D YOUNG & CO PATENT NEWSLETTER no.67

October 2018
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Editorial

With this newsletter a warm welcome to new partner Jana Bogatz who has joined our Munich office team. We are delighted to see our German office IP team continue to flourish in support of high quality service our clients expect of us. It is a busy time for talks and conferences so we look forward to catching up with clients and contacts over the coming months.

Editor:
Anthony Albutt

Events

13-20 October 2018
EPO Mechatronics Delegation, S. Korea
Anthony Albutt will be speaking with EPO directors to applicants and law firms with an interest in the mechantronics and mechanical fields.

15 October 2018
Chemistry Means Business, UK
Garreth Duncan and Rachel Bateman will be attending this London-based conference.

25-27 October 2018
AIPLA Annual Meeting, Washington, US
Solicitors Antony Craggs and Uli Foerstl will be attending AIPLA's annual meeting in October.

30 October 2018
European biotech patent case law webinar
Simon O'Brien and Matthew Caines present our ever popular biotech webinar.

08 November 2018
CIPA Life Sciences Conference, UK
We will be attending the CIPA Life Sciences conference, Wooton Under Edge, UK.

21 November 2018
Patent open afternoon, London, UK
We open our doors to biotech, biochemistry and chemistry undergraduates and postgraduates interested in finding out more about a career as a patent attorney.

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No deal Brexit? UK Government advice for patents, the UPC & SPCs

As part of the UK Government's preparations for a possible "hard Brexit", it has published a set of guidance notes on 24 September 2018 on how intellectual property rights would be affected if the UK leaves the EU in March 2019 with no deal.

This is part of a series of technical notices being issued by the Government to assist businesses in their preparations, although it is widely anticipated that an agreement between the UK and EU will still be possible.

No deal Brexit: the impact on patents

The UK Government has commented[1] on what may happen in the event of no Brexit deal for UK patents and the UK's relationship with the Unified Patent Court and unitary patent.

> The overall message is one of continuity and business as usual, with the Government seeking to maintain the pre-Brexit status quo.

The UK Government also explicitly notes that:

> separate to UK patent matters, European patent attorneys based in the UK, such as D Young & Co, can continue to represent applicants before the European Patent Office, since it is not a European Union body.

This has also been confirmed by the EPO itself[2].

Unitary patent & Unified Patent Court

The Unified Patent Court will hear cases relating to European patents and the new unitary patent – both administered by the non-EU European Patent Office (EPO).

The Unified Patent Court will be an international patent court established through an international agreement (the Unified Patent Court Agreement) between 25 EU countries. However it is unclear whether the Unified Patent Court and unitary patent will start before 29 March 2019.

If there is no Brexit deal, then the UK Government considers two possible scenarios: There is a possibility that the Unified Patent Court will not be fully ratified and never come into effect. In this case there will be no changes for UK and EU businesses at the point that the UK exits the EU. However if it is fully ratified (for its part, the UK has already ratified), then it is currently unknown if the UK would be required to withdraw from one or both of the unitary patent and Unified Patent Court schemes.

If full withdrawal is required, then businesses will not be able to use the Unified Patent Court and unitary patent to protect their inventions within the UK, and so in effect the UK will keep its current status as a separate state to be validated upon grant of an application by the EPO, much like Spain. However, UK business will still be able to use the Unified Patent Court and unitary patent to protect their inventions within the other contracting EU countries.

Hence in the event that the Unified Patent Court comes into force, but the UK needs to withdraw from the Unified Patent Court and unitary patent, then UK, EU and third country businesses will still be able to use the Unified Patent Court and unitary patent to protect their inventions within the EU, and they will be able to validate the UK upon grant of an EP application as before.

In the unlikely event that the Unified Patent Court comes into force before the end of March 2019, the UK Government explicitly assures that any existing unitary patents will give rise to a corresponding separate UK right automatically.

Correspondence addresses & confidentiality

As noted above, European patent attorneys based in the UK can continue to represent applicants before the European Patent Office, since it is not an EU body. Conversely

Notes & links to further information

1. *UK Government paper published 24 September 2018 "Patents if there's no Brexit deal": https://dycip.com/nobrexitdeal-patents*
2. *EPO press release "EPO and CIPA: no impact of Brexit on UK membership of EPO": https://dycip.com/epo-uk-membership*
3. *UK Government papers published 24 September 2018 regarding regulating medicines and medical equipment: https://dycip.com/nodealbrexit-medicines*
4. *UK Government papers published 24 September 2018 regarding regulating veterinary medicines https://dycip.com/nodealbrexit-vetinary*

meanwhile, although prosecution of UK patents is by UK patent attorneys, it is possible for the owner of a UK patent to have an address for service elsewhere in the EEA.

In light of this, the UK Government has now provided assurance that this will continue, and that there is no plan to change current client-attorney privilege for non-UK attorneys in the EEA.

EU Biotech Directive

The UK Government proposes to retain the existing EU law (EU Biotech Directive) relating to biotech inventions after March 2019.

Therefore, the legal requirements for patenting biotech inventions will remain in place - these requirements are already implemented in UK national patent law. Patent examiners will continue to apply the same law when examining patent applications in this area. Third parties who wish to challenge the validity of a patent will be able to do so on the same grounds as at present.

Supplementary protection certificates (SPCs) and regulatory-based protection

The UK Government proposes to retain the existing EU law relating to SPCs after March 2019. Therefore the SPC regime in the UK will continue to operate as before, even if the event of no deal.

The UK Government states that "...all other EU legislation relevant to patents and supplementary protection certificates will be kept in UK law.." The UK Government also states that existing SPCs and licences in force in the UK will therefore remain in force automatically after March 2019, and the legal requirements and application process for new SPCs in the UK will remain essentially the same.

The UK Government has also indicated changes that may occur in the regulation of human[3] and veterinary medicines[4] and the various forms of regulatory-based protection available.

For medicines, existing marketing authorisations (MAs) granted centrally by the European Medicines Agency (EMA) will automatically be converted into UK MAs after March 2019. Existing UK MAs based on the mutual recognition or decentralised procedures will be unaffected.

UK-based European patent attorneys will continue to represent applicants at the EPO

The UK Government also states that regulatory data and market exclusivity will remain available based on UK MAs after the UK exits the EU, and the period of "8+2+1" years for this form of regulatory protection will remain unchanged. After the UK's exit from the EU, the start of this period will be the date of authorisation in the EU or UK, whichever is earlier.

The UK Government also states that paediatric medicines will be regulated by a UK system after the UK exits the EU, and incentives will remain to encourage such medicines onto the UK market. It can therefore be envisaged that the six-month extension will remain available for SPCs for medicines on which agreed paediatric studies have been carried out, although the UK Government indicates that details will be subject to consultation.

The UK Government also states that consultation will take place on the proposed regulatory approach to orphan medicines (for the treatment of rare diseases) after the UK exits the EU. This will include incentives to encourage such medicines onto the UK market. It can therefore be envisaged that some form of market exclusivity for orphan medicines may remain, but details will be subject to consultation.

Finally, the UK Government has indicated that they will retain the existing "EU Bolar" law which exempts from patent infringement trials carried out on generic medicines in order to obtain regulatory approval, for marketing after the patent expires.

Further information & enquiries

We will continue to publish guidance concerning the impact of Brexit on IP rights. Our latest updates will be found in our IP & Brexit 'knowledge bank' at: www.dyoung.com/knowledgebank/ip-brexit.

Should you have any questions please do not hesitate to contact your usual D Young & Co advisor or our Brexit enquiries team at brexit@dyoung.com.

Authors:
Garreth Duncan & Doug Ealey

Gene-edited organisms classified as GM in the EU C-528/16

The Court of Justice of the European Union (CJEU) recently decided that organisms that have been subjected to non-"conventional" mutagenesis techniques must be classified as genetically-modified organisms (GMOs).

This decision has far-reaching implications in that plants engineered using modern directed mutagenesis approaches, such as the CRISPR gene editing technology, are now considered to be GMOs in the EU and thus subject to the associated substantial regulatory burden.

It remains to be seen whether the UK government will continue to follow the same approach following the UK's departure from the EU.

CJEU now considers gene editing technology such as CRISPR to be a GMO

The technology

This case revolves around the different approaches that can be used to engineer the genomes of organisms, in particular plants.

Conventional techniques for engineering new traits in plants typically involve random mutagenesis of a plant's genome, for example using ionising radiation or exposure to mutagenic chemicals, followed by laborious screening and selection for a desired characteristic.

Plants can also be genetically engineered using "transgenesis" approaches, which insert exogenous genetic material giving rise to particular characteristics, such as herbicide resistance, into the plant's genome. However, more recent developments have made it possible to engineer mutations in a precisely targeted manner, which was not previously achievable. Precise targeting of mutations may enable the avoidance of unwanted off-target effects common with earlier techniques.

EU GMO legislation

GMOs and their deliberate release into the environment are regulated in part in the EU by Directive 2001/18/EC (the "Directive"). The Directive itself recites the importance of the protection of human health and the environment, and emphasises that living organisms may reproduce in the environment and that the effects of their release may be irreversible.

The requirements placed by EU legislation on products considered to be GMOs are extensive and include rigorous safety assessments, registration and clear labelling. Products that are not classified as "GMO" therefore enjoy a commercial advantage over those that are.

The Directive defines a GMO as: "an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination"

The Directive also recites a non-exhaustive list of methods regarded as genetic modifications, which includes techniques involving the direct introduction into an organism of heritable material prepared outside the organism (ie, transgenesis).

However, the Directive expressly excludes organisms produced by "mutagenesis" from the scope of GMOs.

The decision

The present case (C-528/16) hinged on what is to be regarded as "mutagenesis" and hence excluded from the definition of a GMO.

Questions were referred to the CJEU by the French Conseil d'État relating to whether organisms generated by mutagenesis fall within the scope of the Directive. The questions originated during proceedings brought by the agricultural union Confédération paysanne and eight other parties that were seeking revocation of part of the French Environmental Code that excludes mutagenesis from the definition of techniques giving rise to genetic modification.

In its decision, the CJEU did not follow the earlier opinion of the Advocate General, but ruled that: (a) organisms obtained by methods of mutagenesis constitute GMOs within the meaning of the Directive; and (b) with regard to "mutagenesis", only organisms obtained by methods that have "conventionally been used in a number of applications and have a long safety record" are excluded from the scope of the Directive.

The CJEU has appeared to place weight on the views that direct modification of an organism's genetic material makes it possible to achieve the same effects as those brought about by transgenesis, and that the development of such new

techniques makes it possible to produce genetically modified varieties at rates unlike those resulting from "conventional methods of random mutagenesis".

In effect, the CJEU has drawn a distinction between "conventional methods of random mutagenesis", such as those brought about using radiation and chemical mutagens, and new techniques that have been developed since the Directive was adopted. The defining difference between the two apparently being the lack of a "long safety record" of the state of the art methods.

Implications

This decision has been welcomed by campaigners against GM foods, but regarded with dismay by many scientists in the field. In particular, the EU's approach is believed likely to set back research into gene-editing technologies in Europe and may force scientists and investment in this revolutionary field overseas.

However, it will be interesting to see whether the same approach continues to be applied in the UK after its departure from the EU. A number of leading scientists have recently written to the Environment Secretary requesting the UK government considers how research and future use of gene-edited crops will be carried out following Brexit. A Department for Environment, Food & Rural Affairs (Defra) spokesman noted in response: "The Government has always been clear that we take a science-based approach to GM regulation and our priority is safeguarding health and the environment.

Our view remains that gene-edited organisms should not be subject to GM regulation if the changes to their DNA could have occurred naturally or through traditional breeding methods."

If the UK does not remain bound by this seemingly controversial aspect of EU law, an advantage may be provided to UK-based parties over their EU competitors in developing gene editing technology.

Author:
Matthew Caines

New partner and German qualified lawyer Jana Bogatz joins our Munich office team

We are delighted to announce that Jana Bogatz, partner and German qualified lawyer, has joined D Young & Co's Munich office.

Jana advises on both the contentious and non-contentious aspects of national and international trade mark, design, copyright and unfair competition law.

> Jana's recruitment represents another significant step in the development of our presence in Germany following the recruitment in 2017 of Uli Foerstl and Dr Hanns-Juergen Grosse, both partners in the firm's Munich office.

Neil Nachshen, D Young & Co Chair, comments: "We're delighted that Jana will be joining our growing team in Germany; we know Jana well having worked alongside her on various matters in the past and we're convinced that she will be an extremely valuable member of our team. Whilst it was always our intention to develop a strong strategic offering in Germany we have also had in mind the potential impact of Brexit on some areas of our business and Jana's arrival allows us to continue to offer the one stop shop for trade mark, design and patent advice for which we have always had a stellar reputation."

About Jana Bogatz

Jana's legal advisory work includes all contentious and non-contentious aspects of national and international trade mark, design, copyright and unfair competition law.

Her focus is in particular on the development of global trade mark and design filing strategies, the optimization of trade mark and design portfolios, the enforcement of trade marks, designs and domains against

Jana Bogatz, Partner, Rechtsänwaltin

infringements and dilution by third parties through court actions, as well as negotiation and conclusion of IP related agreements.

She represents clients in proceedings before the German Patent and Trade Marks Office, the Federal German Patent Court, all German civil courts, the EUIPO and the European Courts in Luxemburg (GC and CJEU).

Jana was admitted to the bar in 2007 and is a certified expert for IP law (Fachanwältin für Gewerblichen Rechtsschutz) since 2014.

Jana joins us from Bird & Bird but had previously worked for the IP boutique law firm JONAS in Cologne and as an Examiner at the European Trade Mark and Designs Office (EUIPO) in Alicante.

She also has experience of working as an in-house lawyer for an international retail company in Düsseldorf and acquired further valuable insight into the role of legal advice in business decision-making through two client secondments to a leading company from the luxury goods industry in Geneva.

Jana speaks German, English, Italian and Spanish.

Notes to editors

For more information, please contact Rachel Daniels, Marketing Communications Manager: rjd@dyoung.com or +44 (0)20 7269 8550.

Rising stars
IP STARS best performing attorneys

We are very pleased to report that Rachel Bateman Alan Boyd and Antony Latham have been highlighted as best-performing patent attorneys in IP STARS' newly published Rising Stars 2018/19.

Managing Intellectual Property's IP STARS is a specialist guide to IP firms and practitioners who have the appropriate expertise and high quality service levels to be ranked in the guide. D Young & Co is ranked top tier for our patent and trade mark services, and our partners feature in IP STARS 2018 as leading individuals in the IP profession. The new 'Rising Stars' feature to the guide acknowledges non-partners who have contributed to the success of their firm and clients in recent years.

Rachel covers a wide range of chemical subject-matter and her day-to-day work includes drafting patent applications, coordinating multi-territory prosecution, handling EPO opposition and appeal cases, as well as preparing freedom-to-operate opinions for pharma generics or innovators. Read more about Rachel: www.dyoung.com/rachelbateman.

Alan has a great deal of experience in drafting and prosecuting patents for a range of clients and has expertise in computer architectures, software, embedded systems, digital electronics, telecommunications and networks. Read more about Alan: www.dyoung.com/alanboyd.

Antony has a wide range of technical expertise in the fields of pharmacology, biochemistry, molecular biology, biotechnology and organic chemistry. He advises a range of clients on the drafting, prosecution, opposition and defence of patents. Read more about Antony: www.dyoung.com/antonylatham.

Our congratulations to Rachel, Alan and Antony and our thanks to colleagues and clients for their positive feedback to the legal directory researchers.

DOCERAM v CeramTec
CJEU considers aesthetic v functional design protection

This CJEU decision confirms the Advocate General's opinion that design features are not protectable by design law, if, from an objective point of view, they have been chosen solely on the basis of considerations of functionality. The CJEU confirms that the correct approach is one of "no aesthetic consideration" instead of the "multiplicity of forms" test settling a long-lasting dispute regarding the relevant standard.

Background

Doceram is a manufacturer of technical ceramic components. It owns various registered Community designs protecting the shape of a welding pin. CeramTec also manufactures welding pins and Doceram had claimed that CeramTec's pins infringed their design registrations. CeramTec counterclaimed that Doceram's design registrations were solely dictated by their technical function and were therefore invalid. Doceram appealed and in a 2016 decision, the Higher Regional Court of Düsseldorf issued a request for a preliminary ruling on the interpretation of Article 8 CDR. The court asked the CJEU the following questions:

1. Are the features of appearance of a product solely dictated by its technical function, within the meaning of Article 8(1) of [Regulation No 6/2002] which excludes protection, also if the design effect is of no significance for the product design, but the (technical) functionality is the sole factor that dictates the design?

2. If the court answers question 1 in the affirmative: From which point of view is it to be assessed whether the individual features of appearance of a product have been chosen solely on the basis of considerations of functionality? Is an "objective observer" required and, if so, how is such an observer to be defined?'

The question of whether it is right to adopt the so called "no aesthetic consideration" approach or the "multiplicity of forms" test has been open to interpretation since the Community Design Regulation (CDR) came into effect. The debate has been centred on the interpretation of the word "solely". The "multiplicity of forms" theory says that it is decisive if there is an alternative design possible (if there is, a design cannot be said to be "solely" dictated by its function). According to the "no-aesthetic consideration" it is decisive if only technical reasons were used to design the product. Whether or not there are existing design alternatives is, according to this theory, not decisive.

Outcome

The CJEU, in line, with the Advocate General, said:

1. In order to determine whether a characteristic of a product is caused exclusively by the technical function, you must determine whether this function is the only factor that determines the characteristic. It therefore confirmed that the correct standard is to adopt the so called "no aesthetic consideration" approach. The CJEU therefore rejected the "multiplicity of forms" test. The CJEU made the point that, if this were not the case, there is a danger that the Community design will achieve protection equivalent to patent protection when it is applied. An applicant could, for example, obtain various design registrations of different possible forms of products incorporating features solely dictated by technical function.

2. Regarding the second question, the CJEU said that it is for the national court to determine this within the meaning of Article 8(1), taking account of the objective circumstances of each case including (but not limited to) the view of an "objective observer".

Comment

This case emphasises that registered designs are intended to protect the aesthetic appeal of a product (as opposed to the technical appeal protected by patents).

The judgment will provide legal certainty and assist with design filing strategies but will arguably make it more difficult to counter an Art. 8(1) CDR defence. Now a claimant will need to prove that the design was not solely based on technical considerations and must rely not only on design alternatives but also on other evidence.

Author:
Richard Burton

UK v US patent law

Chugai v UCB Pharma
English courts construe US patent

Can an English court construe the scope of a licensed US patent? In Chugai Pharmaceutical v UCB Pharma & Others [2018] EWHC 2264 (Pat), the English Patents Court has held that, on the facts in issue, it could.

Here, UCB Pharma licensed Chugai for a portfolio of patents in relation to the drug tocilizumab. The licence was governed by English law and the English Courts. During the course of the licence, all except one patent, US Patent 7,556,771, ceased to be in effect.

Chugai was of the view that the drug (which was, in part, manufactured and sold in the US) fell outside the scope of US '771 and, therefore, royalties were not payable. It therefore sought a declaration from the English Patents Court to this effect.

UCB Pharma initially sought to strike out the claim arguing that Chugai's construction of the patent gave rise to issues of validity which fell outside the scope of the English court's jurisdiction. This application fell to be determined in May 2017, with Mr Justice Carr finding against UCB Pharma.

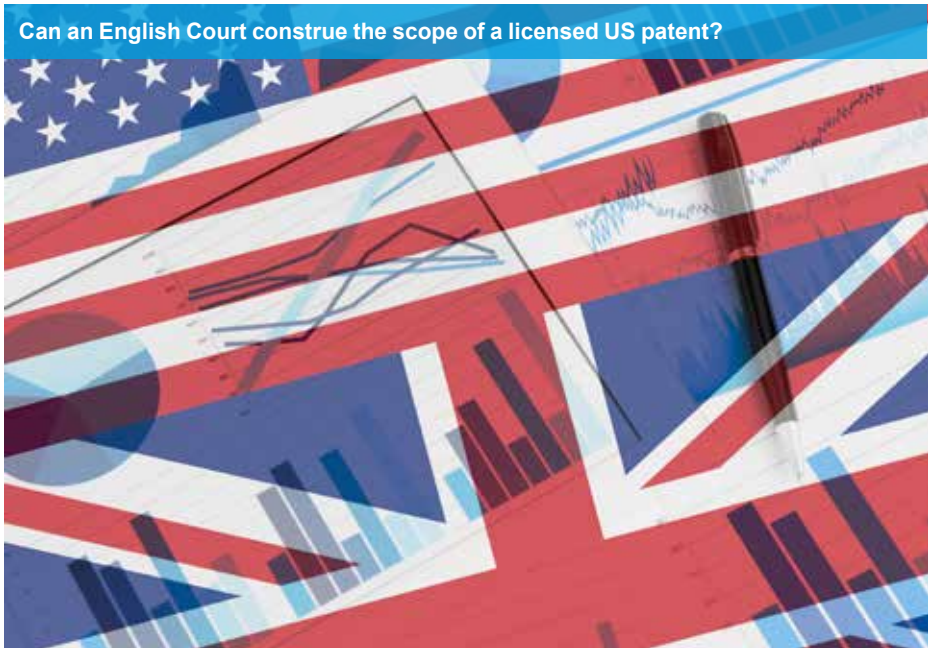
When giving judgment, Mr Justice Carr reasoned that, on Chugai's construction, it was arguing that the patent was valid but not infringed. It was only arguing that the patent would be held invalid if construed, as UCB contended, so that it was infringed. In effect, he held that Chugai was entitled to point to the invalidity consequences as an aid to construction. In drawing these conclusions, Mr Justice Carr considered the decisions in British South Africa Co v Companhia de Moçambique and Lucasfilm Ltd v Ainsworth.

The action then progressed to trial in February 2018. Applying US laws of construction, the trial judge, Mr Justice Birss, concluded that the drug in question fell outside the scope of the licensed US patent and that no royalties fell due.

The cases demonstrate the broad jurisdiction that the English Patents Court holds when addressing patent licence and infringement issues. Patentees may want to give consideration to this judgment when considering the governing law and governing jurisdiction of patent licences.

Author:
Antony Craggs

Can an English Court construe the scope of a licensed US patent?



IPEC

Technetix v Teleste
Adjournment of patent trial

In an extraordinary turn of events, on the first day of a patent infringement trial, the Intellectual Property Enterprise Court has granted an adjournment.

While the English courts are, in general, accommodating of changes to the timetable up to trial, this is usually on the proviso that such changes do not affect the trial window (once fixed).

In Technetix v Teleste, on the first day of trial, Technetix applied to have the trial adjourned. This was so that it could run a new argument, first developed in its skeleton argument submitted shortly before trial, and the parties could adduce evidence accordingly. This was necessary because, without being able to advance the new argument, Technetix accepted that it would have to concede that its patent was anticipated by the cited prior art.

> The trial judge, His Honour Judge Hacon, agreed to the adjournment, reasoning that there would be serious prejudice to Technetix, should it not be able to run the argument (namely, the revocation of the patent). By contrast, the prejudice suffered by Teleste would only be financial.

His Honour Judge Hacon ordered that Technetix pay Teleste's costs thrown away in preparing for trial. Further, he held that these costs should not be subject to the phase or total costs cap of the Intellectual Property Enterprise Court.

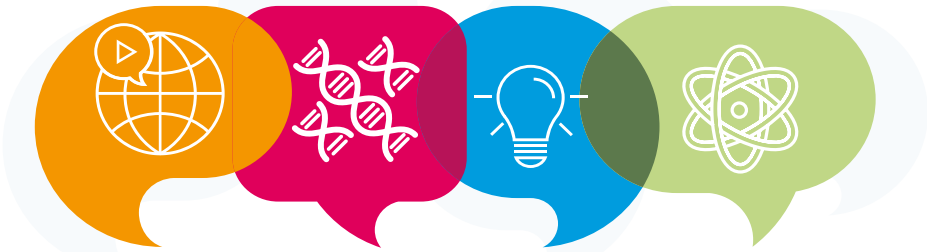
This is a further salutary warning from the Court that a litigant must have its arguments and evidence marshalled well in advance of trial.

Author:
Antony Craggs

And finally...

Webinars

European biotech patent case law
Tuesday, 30 October 2018



Our regular European biotech patent case law webinar returns on Tuesday 30 October at 9am, noon and 5pm GMT with a round up of recent and significant EPO decisions from European Patent Attorneys Simon O'Brien and Antony Latham.

You can sign up to attend the webinar at a time convenient to you via our website at https://dycip.com/oct-biowebinar. This is a popular event so early registration is recommended in order to secure your webinar seat.

NEW for 2019 - UK, Germany & European patent case law

Early in the new year we would like to run a webinar round up of important European patent decisions across all technical areas.

If you would like further information or to suggest a particular subject area to be included please do get in touch by emailing us at registrations@dyoung.com.

Warning - client alert - unsolicited invoices and mail

IP applicants appear to be receiving unsolicited mail from companies requesting payment for services such as publication, registration or entry in business directories and renewal/annuity fees. This is a new scam where they are requesting payment for renewal/annuity fees using headed paper from no known renewal fee providers. Should you have any doubts about unsolicited mail please do not hesitate to contact us. If you receive an such an invoice please: do not pay it; contact your usual attorney or solicitor to inform them (and if possible forward a copy); alert colleagues who may also receive such communications.

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