

International Product Liability Review

Issue 60

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About our Product Litigation, Compliance and Mass Torts Practice

Hogan Lovells has the leading international product liability practice covering all aspects of product liability, compliance and mass torts. We have experience of acting for clients around the world in respect of a wide range of products including food and beverages, pharmaceuticals and medical devices, cars, tobacco, mobile phones, cosmetics, electrical and electronic products, chemicals and hazardous substances, toys and children's products, sporting goods, aircraft and machinery. Hogan Lovells' product liability and product safety lawyers are supported by a dedicated Science Unit and Project Management Unit.

If you would like more information about Hogan Lovells product litigation, compliance and mass torts practice, please visit our website at www.hoganlovells.com or contact the Product Liability Group Leader, Rod Freeman, at rod.freeman@hoganlovells.com or any of the lawyers listed on the back page of this publication.

ABOUT INTERNATIONAL PRODUCT LIABILITY REVIEW

In December 2000, Lovells (as it then was) launched its quarterly *European Product Liability Review*, the only regular publication dedicated to reporting on product liability and product safety developments in Europe for international product suppliers, and others interested in international product issues. Over the next ten years, this unique publication featured hundreds of articles, from authors across our network, covering issues in Europe and, increasingly, further afield. Reflecting the growing globalisation of product risks, and following the creation of Hogan Lovells through the combination of Lovells with Hogan & Hartson in May 2010, the publication was renamed *International Product Liability Review* in March 2011.

Hogan Lovells *International Product Liability Review* continues to be the only regular publication dedicated to reporting on global developments in product liability and product safety regulation. It is distributed worldwide free of charge to our clients and others interested in international product issues. If you would like additional copies of this publication, please return the form enclosed with this edition, or contact a member of the editorial team by e-mail:

Rod Freeman
rod.freeman@hoganlovells.com

Valerie Kenyon
valerie.kenyon@hoganlovells.com

Cécile Burgess
cecile.burgess@hoganlovells.com

Anthea Davies
anthea.davies@hoganlovells.com

Caroline Hibberd
caroline.hibberd@hoganlovells.com

With thanks to Samantha Tharle

This issue of *International Product Liability Review* is produced with the support of our International Co-ordination Panel:

Jacopo Bartolomeo (Milan)
jacopo.bartolomeo@hoganlovells.com

Valerie Kenyon (London)
valerie.kenyon@hoganlovells.com

Carolin Gierth (Munich)
carolin.gierth@hoganlovells.com

Colleen McKnight (Baltimore)
colleen.mcknight@hoganlovells.com

Laura-Jean Van De Ven (Amsterdam)
laura-jean.vandeven@hoganlovells.com

Eugenio Vázquez (Madrid)
eugenio.vazquez@hoganlovells.com

Pauline Faron (Paris)
pauline.faron@hoganlovells.com

Phoebe Yan (Shanghai)
phoebe.yan@hoganlovells.com

Our market recognition

We have been ranked for our product liability work in various major legal directories around the world, including in the major directories in France, Germany, Italy, the UK and the US.

- Option Droit & Affaires 2015: **Band 1** – Product Liability (France)
- Decideurs Stratégie Finance Droit 2015: **Tier 1** – Product Liability Litigation (France)
- JUVE Handbook 2014/2015: **Tier 1** – Product Liability (Munich, Germany)
- International Law Office: **Client Choice Award 2015** – Product Liability (Italy)
- Chambers UK 2015: **Band 1** – Product Liability, Mainly Defendant and Product Liability, Food (UK)
- Legal 500 UK 2014: **Tier 1** – Product Liability, Mainly Defendant (UK)
- Legal 500 US 2014: Rankings in Product Liability – Automotive/Transport and Consumer Products (including tobacco)
- Who's Who Legal – Product Liability Defence 2015 – recognised in seven jurisdictions, more than any other law firm.

OUR PRACTICE

Chambers & Partners compiles its rankings based on interviews with clients and other law firms. In 2015, it has said of our Product Liability and Product Safety practice

"Strength across a number of product liability areas, with the ability to handle significant medical device and pharmaceutical work as well as defending large industrial, consumer and asbestos claims. Also offers scientific expertise to various technical and medical clients."

"They are well suited to large and complex international matters."

"Medical device cases have become more complex and require a scientific background, and Hogan really does have that."

Legal 500 similarly speaks highly of our International Product Litigation, Compliance and Mass Torts Practice

"Hogan Lovells has a diverse client list indicative of its versatility; it is an 'excellent' practice, with industry expertise ranging from pharmaceutical and medical devices to food, tobacco, and transport, with the majority of instructions international in nature."

Legal 500 USA highlights our product liability practice as having

"strong ties with the automotive industry and an excellent track record handling consumer class action cases."

Who's Who Legal – Product Liability Defence 2015 writes that

"the merger of Hogan & Hartson and Lovells in 2010, as well as Hogan Lovells' subsequent expansion, has created a new force in this area. The firm markets itself on the ability to assist clients in managing product liability risks globally, which is supported by the fact that six of its offices outside of the US are recognised as having at least one leader in this field – more than any other firm."

Meet the team

We are pleased to introduce two of the authors who have contributed to this edition of *International Product Liability Review*: Christopher Wolf (Washington DC) and Nicole Böck (Munich).



CHRISTOPHER WOLF

Partner – Washington DC

christopher.wolf@hoganlovells.com



Christopher Wolf is a director of Hogan Lovells Privacy and Information Management practice in the US.

Chris was one of the first lawyers in the US to focus on privacy law for clients, and he remains a leader in the field.

Chris helps clients with the entire spectrum of domestic and international privacy and data security issues they face. He is a thoughtful compliance counsellor focused on risk management and an effective advocate in federal court, at the FTC, or before state agencies, on the entire range of international and domestic privacy issues.

As the privacy law compliance challenges evolve and as big data, cloud computing, mobile technology, social media, the Internet of Things, connected cars and telematics, online tracking, cross-border transfers of data, and other technology-related issues present new problems to solve, Chris is at the forefront of lawyers tackling those problems. Chris helps clients with cutting-edge privacy issues.

See page 41 for Christopher's article "The auto industry is serious about connected car privacy"



NICOLE BÖCK

Associate – Munich

nicole.boeck@hoganlovells.com



Nicole Böck is an associate in Hogan Lovells Munich office and a member of our Litigation and Arbitration practice. She focuses on product liability law. Nicole joined Hogan Lovells Munich following her qualification at the firm in 2013.

Nicole advises national and international clients from various industries on national and international product liability and safety issues. Moreover, she has expertise in working on the development of multinational litigation and defence strategies.

See page 15 for Nicole's article "CJEU confirms that Germany must align national law on chemical restrictions in toys with the Toy Safety Directive"

In this issue...

1 Overview

FEATURE

2 The concept of "defect" under the product liability directive – a 30 year retrospective

In this article, Rod Freeman and Natalie Burton (London) revisit the definition of "defect", the burden of proof and consider some of the key "defect" themes which have arisen in cases across the Member States in past years since the Product Liability Directive 85/374/EEC was implemented.

EUROPE – EU

6 The draft EU Data Protection Regulation: potential impact on the life sciences sector

If adopted in its current form, the draft EU Data Protection Regulation will significantly impact the conduct of clinical trials and other activities by healthcare companies involving the processing of personal data. Elisabethann Wright, Ciara Farrell and Helen Kerr (Brussels) summarise key aspects of the Draft Regulation.

9 Time to get your house in order: the European Court of Justice resolves the "entire article" vs "component article" debate

Valerie Kenyon (London) and Markus Burckhardt (Munich) summarise a recent decision by the Court of Justice of the European Union that favoured taking a "component article" approach towards the obligations of importers and suppliers. As they point out, this could have potentially far-reaching impacts for the notification and information obligations of parties throughout the supply chain where "substances of very high concern" are involved.

11 The EU Timber Regulation: pulp friction in the supply chain?

Christopher Norton (London) comments on the EU Timber Regulations (EUTR), which establish rules for those who import and sell timber and timber products on the EU market. A significant impact of these regulations for some organisations, particularly SMEs that may not have had to implement due diligence processes until now,

will be the systems and processes needed to assess the legality of materials.

EUROPE – GERMANY

15 CJEU confirms that Germany must align national law on chemical restrictions in toys with the Toy Safety Directive

A recent decision by the Court of Justice of the European Union (CJEU) provides clarity for manufacturers, importers and/or distributors of toys active in the German market with regard to permissible limit values for heavy metals. Nicole Böck and Kolja Helms (Munich) and Katie Vernon (London) summarise developments and assess the implications.

EUROPE – NETHERLANDS

17 Dutch product safety regulations: increased administrative fines due to be introduced

A significant increase in the maximum fine that can be imposed for violations of the Dutch Commodities Act will soon come into effect. Karen Jelsma and Noor Hogerzeil (Amsterdam) discuss the implications of this amendment for producers and suppliers in the Netherlands, and outline the ways in which the existing legal framework under the Act will be changed.

EUROPE – UK

19 Changes to English rules governing offers to settle: what practical impact will they have?

Giles Hutt (London) summarises the impact of recent changes to Part 36 of the English Civil Procedure Rules. Although most of these are technical, a few have important consequences for parties involved in settling actual or prospective court proceedings and/or seeking to limit their cost.

In this issue...

22 UK Supreme Court confirms success fees and ATE premiums are compatible with ECHR

Charles Brasted, Giles Hutt and Emma Childs (London) report on a recent decision in *Coventry v Lawrence*, in which the UK Supreme Court considered the liability of a losing party for an opponent's success fee and after-the-event insurance premium in light of the European Convention on Human Rights.

23 Foods: when is an on-pack picture of an ingredient misleading?

A recent decision by the Court of Justice of the European Union highlights the need for food companies to consider the overall impression given by the packaging of their products, rather than relying solely on the ingredients list. Richard Welfare, Jane Summerfield and Amy Merrick (London) summarise the decision and assess its implications for companies in the UK.

25 Resolving consumer disputes – what changes from 1 October 2015

Valerie Kenyon and Samantha Tharle (London) report on the UK implementation of new EU rules for consumer disputes, requiring traders to inform consumers about their ADR procedures and introducing an online dispute resolution platform.

27 The shorter and flexible trials pilot schemes: recognising the differences between the two and understanding their impact

Recently launched in the High Court, the Shorter Trials Scheme and the Flexible Trial Scheme are designed to encourage courts and litigants to think more creatively about how proceedings can be made more focused and more cost effective. Giles Hutt (London) assesses the impact of both schemes.

NORTH AMERICA – CANADA

29 Duties arising from consumer product-related incidents: Health Canada publishes industry guide on reporting requirements

Health Canada recently published guidance for manufacturers, importers and sellers on reporting

requirements under section 14 of the Canada Consumer Product Safety Act. Reviewing the scope and impact of these requirements, Siobhan Sams (Harper Grey LLP, Vancouver) highlights the need for participants in the supply chain to put in place mechanisms that ensure they are kept fully informed of any product-related issues that may arise.

32 Jurisdiction and enforcement: Ontario court eschews the "real and substantial connection" test in ruling that it lacks jurisdiction over foreign class members

Siobhan Sams (Harper Grey LLP, Vancouver) summarises a recent class action case that turned the spotlight on the "real and substantial connection" test. Although the decision may be appealed, if it sticks, and its influence spreads, it is possible that putative claimants may begin to find it more difficult to certify global class actions in Canada.

NORTH AMERICA – US

34 Access to investigational drugs: is federal government jurisdiction threatened by "Right to Try" legislation?

The likelihood of federal preemption has not deterred state lawmakers from proposing and passing "Right to Try" legislation. Colleen McKnight (Houston) and Brenna Nelinson (Baltimore) summarise developments in this area, and point out that, regardless of the treatment the laws receive in the courts, there is mounting pressure on the federal government to loosen compassionate-use limits and expedite the "Expanded Access Programme".

37 Potential impact of imminent US Supreme Court cases on product liability class actions

The US Supreme Court has granted certiorari in three class action cases, with oral argument scheduled for October/November 2015. Phoebe Wilkinson and Samuel Zimmerman (New York) summarise the cases and discuss the potential implications where plaintiffs are attempting to pursue US class actions in product liability litigation.

In this issue...

41 The auto industry is serious about connected car privacy

Christopher Wolf (Washington DC) reviews recent developments that demonstrate the US auto industry's determination to build trust in the privacy of connected car information. In particular, the recently crafted Privacy Principles developed by the industry mark an important step forward in this area and provide baseline protections that automakers can build upon.

ASIA-PACIFIC – AUSTRALIA

43 Does it come from a land down under? Country of origin food labelling in Australia

A recent food product recall in Australia focused public attention on country of origin food labelling. Michael Sutton and Amanda Wong (DibbsBarker, Sydney) summarise the current legal regime, as well as highlighting proposed reforms in this area. As they point out, it remains to be seen how effective these reforms will prove to be in addressing consumer concerns.

ASIA-PACIFIC – INDIA

46 Proposed amendments to consumer protection laws in India

Rohit Kochhar and Chandrasekhar Tampi (Kochhar & Co, New Delhi) comment on the far-reaching impact of the Consumer Protection (Amendment) Bill 2014, currently before the lower house of parliament. If implemented, the Bill's provisions will open the door to class action lawsuits, as well as providing much more robust protection for consumers in the area of e-commerce.

Overview

As we continue to track the development of product liability law around the world, in this issue of *International Product Liability Review* we reflect on that growing body of case law in Europe, specifically as it has considered the fundamental concept of "defect" under the Product Liability Directive, which has now been part of the legal landscape in the EU for some 30 years (page 2). The key message that emerges from this analysis is that almost all of the key liability issues remain unsettled, and there is significant scope for defendants to argue positive positions in their defence of claims in order to achieve an appropriate result.

Liability risks for product manufacturers continue to evolve, and the rules concerning the protection of confidential data is increasingly becoming a key source of "product liability" risk. In this issue, we report on how the automotive industry in the US is taking the initiative to develop solutions to the issues that arise, particularly in relation to the deployment of new technologies in "connected cars" (page 41). In the meantime, the EU continues on its path to significantly strengthen data protection laws, and in this issue we focus in particular on the implications on the life sciences sector of some of the proposed changes (page 6).

In the US, we look at three cases currently before the Supreme Court, none of which are themselves product liability cases, but the outcome of which will potentially have a significant impact on future product liability class actions in that country (page 37). These developments will be watched carefully, and the results will be reported in future issues of *International Product Liability Review*.

We also report on the recent decision of the Court of Justice of the EU (the highest court in Europe) interpreting a key aspect of REACH – the European regime for regulating the safety of chemicals (page 15). This decision has important ramifications for a broad range of industries, and is significant as an example of the European Court interpreting the regulation, with retrospective effect in direct contradiction to official guidance published by the EU, and which had been relied upon by industry for many years. It illustrates graphically that non-binding guidance, even when published by the competent the EU agency itself, may not be entirely reliable when interpreting European law, and companies need to

take a broader approach when finding solutions to overcome the ambiguities that so often arise in European regulation.

As this issue goes to print, many members of the international product safety community are preparing to meet in Denmark for the annual International Symposium of the International Consumer Product Health and Safety Organization (ICPHSO). This symposium will feature important discussions led by representatives of product safety regulators (including the European Commission and the US Consumer Product Safety Commission), representatives of leading brand names, and other product regulation experts. For those of our readership who cannot make it to Denmark for this event, we will report on key aspects of the discussions in the next issue of *International Product Liability Review*.



Rod Freeman
London
rod.freeman@hoganlovells.com