

International Product Liability Review

Issue 59

Contents

Overview	1	North America – US	27
Feature – Defective Products	2	Asia Pacific – China	31
Europe – EU	6		
Europe – France	12		
Europe – Netherlands	15		
Europe – UK	17		

JUNE

2015

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

Anthea Davies
anthea.davies@hoganlovells.com

Cécile Burgess
cecile.burgess@hoganlovells.com

Caroline Hibberd
caroline.hibberd@hoganlovells.com

With thanks to Hayley Upton and 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 Konzal (Munich)
carolin.konzal@hoganlovells.com

Colleen McKnight (Houston)
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 members of our international Product Litigation, Compliance and Mass Torts team: Markus Burckhardt (Munich) and Colleen McKnight (Houston).



MARKUS BURCKHARDT

Counsel – Munich

markus.burckhardt@hoganlovells.com



Markus Burckhardt is a counsel in Hogan Lovells Munich office and specialises in product liability litigation. He has seven years of professional experience and has also worked in-house for a German DAX 30 automotive company.

Markus advises and represents international and German clients from the automotive, electronics and life sciences industry on all product liability and product safety aspects and on product-related compliance issues. He provides advice on the coordination of multinational product liability disputes and the associated strategic as well as insurance related issues. Markus has special experience in defending product liability claims in court proceedings and has acted as defence counsel against product liability claims of end-users and in supply chain disputes.

Markus is the author of various publications in the field of product liability and product safety. Amongst others, he co-authored the product safety and product liability chapter of the reprint of an extensive compliance handbook.

See Markus' Feature article "Defective Products: European Court of Justice hands down judgment on product defect due to increased risk of failure and defectiveness of medical devices"



COLLEEN MCKNIGHT

Associate – Houston

colleen.mcknight@hoganlovells.com



Colleen McKnight is an associate in Hogan Lovells Houston office.

Colleen's practice focuses on complex commercial, product liability, and insurance litigation, with a particular focus on clients in the energy and life sciences industries. Her work includes cross-border disputes, international matters, and representing clients in large mass tort matters. She assists clients in all stages of litigation, including case assessment, factual investigation, electronic discovery, dispositive motions, mediation, depositions, and trial preparation.

As a member of the US national product liability team, Colleen has represented several medical device manufacturers and pharmaceutical companies in lawsuits following international recalls. Colleen also advises clients in the life sciences and manufacturing industries on all product liability and related concerns, and has a growing practice advising and representing clients concerning consumer products regulations and liability in the US.

See page 27 for Colleen's article "New addition to California's "Prop 65": businesses must provide clear warnings if products contain Bisphenol A"

In this issue...

1 Overview

FEATURE – DEFECTIVE PRODUCTS

2 Court of Justice of the European Union hands down judgment on product defect due to increased risk of failure and defectiveness of medical devices

Markus Burckhardt, Susanne Küppers and Stephan Hillenbrand (Munich) comment on a recent judgment handed down by the Court of Justice of the European Union in the area of defective medical products. As they point out, the judgment could have far-reaching consequences for manufacturers and distributors of medical products in the EU, even extending to the creation of a general liability in certain cases.

EUROPE – EU

6 The Digital Single Market Strategy for Europe: how will it impact businesses?

As its 16 initiatives are phased in over the next two years, the European Commission's Digital Single Market Strategy will impact businesses in every industry sector, whether or not they see themselves as "digital players". Penelope Thornton and Alexandra Grundy (London) summarise the significant changes that will now be introduced across Europe's regulatory landscape.

9 Shifting the burden of proof under the European Consumer Guarantees Directive

A recent judgment of the Court of Justice of the European Union has provided important clarification regarding what a consumer must prove in order to bring a case against a seller under the Consumer Guarantees Directive. Rod Freeman (London) and Laura-Jean van de Ven (Amsterdam) comment on the implications for consumers and for sellers.

EUROPE – FRANCE

12 The "DES" decisions of 10 April 2014: has market share liability been introduced to French law?

Two recent civil court decisions could prove to be a stepping-stone towards an application of market share liability in France. Cécile Derycke and Cléa Dessault (Paris) report on the background to these decisions and assess their potential impact.

EUROPE – NETHERLANDS

15 The Dutch Data Breach Notification Act: what does it mean for your company?

The Dutch Parliament recently approved a bill introducing a broad data breach notification requirement for companies that are responsible for processing personal data. Joke Bodewits and Laura-Jean van de Ven (Amsterdam) assess the likely impact of this bill once it becomes law and advise on the changes that may need to be addressed with regard to companies' agreements with providers of data processing services.

EUROPE – UK

17 The difficulties of reopening settled cases even where a party acted fraudulently

A recent decision of the English Court of Appeal underlines the paramount importance attached to the finality of settlements. Lydia Savill and Michael Armstrong (London) point out that this judgment makes it more difficult to reopen settled cases on the basis of fraud, except where it can clearly be shown that there was no suspicion of any fraud at the time of the settlement.

19 Compensation Act: insurers' pro rata right of recovery reinforced

Although specific to the law in Guernsey, a recent judgment of the English Supreme Court provided valuable analysis (obiter) of insurers' pro rata right of recovery in cases where they have been fixed with 100% liability under the Compensation Act 2006. Nick Atkins, Jamie Rogers and Michael Armstrong (London) provide an overview of the case, which reinforces the

In this issue...

longstanding market practice of liability sharing between all relevant insurers.

21 The UK Consumer Rights Act – What to expect?

In October 2015 the UK Consumer Rights Act will come into force, resulting in the largest overhaul of consumer law in the UK for decades. Valerie Kenyon and Natalie Burton (London) summarise the key changes affecting consumer transactions and consumer notices, and comment on the impact these changes will have on businesses.

NORTH AMERICA – US

27 New addition to California's "Prop 65" businesses must provide clear warnings if products contain Bisphenol A

Bisphenol A was recently added to the list of hazardous substances under California's Safe Water and Toxic Enforcement Act ("Prop 65"). As Colleen McKnight (Houston) and David Skaar (Los Angeles) report, the decision is under appeal, but for the time being, businesses that produce, distribute, or sell products in California that may expose the public to this substance will need to provide clear warnings.

ASIA PACIFIC – CHINA

31 China launches new rules on food recall system

Jun Wei, Roy Zou, Michael Zou and Jessie Xie (Beijing) and Philip Cheng and VC Leow (Shanghai) provide an overview of top-to-bottom changes in China's legislative and regulatory framework, which underline the country's determination to overcome its food safety issues and likely signal a new chapter in China's never-ending battle against unscrupulous food suppliers.

Overview

It has been 30 years since a no-fault product liability regime was first introduced in European law. The European Product Liability Directive was controversial from the time it was first proposed. Many apprehended that the introduction of tort liability without the need to prove fault would lead to runaway litigation in Europe, and an explosion of liability costs for product manufacturers and their insurers. That, of course, did not happen. The practical experience of the Product Liability Directive is that, for the most part, it strikes the right balance between the interests of consumers in being able to receive fair compensation when injured by a genuinely faulty product, and the interests of product manufacturers and suppliers who need to be able to market their products efficiently without fear of unfair or excessive liability risks.

As we have reported regularly in *International Product Liability Review*, product liability litigation is steadily increasing in many European countries. But, surprisingly, there have been relatively few cases that have grappled with the most controversial aspects of the Product Liability Directive, and very few of those issues have been resolved in any definite way. Having said that, earlier this year the Court of Justice of the European Union ("CJEU") handed down a judgment that could potentially alter the definition of "defective products" and create a general liability in cases involving suspected product defects. In this issue, we focus on some of the key elements of this controversial decision, which could have widespread consequences for manufacturers and importers (page 2).

France remains a key jurisdiction in Europe for the development of novel liability concepts; in this issue we report on a significant judgment of the Court of First Instance of Nanterre, France, applying principles of market share responsibility in a product liability case for the first time (page 12). Clearly, this will potentially give rise to significant liability risks for product manufacturers, particularly in the life sciences sector, and future developments will need to be watched carefully.

Product safety regimes continue to develop around the world. In this issue we focus on some of the key reforms to the food safety regime in China (page 31). These changes are indicative of a global trend whereby countries that, historically, have not imposed

burdensome product safety regulations are now adopting measures that create significant risks for companies that do not comply.

Almost all product sectors are now concerned by the rapid development of the "internet of things", and the new liability issues raised in this arena are increasingly important for manufacturers, their insurers, and their legal advisers. Developments in this sphere arise against a background of growing regulatory intervention, as lawmakers around the world race to keep pace with the rapid development of technology and its commercialisation. This issue of *International Product Liability Review*, for example, includes a report on some significant regulatory changes in data protection laws in the Netherlands (page 15).

The product safety implications of emerging technologies will be a point of focus at the upcoming International Symposium of the International Consumer Product Health and Safety Organization (ICPHSO), to be held in Billund, Denmark on 20 and 21 October 2015. This will be an important forum where major stakeholders will discuss key issues and future trends in product safety practice and policy. It will be well-worth attending. Further information can be found at www.icphso.org or by contacting Rod Freeman at rod.freeman@hoganlovells.com.



Rod Freeman
London
rod.freeman@hoganlovells.com