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Mass Tort Without Borders

By Peter Pliszka, Michal Imbroscio and Alexandre Einsfeld

Overview of Law & Process in Three Non-U.S. Jurisdictions

"This article will provide an overview of more salient aspects of the legal regimes in those three jurisdictions that are relevant to mass tort litigation against drug and medical device companies (and beyond)."

Mass tort litigation originated in the United States, and it has become a fact of life for companies that design and manufacture drugs and medical devices. However, its geographic scope is not restricted to the United States; it has transcended national borders and has become a global litigation phenomenon.

Nowadays, when an alleged defect arises in a medical product that is sold in multiple countries, the manufacturer likely will face lawsuits in multiple jurisdictions around the world. In-house counsel, who is responsible for managing this widespread morass of claims, needs to retain outside litigation counsel in each of the jurisdictions where claims have been filed. The wide variation of legal procedures, substantive laws and timelines across the jurisdictions presents complex challenges for the client.

Three of the more common jurisdictions outside of the U.S. where these types of "copycat" claims against drug and medical device companies are often pursued are Canada, the European Union and Brazil. This article will provide an overview of more salient aspects of the legal regimes in those three jurisdictions that are relevant to mass tort litigation against drug and medical device companies (and beyond).

CANADA

LEGAL FRAMEWORK

Canada comprises 10 provinces and three federal territories. Nine of the provinces and the three federal territories are common law jurisdictions, conceptually similar to 49 of the states of United States, save Louisiana. The tenth province – Québec – is a Civil law jurisdiction; in Québec, private civil law is governed not by the common law but by the written Québec Civil Code (QCC), which contains







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a comprehensive set of legal principles covering all aspects of civil law, supplemented by provincial statutes. The general principles of Québec product liability law are contained in the QCC. Specific provisions only applicable to consumers are contained in the *Consumer Protection Act* (Québec CPA).

Products in Canada are governed by both the common law (or QCC) and any applicable regulating statute which may apply to a given product (e.g., the federal *Food and Drugs Act*). Minimum regulatory standards for a product can be set by statute or regulation. Imposed on top of statute or regulation is a general common or civil law duty on the manufacturer requiring its products to be reasonably safe and without defects. While proof that a product meets the regulatory standard can be found to be *prima facie* evidence that the product is reasonably designed and manufactured, it is not dispositive proof that the product meets the legal standard of being reasonably safe. The law recognizes that regulatory standards may not apply to every situation or may be lower than the common law standard of care.

TYPICAL CAUSES OF ACTION IN PRODUCT LIABILITY CLAIMS

A manufacturer or supplier of a defective product can be liable under contract or tort law principles to a consumer or other party injured by a product.

If there is a contractual relationship between the manufacturer and the customer, liability is normally founded on contract or warranty law principles, although independent and concurrent liability in tort law may also exist.

In the common law provinces, tort liability is the most frequent type of liability. There is no strict liability in tort law for manufacturers in Canada. Tort liability for damages caused by a defective or dangerous product is based on a negligence claim.

Similar to the US, Canada applies three main types of negligence establishing tort liability for injuries caused by defective products:

- Negligent manufacture.
- Negligent design.
- Negligent failure to warn.

To prove negligence, the plaintiff (claimant) must plead and establish all of the following elements:

- The product as designed or manufactured was defective or unreasonably dangerous.
- The defendant owed a duty of care to the claimant relating to the design and manufacture of the product.
- The defendant failed to meet the applicable standard of care in designing or manufacturing the product or providing warnings relating to the use of the product.
- The defendant's negligence which led to the defect or the unreasonable danger caused or contributed to the claimant's damages.
- The claimant's damages were reasonably foreseeable and not too remote.

To establish a negligence claim, it is normally necessary for the defective product to cause personal injury or damage to physical property. Product liability claims for pure economic loss in tort are normally not permitted unless the claimant can establish that the defective product creates an imminent and unreasonably dangerous condition that requires immediate repair to avert the risk of harm. Even if such a situation exists, the recoverable damages for pure economic loss are limited to the cost incurred by the plaintiff to avert the risk of harm either by repairing the product or disposing of the product.

If there is a contractual relationship between the claimant (typically the consumer) and the defendant manufacturer or supplier of the product, the claimant may enforce the express terms of the contract or warranty under contract law. Claims for breach of contractual warranty are normally limited to the remedy promised under the warranty.

Additionally, consumer contracts in Canadian common law provinces are typically governed by provincial sale of goods and consumer protection legislation. These acts legislate into consumer contracts (which include most retail sales of products) implied conditions as to description, fitness, merchantability, and durability. Further, the United Nations Convention on Contracts for the International Sale of Goods (CISG) has been incorporated into Canadian law, and applies to certain sale contracts between Canadian and foreign parties.

In most lawsuits alleging defects in drugs or medical devices, the plaintiff does not have a claim in contract against the manufacturer because for most drugs and medical devices, the consumer/patient has not purchased the product directly from the pharmaceutical or medical device manufacturer. However, Québec is different. In Québec all sellers are bound by the legal warranty of quality in the QCC and



its *Consumer Protection Act* , and "sellers" is broadly defined in the QCC to include not just the entity that actually sold the product to the consumer/patient, but also manufacturers, distributors, importers and wholesalers. As such, in Québec, a buyer of a defective product has a "contractual" recourse against anyone involved in the manufacturing and sale of the product.

MASS TORT LITIGATION IN CANADA = CLASS ACTIONS

Generally, for the past 30+ years, mass tort litigation claims in Canada have been asserted as class actions. All 10 Canadian provinces have enacted class proceedings legislation which permits claims to be aggregated into the form of a class action. In order for an action to proceed as a class action, it must be certified by the court. Generally, the test for certification (or "authorization", as it is called in the province of Québec) of a class action in the nine common law provinces comprises five elements, all of which the plaintiff must establish in order for a proposed class action to be certified:

1. the Statement of Claim (the Canadian equivalent of a "Complaint" in U.S. legal proceedings) discloses a legally cognizable cause of action;
2. there is an identifiable class of two or more persons;
3. the claims of the class members raise one or more issues that are common among all class members;
4. there is no other procedure preferable to a class proceeding for the resolution of the common issues; and
5. the representative plaintiff will fairly represent the interests of the class.

The legal threshold to be met by the plaintiff for the first element of the test is the same as that applicable to a motion to strike a pleading – i.e., no evidence is admissible for the assessment of this element, and the court is to assess whether the claim as pleaded, assuming all of the

allegations pleaded in the claim are true, states a legally viable cause of action.

By contrast, elements 2 through 5 require evidence, albeit not much. Specifically, the plaintiff is required to adduce evidence which establishes "some basis in fact" that each of those elements has been met. Canadian courts have never provided a precise definition of the "some basis in fact" standard, other than to note that it is substantially lower than the usual evidentiary standard in civil litigation of a balance of probabilities. The rationale for this low evidentiary threshold at the certification motion is that certification is a procedural stage which is not intended to involve an assessment of the merits of the claim, and occurs before the plaintiff has had the benefit of any discovery procedures (in Canada a defendant is not required to produce documents prior to the hearing of the certification motion).

In Québec, the requirements for authorization of a class action differ, as follows:

1. the recourses (i.e., claims) of the members raise identical, similar or related questions of law or fact;
2. the facts alleged seem to justify the conclusions sought;
3. the class proceeding would be the preferable procedure for the resolution of the common issues; and
4. a representative who can represent the members adequately.

In most class actions in Canada, the primary battleground in a certification motion revolves around the elements of common issues and preferable procedure. With respect to the common issues, Canadian courts require the plaintiff to establish, with evidence to the "some basis in fact" standard, that (a) each proposed common issue actually exists, and (b) each proposed common issue can be determined on a class-wide basis. A major difference between the test for certification under U.S. Federal Rule of Civil Procedure 23 and the test for certification in Canada (with the exception of class actions issued in the province of Ontario since October 1, 2020, addressed below), is that predominance is *not* a requirement for certification in Canada. That is, common issues do not have to predominate over individual issues. Rather, the plaintiff need only establish a basis in fact that there is one or more common issues, the determination of which will materially advance the adjudication of the claims of all of the class members.

The determination of the preferable procedure element essentially involves a consideration of whether, and the extent to which, a proposed class action would achieve the three generally-recognized objectives of class actions:

- judicial economy;
- behaviour modification; and
- access to justice.

As a result of amendments to the *Class Proceedings Act* of Ontario effective October 1, 2020, the test for assessing whether a proposed class action is a preferable procedure also requires that the common issues must predominate over the individual issues. To date there has been little case law providing extensive guidance about the effect of this higher threshold test on certification motions in Ontario. In part that is because following the amendment to the Ontario certification test, many plaintiffs' lawyers in Ontario ceased filing their proposed national class actions in Ontario (particularly product liability class actions), and instead they have been filing such class actions in other provinces, primarily British Columbia.

Following certification of a class action, notice of the certification order is disseminated/published through various means. In addition to specifying the mode of dissemination of notice, the court's "notice order" will also specify the manner in which any people who fall within the definition of the class may exercise a right to "opt out" of the class action, and the deadline date by which that must be done. In all but two provinces – New Brunswick and Newfoundland & Labrador – class membership is based on an "opt-out" system – i.e., every person who falls within the definition of the class is deemed to be in the class action unless he/she opts out. (In contrast, determination of class membership in New Brunswick and Newfoundland & Labrador is bifurcated between an opt-out system for residents of the province and an opt-in system for persons residing elsewhere in Canada.) Individuals who fall within the definition of the class and who do not opt out are deemed to be members of the class and are bound by the result of the common issues trial or a court-approved settlement agreement made by the representative plaintiff.

After an action has been certified to proceed as a class action, and the notice and opt out procedures have been completed, the action proceeds to the next stage – the trial of the common issues. In that regard, the action follows the same litigation process as applies to any civil action in Canada – e.g.,

production of documents, oral examination for discovery (the Canadian term for what is known as "depositions" in U.S. legal proceedings), exchange of experts' reports – leading up to a trial of the common issues.

If the common issues trial is determined in favour of the plaintiff class, then the proceeding moves to the final stage – determination of individual issues. Canadian class proceedings legislation does not prescribe a specific mode of resolving the individual issues in a class action. Rather, that is left to be determined by the judge and the parties following the common issues trial determination, and it will vary depending on the nature, number, and complexity of the individual issues.

DOCUMENT PRODUCTION

Pre-trial document production obligations in Canadian common law civil cases are very broad. The exact scope of document production varies from province to province, depending on the rules and law of the province and court. However, parties to Canadian common law civil litigation are generally required to disclose all documents in their possession or control which may be relevant to matters in issue in the litigation.

In the common law provinces, it is not necessary for an opposing party to initiate the production of documents by serving a document request. Each party has an obligation to identify of its own volition and produce its relevant documents to opposing parties.

The burden of disclosure on defendants in product liability matters can be very onerous. A defendant manufacturer in a negligent design or manufacture or failure to warn claim is typically required to produce all relevant documents relating to the design, testing, manufacture, distribution, and/or sale of the product. Manufacturers may also be required to produce documents generated after the incident, including documents relating to similar complaints or adverse events, warranty claims, recalls, design changes, and related litigation in other jurisdictions.

If a party believes that another party has not produced relevant documents, that party can demand disclosure. If disclosure is refused, the demanding party can apply to court for an order compelling disclosure. Disputes about the scope of document disclosure by manufacturers in product liability matters are not uncommon.

In Québec, document discovery (disclosure) is usually done through requests by the parties before or during pre-trial oral examinations. These requests are referred to as "undertakings." While the parties have a general duty to preserve and disclose relevant evidence, there is no requirement that they proactively identify and produce to opposing parties the relevant documents in their possession.

ORAL DISCOVERY (I.E., DEPOSITIONS)

Generally, each party is entitled to conduct an examination for discovery (Canadian term for "deposition") of each party that is adverse in interest. Examinations for discovery are audibly recorded and transcribed, but they are rarely video-recorded. The examination procedure is similar to depositions in US litigation but there are some key differences.

If the party is a corporation, it is generally only required to produce one representative knowledgeable of the litigation. A small number of provinces permit multiple examinations (questionings) of current and former employees of corporate parties without leave.

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The scope of questions in examinations for disclosure is normally very broad and similar to the scope of document disclosure. However, a party's counsel is entitled to object to a question – and to direct the witness not to answer the question – based not just on legal privilege but also lack of relevance. If the representative witness who is being examined is not able to answer a question because he or she does not have the requisite knowledge, the examining party can require the representative to undertake to make inquiries at the company and respond in writing (through counsel).

Pre-trial examinations of non-parties, including experts, is *not* permitted without leave of the court. The circumstances in which the court will grant leave to examine a non-party before trial are very limited. Pre-trial depositions, including foreign depositions of non-parties, may be permitted with leave if it can be shown that the witness is not available for trial or cannot be subpoenaed for trial.

In Québec, pre-trial depositions are permitted but generally their scope is more limited than in the common law provinces.

EUROPEAN UNION

In late 2024, the European Union significantly overhauled its product-liability framework with the passage of the new Product Liability Directive (EU) 2024/2853 (the "PLD"). The PLD requires EU Member States to align their existing national product-liability regimes with the PLD's framework by December 9, 2026. These amendments are expected to significantly increase the number of product-liability claims brought within the EU and to change how those claims are litigated.

For more than three decades, EU product liability has been governed by Directive 85/374/EEC (the "Current Regime"), which imposed strict liability for defective products causing limited categories of damage; focused primarily on tangible goods and manufacturers; placed the full burden of proof on plaintiffs; and did not grant them any disclosure rights or presumptions. The PLD departs from this model in several significant respects.

SCOPE OF LIABILITY

The PLD expands the scope of product liability by (i) broadening the products covered and the categories of liable parties, (ii) expanding when liability may arise across a product's lifecycle, (iii) widening the factors for assessing defectiveness, and (iv) increasing the types of recoverable damage.

1. Expanded Scope of Products

While the Current Regime focused in practice on tangible products, the PLD will explicitly include digital products such as software, including software that incorporates artificial intelligence. Software is covered whether supplied on a standalone basis, embedded in a product, or provided via the cloud. The PLD also adopts an expanded definition of "component," covering both tangible and intangible items that are integrated into, or interconnected with, a product. Although services are generally excluded, the concept of a component now extends to certain "related services," meaning digital services that are integrated into, or interconnected with, a product such that the product would be unable to perform one or more of its functions in the absence of that service. Together, these changes significantly expand the range of products and product elements that may give rise to liability for defects.

2. Expanded Scope of Liable Parties

Under the Current Regime, liability is focused primarily on the manufacturer of a defective product and, in certain circumstances, the importer. A component manufacturer may be liable only where it qualifies as a producer of a defective product, and suppliers may be treated as producers solely as a fallback where the manufacturer or importer cannot be identified. As a result, liability generally does not extend across the full chain of distribution.

Manufacturer. Under the PLD, a product's manufacturer may be held liable for defects in the product, but the range of potentially liable parties is expanded.

Component. Where a defect is attributable to a product's component, the manufacturer of that component may be held liable, potentially alongside the manufacturer of the final product. Plaintiffs may elect to pursue either or both the product manufacturer and the component manufacturer, without prejudice to rights of recourse between them.

Manufacturers Established Outside the EU. Where a manufacturer is established outside the EU, the EU importer and authorized representative may be held liable for harm caused by defective products, without prejudice to the liability of the manufacturer itself. Where there is neither an importer nor an authorized representative in the EU, liability may attach to the fulfilment service provider. EU regulations require foreign manufacturers to have an "economic operator" responsible for ensuring that products on the EU market comply with applicable requirements (Regulation (EU) 2023/988). The PLD tracks this language, expressly addressing "[l]iability without fault on the part of economic operators" and holding "economic operators" liable for alleged defects (Regulation (EU) 2024/2853).

Modifications. When an individual or company substantially modifies a product outside the manufacturer's control and makes it available on the market or puts it into service, that person is treated as the manufacturer and may be held liable for defects in the modified product.

Distributors and Online Platforms. If no EU-based manufacturer, importer, authorized representative, or fulfillment service provider can be identified, ***each*** distributor may be held liable if, upon request, it fails within one month to identify the supplier of the product. The same fallback rule applies to online platforms, which cannot rely on the

Digital Services Act safe-harbor protection as a neutral intermediary.

Because some EU Member States provide under national law for criminal liability of individuals, and in certain cases administrative or quasi-criminal liability of legal entities, for harms caused by defective products (for example, in Germany), it remains to be seen whether the expansion of potentially liable economic operators under the PLD has any indirect impact on criminal exposure at the national level.

3. Expanded Scope of Timing of Liability

Under the Current Regime, liability is largely assessed by reference to whether a product was defective at the time it was placed on the market or put into service, reflecting a predominantly static view of products at the point of initial supply. The PLD adopts a more dynamic approach, recognizing that many products—particularly connected products—remain under the "manufacturer's control" after initial placement on the market, including through the ability to issue software updates, upgrades, patches, or other changes affecting the product's functioning or safety. As a result, a product may be considered defective not only where a defect arises or is introduced through post-market updates, but also where a failure to provide necessary updates or interventions results in a lack of safety, expanding potential liability beyond the moment of first supply.

4. Expanded Factors for Assessing Defectiveness

Under the Current Regime, in addition to general safety expectations, courts are expressly directed to take into account the product's presentation, instructions, warnings, and information provided to users, as well as its reasonably foreseeable use or misuse. The PLD expands the factors courts must consider when assessing whether a product is defective. Under the PLD, the assessment will also include how the product interacts with other products or systems, including digital components and related services, and, for technologically complex products, aspects such as cybersecurity features and protection against external interference. Courts will also have to consider the effect on the product of any ability to continue to learn or acquire new features after it is placed on the market or put into service. Taken together, these expanded factors broaden the circumstances in which a product may be found defective, particularly for complex or connected products.

5. Expanded Scope of Damages

The PLD expands the scope of compensable damage compared to the prior regime and therefore increases the potential amounts at stake in product liability litigation. In addition to death, personal injury, and qualifying consumer property damage under the Current Regime, the PLD expressly recognizes medically recognized psychological harm as recoverable damage. It also extends compensation to certain data-related harm, including the loss or corruption of data that is not used exclusively for professional purposes. Unlike the Current Regime, which permits recovery for property damage only above a €500 statutory threshold, the PLD removes that monetary threshold. While the PLD continues to exclude purely economic loss and damage to the defective product itself, the expanded categories of non-material and data-related damage broaden the types of harm for which plaintiffs may seek recovery.

DISCLOSURE

The PLD expands the scope of compensable damage compared to the prior regime and therefore increases the potential amounts at stake in product liability litigation.

The PLD expands defendants' disclosure obligations. It introduces a harmonized EU-level disclosure mechanism in product-liability cases that does not exist under the Current Regime and that will operate through national procedural law. Under the PLD, plaintiffs must provide "facts and evidence to support the plausibility of the claim for compensation" to justify disclosure. Having done so, the burden shifts to the defendant to produce necessary and proportionate evidence that the plaintiff can use to support the claim. While Member States may adopt rules to protect confidential or privileged information, and existing EU law (including trade-secret protection) continues to apply, the PLD itself does not set out detailed confidentiality safeguards.

Disclosure, however, is limited to what is necessary and proportionate to support a claim, and any disclosure must be "in accordance

with national law." Both are important limitations, and individual Member States will apply or further develop disclosure rules within their existing procedural frameworks. In practice, these requirements may reinforce incentives for plaintiffs to bring claims in jurisdictions that already have, or that later develop, more disclosure-friendly regimes under national law.

PRESUMPTIONS

The new PLD changes the plaintiff's burden of proof. The top line remains the same: plaintiffs must prove defect, damage, and a causal link between the two. But the PLD introduces a series of rebuttable presumptions under which a defect, a causal link, or both are ***presumed*** to exist. In that situation, the burden falls on the ***defendant*** to rebut the presumption. A defect is presumed where (1) a defendant fails to disclose evidence when ordered to do so; (2) the product does not comply with mandatory safety requirements; or (3) the damage was caused by an obvious malfunction during reasonably foreseeable use.

Causation is presumed where the product is defective and the damage is of a kind typically consistent with that defect. Most notably, ***both*** defect and causation are presumed where, after disclosure of relevant evidence, (1) the plaintiff faces excessive difficulty proving its case due to technical or scientific complexity and (2) it is likely that the product was defective, that a causal link exists, or both.

How this works in practice remains to be seen. A defendant may rebut these presumptions, but it is unclear what evidence will be sufficient. Moreover, the "technical or scientific complexity" of a product is a factual question that national courts will need to determine on a case-by-case basis. Accordingly, there is a risk that different countries will define the phrase differently. Defendants should also consider how arguments they make in EU litigation (most likely, that a product is ***not*** technically or scientifically complex) may be used in the United States, where it is frequently helpful for products to be complex (which may trigger requirements for plaintiffs to present reasonable alternative designs through expert testimony).

DEFENSES

As under the Current Regime, the PLD preserves a number of key exemptions from liability, including where the relevant economic operator did not place the product on the market, where the defect did not exist at the relevant time, where the defect is due to compliance with mandatory legal requirements, or where the defect was not discoverable given the state of scientific and technical knowledge. The PLD also maintains specific defenses for component manufacturers and for persons who substantially modify a product, where liability is attributable to the design or instructions of another manufacturer or to parts of the product unaffected by the modification.

However, the PLD significantly refines these exemptions by tailoring them to different categories of economic operators and by narrowing the availability of the defense that a defect arose after the product was placed on the market. In particular, that defense does not apply where the defect results from software, related services, a lack of necessary software updates, or other changes within the manufacturer's control, reflecting the PLD's focus on digital products and ongoing post-market control.

COLLECTIVE REDRESS AND TRANSPARENCY IN PRODUCT LIABILITY CLAIMS

The practical impact of the PLD must be viewed alongside the EU's Representative Actions Directive (the "RAD"), which enables designated consumer-protection organizations to bring representative actions for redress on behalf of consumers, including with the use of third-party litigation funding, subject to national procedural safeguards (Directive (EU) 2020/1828, applicable since 2023). The RAD is beginning to contribute to increased collective consumer litigation in certain Member States. The PLD further promotes transparency by requiring Member States to ensure access to final judgments in product-liability cases, including decisions of higher national courts. Greater visibility into these judgments may facilitate follow-on claims by allowing plaintiff firms to track how the PLD is interpreted across jurisdictions, potentially supporting more strategic forum selection.

BRAZIL

Brazil is a country with a population of approximately 213 million people. It has around 1,500,000 lawyers (a ratio of 142 inhabitants per attorney) and an estimated 1,500 to 1,800 law schools, which together graduate approximately 120,000 new lawyers each year.

According to the most recent data published by the National Council of Justice, as of December 2024 there were 80.6 million cases pending before Brazilian courts. The

Brazilian judicial system is relatively complex and is divided into Federal Courts (with jurisdiction over cases involving the Federal Government, federal agencies, and state-owned companies), Labor Courts (which are federal courts with jurisdiction over employment-related disputes), Electoral Courts, Military Courts, and State Courts (a separate system for each of the 27 Brazilian states).

The courts of first and second instance within these systems are subject to review by four superior courts. For the purposes of this article, special mention should be made of the Superior Court of Justice, the highest non-constitutional court in the country, responsible for harmonizing the interpretation of federal law, and the Supreme Court, Brazil's constitutional court.

The Brazilian judicial system and its complexities create fertile ground for litigation, which naturally includes disputes involving pharmaceuticals and medical devices.

CONSUMER PROTECTION LEGISLATION

The Brazilian legal system provides broad access to the judiciary. The Federal Constitution recognizes access to the courts as a fundamental right, regulated by a variety of infra-constitutional statutes. From the perspective of litigation involving product defect or product liability, the Civil Code contains the general rules governing civil liability, which are supplemented by specific legislation, namely the Consumer Protection Code (Law No. 8,078/1990).

Under the Civil Code, anyone who causes harm to another is obliged to provide compensation. The law allows recovery for material damages (actual damages and lost profits) and non-material (moral) damages, which include harm to reputation, aesthetic damages, and psychological suffering, measured according to the extent of the injury. As a general rule, compensation should correspond to the damage actually suffered, and quantification depends on the evidence produced by the party seeking damages.

It is primarily within the scope of consumer law that the specific grounds for civil liability arising from product defect or product nonconformity are found. Brazilian consumer law was inspired by the original European directive and directly incorporated some of its provisions. In general terms, under the Consumer Protection Code:

- Basic consumer rights include "the effective prevention and compensation for material and moral, individual, collective, and diffuse damages", "access to judicial and administrative bodies for the prevention or compensation of material and moral, individual, collective, and diffuse damages" and "the facilitation of the defense its rights, including the shifting of the burden of proof, in their favor";
- The liability of the manufacturer, producer, or importer is strict, i.e., it does not depend on proof of fault. Once the consumer demonstrates the occurrence of damage, the existence of a defect, and a causal link between them, an obligation to indemnify arises;
- A product is deemed defective when it "does not offer the safety that one may legitimately expect," taking into account its presentation, the reasonably foreseeable uses and risks, and the time at which it was placed on the market. A product is non-compliant upon deviations in "quality or quantity that render the product improper or inadequate for its intended use or reduce its value";
- There is joint and several liability among suppliers of products and services, which, for purposes of the law, include those who produce, assemble, create, build, transform, import, distribute, or market products to consumers (the latter being liable when it is not possible to identify the manufacturer, constructor, or producer, or when the product has not been adequately preserved).

The legislation further provides that, in addition to judicial enforcement of consumer rights, the Public Administration is responsible for the National Consumer Protection System, composed of a federal body (the National Secretariat for Consumer Affairs – SENACON), as well as state and municipal PROCONs (administrative consumer protection agencies) throughout the 27 Brazilian states and in various cities.

INDIVIDUAL ACTIONS VS. COLLECTIVE ACTIONS

Under the Brazilian system, consumer rights may be enforced individually or collectively, with individual lawsuits being more common.

A consumer seeking individual compensation for alleged damages arising from product defect or product nonconformity may rely on two main procedural avenues:

- Small Claims Courts: These courts offer simplified proceedings designed for cases

of lower complexity. There are limitations on evidentiary production, particularly expert evidence, which is generally indispensable in litigation involving pharmaceuticals and medical devices. Legal representation by an attorney is not mandatory at first instance depending on the amount claimed, but is required for appeals, which also follow simplified procedures. Compensation is capped at 40 times the minimum wage (approximately USD 13,000.00 in current figures).

- Ordinary Civil Courts: This forum allows for the fullest exercise of due process. Proceedings are divided into pleading (complaint, answer, reply, and rebuttal when applicable), evidentiary (production of evidence), and judgment phases. During the evidentiary phase, the broadest possible range of evidence is admissible, including party depositions, documentary evidence, production of documents by third parties upon court order, witness testimony, court-appointed expert opinions, and judicial inspections, whereby the judge may personally conduct inquiries to clarify relevant facts. There is broad availability of interlocutory and merits appeals, including access to the higher courts (Superior Court of Justice and Supreme Court), subject to specific statutory requirements.

In both Small Claims Courts and Ordinary Civil Courts, the parties may request urgent relief – both precautionary measures and preliminary injunctions – aimed at imposing obligations to act (e.g., replacement of a product or payment for medical treatment) or obligations not to act, subject to daily fines for noncompliance.

In the Ordinary Civil Courts, multiple consumers may join in a single action when their claims arise, essentially, from the same facts (communion of rights and obligations or affinity between questions of fact or law). There is no objective limit on the number of plaintiffs in a single lawsuit, although under the Code of Civil Procedure the judge may limit the number if it jeopardizes an efficient solution or the defendant's right of defense. Despite being legally possible, it is uncommon in practice for multiple consumers to jointly file a single action to litigate product liability claims.

Collective enforcement of consumer rights may occur when the case involves:

- Diffuse rights or interests: indivisible rights held by indeterminate or indeterminable persons linked by a factual circumstance (e.g., citizens of a municipality seeking remediation of environmental pollution);
- Collective rights or interests: indivisible rights held by a group or class connected by a legal relationship (e.g., users of a public service provided by a private concessionaire);
- Homogeneous individual rights: divisible rights held by identifiable individuals arising from a common origin (e.g., consumers of a defective pharmaceutical product).

Collective actions may be brought by the Public Prosecutor's Office, the Federal Government, states, municipalities, public agencies authorized by law (such as Public Defenders' Offices and PROCONs), and consumer associations that satisfy statutory requirements (including minimum duration of existence and express authorization in their bylaws). In such cases, the injured parties do not litigate in their own names but are represented by these entities.

In cases involving homogeneous individual rights, if the collective judgment recognizes the defendant's liability, it generally sets out the parameters for compensation. This judgment may be enforced collectively or individually, followed by (i) a liquidation phase to quantify each claimant's damages; and (ii) an enforcement phase to obtain payment, both of which may also proceed collectively or individually.

Although governed by specific rules, collective consumer actions follow the same evidentiary framework applicable to Ordinary Civil Court proceedings, allowing broad evidentiary production and extensive appellate review of both interim decisions and final judgments on the merits.

An additional feature of collective actions is the possibility of awarding collective moral damages. Although punitive damages do not exist under Brazilian law and are expressly rejected by the jurisprudence of the Superior Court of Justice, this mechanism seems to be the closest functional equivalent. These damages do not compensate individual harm, but rather address collective injuries deemed so severe that they affect the safety, well-being, or dignity of a group (e.g., environmental harm caused by negligence). The amounts awarded may be

considerably higher than individual damages, but they are not paid to individual claimants; instead, they are directed to a public fund supervised by the Public Prosecutor's Office, whose resources must be allocated to "the restoration of the harmed interests."

PROCEDURAL PERSPECTIVE

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From a strictly procedural standpoint, the Brazilian system presents particular features relevant to consumer litigation, some of which are the following.

1. Burden of Proof

As a general rule, under Brazilian civil procedure the burden of proof rests with the plaintiff. However, in consumer cases governed by the Consumer Protection Code, courts may shift the burden of proof to the supplier, requiring it to prove the absence of a product defect or nonconformity. This occurs frequently in individual lawsuits – both in Small Claims Courts and in Ordinary Civil Courts – and is also possible in collective actions. The burden of proof may be shifted when the plaintiff's allegations are deemed *prima facie* plausible or when evidentiary production would be excessively difficult for the consumer from a technical standpoint.

Brazilian law does not provide for American-style discovery. Nevertheless, during the proceedings various forms of evidence may be produced by either party, including court-ordered production of documents and information by third parties.

2. Costs and Litigation Expenses

It is very common in consumer litigation for plaintiffs to be granted legal aid. In such cases, plaintiffs are exempt from paying filing fees, appellate fees, litigation expenses (including expert fees), and, at the end of the lawsuit, they are not subject to the "loser pays" rule for attorneys' fees and reimbursement of expenses. This waiver generally does not apply to defendants (corporate manufacturers or suppliers *lato sensu*), who must bear all procedural expenses for which they are responsible, including, in many cases, court-appointed expert fees. Given the frequent inversion of the burden of proof, advancing the costs of expert evidence to demonstrate the absence of a product defect may be in their best interest.

Attorneys' fees in individual actions may be structured on a pure contingency basis, which may result in increasing litigation volume. Public and private entities authorized to bring collective actions are typically exempt from court costs and expenses; however, if a collective action is brought by a private association, the defendant may be ordered to pay attorneys' fees if it loses. As a general rule, such fees are not awarded in actions brought by public entities.

3. Damages Parameters

There is a contrast between damage awards in the United States and those typically granted in Brazil.

As noted above, compensation for material damages must correspond to what is proven by the claimant. Moral damages, although inherently subjective, are generally awarded in amounts that cannot be considered excessive. Even in complex cases involving permanent injury or death, awards exceeding BRL 1,000,000.00 (approximately USD 200,000.00) are uncommon, though not impossible. Significant distortions are also not typically observed in the setting of collective moral damages.

4. Piercing the Corporate Veil

Piercing the corporate veil is provided for under the Civil Code and the Code of Civil Procedure, and is also expressly contemplated in the Consumer Protection Code. Courts may authorize veil piercing when consumers are harmed by abuse of rights, excess of power, violation of law, illicit acts, or breach of corporate bylaws. It may also be applied in cases of bankruptcy, insolvency, or inactivity of the supplier.

TRENDING TOPICS

As demonstrated above, the Brazilian system creates an environment in which litigation is inherently prevalent. The wide range of procedural tools available to claimants and the limited barriers to accessing the judiciary (including the ease of obtaining legal aid, the high number of lawyers, and minimal downside risk in the event of loss) result in a large volume of lawsuits, often in cases where the existence of material damages could itself be questionable.

1. Artificial Intelligence

As in other jurisdictions,

artificial intelligence has begun to impact consumer litigation in Brazil.

From an informational standpoint, AI creates new challenges for legal professionals and companies subject to consumer regulations: issues that might otherwise attract limited attention become easily accessible. Judicial outcomes from other countries – such as the United States, Canada, and the European Union – are increasingly cited by plaintiffs' attorneys in Brazilian proceedings involving global products. Even technical facts and arguments unrelated to a specific case, but addressed in foreign litigation, have found their way into Brazilian court records.

Conversely, inconsistencies have been identified in judicial documents produced with the aid of AI. Court decisions exhibiting structure and content clearly compatible with materials generated by popular AI tools have already been issued. Court-appointed expert reports have also been identified in different cases, produced by the same expert, reaching diametrically opposed conclusions on the same subject – a contradiction characteristic of research conducted using different sources with varying interpretive biases.

2. Predatory Litigation

Brazilian judges have shown increased concern regarding predatory litigation, understood as the abusive filing of large volumes of lawsuits based on standardized pleadings, generic legal theories, and, in some cases, evident documentary defects, including issues of representation (e.g., powers of attorney bearing questionable signatures or granted by individuals unaware of the generic authorization they allegedly provided). The Superior Court of Justice has recently issued a decision authorizing judges to require proof of standing and authenticity of claims where predatory litigation is suspected.

3. Potential Internationalization of Litigation

A recent case involving the Brazilian mining company Vale, which is facing litigation in England brought by Brazilian claimants in connection with the collapse of a dam in Brazil, highlights a new potential facet of high-impact consumer and mass tort litigation: the internationalization of disputes, transferring to foreign courts controversies arising from legal relationships formed within Brazil.

CONCLUSION

Understanding the particular features of the three legal systems examined in this study reveals some points of convergence which, when effectively leveraged, may provide strategic advantages in addressing the challenges of multi-jurisdictional litigation. At the same time, awareness of the differences among these jurisdictions can create additional opportunities to benefit clients through the strategic and efficient coordination of the sequence and timing of proceedings. In this context, close collaboration and coordinated teamwork between the client and their various external counsel are essential to the success of such an approach.



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