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In this issue:

European patent oppositions in the field of electronics and computing
Strategies for challenging and proving prior art 04

Activis v Lilly
Is there now file wrapper estoppel in the UK? 05

The Nagoya Protocol
Actions for genetic researchers 06

Clear and safe extensions
CJ rules safeners eligible for SPC protection 07

Early certainty from search scheme
EPO streamlines patent application to grant 08

Substantive patent law harmonization Tegernsee nails down the fundamentals

Full Story Page 02



Welcome to our August newsletter. In this edition I am pleased to announce the recent arrival of Bart Kiewiet and JoAnna Emery to the firm. Bart joins D Young & Co as Plant Variety Rights Consultant and is working closely with our biotechnology patents team in advising clients on IP protection, research and registrations in respect of new plant varieties in the European Union (eg, using the CPVO) as well as the registration of new varieties in other countries. JoAnna will be leading our in-house information systems team as Head of Practice Services.

As always, I hope you find this newsletter a valuable resource and welcome any feedback or questions you may have with regard to its articles and commentary.

Editor:
Aylsa Williams



Events



25 September 2014
Patent protection for software and business related inventions, London UK
Ian Harris will be presenting this management forum hosted seminar.

09 October 2014
British Engineering Excellence Awards, London, UK
D Young & Co proudly sponsors the small company of the year award at the BEEAs.

15 October 2014
European Biotech Patent Case Law Update
Join us for regular update of recent biotech European decisions.

22-23 October 2014
Engineering Design Show and Electronics Design Show, Coventry UK
D Young & Co will be exhibiting and speaking at this year's design show in Coventry.

19 November 2014
Business Show, Southampton UK
D Young & Co will be answering IP questions for local businesses at this Hampshire show.

19 November 2014
Institution of Engineering and Technology Innovation Awards, London UK
D Young & Co proudly sponsors emerging technology design category in the IET awards.

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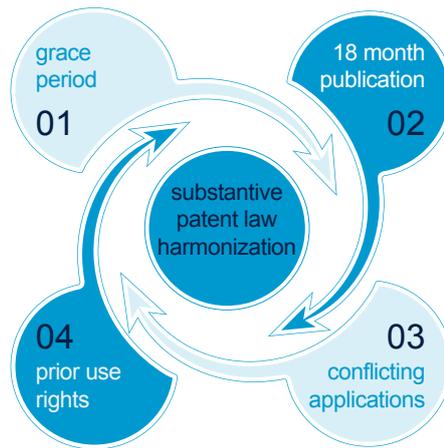


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Article 01

Substantive patent law harmonization Tegernsee nails down the fundamentals

In 2011, the international landscape of substantive patent law changed significantly with the adoption of the America Invents Act (AIA) in the US, and modifications to the Patent Law in Japan. These changes and the ongoing debate of harmonizing substantive patent law triggered the Tegernsee Joint Questionnaire (TJQ) - a detailed study on four key issues for patent law harmonization: grace period, conflicting applications, 18 month publication and prior use rights:



The TJQ included specific questions from the European Patent Office (EPO), and was posted on the EPO website from 10 January 2013 until 01 March 2013.

Before looking at the results of the TJQ, a few caveats should be noted. First, the sample of users was small and not representative. The composition of the group was distorted by the fact that some national user groups responded to the TJQ in only their own countries. Two segments of European users are also underrepresented: SMEs and universities. The TJQ therefore mainly shows the opinions of patent practitioners and large corporations in industry. Despite these caveats,

the TJQ is still the largest, most detailed survey on fundamental issues of substantive patent law harmonization.

1. Grace period

Perhaps unsurprisingly, the grace period section of the TJQ was the one which generated the most interest. It is also not surprising that the most frequent cause of pre-filing disclosure is a disclosure in an academic publication or an error by the inventor or an employee. For 63 percent of respondents, however, the grace period had either never been relied upon, or pre-filing disclosure was an extremely remote occurrence.

Despite the rare use of grace periods, it is clear from the results of the TJQ that it is a polarizing issue amongst European users.

Only 52 percent were in favour on principle, and 39 percent of those included the caveat that the grace period must act as a safety net, ie, not for third party disclosures. The main reason for not having a grace period was that it diminishes the predictability and legal certainty of the patent system. However, an overwhelming majority took the view that if there were a grace period, it should be harmonized internationally (78 percent).

Overall, it appears that the majority of European users would support a six month safety net grace period, computed from the priority or filing date, with a mandatory declaration, and mandatory prior user rights arising until the priority or filing date.

Provided that this grace period was harmonized multilaterally within a substantive patent law harmonization treaty (SPLH) package, including a classical first-to-file system, and mandatory 18 month publication.

2. 18-month publication

Publication after 18 months is common to many of the world's patent systems. However, whilst it represents a balance of interests between inventors and third parties, it also provides competitors with sufficient time before grant to copy or design around technologies. Additionally if search or examination results are not

➤ **Figure 1**
Treatment of conflicting applications in the three main jurisdictions Europe, the US and Japan.

	Europe	US	Japan
Relevant for novelty?	yes	yes	yes
Relevant for inventive step?	no	yes	no
Anti self-collision provided for?	no	yes	yes

provided before publication, applicants are not able to easily decide whether to withdraw an application to avoid publication and keep the invention as a trade secret.

Despite these issues, the majority of European users indicated in the TJQ that a maximum time period of 18 months is reasonable for applicants (80 percent), and third parties (72 percent). 85 percent also believed that search/examination results should be required to be provided before publication. Although several commented that this information was needed much earlier, ie, within the priority year.

One of the only jurisdictions where publication at 18 months is not mandatory is the US. Interestingly, however, the publication opt out rate in the US has been declining for the last several years and is currently at approximately 6 percent of applications filed per year. In line with this trend, 68 percent indicated in the TJQ that opting out of 18 month publication in the US does not influence their business strategies.

3. Treatment of conflicting applications

Conflicting applications are those which have an earlier priority date or filing date than the application being examined, but which are published later. These can be third party applications or applications from the same applicant (known as self-collision).

Treatment of conflicting applications varies between the three main jurisdictions Europe, the US and Japan as shown above right (figure 1).

There are also significant differences in the treatment of earlier-filed, later-published PCT applications. Japan and Europe treat such applications as prior art if they enter into the respective national/regional phase, and if they have translated into the prescribed language. Whereas the US treats these applications as prior art merely upon designation of the US in the PCT application.

The empirical data collected from the TJQ showed that conflicting applications are a rare occurrence. Nevertheless, European

users indicated that the harmonization of this issue was important (46 percent) or critical (46 percent), since it is part of the definition of prior art. Users also indicated that they are prepared to be flexible on this point: almost 79 percent were prepared to consider the modification of rules in their jurisdiction as part of harmonization.

Generally the European patent treatment of conflicting applications was seen as best practice.

The majority of European users were also against anti-self-collision. The issue of PCT applications becoming prior art merely upon designation was, however, controversial.

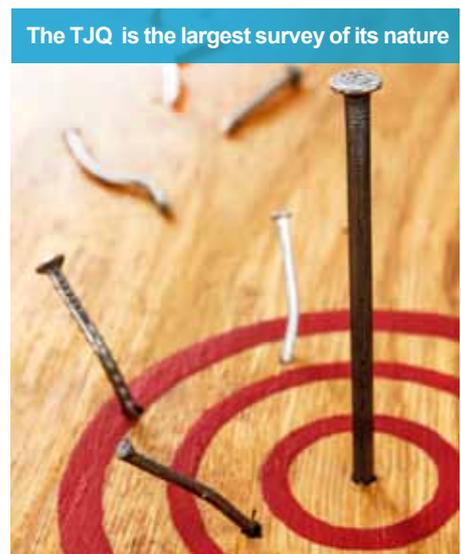
4. Prior user rights

Prior user rights are dictated by national patent legislation and they vary within Europe. In the UK for example, a person has the right to continue an act already begun (or in preparation) before the priority date of an invention, which would otherwise be an infringement of a patent for the invention.

The TJQ results showed that the issue of prior user rights does not arise very frequently. Perhaps unsurprisingly, the results also showed that the main role of these rights is to redefine bargaining positions of parties in a conflict situation, and occasionally these rights are effective in deflecting litigation.

When considering best practice, 56 percent held that prior user rights should be available to a prior user who has used the invention in good faith and derived knowledge from the applicant. 76 percent also indicated that at least "substantial" preparations should suffice for prior user rights to arise.

Considering harmonization, 87 percent found that the harmonization of prior user rights is important or critical if within the framework of the harmonization of the grace period, ie, a prior user using the invention in good faith and having derived knowledge from the applicant. Additionally many European users believed that prior user rights,



before they form the object of international substantive patent law harmonization, should be harmonized within Europe.

Conclusions

It appears that a majority of European users could accept an internationally harmonized safety net grace period, including mandatory prior user rights arising until the priority or filing date, as part of a harmonization package comprising also classical first-to-file, 18 months publication and possibly also conflicting applications. There also seems to be a certain flexibility within European users for the change that would be required to reach this level of harmonization.

Further information

In our next newsletter we will compare user data collected in Europe, the US and Japan for these four fundamental issues of harmonization.

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Useful link

More information on substantive patent law harmonization, the Tegernsee process and the TJQ can be found on the EPO website:

<http://dycip.com/patentlawharmonisation>

European patent oppositions in the field of electronics and computing

Strategies for challenging and proving prior art

When it comes to oppositions at the European Patent Office (EPO) every technical field has its own peculiarities. In the field of telecommunications, mobile technology and broadcast technology, standardisation plays a vital role. For this reason, standards related patents are extremely valuable. As we have seen in some of the recent court battles (Samsung v Apple and Motorola v Apple for example) the weapon of choice for established telecommunications companies is standards related patents. This article introduces the first in a series of guides to tactical opposition, both as opponent and defendant, for businesses and innovators in the electronics and computing sector.

Standards bodies

It is not uncommon for engineers to exchange documents in order to establish a particular technology. Nowadays, standards bodies allow their members to upload documents to a shared server so that those members can easily access and review them in order to assist in defining a standard. Quite often a standards body will have an IPR policy to say that any contribution made by a member represents publication of that technical contribution and so others are free to use that technical contribution. Of course that means that any party making a contribution to the standard will file a patent application relating to that technical contribution before disclosing to the standards body. However, what is the status of documents which are exchanged between engineers (or known to engineers) before the standards body is established?

Prior art

Typically because of the time constraints for filing an opposition it is usual to assume that any document that has been acquired is in the public domain. However, just because a document is dated, does not necessarily mean that that document was in the public domain on that date. For example, typically before work on a standard begins, the standards body sends out a call for technologies. Often documents are submitted in response to that call for technologies and may be presented to other parties. At this point these documents

Engineers' witness statements can be key evidence when publication dates are challenged



are not necessarily published on a server or submitted to the standards body but are exchanged between the parties intending to contribute to the formation of the standard.

These documents can represent very useful prior art for an opponent wishing to attack a patent. If opposing a patent with documents acquired from engineers, a classic defence is for the patent proprietor to assert that these were not published (or in the public domain) or at least not published on the date that appears on the document itself.

Defence: witness statements

The opposition procedure is relatively streamlined. This means that analysis of evidence and documents is as rigorous as time allows by this relatively streamlined procedure. Typically there is also no cross examination of witnesses because the opposition is usually based on written evidence. One thing an opponent can do if a publication date is challenged is to prepare witness statements establishing the what, when, where, how and to whom a disclosure was made. For example, an engineer's witness statement would detail how long they worked for an organisation, in what role, and note that they were a member of a group which reviewed documents before the establishment of a standards body. This statement should be signed and dated and possibly countersigned. Clearly, the greater the number of witness statements supporting disclosure of a document the better. Furthermore, a witness statement prepared and signed by a person working for a party other than the opponent, though often difficult and time consuming, will add credibility to the witness statement.

Opposition: challenging witness statements

So what does the opponent do in response?

Even with the witness statements prepared and filed, that is not necessarily the end of the story. A patent proprietor can still challenge or refuse to acknowledge the witness statements, leaving the opposition division to decide on whether they accept that this document was published on the alleged date or not. The patent proprietor can also use any inconsistency to their advantage. For example, a witness statement purporting to support the disclosure of document A on a certain date which does not mention another document B can be used by the patent proprietor to imply that document B was not published.

Conclusion

The opposition procedure at the European Patent Office represents a very effective way of attacking the intellectual property position of a party. It is relatively inexpensive and can provide rapid results. In some business situations, for example for standards related patents, the validity of the patent is the only factor in question. If the patent is related to a standard then the issue of infringement is rarely reviewed. This means that the opposition may be the only time the patent is challenged.

The supporting evidence and arguments which surround the publication dates of documents can be crucial in successfully opposing or defending an opposition against a European patent. The opposition division should accept the evidence on the balance of probabilities but in reality will be reluctant to revoke a European patent unless certain that a relevant document was indeed in the public domain on the date asserted by an opponent.

Author:
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Actavis v Lilly

Is there now file wrapper estoppel in the UK?

In the seminal UK case on claim construction, *Kirin Amgen v Hoechst Marion Roussel*, Lord Hoffmann, who gave the leading speech, commented that because Article 69 EPC focuses the scope of protection on the language of the claims, there was no doctrine of equivalents in Europe. Accordingly, unlike in the US where there is a doctrine of equivalents, there is no need to balance this with the further doctrine of 'file wrapper estoppel'. He also went a little further, commenting that reference to the prosecution history generally for the purposes of construing patent claims in Europe was something which was not generally desirable. He said: *"The courts of the United Kingdom, the Netherlands and Germany certainly discourage, if they do not actually prohibit, use of the patent office file in aid of construction. There are good reasons: the meaning of the patent should not change according to whether or not the person skilled in the art has access to the file and in any case life itself is too short for the limited assistance which it can provide."*

Rohn and Hass v Collag

In a previous case (*Rohn and Haas v Collag*) the Court of Appeal had found guidance on reference to the prosecution history to be useful (given by the Dutch Supreme Court in *Ciba-Giegy v Ote Optics*). That guidance essentially said that the file history should only be referred to as a last resort where the claims remained open to interpretation after consideration of their meaning in the light of the description and drawings.

Accordingly, until very recently, the view in the UK had been that reference to the file history on the question of claim construction should only be permissible in very limited circumstances, and certainly not as a means to provide some form of estoppel similar to that in the US.

Activis v Lilly

However, in *Activis v Lilly*, Mr Justice Arnold recently referred to the file wrapper as part of his assessment of the meaning of the claims in issue. While he acknowledged that courts should be cautious in so doing, and he expressly recognized that there is no doctrine of file wrapper estoppel in the UK, the judge said: *"Consideration of the prosecution file may assist in ensuring that patentees do not abuse the system by accepting narrow claims during prosecution and then arguing for a broad construction of those claims for the purpose of infringement."*

In this case, during prosecution the patentee narrowed the claims of the application to overcome both clarity/sufficiency and added matter objections. In order to overcome these objections, the patentee ultimately restricted the claim to a preferred embodiment using a particular compound. The patent was duly granted. It was noted by Mr Justice Arnold that the examiner's objections were neither challenged nor appealed, and that the patentee admitted that making the amendments *"was a deliberate and conscious act"*.

The judge ultimately construed the claims as being limited to the particular compound specified in the claims, as this provides the patentee *"with fair protection and does not expose [the patentee] to the risk of the patent being invalid on the grounds of added matter and/or sufficiency. Construing the claim [any broader] would not provide a reasonable degree of certainty for third parties."*

In reaching this conclusion, the judge applied several considerations as to why the claim should be so limited. One of these was the prosecution history, including the conduct of the patentee in seeking limiting amendments during prosecution, including why they were sought.

Conclusions from Activis v Lilly

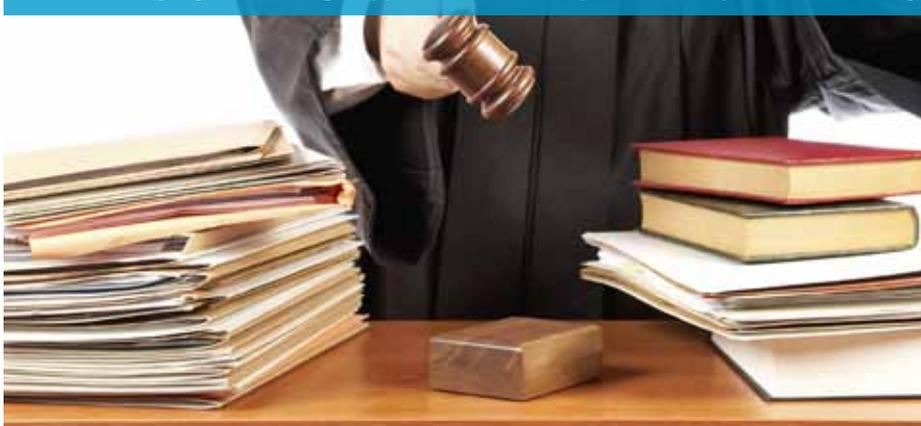
While he acknowledged that there is no doctrine of file wrapper estoppel in the UK and that courts should be cautious before relying on the file wrapper for construction generally, Mr Justice Arnold does seem to have placed significant weight on both the file wrapper generally and, in particular, the conduct of the patentee, in construing the claims of the patent in issue.

File wrapper estoppel in the UK

This case is likely to go to appeal and it is difficult to predict the extent to which this aspect, of what is a long and detailed decision, will be affected by the Court of Appeal. Until such time as we know the answer to that question, it is difficult to predict whether this represents a shift in attitude of the UK courts on the use of the prosecution history in claim construction, and in particular how statements made in prosecution may be used to the detriment of the patentee.

It is certainly worth reminding ourselves that one should consider carefully both amendments and statements made during the prosecution since they may, whether expressly or implicitly, be used in the UK and elsewhere to restrict the ability of patentees to argue for a broad claim construction in subsequent litigation.

In *Activis v Lilly* significant weight appears to have been placed on the prosecution history



Authors:

Jonathan Jackson & Richard Willoughby

The Nagoya Protocol Actions for genetic researchers

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization was adopted by contracting states on 29 October 2010, and ratified by the European Union (EU) in a Regulation on 16 May 2014. The Nagoya Protocol is a supplementary agreement to the Convention on Biological Diversity (CBD). The CBD itself is a multilateral treaty centred on achieving three main goals, namely:

1. The conservation of biological diversity.
2. Sustainable use of its components.
3. Fair and equitable sharing of benefits arising from genetic resources.

A notable non-signatory to either the CBD or Nagoya Protocol is the US.

It was hoped that the CBD would stimulate the use of genetic resources however over time it was apparent that this hope would not be fulfilled. This is one of the reasons for which the Nagoya Protocol was devised. Further aims of the Nagoya Protocol are the establishment of more predictable conditions for access to genetic resources and to help ensure benefit-sharing.

Key points of the Nagoya Protocol

The Nagoya Protocol surrounds the utilization of genetic resources which it defines as any non-human genetic resources. The term 'utilization' refers to research and development on the genetic and/or biochemical composition of genetic resources including through the use of biotechnology. The breadth of this term therefore encompasses both commercial and academic research.

The Nagoya Protocol gives provider countries the rights to control access to genetic resources found within their jurisdiction, thereby reaffirming a provider country's sovereignty over these resources. A provider country can be either: an originating country where the genetic resource exists *in situ*; or one where the genetic resource exists *ex situ* and where it has been obtained

from an originating country under the CBD. It is yet to be confirmed, but would appear that an originating country may be able to impose terms on subsequent provider countries.

A key part of the Nagoya Protocol is that the burden will be placed on the user (ie, researcher) to show that any genetic resource on which they are conducting research was legally obtained in accordance with the Nagoya Protocol. To do this a user must obtain the prior informed consent of a providing country before access to a genetic resource is permitted (Article 6 of the Nagoya Protocol). There must also be fair and equitable sharing of benefits arising from utilisation of genetic resources with the party providing access thereto on mutually agreed terms (Article 5 of the Nagoya Protocol).

Article 4 of the EU regulation implementing the Nagoya Protocol requires users to exercise due diligence to ascertain that genetic resources have been accessed in accordance with the access and benefits sharing regulatory requirements. Additionally for 20 years following the end of utilisation the user must keep the internationally recognised certificate of compliance or information/documents concerning:

- the date and place of access;
- the description of genetic resource utilised;
- the direct source of genetic resource and subsequent users; and
- access and benefit sharing (ABS) agreements, access permits, mutually agreed terms including benefit-sharing, and any rights or obligations related to ABS.

Although the EU regulation introduces much of the Nagoya Protocol as national law for member states, national governments have been allowed to decide how to implement:

- the issue of traditional knowledge associated with genetic resources that is held by indigenous and local communities (Nagoya Protocol Articles 7 and 16);
- the appointment of the competent authority to administer the Nagoya

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regime in the member state;

- details of how declarations of due diligence are to be made; and
- enforcement and sanctions for failure to comply with due diligence obligations - civil sanctions and criminal offences.

Focal points and competent authorities

It is also envisaged that under the Nagoya Protocol national focal points (NFPs) and competent national authorities (CNAs) will be established to serve as contact points for information, grant access or to cooperate on issues of compliance.

The Nagoya Protocol in the UK

The UK's Department for Environment Food and Rural Affairs (DEFRA) will be responsible for implementing the EU regulation relating to the Nagoya Protocol. As yet there is no set guidance on how the due diligence requirements will be implemented. The EU regulation requires that the penalties for non-compliance with the due diligence requirements of the Protocol must be "effective, proportionate and dissuasive." Details of such penalties have not yet been published, but DEFRA have suggested a fine of up to £250,000 as well as possible criminal sanctions.

Actions for researchers

1. Ensure all existing materials are documented as having been accessed pre-Nagoya (as the regulation will not be retroactive).
2. Put in place systems to ensure that new materials are documented in compliance with the Nagoya Protocol.
3. Ensure employees know about the Nagoya Protocol and associated regulation and that, in future legal possession of a genetic resource does not necessarily imply the right to do any work on it.
4. Be cautious of the origin of material that you might wish to use for research.
5. Consider whether you want to be involved in setting best practices concerning work practices to conform to the legislation.

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Clear and safe extensions CJ rules safeners eligible for SPC protection

➤ **Related news**
D Young & Co is pleased to announce the appointment of plant variety rights consultant Bart Kiewiet. Previous Chair of the National Board for Plant Variety Rights, and subsequently Chair of the Community Plant Variety Office (CPVO) until 2011, Bart is considered a leading specialist in plant variety law. For more information please see www.dyoung.com/news-plantvarietyrights

In a recent decision (case C-13/11), the Court of Justice of the European Union (CJ) has ruled that a supplementary protection certificate (SPC) can be granted for a safener. The decision is welcome news for applicants and much clearer than recent SPC decisions which have raised more questions than answers.

Supplementary protection certificates
SPCs have been available in EU countries for plant protection products, such as pesticides or herbicides, since the mid-1990s. The regulatory approval process for plant protection products involves demonstrating to the regulator that the product is both sufficiently effective and does not cause any harmful effect on human or animal health or unacceptable influence on the environment. As performing the necessary tests can involve significant amount of time and investment, SPCs were introduced to compensate the patent holder for the delay in commercial exploitation of the product due to the requirement to carry out these tests to obtain marketing authorisation.

Safeners
A safener is an ingredient contained in the formulation of a plant protection product. Although safeners do not have pesticidal or herbicidal activity when administered on their own, they are included in the formulation order to reduce the toxic effects of the active ingredient on certain plants. Safeners may thereby increase the effectiveness of a plant protection product by improving its selectivity and by limiting its toxic or ecotoxic effects.

Bayer's SPC request for isoxadifen
Like any other chemical product, safeners may themselves be patented, independently of the plant protection product with which they are formulated. Bayer hold a patent for isoxadifen, a safener which forms part of the formulation of two approved plant protection products. Bayer looked to extend the patent term for this substance by means of an SPC. The German Patent Office and German Federal Patent Court were uncertain, and referred the matter to the CJ.

Regulation 1610/96 (the plant protection SPC



regulation), which permits SPCs for plant protection products, defines the term 'product' as "the active substance or combination of active substances of a plant protection product". The question the CJ had to answer, given that safeners have at the most an indirect effect on plants or harmful organisms, was whether a safener was covered by the term 'active substance' within the meaning of the plant protection SPC regulation.

The court noted that the term 'active substances', in the plant protection SPC regulation relates to substances which have a toxic, phytotoxic or plant protection action of their own. However, the regulation makes no distinction according to whether that action is direct or indirect, and saw no reason to restrict the term 'active substances' to those whose action may be considered direct.

In addition, the CJ noted that the regulations for grant of an SPC are a separate act of legislation from those relating to the regulatory approval process itself. Therefore, even though safeners are regulated differently from active substances, it is still necessary to submit data concerning the other ingredients when making a submission for marketing approval of the active substance.

Findings of the CJ
Based on the above, the court considered that the regulatory submission for a plant

protection product containing a safener would delay the commercial exploitation of a patent for that safener. For those reasons, the court interpreted the term 'product' in the plant protection SPC regulation to mean it may cover a substance intended to be used as a safener, where that substance has a toxic, phytotoxic or plant protection action of its own.

This view of the CJ is slightly at odds with its previous viewpoint on pharmaceutical excipients, which, in the MIT decision (C-431/04), it considered ineligible for SPC protection in their own right. However, the CJ distinguished that case on the grounds that the means of action of a safener is not necessarily comparable to that of an excipient in a medicinal product and that a safener is sometimes essential for the use of an active substance - the active substance may not receive regulatory approval without the safener.

A clear view for SPC applicants
The court's decision is straightforward, especially in comparison with its recent decisions on SPCs for combination products. Consequently, SPC applicants are for once clear on where they stand on this matter. For more details, please contact your usual D Young & Co adviser.

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D YOUNG & CO INTELLECTUAL PROPERTY

And finally...

Early certainty from search scheme EPO streamlines patent application to grant

Frustration and grumbles about the sometimes extraordinary lengths of time the European Patent Office (EPO) can take to process a patent application through to grant are commonplace. Following consultation the EPO has now announced an 'Early Certainty from Search' scheme aimed at improving its service. The scheme, which came into force in July 2014, has the following objectives:

- Search reports and accompanying patentability opinions should be issued within six months from filing for all applications. At present this service is limited to European applications which are first filings (about 20% of all European applications).
- Completion of examinations which have already been started will be prioritised over starting new examinations. This is aimed at clearing the back-log of partially examined old applications.
- Grant of applications which have received a positive search report and opinion will be expedited.
- Processing of applications on which non-anonymous substantiated third party observations are filed will be prioritised, using the existing PACE programme for accelerated prosecution. This ability to accelerate prosecution of another party's application offers an interesting new competitive tactic. However, many PACE requests currently filed do not produce the desired acceleration owing

to excessive EPO workloads, so the tactic may not prove of use or interest.

- Handling of opposition, limitation and revocation cases will be prioritised. This will presumably be at the expense of some other procedures, although which might suffer has not been made clear. However, a faster opposition process will no doubt be welcome news to many. Oppositions can currently drag on for several years and so compare unfavourably with the USPTO's new (albeit much more expensive) post-grant and inter-partes review procedures which must conclude within a year.

Hence, the scheme does not offer increased speed across all stages of prosecution. Indeed, one wonders what will become of those applications which have received the promised prompt search report and opinion but not yet had an examination report, and which therefore fall between two tenets of the scheme. The EPO's intention is not to provide a swift grant for all, however (probably this is too ambitious, and indeed is not always desired by applicants). Rather, the concentrating of examiner time on searches aims to improve certainty for companies and inventors by providing meaningful patentability data to inform patenting strategies at an early stage. Benefit to the public in the form of enhanced transparency by offering an early overview of prior art and patentability is also cited.

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