HOFFMANN EITLE

HOFFMANN EITLE December 2022 QUARTERLY

Driven by Technology: Patenting AI Before the European Patent Office (Part III)

In this third article of our series on artificial intelligence (AI) inventions (see the first here and the second here), we focus on inventive step and technical effects with respect to inventions in that field, with an eye to ensuring the claimed AI can support an inventive step and to proving the presence of a technical effect resulting from the claimed AI.

1. Inventive step and the COMVIK approach in view of AI

As with other jurisdictions worldwide, the EPO requires a claimed solution to be inventive over the prior art.[1] That is, the journey[2] the skilled person would have had to take to get from the existing state of the art to the claimed invention cannot be trivial or obvious.

As outlined in the first article of the present series,[3] EPO case law has developed the so-called *problem-and-solution approach* for assessing inventive step as objectively as possible based on the technical effect achieved by the claimed solution over the state of the art. This approach has been modified for handling computer-implemented inventions (CII) in the now-called COMVIK approach. Since AI is considered by the EPO as a sub-category of mathematical models implemented on a computer and thus as falling under the family of CII, the COMVIK approach applies to AI inventions too. The gist of the COMVIK approach is that non-technical features, which do not contribute to the technical character of the invention, are disregarded (i.e., ignored) for inventive step even if recited in a claim. In this context, the EPO has deliberately decided not to provide a definition of what is technical, so that a case-by-case assessment is required.

Fortunately, the EPO Guidelines give indications, for example, by stating that technicality may be recognized if an AI claim is limited to a technical purpose, such as controlling a technical system or process, classifying digital images, videos, audio or speech signals based on low-level features (e.g., edges or pixel attributes), identifying irregular heartbeats, etc. Technicality may also be achieved if the claimed AI solution is adapted based on the technical considerations of the internal functioning of the computer on which it runs.[4] An example given in the Guidelines is to utilise the parallel processing capability of a device having central and graphical processing units (CPU and GPU) by allocating the data-intensive training of the AI to the GPU and the preparatory steps to the CPU. Another (hypothetical) example in which an AI can be adapted to a specific technical implementation would be if a neural network had layers of a size adapted to be a multiple of the word size of the computer on which it is to run.[5]

[1] This requirement is set out in Articles 52(1) and 56 EPC.
[2] Rule 42(1)(c) EPC requires that the technical problem that is aimed to be solved by the invention can be understood from the description. Hence the description would allude to the beginning of this journey.
[3] Michele Baccelli, "Driven by Technology: Patenting AI Before the European Patent Office (Part I)", HOFFMANN EITLE Quarterly, June 2022, pp. 2-5.
[4] The technical purpose and the adaptation based on the functioning of the computer were also referred to as the first situation and second situation discussed in our first article of the series.
[5] The EPO would consider the computational efficiency of an AI invention as a technical effect only if the claimed invention is limited in one of the two situations (see footnote 4 above) necessary for technicality. This is based on the notion that it is always possible to find a slower/less efficient algorithm, see e.g. the Guidelines for Examination in the EPO, Part G-II, 3.3.

2. AI and technical effects

Notwithstanding the above, it can be challenging in some cases to establish whether an AI solution produces a technical effect that allows the AI solution to support the presence of an inventive step. Even when the model underlying an AI invention may be precisely described according to a deterministic model, explaining accurately how a certain technical effect is achieved may not be straightforward due, for example, to the complex interactions between a large input data set and the underlying neural network. To a certain extent, such a situation is similar to the case of a chemical compound producing a technical effect that cannot be readily explained.

A technical effect should also be credibly achieved over the whole area claimed.[6] It is thus important to prove, to the satisfaction of the EPO, the presence of a technical effect across the whole scope of the claim so that the AI-related claim features will not be ignored when assessing inventive step.

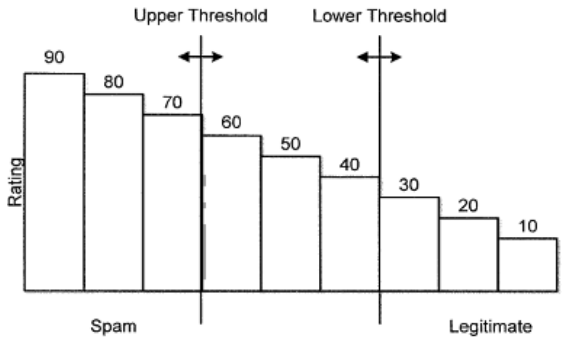
3. Proving the presence of a technical effect

Two possible scenarios may arise: the case in which it can be explained how the invention produces a technical effect and the case in which a convincing explanation is not readily available. In the first case, it is highly recommended to provide the explanation in the description and to have adequate basis for introducing the technical effect in the claim, should the need arise. In the second case, an empirical approach to support the presence of a technical effect may be considered.

3.1 Documenting the technical effect in the application

In decision T 2147/16,[7] the Board of Appeal was not satisfied with the available proof for the presence of a technical effect.

The invention underlying this decision relates to spam detection using clustering and rating of emails. In more detail, emails are grouped into clusters, which are then rated based on metadata to determine the category (spam or legitimate) of an email. The metadata is information that identifies each email and its sender and may include, for example, a hash sum of the email, IP addresses of sender, etc. Once different clusters are obtained and rated, each cluster rating is compared against upper and lower thresholds to determine whether an email is legitimate or spam, as exemplified in the following picture reproduced from the application.



Simply put, a computer uses an algorithm for determining whether an incoming email is legitimate or spam, which, according to the application, is accurate and improves the performance of the computer.

The Board held that the mere assumption that an algorithm is optimized for the computer hardware and may have a technical effect was not sufficient. Rather, it must be proven (not only assumed) that a further technical effect going beyond the mere implementation of the algorithm is achieved.[8] The term "further" suggests that the Board considered that a deterministic computer algorithm inherently always provides more reliable results compared to some other known algorithm; a technical invention, however, must provide a technical effect going beyond that.[9] The Board also held that the further technical effect should be reflected in the claim wording.[10]

[6] See, e.g., "Case Law of the Boards of Appeal of the European Patent Office", 10th edition 2022, I.D.4.1 referring to "the entire range covered by a claim" or "across the whole scope of the claim".
[7] T 2147/16 of 7 September 2021, Kaspersky Lab. This case does not expressly deal with AI but rather with an algorithm. Since AI and algorithms are treated by the EPO substantially in the same way, the present case is nevertheless of interest.
[8] T 2147/16, point 5.3.12.
[9] We infer this interpretation of "further technical effect" from points 5.3.7, 5.3.10, 5.3.12, and 5.3.15 of the decision, in addition to the common meaning given by the EPO to the "further technical effect" in the Guidelines for Examination in the European Patent Office, Part G-II, 3.6.1; and G 1/19.
[10] T 2147/16, point 5.3.7.

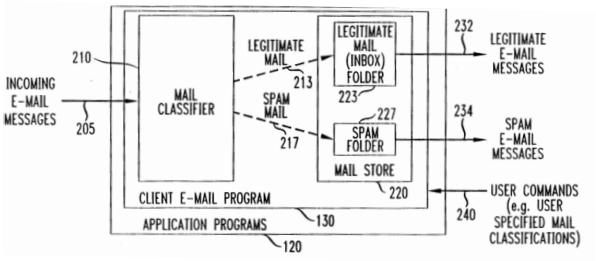
In the case at issue, the description stated that the cluster size had to be optimized to reduce the load on the computer; however, no further details on relevant parameters were given, such as the range of the optimal cluster size, the amount of memory saved, etc. Had the description included an explanation on how the range of the mentioned parameters contributed to achieving the asserted technical effect, the applicant's case for technicality may have been stronger.[11]

It is thus recommended to document in the patent application how an AI invention, and in particular the parameters characterizing the data and/or the underlying neural network, play a role in achieving a given technical effect. The claim wording must also reflect the further technical effect, at least in dependent claims (as this limitation may be required at the EPO only, it may be preferable not to have it in an independent claim at filing, to avoid limiting the protection in other desired jurisdictions) with adequate support in the description.

3.2 Can experimental data represent adequate proof?

Credibly explaining why and how a technical effect is achieved may be challenging in some cases. Even if a neural network and the training data may be precisely described for example by means of a model, the actual interrelations between large data sets and the neural network processing them may not be readily explainable. In these situations, whether experimental data may be used to prove the presence of a technical effect should be considered.

In that respect, T 22/12[12] deals with text classification and, in particular, with classifying certain incoming email messages as junk mail similar to the decision discussed above. This is represented in the figure below (which is Fig. 2 of the underlying application).



More specifically, the text classification is applied to emails using a probabilistic classifier trained on past classifications of message content and based on two types of feature:

1. handcrafted features, i.e. features determined through human judgement alone, and

2. word-oriented features, like presence of particular words, or stems of words.

The probabilistic classifier outputs a confidence level of whether an incoming email is legitimate, and a sigmoid function is then used for classifying the email as spam or legitimate based on the confidence level output by the probabilistic classifier.

According to the applicant, the use of the two types of feature reduced the processing load compared to the use of only the word-oriented features. Furthermore, performing the method in two stages, i.e. using a probabilistic classifier together with a sigmoid function, would have the technical effect of reducing processing load.

The Board was not persuaded that the effects of less complex computer implementation and reduced processing load were achieved. In particular, the Board considered there was no evidence that the alleged technical effect was only achieved when using both claimed types of feature, as opposed to using only one. The Board's doubts apparently stemmed also from the fact that some of the features seem to be based on linguistic factors or human judgement, which are per se usually regarded as non-technical.

In similar situations, applicants should carefully consider how to show that an alleged technical effect is achieved. Providing test results in the description, preferably involving several data sets and comparative experimental data, should therefore be considered. Doing so may be useful not only for proving the technical effect that the claimed invention has to produce to comply with the inventive step requirement, but also for complying with the sufficiency of disclosure requirement.[13]

[11] See e.g. point 5.3.11 of T 2147/16.

[12] T 22/12 of 16 November 2015, Microsoft Technology Licensing. The underlying invention relates to a probabilistic classifier; for the present discussion, we assimilate it to an AI invention, also because the EPO would likely treat probabilistic classifiers and an AI classifier equally on grounds that they are sub-categories of mathematical models implemented on a computer.

[13] Eve O Connor, Michele Baccelli, "Driven by Technology: Patenting AI Before the European Patent Office (Part II)", HOFFMANN EITLE Quarterly, September 2022, pp. 2-5.

4. Conclusion

- The EPO Guidelines provide helpful indications on AI claim features that are generally considered technical and therefore must be taken into account in assessing inventive step at the EPO.
- It is highly recommended to explain in detail the technical effect in the application and to also make sure that the features that reflect the purported technical effect are properly recited in the independent claims (or that the application provides support for introducing these features in the independent claims when entering the European phase of a PCT application).
- When it is not possible to provide a credible technical explanation, providing test results as evidence that the AI invention achieves a certain technical effect should be considered.

Stephanie Rupp

M.Sc.
(Electrical Engineering)

German and European
Patent Attorney

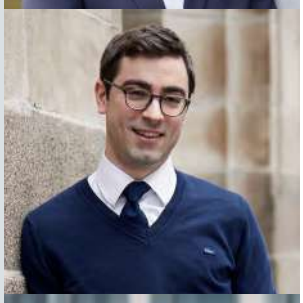
HE Electrical Engineering &
IT practice group

Rifat Camurdan

B.Eng. (McGill, Canada)

British and European
Patent Attorney

HE Electrical Engineering &
IT practice group



Michele Baccelli

Dipl.-Ing.
(Electrical Engineering)

Partner | Italian and
European Patent Attorney

HE Electrical Engineering &
IT practice group

Amendments After Grant and Indirect Infringement – "Broader Protection" Due To Narrower Scope?

Claims can be amended after grant in opposition, nullity or limitation proceedings – but only if the scope of protection is not extended. This article addresses the criteria for assessing a potential extension in the EPO and Germany and discusses the relevance of indirect infringement in this regard.

1. Introduction and recent EPO decision

Even if the subject matter of a granted claim is narrowed by including additional features, certain acts can arguably be considered to infringe the narrowed claim but not the granted claim – indirectly, that is, because there is an additional element in the narrowed claim to which a (potentially) contested component may relate, which is a requirement for indirect infringement.[1]

This seeming paradox surfaces every now and then – most recently in the EPO practice in decision T 970/17: the granted claim 1 was for a "septum" of an access port (a medical device for vascular access to a patient). The proprietor amended claim 1 so as to be directed to an "access port comprising such septum". The opponent argued that this amendment extended the protection in violation of Art. 123(3) EPC because a competitor offering an access port without a septum would not infringe the claim as granted, but might (indirectly) infringe the claim as amended, namely when supplying the port to a customer that intends to provide the port with a septum according to the patent.

The Board of Appeal rejected this argument. It found that arguments relating to indirect infringement are not relevant for assessing potential extensions of the scope. The Board stressed that "assessing compliance with Article 123(3) EPC does not include a test taking into account national infringement laws such as the rules on contributory infringement."[2]

Does the EPO, by ignoring implications under national infringement laws when assessing compliance with Art. 123(3) EPC, allow the proprietor to improve its position regarding potentially infringing acts through the backdoor of potential indirect infringement?

2. General EPO approach: distinction between "scope" and "rights"

A European patent "may not be amended in such a way as to extend the protection it confers" (Art. 123(3) EPC). In this regard, the EPO has to determine the *scope of protection*,[3] which is determined by the claims interpreted in the light of the description and the drawings,[4] while balancing a "fair protection for the patent proprietor" with a "reasonable degree of legal certainty for third parties."[5] Art. 123(3) EPC protects third parties by prohibiting the broadening of the scope of a *granted* patent, even if there is a basis under Art. 123(2) EPC for such broadening in the application as filed.[6]

[1] Also known as contributory infringement. According to national provisions, which are similar in most EPC member states, the offer or supply of a means in one country indirectly infringes a patent if (i) the means relates to an essential element of the invention and (ii) the supplier knows that it will be used to work the invention in such country.
[2] See also "Case Law of the Boards of Appeal of the European Patent Office", 10th edition 2022, II.E.2.3.1b).
[3] The terms "scope", "extent" and "protection" are used synonymously in this context.
[4] Art. 69(1) EPC.
[5] Article 1 of the Protocol on the Interpretation of Art. 69 EPC.
[6] G 1/93.

The EPC also includes provisions on the *rights* conferred by a patent. Art. 64 EPC provides that, in each state, a European patent shall confer the same rights as would be conferred by a national patent, whereas infringement is subject to national law. Hence, Art. 64 EPC concerns remedies and implications under national law that are not addressed by the EPC.

In its landmark decision G 2/88, the EPO's Enlarged Board of Appeal held that "there is a clear **distinction** between the **protection** (...) and the **rights** (...) conferred by a European patent" (emphasis added) and that alleged violations of Art. 123(3) EPC are assessed based on the *extent of protection* rather than on the *rights* conferred by the patent (Art. 64 EPC), meaning that national law is *not* to be taken into account when assessing Art. 123(3) EPC.

Provisions on indirect infringement can only be found in national law and not in the EPC. In the EPO's view, such "rights" are not related to Art. 123(3) EPC. Thus, recent decision T 970/17 is in line with this established EPO approach.

3. Article 123(3) EPC in practice

However, Art. 123(3) EPC aims to prevent the situation where an act which would not infringe the patent as granted would infringe the patent as amended (e.g. T 1898/07). From this, it is fair to conclude that Art. 123(3) EPC inevitably involves at least some infringement considerations – if only in terms of the "realization of claimed features". This is reflected in tests applied by the Boards of Appeal for assessing compliance with Art. 123(3) EPC such as:

> *"Is the subject-matter defined by the claims more or less narrowly defined as a result of the amendment?"*[7]

> *"Is it possible to identify some subject-matter which did not fall under the scope of protection in the granted version of the patent, but would do so if the amendment in question would be allowed?"*[8]

These questions do not involve aspects of infringement under national law, such as exhaustion or indirect infringement. This does, however, not mean that the EPO has no means at its disposal to protect third parties from becoming *indirect* infringers as a result of an amendment, as analysed in the following.

4. EPO decisions applying "auxiliary considerations"

Discussions on indirect infringement before the EPO are often triggered by amendments that introduce a new feature representing *another entity*. In such cases, whether the proprietor can shift the claim to a "new entity" is examined, also considering aspects that relate to infringement.

In T 547/08, the granted claim was for a *user interface and screen display apparatus for a dialysis machine*, whilst the amended claim was directed to the *dialysis machine comprising the user interface and screen display apparatus*. The opponent argued that the scope of protection had been broadened since entities who could not be sued on the basis of the claims as granted could be sued for indirect infringement of the amended claims. The Board held that potential indirect infringement was not relevant for Art. 123(3) EPC and acknowledged compliance with it on the grounds that the user interface and screen display apparatus were (i) defined in the granted claim with reference to the dialysis machine and (ii) closely related to its *functional interaction* therewith.

In T 867/05, the claim was amended from a *membrane material* to *an artificial kidney with such membrane material*. The opponent argued that the scope had been extended by the amendment because purchasing the membrane material from the proprietor and providing an artificial kidney therewith would, due to exhaustion, not have infringed the patent, but would infringe the amended claim.

[7] T 1673/11 (referring to G 2/88, point 4.1).
[8] T 1481/05.

The Board found that Art. 123(3) EPC was not complied with for other reasons: it considered that the amendment to the "artificial kidney" implied operative apparatus components (the casing, the tubing, the valves, etc.) which had not been defined in any of the granted claims and which did not interrelate with the membrane (defined by its chemical composition), i.e. were *not suitable to impart any limitation* to the membrane. The Board concluded that the amendment would extend the scope of protection to subject matter not encompassed by the granted claims and, thus, establish an "*aliud*"[9] contrary to Art. 123(3) EPC.[10]

These decisions indicate that the EPO may take auxiliary considerations into account when assessing compliance with Art. 123(3) EPC, such as a functional interrelation between a newly added feature or entity and the granted features or entity. This restricts the proprietor's freedom to make amendments towards another entity, which may in some cases protect competitors against indirectly infringing a claim due to an amendment after grant. However, these restrictions are based on considerations unrelated to the potential liability for indirect infringement caused by the shift to a different entity and thus do not guarantee that any extension to new indirect infringements is excluded. This may in particular be relevant in cases where the new claim merely narrows down the claimed subject matter without shifting it to an (arguably) new entity. In such a case, it is unlikely that the amendment will be considered as an inadmissible extension even though a competitor may face a potential liability for indirect infringement as a result of a post-grant amendment which introduces a feature that (i) relates to an essential element of the invention and (ii) encompasses a component that the competitor supplies its customers with.

5. Comparison with Germany

Section 22(1) of the German Patent Act (GPA) corresponds to Art. 123(3) EPC. In contrast to the EPC, the German Patent Act (of course) contains a provision on indirect infringement, namely Section 10 GPA, according to which the supply of a means relating to an essential element[11] of the invention in Germany indirectly infringes the patent if the supplier knows that it will be used to work the invention in Germany.

According to German practice, the scope is usually not considered to be extended if the skilled person can recognize that the newly claimed feature belongs to the subject matter covered in the granted claims.[12] However, if a feature to which the granted claims are not directed is included in the granted independent claim, the subject matter protected by the patent as granted would be shifted to an "*aliud*" – which is not allowable.[13]

For example, the Federal Patent Court did not allow a granted claim to be changed from "*a panel element for a wall and ceiling cladding*" to "*a wall and ceiling cladding comprising panel elements (...) and fixing clamps*".[14] The Federal Patent Court considered that the amendment would entail an "*aliud*" and stated that considerations on direct and indirect infringements render this evident. In detail: although the functional link between the panel element and the fixing clamps played a central role in the patent and belonged to the invention as originally disclosed, it did not belong to the subject matter protected by the granted patent. The inclusion of the fixing clamps in the independent claim was regarded as "something else", which was outside the "panel element" as defined in the granted independent claim – regardless of a functional interaction between the fixing clamps and the panel element. Furthermore, and most interestingly, the Federal Patent Court expressly referred to potential indirect infringement and the newly claimed fixing clamps, thus establishing a link between a potential indirect infringement due to a claim amendment and possible extension of scope caused thereby, which link is clearly absent from the case law of the EPO.

[9] The amended claims and the granted claims are directed to different subject matter.

[10] In recent decision T 970/17 (see above), the facts were arguably different from those underlying T 867/05 in that both entities were functionally related. The access port captured the septum and both entities were defined as to their structural characteristics. Also, in addition to claim 1 directed to the septum, a dependent claim 2 was directed to the "septum in an access port", providing a justification for the amendment, as the scope is defined by the totality of claims, cf. footnote 19 and the corresponding discussion in section 6 below.

[11] Which can be a newly introduced claim feature.

[12] BGH GRUR 1991, 307 – Bodenwalze.

[13] BGH GRUR 1990, 432 – Spleißkammer.

[14] BeckRS 2009, 10658 - 3 Ni 77/06 – Panelelement.

Confirming the approach of rejecting inclusion of subject matter which was not protected by the patent as granted, the Federal Court of Justice found that a granted claim directed to an "*electronic module*" could not be directed to a "*device having a plastic support and an electronic module*". Otherwise, subject matter not protected by the granted patent would have been included.[15]

In line with this, the Federal Court of Justice[16] did not allow a granted claim on a "*circuit arrangement for operating a semiconductor light source*" to be amended to a "*circuit arrangement for operating a semiconductor light source, provided with (...) said semiconductor light source*". The reason was that the semiconductor light source in its spatial configuration had not been part of the granted main claim.

Interestingly, the Federal Court of Justice made a hypothetical comparison with the EPO approach. Had the EPO had to deal with this case, it would likely have come to the same finding, although based on a different reasoning: the EPO would have assessed the existence of a functional interrelation with the subject matter of the granted main claim. In that case, there was no functional interrelation between the circuit arrangement and the additional semiconductor light source, since the latter served for light generation and was, hence, not related to the circuit arrangement as such. The Federal Court of Justice thus concluded that the EPO's approach would have led to a denial of the amendment, i.e. to the same conclusion.

In a recent decision,[17] the granted claim was directed to a "*method for providing a messaging service on a sender's mobile wireless device*". By amendment, a step including cooperation with a "*message server*" was added. The Federal Court of Justice regarded this as detailing a feature of the granted main claim, so that the amendment represented a concretization[18] of the granted feature – which is allowable.

These decisions show that the German approach is mainly driven by whether a new feature merely defines the subject matter in more detail or whether it shifts the subject matter to an "*aliud*", resulting in potential new infringing activities.

6. Conclusion and recommendations

Before the EPO, the scope of protection may possibly be shifted to a new (and usually larger) entity by a post-grant amendment such that a third party may newly become liable for indirect infringement. This possibility is to some degree limited by the requirement of a functional interrelation between a newly added feature or entity relative to the granted features or entity.

The German approach seems to be stricter in that a shift to a different entity is less likely to be allowed. An opponent unsuccessfully arguing before the EPO that an extension of scope is not allowable based on a "new" indirect infringement may have better chances in this respect in a nullity action against the German part of the European patent before the FPC.

Prior to grant, applicants can take measures to improve their position in this respect.

It is established EPO case law[19] that the legal notion of "protection conferred" in Art. 123(3) EPC refers to the *totality of* claims as granted rather than to the wording of each single claim as granted. In other words, what is compared is the *totality of protection* before and after the amendment. Thus, to avoid restrictions to amendments after grant, applicants may during prosecution add additional claims directed to larger entities with references to the preceding claims directed to smaller entities. As a result, the larger entity will be comprised in the granted claims and thereby contribute to the determination of the "protection conferred" before grant. This can avoid discussions on a potential extension of scope after grant.

[15] BGH GRUR 2005, 145 – elektronisches Modul.
[16] BGH GRUR 2019, 389 – Schaltungsanordnung III.
[17] BGH GRUR 2021, 579 – Nachrichtenübermittlungsdienst.
[18] In the sense of a more detailed definition in the claim.
[19] G 2/88, T 579/01, T 1898/07.

In this context, the German Federal Court of Justice confirmed that a claim set comprising a claim directed to a smaller entity and a larger entity referring to the smaller entity, here a microprocessor and a claim directed to a computer comprising the microprocessor, is admissible in that legal interest for both claims is acknowledged.[20]

In summary, including independent claims for different entities in the pre-grant stage for European and German applications is highly recommendable both in view of prosecution and enforcement. Especially, a claim set may comprise an independent claim directed to a smaller entity and one directed to a larger entity comprising the smaller entity. This should, after grant, allow the proprietor to target amendments more easily at the larger entity. Claims directed to one of these entities (especially the smaller entity) should, however, not be removed without thorough considerations on enforcement.

Michaela Weigel-Krusemarck

Dr. rer. biol. hum., Dipl.-Phys. (Univ.)

Partner | German and European Patent Attorney

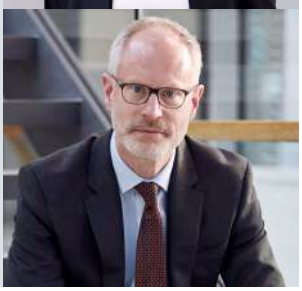
HE Mechanical Engineering practice group

Niels Hölder

Dr. jur., LL.M. IP

Partner | Attorney-at-law and Certified Specialist IP Lawyer

HE Patent Litigation & Contracts practice group



[20] BGH GRUR 2006, 748 – Mikroprozessor; the FCJ indicated that a potential overlap in the scope of protection should be dealt with on the basis of the principle of exhaustion, implying that after buying the smaller entity from the proprietor or its licensee, the acquirer may use that smaller entity (here: microprocessor) to make the bigger one (here: computer). However, the FCJ also ruled that it is up to the proprietor which of various independent claims it wishes to enforce and that exhaustion needs to be separately assessed for each individual independent claim, making it e.g. possible to pick the claim in relation to which exhaustion is the least likely to occur (BGH Trommeleinheit, GRUR 2018, 170, margin 43).

Genome Editing and Morality at the EPO

What triggers an objection of exception to patentability under Article 53(a) and Rule 28(1)(d) EPC for genome editing inventions? Is a mere possibility of abuse of the invention for modifying the genetic identity of cells or non-human animals sufficient to deny patent protection in Europe? These questions are explored using as an example an opposition to a European patent covering CRISPR-based genome editing and a number of decisions of the Boards of Appeal of the EPO.

Hailed as a game changer in biotechnology, CRISPR-based genome editing technology has shown remarkable progress at a tearing pace,[1] and earned Jennifer Doudna and Emmanuelle Charpentier the Nobel Prize in Chemistry.[2] Earlier this year a gene-edited pig's heart was transplanted into a human for the first time.[3] Edits to a cholesterol gene in a first patient in New Zealand could pave the way for stopping heart attacks - the biggest killer on earth.[4] The versatility and effectiveness of CRISPR-based technologies hold enormous promise. It has also led the European Patent Office (EPO) to dust off its morality reflections and related exclusions from patentability.

Article 53(a) EPC[5] supplemented by Rule 28(1) EPC[6] defines four categories of biotechnological inventions excluded from patentability, the commercial exploitation of which *would* be contrary to "ordre public" or morality. This implies that some degree of certainty of breaching this statute – rather than the mere hypothetical possibility – should be required for triggering an objection.

The mere possibility of modifying human germ line genetic identity triggers Rule 28(1)(b) EPC

A foundational patent on CRISPR-based genome editing was recently upheld in amended form[7] in EPO opposition proceedings (ongoing appeal T 1549/22). The claims in question concern methods for genetic modification in vitro or in a cell ex vivo. The Opposition Division held that the "cell" potentially encompassed human germ line cells against Rule 28(1)(b) EPC,[8] irrespective of the fact that neither the claims nor the description mentioned such subject-matter.[9] A disclaimer to exclude human germ line cells was deemed necessary. On the other hand, the Opposition Division held that the claims for modifying a cell did not violate the exclusion of processes for modifying the genetic identity of animals (Rule 28(1)(d) EPC), since such application was not concretely derivable from the patent.[10]

[1] Henderson, CRISPR Clinical Trials: A 2022 Update, Innovative Genomics Institute Perspectives, 29.03.2022, retrieved on 04.12.2022 from https://innovativegenomics.org/news/crispr-clinical-trials-2022/.

[2] Genetic scissors: a tool for rewriting the code of life, Nobel Prize® press release, 07.10.2020, retrieved on 04.12.2022 from https://www.nobelprize.org/prizes/chemistry/2020/press-release/ . A summary of the CRISPR technology can be found, e.g., in the form of a short 15-minute talk by Jennifer Doudna at TED, retrieved on 04.12.2022 from https://www.ted.com/talks/jennifer_doudna_how_crispr_lets_us_edit_our_dna.

[3] Reardon, First pig-to-human heart transplant: what can scientists learn?, nature news, 14.01.2022, retrieved on 04.12.2022 from https://www.nature.com/articles/d41586-022-00111-9.

[4] Regalado, Edits to a cholesterol gene could stop the biggest killer on earth, MIT Technology Review Biotechnology, 12.07.2022, retrieved on 04.12.2022 from https://www.technologyreview.com/2022/07/12/1055773/crispr-gene-editing-cholesterol/.

[5] Cf. also Article 27(2) TRIPS, Article 6(1) of EU Directive 98/44/EC on the legal protection of biological inventions.

[6] Previous Rule 23d EPC 1973; identical to Article 6(2) of the EU Directive 98/44/EC.

[7] EP3401400, auxiliary request 10 of 5.8.2020; retrieved on 04.12.2022 from https://register.epo.org/application?documentId=E432G1NE8139DSU&number=EP18152360 (pending appeal T 1549/22).

[8] Rule 28(1)(b) EPC in combination with EU Directive 98/44/EC, recitals 16 and 40, as supplementary means of interpretation (Rule 26(1) EPC).

[9] The term "germ cell" is disclosed as an element of a list of cells in the patent application (cf. EP 3401400A1, e.g., par. [0017], [0024-26]).

[10] EP3401400, Opposition Division's decision of 25.04.2022 (in the text also referred to as "CRISPR decision"), point 48.1.6.2.

In the Opposition Division's decision, morality under Rule 28(1) EPC is measured by different yardsticks: the *mere possibility* of including modifications of human germ cell genetic identity triggers the exclusion (Rule 28(1)(b) EPC), whereas the *mere possibility* that the method – via non-human animal germ cells – may *subsequently* lead to animal suffering does not (Rule 28(1)(d) EPC).

Contradictory guidance from the Enlarged Board of Appeal on Article 53(a) EPC

An "unanimity of doctrine" has been postulated[11] that patent protection must be granted if *at least one* exploitation or use of the invention does not infringe "ordre public" or morality. G 1/98 exemplified this approach by a copying machine which can be used in morally acceptable ways, even if amoral uses (producing counterfeit money) may also fall under the claim.[12] By the same token, morality exceptions would have to be construed narrowly, in that the amoral exploitation would have to be more than a mere possibility and would have to be sufficiently substantiated.[13] In contrast to this guidance, the mere possibility of genetic modification of human germ line cells triggered the objection in the CRISPR decision, irrespective of the morally acceptable uses described in the patent.

G 1/03 considered examples of disclaimers necessary to satisfy Article 53(a) EPC. For example, avoidance of offspring due to certain properties (sex, color, health) may be quite legitimate for domestic animals whereas in humans it would be contrary to "ordre public" or morality.[14] The disclaimer "non-human" was held acceptable for a theoretical, amoral embodiment within a broad teaching on "mammals". This guidance seems to reflect current EPO practice for Rule 28(1) EPC, even though the recent CRISPR decision did not rely on G 1/03.[15]

The Rule 28(1)(d) EPC test is triggered by expressly claimed subject-matter or the "avowed use"

According to early landmark decisions (T 19/90, T 315/03) followed by more recent decisions (T 606/03, T 682/16, T 789/16, T 186/18), a Rule 28(1)(d) EPC objection is triggered if the claim *expressly mentions* genetically modified "animals" or methods of producing them,[16] but is not triggered if the claim concerns the genetic modification of a "cell".[17] While genetic modification of a cell may encompass genetic modification of a non-human animal germ cell, and thus may lead to a "subsequent" genetically modified animal, this is not considered critical.[18]

When animals are involved, Rule 28(1)(d) EPC has been broadly applied in an analogous way (*per analogiam*) even without the modification of the genome of the animals *per se*. T 1262/04 related to the administration of genetically altered tumor cells to mice. Even though the genome of the animal itself was not modified, the deciding Board considered a broader concept of the "character of the claimed subject-matter"[19] as decisive for triggering an objection under Article 53(a) in combination with Rule 28(1)(d) EPC.

This raises interesting questions for, e.g., a product claim to genetically altered tumor cells. If the specification describes the cell as an *in vitro* model for studying cancer, applicants may benefit from absolute product protection. If, conversely, the specification discloses, as the "avowed use" of the cell, the generation of an animal model, the same subject-matter may give rise to an objection under Rule 28(1)(d) EPC *per analogiam*.

[11] T 866/01, Reasons 9.6; also, e.g., G 1/98, Reasons 3.3.3, T 315/03, Reasons 11.8.
[12] G 1/98, Reasons 3.3.3.
[13] This includes qualifying the objective facts, namely publication or exploitation of the invention, as contrary to "ordre public" or morality (cf., e.g., G 1/98, Reasons 3.3.3; T 866/01, Reasons 5; T 356/93, Reasons 18.5; Guidelines for Examination in the EPO, G-II 4.1, G-II 5.3).
[14] G 1/03, Reasons 2.4.1.
[15] EP3401400, Opposition Division's decision of 25.04.2022, point 48.1.5.4.
[16] T 19/90, T 315/03, T 606/03.
[17] T 789/16, Reasons 10; T 682/16, Reasons 10; cf., e.g., new main request of 8.4.2020 "a host cell" in claims 36, 39, 42, 45, retrieved on 04.12.2022 from https://register.epo.org/application?documentId=E4M3D7IB0626DSU&number=EP02714955.
[18] T 606/03, Reasons 13.
[19] T 1262/04, Reasons 14.

Under the Rule 28(1)(d) EPC test, the mere possibility of excluded subject-matter is decisive

Under the so-called "balancing test" (T 19/90 and T 315/03), the EPO assesses the correspondence of suffering in the genetically modified animal with substantial medical benefit to human or animal (Rule 28(1)(d) EPC).

Lack of correspondence was attested by the EPO based on hypothetical examples of animals or genes falling within the scope of broad claims, even if they are not named as the "avowed use" in the specification,[20] such that substantially all (hypothetical) embodiments falling within the claims must meet the balancing test.[21] By this standard, broad method claims are doomed under Rule 28(1) EPC, forcing applicants to narrow or abandon the claimed subject-matter.

Conclusion

Currently, the EPO raises objections under Rule 28(1) EPC if the mere possibility exists that a claim embraces amoral embodiments based on the expressly claimed subject-matter, the "avowed use" or "character of the claimed subject-matter", and the scope of the claims.

The best chance for obtaining broad claims covering genome editing inventions seems to be with claims for modifying cells combined with a disclaimer of human germ line modifications. The Board in the ongoing appeal T 1549/22 has yet to confirm this approach, however.

Saskia Gressel

Dr. rer. nat., M. Sc. (Biochemistry)

HE Biotechnology practice group

Andreas Stefferl

Dr. rer. nat., Mag. rer. nat. (Biology)

Partner | German and European Patent Attorney

HE Biotechnology practice group

[20] For example, the hypothetical use of lions was used to allege suffering without medical benefit (T 315/03, Reasons 9.1) and objections to generic definition of genes were raised (T 315/03, Reasons 12.2.1; T 606/03, Reasons 2; Preliminary Opinion of T 789/16, points 18.3, 26; Preliminary Opinion of T 682/16, points 19, 24, 28; Preliminary Opinion of T 186/18, points 20, 30).

[21] T 606/03, Reasons 2; Preliminary Opinion of T 789/16, points 17, 18.3; Preliminary Opinion of T 682/16, point 19.

"BLESSED": Owning a Trade Mark Is Not Always a Blessing

The Higher Regional Court Frankfurt (OLG Frankfurt) held in its decision 6 U 40/22 of June 2, 2022 that the imprint of a commonly known verb on the front of a garment would be perceived as a descriptive term by the public. This led the Court to decide that the word had not been used as a trade mark and thus its use could not infringe prior trade mark rights for the identical term "BLESSED".

In 2020, the word and figurative mark shown in Fig. 1 below was filed inter alia for the goods "Clothing" in Class 25 and was successfully registered.

Fig. 1

The defendant in this case was a well-known German sporting goods manufacturer, who had launched a clothing line in collaboration with their brand ambassador, a famous Brazilian football player. One of the offered clothing items was a dark hoodie with the word "BLESSED" written in capital letters on the front of the hoodie:

Source: OLG Frankfurt a. M. Urt. v. 2.6.2022 – 6 U 40/22, GRUR-RS 2022, 22858

On this basis, the applicant claimed that his trade mark rights had been infringed, and he applied for injunctive remedies.

The Frankfurt District Court (LG Frankfurt) dismissed the case in first instance.[1] Subsequently, the Higher Regional Court Frankfurt as Court of Appeal concurred, resulting in the appeal being dismissed.

A necessary prerequisite for a claim for injunctive relief is that the sign "BLESSED" of the defendant is used as a trade mark. Generally, a sign is used as a trade mark if it is capable of distinguishing the goods of one undertaking from those of other undertakings. For this purpose, the perspective of the relevant public, i.e., the average consumer who is reasonably well informed and reasonably observant and circumspect, is taken into account.

The question which the Court had to address was: Will a sign or word that is placed on a clothing item be perceived as an indication of origin or as a mere decorative element by the relevant public? As usual, the answer was: There is no easy answer.

[1] GRUR-RS 2022, 22859.

The Court regarded the answer as depending very much on the individual placing of the sign in question, which ought to be determined on a case-by-case basis. Generally, when using images, motives, symbols, or words on the front or back of garments, the public will not perceive them as an indicator of origin, unless the images, motives, symbols, or words are well-known to the public as a product sign. In particular, a sign will not be understood as an indication of origin when the sign consists of words or phrases used in the German language or a common foreign language that are solely understood as such and not as an indication of origin. Insofar as this is the case, it cannot be assumed that, in the mind of the average consumer, such letterings and logos on clothing will be associated with a trade mark.

In the present case, the Court found that "BLESSED" would be perceived as a word of purely descriptive nature. Although the average consumer is most likely not familiar with the fact that the brand ambassador and famous Brazilian football player has the word "BLESSED" tattooed on his neck to express gratitude for his life and career, its imprint on the defendant's hoodie will be thought of as a decorative element. In this context, the Court held that most people would recognize "BLESSED" as an English word which translates into the German word "gesegnet". Even those consumers who are not familiar with the English term "BLESSED" may still easily, due to the ending in "-ed", identify "bless" as a verb used to describe something.

In fact, the word "BLESSED" can be frequently found printed on T-Shirts, which could result in the public being somewhat accustomed to such imprints on clothing items. Since the applicant's mark was in addition rather unknown, the Court concluded that, overall, the imprint lacked a trademark-corresponding usage. As such, the trade mark could not be enforced against the defendant for that specific usage.

Michaela Ring

Partner | Attorney-at-law,
Certified Specialist
IP Lawyer

HE Trademarks & Designs
practice group

The History and Entanglement of the "Spezi" Trademark; Paulaner's "Spezi" Will Remain on the Market for Now

In the last issue of the HOFFMANN EITLE Quarterly,[1] we reported on the trademark dispute between the brewery Paulaner Brauerei Gruppe GmbH & Co. KGaA ("Paulaner") and the brewery Brauerei S.Riegele, Inh. Riegele KG ("Riegele") regarding the use of the name "Spezi" for Paulaner's Cola and Orange soda mix drink.

In 1974, Riegele entered into a contract with Paulaner, which allowed Paulaner to use the name "Spezi" for the mix drink for a one-time payment of 10,000 German Mark (roughly 5,000 Euro). Since then, the mix drink has reached cult status.

In 2021, Riegele terminated the contract, arguing that the original agreement could no longer be reasonably upheld as the market conditions had changed since the conclusion of the contract. If Riegele had been aware of the development of the market at that time, Riegele would not have concluded the contract as they did.

Paulaner objected to the termination and filed a lawsuit to have the original agreement declared valid.

The two main subjects of the dispute that had to be decided by the Regional Court Munich I (Germany) were the type of contract that had been concluded (demarcation agreement or license agreement) and whether the termination by Riegele was justified.

Meanwhile, the parties did not settle, and the Court has issued its decision.

The Court agreed with Paulaner's plea and found the contract to be a demarcation agreement. The Court also found the termination of the demarcation agreement by Riegele to be unjustified.

The parties entered into a demarcation agreement

In general, legal declarations, such as contracts, must be interpreted if there is an uncertainty about the content and the legal consequence of the declarations. In the present case, after interpreting the contract, the Court found that the parties originally concluded a demarcation agreement.

The Court found that this also applies even if the contract also speaks of "license". The purpose of the agreement was clearly to settle earlier disputes between the parties concerning the use of the name "Spezi" for a mixed drink containing cola. In particular, whether the name "Spezi" could be protected as a trademark at all for the mixed drink in question was also uncertain at the time the parties concluded the contract. In view of this, the Court considered the use of the word "license" as being merely an editorial inaccuracy.

To reach the finding that the agreement was a demarcation agreement, the Court also considered that the agreement had not been concluded for a definite period of time, nor did it provide any possibility for termination. No reoccurring fee was agreed upon either, only a one-time payment. The conclusion of a contract for a definite period of time and the obligation to pay a reoccurring fee would be, in contrast, typical characteristics of a license agreement.

The Court even found immaterial the obligation to put a note on the label of Paulaner's product stating "Spezi licence", while mentioning the registration number of the trademark owned by Riegele. Here, the parties agreed that the reference on the label was just to prevent a weakening of Riegele's trademark.

[1] Maike Lorenz, The History and Entanglement of the "Spezi" Trademark; What did Riegele and Paulaner Agree Back Then?, HOFFMANN EITLE Quarterly, September 2022, pp. 9-10.

The contract could not be terminated

Further, the Court held that the agreement could effectively not be terminated. *Inter alia*, no good cause for a termination could be found. Paulaner unquestionably complied with the contractual obligations, and Riegele's desire to participate in the Paulaner's considerable success did not constitute a good reason for termination.

In the meantime, Riegele announced that they would file an appeal against the Court's decision. The litigation is therefore expected to continue.

Maike Lorenz

LL.M., Attorney-at-law

HE Trademarks & Designs practice group

Plausibility and G2/21

The referral G 2/21 to the Enlarged Board of Appeal (EBoA) asks if and under what circumstances post-published evidence can be relied upon when assessing a technical effect for inventive step. The EBoA seems to consider that post-published evidence can be relied upon, unless there were significant reasons to doubt the effect on the date of filing.

Case background

The patent underlying the present referral concerns an insecticide composition comprising thiamethoxam and a further compound specified by a Markush formula. Both thiamethoxam and compounds falling under the Markush formula were identified in the prior art *individually*. By contrast, the patent specification explains – without corroborating evidence – that their *combination* achieves an advantageous synergy. This synergy was confirmed by the Patentee solely on the basis of post-published evidence.

Consequently, the evaluation of inventive step hinges on the post-published evidence. If the evidence can be relied upon, the patent should be maintained based on the unexpected synergistic effect. If not, it should be revoked.

Current situation: Diverging case law

At the EPO, inventive step is analysed using the 'problem and solution approach'. First, the 'closest prior art' (CPA) is identified. This is usually a reference having the same purpose as the invention. Next, the distinguishing feature(s) of the claimed invention are identified *vis-à-vis* the CPA, and the technical effect(s) resulting from the distinguishing feature(s) used to formulate the 'objective technical problem'. Finally, it is assessed whether it would have been obvious, in view of the objective technical problem, to modify the CPA to arrive at the claimed invention. More ambitious objective technical problems (e.g., providing an improvement) are usually more likely to result in an acknowledgement of inventive step than less ambitious problems (e.g., providing a mere alternative).

Consequently, the technical effect plays a central role in the assessment of inventive step. Under what circumstances can post-published evidence be relied upon for the technical effect? Different Boards of Appeal have given diverging answers to this question.

On the one hand, the Boards widely apply the principle of free evaluation of evidence. This principle could be interpreted such that post-published evidence may always be relied upon, even if the technical effect disclosed in the application/patent is based on pure speculation. On the other hand, numerous decisions of the Boards have tried to distinguish purely speculative applications/patents from those that contain a credible technical disclosure.

A first line of EPO case law suggests that post-published evidence can be considered only if it is already plausible from the disclosure in the application that the problem is solved ("*ab initio plausibility*"). Put simply, the skilled person would need a reason to recognise, from the application as filed, that the effect would be achieved. Consequently, post-published evidence could only be used to (further) support a teaching derivable from the application as filed, but could not serve as the sole source of evidence.[1] In practice, this may require that the application as filed contains evidence of the technical effect. A credible scientific explanation may also be sufficient.

The EPC does not provide any legal basis for the requirement of "ab initio plausibility". Rather, this approach derives its main justification from the concept that an invention should be a technical contribution to the art, as opposed to pure speculation.

[1] See Case Law of the Boards of Appeal, section I-D, 4.3., in particular T 1329/04, T 603/01, T 488/16.

However, arguably, this requirement puts the applicant in the difficult situation of having to try to predict the assessment of inventive step under the problem and solution approach. This is complicated by the fact that the CPA may change, possibly resulting in a different technical effect and a different objective technical problem.

A second line of case law applies a more lenient approach, stating that post-published evidence can be relied upon unless there were reasons to doubt that the purported technical effect could be achieved at the filing date ("*ab initio implausibility*").[2] Such doubt may arise if the application as filed, common general knowledge or other prior art indicates that the purported technical effect cannot be achieved.

While this approach is more lenient and may strike a fairer balance between the free evaluation of evidence and the desire to prevent speculative applications, it risks reversing the burden of proof for the technical effect. Applying the "*ab initio implausibility*" approach could result in a practice in which technical effects are considered plausible unless proven otherwise by the Examining Division or an opponent.

A third line of case law rejects the concept of plausibility ("*no plausibility*").[3] This line of case law is in line with the literal reading of the law and its lack of explicit reference to "plausibility". On the flipside, the "*no plausibility*" approach would do very little to address speculative applications.

Of the three lines of case law presented, the "*ab initio plausibility*" and "*no plausibility*" approaches represent the most extreme cases. If applied strictly, the former approach could mean that applicants receive a patent only if experimental data or other substantiation is contained in the application as filed that makes the effect invoked for inventive step plausible. On the other hand, the latter approach would invite applicants to file applications for anything that might possibly be proven later to bring about a technical effect.

As an additional complication, case law suggests that plausibility of a technical effect can also be considered under sufficiency of disclosure, namely, if the technical effect is included as a functional feature in the claim.

The referred questions

Separating out the different approaches outlined above, the referring Board essentially asked whether, in the context of inventive step, (1) the concept of plausibility should, in light of the principle of free evaluation of evidence, be rejected generally (the "*no plausibility*" question). Dependent on the answer to this question, two further questions were asked, namely, if the concept of plausibility is not rejected generally, whether post-published evidence can still be taken into account (2) if there is "*ab initio plausibility*" or (3) if there is no "*ab initio implausibility*".

The EBoA's preliminary opinion and oral proceedings

The preliminary opinion provided by the EBoA in advance of the oral proceedings does not provide detailed reasoning. The EBoA indicated that the principle of free evaluation does not allow disregarding of evidence *per se*. Notwithstanding this principle, a technical effect, if invoked for inventive step, must, in the EBoA's view, be encompassed by the original teaching of the invention. If – and only if – there were significant reasons to doubt the effect based on said teaching and the common general knowledge, post-published evidence cannot be relied upon for inventive step.

This standard appears to be similar to the "*ab initio implausibility*" approach of the existing case law. If confirmed by the EBoA in its written decision, G 2/21 would stipulate a lenient approach to the assessment of inventive step. This may be helpful for patent applicants and owners. However, it will be interesting to see whether the decision of the EBoA further expands on the additional requirement that the technical effect must encompassed by the original teaching of the invention. This requirement might serve to avoid purely speculative patents/applications.

The EBoA further stated that it does not consider it appropriate to extend the scope of the referral to sufficiency of disclosure.

[2] See, e.g., T 919/15 and T 578/06.
[3] See T 31/18 and T 2371/13.

At the oral proceedings, arguments from the representatives of both parties, as well as arguments on behalf of the President of the EPO, were heard. The proprietor argued that only serious doubts that the technical effect is achieved should prevent the filing of post-published evidence ("*ab initio implausibility*"). By contrast, the opponent argued that the "*ab initio implausibility*" approach risks granting patents based on pure speculation, while the "*ab initio plausibility*" approach ensures that patents are only granted for bona fide inventions. The opponent even proposed a two-step test to assess whether a technical effect can be considered plausible: (1) determine whether the skilled person was fully satisfied that the purported effect will occur in view of their common general knowledge and the application as filed, and (2) determine whether the skilled person was fully satisfied that the effect occurs over the whole scope of the claim.

Notably, both parties also commented on the applicability of the respective approaches to sufficiency of disclosure. The proprietor's position was that Article 56 EPC (inventive step) does not even mention the application. Consequently, a low threshold relative to the original disclosure must be applied. By contrast, Article 83 EPC (sufficiency of disclosure) specifically refers to the application. Consequently, a stricter approach relative to the original disclosure should be taken for sufficiency. Interestingly, the Board pointed out that Article 83 EPC, however, does not refer to the "application as filed" but only to the "application". This might suggest that the EBoA does not favour a stricter standard for sufficiency of disclosure.

The EBoA did not announce a decision or give an update on its preliminary opinion during the oral proceedings. Only the written decision will show whether the EBoA follows its preliminary opinion and provides more extensive reasoning, including a more detailed definition of the standard for (im)plausibility.

Impact on current practice

A written decision is expected within the next six months. Until then it seems best for applicants to err on the side of caution and assume that the stricter approach of "*ab initio plausibility*" will be applied, even if the standard might eventually be more lenient. Therefore, applicants should make sure that at least the problem mentioned in the application is solved. Opponents, on the other hand, should develop arguments that the effect was implausible at the date of filing in order to maximise their chances.

Daniel Offenbartl-Stiegert

Ph.D. (Chemistry), M.Res, B.A.

HE Biotechnology practice group

Lasse Weinmann

Dr. rer. nat., Dipl.-Biochem.

Partner | German and European Patent Attorney

HE Biotechnology practice group

Preliminary Injunction Proceedings in Germany – New Opportunities for Patentees in Munich?

This update summarizes two recent decisions on the validity assessment in German provisional injunction (PI) proceedings.[1] Although the relevant parts of the decisions are obiter dicta (i.e. the outcome of the decisions did not depend on these considerations), they indicate that

- the Regional Court (RC) Dusseldorf will hold course by applying a strict standard for granting PIs, i.e. absent special circumstances only if the asserted patent's validity has already been confirmed in post-grant proceedings;
- the RC Munich wants to follow a more patentee-friendly approach in the future by affording every granted (European) patent a presumption of validity.

1. Background: ECJ decision

In the June issue of the HOFFMANN EITLE Quarterly,[2] we reported on the Phoenix v. Harting decision of the European Court of Justice (ECJ), which held that EU law would be violated if PIs in patent litigation were generally refused unless the validity of the asserted patent has been confirmed in validity proceedings, at least at first-instance. That decision was a preliminary ruling in response to a request by the RC Munich I.

In our June article, we predicted that the Dusseldorf court would continue to apply a strict standard on validity: absent certain exceptions it would refuse to grant a PI unless the asserted patent has been confirmed by a post-grant validity ruling. The exceptions would be:

- without a PI there would be exceptionally high irreparable harm, *e.g.* the patent is about to expire or it is enforced against a generic early entry, and/or
- the validity can be considered to be confirmed for other reasons, *e.g.* because competitors have taken a license or have filed objections but failed in that respect during prosecution.

We also deemed it unclear whether other German courts would change their practice, for example by adopting a more patentee-friendly approach that would allow PIs in more situations or by assessing validity on a case-by-case basis. Now, the picture has become clearer.

2. Recent case law

As expected, the **Dusseldorf court** did not change its course. For example, in a recent decision regarding the multiple sclerosis (MS) drug Tecfidera, the court denied a PI as it considered that the patent's validity was not sufficiently certain: the patent's parent was revoked by the EPO's Opposition Division for lack of inventive step and revocation was affirmed on appeal due to added matter. Even against generics, it can be difficult to get a PI based on a divisional patent if the parent patent has already been revoked (the Judicial Court Paris also saw reasonable doubts as to the validity of the patent and refused to grant a PI).

[1] Regional Court (RC) Dusseldorf, Decision of September 22, 2022 (Case no. 4b O 50/22), GRUR-RS 2022, 26959; Regional Court (RC) Munich, Decision of September 9, 2022 (Case no. 7 O 4716/22), GRUR-RS 2022, 26511.

[2] Jeremias Wollschlaeger, Mike Gruber, "The ECJ Rules on the Requirement of Validity of the Asserted Patent in Provisional Injunction Proceedings", HOFFMANN EITLE Quarterly, June 2022, pp. 15-16.

But the Dusseldorf court took the opportunity to also make a general observation on the impact of the ECJ's decision stating that "*the grant as such [...] does not result in a presumption of validity*" (Decision of September 22, 2022 – 4b O 50/22, translation):

> "*The grant of the asserted patent as such – without taking into account the fact that objections by third parties were subject of the patent examination proceedings – does not give rise to a presumption of validity of the asserted patent. Even if the statements of the ECJ in its decision [Phoenix Contact v. Harting], according to which there is a presumption of validity for European patents from the time of publication of their grant (ECJ, GRUR 2022, 811, para. 41), are to be understood in such a way that a presumption in the legal sense is meant – which is doubted by this court – , [...].*"

The court's statement is *obiter dictum* as it is not relevant for the decision. The court apparently wanted to put it in writing in a decision that it will not change its case law in light of the ECJ decision. This clarification was not necessary as several comments by judges of the RC and HRC Dusseldorf court shortly after publication of the ECJ decision had left no doubt in that regard. However, a decision provides an even better opportunity to make such a point.

By contrast, the **Munich Court** seems to adopt a different approach: in a recent decision concerning the MS drug Fingolimod, the court rejected an objection against the grant of its PI. It noted that in the situation under consideration also the case law of the Dusseldorf courts would allow a PI as the patent was enforced against a generic early entry. In such situations, for issuing a PI also the Dusseldorf courts do not require that the asserted patent's validity has already been confirmed in post-grant proceedings. The Munich Court also explained its general view on granting PIs in light of the ECJ decision (Decision of September 9, 2022 – 7 O 4716/22, translation):

> "*Even if this is not relevant in the present case, [...], the court assumes (at least) for European patents, in line with the European Court of Justice (see [Phoenix Contact v. Harting]), that a presumption of validity applies to European patents from the time of publication of their grant. For [...] assessing whether the asserted patent's validity is sufficiently certain, this means, in the opinion of the court, that (now) due to the presumption of validity, it is to be assumed that validity is sufficiently certain, and it is incumbent on the [Respondent] in the inter partes preliminary injunction proceedings to refute this presumption. The presumption of validity is as a rule refuted by the submission of a (preliminary) negative assessment of the validity of the asserted patent from validity proceedings. This also applies in principle to (preliminary) negative assessments from domestic or foreign validity proceedings concerning parallel rights claiming the same priority (see [...]).*"

The **differences between the approaches** applied in both decisions are clear:

- In Dusseldorf, the starting point is that a PI is not issued unless validity of the patent has already been confirmed in post-grant proceedings unless other exceptions apply. Thus, the burden is on the patentee to show that the situation merits the grant of a PI. If validity has been confirmed in a post-grant ruling, the alleged infringer may try to convince the court that this ruling is obviously erroneous, a standard that is almost impossible to meet.
- In Munich, the starting point is that every granted (European) patent has a presumption of validity. Thus, it is on the alleged infringer to show that the request for a PI should be rejected. A post-grant ruling considering the patent to be invalid will be sufficient unless the patentee can convince the court that this ruling is erroneous and will (very) likely be reversed.

3. Outlook: What will the Higher Regional Courts do?

There are no indications that the Higher Regional Court (HRC) Dusseldorf will change its case law.

However, the HRC Munich may follow the new approach of its lower court. It appears likely that Judge Dr. Zigann who used to preside over the 7th panel in the first-instance court will agree with the approach adopted by his colleagues of the 21st panel who have triggered the ECJ's decision with their request for a preliminary ruling. Judge Zigann will soon move up to the HRC Munich and will preside over one of the two patent panels. His view is expected to influence how that court will reconsider its previous case law in light of the ECJ decision. It would not be surprising if the HRC Munich adopts a more patentee-friendly approach which, at least in some situations, would make the Munich courts a more attractive venue for seeking PIs than the Dusseldorf courts.

Jeremias Wollschlaeger

Dipl.-Phys.

German and European Patent Attorney

HE Mechanical Engineering practice group

Mike Gruber

LL.M. IP (The George Washington University)

Partner | Attorney-at-law

HE Patent Litigation & Contracts practice group

The UPC Might Not Be Quite Ready Yet, but You Can Be – The Practitioner's Handbook

The Unified Patent Court (UPC) has once again postponed the start of its operations as a court, now to June 1, 2023. The corresponding shift of the sunrise period (now starting on March 1, 2023) will give practitioners more time to acquire the necessary hardware, software and certificates to use the UPC's Case Management System (CMS). What many found challenging is identifying a provider for the so-called Authentication Certificate, which the UPC recently introduced as a necessary means for accessing the CMS. At last, the UPC has now published who have informed the Court that their certificates meet the required technical standards. Other than this last technical hurdle, the UPC confirmed that all preparatory work is on track.

This short deferral gives the international patent community also more time to become more familiar with this complex new system, comprising the European patent with unitary effect and the new Unified Patent Court. And, we may just have the right reading material.

We are delighted to announce the publication of the 2nd Edition of our practitioner's guide, originally published as the EU Patent Package Handbook in 2014.

This book, now named *The Unified Patent Court and Unitary Patent: A Practitioner's Handbook*, is available for free download as an e-book, and will be available shortly as a paperback via Amazon.

In addition to the updated and expanded summary (Part A) and detailed guide (Part C) of the 1st Edition, we have now included three chapters on strategic considerations for prosecution, opt-out, and litigation (Part B).

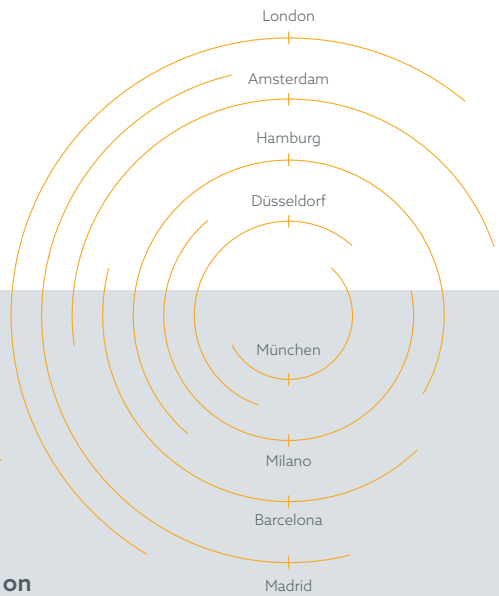
hoffmanneitle.com/upc-handbook

Clemens Tobias Steins

Dr. jur., Master of Laws (University College Dublin)

Partner | Attorney-at-law, Certified Specialist IP Lawyer

HE Patent Litigation & Contracts practice group



HOFFMANN EITLE | Patent- und Rechtsanwälte PartmbB

Arabellastraße 30 | 81925 München
P +49 89 924090 | F +49 89 918356
pm@hoffmanneitle.com | **www.hoffmanneitle.com**

Follow us on

www.hoffmanneitle.com/en/newsletter-subscription/
www.hoffmanneitle.com/en/legal-notice/