When diagnostic patents are »diagnosed« with implausibility

Credibility and evidence requirements for diagnostic inventions in Europe

Diagnostic methods play a crucial role in modern medicine by enabling the identification, prognosis, and surveillance of diseases. The COVID-19 pandemic is the latest example demonstrating the clinical and economic importance of diagnostic inventions, which have been essential for disease detection, monitoring, and public health management.

However, obtaining patent protection for such inventions in Europe is often challenging. A central hurdle is the requirement of **plausibility**: a patent application must credibly demonstrate that the claimed diagnostic effect exists. This principle was emphasized in the recent decision T 0589/22, in which the Board of Appeal revoked European patent EP 2 419 741 for an *in vitro* diagnostic method on the grounds that the claimed diagnostic effect was not rendered plausible.

This article explores the patent eligibility of diagnostic methods in Europe, the concept of plausibility and its relationship to sufficiency of disclosure, as well as the lessons from T 0589/22 and UPC case UPC_CFI_201/2024.

Patent eligibility of diagnostic inventions in Europe

As the patent eligibility of diagnostic inventions varies considerably between countries, it is important to first clarify the extent to which such inventions are patentable under the European Patent Convention (EPC).

Diagnostic methods performed on the human or animal body are **excluded from patentability under Article 53(c) EPC** if they comprise all of the following steps:

(1) collecting data
(2) comparing it with standard values
(3) identifying a deviation from normal, and
(4) attributing that deviation to a clinical diagnosis

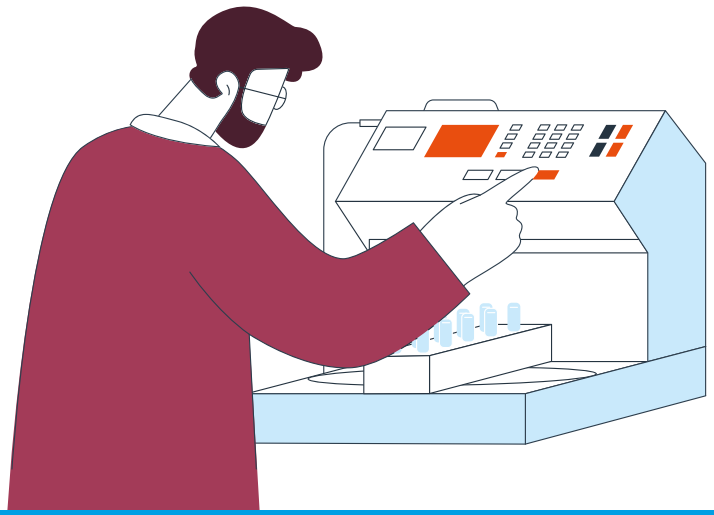
(Decision G 1/04 of the Enlarged Board of Appeal (EBoA), Reason 5).

Accordingly, if any one or more of steps (1) to (4) is omitted, or if the method is performed outside the human or animal body, the **diagnostic method may be patentable**. Hence, *ex vivo* or *in vitro* diagnostic methods performed on a sample taken from the body, such as blood or tissue samples, are generally patent-eligible (T 1920/21, Reason 26).

Consequently, unlike in some other jurisdictions, such as the US, a claim directed to a **method of diagnosing a disease by detecting the presence or quantity of a biomarker** is generally eligible for patent protection at the European Patent Office (EPO).

In addition, **software-based diagnostic methods** may be patentable if they involve technical steps and produce a technical effect, even when the reasoning phase is performed by a human. The technical requirement (to overcome the exclusion of Article 52(2) EPC) is typically satisfied when the method is implemented on a device.

Of course, **diagnostic products**, such as substances, compositions, or devices used in diagnostic methods, are patentable under European practice.



The concept of plausibility and its relationship to sufficiency of disclosure

Clearing the hurdle of patent eligibility is only the first step for diagnostic inventions. The more complex challenge can often be demonstrating that the claimed diagnostic effect is plausible. The EPO applies the concept of plausibility in various contexts, including sufficiency of disclosure and inventive step.

To understand the concept of plausibility and its relationship to sufficiency, it is helpful to understand the standard for basic sufficiency. Article 83 EPC requires that a European patent application describes the invention clearly and completely, enabling a skilled person to carry it out. An objection under insufficiency must be supported by serious, fact-based doubts that the invention can be put into practice (T 19/90, T 890/02). While a single working example may suffice for narrow claims, broader claims generally require multiple examples or alternative embodiments. Furthermore, if a technical effect is a feature of a claim, it must be demonstrated that this effect can be achieved; otherwise, sufficiency of disclosure may be questioned.

In decision G 2/21, the EBoA confirmed that, while »plausibility« appears in case law on sufficiency, it is not a separate legal requirement under the EPC (Reason 92). The EBoA also held that, for sufficiency, particularly in second medical use claims, the patent must *»make it credible«* at the filing date that the known therapeutic agent is suitable for the claimed use (Reason 74).

Accordingly, some inventions, particularly therapeutic or diagnostic claims, face greater inherent doubt about whether a skilled person can carry them out. The EPO addresses this through »plausibility«, meaning more evidence may be needed to show the invention works as claimed. Although not a separate legal standard, the plausibility standard influences the amount of supporting information required, especially for therapeutic and diagnostic claims. To meet the standard of sufficiency, the patent must provide enough information to make the claimed therapeutic or diagnostic use plausible.

In *inter partes* proceedings, the opponent generally bears the burden to prove that the patent does not sufficiently disclose the invention. If the patent gives no information on how a feature can be put into practice, there is only a weak presumption of sufficiency. In these rare cases, the opponent can challenge sufficiency with plausible arguments alone, and it is then up to the patentee to show that a skilled person could actually carry out the invention using common general knowledge.

EPO Appeal Case T 589/22: The need for data in diagnostic patent applications

EPO appeal case T 589/22 of 25 February 2025 relates to European patent EP 2 419 741 (EP741), owned by B.R.A.H.M.S GmbH, which was opposed by Radiometer Medical ApS on several grounds, including insufficiency of disclosure.

The patent relates to an in vitro diagnostic method for identifying subjects with a primary non-infectious disease who are at increased risk of an adverse outcome from antibiotic administration based on the measurement of a biomarker (Procalcitonin) in blood, plasma or serum.

Claim 1 of EP741 read as follows (emphasis added):

»In-vitro diagnostic method for the identification of a subject suffering from a primary non-infectious disease having an increased risk of an adverse outcome potentially being induced by the administration of an antibiotic to said subject, comprising the steps of:

(i) determining in a sample of blood, plasma or serum from said subject suffering from a primary non-infectious disease the level of Procalcitonin (PCT) or a fragment thereof or a precursor or fragment thereof having a length of at least 12 amino acid residues,

(ii) correlating the determined level to a potential risk induced by the administration of an antibiotic,

(iii) wherein a concentration of PCT or a fragment or a precursor or fragment thereof having a length of at least 12 amino acid residues below 200 pg/mL in said sample correlates to an increased risk induced by the potential administration of an antibiotic and ***wherein said subject does not exhibit any symptoms of a bacterial infection****«.*

The central issue in the appeal proceedings was the patient group, particularly the disclaimer *»wherein said subject does not exhibit any symptoms of a bacterial infection«*. The examples disclosed in EP741 were based on a study involving patients with acute heart failure, all of whom were required to have »shortness of breath« as an enrollment criterion (paragraph [0049] of EP741). The Opponent argued that since »shortness of breath« is a symptom of bacterial infection, the patent examples do not show that the claimed method can achieve its intended diagnostic purpose and is therefore insufficiently disclosed.

Accordingly, the Board of Appeal first addressed the interpretation of the disclaimer *»does not exhibit any symptoms of a bacterial infection«* (Reasons 14-16 of T 589/22). While the Patentee had argued that these disclaimed symptoms are only symptoms that are **specifically indicative** of a bacterial infection, the Board of Appeal agreed with the Opponent that such symptoms are merely symptoms that can be attributed to a bacterial infection but do not need to be specific for the diagnosis of a bacterial infection (Reason 14 of T 589/22). Hence, the Board of Appeal concluded that claim 1 excludes subjects who show **any symptoms** of bacterial infection, regardless of their actual infection status, but does not exclude subjects who have a bacterial infection without symptoms (Reason 14 of T 589/22). Further, the Board of Appeal agreed with the Opponent that »shortness of breath« may be a symptom of infection of a bacterial origin and that »shortness of breath« is not as an exclusive symptom of heart failure as asserted by the Patentee (Reason 16 of T 589/22). Hence, the Board of Appeal concluded that claim 1 of EP'741 excludes subjects with shortness of breath.

In view of the above, the next question was whether the diagnostic effect is then sufficiently disclosed with respect to Article 83 EPC. The Board of Appeal emphasized that *»since claim 1 is directed to a diagnostic method, the purpose of the method (i.e. »identification of a subject suffering from a primary non-infectious disease having an increased risk of mortality potentially being induced by the administration of an antibiotic to said subject«) is an effect that has to be achieved and thus is* ***a functional technical feature of the claim****«* (Reason 17 of T 589/22; emphasis added). The Board of Appeal further emphasized that *»for the requirements of Article 83 EPC to be fulfilled, the patent has to provide suitable evidence that the claimed method allows the diagnosis to be made, or this must be derivable from the prior art or common general knowledge«*.

The Board of Appeal held that, since all patients in the patent's examples had shortness of breath, a symptom of bacterial infection, none of the examples fell within the scope of the claim (Reason 18 of T 589/22). As a result, the patent does not provide evidence that the claimed method achieves its intended diagnostic effect for the relevant patient group, and there is no support from the patent, prior art, or general knowledge to make this plausible. Therefore, the claimed subject-matter was deemed insufficiently disclosed (Reason 18 of T 589/22).

The Board of Appeal further clarified that, under Article 83 EPC, an application must provide proof of any claimed therapeutic or diagnostic effect at the time of filing. If the effect is not credible to a skilled person, without experimental data that show that the effect can be achieved, post-published evidence cannot remedy this (G 2/21; T 814/12) (Reason 19 of T 589/22). Hence, the Board of Appeal did not consider any post-filed data from the Patentee.

Finally, the Board of Appeal noted that, since the patent application, prior art, and common knowledge did not establish the plausibility of the claimed diagnostic benefit, there was no need for the Opponent to provide serious doubts supported by verifiable facts to challenge sufficiency under Article 83 EPC; thus, previous decisions requiring such proof did not apply to this case (Reason 20 of T 589/22).

Consequently, the Board of Appeal revoked patent EP741 due to a lack of sufficient disclosure.

Plausibility at the UPC?

So far, the UPC has yet to establish whether plausibility constitutes a criterion for sufficiency of disclosure in the context of therapeutic or diagnostic effects. To date, the only decision that addresses plausibility is UPC_CFI_201/2024, issued on 27 August 2024 by the Local Division Munich.

This decision relates to European patent EP 2 152 073 (EP073), owned by Syngenta Limited, who requested provisional measures against Sumi Agro Limited and Sumi Agro Europe Limited due to infringement of the patent. EP073 protects a herbicide composition comprising at least one sulfonylurea herbicide, **at least one HPPD-inhibiting herbicide; and at least one saturated or unsaturated fatty acid from 1% to 95% by weight** (claim 1 of EP073).

The Respondents objected that the claimed invention is unjustifiably broad because the examples only showed a narrow fatty acid range (63.5-68.5%) while claiming 1-95%, and hence is not sufficiently clear and complete for it to be carried out by a skilled person (section C c) aa) on page 25 of UPC_CFI_201/2024). The Court, however, found that the claimed range could be readily achieved by a skilled person, who would simply need to select an appropriate source of the fatty acid (section C c) ee)-ff) on page 26-27 of UPC_CFI_201/2024).

The Court further held that »plausibility« with respect to G 2/21 is not a requirement for patentability, as there is not a single article in the EPC dealing with it. Thus, the problems related to the catchword »plausibility« have to be solved in the context of Articles 56 or 83 EPC. However, the Court held that even if the UPC were to apply the obviousness test as set out in the recent case law of the EBoA in G 2/21, the validity of the patent-in-suit would not be called into question (section C c) ff) on page 27 of UPC_CFI_201/2024).

Hence, as such it cannot be ruled out that the UPC will also consider »EPO-type« arguments relating to the plausibility/credibility of a therapeutic or diagnostic benefit.

Takeaways

- For diagnostic inventions, T 589/22 confirms that the EPO's plausibility standard for sufficiency of disclosure remains unchanged after G 2/21.
- Inventions with higher levels of underlying doubts regarding the achieved technical effects, such as diagnostic methods, require robust supporting data in the patent application.
- It is fundamental that claim limitations accurately reflect what is demonstrated in the examples, particularly in biotech, where experimental data is key to patent validity.

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