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Compliance with Product Safety Standards as a Defense to Product Liability Litigation

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Product liability has created problems for manufacturers and product sellers for many decades. These problems have been exacerbated by the expansion of product liability laws throughout the world. In addition, there has been a proliferation of safety regulatory requirements, starting in the United States and then moving to the European Union. In addition, countries such as Japan, China, Australia, Canada, Brazil and South Africa have all recently established or strengthened their product safety regulatory regimes and requirements.

This all creates additional challenges for companies who want to and must comply with all laws, regulations and standards in any country where they sell their products. Such companies may also need to consider safety requirements in countries where they do not sell products to the extent they believe that these requirements establish a "state of the art" that they want to meet.

This article will discuss the basic kinds of defects that can be alleged in any product liability case. Next, I will discuss the law as it pertains to compliance with standards. And finally, this article will discuss the EU directives applicable to electrical products and the effect of those directives on products sold in the EU and the United States.

U.S. Theories of Liability

Manufacturing Defects

A manufacturing defect exists if the product "departs from its intended design even though all possible care was exercised in the preparation and marketing of the product." In other words, even if the manufacturer's quality control was the best in the world, the fact that the product departed from its intended design meant that it had a manufacturing defect. The plaintiff need not prove that the manufacturer was negligent, just that the product was defective. The focus is on the product, not on the conduct of the manufacturer.

Common examples of manufacturing defects are products that are physically flawed, damaged, incorrectly assembled or do not comply with the manufacturer's design specifications. The product turned out differently from that intended by the manufacturer. If that difference caused injury, the manufacturer will be liable. There are very few defenses.

Design Defects
A product is defective in design if a foreseeable risk of harm posed by the product "could have been reduced or avoided by the adoption of a reasonable alternative design" and the failure to use this alternative design makes the product not reasonably safe.

An alternative definition used by some courts is that a product is defective in design if it is dangerous to an extent beyond that which would be contemplated by the ordinary consumer.

These tests are much more subjective than the test for manufacturing defects and this subjectivity is the cause of most of the problems in product liability today. Manufacturers cannot easily determine how safe is safe enough and cannot predict how a jury will judge their products based on these tests. It is up to the jury to decide whether the manufacturer was reasonable or should have made a safer product.

Warnings and Instructions
The third main kind of defect involves inadequacies in warnings and instructions. The definition is similar to that of design defects and says that there is a defect if foreseeable risks of harm posed by the product "could have been reduced or avoided by …reasonable instructions or warnings" and this omission makes the product not reasonably safe.

Again this is an extremely subjective test that uses negligence principles as a basis for the jury to decide. This makes it difficult for a manufacturer to know how far to go to warn and instruct about safety hazards that remain in the product.

Post-sale Duty to Warn
One other theory of liability that is very important in a product liability case is post-sale duty to warn. A manufacturer may have a duty, after sale, to warn customers about hazards the manufacturer learns about after sale. This duty can arise even if the product was not defective or hazardous when sold. This duty is clearly based on negligence and involves any of the three kinds of defects described above.

Law of Design Defects

There are two kinds of design defect cases: those involving "inadvertent design errors" and another involving "conscious design choices." Design errors are like manufacturing flaws and are treated easily by the courts. The design was wrong because someone made a mistake. The mistake created a hazard and someone was hurt. In that case, there is virtually no defense and the manufacturer would usually settle the case.

The more important type of design defect case involves conscious design choices. In these cases, the design turned out as intended by the designer and manufacturer. It had the level of safety expected by the designer for the intended use. However, the product still hurt someone who claims that the product should have been made safer. The plaintiff argues that an alternative safer design should have been used and the court must decide whether this alternative was preferable.

The development of the law in this area has caused confusion. There are several tests that have been developed for helping courts and juries decide whether there was a defective design.

Test for Design Defect
The predominant test in the United States for determining whether a product was "reasonably safe" involves, as mentioned above, whether there was a reasonable alternative design available. In many states, to answer this question, the jury is instructed to consider the following factors:

- Usefulness and desirability of the product.
- Safety of the product – the likelihood that it will cause injury and the probable seriousness of the injury.
- The availability of a substitute product that performed the same function and was safer.
- Ability of the manufacturer to eliminate the unsafe characteristic of the product without lessening its usefulness or making it too expensive.
- User's ability to avoid harm by being careful when using the product.
- User's awareness of the risk, either because it is obvious or because of suitable warnings and instructions.
- Feasibility by the manufacturer to spread the risk by way of price increases or purchasing insurance.

These factors provide a more comprehensive and understandable basis for a jury to make a decision. They also provide more guidance to the litigants to evaluate their case. Also, as importantly, they provide a basis by which a manufacturer could evaluate the safety of its product before sale and decide what is "reasonably safe."

Compliance with Standards

Another complex area involves laws, standards and regulations. As part of the initial analysis, a manufacturer must identify those that apply to its product. Sometimes, that is not easy to determine or there are numerous and different ones that must be reconciled, especially if the product is sold internationally.

Official laws and regulations, such as those passed by a state or national legislature, that apply to the product's design must be complied with. If the product does not comply and this noncompliance caused the injury, then the manufacturer can be liable. Unfortunately, on the flip side, compliance with all applicable laws and regulations is not, for most products, an absolute defense in a product liability case. Therefore, a jury could come back and say a manufacturer should have exceeded laws and regulations pertaining to safety.

Similarly, industry standards and even certifications like UL are considered minimum. As a result, compliance with standards and certifications is not an absolute defense although it is pretty good evidence that the product was reasonably safe. Therefore, as with laws and regulations, the plaintiff can argue that you should have exceeded the standards. However, noncompliance is a problem if it caused or contributed to the injury. The reason is that the standard establishes a reasonable alternative design and the manufacturer has to justify why it didn't comply.

So where does this lead the manufacturer? You should meet or exceed all applicable laws, regulations and mandatory or voluntary consensus standards in the countries where you sell

products. If you don't or can't, then document the reason and make a reasonable judgment as to why your product is still reasonably safe.

This is easier said than done. First, given the plethora of U.S. and international laws, regulations and standards, it is no easy task just to identify those that could apply to your product. Then, you need to figure out which ones take precedence over others where there is overlap.

In the European Union, there are ISO standards, EN/ISO standards and then Directives. Directives are similar to laws and EN/ISO standards have more authority than ISO and ANSI standards. So some are more important to comply with. But the bigger problem is figuring out which ones apply as there can be substantial overlap. Some U.S. and EU laws, regulations and standards are general and apply to a wide range of products. Some are much narrower. Generally, you want to first look to the narrower product specific document and then look to the more general requirements. The problem is figuring out where the "gaps" are in the narrower document that are then filled by the more general document. This is difficult to do and manufacturers need to also consider interpretations and guidances concerning directives and standards that are sometimes issued by government agencies, the EU and industry groups.

EU Directives

In the United States, there are various industry standards, some of which are voluntary and some of which are mandatory in that some federal, state or local agency adopted the standard and made it the law.

In the European Union, they developed a variety of directives that pertain to health and safety. A manufacturer must meet the requirements of applicable directives and obtain a CE mark to sell their products in Europe. These directives must be enacted by each member country of the EU during a given period of time. However, each country can try to modify the directive to meet their own needs and desires. Some directives allow such leeway, others don't.

One problem with these directives, some of which are described below, is that they may become worldwide safety requirements and raise the "state of the art" beyond what is required in the U.S. Therefore, if a manufacturer sells a "safer" product in Europe that complies with the EU Directives and a "less safe" product in the U.S. that complies with, let's say, ANSI standards, this could be a problem. Obviously, the safer product constitutes a "reasonable alternative design" and can be used by the plaintiffs to support a case of defective design.

So, you need to be especially careful when you have a safer product sold in Europe or elsewhere. While U.S. law allows different levels of safety in a product (i.e. automobiles), you may need to justify the reasonable safety of your less safe product to a government agency or jury sometime in the future.
I want to describe some of the Directives that generally apply to electrical products.

General Product Safety Directive ("GPSD")

GPSD, Directive 2001/95/EC, was adopted in December 2001 for implementation no later than January 15, 2004. This directive establishes general safety requirements of many products, even those that would not be considered consumer products. This directive provides that

manufacturers must sell safe products, defined as follows:

"safe product" shall mean any product which, under normal or reasonably foreseeable conditions of use including duration and, where applicable, putting into service, installation and maintenance requirements, does not present any risk or only the minimum risks compatible with the product's use, considered to be acceptable and consistent with a high level of protection for the safety and health of persons,

There is also a reporting requirement for products that do not meet the above safety requirement. It says:

Where producers and distributors know or ought to know, on the basis of the information in their possession and as professionals, that a product that they have placed on the market poses risks to the consumer that are incompatible with the general safety requirement, they shall immediately inform the competent authorities of the Member States thereof…

There are also EU documents issued after 2004 which discuss the relationship of GPSD to products that fall under other directives, such as some of those discussed below.

The EU is undertaking further implementation and revisions to GPSD so that it conforms to their so-called "New Legislative Framework" which contains measures that have the objective of removing the remaining obstacles to free circulation of products between EU Member States.

Low Voltage Directive ("LVD")
The most recent edition of the EU's Low Voltage Directive is dated December 12, 2006. It is designated "Directive 2006/95/EC" and includes a conformity assessment procedure that is applied to equipment before placing it on the market. Compliance with this directive should confirm that the equipment meets the EU's Essential Health and Safety Requirements (EHSRs) which such equipment must meet. The intent is for this Directive to cover all health and safety risks, thus ensuring that the electrical equipment is safe for its intended use. The manufacturer, and not a third party, is allowed to perform the conformity assessment. This Directive will be modernized and is part of the so-called "New Legislative Framework" which will deal with market surveillance, conformity assessment and accreditation and the meaning of the CE mark.

Electromagnetic Compatibility (EMC)
This Directive was enacted in 2004 and designated Directive 2004/108/EC. The purpose of the directive is to keep the side effects of electromagnetic interference under reasonable control. There is a new guide to this Directive dated February 8, 2010

Machinery Directive
The original Machinery Directive was passed in 1998. It subsequently was replaced in 2006 by Directive 2006 42/EC. This new directive is also part of the "New Legal Framework" which promotes harmonization through a combination of mandatory requirements and voluntary harmonized standards. The EU just issued an extensive guide to the 2006 Directive, dated June 2010. There are significant electrical safety requirements in this directive. In addition, there may be portions of other directives that apply to machinery.

Medical Device Directives ("MDD")
EU Directives related to medical devices were harmonized in the 1990s. There are three directives that form the main legal framework for such products: active implantable medical devices (Directive 90/385/EEC), medical devices (Directive 93/42/EEC) and in vitro diagnostic medical devices (Directive 98/79/EC). These directives have been supplemented by additional directives, such as Directive 2007/47/EC, and the EU is considering revisions to this legal framework which will strengthen requirements for safety and surveillance.

The original Machinery Directive excluded medical devices. The current 2006 version does not exclude them and the EU issued an interpretation in August of 2009 on the relationship between the Machinery Directive and the active implantable portion of the MDD, Directive 93/42/EEC.

CE Marking

The CE mark is supposed to indicate that the product to which this is attached conforms to all relevant safety, health, environmental and other requirements in harmonized EU legislation. And all products in certain categories where EU directives exist must have the CE label attached to be sold in the EU. This includes electrical products.

Depending on the applicable directive's requirements, conformity assessment can be performed by the manufacturer or by a "notified conformity assessment body." Improperly affixing the CE mark to a product has significant legal ramifications, including criminal sanctions.

As with U.S. standards, while meeting the EU's requirements in these directives allows the manufacturer to attach the CE mark, these requirements are a minimum and an individual member state can impose additional safety requirements for products sold in their country. Unfortunately, this diminishes the usefulness of harmonized standards based on directives.

Also, the CE mark has no legal significance in the U.S. Compliance with EU Directives can be helpful in proving that the product sold in the U.S. was reasonably safe in the U.S., but there is no extra weight given to the fact that a European legislative body enacted these requirements. This is no different than the weight that is given to U.S. enacted laws and regulations.

Conclusion

Product liability in the U.S. is based, in large part, on the plaintiff offering a safer design and arguing that the manufacturer should have sold this safer product. EU requirements are, in many respects, much more rigorous than U.S. requirements. They are more detailed and overlapping and difficult and costly to comply with. Manufacturers could decide to sell only the safest product in the U.S. and elsewhere, even if that safer product is not required by laws and standards.

The trouble is that competitors might sell products with different levels of safety that might put the manufacturer at a competitive disadvantage. This is a costly decision for any manufacturer. Selling a safer product in the EU than you sell in the U.S. can result in significant liability. Selling a safer product in the U.S. that is not required by laws or standards may reduce liability by being more defensible. Unfortunately, it could also result in reduced sales that exceed any

savings in litigation.

This can be a tough choice for a manufacturer from a financial, commercial and ethical standpoint. But one that must be made.

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