# D YOUNG & CO PATENT NEWSLETTER no.65

June 2018
In this issue:



Also, your invitation to our European biotech patent case law webinar, 17 July 2018.

## After Actavis
## UK patent decisions post Actavis v Lilly

Full Story Page 02

## Editorial

World IP day recently brought news that the UK had ratified the Unified Patent Court Agreement. As the UK IP Minister, Sam Gyimah MP stated, "ratification of this important Agreement demonstrates that internationally, as well as at home, the UK is committed to strong intellectual property protections". With German ratification still uncertain and with Brexit negotiations ongoing, be assured that we are keenly interested in following developments in this area and will keep readers abreast of the important factors to bear in mind. Please do get in touch as we are more than happy to answer any specific questions you may have.

**Editor:**
**Aylsa Williams**

## Events

**04-07 June 2018**
**BIO, Boston, US**
Aylsa Williams, Simon O'Brien and Garreth Duncan will be attending this convention. Simon will be speaking at the BIO breakout session "Legal Certainty at an Affordable Price - The European Opposition Procedure" at 3pm on June 06, 2018.

**05-10 June 2018**
**FICPI World Congress, Toronto, Canada**
European Patent Attorney Jonathan DeVile will be attending this event.

**25-27 October 2018**
**AIPLA Annual Meeting, Washington, US**
Solicitor Antony Craggs will be attending AIPLA's annual meeting in October.

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*Scope of protection*

# After Actavis UK patent decisions post Actavis v Lilly

In Actavis v Lilly the Supreme Court introduced a doctrine of equivalents and a limited form of file wrapper estoppel into UK law. This case law has been applied in Generics v Yeda, L'Oréal v RN Ventures and Fisher & Paykel v Resmed.

### Normal interpretation

Before considering variants, Actavis requires that the "literal" or "normal" meaning of the claims is determined. In Generics v Yeda, "normal interpretation" was understood to be an issue of purposive and not literal construction; the same approach was taken in L'Oréal v RN Ventures and Fisher & Paykel v Resmed.

### Scope of pre-grant and post-grant claims

A consequence of Actavis is the apparent imbalance between the apparent scope of the pre-grant and post-grant claims.

Generics v Yeda touched on the question of a prior art disclosure which does not infringe the literal wording of the claims but is later found during infringement proceedings to be an infringing equivalent. In this decision it was confirmed that the assessment of novelty, under "normal interpretation" continues to exclude equivalents.

### Specification disclaiming protection by the claims

In L' Oréal v RN Ventures it was concluded that the feature in issue produced substantially the same result in the same way as the patent, and obviously so. However, it was noted that the patentee had discussed the variant at length in the specification and chosen to exclude it from the claims.

The judge concluded that the skilled reader would have assumed that the patentee intended to do so for a reason and therefore, he would have concluded that the variant was not an equivalent, in light of the third Actavis question.

RN Ventures sought to rely on a principle from the German courts "that as a rule there is no patent infringement by equivalence if the description discloses several possibilities as to how the technical effect can be achieved, but only one of those possibilities is included within the claims".

The judge refused to decide whether the German doctrine of "deliberate selection" should be applied as part of the UK doctrine of equivalence and stressed that the conclusion in this case was based on the specification and did not establish any wider principle.

### Reference to the prosecution history for construction

In Actavis the Supreme Court introduced limited file history estoppel such that reference to the prosecution history would only be appropriate where:

**In Actavis v Lilly the UK Supreme Court rewrote the scope of patent protection in the UK**

*Case details at a glance*
*Jurisdiction: England & Wales*
*Decision Level: Patents Court*
*Parties: L'ORÉAL SOCIÉTÉ ANONYME, L'ORÉAL (UK) LIMITED (claimants) and RN VENTURES LIMITED (defendants)*
*Date: 05 February 2018*
*Citation: [2018] EWHC 173 (Pat)*
*Link to full decision (bailii): http://dycip.com/patentscourt-loreal-ventures*

1. the point of construction was "truly unclear" but the contents of the prosecution file "unambiguously resolve the point"; or
2. it would be "contrary to the public interest for the contents of the file to be ignored".

RN Ventures tried to argue that during prosecution L' Oréal had limited Claim 1 to a tension/compression mode to support inventive step. The examiner had then requested that dependent claims to the shear mode be deleted. RN Ventures argued that this indicated that the examiner understood that L'Oreal was excluding the "shear mode".

RN Ventures contended that the second circumstance applied, submitting that "the examiner had gained the impression that L'Oréal was choosing to exclude the [shear mode] from the claims, and L'Oréal should have explained to him that this was not the case, rather than electing to approve the text".

The judge rejected this, noting that the interpretation is a matter for the national courts and not the examiner. The judge echoed the Actavis decision, saying that "[i]t should be emphasised that reference to the prosecution history is the exception, and not the rule".

### Conclusions

- The Patents Court has not yet widened Actavis' narrow interpretation of when the prosecution file may be relied on for construction of the patent post-grant.
- The use of prosecution history must support at least one of the two instances identified by Lord Neuberger in Actavis v Lilly.
- Be cautious of language in the specification which could be construed as disclaiming protection by the claims. The German principle of deliberate selection or the US disclosure-dedication doctrine have not entered into English patent law but we expect the Courts to inspect the language of the specification more closely following Actavis.

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**Emma Hamilton**





# Unified Patent Court
# Next steps following UK ratification

The UK Government announced on 26 April 2018 that it had ratified the Unified Patent Court (UPC) Agreement. The UK becomes the 16th member state to ratify the UPC Agreement.

When it comes into effect the new system will come in two parts: a unitary patent and the Unified Patent Court. The unitary patent will be a single patent right that will be effective in up to 25 member states of the EU (possibly more over time). The unitary patent will be enforceable in a new international court, the UPC. The UPC will also have jurisdiction over traditional (conventional) European patents, subject to an important opt-out.

### CIPA welcomes UK ratification

President of the Chartered Institute of Patent Attorneys (CIPA) Stephen Jones said: "CIPA welcomes the UK's ratification of the Unified Patent Court Agreement. The UPC has the potential to benefit businesses by streamlining the process of enforcing patents. CIPA believes that the UPC will be a better system with UK involvement. The UK has well established regimes for enforcement of patents and judges who are respected in Europe and worldwide for their understanding of patent law. The UK has been extensively involved in the discussions leading to the establishment of the UPC and CIPA has been pleased to play a part in that. The UPC Agreement is not an EU instrument so it is an initiative in which the UK is able to play a full part despite Brexit. It is a good example of international cooperation which is consistent with the UK moving forward as an innovation led economy".

### When is the new system likely to come into effect?

Only ratification by Germany is now required before the UPC and unitary patent system can come into effect. France – the other mandatory ratification for the system to start - has already ratified.

As previously reported, there is a constitutional complaint pending before the Federal Constitutional Court (FCC) in Germany, challenging its participation in the UPC. The complaint has been listed as one of the cases the FCC intends to resolve in 2018 but we understand this does not necessarily mean that it will in fact do so. We do not expect a rapid decision in Germany although it is possible we may hear something mid 2018.

As and when barriers to German ratification are removed (i.e. if the FCC dismisses the complaint) and Germany indicates formally that it is in a position to ratify, there will be a provisional application period, intended to last between six to eight months prior to actual commencement of the UPC, during which the UPC will come into existence and essential pre-commencement administrative steps can be taken. These include recruiting judges and filing by users of pre-commencement opt-outs during a sunrise period.

With uncertainty surrounding the position in Germany and the impact of the post-Brexit status of the UK, it is impossible to make any predictions as to when the UP and UPC might be up and running. If the complaint before the FCC is dismissed in enough time to allow the system to begin before the UK leaves the EU, then it is possible that the UP and UPC could be up and running before Brexit in March 2019. However, time is very short to carry out all that will be necessary to meet the March 2019 deadline, both in terms of preparing for the UPC itself and in assessing the impact of Brexit upon it.

### How do I find out more?

We will continue to monitor the situation and will report on any significant changes as soon as we know them.

### UP & UPC updates


Bookmark our UP & UPC website page to keep up to date on this subject: **www.dyoung.com/knowledgebank/up-upc**.

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# Inter partes review
# Challenges at the US Supreme Court

*Related articles*
*US tribal sovereign immunity - Allergan & Saint Regis, Anton Baker, 24 April 2018: https://dycip.com/tribal-immunity*

*Oil States Energy v Greene's Energy: Are IPRs unconstitutional? Holly Cowie, 26 February 2018: https://dycip.com/oilstates*

In two recent decisions published simultaneously the US Supreme Court examines the constitutionality and the extent of inter partes review (IPR) at the Patent Trial and Appeal Board (PTAB).

As discussed in our previous issues, most recently in our article on US tribal sovereign immunity (see related articles, above right) US law provides for a number of post-grant challenges to be made to the validity of patent rights.

The two recent cases handed down in late April 2018 concern one route to challenging granted US patents known as the inter partes review (IPR). Controversially, IPRs are conducted in front of the PTAB which is an administrative law body of the United States Patent and Trademark Office (USPTO) as opposed to an "Article III" judicial Federal Court.

### Oil States Energy Services v Greene's Energy Group

The first case, Oil States Energy Services v Greene's Energy Group, has been highly awaited as it considers head-on this controversial issue of whether an administrative body has the constitutional power to deprive a party of a patent right once granted. The background to this case was discussed in detail in our February 2018 newsletter (see related articles, above right).

Specifically the question considered was whether IPR proceedings violate Article III of the Constitution or the Seventh Amendment to the US Constitution.

The introductory portion of Article III reads: "The judicial Power of the United States, shall be vested in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish."

The issue in the present case is that the PTAB is not an Article III court. If the ability to contest the validity of patents post-grant is restricted to Article III courts, then the PTAB is not a valid venue.

The Seventh Amendment reads: "In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise re-examined in any Court of the United States, than according to the rules of the common law."

**The USPTO had revoked Oil States Energy Services' fracking-related patent**

As patent cases typically exceed twenty dollars in value, the problem here is that the PTAB as an administrative body does not use a jury, it instead uses administrative patent judges. Hence IPRs may violate the Seventh Amendment right to a trial by jury.

In the Supreme Court's decision, Justice Thomas, writing for the 7-2 majority, concludes that the grant of a patent should be considered as akin to a public right as opposed to a private property right. As such, the Constitution does not prohibit the USPTO from resolving issues of validity post-grant in a venue other than an Article III Court.

Important to this analysis was that the court considered that there was a lack of any meaningful distinction between the initial grant of the patent by the USPTO and IPR proceedings: "[p]atent claims are granted subject to the qualifications that the PTO has 'the authority to reexamine – and perhaps cancel – a patent claim' in an inter partes review."

### SAS Institute Inc v Iancu

The second case, SAS Institute Inc v Iancu, was far less keenly awaited but may end up having the greater effect on practice going forward. The case was on the narrow, but significant, point of whether the PTAB when instituting (that is, deciding to proceed with) a case may proceed on a subset of claims or whether they must proceed on every challenged claim.

The current practice, as set out by rule 37 C.F.R. § 41.108(a), was that the PTAB could institute an IPR on only a subset of the challenged claims.

The decision was a close one (5-4), which is unusual for patent cases heard in the Supreme Court. The majority decided to overturn current practice, stating that the decision to institute is binary: either the PTAB decides to institute, in which case a decision must be given on all challenged claims; or the PTAB can decide not to institute at all.

### Conclusion

While these cases represent an important step towards certainty with regards to IPRs, a number of important aspects remain undecided. For example, while IPRs have been confirmed as constitutional, it remains undecided whether the retrospective effect of IPRs on patents granted before the America Invents Act is constitutional. Of most practical immediate effect, the judgement in SAS Institute Inc v Iancu leaves the status of the hundreds of outstanding appeals from the PTAB at the Federal Circuit that were instituted on only a subset of the petitioner's challenged claims in legal limbo.

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**Anton Baker**

# Supplementary protection certificates

## AG opinion in the "thorny issue" of the Truvada SPC case

Advocate General (AG) Wathelet has given his opinion in relation to the question referred by the English Court concerning the interpretation of Article 3(a) of the supplementary protection certificate (SPC) regulation, particularly what are the criteria for deciding whether a product[1] is "protected by a basic patent".

The AG has answered the question as follows: "A product is protected by a patent within the meaning of Article 3(a) of that regulation if, on the priority date of the patent, it would have been obvious to a person skilled in the art that the active ingredient in question was specifically and precisely identifiable in the wording of the claims of the basic patent. In the case of a combination of active ingredients, each active ingredient in that combination must be specifically, precisely and individually identifiable in the wording of the claims of the basic patent."

The opinion is not binding on the Court of Justice of the European Union (CJEU) but if it is followed it will likely make obtaining SPCs more difficult, particularly where the basic patent does not explicitly disclose the active ingredient(s).

In reaching his conclusions the AG rejected the proposal of the English Court and Gilead on the correct interpretation of Article 3(a). However the AG provided little guidance of his own on what is meant by "specifically and precisely identifiable". As such, if this opinion is followed, it seems unlikely that this will be the last the referral on the interpretation of Article 3(a) of the SPC regulation.

### Background

Gilead is the owner of a SPC (SPC/GB05/041) protecting the product TRUVADA which contains a combination of tenofovir disoproxil and emtricitabine as active ingredients for treating HIV infection.

The basic patent (EP0915894) on which the SPC is based expired in 2017. A number of pharmaceutical companies (Teva, Accord, Lupin and Generics UK) challenged the validly of the SPC in the English Court on the basis that the basic patent did not protect the product.

The claim in the basic patent relates to "A pharmaceutical composition comprising [tenofovir disoproxil] together with a pharmaceutically acceptable carrier and optionally other therapeutic ingredients."

Teva et al essentially argued that following the previous decisions of the CJEU in Medeva[2] and Daiichi Sankyo[3], the product had to be "specified (or identified) in the wording of the claims[4]. They noted that emtricitabine was not mentioned anywhere in the basic patent, nor was there any evidence that is was known to be efficacious at the priority date.

**If this opinion is followed in the CJEU it will make obtaining SPCs more difficult**

Gilead took the view that since the product falls within the scope of protection of claim 27, then that was sufficient.

The judge was of the opinion that despite the previous CJEU decisions the situation remained unclear and instead put-forward a test in which the 'core inventive advance' of the basic patent was to be taken into consideration.

### Discussion

The AG roundly rejected the 'core inventive advance' test suggested by the judge, as potentially giving rise to confusion with the requirements of patentability. Instead the AG recognized that only the wording of the claims is to be used in determining whether a product is "protected by a basic patent".

In doing so, the AG noted that the name of the active ingredient or its chemical composition need not be referred to expressly in the claims, thus potentially giving rise to the possibility of a product being defined in the claims functionally or by a Markush formula. However, the AG specifically dismissed the possibility of claims referencing a 'diuretic' or a 'non-steroidal anti-inflammatory' as not being sufficient.

Overall, the AG offered no clear test as to what is meant by "specifically and precisely identifiable"; although, unsurprisingly, in his view TRUVADA is not "protected by a basic patent" as there is no mention of emtricitabine anywhere in the basic patent.

Interestingly, in the AG's view the test of whether a product is protected by a basic patent is to be determined on the priority date. This potentially gives rise to difficulties if the subsequently approved medicinal product is only included in the basic patent on filling, but is not present in the priority application.

Moreover, although outside the scope of the present case, the AG gave an unfavourable opinion of post grant amendments to include claims to approved combinations of active ingredients which were not in the originally granted claims, as was attempted in Actavis[5].

*Notes*

1. *'Product' means the active ingredient or combination of active ingredients of a medicinal product.*
2. *Medeva (C 322/10, EU:C:2011:773).*
3. *Daiichi Sankyo (C 6/11, EU:C:2011:781).*
4. *The AG considered that these terms are synonymous and used by the CJEU interchangeably.*
5. *Actavis Group PTC and Actavis UK (C 577/13, EU:C:2015:165).*

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# T 0261/15
# Novelty of overlapping ranges

In T 0261/15, a European Patent Office (EPO) Board of Appeal upheld a decision of the Opposition Division maintaining European patent No. 2247764 (British Steel Ltd) as granted.

Significantly, the Board of Appeal decided that the limit values of a known range, although explicitly disclosed, are not to be treated in the same way as the examples. As a result, the Board of Appeal found that the claimed composition, although overlapping with the generic composition disclosed in the prior art, was novel.

## Background to T 0261/15

EP 2247764 relates to a high-strength pearlitic steel rail which is defined by its composition of alloying elements. More specifically, claim 1 as granted reads: "A high-strength pearlitic steel rail with an excellent combination of wear properties and rolling contact fatigue resistance wherein the steel consists of 0.88% to 0.95% carbon, 0.75% to 0.95% silicon, 0.80% to 0.95% manganese, 0.05% to 0.14% vanadium, up to 0.008% nitrogen, up to 0.030% phosphorus, 0.008% to 0.030% sulphur, at most 2.5 ppm hydrogen, at most 0.10% chromium, at most 0.010% aluminium, at most 20 ppm oxygen, the remainder being iron and unavoidable impurities."

> The patent was opposed by a single opponent on the grounds of lack of novelty and inventive step.

In particular, the opponent argued that the granted patent lacked novelty over EP 2006406 (D1).

D1 also relates to a high strength pearlitic steel rail defined by its composition of alloying elements. The composition of claim 1 of the granted patent and the broad composition disclosed in D1 are compared in the table, above right (in wt%).

The opponent argued that the granted patent relates to a selection invention but does not satisfy the criteria that the case law has identified for a selection invention.

| Element | Claim 1 of granted patent | D1 (claims 1, 2, 3 and 6) |
|---|---|---|
| C | 0.88 - 0.95 | 0.6 - 1.0 |
| Si | 0.75 - 0.95 | 0.1 - 1.5 |
| Mn | 0.080 - 0.95 | 0.4 - 2.0 |
| V | 0.05 - 0.14 | 0.5 or less |
| N | up to 0.008 | |
| P | up to 0.030 | 0.035 or less |
| S | 0.008 - 0.030 | 0.0005 - 0.010 |
| H | at most 2.5 ppm | |
| Cr | at most 0.010 | 1.5 or less |
| Al | at most 0.010 | |
| O | at most 20 ppm | 0.004 or less |
| Other | | Cu: 1.0 or less<br>Ni: 1.0 or less<br>Mo: 1.0 or less<br>W: 1.0 or less<br>Nb: 0.05 or less<br>Optional - Ca: 0/001 - 0.010 |

## The case law

The case law on the novelty of selection inventions was developed in particular in T 198/84, which was then summarised in T 279/89. According to T 279/89 a selection of a sub-range of numerical values from a broader range is new when each of the following criteria is satisfied:

a. the selected sub-range should be narrow;

b. the selected sub-range should be sufficiently far removed from the known range illustrated by means of examples;

c. the selected area should not provide an arbitrary specimen from the prior art, that is, not a mere embodiment of the prior description, but another invention (purposive selection).

In the case of overlapping ranges, the Board of Appeal held in T 666/89 that there was no fundamental difference between examining novelty in situations of so-called "overlap" or "selection". Hence, the same principles should be applied for the assessment of novelty in case of overlapping ranges that are applied in the case of selection inventions. Namely, it has to be determined which subject matter disclosed in a prior art document has been made available to the public.

In decision T 26/85, the board suggested a specific test for determining whether a technical teaching had been made available to the public or not. In particular, the Board of Appeal proposed asking: would the skilled person, in light of the technical facts and taking into account the common general knowledge, seriously contemplate applying the technical teaching of the prior art document in the range of overlap? This question has been adopted in several subsequent Board of Appeal decisions.

## Arguments at appeal

At appeal, the appellant (opponent) argued that the claimed composition overlapped with the generic composition of the pearlitic rail disclosed by D1. The appellant argued that:

1. The ranges for the alloying elements of claim 1 were not narrow in comparison with the corresponding ranges disclosed in D1; and

2. The claimed range was not sufficiently far removed from the end points of the known ranges.

The latter argument was taken from the Guidelines for Examination, which recites at Part G, Chapter VI, Paragraph 8 that a sub-range selected from a broader numerical range of the prior art is considered novel, if "(b) the selected sub-range is sufficiently far removed from any specific examples disclosed in the prior art and from end-points of the known range".

> The Board of Appeal ruled that D1 does not provide any teaching which would lead the person skilled in the art to seriously contemplate working in the claimed composition. Therefore, the claimed composition was novel over D1.

**Reasons for the decision**

The Board of Appeal agreed that the claimed composition overlapped with the generic composition disclosed by D1. However, the Board of Appeal noted that since the different alloying elements interact with each other to form precipitates and solid solutions their content ranges are not to be considered in isolation but in combination. Hence, the Board of Appeal ruled that the range of overlap was narrow in respect of the composition of D1.

In respect of the argument according to which a selected sub-range has to be sufficiently far removed from the end-points of the known range, the Board of Appeal noted that it was not aware of any jurisprudence stating this condition in such a general way. The Board of Appeal pointed to the Guidelines for Examination (Part G, Chapter VI, Paragraph 8) which recites this criterion as a condition for acknowledging novelty of a numerical selection under point (ii)(b), however, noted that neither decision T 198/84 nor T 279/89, which are cited in this passage of the Guidelines for Examination, stipulate this condition.

In the Board of Appeal's view, the limit values of a known range, although explicitly disclosed, are not to be treated in the same way as the examples. The Board of Appeal further stated that the person skilled in the art would not, in the absence of further teaching in this direction, necessarily contemplate working in the region of the end-points of the prior art range, which are normally not representative of the gist of the prior art teaching.

The Board of Appeal ruled that in the present case D1 did not provide any teaching which would lead the person skilled in the art to seriously contemplate working in the claimed composition. Thus, the Board of Appeal decided that D1 was not novelty destroying. The Board of Appeal also found that claim 1 was inventive over the cited documents, therefore, the appeal was dismissed and the patent was maintained as granted.

> This decision provides further details on the assessment of novelty of overlapping ranges at the EPO. However, it also provides a subtle caution for those citing the Guidelines for Examination at appeal.

The Guidelines for Examination may develop over time to include elements that were not recited in the original decision upon which the cited section of the guidelines is based. In these instances, as was the case above, the Board of Appeal may not consider the additional elements included in the Guidelines for Examination to be a requirement and may instead rely on the information provided in the original decision.

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*Witness evidence*

# Expert witness cross-examination Boston Scientific v Edwards

In Boston Scientific Scimed v Edwards Lifesciences, the Court of Appeal of England & Wales has offered guidance regarding the cross-examination of expert witnesses. In particular, it has said that if a party elects not to cross-examine a witness, it should raise this decision in advance with both the other side and the court so that the latter may give directions.

The issue arose out of the rule of evidence that, if a party wants to submit to the court that a witness' evidence on a point should not be accepted, the witness should be challenged on that point in cross-examination.

In the case at hand the defendant to the patent infringement action, Edwards Lifesciences, did not cross-examine one of the patentee's, Boston Scientific Scimed's, expert witnesses on the prior art. The Patents Court subsequently held that one of the patents was invalid for obviousness (the other patent being held to be valid and infringed).

Both parties appealed, Boston Scientific Scimed arguing, among other things, that the trial judge erred in his conclusions on obviousness in the absence of such cross-examination. The Court of Appeal acknowledged the rule of evidence, but noted that it was not inflexible. It emphasised that (as is common with English patent litigation), multiple expert reports (in chief and reply) had been exchanged. The issues in the case had, therefore, been defined and the expert was apprised of these. Further, in its view, there was some overlap between Boston Scientific Scimed's expert witnesses' evidence. It did, however, encourage practitioners who did not wish to cross-examine a witness (for example, to save time and cost) to raise this issue in advance with the other side and the court so any issues could be raised and directions given.

The Court of Appeal upheld the first instance decision.

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## And finally...

*Webinar invitation*

# European biotech patent case law Webinar, July 17, 2018

**Registration is now open for our popular European biotech patent case law webinar**

We are pleased to announce that our European biotech patent case law webinar returns this July with a round up of recent and significant EPO decisions from European Patent Attorneys Matthew Caines and Antony Latham.

Matthew and Antony will be presenting a summary of European biotech case law three times on Tuesday 17 July so that our clients, associates and contacts from around the world are able to listen in at a time that is convenient to you. You can sign up to attend the 9am, 12pm or 5pm webinar (BST) via our website at https://dycip.com/biowebinar.

This is usually a popular webinar subject so early registration is recommended in order to secure your webinar seat.

If you are unable to attend this particular webinar but would be interested in signing up to receive notifications of future events of this nature, please email your contact details to: subscriptions@dyoung.com

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