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Under the Microscope

How 2014's legal developments could affect Lifescience businesses in Europe in 2015

2014/15

Introduction

Hello and welcome to our look back at 2014 at some of the key legal developments in the European marketplace last year which we think will have a significant impact for companies with Lifescience businesses in Europe or which mark some of the business trends and opportunities for those companies in 2015.

The challenging European austerity market has continued throughout 2014 with increased member state focus on prices even to the point where this threatens to overturn the EU regulatory framework for products like medicines. CMS in Italy and France report on the actions taken by the competition authorities and legislators to relax the legal restrictions on supply and use of off-label or unauthorised medicines on purely economic grounds in their countries. At an EU level the Commission issued its 5th patent settlement report in December 2014 against a backdrop of continuing enforcement action against reverse payment settlements. Companies with strong market presence in narrowly defined markets will also have to be mindful of the European General Court's June decision against Intel (concerning the anti-competitive nature of exclusivity rebates) when developing commercial strategy.

Although the medical and diagnostics devices sector continued its wait throughout 2014 for the completion of the EU revision of the sectoral legislation, the publication of the EU Clinical Trials Regulation in May 2014 means pharmaceutical companies should start preparing early for the new regime which will introduce significant changes to administrative procedures and liability exposure and also the data transparency framework, which has also been changed by the EMA's policy on publication of clinical data released in October 2014.

2014 also saw some highly significant developments for compliance. Germany's supreme court relaxed the prohibition on gifts to health professionals in some circumstances while the pharmaceutical industry tightened its own rules and also geared up for EFPIA transparency. Meanwhile in the medical devices sector MedTech Europe adopted a different approach and started planning for a switch away from directly sponsoring health professionals at medical congresses by 2018. Switzerland, however, finished 2014 with no less than three different drafts of the revised Therapeutics Products Act to change the law on discounts and incentives for pharmacists and health professionals for pharmaceutical, and possibly also medical device companies.

A number of Intellectual Property developments occurred in 2014 which could positively impact European businesses in the future. We report on further progress made towards the EU Unitary Patent and Unified Patent Court, paving the way towards a harmonised patent system in Europe. We also highlight a key decision from the European General Court which provides much needed clarity on the IP protection available for stem cell researchers, and CMS Germany highlight an important German Court decision which promises to provide extended opportunities for those seeking patent protection via second medical use claims.

While we all await the outcome of the latest round of TTIP negotiations between Europe and the United States on regulatory compatibility and sectoral regulatory cooperation and the new opportunities for pharmaceuticals and medical devices which these are promised to bring, we hope you find our selection and collected analyses a helpful guide for Lifescience businesses during 2015.

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Regulatory/Competition

Off-label reimbursement – a new method for reducing drug prices?

Significant new reimbursement legislation was passed in Italy and France during 2014, the effect of which is to relax the law on the off-label use and reimbursement of medicines on economic grounds.

The new measures are aimed at reducing drug prices and (in Italy's case) discouraging anti-competitive agreements between pharmaceutical companies which seek to unlawfully keep drug prices high. While industry considers how to react to these developments, the introduction by national governments of off-label reimbursement rules on costs grounds is now also under scrutiny by the European Commission as part of the study it has commissioned into off-label use.

Background of enforcement action by Italy's competition authority

On February 27th 2014, the Italian antitrust authority ('**AGCM**') fined Roche and Novartis (€90.5 and €92 million respectively) for engaging in an anti-competitive agreement in the market for ophthalmic drugs used to treat vascular eyesight conditions, specifically by creating an artificial product differentiation by suggesting that Roche's Avastin might have a poorer safety profile than Novartis' Lucentis, thereby influencing the prescription rates of these drugs. Following this case Italy enacted legislation permitting (under certain conditions) off-label use and reimbursement on cost grounds (see below).

Avastin, authorised for the treatment of cancer, is being used off-label in a modified format for treating eyesight conditions such as age-related macular degeneration ('**AMD**'). Lucentis, on the other hand, contains an active substance with a similar mechanism of action to Avastin but is authorised for treating AMD. Since there is a significant difference in price (in Italy: €900 for a Lucentis injection versus €81 for Avastin), the AGCM found that Roche and Novartis had set up a complex collusive strategy in order to avoid the commercial success of Lucentis being adversely affected by the ophthalmic application of Avastin.

The AGCM's decision to fine was upheld by the Italian Administrative Court of Lazio (judgment no. 12168/2014 of December 8th 2014) but is likely to be subject to further appeal before the Council of State, the Italian administrative court of final instance. Meanwhile, the results of a reported investigation by the French competition authority are not yet known.

The 2014 legislation in Italy and France

On May 21st 2014 Law No. 79/2014 came into force in Italy, providing for the Italian National Healthcare System to permit and reimburse off-label use of an authorised drug if its cost is cheaper than the cost of other drugs which are specifically authorised for the particular condition.

The off-label therapeutic use under the new law must nevertheless be supported by medical and scientific research evidence, obtained both nationally and internationally. The off-label use must also satisfy criteria of affordability and suitability. Specific authorisation by the Italian Medicines Agency ('**AIFA**') is also required.

In France, Article 10 of the Amended Social Security Financing law for 2014 no. 2014-892, dated August 8, 2014, modified article L.5121-12-1 of the French Public Health Code by deleting the previous reference to an obligation which restricted off-label prescribing to situations where it was necessary in order to prevent a grave clinical risk arising or for the avoidance of expense which would have a significant impact on social security expenditure. This effect of this amendment appears to be that, where there is an appropriate alternative which has a marketing authorisation for the same indication, off-label prescription of a medicine is permitted purely on economic grounds.

This 2014 legislation took effect by modifying French law no. 2011-2012, dated December 29, 2011, on measures strengthening the safety of medicinal and health products, which itself inserted specific provisions on off-label use by creating article L.5121-12-1 of the French Public Health Code. Under the 2011 provisions, in the absence of a suitable alternative, a medicine can be prescribed by a responsible person even if marketing authorisation (MA) has not been granted by the French medicines authority ('**ANSM**') for that specific indication, provided that the following conditions are met:

— a temporary use recommendation issued by ANSM is in force; or

— the responsible person judges, in view of the scientific evidence, that such a prescription is essential for patient improvement or stabilisation.

Where an appropriate, authorised alternative medicine existed, French law no. 2012-1404, dated December 17, 2012 had subsequently provided that a specialty medicine could be subject to a temporary use recommendation (in consequence of which an off-label prescription would be authorised) only if its use was for the purpose of preventing grave clinical risk arising or for the avoidance of expense which would have a significant impact on French social security expenditure. It is this provision which has been deleted by the 2014 legislation.

As in the case of Italy the European Federation of Pharmaceutical Industries and Associations (EFPIA) has strongly disapproved of these developments in France, pointing out that a law permitting off-label medication for purely economic reasons is incompatible with the EU's pharmaceutical regulatory framework. Particularly relevant in this context is the fact that one of the objects of the EU pharmaceutical regulatory framework is to safeguard public health.

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Pay-for-delay – another patent settlement monitoring report

The European Commission's fifth patent settlement monitoring report was published on 5 December 2014. The Commission started monitoring patent settlements between originator and generic companies following the publication of its report into the EU pharmaceutical sector in 2009.

The Commission's stated aims as regards the monitoring exercise are '*to better understand the use and type of agreement and to identify those agreements that delay generic entry to the detriment of the European consumer possibly in violation of EU competition law*'. The fifth report comes against a backdrop of continuing enforcement activity on this theme, most recently the prohibition decisions adopted in the *Lundbeck* and *Servier* cases (2013 and 2014 respectively), where the Commission concluded that so-called 'reverse-payment settlements,' that is, settlements containing restrictions on generic entry and involving a 'value transfer' from the originator company to the generic firm, are restrictions of competition by object.

The Commission's views on pay-for-delay cases have always been strongly contested. There is a widespread belief that few patent settlement agreements, even if they involve value transfers and could be called 'pay-for-delay' agreements, have true anti-competitive effect. Some may be the reasonable result of a genuine patent dispute and will not leave anti-competitive impacts on the market, e.g. because they may avoid protracted litigation which could itself significantly delay generic entry. For this reason, many pharmaceutical suppliers and other parties believe that it is a fallacy to conclude that pay-for-delay agreements should be considered infringements of the competition rules by object and that the authorities should indeed consider the individual circumstances of each case.

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Intel – exclusivity rebates are inherently anti-competitive

The most significant EU competition law judgment of 2014 was the General Court's judgment of 12 June, dismissing an appeal by Intel Corp. against a 2009 decision by the European Commission ('**Commission**') to fine Intel Corp. €1.06 billion for the abuse of a dominant position in breach of Article 102 of the Treaty on the Functioning of the European Union (TFEU).

The main abuse considered was exclusivity rebates, which are rebates conditional on the customer obtaining all or most of its requirements from the dominant company (and it is not helpful that this and earlier cases all fail to define the threshold at which the purchase requirement becomes 'most' of the customer's requirements).

The judgment's principal finding is that exclusivity rebates granted by a dominant company are, by their very nature, likely to be anti-competitive and that, as result, there is no requirement to demonstrate anti-competitive effect in the circumstances of an actual case. This approach arguably contradicts the existing enforcement practice of the Commission itself, which the Commission has stated in guidelines will involve the economic assessment of anti-competitive effect.

The Commission and other competition authorities have consistently defined pharmaceutical and other Lifescience markets on a narrow basis with the result that it is advisable that the commercial policies of many companies in this sector comply with the abuse rules under Article 102. Such a strict statement of the law can be expected to have a major impact on the commercial strategy of companies with a strong market presence, forcing them to consider a cautious approach of avoiding potentially non-compliant discount offerings which may be commercially attractive and may appear to represent innocuous and customary business practices.

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Testing times: preparing for the EU Clinical Trials Regulation

EU Regulation 536/2014/EU regulating clinical trials in Europe was enacted in May 2014 to make the EU more attractive for pharmaceutical clinical research. The new Regulation will introduce significant changes to the administrative procedures governing the authorisation and conduct of clinical trials in the EU. From a practical perspective, the new regime is expected to fulfil the main objectives of lowering administrative burdens, streamlining processes and increasing transparency. At the same time, it poses significant challenges to the pharmaceutical industry.

The Regulation has the same scope as the Directive, which it replaces, and applies to all clinical trials conducted within the EU for medicinal products with the exception of non-interventional studies. The authorisation procedure will involve a single regulatory and ethics application made by the sponsor in respect of all target Member States through a single submission portal operated by the European Medicines Agency, whether for single centre or multi-centre studies. One of the key challenges will be meeting the tight deadlines for the sponsor to provide additional information requested by the Member States during the authorisation procedure.

Ex-EEA sponsors must establish at least a contact person in the EU though Member State(s) may also require the legal representative to be responsible for ensuring compliance with the sponsor's obligations under the Regulation. Legal representatives should therefore clarify in advance what their direct potential liability exposure could be in relevant Member States and should ensure adequate intra-group controls, arrangements and possibly insurance are in place to protect them.

Under the Regulation's co-sponsorship rules co-sponsors can allocate legal responsibility amongst themselves by a written contract. If responsibility for a particular aspect of the trial is not specifically attributed to a co-sponsor, all co-sponsors will be deemed to have joint responsibility. Co-sponsorship agreements must therefore adequately address allocation of responsibility. Outsourcing agreements, e.g. with sites, should then reflect this.

Although May 2016 is the earliest entry into force date, companies should start preparing now for the new regime focussing on frontloading of preparation for trial authorisations and amendments; checking responsiveness of global and local teams (both internally and externally); ensuring completeness of clinical trial registration and data filing and reviewing contractual templates and patient consent documentation - to check compliance but also to ensure potential liability exposure is adequately managed under the new regime.

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Compliance/Transparency

New developments in Germany relating to gifts in the healthcare sector

Contrary to the general approach taken by unfair competition law, gifts – either to professionals or to the general public – are heavily regulated in the healthcare sector.

In this respect, two recent important (and contradictory) developments in Germany need to be taken into account by the pharmaceutical industry: on the one hand, the code of conduct of a pharmaceutical industry association was tightened and now prohibits promising, offering or granting gifts to healthcare professionals; on the other hand, a recent decision of the German Federal Court of Justice (Bundesgerichtshof, 'FCJ') has liberalised promotion with gifts to healthcare professionals.

Tightening of the FSA Code of conduct on the collaboration with healthcare professionals

With effect from 1 July 2014, the provision of the FSA Code of Conduct on Collaboration with Healthcare Professionals ('**Code of Conduct**') governing gifts to healthcare professionals has been tightened. The Freiwillige Selbstkontrolle für die Arzneimittelindustrie e.V. ('**FSA**') is an industry association of around 60 pharmaceutical companies that, as a result of their membership, agree to comply with the FSA codes of conduct.

Apart from some very limited exceptions, the amended provision of the Code of Conduct prohibits promising, offering or granting gifts to healthcare professionals, irrespective of whether or not the promotion is related to a specific product. Violations of the Code of Conduct can be referred to an arbitration board.

The Code of Conduct applies to promotions directed at healthcare professionals and not those directed at the general public. Furthermore, it only applies to the promotion of prescription-only medicinal products for human use (Rx) and does not regulate the promotion of over-the-counter (OTC) medicinal products.

Liberalisation of law governing gifts to healthcare professionals

In contrast with the changes introduced by the industry Code of Conduct, the FCJ rendered a decision that effectively liberalises the law in relation to gifts granted to healthcare professionals (FCJ, Case I ZR 83/12 – '*Testen Sie Ihr Fachwissen*').

The FCJ had to assess a pharmaceutical company's promotion for a medicinal product by means of a competition. Pharmacy technicians could win wallets valued at €12 each, if they correctly answered a set of questions relating to the (OTC) medicinal product advertised. The answers could be found in an information leaflet on the medicinal product provided by the pharmaceutical company. The questionnaire was printed on the last page of the leaflet.

Contrary to the decisions of the lower courts, the FCJ held that there was no violation of the statutory prohibition against giving promotional gifts contained in the German Act on Advertising in the Healthcare Sector (*Heilmittelwerbegesetz*). According to the FCJ (and contrary to previous practice), the prohibition on gifts did not apply as the promotional contest did not trigger an economic interest in recommending or prescribing the medicinal product advertised, and therefore did not create any relevant risk of non-objective influence on those targeted by the promotion.

Conclusion

Whereas in the Rx sector promotion with gifts has been prohibited, the possibilities for promotions in the OTC-sector have been expanded. With respect to the Code of Conduct, former practices will have to be carefully re-evaluated with a view to safeguarding important tools for providing legitimate information on medicinal products.

With respect to the relaxation of the statutory prohibition of gifts, there appears to be scope to develop a new approach. Provided that the granted benefit is neither directly nor indirectly connected with certain expected behaviour of the healthcare professional, there can be good arguments in favour of gifts to such professionals being more generally permitted.

As the FCJ's decision only concerned a promotion by means of a competition directed at professionals, it remains open as to the extent to which the courts will apply the liberalised concept to other cases of promotion not involving competitions or even (but less likely) in relation to promotion directed at the general public.

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Proposed changes to the Eucomed Code

Medical device and IVD companies subscribing to the Eucomed or counterpart national business ethics Codes will have to start preparations to cease direct sponsorship of healthcare professionals (HCPs) to third party medical congresses. Companies will need to consider if and how they will switch to indirect sponsorship if they intend to continue their support for HCPs' continuing medical education (CME) in the devices and IVD sectors.

This step change for the funding of CME follows MedTech Europe's[1] October 2014 recommendation to its member trade associations and companies that they completely phase out direct sponsorship of HCPs by no later than January 2018. In practice, this will mean affected companies will cease all direct payments for some or all of the travel, lodging and conference registration fees for European HCPs attending third party medical congresses. This is currently a significant part of industry's ongoing support for HCP CME the ultimate aim of which is to promote improved outcomes for patients. Those companies intent on continuing CME support will instead have to arrange indirect sponsorship, for example via grants to medical societies, hospitals, conference organisers or possibly governmental bodies who will themselves then allocate the funds to pay certain expenses of HCPs to attend CME conferences.

The planned switch from directly sponsored medical congresses (some of which have been criticised as 'vanity meetings' by the UK criminal appeal court) to indirect sponsorship represents the latest evolution of MedTech's commitment to business integrity and builds on the Eucomed conference vetting system, which is now binding upon member companies for European medical congresses. It marks a definite divergence from the course taken by the European pharmaceutical industry which continues to directly sponsor individual HCPs' attendance and other costs in connection with medical congresses. Of course, indirect sponsorship carries its own potential compliance risks. Companies will therefore need to carefully appraise these risks when implementing indirect sponsorship programmes. They will also have to take account of the detailed compliance guidelines for indirect sponsorship which MedTech will develop as part of its current review of its Code of Ethical Business Practice.

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[1] MedTech Europe is an alliance of medical devices and in vitro diagnostics trade associations in Europe.

Bribery in China – a bitter pill for GSK?

May 2014 saw the UK Serious Fraud Office (SFO) and a number of other international authorities (including the US Department of Justice (DoJ)) open investigations into GSK's sales practices in China.

These investigations followed a very public investigation by the Chinese authorities into GSK's hospitality practices, with almost daily reports in the global press about the allegations of corrupt behaviour. In particular, the authorities alleged that GSK were bribing local doctors and officials in order to secure drug orders. Following a one day trial in China in September 2014, GSK was found guilty of bribery and was fined USD 490m. Five GSK executives were also given suspended jail sentences. The former head of Chinese operations, Mark Reilly (a British national), was given a three year suspended jail sentence and deported from China.

With investigations by the SFO and DoJ ongoing, this may not be the end of the matter for GSK but, notwithstanding the substantial fine, the global negative publicity alone has caused significant damage to GSK as a brand and caused a number of multinationals, particularly in the Lifesciences sector, to consider whether their operations could fall victim to the changing regulatory and political environment in China.

Lessons learnt

Incentive arrangements: One of the key criticisms arising out of the Chinese authorities' investigation was that GSK's pay/bonus packages focused too heavily on sales performance, which it considered incentivised people to engage in bribery. Those looking to reduce risk may wish to review the way in which they reward staff to stop people behaving unethically to maximise their remuneration.

HQ oversight: From the outset of the investigation, GSK's UK HQ maintained that it had no knowledge of the practices undertaken by its Chinese subsidiary, in breach of the company's governance and compliance procedures. The UK Bribery Act corporate offence is a strict liability offence, and so a lack of knowledge of bribery committed by associated persons (such as subsidiaries or employees) after 1 July 2011 for the benefit of the UK business would not avoid liability. The only defence will be where the UK HQ had "adequate procedures" to prevent or mitigate the risk of bribery occurring. What constitutes adequate procedures is yet to be tested or clarified by the courts but one may expect the courts to look closely at whether the defendant company was aware of market or country specific risks and had taken steps to mitigate them, was monitoring the effectiveness of its policies by its global subsidiaries, and had sufficient management reporting on corruption risks.

Understand the country risk: Multinationals operating globally need to understand the unique risks and issues presented by the jurisdictions in which they do business. The changing political and regulatory climate in China meant that GSK (and other multinationals operating within China) faced a greater risk in relation to practices that historically may have been acceptable or at least overlooked by the relevant authorities. It is important to understand how a changing environment (either as a result of changing laws, governments, economic or regulatory situations) may impact on the level of risk posed to the company, so that applicable governance and compliance programmes may be adapted to reduce any additional risks. It is also important to be alive to the types of methodologies employed in different sectors and jurisdictions to facilitate corruption - in the GSK example in China, there was reportedly wide use of bogus travel agents to mask and enable the funding of improper payments.

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Revision of the Swiss Therapeutic Products Act

As at the start of 2015, three different versions exist of the revised Swiss Therapeutic Products Act, which will change the law on discounts and incentive systems for those falling within its scope.

Key questions which remain unanswered are: first, whether the revised provisions will only be applicable to (prescription) drugs or also to medical devices; and secondly, to what extent discounts and incentive systems will be permissible. For medtech companies it will be particularly important to closely monitor future developments in 2015 since, should the revised provisions also be applicable to medical devices, the medtech industry will be faced with a new set of legal rules which will have considerable impact on the distribution and marketing of medical devices.

The current legislation on rebates and incentive systems in the Swiss Therapeutic Products Act entered into force on 1 January 2002 and has kept pharmaceutical companies and lawyers busy ever since. This legislation is currently undergoing a revision, which is supposed to enter into force on 1 January 2016. At the moment, however, there are still some uncertainties with respect to the scope of the revised legislation and whether it will only be applicable to drugs – similar to the current legislation – or also to medical devices.

Art. 33 of the Therapeutic Products Act currently prohibits pharmaceutical manufacturers from granting, and medical persons from accepting, material benefits, if such benefits are likely to influence a medical person's prescription or dispensing behaviour. Permitted are: (a) material benefits of modest value (up to CHF 300) and which are related to the medical or pharmaceutical practice; and (b) commercially and economically justified discounts which are directly reflected in the price. This provision has been said to be unclear and unsuitable for the effective targeting and prevention of incentives offered by pharmaceutical companies to doctors and pharmacists. As a result, there has been legal uncertainty which has led to several administrative and criminal proceedings, not only against pharmaceutical companies, but also against doctors and pharmacists.

The aim of the current revision is to provide more clarity on the admissibility of discounts and incentive systems in the therapeutic products industry. In 2012, the Swiss Federal Council issued draft legislation that would have led to a prohibition of all kinds of discount and rebate systems for prescription drugs, unless such rebates would have been fully passed on to the patients. Additionally, the draft contained far-reaching transparency and disclosure obligations which would have required doctors and pharmacists to disclose their commercial ties with pharmaceutical and medtech companies.

In mid-2014, the Swiss National Council changed the draft considerably. According to the National Council, the provision regarding discounts and incentive systems shall not only apply to (prescription) drugs but also to medical devices – which would constitute a significant expansion compared to the current legislation. On the other hand, the National Council deviated from the Federal Council's position that discounts shall not be allowed at all and defused the far-reaching transparency and disclosure obligations foreseen in the Federal Council's draft. Discounts and incentive systems would, in the National Council's opinion, still be possible but should be made transparent in the books and records of the pharmaceutical and medtech companies as well as in those of the doctors and pharmacists.

In November 2014, the second chamber of the Swiss Parliament, the Council of States, also deliberated over the revision of the Therapeutic Products Act, the draft of the Federal Council and the changes decided by the National Council. In accordance with the Federal Council but contrary to the views of the National Council, the Council of States decided to limit the applicability of the provisions regarding discounts and incentive systems to prescription drugs only. Additionally, the Council of States further amended the requirements for admissible discounts and incentive systems. Contrary to the recommendation of the National Council and in accordance with the approach of the Federal Council, the Council of States decided to apply the transparency obligations to all therapeutic products (i.e. drugs and medical devices).

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Intellectual Property

Is Europe closer to a harmonised patent system?

The introduction of the two new Unitary Patent Regulations (the '**Regulations**') in 2012[1] and the signing of the Unified Patent Court ('**UPC**') agreement in February 2013, represent the most significant change in patent law across Europe in 40 years. In 2014, further progress has been made towards the goal of harmonisation of the patent system in Europe.

UPC - Draft Rules of Procedure published

A key factor for the success of the UPC will be the Rules of Procedure ('**Rules**') that govern how proceedings in the UPC will operate for the actions over which the court has competency. 2014 has seen the publication of the 16th and 17th drafts of the Rules; these drafts having resolved many of the previously outstanding issues. It is expected that the 17th draft will be the last before the final version of the Rules is published in early 2015.

AG's opinion on Spain's challenges to the Unitary Patent

On 18 November 2014, Advocate General ('**AG**') Bot delivered his opinion on the Spanish challenge to the two Regulations. Spain had refused to agree the Regulations on a number of grounds, the most important of which were the supposed lack of legal basis for their introduction using the 'enhanced cooperation procedure', and a plea that the Translation Regulation was discriminatory to those whose mother tongue was not English, French or German.

The view of the AG is that all of the actions should be dismissed. The AG considers that the Regulations were validly adopted, providing for unitary effect and uniform protection within the participating member states. Whilst the AG recognises that the selection of French, English and German for the language regime is potentially discriminatory, it may be justified on the grounds of practicality, proportionality and costs.

If followed by the CJEU, the Spanish challenge will fail and the Regulations and associated transitional arrangements are likely to come into force following ratification of the UPC agreement by at least 13 of the 25 participating countries, which could be as early as the end of 2015.

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[1] Regulation (EU) No 1257/2012 (the '**UP Regulation**') and Regulation (EU) No 1260/2012 (the '**Translation Regulation**').

New opportunities for second medical use claims in Germany

On 24 February 2014, the German Federal Court of Justice (Bundesgerichtshof, 'FCJ') handed down its decisions *Kollagenase I* and *Kollagenase II* (file numbers X ZB 5/13 and X ZB 6/13) on the patentability of second or further medical use claims specifying the term 'specific use' under Article 54(5) EPC and Section 3(4) German Patent Code (PatG) respectively.

The decisions of the FCJ clarify the interpretation of the term 'specific use', and set a precedent for the patentability of second medical uses in Germany. The decisions are of great interest to the pharmaceutical industry, as they open up new opportunities for patent protection following the expiry of a composition of matter patent.

The factual background of the decisions

The FCJ was asked to rule on the validity of patents claiming the use of collagenase for the treatment of Dupuytren disease and Peyronie disease. The use of collagenase to treat these two diseases was already known and the only feature of the patents in question not known from the prior art was the instruction that the treated body parts should be kept immobilised for several hours following the injection of the substance.

The findings of the court

The FCJ has held that patentability is not excluded even if a dosage instruction is the only feature of a patent which is not found in the prior art. Furthermore, patentability is also not precluded where instructions contained in the patent claims relate not to the dosage but to other modalities of the use claimed by the patent.

The FCJ reasons that the 'specific use' requirement within the meaning of Article 54(5) EPC, and the wording of Section 3 PatG respectively, does not require the treatment of a different disease. In fact, the court considered that, in addition to the dosage and the target indication, other aspects such as the method of administration, the consistency of the substance or the specific patient population, are also of importance for assessing the specific use.

Moreover, the FCJ continues to consider that, according to Section 2a(1)(no.2) PatG and Article 53(c) EPC, aspects of the claimed use which do not relate to substance properties and the effect of the substance on the human body must not be considered when assessing patentability. Therefore, according to the FCJ, in order for treatment instructions to contribute to patentability, these instructions must objectively aim to enable, strengthen, catalyse or otherwise improve the effect of the substance, provided that these instructions do not relate to therapeutic methods suitable for treating the disease in question, the effects of which are additional to and independent of the substance itself.

The FCJ referred both cases back to the German Federal Patent Court (Bundespatentgericht, BPatG) and considered the findings of the BPatG insufficient to deny patentability of the patents in question. The BPatG therefore has to reassess the cases in the light of these rulings.

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CJEU decision provides certainty for stem cell researchers?

On 18 December 2014, the CJEU ruled on the question referred to it by the High Court, in *International Stem Cell Corporation v Comptroller General of Patents, Case C-364/13*, an important case concerning the patentability of parthenotes, a cell type originating from unfertilised human ova. The CJEU decision has significantly expanded the scope of patentability of inventions in this area and is likely to provide a much needed boost for companies investing in embryonic research.

The question referred to the CJEU

'Are unfertilised human ova whose division and further development have been stimulated by parthenogenesis, and which, in contrast to fertilised ova, contain only pluripotent cells and are incapable of developing into human beings, included in the term 'human embryos' in Article 6(2)(c) of Directive 98/44 on the Legal Protection of Biotechnological Inventions?'

The Judgment of the Court (Grand Chamber)

In *Oliver Brüstle v Greenpeace eV, C-34/10*, the CJEU had previously ruled that parthenotes were human embryos capable of developing into a human being and, therefore, are excluded from patentability on moral grounds, under Article 6(2)(c) of the Biotechnology Directive. However, in this case, the CJEU, following the Advocate General's opinion given in July, determined that the decision in *Brüstle*, to the extent that it equated unfertilised ova (which were incapable of developing into a human being unless genetically modified) with fertilised ova, appeared to have been based on incorrect facts provided to the court. Applying the general principle laid down in that case, such organisms were not human embryos and not within the exclusion from patentability in Article 6(2)(c) of the Biotechnology Directive.

Significance of the Judgment

The decision in *Brüstle* was widely considered to have serious implications for the future progress of science in this important area, potentially discouraging biotechnology companies from further investment in stem cell research technologies due to the uncertainty of whether or not their inventions would be patentable.

It is likely that, as in *Brüstle*, the EPO will declare that their practice will follow the CJEU's decision. The decision and such a statement from the EPO is likely to be welcomed by companies and researchers active in this area, providing more certainty and potentially encouraging further investment.

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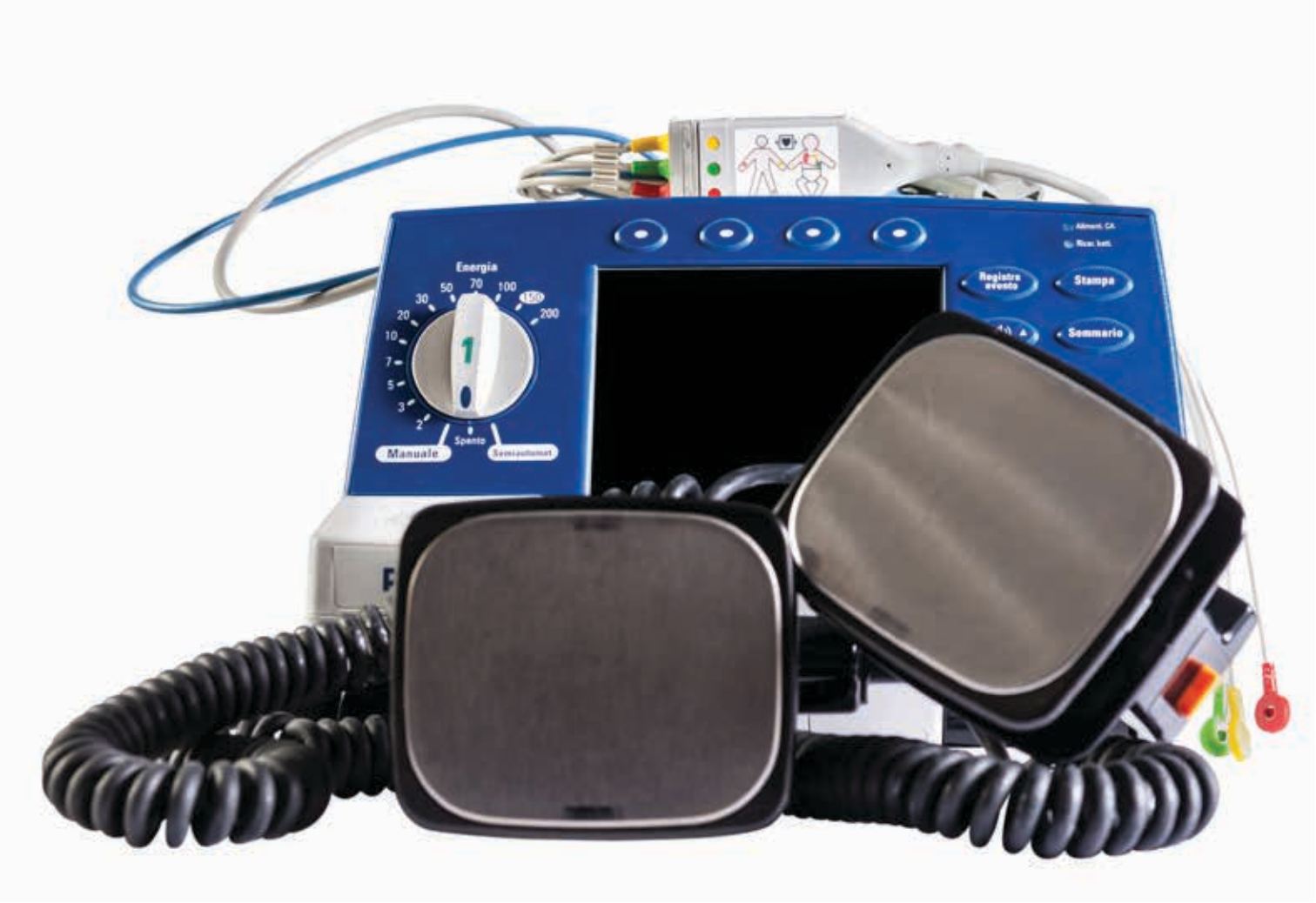
Product Liability



Forum shopping in cross-border product liability litigation

Defendants to product liability claims brought under the EU's Product Liability Directive 85/374/EEC, especially defendants in group litigation with cross-border claims, should take note of the March 2014 judgment by the English 1st instance court in *Allen & Others v Depuy International Limited*[1] in the context of non-contractual compensation claims relating to allegedly defective medical device hip implants. This judgment is relevant to identifying the applicable law for long-tail, latent damage claims as well as whether claims are available under the Product Liability Directive for claimants who suffer damage outside of the EEA.

Since 11 January 2009, when Rome II[2] took effect, the applicable law of a claim governs various key defence issues such as liability, limitation, burden of proof, contributory negligence as well as the available heads of damage and their quantification. Rome II also sets out the rules for determining what is the applicable law in cross border personal injury claims but, for events giving rise to the damage (EGRD) before 11 January 2009, national rules[3] apply to determine applicable law. For defendants facing allegations concerning long-tail, latent damage it is therefore important to understand what are the EGRD. Largely for reasons of consistency with European Court case law, the English court decided that EGRD were the manufacture and despatch from the factory of the implants, or failing that, the date of implantation as this aligns with another 2014 European Court ruling identifying the place of manufacture of a product as the place giving rise to the damage for purposes of establishing jurisdiction for tort claims under Regulation (EC) 44/2001.[4] In any event, EGRD were NOT the date of damage in the form of onset of each individual claimant's own biological reaction leading to symptoms and revision surgery.

For EGRD pre-dating Rome II, where the events constituting the tort did not all arise in one country, the court decided the general rule should apply in all cases but one, namely that the applicable law should be the law of the country where the injury was sustained and that it was not relevant to consider that the non-UK domiciled claimants were claiming as part of a much larger group of UK-domiciled claimants.

Additionally, the English court decided that the focus of the EU Product Liability Directive is the liability of producers for defective products within the EEA causing damage to consumers within the EEA. Consequently the English court decided that consumers who suffer damage outside the EEA, with no connection with the EEA, in circumstances where marketing and supply of the allegedly defective product were also outside of the EEA, are not within the scope of the Directive though it acknowledged that drawing the line in difficult cases will be very fact-sensitive.

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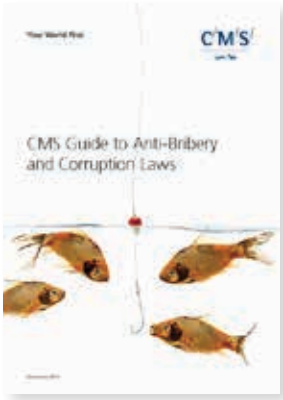
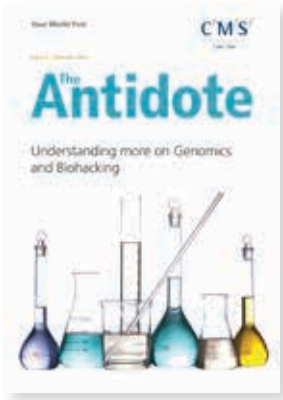
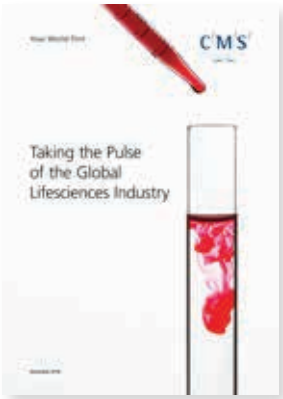
[1] Allen & Others v Depuy International Limited [2014] EWHC 753 (QB)
[2] EC Regulation 864/2007 on the law applicable to non-contractual obligations
[3] Private International Law (Miscellaneous Provisions) Act 1995
[4] EC Regulation 44/2001 on jurisdiction and recognition of enforcement of judgments in civil and commercial matters and case C-45/13

Other CMS publications you may find helpful







If you would like a copy of any of these publications, please contact us.

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