic discovery, defendants store and must potentially produce an incredible amount of information. A defendant is required by law to preserve and maintain all discoverable documents once it is notified that a suit has been initiated.[131]

The plaintiff's focus at this early point in discovery is to determine simply how much information he must handle, how the information is kept, how the company operates, and who has information about the product. The plaintiff tries to get basic information and starts to think about whom he may want

130. See *supra* 6.3, 6.4.

131. See Fed. R. Civ. P. 16(b)(3)(A)(iii), 26(b)(2)(B)-(C), 26(f)(3)(C), 34, 37(f), 45(a)(1)(C), 45(d). For more on electronic discovery obligations and potential sanctions for noncompliance see, e.g., *Pension Comm. of Univ. of Montreal Pension Plan v. Banc of Am. Sec., LLC*, 685 F. Supp. 2d 456 (S.D.N.Y. 2010); *Zubulake v. UBS Warburg LLC*, 229 F.R.D. 422 (S.D.N.Y. 2004) (*Zubulake V*); *Zubulake v. UBS Warburg LLC*, 217 F.R.D. 309 (S.D.N.Y. 2003) (*Zubulake I*).

to depose. He may even go ahead and depose key people if he already has a theory of what went wrong and how. The purpose of this first round is simply to get information and begin determining where to focus future discovery.

The second round of discovery is the longest and most expensive for the plaintiff. The goal of this stage is to gather information from which hired experts can later form opinions. Oral depositions,[132] often lasting several days for a single witness, are the main means of discovery used in this stage. The extreme time and expense of producing documents and individuals to depose is an advantage for the plaintiff. The plaintiff can investigate anyone and anything in the company that may have information, which is an incredible burden and disruption to the defendant. In contrast, because of the nature of the parties' relative positions in the litigation, the defence can merely depose health care providers and fact witnesses in an attempt to create an alternative causation theory. The defence will depose employers, friends, and family of the plaintiffs to find out if they are truly as injured as they allege, as well as what other risk factors they may have for the alleged injury, other than the product at issue.

After the plaintiffs further refine what they are looking for in the second round of discovery, they begin a third round that involves using experts to give professional opinions based on the information gathered. The plaintiffs and defendant use the documents, medical records, and depositions that they have and find experts in various fields to interpret the data. They ask the experts what the information means, and the experts educate the legal team. In a medical case, the various experts usually include an epidemiologist and a biostatistician, though experts used at this stage will not necessarily testify at trial. Instead, the experts serve as consultants, who help the parties further refine their theories.[133]

In the last stage of discovery, the parties prepare for trial. They must make strategic decisions about which experts and fact witnesses should testify. This is based not only on the experts' credentials in his or her field, but on the experts' ability to be interesting, articulate, engaging, and likeable. Since these cases are tried to juries of laypeople, the parties do not want to present too much detail that will confuse or bore the jury. Instead, it is important that the experts be able to explain complicated processes in simple terms, engage the jury and win its confidence and trust. At the same time, however, the parties must consider their appeal of the case, which will inevitably follow the trial. To have a basis for appeal, there must be a certain level of detail in the record. Balancing these competing concerns is one of the major challenges of preparing for trial.

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132. See *supra* 6.6.
133. For more on considerations related to experts, see *infra* § 13.

13. USE OF EXPERTS

All parties may present expert testimony at trial; in addition, the court may also appoint an expert,[134] although this is extremely rare. The definition of an expert is very broad under the federal rules, encompassing anyone whose specialized knowledge would help the jury to understand the case or any fact at issue.[135] A party is entitled to take the deposition of any expert whose testimony an opposing party wishes to present at trial.[136] In contrast, parties ordinarily cannot discover even the identity of an opposing party's expert who will *not* be testifying at trial.[137] The rules place no limit on the number of experts a party may use, but the expert's report and testimony must conform to certain procedural and substantive requirements.[138] Duplicative testimony, however, will almost always be prohibited by the trial judge.[139]

Procedurally, a party must disclose the identity of experts whom it expects to testify at trial. A written report must accompany the disclosure, stating the expert's opinions, the data on which he relied, any exhibits he intends to use, his qualifications, a list of other cases in which he has testified, and whether and how much he was compensated for the study and testimony. The court may set a particular date by which expert reports are due. In the absence of any court order, expert reports are due at least ninety days before trial, or in the case of rebuttal testimony, thirty days after the other party's expert disclosure.[140]

Substantively, the rules that govern what expert testimony is admissible at trial are relatively liberal. Under the Federal Rules of Evidence and United States Supreme Court case law interpreting those rules, an expert may testify if his testimony is relevant, is based on reliable scientific procedure, and could help the finder of fact (usually the jury) to understand the evidence or decide an issue of fact. The district court judge is empowered to inquire into a proposed witness's qualifications as an expert, as well as whether his study is sufficiently reliable to be presented to the jury. The Supreme Court has rejected the argument that an expert's methodology must have ''general acceptance'' within the scientific community in order to be admissible.[141]

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134. Fed. R. Evid. 706.
135. Fed. R. Evid. 702.
136. Fed. R. Civ. P. 26(b)(4)(A).
137. Fed. R. Civ. P. 26(b)(4)(B).
138. See *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993); *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999); Fed. R. Evid. 702–706; Fed. R. Civ. P. 26(a)(2); Fed. R. Civ. P. 26(b)(4).
139. See Fed. R. Evid. 403 (''Although relevant, evidence may be excluded if its probative value is substantially outweighed ... by considerations of undue delay, waste of time, or needless presentation of cumulative evidence.'').
140. Fed. R. Civ. P. 26(a)(2).
141. See *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993); *Kumho Tire Co. v. Carmichael*, U.S. 137 (1999); Fed. R. Evid. 702–703.

If experts in a field routinely rely on a particular type of evidence, the expert may rely on such evidence even if the evidence itself would not be admissible at trial and even if the expert did not learn of the evidence through first-hand experience.[142]

14. JUDGMENT

After hearing the testimony of the expert and fact witnesses, and after instruction by the trial judge on the law, the jury decides who, if anyone, is responsible for the plaintiff's alleged injury. The jury may answer written questions submitted to it by the judge, or just enter a general finding of liability.[143] In either case, the suit ends with the jury's verdict, which is converted by the judge into a judgement against one of the parties.

15. A CASE STUDY INVOLVING A PHARMACEUTICAL PRODUCT

Equal Pharmaceutical Company (''Equal'') has been working for the past decade to develop a drug to help control high blood sugar levels in diabetics. The purpose of the drug was to maintain good sugar control and avoid side effects associated with existing blood sugar control drugs such as weight gain and other adverse events.

Following the completion of all required clinical trials, which showed its drug to be effective at lowering and maintaining blood sugar levels in diabetics, and the submission to and consideration by the relevant regulatory authorities, Equal was granted approval to market its drug, which it now called ''Panacrea'', for the single indication of managing blood sugar levels in diabetics.

The drug was very successful, with more than five million prescriptions written in 2005, the first year of approval. Equal, in an attempt to find and document further approved applications for Panacrea, ran a year-long clinical trial versus placebo to determine if stronger efficacy claims or different safety claims could be made for Panacrea. Unfortunately, while the sugar control results were excellent in this post-marketing clinical trial, the data showed a significant increase in the rate of dementia among patients in the Panacrea arm of the study.

The results of the study were published, and picked up by virtually all national newspapers. Almost immediately following the press reports, the

142. Fed. R. Evid. 703.
143. Fed. R. Civ. P. 49.

plaintiffs law firm of Fleasum and Howe began running both print and television advertisements throughout the country, as well as a ''user-friendly'' website seeking patients who had taken Panacrea and seemed to be experiencing some symptoms of dementia. The advertising campaign was a great success, and within three months, the Fleasum firm had over 5,000 plaintiffs who had filed suit. Each of these individuals entered into a contingent fee agreement with the Fleasum firm, under the terms of which 40% of any recovery was to be paid to plaintiff's counsel from the gross settlement or judgment amount, and before the deduction of any court fees, discovery and expert fees.

Complaints were filed in federal court in various jurisdictions, with some cases being proposed class actions and consolidated into a multidistrict litigation. The complaints alleged that Equal was liable to the plaintiffs under theories of strict liability, negligence, breach of warranty, and various state consumer fraud statutes. The complaints were answered in due course, and preliminary motions to dismiss based on the lack of reliable or established scientific proof to support plaintiffs' claims were denied. Class certification was denied because of the inherently individual nature of the medical claims (different medical histories, different product usage, etc.). Then, following an initial scheduling conference with the MDL court, the litigation began in earnest.

The plaintiffs served written interrogatories on Equal seeking the identity of all individuals within the company who had any part in the initial development, clinical trials, marketing and pharmacovigilance concerning Panacrea. The plaintiffs also served broad document requests seeking, essentially, every piece of data, internal correspondence, emails, databases and any other form of documentation, electronic or otherwise, that concerned the creation, development, approval, sales or marketing of Panacrea. The plaintiffs also requested the depositions of various corporate executives, particularly those who headed up the divisions of Equal that had oversight responsibility for the development and testing of the drug. The purpose of this initial discovery by the plaintiffs was not only to identify all relevant company personnel who may have knowledge concerning Panacrea and its potential side effects, but also to gain access to all pre-approval clinical trial data, to see if re-examination of that data by plaintiffs' consulting experts – pharmacologists, toxicologists, epidemiologists, and endocrinologists – could find any earlier indication of dementia as a potential side effect of Panacrea. More than 50 million pages of documents were produced by Equal in response to these discovery requests.

On the defence side, the defendants began the process of collecting all medical records for the plaintiffs, and began to schedule the depositions of the plaintiffs themselves, in order to identify with particularity their health history, family health histories, education, employment and any other factual material that may help in establishing alternate causation for the claimed

dementia. The fact that dementia was the alleged injury made these oral depositions particularly challenging.

Once this initial discovery was completed, plaintiffs were prepared to begin discovery in earnest. More refined interrogatories and document requests were served, based on information found through the initial discovery. Even more importantly, based on their review of all the documents produced, the plaintiffs scheduled approximately thirty depositions of company personnel, particularly scientific and medical personnel, as well as the heads of the sales and marketing departments. These depositions were very detailed, tended to last two to three full days each, and were geared toward establishing either that Equal knew of a potential for the development of dementia in patients taking Panacrea, or that they should have known it based on several new post hoc analyses of various clinical trial subgroups that plaintiffs' experts had performed. The Fleasum firm became much more aggressive in trying to establish that the company knew of the possibility of this side effect and either destroyed or failed to publish data that indicated the possibility of this side effect, and that certainly the company ''hid'' this data from the regulatory authorities. This, of course, was all geared toward establishing a foundation for punitive damages in the actual jury trials. Plaintiffs paid particular attention to the clinical trials themselves, focusing on how participants were selected, how and where the trials were actually conducted, what physical signs and symptoms were monitored, and how the statistical analysis was conducted on all resulting data. Emphasis was also placed on the publication and reporting of all aspects of the data, including informal follow-up studies that Equal conducted after the closing date of the actual clinical trials.

The defendants meanwhile had retained their own experts, particularly in the fields of psychiatry and endocrinology. These experts began detailed analyses of individual plaintiffs' claims, opining that the dementia that plaintiffs experienced (if any) was easily explained by genetic factors and past medical history, and had nothing whatsoever to do with a plaintiff's ingestion of Panacrea. The defence experts were particularly strong in their opinions that there was no plausible biologic mechanism by which Panacrea and its effects on blood sugar levels could possibly affect higher level mental faculties resulting in dementia-like symptoms. No such association had ever been reported in a single piece of peer reviewed medical literature. The defence also employed biostatisticians and epidemiologists who carefully studied the post-marketing trial that showed the increased risk of dementia. Each of these experts concluded that the results, although statistically significant, were probably due to some combination of chance and other factors that were unknown at the present time. In particular, the scientists argued that follow-up trials would be needed to establish whether the original indication of increased risk had any meaning at all.

With the close of all discovery, trial preparation began. The plaintiffs produced final expert reports in a wide range of subject areas. These included reports from toxicologists and pharmacologists whose opinions were that given the chemical nature of the Panacrea molecule and its poorly understood mechanism of action, certain side effects, such as dementia, were likely to be seen, and that Equal was negligent in not pursuing more detailed studies on the mechanism of action prior to regulatory approval. The plaintiffs also produced reports from diabetologists, endocrinologists, and psychiatrists saying that, while the exact mechanism of causation between Panacrea and dementia remained unknown at this early time, the clinical trial data clearly showed the risk and proved that the risk was real, and that the drug was defective and dangerous in that it caused this serious side effect. The plaintiffs also produced a regulatory expert who claimed that Equal was not completely truthful and forthcoming in the data it shared with the regulatory authorities, that it should have been more diligent in its preapproval trials, and that the form in which it presented the data to the regulatory authority was, at a minimum, misleading and extremely difficult to understand. Finally, the plaintiffs produced economic experts who were prepared to testify about the economic costs of dementia as it related to each plaintiff – lost wages, medical treatments, assisted living necessities, and the like. These experts also detailed the difficulties of living with dementia and the emotional and psychological burdens the disease placed on the patient and patient's entire family. The defendants had the right to, and indeed did, take the oral deposition of each of the plaintiffs' experts in order to establish a basis for challenging their expertise and their ability to testify at trial.

At the same time, the defendants produced their own expert reports which included reports from physicians saying that the connection between Panacrea and dementia simply made no biologic sense, that there was no plausible causation mechanism to be found, and that the clinical trial results were simply some sort of statistical anomaly, probably due to the choice of study subjects. This latter point was bolstered by expert testimony from epidemiologists and biostatisticians, who had various explanations of why the statistically significant results may have occurred even in the absence of any actual causal connection between Panacrea and dementia. The defendants did not produce any economic expert reports, choosing to rely on cross-examination of the plaintiffs' expert to challenge the claimed damage figures.

Finally, in support of the consumer fraud claims, plaintiffs produced marketing experts who claimed that Equal ''over promoted'' Panacrea, made false and misleading statements regarding its true level of efficacy, and thus induced many doctors and patients to use the drug when other, cheaper alternatives were available. These experts claimed that the higher price of Panacrea was unjustified given that it had equal efficacy to other, generic blood sugar control drugs, and a much worse side effect profile.

As trial neared, each side filed motions challenging the qualifications and the testimony of the other side's experts. Live hearings were conducted by the judge, who decided that while the experts may have opinions which are not ''generally accepted in the scientific community'', they did have some valid bases for their conclusions, and that the question of whether they should in fact be believed was a question for the jury. In short, all of the experts were allowed to testify.

At trial, the plaintiffs' case consisted almost completely of expert testimony on the issues discussed above. The shortcomings in the preapproval trials was stressed, and the company was characterized as sloppy at best, and dishonest at worst in its development and marketing of the drug. The company put ''profits over patient safety'', cut regulatory corners and was only interested in making as much money as quickly as possible, even at the expense of patient health. This was the theme of the plaintiffs' case. Additionally, each plaintiff testified about how her life had been ruined by the onset of dementia, testimony that was backed up by several other family members.

Equal put its experts on to testify that there was absolutely no demonstrable biologically plausible connection between Panacrea and dementia. Other experts testified about the meaning of the trial results, but the key testimony was that introduced from the plaintiffs' treating physicians, as well as defence experts, concerning the plaintiffs' medical conditions prior to ever taking Panacrea. In particular, the defendants stressed that each plaintiff had multiple risk factors for the development of dementia independent of Panacrea, that each plaintiff was already beginning to display signs of mental deterioration prior to the use of the drug, and, in short, that the drug had nothing to do with the plaintiff's diminished mental capacity.

After three full weeks of trial testimony, the judge instructed the jurors on the law of strict liability, negligence, and consumer fraud (plaintiffs having dropped their breach of warranty claim). As of this writing, the jury is still deliberating over liability and damages.

16. FURTHER SUGGESTED READING

The Federal Rules of Civil Procedure. (United States version).

Product Liability (2nd edn). Noel Phillips, West Publications.
Mass Tort Litigation. Linda Mullenix, West Publications.
Class Action Dilemmas, Hensler, et al. Rand Institution for Civil Justice.
CCH Product Liability Reporter. West Publications.
CCH Law of Product Liability. M. Shapo.
Liability, Design and Manufacturing Defects. L. Bass (West 2001).