Hogan Lovells

International Products Law Review

Issue 75

2019

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.

If you would like more information about Hogan Lovells Global Products Law Practice please contact Lauren Colton at lauren.colton@hoganlovells.com, or any of the partners listed on the back page of this publication.

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.

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See page 16 for Alexander's article "Medical devices: updated Borderline Manual released"

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See page 18 for Elisa's article "New class action law: full steam ahead!"

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Feature

Whistleblowing: new service launched for consumers in France

On 25 March 2019, the French General Directorate of Competition, Consumer Affairs and Fraud Control (Direction Générale de la Concurrence, de la Consommation et de la Répression des Fraudes, "DGCCRF") published its activity report for 2018. As part of the drive by DGCCRF to better inform consumers, the report mentioned the launch of a new mobile app and website[1] – called "SignalConso" – to allow consumers to notify problems encountered in stores and restaurants.

How Signalconso Works

The "SignalConso" mobile app and website were first launched on an experimental basis in December 2018 in one region of France (Centre-Val de Loire). Since then, the experiment has been extended to two other regions: Occitanie and Auvergne-Rhône-Alpes. It should be extended to all French territories by the end of 2019.

Currently, the whistleblowing public service only targets physical retail stores and restaurants. In the future, its scope will also cover online shops and products purchased online.

Consumers can notify DGCCRF about various issues, including hygiene practices, quality of food stuffs, recalled products still available, false or missing information, incorrect prices or prices not being displayed.

Some of the problems that consumers encounter – such as dangerous products, adverse effects on health and food poisoning – require special analysis by DGCCRF and, consequently, are outside SignalConso's scope. A specific form must be filed to notify DGCCRF in those cases.

The new whistleblowing service has three stages:

First, the consumer must complete a form and provide their contact information (name and email address), as well as detailed information about the issue they encountered and the store or restaurant involved.

Next, provided the notification they've received is valid, DGCCRF will inform the store or restaurant. If they take the necessary measures to solve the problem, they will not face any sanction. If a consumer has expressly agreed (in the notification form) to have their contact information disclosed, the store or restaurant can contact them directly to keep them informed of progress.

The notification is recorded in DGCCRF's database. DGCCRF may decide to launch an investigation if frequent and/or serious notifications are received for a particular store or restaurant.

Comment

Consumer associations are already very active in France. Their members will be further empowered by this easy-to-use tool, which is likely to be used frequently. Companies operating in France should closely monitor the SignalConso service and promptly address any notifications to mitigate the risk of investigations being triggered by DGCCRF.

In the coming months, as this experiment is extended to other territories and sectors, it should be possible to make a provisional assessment determining whether the tool has resulted in any multiplication and/or reinforcement of DGCCRF's investigations.

1 https://signalconso.beta.gouv.fr/

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Science Update

Artificial intelligence: uses, risks and "trustworthiness"

Introduction

In its April 2018 Communication on *"Artificial Intelligence in Europe"*, the European Commission defined AI as:

> *"systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals."* [1]

The simplicity of this statement belies the breadth of different technologies encompassed within it. Researchers have proposed multiple more granular ways to classify AI systems: some based on the **nature of the action** carried out (for example, *"speech to text"*, or *"image recognition"* technology); others on the basis of the underlying technology (*"speech to text"* is a subset of *"natural language processing"* technology) and still others dependent on the **level of advancement of the technology** in question (*"deep learning"* is in fact a more technologically advanced subset of *"machine learning"*, which in turn is just one type of AI rather than synonymous with the term).

As evident in the breadth of these categorisations, AI systems operate in many different ways, and in fact there are many different forms of AI currently in development. These include systems which "learn" by a reward/punishment system, learn by copying examples provided, learn by analysing data provided using mathematical principles or a neural net where multiple inputs result in reinforcement of the most advantageous results.

Uses of AI relevant to products

At present, different types of AI permeate all aspects of the consumer products sector, and AI-based systems are already active in everyday objects. Smart voice assistants on our mobile phones or speakers rely on natural language processing to convert speech to recognisable commands for the "assistant" to execute; meanwhile it's an AI system parsing a vast database in seconds that enables your device to recognize the audio signature of music played on your phone and display the name and artist on the screen.

In the healthcare sector AI systems such as IBM Watson are already being used to facilitate new drug target identifications. On a more general level relevant to both the consumer and healthcare spheres, AI systems are poised to be crucial in the effective deployment, continuous monitoring and operation of the 5G networks that promise to power the future of IOT products.

AI also has a particular role to play in product design and monitoring product safety. Through integration within the manufacturing phase (particularly testing and development) AI has the potential to facilitate the production of safer, more effective and more sustainable products. And, the potential of AI systems to scan the internet for early indicators of issues reported with products which indicate a need for corrective action or recall, may herald a significant change in the field of product safety.

Risks of AI relevant to products

The potential risks are wide ranging. Aside from the significant issues of breaches of privacy and lapses in cybersecurity which represent serious risks particularly where reliance on a data-driven system is concerned (and which we discussed extensively in relation to the GDPR in our last issue), [2] there are very real risks associated with the potential opaqueness of the computations involved in any AI-system, including problems with the system's ability to acquire and process data.

Particularly with systems that do not rely on existing data stores or active input from human sources to form the basis of their operations, but instead are advanced enough to collect their own data (think of a self-driving vehicle continually gathering information about road and traffic conditions) and perform automated data extraction, there are multiple scenarios where things may go "wrong", and lead to some level of injury to humans. For example, the camera sensor on a robot or vehicle may not being able to operate in low light, or point in

1 Communication Artificial Intelligence for Europe (April 2018) https://ec.europa.eu/digital-single-market/en/news/communication-artificial-intelligence-europe

2 See Valerie Kenyon and Anthea Davies, "Data Protection and "smart" products: a new perspective on safety", *International Products Law Review*, Issue 74, p. 12

the wrong direction, such that despite sophisticated programming to facilitate navigation around difficult terrain the robot "falls at the first hurdle".

As a more complex problem, the nature of machine learning is such that actions are considered on the basis of the probability that each action is the right one rather than on the basis of strict instructions. As such it is possible that an algorithm could select an outcome unforeseen by the creator of the device - which could have catastrophic consequences, including physical harm to persons. As AI grows more sophisticated, it may become increasingly difficult to "unpick" the process and identify the point at which a poor decision was made. This leads to an increasingly complex landscape for who should be attributed liability in these circumstances, and has led (as previously discussed in this publication)[3] to the controversial suggestion of attributing legal personhood to the AI system in question.

The evolution of "Trustworthy AI"

Given the potential issues, is there a direction of growth for AI that prioritises risk-management and ethical development? EU policy-makers certainly think so. In June 2018 the European Commission set up a High-Level Expert Group on Artificial Intelligence (the "**Expert Group**"), comprised of a variety of stakeholders in AI across academia, civil society and industry. On 8 April 2019, the Expert Group published its first deliverable: *Ethics Guidelines for Trustworthy AI* (the "**Guidelines**").

The Guidelines set out a particular vision of Europe's goal for a human-centric AI, aiming for an ethical framework which would promote the development of what has been titled "Trustworthy AI". Trustworthy AI consists of AI systems that are **lawful** (compliant with applicable laws and regulations), **ethical** (ensuring adherence to ethical principles and values, and **robust** (both from a technical and social perspective, particularly recognising that even with good intentions AI systems can cause unintentional harm).[4] The three headline ethical principles outlined are respect for human autonomy, prevention of harm, and fairness and explicability. Seven key requirements are then elucidated for ensuring these principles (for example human agency and oversight; technical robustness and safety; privacy and data governance).

The Guidelines also provide a checklist, or "assessment list" to be used by stakeholders in developing and utilising their AI systems. From 26 June 2019 to 1 December 2019 the assessment list is undergoing a piloting phase during which stakeholders are invited to test the list and provide practical feedback on how it can be improved.

Following this, on 26 June 2019 the Group published its second deliverable: *Policy and Investment Recommendations for Trustworthy AI* (the "**Recommendations**"). The 33 recommendations clearly signal the EU's ambition to emerge as a competitive and sustainable force in the sphere of a very specific kind of AI revolution: one which empowers and benefits humans. Having identified four key sectors crucial to the development of AI (public; private; general society; and research and academia), the Recommendations then discuss four key enablers that may set the correct foundation for the proliferation of ethical AI: data and infrastructure; education and skills; governance and regulation; and funding and investment.

What about liability for Trustworthy AI?

The Guidelines do not engage in detail with the "lawfulness" aspect of Trustworthy AI. However they do remind us that some existing rules at European, national and international level may already apply or be relevant to the development, deployment and use of AI systems today, including existing civil liability and product liability regimes. This is a welcome reminder for stakeholders in the area to not assume their potentially novel product, or AI system, is automatically excluded from the scope of any existing general or sector-specific regimes. In fact, two of the questions included in the current draft of the assessment list are designed to prompt this awareness:

3 See Christelle Coslin and Gunou Choi, "Artificial Intelligence: what's the plan for France?", *International Products Law Review*, Issue 73, p.20

4 As summarised on page 4 of the Ethics Guidelines.

"Did you assess whether there is a probable chance that the AI system may cause damage or harm to users or third parties?"

"Did you consider the liability and consumer protection rules, and take them into account?"

The Recommendations do identify governance and regulation as a key foundational layer which will enable the development of AI and suggest a comprehensive mapping of existing EU laws to assess the extent to which the laws are still fit for purpose in an AI-driven world. At least in the context of product liability, this mapping exercise is already underway. As we have previously discussed in detail in this publication[5], the question of whether the Product Liability Directive applies to various AI technologies has been under significant scrutiny in the past year and the publication of the European Commission's guidance on this later in 2019 will be a welcome development in providing clarity in this area.

Until then, the Recommendations signal some clear policy positions which may indicate the direction of future discussions around liability for AI systems in Europe. In particular, recommendation 29.7 urges policy-makers to refrain from establishing legal personality for AI systems or robots. Meanwhile, recommendation 27.2 suggests traceability and reporting requirements to facilitate the auditability of AI, an obligation for meaningful human intervention when using AI in specific sectors (for example, human doctors checking medical treatment decisions), and supplementing civil liability frameworks with mandatory insurance provisions to ensure adequate compensation in case of harm.

Comment

We would recommend that all parties involved in the development, use, and utilisation of AI systems carefully monitor the progress of the Expert Group and the discussions its publications inspire within the European Commission, as well as keep a look-out for the European Commission's forthcoming guidance on the Product Liability Directive.

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5 See Matthew Felwick et al, "Under the microscope: is the European Product Liability Directive fit for the tech revolution?", *International Products Law Review*, Issue 73, p.6

Europe *EU*

Appeals to the CJEU: new procedural rules introduced

The Court of Justice of the European Union (CJEU) recently introduced new rules on whether or not to allow appeals to proceed in cases that have already been considered twice – once by an independent board of appeal and once by the General Court. These amendments came into effect on 1 May 2019.

Why change the existing rules?

The number of cases submitted to the CJEU has increased enormously in recent years. Statistics show that the Court dismisses many of these appeals for being "clearly unsubstantiated" or "obviously inadmissible".[7]

To address this, on 9 April 2019, approval was granted for the introduction of a new filtering mechanism for appeals in special procedures. This followed negotiations between the CJEU, the European Commission, the European Parliament and the Council of the European Union (EU).

The aim of these new procedural rules is to make the work of the CJEU more efficient and to improve legal protection in the EU. The CJEU has now introduced a mechanism to decide whether or not to admit an appeal in cases that have already been considered twice – once by an independent board of appeal and once by the General Court. The Protocol on the Statute of the CJEU[8] and the Rules of Procedure of the CJEU[9] have been amended accordingly.[10]

The newly introduced filter mechanism enables the CJEU to decide whether or not to admit an appeal in such circumstances. Admittance will only be granted when the appeal raises an issue that has significance for the unity, consistency or development of EU law. The decision will be made by a chamber set up specifically for this purpose.

Which procedures are affected?

Cases will only be subject to this additional procedural requirement where the appeal to the CJEU concerns decisions of the General Court relating to decisions of an independent board of appeal in the following offices/agencies:

- the European Chemicals Agency ("ECHA") (Helsinki/Finland)
- the European Union Aviation Safety Agency ("EASA") (Cologne/Germany)
- the Community Plant Variety Office ("CPVO") (Angers/France) and
- the European Union Intellectual Property Office ("EUIPO") (Alicante/Spain).

Are there any significant changes for important proceedings?

Only specific procedures are concerned.[11] In particular, the competence and procedure relating to preliminary rulings according to Article 267 of the Treaty on the Functioning of the European Union ("TFEU") will not change.[12]

When will an appeal still be admissible?

An appellant will now have to attach to its appeal a request outlining why the appeal should be admitted.

Without this additional request, an appeal will be immediately declared inadmissible. If the CJEU considers that the request is admissible, it will rule on whether or not to allow the appeal to proceed.

7 OJL 111, 25.4.2019, in particular reason 3 and 4 on page 1.

8 In particular Art. 58a of the Statute of the CJEU.

9 In particular Chapter 1A in Title V of the Rules of Procedure of the Court of Justice of 25 September 2012.

10 Press Release No 53/19 of the Court of Justice of the European Union of 30 April 2019.

11 New Art. 58a of the Statute of the Court of Justice of the European Union.

12 OJL 111, 25.4.2019, reason 2 on page 1.

What is the impact on specific cases?

These recent changes mean that gaining access to the CJEU could require enhanced effort. This is an important consequence. Admittance will only be granted when an appeal raises an issue of significance to the unity, consistency or development of EU law.[13]

Understanding the procedural changes

To illustrate the impact of these changes, this is how an ECHA decision[14] could now be appealed:

The situation

An appellant does not approve a decision of the ECHA. They appeal against it. In this situation, the General Court of the European Union deals with the appeal according to Article 56 of the Statute of the CJEU.

The task of the ECHA, as an EU authority, is to regulate the technical, scientific and administrative aspects of the registration, evaluation and authorisation of chemicals. In particular, it is responsible for ensuring the registration, evaluation, authorisation and restriction of chemical substances in a uniform procedure within the European Union.[15]

This means it is competent to interpret Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning Registration, Evaluation, Authorisation and Registration of Chemicals (REACH), establishing a European Chemical Agency.[16]

REACH was introduced as an integrated system for the control of chemicals, including their registration, evaluation, authorisation and, where appropriate, restrictions on their use. REACH lays down procedures for collecting and assessing information on the properties and harmful effects of substances.[17]

a. Previously...

Under the old law,[18] it was possible for the appellants to lodge an appeal directly with the CJEU for annulment of the decision of the ECHA by the General Court of the European Union,[19] without a limitation on the approval.

In this specific case, however, the CJEU decided to dismiss the appeal. It upheld the legal opinions of the ECHA and of the General Court of the European Union because it shared their view that acrylamide is a substance of very high concern under Art 57 REACH and that intermediate products should also be included in the definition of "intermediate" provided by Art 3 No 15 REACH. The CJEU therefore confirmed that the inclusion of acrylamide in the list of substances of very high concern in ANNEX XIV REACH was correctly decided by ECHA.

b. ...and under the new procedural rules

This procedure has changed. The fact that an appeal was brought against a decision of the General Court of the European Union concerning a decision of an independent board of appeal (the ECHA's decision) would now mean that the appeal could not proceed unless the CJEU first decided that it should be allowed to do so.[20]

The appellants would first have to file a special application for an appeal to the CJEU, according to Art 58a of the Statute of the Court of Justice of the European Union.

A chamber at the CJEU set up specifically for applications like these would examine whether the formal requirements had been fulfilled.[21] This means that one of the three criteria (the appeal raises an issue of significance to the unity, consistency or development of EU law) would have to be proved for admission to be accepted.[22]

13 OJL 111, 25.4.2019 , page 3.

14 Decision of 22 Dec. 2009.

15 https://europa.eu/european-union/about-eu/agencies/echa_en.

16 Amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC ("REACH")

17 https://echa.europa.eu/en/regulations/reach/understanding-reach

18 Cf. Art. 58 of the Statute of the Court of Justice of the European Union.

19 Judgment of 25 Sept 2015, PPG and SNF/ECHA - T-268/10 RENV.

20 Cf. Art. 58a of the Statute of the Court of Justice of the European Union.

21 Press Release No 53/19 of the Court of Justice of the European Union of 30 April 2019.

22 OJL 111, 25.4.2019 , page 3.

If the chamber concludes that none of the criteria were present, the General Court's decision would become final and binding on the appellants.

It's important to note that the scope of the new procedural rules remains limited when it comes to ECHA decisions because the procedures laid down in REACH apply only to specific substances. Medicines, in particular, are completely exempted from REACH requirements (Art 2 REACH).

Comment

Because access to the CJEU is now no longer automatically granted in all cases, achieving access may well require extra effort.

To enhance the chances of admissibility, companies should take these specific procedural requirements into account from the start of any litigation.

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Europe *EU*

Medical devices: updated Borderline Manual released

Introduction

The European Commission has updated the Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices (the "Borderline Manual"). This is intended to help manufacturers determine whether their product falls within the definition of a medical device laid down in the Council Directive 93/42/EEC concerning medical devices (the "MDD").

A product will generally fall within the definition of a medical device if it has a medical purpose and if the product functions primarily in a way that is neither metabolic, immunological or pharmacological. Determination of whether a product has a medical purpose will be based on its intended purpose.

The MDD includes several rules for the exact classification of a medical device. The Borderline Manual provides guidance for a broad range of "borderline" products like water filters, shoe covers, radiation shields, fluid collection bowls and hand disinfectants.

The European Commission has updated the Borderline Manual with guidance for the classification of three products: automated external defibrillator storage units, lubricants for the alleviation of vaginal dryness and medication decisions support software.

Updated products

Automated external defibrillator storage units

Automated external defibrillator ("AED") storage units are available in an increasing number of settings and locations. The Borderline Manual provides guidance for the classification of a storage unit of an AED. Storage units can be classified as Class I accessories to a medical device if they're intended to maintain the required environmental conditions for the AED.

Article 1.2 (b) of the MDD provides that an accessory to a medical device is

> "An article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device."

The Borderline Manual provides that, if the AED storage unit is not intended to maintain the required environmental conditions for an AED to perform as intended, the storage unit should not be qualified as an accessory to a medical device.

Water- or silicone-based lubricants

The Borderline Manual provides that water- or silicone-based lubricants intended for the alleviation of vaginal dryness during sexual intercourse should be qualified as medical devices. As invasive medical devices intended for short-term use, they should be classified in Class I or IIa, depending on how long they are expected or likely to remain in the body.

Medication decision-support software

There's been an exponential increase in software designed to be used by healthcare professionals to optimise a patient's medicinal product intake. Medication decision-support software gathers data on the medicinal products that will be administered. It could, for example, identify possible contraindications, provide warnings about interactions of medicinal products and/or suggest options for treating previously untreated conditions.

The Borderline Manual provides that medication decision-support software falls within the definition of a medical device.[23] This is because the medication decision-support software is used for the purpose of prevention, monitoring, treatment or alleviation of a disease. The prevention, monitoring, treatment and alleviation of a disease is one of the possible purposes of a medical device provided by Article 2 (a) MDD.

23 Software classified as a medical device is commonly referred to as "medical device standalone software".

Comment

Manufacturers of the abovementioned medical devices should assess whether they need to take any steps to ensure regulatory compliance.

Manufacturers that have not considered the abovementioned products to be medical devices should conduct a conformity assessment procedure. Depending on the classification of the medical device the manufacturer will have to involve a Notified Body in the conformity assessment procedure.

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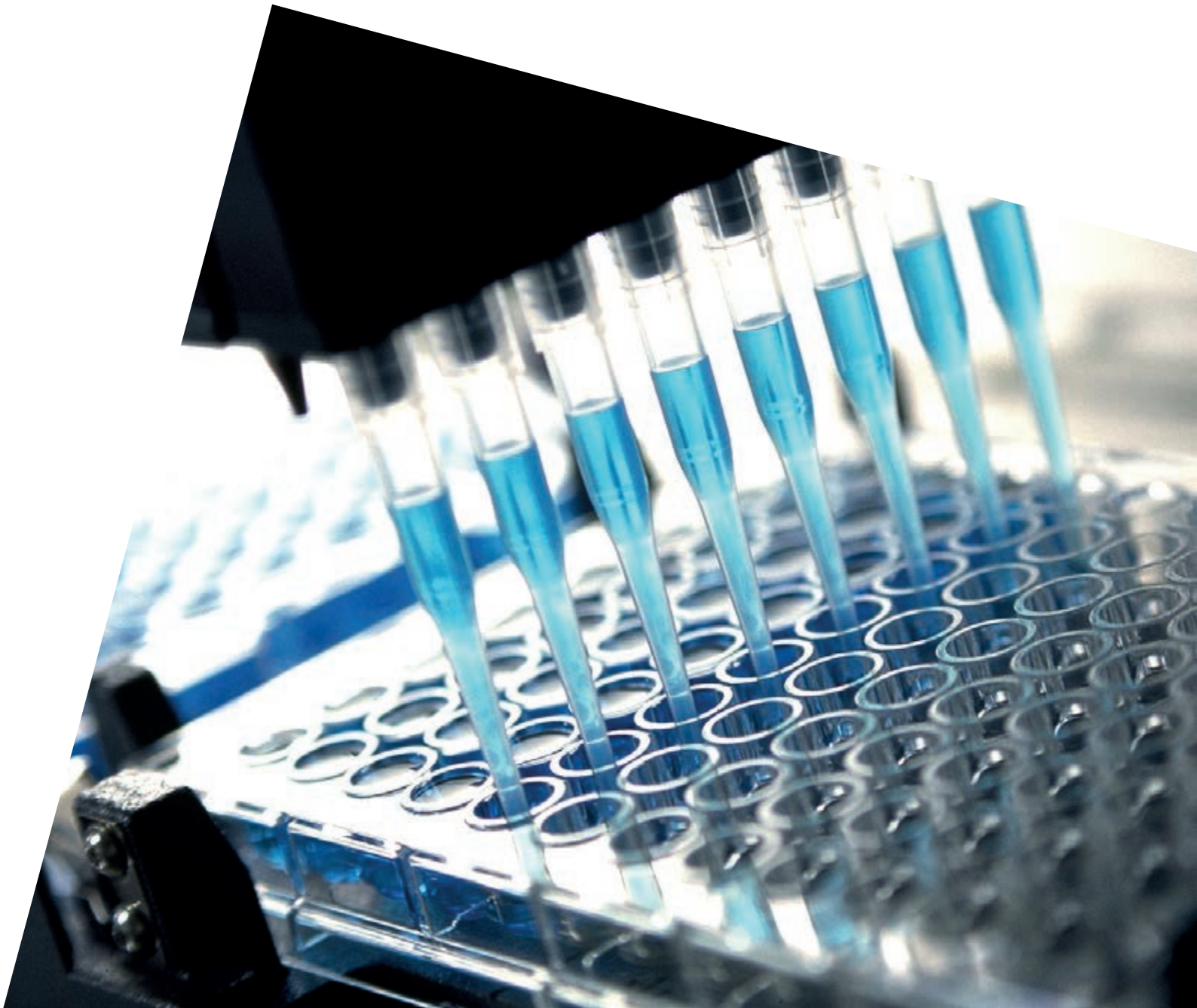

Europe *Italy*

New class action law: full steam ahead!

When it comes into force on 19 April 2020, Law 12 April 2019, no 31 will introduce significant change to Italy's class action mechanism. By providing material incentives that expand the current limited recourse to such actions, the new law will expose businesses and public service providers to higher risk by making claimants more likely to bring class actions. The ability to join a class action after a favourable decision on the merits also represents a serious threat.

Broader scope of application.

The new class action law significantly expands the number of possible claimants eligible to file a class action, as well as the rights that are protected. It will allow class actions to be brought for the enforcement of anyone's "homogeneous rights", instead of the consumers and users specified by the law now in force.

This means future class actions could be instrumental in protecting a wide range of contractual or non-contractual rights that go beyond consumer protection. That could include, for instance, the protection of rights in the fields of environmental law and financial services.

Opt-in mechanism

The right to join a class (opt-in) is allowed in two phases of the proceedings (i) at the beginning, following the publication of the court order declaring the class action's admissibility and (ii) later on, after the publication of a decision on the merits upholding the collective redress claim.

The claimants' use of the second opt-in window might be mildly discouraged by the unclear wording of the relevant provisions. These appear to limit the right to join the class after a decision on the merits to claimants who weren't able to exercise their rights within the first opt-in deadline. Italian case law will play a key role in clarifying how the relevant provisions should be interpreted.

The long opting-in window is clearly unfavourable to businesses. It creates real uncertainty over the number of potential members who could join a class at a very late stage in the proceedings (after judgment on the merits has been handed down).

Evidentiary phase

The new class action law introduces a form of discovery, significantly enhancing the investigating powers of the judge who will be able to order the defendant to disclose documents or evidence supporting the class action. The judge may also base their assessment of the case on unconventional evidence, like presumptions or statistical data.

Monetary rewards and further costs

The new law charges the defendant with additional costs to those normally awarded to a winning party (ie compensation and legal fees).

Where the judge upholds a class action, they will also order the defendant to pay a monetary reward directly in favour of the attorney assisting the class. The new law also introduces a monetary reward for the class representative (ie the party chosen by the court to represent the class during the third phase of the proceedings).

The monetary rewards for the attorneys of the winning party and for the class representative will be determined according to a table set out by the law. This provides fixed percentages on the total amount due to class members, decreasing as the number of class members increases. Where the monetary award for attorneys is concerned, the amount can be reduced by the judge by up to 50%. The reward for class representatives can be increased or decreased by a maximum of 50%.

The defendant will also have to cover the costs of any expert opinion ordered by the judge.

Comment

The new law substantially broadens the situations in which companies can be the target of a class action. And, in the absence of clear criteria for the admissibility of the class, it exposes them to great uncertainty over their potential financial exposure.

The innovations introduced, including monetary rewards and claimants' right to join a class after a favourable decision on the merits, might encourage the proliferation of actions based on the same title. There's also a risk that the new law will impose a disproportionate burden on defendants if it is used opportunistically. Additionally, the fact that the evidentiary phase of these proceedings is geared for speed could significantly compress a business's right of defence.

At the moment, the actual impact of this new class action law is hard to predict. Some of its provisions remain unclear and will require case-law interpretation. As they wait for the law to come into force, businesses should get prepared and consider their risk-mitigating strategies.

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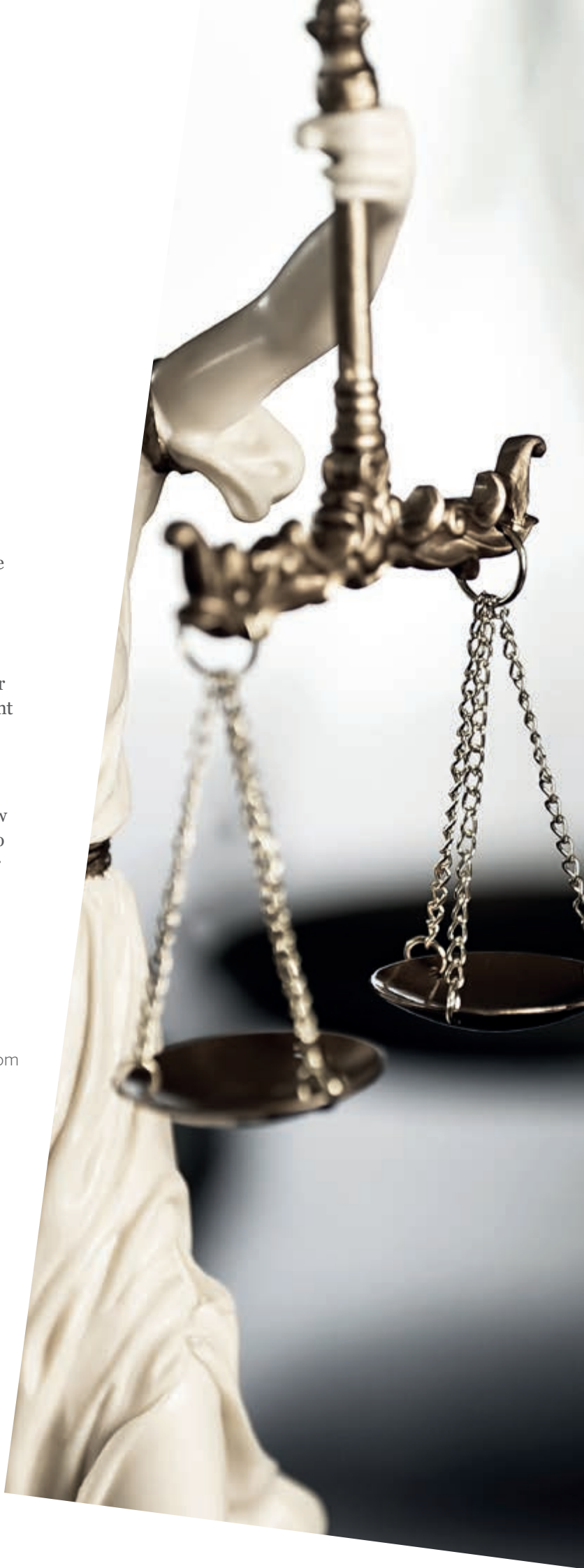

Europe *UK*

Internet of Things: proposals for cyber security regulation

The UK government is considering moving towards regulating security standards for consumer Internet of Things ("IoT") devices. The Department for Digital, Culture, Media and Sport pushed ahead with a consultation process in May 2019 around proposals for regulation, though the UK government had only recently published a voluntary code of practice – the Code of Practice for Consumer IoT Security – in October 2018.

The voluntary code published in October promoted 13 principles for IoT security

- no use of default passwords
- provision of a public point of contact for anyone concerned about security vulnerability
- keeping software updated and telling consumers the minimum length of time that their device will be supportedAn option t
- secure storage of credentials and personal information
- secure management of information flow
- minimising potential points of attack, including turning off unused functions
- maintaining software integrity and preventing unauthorised software changes
- compliance with GDPR
- resilience to power loss and network unavailability
- usage monitoring for security anomalies
- consumers able to delete personal data
- updates and maintenance should be easy for consumers involving minimal steps and
- data in-putted should undergo validation.

It was followed in the EU with the same 13 principles being reworked into an EU-recognised technical standard ETSI 103 645 "Cyber Security for Consumer Internet of Things", published in March 2019.

Security by design is fundamental

The prompt for action by UK regulators is concern that as more devices in the home connect to the internet, consumers are entrusting their personal data to an increasing number of online devices and services. Products and appliances that have traditionally been offline are now becoming connected and exposed to cyber threats. Margot James has stated that "security by design is fundamental if we are to progress with the internet of things".

So, after only seven months of the code of practice being live in the UK (the consultation period was relatively short, opening on 1 May and closed on 5 June) the UK Government is looking at moving from voluntary adoption of best practice to mandating how companies should design their IOT consumer devices and products.

The UK Government wants to introduce three mandatory requirements for connected devices based on three of the principles from the Code of practice and ETSI standard

- No default passwords: All IoT device passwords shall be unique and shall not be resettable to any universal factory default value
- Providing a public point of contact: The manufacturer shall provide a public point of contact as part of a vulnerability disclosure policy in order that security researchers and others are able to report issues
- Telling consumers how long the product would be supported: Manufacturers will explicitly state the minimum length of time for which the product will receive security updates.

The consultation process has also included proposals around how information about the IOT security measures proposed should be communicated to consumers to demonstrate that the product complied with IOT security regulations. A new mandatory or voluntary labelling scheme is being proposed.

Consultation on the scope of implementing regulations

The UK Government is considering three options for implementation

- Option A (preferred option): Mandate retailers to only sell consumer IoT products that carry the proposed IoT security label, with manufacturers to self-assess and implement a security label on their consumer IoT products
- Option B: Mandate retailers to only sell consumer IoT products that adhere to the "top three guidelines" of the Code of Practice for IoT Security, with manufacturers to self-assess that their consumer IoT products adhere to these top three guidelines and
- Option C: Mandate that retailers only sell consumer IoT products with a label that evidences compliance with all 13 guidelines of the Code of Practice, with manufacturers expected to self-assess and to ensure that the label is on the appropriate product packaging.

Following the consultation and after the introduction of the voluntary security labelling scheme, the UK Government said it would make a decision as to which of the above options should be taken forward into legislation.[24] Now with a new Minister and Prime Minister in office it will be interesting to see if policy changes or the planned regulation is delivered.

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24 See also https://www.gov.uk/government/consultations/consultation-on-regulatory-proposals-on-consumer-iot-security

LATIN AMERICA *Mexico*

The Mayan effect: punitive damages claims are on the rise

Introduction

Most legal systems in Latin America, including Mexico, are civil law-based. They rely heavily on codified law, with precedent playing a secondary role.

In civil law-based systems, court decisions are judicial interpretations of codified provisions. Their primary role is limited to filling in some of the gaps in written laws. However, in Mexico, recent court decisions have gone further by offering a broader interpretation of codified provisions. That's what happened in 2014 in the "Mayan Case", a landmark decision where the Mexican Supreme Court ruled that punitive damages could be awarded to plaintiffs.

Background

The Civil Code (the Federal Civil Code and the Civil Code of each state) provides a general liability system, which applies to every kind of liability – from product liability, personal liability and moral damages to extra-contractual and strict liability. The general rule is that anyone acting against the law or contrary to public morals is liable for those acts. According to the Civil Code, damages should, when possible, aim to restore the previous situation of fact. Otherwise, they should reflect payment of any loss/lost profit.

Punitive damages and punitive compensation do not exist in the Mexican Civil Code or in Mexican legislation. That's why the 2014 decision was so significant: for the first time, the Supreme Court[25] had, many practitioners believe, implicitly recognized punitive damages as part of Mexican legislation.

The case arose from an accidental death in a five-star resort, the "Mayan Palace Resort". Moral damages were awarded, and justification for the amount of the indemnity was based on a two-part standard. First, as compensation for damages suffered as a result of the perpetrator's unlawful actions. Second, as compensation intended to discourage similar behaviour in future. The Supreme Court ruled that this second aspect should be termed "punitive damages" and accordingly, should be considered as part of the right to obtain fair compensation. This was the first court decision in Mexico to expressly refer to the concept of "punitive damages", as well as being the first in which a party was penalised in this way.

There is, however, nothing innovative about the concept of "fair compensation" – which the Court relied on as a basis for awarding punitive damages. Article 63.1 of the American Convention on Human Rights states that, in cases involving the violation of a right or freedom protected by the Convention, the injured party must be restored to full enjoyment of the violated right or freedom. It also states that, if appropriate, fair compensation should be paid to the injured party.

According to Articles 1 and 133 of the Mexican Constitution, the Constitution itself and international treaties concerning human rights should be considered as the supreme law. In other words, the American Convention on Human Rights has the same legal authority as the Mexican Constitution.

Comment

This case is still not binding precedent. And the lack of any regulation in the Civil Code governing punitive damages (and the scope of "fair compensation") may result in different interpretations from now on. It's possible, therefore, that future decisions may not recognise the concept of punitive damages at all.

That said, since the Mayan Case, we have seen an increase in the number of claims for punitive damages based on the precedent established in that decision. The Supreme Court may also rule on product liability claims for punitive damages soon. It's a fluid situation, and we'll be monitoring it closely.

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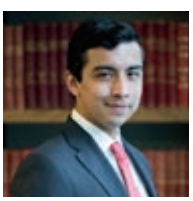

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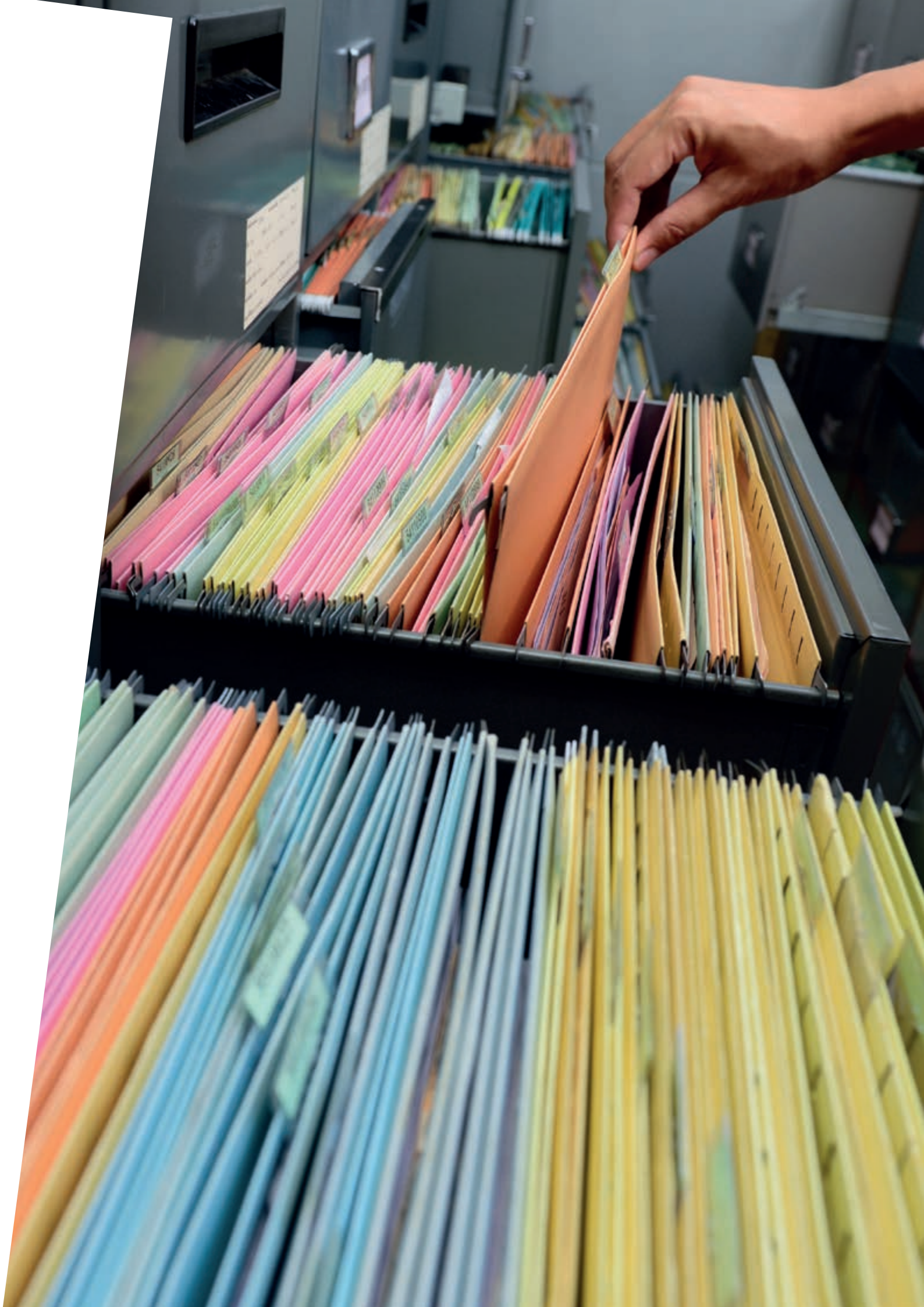
25 First Chamber of the Supreme Court: Amparo Directo 30/2013 and 31/2013.



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