"Nobody Used This Design Back Then: Getting Evidence of Industry Practice Admitted in Product Liability Litigation"

International Association of Defense Counsel
Mid-Year Meeting
February 25, 2020

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The author acknowledges the assistance of Joseph Marando and the Product Liability Group at BLG

Canada's legal system is based on a combination of two legal traditions: English common law, applied in nine of Canada's provinces and three territories; and French civil law, applied in the Province of Quebec. Although important differences exist between the common law provinces, the general principles are usually portable. Canada's court system is somewhat different from the court system in the United States. Each Canadian province and territory has its own court system. Each province's and territory's courts have inherent jurisdiction to hear cases on any subject except those that are specifically limited to another level of court by statute (e.g. small claims courts, which hear civil matters involving claims below a set monetary amount). As a result, virtually all civil claims may be brought in these provincial or territorial superior courts.

While Canada has a parallel federal court system, the Federal Court of Canada has civil jurisdiction, limited to matters identified in specific federal statutes in actions against the federal government or a federal ministry or Crown agency. Canada's Supreme Court is the final appellate Court for all matters in Canada. There is no multidistrict litigation system in Canada in which to aggregate claims commenced in provincial or territorial courts.

With this court system in place, virtually all product liability claims will be litigated in the court system of the province or territory in which the action is commenced. In the context of Canadian litigation, issues of admissibility of evidence in relation to industry standards or state of the art technology typically arise in the context of negligent design claims. For instance, a user of a product may argue that as a result of the manufacturer's negligence during design (not up to industry standards) the product was defective and caused them to suffer damages. As will be discussed below, state of the art evidence is most often brought up as a way for the manufacturer to argue a defense in response to the plaintiffs claim (e.g. if they were using state of the art technology, they could not have been any more prudent).

Specific Types of Liability in Canada

(1) Negligence in the Manufacturing Process

(i) The Test

In Canada, a plaintiff alleging that a product was negligently manufactured must prove that:

- the product in question was defective in that it was not manufactured in accordance with the specifications that the manufacturer intended;
- the defect arose as a result of the manufacturer's failure to take reasonable care; and
- the plaintiff sustained harm that was caused by the defective condition of the product.

The plaintiff must prove all of the above elements for the manufacturer to be found liable.

Canadian law does not impose strict liability on manufacturers such that they are liable for all harm caused without proof of negligence. As such, a manufacturer is not required to produce products that are accident proof.

(ii) Proof of Defect

Proof of a defect in a product is a threshold issue: Unless a defect is established, it is unnecessary to consider the other elements of negligence. Court decisions in Canada in the area of product liability generally require actual – not circumstantial – proof of a defect.

Where the presence or absence of a defect can be definitively determined by scientific analysis and testing, the courts have required plaintiffs to produce such proof. Thus, the plaintiff must retain an expert to examine the product and provide expert evidence that establishes the presence of a defect. Without such proof, a plaintiff's claim should fail.

However, in circumstances where it is impossible to physically produce the proof, courts may still infer the presence of a defect where there is sufficient circumstantial evidence to prove, on a balance of probabilities, that a manufacturing defect was present in the product.

To satisfy this test, a plaintiff will generally have to establish the absence of any other reasonable explanation for what happened. The courts have found that a trier of fact can draw an inference of proof of defect where the cause of the defect is unknown.

For goods supplied under a service contract, a court will consider whether a defect existed at the time the defendant installed the allegedly defective product.

(iii) Proof of Negligence

Even when a defect in the product can be shown, the plaintiff must additionally show that the defect arose as a result of some lack of care by the manufacturer. However, this is a fairly easy requirement for plaintiffs to satisfy: Proof that the product was allowed to leave the manufacturer's plant in a defective condition is usually sufficient to prove that there was some lack of care.

For all intents and purposes, where the product in question has been shown to be defective, the manufacturer bears an evidentiary burden to prove the defect was not the result of its failure to take reasonable care. Courts have imposed liability on manufacturers for having faulty assembly, faulty fabrication and/or failing to have in place proper systems of inspection, quality assurance and quality control. Even where near-perfect systems have been devised, the possibility of human error remains.

Accordingly, in defending a negligent manufactured product case, a manufacturer will have to show that it had proper procedures and protocols in respect of employee training, inspection and quality control.

(2) Negligence in Design

Canadian courts have not clearly defined the law of negligent design. However, much like in a negligent manufacturing case, the plaintiff must first prove that a product was defective in order to establish liability on the part of the designer. It is generally thought that a design defect arises when the product is manufactured as intended, but the design gives rise to malfunction or creates an unreasonable risk of harm that could have been reduced or avoided through the adoption of a reasonable alternative design.

(i) The Test

In determining whether the design defect creates an unreasonable risk of harm, courts generally apply a risk-utility test: "Was there a reasonable alternative design that was safer?" Generally,

the fact that a manufacturer took post-loss remedial measures to address an issue is not an admission of negligence. Evidence of post-loss remedial measures is potentially admissible at trial. Although such evidence was argued not to be admissible in a negligence action for lack of relevance and on policy grounds, recently the Ontario Court of Appeal in *Sandhu v. Wellington Place Apartments,* 2008 ONCA 215 (CanLII), relying on an earlier Supreme Court of Canada decision, held that the relevance of such evidence was dependent on the particular circumstances of each case. Admissibility of evidence of remedial measures was held to require the trial judge to balance the probative value of that evidence against its prejudicial effect. The Court held that the "prejudicial effect includes whatever weight the trial judge might give to the policy argument for exclusion, but also includes considerations such as whether the evidence will unduly lengthen the trial or may be misused by the jury."

The risk-utility analysis necessarily involves a determination of the state of the knowledge and technology in the industry responsible for the design of the allegedly defective product at the time it was designed.

(ii) Factors to be Considered

In assessing whether there was, at the relevant time, a reasonable alternative design, the court will consider many factors, including:

(a) the utility of the product in question to the public as a whole and to the individual user, which is to be contrasted against the product with the alternative design);
(b) the likelihood the product will cause harm in its intended use;
(c) the severity or magnitude of the harm that may be caused by the product;
(d) the availability and consequences of adopting the alternative design;
(e) the probability and severity of harm that may be present in an alternative design;;
(f) the effects of the alternative design on the product's function and cost;
(g) the manufacturer's ability to spread any costs related to improving the safety of the design; and
(h) whether the product was adequately tested for risks of harm before being sold to the public. (A manufacturer must take steps to identify foreseeable risks involved in the use of its product and cannot use its own lack of testing to argue that the harm was not foreseeable.)

Although they are not factors which address the risk-utility test, the court will also consider the following additional factors:

(a) whether the design complied with any applicable statutory, regulatory or industry standards. (Showing that a product complied with a particular standard will not absolve liability, but it will, however, greatly assist in showing that the design was reasonable; and
(b) the ability of the plaintiff to have avoided injury by careful use of the product. If the manufacturer is able to point to the plaintiff's misuse of its product to establish that its design was not defective, or it can use this evidence to establish contributory negligence on the part of the plaintiff.

None of these factors alone are determinative of whether there is a design defect. They are not given the same weight, but are considered together and balanced by the court to reach a conclusion.

In some cases, the product produced by a manufacturer will be inherently risky and there is no way for the manufacturer to avoid such risk in the design process (despite keeping up with industry standards or adopting state of the art technology). In situations where a consumer suffers a loss as a result of one of these inherently risky products, a manufacturer will not necessarily automatically be at fault. Rather, courts will engage in a risk-utility analysis to determine if the manufacture ought to be held liable. The risk-utility analysis is relevant for the purposes of our discussion given that it can be a critical step in the analysis of determining if a manufacturer will be found negligent with respect to design.

(3) Failure to Warn

If a manufacturer knows, or ought to know, of a danger associated with the use of its product, the manufacturer has a duty to warn all consumers of the potential danger.

By the same token, users of products have a duty to read-and heed-warnings and instructions supplied with a product, or bear the consequences of any resulting injuries. All warnings must be reasonably communicated and manufacturers need to ensure that any warnings supplied with a product are visible, permanent, clear and unambiguous.

The manufacturer or distributor must also warn of any foreseeable misuse of the product. Where a danger is obvious, such as the sharp blade of a knife, a manufacturer has no duty to warn of the danger of injury. Likewise, if a product is only designed for use by a skilled person, rather than the general public, there is no need to warn against the danger that should be obvious to such a skilled person.

The duty to warn and the level of warning must be commensurate with the risk of harm and the complexity of use. Where a manufacturer or distributor becomes aware of a danger in the use of the product, the courts have imposed a very high standard upon them to devise a program to alert owners about the potential danger. Generally, post-sale warnings to customers about defects must contain clear language bringing the danger to the customer's attention and must clearly advise the customer to stop using the product.

Manufacturers and distributors not only have an ongoing duty to inform users of all known defects or dangers associated with a product, but they must also warn them where there is reason to suspect that there is a danger associated with the use of the product. Accordingly, failure to act early in initiating a public warning campaign could result in the manufacturer or the distributor being liable for any injuries caused as a result of the suspected defect.

There are significant statutory consequences to inadequate and improper marketing. For example, the *Canada Consumer Product Safety Act* makes it an offence to label or package a consumer product in a manner that creates "an erroneous impression regarding the fact that the product is not a danger to human health or safety", or that is misleading as to safety certification or compliance with applicable standards. It is also an offence to advertise or sell such a product.

Industry Standards

Current and most widely used industry standards play an important role in determining the requisite standard of care. Further, a manufacturer's ability to demonstrate that its product was in line with industry standards (or government standards), can be sufficient to demonstrate that it has met the requisite standard of care. Generally speaking, evidence that a product manufacturer

met industry or regulatory standards, is admissible at trial. However, proving that one's product meets industry standards is not determinative. If for instance an entire industry practice does not meet the standard of care, demonstrating alignment with industry practice would be an inadequate defence. Similarly, compliance with regulatory standards can be considered minimum standards which the manufacturer has to meet. While failing to meet regulatory standards is detrimental to any defence, that such standards were met may not absolve a manufacturer of liability, particularly if the standard being applied generally in the industry is above the minimum regulatory standard.

In the case of *Piche v Lecours Lumber Co* 1993 CarswellOnt 2306, the Court described the standard to be one of "reasonable care in the circumstances" and stated the following:

> 466 Accepting that the standard is one of reasonable care, that standard was met by adopting and following industry or government imposed standards. It seems clear that compliance with such standards could not foreclose, in certain circumstances, findings of negligence. At the same time, the Courts have held that there is a heavy onus on a plaintiff or claimant to show that in following the standards set by government regulation or an industry standard, the third parties were nevertheless negligent.
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> 467 In the case of adherence to industry standards, this principle was canvassed by McIntosh, J. in *Moss v. Ferguson and Latham* (1979) 35 N.S.R. (2d) 181 at 185-7 where he held, "that trade custom is prima facie proof of a standard of reasonable care and that the burden is on the plaintiff to establish that such was not the case".
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> 468 In the *Queen v. Saskatchewan Wheat Pool*, [1983] 1 S.C.R. 205 at 228, Dickson, J. held that a statutory formulation of the duty may afford a specific and useful standard of reasonable conduct.

The *Piche* decision was recently cited in March of 2019 in Ontario in the case of *Lebko v Toronto Standard Condominium Corp*. 1892 2019 ONSC 1602 as standing for the proposition that:

> 49 Where governing legislation stipulates a specific standard of care to be followed, and the defendant complies with the government standard, the plaintiff bears a "heavy onus" to prove negligence by the defendant, notwithstanding such compliance.

State of the Art Technology

Use of state of the art technology by a manufacturer bears relevance to the strength of a manufacturer's defence regarding product liability. This is grounded in the understanding that because Canadian law does not embrace the notion of strict product liability, plaintiffs will often argue that a manufacturer was negligent in manufacturing, designing, or labeling a product. In this analysis the manufacturer's technologies as measured against state of the art technology of the time is therefore relevant and admissible.

The case of *Baker v Suzuki Motor Co.*1993 CarswellAtla 99 is cited as an example of such consideration. In that case, the manufacturer knew that one of its motorcycle models would leak a small amount of gas because of the design of the gas cap used. However, the gas cap was state

of the art technology, and the manufacturer's inability to produce a safer alternative was relevant to the Courts finding that the manufacturer was not liable.

However, similarly to the case of industry standards (discussed above), the above does not mean that a manufacturer can avoid liability because of its use of state of the art technology. In certain circumstances, a manufacture can be found liable even though it used state of the art technology. In the case of *Brunski v Dominion Stores Ltd. 1981* CasrwellOnt 591*,* a case that involved exploding soft drink bottles, the Court found that the manufacturer was liable despite the fact that it used state of the art technology. One of the factors contributing to this conclusion was that food producers are subject to a heightened standard of care. Notwithstanding its finding of negligence on the defendants, at paragraph 32 of the decision the Court stated:

> 32 As for negligence in design, I have not been convinced, on the evidence before me, that the design was negligently done with regard to the state of the art at the time this bottle was produced in 1976. It was suggested that a plastic covering would have reduced explosions and the damage caused by them. The evidence was that the cost of the plastic covered bottle is something like a dollar, which is significantly greater than the 55¢ or so that the uncovered bottle costs to produce. There is no evidence that there was any knowledge of this alternative process in existence anywhere at the time of the production of the bottle. Nor was there any evidence that plastic coverings were in use anywhere then. The fact that government and the industry are *now* considering this covering does not mean that in 1976, a reasonable person in the situation of either of these two defendants should have been expected to use that technology (emphasis added).

An additional nuance that is highlighted by the *Brunski* decision is that when measuring a manufacturer's product against state of the art technology, the relevant measure is the state of the art technology at the time the manufacturer produced the product in dispute. In other words, a manufacturer's product will not be measured against current state of the art technology for a product produced in the past.

The *Brunski* decision was cited by the Alberta Court of the Queens Bench in September of 2019 in the case of *St Isidore Co-Op Limited v. AG Growth International Inc* 2019 ABQB 793 for the proposition that:

> 43 In determining what the manufacturer knew or ought to have known, the Court will "consider the state of knowledge and technology at the time the product was manufactured in assessing negligence in design" so as not to fall into the trap of assessing the issue with the wisdom of hindsight.

From the perspective of implantable products, evidence of state of the art technology factored into the court's decision in *Harrington v. Dow Corning Corp.*, 2000 BCCA 605, 193 D.L.R. (4th) 67 (B.C. C.A.), at paras. 42-43 and 45, leave to appeal to S.C.C. refused, [2001] S.C.C.A. No. 21 (S.C.C.):

> 42 At the risk of oversimplifying a complex decision-path, I venture to suggest the first step in every products liability case alleging negligent design, manufacture, or marketing is the determination of whether the product is defective under ordinary use or, although non-defective, has a propensity to injure. Some American authorities refer to

this step as "general causation", whether a product is capable of causing the harm alleged in its ordinary use.

43 The second step is the assessment of the state of the manufacturer's knowledge of the dangerousness of its product to determine whether the manufacturer's duty was not to manufacture and distribute, or to distribute only with an appropriate warning. It may be prudent to refer to this as an assessment of the state of the art; it may be that a manufacturer did not but should have known of its product's propensity for harm.

Risk Utility Test

The risk utility test is quite relevant for the purposes of our discussion given that it often comes up in the same breath as industry standards or state of the art technology. The roots of this test in the Canadian context can be found in the case of *Rentway Canada Ltd. v Laidlaw Transport Ltd.* 1989 CarswellOnt 23 (“*Rentway”).*

In *Rentway* one of the issues before the court was whether a vehicle manufacturer was negligent in its design of a tractor trailer, resulting in a collision of two tractor trailers and the death of both drivers. In working to determine if the manufacturer was negligent in its design, Justice Granger reviewed US case law on the issue and adopted a set of criteria from the case of *Voss v. Black & Decker Manufacturing Co*., 450 N.E. 2d 204 (1983), which would form the basis for the risk-utility test as it is now applied in the Canadian context.

In the context of implantable medical devices, the risk utility test was adopted in the decision of *Andersen v. St. Jude Medical Inc.* 2012 ONSC 3660, one of the first medical device/product liability class actions to proceed to trial in Canada.

The Court ultimately found in favour of the defendants and dismissed the action. However, the court did find that the Silzone coating did increase the risk of the device. Nonetheless, St. Jude’s was not found to have breached the standard of care. The relevant factors of the risk utility test were considered and assisted the Court in reaching its decision. In rendering her decision, the trial judge stated as follows:

60 The parties agree that the standard of care applicable to St. Jude as a medical device manufacturer required it to perform a risk utility assessment and to exercise reasonable care in doing so. They disagree on (i) the degree of certainty the defendants were required to have about the benefits of Silzone before distributing the product, (ii) the reasonableness of the product development process including the testing undertaken and the manner in which the testing results were interpreted and, (iii) the role and impact of industry and regulatory standards and practices and regulatory approval.

95 The availability of safer products to meet the same need is a factor in the risk utility analysis, but the plaintiffs' argument ignores that PVE was a known risk with the conventional valve that the Silzone valve had the potential to address. Every heart valve patient who received a conventional St. Jude valve was at a small but serious risk of experiencing this complication that is difficult to treat and associated with high morbidity and mortality. This was the need that was being addressed. The risk utility analysis did

not require St. Jude to assess whether the benefits of the Silzone valve outweighed the benefits of the conventional valve relative to their risks. Rather, it was required to consider whether the potential benefits associated with the addition of Silzone outweighed the potential risks of Silzone.

96 As well, the plaintiffs' argument is premised on the assumption that there was an increased risk with the Silzone valve over the conventional valve. In January 2000, the AVERT data showed that some Silzone valve recipients were at an increased risk of explant due to PVL, but this was not known or foreseeable at the time the valve was distributed. While in some cases the existence of a safer alternative to meet the same need can be a relevant factor in the risk utility analysis, in the circumstances of this case, this reasoning imports a hindsight analysis. In any event, the conventional valve did not meet the same need as the Silzone valve because it did not address the risk of PVE.

117 A failure to meet industry guidelines for testing is a relevant factor in the standard of care analysis, but in this case, the evidence shows that standard tests were performed that met the testing recommended by the Heart Valve Guidance and ISO standards. The essence of the plaintiffs' position is that St. Jude should have performed different tests or used alternative methods of testing or performed more tests, but there is no direct evidence that this testing was necessary or that it would have changed anything. It is not sufficient to claim that the defendants should have done more testing without also showing (a) that such tests were possible, and (b) that this would have affected the risk utility assessment and made it unreasonable for St. Jude to manufacture and market Silzone products. This evidence was lacking on both counts.

More recently, the risk utility test was cited and relied on in assisting the court to reach its decision in *Kuiper v Cook (Canada) Inc.* 2018 ONSC 6487 ("*Kuiper*"), a case which involved a proposed class action against a manufacturer for negligence in design with respect to an IVC filter (an implantable medical device). Ultimately, the certification motion was dismissed.

On the point of viable alternatives the case of *Nicholson v John Deere* 1986 CarswellOnt 965 ("Nicholson") is a case that dealt with a situation where the manufacturer was found liable due to the position of the lawn mowers battery in relation to the fuel tank. The Court found that because a viable (and less dangerous) alternative was available, the manufacture was liable. The *Nicholson* decision was also referenced and relied on the case of *Kuiper.*

Conclusion:

In the context of a Canadian product liability action, there is little doubt that evidence as to industry custom and state of the art will be admitted at trial in order to prove or disprove negligence on the part of a manufacturer. The weight given to the evidence will be determined by the trial judge hearing the case in a bench trial and in the case of a jury trial the jury will be instructed by the judge as to the potential weight which they give to the evidence.