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New EU Legislation Proposals (Part III): Centralised Examination Procedure for SPCs and Legal Remedies

In our last contribution to the Hoffmann Eitle Quarterly,[1] we looked at the new SPC landscape proposed by draft EU legislation issued in April 2023. This includes a framework for unitary SPCs[2] – as an extension of the European patent with unitary effect (EP-UE) – and an overhaul of the procedure for obtaining the traditional, national SPCs which are granted by national patent offices.[3] Whilst our last article focussed on the eligibility and jurisdiction of each type of SPC, we now turn to the centralised examination procedure and the legal remedies which will be available to parties. Finally, we look at recent changes to the April 2023 proposals[4] and the current state of the legislative procedure.

Brief recap – Office for central examination of SPCs and eligibility for this route

In two draft regulations, for Medicinal Products (MP-SPCs) and Plant Protection Products (PPP-SPCs) respectively, the EU has proposed to introduce a centralised examination procedure for the grant of national SPCs. Likewise, two new regulations creating a new unitary MP-SPC and unitary PPP-SPC have been drafted. Under the new regulations, the unitary and national SPCs will share a centralised examination procedure.

The central examination procedure of SPCs will be conducted by the European Union Intellectual Property Office (EUIPO) in Alicante, Spain, with support from experienced SPC examiners from national patent offices. This is a new competence for the EUIPO which up to now is only responsible for the registration of EU trademarks and registered Community Designs (RCD). A new Supplementary Protection Certificates Division (SPC Division) will be created within the EUIPO to handle all SPC matters.

All SPC applications for medical products (MPs) having received a central marketing authorisation (MA) by the European Medical Agency (EMA) *and* which are based on European patents (EPs), including European patents with unitary effect (EP-UEs), will be exclusively subject to the central examination procedure. The national MP-SPC application route will only be available for products with a national marketing authorisation *or* SPC applications based on national patents.

Since no central marketing authorisations exist for plant protection products (PPP), the eligibility criteria differ from those for MP-SPCs as follows. If the basic patent is a European patent (EP), including a European patent with unitary effect (EP-UE), applicants can choose between the existing country-by-country filing procedure for national SPCs and the newly created centralised application at the EUIPO. The SPC application is eligible for the centralised procedure if, at the date of filing, a national marketing authorisation (MA) has been granted in at least one designated Member State. Applications for PPP-SPCs with unitary effect are however always examined in the EUIPO's centralised procedure.

[1] Johannes Osterrieth, Bianca-Lucia Vos, Klemens Stratmann, New EU Legislation Proposals (Part II): Creation of a New SPC Landscape for Europe, Hoffmann Eitle Quarterly, September 2023, pp. 6-11.

[2] COM(2023)221 and COM(2023)222.

[3] COM(2023)223 and COM(2023)231.

[4] For the initial proposals, see Proposals for regulations on supplementary protection certificates - European Commission (europa.eu). The latest amendments can be found here: A9-0022/2024, A9-0019/2024, A9-0023/2024, and A9-0020/2024.

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

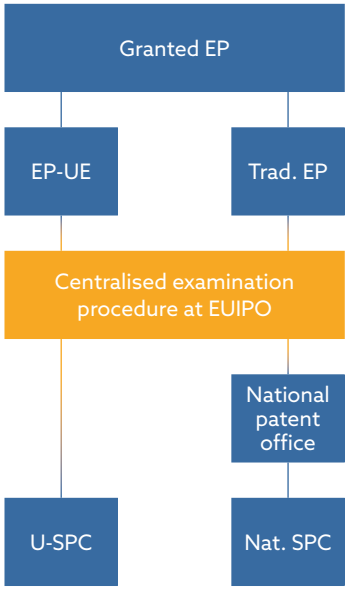

Fig. 1 | A granted EP can be validated for unitary effect (EP-UE validation) or as a traditional EP bundle (Trad. EP). Based on both types of patent rights, an SPC application can be made via the centralised examination procedure at the EUIPO, which however is mandatory if the SPC application is based on a central MA for a medicinal product. The centralised examination procedure is the focus of this article. A combined application for national and unitary SPCs can also be made.

The EUIPO will be the granting authority for unitary SPCs. For national SPCs eligible for the centralised examination procedure, a different mechanism is chosen by which the EUIPO transmits its legally binding examination opinion to the competent national patent offices, which then grant the SPC.

Centralised examination procedure

In a first step of the centralised examination procedure, the EUIPO examines the **admissibility** of an SPC application. This is largely an examination of formalities, in particular whether the six-month deadline for filing the SPC application has been met, the application fee has been paid, the Member States in which certificates are sought have been duly designated, and the required information and documents, e.g. MA copies, have been provided. The current draft of the regulations seems to allow the use of **any official language** of the European Union, i.e. one of 24 languages, for the documents and information sent to the EUIPO. If the admissibility requirements are met, the EUIPO **publishes the application** in a **register**. This register will be maintained throughout the application to give third parties the opportunity to monitor its progress.

The application then enters a phase of **substantive examination** before an examination panel ("SPC Division") which assesses whether the substantive conditions for SPC grant of Art. 3[5] are met and the applicant is entitled to the certificate (Art. 6). This panel consists of three members – one member of the EUIPO and two examiners from national patent offices who, according to the latest revision of the draft regulations, are required to have a minimum of five years of experience in the examination of SPCs.

The substantive examination concludes with the examination panel drawing up an **examination opinion ("EO")**, which may be positive or negative with respect to all or some of the designated Member States. The EUIPO notifies the applicant of the opinion, followed by its **publication** in the register. According to recently proposed changes to the draft legislation, this is generally intended to occur within six months of the publication of the application in the register. If a request for an **expedited examination procedure** is made, the Office normally issues its examination opinion within four months. However, these intended timelines only apply for MP-SPC applications since marketing authorisations for PPPs must be obtained from the national authorities, which can lead to substantial delays in some EU member states.

[5] If not stated otherwise, the cited articles are included in all four draft regulations.

Pre-grant challenges by third parties

The new procedure provides the opportunity for third parties to file observations on a positive examination opinion or to challenge SPC grant as party to the proceedings. Specifically, a new pre-grant opposition procedure has been proposed in addition to the possibility of challenging a granted SPC in invalidity proceedings.

Third party observations concerning the eligibility for SPC protection may be submitted by any member of the public during the substantive examination phase *within three months after the publication* of the application in the register, or *within 6 weeks* in case of the expedited procedure. Interestingly, at present, it does not seem envisaged that the third party observations (TPO) themselves be published in the register. By means of such TPOs, the third party does not become a party to the proceedings and has no right to appeal an examination opinion rejecting the observations and the requests made therein.

By contrast, if an **opposition** is filed against any positive examination opinion, the opponent becomes a party to the proceedings. The procedure can be instigated by any person within a *period of two months following the publication of the examination opinion* in respect of the application. This is a notable departure from the current practice of most intellectual property offices (IPOs) according to which oppositions are launched against granted patents rather than examination opinions. This mechanism is however required to conduct opposition proceedings before the EUIPO for both unitary and national SPC applications, since for the latter the EUIPO does not grant the SPCs. The proceedings will take place before an opposition panel having basically the same composition as an examination panel (one EUIPO examiner supported by two national patent office examiners). However, none of the examiners included in the examination stage is allowed to sit on the opposition panel.

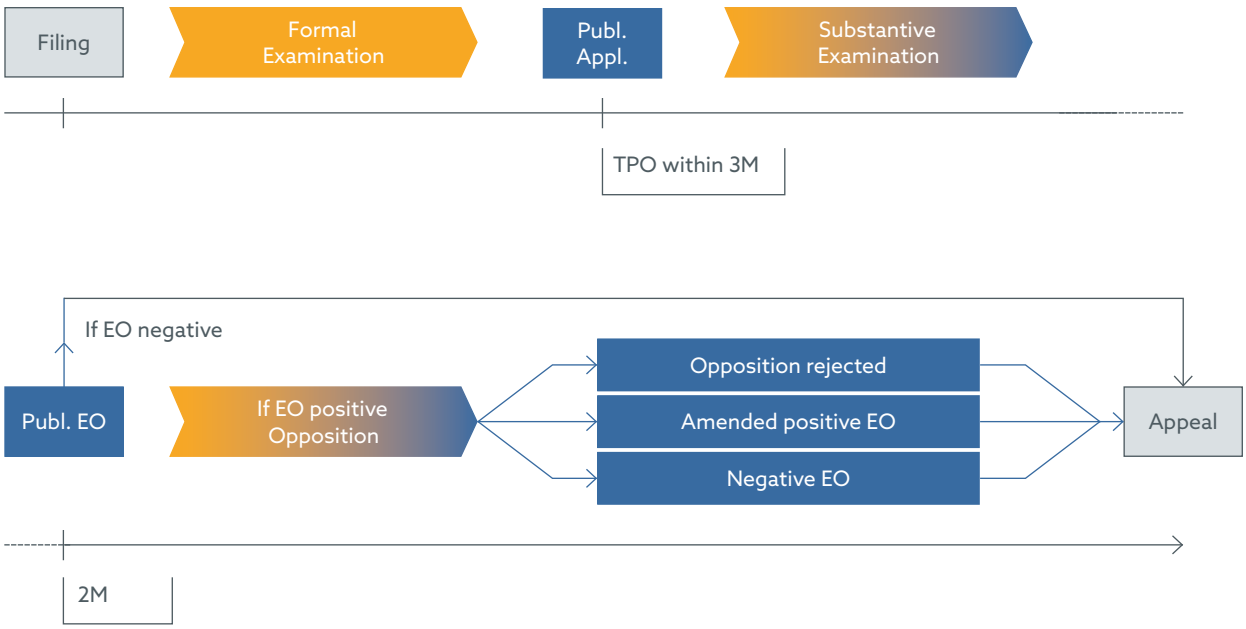

Fig. 2 | *Schematic overview over the proposed centralised examination procedure for national and unitary SPCs before the EUIPO, including possible opposition and appeal proceedings (TPO = third party observations; EO = examination opinion).*

According to the latest version of the draft regulations for the centralised examination of national SPCs, an **opposition** may only be filed on the **grounds** that the provisions set out in Art. 3 (substantive conditions a) to d) for grant) or Art. 6 are not fulfilled.[6] Art. 6 concerns the entitlement to the certificate including the now required consent of the MA holder if the product of the SPC application is the subject of an authorisation held by a third party.

It is intended that decisions in oppositions, including a detailed reasoning, are delivered within 6 months unless the complexity of the case requires a longer period. In contrast to EPO opposition proceedings, the losing party will normally be liable to bear all costs of the other party within the maximum rates set in the implementing act still to be adopted.

Appeal procedure during examination and opposition and oral proceedings

Decisions issued by the EUIPO examination panel, including the examination opinion, can be formally appealed before the EUIPO's Board of Appeal within two months of the notification of the decision. The same two-month deadline applies to decisions of an opposition panel if any party is adversely affected thereby. Basically, the appeal procedure is under a similarly strict timeframe as the examination proceedings. The statement setting out the grounds of appeal must be filed within four months of the notification of the appealed decision and any reply thereto within three months of the filing of the statement of grounds. The board will then set a date for oral proceedings within three months from filing the reply, or six months from the statement of grounds, whichever is earlier. Decisions of the EUIPO's Board of Appeal can be appealed before the General Court of the European Union and, possibly, if the legal conditions can be met, before the European Court of Justice.

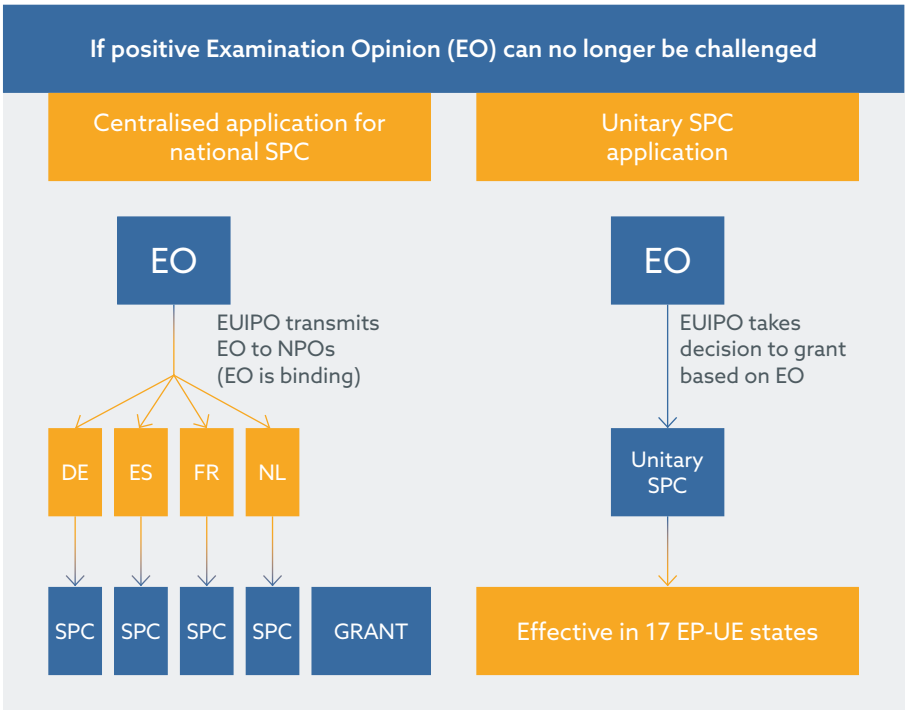

Fig. 3 | *SPC grant and national implementation of examination opinion (EO) for national and unitary SPCs (Left column: centralized SPC applications based on a traditional EP patent that was validated only in DE, ES, FR and NL; right column: application for a unitary SPC based on an EP patent with unitary effect (EP-UE))*

[6] Interestingly, the opposition ground of Art. 6(2) is missing from Art. 15 of the draft regulations for unitary SPCs while it has been added as invalidation ground to Art. 21 (PPP SPC) and Art. 22 (MP SPC). The reasons for this distinction between opposition grounds for national and unitary SPCs, respectively, are not entirely clear.

Any oral proceedings in examination, opposition, invalidity, and appeal proceedings are held in public. This is a move towards more transparency from the original draft legislation where only appeal board hearings were intended to be public.

Effect of examination opinion, SPC grant and national implementation

As mentioned before, the draft regulations provide for a different implementation of the examination opinion depending on whether it concerns a unitary SPC or a national SPC. In any event, the implementation can only take place if no appeal or opposition has been duly filed or, after the termination of such proceedings, a final decision on the merits has been issued.

In the case of an application for **unitary SPC**, the EUIPO will directly grant the SPC if the examination opinion was positive. Otherwise, the application will be rejected.

Since the EUIPO does not have the authority to grant **national SPCs,** the office will transmit the examination opinion and its translations to the IPO of each designated member state. The examination opinion is legally binding for the national patent offices which must grant the corresponding national SPC, if the opinion was positive. As mentioned before, only if the relevant part of the basic patent is no longer in force (invalidation grounds of Art. 15(1), points (b) or (c))[7] or the MA underlying the SPC application has been withdrawn, the IPOs of the member states may depart from a positive opinion of the EUIPO and reject the application. In case of a negative examination opinion, the SPC application will also be rejected by the national IPO and not the EUIPO.

Post-grant invalidity proceedings

The two draft regulations for the central examination of **national** SPCs do not include any provisions for post-grant invalidity proceedings because any challenge thereof is determined by national law.

Conversely, the draft regulations for **unitary SPCs** set the framework for an action for a declaration of invalidity of a granted unitary SPC which is to be examined by an invalidation panel of the EUIPO. As to the composition of such panel, the applicable timelines and possible appeal proceedings, similar rules apply as for opposition proceedings. In the explanatory memorandum for the two unitary SPC draft regulations, the legislator also sets out that, where the applicable conditions are met, counterclaims for a declaration of invalidity could be raised before the competent court of a Member State, including the Unified Patent Court (UPC).[8]

Conclusion and state of legislative efforts

The new centralised examination procedure for national and unitary SPCs is intended to streamline the various existing procedures, as well as allow for greater transparency and third party involvement.

At the time of writing of this article the legislative efforts are taking swift steps forward which may be related to the impending European elections in June 2024. Recent changes to the draft proposals have been approved by the European Parliament's Committee of Legal Affairs (JURI Committee) in January 2024 which include some procedural amendments briefly discussed above and some important clarifications.

For instance, the meaning of "*economically linked*" in connection with the revised version of Art. 3(2) was clarified as also recommended in our previous article. According to the revised version of Art. 3(2), if two or more SPC applications concerning the same product are submitted by two or more holders of different patents, one certificate may be granted to each applicant provided that the applicants are not "*economically linked*". Meanwhile, this expression has been defined as "*[meaning] that one holder, directly or indirectly through one or more intermediaries, controls, is controlled by or is under common control with another holder*". Two independent companies that hold different patents for the same product and conclude a licensing agreement do not fall under this definition and should thus be able to obtain one SPC each.

[7] Art. 15(1) of the two draft regulations for the centralized examination of national SPCs.

[8] However, this would require an amendment of the UPCA because Art. 2(h) UPCA defines "SPC" as SPC granted under Regulation (EC) No 469/2009 or under Regulation (EC) No 1610/96.

One issue that has not (yet) been addressed by the legislator is the possible delay of SPC grant by the newly introduced pre-grant opposition procedure. Especially if SPC applications are filed shortly before the expiry of the basic patent, the opposition procedure and two full appeal instances - before the Board of Appeal of the EUIPO and the General Court of the European Union - will give (generic) competitors the opportunity to delay SPC grant beyond the expiry of the basic patent. Even if an expedited examination has been requested by the SPC applicant, in which case the EUIPO renders an examination opinion within only 4 months, it can be roughly estimated that subsequent appeal proceedings over two instances may cause a further delay of up to 2 years. In extreme cases, combined opposition-appeal proceedings may prevent SPC grant before the hypothetical expiration date of the SPC. At any rate, it will be impossible for the SPC holder to effectively enforce the SPC after the expiry of the basic patent since it is very unlikely that any court will grant injunctions based on a pending SPC application. Despite the criticism voiced by several member states, including Germany, on the planned introduction of a pre-grant opposition procedure, it appears unlikely that substantial amendments will still be made before the new SPC regulations are finally adopted, mainly because the current legislative period is soon coming to an end.

A first plenary reading of the amended drafts took place on February 27, 2024, before the European Parliament which approved of the proposed amendments. The amended draft regulations are thus now awaiting the Council's first reading position. Whilst it is difficult to foresee when the legislation will be passed and come into effect, we will keep you updated of any major development.

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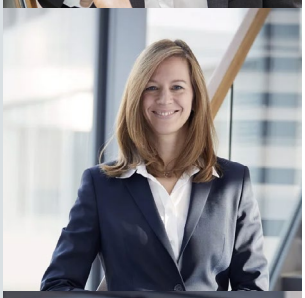

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New EU Legislation Proposals (Part IV): Regulation for a Union Compulsory License for Crisis Management

Last year, the European Commission presented proposals for new patent rules[9] including a draft EU Regulation on compulsory licensing for crisis management.[10] If accepted by the EU Parliament and the Council of the EU, the regulation would create a new EU-wide compulsory licensing instrument that complements EU crisis instruments in the life science field. During the COVID-19 pandemic, the lack of such an instrument was criticized. The new rules can only be activated in case of a major EU-wide crisis.

1. So far, no EU-wide compulsory license

Currently, compulsory licenses are only available on a national level.[11] There is a patchwork of different national rules and procedures on compulsory licensing. These procedures are limited in their territorial reach, and they do not include exceptions for other protective measures for pharmaceutical products.

In an EU-wide crisis, compulsory licenses would have to be requested before the competent national authority in several Member States. Due to different rules,[12] it is unlikely that the existing laws allow compulsory licenses to be obtained in all relevant countries. Even if it were possible to obtain parallel compulsory licenses in different countries, the process would not be efficient and would increase transaction costs, reducing the incentive for anyone to seek compulsory licenses, even when they are needed to address a crisis.

The existing laws also do not take cross-border situations into account. For example, German law does not provide for granting a compulsory license if the public interest is only present in another Member State. This creates problems when the facilities to produce a patented product under a compulsory license are not located in the same Member State where they are needed or, as is often the case in systems with complex supply chains, across multiple Member States. Products made under a compulsory license could also not be marketed EU-wide as the principle of exhaustion (first sale doctrine) does not apply in that situation.

Further, the present rules do not consider European patents with unitary effect. The UPC cannot grant compulsory licenses – not even for European patents with unitary effect, for which it has exclusive jurisdiction.

Lastly, if a compulsory license allows the use of patented inventions, this does not provide an exception to the rules on data exclusivity and market protection. For pharmaceutical products, protection under these rules can overlap with patent protection so that the use of the patented invention can be precluded even if a compulsory license has been granted. Member States cannot change these rules as both are based on EU law.

[9] The EU patent package also provides for the introduction of a system for Unitary Supplementary Protection Certificates (SPCs) and an initiative on standard essential patents (SEP). See the first three parts of our current series on this topic: (i) Michele Giunta, New EU Legislation Proposals (Part I): A First Look at the Draft SEP Regulation, Hoffmann Eitle Quarterly, issue September 2023, pp. 2-5; (ii) Johannes Osterrieth, Bianca-Lucia Vos, Klemens Stratmann, New EU Legislation Proposals (Part II): Creation of a New SPC Landscape for Europe, Hoffmann Eitle Quarterly, September 2023, pp. 6-11; and (iii) the first article in the present issue: Johannes Osterrieth, Bianca-Lucia Vos, Klemens Stratmann, "New EU Legislation Proposals (Part III): Centralised Examination Procedure for SPCs and Legal Remedies".

[10] COM(2023) 224 final dated April 27, 2023, see https://single-market-economy.ec.europa.eu/publications/com2023224-proposal-regulation-compulsory-licensing-crisis-management_en.

[11] Previous provisions on compulsory licenses in EU law were limited to export to countries with public health problems (Reg. (EC) 816/2006) or to interdependencies between community plant variety and patent rights (Art. 12 of Dir. 98/44/EC).

[12] The general conditions under Art. 31 TRIPS do not set specific requirements for granting compulsory licenses.

2. Current proposal

The proposed rules would create a compulsory license that can be granted by the EU Commission in a centralized procedure and is applicable in the whole territory of the Union. To ensure that a product can be manufactured and supplied across the EU, it would not be necessary to obtain additional compulsory licenses for each EU Member State in which patents, utility models and supplementary protection certificates are in effect. The proposed rules leave national compulsory licensing systems untouched.

2.1 Scope

The scope of the proposed Union compulsory license would be broader than under existing national laws. For patents, it would allow using national, European patents, and European patents with unitary effect and patent applications. It also covers utility models and supplementary protection certificates. In addition, the proposed compulsory license provides for a suspension of regulatory data and market protection (this suspension does not extend the original duration of regulatory data protection).

2.2 Requirements

The Union compulsory license is only available after a crisis mechanism has been activated or declared. The main requirement is a need for a compulsory license, e.g. a shortage of a crisis-relevant product. Although the licensee and rightsholder may reach a voluntary agreement, there is no requirement that the licensee attempts to obtain a license first.

The proposal aims to ensure that under a compulsory license, only a qualified person able to manufacture the crisis-relevant product and to pay a reasonable remuneration to the rightsholder is permitted use of the invention.

2.3 Procedure

In taking its decision, the Commission is assisted by an advisory body early on and it may be the same body that is involved in the underlying crisis or emergency mechanism. The advisory body shall advise the Commission on the need of compulsory licensing at Union level and its conditions, but its opinion is non-binding. The rightsholder and the licensee will be given the opportunity to comment. The public will also be informed of the initiation of a compulsory license procedure.

As it can be difficult for the Commission to identify all intellectual property rights and their respective rightsholders it can be sufficient to only identify the non-proprietary name of the product for which a compulsory license is sought.

2.4 Limitations

The proposal emphasizes the "exceptional nature" of a compulsory license and includes limitations on the scope and term of the license and provisions on compensation for the patent owners. The compulsory license will be limited in scope, duration, and territorial coverage. The duration, in particular, shall not extend beyond that of the underlying crisis.

The Commission will also determine the renumeration to be paid by the licensee to the rightsholder. The amount of the remuneration shall take into account the economic value of authorized use under the license, any public support received by the rightsholder to develop the invention, the degree to which development costs have been amortized as well as humanitarian circumstances relating to the granting of the Union compulsory license. Renumeration will be limited to 4% of total gross revenue.

Products marketed under a compulsory license to address a Union crisis must be clearly identifiable, through specific labelling and marking, and their export from the EU is prohibited. The proposal also allows the Commission to grant EU-wide compulsory licenses for export to countries with public health problems in the context of a cross-border manufacturing process.

3. Discussion

The proposal has been heavily criticized, especially by rightsholders in the pharmaceutical industry. One of their arguments against introducing a centralized proceeding for compulsory licenses in the EU is that the COVID-19 pandemic has shown no need for such measures. Intellectual property rights did not hinder overcoming this crisis, the difficulties were related to the management of supply chains that relied heavily on goods and materials sourced from outside the EU, and the challenges of ramping up production of new pharmaceutical products to meet a very high demand in a short period of time.

However, a fragmented system for compulsory licenses and the lack of harmonization does not fit the idea of a single market in the EU. If one accepts that a centralized procedure for EU-wide compulsory licenses is lacking, the next question is whether the current proposal takes the interests of all parties into account. Unfortunately, the short answer is no.

First, intellectual property rights encourage innovation, and patents are of particular importance in the pharmaceutical field. Any measures that weaken patent rights should be a last resort and, accordingly, the existing mechanisms for compulsory licenses in the Member States set high requirements for obtaining such licenses.

By contrast, the proposal fails to set clear requirements for granting compulsory licenses. It does not even define what a "crisis" is, although this is the main requirement for its application. It refers to two existing crisis mechanisms, but they do not address intellectual property rights. The proposal also does not clearly explain when a compulsory license is needed; it is certainly not needed automatically in every crisis, and compulsory licenses are not intended to address crises. The only guidance in the proposal is that the advisory body shall take into account for its opinion "*the shortage of crisis-relevant products and the existence of other means* [to] *remedy such shortage*" (Art. 7(1)(c) of the proposal). This opinion is not binding on the Commission.

The rightsholder and the licensee shall be given an opportunity to comment *inter alia* on the need for a compulsory license but again the proposal is unclear on how the Commission shall assess this need. The proposal requires the Commission to consider the advisory body's opinion, whether there are national compulsory licenses, and the rights and interests of the rightsholder and the licensee. Yet, it gives no guidance on how the Commission shall balance these interests, which in most cases will be opposed.

Second, the Commission has no special qualification for making decisions in the patent field. Why then shall the Commission be tasked with making decisions on compulsory licenses?

The reason seems to be that this proposal would increase the Commission's negotiation power with rightsholders. It would allow the Commission to threaten the grant of a compulsory license if the rightsholders are reluctant to meet the contract terms favored by the Commission. Especially in this context, it is striking that the maximum renumeration is limited to a royalty rate of 4% without considering the nature of the crisis-relevant products or other circumstances. The proposal provides no basis for this limitation of the renumeration. Such a blanket limitation likely violates Art. 31(h) TRIPS, which requires an "adequate" renumeration.

In addition, the proposal does not expressly mention legal remedies against the grant of a compulsory license. The only safeguard for the rightsholder seems to be that the proposal applies when a crisis mechanism has been activated or declared, which should be a rare occurrence.

Third, the low maximum renumeration could give licensees an incentive not to take a license in arm's length negotiations if the adequate royalty is higher. The proposal does not even require a licensee to first try to obtain a license under a voluntary agreement with the rightsholder. However, the COVID-19 pandemic has shown that free market negotiations can facilitate the innovation and production of new pharmaceutical products in a short period of time. There is no evidence that this can be improved by allowing the Commission to intervene artificially in the market, but there are concerns that it may even stifle innovation and cooperation.

4. Outlook

It is unclear whether the current proposal will become law. Currently, the Council is discussing the proposal, before the European Parliament considers and votes on it. As the main beneficiary under the proposal seems to be the Commission itself, which drafted the proposal, it is to be expected that Member States which are interested in strong intellectual property rights and the rightsholders in the pharmaceutical field, will make their concerns heard in the legislative process.

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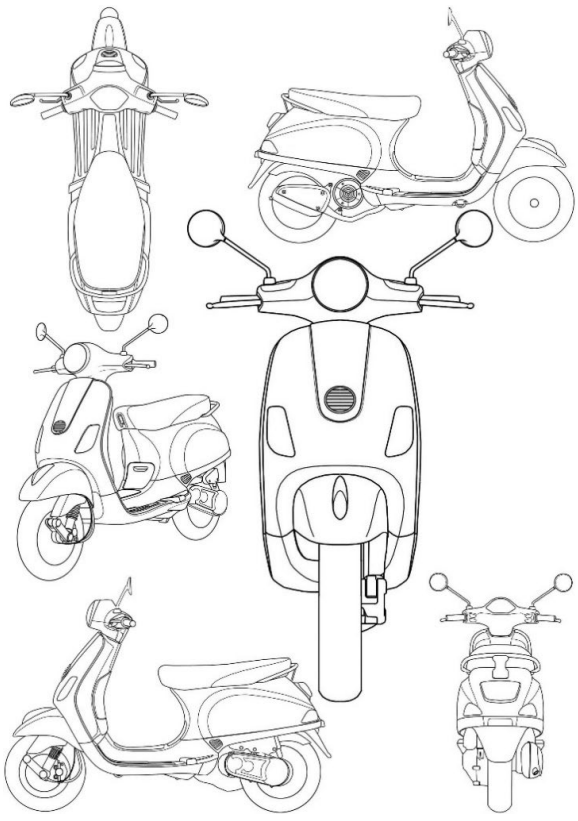
The European General Court Keeps the Vespa Moving: The Legal Challenge of Preserving the Protection of a 3D Trademark

- In its decision of November 29, 2023 (Ref.: T-19/22), the European General Court found that the three-dimensional mark representing a Vespa model had no intrinsic distinctiveness but rather had acquired distinctiveness and that the mark is therefore eligible for trademark protection.
- The General Court clarifies standards for establishing the acquired distinctiveness through use.
- The General Court considers that the Vespa has an iconic character and shall be protected against counterfeits.

Facts of the case

In 2013, Piaggio – the manufacturer of the well-known motor scooters called "Vespa" – applied for the following sign as a three-dimensional mark (hereinafter "3D mark") for *inter alia* "scooters" in the European Union ("EU").



1: Graphical representation of the EUTM No. 011686482; Source: https://euipo.europa.eu/eSearch/#details/trademarks/011686482

The trademark was finally registered in 2014, after the applicant provided material for the distinctive character of the trademark acquired through use.

In 2014, a competitor, also a manufacturer of scooters, applied for a declaration of invalidity of the trademark, inter alia on the grounds that the trademark would be devoid of distinctive character. The Board of Appeal of the EUIPO found that the distinctive character acquired through use had not been sufficiently proven and therefore declared the subject trademark invalid in respect of all designated goods. The proprietor contested the decision and brought an action against this decision before the General Court.

Decision

In its decision of November 29, 2023, the General Court annulled the decision of the Board of Appeal. The General Court found that the proprietor of the trademark at stake had sufficiently demonstrated the acquisition of distinctive character through use throughout the EU.

In its assessment of the material provided for establishing the acquired distinctiveness of the trademark at stake, the General Court first clarified that a non-distinctive EU trademark can only be registered and remain registered if it is proven that the trademark has acquired distinctive character through use in the part of the EU in which it had no inherent distinctive character. However, the Court held that it would be exaggerated to demand that proof of such acquisition

must be provided separately for each Member state of the EU. Evidence may also be relevant for several Member States or even the entire EU if, for example, several Member States can be grouped together within the same distribution network or, due to the geographical, cultural or linguistic proximity between two Member States of the EU, especially if the relevant public of the former has sufficient knowledge of the national market of the other Member state of the EU.

In the present case, the applicant was deemed to have provided evidence that is relevant to the EU as a whole.

As far as Piaggio presented evidence of the use of the sign representing various models with slightly different shapes, i.e. not only and exactly the shape reproduced by the trademark, the Court reasoned that certain features of the shape of the scooter, which are also reproduced in the trademark, have recurred in all models since 1945. It could not be ruled out that the public would recognize all shapes as originating from a particular company because the overall appearance remains the same.

Key take-away

With this decision, the European General Court has clarified the standards for establishing distinctive character acquired through use.

However, the subject case is special because it concerns a 3D mark representing the "Vespa", which the Court itself recognized as having iconic character. The worldwide fame of the "Vespa" and its shape is likely to have contributed significantly to this favorable decision for the proprietor of the trademark at stake.

Overall, it should be kept in mind that according to the established case law the criteria for assessing the distinctiveness of three-dimensional trademarks consisting of the shape of the product itself are no different from those applicable to other categories of trademarks. However, when applying these criteria, the perception of the average consumer is not necessarily the same in the case of a three-dimensional trademark, consisting of the appearance of the product itself, as in the case of a word or figurative trademark, which consists of a sign independent of the appearance of the goods it designates.

The closer the shape applied for as a trademark is to the shape most likely to be taken by the product in question, the more likely it is that that shape is devoid of (inherent) distinctive character within the meaning of Article 7(1)(b) EUTMR. In those circumstances, only a trademark which significantly diverges from the norm or customary practice in the sector and is therefore capable of fulfilling its original essential function is not devoid of distinctive character within the meaning of that provision.[13]

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[13] See CJEU, decision of October 7, 2004 - C-136/02, *P Mag Instrument v OHIM* [2004] para. 31, and of European General Court, decision of February 5, 2020 - T-573/18 Hickies v EUIPO (Shape of a shoelace), para. 29.

The Skilled Person Uses "They/Them" Pronouns, and Why You Should Care

— Embracing inclusivity: The growing importance of gender-neutral language in legal (con)texts.

— Hoffmann Eitle looks at the status of using inclusive language in legal (IP) texts, and the consequences of its non-use from both a business and legal perspective.

I – Gender-neutral language

In 2020, legal representatives across Europe saw the EPO amend the Rules of Procedure of the Boards of Appeal to ensure all language was made gender-neutral. One of the reasons the final instance in proceedings before the EPO enacted such a change was partly due to how powerful of a tool language can be used to influence perceptions and behaviour – in particular, to update social norms to 2024 standards by reducing gender stereotyping, discrimination, or bias. Going beyond political correctness, IP lawyers ought to be at the forefront of ensuring inclusive language pushes gender equality and recognises legal statuses outside the gender binary – this is key to reflecting IP's involvement in a rapidly evolving field, where innovation is core to technologies, brand and the creative arts, as much as it lies in its people.

So, what is gender-neutral language exactly? The European Parliament defines it on page 3 of their 2018 Guidelines as any syntax which is perceived as gender-fair, non-sexist and conclusively, above-all, inclusive[14]. Examples of this cover the use of "*they/them/their*" pronouns or the use of "*chairperson*", "*chair*" and "*layperson*", contrasted to the time-honoured "*he/him/his*", "*chairman*" and "*layman*".

Traditionally, the legal system has been grounded in binary gender distinctions - male or female. This is made evident illustratively in the 23 occurrences of the word "*him*", "*himself*" or "*his*" in the EPO guidelines[15] - for example at E.IV-1.6.7 or H.III-3.5.2 - one of which was corrected in Part A since the 2023 edition. The UKIPO Trade Marks Tribunals also often commence their letters with *"Dear Sirs"* despite it now being commonplace in proceedings to only have women as both representatives and clients. However, our understanding of gender has expanded beyond this binary, recognizing that individuals may not fit neatly into these categories. To address this, the use of "*they/them*" pronouns has become an essential aspect of legal language.

The use of neutral gender pronouns - even in their *a priori* plural form - is defined by the Oxford dictionary as appropriate, even in singular form. This therefore results in an ease with which to transform any legal – or non-legal – English text without resorting to extortionate grammatical exercises. To not find the time to adapt texts to be more inclusive is sending a clear message to others on one's non-intention.

II – From a European standpoint

EPO changes to legal texts in the English language only constitute a third of the total amount of law which needs updating. The use of gender-neutral language is *prima facie* accessible for the German-language version of the Guidelines, and substantively more challenging for the French-language equivalent.

Indeed, in French, the intrinsically gendered language makes it challenging to neutralise, due to the sheer volume of bias. This forced binarization resulted in the Opponent (l'Opposante) and the Proprietor (la Titulaire) both being female, but the skilled person (l'homme du métier) being male, although all can easily be gender reversed by using another pronoun. This binarization is however, still, made non-accessible to non-binary people. A potential solution to this would be the use of the contemporary epicene formulation in conjunction with the median interpoint "*i·e·l·s*", however this would

[14] Gender-Neutral Language in the European Parliament – 2018 Guidelines.
[15] Dr. Michael Ford, Haseltine Lake Kempner.

in practice require corresponding verbs and grammatical precedents to also be adapted (for example adapting "*il est ingénieur*" to "*iels sont ingénieur·e·s*"), thus having to adapt three words instead of the sole pronoun in English.

In German, the EPO Guidelines explicitly refer to the need for a "*generisches Maskulinum*" (generic masculine) interpretation of any gendered term as being gender-neutral. However, such broad, sweeping, statement cannot excuse biases in uses of "*der Fachmann*" (the skilled man), "*der Anmelder*" (the applicant), or "*der Patentinhaber*" (the proprietor) when referring to legal concepts. These references were also left unchanged following the Second Act of the Simplification and Modernisation of German Patent Law that entered into force on August 18th, 2021. Native German speakers have challenged the use of fabricated – yet more neutral – terms such as "*Fachperson*" on the basis that it sounded too "*artificial*" and "*awkward*", despite the German Federal Supreme Court (BGH) and the German Federal Patent Court both adopting "*Fachperson*" in their decisions.[16] Unfamiliarity and aversion to change should not be barriers high enough to prevent more frequent use of inclusive language, and consequently attract more diverse talent to the industry. Even more so in light of German (and Austrian) law recognising a third gender altogether.

For both French and German, the masculine skilled person in the assessment of inventive step is so baseless, such that no apparent reason subsists for gendering the legal concept.

III – A universal (?) view

IP legal texts in English also need updating on a more global scale.

In the United States, the story is reversed. The very first Patent Act of 1790 already referred to a gender inclusive lists of pronouns - "*he, she, or they*" - to be used for inventors. The female pronoun was unfortunately scrapped by Congress from legislative texts only three years later,[17] contributing perhaps to one of the reasons only 72 patents were accredited to women inventors during the first 70 years of the U.S. patent system. The recodified 1952 Patent Act referenced a gender neutral "*whoever*", but nonetheless persisted in maintaining other references to the masculine – such as the USPTO Director being male. The majority of these references were subsequently removed during introduction of the America Invents Act of 2011. More recent developments on the topic across the Atlantic look at arguments maintaining gender-binary language ("he" + "she", as opposed to "they"), in the context of Section 115 AIA: to prevent including AI as a possible inventor, but concurrently likening and/or grouping any non-binary individual to AI. An additional layer of complexity arises when looking at state-by-state convergence of the non-binary gender's legal recognition.

In India,[18] a similar boiler-plate clause for gender interpretation of legal texts – albeit less inclusive than the German one (as only referencing "females" instead of all genders) – is featured in section 13(1) of The General Clauses Act 1897, thus leaving The Indian Patents Act 1970 unamended in its bias. The latter references the words "*he*", "*his*" or "*him*" a staggering 248 times, to the extent that Indian case law created a female figure ("*Ms P Sita*") as person skilled in the art in the Enercon decision before the Intellectual Property Appellate Board.

[16] BPatG decision 9 W (pat) 55/19, dated 10.11.2021, BGH decisions of 28.01.2021 - X ZR 178/18, of 17.12.2020 - X ZR 15/19, of 26.01.2016 – II ZR 394/13. As quoted by Dr. Sabine Koch, Grünecker.

[17] Kara W. Swanson, Making Patents: Patent Administration, 1790-1860, 71 Case W. Res. L. Rev. 777, 818 n84 (2020).

[18] Priya Singh, Managing Associate at Anand and Anand.

IV – Concrete actions & repercussions (i.e. why you should care)

From a business development and retainment perspective, the use of inclusive language is primordial. Women and non-binary clients, foreign agents and foreign counsel alike will inevitably (ideally) compose more than 50% of clients at some point in the future. The latter will manifestly want to work with legal professionals who care to take the time to be inclusive. To be negligent in their retention could make the difference between profitable law firms and those lagging behind.

Legal professionals ought to actively ensure no accidental misgendering occurs. Legal documents, such as identification cards, contracts, or court proceedings, should accurately represent an individual's identity to prevent any harm. Embracing "*they/them*" pronouns acknowledges and respects individuals whose gender identities do not necessarily align with the traditional binary. Such use ensures that everyone, regardless of their gender identity, feels seen and heard within the legal system.

The use of target quotas for diversity at both board/partnership-level and more ground-level during client onboarding is becoming more and more prevalent. To be inclusive and more aware computationally transpires to be profitable. Correspondingly, law firms have made efforts to switch to gender neutral salutations in their letters to clients, foreign counsel, the UKIPO or the EPO, and avoid gendering their opponents in *inter partes* proceedings.

These changes are in line with the growing adoption of gender-neutral language by international bodies, thus acting as a steering direction for cross-jurisdiction legislation in the context of IP.

V – Conclusion

The malleability of languages over time results in our everyday vocabulary constantly evolving, this cannot exclude newfound use of "*Fachperson*" to designate the skilled person.

"*Ultimately, it rests on the legislators to ensure that gender-specific words and taglines are used in legislation so far as it is practicable, and at no more than a reasonable cost to brevity or intelligibility*."[19]

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[19] Das, Deb Zyoti; Rohilla, Bhanu Singh; Gender Neutral Legislative Drafting In India (June 17, 2020). Book titled "*Perspective on Gender Justice*" ISBN No: 9798653618970, Available at SSRN: https://ssrn.com/abstract=3662147

Hoffmann Eitle's Significant Contributions to the Development of European Case Law in 2023

Attorneys at Hoffmann Eitle work at the cutting edge of European intellectual property law. Our advocacy for our clients resulted in many interesting case law developments in 2023. In the following, we outline some of these.

The referral in G 1/23

One of the most significant EPO developments in 2023 was the referral to the Enlarged Board of Appeal in G 1/23, which is likely to have an important impact on the discussion of patentability in chemistry, biotech and beyond.

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".[20]

First UPC Court of Appeal ruling: UPC_CoA_320/2023

The UPC is in its early stages, and certain rules still require clarification. In the first appeal case (UPC_CoA_320/2023), a pragmatic interpretation of the rules of procedure was adopted, even if it differs from the practices of some national courts. The specific issue addressed was the scenario where a claimant fails to include exhibits with their statement of claim. The Court of Appeal ruled that the brief is deemed validly filed, but the clock for the defendant's response term only starts when also the exhibits have been provided. As a result, claimants are reminded to follow the new rules to avoid a delay of their cases.

First case to apply the key plausibility test in G 2/21: T 873/21

The million euro question in European patent law last year was undoubtedly "how will the Boards interpret the plausibility test in G 2/21?" T 873/21 was the first case to answer this question.

In the case at hand, the post-published evidence related to a synergistically improved insulin sensitivity with the claimed combination of compounds. Both compounds were generally known to have metabolic effects, and the application generally stated that the invention delivers improved insulin sensitivity compared to monotherapy. The specific combination of compounds was also identified as preferred.

Applying the test in G 2/21, the general statements and known activity of the compounds in T 873/21 were enough for the synergistic effect to be "derivable" at reason 3.3.2 such that the data was considered as providing the quantification of the obtained improvement. It also seems to have been considered "encompassed by the technical teaching" of the application for the same reason. The fact that both were preferred also meant that the effect was "embodied by" the claimed combination – see reason 3.3.3. So the data could be relied upon and inventive step was acknowledged.

This decision has generally been welcomed by patentees, as the Board adopted a position which makes it easier for parties wishing to rely on post-published evidence to support inventive step at the EPO.

[20] For more information, we refer you to our earlier article on this subject: Timo Pruß, Referral G 1/23: The Public Availability of Products in a New Light, Hoffmann Eitle Quarterly, September 2023, pp. 14-16.

Developments on the burden of proof on insufficiency: T 1076/21

Insufficiency objections at the EPO often stand or fall depending on whether the Opponent or Patentee has the burden of proof. This is why T 1076/21 attracted significant attention in 2023 - it established that this burden does not shift from the Opponent to the Patentee just because the patent has been revoked in the first instance on grounds of insufficient disclosure.

In more detail, following revocation by the Opposition Division for insufficiency, the Board explained that it is down to the Proprietor to substantiate on appeal why that decision is wrong. However, the burden of proof on the substance (and in consequence the benefit of the doubt) is only shifted when the Opposition Division's assessment that the presented facts, arguments and evidence were sufficient to discharge the Opponent's burden of proof turns out to be correct. The Board clearly distinguished between the "burden to substantiate" and the "burden of proof on the substance". If a patent is revoked due to a lack of sufficient disclosure, the Proprietor has the burden to substantiate on appeal why the decision of the Opposition Division was wrong. However, the burden of proof to show that the patented invention is actually sufficiently disclosed does not automatically shift to the Proprietor in such cases.

The decision of the Board is reasonable and pragmatic from a Proprietor's perspective. If there would be an automatic shift in the burden of proof on the substance following revocation based on a lack of sufficient disclosure, the Proprietor would face high extra efforts when entering the appeal stage trying to prove sufficiency. From an Opponent's perspective, the decision advises caution in that one cannot rely on a favourable decision of the Opposition Division, and assume that it is up to the Proprietor to prove sufficiency in the appeal stage. Instead, Opponents are advised to review the strength of their first instance presentation on lack of sufficient disclosure and consider filing further evidence as early as possible in the appeal stage where they consider this necessary.

When can the description be relied upon for claim interpretation at the EPO? T 42/22

Can the description be used for claim interpretation, and if so, when? This question has been a major topic of recent EPO case law, and T 42/22 provides further guidance on this issue.

Added subject-matter in that case turned on whether a claimed chemical group was to be interpreted based on its literal wording and chemical standard (IUPAC) nomenclature, or whether the description could be used to reinterpret the contested feature.

The Board confirmed earlier case law stating that if a claim is clear as such and can be interpreted in a technically sensible way, the description should not be used for claim interpretation. The Board reasoned that in the case at hand, the claim was clear, because there were no inconsistencies in the claim. In this regard, the Board also indicated that in situations where multiple readings of a claim are possible, it is not necessarily justified to use the description for interpretation. If the claim merely comprises several embodiments which can be identified, this does not constitute an ambiguity, and hence, the description should not be considered.

The Board also commented on the question of whether claim 1, which was a product claim, should be interpreted in the context of another independent claim, method claim 6. The Board disagreed with the Patentee's view that an independent product claim is to be interpreted based on a method claim and held that neither the case law nor Art. 84 EPC supports such an approach to claim interpretation. Even if additional interpretations of a claim are possible, a technically sensible interpretation cannot be disregarded.

As the literal interpretation could be adopted, the patent was revoked due to added subject-matter.

The meaning of "admissibly raised" in Article 12(4) RPBA: T 364/20

There is little case law on the application of the *"admissibly raised and maintained"* part of Article 12(4) of the Rules of Procedure of the Boards of Appeal (2020). T 364/20 provides clarification on this issue.

Article 12(4) RPBA (first sentence) states that *"[a]ny part of a party's appeal case which does not meet the requirements in paragraph 2 is to be regarded as an amendment, unless the party demonstrates that this part was admissibly raised and maintained in the proceedings leading to the decision under appeal."* In T 364/20, the Board had to decide on the admissibility of claim requests which were filed at first instance and not withdrawn, but which were not part of the Opposition Division's decision. They provided several generally applicable conclusions.

Firstly, the Board held that claim requests filed within the term set under Rule 79(1) EPC for responding to a notice of opposition are never late-filed and, as a rule, are admissible. However, the Board stresses that the admittance of such claim requests is not a given. Opposition Divisions have discretion to refuse to admit claim requests filed within the Rule 79(1) term if there are "*truly exceptional*" circumstances, such as a high number of requests which diverge and are not fully substantiated. This represents a divergence from the EPO's own Guidelines for Examination, part E-VI, 2.1 of which states that *"[i]f a patent proprietor replies to a notice of opposition by amending the patent, such a request for amendment cannot be considered as late-filed and has to be admitted into the proceedings (Rule 79(1))."*[21]

Secondly, the Board held that claim requests filed after the expiry of the term for responding to a notice of opposition but before the deadline under Rule 116(1) EPC are not necessarily timely filed. According to the Board, it depends on whether the claim requests were filed *"in direct and timely response to a change to the subject of the proceedings introduced by the opponent or the opposition division"*. If this is not the case, there is a risk that the claim requests will be found to be late-filed. This is significant because it means patentees cannot assume that claim requests filed before the Rule 116(1) deadline are timely filed and therefore admissible. Again, there is a divergence from the Guidelines for Examination. Part E-VI, 2.2.2 of the Guidelines states that *"[a]mendments submitted before the date set under Rule 116(1) cannot, as a rule, be considered as being late-filed."*[22]

Thirdly, the Board held that if claim requests filed before the Rule 116(1) deadline are considered late-filed under the above-mentioned assessment, the Opposition Division, and therefore also the Board, has discretion regarding admittance of the claim requests. Relevant criteria to consider include those set out in the final sentence of Article 12(4) RPBA, namely the complexity of the amendments, procedural economy, and the suitability of the amendments to overcome attacks without creating new issues. However, the Board stresses that these criteria should not be applied as strictly as for amendments filed during the appeal procedure, bearing in mind that the first instance is an administrative procedure. This aspect of the decision softens the impact of the Board's strict approach to the assessment of whether claim requests were late-filed.

Conclusion

As can be taken from the above, Hoffmann Eitle have been involved in some of the key cases in 2023, regarding a range of issues including claim interpretation, sufficiency, disclosure, inventive step as well as formal requirements both at the EPO and the UPC.[23]

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[21] This statement has not been amended in the latest edition of the Guidelines, which came into force on 1 March 2024.

[22] This statement has not been amended in the 2024 edition of the Guidelines, either.

[23] The following further attorneys also contributed to individual sections of the article: Timo Pruß, Mike Gruber, Michael Müller, Lasse Weinmann, and Matthew Birkett.

EPO Amends the Rules of Procedure of the Boards of Appeal (RPBA)

Last year, we discussed and provided a critical analysis of the proposed amendments to the RPBA,[24] which govern appeal proceedings before the EPO Boards of Appeal. The EPO has now amended the RPBA, taking some of our concerns into account. The amended RPBA came into force on 1 January 2024,[25] and in the following we highlight the main amendments which relate to Articles 13(2) and 15(1).

Article 13(2) governs the third convergent stage of appeal proceedings, during which amendments to the appeal case are extremely difficult. In particular, the RPBA state that such amendments shall not be taken into account unless there are exceptional circumstances. Under the amended RPBA, this strictest stage will typically start with the notification of the communication under Article 15(1) (with which the Board generally provides a preliminary opinion). Previously, this stage of the appeal proceedings generally started with the notification of the summons.

> **Article 13(2):**
> Any amendment to a party's appeal case made after the expiry of a period specified by the Board in a communication under Rule 100, paragraph 2, EPC or, where such a communication is not issued, after notification of a ~~summons to oral proceedings~~ **communication under Article 15, paragraph 1**, shall, in principle, not be taken into account unless there are exceptional circumstances, which have been justified with cogent reasons by the party concerned.

In most cases, this change will give parties longer to make submissions during the appeal proceedings before the strictest third convergent stage begins. It has therefore been met with a warm reception from EPO users, and seems to us to be a pragmatic amendment.

Unfortunately, this welcome change to Article 13(2) is accompanied by the amendment to Article 15(1) which is less user friendly. This changes the earliest date on which the Board can issue the communication referred to in amended Article 13(2) above in inter partes proceedings. It has been reduced from two to one months from the receipt of the response(s) to the Grounds of Appeal.

> **Article 15(1):**
> Without prejudice to Rule 115, paragraph 1, EPC, the Board shall, if oral proceedings are to take place, endeavour to give at least four months' notice of the summons. ~~In cases where there is more than one party, the Board shall endeavour to issue the summons no earlier than two months after receipt of the written reply or replies referred to in Article 12, paragraph 1(c).~~ A single date is fixed for the oral proceedings. In order to help concentration on essentials during the oral proceedings, the Board shall issue a communication drawing attention to matters that seem to be of particular significance for the decision to be taken. The Board may also provide a preliminary opinion. The Board shall endeavour to issue the communication at least four months in advance of the date of the oral proceedings. **In cases where there is more than one party, the Board shall issue the communication no earlier than one month after receipt of the written reply or replies referred to in Article 12, paragraph 1(c).**

This amendment significantly increases the time pressure on parties to respond to any response to the Grounds of Appeal, if they wish to avoid the risk that their submissions are made after the Board issues its communication under Article 15(1) RPBA and the preliminary opinion that is usually contained therein, i.e. after the start of the strictest third convergent

[24] Adam Lacy, Proposed Amendments to the EPO Rules of Procedure of the Boards of Appeal: A Critical Analysis, Hoffmann Eitle Quarterly, September 2023, pp. 21-23.

[25] Decision of the Administrative Council of 13 December 2023 approving amendments to the Rules of Procedure of the Boards of Appeal (CA/D 24/23), OJ EPO 2023, A103, published online on 22 December 2023.

stage. In our view, this increased time pressure introduces significant disadvantages without bringing any advantages. It will have no meaningful impact on the timeliness of EPO appeal proceedings anytime soon, because it is extremely rare for the Board to issue the communication so early in the appeal proceedings. Nevertheless, parties will now feel impelled to respond by making possibly complex submissions on a very short timescale. As such, we expect it to have a negative impact on the debate before the Boards of Appeal and the quality of decisions.

In addition, the unusual way the "*one month*" is defined may realistically leave parties with significantly less than one month to respond. It starts from the "*receipt of the written reply*", rather than the "*notification of the written reply*", which is standard when setting terms at the EPO. The Board often receives the written reply some time before it is notified to the other parties. So in many cases the time available to parties will be less than one month once the written reply has actually been notified to them.

The most controversial proposed amendment was to Article 12(1)(c) RPBA, to reduce the default period for response to Grounds of Appeal from four to two months. We are pleased to report that the EPO decided not to implement this change following the negative reception from EPO users (including Hoffmann Eitle) in the user consultation. As we discussed previously,[26] it was generally objected that this amendment would:

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

As such, it would have introduced significant disadvantages without bringing any advantages. While the removal of this proposed amendment is a welcome sign that the EPO listened to the feedback in the user consultation, it seems that the EPO is still considering implementing this amendment at a later date. The announcement of the amendments on the EPO website stated that:[27]

> *Such an amendment will be reconsidered once experience with the new timeliness objective for the Boards of Appeal (settling of 90% of cases within 24 months by the end of 2025) is evaluated.*

Readers can therefore expect to hear more on this subject in future issues of the Hoffmann Eitle Quarterly.

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[26] Adam Lacy, Proposed Amendments to the EPO Rules of Procedure of the Boards of Appeal: A Critical Analysis, Hoffmann Eitle Quarterly, September 2023, pp. 21-23.

[27] "Amended Articles 13(2), 15(1) and 15(9)(b) of the Rules of Procedure of the Boards of Appeal (RPBA) enter into force on 1 January 2024", Boards of Appeal of the European Patent Office, 13 December 2023.

Electronic Signatures Accepted Again: The EPO Reacts Quickly After J 5/23

Documents providing evidence of a transfer of rights at the EPO must be signed (Art. 72 EPC). A Notice dated 22 October 2021 provided that qualified electronic signatures, in addition to handwritten signatures, would be accepted in respect of evidence filed in support of requests for registration of a transfer of rights, licences or other rights. The Legal Board of Appeal overturned this Notice in decision **J 5/23** and clarified that the signatures required under Art. 72 EPC had to be handwritten signatures; text string signatures or qualified electronic signatures were not considered valid. The Administrative Council has now amended the Implementing Regulations to the EPC to again allow digital signatures, text string signatures and text facsimile signatures in this specific context.

European (EP) patent applications and EP patents are objects of property and as such can be transferred between parties. An assignment of an EP patent or application is the act of transferring ownership from the assignor to the assignee. For granted patents after the opposition period or after opposition proceedings, the transfer must be recorded on a country-by-country basis. However, the transfer of an application before grant or of a patent[28] during the opposition period or during opposition proceedings can be registered centrally at the EPO, upon fulfilment of certain requirements laid down in Art. 72[29] and R. 22[30] EPC.

Validly recording the transfer of rights at the European Patent Office (EPO) is of utmost importance; for instance, the registered applicant is deemed to be entitled to exercise the right to a European patent.[31]

According to Art. 72 EPC, the assignment of an application (or patent, as indicated above) must be made in writing and requires "the signature of the parties to the contract". With the Notice dated 22 October 2021[32] concerning electronic signatures on documents submitted as evidence to support requests for registration of a transfer of rights ("the Notice"), the EPO informed that, besides an original handwritten signature, the Legal Division would also accept *qualified electronic signatures* as defined in Regulation (EU) No 910/2014.[33]

The Legal Board of Appeal (LBoA) in decision **J 5/23**[34] overturned this Notice, and set the signature requirements for an assignment to be validly recorded at the EPO. According to the LBoA, only a handwritten signature would be acceptable for the assignment to be validly registered.

The case in hand hinged on how the term "**signature**" in Art. 72 EPC was to be understood and, in particular, whether it encompasses electronic signatures in the form of "*text string signatures*" without any further qualification.

[28] R. 85 EPC.
[29] Art. 72 EPC.
[30] R. 22 EPC.
[31] Art. 60(3) EPC.
[32] OJ EPO 2021, A86.
[33] Regulation (EU) No 910/2014 (Art. 3(12)): "'*qualified electronic signature' means an advanced electronic signature that is created by a qualified electronic signature creation device, and which is based on a qualified certificate for electronic signatures*".
[34] J 5/23.

The then registered applicant of EP 21204983.7, Gyrus ACMI, Inc. D/B/A Olympus Surgical Technologies America, requested the registration of the transfer of the application to Olympus Medical Systems Corporation. A copy of the assignment agreement was provided, and it was signed as follows:

IN WITNESS WHEREOF, we have hereunto set hand and signed on the date indicated below:

ASSIGNOR Gyrus ACMI, Inc	ASSIGNEE Olympus Medical Systems Corporation.
By: /Mark D. Lavender/	By: /Kazuo Mikami/
Name: Mark D. Lavender	Name: Kazuo Mikami
Title: Executive Director, IP Counsel	Title: Director of IP Portfolio 1
Date: 11/2/2021	Date: 11/1/2021

The signatures of both the assignor and the assignee were, as shown above, *text string signatures* (i.e., a string of characters preceded and followed by a forward slash (/)). The Legal Division rejected the above evidence as lacking a qualified certificate within the meaning of Regulation (EU) No 910/2014. It invited the applicant to re-submit the document in PDF format bearing either verifiable electronic signatures or handwritten signatures.

The Applicant filed an appeal instead and argued that the signatures of the parties to the assignment contract as required under Art. 72 EPC may also take the form of *text string signatures* without any further qualification.

In its decision, the LBoA reviewed the definition of "signature" and the principles of interpretation of the EPC, and concluded that only handwritten signatures are valid for the assignment to be registered:

> *"[...] the term "signature" in Article 72 EPC - in the absence of a different definition in the Implementing Regulations [...] - must be understood as referring to a handwritten depiction of someone's name [...]"*
>
> J 5/23, Reasons 2.9

The LBoA stated that the Notice dated 22 October 2021 (which, as a result of **J 5/23**, will officially cease to have effect as of April 1, 2024[35]) deviated from Art. 72 EPC as interpreted by the LBoA, and concluded that it "is not a legal instrument passed by a competent legislative body, so it can neither implement nor specify any articles of the EPC".[36] The LBoA suggested that, if it so decided, the Administrative Council could define the term "signature" to have a broader meaning in the Implementing Regulations to the EPC.[37]

The Administrative Council ("the Council") has now taken the baton and has amended the Implementing Regulations to allow assignments to be signed, *inter alia*, electronically, as of April 1, 2024. The Council is one of the two organs of the European Patent Organisation (EPOrg), the other being the EPO. The Council acts as the Office's supervisory body and is also competent to amend the Implementing Regulations.[38] Specifically, the Council has now amended R. 22 EPC[39], which will, as of April 1, 2024, refer back to R. 2(2) EPC[40] and thus allow digital signatures on contracts and declarations submitted as evidence to support requests for the above registrations, as well as facsimile signatures and text string signatures.[41] With the amendment to R. 22 EPC,

[35] Notice from the European Patent Office dated 9 February 2024 concerning revised Rule 22 EPC, item 11.
[36] J 5/23, Reasons 2.8.3.
[37] J 5/23, Reasons 2.11.
[38] Arts. 33(1)(c) and 164(1) EPC.
[39] Decision of the Administrative Council of 14 December 2023.
[40] R.2 EPC.
[41] Decision of the President of the European Patent Office dated 9 February 2024 and Notice from the European Patent Office dated 9 February 2024 concerning revised Rule 22 EPC.

the Council broadens the applicability of R. 2 EPC to not only formal requirements for filing documents in proceedings before the EPO but also to formal requirements for assignment contracts.

Despite the short-term inconvenience, the EPO has acted quickly to maintain its commitment for the digitalisation and simplification of its procedures by accepting digital signatures, facsimile signatures and text string signatures on contracts and declarations submitted as evidence for the registration of assignments of rights. As it turns out, this could not be done by simply publishing a Notice in the Official Journal. The LBoA made it clear that these notices are not legal instruments passed by a competent legislative body, so they can neither implement nor otherwise qualify any articles of the EPC. The Implementing Regulations have now been amended and so has the meaning of the term "signature" in Art. 72 EPC.[42]

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[42] J 5/23, Reasons 2.5.4 and 2.5.6.

UPC CoA Revokes Provisional Injunction Against NanoString

The provisional injunction (PI) granted by Local Division (LD) Munich on 19 September 2023 received a lot of attention. It was the first decision by the new court addressing the key aspects of validity and infringement in greater detail and it showed that the judges had no difficulty handling complex biotech patents, even in PI proceedings. The decision also had a notable economic impact. Shortly after the decision had been announced, NanoString's stocks fell by 30%. Recently, the company initiated Chapter 11 proceedings in light of the negative outcome of separate US patent litigation (with a $ 31.5 million damages award to competitor 10x Genomics).

On 26 February 2024, the UPC Court of Appeal (CoA) revoked the LD's order and rejected the PI request.[43] While confirming some of the main aspects of the LD's decision, the CoA considered that claim 1 of EP 4 108 782 (EP'782) had been interpreted incorrectly and that based on the correct interpretation the patent was likely invalid for lack of an inventive step.

The CoA confirmed the principles of claim construction applied by the LD. In accordance with Art. 69 EPC, the patent claim is not only the starting point, but the decisive basis for determining the scope of a European patent. The description and the drawings must, however, always be used as explanatory aids for the interpretation of the claim, not only to resolve any ambiguities. These principles apply equally to the assessment of infringement and validity.

Claim 1 of EP'782 covers a method for detecting a plurality of analytes in a cell or tissue sample comprising several steps, e.g. an incubating and binding step (feature 3) and a detection step in a temporally-sequential manner (feature 4) comprising a series of sub-steps. According to the LD, the claim required that the detection reagents must remain bound to the respective analytes throughout the repeated sequence of detection steps pursuant to feature 4. However, the CoA considered that feature 4 was not limited in that way and that the claim also encompassed the possibility that the detection reagents are completely removed from the analyte after each detection step. The CoA further argued that since the claimed method "comprises" the incubating and detecting steps, the former may also be carried out multiple times.

In light of this broader interpretation, the CoA considered that the only distinguishing feature of claim 1 over the prior art document D6 was that the plurality of analytes was "in a cell or tissue sample" (*in situ*). The analysis in D6 was conducted on so-called amplified single molecules (*in vitro*). The CoA considered that the skilled person had an incentive to transfer the *in vitro* method disclosed in D6 to the *in situ* detection of analytes in cell or tissue samples, which had already been successfully attempted with respect to another method by the priority date.

According to the CoA panel, to grant provisional measures, the court must at least find that it is more likely than not that the applicant is entitled to initiate proceedings and that the patent is infringed. This would not be the case if it is more likely than not that the patent is invalid. The panel moreover held that the burden of presenting and proving facts relating to the validity of the patent is on the defendant (unless the matter is to be decided without hearing the defendant). The applicant bears the burden of presentation and proof of facts regarding all other aspects allegedly supporting the applicant's request, such as entitlement to initiate the proceedings and actual or imminent infringement.

As the CoA revoked the PI there was no need to discuss other issues that have been debated after the LD decision. This included, for example, whether an auxiliary request filed only in the oral proceedings before the LD is admissible at all (the CoA decided that claim 1 of this request would most likely be invalid for obviousness), how such requests are to be handled in PI proceedings, and how the respective harm for the parties shall be assessed and weighted.

[43] Order of the Court of Appeal of the Unified Patent Court issued on 26/02/2024 in the proceedings for provisional measures concerning EP 4 108 782, Action number: UPC_CoA_335/2023 App_576355/2023.

The CoA panel under presiding judge Grabinski (DE), who also acted as judge-rapporteur in this case, consisted of five judges (three legally qualified judges from Germany, France and the Netherlands and two technically qualified judges from Germany and the Netherlands). The first substantive decision of the UPC CoA provides guidance on the interpretation of the claims of a European patent and the role of the description and drawings in this respect.

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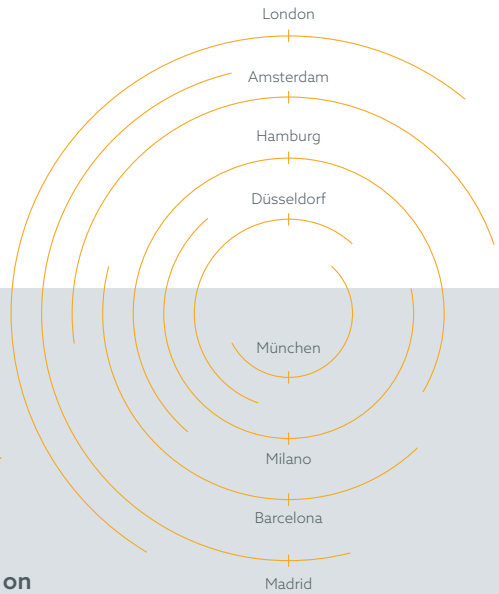
HE Patent Litigation & Contracts practice group



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