Available online at www.sciencedirect.com
ScienceDirect
Safety Science 45 (2007) 11–30
SAFETY SCIENCE
www.elsevier.com/locate/ssci

Liability and its influence on designing for product and process safety

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Abstract

This paper sketches the regulatory framework within which design takes place and then focuses on tort liability in the USA and European Union domains, its doctrines of fault-based liability and strict liability, and their relevance to product and process design. It also discusses new environmental liability laws and other recent developments which have design implications. Finally, it discusses company decision-making on product and process design, a context in which the deterrent effect of tort liability, and many competing factors, are considered.

Keywords: Safe design; Tort law and liability; Company design decisions

1. Introduction

Developed nations encourage corporate development of new products and industrial processes, and rely on various social controls to assure that these technological advances do not pose unreasonable risks to health, safety, property, and the environment. The social controls, in the form of government regulation, private self-regulation, market forces, and tort liability doctrines, are expected to be responsive to risk and harm. Thus, the social controls are expected to have preventive and corrective functions: to shape or influence the design and preparation of new products and processes so they will not be harmful when they are put to their intended use; and if harmful after being put to use, to bring about

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0925-7535/$ - see front matter
doi:10.1016/j.ssci.2006.08.022

corrective changes in design or modes of use in order to reduce residual risks and prevent recurrence of the harms.

Among the social controls in the USA and European Union, tort liability has gained prominence for several reasons. It can be applied to the broadest range of harm-causing products and processes. It can be quickly activated when new evidence emerges that a particular advance is injurious. It can be the most sudden and severe social control, capable of quickly causing economic loss for a company whose product or process is found to be harmful. And it is feared by companies and therefore has a preventive function in that it deters companies from disregarding risks when designing new products and processes.

2. Progressive risk reduction and safe design

Technological advance in the form of a new product or industrial process often poses risks to health, safety and the environment. The product may cause harm to consumers or workers who use it and to bystanders passively exposed. It may cause environmental contamination during its life cycle and long after its disposal. The process may similarly harm workers, communities and the environment. For both types of technological advance, the harms may arise inadvertently from normal or intended use as well as from error, ignorance, accident, deliberate misuse and other special circumstances.

In theory, a sequence of activities reduces the incidence of such harms over time. During the pre-market or developmental phase of a new product or process, attention must be given to eliminating hazardous features from its design, testing prototypes, and defining safe use procedures, to the extent feasible, and certainly to the extent required by regulation. Then, during the market phase when the product or process is put to use, best practices for implementing the safe use procedures should be followed and any residual risks should be promptly identified and evaluated. Finally, in the maturing market phase, the residual risks should be addressed by remedial measures, such as design change and improved safe use procedures.

In practice, pre-market efforts to eliminate risk are usually incomplete because of cost and considerable uncertainty about hazardous features, especially if the technology is new and complex (e.g. genetically modified crops or processes using nanotechnology). Another reason is that most corporate attention at that time is usually given to assuring that the product or process will work as intended, function efficiently, meet pricing objectives for competitive advantage, and appeal to likely customers and users. Thus, the market phase, when such advances are put to actual use, provides the opportunity for identifying residual risks and for subsequently taking remedial actions, such as design or operational change, that will eliminate the residual risks or at least reduce them to a level which is acceptable to customers, users, agencies, and the public.

This process of progressive risk reduction encourages rapid entry of technological advances into commerce, but is problematic in several respects. It allows companies to do less about identifying and eliminating foreseeable risks when designing the advances in the pre-market stage, unless required by regulation (e.g. food and drug regulations), and induces them to wait for harmful consequences to accrue in the market phase. It thereby causes workers, the public, and the environment to be exposed to, and harmed by, a stream of new products and industrial processes which are insufficiently safe. And by not requiring that safety be more rigorously addressed in designing these advances during the pre-market phase, the progressive approach to risk reduction often leads to product recalls, process

shutdowns, liabilities and other business losses until companies subsequently make costly design changes or take other remedial actions.

3. Social controls for reducing risk

3.1. Marketplace

Developed nations rely on several systems of social control to progressively reduce risk. The most basic system is the marketplace, wherein industrial customers, household consumers and other users choose among competing products or processes which are similar in terms of function and cost, and usually express preference for those which can be used with less risk and regulatory burden. Feedback from the marketplace, in the form of such preferences, can quickly force a company to change to an inherently safer design, as in the case of household products or tools or industrial processes. But market forces have proven to be an insufficient means of promoting safety for many reasons, and this has caused greater reliance on regulation.

3.2. Self-regulation

Another system for controlling technological risk involves corporate and professional self-regulation, which has been shown to reduce risk by influencing the design of products and processes. It is certainly encouraged in developed nations, and driven by corporate and professional associations which strive to avoid government regulation. As a result, various privately developed safety rules, protective standards, quality controls, and self-certification programs promote safer design and safer means of using products and processes. The self-regulatory approach to industrial safety is a particularly strong and reliable tradition in Germany where trusted industrial and engineering organizations, such as T.Ü.V., develop standards and procedures, some of which are later adopted by government regulatory programs. Other notable forms of self-regulation include the Codes of Management Practices developed by the chemical process industry in many nations. However, the credibility of self-regulation is quickly diminished when harms occur, and is mistrusted by many because of its potential for bias, lack of transparency, and inadequate self-enforcement, as in the USA.

3.3. Government regulation

The most visible system of social control over technological advance in each developed nation is its universe of government regulation. Empowered by laws or directives, public agencies enact many types of regulation: for example, rules and standards which may prescribe features of design and use for a specific type of product or process, establish risk and exposure parameters, require testing and monitoring, and impose pre-market approval and permit requirements. These are supplemented by other rules which provide for enforcement and sanctions against companies which fail to comply.

Regulation has become the dominant approach for reducing the risks posed by industrial *processes* which discharge pollutants into air and water and generate toxic wastes during routine operation. As a result, the design and operation of many industrial processes is shaped by a multiplicity of regulations such as construction and operating permit

requirements, ambient environmental standards and discharge limitations, and detailed rules for waste handling and disposal. Other sectors of risk regulation also have major influence on process design and operation, such as rules and standards which protect worker health and safety and prevent major accidents.

Regulation to make *products* safe is also prevalent in developed nations, and is particularly comprehensive for medical, food, automotive, and chemical products. Most other types of products are not regulated in the USA. But in the European Union (E.U.), enactment of the Machinery Directive in 1998 provided a coherent mandate for regulating an expanding universe of products, starting with machinery products activated by a power source. Machines are required to be safe according to generic criteria which reference various European and international standards. The standards address essential health and safety aspects of a product's design and fabrication, and prescribe methods of hazard analysis and risk assessment for the manufacturers to follow.

For example, a European standard, EN 292-1,2 is being applied to define steps in the machine design process that ensure adequate incorporation of safety considerations. Member nations may set additional requirements consistent with the Directive, but may not restrict or impede conforming products from entering their markets or from being put to use therein. Although the Directive excludes many products such as storage tanks and pipelines for fuels, flammable liquids and dangerous substances, transport equipment, and machinery for nuclear purposes, these are subject to other regulatory programs and their design and use standards. Thus, the formulation and implementation of product standards, and ultimately their harmonization across E.U. member nations, has become a major E.U. enterprise.

Since regulations are enforceable, and non-compliance is a violation of law, it is clear that companies must be attentive to existing and pending regulations that have direct and indirect implications for the design of their products and processes. For example, in the automotive sector, manufacturers must (re)design vehicles to conform to a continuum of safety and environmental regulations. In the pharmaceuticals and medical device sectors, products such as a new therapeutic drug, gene therapy or biomaterials implant must undergo extensive testing and clinical trials on human subjects to determine if they meet agency requirements regarding safety, efficacy, and quality control and can thereby be approved for public use. Obviously, such a regulatory process has great influence on the design of health care products.

Regulation also has important indirect effects on product and process design. Significant investment in a company's development of a product or process will usually not be forthcoming until there is assurance that the product or process design enables its sale and use within the parameters set by regulations. Similarly, affordable insurance coverage may not be available unless the technological advance is designed in conformity with regulatory requirements. Nevertheless, regulations do not fully guarantee safe use, and subsequent development of more stringent regulations to address residual risks which become apparent in the market phase is a costly and conflicted process. For these and many other reasons, nations supplement regulation with a fourth approach to safe design and use.

3.4. Tort law

The fourth method of social control for achieving product and process safety is provided by tort liability doctrines and special liability systems. Basic principles of tort liability

are set forth in the civil codes of E.U. nations, E.U. Commission Directives, and the common law of the USA and the UK. Their main purpose is to enable compensatory justice by establishing the right of a person harmed by another party's negligent behaviour or unreasonably dangerous product or activity to seek compensation for damages from that party in court. In the USA, punitive damages may also be awarded to the victim if it is determined that the party causing the harm acted with gross indifference to the safety of others. Thus, tort law empowers courts to impose liability on a company whose product or process inadvertently caused harm when the claims brought by the injured person meet specified doctrinal criteria, comply with procedural and evidentiary rules, and are presented with sufficient factual support.

4. Tort law and liability

4.1. Basic features

Tort law in the USA and the E.U. domains contains several liability doctrines, two of which are most relevant to product and process design and commonly referred to as fault-based liability or negligence, and strict liability. Simply put, negligence doctrine requires that the injured party prove that the company or other party brought to court as the defendant in a tort lawsuit is legally responsible for the harm because its behaviour failed to meet a legally-defined standard of care owed to the victim, and that this flawed behaviour was the main or proximate cause of the injury for which compensation is sought. Thus, a company may be found liable if it is convincingly shown that it behaved inadequately or erroneously when it designed, tested, made or used its product or process or instructed customers or others in its use, and that such behaviour was the cause of the claimant's injury.

Strict liability, in brief, requires proving that the company sold a product or process which was unusually or unreasonably dangerous, and that this defective condition was the main or proximate cause of the harm at issue. Strict liability therefore eliminates the need to prove that a company behaved inadequately or erroneously, and may apply even if the injured party was not the purchaser of the product. As with negligence, persons with compensable injuries may include bystanders and rescuers in addition to purchasers and users.

These are mere summaries of complex doctrines, which differ in many details from state to state in the USA. and from nation to nation in the E.U., despite ongoing efforts to harmonize tort law in each of the two domains. Thus, generalizations cannot be carried too far without being misleading. In addition, the applicability of the doctrines and predictability of outcomes in each state or nation depends greatly on the facts of each case, on the rules governing legal procedures and the admissibility of evidence, on the competency of the lawyers and judges involved, and other aspects of the legal infrastructure and its larger cultural context.

Tort law is also highly dynamic because it is continuously being invoked to deal with new factual scenarios. For example, consider the issue of vicarious liability. Should a company be held liable for harm caused by the negligent behaviour of another party? In many nations, courts have held that a company is responsible for the harmful consequences of an employee's negligent performance of assigned work. Should this principle be applied to a case in which an employee intentionally disregarded the company's elaborate safety procedures? To a case where he had previously and repeatedly deviated from company procedures? What if the harm was caused by the negligent act of an independent engineering

contractor, a design consultant, a subcontractor, or materials supplier? As such cases arise, the basic principle of vicarious liability grows over time into a complex sub-sector of negligence law.

Courts are also responsive to changing societal conditions, perceptions, and values, and to the enactment of other laws, in interpreting negligence doctrine. For example, emotional distress is gradually being recognized as a compensable injury, and some courts have gone so far as to recognize bystander trauma, due to witnessing a particularly emotional and tragic event. Other topical examples include the following; it has been predicted that courts will interpret negligence doctrine to hold companies liable for failing to minimize harm during the emergency response following a facility accident, and also for failing to prevent harms caused by terrorists, because these risks are increasingly seen as foreseeable in some industrial contexts.

Whereas regulations are aimed at specific targets (e.g. pharmaceutical products, nuclear facilities), usually prescribe in technical detail what must be done for safe design and use, and require considerable investment of public resources for their development and enforcement, tort liability doctrines differ in many respects. They are briefly stated, are generically applicable to virtually all companies making a product or operating an industrial process, and provide qualitative criteria, which are somewhat vague and ambiguous until interpreted and applied by a court in the factual context of a specific case. Between these two extremes stand the special liability systems, which combine features of regulation and liability law in that they specify the compensable incidents or types of harm, apply only when certain types of firms or activities or substances are involved, and use administrative or judicial forums to impose liability and penalties.

4.2. Special environmental liability doctrines

Historically, tort liability has been used only to redress personal injuries, and in some nations, also to compensate for damage to private property. But with increasing recognition of the value of environmental quality over recent decades, the need for specially crafted liability systems to provide remedies for damage to public infrastructure and natural resources has become apparent. As a result, numerous special liability laws have been enacted in the USA and E.U. nations to enable agencies to impose clean up costs, other remediation expenses, and penalties on companies which improperly dispose of hazardous materials and wastes, spill fuels and toxic substances, contaminate water supplies, or cause other environmental harms. An EU Directive on Environmental Liability, to take effect in 2007, and other E.U. initiatives, will require member nations to extend such liability to specific industrial or other activities involving genetically modified organisms.

These liability systems are triggered by specific types of harmful industrial incidents, such as a spill or other accidental release of a toxic substance, and usually do not require proving that the company activity involved was conducted in a negligent manner. This signals companies that the products and processes they use should be designed so that their capability for creating such harms is minimal. Another important distinction from tort liability is that environmental liability systems usually require that compensation be paid to public authorities and do not provide for personal compensation. If a person has been injured as a result of an environmental harm, that person usually must turn to tort liability for redress in a separate legal action. However, it should be noted that these are generalizations about many differing environmental liability systems.

4.3. Deterrent effect

Tort liability can only be imposed by a court after a lawsuit is successfully brought by an injured party, but the qualitative criteria for holding a company legally responsible and the prospect of liability are well established and known. Environmental liability is triggered by certain harmful incidents, and its features are even more certain and known. It is therefore generally assumed that information about prospective liability has the effect of deterring a company from giving insufficient attention to the harms and losses their product or process may cause. It is further assumed that the deterrent effect is amplified by the foreseeable transaction costs of defending against liability claims (e.g. fees for attorneys and experts), which can exceed liability awards in scenarios where many have been harmed by a widely sold product or a major accident at a process facility.

Numerous studies and personal experience indicate that most companies are, to a great extent, rational actors and therefore attentive to such potential losses and the threat they pose to their economic health and reputation. Thus, companies consider potential liability when designing new products and processes in the pre-market phase, and are thereafter prompted by the occurrence of harms and actual liability in the ongoing market phase to consider redesign.

But company deliberations about potential liability and its implications for design take place in a business context where safety measures must be evaluated as to their technical feasibility and their costs and benefits. Thus, the likelihood of risk, harm, liability and other loss consequences needs to be considered by the company, in conjunction with other factors such as the availability of affordable insurance, investor interests, competitive pressures, productivity and profitability. Some of these factors may outweigh or blunt the safety-forcing effect of liability on product and process design in the business decision context. With this in mind, we now discuss the uncertainties and vagaries of tort liability, some national differences, and subsequently review the competing considerations involved in the business decision process.

5. Liability and injurious products

5.1. Negligence

Negligence theory has been invoked in a multitude of cases, across many nations, in which workers and consumers were harmed as a consequence of using a product as the manufacturer intended, or harmed as bystanders to another person's use of the product. In addition, courts increasingly find that harm arising from misuse of a product is also compensable when the type of misuse was common and known to the company. On the other hand, courts frequently deny the claimant if the harm was caused by a product whose dangerous feature is common knowledge and was obvious to the user (e.g. alcoholic beverages).

All cases in which a manufacturer of an injurious product has been held liable for harm due to negligence, in both the USA and the E.U., have been based on the finding that the negligence involved one or more of the following types of behaviour: selling a product which was injurious because it was *defectively manufactured*, or *defectively designed*, or *defectively presented* to customers and users in that it lacked the warnings and instructions needed to assure its safe use for its intended purpose.

A *defectively made product* is generally one that the manufacturer sells without realizing that the product fails to meet its own design specifications. The injured claimant will need to prove negligence in the manufacturing process, such as inadvertent use of inferior material or components (e.g. corroded metal, impure ingredient), a flaw in production or assemblage (e.g. machining or batching error), or inadequate quality control (e.g. inadequate testing, inspection, screening).

A *defectively designed product* is a more complex concept, and there is probably no simple and succinct way of defining it. Generally one can say that it pertains to a product with a design feature that makes the product unsafe for its intended function, during its intended lifetime, when used under foreseeable circumstances. The design feature may relate, for example, to its operational or functional characteristics, the quality of the materials or components specified by the maker, its controls, or its safeguards against misuse. A technologically sophisticated product presents the most difficulty for the claimant because it calls for considerable and costly expertise to prove that any of such features were designed by the manufacturer with insufficient regard for the safety of users or bystanders, and that such a feature was the main cause of the injurious result.

Thus, it must be proven that the manufacturer's conceptualisation of the product, embodied in its design specifications, was flawed in a manner which was not sufficiently mitigated by the warnings and safe use instructions it provided to purchasers and users. To prevent superficial or excessive claims of design defect, many courts now require that the claimant must also prove that an alternative design of functional equivalence was available to the manufacturer, was technically and economically feasible for the company to make, would have attracted the same purchasers, and would have avoided the harm.

A *defectively presented product* is generally one that cannot be safely used as intended because it is not accompanied by sufficient warnings to the foreseeable user about its hazardous features, or by sufficient instructions which would enable the user to safely operate, store, and dispose of the product. It is by far the most common type of product liability claim because it is easy to make, and courts have been quite receptive to arguments that the warnings and instructions that had been provided by the manufacturer were insufficiently informative, or failed to attract the user's attention. With the increase in migrants to developed nations who are not literate in the national language, courts increasingly find a company's warnings or instructions defective for not being presented in universal symbols or multiple languages when it was foreseeable that such persons were at risk and could only be effectively informed by these means.

It is generally assumed that manufacturers prefer to address a hazardous product problem by amplifying warnings and instructions, rather than by doing more costly design change, in order to prevent harms and liability claims.

5.2. Strict liability

Strict liability theory may also be invoked by the person claiming harm from using or being exposed to an injurious product. The majority of state tort law systems in the USA have adopted section 402A of the Restatement 2d of Torts, which provides that "one who sells a product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property", and that this rule applies even if "the seller has exercised

all possible care in the preparation and sale of his product, and . . . the user or consumer has not bought the product from or entered into any contractual relation with the seller''. Many state courts have extended the rule to bystanders and have developed other modifications, including some, however, which create exceptions or defences to the disadvantage of the claimant. Thus, strict liability focuses on the dangerous condition of the product, and does not require that the claimant prove behavioural fault by the manufacturer.

In the E.U., the 1985 Directive on Liability for Defective Products requires that member nations bring their laws into conformity with this Directive's mandate for strict liability, a harmonization process which is still ongoing. Articles I, IV and VI of the Directive provide for strict liability: ''The producer shall be liable for damage caused by a defect in his product''; ''The injured person shall be required to prove the damage, the defect and the causal relationship between defect and damage''; and ''A product is defective when it does not provide the safety which a person is entitled to expect, taking all circumstances into account . . .''

But the Directive precludes strict liability for product defects that were not discoverable due to the state of scientific and technical knowledge when the product was sold (the ''development risk'' exception), and for product defects that were due to company compliance with mandatory government regulations. These limits on strict liability in the E.U. have not been as authoritatively expressed or broadly applied in the USA where there is no national consensus on these exceptions which are commonly referred to as ''the state of the art'' defence and the ''regulatory compliance defence.

Experience with strict liability in the USA and E.U. domains is mixed. Although strict liability focuses on the quality of the product when sold (whether it is defective) and excludes a requirement that the claimant prove negligent behaviour or other fault by the manufacturer, the types of defective products for which companies are held strictly liable are those which have a manufacturing defect, design defect or presentation (warning or instruction) defect. Since these three categories of product defectiveness parallel the three categories of negligent behaviour regarding injurious products, many feel that there is not much of a substantive difference between the two theories of liability, and that ultimately the main difference is merely semantic in many cases.

Nevertheless, strict liability has been a stimulus for litigation and proven advantageous to many claimants in the USA, particularly for injuries caused by asbestos and a few other ubiquitous products that are intrinsically hazardous. There is no evidence, however, that strict liability has had similar effect in the E.U. This is probably due to several differences in the legal systems. In the USA, a judge presiding over a lawsuit is capable of adopting or adapting strict liability doctrine for a state legal system and many have done so readily, at least until recently. But in the E.U., a cumbersome legislative process is required and many nations have made slow progress in conforming their laws to the E.U. Directive. Among the many other differences, the time period in which a strict liability suit may be brought is more limited under the E.U. Directive than it is in the legal systems of many US states. Further, most E.U. nations do not permit claimants to hire attorneys on a contingent fee basis, unlike the USA where states permit claimants to retain an attorney on the basis that they will pay for services only if they prevail and damages are awarded.

Fear that strict liability will be unduly harmful to business fuels continuing efforts to restrict its applicability in both domains. In the USA, many courts now require that proof of a ''. . . defective condition unreasonably dangerous to the user . . .'' be supported by a risk-benefit analysis rather than the previously favoured and highly subjective consumer

expectation test. This trend is reflected in the Restatement 3d of Torts, the most recent version of this influential guidance developed by the American Law Institute, a private organization. Those state courts which adopt this feature of the Restatement 3d will essentially convert strict liability claims of design defect and presentation defect into claims in which the negligence of a company in designing or presenting a product is at issue. Thus, many predict the gradual demise of strict liability for injurious products in the USA. In addition, industry attorneys are arguing, often successfully, that federal statutes and regulations which apply to certain types of products such as drugs, medical devices, pesticides, and vehicles have pre-emptive effect and bar liability lawsuits against the makers of such products.

A similar purpose to weaken strict liability is at work in the E.U. even though strict liability has had no discernable effect. As noted earlier, the 1985 E.U. Directive on Liability for Defective Products, which authorizes strict liability, exempts products from such liability when their defects arise from compliance with mandatory government regulations. Since enactment of the E.U. Machinery Directive in 1998, which covers many types of machinery and which has been amended to also cover additional products, the E.U. and member nations are engaged in a major effort to create a universe of mandatory product standards. Other laws in the E.U. domain also provide mandatory standards for drugs and various consumer and industrial products. Thus, it appears that these regulatory developments will, over time, substantially shrink the applicability of the E.U.'s 1985 Directive on strict liability.

5.3. Defences

In courts in the USA and E.U. domains, manufacturers have ample opportunity to defend against claims based on negligence and strict liability doctrines, and may choose to be represented by their insurers, since insurance contracts for coverage of liability to "third parties" usually provide that the insurer has a duty to defend its client against such claims. At the outset of the trial, the company named as the defendant can petition the court to dismiss a claim on the grounds that the claimant failed to present a case sufficient to be heard by the court, or that the claim is pre-empted or precluded by another law or regulation, or that the time for bringing the lawsuit has lapsed, as noted above. If these petitions are denied and the trial proceeds, company attorneys will then try to refute key elements of the claim by presenting opposing legal interpretations of the doctrines, by disputing the facts presented by the claimant, by trying to establish that the harm was caused by the claimant's unforeseeable misuse of the product or the claimant's own negligence, and by disputing and undermining the claimant's causation argument.

Defence strategy may also involve petitioning the court to rule that certain evidence the claimant wants to introduce and use is inadmissible under generic rules of evidence. In the USA courts strive to preclude use of evidence that has an insufficient technical or rational foundation. This often creates a major if not fatal obstacle for a claimant who needs to prove disease causation which has not been recognized by "mainstream science", or needs to prove that a reasonable alternative design was available and feasible in order to establish design defect. Similarly, courts often preclude evidence that seems broadly relevant or has emotional appeal but is of dubious value for determining whether a manufacturer was negligent or a product was design defective in the specific case at hand. For example, evidence that following the claimant's injury, the manufacturer changed the design of the

product may be ruled inadmissible. The manufacturer's defence may also be frustrated by evidentiary rulings, as in cases where courts rule that evidence of no prior injury claims is inadmissible regarding issues of negligence and design defect in the particular case at hand.

A particularly important defence in the E.U. is the "development risk" defence. It enables a company to prevail against a strict liability or negligence claim by proving in court that the risk or defect at issue could not have been detected at the time the harmful product was sold, given the state of scientific and technical knowledge at that time. E.U. nations have discretion as to whether to allow this defence to be used, or to define it differently. French courts, for example, have excluded this defence in cases involving contaminated blood transfusion products, after a national scandal involving the deliberate sale of such products was revealed, and the exclusion has been expanded by legislative action in France to cases which involve the producers of any products derived from the human body.

Somewhat similar is the "state of the art" defence allowed in many states in the USA. However, courts have used at least three different definitions of "state of the art". Some have said it means merely showing that the manufacturer followed the customary practice of its industrial sector. Others have more stringently defined the defence, requiring that the manufacturer show that it did what was technically and economically feasible at the time of sale. And other courts have applied the most stringent definition, requiring the company to establish that it did what was technically doable irrespective of economic feasibility or other business considerations.

Industry and government strongly support this type of defence as necessary to prevent liability from stifling technological innovation. Critics of this defence claim that it has created a huge loophole for industry sectors which have not sought to advance safety or reduce uncertainties regarding their products. The defence is likely to become especially controversial in the context of future cases involving biotechnology products which pose many uncertainties, such as genetically modified crops, foods, and pesticidal micro-organisms intended for agricultural use.

6. Liability and injurious processes

6.1. Scenarios

Persons and property may be injured by routine operation of an industrial process (e.g. by its chemical, physical, biological or radiological features), or by process malfunction, upset, explosion, fire or other accidental occurrence. In such cases, several liability scenarios may develop as the injured seek damages in court.

In one scenario, the injured seek to recover damages from the company which designed and made the process and sold (or leased) it as a product for use by other companies. Since sale of a standard, "off the shelf" product is involved, the ensuing lawsuit will likely be based on tort liability theories of negligence and strict liability as these theories have been applied to manufacturers of injurious products. Thus, tort law applicable to this scenario is essentially that which has been discussed earlier in this paper, and is not discussed further in this section.

In a second scenario, the company designed and made the process for a particular customer. It was therefore informed by, or followed specifications provided by, its customer company, whose subsequent use of the process proved to be injurious. Here, a complex

situation emerges in which each company will try to avoid liability by blaming the other company for negligence and breach of contract. Depending on the applicable laws, persons who have been injured may be able to sue either company, or join both as defendants in a single lawsuit, or sue each company in separate actions. But to minimize complexity and legal uncertainties, it seems that the most efficient course of action for the person harmed is to sue the customer company which operated the process. This option is outlined in the third scenario below. (If found liable, the customer company will have the opportunity to sue the other company for negligence or breach of contract in a separate action to try to recover its losses.)

The third scenario, which is the most likely, is one in which the injured go to court to recover damages from, and secure restraints against, the company which operated the process in a harm-causing manner, irrespective of whether this company purchased the process or developed or co-developed the process itself. Here, the ensuing lawsuit will likely be based on multiple theories of liability: negligence, strict liability for conduct of an unreasonably dangerous activity, and nuisance theory.

In each scenario, the process may also have caused harm to the environment, natural resources, or public infrastructure. This introduces the prospect of additional liability and losses for the company which operated the process. Public officials usually have authority to impose penalties on the process operator, recover damages to compensate the government, and impose various restraints on further operation of the process. These actions would be taken pursuant to special liability laws for harm to the environment and other public interests, and usually do not require proving company negligence, as discussed earlier in this paper.

For each of these scenarios, the liability theories, exceptions, and defences that apply will differ from nation to nation, and in some nations, between its political subdivisions (e.g. the fifty states in the USA). In addition, a multitude of other laws in each jurisdiction may control certain aspects of a claimant's case. For example, if company employees have been harmed in the course of employment, their ability to bring a negligence or other liability action against their employer may be precluded by Workers Compensation law which limits redress for employees to scheduled payments from company-purchased insurance coverage according to disability or injury, as in Germany and the USA. Thus, the influence of liability on process design will vary in accordance with highly particularized legal and factual circumstances.

6.2. Liability theories

Negligence doctrine provides a path to recovery, in each scenario, for persons who have been injured by routine or non-routine aspects of a company-operated process. As previously discussed, it requires proving that the company was at fault in that its behaviour failed to meet a legally defined standard of care owed to the claimant, and that the behavioural fault was the proximate or substantial cause of the harm suffered. Thus, the company may be held liable if it is established that it failed to follow appropriate practices in designing, maintaining or operating its process according to expert knowledge known to it or to others, and that following such practices would have prevented the harm at issue.

In addition, the company may incur vicarious liability for harm caused by an employee who deviated from company procedures, by the professional negligence of its design or engineering consultant, or by a supplier who provided defective materials or components.

Such vicarious liability is supported by long-standing public policy in many nations, and is increasingly being applied to cases involving harm caused by the negligence of the company's independent contractors. If held vicariously liable under such circumstances, the company or its insurer may subsequently seek recovery of its liability from the consultant, supplier or contractor in a separate legal proceeding, usually on the basis that such party breached its contractual obligation to the company or had previously entered into an agreement with the company to indemnify it for losses in the event of their negligence or breach of contract.

Negligence law usually works adequately for victims (other than employees) of process upsets and accidents. It is relatively easy for the victims to establish injury causation, the incident is universally regarded as unacceptable to the public as well as to industry and thereby compels recognition that inadequate company performance was involved, and given these factors, companies and insurers usually try to settle claims quickly out of court.

But negligence can be problematic for persons who have been harmed by the routine release of pollutants from a process operated by a company which is fully in compliance with laws, regulations, standards and permits governing its operation and releases. It will be difficult to establish that such a company was negligent in the design or operation of its process, and impossible to recover for negligence if such laws and regulations pre-empt and preclude tort liability, or if compliance with regulations is regarded as a conclusive defence. A further difficulty confronting the claimant in such a "toxic tort" lawsuit claiming illness due to toxic emissions is proving causation of harm, i.e. that the specific illness was caused by exposure to the routine discharge or emission of a particular pollutant at the low levels prescribed by regulation.

A second path to recovery may be provided by strict liability doctrine. In the USA and the UK, this approach is unlikely to succeed because courts and legislators have consistently refrained from applying strict, no-fault liability to the owner or operator of a harm-causing process. The few exceptions have involved older types of notorious industrial activities traditionally viewed as being abnormally dangerous or ultra-hazardous because of their unusually dangerous features and their location in densely populated places where many are at risk: e.g. making, storing or using explosives in an urban area. It has rarely been applied to modern, mainstream types of hazardous industrial activities such as chemical and petroleum process facilities. However, other nations authorize strict liability more expansively, and the example of Germany is discussed below.

A third but less certain path to recovery of damages from the operator of an injurious process may be provided by nuisance law. In the USA and the UK, the common law of nuisance provides that persons whose use and enjoyment of their property is adversely affected by a neighbour's unreasonable activity may recover damages or other relief, such as a court order enjoining the activity. Similar doctrines are also provided by statutes or civil codes of other nations, again as in the example of Germany.

Nuisance actions are usually brought when the harm at issue (impairment of health or property) arises from the routine release of pollutants by an industrial process. But recovery of damages or securing injunctive relief for nuisance, which is often a local problem, is increasingly difficult to reconcile with national needs for commercial and industrial enterprise, as in cases of airport noise pollution and power plant emission of particulates. In addition, the need for nuisance law is diminished by growing government regulation of polluting activities: e.g. emission standards which limit the generation of noise and

particulates, and off-site ambient standards and exposure limits which safeguard public health and environmental quality.

Nevertheless, nuisance doctrine remains a viable option for certain local problems, and as these problems proliferate and are brought to court, the resulting decisions (e.g. damage awards, injunctions) establish parameters for what is permissible. Thus, companies whose process activities have nuisance potential are made aware of the need for design and operational modifications.

To sum up with a broad generality, each nation provides various liability doctrines applicable to cases involving injurious processes, and those doctrines that prove to be most useful to injured persons will ultimately have most influence on the design and operation of these processes. To the extent that local and national regulation of the processes become increasingly protective and fewer harms are caused as a result, the influence of liability on process design and operation will be supplanted by regulatory influence.

6.3. National differences and complexity

E.U. nations provide, in their civil codes and statutes, various negligence, nuisance and strict liability pathways to recovery for persons harmed by process accidents, mishaps and routine releases. But there are considerable differences between these nations according to authoritative studies by E.U. legal analysts. Thus, despite E.U. directives mandating harmonization of laws, and growing harmonization of standards and other regulations in particular, companies and their attorneys still consider each E.U. nation as having a unique legal framework of liability doctrines.

Although each nation provides some form of fault-based liability for harm caused by company negligence in designing or operating a harmful industrial process, the criteria for liability, and the procedures, evidentiary requirements, exceptions and defences differ between the nations. The differences are even greater with regard to their strict liability doctrines, which take many forms because they have usually been enacted to narrowly address specific circumstances of national concern.

German law, highly advanced with regard to technological matters, demonstrates how intricate liability doctrines are developed over time and accumulate to create considerable legal complexity. A brief description here is sufficient to indicate the complexity and uncertainty involved in evaluating liability potential and its influence on companies whose activities make them subject to German law.

For example, the German Civil Code Article 823 expansively provides that: "(1) A person who, wilfully or negligently, unlawfully injures the life, body, health, freedom, property or other right of another is bound to compensate him for any damage arising therefrom... (2) The same obligation is placed upon a person who infringes a statute intended for the protection of others... [but] the duty to make compensation arises only in the event of fault." Article 906 then deals with such harm when caused by specific types of pollutants that have been emitted at levels exceeding regulatory requirements.

The 1996 Water Management Act follows by establishing strict liability for harms arising from the discharge of pollutants that degrade water quality. More strict liability is authorized by the 1996 Environmental Liability Act for environmental damage caused by specified types of industrial activities (e.g. pipelines, nuclear facilities, genetic engineering activities, various types of industrial facilities discharging pollutants, etc.), and for injury to persons or property caused as a consequence of the environmental damage, even if the party

directing the activity had taken all precautions and used best available technology. However, recovery for property damage is not provided if the damage is insignificant and the activity had been in full compliance with applicable regulations and permits.

The Environmental Liability Act has many other features. It provides that the claimant need only prove that the company conducting the activity emitted certain substances, that the claimant was exposed and suffered injury, and that there is a known causal link between such pollutants and the type of injury suffered. Thus, the claimant need not prove specific causation of his own injury, which is usually far more difficult to establish. But again, an exception is provided. If the company had been in compliance with applicable regulations, the claimant must prove specific causation. Under this Act, company adherence to the state of the art is not a viable defence, and it appears that only *force majeure* would suffice. Limits on liability awards are set by the Act. In addition, other laws limit the Act in various ways: e.g. precluding worker claims against an employer under the Act and directing the worker to claim payment from compulsory insurance.

In contrast, the French Civil Code does not explicitly address environmental liability or its personal injury consequences, broadly provides for fault-based and strict liability without expressly making many exceptions, holds an employer vicariously liable for harms caused by the negligent act of an employee, and provides a "first user "defence which enables a company to prevail against a claimant who had moved next to it and been voluntarily exposed.

These examples indicate that little progress has been made in harmonizing liability law for dangerous processes among E.U. nations, possibly because processes involve land use and resource allocation decisions, community concerns, and other particularized features of national culture. This contrasts with harmonization programs for product standards and liability in the E.U., which are driven by economic aspirations for a single market. Thus, national liability systems for processes prevail, with each having distinctive features. Whether the new EU Directive on Environmental Liability, to take effect in 2007, will accomplish harmonization of the very diverse approaches taken by member nations to process liability scenarios is an open question at this time.

7. Company decision making

Liability doctrines for injurious products and processes in the USA and E.U. nations pose many uncertainties, have numerous limitations, and are also in considerable flux. These conditions impair the ability of companies to estimate potential liability, and may cause certain companies to undervalue liability potential when designing products. But uncertainty about potential liability may also cause other firms, which are more risk averse or prudently managed, to overvalue liability from a business perspective. And in either case, a company may choose the less expensive path of adding additional warnings and instructions to a product or process rather than change its design, because liability law fails to provide clear guidance on this matter. As a result, the deterrent effect of liability and its ability to promote safer design will depend on a company's culture and its business characteristics, in addition to its appraisal of loss potential.

Although potential liability may be difficult to estimate, companies are nevertheless concerned about tort actions and their loss consequences, and devise many strategies to minimize loss. Probably the worst-case scenario for a company is one which involves numerous lawsuits, as in the case of a widely sold product capable of injuring many people

(such as asbestos or a drug) or a process capable of causing many deaths and injuries in the event of an accident (such as a Bhopal type tragedy). Ruinous loss could result from the multiple liabilities incurred in such "mass tort" scenarios and the legal "transaction costs" of defending against them.

In addition, companies with name recognition, or whose competitive position is dependent on reputation and public trust, fear the adverse publicity and loss of business that can result from a highly visible lawsuit or a multiplicity of lawsuits, as in the case of food, pharmaceutical and medical device manufacturers. Even firms unknown to the public, which sell to or license other firms, fear liability actions because it drives their downstream customers to other sources with safer products and processes. Other fearsome consequences, discussed previously, include adverse effects on shareholders and investors, lawsuits against top management, higher insurance costs, and ultimately new regulations and other forms of governmental intervention in their business operations.

These are among the many reasons why companies and their trade associations develop self regulatory programs and use best management practices, and why leading firms try to build a safety culture for product development and process management. These initiatives are intended to improve company commitment and performance regarding safety and to assure many stakeholders that harms are being diligently prevented (e.g. regulators, lenders, investors, product customers and communities hosting facilities). These efforts will also provide evidence, in the event harms occur and liability claims are made, that the company acted with reasonable care, was not negligent despite the occurrence of harm, and that penalties and large damage awards are not warranted.

The prime example of self-regulation is the Responsible Care program enacted by the chemical process industry in over thirty nations. These companies follow several "codes of management practices" for product stewardship, accident prevention, employee safety, and other risk management sectors. Initially viewed by the public and regulators with scepticism because of their voluntary status, the industry subsequently acted to make compliance with the management practices enforceable through procedures for auditing company compliance and terminating the trade association membership of non-complying companies, thereby making the terminated firms more vulnerable to government intervention, loss of reputation and customers, and liability actions.

Thus, the spectre of liability looms large in business sectors whose products and processes are inherently hazardous, despite the difficulties facing persons who seek compensation under tort liability doctrines. As a result, major firms deliberate about risks and potential liabilities, the extent to which resources should be committed and efforts increased to identify risks, and the steps to be taken to minimize potential liabilities and other losses. But how much will be done in this regard, and whether it leads to a particular initiative such as changing the design of a product or process, are matters to be resolved by considering and weighing many factors and options unique to a company at a particular point in time and the company activity at issue. For example, internal conflicts such as process safety versus productivity, and product safety versus product pricing and marketing, must be resolved.

The deliberative process on safety matters will, as a result, involve technical, economic and legal considerations. When carried to the fullest extent, it is likely to cover five sets of issues, but there is no assurance that the outcome will bring about greater attention to safety in designing products or processes.

The first set of issues likely to be considered deals with intrinsic hazards of the product or process in question and their potential for causing harm: e.g.

- Does the product have intrinsically hazardous features (e.g. toxicity, flammability), which may cause harm over the course of its life cycle (i.e. manufacture, distribution, storage, use, disposal) under normal conditions (e.g. intended use, normal exposure) and reasonably foreseeable special circumstances (e.g. deliberate or inadvertent misuse, acute exposure)? Similarly, does the process have hazardous features which may cause harm under normal operating conditions and foreseeable special circumstances (e.g. accidents, storms, sabotage)? Are we sufficiently knowledgeable about these matters or is further testing or risk assessment needed to meet legal requirements about the level of risk knowledge we are supposed to have?
- What types of harms may occur and for each type, what is its likelihood, incidence, magnitude and temporal features (time frame)?
- Who and what may be harmed (e.g. workers, customers, bystanders, neighbours, company assets, private and public properties, environmental quality, natural resources)?
- What regulatory requirements for minimizing the harms (e.g. product or process design standards, testing and training requirements, permits and licenses, compliance procedures) need to be met in order to lawfully sell the product or build and operate the process in question? Are we in conformance with industry practice?

The second set of issues addresses the likelihood that the company will be found responsible and liable, pursuant to tort law and other liability doctrines, for the harms likely to occur even though regulatory requirements have been met: e.g.

- Which harms are legally actionable under negligence and strict and special liability doctrines, who is eligible to bring a lawsuit to secure compensation (and other remedies and sanctions) for such harms, to what extent are these eligible parties likely to bring such lawsuits, and in which nations or courts?
- To what extent will claimants be capable of proving what is legally required to establish liability (e.g. fault, causation, unreasonably dangerous product, abnormally dangerous activity, deviation from industry practice and violation of regulatory requirements)?
- What defences are available to the company and how effective are they likely to be?
- To what extent have lawsuits involving the same or similar products or processes, and harms, succeeded, failed, or been settled out of court?

The third set of issues pertains to estimating the company's potential losses: e.g.

- What are the likely number of damage awards and out of court settlements, their amounts and attendant transaction costs, and their distribution over time?
- What losses would be caused if product recall (or process shutdown) is necessary?
- To what extent is the company financially capable of bearing these liabilities and costs?
- To what extent would such damage awards and subsequent publicity harm the company's reputation, competitive position, investor and shareholder interests, and future insurance coverage, and cause recall of products, process shutdown, or other business interruptions?
- To what extent would such damage awards prompt government investigation, regulations, new reporting and compliance burdens, and provoke government prosecution (civil, criminal) of the company, its top officials and management personnel?

At this point, the more compassionate or morally-responsible firm will next examine the technical and economic feasibility of making safety-enhancing, harm-reducing changes in the design, distribution, and marketing of the product at issue, or the planning, siting, design, management and operational features of the process at issue. However, other firms driven by cost-benefit analysis, an approach which subordinates safety and harm to economic considerations, may instead choose to next address methods of mitigating loss which do not necessitate risk and harm reduction. The former type of firm will therefore consider the fourth set of issues below prior to considering the fifth set of issues which then follow, whereas the latter type of firm is more likely to consider the fifth set of issues prior to addressing the fourth set of issues.

The fourth set of issues deals with company options for mitigating loss by reducing the risks posed by the product or process: e.g.

- To what extent will warnings and safe use instructions prevent the risks, harms and losses posed by the product, or to what extent will worker training, personal protective equipment, and enhanced management practices prevent the risks, harms and losses posed by the process?
- Within parameters of technical and economic feasibility, to what extent will change in the design of the product or the process prevent the residual risks, harms and losses which remain after the prior initiatives, noted immediately above, (e.g. warnings, training, etc.) are undertaken.
- If either option, or a combination of the options, is chosen, will the safer product or process generate the desired business outcomes?

The fifth set of issues deal with company options for mitigating or deflecting the losses without reducing the risks posed by the product or process: e.g.

- To what extent is adequate and affordable insurance available to cover the transaction costs of defending the company and the liability awards and other losses it may incur (e.g. various coverages for liability, business interruption, etc.)? For potentially huge losses, is securitisation of the risk or another form of "alternative risk transfer" feasible?
- Would the company be able to have any other parties joined as co-defendants in the lawsuits brought by the injured persons to share liability, or be able to separately sue such parties and recover contribution towards the company's liability?
- To what extent will indemnification clauses in contracts assure that such losses will be recovered from, or transferred to, other parties such as (a) product design consultants, testing labs, suppliers of components and materials, distributors, downstream purchasers and users, or (b) process facility architects and engineering consultants, construction contractors, materials suppliers, toll contractors, maintenance firms and subcontractors?
- Is it likely that public relations will be able to restore reputation and competitive position?

The goal and outcome of such a deliberative process, or an abbreviated version, is the selection of the most cost-effective set of options for mitigating the potential loss posed by

the product or process, and may not include a safer design, which is often a more costly option. In other words, design change is often no more than one of many options for addressing the company's main goal of minimizing economic loss.

As a result, dangerous products may continue to be sold without design change despite numerous lawsuits, and dangerous processes may continue operation without design change despite accidents and liability awards, until regulatory action is taken, or liability and other losses become overwhelming, or the marketplace or public outrage forces the company to respond with a safer design. Thus the hypothesis that tort liability promotes safer design needs to be replaced with the more hesitant hypothesis that it promotes company deliberations about mitigating loss which may, under certain circumstances, lead to design of a safer product or process.

8. Conclusion

This paper has presented some of the main features of tort law in the USA and E.U. domains, noted key differences and trends, and discussed the relevance of negligence and strict liability doctrines to product and process design. It has also critiqued the common assumption that fear of tort liability causes companies to emphasize safety and minimize risk in designing and developing a new product or process. Given the unavailability of empirical data, it draws on personal experience and case studies and holds that the fear is real but the influence is highly variable because tort liability is merely one of many factors considered in company decision processes. By outlining these factors, it also suggests that the weight they are given in a company decision process is shaped by the company's "culture", a simple term masking a complex set of values and attitudes.

Nevertheless, tort law is a necessary supplement to regulation for progressively reducing product and process risks and promoting the humanistic advance of technology. It represents a nation's moral commitment to protecting each individual from those residual risks which regulation, narrowly applied and preoccupied with setting optimal levels of risks for society to bear, fails to prevent. Tort law is responsive to another regulatory limitation by assuring that individuals who suffer harm caused by a company's negligent behaviour or dangerous activity will have access to a personal remedy. And it provides a means of social control over advancing technology which is more flexible and adaptive to meet new circumstances, and less susceptible to capture by business interests, than regulation. In these and many other ways, tort law continues to serve societal interests.

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