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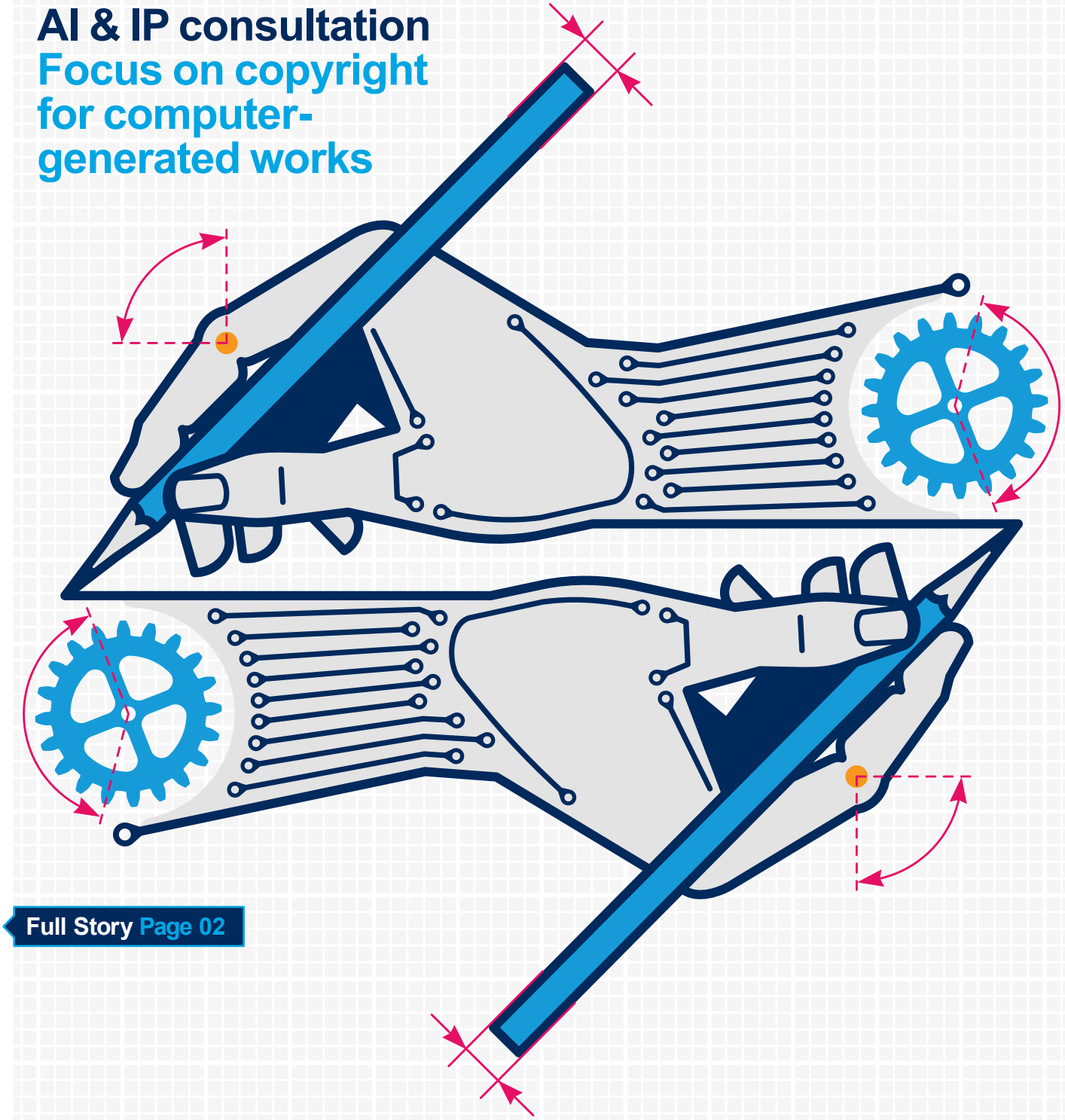

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Editorial

Welcome to the Spring edition of our newsletter. We hope that life is moving back to normal for all of our clients, contacts and friends. International travel is starting and our attorneys look forward to meeting you in person as and when we can.

We hope you find this selection of articles interesting. One very important issue this year will be the UPC, which is now taking shape. Our article on page 10 sets out some issues you and your clients should consider in advance of commencement. Our website is also full of more detailed information (www.dyoung.com/upandupc). As always, we are here to help and support and so please contact us if you have an questions.

Anthony Albutt, Editor

Webinars on demand

European Biotech Patent Case Law
Catch up with our latest round up of important and recent European biotech case law, presented by Simon O'Brien and Tom Pagdin. First broadcast 08 February 2022.

UPC: representation and judges
Alice Stuart-Grumbar provides a summary of UPC representation, including discussion of judges, panels, nationalities, arbitration and mediation.

UPC: structure, language and where to start a case
Alice Stuart-Grumbar presents a short summary of the structure of the Unified Patent Court including proceedings, where to start a case, local, regional and central divisions, revocations and actions for a declaration of non-infringement, and language considerations.

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Artificial intelligence

AI & IP consultation
Focus on copyright for computer-generated works

In view of the increasing use of artificial intelligence (AI) in creative fields, the UKIPO considered that a consultation focussing on potential changes to copyright, as well as patent, law was needed. In this article we explore the issues considered by the consultation and explain the reasoning behind D Young & Co's input to the consultation, with a particular focus on copyright of computer-generated works. In an earlier newsletter we explored the issues surrounding patents in more detail: https://dycip.com/ai-ip-patents.

Section 9(3) of the Copyright, Designs and Patents Act 1988 (CDPA), accords authorship of a copyright work to the person "by whom the arrangements necessary for the creation of the work are undertaken".

As AIs become increasingly autonomous and complex, the current consultation seeks to establish whether this definition is fit for purpose, or whether changes are required to account for the increasing creativity of AIs.

As part of the consultation the UKIPO has identified three potential ways forward for protection of computer-generated works. These are as follows:

Computer generated works	
Option 0	Make no legal change.
Option 1	Remove protection for computer-generated works.
Option 2	Replace the current protection with a new right of reduced scope/duration.

Making no legal change is the preferred option

Contrary to the situation for determining inventorship of patents, in our opinion the UKIPO's current system for determining authorship of copyright works made using an AI is fit for purpose, such that no legal change is required. In our response to the consultation we therefore advocated for option 0.

The definition provided by Section 9(3) of the CDPA appears to offer a reasonable approach and treats the AI as a tool like any other computer based art tool whose programming contributes to the overall aesthetic of a copyright work. An AI may be a more sophisticated (or perhaps just more opaque) tool, but it is a tool nonetheless. Therefore, even once AIs advance to become more autonomous, there would still be "arrangements necessary for the creation of the work", as recited in Section 9(3). This definition would therefore appear to render the current provisions fit for purpose now, and in the future.

Removing protection for computer-generated works should be discouraged

In our response to the consultation we argued that removing protection for computer-generated works would seem to be a disincentive to the production of such works, and also seemingly an unjustifiable punishment inflicted because of an apparent intractability with the law rather than because of any lack of artistic merit in works developed using an AI.

Removing, or limiting, protection for computer-generated works would also lead to a significant problem in defining which works should have their protection altered. Here it will be understood that many works generated using a computer do not use an AI, and it is unclear whether the present consultation intends all computer-generated works to be considered together, irrespective of whether such works require the use of an AI or not.

It is also unclear at what point a work should become a "computer generated work", regardless of whether AI is used. For example, it will be appreciated that many artworks, and indeed photographs, are routinely generated using computational methods. On the one hand, computers are utilised to determine how digital brushstrokes blend within an image, or how a model is airbrushed or warped by algorithms, and it is likely that these could be considered to contribute to the work being considered "computer-generated".

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UP & UPC webinars

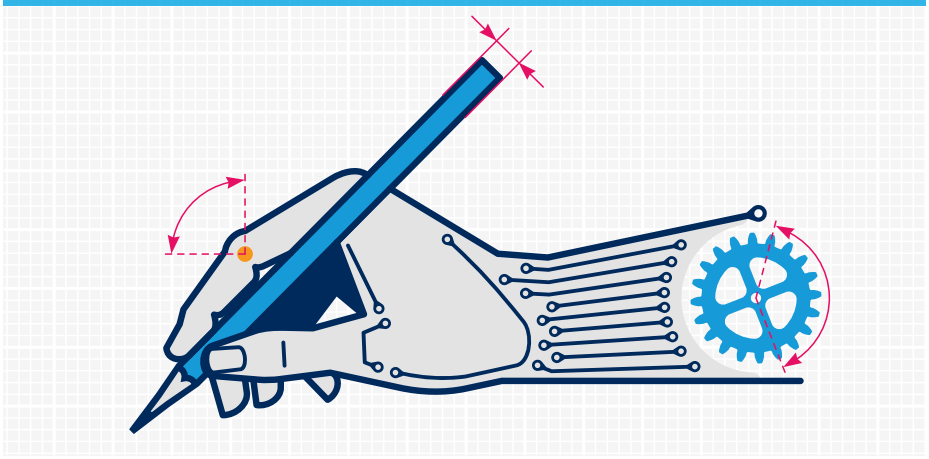
We are growing a library of UP & UPC webinar guides that can be viewed on demand:

- *Introduction to the UP & UPC*
- *UPC opt out*
- *Unitary patent v European patent validation*

Newly published, April 2022

- *UPC: representation and judges*
- *UPC: structure, language and where to start a case*

The AI & IP consultation includes consideration of copyright for computer-generated works



However, it is also commonplace to use an in-camera computer for dynamic range computation, aperture selection, exposure compensation, colour saturation, focus selection, and many other elements of composition – including in some cases when to take the photo itself – that would previously have been used in support of according copyright to a photographer. It is significantly less clear which of these should be considered to contribute to a work being considered "computer-generated", even if the selections are made by something claimed to be an AI.

It does not seem justified to remove protection for a certain category of artistic works merely because new developments in technology make it more difficult to determine the appropriate level of protection.

Replacing the current protection with a new right of reduced scope/ protection should also be discouraged.

The final option proposed in the UKIPO consultation is to replace existing copyright protection with a new right for computer-generated works of reduced scope/ duration. Whilst we consider that this may represent an acceptable middle ground if it is deemed that amendments to the current legislation are required, the introduction of a new right may lead to additional issues making it an unattractive proposal.

One may assume that an AI has no inherent artistic capability, and/or that it is not entitled to moral rights or rights that reflect a personal investment in the artistic properties of the work, as is the aim of copyright protection. As such, an AI could be treated as a design engine, whose output is commercialised by another party, and so the rights afforded to its output may be more suitably protected with a right which is similar to a registered design.

If we were to equate rights provided for computer-generated works with design right, a duration of about 25 years, similar to design right, would seem appropriate. Even if the commercial exploitation is to sell it as an artwork, it will be appreciated that an AI can produce an endless stream of such works without tiring (or without new inspiration) by randomly exploring the training space its internal weights represent, and a reduced duration of right for such works would seem appropriate.

However, there are many works which an AI would not produce itself if the user had not provided the necessary prompt; for example the snail harps and avocado chairs generated by GPT-3: https://dycip.com/avocado-armchair. There is therefore a question of whether the user is a co-author of the work, or whether they simply provided the system with a design brief. For human artists, the latter may be true, but for an AI where the input directly influences the AI's search within its state-space, this is less clear-cut, particularly since the phrasing of the same basic requests to GPT-3 would result in different works being produced. As such the user's input may again be equated with the "arrangements necessary for the creation of the work" under Section 9(3) of the CDPA.

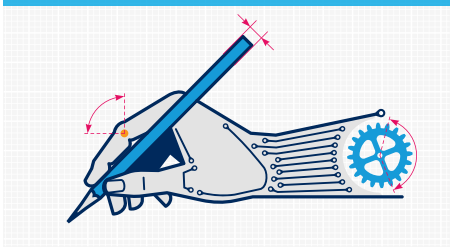
We note that, as acknowledged in the consultation itself, typically the dissemination of a computer generated work by the owner of the computer will itself attract additional copyright protection that greatly exceeds the existing 50 year term available to the person running the computer. As a result, any changes to the duration accorded directly to that person are likely to be ineffectual unless they also percolate downstream to other uses of the work (for example, dissemination by the owner of the computer).

If the duration of protection afforded to a computer generated work was reduced without alteration of the downstream rights, an unnecessarily complex scenario is likely to develop where a piece of computer aided art comprises within itself a mix of rights of different durations (for example where there are computer-generated special effects in a movie). This could lead to significant enforcement issues.

Hence this option appears to suggest either a relatively ineffectual change to the duration of the right, to reflect the diminished artistic stature of the source, or the creation of complex networks of rights within a work, which may have different durations. This would appear to be the case unless corresponding changes to reduce the duration of protection were allowed to pass through other phases of the creative and commercial processes of making the art accessible. This would appear to represent a more fundamental, and far reaching, change to copyright protection.

Further, as discussed above, removing computer-generated works from copyright protection and setting up a new right would require an accurate definition of a

AI & IP consultation: continued from page 03



"computer-generated work". Since not all computer-generated works involve the use of an AI, careful consideration would also need to be given to whether the new right would apply to all computer-generated works or only those made using an AI, as well as how an AI should be defined. In a field which is developing as quickly as AI, providing these definitions represents an ongoing and substantial challenge.

Finally, it will also be appreciated that such a new right may not transfer smoothly to other Berne convention countries, making the dissemination of such works even more complex.

Copyright in text and data mining (TDM)

As well as the copyright in computer-generated works discussed above, the current UKIPO consultation also considers issues of copyright in text and data mining. In our response to the consultation we advocated that the UKIPO should extend the existing TDM exception to cover commercial research and databases.

The present framework of TDM allows non-commercial research. However, the findings of such research are often subsequently used for, or inform, commercial purposes.

It will be understood that many "big data" AIs ingest huge quantities of data, and it will be frequently impractical to determine the copyright status of every training item, or to subsequently separate an AI from the source material or training set. For example, where a commercial AI is the result of any non-commercial research phase of developing such an AI, or its training set, it is not then possible to separate the AI from the source material in a sense that safely makes the exploitation of the AI a subsequent and separate commercial act.

In order to allow the commercialisation of AIs that are trained on datasets which include copyright works, we therefore consider that the current TDM exception should be extended to cover commercial research and databases. Notably, however, this should not remove from the persons responsible for the AI any liability for copyright infringement by the results of the AI; an AI should not be used to "wash" the copyright from an earlier work it has been trained on.

Conclusion

It is apparent that AIs will make a comprehensive contribution to computer-derived works over the coming years. There is therefore a need to ensure that such works are appropriately protected. We believe that in most cases where a person makes the arrangements necessary for the creation of the work, the current law is fit for purpose. However, if the production of artistic works by an AI is considered akin to using the AI as a design engine, it could be appropriate for the duration of protection to be similar to design right, that is, 25 years.

If changes in the scope of protection afforded to such works are going to be made, it will be important to distinguish between works derived using an AI, and computer-derived works which do not use an AI. This may also be affected by the definition of an AI, which is likely to change over the coming years as AIs develop and become more autonomous, and as AIs are increasingly used in both the creative and functional aspects of a computer-generated work.

With respect to TDM, copyright provisions with respect to AI will also need to be considered as the use of AI expands. Specifically, it will need to be appreciated that an AI is inextricably linked to its training set, and that removing a training set for commercial exploitation of an AI, which was permitted during non-commercial development, may be particularly difficult.

Authors:
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Ebook download

EPO Board of Appeal Decisions Third edition ebook

The third edition of our book of decisions from the European Patent Office (EPO) Boards of Appeal is now available as an ebook download. The selected Board of Appeal decisions have been chosen on the basis of many years of experience in arguing cases before the EPO. In general, they represent some of the most useful and frequently cited decisions used by D Young & Co's patent group during both our defence of and opposition to European patents. In this third edition we have included a number of additional cases and an updated section on the Rules of Procedure of the Boards of Appeal of the European Patent Office. We have also included a new section on oral proceedings being held by video conference (ViCo).

Contributors

The book was written and co-edited by members of our biotechnology, chemistry and pharmaceuticals patent group - Charles Harding, Antony Latham, Matthew Gallon and Rachel Bateman.

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www.dyoung.com/epo-book-2021

UK IP counter-infringement strategy 2022-2027

Tackling IP infringement in a changing political and technological landscape

The UKIPO recently published the UK IP Counter-Infringement Strategy for 2022-2027. This document sets out the UKIPO's approach to tackling IP infringement in the UK given the changing political and technological landscape, and in particular sets out a number of objectives and commitments for this period. In particular, this is seen as being an important step for maintaining the UK's excellent reputation for protecting IP rights.

Embracing a new strategy is seen as being particularly timely in the wake of Brexit, with this leading to changes in the market both in terms of domestic business and international relationships, and further still as a part of the UK Government's recovery strategy post-Covid. Technological changes have also had an impact on the market in recent years; increasing use of social media over traditional advertising can offer more opportunities for infringers to thrive, and newly-emerging unregulated products (such as non-fungible tokens - NFTs) are offering unique challenges to IP rights. In view of these challenges it is clear that there is a need for the UKIPO to take an active approach to combating IP infringement which includes a strategy that is responsive to the changing political, economic, and technological landscape.

In line with this, the UKIPO's new counter-infringement strategy seeks to build upon the work done by organisations such as the Border Force, Trading Standards, and the police (including their police intellectual property crime units) to ensure that infringement is tackled in an effective and efficient manner. This strategy has three broad components, summarised by the following themes:

- **Partnership: to co-ordinate the UK's fight against IP crime and infringement.** We will provide clear steps to identify and tackle IP crime and infringement, ensuring that routes to enforcement are accessible to all and effectively targeted to have the most impact. We will do this by working collaboratively with partners, both domestically and internationally.

The UKIPO has published its UK IP Counter-Infringment Strategy for 2022-2027

- **Leadership: to continue be a world leader on IP enforcement.** We will drive the fight against IP crime and infringement and support innovation and creativity to make the UK the best place in the word for businesses to start and grow. We will do this by striving for a gold standard framework domestically and internationally, which recognises the importance of a balanced, effective IP enforcement environment.

- **Education: to empower consumers and businesses and raise awareness and understanding of IP crime and infringement and risks surrounding it.** We will work towards a time where IP crime and infringement is seen as socially unacceptable to all. We will do this by helping consumers identify and report infringing goods and helping them understand the benefits of buying genuine goods and the wider harms of buying infringing ones. And we will support business to understand and protect their IP.

These overarching themes encompass 13 separate commitments, each of which will be pursued in an intelligence-driven, harm-focused, and continuously-improved manner. Some of the key commitments provided in the report include:

- The establishment of a national centre of excellence to coordinate intelligence, research, taskforces, training, and any other projects;

- Development of the existing IP Crime Group to create a new Strategic Operational Leadership Group for coordinating efforts between government, enforcement agencies, and industry;

- Working with the Department for International Trade to ensure that new trade deals do not negatively impact the UK IP regime, and that instead they increase the protection available to UK businesses overseas by strengthening IP enforcement abroad; and

- Continuing to support and develop campaigns to educate consumers with the goal of reducing IP crime and infringement.

Initial phases of the strategy will focus on setting up the new structures and processes, including recruiting new staff and raising awareness amongst partner organisations such as the police and the Border Force. In addition to this, the first 12-18 months will involve action to increase the amount of intelligence that can be handled as well as identifying how best to use this intelligence – this will be realised in part with the creating of the new Strategic Operational Leadership group.

The progress made with the strategy will be monitored against agreed milestones set by the UKIPO Board in consultation with ministers, partners, and stakeholders, with new objectives being set throughout the five-year period.

It is hoped that this new strategy from the UKIPO will be effective in reducing the amount of IP infringement going forwards, both through educating consumers and more effectively targeting infringers. This would represent a significant strengthening of UK IP rights, adding substantial value to these rights and protecting businesses operating in the UK.

Authors:
Ryan Lacey

Can we finally advance? CJEU again to consider SPC eligibility of patents for combination products

The Irish Supreme Court has referred a number of questions to the Court of Justice of the European Union (CJEU) on issues relating to the eligibility of combination medicinal products for protection by supplementary protection certificates (SPCs). The referral has the potential to decide Europe-wide litigation on a combination product and provide some much-needed clarity to a matter which has vexed courts in the EU for over a decade.

Background

In EU and EEA countries (as well as the UK and some other European countries), SPCs provide an extension of the term of patents for pharmaceuticals and plant protection products which require a marketing authorisation (regulatory approval) before they can be placed on the market. The aim of SPCs is to, at least partially, restore some of the patent term during which a product cannot be marketed because of the need to obtain regulatory approval. An SPC is limited in scope to the authorised product, and can last for up to five years, with a further six months' extension available if paediatric studies are carried out on the approved pharmaceutical. SPCs are therefore critical to the research-based pharmaceutical industry, with every additional day of term extension being worth millions of dollars.

As part of the criteria for SPC eligibility, Article 3(a) of the SPC Regulation (469/2009) requires that the approved product be "protected" by a basic patent in force. However, the precise meaning of "protected" has been the subject of fiercely contested litigation in Europe for over a decade. Despite multiple references to the CJEU on this question, there is still a considerable lack of clarity on exactly what is required for the approved product to be "protected" by the basic patent. Three possible tests for compliance with Article 3(a) have been considered by the courts:

1. **The "infringement" test:** under this test, it is simply sufficient that the approved product falls within the claims of the basic patent, with no additional criteria.
2. **The "specifically identifiable" (or "identified" or "specified") test:** under this test, the approved product must not only fall within the claims of the basic patent, but also be sufficiently identifiable (preferably as a specific compound) within the claims and/or description of the basic patent.
3. **The "inventive advance" (or "invention" or "sole subject-matter of the patent") test:** under this test, the approved product must also reflect the inventive contribution made by the patent.

Neither of tests 2 or 3 have any specific legal basis in the wording of the SPC Regulation. However, like all EU legislation, the SPC Regulation is interpreted in line with its aims and objectives (a so-called "teleological" interpretation). Both tests 2 and 3 can be considered to have their basis in the doctrine that the SPC should reflect the research that led to the basic patent, and should exclude from SPC protection products which had not been invented at the filing date of the basic patents. For example, the case law discussed below appears to have the intention of excluding SPCs based on patents where a biological target of a particular disease had been identified but drugs acting on it had not yet been invented. In relation to the issue of combination patents specifically, the case law appears to try to exclude the grant of an SPC to a combination where a drug had been discovered to work as a mono-product but combination products containing it had yet to be invented.

Prior CJEU case law on SPCs

For most of the first 20 years of SPCs in Europe, test 1 was largely considered to be the sole test relevant for interpreting Article 3(a) of the SPC Regulation. However, in Medeva (C-322/10), the CJEU specifically rejected an "infringement" test when ruling that a SPC for a combination vaccine product was invalid, and introduced test 2 into EU SPC case law for the first time. Subsequent CJEU decisions, in Actavis v Sanofi (C-433/12) and Actavis v Boehringer (C-577/13) confirmed this test and additionally introduced a version of test 3 in also rejecting combination product SPCs.

In Teva v Gilead (C-121/17), the CJEU was once again asked to consider the validity of SPCs for combination products. The court laid down a two-part test for whether a combination product met the requirements of Article 3(a), as follows:

(i) the combination of actives necessarily, in the light of the description and drawings of that patent, fall under the invention covered by the patent, and
(ii) each of those active ingredients must be "specifically identifiable", in the light of all the information disclosed by the patent, at the filing or priority date of the application.

Part (ii) of the Teva test corresponds to test 2 outlined above. However, the CJEU notably did not use the term "inventive advance" in deciding Teva. This raised the question as to whether test 3 was still relevant in deciding SPC eligibility under Article 3(a) – in particular, did "the invention" mean the same as test 3?

In Royalty Pharma (C-650/17), the CJEU affirmed the "specifically identifiable" test, and also ruled that a functional definition of the product in the basic patent did not meet Article 3(a) if the approved product was "developed after the filing or priority date of the basic patent, following an independent inventive step". In that decision, the CJEU notably opined that the "core inventive advance" was not relevant in determining the compliance with Article 3(a) – but nevertheless quoted the wording of the two Actavis cases. This once again raised the issue of whether test 3 was still relevant for compliance with Article 3(a), or indeed whether the new test amounted to the same thing in different words.

The Merck v Clonmel litigation – ezetimibe and simvastatin

The case before the CJEU resulted from long-running litigation on a family of SPCs based on EP720599. The basic patent claimed the approved compound ezetimibe both generally and specifically, and also contained claims directed to combination products with statins, specifically reciting simvastatin. However, the patent contained no data showing the combination of ezetimibe and simvastatin (or any other combination

partner) was independently inventive over and above ezetimibe as a mono-product.

Ezetimibe was first approved in Europe as a mono-product, and Merck obtained a first family of SPCs (SPC 1) based on the above basic patent and the mono-product approval. Subsequent to the grant of these SPCs, the combination of ezetimibe and simvastatin was separately approved, and Merck obtained a second family of SPCs (SPC 2) for this combination based on that approval and the same basic patent. The SPC 2 family was filed and, mostly, granted before Medeva and subsequent case law were decided by the CJEU.

Following expiry of the basic patent and the SPC 1 family, the generic pharmaceutical manufacturer Clonmel began to market a combination ezetimibe / simvastatin product. Merck sued them for infringement of the patent and SPC 2 family, and Clonmel counter-claimed for revocation of the SPC 2 family.

It was not in dispute that both ezetimibe and simvastatin were "specifically identified" in the basic patent and therefore test 2 was met. However, Clonmel argued that SPC 2 was invalid on two grounds. First, they argued that test 3 was not met and SPC 2 therefore did not comply with Article 3(a). Second, they argued that the grant of SPC 1 before SPC 2 was filed precluded the grant of SPC 2 under Article 3(c), which requires that the approved product not already be the subject of an SPC.

Merck counter-argued that the "inventive advance" approach had been specifically rejected by the CJEU in Royalty Pharma, and therefore test 3 was no longer required to be met for the patent to be eligible for SPC protection under Article 3(a). However, the Irish High Court favoured Clonmel's arguments in finding SPC 2 invalid under both Articles 3(a) and 3(c), and the Irish Court of Appeal agreed.

Differing decisions were reached in parallel litigation in courts across Europe. The Belgian, Portuguese and Czech courts found SPC 2 valid. In Italy, although a decision has not yet been reached by the court, the majority of expert opinions advising the court have also considered it valid. However, the French courts found SPC 2 invalid under both Articles 3(a) and 3(c), and the German and Spanish courts found it invalid under Article 3(c) without reaching a decision under Article 3(a).

Questions referred to CJEU

In view of the uncertainty in the current case law and the widely differing views of European courts, the Irish Supreme Court decided to refer the matter to the CJEU. The questions raised were as follows:

"1.(a) For the purpose of the grant of an SPC, and for the validity of that SPC in law, under Article 3(a) of [the SPC Regulation], does it suffice that the product for which the SPC is granted is expressly identified in the patent claims, and covered by it; or is it necessary for the grant of an SPC that the patent holder, who has been granted a marketing authorisation, also demonstrate novelty or inventiveness or that the product falls within a narrower concept described as the invention covered by the patent?

1.(b) If the latter, the invention covered by the patent, what must be established by the patent holder and marketing authorisation holder to obtain a valid SPC?

2. Where, as in this case, the patent is for a particular drug, ezetimibe, and the claims in the patent teach that the application in human medicine may be for the use of that drug alone or in combination with another drug, here, simvastatin, a drug in the public domain, can an SPC be granted under Article 3(a) of the Regulation only for a product comprising ezetimibe, a monotherapy, or can an SPC also be granted for any or all of the combination products identified in the claims in the patent?

3. Where a monotherapy, drug A, in this case ezetimibe, is granted an SPC, or any combination therapy is first granted an SPC for drugs A and B as a combination therapy, which are part of the claims in the patent, though only drug A is itself novel and thus patented, with other drugs being already known or in the public domain; is the grant of an SPC limited to the first marketing of either that monotherapy of drug A or that first combination therapy granted an SPC, A+B, so that, following that first grant, there cannot be a second or third grant of an SPC for the monotherapy or any combination therapy apart from that first combination granted an SPC?

4. If the claims of a patent cover both a single novel molecule and a combination of that molecule with an existing and known drug, perhaps in the public domain, or several such claims for a combination, does Article 3(c) of the Regulation limit the grant of an SPC;
(a) only to the single molecule if marketed as a product;
(b) the first marketing of a product covered by the patent whether this is the monotherapy of the drug covered by the basic patent in force or the first combination therapy, or
(c) either (a) or (b) at the election of the patentee irrespective of the date of market authorisation?
And if any of the above, why?"

The answers to questions 1 and 2 will likely decide the Article 3(a) issue in this litigation, and hopefully provide some clarity about whether test 3 is still relevant for determining compliance with Article 3(a). Questions 3 and 4 will likely decide the Article 3(c) issue.

The CJEU registry has entered this case onto its records as C-149/22, and the court will likely decide the case some time in 2023. After over a decade of uncertainty, can the court finally end its opaqueness on these issues and provide a clear ruling on SPC eligibility that both the research-based and generic pharmaceutical industries have been crying out for?

Of course, following Brexit, the UK courts are not bound by new decisions of the CJEU, and the UK Court of Appeal and UK Supreme Court are free to depart from existing CJEU case law. However, we expect that, at least for now, the UK courts will continue to follow SPC case law generated by the CJEU, and the outcome of the present referral therefore remains relevant to the UK, as well as to the rest of Europe.

Author:
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Divisionals from a PCT (UK) patent application Beware the lurking compliance date!

In the context of an international PCT patent application, one of its primary benefits is that it essentially allows the cost of obtaining patent protection in multiple territories around the world (including the territory of the UK, which is a territory that can be designated in a PCT patent application), to be extended from around 12 months after, to around 30/31 months after (depending on the territory), the date when any first, priority, patent application relating to the PCT patent application was applied for.

In so far as protection in the UK is ultimately sought from a PCT patent application, through making an appropriate request before the UK Intellectual Property Office (UKIPO) within 31 months of the earliest priority date from the PCT patent application, this UK patent application will then be subjected to examination by the UKIPO, which is the entity responsible for handling UK patent applications, to determine whether the application is allowable.

For any UK patent application, including those pursued via the above PCT route, the application must be in order for grant by a compliance date. This date is the later of 4.5 years from the earliest priority date of the application, or 12 months from the date when the first examination report is issued by the UKIPO in respect of the UK patent application. Particularly for UK patent applications pursued via the PCT route (often also called a PCT (UK) patent application), the compliance date is often set by the latter scenario, noting PCT (UK) applications are not typically examined very quickly after they are entered into the UK national phase, assuming they are pursued towards the end of the above 31 month period and without any form of acceleration.

It is to be noted that this same compliance date applies not just to the PCT (UK) application, but also to any divisionals, or cascaded/second-generation divisionals which ultimately stem from this first pursued PCT (UK) patent application. That being the case, and for a given PCT patent application, **all** UK patent applications stemming from this PCT patent application will usually be impacted by the same compliance date. It is possible to extend the compliance date for a given UK patent family by two months, but this extension of time may practically only provide so much assistance.

Consider divisional patent applications as soon as possible before the compliance date

So for those considering patent protection in the UK from a PCT patent application, and in so far as any divisionals may be contemplated, it is always worth considering pursuing such divisional patent applications **as soon as possible**, and not wait unduly until after the first examination report has been issued by the UKIPO, by which time there may only be less than 12 months for having any required UK divisional patent applications submitted; searched; examined; and allowed, before the compliance date for the UK patent family is reached.

Additionally, where a UK divisional patent application is contemplated, to avoid being pressed up against the compliance date, it can be helpful to consider whether accelerated examination may be of use, noting without such acceleration, this may mean that any examination reports from the UKIPO relating to such a divisional patent application may end up being issued proportionately close to the compliance date, thus leaving a relatively small amount of time to navigate the examination procedure of the application with the examiner.

In so far as accelerated examination is contemplated for a UK patent application, there is no official fee payable to the UKIPO to make such a request. That being said, a reason is required for the acceleration to be allowed - though the UKIPO is fairly pragmatic at allowing an acceleration request in so far as the provided reason is at least vaguely relevant and commercial. Indeed, valid reasons can often include:

1. needing the allowance of the UK patent application for its potential use as a base application for a subsequent PPH request relating to another patent application in another territory;

2. becoming aware of a potential infringement to which the UK patent application is relevant; or

3. allowance of the UK patent application being required for the purposes of securing investment related to the UK patent application.

For providing yet further time to navigate the examination procedure of a UK divisional patent application(s) which is ultimately pursued from a PCT patent application, early entry into the UK national phase may also be beneficial. In other words, rather than entering the UK national phase at the end of the above 31 month period,

pursuing earlier entry into the UK national phase may provide more time to navigate the examination procedure for all required divisional patent applications that might be contemplated, before the compliance date for the UK patent family is reached.

Noting the compliance date for UK national phase patent applications principally applies to **all** UK patent applications from the patent family, it can be seen that this compliance date may practically limit the extent to which cascading divisionals (that is, divisionals pursued from divisionals) can be pursued for a UK patent family. That being said, for particularly important patent applications relating to the UK, it is to be noted that European patent applications designating the UK (which are patent applications applied for at the European Patent Office, not the UKIPO) do **not** employ such a respective compliance date. Consequently for a European patent application, cascading divisionals are possible in principal. However, it is to be borne in mind that unlike a UK patent application where renewal fees are not payable before grant, European patent applications designating the UK require renewal fees to be paid each year whilst the European patent application remains pending. Furthermore, for European divisional patent applications, it is also necessary around the time of pursuing the divisional to pay **all** of the backdated renewal fees which would have been otherwise payable had the divisional patent application been pursued earlier on. This practicality can therefore make pursuing a European divisional patent application, particularly a cascaded divisional patent application, relatively expensive to pursue in comparison to a UK divisional patent application.

So for those contemplating divisional patent protection relating to the UK, it is always worth considering whether such protection should be sought sooner rather than later. Indeed, the compliance date waits for no-one!

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Germany / DPMA

National phase entry
Germany adopts 31-month time limit

Germany offers an outstanding system for IP protection – its patent and trade mark office (the DPMA) is the largest national IP office in Europe and fifth largest in the world.

Of 67,432 patent applications filed at the DPMA in 2019 and 62,105 patent applications filed in 2020, 7,507 (11.1 %) and 7525 (12.1 %), respectively, were national phases of international (Patent Cooperation Treaty - PCT) patent applications. Of these national phase applications, 6,406 (85.3 %) in 2019 and 6354 (84.4 %) were filed for applicants from abroad (according to the DPMA Annual Report 2020).

For many years, the (non-extendable) time limit for entering the national phase at the DPMA was 30 months from the relevant date (that is, the international filing date or, in case that priority is claimed, the earliest priority date), irrespective of entering the national phase via Chapter I PCT with the DPMA acting as designated office, or via Chapter II PCT with the DPMA acting as elected office.

The Second Act on the Simplification and Modernization of Patent Act of 10 August 2021 has simplified and modernised the Patent Act and other laws in the field of industrial property protection, including Article III of the Act on International Patent Conventions (the IntPatÜbkG), relating to proceedings under the PCT.

> From 01 May 2022 onwards, the time limit for entering the national phase at the DPMA is 31 months from the relevant date.

The DPMA intends to apply the amended provisions to all PCT applications for which the previously applicable 30-month time limit has not already expired before 01 May 2022 (source, Notice No. 3/2022 of the President). Having said that, for PCT applications for which the previously applicable 30-month time limit expires on Saturday, 30 April 2022, the time limit for entering the national phase at the DPMA extends automatically to the next working day, which will be Monday, 02 May 2022 (Section 193 German Civil Code).

New time limit from 01 May 2022

Thus, for entry of the national phase at the DPMA, the same 31-month time limit applies as for entry of the regional phase at the European Patent Office (EPO) and entry of the national phase at the UK Intellectual Property Office (UKIPO).

The longer, harmonised time limit not only provides for more time of decision-making, but also reduces haste and waste. Especially applicants from abroad, whose national phase applications very often require certified or authorised German translations of the corresponding PCT publications, can benefit from the longer time limit.

Moreover, with reference to imminent developments regarding European patents and European patent with unitary effect (unitary patents), Germany's adoption of the 31-month time limit for national phase entry may provide applicants with additional leeway.

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Useful links
DPMA Annual Report 2020 (PDF download):
https://dycip.com/dpma-ar2020

And finally...

UP & UPC

UPC preparations
Five actions to take now

After several false-starts, the biggest change in the European patent landscape, namely the introduction of a unitary patent (UP) and launch of the Unified Patent Court (UPC), is looking like a real possibility in 2022 or early 2023. There are a few key actions that patent owners can carry out over the next few months:

1. **Conduct a European patent and SPC audit to have full visibility of your portfolio, including "who owns what".** This is critical for validly filing any opt-outs. An assumption is made that the patent owner indicated on the European or National Patent Registers is the "true" proprietor. It may therefore be prudent to update the European/National Patent Registers in advance of the sunrise period.

2. **Consider opt-out options and your strategy to enable decisions to be made for the sunrise and transitional periods.** This may include filing one or more divisional applications, if there is a European patent application pending, so that a single patent family can include "opted-out" and "opted-in" European patent rights. A divisional patent is treated as an independent right and does not need to "follow" the parent patent. The decision of whether to opt-out is likely to be case dependent.

3. **Discuss and agree your patenting and opt-out strategy with all co-owners of any patents and SPC holder(s).** Explicit consent from all co-owners and SPC holder(s) is required for a validly filed opt-out. It is not possible to divide a European patent between co-owners or for any SPC to be subject to the jurisdiction of the UPC when the patent on which it is based is opted-out, and *vice versa*.

4. **Monitor competitor or third-party patents to understand patenting v opt-out strategy.** It may be possible to deduce from competitor activity which patents are considered business-critical and therefore opted-out of the UPC. The filing of any divisional applications(s) may also be informative.

5. **Review patent and SPC licences and agreements for UPC/UP clauses.** Such clauses could, for example, address whether the patent and SPC will be opted-out, whether unitary effect will be requested once a European patent application grants, whether the licensee is able to bring an action in the UPC or a national court, and the arrangements if a third party approaches a licensee for acknowledgement of a non-infringing act.

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