This quarterly newsletter is designed to keep lawyers in the life sciences industry abreast of changes in the law.

The winter edition includes articles from authors across Eversheds’ international life sciences group including the UK, France, Belgium, Hungary and Spain.

If you would like to discuss any areas raised in this newsletter further please do not hesitate to contact myself or the author of any article direct.

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EU takes action on R&D and protecting trade secrets

The European Union has stated that cross-border innovation in science is being hindered by the current fragmented legal framework on the protection of trade secrets across member states. It recognises that intellectual property rights are an essential part of an innovation policy. Without a supportive and secure environment for R&D, the private sector will be reluctant to invest. As such, it has a commitment to harmonise laws protecting trade secrets in the EU.

Draft Directive on the protection of trade secrets

An EU study in 2013 on the legal protection of trade secrets throughout the EU confirmed the fragmented and diversified nature of the existing protection and found it to be opaque, imposing unnecessary costs and risks and weak at a cross-border level. Those businesses consulted indicated their support for an EU legislative proposal.

A draft Directive has been published by the Commission, the Council has published its opinion and the EU Parliament has recently published a draft report scheduled for mid-January. The Directive is to establish a minimum legal framework across Europe to include the following main features:

- a minimum harmonisation of the different civil law regimes, whilst allowing member states to apply stricter rules;
- the establishment of common principles, definitions and safeguards as well as the measures, procedures and remedies that should be made available for the purpose of civil law redress;
- a limitation period of six years for claims or bringing actions before courts;
- the preservation of confidentiality in the course of legal proceedings, while ensuring that the rights of the parties involved in trade secret litigation are not undermined;
- the establishment of a special regime for employees in relation to their liability for damages (reflecting a concern that employees may be unintentionally caught by the new framework in some instances and have limited financial means).

At this stage in the legislative process, it appears that there is broad support for a common legal framework to better protect the confidentiality of trade secrets. However, amendments have already been proposed by the Council in its opinion and there are a number of objections being voiced in the Parliament, with some MEPs expressing concerns over key definitions in the Directive and the delineation between the Directive and national laws.

MEPs are expected to continue discussions with a draft report scheduled for mid-January. The Directive is not expected to be implemented in member states before 2017. For further information, read the EU’s report on the draft Directive.

Eversheds is tracking and analysing the proposals, as they are refined, and will provide further updates. In the meantime, for further information, please contact:

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Privacy and information law update

How Big Data can bring medical benefits, without compromising privacy rights.

United Kingdom

The use of “Big Data” is becoming more widespread, with a real potential to positively transform the way the world uses and shares data to make predictions, including in the field of health, scientific research and dealing with highly dangerous epidemics. However, the use of such vast amounts of potentially personal information needs to be approached carefully against the back drop of a UK privacy law which highlights individuals’ rights to privacy and has data minimisation as one of its core principles.

“Big Data” is a moving term coined to mean a voluminous amount of unstructured, semi-structured and unstructured data, a data set that is so large and complex that it cannot be processed using database management techniques, but requires more sophisticated processing tools. In technical terms, this refers to petabytes or exabytes of data, potentially holding billions to trillions of records on millions of people. Often it is characterised by the “three V’s”: “volume, variety and velocity” of data.

The idea of Big Data analytics is to mine this data, by using tools developed to manipulate and analyse the information in order to make quicker, novel and/or more intelligent decisions/findings. Organisations (both private and public sector) are naturally keen to use these techniques as they can provide valuable insight into the market, customers/clients’ preferences and future trends. However, the potential benefit of Big Data to individuals (both individually and collectively) across the globe are also being recognised and it is being used more frequently, not necessarily for competitive gain, but for the “greater good”, such as in the fight against deadly diseases.

The sources of “Big Data” are wide ranging, from internet search data to social media postings to data collected by cameras, mobile phones, radio-frequency identification and by monitoring devices worn by patients in clinical trials. Essentially then a lot of the information collated may contain personal information, ie any information which (alone or combined with other information) allows a living individual to be identified. This could include names, dates of birth, medical data or individuals’ opinions/comments on specific topics. In addition, new personal information could be created by Big Data analysis, e.g. by combining test results of a clinical trial with information posted on social media about the patient’s lifestyle to work out if they are likely to develop any medical conditions.

Using personal information

In the UK, the use of personal information is governed by the Data Protection Act 1998 (“DPA”). Any organisations collating personal information (whether from scratch, or using their existing records) for their own purposes in relation to Big Data therefore need to be aware of their obligations under the DPA. The Information Commissioner’s Office (the regulator in this area), strongly recommends that before organisations take any steps to collate/create Big Data they should carry out a privacy impact assessment (“PIA”). The aim of a PIA is to assess whether the organisation’s proposals would be appropriate and what the risk is in terms of compliance with the law.

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Where collating personal information for the purposes of Big Data, organisations need to consider whether this would be expected by the relevant individuals (“data subjects”).

- What were they told would be done with their information?
- Would they reasonably expect their personal information to be analysed/shared with another company for analysis in this way?
- Would the use for Big Data be incompatible with the reasons it was collected in the first place (subject to the research exemption, see below)?

Transparency is key. In addition, the organisation needs to be confident that the information being used is adequate, relevant and not excessive for the proposed purposes, eg, does the name/address etc of the data subject really need to be included to analyse the success of a new heart monitor being trialled? Can the data being minimised be limited? With more and more stories in the news about data security breaches, organisations need to think carefully about the adequacy of the security steps they are taking. This is particularly relevant where the data being analysed is stored in a cloud, potentially hosted by a third party and potentially located outside the UK (which raises concerns due to the laws in the host country), or where it is being shared with another organisation (even if in Group), to carry out the analysis.

In some cases, in particular where sensitive personal data (eg health data, religious or other beliefs, race/ethnicity etc) is being used, the data subjects’ consent may need to be obtained, in others the organisation may be able to demonstrate that the use for Big Data is necessary in the legitimate interests of that company (provided this causes no unwarranted prejudice for the individual). For the latter condition, if the purpose of the Big Data analysis is likely to be in the public interest, eg, the trial of a new drug to fight cancer, or the analysis is designed to stop the spread of a deadly disease, this is likely to provide a stronger ground in favour of the processing.

Research

There is an exemption under the DPA, which is potentially useful for Big Data analysis purposes. This exemption would allow the use of personal information for Big Data analysis, where the information was not collected with the aim of carrying out this analysis (so the Big Data analysis is potentially incompatible with the initial purpose and in breach of the DPA), but the organisation now intends to use it for research purposes. The DPA does not define ‘research’, but it is likely to include research for scientific or historical purposes, as well as commercial purposes (eg, market research). If the research is used to make a decision affecting an individual or is likely to cause substantial damage or distress to an individual, then the exemption would not apply. An example might be where the purpose of the research obtained through a drug trial (which contains sensitive personal data (ie, not anonymised data)) is for the organisation to share it with insurance companies (without the volunteers’ knowledge), and for these companies to use the data to alter the volunteers’ insurance premiums and to send tailored marketing for particular medical insurance products to those individuals. Please note that if this exemption applies, it does not provide carte blanche with regard to the use of the data and many of the requirements under the DPA still stand. Proceed with caution therefore when intending to rely on this exemption.

Anonymisation

To get round the numerous hoops that must be jumped through to ensure compliance with the DPA, many organisations choose to anonymise the data they are preparing for analysis. True anonymisation of data can be difficult to achieve, however. Essentially, the original identifying information should be totally irretrievable and the “key” to unlock it thrown away! With the vast quantity of data now available on individuals it can be extremely difficult to say with certainty that there is no other data in the world that, when combined with the result data could not identify the individual. The answer therefore is to carry out a thorough PIA, and not to proceed with the analysis unless re-identification is extremely unlikely. Transparency with regard to this process will help to satisfy the data subjects concerns about the onward use of their data and helps to install trust in that organisation. The DPA then no longer applies, as anonymised information is no longer personal data.

For organisations carrying out clinical trials, this is obviously the preferred method. The results of any tests would contain sensitive personal information and it is unlikely that patients would volunteer if there was a chance that they could be identified from the published findings of the trial. A recent example of the use of anonymised data on a wide scale is in relation to the Ebola virus. Anonymised text and voice data from mobile phones was collated by a telecommunications company located in one of the African countries hit by the virus to allow a non-profit organisation to produce maps of the populated areas in the region, allowing authorities to then work out where to locate treatment centres and how they may be able to contain the disease by restricting travel. In addition, mobile phone mast activity information from mobile operators is being collected by the US Centers for Disease Control and Prevention to work out where most calls to helplines are being made from and thus where resources should be allocated.

In addition, the use of Big Data for medical purposes is being addressed in relation to the proposed implementation of the NHS care.data scheme, which is being designed to allow analysis of health information collected by GPs on an unprecedented scale. The intention is for any such studies to be carried out an anonymous basis, but there have been widespread concerns raised regarding the true anonymity of the data extracted from these records.

Future developments

When the DPA was drafted (roughly 20 years ago) the possibility of data being used on such a large scale was very unlikely to have been considered. Arguably the fundamental principles are designed to deal with personal data, no matter in what format this is processed. However, should the Proposed EU General Data Protection Regulation be adopted, this would seek to clarify any grey areas that have developed, in particular in relation to the anonymisation of data. In addition, it would introduce a specific requirement for organisations to carry out privacy impact assessments where particularly “risky” use or other processing of personal information is envisaged and aims to provide greater rights for individuals.

The willingness of organisations to assist in Big Data analysis where there is chance of helping in the fight against deadly diseases/illnesses is, of course, highly commendable, but, organisations must not forget their obligations under the DPA. The consequences of getting it wrong and being found in breach of the DPA are significant, with potential fines of up to £500,000 fines at present (which may increase to 5% of global turnover—€100million whichever is the greatest) if the proposed EU General Data Protection Regulation comes into force). As such, appropriate safeguards, whether this is carrying out an in-depth PIA, consulting with individuals, or anonymising the data should be carefully considered.

For regular updates on Privacy and Information law, please follow us on Twitter @PrivacyGlobal.

If you have any questions regarding this area, please contact Paula Barrett or Georgina Lawrence in our Privacy and Information Law team.

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Bill on the use of vegetal and animal genetic resources

France

The French Parliament is currently considering new legislation on biodiversity. The Bill will introduce important changes for companies and researchers in the pharmaceutical, cosmetics and agri-food sectors that use genetic resources from vegetal, animals and micro-organisms.

Legal background

Despite the existence of international conventions (the Convention on Biologic Diversity, 1992 and the Nagoya Protocol), companies have, so far, been independent in the performance of their activities. Biodiversity has proved to be a tremendous source of innovation and production.

At EU level, Regulation n° 511/2014 on compliance measures for users from the Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilisation in the Union (the “Regulation”) was adopted. The Regulation implements the Nagoya Protocol since its entry into force (i.e. 12 October 2014). The Regulation also designs the legal framework for the access and benefit sharing arising from genetic resources and associated traditional knowledge.

Purpose of the new Bill in France

Along with the EU Regulation, France, as a significant provider and user of natural resources, has decided to frame its own national legislation in order to regulate bio-prospection and particularly the practice of patenting genetic resources and associated traditional knowledge. Most of the Bill’s provisions on this issue implement and develop the Regulation.

The purpose of the new legislation will be to facilitate the access to genetic resources and associated traditional knowledge for users (such as researchers and firms) and establish a clear legal framework for R&D.

In that respect, providers of genetic resources are sometimes not considered to receive the reward they deserve where the genetic resources at stake are used. Nevertheless, researchers and firms operating in this field need to maintain a high level of competitiveness and further scientific research. The Bill is therefore intended to conciliate human activities and biodiversity.

Main legal provisions

The new framework will include three main aspects:

- Regulation of the access and their utilisation in R&D of:
  - genetic resources, and
  - associated traditional knowledge.
- Sharing of benefits, which will depend on the use of the resources.
- Compliance with the Nagoya Protocol and related legislation (in France and overseas).

Key changes on the access and use of genetic resources and associated traditional knowledge

- Depending on the activities carried out, access to genetic resources or associated traditional knowledge is subject to either prior notification, or prior approval by the providers (i.e. Nations/the State for genetic resources, and local communities for associated traditional knowledge) depending on the final purpose of the exploitation.
- With regard to traditional knowledge associated with genetic resources, the French public authorities will consult local communities in order to negotiate the benefit sharing contract with the user and possibly to manage the economic advantages for these communities.
- The new legislation will also provide rules on the reinvestment, in the preservation and restoration of biodiversity, of the profits created.
- According to the future article L. 412-4 II of the French Code of Environment, the triggering criteria of the legal provisions application is the use within R&D (which involves pharmaceutical use in particular), but not the access to resources or knowledge as such.
- In the event of genetic resources or associated traditional knowledge collected before the entry into force of the legislation, the obligations of the user will be triggered by any further use.
- Compliance with French regulation will be reviewed by public authorities in case of public funding or at the time a product or process based on genetic resources or traditional knowledge is placed on the market, which may lead to the filing of a patent application.
- The Bill provides for new rules regarding French companies, which are active abroad within the limits of the signatory states of the Nagoya Protocol. These companies must prove to public authorities that their access to genetic resources and associated traditional knowledge is compliant with their international compliance certificate (provided by the relevant Authorities).
- Non-compliance with French law on biodiversity can lead to a fine of € 150,000 and up to one year imprisonment. Moreover, any fraudulent commercial use will be subject to a fine of € 1,000,000.

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New Belgian Government announces important reforms in health sector

Belgium

In its Coalition Agreement of 9 October 2014, the Belgian Government listed different measures it will implement in the health sector during this legislature, which are important from a life sciences perspective.

They can be divided into two main categories:

- measures concerning the price/reimbursement of medicinal products, implants and medical devices; and
- measures promoting new medicinal products, innovative treatments and R&D activities in the pharmaceutical sector in Belgium.

The proposed legislative initiatives at price/reimbursement level can be summarised as follows:

- more transparency on cost pricing of medicinal products and medical materials;
- the reimbursement of implants and medical devices will be further aligned with the reimbursement of medicinal products;
- measures aiming at obtaining lower prices for patients and the social security, such as generating more competition on the off-patent market and the possibility to review the reimbursement conditions of patented medicinal products on the basis of therapeutic value and cost efficiency arguments.

The new government also wants to create important incentives for the development of new medicinal products, innovative treatments and R&D activities in the pharmaceutical sector in Belgium. The following measures are set forth:

- particular interest will be paid to “unmet medical need” programs making available medicinal products for innovative treatment of patients with a seriously debilitating disease or whose disease is considered to be life threatening and who cannot be treated satisfactorily by an authorised medicinal product, even in case such medicinal products are not yet authorised at EU-level or before authorisation of a new indication for which exists a medical need that has not yet been met by an already authorised medicinal product;
- concerning clinical trials: a faster procedure for approval, making the inclusion of patients easier; simplifying the system evaluation by the national health authority (FAGG-AFMPS) and ethical committees;
- continuing to improve the existing administrative procedures to obtain a marketing authorisation for new medicinal products which are already approved on the basis of the centralised or mutual recognition procedure (e.g. by shortening the time-limits for the authorities to take a decision on applications and by avoiding duplication of work (i.e. work that has already been done by EU or national competent authorities));
- the “Biopharma R&D consultation platform” that has been set up in the past between the Belgian pharmaceutical sector and the government in order to create a well-established legal framework for R&D activities in the pharmaceutical industry, will continue its work.

The policy of the new Belgian Government, although ambitious, is clearly to promote innovation in the pharmaceutical sector, on the one hand, and, to further expand the market of “cheaper” medicinal products, on the other hand. The next months and years should therefore be very important for pharmaceutical and other companies in the health sector in Belgium.

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Public Consultation announced for EU Clinical Trial Regulation

Public consultation on how the transparency rules of the EU Clinical Trial Regulation (no. 536/2014) (“Regulation”) are to be applied in the new database for clinical trial information has been launched by the European Medicines Agency. Participants have until Wednesday 18 February 2015 to comment.

The Regulation is intended to apply from May 2016 and aims to ensure consistency in the approach to clinical trials throughout the EU. The aim is for there to be more transparency on authorisation, conduct and results which will in turn change the level of publically available information. The database will be an important tool for clinical trial applicants.

The consultation is available on the EMA website at www.ema.europa.eu/ema.

Restrictions on pharmacy ownership in Hungary and the EU’s recent challenge against them

Hungary

Since the introduction of a new law in 2011, the rules governing pharmacy ownership in Hungary have been made stricter each year, resulting in one of the most restricting regimes in Europe. This has happened in spite of fairly significant lobbying by European and local pharmacy chain owners. The express purpose of the strict requirements was to protect the interests of local individual private pharmacists by excluding (typically non-Hungarian) institutional pharmacy chains from the Hungarian market. This has understandably raised strong concerns among the EU institutions, eventually resulting in the Commission recently starting a formal infringement procedure against Hungary by sending an official “Letter of Formal Notice” to this effect.

Under current laws, the acquisition of majority shares in pharmacies by professional investors is effectively made impossible. In newly established pharmacies at least 51 per cent of the shares must be held by local, private individual pharmacists and the voting rights cannot be diverted from the proportional shareholdings.

Institutional investors in existing pharmacies were obliged to appoint a local pharmacist as director of the pharmacy and to sell at least 25% of their shareholding to the director or other private pharmacists by January 2014. By 2017 there is an obligation on investors to sell at least 51 per cent of the pharmacy to the pharmacists, thus effectively putting all pharmacies under the control of individual local pharmacists. There is an additional restriction, limiting the maximum number of pharmacies which may be owned by one individual pharmacist to four, with the evident intention of outlawing pharmacy chains.

Initial complaints were lodged with the Commission back in 2012. Prior to starting the formal infringement procedure, it carried out a lengthy so-called pilot procedure during which the detailed regulations were carefully examined. The Commission has raised its recent objections due to the limits the law poses on the free movement of capital and of persons. Additionally it is investigating whether and at what price the non-Hungarian investors will be able to dispose of their existing interests in pharmacies, as required by the law. An additional element of concern is the differentiation in the law between local and non-Hungarian investors, the former clearly being favoured by the Hungarian legislators.

The Letter of Formal notice was sent by the Commission late September 2014 and under the EU Treaty Hungary must provide a formal reply within two months. If the Commission is not satisfied with the response, it may send a formal request to comply with EU law, calling on Hungary to provide information on the measures it intends to take within a further two month period. If Hungary continues not to comply, the Commission has the right to refer Hungary to the Court of Justice for the issuance of a judgment. If, despite a negative judgment Hungary continues not to comply, it may be referred back to the Court of Justice under a second infringement procedure following which financial penalties may be imposed by the Court.

As with all potential conflicts between EU member states and the European institutions, it remains to be seen how far the two sides are prepared to go in the battle between compliance and protection of local lobbying interests.

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“Hindering acts” in Spain deemed unfair competition behaviour

Spain

The Provincial Court of Barcelona (Spain) recently upheld a petition made by an innovative pharmaceutical company that a hindering act in the market carried out by a generics pharmaceutical company be considered as an act of unfair competition.

Although hindering acts in the market per se lack specific provision in the Spanish Unfair Competition Act, they can be included in the general article of the law which prohibits any behaviour objectively contrary to good faith.

The Court defines “commercial hindering acts” as those that, without objective justification, adversely affect a third party’s position in the market, or in any way interfere in the normal course of their business.

In this case, a generics company applied to the Spanish Drug Agency (“Agencia Española de Medicamentos y Productos Sanitarios”) for authorisation to market their generic drug, 11 months before the innovative pharmaceutical company’s patent protection rights expired.

Marketing authorisation was granted, which automatically enforced specific measures by the Spanish National Health System to enable a dramatic decrease in the price of the drug. The innovative pharmaceutical company requested that the generic company apply for a temporary suspension of the marketing authorisation to avoid negative economic consequences, though it refused to do so.

The court ruled that the generics company’s refusal to apply for temporary and revocable suspension of the marketing authorisation of its drugs lacked reasonable justification and adversely interfered with the development of the activity of the innovative company in the market.

This ruling opens a new path to protect the rights of the innovative pharmaceutical industry, particularly where the usual ways to protect their patent rights are exhausted.

EVERSHEDS NICEA litigation team lead by Kiko Carrión and made up of Jose Mariano Cruz (partner), Inmaculada López (Senior Associate) and Marta Gonzalez (Associate), in collaboration with Alberto Dorrego (partner of the public law department), assisted the innovative pharmaceutical company throughout this case.

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Eversheds advises Cell Therapy Catapult on cell therapy joint venture

Eversheds has advised the Cell Therapy Catapult on an innovative partnership with UCL Business (UCLB) and Imperial Innovations for the advancement of a novel cell therapy approach to treat acute myeloid leukaemia.

The joint venture, named Catapult Therapy TCR Limited, will develop a new therapy which modifies a patient’s T cells through gene therapy so that they will target and destroy the patient’s malignant cells when infused back into the body. It has potential particularly in the treatment of acute myeloid leukaemia and haematological disorders such as myelodysplastic syndrome.

Under the terms of the agreement, UCLB and Imperial Innovations have contributed their relevant patents and expertise to Catapult Therapy TCR Limited, and will be eligible to receive late-stage development milestones and royalties over the course of the therapy development. The Cell Therapy Catapult will invest up to £10m to take the therapy into and through Phase II trials, providing a full range of expertise including manufacturing development and clinical trial sponsorship.

The clinical trials are expected to begin patient enrolment in 2015. Manufacture is being undertaken at the world-leading UCL Institute of Child Health/Great Ormond Street Hospital cell therapy production unit.

The Eversheds team was led by IP partner, Adrian Toutoungi, working alongside Global Sector Group Head of Health & Life Sciences, Simon Crossley, corporate partner Steven Hacking and principal associate Tim London advising on state aid issues.

Adrian Toutoungi commented:

“Cell therapy products, along with gene therapies and tissue-engineered products, are at the cutting edge of medical technology. We are delighted to have advised the Cell Therapy Catapult on this trailblazing transaction, and look forward to supporting it to achieve further strategic goals.”
Patent pathway for parthenotes?

EU

The Court of Justice of the European Union (CJEU) recently handed down judgment on whether stem cells obtained from parthenogenetically stimulated human ova are excluded from patentability as “human embryos”. Since the Brüstle decision in 2011, the position has been that stem cells obtained from human embryos whether directly, or indirectly, are unpatentable. However, following the CJEU’s recent decision in International Stem Cell Corporation v Comptroller General of Patents the position appears to have changed.

Embryonic stem cell research has been a controversial topic since its inception in the late 1990’s when James Alexander Thompson developed the first embryonic stem cell lines at the University of Wisconsin. Stem cell technology is thought to hold the key to some of the most innovative treatments of our generation but research has often been curtailed by questions of moral and ethical considerations.

Approach to stem cell research throughout the world

There are a wide variety of sources commenting on the approach to stem cell research throughout the world. It is reported that Asia is at the forefront of stem cell research and Singapore is the “Asian stem cell centre” with over 40 stem cell research groups. Research is authorised for therapeutic purposes on embryos no more than two weeks old.

In China, it appears that research has progressed without much legal interference and it has some of the most relaxed policies in the world (this is arguably connected to the Chinese cultural notion that life begins on birth) and Japan allows stem cell research for therapeutic purposes (although there are no formal guidelines).

Commentary suggests that South Korea has made strong advancements in stem cell research because of its flexible policies regarding research which have propelled South Korea to the forefront of stem cell research. Stem cell lines have been produced that are a perfect genetic match to patients of all races and genders.

The UK (under the the Human Fertilisation and Embryology Act 2008) permits the destruction of embryos for human embryonic stem cells and authorises Somatic Cell Nuclear Transfer. This is on the proviso that these acts are done in order to increase knowledge about the development of embryos or serious disease.

The EU enacted the Biotechnology Directive (“Directive”) in 1998 in order to bring about harmonisation in relation to the approach to legal protection of biotechnological inventions. Under the Directive, inventions based on the use of human embryos for industrial or commercial purposes could not be patented on moral grounds. This left many questions open as to whether the meaning of “human embryos” included stem cells derived from human embryos and if methods derived from human embryonic stem cells were patentable.

This ambiguity was enough for differences to appear in the application of the Directive by the different patent offices and the UK saw 100 patents for human embryonic stem cell inventions granted by 2009 whilst in Germany the Federal Patent Court refused to grant them.

The Court of Justice of the European Union (CJEU) considered the ambiguities of stem cell patentability in the Brüstle case. In this case, the CJEU determined that “use of human embryos for industrial or commercial purposes” included scientific research and this effectively banned patents for embryonic stem cell research. It was a decision condemned by medical researchers and those who believed stem cell research capable of revolutionising medical treatments.

The latest position

The question of human parthenote patentability has however recently been thrust back into the spotlight in the recent International Stem Cell Corporation case.

On 18 December 2014 the CJEU made a crucial distinction between embryonic stem cell technologies based on fertilised human ovum and those based on unfertilised human ovum stimulated by parthenogenesis. The court held that unfertilised human ovum stimulated by parthenogenesis does not constitute a “human embryo” within the meaning of the Directive and as such unfertilised human ovum stimulated by parthenogenesis were patentable.

The technology at the centre of the dispute used parthenogenetic activation of oocytes and so did not involve the destruction of a fertilised ovum capable of developing into a human being. The case concerned two patents for technology that produced stem cell lines and corneal tissue from the parthenogenetic activation of an unfertilised ovum.

It was common ground in the case that such parthenogenetically-activated ova did not produce totipotent stem cells , but instead pluripotent cells , and were therefore not capable of developing into a human being.

The ruling will no doubt open the door for other patent applications using similar methods and may open up arguments that other research methods are also patentable. It is important to note that the CJEU specifically flagged that parthenotes which have been the subject of manipulation by genetic engineering fell outside the remit of the case, which strikes a warning to those considering inventions which involve such activity.

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Online registration, notification and reporting of Employee Share Plans

United Kingdom

A new online registration, certification and reporting system was recently introduced in the UK, applying to all employee share plans and arrangements. The first major deadline for online reporting is approaching (6 July 2015) and employers in the sector should be aware of the new requirements in order to prepare for online registration and reporting of their arrangements.

It is recommended that companies take action early as it is effectively a two stage process. If action is not taken in time, the tax advantages associated with certain of your employee share plans may be lost.

New online reporting system

From 6 April 2014, a large part of the employee share plans administration process for both tax-advantaged and non tax-advantaged arrangements moved online.

In the case of tax-advantaged arrangements, an annual declaration that each plan complies with the legislation (self-certification) will be required to be made online, including for commonly used arrangements such as share incentive plans (SIPs), company share option plans (CSOPs) and save as you earn option plan (SAYE option scheme). These types of arrangements are very common and many companies in the Life Sciences sector operate them.

All new and existing tax-advantaged arrangements will be required to ‘self-certify’ if they wish to qualify for the applicable tax treatment. By notifying and self-certifying the arrangements, the tax advantages are protected. Failure to notify will mean any tax advantages may be lost.

In addition, the annual reporting of ‘non-tax advantaged’ plans and arrangements must be linked to a registered arrangement. Therefore, in order to complete an electronic annual return, it will be necessary to have first electronically notified the existence of the plan, scheme or arrangement to HM Revenue & Customs.

The registration process

The registration of employee share plans has been developed by HM Revenue & Customs as part of the Pay-As-You-Earn (PAYE) online portal. Many companies will already have access to this service for payroll purposes. However, companies that do not have access to HMRC online will need to register. Once registration has been requested, an activation code is sent to the company and it will be able to use this to access the PAYE portal.

It is also possible for agents to be granted access to PAYE online and multiple agents are allowed for each company. It is worth noting that agents must be registered before they can have access, so if clients anticipate asking an agent to complete their returns they will need to allow sufficient time to get them registered (and to complete the returns).

Issues and considerations

The introduction of the online reporting system has also been accompanied by new penalties for companies that fail to comply with the reporting requirements. From 7 July 2015, HMRC will be able to issue automatic penalties to companies who fail to meet the deadlines and/or if the information is not reported to them in the required format.

In order to meet the deadline, it is therefore recommended that companies prepare well in advance, as it is effectively a two stage process to register and then submit an annual return (there is typically a short delay between registration of plans and issue of unique reference numbers that are required for annual reporting).

As this is the first year of online registration and filing, there is likely to be an increase of companies using the online portal as the July deadline approaches. Whilst this may proceed smoothly, clients should be advised to register as early as possible in case the system struggles nearer the deadline.

There may also be problems in defining what should be reported and what should not. If clients have any doubts about whether an arrangement requires registration, notification or reporting, they should consult an Eversheds Employee Incentives specialist.

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The Eversheds Employee Incentives Team advises on all aspects of share plans and employee incentives, including the implementation of LTIPs, tax advantaged arrangements, EMI Schemes, cash bonus plans and numerous bespoke arrangements designed to achieve tax efficiency. The Team advise a wide range of clients in the Life Sciences sector, including both listed and private companies, on issues relating to employee incentives generally.
DC pension reforms 2015

United Kingdom

2015 will see significant changes in relation to defined contribution (DC) pensions. Some of the key issues that employers, trustees and pension providers will need to consider in respect of the changes are highlighted below.

New pension freedoms

In March 2014, the Chancellor announced radical changes to the tax rules that apply when accessing pension savings from a DC pension plan. From the start of the 2015-16 tax year, savers will essentially be able to choose what they want to do with their DC savings from age 55, and will not be forced to buy an annuity.

From 6 April 2015, individuals with pension savings in a DC arrangement will be permitted to:

- take their pension savings as cash in one go or in instalments. The first 25% of each payment will be tax free, with the remainder being taxed at the individual’s marginal tax rate;
- purchase a lifetime annuity and take 25% of the amount accessed as tax free cash;
- allocate funds to a flexible drawdown account (referred to as ‘flexi-access drawdown’) under which they will be able to keep their funds invested and draw them down as and when they want to. 25% of the amount allocated can be taken as tax free cash;
- receive a scheme pension and take 25% of the amount accessed as tax free cash; or
- select a combination of the above.

If an individual wants to select one of the options outlined above and their scheme does not offer it, they will have the right to transfer their savings into an arrangement that does. There will also be a new statutory power which will enable trustees and pension providers to allow members access to the new pension freedoms, even if the plan rules would otherwise prevent this.

Members of defined benefit (DB) plans will also be able to take advantage of the new pension freedoms by transferring to a DC plan. However, except where the capital value of their DB benefits is below £30,000, the trustees of the DB plan must check that the member has received independent financial advice from a FCA-authorised adviser before making the transfer. The new flexibilities will apply directly to money purchase additional voluntary contributions (AVCs) in a DB plan.

All DC savers will have access to free guidance to help them understand their options, and trustees and pension providers will need to inform members about this as they approach retirement.

Action:
- Trustees and providers need to understand the new tax rules and new benefit options and decide which of the options, if any, to offer members under their scheme.
- Member communications will need to be updated to make members aware of their new options and to signpost members to the new guidance service.
- Procedures for authorising transfers from DB plans should be updated to ensure the new legal requirement for receiving appropriate financial advice is met.

Abolition of short service refunds

Currently, a member of an occupational pension scheme who leaves the scheme within the first 30 days of membership can have a refund of their contributions. From October 2015, refunds may only be paid from DC occupational schemes where members leave the scheme within the first 30 days of membership.

Action:
- Contract-based schemes need to establish an Independent Governance Committee from April 2015.
- Employers need to consider how the charge cap and other planned changes may affect their arrangements in relation to any auto-enrolment qualifying scheme.
- If they do not already have one, DC occupational schemes should start identifying candidates for chair of trustees.

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Shift work a hazard to health!
What next?
United Kingdom

A study by the University of Surrey in the UK has received much publicity recently about hazards to health of shift work. The headlines are of long-term health damage with links to type 2 diabetes, heart attacks and cancer. The study talks about Chrono-chaos when the rhythmic genes are thrown out of sync, explaining why jet lag affects us in the way it does.

Wading through the bold and eye-catching headlines the point being made seems to be that it is the change of sleep times that causes the problem. For most of us, jet lag may occur once or twice a year after holidays, and it is not clear from the study the impact of a few days disrupted sleep patterns would have on long term health taking into account the multitude of other factors in life. But what if your job requires constant changes to your sleep patterns, for example airline pilots and crew on long haul flights, or health workers who may change shifts on a fortnightly basis. What would the cumulative affect be over many years of work?

This new study may not be a game changer in the same way as in 1963 when the Minister of Labour published “Noise and the Worker”, the first major publication on the subject, which made employers aware of the dangers of excessive noise in the workplace. The study does, however, at the very least put the issue of the health concerns due to sleep patterns or long haul travel should be on notice that now is the time to start to review your work practices, otherwise in the future an employee with health problems linked to shift work will be saying to you, “You should have known back in 2014 that shift work was bad for my health!”.

For further details on this briefing please contact:

Employers in industries with established shift work patterns or long haul travel should be on notice that now is the time to start to review your work practices, otherwise in the future an employee with health problems linked to shift work will be saying to you, “You should have known back in 2014 that shift work was bad for my health!”.

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Swiss Court decision on group financing and cash pooling

Switzerland

In a landmark decision the Swiss Federal Supreme Court recently decided whether a dividend distributed by a Swiss company that participated in a zero balancing arrangement had been distributed lawfully. The decision will impact on group internal financing and cash pooling for health and life science sector clients with Swiss operations and, although not specifically dealt with by the court, is also likely to have a severe impact on Swiss tax matters.

The court upheld that up-stream and cross-stream loans within a group may only be granted by a Swiss company if the “arm’s length test” is satisfied. The Court did not establish clear rules on the conditions for the arm’s length test, but stated that meeting the arm’s length test includes analysing the credit-worthiness of the debtor, potential securities and any required documentation. The court raised the question whether it is at all possible for a Swiss company to enter into a zero balancing cash pooling, however, the court did not provide an answer.

Further, the court stated, that for up-stream or cross-stream loans that do not fulfil the arm’s length requirements, a Swiss company needs to create a corresponding reserve which is not available for distribution. As a result, there is a limitation on dividend distributions as up-stream and cross-stream loans that are not at arm’s length need to be covered by a reserve which reduces distributable equity. It is also important to note that in order to decide whether or not a dividend can be distributed, only the situation as of the relevant date needs to be considered.

While the court did not deal with tax aspects of up-stream and cross-stream loans and cash pooling, it has to be assumed that the Swiss tax authorities will challenge financing arrangements of Swiss companies that do not meet the arm’s length test more often than in the past. In case a company needs to create a reserve for granting financing not at arm’s length, the financing should be expected to be challenged on the tax side. The tax consequences may be severe. The entire loan could be considered a hidden dividend distribution subject to 35% withholding tax (or even 54%, if grossed-up). Until now Swiss tax authorities did not often challenge intra-group financing if interest was charged at arm’s length and there was no loan default.

Swiss companies are advised to review their internal financing arrangements having regard to the arm’s length condition, whether they have the required documentation and any potential protective measures that can be taken.

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Useful resources

The competition law online toolkit

The Competition Law Online Toolkit is an award-winning e-learning programme. The Toolkit delivers effective antitrust compliance training to directors and employees of companies. All content is tailored to make it relevant to your day to day conduct. The course is written in straightforward business English and we have translated client courses into over 25 languages.

Click here to download your competition law online toolkit.

Unified Patent Court

A comprehensive overview of the Unified Patent Court, including its structure, where it will be based, how it will operate in practice, areas of continuing controversy and strategic decisions your business needs to make now.

Click here to view the UPC guide.

Global corporate real estate guide

Eversheds have released a new interactive corporate real estate guide which features insight into the legal issues affecting companies operating in jurisdictions around the world accompanied by Eversheds’ expertise in meeting the international real estate needs of these companies.

Click here to view the interactive guide.

Interactive global employment and pensions law guides

This app is an easy to access reference source for employment and pensions law across the globe and allows you to compare legislation in different jurisdicitions.

Click here to download the interactive global employment and pensions law app.

Eversheds international merger control guide

Eversheds use technology and project management skills to streamline the process of identifying and managing merger control filings. As a result, we can help you clear merger control hurdles quickly and efficiently.

Click here to view the international merger control guide.

M&A blueprint: benchmarking tool

This toolkit allows you to create your own personalised benchmarking blueprint to compare your approach to the due diligence and integration phases of deals with comparable companies.

Click here to use the M&A benchmarking tool.

Fit for work: a new way of looking at sickness absence

This guide gives an overview of the Government’s new fit for work scheme and the legal implications affecting employers.

Click here to view the fit for work guide.