



International Product Liability Review

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**Hogan
Lovells**

About our Product Litigation and Compliance Practice

Hogan Lovells has the leading international product liability practice covering all aspects of product liability, compliance and mass torts. We focus on acting for clients around the world covering all products sectors 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 and compliance 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 litigation and product 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:

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Meet the team

We are pleased to introduce two of the authors who have contributed to this edition of *International Product Liability Review*: Tobias Ackermann (Munich) and Brenna Nelinson (Baltimore).



Tobias Ackermann

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Tobias is a senior associate in Hogan Lovells Munich office.

He advises clients on product safety, product liability and product-related supply chain disputes worldwide. He has relevant experience in representing clients in court proceedings on various levels. He also advises clients on cross-border product liability cases, on recalls across the globe and product compliance issues.

His industry focus lies in the automotive, transport, consumer goods, life sciences and electronic industry. Tobias assists clients in coordinating court proceedings in various countries and communicating with customers, courts, authorities and the public. He knows the challenges companies are faced with in conflicts between defending claims, enforcing own claims and maintaining the business relationship.

At the moment, Tobias is advising and representing a client in a complex product-related supply chain dispute with court proceedings, arbitration proceedings and criminal investigations in Singapore, Norway, Sweden, Denmark and Germany.

See page 12 for Tobias' article "*Keeping consumer claims out of court: cooperation, conciliation and cost cutting?*"



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Brenna's practice focuses on complex commercial and product liability litigation, and white collar criminal defence, with a particular focus on clients in the life sciences industries. Her work includes international matters, representing clients in large mass tort matters, as well as assessing risk and liability for individual claims against pharmaceutical companies. She assists clients in all stages of litigation, including case assessment, factual investigation, electronic discovery, motions practice, mediation, depositions, and trial preparation.

As a member of the US national product liability team, Brenna has represented several medical device manufacturers and pharmaceutical companies in lawsuits following international recalls. Brenna also advises clients in the life sciences and pharmaceutical manufacturing industries on all product liability and related concerns.

See page 20 for Brenna's article "*Design defect claims in pharma: federal pre-emption and the uncertain protection of "Comment k"*"

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2 Towards better enforcement of European product safety laws – PROSAFE Market Surveillance Meeting and Workshop held in Slovenia

European product safety authorities met recently in Slovenia to discuss current projects, policy issues and future planning for enforcement. Hogan Lovells was there, representing product manufacturers, importers and distributors. Rod Freeman (London) reports on the discussions.

3 Blue Guide 2016: catching up with online retail and introducing greater market surveillance

Following publication of the European Commission's revised Blue Guide, Caroline Hibberd and Tom Caldwell (London) summarise the main changes and take a closer look at amendments relating to online sales and market surveillance.

EUROPE - FRANCE

6 Special product liability regime or general liability regime? You can't have it both ways

Christophe Garin and Xavier Philipps (Paris) look at a recent judgment of the French Supreme Court which has helped to provide producers, sellers and other supply chain actors with a clearer understanding of their respective exposures in product liability cases.

EUROPE - GERMANY

9 Bring on the digital healthcare revolution: legal issues with digital health products and how to tackle them

Medical device manufacturers, software developers and pharmaceutical companies are collaborating to develop new digital health products. These products create

huge opportunities for innovative approaches to healthcare. They also create legal exposure in a number of areas. Dr Matthias Schweiger (Munich) summarises some of the key areas of exposure and suggests questions that manufacturers should bear in mind in a digital health marketplace.

12 Keeping consumer claims out of court: cooperation, conciliation and cost cutting?

The EU's Alternative Dispute Resolution Directive was recently implemented in Germany. Tobias Ackermann and Maike Huss (Munich) consider the impact this development is likely to have on disputes between consumers and traders and summarise the new procedural issues that have arisen. As they point out, although traders can decide whether or not to accept this new procedure, if they do not, there may well be a tightening of the law to ensure a consumer-friendly alternative to litigation.

EUROPE - NETHERLANDS

15 Risk assessment for nanomaterials in cosmetics in the Netherlands

Karen Jelsma and Laura-Jean van de Ven (Amsterdam) report on developments in the Netherlands in the regulation of the use of nanomaterials in cosmetic products, where the authorities are currently developing a web-based tool to help producers and agencies with risk assessments in this area.

EUROPE - UK

18 Fatal accident claims: recent judgment changes approach to damages calculations

Following a recent Supreme Court decision, defence teams in fatal accident claims should be aware that the method for calculating damages has changed in England and Wales. As a result, defendants may have to pay more than they did before. Natalie Burton (London) summarises this judgment and assesses its impact.

NORTH AMERICA - US

20 Design defect claims in pharma: federal preemption and the uncertain protection of "Comment k"

Lauren Colton and Brenna Nelinson (Baltimore) sum up recent US case law which creates confusion for drug manufacturers over when and how the doctrine of federal preemption and the liability exemption in Comment k will be applied in design defect claims.

25 3D printing: new technology and new product liability concerns

3D printing presents an exciting opportunity for product manufacturers: it has the potential to create new products, reduce the cost of production of existing products, and disrupt traditional supply-chain logistics. However, when the new technology meets traditional product liability law, novel issues arise. Phoebe Wilkinson and Samuel Zimmerman (New York) discuss the technology and how it may impact the legal environment in the United States for product manufacturers.

ASIA-PACIFIC - AUSTRALIA

28 Australian consumer protection and competition regulator flags its priorities for 2016

Earlier in 2016, the Australian Competition and Consumer Commission (ACCC) released its Compliance and Enforcement Policy for 2016, setting out enforcement priorities and strategies for the year ahead. Hayley Upton (DibbsBarker, Brisbane) and Scott Sloan (DibbsBarker, Sydney) summarise the ACCC's objectives, which give stakeholders operating within in-scope industries an opportunity to measure their practices against Australian competition and consumer laws.

Overview

A consistent theme in *International Product Liability Review* over past years has been that, in a world where product manufacturers are constantly innovating in new technologies, regulatory and liability regimes can come under strain and may need to adapt. The theme continues in this issue.

Companies across a wide range of sectors are making great strides in developing the concept of "digital health", with innovations that promise to bring great benefits to patients and to health management in the community generally. In this issue, we take a look at some of the liability and regulatory challenges that companies face when seeking to innovate in this area (page 9). Our author, Matthias Schweiger, predicts that we are but "in the first minutes of the first day of the digital health revolution", which is an exciting prospect, but one that promises to bring with it plenty of issues for companies to grapple with as they manage their compliance and liability risks internationally.

Similarly in the field of nanomaterials, despite the fact that commercialisation of the technology has been with us for decades, the regulatory risk landscape remains uncertain. The development of nanotechnology is already well established in the cosmetics industry, where it presents many opportunities for companies and benefits for consumers. However, regulators around the world have still not reached a landing point on how the safety of products containing such technology should be regulated. In that regard, we see some interesting developments in the Netherlands, where the Dutch Authorities have proposed the development of a web-based tool to assist authorities and product manufacturers to undertake risk assessments for cosmetic products using nanotechnology (page 15). It will be worth watching these developments closely, as any concrete initiatives that flow from this proposal may well influence the approach taken by authorities elsewhere in Europe, and beyond.

We also see rapid commercialisation of "3D printing" technologies, again presenting exciting possibilities and benefits for companies and consumers. As this technology starts to become more commonplace both at an industrial and a consumer level, interesting liability issues will emerge that will need to be resolved. We take a look at some of those issues from page 25.

We also report on some developments in the enforcement of product safety in Europe. The PROSAFE Market Surveillance Meeting and Workshop held in Slovenia in May 2016 provided some interesting insights into the priorities for the national market surveillance authorities around Europe over the coming year (page 2). The publication by the European Commission of the revised "Blue Guide" was also significant, introducing some important changes to the interpretation of European product regulation, including in relation to "on-line" sales (page 3).

In October this year, Hogan Lovells will be hosting its annual Product Liability Summit in Europe. Following on from the success of our event in Munich last year, this year we will be taking the Summit "on the road", providing an opportunity to participate in the discussions in Germany, France and Italy. Our theme for this year is "Preparing now for challenges in 2020", and will include presentations led by some of the world's leading experts from within our own team, and from major companies. This is a "must attend" event, and the Hogan Lovells International Products Team is looking forward to seeing many of our friends join us. Please email emma.lenze@hoganlovells.com for further details.



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