

**International Product Liability Review**  
(incorporating European Product Liability Review)  
Issue 46 - March 2012



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### About our Product Liability Practice

Hogan Lovells has the leading product liability practice covering all aspects of product safety as well as civil and criminal liability. We have experience of acting for clients in respect of a wide range of products including food, pharmaceuticals, cars, tobacco, mobile phones, cosmetics, electrical and electronic products, toys and children's products, sporting goods, blood products, aircraft and machinery. Hogan Lovells' product liability lawyers are supported by a dedicated Science Unit and Project Management Unit.

If you would like more information about Hogan Lovells' product liability practice, please visit our website at [www.hoganlovells.com](http://www.hoganlovells.com) or contact the Product Liability Group Leader, John Meltzer, at [john.meltzer@hoganlovells.com](mailto:john.meltzer@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](mailto:rod.freeman@hoganlovells.com)

**Siobhan Thomson**

[siobhan.thomson@hoganlovells.com](mailto:siobhan.thomson@hoganlovells.com)

**Claire Taylor**

[claire.taylor@hoganlovells.com](mailto:claire.taylor@hoganlovells.com)

**Valerie Kenyon**

[valerie.kenyon@hoganlovells.com](mailto:valerie.kenyon@hoganlovells.com)

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](mailto:jacopo.bartolomeo@hoganlovells.com)

**Christelle Coslin (Paris)**

[christelle.coslin@hoganlovells.com](mailto:christelle.coslin@hoganlovells.com)

**Lindsay S Goldberg (Baltimore)**

[lindsay.goldberg@hoganlovells.com](mailto:lindsay.goldberg@hoganlovells.com)

**Karen Jelsma (Amsterdam)**

[karen.jelsma@hoganlovells.com](mailto:karen.jelsma@hoganlovells.com)

**Ji Jienji (Shanghai)**

[ji.jienji@hoganlovells.com](mailto:ji.jienji@hoganlovells.com)

**Valerie Kenyon (London)**

[valerie.kenyon@hoganlovells.com](mailto:valerie.kenyon@hoganlovells.com)

**Carolin Konzal (Munich)**

[carolin.konzal@hoganlovells.com](mailto:carolin.konzal@hoganlovells.com)

**Eugenio Vázquez (Madrid)**

[eugenio.vazquez@hoganlovells.com](mailto:eugenio.vazquez@hoganlovells.com)

## In this issue...

### 1 Overview

#### FEATURE

### 2 European Commission publishes revised Guidelines for Businesses to manage Product Recalls and other Corrective Actions

Following a lengthy review process with stakeholders, revised guidelines have been published which offer practical advice to businesses for managing product recalls and other corrective actions in respect of unsafe products. Rod Freeman and Claire Taylor (London) reports on the key changes that have been introduced.

#### EUROPE - FRANCE

### 4 European and French developments of the "breast implants case"

In late 2009, the French Agency for the Safety of Medicines and Health Products received increasing reports of bursting breast implants manufactured by Poly Implant Prothèse. Charles-Henri Caron and Chloé Cuilleron (Paris) consider recent developments in the case, and European and French proposals for the future.

### 7 The precautionary principle in French public health matters: hesitant application but constant reflection

Cécile Derycke, Christine Gateau, and Charles-Henri Caron (Paris) describe the operation of the precautionary principle in cases relating to electromagnetic fields emitted by base stations and the safety of health products, noting that the precautionary principle is having an increasing influence on health matters in France.

### 11 Expert proceedings in France: how to work your way out effectively

Court appointed experts are routinely used in French product liability proceedings. Sylvie Gallage-Alwis (Paris) takes readers through the various stages involved in such proceedings, and highlights some of the traps to be avoided.

### 14 The ECHR favours freedom of expression over secrecy of criminal investigations – plaintiffs' counsel entitled to comment on confidential information

The European Court of Human Rights has upheld a lawyer's right to freedom of expression in a case in which the lawyer had discussed with the French media

the contents of an expert report that had recently been filed with the Court. Cécile Derycke and Raphaëlle Monjou (Paris) take a critical look at the Court's decision.

#### EUROPE - ITALY

### 18 Class Actions: Rome Court of Appeals confirms dismissal for non-admissibility of the first class action filed in Italy against the tobacco industry

The Court of Appeals of Rome has confirmed the inadmissibility of a class action filed by the primary Italian consumers association Codacons and three smokers against British American Tobacco Italia S.p.A. Francesca Rolla and Filippo Chiaves (Milan) explore the decision and its potential impact.

#### EUROPE - NETHERLANDS

### 21 The Dutch Act on Collective Settlement of Mass Damages

Karen Jelsma (Amsterdam) considers the success to date of the Act on Collective Settlement of Mass Damages and looks at some of the key amendments that have been proposed to try and increase its effectiveness.

#### EUROPE - SPAIN

### 24 Audiencia Provincial of Madrid confirms criteria for establishing a car manufacturer's liability for the non-deployment of its airbags

Eugenio Vázquez Gutiérrez (Madrid) reports on an interesting decision of the Regional Court of Madrid, in which an assessment was made of the criteria a claimant will have to prove against a car manufacturer to recover damages for non-deployment of an airbag, in cases where a specific defect in the airbag cannot be identified.

### 26 Liability of suppliers of defective materials used in construction projects

Contrary to precedent, the Court of Appeal of Murcia has held a sub-supplier of materials, rather than the building contractors, directly liable to the owner of a building. Cristina Redondo Belda (Madrid) analyses the reasoning behind the court's decision.

## EUROPE - UK

### 28 "Light" asbestos exposure after 1965: was injury reasonably foreseeable?

Alex Woods (London) reports on a recent English Court of Appeal case which provides useful guidance on the question of breach of duty in asbestos cases, including the relevance of the defendant's state of knowledge.

### 31 Quantifying damages in mesothelioma litigation – the court's departure from the JSB guidelines

The English High Court recently considered in some detail the way in which the Judicial Studies Board's guidelines for the assessment of personal injury damages ought to be applied in mesothelioma cases, focusing particularly on the lower range of damages suggested in the most recent edition. Rod Freeman and Richard Brown (London) report.

## NORTH AMERICA - US

### 33 Applicability of the pre-emption doctrine in US drug law based on the decision of the US Supreme Court in *PLIVA Inc v Mensing*

The US Supreme Court has ruled that state law liability claims against manufacturers of generic pharmaceuticals are pre-empted because it is impossible for such manufacturers to comply with both state and federal law labelling requirements. Ina Brock and Dr Matthias Schweiger (Munich), together with Lauren S Colton and Lindsay S Goldberg (Baltimore) explore the decision in light of earlier case law, and consider its potential consequences.

## NORTH AMERICA - CANADA

### 38 Appeal court puts to rest spectre of liability for standards development bodies

Siobhan Thomson and Zen Cho (London) report on the decision of the British Columbia Court of Appeal in *More v Bauer Nike Hockey Inc*. In overturning a first instance decision, the Court of Appeal addressed the question of whether the Canadian Standards Association owes a duty of care to an individual who is physically injured while using a certified product. Its opinion - although *obiter* - was that it did not.

## ASIA PACIFIC - CHINA

### 40 The PRC Tort Liability Law: a year and a half with how much to show?

Eugene Chen and Jieni Ji (Shanghai) consider The Tort Liability Law of People's Republic of China, which came into force on 1 July 2010. There has been a great deal of public focus on the new rules relating specifically to product liability; those new rules are considered in the context of recent case law and experience.

## Overview

This issue of International Product Liability Review highlights some significant developments for product manufacturers, from around the world.

In Europe, we report on the trend to introduce the "precautionary principle" into public health considerations in France (page 7). While it might be going too far to suggest that this trend gives "junk science" a new foothold in public health policies, it certainly does raise some real cause for concern for producers in a range of industries, especially the life sciences and food sectors, as the authors of our article point out. This trend is strongest in France, but its influence could quickly spread throughout Europe. This is an area to carefully be monitored.

Over in the United States, the issue of federal pre-emption is again hitting the headlines. This time, we see the Supreme Court reaching a decision, based in its interpretation of federal legislation, that creates a bizarre situation in which the consumer's right to be warned of risks differs depending on whether the drug they are given is manufactured by the innovator or by a generic manufacturer (page 33). Whilst we can be sympathetic with the court in this decision, having regard to the way in which the legislators decided to deal with the obligations of generic drug suppliers, this case does highlight the fact that the operation of tort law can often have little to do with proper consideration of the interests of consumers in being protected from risks. Clearly, this is an issue that needs to be reconsidered by the federal legislators in the US.

In China, we report on the gradual evolution of a liability regime that is starting to reflect influences from other parts of the world (page 40). Whilst the scope of provisions that allow for unlimited punitive damages are just starting to be tested, companies operating in the Chinese market will want to keep a close eye on the trends, especially if there develops a sense that US trends may start to take hold. Developments in the field of product safety regulation, probably influenced much more by European trends, are happening more quickly. To the extent that these developments create greater predictability in the Chinese market for international companies, this can be seen as good news. But clearly there is a long way to go before international businesses can start to feel fully confident about the obligations and risks that exist when marketing products in that part of the world.

Back in Europe, the publication by the European Commission of PROSAFE's new Corrective Action Guide is a major development (page 2). This will become the key handbook that businesses in Europe will be expected to consider when dealing with unexpected consumer product risks - in particular the use of the new risk assessment methodology incorporated in this document. Hogan Lovells worked closely with PROSAFE as a member of the working group that drafted this guide, and we already have extensive experience in working with companies in a range of product

industries to use the new risk assessment methodology to deal with particular problems. Our experience of using that methodology has generally been very good, and already it is starting to be considered as a "state of the art" tool that can assist companies (and authorities) when dealing with product safety issues in other parts of the world.

### **Rod Freeman**

London

rod.freeman@hoganlovells.com