

## Science Update

# The development risks defence: how future-proof is it?

### Introduction

Article 7(e) of the Product Liability Directive sets out the “development risks defence”

The producer shall not be liable as a result of this Directive if he proves:

“that the state of scientific and technical knowledge at the time when he put the product into circulation was not such as to enable the existence of the defect to be discovered.”

Although Member states may opt to derogate from Article 7(e), it provides an important defence to producers facing product liability claims in the EU, particularly those involving medicines, medical devices and other complex or innovative products.

Capturing the “state of scientific and technical knowledge” at the time a product was put into circulation can be very difficult. What this means was considered by the Court of Justice of the European Union (CJEU) in the case of *Commission v UK*,<sup>1</sup> where the Court held that

“the clause providing for the defence in question does not contemplate the state of knowledge of which the producer in question actually or subjectively was or could have been apprised, but the objective state of scientific and technical knowledge of which the producer is presumed to have been informed.” (Paragraph 27)

This was qualified by the criterion of the accessibility of this knowledge

“However, it is implicit in the wording of the Article 7(e) that the relevant scientific and technical knowledge must have been accessible at the time when the product in question was put into circulation.” (Paragraph 28)

### Understanding Accessibility

In his Opinion the Advocate-General had illustrated this point by differentiating between a study by an American university, published in an international English-language journal and similar research carried out by an academic in Manchuria, published in Chinese in a local scientific journal that is not circulated outside the region.

Judgment in this case was delivered in 1997 when digital search was still in its infancy. To obtain copies of the materials at that time, it would have been necessary either to physically visit a library which held the relevant journals, or to send written requests for paper copies to institutions such as the British Library.

The subsequent revolution in scientific publishing and accessibility means that it now takes just a few seconds to locate a Chinese journal and, if there is no English version of the webpage available, load the contents into an online translation tool, such as Google Scholar, and access a summary, if not the entire content of the paper instantly.

How does this revolution affect the usability of the development risks defence? Certainly now, and for a number of previous years a lack of accessibility cannot realistically be claimed.

Arguably, there is now a new and potentially more challenging difficulty than accessibility: the ability to assimilate, rationalise and appraise all the relevant literature. A search conducted in 2000 for measles and encephalitis, for example, would have produced a few hundred papers. The same search today would provide many tens of thousands of results for review.

The number of results has been boosted by an expansion in journal numbers and online publishing, as well as by the profusion of “grey literature”.<sup>2</sup> The proliferation of such publications, lacking rigorous peer review, means that papers which represent “accurate” knowledge may be lost in a sea of unreplicated, uncontrolled literature which a producer would have little hope of navigating or adequate resources to review.

Legal cases involving large volumes of scientific literature have for many years relied heavily on empirical measures of quality, such as peer review and statistical significance. Assessing the state of scientific information relied on examining papers which demonstrated a significant result using appropriate methodology, published in a peer-reviewed journal and demonstrating results which could claim statistical significance.

<sup>1</sup> C-300/95 [1997] ECR

However, the peer-review process has been under considerable strain for many years as the increased pressure of publication and production has edged out the worthy role of peer review for many academics and the vaunted status of “statistical significance” has led to its attainment being the starting aspiration of experimental design rather than it being employed as guidance on the interpretation of scientific result.

The ease of publication on the internet now means that a summation of all available knowledge on a topic is unlikely to provide an accurate picture. A 2016 survey reported that “70% of researchers have tried and failed to reproduce another scientist’s experiments, and more than half have failed to reproduce their own experiments”<sup>3</sup> citing pressure to publish and selective reporting as the cause.

Selective reporting may be addressed in part by the momentum towards open access<sup>4</sup>: “making research findings available free of charge for readers”. But this may provide additional difficulties for those attempting to review the totality of literature available on their product as ‘open access’ would include making available the underlying research data. Should this also be appraised to assess the state of technical and scientific knowledge?

One should also consider the longevity of much of the information currently accessible. Given the transient nature of websites it is highly unlikely that the current state of knowledge, other than published literature, will be reproducible in a few years’ time.

Potentially the issue should now not be so much the practical accessibility of information allowing a defect to become discoverable but more the ability to unearth the relevant accurate/valid information. Any such appraisal, is likely to require extensive resources and expertise.

One solution could be the adoption of artificial intelligence (AI) to support this process. Various providers are developing AI with a view to literature

review: Dimensions, Semantic Scholar and others are providing software that aims to answer scientific and/or technical questions by searching and rationalising the search results to make them more accessible.

However, this solution does not address the issues of validity, reproducibility or conflicting findings. Perhaps of even greater potential are organisations such as IRIS.ai which has the ultimate aim of evaluating the literature in addition to providing the search results.

Aware of the need to consider revision of the Product Liability Directive to deal with new technology, the EU Commission convened an expert group on liability and new technologies in 2018. When it reports in mid-2019, it will be interesting to see whether it will provide guidance on the approach to assessing scientific and technical knowledge.



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<sup>2</sup> “That which is produced on all levels of government, academics, business and industry in print and electronic formats, but which is not controlled by commercial publishers.” <http://www.greylit.org/about>

<sup>3</sup> <https://www.nature.com/news/1-500-scientists-lift-the-lid-on-reproducibility-1.19970>

<sup>4</sup> <https://ec.europa.eu/programmes/horizon2020/en/h2020-section/open-science-open-access>