D YOUNG & CO PATENT NEWSLETTER no.77

June 2020
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Editorial

Writing this newsletter during the current Covid-19 pandemic we are mindful that many of our readers will be personally affected by the crisis - our sympathies are with you and also our best wishes to keep safe and well. We applaud our clients who are rapidly innovating solutions to fight the virus and are grateful to those on the frontline working to protect us and our families. Details of our current work processes can be found at: www.dyoung.com/covid-19-service.

Editor:
Anthony Albutt

News

June 2020

IAM Patent 1000

We are delighted to be again ranked as "highly recommended" (top tier) for UK patent services in the annual review of The World's Leading Patent Professionals by IAM Patent 1000 and as gold (top tier) in the IAM Patent European Patent Office directory. IAM Patent 1000 writes that D Young & Co is a "strong, consistent performer" in a plethora of technical fields. The EPO is like a second home to its practitioners".

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Events

Wednesday 08 July 2020

European biotech patent case law

European patent attorneys Catherine Keetch and Simon O'Brien present this ever popular update on new and important EPO biotechnology patent case law. The webinar will run at 9am, noon and 5pm for our international clients in Asia, Europe and the Americas. Register to secure your webinar seat at: https://dycip.com/biotechwebinar-jul20.

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G 3/19
Plants produced by essentially biological processes are excluded from patentability

The Enlarged Board of Appeal has handed down its decision regarding the allowability of product and product-by-process claims in which the product is exclusively obtained by an essentially biological process.

The main judgment is as follows: "Taking into account developments after decisions G 2/12 and G 2/13 of the Enlarged Board of Appeal, the exception to patentability of essentially biological processes for the production of plants or animals in Article 53(b) EPC has a negative effect on the allowability of product claims and product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process features define an essentially biological process".

Whilst this is not a favourable outcome for applicants, there is some positive news as the Enlarged Board of Appeal also decided that: "This negative effective does not apply to European patents granted before 1 July 2017 and European patent applications which were filed before that date and are still pending."

The reason for this distinction is that the Enlarged Board of Appeal's current decision to change its previous interpretation of Article 53(b) EPC was based on new Rule 28(2) EPC, which came into force on this date.

Previous interpretations of Article 53(b) EPC

The Enlarged Board of Appeal has provided interpretations of Article 53(b) EPC on a number of previous occasions (see G 1/98, G 2/07 & G 1/08, G 2/12 and G 2/13).

Article 53(b) EPC itself states: "European patents shall not be granted in respect of:…plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof…"

Following G 2/12 and G 2/13, it appeared that the Enlarged Board of Appeal had provided a comprehensive analysis of Article 53(b) EPC. Notably, in G 2/12 and G 2/13 it explicitly held that Article 53(b) EPC did not negatively impact the allowability of product claims directly obtained or defined by an essentially biological process.

However, these decisions faced criticism from a range of groups - including lobbying groups and certain national governments - who considered that the extent of patent protection available in this field should be limited.

The European Commission (EC) subsequently adopted a notice on certain articles of the Biotech Directive (Notice 2016/C 411/03). In this notice, it was considered that in trying to assess the intentions of the EU legislator when adopting the Biotech Directive, the relevant preparatory work to be taken into consideration was not the work that preceded the signature of the European Patent Convention (EPC) in 1973, but the work relating to the adoption of the Biotech Directive.

The EC concluded that the legislator's intention when adopting the Biotech Directive was to exclude from patentability products obtained by means of essentially biological processes. Accordingly, the EC considered that the rulings in G2/12 and G2/13 to allow claims to products obtained from an essentially biological process were contrary to the intentions of the Biotech Directive.

As a result of the EC's notice, on 01 July 2017 the EPO's Administrative Council issued Decision (CA/D 6/17) to add Rule 28(2) EPC, which states: "Under Article 53(b), European patents shall not be granted in respect of plants or animals exclusively obtained by means of an essentially biological process."

This caused a direct conflict between the Enlarged Board of Appeal's interpretation of Article 53(b) EPC in G 2/12 and G 2/13, and the revised Implementing Regulations for Article 53(b) EPC provided by new Rule 28(2) EPC.

Following this, the Technical Board of Appeal in T 1063/18 held that Rule 28(2) EPC was not relevant for the interpretation of Article 53(b) EPC, and applied the Enlarged Board of Appeal's interpretation from G 2/12 and G 2/13 to allow a claim directed to a product

Related event

Our European Biotech Patent Case Law webinar will run at 9am, noon and 5pm on Wednesday 08 July 2020, presented by European patent attorneys Catherine Keetch and Simon O'Brien from our biotechnology, chemistry & pharmaceuticals team. For more information and to register, please visit: https://dycip.com/biotechwebinar-jul20

G 3/19 concerns product-by-process claims

obtained from an essentially biological process.

Summary of the present decision

Both the Administrative Council's amendment to Rule 28 EPC, and the Technical Board of Appeal's subsequent decision disregarding the amendment, caused controversy.

In April 2019, the EPO President made the present referral to the Enlarged Board of Appeal containing the following questions:

> "**1.** Having regard to Article 164(2) EPC, can the meaning and scope of Article 53 EPC be clarified in the Implementing Regulations to the EPC without this clarification being a priori limited by the interpretation of said Article given in an earlier decision of the Boards of Appeal or the Enlarged Board of Appeal?
>
> **2.** If the answer to question 1 is yes, is the exclusion from patentability of plants and animals exclusively obtained by means of an essentially biological process pursuant to Rule 28(2) EPC in conformity with Article 53(b) EPC which neither explicitly excludes nor explicitly allows said subject-matter?"

There were questions as to the admissibility of the referral. Under Article 112 EPC, the EPO President is only permitted to refer a point of law to the Enlarged Board of Appeal where two Technical Boards of Appeal have given different decisions on that question.

The Enlarged Board of Appeal deemed the referral admissible on the grounds that there was a fundamental point of law to be addressed because of the evident conflict between decision T 1063/18 and the regulatory intention underlying Rule 28(2) EPC. In addition, the Enlarged Board of Appeal determined that, in contrast to T 1063/18, there were other decisions of the Technical Board of Appeal which could be read as acknowledging that a subordinate but later provision of the Implementing Regulations can have an impact on the interpretation of a higher-ranking, previously enacted provision of the EPC, irrespective of a particular interpretation given to the latter in an earlier decision by a Board of Appeal (see T 272/95, T 666/05 and T 1213/05).

The Enlarged Board of Appeal did however, rephrase the referred questions, at least in part because it considered the phrasing of question 1 to be too general and unspecific in that it was deemed to broach an institutional topic which reaches well beyond the ultimate object of the referral.

The Enlarged Board of Appeal rephrased the referral as the following single question: "Taking into account developments that occurred after a decision by the Enlarged Board of Appeal giving an interpretation of the scope of the exception to patentability of essentially biological processes for the production of plants or animals in Article 53(b) EPC, could this exception have a negative effect on the allowability of product claims or product-by-process claims directed to plants, plant material or animals, if the claimed product is exclusively obtained by means of an essentially biological process or if the claimed process feature define an essentially biological process?"

It thus appears that the Enlarged Board of Appeal attempted to cast the question such that it was specific to the wording of Article 53(b) EPC.

Once the referral was deemed admissible and the question rephrased, the reasoning underlying the new interpretation is short and concise. The Enlarged Board of Appeal endorsed its previous interpretation in G 2/12 and G 2/13 based on the facts that were available at that time, but acknowledged that the legal and factual situation has changed because of new Rule 28(2) EPC: "the Enlarged Board recognises that, with the introduction of Rule 28(2) EPC, the legal and factual situation underlying decision G 2/12 (supra) has substantially changed. This amendment constitutes a new aspect or consideration which has arisen since the EPC was signed which **may give reason to believe that a grammatical, and restrictive, interpretation of the wording of Article 53(b) EPC conflicts with the legislator's aims, whereas a dynamic interpretation may bring a result that diverges from the wording of the law**."

In view of new Rule 28(2) EPC, the Enlarged Board of Appeal concluded that Article 53(b) EPC should be interpreted to exclude product claims directly obtained and/or defined by an essentially biological process.

As noted at the beginning of this article, in order to protect the legitimate expectations of applicants prior to the amendment to Rule 28 EPC, the new interpretation only applies to patents and applications with an effective filing date after 01 July 2017.

The situation following G 3/19

G 3/19 results in a bifurcated system, whereby patent applications with a priority date before 01 July 2017 can include claims directed to a product or product-by-process which is directly obtained or defined by an essentially biological process; but applications with a priority date after 01 July 2017 cannot.

An important consideration will be to ensure that the correct interpretation of Article 53(b) EPC is applied to applications and patents in proceedings before the EPO. Further details on practice points in this area may be found in the EPO's Guidelines for Examination; Part G-II; 5.4.

Authors:
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Digital documents and signatures
European patent practice

Related article
For more information regarding electronic signatures and remote execution of documents generally, please refer to our recent article: https://dycip.com/electronic-signatures

With large numbers of patent attorneys and clients working remotely across the globe, the ability to substitute handwritten signatures and original documents with electronic equivalents has been a concern of many. In this article, we discuss the electronic filing of documents and digital signatures in European patent practice.

Electronic filing of documents

All documents other than priority documents may be filed with the European Patent Office (EPO) electronically using the different EPO online filing platforms – the Online Filing software, Case Management System (CMS) and web-form filing. However, authorisations may only be filed using the Online Filing software or CMS.

Documents may also be filed with the UK Intellectual Property Office (UKIPO) electronically via its website, or using the EPO's Online Filing software.

Under European patent practice, all documents filed with the EPO apart from annexes must be signed by the applicant or their representative. If the signature is missing, or if the document is signed by an unentitled person, the EPO will issue an invitation to sign the document within a specified time limit. If the time limit is met, the document retains its original filing date. For patent applications, if the time limit is not met but the signature is received before preparations are made for publication, the application will still retain its original filing date. Otherwise, the application is refused, or subsequently filed documents are considered to have not been received. Similarly, the UKIPO will issue an invitation to sign the request for grant, if the signature is missing.

Accepted forms of signature

When documents are filed electronically, the EPO and UKIPO accept three different types of signature:

- Facsimile signature, which is an image reproduction of the handwritten signature;
- Text string signature, which is a string of characters between two forward slashes, for example, /D Young/; and
- For representatives only, enhanced electronic signature confirmed with digital certificates accepted by the patent office, for example, electronic signatures created using an EPO smart card.
- Initials or other abbreviated forms will not be accepted as a signature.

The UKIPO and EPO accept three types of signature with electronic filings

Assignments

Transfer of ownership of a patent/application may be recorded on the registers of the EPO and the UKIPO. As discussed in our previous article here, when recording a transfer of ownership with the EPO, evidence of the transfer must be provided in the form of a written document, and this must be signed by all parties. An indication of each signatory's entitlement to sign must also be provided. When any party is an organisation, proof of the entitlement to sign is required for any signatory who is not a director, president or CEO of the organisation. The EPO does not require original or copies of the assignment documents, and the signatures do not need to be witnessed or notarized. Therefore, the parties may separately sign counterparts of confirmatory assignment documents.

The UKIPO does not require evidence of a transfer when the application for registering the transfer is signed by the assignor or their representative.

If transfer of a European patent is anticipated, we recommend registering it with the EPO before grant, as some national patent offices require assignment documents to be notarized.

Powers of attorney

A number of European patent offices require applicants/patentees to file a power of attorney authorising their representative to act on their behalf in proceedings before the patent office. In our experience, scanned copies of these authorisations may be accepted in the short term, but usually original copies are ultimately required.

The EPO and UKIPO only require registered European or UK patent attorneys to file a power of attorney in limited circumstances. However, if the EPO does require a power of attorney to be filed, it must be signed by the applicant/patentee.

Emails

Emails are not considered a formal method of communicating with the EPO, and cannot normally be used to carry out procedural acts. However, documents may be filed by email during oral proceedings or interviews with the EPO that are held by video conference. This includes oral proceedings before opposition divisions, for example those being carried out in the EPO's pilot program that commenced on 04 May 2020. When emailed documents require a signature, it may be applied to the document itself, or otherwise included in the text of the accompanying email.

The UKIPO accepts emails for particular acts such as filing observations, post-grant amendments, withdrawing patent applications and requesting extensions, whereas some other acts (including filing amendments and requests for acceleration) are not normally accepted by email. However, as a replacement to the UKIPO's currently unavailable fax service, documents may be emailed to paperformcontingency@ipo.gov.uk.

Author:
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Coronavirus
European IP offices change practices

In response to the new coronavirus disease (Covid-19) outbreak, intellectual property offices in Europe have implemented special measures to offer some level of flexibility to rights holders whilst Europe is working under new and uncertain conditions. Whilst this flexibility is welcomed, we will continue to work to original deadlines.

We are regularly updating this information and will publish the latest news at:
https://dycip.com/covid-19-ip-offices

European Patent Office (EPO)

The EPO's blanket provisions for extending deadlines in response to Covid-19 ended on 02 June 2020. Requests for missed deadlines to be excused will now be considered on a case-by-case basis in accordance with the EPO's normal provisions for excusing missed deadlines due to circumstances beyond the applicant's control.

The EPO has also postponed oral proceedings before the opposition divisions that are scheduled until 14 September 2020 (previously until 02 June 2020) unless already confirmed to take place by videoconference or the parties agree for them to be held by videoconference. The EPO intends to maintain oral proceedings in opposition which have been scheduled to take place on the premises of the EPO on or after 15 September 2020. Oral proceedings before the examination divisions will continue to be held by videoconference in accordance with the EPO's previous notice. This means for summons issued from 02 April 2020, oral proceedings before the examination divisions will be by videoconference unless there are serious reasons for holding them in person. For summons issued before 02 April 2020, oral proceedings before the examination divisions will be held by videoconference if this was already confirmed or if the applicant subsequently agrees for them to be held by videoconference.

The Boards of Appeal resumed the holding of oral proceedings, to a limited extent, from Monday 18 May 2020. Parties will be contacted accordingly by communication and will be requested to confirm whether they are able to attend in person and that they do not anticipate being affected by travel restrictions. Video conferencing is now available for the conduct of oral proceedings before the Boards of Appeal, in agreement with the parties concerned, who will be sent an advanced communication in this regard.

UK Intellectual Property Office (UKIPO)

The UKIPO has declared 24 March 2020, and subsequent days until 29 July 2020, to be interrupted days.

Any deadlines and applications for patents, supplementary protection certificates, trade marks and designs which fall on an interrupted day will be extended until 30 July 2020. This decision applies to all statutory time periods set out in UK legislation, and to all non-statutory periods set by the UKIPO. This decision does not apply to time periods set out under the various international IP treaties, such as the Patent Cooperation Treaty, European Patent Convention, or the Madrid system, where the UKIPO may be acting as a Receiving Office.

The first normal day of operation when all interrupted days deadlines expire will be 30 July 2020. All deadlines falling after 30 July 2020 will be treated as usual.

The German Patent and Trade Mark Office (DPMA)

During March 2020 the DPMA automatically extended all time limits to 04 May 2020. Separate notifications about the amended deadline expiry dates were not issued. The DPMA has not issued any further automatic extensions and further extensions are not expected to be issued at this time.

The World Intellectual Property Organization (WIPO)

The majority of WIPO staff have been working remotely since 17 March 2020. To date, unlike the EPO, no blanket extensions of time have yet been issued by WIPO.

Remote working
We're EPO VICO ready!

Building on our experience with video conference oral proceedings, we are able to confirm that following extensive testing with the European Patent Office (EPO), our attorneys and solicitors are able to conduct all proceedings remotely using video conferencing (VICO) systems.

Videoconferencing at the EPO

All of our qualified staff and partners have access to our videoconferencing system which interfaces well with the EPO's own system. We can conduct telephone interviews, oral proceedings before the examining divisions and opposition divisions, and also hearings before the Boards of Appeal.

Our internal IT infrastructure team, working with our practice committee, have devised internal procedures and processes which allow us to replicate the normal channels of communication between D Young & Co and EPO officials, and also to create separate and confidential communication channels between our attorneys, solicitors and clients, who will also be remote and possibly in different time zones.

Our litigation team has already conducted remote hearings at the High Court, with more listed soon in the UKIPO, IPEC and County Court, putting us at the forefront in the 'new normal' of virtual courtrooms and tribunals.

We are pleased with the reliability of our procedures which are already allowing us to conduct hearings successfully for our clients under the new regime - a regime that is likely to remain in place.

More to follow on this subject in our next (August) newsletter.

Author:
Anthony Albutt

Please specify me! CJEU tightens the net on SPC eligibility

The Court of Justice of the European Union (CJEU) has once again tightened the criteria on what types of patents for authorised pharmaceutical products can be extended by means of supplementary protection certificates (SPCs). This decision could have wide repercussions for many SPCs, both existing and in the future, and may cause innovator pharmaceutical companies to re-think their entire SPC strategy in Europe.

Background

It is common that a number of patents are filed and issued during the pharmaceutical research cycle. For example, early-stage research may identify a biological target which must be acted upon in order for a drug to treat the disease of interest. In addition to patenting the target itself, the innovator may look to claim compounds defined in a functional manner to act against this target, even before any such compounds have actually been made or tested.

Once the research cycle moves to the next step of making and testing the compounds, a patent application is typically filed claiming these compounds by means of a broad general formula (a so-called "genus" claim). However, it is sometimes the case that the specific compound which turns out to be the most suitable for development as a pharmaceutical only emerges from research carried out after the genus patent application is filed.

The combined effect of the above is that the same compound which is ultimately approved may fall under more than one patent. In addition to being disclosed and claimed specifically (a species claim) in a later-filed patent application, it may fall under the functional definition of the earlier target patent, as well as within the general formula of the genus patent, without being specifically disclosed in either. Sometimes, the species is never itself patented (as selection patents directed to the species are sometimes difficult to obtain) and the innovator is forced to rely purely on functional and/or genus claims to cover an approved product.

Article 3(c) of the EU medicinal products SPC Regulation (469/2009) permits only one SPC to be granted to each patent holder for a particular authorised product. Therefore, when the patent holder is faced with a choice of patents on which to base SPC protection (the basic patent), this can often be a tricky decision in which a number of competing factors must be balanced, including the strength and scope of the basic patent, the potential expiry date of the SPC, and the eligibility of the basic patent for SPC protection. It is the last of these issues which has been the subject of controversy in the EU for almost a decade.

Prior SPC case law – the specified test emerges

Article 3(a) of the SPC Regulation requires that, to be entitled to an SPC, the authorised product must be "protected" by a basic patent in force. There is general consensus among European SPC practitioners that this is not simply a matter of whether the product falls within the claims of the basic patent (the infringement test), but considerable uncertainty remains about what additional criteria must be satisfied.

The CJEU's decision in Medeva (C-322/10) introduced into EU law the concept that the authorised product must be "specified" in the basic patent, in order for that patent to "protect" the product for the purposes of Article 3(a). However, despite many further referrals to the CJEU on this point, the court has repeatedly declined to give a clear answer on exactly what degree of "specificity" is required for the patent to be eligible for an SPC under Article 3(a).

In particular, to date the CJEU has provided no guidance as to whether the specified test of Article 3(a) allows a patent which covers an authorised product via a functional claim, or a genus claim, but does not specifically disclose the product, to "protect" the product for SPC purposes.

C-650/17 - the facts

The SPC which was the subject of the case is based on European patent no. EP1084705. This patent was based on early-stage research into inhibitors of the enzyme dipeptidyl peptidase IV (DPPIV), which were found to reduce blood sugar levels. The patent therefore claimed the use of DPPIV inhibitors, in a functional manner, to reduce blood glucose levels. However, it did not disclose or claim any specific DPPIV inhibitors. Following a number of assignments, the patent was granted to Royalty Pharma Collection Trust.

After this patent application was filed, a number of specific DPPIV inhibitors (gliptins) were developed and ultimately received marketing authorization (MA). Sitagliptin is one of these DPPIV inhibitors: it is sold as Januvia® by Merck. Sitagliptin specifically was also the subject of a later patent, which itself was extended by an SPC following issuance of the MA.

Royalty Pharma filed an SPC application for sitagliptin with the German Patent and Trade Mark Office (DPMA), on the basis of EP1084705 and Merck's MA for Januvia®. They also filed a number of other similar SPC applications for other gliptins when these received MAs in the EU.

The DPMA refused the SPC application on the grounds that Article 3(a) was not met. Although acknowledging that sitagliptin met the functional definition of the DPPIV inhibitor in the patent, the DPMA held that, as the patent does not contain any specific disclosure of this product, the authorised product had not been provided to the skilled person. Based on this, the DPMA considered the grant of an SPC would be contrary to the objectives of the SPC Regulation.

Royalty Pharma appealed this decision to the German Federal Patent Court (Bundespatentgericht – BPatG), arguing the fact that the functional definition is met by sitagliptin should be sufficient for Article 3(a) to be met. It noted that other countries, including the UK, had granted corresponding SPCs. The BPatG referred the matter to the CJEU, asking the following three questions:

1. Is a product "protected" by a basic patent in force pursuant to Article 3(a) [of the SPC Regulation] only if it forms part of the subject matter of protection defined by the claims and is thus provided to

Related webinar

Our January 2020 SPC webinar is now available on demand and covered key SPC case law including Teva v Gilead - C-121/17 and the UK court's interpretation, C-650/17 and C-114/18 (how specific must you be?), C-239/19 (third party SPCs) and SPCs and Brexit. Email us at registrations@dyoung.com for access details.

Related event

Our European Biotech Patent Case Law webinar will run at 9am, noon and 5pm on Wednesday 08 July 2020, presented by European patent attorneys Catherine Keetch and Simon O'Brien from our biotechnology, chemistry & pharmaceuticals team. For more information and to register, please visit: https://dycip.com/biotechwebinar-jul20

Royalty Pharma filed SPC applications for a number of DPPIV inhibitors (gliptins)

the expert as a specific embodiment?

2. Is it not therefore sufficient for the requirements of Article 3(a) if the product in question satisfies the general functional definition of a class of active ingredients in the claims, but is not otherwise indicated in individualised form as a specific embodiment of the method protected by the basic patent?

3. Is a product not protected by a basic patent in force under Article 3(a) if it is covered by the functional definition in the claims, but was developed only after the filing date of the basic patent as a result of an independent inventive step?

The CJEU's decision

In reaching its decision, the CJEU referred to its earlier decision in Teva v Gilead (C-121/17). In that case, relating to a combination drug, the CJEU ruled that Article 3(a) was complied with if the following two tests were met:

(1) 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

(2) 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.

The CJEU applied the same test to the present case, thereby confirming that it applies to mono-product SPCs as well as those for combination products.

In the present case the CJEU considered that test (1) was met: as sitagliptin met the functional definition of the patent, it fell under the invention covered by the patent. However, the CJEU was doubtful whether test (2) was met at the priority date of the patent given that sitagliptin was not individualized as a specific embodiment in the patent.

The CJEU reasoned that, even when the product which is the subject of the SPC application is not individualised as a specific embodiment within the teaching of the basic patent, the granting of an SPC based on this patent is, in principle, not excluded. However, in this particular case, the CJEU reasoned the skilled person must be able, at the filing or priority date, to infer directly and unambiguously from the specification of the patent as filed that the product for which SPC protection is sought falls within the scope of the protection of this patent.

Based on this, the CJEU answered questions 1 and 2 as meaning that a product is "protected" for the purpose of Article 3(a) if it meets a functional definition in the claims of the basic patent, without being individualised as a concrete embodiment to be learned from the teaching of said patent, provided that it is specifically identifiable, in the light of all the elements disclosed by the same patent, by the skilled person, on the basis of their general knowledge in the field as of the filing or priority date of the basic patent.

In answering question 3, the CJEU reasoned that if the results of research carried out after the filing or priority date of the patent could be taken into account for the purpose of SPC eligibility, such an SPC could allow its holder to unduly benefit from protection for these results, even though these were not known at the filing or priority date. The CJEU considered this would be contrary to the objective of the SPC Regulation, as such an SPC would not relate to the results of the research claimed under the patent.

Based on this, the CJEU ruled that, if the product was developed after the filing or priority date of the basic patent, following an independent inventive step, that product is not "protected" by the basic patent and Article 3(a) is not met.

Impact of the decision

It is regrettable that, yet again, the CJEU declined to give a clear answer on exactly what degree of "specificity" was required for the "specifically identifiable" test of Article 3(a) to be complied with, considering this was a matter for the referring court. It is notable, however, that the Court has now dispensed with the "core inventive advance" test developed in prior case law, considering it irrelevant as regards whether the basic patent "protects" the product under Article 3(a).

The CJEU's answer on question 3 could have significant repercussions far beyond this particular case. Its ruling could call into question the validity of any SPC based on a patent having a functional claim or a genus claim, but where the product is only specifically disclosed in a later patent application which exhibits an inventive step over the earlier application. This could include many existing SPCs based on functional or genus patents, where a later species patent exists.

This decision may prompt the innovator pharmaceutical industry to re-think their SPC strategy in Europe and pivot towards filing SPCs based on patents which define the product more specifically, even if those patents are considered less robust than earlier-filed genus patents. Our firm's SPC experts would be pleased to assist with development of this strategy.

Author:
Garreth Duncan

Unified Patent Court and unitary patent
End of the road or just another bump?

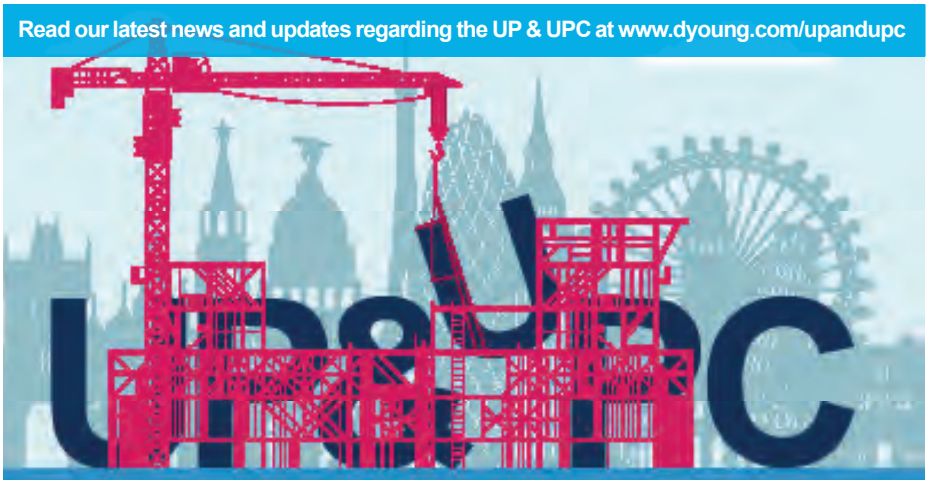
At the end of March 2020, EPO President Campinos pronounced strong support for the statement by the German Minister of Justice and Consumer Protection, Christine Lambrecht, of her intention to remedy the deficiencies in the legislative procedure which led to the German Federal Constitutional Court (FCC) declaring the agreement by the German Parliament (Bundestag) of the Unified Patent Court and the Unitary Patent (UPCA) to be void. So was that just another bump in the road for the UPCA?

The Unified Patent Court and the Unitary Patent Agreement (UPCA) was agreed in 2013 and enough countries had ratified the agreement for it to come into existence, that is, if Germany had ratified. Of course the concept of the UPCA is even older than the European Patent Convention; the UPCA being its latest incarnation.

Even after the Brexit vote in 2016, the UK Government under Prime Minister May ratified the UPCA in 2018, perhaps encouraged by a legal opinion obtained by the Chartered Institute of Patent Attorneys (CIPA) that the UPCA was an international treaty and therefore open to the UK after Brexit. Then came a complaint in 2017 filed by a private citizen to the German Federal Constitutional Court (FCC) that the vote in the Bundestag violated the constitutional rights of German citizens.

In March 2020 the FCC ruled partially in favour of the complaint that the vote in the Bundestag in 2016 for Germany to adopt the UPCA was unconstitutional and therefore void. The Bundestag requires a majority of two thirds of its members to adopt an Act affecting the constitutional rights of German citizens. According to the FCC, although those members of the Bundestag present at the time voted unanimously to adopt the UPCA, the formal requirement for a majority of two thirds of the members of the Bundestag had not been satisfied. However there is some nuance in respect of the analysis and the conclusion in reaching this decision by the FCC, which would appear to have wider ramifications.

Read our latest news and updates regarding the UP & UPC at www.dyoung.com/upandupc



In reaching this conclusion the FCC determined that the UPCA was only open to member states of the European Union because it establishes a common court of the contracting member states and therefore the UPCA confers powers from the member states to the court. It does not matter that not all member states of the EU have agreed the UPCA (Spain and a Poland did not agree), because the aim of the UPCA was to provide further EU integration and enhance the single market. As such, one conclusion of the FCC's reasoning is that the UK can no longer be a party to the UPC after Brexit, which seems contrary to the opinion obtained by CIPA.

In a further twist, on 08 June 2020, the Federal Ministry of Justice issued an invitation for comment on a draft bill of the UPCA Approval Act, which aims to repeat the vote in the Bundestag before September 2021. It also issued an explanatory note which appears to suggest that if Germany voted to adopt the UPCA, then the UPC would come into effect because currently the UK has ratified the UPCA, regardless of whether the UK later withdraws. It also suggested that, as a non-EU member, the UK could not host a division of the central court in London, and as a temporary measure the functions of that division would be adopted by the other central divisions in Paris and Munich.

The UK Government appears to have ended the UK's participation in the UPCA notwithstanding the UK's ratification.

However, is the UPCA even viable without the UK, being with Germany one of the industrial nations which has shaped IP law in Europe? The UK represents about 17% of the total GDP of the European Union, compared with France 14% and Germany 20% (these obviously vary). A typical European patent in the mechanical and electronics field designates Germany, France and the UK, which represents over 50% of the GDP and the population of the EU. The attraction of the UPCA is that it would be possible to obtain injunctive relief across all of the designated states of a European patent from a decision of one court, and with a unitary patent it would be possible to obtain an injunction across all member states. This could represent a value which would rival the mighty US patent. However, without the UK there is clearly a loss of value in any unitary patent. Furthermore losing in one court would be a loss in all states, which was part of the rationale for some companies to opt out of the UPC during the transitional period. With the UK not part of the UPCA, enforcement of a European patent with the above designations would require separate actions in the UK and UPC (for Germany and France) which would certainly lead to greater complexity and cost.

One thing is perhaps self-evident; the UPCA is more likely to be a success if the UK were to remain an active member.

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Time to be demanding
Getting additional value from the PCT patent application procedure

In the context of obtaining patent protection in a number of territories around the world, this is often achieved via the use of an international PCT patent application.

A PCT patent application must be applied for within 12 months of any first (priority) patent application made in respect of an invention. Once applied for, the PCT application then acts a single application from which any required national/regional patent applications can ultimately be pursued. The deadline for pursuing such national/regional patent applications, in most of the possible territories covered by the PCT procedure, is either 30 or 31 months from the underlying priority date of the PCT application. In essence therefore, one of the primary benefits of the PCT procedure is that it can effectively buy an additional 18 months of time before having to decide where to pursue any required patent protection (and incur the associated cost) overseas.

Aside from buying time, another procedural benefit of the PCT patent procedure is that it includes the provision of an accompanying international search report and written opinion (ISA-WO), which provides the owner of the PCT patent application with an initial indication on the potential allowability of the invention outlined in the PCT application.

Based on the results of this international search report, which is usually received no later than 18 months from the priority date of the PCT patent application, the owner of the PCT application can make a more informed decision on whether there is a commercial benefit in pursuing, and incurring the associated cost of, any required national/regional patent applications deriving from the PCT application - which invariably must be made by the 30/31 month deadlines.

An important consideration in respect of the above is that the international search report is ultimately made available for anyone to see. Importantly, this also includes the patent offices where any national/regional patent applications are pursued from the PCT patent application, which consequentially will often base their examination off the back of the contents of the international search report. That being the case, a negative international search report can complicate, and increase the cost of navigating, each of these national/regional patent examination procedures.

The demand procedure

Conscious of the above, an often overlooked and under used optional procedure in the PCT process is that of requesting international preliminary examination (also called filing a demand) in receipt of a negative international search report and written opinion. Pursuit of a demand, and the payment of corresponding official fees, allows the owner of the PCT patent application to respond to the findings of the negative search report, via the use of written arguments and optional corresponding changes/restrictions to the scope of the claims. If ultimately deemed persuasive, these submissions can then result in the issuance of a more positive written report concerning the allowability of the PCT application, which may result in a more simplified and reduced-cost examination procedure in respect of each pursued national/regional patent application at the end of the PCT procedure. That being the case, the short-term cost of pursuing a demand during the PCT procedure can result in longer term, and potentially more extensive, cost savings during the national/regional patent application stage, as a result of less substantive examination being potentially needed on each of such national/regional patent applications.

The European perspective

Particularly in the context of European patent applications deriving from the PCT application, and where the European Patent Office (EPO) was responsible for preparing the international search report, pursuing a demand effectively provides for a further round of written correspondence before the EPO in trying to convince them that the content of the PCT/European patent application is allowable. This additional round of written correspondence is particularly valuable now more than ever, noting the EPO's progressive shift towards providing fewer rounds of written correspondence before deciding on the allowability of a European patent application[1].

In this respect as well, if a demand is pursued in the PCT procedure where the EPO was responsible for preparing the international search report, the official examination fee payable on the European patent application deriving from the PCT patent application is also reduced by 75%, so making the demand procedure in such instances particularly cost effective.

Summary

If pursuing a PCT patent application and the results of the international search report are negative, and particularly where the EPO is responsible for preparing the international search report, do consider whether pursuing a demand might be worthwhile under the circumstances to try convert the report into something more positive. Indeed, doing so can often then place the PCT patent application in a much stronger position upon its entry into any required national/regional territories of interest, and can simplify the extent of any required examination.

Filing a demand in the PCT application process may be a cost-effective strategy

Notes

1. *The EPO's current performance metric is for the examination procedure of any given European patent application to be completed in just 12 months: https://dycip.com/epo-timeliness*

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G 4/19
Double patenting at the European Patent Office

The pending referral G 4/19, from the appeal of T 318/14, seeks answers from the Enlarged Board of Appeal regarding the issue of double patenting at the European Patent Office (EPO). G 4/19 is a referral to the Enlarged Board of Appeal under the provisions of Article 112(1) EPC, where an appeal board may refer a question, or set of questions, to the Enlarged Board of Appeal in order to ensure uniform application of the law (in the event of divergence of the case law) or where a point of law of fundamental importance arises.

As of yet, no decision has been received from the Enlarged Board of Appeal in G 4/19. In this article, we will take a look at both the underlying patent application and the appeal which led to this referral. Furthermore, we look at the current status of the referral and consider what we may learn from the Enlarged Board of Appeal's decision in G 4/19.

Double patenting

Double patenting in the context of this referral, considers a specific situation where there are two European applications directed to the same subject matter, having the same effective date and being filed by the same applicant (see point 21 of T 318/14). Moreover, the specific situation under consideration requires the two patents, or applications, to claim the same or identical subject matter; merely overlapping claim scope is not considered to be double patenting and is generally allowable at the EPO (see T 877/06 and G 2/10).

In this context, there are three situations where double patenting of the type considered in this referral may arise.

1. The first of these situations is where an applicant files two or more European patent applications on the same day, with those European Patent Applications being directed to the same subject matter.

2. The second of these situations is through the filing of divisional applications (where an applicant branches off one or more divisional applications from a parent European patent application). Divisional applications share the same effective date as their parent. As such, if the divisional applications are directed to the same subject matter as the parent, there will be double patenting.

3. Finally, the third of these situations is through an internal priority claim. This is where a first European patent application directed to certain subject matter is filed and, subsequently, a second European patent application is filed validly claiming priority from the first application. If the second European patent application is directed to the same subject matter as the first application, then there will be double patenting.

In each of these situations, it is noted that the prohibition on double patenting does not prevent the filing of the subsequent application to the same subject matter. Rather, double patenting is considered to prohibit the grant of a second patent to the same subject matter when a first patent to that subject matter has been granted (see point 13.4 of G 1/05 and G 1/06).

T 318/14

T 318/14 is an appeal against the refusal of an application by the examining division on the grounds of double patenting. The written decision to refer questions to the Enlarged Board of Appeal was issued in December 2019.

In the underlying application refused by the examining division, the applicant (Société des Produits Nestlé SA) sought protection for a composition for the treatment of allergic diarrhoea. However, the applicant had already received a granted patent at the EPO for this same subject matter, the granted patent originating from an application from which the application refused by the examining division claimed priority. Accordingly, the double patenting in this case arose by means of an internal priority claim (the third situation above).

Since these two applications shared the same effective date (owing to the priority claim) the later application could not be refused for lack of novelty (because the earlier application, from which priority was claimed, was not citeable as prior art). However, the examining division refused the grant of the later application on the grounds of double patenting.
As legal basis for the refusal, the examining division cited Article 97(2) EPC "in conjunction with Article 125 EPC" (see point 1 of T 318/14). The examining division also referred to previous decisions from the Enlarged Board of Appeal in the form of G 1/05 and G 1/06.

In G1/05 and G1/06, the Enlarged Board of Appeal noted that, "The Board accepts that the principle of prohibition of double patenting exists on the basis that an applicant has no legitimate interest in proceedings leading to the grant of a second patent for the same subject-matter if he already possesses one granted patent therefor" (see point 13.4 of G 1/05 and G 1/06).

In the appeal, the applicant (the appellant) argued that G 1/05 and G 1/06 were limited to the case of double patenting arising in a different situation (that is, from a divisional application) and not from an internal priority claim. Moreover, the appellant argued that it had been acknowledged in T 1423/07 that a legitimate interest exists in the specific situation of double patenting from an internal priority claim. Specifically, double patenting arising from an internal priority claim offers an applicant a 21 year term of protection for certain subject-matter (beyond the maximum 20 year term specified in Article 63(1) EPC for a single patent) as the term of protection is determined based on the date of filing and not the date of priority.

The Board of Appeal considered these arguments in detail in the written decision of referral dated December 2019 (the questions already being announced during the oral proceedings of February 2019). The Board of Appeal noted that the principle of a prohibition on double patenting set out in G 1/05 and G 1/06, while made in the context of answering questions on divisional applications, appeared to apply more generally to double patenting arising by other means, such as from an internal priority claim (see point 11 of T 318/14).

Furthermore, the Board of Appeal acknowledged that, in T 1423/07, it had been held that the longer term of protection possibly available to an applicant, owing to double patenting arising from an internal priority claim,

Two patents filed by the same applicant, with the same subject matter and effective date

constituted a legitimate interest. However during an analysis of the case law, the Board of Appeal noted that T 2461/10 appeared to raise doubts about the legal consequence of T 1423/07, particularly in view of the wording and intention of Article 63(1) EPC (see point 14 of T 2461/10). As such, in view of the divergence in the case law, the Board of Appeal decided that a decision on the appeal could not be reached until a referral had been made to the Enlarged Board of Appeal (see point 14 and point 15 of T 318/14).

Finally, the Board of Appeal reviewed the legal basis for double patenting in the EPC more generally, and noted that there does not appear to be any express legal basis in the EPC which prohibits double patenting of this kind (see point 78 of T 318/14).

In particular, the Board of Appeal noted that the Guidelines for Examination (G-IV-5.4) appeared to imply that Article 125 EPC provides legal basis for the prohibition on double patenting (with the Guidelines for Examination citing also G 1/05 and G 1/06 in this context). However, in view of an analysis of the case law and the legislative history of Article 125 EPC, the Board of Appeal considered that it was questionable whether Article 125 EPC was appropriate as a legal basis for a prohibition on double patenting. In fact, the Board of Appeal stated that Article 125 EPC could not serve to introduce a new condition for patentability or a ground for refusal (see points 63 and 64 of T 318/14).

Furthermore, on the apparent gap in the EPC regarding double patenting of this kind, the Board of Appeal noted that reasonable doubt existed regarding the legislator's intention in respect of double patenting and considered that it may be necessary for the Boards of Appeal to refrain from filling any perceived gap in the law in this regard (see point 75 of T 318/14).

Questions of referral

In view of this analysis, the Board of Appeal referred the following questions to the Enlarged Board of Appeal:

"1) Can a European patent application be refused under Article 97(2) EPC if it claims the same subject-matter as a European patent which was granted to the same applicant and does not form part of the state of the art pursuant to Article 54(2) and (3) EPC?"

This first question is really asking whether or not a prohibition on double patenting (of the type considered in this referral) can be maintained in absence of an apparent lack of express legal provision in the EPC.

"2.1) If the answer to the first question is yes, what are the conditions for such a refusal, and are different conditions to be applied depending on whether the European patent application under examination was filed a) on the same date as, or b) as a European divisional application (Article 76(1) EPC) in respect of, or c) claiming the priority (Article 88 EPC) in respect of a European patent application on the basis of which a European patent was granted to the same applicant?"

This second question specifically identifies the three individual types of double patenting situations considered above and also asks whether or not there should be any difference in the treatment of these three types.

"2.2) In particular, in the last of these cases, does an applicant have a legitimate interest in the grant of a patent on the (subsequent) European patent application in view of the fact that the filing date and not the priority date is the relevant date for calculating the term of the European patent under Article 63(1) EPC?"

Finally, this second part to the second question explores the issues most relevant to the case underlying the appeal and, in particular, asks whether the extended term of protection which could be afforded through the third situation of double patenting identified above (the internal priority claim) provides a legitimate interest which justifies the double patenting of the same subject matter by an applicant.

Where are we now?

At present, the referral G 4/19 is pending so we do not have any answer to these questions which have been referred to the Enlarged Board of Appeal. However, there is a notice in the Official Journal of the EPO that proceedings before the examining division and opposition division in which the decision depends entirely on the outcome of G 4/19 will be stayed ex-officio until the Enlarged Board of Appeal issues a decision in G 4/19 (see OJ EPO 2020, A20).

Regarding G 4/19, it will certainly be interesting to see how the Enlarged Board of Appeal answers these questions and addresses the legal analysis provided in T 318/14. In particular, it will be interesting to learn whether or not the Enlarged Board of Appeal considers that a prohibition on double patenting can be maintained in the absence of an apparent lack of express legal provision in the EPC. Furthermore, we hope to receive further clarification on what constitutes a legitimate interest, and whether or not the extended term of protection afforded from double patenting arising from an internal priority claim, provides a legitimate interest which justifies double patenting.

We look forward to receiving further clarification from the Enlarged Board of Appeal on the issue of double patenting at the EPO in due course.

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And finally...

WIPO alert
Requests for payment of fees

WIPO has issued an alert to PCT applicants and agents regarding scam fee requests

The World Intellectual Property Organization (WIPO) has recently alerted PCT applicants and agents to a new scam where rogue invitations are being sent requesting fees. These invitations have not been sent from WIPO and are unrelated to the processing of international applications under the PCT. WIPO warns that the registration services offered in these invitations bear no connection to WIPO or any of its official publications.

WIPO further clarifies that it is solely WIPO which publishes all PCT applications promptly after the expiration of 18 months form the priority date and there is no separate fee for such international publication.

Further information can be found on the WIPO website here: https://dycip.com/wipo-pct-warning.

If your receive such an invoice or invitation, please:

- Do not pay it.
- Contact your usual attorney or solicitor to inform them (and if possible, send them a copy).
- Alert any colleagues who might also receive such communications.

Should you have any doubts about unsolicited mail please do not hesitate to get in touch.

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