HOFFMANN EITLE

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Inventorship for AI-Assisted or AI-Generated Inventions in Europe and the U.S.

By now, it is impossible to imagine the patent world without artificial intelligence (AI). At the same time, there is uncertainty for companies and inventors as to how AI inventions should be handled. For example, when is a human contribution sufficient to rise to the level of inventorship, or when is it necessary to designate the AI as inventor? Is it even possible for AI to be the inventor? What happens if the wrong inventor is designated? In the U.S, there is a danger that incorrectly listing inventorship on a U.S. application will render the patent invalid. This article is intended to help shed some light on inventorship for AI-assisted/generated inventions in the U.S. and Europe.

1. AI-assisted/generated inventions and DABUS

It is already common practice in various industries to use AI as a tool in the inventive process. For example, there are a number of AI tools that are used in drug discovery to select drug candidates. With these AI-assisted inventions, the question arises as to who is the inventor: is it the data provider, the AI model developer, or the owner of the AI who uses the AI to make the invention?

With regard to AI-generated inventions, i.e. inventions that are made autonomously by AI, without human input, it is often questioned whether AI is truly capable of inventing autonomously. Whether or not there are any real AI-generated inventions today, the DABUS applications have sparked worldwide discussions about recognizing AI as an inventor. AI DABUS was developed by Stephen Thaler, who filed patent applications in several countries and claimed that the inventions had been made by DABUS without human input. For these applications, Stephen Thaler listed the AI as the sole inventor. Although his applications were dismissed in several countries (except South Africa), the DABUS applications shed light on difficult IP policy questions relating to AI inventorship.

2. AI inventorship in the U.S.

The United States Patent and Trademark Office (USPTO) requires that inventors named on US patents and patent applications be natural persons. The USPTO's decision to deny Thaler's petitions to name DABUS on a pair of patent applications was upheld by the Federal Circuit on the basis that inventorship is limited to natural persons and, accordingly, US patent applications and patents cannot name an AI system as an inventor.[1]

However, the USPTO has also made clear that AI-assisted inventions are not categorically unpatentable. The USPTO's February 2024 guidance[2] on inventorship for AI-assisted inventions instructs that a natural person can qualify as an inventor of an invention made using AI provided the natural person has made a "significant contribution" to the claimed invention.

The USPTO does not provide a bright-line rule for determining what level of contribution from a natural person is significant. However, the guidance does provide some principles derived from the *Pannu v. Iolab Corp.*[3] case which addressed joint inventorship. For example, a natural person may qualify as an inventor of an AI-assisted invention so long as that person "contributes significantly to the AI-assisted invention", as use of an AI system by a natural person "does not negate that person's contribution as an inventor" (Guiding Principle 1). Presenting a problem to an AI system to solve may not, on its own, be sufficient

[1] *Thaler v. Vidal*, 43 F.4th 1207 (2022).
[2] https://www.federalregister.gov/documents/2024/02/13/2024-02623/inventorship-guidance-for-ai-assisted-inventions
[3] *Pannu v. Iolab Corp.*, 155 F.3d 1344 (1998).

to rise to the level of a significant contribution, but the manner in which a person instructs an AI system in view of a specific problem to obtain a particular solution may demonstrate a significant contribution (Guiding Principle 2). Recognizing and appreciating the output of an AI system as inventive does not necessarily rise to the level of inventorship, while a natural person who makes a significant contribution to the output of an AI system (e.g., conducting an experiment using the output) may be an inventor (Guiding Principle 3). A person who develops "an essential building block from which the claimed invention is derived", for example, someone who "designs, builds, or trains an AI system in view of a specific problem to elicit a particular solution", may be considered to have made a significant contribution to an invention developed using the AI system (Guiding Principle 4). By contrast, "simply owning or overseeing an AI system" does not, without more, constitute a significant contribution (Guiding Principle 5).

These guiding principles illustrate that the "significant contribution" can be found in one or more ways, including in how the AI system is designed and developed, how the AI system is prompted, and/or how the output of the AI system is used. For example, a patent applicant can demonstrate a "significant contribution" by prompt engineering, or how a person constructs a prompt as entered into an AI system. The prompt can be designed in view of a specific problem to elicit a particular solution from the AI system (Guiding Principle 2). The USPTO Guidance, therefore, highlights that good practice is to keep a log of prompt entries into AI systems should the need arise to prove inventorship based on prompt engineering. On the other hand, a natural person who only presents a problem to an AI system may not be a proper inventor or joint inventor of an invention identified from the output of the AI system.

The USPTO has supplemented its guidance with examples to help in determining whether a natural person has made a significant contribution to an AI-assisted invention.[4] The first example relates to use of an AI system to create a preliminary design for a transaxle for a remote control car. The second example relates to using an AI system to develop therapeutic compounds for treating cancer.

3. AI inventorship in Europe

To avoid refusal by the European Patent Office (EPO), an inventor must be designated in the European patent application.[5] However, the AI cannot be designated as an inventor, because the inventor must be a natural person.[6] The reason therefor is that the designation of an inventor has a number of legal consequences, "notably to ensure that the designated inventor is the legitimate one and that they can benefit from rights linked to this status".[7]

Once an inventor is designated, the EPO does not verify the accuracy of the designation.[8] The function of the designation is "informing the public on the possible origin of the right, so that determined third parties, who may be entitled to the subject-matter disclosed in the application, can react and start proceedings in national courts".[9]

But how do national courts assess inventorship? In Germany, for example, the Federal Court of Justice recently decided that an inventor is understood to be the natural person whose creative activity led to the invention.[10] The designation of a natural person as inventor is also possible in cases where an AI system has been used[11] and does not require that the subject-matter of the application is patentable. It merely indicates which persons, to the applicant's knowledge, were involved in a legally significant manner in the discovery of the claimed teaching and have therefore acquired the original rights to the invention.[12]

Based on these principles, the Federal Court of Justice decided that, in the case of a technical teaching discovered with the aid of AI, a human contribution that significantly influenced the overall success of the development of the invention was sufficient to confer

[4] The USPTO examples, and other information, can be found at https://www.uspto.gov/initiatives/artificial-intelligence/artificial-intelligence-resources

[5] See Art. 81 EPC.

[6] See European Patent Guide, 23rd edition, July 2023, Chapter 4.1, "Designation of inventor".

[7] See Art. 60 and 62 EPC, and https://www.epo.org/en/news-events/in-focus/ict/artificial-intelligence

[8] See R. 19(2) EPC, and EPO decision J 8/20 of 21 December 2021, item 4.2.3: This decision is about the DABUS applications filed by Stephen Thaler at the EPO.

[9] See EPO decision J 8/20 of 21 December 2021, item 4.6.3.

[10] Decision of the Federal Court of Justice dated 11 June 2024, X ZB 5/22, pg. 7, item 24 bb): This decision is about the DABUS applications filed by Stephen Thaler at the German Patent Office.

[11] Ibid., pg. 9, item 32 aa).

[12] Ibid., pg. 9, item 35.

the status of inventor. The question of the nature or intensity of the human contribution required to justify such an attribution is not decisive. In particular, it is not necessary to conclusively determine whether the position as manufacturer, owner, or possessor of such a system is sufficient or whether actions more closely connected with the technical teaching found are required, such as: special measures of programming or data training, initiating the search process that brought the claimed teaching to light, checking and selecting from several results proposed by the system, or other activities. Irrespective of how these questions are to be assessed, it remains possible to identify such human contributions even when using AI and to derive the status of inventor from this through legal assessment. According to the current state of scientific knowledge, there is no such thing as a system that searches for technical teachings without any human preparation or influence.[13]

4. Conclusion

- Both the EPO and USPTO prohibit naming AI as an inventor, as both jurisdictions find inventorship to be limited to natural persons.
- At the EPO, the examination of the inventor designation is only a formal assessment. National courts are responsible for verifying the accuracy of the inventor designation.
- When preparing a patent application, it is helpful to understand whether and how AI was used in the development of a claimed invention to determine whether at least one natural person qualifies as an inventor of the claimed invention, particularly in view of the "significant contribution" requirement in the US.
- In Germany, the Federal Court of Justice held that it is always possible to identify human contributions even when using AI.

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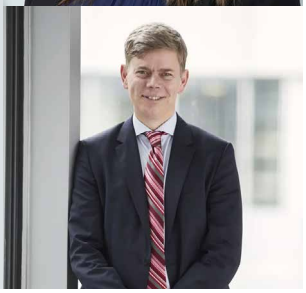


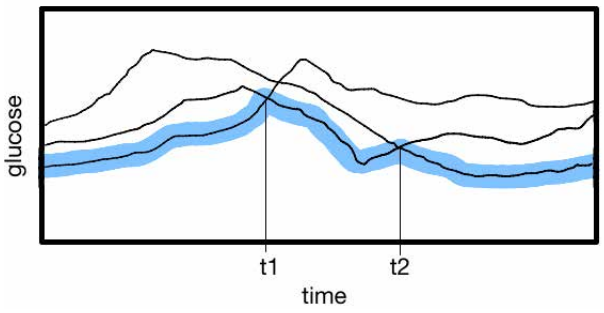
[13] Ibid., pg. 10, item 38 to pg. 11, item 40.

Is Obtaining New Data From Measured Data Inventive? The Board in T 1741/22 Says Likely No

- An application for analyzing glucose levels in a bodily fluid included a novel aspect of generating and displaying new data from already obtained measurements. These features were found not to contribute to any technical effect, and thus disregarded for inventive step.
- According to the decision, obtaining a maximum or minimum value by evaluating or interpreting measured values amounts to a cognitive or a mathematical exercise that is inherently non-technical.
- This remarkable decision may be useful for opponents to raise inventive step attacks, and highlights diverging opinions within the EPO, in particular with the earlier decision T 2681/16 on whether providing "an overall measure of the glucose variability and a prediction of glycemic events" is a technical effect.

Invention

In the application[14] underlying decision T 1741/22, the claimed invention included the reception of continuous glucose monitoring data that comprise continuous glucose profiles measured for successive measurement periods of 24 hours. Each glucose profile has a glucose value measured at different sample times over the 24 hours. For each sample time the glucose profile corresponding to the minimum and/or maximum glucose value is determined, and a curve of the minimum or maximum glucose values is then displayed on a display device (see a simplified example in blue below, corresponding to a first profile until t1, a second between t1 and t2, and a third profile after t2):



Inventive step

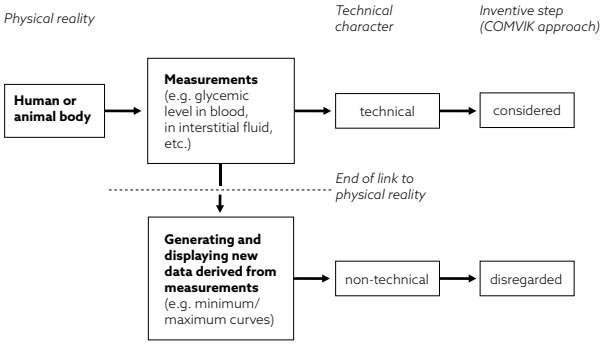
Following the EPO's problem-and-solution approach, the novel features of the claims relative to a document cited by the EPO were identified to be the determination of the minimum or maximum values and the display of the corresponding curve. In the appealed decision, these features were deemed to relate to non-technical matter, namely a mathematical method and a presentation of information (both excluded from patentability at the EPO *as such*). The inventive step was therefore assessed by following the EPO's "COMVIK approach" for claims including both technical and non-technical features. According to the COMVIK approach, inventive step can only be achieved by the novel features if they contribute to a technical effect (and thus to the *technical character* of the invention).

The Applicant argued that these features provided new data from the glucose monitoring data, namely medically relevant values which would have been missed in the prior-art method. They emphasized that the technical effect lay in that "new data was generated" and accordingly they identified the objective technical problem as improving the analysis of glucose monitoring data which was argued to be a technical effect.

[14] EP 16 153 964.8. The applicants are Roche Diabetes Care GmbH and F. Hoffmann-La Roche AG. The EP register can be accessed here.

This was not followed by the Board. In their view, "new data" can be one of two things: a new "collection" of data from the human or animal body, i.e. a "measurement" (here the Board refers to the decision G 1/19 relating to computer-implemented simulations[15]) involving the calculation of the physical state of an object. Or, as in the present case, they can be "new data" resulting from processing *already measured* and received data to generate and display further data. However, such subsequent processing in the Board's view cannot contribute to the technical character of the invention.

The Board specifically mentions that any mathematical method would generate "new data" and thus the mere generation of "new data" could not be sufficient to indicate a contribution to the technical character of an invention.



Deviation from T 2681/16

The Board in T 1741/22 deviated from an earlier decision (T 2681/16) in which it was agreed that the novel features relating to an algorithm to process already acquired, i.e. measured, blood glucose data points, provided the technical effect of an overall measure of the glucose variability and a prediction of glycemic events.

However, according to the Board in T 1741/22, the processing of already collected data to generate further data does not have an interaction with physical reality (i.e. the patient's bodily fluid), the Board interpreting G 1/19 to require such interaction for a measurement to have technical character.

The Board specifically considered that the interaction with physical reality ends once the blood glucose measurement has been carried out, and that providing an overall measure of the glucose variability and predicting glycemic events have no such interaction with physical reality, as they are merely mathematical steps or intellectual activities.

G 1/19 discussed in point 99 the use of indirect measurements, such as "the measurement of a specific physical entity at a specific location by means of measurements of another physical entity and/or measurements at another location", and that such indirect measurements should be considered of technical nature even if they involve "significant computing efforts".

The decision at hand discusses what should qualify as a "measurement" having a technical character. The Board states that "measurements" that are "*based* on the interaction with physical reality" have technical character, even if they are carried out indirectly, and further mentions that generating new data as a consequence of the interaction with the physical reality could result in "measurements" of a technical nature.[16] But, in the opinion of the Board, the generation of maximum or minimum values in the case at hand does not qualify as a "measurement" having a technical character within the above meanings. The Board appears to consider only the measurement of blood glucose, e.g. by measuring the glucose in another bodily fluid, to be an indirect measurement. The Board also considers that, in the case at hand and in the case underlying T 2681/16, the interaction with the physical reality, i.e. the patient's blood, ends once the blood glucose measurements have been carried out, so that the further evaluation or interpretation of the blood glucose measurements is entirely decoupled from any interaction with the patient's blood and amounts to a cognitive or mathematical exercise that is inherently non-technical.

The different specializations of the Boards who handled T 1741/22 and T 2861/16 may have also played a part in the difference in opinion: T 1741/22 was issued by Board 3.5.0.5 handling cases on digital computation, whereas T 2861/16 was issued by Board 3.2.02 handling cases on diagnostic methods.

[15] Danche Spirkoska Jovanov, G 1/19 – More Clarity on Computer-Implemented Simulations at the European Patent Office (EPO), *HOFFMANN EITLE Quarterly*, June 2021, pp. 8-10.

[16] See decision T 1741/22, reasons 2.3.6, penultimate sentence.

Rejection of an example presented in the Guidelines

The decision also criticized the section[17] of the Guidelines for Examination in the EPO relating to mathematical methods.

In the decision at hand, the Board took issue with the Guidelines' example that "providing a medical diagnosis by an automated system processing physiological measurements" would have technical character, stating that this was erroneous since providing a medical diagnosis was held to be devoid of technical character in decision G 1/04 of the Enlarged Board of Appeal (relating to diagnosis methods).

The rejected application in the present case referred to hypoglycemia boundaries, but, in the Board's view, the claims did not go beyond displaying the minimum or maximum glucose values and in particular the claimed system did not appear to be making a diagnosis.[18]

However, rather than dismissing the Guidelines' example as not applicable, the Board preferred to point out an inconsistency between the Guidelines and case law. This may indicate that the Board would reject similar inventions even if the claimed device interprets the data to make a diagnosis itself (rather than merely displaying the maximum or minimum values).

Takeaways

This case provides useful insight in the field of medical measurements for diagnostic or therapeutic purposes. It is also less patentee-friendly than decision T 2681/16 and may help opponents build stronger inventive step attacks, by providing arguments that claimed features relating to the processing of already obtained measurements should not be considered when assessing inventive step at the EPO.

The divergence between decisions of the boards highlighted in the decision T 1741/22 is itself remarkable. Future decisions may follow only one of these, or divergent branches of case law may appear, which would have to be resolved by the Enlarged Board of Appeal of the EPO.

When drafting an application for an invention that lies in the processing of measurement data from a human or animal body, including explanations about technical uses of the processed data, for example the control of another device, may be a useful fallback position to support inventive step in case a European patent is desired. However, this could push claims to go beyond the mere provision of medically-relevant information to a medical practitioner.

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[17] Part G, Chapter II, section 3.3 describes how a mathematical method may contribute to the technical character of an invention, providing positive examples divided into two categories: by being applied to a specific field of technology (technical applications) or by being directed to a specific technical implementation depending on the machine (computer or network) in which it is to be implemented. This section is often cited by applicants faced with objections that their novel features are non-technical.

[18] Decision G 1/04, reasons 5, defines diagnosis as "the determination of the nature of a medical or veterinary medicinal condition intended to identify or uncover a pathology". Further, "[i]t includes a negative finding that a particular condition can be ruled out", and that a diagnostic method requires the comparison of collected data with standard values leading to the finding of a significant deviation (i.e. a symptom).

J 1/24: Filing a Divisional After Grant at the EPO

It has long been established that divisional applications can still be filed following an appeal by the applicant against a decision to refuse an application. This is the case regardless of the outcome of the appeal in the parent case. **J 1/24** proposes that, in contrast to previous case law, the same might also be true after the publication of the decision to grant a European patent. That is, applicants might still be able to file divisional applications post grant after having filed an appeal against the decision to grant, irrespective of the fate of the appeal.

Case background

In the case underlying decision **J 1/24**, the decision to grant the earlier application was issued on February 18, 2021, with an original date of publication of the mention of the grant of March 17, 2021. On April 16, 2021, the applicant timely filed a notice of appeal against the decision to grant the earlier application and subsequently filed a divisional application on May 24, 2021.

As a result of the appeal, as is current EPO practice, the date of publication of the mention of the grant had been deleted, with the deletion to be published in the EPO Bulletin. The applicant then timely filed their grounds of appeal, but later withdrew their appeal against the decision to grant the earlier application. The Examining Division advised the applicant of the new publication date of the mention of grant in respect of the earlier application, namely June 15, 2022 (long after the filing of the divisional application). This communication noted that the original decision to grant of February 18, 2021 (before the filing of the divisional application) remained valid.

As a result, the Receiving Section issued a notice of loss of rights for the divisional application and, ultimately, a decision refusing the divisional application. The applicant lodged an appeal against the decision to refuse the divisional application, leading to decision **J 1/24** in which the Board finally held that the divisional application had been validly filed.

Practice at the EPO irrespective of J 1/24

Divisional applications can be filed with the EPO while the parent case is still "*pending*" (R. 36(1) EPC). However, the EPC does not contain a legal definition of what constitutes a "*pending*" application.

In most cases, and as is still common practice, the standard scenario is that divisional applications can be filed until the day before the publication of the mention of the grant.

The situation is more nuanced in case of a "*negative*" outcome of prosecution of the earlier application. In **G 1/09**, the Enlarged Board held that a "*pending*" application exists if substantive rights are still derivable. Importantly, a "*pending application*" does not require "*pending grant proceedings*". Instead, the Enlarged Board held that the relevant criterion for pendency was whether there was still provisional protection under Art. 67 EPC, i.e., a substantive right, which in turn only ceases when the application is withdrawn, deemed to be withdrawn or finally refused. This is possible even during the term for filing an appeal if no appeal is filed.

Consequently, if an application has been refused, a divisional application may still be validly filed after the applicant has appealed the decision, as the appeal has suspensive effect (Art. 106(1) EPC).

Following previous case law **J 28/03**, the same did not apply for appeals in cases in which the patent had been granted. In the case underlying **J 28/03**, the date of publication of the mention of the grant was not deleted as a result of the notice of appeal (contrary to current EPO practice, as mentioned above), so that the grant of the patent became effective. In **J 28/03**, the Board stated that an appeal against a decision granting a patent and resulting in the publication of the grant of the patent would be expected to be inadmissible, as the decision to grant is almost always fully in line with the intention to grant to which the applicant agreed. Therefore, the decision to grant is final and, unlike in the case of refusal, the application is no longer "*pending*". Only if the appeal was ultimately successful could a divisional have been validly filed in the meantime.

Deviating decision J 1/24

By contrast, the Board in **J 1/24** points out that the current practice of the EPO is to treat appeals against the grant of a patent as validly filed, with the consequence that the date of the mention of the grant is deleted, as was done in the case underlying the decision. Further, the Board states that it would be inconsistent to consider an appeal in two different ways: firstly, for the mention of the grant to be deleted, the appeal only needs to be admissible, and secondly, for the suspensive effect to apply (on which the "*pending*" status of the application hinges), the appeal needs to be successful, as was the case in **J 28/03**.

The Board resolved this inconsistency by applying the approach of G 1/09 to all examination appeal cases, holding that an appeal generally has suspensive effect. The suspensive effect of the appeal re-establishes pendency and thus allows a valid filing of a divisional application. Only a clearly inadmissible appeal should have no suspensive effect, e.g., an appeal that does not find basis in the EPC, such as one filed by a third party. Equally, the subsequent withdrawal of the appeal is not relevant.

Impact on practice

Decision **J 1/24** suggests that if an appeal is filed against the grant of a patent, it may still be possible to file a divisional application once the mention of the grant is deleted.

J 1/24 may thus offer a glimmer of hope to applicants wishing to file a divisional application based on a recently granted patent (e.g. those who missed the opportunity to file a divisional application prior to grant, or applicants whose parent patent was granted based on sub-optimal documents).

J 1/24 represents a significant departure from current established practice. At present it is not clear whether other instances of the EPO will follow this decision. Thus, for the time being the decision should rather be seen as providing a last resort if something went awry in a particularly important case, but should not be taken as a solid basis for devising a filing strategy.

Even if used as a last resort, there are risks associated with the criterion of "*clear (in)admissibility*". In its decision, the Board states that only a clearly inadmissible appeal should have no suspensive effect, giving the example of an appeal by a third party. However, it is unclear whether the EPO would consider all appeals that in principle have basis in the EPC to be not clearly inadmissible. As long as the appeal is based on amendments that the applicant had approved in the text intended for grant (such as in the case underlying **J 1/24**), care should be taken to substantiate the appeal as far as possible.

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DOE at the UPC

In the first decision on an infringement under the doctrine of equivalents, the Dutch local division of the UPC has developed and applied four questions to test for equivalent infringement. We conclude that the way the local division has derived its test may well be challenged as being inappropriate under the UPC.

On November 22, 2024, the Local Division The Hague ("LD") of the Court of First Instance of the Unified Patent Court ("UPC") has delivered a decision on the validity and a possible infringement of EP 2 137 782 B1.[19] The LD found the patent to be valid and infringed by equivalence. It was the first decision on the merits by the UPC on an infringement under the Doctrine of Equivalents ("DOE"). In the following, we will cover the part of the decision dealing with infringement by equivalence.

Broadly speaking, the patent concerns an invention related to a microbial fuel cell. The basic principle of microbial fuel cells was already conceived in the early 20th century.[20] Microbial fuel cells are based on the idea of using microorganisms to produce electricity, more specifically by diverting electrons from reduced compounds to oxidized compounds. The electrons are produced by having the microorganism oxidize the reduced compounds, which are also known as "the fuel" or the electron donor. The oxidized compounds are correspondingly the electron acceptor. The electron donors are on an anode and the electron receptors are on a cathode. The anode and cathode are in a reactor. The electrons are diverted through an external electrical circuit. Prior art microbial fuel cells had the disadvantage that they required an external supply of the fuel to maintain the production of electricity.

The patent was granted with two independent claims. Claim 1 is directed to a device, claim 11 to a method for converting light energy into electrical energy and/or hydrogen. Of interest for the court decision was the independent method claim. It has the following features (split and numbered as in the court decision):

11.1 Method for converting light energy into electrical energy and/or hydrogen,

11.2 wherein a feedstock is introduced into a device that comprises a reactor,

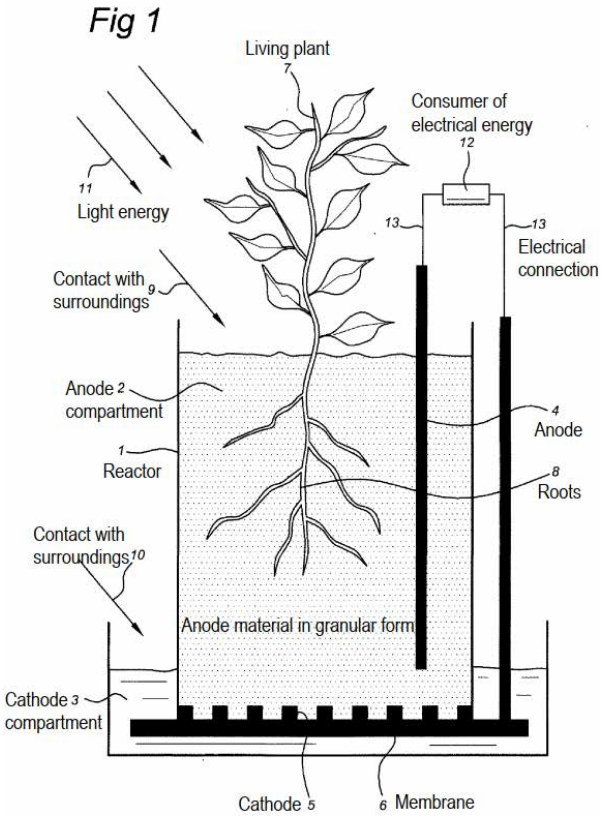
11.3 where the reactor comprises an anode compartment (2) and a cathode compartment

11.4 and wherein the anode compartment comprises a) an anodophilic microorganism capable of oxidizing an electron donor compound,

11.5 and b) a living plant (7) or part thereof, capable of converting light energy by means of photosynthesis into the electron donor compound,

11.6 wherein the microorganism lives around the root (8) zone of the plant or part thereof.

The invention is thus based on the concept of having a living plant, or part thereof, in the anode compartment of the fuel cell. When the living plant converts light by photosynthesis into organic material it constantly supplies organic material (fuel) to the microorganism in the reactor. The method is illustrated as follows in Fig. 1 of the patent:



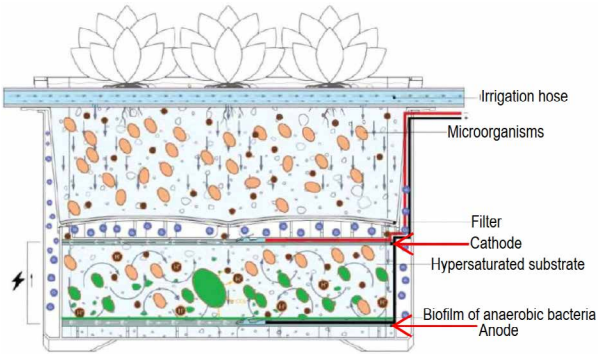
[19] UPC CFI LD The Hague, Decision of 22 November 2024 – UPC_CFI_239/2023 – Plant-e Knowledge B.V. et al vs Arkyne Technologies S.L.

[20] Microbial fuel cell, https://en.wikipedia.org/w/index.php?title=Microbial_fuel_cell&oldid=1248026802 (last visited Dec. 8, 2024).

The incoming light is illustrated at 11 and is ultimately converted into the electrical energy used by the consumer at 12 (feature 11.1). The reactor is shown at 1. Some of the feedstock can be seen in the anode compartment of the reactor, as "anode material in granular form" (features 11.2, 11.4). The anode compartment is shown at 2, the cathode compartment at 3 (feature 11.3). The living plant (feature 11.5) is shown at 7. Its roots are at 8 in the anode department and surrounded by the anode material in granular form (feature 11.6).

The patent was granted to Plant-E Knowledge B.V. who was also one of the claimants and will be referred to as "Plant-e" (as done in the decision). Plant-e brought an action against Arkyne Technologies S.L. who marketed products under the designation Bioo. The decision therefore refers to defendant as "Bioo". Both Claimant and Defendant were represented by Dutch practitioners. Plant-e argued literal infringement of the method of claim 11, and alternatively, in case claim 11 was not deemed literally infringed, infringement by equivalence. The dispute on infringement focused on claim interpretation and on whether a device called "Bioo Panel" fell within the scope of protection of claim 11.

The Bioo Panel can be illustrated as follows:[21]



From its interpretation of the claim and the evidence before it, the LD concluded that the Bioo Panel has two independent compartments assembled in a single device, that it contains a cathode at about half-height, and an anode at the bottom. The anode and cathode are separated by soil. The microorganism and organic material from soil and fertilizers are dragged into the lower part of the Bioo Panel by irrigation and rainwater. They serve as feedstock. The LD also affirmed the presence of a plant at the top, and that the roots in the Bioo Panel contribute to the conversion of light energy as claimed. The feature giving rise to the finding on equivalence related to the placement of the living plant (features 11.4 and 11.5). Whilst the claim required a placement in the anode compartment, Bioo was found to have placed the plant at the top and the anode compartment at the bottom of the Bioo Panel. The LD then concluded that the Bioo Panel did not fall under the literal scope of protection because of this variation.

In reaching this point, the LD acknowledged that the Agreement on a Unified Patent Court ("UPCA") contains no provision on the scope of protection of a patent[22] and sought guidance in Art. 69 EPC, which is applicable as a source of law as confirmed by case law from the Court of Appeal of the UPC.[23] Having denied a literal infringement, the LD additionally acknowledged that the UPCA contains no provision on the doctrine of equivalence.[24] However, the LD considered the Protocol on the Interpretation of Art. 69 EPC, which is an integral part of the EPC and mentions that, for the purpose of determining the extent of protection conferred by a European patent, due account shall be taken of any element which is equivalent to an element specified in the claims. The LD then continued its analysis by investigating an infringement under the DOE. However, there was no established test for doing so. Art. 24(1) UPCA required the LD to base its decision on (a) Union law, (b) the UPCA, (c) the EPC, (d) other international agreements as applicable to patents and binding on all the Contracting Member States of the UPCA, and (e) national law. However, in as much as the author is aware, none of these sources of law have provisions on how the DOE is to be applied.

From the decision, it seems that the LD has also not found any such provision in the applicable sources of law so that it decided[25] to

> *"apply a test based on the practice in various national jurisdictions, in line with what both parties proposed (partly upon questioning by the court) in this case".*

[21] Image taken from p. 31 of the decision and slightly adapted.
[22] Margin note 38.
[23] Order of the CoA of 11 March 2024 in case CoA 335/2023, Nanostring/10 x Genomics, page 24.
[24] Margin note 86.
[25] Margin note 88.

It concluded that a variation is equivalent to an element specified in the claim if the following four questions are answered in the affirmative (highlighting in the original):

"I. **Technical equivalence:** does the variation solve (essentially) the same problem that the patented invention solves and performs (essentially) the same function in this context?

II. Is extending the protection of the claim to the equivalent proportionate to **a fair protection for the patentee:** in view of his contribution to the art and is it obvious to the skilled person **from the patent publication** how to apply the equivalent element (at the time of infringement)?

III. **Reasonable legal certainty for third parties:** does the skilled person understand **from the patent** that the scope of the invention is broader than what is claimed literally?

IV. Is the allegedly infringing product **novel and inventive** over the prior art? (i.e. no successful Gillette/Formstein defence)"

The LD went through the questions and ultimately found Bioo to have infringed claim 11 with equivalent means.

The first question was affirmed because the LD was convinced that in the Bioo Panel, nutrients and microorganisms can pass from the roots in the upper compartment to the lower compartment. The energy conversion then worked on the basis of the claimed principles.

Fair protection for the patentee was affirmed because the patent was found to claim a new category of microbial fuel cells, by introducing a plant into the device/reactor and to obtain electricity from organic material originating from the photosynthesis by that plant and thus from light energy. The accused device was of the same category. The LD found it to have been obvious that the organic material produced in the upper compartment can reach the lower compartment as feedstock. How this obvious modification is arrived at from the patent publication does not seem to be explained in the decision.

In applying the third question, the LD simply stated that the teaching of the patent is clearly broader than the wording of the claim. It reduced the teaching to the addition of a plant to a microbial fuel cell to provide additional feedstock and make the fuel cell independent of externally provided feedstock.

In developing its questions as the test for an infringement under the DOE that is relevant under the UPCA, the LD referred to the decision of November 27, 2020, from The Hague Court of Appeal in Eli Lilly/Fresenius.[26] This is not a UPC decision. The proposals from the parties, both represented by Dutch attorneys, and reference to this Dutch national decision suggest that the Dutch LD simply took on board prior case law from the Dutch courts, presumably because all actors were familiar with it.

The referenced decision is one that has received significant attention. It was part of the multinational "Pemetrexed" litigation in which several courts across Europe proposed and applied tests for an infringement under the DOE. In the German part of the same litigation, for instance, the German Federal Court of Justice applied the following test:[27]

I) Firstly, the embodiment must solve the problem underlying the invention by (albeit modified, but) objectively equivalent means.

II) Secondly, the skilled person's technical knowledge must enable him to identify the modified embodiment with its deviating means as having the same effect.

III) Thirdly, the considerations which the skilled person must make in this respect must be oriented towards the literal meaning of the teaching protected in the claim such that the skilled person considers the deviating embodiment with its modified means as a solution of equal value to the (literal) solution.

In doing so, the German court expressly addressed the UK part of the litigation, which at that time had yet to be decided by the UK Supreme Court. The German court mentioned that its third question corresponded to the third of the questions posed in the test applicable in the UK at that time.[28] According to the understanding

[26] ECLI:NL:GHDHA:2020:2052; https://ipkitten.blogspot.com/2020/10/hague-court-of-appeal-sets-dutch.html
[27] Decision of June 14, 2016: X ZR 29/15, with reference to, inter alia, X ZR 193/03, Crimpwerkzeug IV, margin note 35; see also X ZR 1/05, Pumpeinrichtung.
[28] Following Improver v. Remington ([1990] F.S.R. 181); https://www.ippt.eu/sites/ippt/files/1988/IPPT19880812_CoA_London_Improver_v_Remington.pdf

of the UK case law by the German court, an embodiment which is not covered by the primary, literal or non-contextual wording of the patent claim may not fall within the scope of protection of the patent, even if the modification has no significant influence on the effect according to the invention and this fact was obvious to the skilled person. An infringement would be denied if the skilled person can infer from the claim that conformity with the primary wording is one of the essential requirements of the invention.

In the UK part of the Pemetrexed litigation, the Supreme Court of the United Kingdom formulated and applied the following test questions:[29]

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

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

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

In comparing the three tests, differences emerge. The first question by the Dutch and German courts commonly focuses on the technical problem underlying the invention. However, the Dutch courts would like to see essentially the same function in this context, whilst the German courts are looking for objective equivalence. The UK courts, conversely, focus on achieving substantially the same result and on the inventive concept of the patent. As regards the second question, the Dutch and the UK courts expressly formulate a test of obviousness over the patent publication, whilst the German courts would like to see the skilled person being enabled on the basis of technical knowledge. On the third question, the German and UK courts focus on complying with the literal meaning of the claim whilst the LD seems to be looking for the inverse, i.e., an understanding derived from the patent that the scope is broader than this meaning.[30]

In a nutshell therefore, the case law in the UPCA member states at the time of drafting was not fully harmonized. The LD has picked one case law. We see room to debate whether this was in line with Art. 24(1) (e) UPCA. An appeal may well (also) be based on this point.

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[29] Decision of July 12, 2017: Actavis UK Limited and others v Eli Lilly and Company; [2017] UKSC 48; https://www.supremecourt.uk/cases/uksc-2015-0181.html

[30] The fourth question formulated by the LD is an additional test in the other two countries discussed here. In view of the German bifurcation, novelty does not play a role in this additional test, but the gist of the fourth question seems to be the same.

EU Competition Law: Teva Fined €462.6 Million for "Playing the Divisionals Game" and Disparagement Campaign

The European Commission has fined Teva €462.6 million for abusing its dominant position to delay competition to its blockbuster medicine Copaxone. The Commission found that Teva artificially extended the patent protection of Copaxone and systematically spread misleading information about a competing product to hinder its market entry and uptake.

On 31 October 2024, the European Commission fined Teva €462.6 million for abusing its dominant position to delay competition to its blockbuster medicine Copaxone (glatiramer acetate), which is used in the treatment of multiple sclerosis.[31] The Commission found that Teva artificially extended the patent protection of Copaxone through misuse of divisional patents and by running a systematic disparagement campaign against a competing product to delay its market entry and uptake.

Playing the divisionals game

The Commission held that Teva artificially extended the patent protection for Copaxone by misusing the rules and procedures of the European Patent Office (EPO) regarding divisional patents, which the Commission referred to as "playing the divisionals game". Briefly, Teva had filed multiple divisional patent applications in a staggered way, creating a thicket of secondary patents around Copaxone focusing on the manufacturing process and the dosing regimen of glatiramer acetate. When competitors challenged these patents, in an attempt to enter the market, and pending review by the EPO, Teva started to enforce the patents to obtain interim injunctions. But when the patents seemed likely to be revoked, Teva strategically withdrew them to avoid a formal invalidity ruling, which would have set a precedent for the other divisional patents. By doing so, Teva forced competitors to repeatedly start new lengthy legal challenges. This strategy allowed Teva to artificially prolong legal uncertainty over its patents and potentially hinder the entry of competing medicines. All of Teva's divisional patents have now been annulled.

Disparagement campaign

The Commission also found that Teva ran a systematic disparagement campaign in an attempt to delay market entry and uptake of a competing product. The campaign, which targeted key stakeholders including doctors and national decision-makers for the pricing and reimbursement of medicines, spread misleading information about the safety, efficacy and therapeutic equivalence of the competing product. Teva did so despite the fact that the relevant health authorities had approved the competing product and confirmed its safety, efficacy and therapeutic equivalence with Copaxone.

Comment

The Commission's decision seems to be the first in which "playing the divisionals game" has been held to be an abuse of a dominant market position under EU competition law. Previously, the Munich Regional Court had granted a preliminary injunction against Teva ordering it to refrain from withdrawing a further divisional application but this order was based on unfair competition law, not antitrust law.[32] Also, it must be stressed that Teva was fined for two reasons, namely "playing the divisionals game" and engaging in a systematic disparagement campaign. It is unclear whether "playing the divisionals game" alone would have triggered such a fine. Unfortunately, only the

[31] "Commission fines Teva €462.6 million over misuse of the patent system and disparagement to delay rival multiple sclerosis medicine", European Commission, Press release, 31 October 2024.

[32] Regional Court Munich I (Landgericht München I), Order of 24 February 2020 (Case no. 7 O 1456/20), available here (in German).

Commission's press release is available at the time of writing and the press release does not provide any clarification on this point. Nonetheless, the Commission's decision serves as a warning sign that divisional applications should at least be properly pursued and defended if challenged. It would seem that the level of the fine is intended to send a clear message that the Commission will not tolerate practices such as those deployed in Teva's case.

The Commission's decision is appealable and we note that Teva has issued a statement announcing its intention to appeal the decision. We will provide a more detailed analysis on the Commission's findings once the full decision is made available, likely in the first half of 2025.

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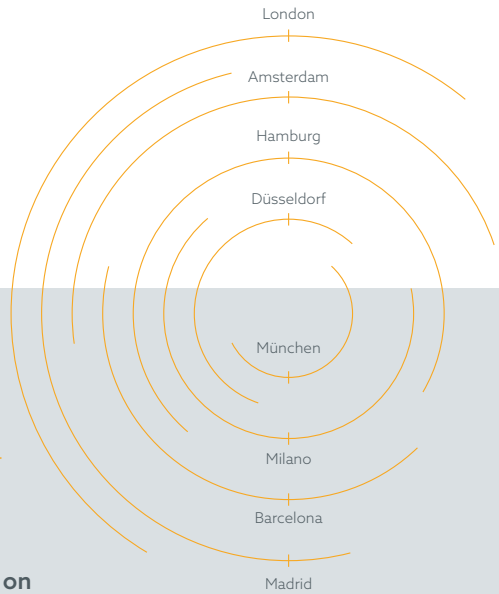

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