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PATENT

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As 2020 draws to a close, what an unusual year it has been. Life around the world has been turned upside down, not least here in the UK, one of the countries most severely affected by the pandemic. Yet as Benjamin Franklin said "out of adversity comes opportunity". In the world of IP we are privileged to have early insights into the brilliance of human endeavour in responding to such challenges. In just one such example, we are proud to see the Oxford University/AstraZeneca Covid vaccine nearing approval.

Our plans for 2021 may have been modified, but our core values at D Young & Co haven't changed. Although transposed into the virtual realm, the constant – which underpins everything we do – is the quality of our people. On that note, ambitious students of electronics, engineering, physics and computer science are invited to join our Patent Easter Internship (virtually, of course) to gain a real insight into life as a patent attorney.

Wishing all our readers a happy and healthy new year.

Nicholas Malden, Editor

Webinars on demand



European patent biotech case law

<https://dycip.com/webinar-bio-nov20>



Simon O'Brien and Jennifer O'Farrell discuss recent and important biotech patent case law.

Goodbye Neurim, hello Santen

<https://dycip.com/spc-nov-2020>



Garreth Duncan reviews the recent CJEU Santen decision which changes the picture on what marketing approvals can support an SPC in the EU.

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CRISPR-Cas9

CRISPR patent appeal decision EPO maintains "all applicants" approach to priority

Earlier in 2020, the Board of Appeal dismissed the Broad Institute's appeal (T 0844/18) against revocation of one of its key CRISPR-Cas9 patents, EP2771468B. Here we discuss the Board of Appeal's recently published decision.

As we reported previously, the proceedings focused on entitlement to claim priority from an application filed by multiple applicants.

Article 87(1) EPC states that "Any person who has duly filed [...] an application for a patent, [...] or his successor in title, shall enjoy, for the purpose of filing a European patent application in respect of the same invention, a right of priority during a period of twelve months from the date of filing of the first application". According to established EPO practice, the "any person" is considered to be all applicants of the priority application, or their successors in title (the "all applicants" approach).

EP2771468B claimed priority from multiple US provisional applications, the earliest two of which included an applicant-inventor who was not an applicant of the subsequent PCT application. No transfer of his rights to claim priority appears to have occurred before the subsequent application was filed. As a result, the opposition division decided that the patent was not entitled to claim priority from the earliest two priority documents, and the patent was revoked in light of novelty-destroying intervening disclosures.

In their appeal, the patentees/appellants set out their arguments in the form of three questions:

1. Should entitlement to priority be assessed by the EPO?
2. How is the expression "any person" in Article 87(1) EPC to be interpreted?
3. Does national law (in this case US law) govern the determination of "any person" who has "duly filed" in Article 87(1) EPC?

We have highlighted some of the appellants' arguments and the Board of Appeal's answers to these questions below.

1. Should entitlement to priority be assessed by the EPO?

Claiming that the EPO should not assess entitlement to priority, the appellants argued that the EPC exhaustively lists the requirements for an applicant to claim priority, but proof of right or an assessment of ownership is not required. Regardless, the EPO does not decide on the ownership of a patent (Article 60(3) EPC). Therefore, the EPO should not introduce an additional formal requirement for claiming priority.

However, the Board of Appeal decided that Article 87(1) EPC clearly requires the EPO to examine who can claim priority, and there is no basis in the EPC for disregarding this requirement. Moreover, there is no requirement that the "any person" was legally entitled to file the application. Accordingly, the EPO merely carries out a formal assessment of the person filing the application. The Board of Appeal also stated that there is no priority-based equivalent to Article 60(3) EPC, and this gap does not necessarily need to be filled by analogy from another EPC provision.

The Board of Appeal recognised that the EPC sets out many formal requirements for obtaining a patent (such as paying fees or meeting time limits); and the loss of a patent due to not meeting formal requirements is a feature of the EPC system.

Therefore, the Board of Appeal concluded that the EPO is empowered and obliged to assess the validity of a priority right.

2. How is the expression "any person" in Article 87(1) EPC to be interpreted?

The appellants argued that, in light of the ordinary meaning of the term "any", and the object and purpose of the Paris Convention, the expression "any person" must be interpreted as 'any one person' (that is, one, a plurality or all applicants of a priority application can validly claim priority). Additionally, neither the EPC nor the Paris Convention specifies that all applicants of the priority application must also be applicants of the subsequent application, to validly claim priority.

However, the Board of Appeal emphasised

➤ **Related articles and further information**
“Broad Institute CRISPR patent appeal: revocation upheld for lack of priority”
14 February 2020, Laura Jennings:
<https://www.dyoung.com/en/knowledgebank/articles/crispr-broad-institute-appeal>

“Broad Institute CRISPR patent revoked: lack of priority” 24 April 2018, Matthew Caines:
<https://www.dyoung.com/en/knowledgebank/articles/crispr-broad-priority>

View full decision: <http://dycip.com/t-0844-18>

that the EPC is a special agreement within the Paris Convention, meaning its provisions cannot contradict the basic principles concerning priority in the Paris Convention. Accordingly, the legal concept of “any person” in Article 4A Paris Convention should be interpreted and applied to the EPC.

The Board of Appeal found that the ordinary meaning of the term “any person” is ambiguous in all authentic texts of the EPC and Paris Convention; and their contexts do not help. However, it considered the “all applicants” approach to be a plausible interpretation of the Paris Convention’s authentic text.

The Board of Appeal and the appellants were in agreement that the object and purpose of the Paris Convention are to safeguard the interests of an applicant in their endeavour to obtain international protection for their invention; and this is assisted by the priority provisions. However, the appellants asserted that the “all applicants” approach allows disputes over ownership to destroy a patent itself; and violates Human Rights, because one applicant could hold the others to ransom by refusing to join in as an applicant for the subsequent application.

In contrast, the Board of Appeal asserted that the “any one applicant” interpretation would allow one or more applicants to deprive others of their rights to a patent in another country, contrary to the object and purpose of the Paris Convention. The “all applicants” approach is not an obstacle to the exercise of a priority right; it is an obstacle to one applicant filing a subsequent application on their own. There is no evidence that the object and purpose of the Paris Convention are to facilitate this. Moreover, an applicant can progress a patent application before the EPO without the active participation of other applicants.

The Board of Appeal decided that if a group of persons together decides to file an application as a unity, the “any person” is this group as such. The Paris Convention seeks to facilitate this action: using priority, applicants can be treated as if they had simultaneously filed the same application in multiple states, which would otherwise be very difficult.

Furthermore, the Board of Appeal found that there is no case law that clearly and unambiguously adopts the appellants’ position. The priority provisions of the Paris Convention have remained essentially unchanged since 1883.

The appellants also attempted to distinguish between “internal” priority claims, where both the priority and subsequent applications are European; and “external” priority claims, where the priority application is non-European. The appellants argued that all of the case law that supports the “all applicants” approach was concerned with the former, and is not applicable to the latter. However, the Board of Appeal considered that the EPO is obliged to apply Article 4A Paris Convention in the same way for internal and external priorities.

Therefore, the Board of Appeal decided that the expression “any person” in Article 87(1) EPC requires that all applicants for the priority application, or their successors in title, are applicants for the subsequent application.

3. Does national law (in this case US law) govern the determination of “any person” who has “duly filed” in Article 87(1) EPC?

The appellants argued that a priority right arises before a subsequent application is filed, meaning that only national law can determine the “any person” in Article 87(1) EPC. Article 87(2) EPC relies on national law to determine whether a filing is a regular filing, so national law should also determine who filed the application. Under US law, an inventor is only an applicant for subject matter they contributed to, whereas the missing applicant in this case was not an inventor of the claimed subject matter. Notably, to validly claim priority from a multi-invention, multi-applicant provisional application under the “all applicants” approach, a US inventor-applicant would either have to be an applicant before the EPO for an invention they didn’t make; or they would have to assign, to a successor in title, their non-existent rights in an invention made by someone else.

However, the Board of Appeal asserted that Articles 87(1) and (2) EPC, and corresponding Articles 4A(1) and (2) Paris Convention, do not refer to the inventor or applicant for a patent

application; instead they refer to the person who filed the application. Whether they are the inventors, or entitled to be applicants, are not issues requiring investigation under the Paris Convention. This is clear from the authentic French text and *travaux préparatoires* of the Paris Convention: reference to the author of the invention was specifically removed from the priority provisions during drafting, to avoid questions of definitive right of ownership.

Therefore, the Board of Appeal decided that the Paris Convention is the law that determines the “any person” in this case, meaning there is no reason to deviate from the answer to the appellants’ second question.

Submission of questions to the Enlarged Board of Appeal

The appellants requested submission of their questions to the Enlarged Board of Appeal. Under European patent practice, a Board of Appeal shall refer a question to the Enlarged Board if it considers that a decision is required to ensure uniform application of the law, or because a fundamentally important point of law arises. Even in the latter case, it is at the Board of Appeal’s discretion whether to refer questions; and the Board of Appeal should consider if it can answer the questions beyond doubt by itself.

The Board of Appeal found that the EPO has always adopted a consistent interpretation of Article 87(1) EPC, and it was able to answer the appellants’ questions beyond doubt. Therefore, no referral was considered necessary, and the appeal was rejected.

Importantly, the Board of Appeal emphasised that applicants wishing to use US provisional applications as priority documents should be aware of the difficulties they face if they use these applications to claim priority for an EP application. Again, this decision is a clear reminder to verify that all applicants of a priority application are listed on the subsequent application; or otherwise that the transfer of rights to claim priority takes place before the filing date.

Author:
Laura Jennings



For whose eyes only?

Disclosure of confidential information in FRAND cases

A standard essential patent (SEP) is a patent with claims that cover an aspect of a technical standard, such that a party who implements the standard will necessarily infringe the SEP. Standard-setting organisations often require the participants in the development of a standard to commit to license their SEPs on “fair, reasonable and non-discriminatory” (FRAND) terms. This allows the participants to protect, and be rewarded for, their technical contribution to the standard, whilst preventing them from using their SEPs to block access to the standard. One way of administering such SEPs is by use of a “patent pool”, in which multiple SEP owners agree to license their SEPs together.

Licensing of SEPs can bring significant revenue for the owner, in particular for standards with wide uptake such as those relating to mobile telecoms. The question of exactly what constitutes a FRAND licence is thus very relevant, and there have been a number of decisions in the past few years centred around this issue. Many of these have been in the telecoms space, but they may well be seen to have wider relevance to patents relating to standards in other technical areas, as practice around standard essential patents in those areas develops further.

Handling commercially sensitive information

In ruling on a FRAND licensing issue, a court must establish what would be FRAND in a given case. This depends on current licensing norms in the relevant industry: there is no one-size-fits-all FRAND licence. In order to establish these norms, a court may need to take evidence on the licensing practice of the litigation parties. For example, in order to establish that given SEP licensing terms are non-discriminatory, it may be necessary to analyse the licensing terms which the SEP owner has agreed with other licensees.

The details of the licensing agreements into which a party has entered can be extremely commercially sensitive. A party who, through patent litigation, obtains access to a competitor's commercially sensitive information may be placed at

A patent pool allows multiple SEP owners to license SEPs together



an unfair commercial advantage.

However, this must be balanced against the need of parties in litigation to understand the proceedings, including the position of their opponent and the reasoning behind any judgment. One common way of achieving this balance is through the use of “confidentiality clubs”, where certain documents are disclosed only to defined people on behalf of the receiving party, such as named employees or external legal advisors.

Background to present case

Mitsubishi Electric Corporation and Sisvel International SA are members of a patent pool relating to 3G and 4G mobile telecom standards. They sued companies in the OnePlus/Oppo and Xiaomi groups for patent infringement. The patents are alleged to be essential to the standards. Mitsubishi and Sisvel indicated their willingness to grant licences under their standard licensing terms, which they asserted were FRAND. OnePlus/Oppo denied infringement and also denied that the proposed licensing terms were FRAND. A technical trial to determine issues of validity and infringement is scheduled for March 2021. Subject to this trial finding validity and infringement, a subsequent trial to establish FRAND licensing terms is scheduled for October 2021.

Mitsubishi and Sisvel were ordered to disclose any licences which involved any patent in the pool. Because of the commercial sensitivity of these documents, the parties agreed a confidentiality regime involving two confidentiality clubs: an

“attorneys’ eyes only” (AEO) club including only lawyers and expert witnesses, and a “highly confidential material” (HCM) club including the AEO members and two named, pre-approved employees of each party.

Mitsubishi and Sisvel disclosed 150 documents, 36 of which they designated AEO. OnePlus/Oppo challenged the AEO designation of six of these documents, and also requested for three of their internal licensing negotiators to be included in the HCM club. Xiaomi challenged the AEO designation of all 36 documents.

An application was made to the court to resolve these issues.

First instance findings

The first instance judge accepted OnePlus/Oppo's request to de-designate the six documents, on the grounds that their request was “considered and targeted”, and related (with evidence) to the specific documents which they thought necessary to plead their case. However, because of the commercial sensitivity of the documents and the risks to third parties, he ordered OnePlus/Oppo's HCM club members to undertake to the counterparty(s) of each de-designated licence that they would not participate in licensing negotiations or litigation with that company.

The judge also dismissed OnePlus/Oppo's request to admit additional members to the HCM club, on the grounds that, amongst other points, “Disclosure to key people who may be involved in commercial negotiations risks causing unnecessary harm”.

➤ **Case details at a glance**
Jurisdiction: England & Wales
Decision level: Court of Appeal
Parties: Oneplus Technology (Shenzhen) Co Ltd & Ors v Mitsubishi Electric Corporation & Anor
Date: 19 November 2020
Citation: [2020] EWCA Civ 1562
Link to decision: <http://dycip.com/ewca-1562>

IP & Brexit

UK address for service Applications after 01 Jan 2021

He further ordered that any alternative nominees should not be involved with licensing or FRAND litigation with Mitsubishi, Sisvel, counterparties to any disclosed agreements, or other members of the patent pool.

Finally, the first instance judge dismissed Xiaomi's application to de-designate all 36 documents, on the grounds that Mitsubishi and Sisvel were entitled to make an initial decision as to which documents should be disclosed to Xiaomi employees and which should not.

Appeal

Both OnePlus/Oppo and Xiaomi appealed the first instance decision. OnePlus/Oppo argued that the restriction to the membership of the HCM club interfered with their right to natural justice, and further that the six documents that they wanted their desired new representatives to access were one-way licenses and therefore would not contain any commercially sensitive information about the counterparties. They also requested for a seventh document to be de-designated from AEO to HCM.

Xiaomi argued that the judge had applied the wrong test to determine whether a given document should be designated AEO, and that the correct test should be whether nothing short of an AEO designation was sufficient to protect confidentiality. They thus asserted that the judge had reversed the burden of proof by allowing Mitsubishi and Sisvel to make the initial determination.

As the outcome of the present decision was relevant to the FRAND trial scheduled for October 2021, the Court of Appeal expedited proceedings: after the first instance hearing was handed down on 09 October 2020, the appeals were held before the Court of Appeal on 05 November 2020, from which judgment was handed down on 19 November 2020.

Appeal decision

Both appeals were dismissed.

Regarding OnePlus/Oppo's appeal, whilst they had requested for their new representatives to be admitted to the HCM club and thus to have access to the large number of associated documents, it had become clear that they

were happy to limit the new representatives' access to the six de-designated documents and one additional document. However, this is not the issue on which the first instance judge had ruled. Furthermore, Mitsubishi and Sisvel had indicated that they would accept a limited disclosure on this basis, subject to some further restrictions to the effect that the new representatives would undertake not to engage in licensing negotiation with the counterparties to the seven documents. The court thus held that the appeal fell away, but that the parties could return to court if Mitsubishi and Sisvel's proposal did not address the issue.

Regarding Xiaomi's appeal, the court held that the first instance judge had applied the correct test and taken account of the relevant considerations, and further that the judge had satisfied Xiaomi's test that nothing short of AEO designation would protect confidentiality. The need for confidentiality would need to be balanced against the need for fairness to the parties, and a staged approach in which the documents were filtered by lawyers and experts to identify the specific relevant ones to de-designate (as was done by OnePlus/Oppo, but not Xiaomi) would have been appropriate. The court further held that the first instance judge had not reversed the burden of proof: Mitsubishi and Sisvel had not been relieved of the obligation to show that the AEO designation was justified.

Comments

This decision may well be appreciated by patentees who are considering litigating in the UK but who had worried that they could be forced to disclose commercially sensitive information to the alleged infringer. In this case, the Court of Appeal has clearly held that whilst an external-eyes-only regime should not be implemented lightly, it is available for sensitive documents where this can be justified. The speed of the case (with less than one month between the first instance decision and the Court of Appeal hearing) also shows how efficiently the UK court system can move when necessary.

Author:
Patrick Scott



UK address for service requirements



The UKIPO recently announced that an address for service in the UK, Gibraltar or the Channel Islands will be required for any new application for a patent, a trade mark or a design filed at the UKIPO from 01 January 2021. This includes European patents validated in the UK.

In addition an address for service in the UK, Gibraltar or the Channel Islands will be required if you wish to challenge or defend a patent, trade mark or design in contentious proceedings at the UKIPO.

More information can be found on the UKIPO's website.

<https://dycip.com/uk-address-service>

Further IP & Brexit guidance

Readers can access our "IP after Brexit" guide on our website at www.dyoung.com/brexit.



The guide is regularly updated and addresses the impact of Brexit on patents, trade marks, designs, copyright and other related IP rights.

From football stadiums to railway stations

Covering the bigger picture with registered designs

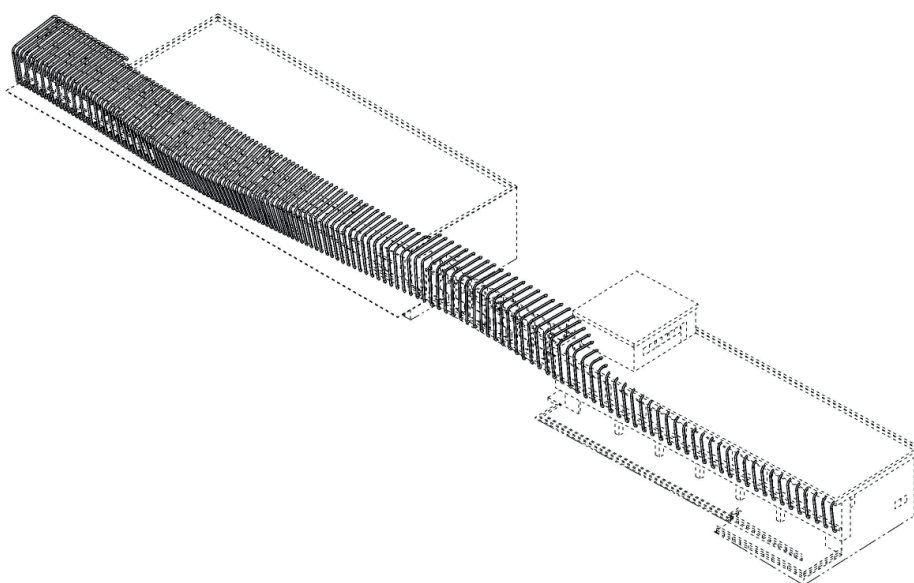
When it comes to registered design protection, frequently seen are those design registrations relating to consumer goods, or other products of a relatively small size. That being said however, often overlooked in the context of registered design protection in many territories around the world is the possibility to protect altogether larger-scale construction projects, which in many of these territories can also be protected with a registered design.

This is so not least in Japan where we are starting to see an increasing number of such large-scale construction projects/ designs being registered. In that respect, recent changes in design law coming into effect from April 2020 now allow Japanese design registrations to be pursued in respect of such larger-scale designs. An example of this is shown (above right) in the Japanese design registration JP 1671774S, recently registered on behalf of the East Japan Railway Company and which is directed to the shape of a station building.

For the sake of completeness, it is to be noted that in the EU, Germany, and the UK as well, such large-scale designs and construction projects are similarly protectable with a registered design. This includes, for example, designs directed to swimming pools; railways stations; football stadiums; racing car tracks; or even a Christmas market.

Appreciating the above, one of the cornerstones of valid registered design protection is the fact that a given design must be suitably new and visually distinctive over what has come before it. In other words, if a given design is publically disclosed before it is pursued as part of a registered design application, this public disclosure might in many territories around the world prejudice the validity of any design registration which is subsequently applied for in respect of the design. Conscious of this, for those contemplating any form of design registration protection in respect of a particularly visually striking large-scale structure, key in this

Japanese design registration JP 1671774S is directed to the shape of a station building



respect will be in registering the design early, that is, at the initial commissioning/ architectural stage of its production, and before the design is publically disclosed.

As early registration of the design may be often necessary in order to achieve valid protection, it is to be noted that there are various mechanisms in place, at least in respect of design registrations made in the UK, Germany, and the EU, to allow for any such designs to be kept unpublished/hidden from the public eye for an initial period of time. This process is called deferring the publication of the design registration. Mindful of this, for those contemplating designs directed to larger scale subject matter as described above, use of the deferred publication scheme may be advisable. In this way, a design registration can be secured sufficiently early on in respect of the commissioning process of the design (that is, before the design is publically disclosed), whilst at the same time then being kept undisclosed itself as part of the deferred publication regime. Such deferred publication status for the design registration can then be retained until the time when the design becomes disclosed through other channels (for example, as

part of a press release announcing the construction of the design), after which the design from the design registration can then be considered for publication too.

Why may design registration protection be advisable in respect of such large-scale designs as outlined above? One of the prime benefits of such protection is that it provides a registered right for better addressing any unauthorised use/reproduction of the design. Enforcement issues aside, the registered right can also provide a further (invaluable) tool for licensing out any potential use of the design covered by the design registration, for example, as part of any merchandising deals covering the design, or perhaps in respect of any request to reproduce the design in some form (either physically or potentially even electronically/virtually, such as in a video game or other simulation software). In this respect as well, from the UK/DE/ EU perspective specifically, it is to be noted that a UK/DE/EU design registration can nominally be enforced in respect of any goods employing the protected design.

A further rationale for pursuing design registration protection in respect of such designs is from the cost perspective. In this

➤ Related links

Design registration JP 1671774S:
<http://dycip.com/design-jp-1671774>

respect, the relative cost of pursuing a design registration covering the appearance of such a large-scale design, in the context of the overall cost for commissioning/ constructing the design, can be minuscule. For instance, a UK design registration can cost as little as £50, a German design is available for 60 EUR, and an EU design registration can cost as little as EUR 350. Tying in with is the associated speed of registration for such designs. In that respect, registered design protection covering the UK, Germany or the EU can be achieved in a mere matter of days or weeks.

Conscious of the above, for those considering registered design protection in respect of any forthcoming structure or large-scale design, whether this be a skyscraper; a stadium; or perhaps even a train station, crucial in this respect will be in ensuring that any ownership of the underlying design is ironed out from the outset. In this respect specifically, noting any design registration may need to be applied for very early on (before the underlying design has been publically disclosed), this might therefore practically mean registering the design whilst it is still at the architectural/ project development stage. That being the case, it will be crucial to ensure that a valid agreement is in place which appropriately assigns any design rights, from each designer responsible for devising the design, to the intended ultimate owner of the design.

So for those involved in the design and commissioning of large-scale designs, or other infrastructure projects, which have a particularly striking visual appearance, do perhaps consider pursuing one or more design registrations in respect of the design, and crucially before the design is publically disclosed in any form. Indeed, seeking this early design registration protection, which may not prove possible if left until later on, may ultimately yield an extremely powerful licensing tool to both you and any ultimate owner of the design. In essence therefore, do not leave pursuing the design registration until it is too late; act as early as possible!

Author:

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www.dyoung.com/newsletters

UP & UPC

UP & UPC Bundesrat passes bill of UPC ratification

On 18 December 2020, the Bundesrat – Germany's upper house of parliament representing the country's sixteen federated states – voted in favour of the legislation for ratifying the Unified Patent Court (UPC).

Ratification of the UPC Agreement (UPCA) by Germany – subject to Presidential formalities – will mean that the required conditions for the UPC and the unitary patent to come into effect will be met. Germany will become the third of the required “three member states in which the highest number of European patents had effect in the year preceding the year in which the signature of the Agreement takes place,” to ratify the UPCA, joining France and the UK despite the UK's withdrawal from both the UPCA and European Union.

The bill of ratification passed the two-thirds majority required in the Bundestag – the lower house of Germany's parliament – comfortably and was expected to do so too in the Bundesrat, so its approval today does not come as a big surprise. However, this is the second attempt to pass the bill, following the voiding of the previous legislation in 2017 by a constitutional complaint.

A challenge to the second attempt by Germany's legislature's passing of the bill may reasonably be expected. However, today's vote brings the UPC and unitary patents (UPs) significantly further along the road towards coming into effect.

Should Germany ratify the UPC Agreement without any issues, the provisional application period will be able to commence in 2021. This period allows the UPC to come into existence before formal commencement of the court itself.

The last three months of the provisional application period will be the “sunrise period” during which patent proprietors will be able to opt-out any existing granted European patents from the jurisdiction of the UPC. We could therefore see the new UPC/UP system starting at the beginning of 2022.

In light of the positive vote of the Bundesrat, we would suggest that clients re-visit their opt-out strategy in early 2021 and identify any proprietorship issues for existing European patents.

A key requirement of the opt-out process is that the opt-out request is filed by the “true” proprietor. If the opt-out is filed in the wrong name then it may be invalid and any correction will not be back-dated. It is also important to check the ownership situation for any SPCs as these will need to be opted-out independently of the underlying patent and may be in a different name.

The attorneys at D Young & Co will be able to handle the filing of opt-outs on behalf of clients, and can advise on strategy as required. In addition, D Young & Co's attorneys will be able to represent clients in the UPC. This representation is in addition to our existing representation rights before the EPO, and means that we are able to meet all of our clients' European patent requirements.

Author:

David Al-Khalili



Useful links

Read the Bundesrat decision of 18 December 2020 (German language):

<http://dycip.com/bundesrat-upc-vote>

“Unified Patent Court & unitary patents on the horizon for 2022?” Rachel Bateman, 27 November 2020:

<http://dycip.com/upc-progress-2020>

EPO sufficiency

Can medical use claims encompass all patients if the majority are non-responders?

If a therapeutic benefit is only observed in a sub-group of patients (in particular, a small group), is a claim sufficient if it claims all patients or do the non-responders need to be disclaimed? This was the question posed in T0421/14¹, an appeal decision concerning the opposition division's decision to maintain patent EP1732548² in an amended form.

According to established case law of the Boards of Appeal, in order to meet with the requirements of sufficiency under Article 83 EPC³, the therapeutic efficacy of the composition and the dosage regime for the claims therapeutic indication must be at least credible/plausible from the description and/or common general knowledge.

In T0421/14 (Acorda Therapeutics Inc v Synthon BV neuraxpharm Arzneimittel GmbH) a key objection asserted against the patent was that the desired therapeutic benefit was only attained in a small subpopulation of "responders" rather than in all patients and, thus, the claims were not sufficient.

The medical use claims at issue in this case concerned the use of a sustained release composition at a specific dose in a specific dosage regime for increasing the walking speed of a patient with multiple sclerosis.

The patent contained data from a clinical trial but no statistically significant difference was found in the trial. However a post-hoc analysis of the data (which was included in the patent) using revised clinical benefit criteria showed that a statistically significant therapeutic benefit was attained; however this benefit was observed in only in a small sub-population of patients.

The appellant-opponents argued that the claims lack sufficiency because the

therapeutic effect was only obtained in a small sub-population of patients.

A secondary issue in this case was whether copies of a poster and slides filed by the patentee in an information disclosure statement on the sister US case were citeable as prior art; in the information disclosure statement the patentee stated these materials had been presented at a public conference. In this appeal the respondent-proprietor argued that there was reasonable doubt that the poster and slides filed in the information disclosure statement were identical to what was presented.

Findings of the Board of Appeal

The Board of Appeal noted that patients with multiple sclerosis experience variability in the occurrence of their symptoms and, because of this, it can be difficult to recognise the clinical benefits of therapies. In this case, only about one third of patients were found to be responders under the revised post-hoc criteria.

The Board of Appeal confirmed that the existence of non-responders is **not** a reason to deny sufficiency of the disclosure. Additionally, they confirmed that non-responders do **not** need to be excluded or disclaimed.

The Board of Appeal highlighted that the existence of a substantial proportion of non-responders is a common phenomenon which is observed with drugs in many treatment areas such as diabetes, migraine and cancer treatment. Additionally they pointed out that it is common practice to treat patients with a drug and change their medication should it turn out that they do not respond to treatment.

Further, the Board of Appeal confirmed that the requirements of Article 83 EPC are met if it can be shown that a relevant proportion of patients benefit from a treatment and

Notes

1. T 0421/14: <http://dycip.com/t0421-14>
2. EP1732548: <http://dycip.com/ep1732548>
3. "The European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art."

that it has acceptable safety because the skilled person has the necessary technical information to perform the treatment. In this case the Board of Appeal found that the alleged therapeutic efficacy and safety was credible/plausible on the effective date of the patent (that is, claims met with the requirements of sufficiency) when restricted to the specific compound used in the examples.

In connection to the poster, the Board of Appeal held that because this evidence was within the power and knowledge of the respondent-proprietor that its admissibility as prior art should be assessed against the standard criteria of "overall balance of probability". The Board of Appeal held that there was little doubt that the poster (even if it had typographical errors) was displayed at the conference. If evidence from witnesses (such as the presenters) had been provided that the poster had not been displayed then the Board of Appeal may have been persuaded otherwise.

In contrast, the Board of Appeal held the slides were not prior art. They noted that slides are typically used as the basis of an oral presentation and that the printed content of slides alone is insufficient for establishing precisely what members of an audience would have understood and retained. The absence of evidence as to what was shown to the audience (such as a handout of the slides presented at the conference) was a persuasive factor in the decision the board reached.

Practical points

The existence of non-responders in data is not, on its own, a reason to deny sufficiency under European patent practice. Moreover, there is no need to disclaim non-responders from medical use claims even if the majority of patients are non-responders. However you do need data to show that the responders do benefit from the therapy and there is acceptable safety (in other words, the therapeutic efficacy is credible/plausible); ideally this data is in the specification. As always, scientists should keep accurate records of what they actually present at public events such as conferences.

A small sub-population of patients attained significant therapeutic benefits



Author:
Stephanie Wroe



Secret prior art A trap for the unwary?

In almost all countries around the world, a patent application is only published after 18 months from the filing date, or where priority has been claimed from the priority date. This raises the interesting question of how the system should handle a second application which is filed after a first patent application has been filed but before the first application has been published. This situation is known as “secret” prior art since, in general, the applicant of the second application has no way of knowing that the first (unpublished) application exists.

Under the usual rules of prior art, only public disclosures are available to be cited against an application. As the first application has not yet been published, it ordinarily would not be citable against the second application. However, if the first application cannot be cited against the second application this could lead to the undesirable outcome where both applications could be granted to the same subject-matter such that the applicant of either granted patent could prevent the other from working the invention and could prevent the invention from ever coming to market.

So, given the desire of governments to avoid potentially extremely valuable patents being blocked from coming to the market, what can be done?

The basic approach taken is to allow the first application to be cited against the second application but to apply various limitations on how the first application can be used, with a view to balancing the rights of both applicants while avoiding overlapping rights that could prevent the invention from coming to market.

Secret prior art - a trap for the unwary?



However, even within this basic approach there are a wide range of options that states can adopt. Unfortunately, global harmonisation has not yet been achieved. While there are many aspects of variance between states, two key aspects of significant variation are:

1. what patentability criteria secret prior art can be used for; and
2. whether self-collision is possible.

The different approaches can be seen in the summary table shown below for a selection of patent offices.

As can be seen, most states strike the balance between the rights of the two applicants by stating that the earlier application can only be cited for novelty purposes. The thinking is that as long as there is no overlap between the two applications (that is, the second application is novel) then the mutual blocking situation described above can be avoided. However, the US takes a very different approach and allows secret prior art to be cited both for novelty and obviousness purposes.

From one perspective, this US approach is a hold-over from before the 2012 America Invents Act: the US previously used a “first to invent” standard, as opposed to the current “first inventor to file” standard.

Under the “first to invent” standard, what mattered was who first made the invention, with it being possible to “swear behind” an earlier filed application if an inventor could prove that they had invented the invention earlier. Accordingly, the usage of the earlier invention as secret prior art for both novelty and obviousness naturally followed.

The second key aspect, as shown in the table below, is whether self-collision, that is, the applicant’s own prior applications, can be cited. As can be seen there is a far more even split on this issue with the UK, Europe and China taking the view that there is no special status to the applicant’s own applications and accordingly these should be fully citable, just as if they were an application by a third party. In contrast, the US, Japan and Korea take the opposite view that they should not be citable.

Conclusion

As we have seen, this is an area where the variety of approaches taken across the world can lead to applications which are granted in one state being refused in another. This often comes as a surprise to applicants who have become used to most aspects of patent law having a good degree of harmonisation across the world.

While there have been moves to harmonise the rules on secret prior art across the world as part of the Substantive Patent Law Treaty, the negotiations have stalled since 2006. As such, it appears that there are no immediate prospects for the law in this area to be harmonised. In the meantime, if you have any questions or concerns regarding this area your D Young & Co representative is here to help.

Author:

Anton Baker



State	UK	Europe (EPO)	US	Japan	Korea	China
Patent office	UKIPO	EPO	USPTO	JPO	KIPO	CNIPA
Citable purposes	Novelty only	Novelty only	Novelty & obviousness	Novelty only	Novelty only	Novelty only
Self-collision	Yes	Yes	No	No	No	Yes

Battery technology

Innovation in batteries and electricity storage

Climate change is a critical issue which has attracted significant global attention and which poses a serious threat to society. However, with new challenges come new opportunities. In recent years, some of the world's biggest technology companies have focused their research and development machines on the area of green technology – a vital component in the fight against climate change. From amongst these green technologies, it has been identified that batteries and electricity storage technologies may hold the key to a greener and more sustainable future. Accordingly, the European Patent Office (EPO) and the International Energy Agency (IEA) have joined forces and developed a joint study of patent innovation in batteries and electricity storage.

The report from this study, titled "Innovation in batteries and electricity storage – a global analysis based on patent data", highlights the rise in patenting activity in the area of batteries and electricity storage. Furthermore, the report outlines a number of key areas for future innovation.

In this article, we take a look at the key findings described within the report. Furthermore, we consider the implications of the report for applicants who are looking to obtain patent protection for new inventions in the field of batteries and electricity storage technology.

Rise of patent filings

The report identifies that patent filings in the field of batteries and electricity storage have rapidly increased within the past ten years (2008 to 2018). Indeed, when it comes to innovations in areas of batteries and electricity storage, an average annual growth rate in patent filings of 14% has been observed over the past ten years. In comparison, the average annual growth rate in patent

filings across all fields of technology over this same period is 3.5%. As such, it is clear that patenting activity in the area of batteries and electricity storage is rapidly increasing – and shows no serious sign of abating.

In fact, more than 7,000 international patent families related to electricity storage were published in 2018, up from 1,029 international patent families in 2000.

The rapid increase in patenting activity in the areas of batteries and electricity storage ramps up the pressure on certain parts of the patent system. With an increase in patent filing, there is increased demand for patent searches and examination. Nevertheless, with the development of this joint study with the IEA, it is clear that this is an issue which patent offices such as the EPO are prepared to tackle.

As previously discussed, the global issue of climate change is responsible, in part, for the rise of patenting activity in areas of green technology. However, the report highlights that there are a number of key issues which have led to the specific rise of patenting activity for the areas of batteries and electricity storage.

Firstly, the report confirms that global energy storage and electricity storage technology is currently not on track to achieve the levels that are called for in the Sustainable Development Scenario of the IEA's projections for the future of global energy. The Sustainable Development Scenario calls for certain actions that are required in order to reduce CO2 emissions, whilst also tackling air pollution and achieving universal energy access – amongst other goals. Indeed, the IEA's Sustainable Development Scenario calls for close to 10,000 gigawatt-hours of batteries and other storage technology across the energy system worldwide by 2040-2050. This is approximately 50 times the size of the current energy storage capacity. Moreover, batteries currently account for less than 3% of global electrical storage (with pumped

storage hydropower accounting for over 90%). Batteries therefore offer significant potential for growth when expanding the global energy storage capacity. Furthermore, beyond 2030, the report identifies that new technologies will be needed to follow the cost and performance trajectories set out in the Sustainable Development Scenario.

Secondly, the report identifies that while the average increase in patenting activity in the areas of batteries and electricity storage have been high, there have been a number of periods where the increase in certain areas – such as innovation at the level of battery cells – has stagnated (for example, between 2014 and 2017). The more recent rapid acceleration in patent filings in this area is testament also to the increasing range of applications of modern batteries and electricity storage technology. Indeed, patents for battery-related inventions targeting electric vehicles overtook those for consumer electronics in 2011.

Evidently, exciting new business opportunities will arise as the range of application of batteries and electricity storage technology further increases. The number of patent filings in these areas of technology is therefore likely set to follow suit in the coming years.

Areas of patenting activity

Amongst the patent filings related to batteries and electricity storage, electrochemical inventions account for approximately 88% of all patenting activity. Electrical solutions to the demands of electrical storage account for a further 9% of the patenting activity in this area.

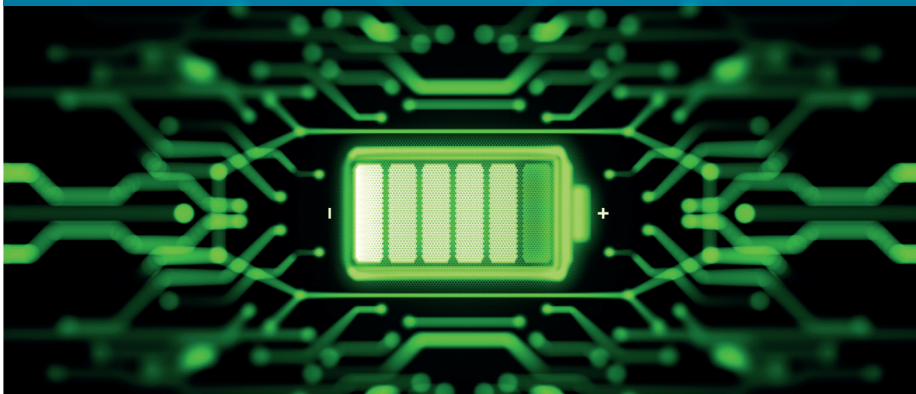
In particular, lithium-ion (Li-ion) technology is currently the dominant technology for portable electronics and electric vehicles. Indeed, the report notes that Li-ion technology has been fuelling innovation in battery technology since 2005 and accounts for the largest single proportion of this technology (45% of patenting activity related to battery cells relates to Li-ion technology).

However, the report identifies that new technology will also be required to address certain limitations of Li-ion technology.

➤ **Useful link**

European Patent Office (EPO) and International Energy Agency (IEA) joint study of patent innovation in batteries and electricity storage: "Innovation in batteries and electricity storage - a global analysis based on patent data", PDF download: <http://dycip.com/innovation-batteries>

Patenting activity in the area of batteries and electricity storage is rapidly increasing



having more recently ramped up their levels of patent filings in this area of technology (including LG Electronics and Toyota). Some of this expansion coincides with the increase in the range of application of batteries and electrical storage technology.

Furthermore, the report highlights that the top 25 applicants account for approximately 47% of all international patent filings related to batteries since 2000. This percentage contribution of the top 25 applicants has even increased slightly over the past five years. However, the cumulative share of the top ten applicants has fallen a little over this period.

Accordingly, with the recent growth in patenting activity in this area from applicants (such as LG Electronics and Toyota) and the apparent diversification of contribution (with a small decrease in the percentage contribution of the top ten applicants) the report suggests that the market for batteries and electricity storage is still growing, and that opportunities for new development are still available.

Conclusion

From the report, it is clear that a number of environmental and technological pressures have led to rapid growth of patent filings in batteries and electricity storage areas of technology. There are no signs of this growth abating – with a number of new opportunities for further development being identified within the report.

In fact, the report (produced jointly with the IEA) serves as a statement of intent from the EPO of their commitment to support innovation in areas of green tech such as batteries and electricity storage.

Accordingly, we believe the report will be met with keen interest by applicants who are looking to capitalise on the vast opportunities presented by the area of batteries and electricity storage technology, and who are looking to establish themselves as leaders in this exciting and rapidly developing field.

Author:
Simon Schofield



In particular, energy density of electrical storage is important for consumer devices (such as portable electronics and the like). However, the requirement for high energy density is even more important still for electrical vehicles, and is in fact seen as a limiting factor in the development of electrical vehicles. New technological developments that can increase the energy density of Li-ion storage technology will be required. Furthermore, the report identifies the limitations of the current ability to recycle and reuse Li-ion batteries. The need to develop reuse and recycling technologies will be more keenly felt as the number of electrical vehicles and storage systems continue to increase.

Redox flow and super capacitors are identified in the report as emerging electricity storage technologies that could have the potential to address a number of apparent weaknesses found in the Li-ion batteries. These technologies may provide substantial improvements in safety. Moreover, these technologies may address more specific requirements of electrical vehicles (such as faster charging). It will be interesting to see how the levels of patenting activity in these emerging electricity storage technologies develops in the near future.

Of course, areas of patenting activity are not only limited to developments in battery technology itself.

Improvements in energy management technology are required in order to

compensate for the inherent supply variability of renewable energy sources (for example, solar power and wind power). Otherwise, peak demand could overwhelm supply in periods where the amount of energy supplied by these renewable energy sources is lower.

Smart charging and vehicle-to-grid solutions may help with energy management, yet have the downside that they may negatively affect battery lifetimes and performance. Accordingly, battery management systems will also play an essential role in any future developments.

As such, while Li-ion technology is the dominant technology that has been fuelling innovation in batteries and electricity storage technology in recent years, it is clear that there are a wide range of new areas of technology ripe for innovation.

Key developers of new technology

The report identifies that development in battery technology is strongly dominated by applicants in Asia, with Japanese companies at the forefront. Indeed, the report recognises that Asian companies account for nine of the top ten global applicants for international patent filings related to batteries- including a number of technology giants such as Samsung [KR], Panasonic [JP], LG Electronics [KR], Toyota [JP] and Sony [JP].

A number of these contributors (such as Panasonic and Sony) are recognised as long-established leaders in the field. Other prominent applicants are identified as

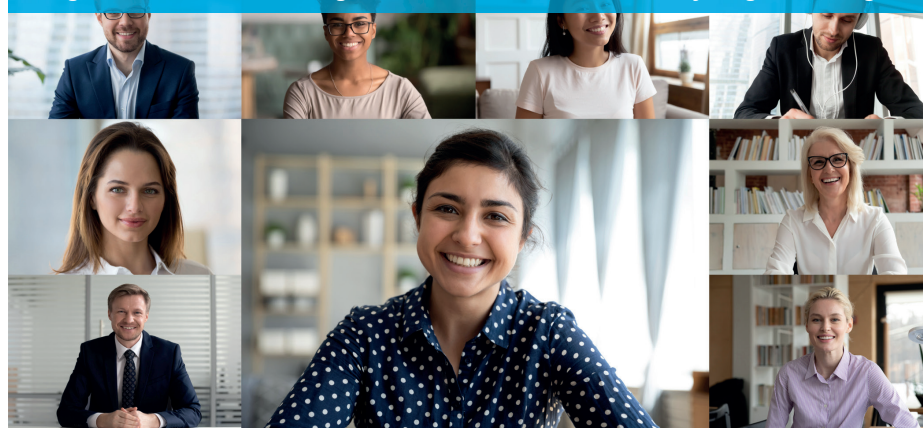
D YOUNG & CO INTELLECTUAL PROPERTY

And finally...

ViCo at the EPO

EPO oral proceedings by video conference What to expect and how to prepare

Our guide to video conferencing at the EPO is now online at www.dyoung.com/vico-guide



Facing up to the challenges that social distancing and travel restrictions bring, the European Patent Office (EPO), like many organisations and businesses in 2020, has significantly increased its use of video conferencing (ViCo) as an important means to facilitate communication. The EPO has explained that this change in practice is “with a view to guaranteeing effective access to justice and to avoid a continuous increase in the number of unresolved oppositions”.

Guide to ViCo at the EPO

We have drawn from our experience of *ex parte* and *inter partes* oral proceedings before the EPO by video conference to prepare a guide for participants covering what to expect and how best to prepare. The guide includes our handy client “Checklist for ViCo”:

www.dyoung.com/vico-guide

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