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CD corporate disputes

PRODUCT LIABILITY, DAMAGES, BUSINESS DECISIONS AND ECONOMIC OUTCOMES

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HOT TOPIC

PRODUCT LIABILITY, DAMAGES, BUSINESS DECISIONS AND ECONOMIC OUTCOMES

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Doug Smith is a partner in the Chicago office of international law firm Kirkland & Ellis LLP. He has litigated cases at both the trial and appellate stage, including commercial, mass tort, product liability, securities, bankruptcy, environmental and intellectual property cases.

CD: Could you highlight some of the trends and developments that you have seen in the product liability space in recent months? What pressing risks and challenges are manufacturers facing?

Egler: The rise of the Internet of Things (IoT) seems to be on everyone's mind at the moment. But the existing product liability regimes, at least in Europe, were not designed to deal with risks inherent to interconnected products. Significant financial risks could stem, for example, from cyber attacks. The European law, and its national adoptions, establishes the liability of producers, vis-à-vis consumers. But is liability limited in cases where a third party intentionally and maliciously hacks into a software system and causes damage? The multitude of parties involved in the production of smart products, both hardware and software, and the novelty of the subject brings legal uncertainty.

Fleming: There appears to have been an uptick in product liability actions brought by governmental entities, such as states and localities, against manufacturers. These types of suits may seek to aggregate large-scale claims, typically under traditional tort law and other theories, in a '*parens patriae*' capacity. They are often brought with regard to subject matter areas where state and federal regulations may differ or where regulators may differ as to appropriate enforcement measures.

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Philipp Egler, Bird & Bird LLP

Smith: Plaintiffs' lawyers continue to pursue serial litigation against various industries, such as the pharmaceutical, automotive and high-tech industries. Once plaintiffs' counsel files one type of lawsuit against a company in a particular industry, it is not uncommon for them to initiate additional litigation against that company after they become familiar with its operations. Likewise, plaintiffs' counsel frequently expand litigation involving similar products to other companies within the same industry. For example, plaintiffs pursuing pharmaceutical litigation against companies manufacturing medications to treat diabetes have sued multiple companies producing

similar treatments; likewise, they have sued in serial fashion against the same company as new products are developed.

CD: In your opinion, do any recent, high-profile product liability cases exemplify the legal and regulatory challenges that manufacturers must navigate?

Fleming: The recent Seventh Circuit decision in the *Dolin* case against GlaxoSmithKline illustrates the line that companies must often walk between federal regulatory duties and claimed state law tort duties. There, the brand manufacturer GlaxoSmithKline was subject to a $3m jury verdict for an injury allegedly caused by a generic version of the medication that it did not manufacture, and despite the fact that four times the Food and Drug Administration (FDA) rejected GlaxoSmithKline's requests to add a warning on its branded medication covering the very injury at issue in the case. The verdict was overturned by the Seventh Circuit on grounds of federal pre-emption, since it would be impossible to give the warning that state law allegedly required where the FDA had repeatedly rejected it. The decision illustrates how manufacturers must navigate the sometimes conflicting demands of federal regulations and state law liability claims to establish, even if it requires litigation through appeal, the defence of pre-emption.

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> *Douglas Fleming, Dechert LLP*

Smith: There have been a series of lawsuits against manufacturers of blood thinning medications, alleging that they result in uncontrollable internal bleeding. These cases involve significant interplay between the regulatory arena and litigation arena. The medications were approved with warnings indicating that bleeding could occur. Regulators determined that the benefits of the products simply outweighed any potential risks. As advances were made in medications to reverse bleeding incidents, regulators were charged with approving those for the market. Accordingly, there were parallel developments in front of regulatory bodies that were significant for the litigation.

Egler: In Germany, 2017 and 2018 did not bring any groundbreaking new case law. Product liability cases involving smart products, for example, have not yet reached the higher courts. What we can see, however, is a steep increase in the level of professionalisation of claimant firms in consumer-focused litigation. The European litigation landscape is changing. This can be seen in the massive litigation – though not in a classic product liability scenario – derived from the so-called Volkswagen 'diesel-gate', which is at least partly financed by big US litigation funding specialists attempting to enter several European markets. 'Diesel-gate' also had an impact on the psyche of politicians and consumers in Europe.

CD: Before initiating a recall of a defective product, what options are available to manufacturers? What considerations need to be factored into the decision of whether and how to proceed?

Smith: The primary objective in any recall determination should be consumer safety and maintaining positive relationships with consumers. Accordingly, manufacturers should move quickly to recall products that have any associated safety issues, and regulatory requirements frequently require prompt notification of relevant regulatory bodies. It is therefore important to have robust mechanisms in place to monitor products and promptly identify problems when they occur. Once such problems are identified, manufacturers must take into account a variety of considerations, including not only their interactions with regulators and consumers, but their relationships with suppliers and other constituencies.

Egler: If there is a very low risk and the product is only used by competent persons, measures, such as information on the correct or safe use or adaptations of the products delivered in the future, may be sufficient, on the basis of a systematic evaluation. Some manufacturers of cars, for example, rectify defects free of charge as part of vehicle inspections in authorised workshops. This so-called 'silent' recall can save manufacturers a lot of money. Manufacturers must also take into account the risk of damage to their image.

Fleming: At the outset, the manufacturer should determine the scope of the potential problem, including whether it relates to a design defect or some other issue, such as product misuse or a manufacturing defect that may affect only certain product units. Since there is generally no common law duty to issue a product recall, counsel should evaluate whether regulations may require one, such as those issued by the Consumer Product Safety Commission, FDA or National Highway Traffic Safety Administration, or whether post-sale warnings may appropriately address the issue. A manufacturer should keep safety at the forefront throughout the

process and engage the organisation's subject matter experts and, where warranted, communicate further with key internal stakeholders. The manufacturer should pay careful attention to privilege issues and the documents it generates throughout the process. If litigation arises, the record will be important in demonstrating that the manufacturer acted reasonably.

CD: When assessing a claim arising from a defective product, how should manufacturers go about calculating potential damages? What aspects need to be examined?

Egler: Manufacturers should identify the hazard, be it the type of defect, the root cause, the affected products, the affected persons and so on, and then they should assess the risk level, such as the probability and degree of injury that may occur, and the number of products on the market or in use. In most jurisdictions in continental Europe, the law does not provide for US-style punitive or multiple damages. The courts will only compensate the damages that actually occurred and will not 'over compensate' consumers.

Fleming: As with recall questions, a manufacturer should evaluate the scope of the potential defect, including whether it involves a single batch or line, a specific time period or a particular use. Estimating potential damages – whether economic, in the form of breach of warranty, personal injury or something else – can be done in a number of ways, such as by consulting with in-house and external experts and researching analogous situations to benchmark settlements, judgments, verdicts and other awards. In some circumstances, it also may be worthwhile for the manufacturer to conduct jury research to evaluate the range of damages that a potential jury might award in its particular situation.

Smith: It is frequently difficult to estimate the scope of potential damages in product liability litigation given that many factors can affect the amount of any potential exposure. Particular jurisdictions in which litigation is filed can have an effect, as can the type of harms alleged and the perceived benefits of the product. In addition, the type of damages available can vary by jurisdiction. For example, while many jurisdictions authorise punitive damages under certain circumstances, others do not. Accordingly, a variety of legal and factual determinations come into play in estimating the potential liability associated with product claims.

CD: To what extent can expert witnesses influence a product liability case? What advice would you give to parties looking to engage an expert witness?

Fleming: Expert testimony, particularly on scientific causation, can frequently be dispositive in product liability litigation, especially where plaintiffs may attempt to 'push the envelope' on claims that are not supported by reliable scientific data. Retention of any expert in product liability litigation should begin with an in-depth review of the science and consultation with individuals with strong credentials and expertise in the subject matter of the case. Any candidates should be thoroughly vetted with respect to their record, including any prior work and statements that may bear on the matters at hand.

Smith: Expert witnesses can be an important component of a product liability case. While jurors in the US frequently approach expert testimony with some scepticism because they know that experts are paid witnesses, expert testimony can support or refute important elements of a product liability case, such as causation and damages. Parties seeking to engage expert witnesses should thoroughly examine their background, given that their prior writings and testimony may be the subject of cross-examination. In addition, the qualifications and methodology of expert witnesses are important given that the court may test the reliability of their opinions and the bases for them. Finally, it helps if experts are familiar with the litigation process and have been through it before. Witnesses who are comfortable with the process and experienced are likely to perform better.

Egler: Product liability cases are some of the most challenging cases for trial lawyers, as well as the courts. The level of complexity will only increase when it comes to the IoT and smart products, with the complicated interdependencies between hardware, software and tele-media services. In all these cases, the court will eventually have to rely on experts. To shape the litigation process, an expert witness retained early in the proceedings can be an invaluable advantage in order to define and substantiate lines of arguments. In some jurisdictions, such as Germany, the court itself will eventually appoint neutral experts if necessary, rather than rely on the parties' experts.

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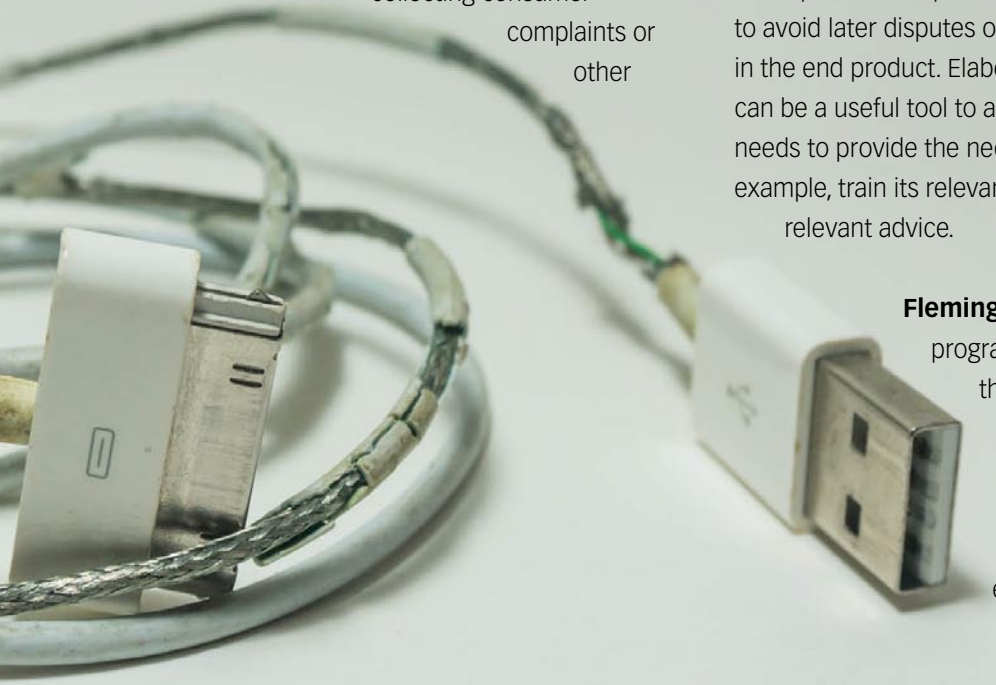
Douglas Smith, Kirkland & Ellis LLP

CD: What steps should manufacturers take to incorporate risk mitigation into the product development lifecycle? How might this influence their business and economic planning?

Smith: Risk mitigation is generally a natural component of any product development cycle. In designing products, manufacturers typically take into account the potential risks and benefits of the products, develop appropriate labelling and ensure that products are safe for use. In addition, manufacturers typically have in place significant mechanisms for monitoring their products in the field, collecting consumer complaints or other evidence regarding the performance of their products. These mechanisms are often necessitated by regulatory requirements but can also be important in heading off product liability litigation.



Egler: Due to the convergence between the regular manufacturers and technology industries, conventional business models and their contractual documentation are being put to the test. An adequate management of liability risks needs to take into account the multitude of companies potentially involved in the development and manufacturing of a product. Manufacturers and their suppliers should take great care to agree on precise technical descriptions and specifications of the parts supplied to avoid later disputes over responsibility for a defect in the end product. Elaborate interface agreements can be a useful tool to achieve this. But a company needs to provide the necessary resources and, for example, train its relevant employees and obtain relevant advice.

Fleming: Strong compliance programmes help companies do the right things in these areas, as well as comply with the law and mitigate risk. In other industries where similar regulatory structures may not exist, a manufacturer, may, where warranted, have a

safety programme in place to monitor for and address any issues that may arise and for which it may bear responsibility. If a legitimate safety issue is identified, requiring action on its part, the manufacturer should address the issue. Doing so is responsible and will limit and mitigate legal risks. Regulators, judges and juries may evaluate the manufacturer's handling of the issue down the road.

CD: Going forward, what are your expectations for product liability claims activity? Are manufacturers doing enough to prepare for potential claims?

Egler: The rise of collective redress and class actions in Europe will lead to more and higher volume litigation in the field of product liability. A lot of manufacturers have already started to prepare for this 'brave new world'. But while a lot of resources flow into research and development for smart products and services, the legal aspects tend to be neglected. Manufacturers should review their templates for contractual documents between them and their suppliers and customers, as soon as possible, to check whether they reflect the new challenges. Manufacturers should also be aware of the litigation risks, at least in the main markets they are operating in. Legal systems, even within Europe, still differ and possibilities for collective redress in the UK will be completely different compared to those in Italy or Germany, for example.

Fleming: Headline jury verdicts and settlements are still frequently made, and even where these verdicts may be reduced or reversed, they attract widespread attention, may impair corporate reputations and spur additional suits by the plaintiffs' bar. Manufacturers should continue to work hard to mitigate risk on the front-end through their own internal programmes. Where liability issues are identified, especially those that may affect an entire product line, manufacturers should invest resources internally and externally to develop the defence of the matter at the earliest possible stages to help prevent headline jury verdicts.

Smith: Product liability claims activity is likely to continue to expand as plaintiffs' lawyers develop new and creative theories of liability and expand the scope of filed litigation to new industries. Manufacturers frequently realise the potential risks associated with litigation. However, companies and industries that do not have a history of litigation may not be as well-equipped to address litigation when it arrives on their doorstep. Manufacturers should pay attention to litigation developments involving other companies and products within their industry or similar industries, in order to prepare in the event that litigation is filed against them. Such proactive measures can ultimately prove to be cost-effective and may improve outcomes when litigation is filed. CD