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Product Liability Update: Q2 2024

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Key Product Liability Cases: Q2 2024 Update

The Product Liability and Mass Torts Group at McCarthy Tétrault LLP is pleased to bring you our analysis of recent decisions for businesses manufacturing or selling products in Canada:

1. The Ontario Superior Court of Justice clarifies the test for design negligence in cases of inherently dangerous products: ***Price v. Smith & Wesson Corp.*, 2024 ONSC 1368**

2. The Ontario Divisional Court upholds redactions justified by European Union law: ***Harris v. Bayerische Motoren Werke Aktiengesellschaft et al.*, 2024 ONSC 2341**

3. The Supreme Court of British Columbia provides a useful review of British Columbia's law of negligent design in ***I.F. v. Gilead Sciences, Inc.*, 2024 BCSC 480**

4. The Superior Court of Quebec skirts a contractual governing law provision in a product liability dispute: ***Entreprises Lefebvre Industri-AI inc. c. Shred-Tech Corporation*, 2024 QCCS 1320**

5. The Superior Court of Quebec applies the learned intermediary doctrine to prescription medicines: ***Jaafar c. Janssen inc.*, 2024 QCCS 200**

The Ontario Superior Court of Justice clarifies the test for design negligence in cases of inherently dangerous products: *Price v. Smith & Wesson Corp., 2024 ONSC 1368*[1]

The Ontario Superior Court of Justice has addressed the test for design negligence in cases involving "inherently dangerous" products like firearms, in the context of a certification motion. The Court confirmed that manufacturers are entitled to make reasonable trade-offs between risk and utility in designing products, including inherently dangerous products.

Background

In July 2018, an individual used a stolen M&P®40 handgun manufactured by the defendant Smith & Wesson to kill two people and injure several others. One of the injured individuals and her family members sought certification of a class action against Smith & Wesson. The plaintiffs alleged that Smith & Wesson had negligently designed the M&P®40 by failing to install it with "authorized user technology" that would have allowed the weapon to fire only when activated by an authorized user. The plaintiffs alleged that the assailant could not have caused the plaintiffs' injuries had the stolen M&P®40 properly been installed with authorized user technology.

The Court previously dismissed an application to strike the plaintiffs' claims.[2] In this 2024 decision, the Court considered, as part of the certification application, whether the plaintiffs had provided some basis in fact to show that Smith & Wesson was negligent in designing the M&P®40 by failing to install it with authorized user technology.

Outcome

The Court dismissed the plaintiffs' motion for certification.

A product is negligently designed only if it contains a design "defect" that creates a substantial risk of harm. A defect results from a manufacturer's "careless decision[] about the composition" of its product.[3] Therefore, to find a defect, the Court must apply a holistic risk-utility analysis, considering not only whether the manufacturer could have designed a safer product, but also whether safer alternative designs would have unduly impaired the utility of the product for its intended users, or greatly increased the product's cost.[4]

Given that framework, the plaintiffs had to show that authorized user technology could have been installed on the M&P®40 at a reasonable cost, without impairing the M&P®40's utility for its intended users – police officers and the military. The plaintiffs did not lead evidence showing some basis in fact for those requirements.[5]

Instead, the plaintiffs led evidence that Smith & Wesson failed to install authorized user technology on the M&P®40 even though Smith & Wesson knew stolen or lost weapons could be used by unauthorized users, and even though authorized user technology had been developed to address that risk.[6]

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[1] *Price v. Smith & Wesson Corp.,* 2024 ONSC 1368.
[2] *Price v. Smith & Wesson Corp.*, 2021 ONSC 1114.
[3] *Price v. Smith & Wesson Corp.,* 2024 ONSC 1368, at para. 8.
[4] *Price v. Smith & Wesson Corp.,* 2024 ONSC 1368, at paras. 51-56.
[5] *Price v. Smith & Wesson Corp.,* 2024 ONSC 1368, at para. 158.
[6] *Price v. Smith & Wesson Corp.,* 2024 ONSC 1368, at para. 157.

But an inherently dangerous product is not necessarily defective only because it could have been manufactured to be safer. There must be a holistic analysis of risk and utility. Without evidence relevant to that analysis, the Court could not certify the proposed common issue in respect of Smith & Wesson's alleged design negligence.

The plaintiffs argued that requiring more detailed risk and utility evidence at the certification stage was unfair because of the "inherent informational imbalance" that favours manufacturers in a product liability case before discovery and disclosure.[7] The Court acknowledged that the plaintiffs might have an information deficit about the defendant's design choices, but held that that deficit did not relieve them from their burden of identifying a design defect or establishing a methodology for conducting a risk-benefit analysis.[8]

The Court also considered causation and other issues, and ultimately declined to certify the class action.

Key Takeaway

1. An inherently dangerous product is not necessarily negligently designed just because it could have been made to be safer. The Court will consider a holistic risk-utility analysis to determine whether the manufacturer made "careless decisions about the composition" of its product, in light of the cost and utility of alternate, safer designs.

The Ontario Divisional Court upholds redactions justified by European Union law: *Harris v. Bayerische Motoren Werke Aktiengesellschaft et al.*, 2024 ONSC 2341

Should an Ontario court consider whether an order it makes could cause a litigant to breach an applicable foreign law? In *Harris v. Bayerische Motoren Werke Aktiengesellschaft et al.*,[9] the Ontario Divisional Court answered "yes."

Background

In *Harris*, the Ontario Divisional Court largely dismissed an appeal of an interlocutory decision that allowed BMW to redact an affidavit of documents due to concerns regarding European Union and German privacy law. The decision relates to an ongoing class action concerning allegedly defective power steering units in Mini Cooper cars.

Outcome

The Divisional Court dismissed the appeal on grounds that: 1) the motion judge did not exceed his jurisdiction or deny the appellant procedural fairness; 2) the motion judge did not err in ordering that BMW could redact customers' data; and 3) the motion judge was not incorrect in finding that redactions should have been allowed if they were required by foreign law.

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[7] *Price v. Smith & Wesson Corp.,* 2024 ONSC 1368, at para. 156.

[8] *Price v. Smith & Wesson Corp.,* 2024 ONSC 1368, at para. 161.

[9] *Harris v. Bayerische Motoren Werke Aktiengesellschaft et al.*, 2024 ONSC 2341.

Key Takeaway

1. The Divisional Court was clear that a domestic court should take foreign laws into account where compliance with those laws would not interfere with the fact-finding responsibilities of the court. Redaction in this case appropriately balanced the fact-finding and disclosure responsibilities of the court and the privacy issues protected by foreign law.[10]

The Supreme Court of British Columbia provides a useful review of British Columbia's law of negligent design: *I.F. v. Gilead Sciences, Inc.*, 2024 BCSC 480

The Supreme Court of British Columbia has provided a useful summary of British Columbia's law of negligent design, and of some of the challenges of obtaining pre-trial dismissal of negligent design cases, in *I.F. v. Gilead Sciences, Inc.*, 2024 BCSC 480.

Background

Gilead Life Sciences, Inc. and Gilead Sciences Canada Inc. (together, "**Gilead**") sought to strike the pleadings of, or in the alternative summary judgment against, the plaintiffs in a proposed class action related to two of Gilead's HIV drugs. The plaintiffs alleged that Gilead intentionally withheld development of a safer, more effective HIV drug formulation (tenofovir alafenamide fumarate, or TAF) between 2004 and 2010 in order to maximize profits from a less effective formulation (tenofovir disoproxil fumarate, or TDF) that it had patented until 2017.

Gilead argued, among other things, that TAF and TDF both effectively treat HIV/AIDS, have different risk-benefit profiles, and received approval from government regulators.

The plaintiffs also sought certification of their class action against Gilead.

Outcome

The Court declined to strike or order summary judgment against the plaintiffs.

The Court in *Gilead* condensed earlier guidance from the Court of Appeal[11] into a set of four inquiries that determine whether a negligent design pleading discloses a reasonable cause of action and therefore should survive a motion to strike:[12]

1. the defendant manufacturer owed a duty of care to the plaintiff;
2. the defendant manufacturer breached that duty by failing to observe the applicable standard of care because:
    i. the manufacturer knowingly marketed a product that has a design defect;
    ii. the design defect created a substantial likelihood of harm;
    iii. there existed an alternative design that was safer and economically feasible to manufacture; and

[10] *Harris v. Bayerische Motoren Werke Aktiengesellschaft et al.*, 2024 ONSC 2341, para. 49.
[11] *Ding v. Canam Super Vacation Inc.*, 2024 BCCA 102.
[12] *I.F. v. Gilead Sciences, Inc.*, 2024 BCSC 480, at para. 47.

iv. based on a risk-utility analysis, the foreseeable risks associated with the product's design outweighed the utility of the chosen design;

3. the plaintiff sustained damage; and
4. such damage was caused, in fact, and in law, by the defendant manufacturer's breach of the duty of care.

The Court held that the plaintiffs' pleadings against Gilead met these criteria and survived the motion to strike. The pleadings alleged that TDF created a substantial likelihood of causing bone and kidney damage, and that Gilead knew that TAF was a safer *and* an economically feasible alternative design to TDF.[13]

Gilead's summary judgment application was also dismissed. In British Columbia, summary judgment will only be ordered when the plaintiffs' proposed claim raises no genuine issues requiring trial. Both parties led expert evidence speaking to the risks and utility of TDF and TAF. There were significant factual disputes regarding the relative efficacy, risks, and utility of TDF and TAF, and since negligent design claims turn essentially on a risk-utility analysis (see, e.g. the analysis of *Price* above), there was a genuine issue requiring trial.[14]

The Court went on to certify the plaintiffs' action against Gilead.

Key Takeaway

1. Since the legal test for negligent design involves complex factual assessments about the relative risks and benefits of alternative designs, it is challenging for a defendant to show that the plaintiffs' claims raise "no genuine issue requiring trial," and to dispose of these claims before trial.

The Superior Court of Quebec skirts a contractual governing law provision in a product liability dispute: *Entreprises Lefebvre Industri-Al inc. c. Shred-Tech Corporation*, 2024 QCCS 1320

In *Entreprises Lefebvre Industri-Al inc. c. Shred-Tech Corporation*,[15] the Superior Court of Quebec declined to give up jurisdiction over a product liability dispute in favour of an Ontario court on grounds of *forum non conveniens*, even though the dispute arose out of a contract that was governed by the laws of Ontario.

In its analysis of the doctrine of *forum non conveniens*, the Court noted that article 3128 of the *Civil Code of Quebec* allows plaintiffs to litigate a product liability suit in the jurisdiction where they acquired the product, even if the contract by which they acquired the product contains a governing law clause.

[13] *I.F. v. Gilead Sciences, Inc.*, 2024 BCSC 480, at paras. 48-61.
[14] *I.F. v. Gilead Sciences, Inc.*, 2024 BCSC 480, at paras. 65-73.
[15] *Entreprises Lefebvre Industri-Al inc. c. Shred-Tech Corporation*, 2024 QCCS 1320.

Background

In 2020, the Quebec-based plaintiff, Lefebvre, bought an industrial shredder from Shred-Tech, a company mainly operating in Ontario. Lefebvre concluded that the shredder was defective. In November 2022, Lefebvre initiated legal proceedings against Shred-Tech in the Superior Court of Quebec.

Shred-Tech acknowledged that Quebec courts had jurisdiction over the dispute, but asked the Quebec court to decline jurisdiction in favour of Ontario courts under article 3135 of the *Civil Code*,[16] among other reasons because the contract governing the sale of the shredder specified Ontario law as the governing law of the contract and therefore Ontario was the more convenient jurisdiction.

Lefebvre resisted Shred-Tech's request. It argued that it could be entitled to the application of article 3128 of the *Civil Code*, which allows the "victim" of a manufacturer's wrong to have the manufacturer's liability determined by either the law of the jurisdiction where the manufacturer has his establishment, or the law of the jurisdiction where the "victim" acquired the property. Lefebvre argued that at a later point in the proceedings, it could avail itself of article 3128 and select Quebec law to govern liability notwithstanding the presence of an Ontario governing law clause in the contract. Since Quebec law could conceivably apply to the dispute, Ontario was not the more convenient forum.

Outcome

The Court agreed that article 3128 of the *Civil Code of Quebec* could apply, and therefore, that it was possible Quebec law would govern the dispute. That meant that Ontario was not the most convenient forum. Furthermore, the Court held that article 3128 of the *Civil Code of Quebec* aims to favour the victims of product defects and that, when applicable, it should take precedence over a contractual clause stipulating the applicable law.[17]

Key Takeaway

1. *Lefebvre c. Shred-Tech* highlights that, in matters pertaining to the liability of a manufacturer, Quebec law provides that the prerogative to choose the applicable law resides with the victim and that this choice supersedes contractual stipulations.

The Superior Court of Quebec applies the learned intermediary doctrine to prescription medicines: *Jaafar c. Janssen inc.*, 2024 QCCS 200

In *Jaafar c. Janssen*,[18] the Superior Court of Quebec provided a helpful reminder on the application of the learned intermediary doctrine in Quebec. In Quebec, the doctrine may apply to a claim against pharmaceutical manufacturers when (a) the claim is in respect of a prescription drug, and (b) the manufacturer of the drug provided learned intermediaries (e.g., doctors and pharmacists) with "sufficient indications as to the risks and dangers [the drug] involves [and]…the means to avoid them," per article 1469 of the *Civil Code of Quebec*. The Court largely applied the analysis of the Court of Appeal in *Brousseau c. Laboratoires Abbott limitée*.[19]

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[16] *Civil Code of Québec*, C.Q.L.R. c. CCQ-1991, article 3135.

[17] *Entreprises Lefebvre Industri-Al inc. c. Shred-Tech Corporation*, 2024 QCCS 1320, para. 31.

[18] *Jaafar c. Janssen inc.*, 2024 QCCS 200.

[19] *Brousseau c. Laboratoires Abbott limitée*, 2019 QCCA 801.

Background

From 2009 to 2015, the plaintiff was treated for Crohn's disease. His doctor prescribed him Remicade, a drug "universally regarded as one of the most effective and safest drugs for combating Crohn's disease."[20] The plaintiff claimed that Remicade caused him to develop vasculitis.

The plaintiff ultimately failed to meet his burden of demonstrating that his use of Remicade caused his vasculitis.[21] However, the Court went on to consider the learned intermediary doctrine as well.

The relevant obligation on manufacturers to warn consumers of risks is found in article 1469 of the *Civil Code of Quebec*: a manufacturer must provide "sufficient indications as to the risks and dangers [the product] involves [and]…the means to avoid them." Where the product in question is a prescription drug that is administered by learned intermediaries rather than by the patient directly, the learned intermediary doctrine may apply, and the manufacturer may discharge its duty to warn by providing sufficient warnings to the intermediaries.[22]

Outcome

The Court noted that Remicade must be obtained on medical prescription and cannot be administered by a patient directly, so the learned intermediary doctrine applied. The manufacturer's duty could be discharged by sufficient warnings to the plaintiff's prescribing doctors of the risks of Remicade. The Court found that Remicade's product monograph contained sufficient information to satisfy this burden.[23]

Key Takeaways

1. The learned intermediary doctrine has been recognized and applied by Quebec courts in the context of prescription medicines.

2. In dealing with the learned intermediary doctrine, a lower court in Quebec has again applied the analysis of the Court of Appeal in *Brousseau v. Laboratoires Abbott limitée*.[24.]

**This publication is for general information only and is not intended to provide legal advice.*

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[20] *Jaafar c. Janssen inc.*, 2024 QCCS 200, at para. 6.
[21] *Jaafar c. Janssen inc.*, 2024 QCCS 200, at para. 25.
[22] *Jaafar c. Janssen inc.*, 2024 QCCS 200, at para. 54.
[23] *Jaafar c. Janssen inc.*, 2024 QCCS 200, at paras. 56-58.
[24] *Brousseau c. Laboratoires Abbott limitée*, 2019 QCCA 801.

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About McCarthy Tétrault's Product Liability and Mass Torts Group

Product liability and mass tort claims are among the most serious challenges an organization can face. When the survival of a brand or a business hangs in the balance, the world's leading companies turn to McCarthy Tétrault. Our deep bench strength and expertise across Canada allows us to help our clients navigate their most complex product liability and mass tort challenges from start to finish. We act for companies in a wide range of matters and industries, including medical products and devices, consumer products and services, transportation and automotive products, toxic chemical and environmental matters, and catastrophic events. Our firm's integrated, industry-focused approach allows us to anticipate issues and help prevent and contain product liability and mass tort lawsuits before they begin.

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