

Intellectual Property & Life Sciences 2013: Legal developments you need to know about



Welcome

This is a short guide to some of the key legal developments for intellectual property in the life sciences sector in 2013.

The developments include a proposed new EU Clinical Trials Regulation, progress of the EU unitary patent package, the UK Patent Box and R&D tax credit coming into effect, reform of the research and Bolar exceptions and a proposed new EU legislative framework for medical devices. They also include developments relating to database rights, exceptions to copyright law, changes to UK design law and a new EU Regulation on data protection.

For further information or advice, please contact your usual contact at Mayer Brown or any of the Intellectual Property Partners in our London Office whose details can be found at the end of this guide.

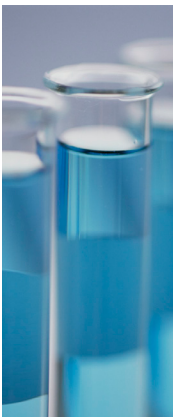
1 January 2013



Binding Corporate Rules (BCRs) for data processors

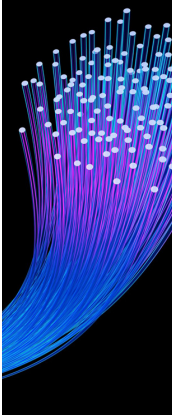
Since 1 January 2013 data processors have been able to implement BCRs to facilitate the movement of personal data outside the EU. The Article 29 Working Party (the influential data protection advisory group set up by the EU) has launched this non-obligatory option so that processors of personal data (e.g. technology outsourcing providers), acting on behalf of data controller clients, can transfer personal data in accordance with EU rules on data protection. This will be welcome news to data processors and data controllers, particularly those that undertake large-scale international data transfers. Data controllers and processors can now use approved BCRs for a processor to ensure that transfers of data outside the EU comply with EU data protection law, thereby avoiding the need to negotiate complicated data protection safeguards for each contract.

2013



New Clinical Trials Regulation and repeal of the Clinical Trials Directive

In July 2012, following a period of public consultation, the European Commission adopted a proposal for a Regulation on clinical trials on medicinal products for human use, repealing the current Clinical Trials Directive. According to the Commission, the Clinical Trials Directive has been heavily criticised by all stakeholders and the number of clinical trials has fallen by 25 per cent in recent years. The proposal aims to harmonise and streamline clinical trials legislation across the EU. It is expected that the proposed Regulation will have its first reading before the European Parliament in the first half of 2013.



EU data protection law reforms

A draft report by the EU Committee on Civil Liberties, Justice and Home Affairs (LIBE) on the amendments to the proposed Data Protection Regulation is expected early in 2013. The Regulation would harmonise data protection rules across EU member states. The proposed changes include the mandatory appointment of a data protection officer for certain organisations; mandatory notification of all data breaches to a regulator within 24 hours; direct liability for data processors in some areas of compliance; and fines of up to 2 per cent of annual worldwide turnover for serious compliance failures. Proposals to replace the current Data Protection Directive with a new legislative framework, including a new Regulation, were published by the European Commission in January 2012.



Confidentiality and passing off

In January 2012, the European Commission published its first study on the protection in EU member states for trade secrets and against parasitic copying (e.g. copycat or lookalike copying). This concluded that the scope and effectiveness of protection varied between member states. The results of a second study on the benefits and negative effects of protecting trade secrets are due in the first quarter of 2013. A subsequent public consultation on the protection of business know-how opened in December 2012 and is due to close in March 2013.



EU unitary patent package

On 11 December 2012, the European Parliament voted in favour of the new EU unitary patent package, which will allow inventors to apply for a unitary patent covering all the EU member states, something that proponents of the package believe will result in a more cost effective and consistent European patent regime. The new framework will come into effect on 1 January 2014 or earlier, if 13 states have signed up to the international agreement on the Unified Patent Court (and provided the UK, France and Germany are among them). The international agreement on the Unified Patent Court will be open for signature in February 2013. The precise arrangements for a European patent court are still unclear, with the European Parliament agreeing a set of principles only. The draft Rules of Procedure are to be formally published for consultation when all member states approve the agreement in principle.



Unjustified threats of infringement (designs, patents and trade marks)

The UK Law Commission expects to open a three-month consultation in February 2013 on whether to repeal, reform or extend legislation relating to unjustified threats of action for infringement of designs, patents and trade marks. Currently in the UK, there are legal risks for those who send letters before action (cease and desist letters) in some IP cases. Where it is found there is no basis to an allegation of infringement, or no genuine intention to litigate, the threat may be deemed unjustified. In these instances, the recipient of a threat of action has a statutory right to claim damages. The Law Commission thinks that the current legal framework is inconsistent and complex.

1 April 2013



UK Patent Box and R&D tax credit

The UK's Patent Box regime, which allows a lower rate of UK corporation tax to be applied to worldwide profits from the exploitation of qualifying patents, comes into effect on 1 April 2013. The full tax benefits will be phased in over a five-year period. The Government will also introduce an 'above the line' R&D tax credit (i.e. a credit against corporation tax) in 2013.

Spring 2013



Online personalised pricing practices

The UK Office of Fair Trading (OFT) launched a call for information in November 2012 with respect to how the use of data about consumers affects online markets. The OFT is considering whether online retailers use data about users to modify prices offered to them on websites; if this is harmful, what is acceptable conduct; and whether any consumer protection laws are being breached. The OFT expects to publish its findings in Spring 2013.



Patent cases before the UK Supreme Court

Cases before the Supreme Court in 2013 include three appeals on issues of patent law. The first two appeals concern the same patent for a bulk container used for transporting liquids, consisting of an outer cage into which a plastic container is fitted. The issues to be considered by the Supreme Court are (i) when the replacement of part of a patented product amounts to ‘making’ that product, which thereby infringes the patent; and (ii) when can the court award costs to an exclusive licensee of the infringed patent, if the licensee did not register its licence with the Patent Office within six months of becoming exclusive licensee, as required to do so by the Patents Act. The third appeal concerns a patent for a medicine to inhibit hypertension and cardiac insufficiency. The issue before the court concerns the availability of a remedy where an injunction is discharged because a UK patent is subsequently invalidated but manufacture of the product would have infringed a valid patent in a different jurisdiction. We will provide further updates over the course of the year.



Technology transfer block exemption

The Technology Transfer Block Exemption Regulation (TTBER) creates a safe harbour for technology transfer agreements (particularly patent and know-how licences) under EU competition law. The existing framework is due to expire at the end of April 2014. The Commission will review the TTBER and associated guidelines in 2013. Its consultation on how the existing TTBER and guidelines have worked in practice, and what improvements are possible, closed in February 2012.



Database rights: More decisions due in Football *Dataco Ltd v Sportradar GmbH*

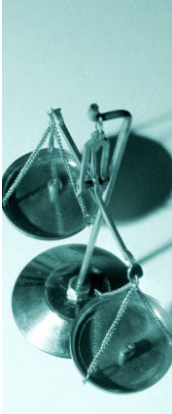
In October 2012, the Court of Justice of the European Union (CJEU) ruled that, where a website operator targets and then provides material which infringes database rights to recipients based in an EU member state over the internet, the act of infringement occurs at least in the EU member state where those recipients are located. This makes it easier for rights-owners to sue in their chosen territory. The decision was a blow to Sportsradar, which had hoped that the CJEU would rule that the case should only be heard in Germany, where Sportsradar's server is based. A trial on the primary liability of the defendants will take place in 2013. In addition, the Court of Appeal is due to hand down a decision in early 2013 following the High Court's ruling in May 2012 on the aspects of the case that were unaffected by the referral to the CJEU (one of the defendants – not Sportsradar – was found jointly liable for users' infringements of Dataco's database rights).



Innocent infringement of registered design rights

Following a UK Intellectual Property Office (IPO) consultation in 2010, the IPO announced in August 2012 that it will introduce rules that remove the limitation on liability of innocent infringers of UK-registered designs and allow the owner of a UK-registered design to seek an account of profits – but not damages – from an innocent infringer of the design as soon as possible. There is currently an anomaly between the financial remedies for an innocent infringement of UK registered and Community registered designs. Whereas an innocent infringer of a UK-registered design is exempt from an account of profits and damages, an innocent infringer of a Community design may be liable for an account of profits or damages. The existing provisions for unintentional infringement of Community designs will be amended to mirror the change (so that an account of profits only will be available).

2013



Consultation on changes to UK design law

Following the Government's 2012 consultation on its proposals for improving the UK designs legal framework (which closed in October last year), it has stated that further consultation in 2013 should focus on improving the way in which existing design rights work rather than completely restructuring UK design law.

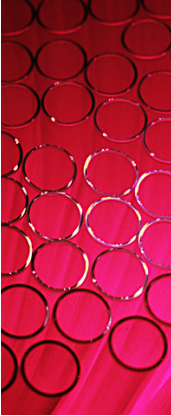
2013



Reform of the Misleading and Comparative Advertising Directive

Following its consultation in 2011, the European Commission intends to introduce proposals to amend the Misleading and Comparative Advertising Directive in 2013. The Directive protects traders and consumers against misleading advertising. The proposed changes are likely to include a list of misleading marketing practices that are banned and rules for effective penalties.

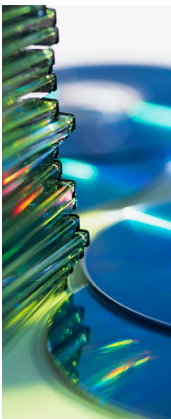
1 October 2013



Reform of the research and Bolar exceptions

In October 2012, the IPO launched a consultation on proposals to amend the Patents Act so that it provides a broader exception to patent infringement for activities involved in preparing or running clinical or field trials which use innovative drugs. This closed in December 2012. Subject to the outcome of the consultation, the IPO intends the proposed legislative changes are implemented by 1 October 2013.

October 2013



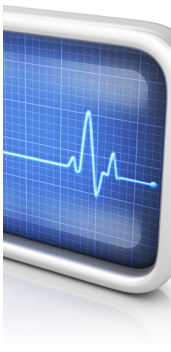
Copyright exceptions

On 20 December 2012, the Government published a report setting out its proposed changes to the framework of copyright 'exceptions'. The changes would allow third parties to use copyright works for economically and/or socially useful purposes without needing to obtain permission from copyright owners. The proposals include introducing a private copying exception allowing copying from one device to another for personal use; a fair dealing exception for educational purposes; a fair dealing exception to allow copying for parody; allowing copying for non-commercial research and private study; and allowing libraries (and similar organisations) to make preservation copies. The Government intends to make the draft regulations available for technical comments and wants all of the proposals to take effect in October 2013.



Supplementary Protection Certificates (SPCs): more questions referred to the CJEU

In October 2012, the UK High Court referred yet more questions on the interpretation of the SPC Regulation to the CJEU. These relate to whether a marketing authority that is not granted pursuant to the procedure laid down in Directive 2001/83/EC constitutes the “first authorisation to place the product on the market” for the purposes of Article 13(1) (which sets out how to calculate the duration of an SPC) and whether a product that is subject to such a marketing authority qualifies for the grant of an SPC under Article 2 (which defines the scope of the SPC Regulation).



Reform of EU medical device legislation

In September 2012, the European Commission proposed a new legislative framework for medical devices. Proposed changes include extending the scope of the legislation; placing clearer responsibilities on manufacturers, importers and distributors; strengthening the rules for clinical investigation of devices; and improving traceability and monitoring of products on the EU market. The proposed Regulations are due for their first hearing before the European Parliament late in 2013.



IP rulings from the CJEU

A number of cases progressing through the CJEU will have implications for various points of intellectual property law, including: the use of devices specifically designed to circumvent protection measures on video games; the liability of service providers who give access to protected films via the internet; interpretation of the EU Database Directive (including whether the cumulative effect of repeated re-utilisation of 'insubstantial' parts of a database amounts to re-utilisation of a 'substantial' part); and jurisdictional issues relating to trade mark infringement and cross-border copyright infringement. We will provide further updates over the course of the year.

Contacts



Mark Prinsley

Partner

+44 20 3130 3900

mprinsley@mayerbrown.com



Sarah Byrt

Partner

+44 20 3130 3832

sbyrt@mayerbrown.com



Jonathan Radcliffe

Partner

+44 20 3130 3230

jradcliffe@mayerbrown.com



Sangeeta Puran

Partner

+44 20 3130 3294

spuran@mayerbrown.com

About Mayer Brown

Mayer Brown is a global legal services organisation advising clients across the Americas, Asia and Europe. Our presence in the world's leading markets enables us to offer clients access to local market knowledge combined with global reach.

We are noted for our commitment to client service and our ability to assist clients with their most complex and demanding legal and business challenges worldwide. We serve many of the world's largest companies, including a significant proportion of the Fortune 100, FTSE 100, DAX and Hang Seng Index companies and more than half of the world's largest banks. We provide legal services in areas such as banking and finance; corporate and securities; litigation and dispute resolution; antitrust and competition; US Supreme Court and appellate matters; employment and benefits; environmental; financial services regulatory & enforcement; government and global trade; intellectual property; real estate; tax; restructuring, bankruptcy and insolvency; and wealth management.

OFFICE LOCATIONS

AMERICAS

- Charlotte
- Chicago
- Houston
- Los Angeles
- New York
- Palo Alto
- Washington DC

ASIA

- Bangkok
- Beijing
- Guangzhou
- Hanoi
- Ho Chi Minh City
- Hong Kong
- Shanghai
- Singapore

EUROPE

- Brussels
- Düsseldorf
- Frankfurt
- London
- Paris

TAUIL & CHEQUER ADVOGADOS

in association with Mayer Brown LLP

- São Paulo
- Rio de Janeiro

ALLIANCE LAW FIRM

- Spain (Ramón y Cajal Abogados)

Please visit www.mayerbrown.com for comprehensive contact information for all Mayer Brown offices.

Mayer Brown is a global legal services provider comprising legal practices that are separate entities (the "Mayer Brown Practices"). The Mayer Brown Practices are: Mayer Brown LLP and Mayer Brown Europe-Brussels LLP, both limited liability partnerships established in Illinois USA; Mayer Brown International LLP, a limited liability partnership incorporated in England and Wales (authorised and regulated by the Solicitors Regulation Authority and registered in England and Wales number OC 303359); Mayer Brown, a SELAS established in France; Mayer Brown JSM, a Hong Kong partnership and its associated entities in Asia; and TaUIL & Chequer Advogados, a Brazilian law partnership with which Mayer Brown is associated. "Mayer Brown" and the Mayer Brown logo are the trademarks of the Mayer Brown Practices in their respective jurisdictions.

This publication provides information and comments on legal issues and developments of interest to our clients and friends. The foregoing is not a comprehensive treatment of the subject matter covered and is not intended to provide legal advice. Readers should seek legal advice before taking any action with respect to the matters discussed herein.

© 2012. The Mayer Brown Practices. All rights reserved.