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About our Global Products Law Practice

Hogan Lovells Global Products Law Practice is internationally renowned for its work in product litigation, safety and compliance. We act for clients around the world covering all product sectors including pharmaceuticals and medical devices, cars, tobacco, mobile phones, cosmetics, electrical and electronic products, chemicals and hazardous substances, toys and children's products, food and beverages, sporting goods, aircraft and machinery. Hogan Lovells product litigation and product safety lawyers are supported by an in-house Science Unit and a Project Management Unit.

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About *International Products Law 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 Products Law 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.

This issue of International Products Law Review is produced with the support of our International Co-ordination Panel:

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Meet the team



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With a passion for medicine and a natural scientific aptitude, Julie Schindel doesn't just grasp the complex medical and scientific issues involved in products liability litigation – she masters them so her clients don't have to. Her ability to steep herself in the subject matter of each case, as well as her clients' business and their industry, enables her to offer counsel that is both nuanced and practical.

Julie's civil practice focuses primarily on product liability litigation, including individual, mass tort, multidistrict litigation, and class actions in federal and state courts across the United States. She also has experience in complex civil and commercial litigation. Julie's clients and team members know they can trust her to learn the details better than anyone else and to translate that knowledge into thoughtful, practical, strategic analyses. This balance of detail-oriented, thorough scientific know how with business-focused insights is the hallmark of her practice.

Julie received her J.D., cum laude, from the University of Maryland School of Law in 2016 and was a summer associate with Hogan Lovells in 2015 and 2014.

See Julie's feature article "US litigation funding arrangements: towards disclosure?" on page 6.



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As part of the firm's market-leading product liability practice, Adeela Khan advises clients on commercial litigation and regulatory issues. She has experience in acting for life science clients in both litigation and arbitration involving allegations of regulatory and contractual breaches. She also advises major manufacturers on EU and UK product regulations. This involves helping clients ensure their products comply with relevant safety legislation, assisting them in their conversations with regulators, and managing potential product safety risks.

Adeela maintains a varied pro bono practice and has assisted with applications for criminal injuries compensation, and advised on the establishment and operations of a charitable incorporated organisation.

As a trainee, Adeela spent six months in our Paris office, where she gained experience in international arbitration. Prior to moving to the UK, she lived in Pakistan where she gained work experience at a corporate law firm.

See Adeela's article "Don't go changing your claim: High Court and Court of Appeal rule on preliminary issue of the scope of the Claimant's claims on defect in the Seroxat Group Litigation" on page 24.

In this issue...

Feature

US litigation funding arrangements: towards disclosure?

There's a greater focus on litigation funding in the US than ever before, with one of the most hotly debated issues being whether or not details of these arrangements should be disclosed during litigation. Now, as Julie Schindel (Baltimore) explains, recent judicial and congressional developments hint at a possible trend towards requiring some form of mandatory disclosure, particularly in multidistrict litigations.

Science Update

Climate Change: The case for businesses to take action heats up

Recent increased focus on the effects of climate change and its contributory factors has meant increased scrutiny on businesses in relation to their climate-related policies and statements. Marion Palmer (London) looks at some of the recent regulatory and legal actions focused on businesses' responses to climate change and considers what companies will need to focus on to achieve greater sustainability.

Europe – Spain

Causation-related factual evidence: ECJ judgment interpreted by Spanish National Court

For the first time, the Spanish courts have applied a landmark 2017 ruling by the European Court of Justice on causation-related factual evidence. Carolina Revenga and Jorge Etreros (Madrid) summarise the facts in these two recent cases in the Spanish National Court and examine the links to the ECJ judgment. As they report, for the moment, the judgments in both cases point to a positive interpretation for manufacturers.

Europe – EU

CJEU: Consent on the internet means “opting in”

A recent decision by the CJEU clarified the issue of what constitutes consent to the use of website cookies. As Eduardo Ustaran and Katie McMullan (London) report, the judgment strongly reaffirms the standard long upheld by regulators, under both the Data Protection Directive and the GDPR, that consent by users must be active and unambiguous. The good news for those tasked with drafting “clear and comprehensive” cookie policies and transparency notices? The CJEU stopped short of saying that service providers must identify third-party data recipients by name.

The new EU Cybersecurity Act: one step closer to a more secure future

To respond more effectively to the new challenges that have emerged from the transformed cyber-threat landscape, on 27 June 2019 the European Commission advanced its EU cybersecurity policy with the entry into force of the Cybersecurity Act. As Charles-Henri Caron and Anne-Laure Morise (Paris) report, this new Regulation provides the EU Agency for Cybersecurity with a strengthened and permanent mandate and creates the first EU-wide cybersecurity certification framework.

Europe – Germany

Consumer ADR: draft bill to amend current regulation

Stefan Mayr (Munich) reports on the draft bill recently introduced to amend the German Act on Alternative Dispute Resolution in Consumer Matters. As Stefan points out, while the draft bill goes a long way towards clarifying areas of the existing legislation that have proved problematic, it has been criticised for, amongst other things, failing to implement fee-based incentives to promote the use of out-of-court conciliation bodies.

Europe – UK

Don't go changing your claim: High Court and Court of Appeal rule on preliminary issue of the scope of the Claimant's claims on defect in the Seroxat Group Litigation

Matthew Felwick and Adeela Khan (London) consider the Court of Appeal's ruling which highlights the importance of case management decisions within UK proceedings and marks the first time the Court of Appeal has endorsed the holistic approach to defect. As they note, the case serves as a reminder that departing from, or seeking expansion of, clearly delineated issues can undermine careful and efficient case management, particularly when it comes to large group actions.



Feature

US Litigation funding arrangements: towards disclosure?

Introduction

It's no secret that commercial litigation in the US is expensive. So it shouldn't come as a surprise that litigation funding – a solution that's been proposed to deal with these ever-increasing costs – has come to the fore in the last few years. But what exactly is litigation funding?

Also called litigation finance or third-party funding, it is the provision of capital to a claimholder or law firm in exchange for a portion of the proceeds from the litigation (or arbitration). In other words, companies will fund costs and expenses on behalf of a party in exchange for a portion of the judgment award if the party prevails. If the party is unsuccessful, the company bears the cost.

According to a survey by a prominent litigation finance firm, since 2013 there has been a startling estimated 414% increase in the use of litigation finance by US law firms. Yet despite this almost exponential growth on the business side, the law surrounding litigation funding has struggled to keep up. With judicial opinion on the topic constantly evolving, there's a current lack of cohesion in the law governing legal issues relevant to cases with litigation funding.

One of the most hotly debated topics in this space is whether the existence and/or details of a funding arrangement must be disclosed in litigation and, if so, to what extent and to whom. Recent judicial and congressional developments hint at a possible trend – albeit a slow-moving one – towards requiring some form of mandatory disclosure, particularly in multidistrict litigations (“MDLs”).

Disclosure developments in the courts

In most states, there is no clear legislative guidance on whether third-party funding must be disclosed at all in litigation, let alone to whom, how, or at what point such disclosure should take place. Rather than wait on the sidelines, some federal judges are taking action on these issues – most notably in the MDL context. Recent orders by Judges Rodgers, Grimm and Polster in the 3M Earplug, Marriott Breach and Opioid MDLs have demanded disclosure of litigation funding information.

Courts moving towards disclosure in MDLs

In MDL cases, one critical mandate for the transferee judge involves selecting counsel for leadership positions. Determining the appropriate leadership structure and selecting the right lawyers to fill those positions is one of the first and most important case-management tasks. Depending on the nature of the claims, the number of individual cases, and the variety and complexity of interests involved, the MDL transferee judge may select attorneys for the positions of lead counsel, liaison counsel, steering committee and/or settlement committee.

Their roles can include presenting positions on procedural issues during the course of the litigation, undertaking administrative matters, handling discovery and other day-to-day aspects of the litigation, and conducting settlement negotiations. In selecting attorneys for these positions, judges have typically focused on qualities like cooperative tendencies, reputation, and expertise. But two MDL judges recently emphasised the importance of considering another factor: the attorney's involvement in litigation funding.

Both Judge Casey Rodgers of the Northern District of Florida and Judge Paul Grimm of the District of Maryland issued orders requiring third-party financing disclosures from counsel seeking leadership appointments in their respective MDLs. However, they limited the scope of these disclosures so counsel would only be required to submit information on litigation funding to the court, not the parties, and submission of the underlying funding agreements was not required.

Although there was no outside financing in the Marriott data breach litigation, Judge Grimm made clear that he would take that into account for selection purposes if such financing existed. He went on to explain how important it is for judges to know the existence of every party with a stake in the case when selecting attorneys for key MDL leadership positions: “If you have third-party funding...[and] [t]hen, when it comes to resolve the case, those people are not in the room, and if they have minimal expectations of what they must recover in order to maximize their investment, that is an influence, a potential influence, in how the litigation is conducted and how the litigation might be resolved.”

Opioid MDL attorneys must also disclose outside funding to the court

Earlier in May 2018, Judge Dan Polster also issued an order in the MDL Opioid litigation requiring attorneys to disclose any financial backers that stand to profit from settlements in the case – but only to the court. The order applies to third-party contingent litigation funding (“3PCL financing”), which the court defined as “any agreement under which any person, other than an attorney permitted to charge a contingent fee representing a party, has a right to receive compensation that is contingent on and sourced from any proceeds of an MDL case, by settlement, judgment, or otherwise.”

Specifically, any attorney in any MDL case that obtained 3PCL financing must provide a description of the financing along with sworn affirmations – one from counsel and one from the lender – that the funding does not create a conflict of interest, undermine counsel’s obligation of “vigorous advocacy”, affect professional judgment, hand over any control of the litigation to lenders or affect party control of settlement.

While Judge Polster’s disclosure order came after the appointment of leadership positions in the Opioid MDL – unlike the circumstances under which Judge Grimm and Judge Rodgers demanded disclosure – these three instances of court-ordered disclosures point to a general growing concern among the judiciary.

This concern arises from the potential for improper influence from litigation funders and recognition that at least some form of mandatory disclosure is warranted to protect the integrity of the MDL structure and process. The orders also signal a general trend of judges ordering narrow disclosures by ex parte submission made only to the court, not opposing parties, and solely for ethics-related concerns.

The Litigation Funding Transparency Act

Unlike the approaches taken by federal MDL judges, lawmakers appear to be pushing for a broader and more aggressive form of mandatory disclosure of litigation funding. In February 2019, Senators Chuck Grassley (R-Iowa), John Cornyn (R-Texas), Thom Tillis (R-North Carolina), and Ben Sasse (R-Nebraska) reintroduced the Litigation Funding Transparency Act (S.2815) (the “LFTA”), a bill aimed at establishing uniform disclosure requirements in certain federal civil cases. A version of the LFTA was first introduced last year but failed to make it out of committee. Notably, the latest version of the bill proposes going much further on disclosure than any of the recent orders from the judiciary.

The current proposal, which seeks to amend title 28 of the United States Code to “increase transparency and oversight of third-party litigation funding”, would require counsel in class actions and MDLs to disclose in writing to both the court and other parties the identity of “any commercial enterprise” that has a contingent interest in settlements or judgments in the case. In addition to the automatic mandatory written disclosure, counsel would be required to turn over any funding agreements “for inspection and copying”. The bill also sets a timeline for disclosure – 10 days from the execution of the funding deal or when the suit is filed, whichever is later.

The reintroduction of the LFTA comes on the heels of similar steps taken by states like California (by local rule) and Wisconsin (by statute) requiring mandatory automatic disclosure of funding agreements in civil cases. It also follows signs of increased support by the Federal Advisory Committee on the Rules of Civil Procedure for modifications to Rule 26 that would explicitly require disclosure of litigation finance arrangements. The future of the LFTA, however, remains unclear at best. It failed to gain traction when Republicans controlled Congress, and with Democrats regaining power in the House, it seems unlikely to pass in the near future, if at all.

Comment

The prominence of the Opioid MDL, as well as the similar disclosure orders recently entered by Judge Rodgers and Judge Grimm in two other major MDLs, may lead other courts – and certainly those in the MDL arena – to adopt a mandatory but narrow disclosure approach when it comes to litigation funding.

On the other hand, Congress and rules committees are certainly contemplating more extensive disclosure requirements motivated by a broader interest in levelling the litigation playing field and increasing transparency between parties, rather than a concern for potential conflicts of interest or other ethics-related issues. In any event, one takeaway seems relatively clear: the number of recent attempts to require more transparency when it comes to litigation funding agreements is a sign that courts, policymakers, and many members of the bar view contingent third-party funding as warranting at least some level of oversight.

How much is required, however, remains to be seen. The Federal Committee on Rules of Practice and Procedure has yet to issue any decision on its own proposed potential rule change for third-party funding disclosure. But the drastic difference in the approaches coming from the judiciary and the legislature may work towards tipping the scale in favour of such a revision.



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Science Update

Climate change: the case for businesses to take action hots up

In a world increasingly focused on the effects of climate change and its contributory factors it is likely that corporations will be closely scrutinised in relation to their climate-related policies and statements. Failure to substantiate claims or claims about actions with little practical effect are likely to be noticed and publicised leading to reputational loss.

Highly motivated groups such as Extinction Rebellion have demonstrated their willingness to target companies involved in ‘green-washing’.¹

In some cases, companies may face actions from regulators such as those brought in the past in relation to claimed product performance.²

Claims that products are ‘energy efficient’ or have been produced in a more ‘environmentally sustainable way’ are likely to undergo greater scrutiny. Increasingly, companies are making claims about offsetting emissions associated with services, flights for example, or manufacturing of products. In such cases it will be important to provide evidence of realistic offsetting, for example, capture of carbon dioxide in a meaningful time frame, such as a few years, rather than the carbon which will be captured by trees growing over the next 50 years.³

Most companies which assess and publicise reductions in their carbon emissions use a formalised carbon auditing framework. The most widely used voluntary standard is that provided by the ‘GHG protocol’⁴ which measures emissions under 3 different scopes:

- Scope 1 audits the emissions derived directly from actions of the company, for example burning of fossil fuels by back-up generators.
- Scope 2 captures indirect emissions associated with purchased or acquired electricity, steam, heat and/or cooling.
- Scope 3 relates to the “Corporate Value Chain” and allows companies to assess their entire value chain emissions impact (upstream and downstream), and identify where to focus their reduction activities. Scope 3 is intended to capture other indirect emissions (falling outside of Scopes 1 and 2 discussed above), such as those associated with the use of sold products and transportation of products and people.

Previously reporting of Scope 3 has been optional under the GHG protocol and not all companies try to assess emissions associated with Scope 3. Recently, however, there has been renewed interest in Scope 3 reporting in order to help companies make more sustainable decisions about their activities and the products they manufacture, purchase and sell.

In addition to the GHG protocol many companies have signed up to Science Based Targets (a collaboration between UN Global Compact, World Resources Institute and others) which recommends “...if a company’s scope 3 emissions are 40% or more of total scope 1, 2, and 3 emissions, a scope 3 target is required.” Some companies have very high scope 3 emissions, such as those due to business travel, and despite indicating that they follow science based targets have not set targets to reduce scope 3 emissions.

Shareholder actions are already being brought against companies in relation to a failure to disclose adequate information concerning climate change business risks to allow an informed choice (for example in relation to pension investments⁵) or for misleading shareholders about the potential financial risks arising from climate change and activities which increase GHG emissions⁶. Other kinds of actions include climate liability claims⁷. These claims against the so called ‘Carbon Majors’, companies which have been identified as being responsible for large scale carbon

1 <http://bianet.org/english/environment/214419-extinction-rebellion-activists-protest-greenwashing-at-istanbul-biennial>

2 *Australian Competition and Consumer Commission v. Goodyear Tyres*

3 *Australian Competition and Consumer Commission v. V8 Supercars Australia Pty. Ltd 2008*

4 “...[m]ore than 9 out of 10 Fortune 500 companies reporting to CDP use GHG Protocol.” <http://ghgprotocol.org/>

5 *McVeigh v. Retail Employees Superannuation Trust* <http://www.lse.ac.uk/GranthamInstitute/litigation/mcveigh-v-retail-employees-superannuation-trust/>

6 *Abrahams v. Commonwealth Bank of Australia*. <http://climatecasechart.com/non-us-case/abrahams-v-commonwealth-bank-australia/>

7 <http://climatecasechart.com/non-us-case/liiuya-v-rwe-ag/>

emissions, are exploring the ability to attribute climate liability to such companies on the basis of emissions associated with the use of their products over a set number of years. The total emissions associated with their products are then measured against the overall volume of anthropogenic emissions and the company assigned a percentage responsibility for climate-related costs of mitigation and adaptation. A 3 year investigation carried out by the Philippines Commission on Human Rights recently concluded that Carbon Majors which played a role in anthropogenic climate change could be held legally liable for their impacts⁸.

Comment

Although climate liability claims would initially be brought against the major carbon emitters it is possible, if the method of liability attribution is accepted, that claimant lawyers may look to companies with deep pockets which have a relatively small carbon footprint but arguably had the resources to reduce that footprint further, for example, relatively new tech companies able to design energy efficiency into their products, business and infrastructure from the beginning. Other businesses whose products are easy to quantify in terms of carbon emissions are also likely to be a target for this kind of litigation.

Future articles in IPLR will focus on the relevance of scope 3 emissions, outcomes from the COP25 meeting in Madrid, and developments in 'attribution science'.



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⁸ <https://www.business-humanrights.org/en/philippines-commission-on-human-rights-reveals-at-cop-25-worlds-most-polluting-companies-can-be-sued-for-contributions-to-global-warming>

Europe EU

The New EU Cybersecurity Act: one step closer to a more secure future

Introduction

The proliferation of connected devices across industry sectors has led to the emergence of a significant and distinct threat to many types of organisations. However, a majority of European companies continue to underestimate just how exposed they are to cyber risk⁹. This lack of awareness translates into low investment in Internet of Things (IoT) cybersecurity and limited legal risk management.

Against this backdrop, the European Commission (the “Commission”) has been developing and adopting the EU Cybersecurity Strategy, with the European Network and Information Security Agency (ENISA), created in 2004, making an active contribution to policy¹⁰. Initially established for a period of five years, ENISA’s mandate has been progressively extended¹¹, revised and modernised.

At launch, ENISA’s mission was principally to provide advice and assistance and enhance cooperation between EU bodies and Member States in the field of cybersecurity. Over the 2013-2016 period, ENISA’s performance, governance and organisational structure were evaluated by the Commission¹². Based inter alia on its findings and on the consultation of various stakeholders, the Commission concluded that ENISA’s mandate was not sufficient and adopted a new cybersecurity package on 13 September 2017¹³. It proposed a new Regulation providing ENISA with a strengthened and permanent mandate and creating an EU-wide cybersecurity certification framework¹⁴.

Enisa’s strong mandate

The cybersecurity ecosystem is changing all the time with new challenges emerging from the transformed cyber threat landscape. To ensure ENISA can fit into and respond to this new environment, the Cybersecurity Act strengthened its powers to improve coordination and cooperation in cybersecurity across the EU and granted it a permanent status from 27 June 2019.¹⁵ The financial and human resources allocated to ENISA have also been increased.

From now on, ENISA will act as the EU’s cybersecurity expert, providing advice and expertise to Member States, private stakeholders, European institutions and policymakers,¹⁶ and helping Member States to implement the Directive on the Security of Network and Information Systems.¹⁷

Its new objectives are to raise cybersecurity standards across the EU by (i) assisting Member States and EU institutions, bodies, offices and agencies in developing and implementing EU general cybersecurity policy,¹⁸ (ii) supporting capacity building and preparedness,¹⁹ (iii) supporting operational cooperation and coordination among the various actors,²⁰ and (iv) promoting the use of cybersecurity certification.²¹ To that end, ENISA will perform various analyses of emerging technologies, cyber threats and incidents. It will also provide advice and guidance, and develop guidelines and best practices.²²

ENISA works with competent authorities to issue warnings targeted at manufacturers and providers, and requiring them to improve the security of their information and communications technology

⁹ European Commission, Commission Staff Working Document, Impact assessment accompanying the document proposal for a regulation of the European Parliament and of the Council on ENISA, the “EU Cybersecurity Agency”, and repealing Regulation (EU) 526/2013, and on Information and Communication Technology cybersecurity certification, Part 1/6, p. 41.

¹⁰ Regulation (EC) No 460/2004 of the European Parliament and of the Council of 10 March 2004 establishing the European Network and Information Security Agency.

¹¹ ENISA’s mandate was last extended until 19 June 2020 by Regulation (EU) No 526/2013.

¹² Study on the Evaluation of the European Union Agency for Network and Information Security, Final Report.

¹³ European Commission, Press release, State of the Union 2017 - Cybersecurity: Commission scales up EU’s response to cyber-attacks, September 19, 2017.

¹⁴ Proposal for a Regulation on ENISA, the “EU Cybersecurity Agency”, and repealing Regulation (EU) 526/2013, and on Information and Communication Technology cybersecurity certification.

¹⁵ Cybersecurity Act, Recital 16.

¹⁶ Cybersecurity Act, Article 3.

¹⁷ Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016 concerning measures for a high common level of security of network and information systems across the Union (NIS Directive)

¹⁸ Cybersecurity Act, Article 5.

¹⁹ Cybersecurity Act, Article 6.

²⁰ Cybersecurity Act, Article 7.

²¹ Cybersecurity Act, Article 8.

²² Cybersecurity Act, Article 9.

(ICT) products and services where these do not meet cybersecurity standards.²³ More generally, it assists Member States and national authorities to prevent and improve responsiveness to cyber threats and incidents.

EU cybersecurity certification framework

The Commission wants connected devices and IoT technologies to incorporate security features in the early stages of development. It is also important that customers should be able to identify the level of security of the products or services they purchase.²⁴ This is particularly true for devices – like connected products and services in the healthcare sector – that require a high level of security. To achieve this goal, the Cybersecurity Act creates the first EU-wide cybersecurity certification framework.

At the moment, security certification schemes exist in some sectors where cybersecurity is a critical consideration, such as automated cars and electronic medical devices.²⁵ But when such certification exists, it is only recognised in the Member State concerned.²⁶ This means that companies have to certify their ICT products in several Member States if they plan to market them across the EU, which is costly for companies and inefficient for the Digital Single Market (DSM).

For that reason, the Cybersecurity Act adopts a uniform approach to prevent “certification shopping”.²⁷ Specifically, it establishes “a European cybersecurity certification framework that lays down the main horizontal requirements for European cybersecurity certification schemes to be developed and allows European cybersecurity certificates and EU statements of conformity for ICT products, ICT services or ICT processes to be recognised and used in all Member States”.²⁸

ENISA will assist with designing candidate cybersecurity certification schemes that will then be adopted by the Commission.²⁹ Every certification scheme will specify an assurance level (“basic”, “substantial”, or “high”).³⁰ Conformity self-assessment is possible for products and services presenting a low risk with a “basic” assurance level. In such cases, manufacturers and providers issue a statement of conformity under their sole responsibility.³¹

ENISA will also launch a European Cybersecurity Certification website.³² This will contain certification schemes, certificates and statements of conformity, and should build trust among end-users.

Each European cybersecurity certification scheme must include inter alia the “maximum period of validity of European cybersecurity certificates issued under the scheme.”³³ ENISA will evaluate each adopted European certificate scheme at least every five years.³⁴

Recourse to European cybersecurity certification is voluntary, unless otherwise specified by EU or Member State law.³⁵

Any existing national certification scheme covered by the new European certification scheme will cease to be effective.³⁶ Any existing certificate issued under a national certification scheme and covered by the new European certification scheme remains valid until its expiry date.³⁷

Comment

The Cybersecurity Act further strengthens EU cybersecurity policy, enabling manufacturers of ICT products to demonstrate – across the EU – that their products are secure. It should also improve access to information and build trust among the end-users of certified connected products.

23 Cybersecurity Act, Recital 51.

24 Cybersecurity Act, Recitals 7 and 10.

25 Cybersecurity Act, Recital 65.

26 Cybersecurity Act, Recital 67.

27 Cybersecurity Act, Recital 70.

28 Cybersecurity Act, Recital 69.

29 Cybersecurity Act, Articles 8 and 48.

30 Cybersecurity Act, Article 52.

31 Cybersecurity Act, Article 53.

32 Cybersecurity Act, Article 50.

33 Cybersecurity Act, Article 54.

34 Cybersecurity Act, Article 49.

35 Cybersecurity Act, Article 56.

37 Cybersecurity Act, Article 57.

The success of the new certification framework will depend on how readily it can be adapted to deal with constantly evolving cyber threats, market developments and industry specifics. The Commission will play a significant role here by regularly assessing “the efficiency and use of the adopted European cybersecurity certification schemes”.

Also, because certification is not mandatory, the framework’s objectives will be met only if ICT manufacturers and providers make full use of it. Last, it remains to be seen how this new Regulation will work with existing regulations, including the General Data Protection Regulation (GDPR) and the NIS Directive.



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Europe *EU*

CJEU: Consent on the internet means “opting in”

Introduction

On 1 October 2019, the Court of Justice of the European Union (CJEU) handed down a crucial decision impacting how consent is obtained on the internet.

The judgment relates to the Planet49 case,³⁸ where the German Federal Court referred a number of questions to the CJEU about the validity of consent to cookies placed by a website operating an online lottery. The questions referred to the CJEU were

- Does a pre-checked box allow for valid consent to be obtained for the placement of cookies?
- Does it matter whether information stored or accessed using cookies constitutes personal data?
- Must users be provided with information about the cookies’ duration of operation and whether third parties are given access to them?

Despite the questions’ apparent simplicity, the CJEU’s decision had to take into account the interaction of various pieces of legislation. While the requirement for consent before cookies are placed originates from the ePrivacy Directive,³⁹ the requirements for valid consent are now found in the General Data Protection Regulation (GDPR).⁴⁰

To complicate matters, both the facts and the initial hearing in this case occurred before the GDPR came into effect. Because the applicable law at that point was the Data Protection Directive,⁴¹ the considerations given by the CJEU to the concept of consent were primarily based on the provisions of that legislation. Rather surprisingly, however, the CJEU’s conclusion on what amounts to valid consent under the Data Protection Directive essentially matches the GDPR’s definition of consent.

Valid consent for cookies

The CJEU’s decision confirmed the key aspects for valid consent

- Consent must be active, not passive.
- Consent must be unambiguous. According to the CJEU “only active behaviour on the part of the data subject with a view to giving his or her consent may fulfil that requirement.”
- The judgment also confirms that giving users the chance to opt out by unchecking a pre-checked box does not constitute valid consent since “consent given in the form of a preselected tick in a checkbox does not imply active behaviour on the part of the website user.”
- Consent must be specific. This means “it must relate specifically to the processing of the data in question and cannot be inferred from an indication of the data subject’s wishes for other purposes.”

Although some commonly used approaches to comply with this obligation (eg consenting simply by using a service or remaining on a webpage) are not specifically discussed, it’s clear from the reasoning above that they would be insufficient.

It’s disappointing that the judgment does not address the requirement under the GDPR that consent must be “freely given” – the most difficult and contentious requirement for valid consent in practice.

The judgment does, however, confirm that this standard of consent applies to the placement of cookies irrespective of whether the information stored or accessed on a website user’s terminal equipment counts as “personal data” under the GDPR.

³⁸ C-673/17

³⁹ Directive 2002/58

⁴⁰ 2016/679

⁴¹ Directive 95/46

Providing information about cookies

The CJEU concluded that the information that must be provided to users about cookies needs to include the duration of their operation and whether or not third parties could have access to them.

This conclusion was reached on the basis that the purpose of providing this information is to put users in a position where they're able to give consent in a sufficiently informed manner – understanding the role of the cookies being used and the consequences of providing consent to them.

The decision stops short of saying that service providers must identify third parties by name, meaning that it will be sufficient to provide details of data recipients or categories of data recipients. This will, no doubt, be a great relief for those tasked with drafting “clear and comprehensive” cookie policies and transparency notices.

On cookie duration, the information that must be provided is the period for which the data will be stored, or if that's not possible, the criteria used to determine that period (in line with the GDPR's transparency obligations).

Comment

The CJEU's conclusions are, overall, unsurprising. They strongly reaffirm the standard long upheld by regulators, under both the Data Protection Directive and the GDPR.

In reaching its decision, the Court has ultimately removed any room for error about the appropriate standard for consent when placing cookies. This puts real pressure on website operators – and regulators – to ensure this standard is upheld from now on.



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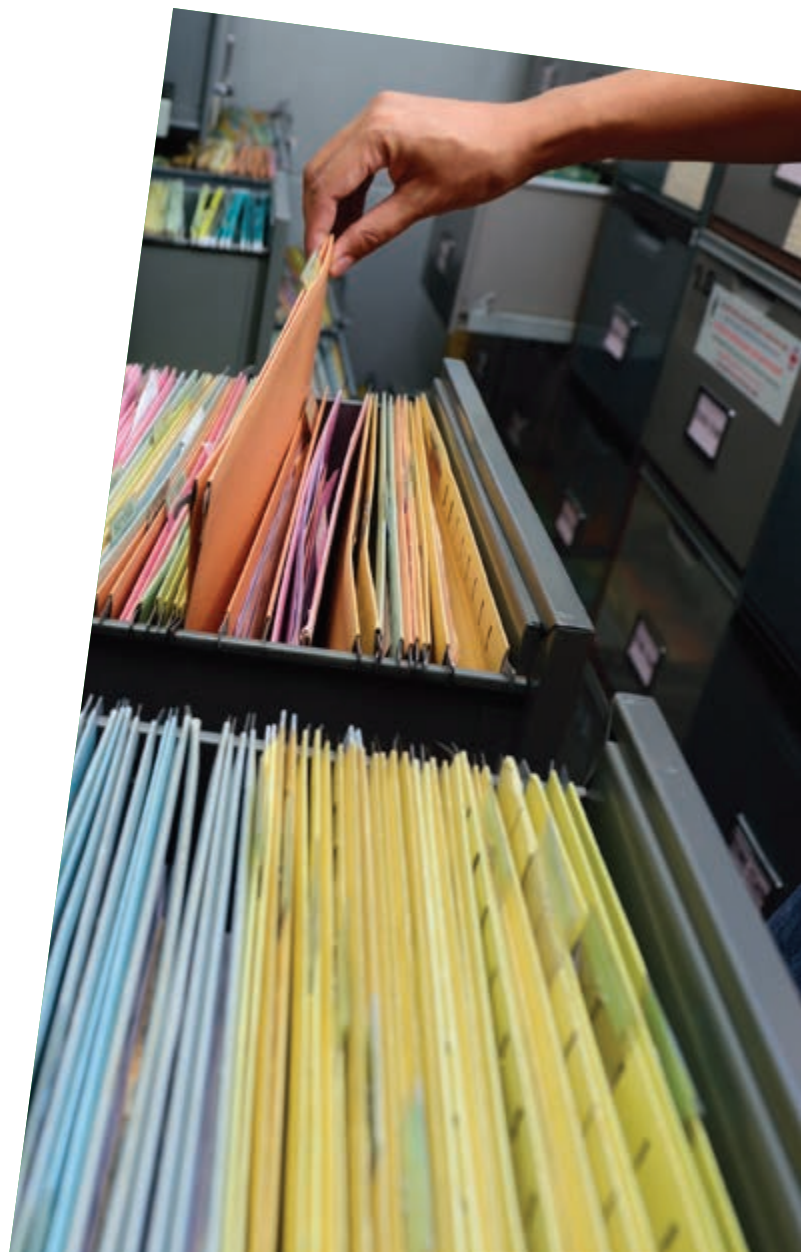


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Europe Germany

Consumer ADR: draft bill to amend current regulation

Introduction

The Federal Government has drafted a bill to amend the German Act on Alternative Dispute Resolution in Consumer Matters (*Gesetz über die alternative Streitbeilegung in Verbrauchersachen – Verbraucherstreitbeilegungsgesetz – “VSBG”*)⁴², in force since 1 April 2016⁴³.

Implementing Directive 2013/11/EU⁴⁴ on alternative dispute resolution for consumer disputes (“**Directive on Consumer ADR**”)⁴⁵, the VSBG created – for the first time in Germany – a framework for consumers to turn to consumer conciliation bodies (*Schlichtungsstellen*) for all disputes with traders.

Introduced to provide an alternative legal tool for out-of-court consumer disputes resolution, the VSBG determines basic conditions as to when consumers can turn to these consumer conciliation bodies and sets out the quality requirements for such bodies. Since coming into force, the number of consumer conciliation bodies and the number of ADR procedures have both slightly increased in Germany.

Background

The draft bill amending the VSBG must be viewed against the background of current developments. In November 2018, a new action in consumer matters (*Musterfeststellungsklage*) was introduced in Germany aimed at facilitating consumer litigation by enabling consumers to rely on a declaratory judgment on legal and factual questions relevant

to their claims. Consequently, lawmakers expect a potential increase of consumer ADR proceedings.

However, participation in the new action is not compulsory for consumers and therefore the action does not replace traditional consumer mass litigation. Only qualified entities, such as registered consumer associations matching strict criteria defined in the Code of Civil Procedure, have standing to sue commercial entities for a declaratory judgment. Consumers can register their claim in a litigation register. A declaratory judgment is binding on the defendant entity and on registered consumers (even where the registered consumers are not parties to the lawsuit in question (*Musterfeststellungsverfahren*)). The action does not however provide awards for the benefit of consumers and individual claims can only be determined in follow-on actions.

This is where the new consumer ADR bill comes into play. The lawmakers expect that, following a *Musterfeststellungsklage*, consumers might choose to bring their claim in ADR proceedings instead of pursuing a slower (and more expensive) follow-on action before the ordinary courts.

Also explaining the draft bill’s introduction, ADR proceedings introduced by the VSBG have encountered a number of issues:

- despite a steady increase in the number of proceedings, a majority of consumers are still unaware that ADR exists;
- determination by a competent consumer conciliation body is complex⁴⁶;

42 English version available at: https://www.gesetze-im-internet.de/englisch_vsbg/index.html

43 For further background information regarding the VSBG see Tobias Ackermann, “Keeping consumer claims out of court: cooperation, conciliation and cost cutting?” *International Product Liability Review* (June 2016), p12

44 Directive 2013/11/EU of the European Parliament and of the European Council of 21 May 2013

45 Available at: <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32013L0011>

46 Since the VSBG came into force, the General Consumer Conciliation Body at the Centre for Conciliation (*Zentrum für Schlichtung e. V.*) in Kehl, which is supported by the Federal Government, has ensured that in cases where no special consumer conciliation body is in place, the consumer can still call a consumer conciliation body. However, since support from the Federal Government ends on 31 December 2019, federal states are obliged from 2020 to set up supplementary consumer conciliation bodies (“Universal Conciliation Bodies”) if they do not have a sufficient range of conciliation services. This has the disadvantage that a large number of supplementary consumer conciliation bodies would need to be set up, with the result that it may be hard to determine jurisdiction.

- there is a lack of clarity over whether a dispute settlement procedure before a consumer conciliation body can be conducted in parallel with a *Musterfeststellungsklage*;
- in pure domestic disputes with online retailers, there is uncertainty whether the German Federal Office of Justice (*Bundesamt für Justiz*), as the German contact for the European Platform for Online Dispute Resolution⁴⁷ (OS-contact), is authorised to inform consumers about competent consumer conciliation bodies; and
- the fact that the German Federal Financial Supervisory Authority (*Bundesanstalt für Finanzdienstleistungsaufsicht*) only has to be informed by financial conciliation bodies recognised by the Federal Office of Justice about the business practices of traders that could significantly impair the interests of consumers that have become known in the course of an arbitration - but the same is not required by recognised insurance conciliation bodies.

Draft bill in focus

To address the issues with the current regulations, the German Federal Government drafted a bill amending the VSGB (*Entwurf eines Gesetzes zur Änderung von Vorschriften über die außergerichtliche Streitbeilegung in Verbrauchersachen und zur Änderung weiterer Gesetze – “Draft Bill”*)⁴⁸. Key provisions of the Draft Bill include:

- establishing a nationwide universal conciliation body (*bundesweite Unviversalschlichtungsstelle*);
- clarifying how an ADR procedure relates to a *Musterfeststellungsklage*;
- increasing the powers of the German Federal Office of Justice; and
- setting out the information obligations of insurance conciliation bodies recognised by the Federal Office of Justice.

⁴⁷ Available at: <https://ec.europa.eu/consumers/odr/main/?event=main.trader.register>

⁴⁸ Published under BT-Drucks. 19/10348; available at: <http://dip21.bundestag.de/dip21/btd/19/103/1910348.pdf>



Provisions in depth

To deal with potential difficulties in determining the competent conciliation body, the Draft Bill provides for the establishment of a nationwide “**universal conciliation body**”. The Draft Bill stipulates that responsibility for supplementary consumer ADR (universal ADR), currently assigned to the federal states, is to be transferred to the Federal Government on 1 January 2020.

The Federal Government should be given the opportunity either to fulfil this task itself (through an official universal conciliation body) or to lend or commission a recognised private consumer conciliation body. This role will fall to the Federal Office of Justice, which would also be responsible for legal and professional supervision.

By operating a nationwide universal conciliation body, the Federal Government would also be fulfilling its obligation under the Directive on Consumer ADR to provide a nationwide infrastructure of consumer conciliation bodies for consumer disputes throughout Germany. Whilst critics have constitutional concerns regarding the competence of the Federal Government to establish a nationwide Universal Conciliation Body, it does seem to be the best way to preserve clarity and legal unity. The alternative would be a division of competence among different bodies in each of the 16 federal states, which would be unnecessarily complex and place a real burden on resources.

The Draft Bill also provides increased powers to the German Federal Office of Justice. Along with supervisory power to withdraw recognition of a consumer conciliation body, the Draft Bill empowers the Federal Office of Justice to also advise consumers and traders in purely domestic disputes if a complaint has been submitted via the European Platform for Online Dispute Resolution.

As the German contact point for the European Platform for Online Dispute Settlement (OS-contact), the Federal Office of Justice can assist consumers and entrepreneurs in resolving disputes relating to complaints submitted via

the OS Platform. This includes assisting with the submission of complaints and, where appropriate, the relevant documents, advising on how the OS Platform operates, explaining the procedures used by dispute settlement authorities, and/or informing complainants about alternative routes to legal protection if dispute settlement via the OS Platform is not possible.

However, there is currently no legal basis for the OS Contact Point to provide advice in purely domestic cases. The Draft Bill therefore envisages extending the role of the Federal Office of Justice under the Consumer Dispute Resolution Act to make it the German contact point for the OS Platform.

In regards to the **relationship** between ADR and the *Musterfeststellungsklage*, the Draft Bill prevents consumers from conducting ADR proceedings if they have registered their claim in connection with a *Musterfeststellungsklage*.

The Draft Bill’s justification for this is that a registered consumer cannot bring a lawsuit against a defendant while the *Musterfeststellungsklage* is pending if the subject matter of the dispute concerns the same facts and has the same declaratory objectives. By extension therefore, the conduct of ADR proceedings before a consumer conciliation body should also be excluded.

Under these circumstances a consumer conciliation body can refuse to conduct ADR proceedings. The registered consumer will not suffer any disadvantages from this as they can try to reach an agreement with the defendant using ADR before registering their claim in connection with *Musterfeststellungsklage*. If they’re unable to reach an agreement, the consumer can still register a claim.

The Draft Bill also obliges private conciliation bodies recognised by the German Federal Office of Justice in the insurance sector to inform the German Federal Financial Supervisory Authority of any business practices of a trader which have become known to them in the course of their arbitration activities that could significantly damage the interests of a large number of consumers.

Comment

Although the Draft Bill contains some improvements, it has been criticised for not providing explicit provisions to promote consumer ADR. For example, proposals such as fee-based incentives to promote the use of out-of-court conciliation bodies have not been implemented. The Draft Bill also means that defendants to a Musterfeststellungsklage will not be forced to face claims from registered consumers via ADR while court proceedings are pending.

It remains to be seen whether further amendments will be made to the Draft Bill. At this point, the German Bundesrat has submitted supplementary proposals and the German Bundestag has carried out an expert opinion. We'll be monitoring developments closely from now on.



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Europe *Spain*

Causation-related factual evidence: ECJ judgment interpreted by Spanish National Court

Introduction

Until recently, the Spanish courts had neither applied nor referenced the 21 June 2017 ruling by the European Court of Justice (ECJ) on the Hepatitis B vaccine. However, that changed in June and July 2019 when the Spanish National Court handed down judgments in two separate cases (for alleged damages following administration of an HPV vaccine), both of which referred to and interpreted the ECJ ruling. This article provides an overview of the conclusions reached by the National Court, as well as the potential implications of its interpretations of the 2017 ECJ judgment.

The 2017 ECJ judgment summarised

By way of background, the European Court of Justice concluded in 2017 that when medical evidence neither establishes nor rules out the existence of a link between a vaccine's administration and the occurrence of a disease, the existence of a causal link between the defect attributed to the vaccine and the damage suffered by the victim could be considered to be established on presentation of certain predetermined causation-related factual evidence, that is when "solid, concrete and concordant evidence" concurs.

In the 2017 case, an expert report had concluded that the weight of the scientific literature did not clearly establish a direct relationship between the vaccine and the disease. However, such a relationship could not be ruled out, given the temporal coincidence between the administration of the vaccine and the onset of the disease. A scientific study supporting the association between the disease and the vaccine was also produced as evidence, along with a decision from the French administration.

Background to the recent Spanish cases

Separate contentious-administrative actions were brought by two girls against the Spanish Ministry of Health and a manufacturer of HPV vaccines. Each plaintiff sought economic compensation for alleged suffering following administration of the vaccine. Both alleged adverse neurological adverse reactions that had not been mentioned in the patient

information leaflet nor in the summary of product characteristics of the vaccine.

The plaintiffs also alleged (i) the liability of the Spanish Ministry of Health for financing the vaccine and including it in the Spanish vaccination calendar, (ii) a lack of safety studies into the vaccine, (iii) the vaccine's ineffectiveness and (iv) lack of compliance by the laboratory with its pharmacovigilance obligations.

The plaintiffs' medical records did not evidence a causal relationship between the alleged diseases and the administration of the vaccine but did indicate that the onset of the alleged diseases happened after the administration of the vaccine. There was therefore an apparent temporal coincidence between the administration of the vaccine and the onset of the alleged diseases.

A large number of clinical trials, studies and papers by worldwide health authorities evidencing the safety and positive risk-benefit profile of the vaccine were filed in support of the lack of causal relationship.

An expert report issued by a neurologist evidenced (i) errors in the medical diagnoses and (ii) the absence of causal relationship on the basis that none of the following three criteria were met: temporal, biological and epidemiological. In relation to the temporal criteria, the expert concluded that the onset of the diseases was either too early or too late to be linked with the administration of the vaccine.

The Spanish judgments in focus

Once it had reviewed the evidence, the National Court issued two 2019 judgments dismissing the actions brought by the plaintiffs on the basis that (i) some of the diseases were incorrectly diagnosed, (ii) the weight of the scientific evidence supported the vaccine's safety and positive risk-benefit profile of the vaccine and (iii) the expert report clearly ruled out a causal relationship between the alleged diseases and the administration of the vaccine.

In relation to the ECJ's June 2017 ruling, the National Court concluded the following (in both its 2019 judgments)

“Finally, the ECJ dated 21 June 2017 (Case C-621/15), provided by the plaintiff, does not obstruct the conclusion reached, since in this case the facts alleged in the lawsuit do not constitute “solid, concrete and concordant evidence” that would allow us to conclude that the vaccine suffers from a defect and that there is a causal relationship between the defect and the disease.”

So although temporal coincidence and the lack of any previous history of related diseases were argued, the National Court reasonably decided not to apply the ECJ judgment. This was because the evidence was not solid enough to conclude both that the vaccine was defective and that there was a causal relationship between the vaccine’s administration and the disease.

Comment

The recent judgments issued by the Spanish National Court, interpreting the ECJ’s 2017 ruling offer helpful guidance in two areas, providing (i) criteria on what can be considered as solid evidence of defect and causal relationship and (ii) the premise used to justify the absence of a causal link between the administration of the vaccine and the onset of the diseases.

Where criteria on what constitutes solid evidence of defect or causal relationship is concerned, the only evidence produced in the two cases before the National Court was (a) an apparent temporal coincidence between the administration of the vaccine and the onset of disease and (b) the absence of any history of related disease in the plaintiffs prior to the administration of the vaccine in question.

Although both facts could have been considered as solid evidence, in light of the ECJ’s ruling, the National Court did not consider them to be solid enough to find the presence of either a causal relationship or a defect. This could be viewed as a positive outcome of the interpretation of the ECJ Judgment for manufacturers given that both judgments set a reasonable standard when interpreting facts and evidence.

On the other key issue – the premise used to justify the absence of any causal link – the Spanish National Court based its interpretation on a lack of solid evidence rather than on the premise that medical evidence ruled out the existence of a link between the administration of the vaccine and the occurrence of disease. This had also been the premise on which the ECJ’s 2017 ruling was based:

“(…) notwithstanding the finding that medical research neither establishes nor rules out the existence of a link between the administering of the vaccine and the occurrence of the victim’s disease”.

This raises two questions (i) what would the National Court have concluded if the evidence had been more solid and (ii) would solid evidence have been enough to discredit the weight of scientific evidence?

In our opinion, even if there had been more solid evidence, the National Court would have reached the same decision on the basis of the weight of the scientific literature and the expert report. This view is based on the fact that, prior to analysing the 2017 ECJ judgment, the National Court clearly ruled out the causal relationship based on the scientific evidence filed on behalf of the manufacturer.

For the moment, this first interpretation of the ECJ’s judgment is positive and suggests that a similar line of reasoning would be followed by the courts in future.



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Europe UK

Don't go changing your claim: High Court and Court of Appeal rule on preliminary issue of the scope of the claimant's claims on defect in the seroxat group litigation

Introduction

On 8 November 2019, the Court of Appeal handed down a unanimous decision on an important preliminary issue in the case of *Bailey and others v GlaxoSmithKline* [2019] EWCA Civ 1924. The decision upholds the 9 May 2019 judgment of Lambert J in favour of the Defendant and is the latest episode in the long-running saga of the Seroxat group litigation – a dispute for which proceedings were first issued in 2007. As outlined below, the Court of Appeal held that the Claimants' case that Seroxat was defective had to remain limited in scope to the argument that Seroxat was "worst in class" regarding the drug's withdrawal symptoms. The Claimants were not permitted to extend the parameters of their case by asserting that Seroxat has no relative benefit over comparator drugs, as this assessment of Seroxat's risk-benefit profile had not been included in the Claimant's initial pleadings.

Background

The Seroxat litigation was originally brought by a group of claimants in 2007, who alleged that Seroxat, a prescription-only antidepressant and one of a class of Selective Serotonin Reuptake Inhibitors ("SSRIs") manufactured by the Defendant, was defective within the meaning of the UK Consumer Protection Act 1987 ("CPA").⁴⁹ Among other things, the Claimants alleged that Seroxat was defective in that it had the capacity to cause adverse effects when discontinued, which prevented or made it more difficult for users to discontinue the drug as compared to other SSRIs.⁵⁰

In 2008, the Defendant issued a Request for Further information to check whether it was part of the Claimants' case that the benefits of Seroxat as compared to other SSRIs were to be taken into account. The Claimants responded in the negative, noting that in the event potential benefits were determined to be of relevance, the Claimants would

deny Seroxat had any greater effectiveness or substantial benefit compared to other SSRIs.⁵¹ The Defendant pleaded in response that the Claimants' approach to defect was flawed, as any proper comparison between medicines would have to include a comparison of the relative risk/benefit profiles of the medicines being compared both generally and the particular claimant in question. The Defendant also challenged the Claimants' case on the facts (i.e. disputing that Seroxat caused greater adverse effects on discontinuance).

The claim was effectively stayed from 2010 to 2015 due to funding issues experienced by the Claimants. Following this, in 2015 case-management judge Foskett J was tasked with determining whether the resumed action should be allowed to proceed given the prolonged interval before it returned to court. In a series of case-management decisions, Foskett J held that fairness dictated that the litigation be allowed to continue, so long as the Claimants' case remained as pleaded at the date of the vacated trial. As stated by Foskett J, a "*risk/benefit analysis had been expressly disavowed*" when setting out the Claimants' pleaded case.⁵² The fresh trial commenced in the High Court before Lambert J in April 2019.

The decisions by the High Court and Court of Appeal

During opening submissions at trial, the Claimant invited the court to infer a "*level playing field*" between Seroxat and other SSRIs, save for the single product characteristic (the greater adverse effects on discontinuance) said to constitute the defect. The Defendant challenged this, stating it required and the inference that Seroxat had no particular benefits compared to other SSRIs, which went beyond the Claimant's pleaded case. The issue had to be determined before the trial could continue.

⁴⁹ Section 3 of the CPA states that a product will be deemed defective "if the safety of the product is not such as persons generally are entitled to expect". Section 3(2) then states that in determining what persons generally are entitled to expect "all the circumstances" shall be taken into account, and sets out a list of non-exhaustive factors required to be taken into account.

⁵⁰ As quoted at paragraphs 9 and 10 of *Bailey and others v GlaxoSmithKline* [2019] EWCA Civ 1924

⁵¹ As summarised at paragraphs 11 and 12 of *Bailey and others v GlaxoSmithKline* [2019] EWCA Civ 1924

⁵² As quoted by the Court of Appeal at paragraph 37 of *Bailey and others v GlaxoSmithKline* [2019] EWCA Civ 1924.

The High Court agreed. In a judgment dated 9 May 2019, Lambert J noted that the opportunity had been open to the Claimants back in 2008 to amend their pleadings so as to include consideration of Seroxat's relative benefits and risks, but the Claimant had not chosen to do so. Further, the Claimants had made no attempt to appeal the case management rulings of Foskett J which had both delineated the scope of the claims allowed to proceed and established the limits of expert evidence to be adduced based on this scope. As to the Claimants' argument that the Defendant had not put forward a *positive* case on the benefits of Seroxat compared with other drugs in the comparator group, Lambert J held that the Defendant was under no obligation to put forward a positive case where the Claimants' had not pleaded a lack of such benefits to begin with. As such, the Defendant's failure to do so did not amount to a concession that no such benefits existed.

The Claimants appealed, pointing out that Foskett J's rulings were given at a Case Management Conference ("CMC") where he was not specifically asked to rule on the question of whether the Claimants were entitled present a risk/benefit case. The Claimant's argued that as the orders made following those CMCs contained no such decision, there was therefore no order made which could have been appealed. As such, the Claimants' position was that Lambert J had erred in her interpretation of Foskett J's judgment.

The Court of Appeal disagreed, holding that Foskett J had clearly identified the issues for trial and set out how the case was to be case managed going forward, including a statement that he would not permit any expansion of the case outside of the parameters he defined. The Court of Appeal's judgment quoted extensively from, and approved Lambert J's judgment, concluding that it was "*plainly impermissible*" for the Claimants to seek to raise the risk/benefits case in opening their case at trial. In particular, raising such arguments now would raise a wide ranging factual and expert inquiry on the relative risks and benefits of Seroxat, which the parties had not carried out.

Comment

The Court of Appeal's ruling is a useful reminder to litigating parties of the importance of case management decisions within UK proceedings. The Court of Appeal emphasised that good case management involves identifying lists of issues which direct the scope of disclosure and the preparation of factual and expert evidence. As such, departing from or seeking expansion of, the clearly delineated issues would undermine the principle of careful and efficient advance management. This is particularly important when managing large group actions.

From a product liability perspective, the Court of Appeal's decision is significant in that it adopted the High Court's decision of *Wilkes v DePuy International Limited* [2018] QB 627⁵³ and in particular the finding of Hickinbottom J that "*assessment of whether the safety of a product is at an acceptable level requires a holistic approach*".⁵⁴ This marks the first time the Court of Appeal has endorsed the holistic approach to defect. Elsewhere, the High Court had already followed this approach in *Gee v DePuy International Limited* [2018] EWHC 1208 (QB).

The case also serves as a reminder to claimants precisely to outline the defect alleged when bringing CPA claims. As stated by the Court of Appeal, it is this articulation of defect that will drive the scope of expert evidence and the focus of the trial, rather than the Defendants response.



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⁵³ Further discussion of the case of *Wilkes v DePuy International Limited* can be found in issue 65 of the International Product Liability Review, December 2016

⁵⁴ As quoted by the Court of Appeal at paragraph 8 of *Bailey and others v GlaxoSmithKline* [2019] EWCA Civ 1924.

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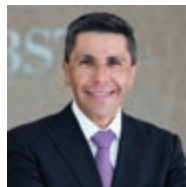


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