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New EU Legislation Proposals (Part I): A First Look at the Draft SEP Regulation

The European Commission published a package of draft regulations concerning patents on 27 April 2023. The package includes support for licencing of standard essential patents (SEP), supplementary protection certificates (SPCs), and compulsory licensing of patents. In the first of a series of articles on this legislative package, we focus on SEPs.

Background

SEPs provide rights on standardised technologies that, owing to said standardisation, have a privileged market position. Examples of such patents include those covering essential aspects of 5G telecommunications, MPEG audio and video compression, or Internet of Things (IoT) communications. According to the EU Commission,[1] "*SEPs represent approximately 2% of the population of the patents that are currently in force*" and the top 50 SEP owners control about 75000 SEP families.

In Europe, enforcement of patents, including SEPs, is currently entrusted to national courts and, as of June 2023, to the UPC, and the licensing of SEP rights is based on free negotiation and ultimately regulated by EU and national competition law.

In the view of the EU Commission, non-uniform interpretation of FRAND[2] conditions by national courts has led to an unpredictable SEP licencing market and to inefficient licensing negotiations in terms of time and cost. In addition, small and medium enterprises (SMEs) wishing to implement technology covered by an SEP often feel excluded from negotiations on SEPs or feel pressured to accept licensing terms under the threat of an injunction.

In terms of overall efficiency of SEP licensing for both the SEP holder and the implementer, the EU Commission considers that drawbacks of the current practice include that it is sometimes difficult to identify an SEP owner and that standard essentiality of a patent is assessed independently by each party of a licensing debate, multiplying the number of essentiality assessments and thus the risk of different assessment outcomes. This can result in long and inefficient licensing procedures.

Proposed Regulation

On this basis, the European Commission has recently released a proposal to regulate the enforcement and licencing of SEPs within the European Union, with the aim of harmonising the licencing market for these patents and making standard essential technologies more accessible to SMEs. How this would work is set out in 72 articles.

An SEP is defined in the proposed Regulation as any patent containing at least one claim "*for which it is not possible on technical grounds to make or use an implementation or method which complies with a standard, including options therein, without infringing the patent under the current state of the art and normal technical practice*"[3], where the standard is a technical specification adopted by a standard developing organization (SDO). In that context, the Regulation proposed by the Commission then envisages three main elements.

[1] Proposal for a Regulation of the European Parliament and of the Council on standard essential patents and amending Regulation (EU) 2017/1001 – Impact Assessment Report, page 8.

[2] Fair, reasonable, and non-discriminatory terms and conditions.

[3] Proposal for a Regulation of the European Parliament and of the Council on standard essential patents and amending Regulation (EU)2017/1001, Art. 2(2).

1. Registration

SEP holders would be required to register their SEPs in a public register, providing various data including the royalty and discount policy of the proprietor, the availability for licencing through patent pools,[4] the result of any essentiality checks by independent evaluators, and any assessments by a Competent Count of a Member State.[5]

EU Member States would not allow patentees to enforce SEP rights or to receive royalties therefrom if the SEP in question is not registered.[6] An SEP in force in a Member State would be entered in the register[7] at the request of the holder and on payment of a fee, and it would be removed from the register if the patent was found to be invalid or not essential.

A Competence Centre, formed within the European Union Intellectual Property Office (EUIPO) in Alicante, Spain, would be in charge of creating and maintaining the register. SEP holders would have the possibility to jointly notify the Competence Centre of an aggregate royalty,[8] i.e., a total royalty amount agreed upon by patent holders for their respective patents essential to a standard.

2. Essentiality check

The EUIPO would annually select a sample[9] of registered SEPs from each holder and each standard, including SEPs voluntarily proposed by the respective SEP owners.[10] Technical observations could be submitted by any stakeholder to evaluators appointed by the EUIPO,[11] who would check standard essentiality of these selected patents and issue a non-legally binding opinion.[12]

The opinion on essentiality could be contested. In this case, the EUIPO would provide for a re-evaluation by a new evaluator and the further essentiality assessment would be appealable before the EUIPO Boards of Appeal.[13] Upon request by the SEP holder, an SEP could be removed from the register[14] in response to a negative result from the essentiality examination.

3. FRAND determination

An out-of-court determination of FRAND licencing conditions by the EUIPO would be initiated at the request of a requesting party, which may be either the SEP holder or an SEP implementer. The request would have to be made prior to the initiation of infringement proceedings before a court of a Member State or prior to any request for FRAND determination before a court of a Member State, respectively.[15]

However, the FRAND terms would only be binding if the determination is accepted by both the requesting and the responding parties.[16] The determination procedure should last no longer than 9 months[17] from the start of the FRAND determination process, and should end with the issuance of a "*notice of termination*" indicating whether the FRAND has been determined or not, and whether the parties have committed to comply with it or not.[18] The proposal also foresees an optional procedure to assist SEP holders in determining the aggregate royalties by EUIPO "conciliators".[19]

Finally, if necessary, litigation could be initiated before a competent court of an EU Member State or before the UPC. However, under the proposed Regulation, this could only take place in presence of the "*notice of termination*" of the FRAND determination procedure.

[4] Ibid., Art 4.
[5] Ibid., Art. 8.
[6] Ibid., Arts. 24 and 56(4).
[7] Ibid., Art. 20.
[8] Ibid., Art. 15.
[9] Ibid., Art. 29(1).
[10] Ibid., Art. 29(5).
[11] Ibid., Art. 30.
[12] Ibid., Art. 28(5).
[13] Ibid., Art. 29(10-11).
[14] Ibid., Art. 25(1).
[15] Ibid., Art. 34.
[16] Ibid., Art. 38.
[17] Ibid., Art. 37.
[18] Ibid., Art. 56.
[19] Ibid., Art. 18.

Analysis

The proposed procedure is intended to offer an independent, expert, and transparent licencing procedure alternative to the current practice, with the aim of creating a marketplace where SEP holders and implementers can promote their mutual business and conduct assisted licencing negotiations. However, it is not clear whether the proposed Regulation will in fact serve to reduce the number of litigations regarding royalty disputes going to court.

In the case of standardised technologies covered by SEPs, the result of technological research is not so much a product itself, but the very definition of the standard. The investment in R&D that has led to the definition of a standard is therefore made possible by the royalties from future licenses.

Historically, SEP holders tend to foresee a risk of 'hold-out" in the SEP market, whereby implementers challenge the validity and the infringement of SEPs in order to delay or avoid paying royalties. On the other hand, implementers main concern is generally 'hold-up', whereby an SEP holder abuses its position to demand excessive royalties.

The proposed Regulation seems to be designed from the latter perspective, as it imposes constraints on SEP holders, such as the registration requirement, the payment of fees to the EUIPO, and the at least one-year delay before being able to go to court, while not imposing any specific constraints on implementers.

We therefore see a real risk that, with this Draft Regulation, technological innovation may be stifled rather than encouraged, as it will be more difficult for SEP holders to obtain economic return from royalties, and companies that participate in defining standards may be discouraged from investing further in research.

In the current European SEP licencing market, licencing agreements are usually concluded without litigation, and only about one out of ten cases ends up with a dispute before a court. Even assuming that this one in ten cases would be resolved without the need for court proceedings thanks to the proposed Regulation, the remaining nine cases would still be affected by additional costs and delays, not to mention the legal impossibility of receiving royalties before obtaining the "*notice of termination*". Whether this will encourage innovation is questionable. This could be a significant reason the proposed Regulation has not attracted much enthusiasm so far.

Some observers have also noted that the EUIPO, as the selected Competence Centre, may not have the necessary competence and expertise to deal with patents, and in particular with standard essentiality assessments. Although the EUIPO will likely hire qualified evaluators, the task of guaranteeing high-quality essentiality assessments seems ambitious in view of the complexity and the technical background required in specific technologies and in view of the technical observations that may be filed. One risk would be a corresponding reduction in the number of sample SEPs checked for essentiality, contrary to the goals of the proposed Regulation in terms of harmonisation.

Moreover, the requirement to register an SEP with the EUIPO before being able to bring an infringement action before the UPC may conflict with the fundamental rights protected in the European Union. This is the opinion of none other than the President of the UPC Court of Appeal, Klaus Grabinski, who referred to the EU Charter of Fundamental Rights in this respect.[20] Grabinski anticipates numerous infringement actions from SEPs holders before the UPC because of its wide jurisdiction in Europe.

[20] Klos, Mathieu (5 June 2023). "Klaus Grabinski, the man without bias". *JUVE Patent*.

Next steps and expected timeline

The proposed Regulation must now be considered by the European Parliament and the Council of the European Union for a first reading, which is likely to result in proposed amendments and possibly negotiations. The resulting second draft will then be submitted to the Parliament and the Council for a second reading and vote. Not only could this process take years, but it could also end with significant changes or with the proposed legislation not being adopted at all. We will closely follow the developments.

Conclusions

The European Commission is proposing a new Regulation to support SEP licensing by establishing a mandatory SEP register and providing guidance on the definition of licencing condition under FRAND. The proposed Regulation raises practical and technical questions as to how it will actually be implemented. The proposal also seems to favour the 'hold-up' viewpoint over the 'hold-out' viewpoint, and the whole framework risks eventually disincentivizing R&D investments rather than encouraging innovation.

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New EU Legislation Proposals (Part II): Creation of a New SPC Landscape for Europe

The European Commission is planning a sweeping reform of supplementary protection certificates (SPC), instruments by which the patent protection of pharmaceutical and plant protection products can be extended by up to 5 ½ years. In late April 2023, it outlined a new SPC landscape in four proposed regulations:

- Two new regulations creating a new unitary SPC, one for medicinal products and one for plant protection products.
- Two regulations that introduce a centralised procedure for the grant of national SPCs, by recasting and repealing Regulation (EC) No 469/2009 for medicinal products ("MP Regulation") and Regulation (EC) No 1610/96 for plant protection products ("PPP Regulation").

Under the new regulations, the unitary and national SPCs will share a centralised examination procedure spearheaded by the EUIPO.

As part of our ongoing series on the new package of EU draft regulations, we have reviewed the above new regulations and the planned changes to the European SPC system. In the present article, we have a look at the creation of the new SPC framework and the changes to the current SPC system. In part III of our series to be published in the next issue of the *HOFFMANN EITLE Quarterly*, we will review the shared centralised examination procedure through which unitary and national SPCs will be obtained in the future.

Historical background

In 2015, the EU Commission published a strategy paper[1] addressing, inter alia, the lack of coherence in the unitary patent system in the absence of a unitary SPC. Although it is currently possible to extend a unitary patent by national SPCs, this approach is inconsistent because the unitary protection conferred by a unitary patent would then be complemented, after the expiry of the patent, by a plurality of legally independent, non-unitary national SPCs. Accordingly, the Commission announced its intention to propose a new legal framework for patents and SPCs in the EU, including a unitary SPC.

With the coming into force of the UPCA and the creation of European Patents with Unitary Effect (EP-UE) – also known as 'unitary patents' – it was only a matter of time before the EU Commission had to react.

[1] European Commission, COMMISSION STAFF WORKING DOCUMENT (SWD(2015) 202 final) A Single Market Strategy for Europe - Analysis and Evidence, Brussels, 28.10.2015.

Eligibility for centralised examination procedure

The first concrete regulation proposals for creating such a new unitary SPC were published on April 17, 2023, both for pharmaceutical[2] and plant protection products,[3] respectively. The new SPC landscape will include unitary SPCs on the one hand, and a new, more efficient procedure for granting national SPCs on the other.[4]

Both types of SPCs will be obtainable through a centralised examination procedure conducted by the European Union Intellectual Property Office (EUIPO),[5] and both will be subject to new eligibility rules. In the present article, we look at the eligibility – including eligibility for the centralised examination – and judicial competence for the new SPCs, whereas Part III will focus on the examination procedure itself.

The new centralised examination procedure is only available for SPCs based on European patents (EPs), including those with unitary effect (EP-UE).

For **medicinal products**, the centralised examination procedure will further be available only for drugs having undergone a central market authorisation procedure, i.e. through the European Medicinal Agency (EMA). Specifically, when a central marketing authorisation has been obtained and the basic patent is a European patent, including a unitary patent, the centralised examination procedure will be the only way to obtain an SPC, both unitary and national. This means that the traditional grant procedure for SPCs through national patent offices will remain open only for medicinal products with national marketing authorisations or SPCs based on national patents.

This framework for medicinal products cannot be applied to **plant protection products**, as for these no central marketing authorisation exists. Moreover, since marketing authorisations for a given plant protection product are often granted at different dates in different Member States, it may frequently happen that, at the date of filing of a centralised SPC application, authorisations have been granted in some of the designated Member States but not in all of them. Consequently, it is therefore proposed to allow an application via a centralised examination procedure for plant protection products protected by a European patent, including a unitary patent, if

- at the date of filing of the SPC application, national marketing authorisations have been *applied for* in each designated state, and
- before the end of the examination process, marketing authorisations have been *granted* in *all* designated Member States.

At the same time, it would be required that the examination opinion is not adopted earlier than 18 months from the filing of the application, to increase the likelihood that the 'missing' authorisations have been granted by then. Where this condition is not met in one of the designated Member States, however, the examination proceedings would be suspended until the 'missing' authorisation has been granted, provided that – for legal certainty reasons – this takes place before the expiry of the basic patent.

[2] COM(2023)222 - Proposal for a regulation of the European Parliament and of the Council on the unitary supplementary certificate for medicinal products (europa.eu).

[3] COM(2023)221 - Proposal for a regulation of the European Parliament and of the Council on the unitary supplementary protection certificate for plant protection products (europa.eu).

[4] COM(2023)223 - Proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for plant protection products (recast) (europa.eu) and COM(2023)231 - Proposal for a regulation of the European Parliament and of the Council on the supplementary protection certificate for medicinal products (recast) (europa.eu).

[5] The EUIPO is currently competent for the registration of EU trade marks and registered Community Designs (RCD).

National and unitary SPCs

If the requirements for centralised examination are met and if the basic patent is a unitary patent, the applicant may apply for a unitary SPC. It will not be possible to obtain a unitary SPC based on a traditional EP bundle patent. National SPCs via the centralised procedure, on the other hand may be based on unitary patents or on traditional EP bundle patents.

As the name suggests, the unitary SPC is intended to have unitary character, meaning that it can only be obtained, limited, transferred, revoked, or lapse in all UPCA member states at once. Any infringement or revocation action will have to be brought before the UPC. In this sense, the unitary SPC is the logical extension of its basic patent, the unitary patent.

Starting from a granted EP patent that was validated as a unitary patent ('EP-UE') in the current 17 UPCA member states and in at least some of the remaining EU states in the traditional manner ('trad. EP'), i.e. country by country, applicants will be able to submit a 'combined application' which, if granted, would result in a unitary SPC for UPCA member states and a bundle of national SPCs in the remaining designated EU states.

As with the unitary patent system in general, one reason for creating the centralised procedure and unitary SPCs is to reduce costs. Under the new system, an applicant will only have to file a single application, thereby avoiding the duplication of application efforts, thus saving legal costs, translation requirements, and other formal hurdles. For applicants seeking EU-wide SPC protection for their respective product, it is estimated by the EU Commission that this new approach could save up to €137,000 per product.

The unitary SPC is also designed to provide greater legal certainty to applicants and competitors by removing the onerous task of reviewing the individual SPC status in each country. To this end, a public register for all SPCs (unitary and national via the centralised examination procedure) will be created to keep the public informed of the status and scope of pending and granted SPCs.

Finally, the new centralised examination procedure will eliminate one major deficiency in the current system, namely the lacking harmonization due to diverging assessments by the national patent offices. Particularly in cases involving legal issues, this may result in the SPC application being rejected or granted with a limited product definition in some EU Member States, while in others the application is granted without difficulty. Further, some national offices, such as those of Luxembourg and Greece, do not examine SPC applications on their merits but normally register them if certain formal requirements are met.

Eligibility – Marketing authorisation held by third party

Both for unitary and national SPCs, a further substantial change is the proposed requirement that, if a basic patent has been granted in respect of a product that is the subject of an authorisation held by a third party, the SPC cannot be granted without the consent of that third party. The possibility of 'passively' applying for SPCs and piggybacking on a third party's regulatory approval efforts, when the patent holder and SPC applicant has not made any investment in research leading to the commercial exploitation of their basic patent and no license agreement with the third party exists, is largely seen as undermining the objective of Regulation No 469/2009.[6] This would be made impossible by the Commission's proposal.

[6] C-493/12 Ely Lily and Company vs HGS Inc., cf. Item 43 of the Reasons.

Eligibility – Number of SPCs per product

Further, the EU Commission proposes to codify that **an SPC applicant holding more than one patent for the same product** shall not be granted more than one SPC[7] for this product, i.e., for the active ingredient and for the combination of active ingredients of a medicinal product or plant protection product, for any given member state. A similar provision already exists in Article 3(2) of the PPP Regulation but, to date, had never been expressly included into the MP Regulation. The double protection in the same UPCA member state by unitary and national SPCs for the same product will not be possible either.

Based on the wording of Article 3(2) of the PPP Regulation, the draft regulation also clarifies that, if two or more SPC applications concerning the same product and submitted by **two or more holders of different patents** are pending in a given Member State, one certificate or unitary certificate for that product may be granted to **each** of those holders. Interestingly, the Commission's proposal goes beyond the scope of the existing provisions of the PPP Regulation by requiring that those holders must **not** be "*economically linked*". This additional condition is likely to prevent the grant of more than one SPC to several **affiliated companies** if they hold different basic patents for the same product. However, in the absence of further guidance, the vagueness of the term "*economically linked*" is likely to cause issues when it will have to be determined whether or not co-pending SPC applications are both eligible for SPC grant. For instance, does the existence of a license agreement between two companies create an economic link that excludes the grant of co-pending SPC applications to both? It may be useful to clarify this during the further legislative process.

Conditions for obtaining certificates, their effects and duration of unitary SPCs

In view of the relevant case law of the European Court of Justice, the reform neither intends to modify nor to further clarify the substantive features currently laid down in the MP and PPP Regulations. The provisions relating to the conditions for obtaining unitary SPCs (Art. 3), the scope of protection (Art. 4) and the rights conferred (Art. 5) by a future unitary SPC thus fully correspond to those existing, currently, for national SPCs.

The duration of a unitary SPC (Art. 20) will be determined in the same manner as laid down in Art. 13 of the existing MP and PPP Regulations, i.e. by calculating the time elapsed between the date of the first marketing authorisation in the European Economic Area (EEA)[8] and the filing date of the basic patent reduced by 5 years, with a maximum extension term of 5 years. A paediatric extension of the SPC duration by 6 months will also be available.

Jurisdiction

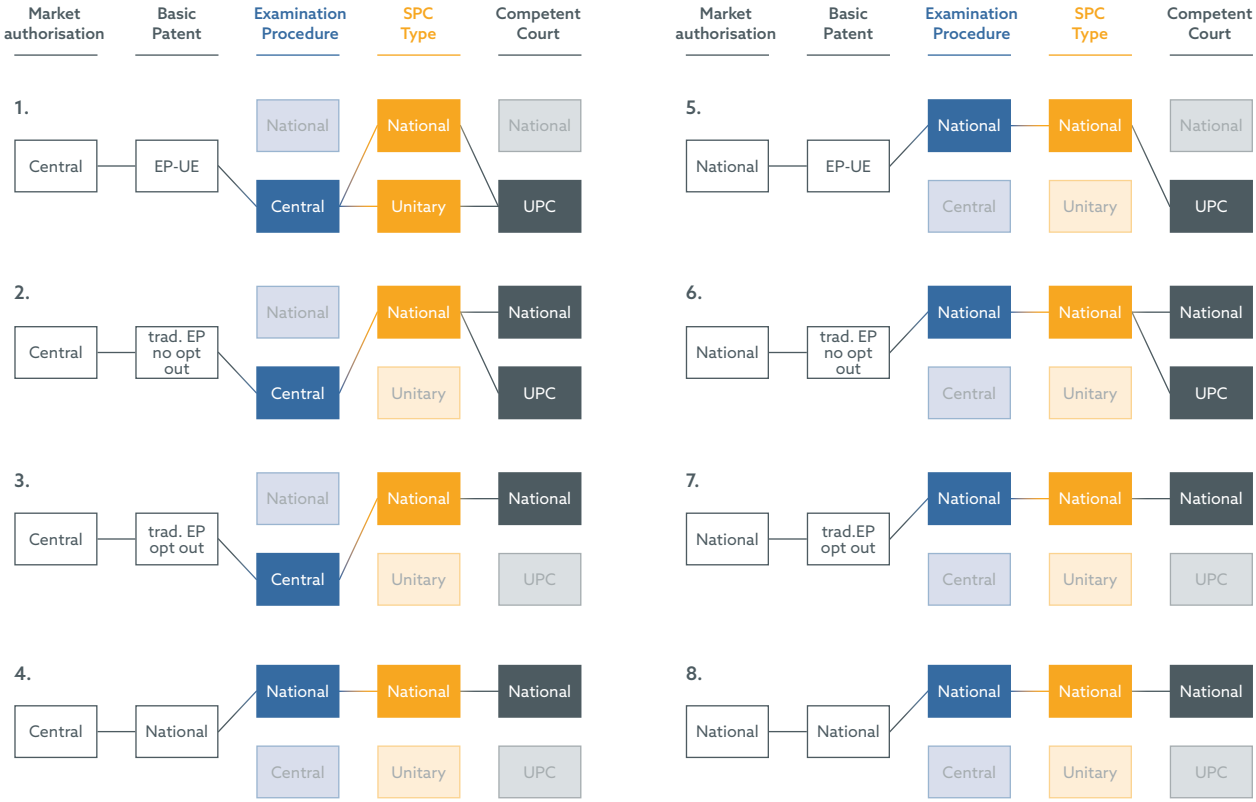
The jurisdiction for the different types of SPCs will be the same as for the basic patent and, most importantly, the jurisdiction for an SPC will always follow that of the basic patent. National SPCs based on traditional EP bundle patents that have not been opted out will fall under the shared jurisdiction of the UPC or a national court depending on where an action is first made pending. The jurisdiction on both national SPCs based on national patents and on national SPCs based on EP patents for which an 'opt-out' has been declared will however remain exclusively with national courts.[9] This is illustrated in the figure below.

[7] Proposed Art. 3(2): *the holder of more than one patent for the same product shall not be granted more than one certificate or unitary certificate for that product for any given Member State*.

[8] This market authorization may differ from the one triggering the six-month period for filing the application.

[9] Rule 5.2 of UPC Rules of Procedure.

a. Examination and Jurisdiction for SPCs



b. Validation of EPs

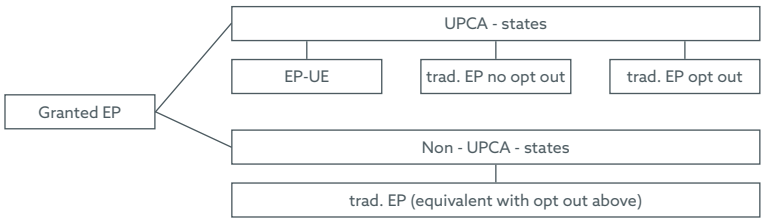


Fig. 1 | a. Proposed SPC landscape for medicinal products in Europe. Note that this figure does not apply to PPPs for the aforementioned reasons. SPC applications based on an EP patent, including an EP-UE, *and* a central market authorisation must go through the central examination procedure. Patent proprietors holding an EP-UE (1) can choose to obtain national or unitary SPCs. Regardless of which kind of SPC is obtained, jurisdiction falls under the UPC since it follows that of the basic patent (EP-UE). No unitary SPCs can be obtained based on a traditional EP patent (2). If no opt out has been declared for this EP patent, the national SPC can become subject to the jurisdiction of the UPC or a national court depending on where an action is made pending first. If an opt out is declared (3), the UPC is no longer competent. The national courts are also competent for SPCs based on national patents (4), which furthermore cannot go through the central examination procedure. SPC applications based on national market authorisations must go through a national examination procedure and only national SPCs can be issued in the process (5-8). The jurisdiction for the national SPC however follows that of the basic patent. This means that national SPCs based on EP-UEs are subject to the UPC (5), and the same opt-out regulations as before apply (6-7). Finally, SPCs based on national patents and national market authorisations (8) are subject to national jurisdiction.

Fig. 1 | b. Overview of validations of granted EP patents. In UPCA states, an EP patent can be validated as an EP-UE or a 'traditional' EP bundle patent, wherein for the latter an opt out can be declared to remove it from the UPC's jurisdiction. Such a patent can be treated in the same way as a traditional EP patent in non-UPCA states.

Analysis and conclusion

With four new proposed regulations, the European Commission launched the most ambitious reform of SPC law in Europe since its creation. The proposals are part of a wider effort to harmonise European intellectual property law and create a more centralised, cost-effective, and transparent system.

The reform will not only be relevant for SPC applications based on unitary patents, rather it will also affect SPC applications based on opted out EP patents and central marketing authorizations.

According to Regulation (EC) No. 726/2004,[10] the centralised European approval procedure has to be used for the approval of certain drugs, especially those with new active ingredients for serious diseases. Moreover, national patents are very rarely applied for life science inventions. As a result, the central SPC examination route via the EUIPO will become mandatory for the vast majority of newly authorized pharmaceuticals and plant protection products.

Basically, the reform launched by the Commission is to be welcomed since it will considerably simplify the process of obtaining SPCs throughout the EU and increase transparency. However, this benefit comes at a price. It constitutes a fundamental change from a system allowing the distribution of risks across many co-pending SPC applications to the new centralised procedure that entitles the applicant to file only one high-stake application. This element of the proposed reform may attract some criticism from originators, given the immense commercial value of SPCs for top-selling pharmaceuticals.

In the next issue of the *Hoffmann Eitle Quarterly*, we will look at the shared, centralised examination procedure through which SPCs will be obtained.

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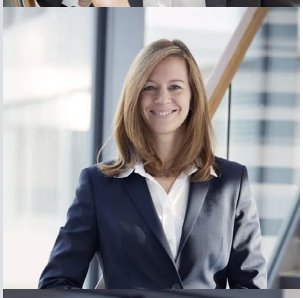

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[10] Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Text with EEA relevance) as amended by Regulation (EC) No 5/2019 and Regulation (EC) No 6/2019 of 11 December 2018

"Eieiei": Stating the Obvious Is Not a Trademark Infringement

Is a slogan a trademark if it describes the obvious? The Higher Regional Court (HRC) Dusseldorf considered this question in a case between two German eggnog manufacturers – and came to a clear decision.

Does the fivefold repetition of the word "Ei" ("egg" in German) in an advertisement for eggnog infringe the registered word mark "Eieiei"? This was the question to be decided by the HRC Dusseldorf in April this year.[1]

Facts of the case

Verpoorten, a spirits producer based in Bonn, Germany, sued its competitor Nordik, based in Jork, Lower Saxony, Germany – how did it come to this?

During the Christmas period of 2019, Nordik advertised on its website five bottles of eggnog with different flavours, using the signs "Ei, Ei, Ei, Ei, Ei" as follows:

Source: http://www.justiz.nrw.de/nrwe/lgs/duesseldorf/lg_duesseldorf/j2022/2a_O_202_20_Urteil_20220112.html ; accessed on August 14, 2023.

According to Verpoorten, this was too close to their word mark "Eieiei", which Verpoorten registered back in 1979 in Nice Class 33 for spirits. Verpoorten asserted that Nordik were using a highly similar sign to identify identical goods, namely eggnog, which would result in a likelihood of confusion as well as an infringement of the well-known trademark "Eieiei".

In Verpoorten's view, the relevant public would understand the fivefold repetition of the word "Ei" as an indication of origin in relation to the product and would also automatically think of Verpoorten's trademark "Eieiei".

Accordingly, Verpoorten requested Nordik to cease and desist using the sign "Ei, Ei, Ei, Ei, Ei" at the beginning of 2020 and also requested reimbursement of the costs incurred for issuing the warning letter. Although Nordik signed an undertaking to cease and desist with a penalty clause, they did not reimburse the requested costs. Three months later, in April 2020, Nordik again advertised eggnog, this time on social media, using the phrase "Ei, Ei, Ei, Ei, Ei". Verpoorten then demanded that Nordik pay a contractual penalty and further cease publishing the advertisement.

[1] HRC Dusseldorf – "Eieiei" (20 U 41/22).

Analysis and decision

At first sight, one might think that this case is a clear trademark infringement. Most Germans are probably familiar with the advertisement jingle "Ei ei ei Verpoorten", the text and melody of which have remained unchanged for sixty years.[2]

However, after the case was dismissed at the first instance before the Regional Court (RC) Dusseldorf, the case then went to the HRC Dusseldorf, which also dismissed Verpoorten's claims. The Higher Court held that the use of the words "Ei, Ei, Ei, Ei, Ei" did not constitute an infringement of the word mark "Eieiei".

In the opinion of the court, the relevant public would understand the fivefold repetition of the word "Ei" as a descriptive reference to the main ingredient of eggnog, being, you guessed it, egg. Thus, the sequence of words would refer to the nature of the advertised product and would therefore not be understood as a trademark, i.e. an indication of origin. However, use of the sign as a trademark is a prerequisite for trademark infringement.

That understanding on the part of the public would not be altered by the fivefold repetition of the word "Ei". In particular, the repetition would not constitute a semantic or syntactic peculiarity, but would rather serve to increase the attention of the customer. Moreover, "Eieiei" in German would be an expression of astonishment, which would have to be regarded as nothing more than a promotional praising and which would not be linked to Nordik's enumeration of five "eggs".

Further, the Court held that Verpoorten failed to prove that its mark "Eieiei" was well-known. Although it was obvious from the material submitted that the slogan "Ei, Ei, Ei Verpoorten" has been intensively used, this would not show that the registered trademark "Eieiei" was well-known. In particular, the registered trademark "Eieiei" would differ from the slogan "Ei, Ei, Ei Verpoorten" since there would not be a separation between the individual elements "Ei" and since further the slogan was used together with the company name Verpoorten which is of individual distinctiveness, and therefore there would be an amendment of the distinctive character of the mark in comparison to the registered trademark.

Finally, the Court indicated that eggnog producers must be allowed to refer to the main ingredient of their drinks, namely eggs, without being accused of a trademark infringement.

Accordingly, the HRC Dusseldorf ultimately dismissed Verpoorten's claims.

This decision shows that if a slogan describes the obvious it will not be considered as a trademark. It is therefore strongly advisable to choose and promote a sign as a trademark which is not descriptive but which will be considered as an indication of origin.

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[2] "Verpoorten-Werbejingle feiert Jubiläum, Pressemitteilung von: Verpoorten GmbH & Co. KG" ("Verpoorten advertising jingle celebrates anniversary, Press release by: Verpoorten GmbH & Co. KG "), openPR, 15 April 2011.

Referral G 1/23: The Public Availability of Products in a New Light

As foreshadowed last year in the HOFFMANN EITLE Quarterly,[1] EPO Board of Appeal 3.3.03 in decision T 438/19 has referred three questions to the Enlarged Board of Appeal (now handled as G 1/23 "Solar Cell") to resolve a perceived divergence in the case law. The referral concerns whether and to what extent a product and technical information partly describing it constitute prior art under Art. 54(2) EPC.

Background – Art. 54(2) EPC and G 1/92

Art. 54(2) EPC defines the state of the art, i.e. the prior art under the EPC, as comprising "everything made available to the public". Here, the term "available to the public" sets a higher threshold than e.g. "everything known or described". For instance, one dictionary defines "available" as "readily obtainable; accessible".[2]

Something that cannot be readily obtained or accessed by a skilled person is not "available" in this sense. A mere description of an entity having desirable properties is thus not "available to the public" if a skilled person is not provided with the necessary information for actually obtaining the entity.

That such a threshold exists in patent law is very sensible if one considers that a major justification for granting patents (i.e., monopolies) is to foster progress in technology. By disclosing the invention and thereby making it "available to the public" (as required by Art. 83 EPC), the inventor enables others to reproduce, test and improve the invention so as to develop the disclosed technology further. In exchange, the inventor gets a patent and can enjoy a monopoly.

This line has also been adopted by the EPO, for instance in G 1/92. Here, the Enlarged Board held under item 1.4:

> *An essential purpose of any technical teaching is to enable the person skilled in the art to manufacture or use a given product by applying such teaching. Where such teaching results from a product put on the market, the person skilled in the art will have to rely on his general technical knowledge to gather all information enabling him to prepare the said product. Where it is possible for the skilled person to discover the composition or the internal structure of the product and to reproduce it without undue burden, then both the product and its composition or internal structure become state of the art.*

G 1/92 appears to be quite clear in that, for a product to be "available to the public", a skilled person must be able to analyse and reproduce it. This is in line with the current version of the EPO Guidelines, section G-VI, 4, stating:

> *Subject-matter described in a document can only be regarded as having been made available to the public, and therefore as comprised in the state of the art pursuant to Art. 54(1), if the information given therein is sufficient to enable the skilled person, at the relevant date of the document to practise the technical teaching which is the subject of the document, taking into account also the general knowledge at that time in the field (see T 26/85, T 206/83 and T 491/99).*

[1] Timo Pruß, When Are Products "Available to the Public" in the Sense of Art. 54(2) EPC?, HOFFMANN EITLE Quarterly, September 2022, pp. 14-16.
[2] "Available". *Dictionary.com*. Retrieved 1 September 2023.

> *Similarly, (...) a chemical compound, the name or formula of which is mentioned in a prior-art document, is not thereby considered as known unless the information in the document, together, where appropriate, with knowledge generally available on the relevant date of the document, enables it to be prepared and separated or, for instance in the case of a product of nature, only to be separated.*

Thus, known products can still be patented if they cannot be reproduced or reverse-engineered based on common knowledge.

Not all products are equal

Some products are easy to reverse-engineer, while others, such as polymers, may be more difficult or impossible to reverse-engineer. Two polymers in the same class, such as polyolefins, often have similar compositions in terms of elements and starting materials but can possess very different physical properties due to differences in their internal structure. These differences in internal structure are a consequence of their methods of manufacture, in particular the choice of polymerization catalyst, its amount, the reaction conditions (temperature, pressure), the presence, identity and amount of auxiliaries, etc. Even for someone skilled in polymer chemistry, in the light of thousands of known polymerization catalysts and a plethora of different reaction conditions and auxiliaries, it is utmost difficult, if not impossible, to reverse-engineer a commercial polymer in the absence of knowledge about the catalyst and synthesis conditions.

Realizing these difficulties, even the referring Board 3.3.03 excluded a polymer having the claimed properties from the state of the art under Art. 54(2) EPC in the absence of detailed information on its synthesis (T 1833/14, T 2916/19).

The present referral

In the underlying case, operative claim 1 relates to an encapsulating material for a solar cell that comprises an ethylene/α-olefin copolymer that satisfies specified ranges for melt flow rate (a common parameter for polymers), density, Shore A hardness and aluminium content.

The Opponent attacked the claim based on an example in a prior art document considered as closest prior art for the inventive step assessment. The example describes an encapsulating material for a solar cell that contains a commercial polymer ("ENGAGE 8400"). The Opponent/Appellant asserted that the commercial polymer satisfied all features of the claim except for the aluminium content, as also derivable from product brochures, and that adjusting the aluminium content did not require inventive skill.

The Patent Proprietor defended the patent *inter alia* by submitting that there was no information in the prior art as to how this specific commercial polymer was to be prepared, and that a skilled person thus would have to perform an extensive research program in order to find the "correct" catalysts and synthesis conditions, without success even being guaranteed. The polymer could thus not be reproduced without undue burden, and therefore had not been made available to the public. The inventive step attack should thus fail, as it lacked a suitable basis, i.e. it was not based on prior art as defined in Art. 54(2) EPC.

Such an approach was taken by the referring Board in e.g. T 1833/14. In the referring decision, however, the Board identified diverging case law and questioned whether it would be justified to exclude an existing product from the state of the art because it could not be exactly reproduced with all of its properties, or whether it would not rather be appropriate to consider that those properties of the product that are either listed in brochures or which can be derived from the product by routine analysis techniques have been made "available to the public".

A further concern of the Board appears to be that the reproduction of a product such that the copy is identical to the original is frequently not possible without further knowledge about the manufacturing process, and that it is unclear how closely a reproduction must match the existing product in order to be considered the same product.

In consequence, the Board referred, of its own motion, the following questions to the Enlarged Board of Appeal:

1. *Is a product put on the market before the date of filing of a European patent application to be excluded from the state of the art within the meaning of Article 54(2) EPC for the sole reason that its composition or internal structure could not be analysed and reproduced without undue burden by the skilled person before that date?*

2. *If the answer to question 1 is no, is technical information about said product which was made available to the public before the filing date (e.g. by publication of technical brochure, non-patent or patent literature) state of the art within the meaning of Article 54(2) EPC, irrespective of whether the composition or internal structure of the product could be analysed and reproduced without undue burden by the skilled person before that date?*

3. *If the answer to question 1 is yes or the answer to question 2 is no, which criteria are to be applied in order to determine whether or not the composition or internal structure of the product could be analysed and reproduced without undue burden within the meaning of opinion G 1/92? In particular, is it required that the composition and internal structure of the product be fully analysable and identically reproducible?*

In the referral, the Board provides a semantic interpretation of G 1/92 and the *Travaux Préparatoires* of the EPC and arrives at the conclusion that "available to the public" might mean simple accessibility of information but not necessarily reproducibility. Thus, the established case law requiring a prior art disclosure to be enabling and item 1.4 of G 1/92 might lack a proper legal basis, according to the Board.

Further, if reproducibility was meant, it would be open to subjective criteria how much deviation is allowed to qualify a reproduced product as being the same as the original. This would lead to a subjective novelty assessment, which is to be avoided and would lead to legal uncertainty.

Outlook

These proceedings, in which HOFFMANN EITLE represents the Patent Proprietor, are significant to a large number of current and further proceedings. The decision will clarify whether, under which circumstances, and to which extent certain observable properties of a non-reproducible entity may be held to be "available to the public", or whether the product and its properties are simply no prior art because the product is not reproducible without undue burden, and hence not "available to the public". The public has the opportunity to submit *amicus curia* briefs until November 30, 2023.[3]

Meanwhile, the President of the EPO has ordered that examination and opposition proceedings, the outcome of which solely depends on the answers given by the Enlarged Board of Appeal, are to be stayed until the Enlarged Board of Appeal decision is available.[4]

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[3] OJ EPO 2023, A72 – Communication from the Enlarged Board of Appeal concerning case G 1/23.
[4] OJ EPO 2023, A68 – Notice from the European Patent Office dated 13 July 2023 concerning the staying of proceedings due to referral G 1/23.

Amendment of the Description Before the EPO: Possible Referral to the Enlarged Board of Appeal

The debate over amendments to the description at the EPO might be about to go into the next round in view of a potential referral to the Enlarged Board of Appeal. The current case law is divided on the topic of whether the description must be brought into strict conformity with the claims and whether embodiments falling outside the scope of the claims must be deleted or labelled as such. A decision by the Enlarged Board of Appeal could bring some long-awaited clarity on the issue.

Background

The EPO's requirement to amend the description prior to grant was tightened with the Guidelines for Examination 2021, which demanded that embodiments in the description falling outside the scope of the claims be *"prominently marked"*.[1] The change was not particularly welcomed by practitioners and applicants as it necessitates onerous and time-intensive review of the description and raises complex issues of claim interpretation and scope.

Consequently, there was much excitement when the Board of Appeal in T 1989/18 ruled that there is no provision in the EPC which requires amendments to the description prior to grant.[2] In the meantime, the case law has been split on the topic with some Boards having the same legal member as T 1989/18 affirming this decision and other Boards insisting on the need for extensive amendments. In a July 2022 legal workshop, the EPO itself confirmed its 'strict' approach laid out in the Guidelines 2021 and many Examiners still insist on firm alignments between the claims and the description.[3]

T 56/21 and a potential referral to the Enlarged Board of Appeal

Roche, the original appellant in T 1989/18, seems intent to settle the matter once and for all. In case T 56/21, Roche is again appealing against a decision of an Examining Division to refuse a patent application because the description had not been brought into conformity with the claims. Board 3.3.04 in T 56/21, whose legal member is the same as that of T 1989/18, recently issued a communication suggesting a possible referral to the Enlarged Board of Appeal.[4]

In the communication, the Board recognizes the previous practice of amending the description but finds no basis for a requirement to do so in the EPC.

A central issue is the interpretation of Art. 84 EPC, which requires that the claims be clear, concise, and supported by the description.

The Board separately reviews the clarity requirement and argues that if the claims in themselves must be clear the description should not be relied upon for claim interpretation. Indeed, the Board sees a tendency to do so as a risk, noting that *"Systematically interpreting the claims [for patentability] [...] considering the description runs the risk of reading additional limitations into the claims [...] Broad claims could thus be granted based on their narrow interpretation considering the description. This might lead to diverging decisions and jeopardize legal certainty"*.[5]

[1] Guidelines for Examination in the European Patent Office, Part F-IV, 4.3.
[2] Toby Simpson, Amendment of the Description: Is It the EPO's Guidelines That Require Adaptation?, *HOFFMANN EITLE Quarterly*, March 2022, pp. 9-10.
[3] Johannes Osterrieth, Michael Müller, Amendment of the Description Before the EPO: An Update, *HOFFMANN EITLE Quarterly*, September 2022, pp. 17-19.
[4] Board 3.3.04's communication dated July 21, 2023, issued in case T 56/21.
[5] Ibid, point 3.2.2.

Regarding the requirement for support of the claims by the description, the Board's position can be thought of as a one-way relationship: "*In short, the disclosure of the description must warrant the definition of the subject-matter of the claims and not the other way round*".[6] In other words, embodiments in the description that fall outside the scope of the claims cannot negate a claim's support because the claim is already supported by other embodiments (*i.e.* those falling inside the scope).

As in T 1989/18, the Board also comments on the role of Art. 69(1) EPC which reads that the protection conferred by the patent shall be determined by the claims, but that the description shall be used to interpret the claims. But Art. 69(1) EPC is under Part II, Chapter III, of the EPC "*Effects of the European patent and the European patent application*" and thus, as the Board argues, not a requirement for grant but rather a consideration for courts, *e.g.* in an infringement action: "*It is not for the Office to harmonise the extent of protection conferred by European patents (and applications) by bringing the description and/or the drawings of an application or patent in agreement with the amended claims held allowable*".[7]

In view of the above, the Board proposes the following question for referral to the Enlarged Board of Appeal:

> "*Is there a lack of clarity of a claim or a lack of support of a claim by the description within the meaning of Article 84 EPC if a part of the disclosure of the invention in the description and/or drawings of an application (e.g. an embodiment of the invention, an example or a claim-like clause) is not encompassed by the subject-matter for which protection is sought ("inconsistency in scope between the description and/or drawings and the claims") and can an application consequently be refused based on Article 84 EPC if the applicant does not remove the inconsistency in scope between the description and/or drawings and the claims by way of amendment of the description ("adaptation of the description")?*"[8]

This question only pertains to *ex parte* proceedings, but it is noted in the communication that it could extend to oppositions.[9]

Roche now has until the end of October to respond to the Board's comments on the possible referral and the Board will then decide whether to refer the question to the Enlarged Board of Appeal.

Implications of a referral

Should the referral be made, it will likely be over a year until any decision by the Enlarged Board is issued, so immediate answers on this issue cannot be expected.

It will also be interesting to see what happens in the meantime since nearly all applications require some kind of amendment to the description before grant. It is difficult to imagine that the EPO will stay the final stage of prosecution in all of these cases pending a decision by the Enlarged Board. The referral could thus add to the already large backlog of applications going to grant.

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[6] Ibid, point 2.2.
[7] Ibid, point 3.2.3.
[8] Ibid, point 5.1.
[9] Ibid, point 4.

T 695/18: To Err is Humane; to Forgive, Divine

Under Rule 139 EPC, mistakes in documents filed with the EPO may be corrected upon request. A recent Board of Appeal decision, T 695/18, has limited the scope of application of this rule as far as procedural statements which immediately terminate proceedings are concerned. In this article, we review this decision and its consequences.[1]

1. Correcting errors in documents filed with the EPO

In proceedings before the EPO, attorneys are expected to exercise a high degree of caution and care when preparing documents to be filed. Nevertheless, it is the case that errors are made, even by the most careful of representatives.

To account for this, Rule 139 EPC[2] makes provisions for the correction of errors in documents filed with the EPO and reads:

> *Linguistic errors, errors of transcription and mistakes in any document filed with the European Patent Office may be corrected on request. However, if the request for such correction concerns the description, claims or drawings, the correction must be obvious in the sense that it is immediately evident that nothing else would have been intended than what is offered as the correction.*

Whilst the second sentence refers to the application documents, the first sentence applies more generally to all kinds of documents that are filed with the EPO.

2. Withdrawing the withdrawal of an appeal

One question that arises is whether this rule applies to a statement (such as a withdrawal of an appeal) that immediately terminates the proceedings. Whilst previous case law[3] has generally found that correcting such a statement was possible, Board 3.5.03 recently held in T 695/18[4] that Rule 139 EPC is inapplicable to correcting such a withdrawal of an appeal.

In the case underlying the decision, an applicant had appealed the refusal of their patent application. Upon receipt of a negative preliminary opinion from the Board of Appeal, the representative filed a statement indicating that the applicant withdrew the appeal. The next day, the representative filed a further submission withdrawing the withdrawal of the appeal, which had been erroneously filed due to the representative misinterpreting the applicant's instructions. The Board initially did not decide on whether the withdrawal of the appeal could be withdrawn and only re-opened ancillary proceedings to deal with this issue once the proceedings had been re-opened due to the appellant filing a successful petition for review by the Enlarged Board of Appeal (R 3/22[5]). In those reopened proceedings, the Board considered the withdrawal of the withdrawal of the appeal to be a request for a correction and found that the request was not admissible.

[1] The line "To err is Humane; to Forgive, Divine" is taken from Alexander Pope, "An Essay on Criticism" (1711).
[2] Rule 139 EPC – Correction of errors in documents filed with the European Patent Office.
[3] Such as T 2148/18 of December 7, 2021.
[4] T 695/18 (Withdrawal of the withdrawal of the appeal/ZTE) of March 3, 2023.
[5] R 3/22 (Decision on an appeal without deciding on a request relevant to that decision) of November 22, 2022.

At first sight, this result seems surprising given the wording of Rule 139 EPC. Clearly an error had been made. Further, the correction had been filed as soon as possible so that it was highly unlikely that third parties had relied on the withdrawal. Thus, a decision to allow the request for correction would have been in line with earlier case law such as T 2148/18, T 610/11[6] and J 10/87.[7]

The Board, however, found that Rule 139 EPC cannot be used to revive EPO proceedings, which, it found, is only permissible under strict conditions and upon payment of a fee (e.g. when requesting a re-establishment of rights or when filing a petition for review). In contrast with this, Rule 139 EPC is very broadly worded and does not have any such qualifications, thus implying, in the Board's view, that it does not enable such a revival of proceedings. Thus, since the requested correction of the withdrawal would have had the effect of reviving the appeal proceedings, the Board found the request for correction to be unallowable.

The Board then discussed the cited case law dealing with the correction of withdrawals of an appeal addressing, inter alia, the question of whether the public had been officially notified of the withdrawal. While the appellant argued that it was unlikely that the public had been informed given the short time between the withdrawal of the appeal and its correction, the Board found that a third party could also have been informed by the presence of the withdrawal in the online file inspection or by contacting a Registrar at the EPO to inquire about the state of the file. The Board took the view that the criteria developed in the previous case law gave rise to concerns for "the protection of the value of legal certainty" and hence decided to deviate from them.

Further, the Board held that Rule 139 EPC is only applicable when proceedings are pending. However, this was not the case in T 695/18, as the appeal ceased to exist immediately upon receipt of the withdrawal of the appeal. Here, the Board was at pains to distinguish the reopened, "ancillary" proceedings subsequent to the successful petition for review from "normal" appeal proceedings. In the Board's view, the limited purpose of the reopened proceedings is to correct the mistake that occurred during the appeal proceedings that was impugned by the petition for review. Thus, since no proceedings were pending, the Board found that Rule 139 EPC was inapplicable and hence rejected the request to correct the withdrawal of the appeal.

3. Conclusion

T 695/18 confirms that more than ever any statements that immediately terminate EPO proceedings must be drafted with utter care. Although the case at hand concerns the withdrawal of an appeal, the same logic should apply to the withdrawal of a patent application, which has the same immediate destructive effect. Here, too, there is case law that would seem to allow such a statement to be corrected. However, it is based on J 10/87 that was found to be flawed in T 695/18 and thus may no longer be seen as persuasive, at least by some Boards.

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[6] T 610/11 (Retraction of withdrawal of the appeal - (no)) of September 8, 2016.
[7] J 10/87 (Widerruf einer Zurücknahme) of February 11, 1988.

Proposed Amendments to the EPO Rules of Procedure of the Boards of Appeal: A Critical Analysis

The EPO[1] has proposed new amendments to the Rules of Procedure of the Boards of Appeal (RPBA) to support more ambitious timeliness objectives.[2] Some of these amendments are unlikely to shorten appeal proceedings, will reduce the quality of decisions, and are unfair on Respondents. In our view, they should not be adopted in full.

Background

Progress has been made in recent years in reducing the backlog before the EPO Boards of Appeal (BoA),[3] but the objective of settling 90% of cases within 30 months is unlikely to be met anytime soon. Amendments to the RPBA have now been proposed to improve timeliness. In our view, the EPO has correctly diagnosed itself as suffering from overly long appeal proceedings. But the proposed treatment will not treat this chronic disorder, and if anything will lead to significant side effects by reducing the quality of decisions and making the proceedings unfair.

Proposed amendment to Article 12(1)(c) RPBA: Default period for response to Grounds of Appeal reduced from four to two months

At present, Respondents have at least **four months** to reply to the Grounds of Appeal. This is a challenging and time-consuming task, and this time is generally required to prepare a comprehensive response. The proposed amendment would reduce the default time for response to **just two months**. While the BoA can set a longer period of up to four months, which can also be extended up to six months on request and at the discretion of the BoA, it is unclear when extra time will be available. Under the amendment, Respondents can expect to have significantly less time to respond to the Grounds of Appeal.

In our view, this proposed amendment:

1) will have no meaningful impact on the timeliness of EPO appeal proceedings in the foreseeable future,
2) will reduce the quality of decisions, and
3) is unfair on Respondents.

As such, it introduces significant disadvantages without bringing any advantages.

[1] The proposals form part of a User Consultation initiated by the Boards of Appeal Committee, a body of the Administrative Council of the European Patent Organisation, and the President of the Boards of Appeal.

[2] Boards of Appeal of the EPO, Draft proposed amendments to the Rules of Procedure of the Boards of Appeal Public draft – online user consultation, 15 June 2023.

[3] European Patent Office, Annual Report of the Boards of Appeal 2022, May 2023.

Concerning 1), the proposed amendment would only have an impact on timeliness if the BoA dealt with files as soon as they are transferred to them such that the response to the Grounds of Appeal is the rate determining step. This is very unlikely to be the case this decade. The main delay is caused by the issuance of the preliminary opinion under Article 15(1) RPBA and any oral proceedings, which typically take place **well over a year** after the Response to the Grounds of Appeal has been filed.

As made clear by the EPO's own data,[4] the BoA are still falling far short of their objective of settling 90% of cases within 30 months, with all technical fields still above 50 months. Based on the current trend, the objective is unlikely to be achieved this decade. Even once this target is hit, the BoA will still be far from dealing with cases immediately – they would need pendency closer to just 14 months for the Response to the Grounds of Appeal to be the rate determining step. The proposed amendment is thus unlikely to improve timeliness anytime soon.

For 2), the EPO's own Quality Working Group highlighted the "*completeness of the examination of relevant factual and legal issues*" as key to the quality of BoA decisions.[5] The proposed amendment halves Respondents' time to reply to the Grounds of Appeal, reducing their ability to bring relevant issues to the attention of the BoA. It will reduce the level of debate before the BoA and the quality of their decisions.

Concerning 3), Appellants already have an advantage over Respondents as they can start to prepare their Grounds of Appeal after announcement of the decision in oral proceedings, typically months before the four-month Appeal period begins. The proposed amendment further tips the balance in favour of Appellants, by giving Respondents **just two months** to respond by default. Appellants still have **four months** to submit the Grounds of Appeal.

This is not only unfair but is also difficult to reconcile with several aspects of EPO law and practice. According to the RPBA themselves, they should "*not lead to a situation which would be incompatible with the spirit and purpose of the [EPC]*".[6] The EPC stipulates that Appellants have **two months** just to file the formal Notice of Appeal, and **four months** to prepare their substantive Grounds of Appeal.[7] The time and effort required to prepare an appeal submission is expressly recognized by and hence within the spirit of the EPC, which is incompatible with the default two-month period for responding to the Grounds of Appeal. In fact, a two-month period is normally only set by the EPO for issues which are "*merely formal or merely of a minor character; if simple acts only are requested*".[8] Finally, it is contrary to the fundamental EPO principle that, in contentious proceedings, parties should be given "*equally fair treatment*".[9]

To balance timeliness, fairness, and quality, this amendment should not be implemented. Other options could be considered for improving timeliness, such as appointing more members of the BoA.

Proposed amendment to Article 13(2) RPBA: Final stage of Appeal with strictest admissibility rules initiated by issuance of BoA preliminary opinion instead of summons

Article 13(2) RPBA lays out the very strict approach to admissibility in the very final stage of EPO appeal proceedings.[10] Currently, this stage is normally initiated by the formal summons to oral proceedings – which may be long before the BoA even look at the case.

[4] Ibid., page 8, Figure 4.
[5] Ibid., page 10.
[6] Article 23 RPBA.
[7] Article 108 EPC.
[8] See Guidelines E-VIII, 1.2.
[9] See G 9/91 reasons 2.
[10] Johannes Osterrieth, Nicolas Douxchamps, Morten Garberg, "The EPO Rules of Procedure of the Boards of Appeal (RPBA) – An Update Two Years After the Entry Into Force of the RPBA 2020 (part I)", *HOFFMANN EITLE Quarterly, December 2021*, pp. 2-5.

The proposed amendment instead specifies that the final stage begins on issuance of the substantive preliminary opinion of the BoA. This has been welcomed by EPO users. The preliminary opinion is generally issued many months after the formal summons, so the amendment means the strictest admissibility standard is implemented later. That said, this proposed amendment should be considered in conjunction with the less popular proposed amendment below.

Proposed amendment to Article 15(1) RPBA: Earliest issuance of BoA preliminary opinion just one month after response to the Grounds of Appeal

As discussed above, the preliminary opinion of the BoA brings in the very strict approach to admissibility under proposed amended Article 13(2) RPBA. The proposed amendment to Article 15(1) RPBA specifies the earliest date the BoA can issue the preliminary opinion as **just one month** after the response to the Grounds of Appeal. This places parties under significant pressure to respond to the response to the Grounds of Appeal immediately to avoid the risk that their submissions fall under the strict admissibility requirements of Article 13(2) RPBA.

Like the proposed amendment to Article 12(1)(c) RPBA discussed above, this introduces significant disadvantages without bringing any advantages. It will have no meaningful impact on the timeliness of EPO appeal proceedings anytime soon, and will only do so once the BoA start to deal with cases immediately. It places parties to the Appeal proceedings under unnecessary pressure to make complex submissions on a very short timescale. As such, it is expected to have a negative impact on the debate before the BoA and the quality of decisions.

As a result, this proposed amendment also should not be implemented at least until the BoA are able to deal with cases as soon as they are transferred to them.

Conclusion

While some of the proposed amendments are welcome, proposed Articles 12(1)(c) and 15(1) RPBA are generally unpopular with EPO users. While many applaud the EPO's desire to improve timeliness, it is unlikely that the proposed changes will deliver this goal. At the same time, they are unfair on Respondents and will likely decrease the quality of decisions. The EPO plans to introduce these changes on 1 January 2024, and it will be interesting to see if they change their position following the concerns raised in the User Consultation.

Our concerns have been submitted in the User Consultation,[11] and a subsequent issue of the *HOFFMANN EITLE Quarterly* will discuss the final form of the RPBA adopted by the EPO and our recommendations for dealing with them.

Based on our previous experiences of EPO User Consultations, we would not be surprised to see the proposed amendments being implemented despite being the wrong medicine.

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[11] "Our response to the proposed new amendments to the Rules of Procedure of the Boards of Appeal (RPBA)". www.hoffmanneitle.com. September 8, 2023.

In Provisional Injunction Proceedings, German Courts Can Disregard an EPO Board of Appeal's Opinion

In a well-reasoned decision,[1] the Higher Regional Court (HRC) Dusseldorf has lifted a provisional injunction (PI) on the basis that the asserted patent is likely to be invalid although the EPO's Technical Board of Appeal (TBA) had previously found the claims to be valid in examination proceedings. The decision provides clarity as to when German infringement courts can and should disregard validity decisions from patent offices or the German Federal Patent Court.

1. Background

Recent cases have focused on how German courts should assess patent validity in provisional injunction (PI) proceedings. On the one hand, patent enforcement is more efficient if an infringement is stopped early on by a PI instead of having to wait for a decision in main proceedings. On the other hand, patents are often limited in scope or revoked entirely when challenged in post-grant (contentious) validity proceedings. To account for the difficulties in assessing patent validity in PI proceedings, German courts have adopted case law that takes both aspects into consideration. If the asserted patent's validity has already been confirmed in post-grant proceedings, a PI is generally available. Otherwise, PIs are only available in certain exceptional situations, e.g., where:

a) patent examination was conducted in a way that makes the outcome particularly reliable (e.g., due to third-party observations),

b) the interests of the patentee greatly outweigh those of the defendant (e.g., patent term is ending soon or for generic early entry cases), or

c) the infringement court considers the validity attack to have no reasonable chances of success.

After the ECJ's decision in *Phoenix v. Harting*, the RC Munich diverged from these long-standing criteria by affording granted (European) patents a presumption of validity so that the defendant has the onus to show that the patent is invalid.[2] However, in almost all cases where validity has been confirmed in opposition or nullity proceedings (even if only a non-final decision or a preliminary opinion is available), the infringement courts follow the assessment in validity proceedings.

If there is a post-grant ruling confirming validity, the alleged infringer may try to convince the court that this ruling is evidently erroneous, but this burden is almost impossible to meet.

The present case shows how the EPO's assessment on validity can successfully be challenged to get a PI rejected – even where two of the above exceptional situations in favor of a PI are present.

[1] Higher Regional Court (HRC) Düsseldorf, Decision of August 3, 2023 (Case no. I-2 U 43/23). Boris Tchitchanov and Joachim Renken (HOFFMANN EITLE) acted as patent attorney representatives for one of the defendants in both instances of the PI proceedings. The other appeal case numbers are I-2 U 42/23, I-2 U 45/23, I-2 U 46/23, I-2 U 47/23, I-2 U 48/23 and I-2 49/23 (all decisions dated August 3, 2023).

[2] Jeremias Wollschlaeger, Mike Gruber, "Preliminary Injunction Proceedings in Germany – New Opportunities for Patentees in Munich?", *HOFFMANN EITLE Quarterly, December 2022*, pp. 21-23.

2. Facts

The patent in suit, EP 2 959 894 B1 (EP'894), claims the active ingredient fingolimod for use in the treatment of relapsing-remitting multiple sclerosis (RRMS) at a daily oral dose of 0.5 mg. In the prior art, doses of 1.25 mg or 5 mg were known to be therapeutically effective from Phase II clinical trials, and a planned Phase III clinical trial to investigate the therapeutic efficacy of the 0.5 mg dose had been announced.

Initially, the EPO's Examining Division (ED) refused the application. On appeal, the TBA ordered EP'894 to be granted. Multiple third-party observations had been filed but the TBA disregarded many of them as late filed.

According to the TBA decision (T 108/21), the announcement of a Phase III trial would have provided the skilled person with a reasonable expectation that the claimed daily dose of 0.5 mg solves the objective technical problem of providing further means to effectively treat RRMS, *unless* there was a dissuasion in the prior art. The TBA saw such dissuasion in a research article postulating that a certain threshold of lymphocyte reduction was required to see efficacy in a mouse model, combined with further prior art reporting that an oral daily dose of 0.5 mg fingolimod did not achieve that threshold. Thus, the TBA confirmed an inventive step.[3]

Upon grant of EP'894, the patentee requested PIs before the RC Düsseldorf against eight generic companies. Multiple oppositions against the patent are currently pending.

The RC Düsseldorf granted a PI, reasoning that the TBA's decision provides sufficient certainty of the patent's validity.

3. Decision

The HRC Dusseldorf lifted the PI, finding that validity of EP'894 was not sufficiently secured for granting a PI. At first, this result may be surprising, as there were several factors in favor of a PI:

- This can be considered a generic early entry case (although in an atypical situation[4]), for which German courts would apply a lower standard for assessing validity in PI proceedings;
- Third-party observations had been filed during examination of EP'894, which—under German case law—is considered to provide a higher degree of certainty on validity because the grant of the patent did not only result from a two-sided process between the applicant and the examiner; and
- Here, the patent was granted following a decision by the EPO's TBA, whose competence is highly regarded by German civil courts.

Yet, several oppositions had been filed against EP'894. German infringement courts must always assess the chances of success of a pending validity attack themselves (even if a non-final decision in opposition or nullity proceedings has been issued), but will, in general, defer to the assessment of those with the legislative mandate to rule on patent validity (i.e., the EPO Opposition Divisions and Boards of Appeal, the German Patent and Trademark Office, and the German Federal Patent Court). Here, having regard to the superior position of the TBA in the legal system, the decision from examination appeal proceedings ordering the grant of EP'894 was considered to be similarly reliable to a decision in opposition proceedings.

[3] For a detailed discussion of this decision, see Claudia Unsin, "Pre-published Clinical Trials: A Sudden Death for Second Medical Use Claims?", *HOFFMANN EITLE Quarterly, March 2023*, pages 7-9.

[4] Compound protection for fingolimod ended in 2018. After regulatory market exclusivity ended in March 2022 one generic competitor entered the market. The parent application underlying EP'894 was filed in 2007 but the divisional patent was granted as late as October 2022. Despite these circumstances the HRC Dusseldorf considered the parties' interests to be sufficiently similar to generic early entry cases.

However, German courts may not blindly adopt the outcome of a previous non-final validity decision. There are two situations where – despite a non-final ruling of a competent authority upholding validity – German courts will refuse a PI due to concerns about the asserted patent's validity:

a) The patent is attacked based on new and promising arguments or prior art not yet taken into account in the previous proceedings on validity, or

b) The infringement court considers the reasoning of the validity ruling to be evidently wrong.

Here, the HRC Dusseldorf's considerations for lifting the PI pertain to both situations. It is only the second time that a German infringement court dared to take issue with the reasoning of a validity decision and not follow the result thereof. The first time was the *Olanzapin* case,[5] decided 15 years ago, also by the HRC Dusseldorf.

In general, infringement courts give deference to the result of a (non-final) decision on validity by a competent authority, especially on the assessment of inventive step. Typically, infringement courts do not command the detailed technical understanding needed to assess the abilities and problem-solving approaches of the skilled person at the priority date.

However, on issues where a profound technical expertise may be less essential, such as added matter, novelty, or the assessment of inventive step in non-complex (mechanical) inventions, infringement courts may make their own assessment. Despite these general comments, the HRC Dusseldorf did not hesitate to look closely into the TBA's obviousness assessment in the present, complex pharmaceutical case.

The HRC Dusseldorf also explained that infringement courts do not have to give deference to a validity decision in case of legal errors and/or logical fallacies. The HRC Dusseldorf's concerns about the TBA decision appear to be also about logical and legal errors, although the decision mainly relies on facts that were not considered by the TBA.

First, prior art documents that the TBA had not considered show that there was a reasonable prospect that an oral fingolimod daily dose of significantly less than 1.25 mg may prove therapeutically useful. In light of this, the announced phase III clinical trials at a dose of 0.5 mg were not a hopeless undertaking, although success was not guaranteed. The new documents showed that (i) the lymphocyte reduction rate for a 1.0 mg dose was comparable to that for a 0.5 mg dose; and (ii) the pharmacokinetic/dynamic modeling based on the Phase II results for the 5 mg and 1.25 mg doses support exploring potentially lower doses in future MS studies.

Second, the HRC Dusseldorf appears to question how the TBA arrived at the conclusion that there was a dissuasion in the prior art that would have taught the skilled person away from the claimed dose. The HRC Dusseldorf appears to consider that the TBA's reasoning is incorrect when it rejected obviousness based on the assumption that efficacy required a certain threshold of lymphocyte reduction, although (a) it was known that the correlation between lymphocyte reduction and clinical efficacy is imperfect and additional mechanisms may be involved in producing a therapeutic benefit; and (b) the prior art relied on by the TBA for concluding that the threshold is not achieved with a 0.5 mg fingolimod dose showed that this threshold is also not met even for the 1.25 mg fingolimod dose already known to treat RRMS effectively.

The HRC Dusseldorf also explained how diverging validity decisions from other jurisdictions can be considered. It is not unusual that technical experts at competent authorities in different jurisdictions disagree on validity issues. This by itself does not put a patent's validity sufficiently into question to refuse a PI.

[5] HRC Dusseldorf, decision of May 29, 2008, case no. I-2 W 47/07.

4. Comments

The HRC Dusseldorf is known to issue well-reasoned decisions and is therefore one of the most respected patent courts in Europe. This decision is no exception. In addition to a detailed analysis of the facts and issues of the case at hand, the decision includes many sections that could be put into a treatise on German patent law without changing a single word.

The decision makes it clear that it will remain an exception for a German infringement court to disregard the validity assessment of a competent authority because it considers its decision to be erroneous. However, patentees should consider that even with a validity decision in their favor this may not be sufficient to obtain a PI if the decision suffers from serious errors. On the other hand, the HRC Dusseldorf decision will encourage parties to attack validity decisions before German infringement courts if the reasons are contradictory or superficial.

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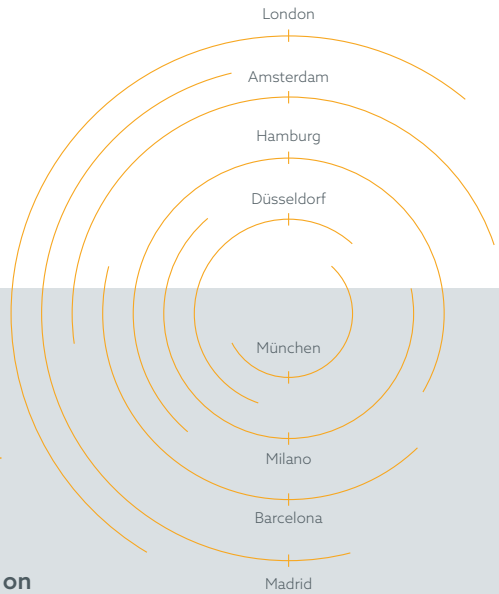

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