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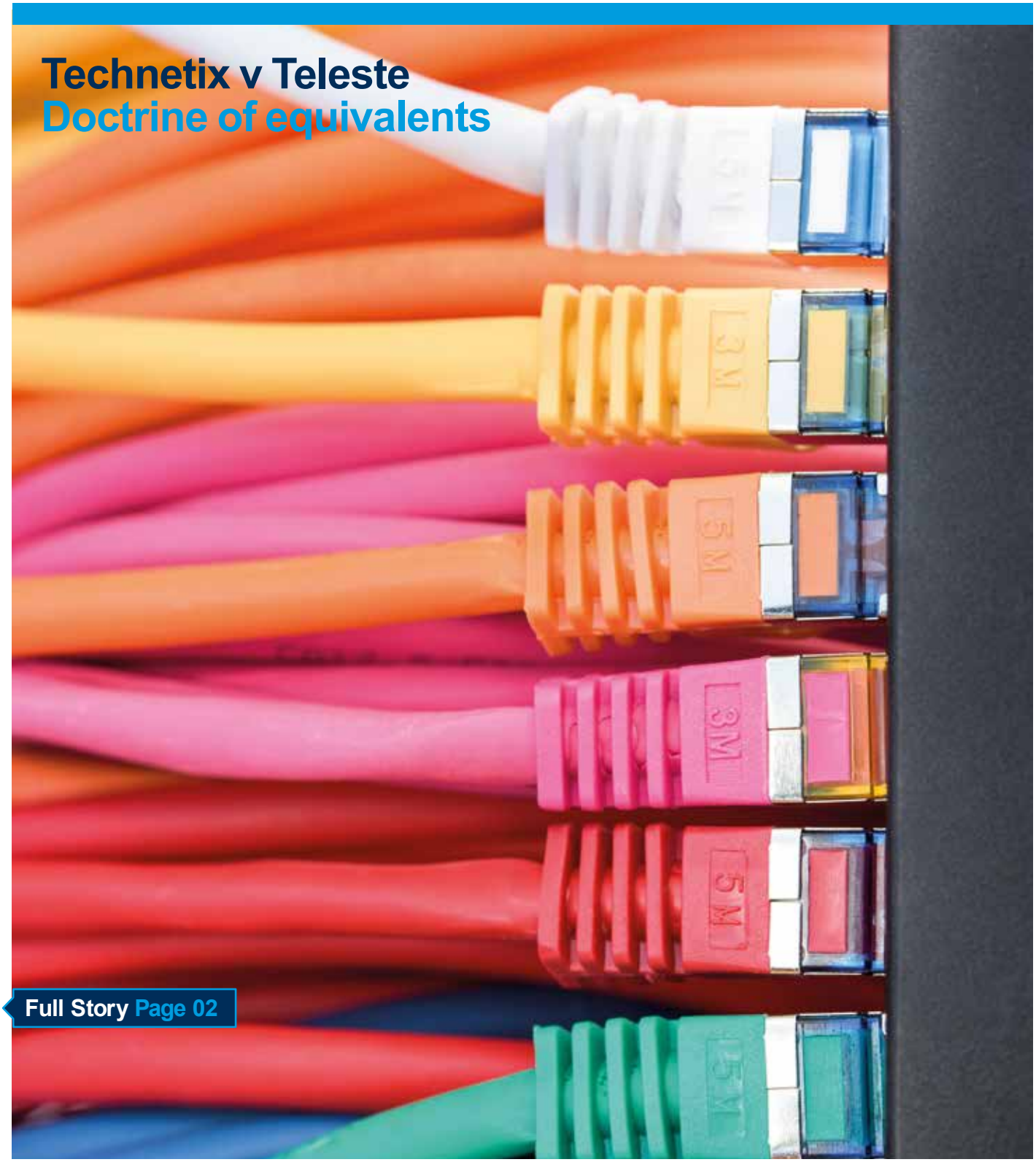

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Editorial

Our latest Brexit update brings news that the EU has agreed to the UK's request for a further extension to the Brexit process. There are several possible dates that have been tabled and all come with conditions attached. A hard deadline of 31 October 2019 is in place but this could be overruled if the UK refuses to take part in the May EU elections. In this instance the UK would leave the EU without a deal in place on 01 June 2019. If the UK Parliament votes through the Withdrawal Agreement then exit day could be brought forward to an, as yet, unknown date that would include a transition period.

As a European firm with an office in Munich we are able to continue to represent all our clients in the UK, Germany and at the EPO and EUIPO regardless of the form Brexit takes and when it happens. Readers are invited to keep up to date with our latest IP & Brexit news at www.dyoung.com/knowledgebank/ip-brexit.

Editor:
Neil Nachshen

Events

21 May 2019
European biotech case law webinar
European Patent Attorneys Simon O'Brien and Matthew Caines present our ever popular European biotech patent case law update in three repeating webinars at 9am, noon and 5pm on Tuesday 21 May 2019.

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Technetix v Teleste
Doctrine of equivalents

Since the introduction of the doctrine of equivalents in the UK in *Actavis v Lilly,* it has been questioned whether a claim can be extended by said doctrine (so that a product infringes the claim) where such an extension would render the claim obvious over the prior art at the priority date. In *Technetix v Teleste*, HHJ Hacon has offered obiter guidance on the point.

Background - Actavis v Lilly

Actavis v Lilly introduced the following questions when assessing infringement:

"1. Does the variant infringe any of the claims as a matter of normal interpretation; and, if not,

2. Does the variant nonetheless infringe because it varies from the invention in a way or ways which is or are immaterial?"

The latter question is further addressed by the following three questions:

"1. Notwithstanding that it is not within the literal meaning of the relevant claim(s) of the patent, does the variant achieve substantially the same result in substantially the same way as the invention, i.e. the inventive concept revealed by the patent?

2. Would it be obvious to the person skilled in the art, reading the patent at the priority date, but knowing that the variant achieves substantially the same result as the invention, t hat it does so in substantially the same way as the invention?

3. Would such a reader of the patent have concluded that the patentee nonetheless intended that strict compliance with the literal meaning of the relevant claim(s) of the patent was an essential requirement of the invention?"

In doing so, the approach to construction of the claims of patent (namely, purposive) remained the same but the scope of protection was broadened. As validity was not in issue in the case, however, the nexus between validity and the doctrine of equivalents was not addressed. This was a particularly acute issue because English law, prior to *Actavis v Lilly*, conflated the test of novelty and infringement, namely a claim lacked novelty if the prior publication disclosed subject-matter which, if performed, would necessarily infringe the claim.
In essence, the test for novelty elided construction with infringement, with the latter now including the doctrine of equivalents.

Generics v Teva

This issue was considered at first instance by Mr Justice Arnold in *Generics v Teva*. He held that it was no longer the law that a claim lacked novelty if the prior publication disclosed subject-matter which, if performed, would necessarily infringe the claim. Rather, the claim would only lack novelty if the prior publication disclosed subject-matter which fell within the claim in its proper construction. It was not sufficient that the subject-matter would infringe the claim applying the doctrine of equivalents. We await a more senior court to consider the issue.

This leaves a potential lacuna between validity and infringement. This is best demonstrated as follows:

Prior art	Product	Patent
A	A	A
B	B	B
X	Y	Z

Prior to *Actavis v Lilly*, if a patent's features were novel and inventive (feature Z over X), a patent was valid.

Further, if a patent's features were not embodied in the alleged infringement (Z is not Y), a patent was not infringed.
It followed that under the above example, the patent would be valid but not infringed.

The position potentially changes after *Actavis v Lilly* because the patent can now be infringed by a product which has an equivalent feature (Y is the equivalent of Z). If Y is obvious over X (but Z is not obvious over X), the patent remains valid but is infringed by an "obvious" product. This is

IP & Brexit

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Technetix brought a claim against Teleste for infringement of its patent for a cable tap unit

an untenable position: it is a fundamental principle of patent law that a party must be free to do that which was either not new or obvious at the priority date.

Gillette defence

A *Gillette* defence may be the answer.

> Broadly, a Gillette defence is where a defendant contends that its (allegedly) infringing product or process was obvious at a particular date and accordingly cannot fall within a valid claim of a later patent.

It is the latter half of the last sentence which is important. This is because, in practice, a *Gillette* defence has been applied as a counterclaim challenging the validity of the patent, not as a stand-alone defence. The rationale for this was two-fold:

1. absent the doctrine of equivalents, a patent could not be valid and infringe a product which was obvious over the prior art (there was, therefore, no need for a stand-alone defence); and
2. as a matter of public policy it was appropriate to address the validity of the patent (as a right in rem), rather than as a defence (as a right in personam.

So is a new stand-alone defence needed?

Technetix v Teleste

In the case at hand, Technetix brought a claim against Teleste for infringement of its patent, GB 2,383,473 for a cable tap unit for receiving and delivering a cable television or Internet signal to subscribers.

Teleste counterclaimed, challenging the validity of the patent.

Following an adjournment of the trial (see *Technetix v Teleste*: Adjournment of Patent Trial: https://dycip.com/tetechnetix-teleste-adjournment), the claim was heard before the Intellectual Property Enterprise Court (IPEC) in November 2018. The patent was held to be invalid, but the court provided its obiter comments on infringement.

> In particular, Teleste argued that if its product fell within the scope of claim 1 of the patent, it was entitled to a stand-alone defence to infringement if the product lacked novelty or inventive step over the prior art.

This defence was fully pleaded on both sides and argued at the trial.

HHJ Hacon declined to hold whether such a defence exists. However, he offered a proposal as to how such a defence (if it exists) may operate. Drawing on the Germany Federal Supreme Court in *Formstein*, he posited that a defence could be adopted in English law so that, if an accused product or process is an equivalent and for that reason is nominally within the scope of the claim, but the equivalent would have lacked novelty or inventive step over the prior art at the priority date, then it is deemed to fall outside the scope of the claim.

HHJ Hacon noted that such a defence also exists under Dutch law, see *Core Distribution Inc v Lidl Nederland GmbH*, and was analogous to the principle of ensnarement in the USA.

Applying this to the facts (on the assumption that the patent was valid), HHJ Hacon held that the patent was not infringed on a purposive construction, but would be under the doctrine of equivalents. Assuming a *Formstein* defence existed, he concluded that the defendant was entitled to the defence.

Author:
Antony Craggs

Are you authorised? CJEU asked to rule on third party SPCs

The UK Patents Court has referred a question to the The Court of Justice of the European Union (CJEU) regarding the grant of supplementary protection certificates (SPCs) to a party which does not have the consent of the marketing authorisation (MA) holder – so-called "third party SPCs". The referral would provide a welcome opportunity for the CJEU to clarify a long-held uncertainty as to whether this practice is permitted by the EU's SPC Regulations.

> Article 6 of the EU medicines SPC regulation states that the SPC shall be granted to the holder of the basic patent. However, unlike in some other jurisdictions, the EU SPC Regulations are silent on whether any legal relationship is required between the basic patent holder and the MA holder.

In many cases, this matter is uncontroversial: for example, it is common for the basic patent holder to be a parent company and the MA holder its local subsidiary, or for the basic patent holder to be the licensor and the MA holder its licensee. However, it has long been uncertain whether the EU SPC Regulations correctly permit a patent holder who is completely unconnected with the MA holder, but who owns a basic patent which covers some aspect of the marketed product, to obtain an SPC without the consent of the MA holder. This is of great commercial significance as, if such SPCs were allowed, the MA holder would require authorisation from the SPC holder to market its own authorised product.

The practice of most patent offices in EU countries is only to check that the SPC applicant and the basic patent holder are the same, and not to take the identity of the MA holder into account. In view of this, many such "third party" SPCs have been granted. While attempts have been made to challenge such SPCs on other grounds, the CJEU has never been asked to directly consider the "third party" issue.

The UK Patents Court has referred a question to the CJEU regarding third party SPCs

The issue of "third party" SPCs was first considered by the courts in the litigation between Human Genome Sciences (HGS) and Eli Lilly on tabalumab.

HGS owned a basic patent based on early stage research which ultimately led to the product and applied for an SPC based on Lilly's MA for this product. Lilly sought a declaration from the UK Patents Court that such an SPC would be invalid, in part, on the basis HGS was an unconnected third party.

In this case, the "third party" issue was not ultimately pursued before the higher courts, so the CJEU did not have the opportunity to consider it. However, the CJEU, in side comments, suggested that the grant of such "third party" SPCs may undermine the objectives of the SPC Regulation, if that third party had not made any investment in research relating to the aspect of the basic patent which led to the authorised product.

The current reference relates to a dispute between Genentech and Lilly in relation to Lilly's authorised product TALTZ (ixekizumab). There is no connection between the parties on this product. Nevertheless, Genentech owns basic patents covering this product, and applied for SPCs based on them and Lilly's MA. Lilly once again sought a declaration from the UK Patents Court that any SPC, if granted, would be invalid due to lack of a legal relationship between the two, and requested a referral to the CJEU if necessary to clarify whether or not "third party" SPCs are lawful under the SPC Regulations.

The basic patent was found invalid in a separate decision from the UK Patents Court. However, the court agreed that the law on "third party" SPCs was not clear. In view of the UK's planned departure from the EU, the court immediately referred a question to the CJEU, as the appellate courts may not have the chance to do so.

> The judge, Mr Justice Arnold, suggested that the question to be referred should be: "Does the SPC Regulation preclude the grant of an SPC to the proprietor of a basic patent in respect of a product which is the subject of a marketing authorisation held by a third party without that party's consent?".

The CJEU is likely to rule on this matter in 2020, and its answer may finally provide clarity on this long-running issue to the industry.

Author:
Garreth Duncan

UK IP rights

US Global IP index
UK ranks 2nd out of 50

UK ranks 2nd in US Global IP index

The UK Intellectual Property Office (UKIPO) was recently pleased to announce that the UK has been ranked second in the US Chambers of Commerce Global IP index, out of 50 countries.The index considers factors that ensure businesses can obtain, exploit and enforce IP rights.

> In the report, the UK is praised for its sophisticated IP environment across all industries and forms of IP, and also for its effective enforcement of those rights.

This was highlighted by the work of its specialist crime unit and cross-industry and government cooperation. The report also highlighted the UK's generous R&D tax incentives and its patent box scheme.

The report recognises the potential challenges presented by the UK's likely withdrawal from the European Union (EU), but notes that the UK government has acted unilaterally to ensure continuity of protection for the UK components of EU IP rights.

> The UKIPO concludes: "The UK provides one of the very best intellectual property (IP) environments in the world".

Author:
Doug Ealey

Designs

UK grants ex-parte pan-EU injunction for design infringement
Philip Morris protects IQOS with registered Community design

In a powerful blow to a Chinese competitor, Philip Morris has deployed its registered Community design (RCD) in order to block sales of a heated tobacco device, obtaining interim pan-EU injunctive relief from the English Court.

> The ability to obtain interim injunctions from national courts in EU countries varies from state to state, and is rarer in the UK than is typically the case in other countries such as Germany. Nevertheless, in the right circumstances, this highly effective form of relief can be obtained from the UK courts.

The ability of the UK courts to grant such pan-EU relief post-Brexit will largely depend on whether a transitional withdrawal agreement can be successfully implemented.

In Philip Morris Products SA & Anr. v Shenzhen Shunbao Technology Co Ltd, Philip Morris alleged infringement of a registered Community design corresponding to its IQOS heated tobacco device, by Shunbao's "AMO" device. The AMO device was already being marketed in China and there were plans to launch it at a major UK trade show, Vaper Expo 2018.

Images of the AMO device, IQOS device and one of the RCD drawings, are shown below:

Serious issue to be tried and presumption of validity

Although the court did not have to make a finding of infringement at the interim injunction stage, the Judge was satisfied that the similarities between the AMO device and the RCD were such that there was a "serious issue to be tried" and that Philip Morris had a "good arguable case".

At this stage, the Judge also proceeded on the basis that the registered design should be treated as valid, in line with the Community Designs Regulation.

Possibility of unquantifiable harm

Having heard submissions as to the possible reputational harm that could be suffered by Philip Morris in the event that the AMO device proved to be of inferior quality, the Judge also factored the possibility of unquantifiable damage into his assessment.

> As a result of the injunction, the AMO device could not be exhibited at a leading vape trade show, nor marketed anywhere in the EU pending a decision on infringement at a future trial.

The power of design

This decision demonstrates the real value of having EU registered design protection.

Quick and inexpensive to obtain, with no substantive examination, an RCD benefits from a presumption of validity and is much easier to obtain than 3D trade mark protection.

As this case shows, in the right circumstances, an RCD can also be used to obtain pan-EU injunctive relief on an urgent basis, and is therefore an effective weapon for tackling look-a-like products.

Author:
Tamsin Holman

Patents Court and EPO disagree
Plus an injunction covering more than the claimed medical use indication.

Novartis Pharmaceuticals UK Limited v Dr Reddy's Laboratories (UK) Limited [2019] EWHC 92 (Pat). Because of a different stance on added matter, Novartis were able to obtain a preliminary injunction from the Patents Court of England and Wales preventing Dr Reddy's Laboratories from launching a generic version of the drug everolimus (which is sold under the name Afinitor). The injunction prevents sales of the generic drug for the claimed medical use and for other medical uses.

Background

90% of the UK market for everolimus is for the treatment of hormone receptor positive breast cancer.

Novartis had an SPC for everolimus per se which was set to expire on 17 January 2019. In addition, Novartis have a patent with a second medical use claim to this drug - EP(UK)2269603 (which was filed on 18 February 2002). The only independent claim of this patent reads: "40-O-(2-hydroxyethyl)-rapamycin in combination with exemestane for use in the treatment of hormone receptor positive tumor, wherein the hormone receptor positive tumor is a breast tumor." The compound 40-O-(2-hydroxyethyl)-rapamycin is known as everolimus.

During EPO opposition proceedings against EP2269603 held in June 2018, the Opposition Division decided that the claim was invalid because it contained added matter. The EPO Opposition Division stated in the written decision that "there is no pointer to the specific combination therapy comprising [everolimus] together with exemestane for the specific treatment of hormone receptor positive [breast] tumor". In addition, the Opposition Division considered that "the skilled person would not have seriously contemplated this combined selection of features as emerging clearly and unambiguously from the content of the application as filed". Hence, the EPO concluded that the claim comprises added matter.

Unsurprisingly, Novarits is appealing this decision and, in view of pending litigation in various European jurisdictions, requested accelerated handling of the appeal proceedings. At the time of writing, no date has been set for the appeal hearing.
A marketing authorisation for everolimus was obtained by Dr Reddy's in July 2018. This marketing authorisation includes, amongst other uses, the use of everolimus as per the above second medical use claim. Dr Reddy's intended to launch generic everolimus after the SPC expired on 17 January 2019.

Novartis sought and was awarded a preliminary injunction to prevent this launch. In the decision from the Patents Court, interesting comments in relation to added matter objections were made by the Patents Court which diverge from the decision made by the EPO Opposition Division. The preliminary injunction prevents not just sales of the generic drug relating to the claimed medical use but also prevents sales for other indications.

Patents Court's position on added matter

Dr Reddy's position was that the launch of generic everolimus would not infringe the patent EP(UK)2269603 because the patent is invalid. In its submissions, Dr Reddy's referred to a section of the EPO's case law book concerning "selection from two lists and deletion of elements from two lists" and asserted that selecting items from two lists means that a claim may comprise added matter.

Novartis submitted an expert report from a Professor of Breast Cancer medicine in which it was his opinion that the claim was disclosed and there is no added matter.

The judge formed a "provisional but clear view that there was no added matter and that therefore the patent was valid".

It was noted in the decision that there is no UK case which puts the principle forward as described in the EPO's case law book. The judge went on to state that "The two list cases may well be examples of cases in which there is added matter" but he did not accept that "as a general statement it is true that a teaching which consists of a combination of two individualised lists…means that the combination is now to be treated as an un-individualised generic disclosure.".
In summary, the Patents Court disagreed with the decision of the EPO Opposition Division. Notably, it was concluded that "[the EPO Opposition Division's] decision appears to take an unduly technical approach which has lost sight of the disclosure of the document as a whole and also lost sight of the prominence of [everolimus] in it".

Scope of the preliminary injunction

Consideration was given to Dr Reddy's selling everolimus for non-breast cancer indications. However, given that breast cancer represents 90% of the UK market for everolimus, it was held that it was not appropriate in this case. It was acknowledged that this would restrain Dr Reddy from supplying the product for lawful uses – namely indications outside the claim.

In granting the preliminary injunction, cross-undertakings were made that if the patent is found to be invalid then Dr Reddy's would be compensated. The judge also provided leave for the Department of Health/NHS to apply to be joined in the cross-undertaking. Considering the cost of everolimus to the Department of Health/NHS, it is likely that they will make the request.

Take home messages

- There is no divergence from EPO case law but a different interpretation of the facts.
- It will be interesting to see if, and how, the comments in this decision by the Patents Court are used in the EPO appeal.
- Moreover, it will be fascinating to see if the EPO Board of Appeal agrees with the Patents Court that the EPO Opposition Division lost sight of the document as a whole.
- Finally, a high market share for a claimed second medical use indication could enable a preliminary injunction to restrain not only product sales for the claimed medical indication but also for indications falling outside the scope of the medical use claim.

This is certainly a case to watch!

Author:
Stephanie Wroe

Double patenting
Will prohibition end at last?

The approach of the European Patent Office (EPO) to prohibition of double patenting is well established and may, at a first glance, also seem well founded.

Broadly speaking, the prohibition of double patenting is meant to mean that two patents cannot be granted to the same applicant for one invention (in the same jurisdiction). At a closer look, there is a plurality of facets, layers and aspects, producing an exhilarating spectrum of double patenting.

Thus, double patenting may arise in three situations where European patent applications are filed by the same applicant:

- Europeans patent applications filed on the same day;
- divisional and parent patent applications; or
- an European patent application claiming priority in respect of another European patent application (internal priority).

However, commentators on European patent practice have never stopped to stress that the European Patent Convention (EPC) does not prohibit double patenting.

> After clarifying and harmonising numerous aspects of European patent practice, the Enlarged Board of Appeal (EBoA) of the EPO now gets a gigantic chance to revisit double patenting.

After the Examining Division decided to refuse European patent application EP 10 718 590.2 in accordance with the applicable Guidelines for Examination at the EPO (Guidelines), G IV, 5.4 under Art. 97(2) EPC in conjunction with Art. 125 EPC, allowing subordinate application of principles of procedural law generally recognised in the contracting states of the EPC, the applicant appealed the decision and auxiliary requested, as occasionally done, that the responsible Board of Appeal (BoA) refers a pivotal question to the EBoA.

The BoA did not, as usually done, discard the idea of referring the question to the EBoA, but also helped to develop the applicant's question into a two-tier question, and decided at the end of oral proceedings held on 07 February 2019 in appeal case T 318/14 to refer a detailed set of questions to the EBoA.

> Answers to the BoA's questions to the EBoA may modernise the approach of the EPO to doubling patenting.

What has happened?

In earlier leading decisions G 1/05 and G 1/06, both relating to divisional patent applications, the EBoA said in passing that the principle of the prohibition on double patenting is based on the notion that an applicant has no legitimate interest in proceedings leading to the grant of a second patent for the same subject-matter if the applicant already possesses one granted patent for that subject-matter. The Guidelines extrapolated therefrom that in case that two or more European applications from the same applicant designate the same state or states and the claims of those applications have the same filing date or priority date and relate to the same invention only one of the applications can be granted.

However, for the present European patent application EP 10 718 590.2 claiming the internal priority of, and claiming the same subject matter as, an earlier European patent application, the applicant has a clear legitimate interest, as it is the filing date and not the priority date that is the relevant date for calculating the 20-year term of a patent. Of course, it is common practise to file a European patent application establishing a priority date for a new invention, towards the end of one year after the priority date to file a PCT application claiming the priority in respect of the European patent application, and towards 31 months after the priority date to enter the regional phase of the PCT application before the EPO.

The BoA agreed with the applicant that there is no uniform practice and even conflicting case law, and referred the following questions to the EBoA:

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

a) on the same date as, or

b) as a European divisional application (Art. 76(1) EPC) in respect of, or

c) claiming the priority (Art. 88 EPC) in respect of a European patent application on the basis of which a European patent was granted to the same applicant?

2.2 In particular, in the latter case, does an applicant have a legitimate interest in the grant of 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 Art. 63(1) EPC?

For answers to the questions raised in T 318 /14, the EBoA may have to probe the real intentions of the legislators by going back to the archives and interpreting the Travaux Préparatoires, the draft documents and minutes produced when the EPC was conceived back in the early 1970s.

There will be plenty of fragments in need of attention, and plenty of leeway for interpretation. However, it will be worth the efforts.

Author:
Hanns-Juergen Grosse

And finally...

D Young & Co news

Promotions and appointments
Welcoming new partners, promotions and appointments

We are delighted to announce that European Patent Attorneys Rachel Bateman, Tamara Milton, Cathrine McGowan and Alan Boyd have been appointed partners in the firm's patent group.

Rachel and Tamara are accomplished attorneys whose appointments strengthen our highly reputed biotechnology, chemistry & pharmaceuticals team. Cathrine and Alan are welcomed as partners to the firm's richly talented team of engineering, electronics & IT attorneys.

Further appointments

Our new patent partners are joined in promotion by Matthew Caines (biotechnology, chemistry & pharmaceuticals) and Holly Cowie (engineering, electronics & IT attorneys)who are now both senior associates. Sophie Blake, Patrick Scott and Martin Bicker have also been promoted to Associate level. Alexandre Pignier, European and French qualified attorney, has also recently joined our engineering, electronics & IT team having previously worked in private practice in Paris, France.

Congratulations to Arun Roy, Ryan Lacey and Robert Kelly who, having successfully qualified as European Patent Attorneys and (UK) Patent Attorneys, are promoted to the position of patent attorney. Congratulations also to technical assistants Sam Keyes, Sam Smith, Jessica Steven-Fountain, Nathaniel Wand, Harry Ventress and Rebecca Price who have all passed their Certificate in IP Law from Queen Mary University of London.

Neil Nachshen, Chair of D Young & Co, comments "We are proud of the collective accomplishments of our attorneys and extend a warm welcome to the partnership to Rachel, Cathrine, Tamara and Alan. We are excited to see our team evolve and grow to meet the needs of our clients. Congratulations to all on their achievements."

Further information and links to biographies of all the team members mentioned above can be found on our website: https://dycip.com/promotions-apr19

Contact details

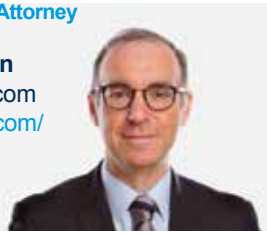
London
Munich
Southampton

T +44 (0)20 7269 8550
F +44 (0)20 7269 8555

mail@dyoung.com
www.dyoung.com

Contributors

Partner, Patent Attorney
Editor
Neil Nachshen
njn@dyoung.com
www.dyoung.com/neilnachshen



Partner, Solicitor
Antony Craggs
arc@dyoung.com
www.dyoung.com/antonycraggs

Partner, Patent Attorney
Garreth Duncan
gad@dyoung.com
www.dyoung.com/garrethduncan

Partner, Patent Attorney
Doug Ealey
dre@dyoung.com
www.dyoung.com/dougealey

Partner, Patent Attorney
Hanns-Juergen Grosse
hjg@dyoung.com
www.dyoung.com/hanns-juergengrosse

Partner, Solicitor
Tamsin Holman
tph@dyoung.com
www.dyoung.com/tamsinholman

Associate, Patent Attorney
Stephanie Wroe
sfw@dyoung.com
www.dyoung.com/stephaniewroe