

Nanotechnology and the European Product Liability Directive

Anne Ware and Brian Kelly discuss potential product liability issues relating to nanotechnology products that may arise in the European Union.

A key area for the development of nanotechnology is in medicines and medical devices. The application of nanotechnology to health, sometimes referred to as “nanomedicine”, raises high expectations for millions of patients for better, more efficient and affordable healthcare and has the potential of delivering promising solutions to many illnesses. Examples of nanomedicine include drug delivery systems, diagnostics and regenerative medicine.

Nanomaterials often have chemical, physical or biological properties that are different from those of their larger counterparts and, as such, they have great potential for use in a vast array of products. However, the possibilities that nanomedicine might offer in the future have to be balanced against the possible risks of this new technology. For instance, nanoparticles, used as vehicles for medicine or as medicines themselves, have an active and large surface-to-mass ratio, meaning they can potentially interact with many targets in the body and can even cross the blood brain barrier.

The European Commission has stated that research and development and technological progress need to be accompanied by scientific investigation and assessment of possible health or environmental risks associated with nanotechnology¹. Furthermore, under the commission’s Nanotechnology Action Plan for Europe², all applications and uses of nanosciences and nanotechnologies must comply with high levels of public health, safety, consumers and workers protection, and environmental protection.

An important piece of legislation intended to protect the health and safety of consumers in the European Union is Directive 85/374/EEC, the Product Liability Directive³. This article discusses some of the potential risks of nanotechnology and the associated product liability issues that may arise. In the absence of generally accepted definitions, the terms nanotechnology, nanoparticles and nanomaterials are used in this article to cover commonly used terminology such as manufactured (or engineered) nano-sized and nanostructured nanomaterials. The article does not address nanomaterials or nanoparticles that occur naturally or are unintentionally produced, eg in combustion.

Product liability

Manufacturers of nanotechnology may be liable for any injury caused to consumers under the product liability laws at national level and under European legislation.

Directive 85/374/EEC, which came into force on 1 March 1988 and has been implemented throughout the EU, applies to a “producer” of products. Article 3.1 defines a “producer” as being “the manufacturer of a finished product, the producer of any raw material or the manufacturer of a component part and any person, who, by putting his name, trademark or other distinguishing feature on the product presents himself as its producer”.

The directive states that a producer will be liable for a “defective product”. To establish liability under the directive, claimants have to establish what the specific defect in the product is, and that this defect caused their particular injury. Article 6.1 states that:

A product is defective when it does not provide the safety which a person is entitled to expect, taking all the circumstances into account, including:

- *the presentation of the product;*
- *the use to which it could be reasonably expected that the product would be put; and*
- *the time when the product was put into circulation.*

However, Article 6.2 states: “A product shall not be considered defective for the sole reason that a better product is subsequently put into circulation”. “Defectiveness” is an objective standard and includes defects attributable to product manufacture, design, packaging, labelling and instructions (including inaccurate or outdated information, illegible or incorrect labels), warnings and storage.

An otherwise unsafe product may be made safe if adequate information and warnings are given. The majority of pharmaceutical product liability claims relate to an alleged failure to warn, or instructions for use or labelling that do not cover the “defect” that the claimant asserts caused the injury they suffered.

The promise of nanomedicine has to be balanced against the possible risks

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Anne Ware is a partner and Brian Kelly is an associate in the London office of Covington & Burling LLP.

Where it is alleged that no warning or an inadequate warning was given, the claimant must demonstrate that his/her injury (i) can be caused by the product (general causation); and (ii) was in fact caused by the product in their particular case (specific/individual causation).

Not all potential safety issues have been identified

Nanotechnology is a relatively new field and not all potential safety issues have been identified at this stage. However, where manufacturers know or suspect that a product may cause a particular injury, they should undertake appropriate research and give relevant information and warnings to consumers or the product may be considered defective. Manufacturers utilising nanomaterials must ensure that they have a robust system in place to record reports of injury or issues arising and regularly review their labelling and advice to ensure it is up-to-date.

State of scientific knowledge defence

For claims made against the producer of a product, there are defences under Article 7 of the directive. Article 7 tries to balance the protection of consumers from defective and dangerous products with the aim of shielding producers, including manufacturers and importers, from unwarranted and unmeritorious claims. The risk of such claims is a particular issue for manufacturers in the pharmaceutical and high technology industries. Manufacturers were concerned when the directive came into force that they would be faced with a significant increase in the number of product-related claims, together with related increases in damages payments, insurance premiums and legal costs. It is therefore essential to consider all possible defences available to a producer.

The defences available under Article 7 are that:

- the producer did not put the product into circulation;
- the defect that caused the damage did not exist at the time the product was put into circulation;
- the product was not intended for sale or distribution for economic purposes, nor manufactured or distributed in the course of the producer's business;
- the defect is due to compliance with mandatory regulation issued by public authorities;
- the state of scientific and technical knowledge at the time the product was put into circulation was not sufficient to enable the defect to be discovered; or
- (for a component manufacturer) a component has been fitted to a product and the design or manufacture of the product is defective.

A "development risks" defence is available under Article 7 of the product liability directive...

Article 7(e) sets out what is known as the "development risks" defence. Although Article 15(1)(b) allows member states to exclude this defence in their implementing legislation, only Finland and Luxembourg have done so.

The precise scope of the defence remains uncertain. One case where it has been relied on successfully is the Dutch case of *Scholten v Sanquin Blood Supply Foundation*⁴. The claim involved the supply of blood infected with HIV. The blood had been tested three times: the first two tests were negative, and the third test, which was a new test, gave a questionable result. The District Court of Amsterdam held that the blood was defective, and the fact that the detection of this defect was not possible was irrelevant to the consumer, as was the producer's compliance with the relevant applicable scientific standards. However, the producer succeeded in establishing the Article 7(e) "development risks" defence because it had not been able, and was not required, to rely on the new test at the time the patient received the product. This appears to be a sensible approach to liability that does not impose an unrealistic standard on producers.

By contrast, however, the English High Court decided in a subsequent case that the defence was not available in what appeared to be similar circumstances. In *A and Others v the National Blood Authority*⁵, 110 claimants had acquired the Hepatitis C virus from contaminated blood transfusions or blood products supplied by the National Blood Authority. It had been known since the 1970s that an unidentified virus was contaminating blood products. The virus was not identified until 1988 and there was no test available to screen for it. Commercially available tests to screen for it were only in use from 1990. These tests were introduced in the UK from 1991.

...although outcomes have varied where manufacturers have used this

The claims made against the NBA were for products supplied to the claimants between 1988 and 1991. In a detailed judgment that considered extensive expert evidence, the judge decided that, under the directive, the NBA was strictly liable for the injuries suffered by the claimants who contracted Hepatitis C before the commercial test was available. He said that it was a "legitimate expectation" of patients to receive uninfected blood. The NBA was liable even though the state of medical and scientific knowledge did not enable it to screen for the virus.

The NBA's case was that the development risks defence in Article 7(e) should apply, but the judge rejected this. This case was not appealed and it stands as a "high water mark" in terms of manufacturers' liability. It places significant burdens on manufacturers and suppliers, particularly in the pharmaceutical, biotechnology and other research-related industries, including those that manufacture nanotech products.

Whether producers of products incorporating nanomaterial would be able to rely on the development risks defence will depend on the facts. The scientific basis to fully understand all properties and risks of nanomaterials is not sufficiently available at this point. However, a number of reviews identifying “knowledge gaps” have been published. For instance, the commission’s Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) and its Scientific Committee for Consumer Products (SCCP) have pointed to the need to improve the knowledge base, in particular regarding test methods and risk assessment (hazards and exposure) methods⁶. In general, there is a consensus in member states and at the international level that further research is necessary. Nevertheless, manufacturers should consider these reviews carefully and incorporate them into risk assessments and audits where appropriate.

Precautionary principle

Where the full extent of a risk is unknown, but concerns are so high that risk management measures are considered necessary, as is currently the case for nanomaterials, the so-called precautionary principle places additional obligations on producers to regularly carry out risk assessment and take precautions against any normal or reasonably foreseeable risks⁷.

This principle is intended to cover products where scientific knowledge is not sufficiently advanced to be able to assess the nature and extent of the risks that may be attached to them. Producers of nanomaterials will be expected to have taken precautions against possible risks. This reinforces the importance of nanotech producers establishing a system of identifying and minimising risks, and giving consumers adequate warning about the possible inherent risks associated with their products.

In addition to the obligation on producers to take precautions against risks, the commission is also required to act in a precautionary manner in the event that a potential public health risk is identified. This is a mandatory principle and has been affirmed on numerous occasions, not least by the European courts. The commission must take precautions even where the available scientific data do not permit a complete evaluation of the risk or even a determination whether the risk is real.

The precautionary principle obliges producers to regularly carry out risk assessment

Managing future product risks – commission proposals

Against the background of the precautionary principle, the commission stated in its June 2008 communication on nanotechnology that action to manage the risks associated with nanomaterials should focus mainly on the following activities:

- improving the knowledge base (eg data on uses and exposures throughout the lifecycle of nanomaterials or products containing nanomaterials, as well as exposure assessment approaches);
- improving the implementation of legislation, especially in relation to risk assessment;
- providing information to users (there are no provisions in Community legislation dealing specifically with nanomaterials. However, without excluding the possibility that a need would be identified for specific labelling requirements, nanomaterials have to comply with the existing provisions of Community law addressing the labelling of products, warnings to consumers and users based on the properties of products, instructions for use, or any other information requirements); and
- market surveillance and intervention mechanisms (special attention will be given to the various instruments in Community legislation that oblige national authorities to exchange information or to intervene when products present or are likely to present a risk, even where they conform with legal requirements)⁸.

The commission has proposed various actions, including improving the knowledge base and market surveillance

A draft report by the environment, public health and food safety committee of the European Parliament, however, has criticised the commission’s communication⁹. The report states that the committee “deplores” the absence of a proper evaluation of the *de facto* application of the general provisions of Community law in light of the actual nature of nanomaterials.

Conclusion

Nanoparticles are available in products now but their use will become more widespread in the coming decades. As more pharmaceutical and consumer products rely on nanotechnology, it will become increasingly important to understand the potential effects of these products.

Although nanoparticles offer companies exciting opportunities, producers must act now to ensure that there are not inadvertent health risks, as happened with asbestos, to minimise liability under the product liability directive. To this end, producers of nanomaterials or products

Producers must act to ensure there are not inadvertent health risks

Recalls of nanotech products may become more frequent in the meantime

incorporating nanomaterials should carry out regular risk assessment and audits that incorporate the latest understanding from institutions, such as the SCENIHR and the SCCP.

Until such time as the commission introduces legislation to manage the specific risks of nanomaterials, it will be forced to rely on the existing regulatory framework. In the meantime, given the rapid expansion in the use of nanotechnology products and the associated uncertainty surrounding this innovative technology, recalls of such products may become more frequent.

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