# D YOUNG & CO PATENT NEWSLETTER no.37

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In this issue:



## TRIPs Can't go Back in Time
## CJEU Has The Last Word


Full Story Page 02

## Editorial

European legal institutions, both existing and proposed, play a significant role in this edition. As we slowly move closer to the establishment of a Unified Patent Court, we hear the views of Richard Willoughby, a patent litigation specialist who recently joined our Dispute Resolution & Legal Group, on the issues that have emerged from the recent Rules of Procedure consultation. It is a pleasure, and excellent timing, for Richard to have joined us. Meanwhile the Court of Justice of the European Union (CJEU) has recently ruled on an aspect of the applicability of the Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreement to European patents, a decision with the potential to allow the appealing of decisions of national courts on issues of unpatentable subject-matter to the CJEU on the basis of TRIPs.

**Editor:**
**Nicholas Malden**

## Events

**16 October 2013 - Webinar**
**3D IP: IP Protection, Enforcement & Future Challenges for 3D Design**
Matthew Dick, Tamsin Holman, Doug Ealey and Cathrine McGowan advise on the protection and enforcement of designs in the UK and Europe.

**23 October 2013 - Webinar**
**European Biotech Patent Case Law Update**
Join Robert Dempster and Simon O'Brien for this ever popular case law webinar.

**24 October 2013 - Awards**
**British Engineering Excellence Awards**
D Young & Co sponsors the Small Company of the Year Award at the BEEAs (London, UK).

**13 November 2013 - Webinar**
**Unitary Patent and Unified Patent Court**
Presented by Richard Willoughby.

**19-20 November 2013 - Seminars**
**Patenting Biotech Inventions, California, US**
Hosted with the California Healthcare Institute (CHI) - guest speaker Fredrik Aslund of the EPO.

**20 November - Awards**
**IET Emerging Technology Award, London UK**
D Young & Co sponsors the Institution of Engineering & Technology Awards (London, UK).

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# TRIPs Can't go Back in Time
# CJEU Has The Last Word

In a recent decision, the Court of Justice of the European Union (CJEU) has ruled on the applicability of the Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreement. While the decision merely confirms the already accepted position for patenting pharmaceutical products, it could have potential significance in opening up a new route of appeal for challenging objections of unpatentable subject-matter in other areas of technology, particularly software.

### Background

The original, 1973 version of the European Patent Convention (EPC) contained a temporary exclusion to the normal patentability criteria: member states were permitted to exclude chemical, pharmaceutical and food products from protection for a certain time period after becoming EPC member states. However, this exclusion did not apply to processes for producing such products. Greece became an EPC member state in 1986, subject to this exclusion, which it also applied to its national patent law. The exclusion expired in 1992.

The TRIPs agreement forms part of the general agreement which established the World Trade Organisation (WTO) in the mid-1990s.

> Article 27 of the TRIPs agreement is aimed at harmonising standards for the availability and scope of intellectual property rights. It requires that patents be available for inventions in all fields of technology, provided they meet the usual criteria of novelty, inventive step and industrial applicability.

However, Article 70 indicates that TRIPs does not place obligations on member states which apply before it came into force in that state. Greece signed the TRIPs agreement in 1995.

The patent which was the subject of the CJEU ruling was a national Greek patent owned by Daiichi Sankyo, relating to the hemihydrate form of the antibiotic levofloxacin. The patent application, filed in 1986, originally claimed both levofloxacin hemihydrate and a process for its production. However, according to the exclusion under Greek national patent law on patenting pharmaceutical products, only the process claims were granted by the Greek Patent Office. The normal 20-year term of the basic patent expired in 2006, and was extended by a Supplementary Protection Certificate (SPC) until 2011.

> Under the EU SPC regulation, the protection conferred by an SPC cannot exceed the limits of the basic patent.

While the SPC was in force, the generic pharmaceutical company DEMO was granted a marketing authorisation for generic levofloxacin hemihydrate. Daiichi Sankyo sued DEMO in the Greek courts to prevent them putting their generic product on the market. DEMO argued that the basic patent, and therefore the SPC, only covered a process for manufacturing levofloxacin hemihydrate, and not the product itself: if they could show their generic product was produced by a different process, they would not infringe the patent and SPC.

The Greek court provisionally ruled in DEMO's favour, but was uncertain whether the provisions of TRIPs could retroactively apply, and therefore allow the patent to extend to cover the compound itself. The court was also uncertain whether the application of TRIPs was a matter for the EU or its member states, and therefore referred the matter to the CJEU.

### The CJEU decision

The EPC is an inter-governmental treaty signed by its member states, and is wholly independent of the EU. As such, the CJEU does not generally have jurisdiction on matters of substantive patentability:

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*We regularly publish IP case updates and articles between newsletters. For up to the minute IP related articles and news visit www.dyoung.com/knowledgebank*

**The Greek court was uncertain whether the provisions of TRIPs could retroactively apply**

only on matters which are the subject of specific EU legislation, such as biotech inventions and SPCs. However, as the TRIPs agreement was negotiated jointly by the EU and its member states, the CJEU had jurisdiction to hear the case.

Article 207 of the Treaty of the Functioning of the European Union (TFEU), in force since 2009, sets out the EU's common commercial policy. The CJEU considered that EU rules on intellectual property rights have a specific link to international trade and therefore fell within the scope of this policy. As the TRIPs agreement has the same overall purpose, the CJEU also ruled that Article 27 of the agreement also fell within the scope of this policy.

Article 27(3) of TRIPs allows member states to exclude from patentability methods of medical treatment, as well as plants and animals and essentially biological processes for their production. The CJEU ruled this exclusion did not apply to pharmaceutical products. However, the court decided that, for patents granted before TRIPs entered into force, and which only claimed processes for manufacturing pharmaceutical products, Article 70 does not oblige member countries to extend such patents to the products themselves.

## Consequences

The CJEU's decision regarding pharmaceutical process patents is not a surprise. On this particular matter, it is also mainly historical, as the temporary exclusions in the original EPC regarding patenting pharmaceutical products have all long expired.

For patents currently in force, the CJEU's stance that it may in effect be competent to judge patent matters on the basis of TRIPs is of interest for those litigating patents in national courts. It may be of particular interest in technical fields wherein the exclusions from patentability under national law differ from those provided in TRIPs.

In particular the current prohibition in the UK on patenting computer programs 'as such', whilst often possible to overcome, would appear more restrictive than that envisaged by TRIPs. There is no such exclusion in Article 27(3) of TRIPs on patenting programs for computers, suggesting that these qualify as a field of technology.

There is no route of appeal from the EPO or its Boards of Appeal to the CJEU (although this may change when the unitary patent comes into force). However, this decision may open up the possibility of appealing decisions of national courts on issues of unpatentable subject-matter to the CJEU on the basis of TRIPs, at least in the field of software. However, it is possible that the CJEU may still choose to resort to the argument that computer programs as such are already protected by copyright as literary works, leaving us in the UK back were we started, arguing about the meaning of the term 'as such'.

In conclusion, whilst the possibility of appeal to the CJEU is an interesting prospect, it may result in little effective change - but on the other hand the CJEU could use this decision as basis for involving itself in matters of software patentability, and open up a Pandora's box. We will await further developments with interest.

**Authors:**
**Garreth Duncan and Doug Ealey**

# Unified Patent Court Rules of Procedure Consultation

By the time this newsletter is published, the consultation on the draft Rules of Procedure of the Unified Patents Court (UPC), launched by the Preparatory Committee at the end of May, will have closed. Numerous companies, industry bodies, practitioner and professional organisations, firms and individuals have participated and it will be interesting to see just how many submissions there are. Indeed, there were apparently 1,800 hits on the webinar that accompanied a recent consultation event held by the UK Intellectual Property Office (UKIPO), Chartered Institute of Patent Attorneys (CIPA) and the IP Federation in early September 2013, so there is no doubt participation has been very significant.

> While there is a huge number of areas of comment, a few common themes are appearing which go to big picture points that the Unified Patent Court Agreement didn't address as well as it might.

It is to be remembered that the purpose of the Unified Patent Court (UPC) is to reduce the cost and complexity of European patent litigation, and provide certainty by avoiding inconsistent judgments. It is also supposed to do away with the significant 'forum shopping' opportunities that currently exist. Unfortunately, the system set out in the Unified Patent Court Agreement raises significant cost issues of its own (associated with the language regime and funding of the court), and also leaves open real possibilities for forum shopping.

It seems that many submissions to the consultation are aimed at trying to address these issues through the Rules of Procedure, to the extent possible. We must wait and see whether the Preparatory Committee, which is the ultimate audience for the consultation, takes note and tries to do something about it. A brief summary of these big points follows.

### Opt outs for European bundle patents

The default position in the system is that existing and future European bundle patents are to be litigated in the UPC. Certain industry sectors in particular were uncomfortable with that and the result was an opt out period. Unfortunately, the Unified Patent Court Agreement did not address what happens before the UPC comes into operation. One could envisage thousands of opt outs being applied for on day one but under the agreement opt outs are not effective on filing. This leaves the relevant patent vulnerable to a pre-emptive challenge. The draft Rules of Procedure attempt to provide a kind of sunrise provision, with the EPO administering pre-commencement opt outs that are effective on commencement. Legally however, this is tricky. Regardless, a way simply must be found to enable an effective pre-commencement opt out and hopefully the Preparatory Committee will take note and one will be found.

> Another big issue on opt outs is whether a fee should be payable and if so, what should it be?

There are forceful arguments against any fee – why should a proprietor pay to opt out of a system they didn't choose to join? On the other hand, there will clearly be an administrative cost, which has to be covered somehow.

### Court fees

The draft Rules of Procedure envisage both fixed court fees as well as value based ones. The latter can be very problematic because they raise satellite debates as to the value of a case, and can be very significant costs in for example multi-patent litigation. No particular basis for assessing these fees is suggested in the draft Rules of Procedure and no doubt there will be some debate when one ultimately is proposed.

However, the draft Rules of Procedure do suggest that not only is a fee payable by a claimant but, if a defendant raises a counterclaim for revocation (and invalidity cannot be raised as a pure defence), a value based fee may also be payable. The question is: why? Is it right that a defendant should have to pay what could be a substantial court fee to defend itself? This seems rather unfair.

### Forum shopping

Perhaps the biggest issue of all that has led to comments is forum shopping. This is a multi faceted issue, and has threads in many different parts of the draft Rules of Procedure. Ostensibly however it all arises from the patentee's choice of forum being very wide. With that choice comes, potentially, a favourable or inconvenient language regime; the possibility to bifurcate infringement and validity; different approaches to evidence and witness hearings; and different approaches to assessing value based fees, for example. The whole area is very complex and a close study of the draft Rules of Procedure suggests a real possibility for there to be multiple but related cases in different divisions, for example. There is also the possibility to bring a case in a division which is actually not very well connected with the dispute but is tactically advantageous to the patentee.

### So what seem to be the comments on this?

Well, first it seems there is a need to beef up the powers of the court to join together related cases, and to broaden the meaning of related cases. This is very important if the system really is going to provide cost savings and consistency, as well as minimize forum shopping.

Secondly, and related to this, it would seem fair to have some kind of transfer provision, empowering the Court to transfer cases commenced in an obviously inconvenient forum. Game playing was not supposed to be allowed in the UPC.

Thirdly, to alleviate the risk for defendants in a bifurcated case (and there are mixed views on whether such cases will be common or rare), more guidance is needed on when an injunction might be granted to a claimant who succeeds on infringement before validity is determined. Such injunctions are really interim injunctions and ought to be awarded on a similar basis.

*Further information online*
*Unified Patent Court website:*
*http://www.unified-patent-court.org*

*Preliminary set of provisions for the Rules of Procedure for the Unified Patent Court:*
*http://dycip.com/draftuprules*

*D Young & Co guide to the proposed UP and UPC, issued May 2013:*
*www.dyoung.com/article-upupc0513*

**Our summary of the proposed UP and UPC can be read and/or downloaded at www.dyoung.com/article-upupc0513**

Fourthly, if the Rules of Procedure don't prescribe guidelines for courts in exercising discretion and making procedural decisions, and that is difficult to do exhaustively, there are very likely to be differing approaches, at least to begin with. It is imperative therefore that procedural decisions can be appealed to the Court of Appeal, and that that court can give permission to appeal if necessary.

### Next steps

There are many other aspects of the Rules of Procedure which have attracted comment and some submissions are likely to have been very detailed indeed. It is naturally going to take several months for these to be waded through, themes to be divined and suggestions for revisions made. The expectation is that this will take place during the rest of this year and that there will be a public hearing early in 2014. That may be a pretty lively affair.

**Author:**
**Richard Willoughby**

# Unified Patent Court Webinar 13 November 2013

As reported in our August newsletter, we are delighted to welcome senior patent litigator Richard Willoughby to the D Young & Co LLP partnership.

Richard further strengthens our Dispute Resolution & Legal Group (Richard is pictured here with colleagues Ian Starr (far right) and Tamsin Holman).

Regarded as a leader in his field by all the major legal and professional directories, Richard is well known for his lobbying efforts in respect of the EU unitary patent and Unified Patent Court. In this webinar he will present the latest developments in the UP and UPC proposal, and will outline key issues presently being debated.

The webinar will run at 9am, noon and 5pm (UK time) on Wednesday 13 November 2013.

Please register online by visiting our website events page:
www.dyoung.com/event-upweb13

# Admissibility of Post-Published Evidence
## Generics v Yeda and Teva

Back in July 2013, the Court of Appeal handed down its decision in Generics [UK] Limited v Yeda Research & Development Co Ltd & Teva Pharmaceuticals Industries Ltd [2013] EWCA Civ 925. This was an important decision for the admissibility of evidence published after the priority date of the patent (post-published evidence).

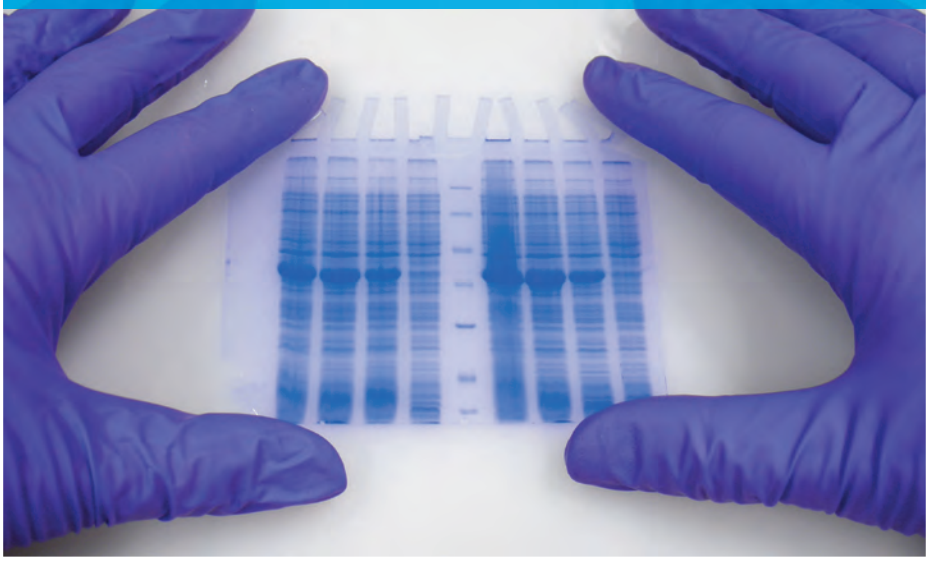
The decision concerned Yeda's patent (EP(UK) 0762888) for an improved composition of a synthetic copolymer known as copolymer-1. Copolymer-1 is a mixture of polypeptides composed of alanine, glutamic acid, lysine and tyrosine in a molar ratio of approximately 6:2:5:1, and is marketed by Teva as exclusive licensee of Yeda's patent, for the treatment of relapsing-remitting multiple sclerosis. Claim 1 of the patent concerns:

> *"A copolymer-1 fraction, wherein said fraction contains less than 5% of species of copolymer-1 having a molecular weight over 40 kilodaltons and wherein over 75% of said fraction is within a molecular weight range from 2 kilodaltons to 20 kilodaltons."*

According to the examples of the patent, the claimed lower molecular weight copolymer-1 material is better than the known copolymer-1 in terms of toxicity and allergy or hypersensitivity reactions.

At first instance, the judge (Arnold J) refused the requests of Generics (who trade as Mylan) for revocation and a declaration of non-infringement in respect of their product. On appeal, Mylan argued that Yeda's patent was invalid for obviousness on the basis of **a lack of technical contribution**. They alleged that the specification did not make it 'plausible' that the described technical problem was solved by the products falling within the claims.

**EP(UK) 0762888 was for an improved composition of a synthetic copolymer**



Although there is nothing in the statute (the European Patents Convention or the UK Patents Act 1977) which dictates that 'lack of technical contribution' is a ground for invalidity, the European Patent Office's (EPO's) problem and solution assessment for inventive step necessarily isolates a technical contribution or effect from the claimed invention.

The patent is compared to the closest prior art and any technical effect associated with the difference(s) is determined, ie, a technical contribution is identified. This technical contribution is then used to formulate the objective technical problem solved by the claimed invention over the closest prior art. It is also established EPO case law that the technical contribution must be shared by everything falling within the claim (see T939/92 – the AgrEvo case [1996] EPOR 171).

After reviewing the EPO's problem and solution approach and T939/92, Arnold J concluded that post-published evidence may be relied on to confirm that:

- the disclosure in the patent does or does not make it plausible that the invention solves the technical problem;

But that such evidence may **not** be relied upon to:

- establish a technical effect which is not made plausible by the specification; or
- to contradict a technical effect which is made plausible.

Arnold J therefore held that if the patent made a technical effect 'plausible' it was not open to Mylan to mount a challenge to the existence of that effect by the use of post-published evidence.

The Court of Appeal disagreed.

The Court of Appeal ruled that post-published evidence showing that the claimed invention does not in fact result in a particular technical effect **will** be admissible, provided that one of the issues to be decided for inventive step is whether the technical contribution has been made.

A party may therefore challenge the existence of a technical effect relied on by the patentee with post-published evidence.

This decision was primarily based on the principle that t**he extent of the patent monopoly should correspond to and be**

**justified by the technical contribution to the art.** The Court of Appeal noted that the problem and solution approach to obviousness requires the court to judge inventiveness by reference to what it is that the invention brings with it.

The technical contribution of the claimed invention in Yeda's patent was defined as

> *"the proposition that copolymer-1 as claimed caused less irritation at the injection site and/or a reduced incidence of systemic side effects".*

Although the examples did not strictly support the molecular weight ranges cited in claim 1, Arnold J held that the general trend shown made it 'plausible' that the claimed copolymer-1 was superior to copolymer-1 falling outside the claim, and hence that the invention provided a technical contribution.

The Court of Appeal agreed with this conclusion and upheld Arnold J's refusal of Mylan's request for revocation and a declaration of non-infringement.

Thus whilst the Court of Appeal's divergence over the admissibility of post-published evidence did not affect the overall decision, it highlights an important point of law which has a general application to all patents.

Furthermore, the court's consideration of the EPO's problem and solution approach and T939/92 shows how the requirement for a patent to have a 'plausible technical contribution' is a development in line with European practice.

**Author:**
**Rachel Bateman**

**Useful links**

The full decision (Generics v Yeda and Teva) can be viewed here:

**http://dycip.com/genericsvyeda**





# Superfast Patent
## UKIPO Halts Proposals for 90 Day Patent

**UKIPO halts 'superfast' patenting service following a consultation process**


The UK Intellectual Property Office (UKIPO) has decided not to implement the proposed 'superfast' patenting service following a consultation process. We reported the proposal for what became known as a '90-day patent' in our August 2013 patent newsletter (article 04, edition no. 36).

In its response following the consultation process, the UKIPO noted:

> *"While some respondents were generally in support of the proposed service, many raised serious concerns, in particular:*
>
> - *A higher risk of granting invalid patents, creating uncertainty for both patent holders and third parties.*
> - *An increased burden on third parties to monitor applications and make observations in a severely shortened timeframe.*
> - *A risk that rapid grant would be perceived as advantageous, when in fact it could be damaging, due to early publication in particular.*
> - *Payment of a large fee for a service which offers very little real advantage over existing free acceleration options, which already meet business needs (and are capable of delivering grant in as little as 6½ months)."*

What is notable, and applaudable, is the UKIPO's decision to back-track from the 'superfast' patent proposal to mitigate against the risk of invalid patents and maintain the reputation of the UKIPO for quality.

The current ways of expediting prosecution, such as filing a formal request for expedited prosecution, The Green Channel, the PPH and the PCT(UK) Fast Track are still in place (for more information on these schemes see www.dyoung.com/knowledgebank or links below).

These schemes, in conjunction with combined search and examination and early publication, can enable you to obtain a granted patent in less than a year, considerably faster than standard patent prosecution before most of the world's patent offices.

Indeed, it is our experience that under the current systems the UKIPO is very co-operative and will work with applicants who require quick grant of a UK Patent.

**Author:**
**Catherine Mallalieu**

**Useful links**

The full response can be found at:

**http://dycip.com/superfastpatent**

'Five Ways to Accelerated Prosecution' - how to obtain a quick grant in the UK written by Bénédicte Moulin:

**http://dycip.com/fastukgrant**

## And finally…

### D Young & Co on the Road 02-03 October 2013
### Engineering Design Show and Electronics Design Show

We are pleased to announce our participation in the 2013 Engineering Design Show and Electronics Design Show, which will include two D Young & Co lead IP workshops and Q&A sessions.

The Engineering Design Show show provides an exhibition and free practical workshops demonstrating and promoting cutting edge technology and innovation from market leading suppliers, providing European design engineers with all aspects of engineering design under one roof.

D Young & Co attorneys and solicitors will be available to provide more information about IP at our exhibition stand (H55) and we will be presenting two workshops over the course of the conference:

**'IP - A Commercial Perspective'**
02 October, presented by Nicholas Malden.

What are the important aspects of IP when taking a product from conception to market? What are the key aspects of products and processes a business should protect and how can this be achieved? What should you do if another party threatens your company with its IP?


**'The UK Patent Box - Maximising Savings for Innovations'**
03 October, presented by Doug Ealey.

The Patent Box is an opt in scheme for obtaining a reduced rate of corporation tax on certain IP derived profits in the UK that seeks to encourage innovation and long-term growth of technology companies in the UK. Doug presents the ins and outs of the Patent Box and how it might benefit you and your business.

The Engineering Design Show and Electronics Design Show take place at the Jaguar Exhibition Hall, Rico Arena, Coventry, UK on 02-03 October. For more information and to register, see *www.dyoung.com/event-eds13*

## Contact details

**D Young & Co LLP**
**120 Holborn, London, EC1N 2DY**
T +44 (0)20 7269 8550
F +44 (0)20 7269 8555

**D Young & Co LLP**
**Briton House, Briton Street**
**Southampton, SO14 3EB**
T +44 (0)23 8071 9500
F +44 (0)23 8071 9800

**D Young & Co**
**International Limited**
**PO Box 283945, Dubai, UAE**
T +971 (0)4 434 2866
F +971 (0)4 434 2877

**www.dyoung.com**
**mail@dyoung.com**

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## Contributors

**Partner**
**Nicholas Malden**
nmm@dyoung.com
www.dyoung.com/nicholasmalden

**Partner**
**Catherine Mallalieu**
clm@dyoung.com
www.dyoung.com/catherinemallalieu

**Partner**
**Garreth Duncan**
gad@dyoung.com
www.dyoung.com/garrethduncan

**Partner**
**Richard Willoughby**
rww@dyoung.com
www.dyoung.com/richardwilloughby

**Partner**
**Doug Ealey**
dre@dyoung.com
www.dyoung.com/dougealey

**Associate**
**Rachel Bateman**
reb@dyoung.com
www.dyoung.com/rachelbateman

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