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Cabazitaxel: Divergent EPO and UPC Rulings on Inventive Step After Clinical Trial Disclosure

Second medical use patents are among the most valuable IP assets in the pharmaceutical sector. Covering new therapeutic indications, patient (sub)groups, or combination treatments, they are often the only means of extending protection beyond the expiry of basic compound patents, SPCs, and regulatory exclusivities. Unsurprisingly, they are frequently the subject of intense disputes.

Such patents typically arise from clinical research, yet clinical trials require extensive public disclosure, which may later be used by challengers as prior art.¹ The EPO Boards of Appeal have issued numerous, evolving decisions on the patentability of second medical use claims in view of clinical trial disclosures.²

Some EPO decisions³ have suggested that the announcement of a detailed safety and efficacy clinical trial protocol in itself provides the skilled person with a reasonable expectation of success (in the absence of evidence to the contrary in the prior art).

Other EPO decisions, including the recent T 136/24, emphasize a case-by-case assessment, balancing "positive and negative pointers".

While the EPO upheld the patent under dispute in T 136/24, the same patent was revoked for lack of inventive step by the UPC Local Division Munich (UPC_CFI_146/2024).⁴ Reconciling these divergent outcomes is challenging but appears possible in light of differences in both factual assessment and legal approach. This article examines those differences and their practical implications.

The EPO Board of Appeal (T 136/24) found no reasonable expectation of success

The patent in suit (EP 2 493 466 B1) relates to the second medical use of cabazitaxel, in combination with prednisone or prednisolone, for treating metastatic castration-resistant prostate cancer (mCRPC) as second-line treatment after failure of a docetaxel-based therapy. The EPO opposition division and the appeal board (3.3.04) held the patent to be valid.

Inventive step was the main issue, with the most relevant prior art relating to the announcement of a phase III clinical trial of cabazitaxel for the same indication (TROPIC study), but without any results being published. The sole distinguishing feature over the study protocol was the "effective treatment" of the claimed indication.

Key was the formulation of the objective technical problem, because that in turn had an influence on the assessment of the skilled person's expectation of success. The board considered the problem was "to put into practice the effective treatment of prostate cancer with cabazitaxel in co-administration with prednisone in patients with mCRPC who have been previously treated with a docetaxel-based regimen and who have prostate cancer that progressed during or after that treatment". The board also equated success (in solving that problem) with an increase in overall survival (OS) relative to the comparative arm, i.e., with favourable results regarding the primary endpoint.

Thus, the core question was whether the skilled person had a reasonable expectation of success that cabazitaxel and prednisone would improve OS in the claimed post-docetaxel mCRPC population.

¹ Irene Martin Badajoz, Boris Tchitchanov, "The EU Clinical Trials Regulation: Implications of the New Transparency Rules on Patenting", Hoffmann Eitle Quarterly, March 2023, pp. 10-12.

² Claudia Unsin, "Pre-published Clinical Trials: A Sudden Death for Second Medical Use Claims?", Hoffmann Eitle Quarterly, March 2023, pp. 7-9.

³ See, e.g., T 96/20.

⁴ UPC LD Munich, decision of 12 December 2025 (UPC_CFI_146/2024, 496/2024, 147/2024, 374/2024, 148/2024, 503/2024).

The board held that the case law cited by the opponents did not support a general or automatic presumption of reasonable expectation of success merely because a Phase III study was underway. Instead, the probative value of a study announcement depended on the specific circumstances of each case. In its assessment of whether a reasonable expectation of success was given, the board evaluated and weighed “positive pointers” and “negative pointers” (dissuading elements) brought forward by the parties and found that:

- a) Cabazitaxel's structural similarity to docetaxel would generally dissuade from expecting an OS benefit after docetaxel failure, and resistance-overcoming was not yet predictably shown;
- b) Preclinical/phase I data was sparse and non-informative for OS, and phase II data in breast cancer could not, as a matter of principle, be extrapolated to prostate cancer;
- c) Usually, an ongoing phase III study could provide a positive pointer if it followed a standard path (phase I → II → confirmatory III), but here that path was “poorly reflected” because of limited or no data in the relevant patient group, so no automatic inference could be drawn;
- d) Given that most phase III studies had failed, it was speculative to infer that the regulatory authorities had decisive, unpublished efficacy data (which was, in any event, irrelevant due to its confidential nature), and it was plausible that the dire prognosis of mCRPC justified proceeding with the study based on “hope” alone;
- e) Mere proximity to completion was neither a positive nor a negative pointer in the absence of knowledge of *interim* monitoring criteria; and
- f) Business decisions to continue development provided no particular inference.

The board concluded that the alleged “pointers” did not create a reasonable expectation of success, and that, in the absence of such expectation, the claimed subject matter involved an inventive step starting from the experimental arm of the TROPIC study. The patent was thus maintained as granted.

The UPC Local Division (UPC_CFI_146/2024) came to the opposite conclusion

The UPC LD Munich expressly disagreed with the EPO's findings in T 136/24 and arrived at an opposite result, finding the patent invalid for lack of inventive step.

The differences concern both questions of fact and legal reasoning, the most relevant of which concerned the overall assessment of reasonable expectation of success.

Slightly different (additional) facts were considered by the UPC, which were mainly derived from the extensive expert testimonies. These essentially stated that data on toxicity, chances of success, and evidence of superiority compared to the control arm are closely monitored and reported to the sponsor of a trial. In the absence of relevant negative or positive triggers, a phase III trial would not be stopped but would continue. A negative trigger might be higher toxicity than previously anticipated. A positive trigger might be clear superiority of the tested drug over the control arm, in which case it would be unethical to withhold the superior treatment from patients in the control arm. The fact that a trial had been ongoing for some time would mean that there had not been a very severe adverse safety signal and that, in a very stringent statistical analysis, the trials were not destined to fail unequivocally.

The LD's different legal reasoning concerned: (i) the formulation of the objective problem, and (ii) the assessment of reasonable expectation of success by balancing positive and negative pointers.

The LD formulated the objective problem (i.e., what had to be reasonably achieved) in a more general manner than the EPO (based solely on the patent and without any pointers to the solution), as a therapeutic option for treating patients suffering from mCRPC who had been previously treated with docetaxel-based regimen and for whom prostate cancer had progressed during or after that treatment, including both increase overall survival and palliative treatment only.

The LD held that the question of reasonable expectation of success of the approach disclosed in the TROPIC trial documents, in terms of assessing inventive step, was different from the question of whether the TROPIC

trial would meet its primary endpoint. The mere fact that a study was nearing completion, in the absence of knowledge of the parameters selected for monitoring, was neither a positive nor a negative pointer when assessing expectation of success. However, the fact that the TROPIC trial had been approved and had been in progress for three years at the priority date without having been stopped, suggested that at least the sponsor of the trial had not considered it disappointing at the start and at no time until the priority date. Based on the expert statements, the LD held that a skilled person would have gained an expectation of success given the late stage of the ongoing clinic trial phase III.

The LD reasoned that, six months before the end of the trial, the skilled person, knowing that in a clinical trial interim results must be periodically evaluated in view of benefits and risks according to the clinical trial plan, and noticing that no negative events had occurred or were published, would have had a reasonable expectation of success for the use of the combination of cabazitaxel and prednisone in the treatment of the patient group in question. In light of the prior art data, the skilled person would have considered that, compared to mitoxantrone plus prednisone (which they knew had only a first-line palliative effect and was not even approved for second-line use), the second-line cabazitaxel plus prednisone experiment in progress in a phase III trial for more than three years had a reasonable chance of showing a favorable effect, including the (moderate) increase in survival. The LD thus found the patent to be invalid for lack of inventive step.

The final outcome of this case now rests with the UPC Court of Appeal.⁵ We will follow up on this when the Court of Appeal has issued its decision.

Practical and strategic implications

These two decisions once again highlight the challenges of defending second medical use patents. While it is still early to derive general trends, the following points may already be useful for future cases.

For patent applicants, it will be helpful to:

- draft applications while taking into consideration any published trial-related disclosures;
- emphasize unexpected effects, especially in difficult-to-treat populations;

- formulate the technical problem as concretely as possible (e.g., directly tied to the primary outcomes of the trial); and
- explicitly state, ideally in the application, “negative pointers” (uncertainties and risks known at the priority date that could indicate an expectation of failure).

Depending on the jurisdiction, it should be kept in mind that such statements in the specification may have an impact on the scope of protection, including the scope assessed under the doctrine of equivalents.

For patent challengers, it will likely be useful to provide as much evidence as possible (including expert declarations and/or testimony) for “positive pointers”, considering both a narrow and a more general formulation of the technical problem.

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⁵ The Patentee has already filed an appeal (UPC_CoA_22/2026, 23/2026, 24/2026, 25/2026, 26/2026, 27/2026).

An End to Aerotel: Emotional Perception at the UK Supreme Court

The landmark UK Supreme Court decision in *Emotional Perception* fundamentally reshapes how computer-implemented inventions are examined in the UK by harmonizing British law with the European Patent Office (EPO). The UK has abandoned the *Aerotel* four-step eligibility test in favour of the EPO's established "any hardware" approach. Claims involving any technical hardware – no matter how generic – now easily bypass Section 1(2) exclusions to qualify as an invention. The hurdle for patentability now rests firmly on the obviousness analysis. The Court introduced a new "intermediate step" filter into the UK's *Pozzoli* framework, requiring examiners to disregard non-technical features (like software or business rules) unless they interact with technical subject-matter to solve a technical problem. Applicants must shift their focus. The debate over "actual contribution" at the eligibility stage is over; success now depends on effectively arguing a "solution to a technical problem" during the assessment of inventive step.

For nearly two decades, seeking UK patent protection for computer-implemented inventions meant navigating the *Aerotel*⁶ four-step test for patent eligibility. This approach often contradicted the EPO framework developed since the *COMVIK* decision.⁷

With the Supreme Court's landmark judgment in *Emotional Perception*,⁸ that era is officially over. The Court has directed UK courts and the UK Intellectual Property Office (UKIPO) to abandon *Aerotel* and adopt the EPO's approach, as most recently outlined in *Bentley Systems*.⁹

While this appears to be a practical move toward international judicial harmonization, it carries far-reaching consequences for how British law distinguishes patentable inventions from routine developments.

Section 1(2) of the British Patents Act 1977 (mirroring Article 52(2) and (3) of the European Patent Convention or EPC) excludes certain subject-matter from being considered an invention, including computer programs and mathematical methods – but only to the extent that a claim relates to them "as such".

Since the Court of Appeal's 2006 *Aerotel* decision, the UK applied a structured test to identify the "actual

contribution" of an invention, asking whether that contribution fell solely within excluded subject-matter. This made the UK an outlier in Europe. British examiners could reject claims at the eligibility stage by arguing the "contribution" was non-technical, even if the claim included physical hardware.

The EPO disagreed. In *Duns Licensing Associates*,¹⁰ the EPO's Board of Appeal viewed *Aerotel* as incompatible with the EPC. They argued that mixing the assessment of "contribution" (which belongs to novelty and inventive step) with "eligibility" (a distinct concept evaluating the claimed invention in isolation) was a legal fallacy.

The catalyst for the UK's overhaul was *Emotional Perception AI Limited's* application to the UKIPO for a patent for their content recognition technology, which used a trained artificial neural network (ANN) to provide subjective media recommendations based on objective physical properties of the files.

The path to the Supreme Court involved several reversals. The UKIPO refused the patent, classifying it under *Aerotel* as an excluded computer program. The High Court overturned this, ruling an ANN was not a computer program "as such".¹¹ The Court of Appeal overturned the High Court, deciding the weights and

⁶ [2006] EWCA Civ 1371.

⁷ T 641/00.

⁸ [2026] UKSC 3.

⁹ G 1/19. For a discussion of this decision, see e.g. 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.

¹⁰ T 154/04.

¹¹ See Mark A.G. Jones, Axel T. Esser, "AI in the UK – Not Coded by a Human, No Problem", *Hoffmann Eitle Quarterly*, December 2023, pp. 2-5.

biases from ANN training were a species of computer program, validating the UKIPO's refusal.¹²

In its judgment, the Supreme Court did not just revise *Aerotel*; it buried it. The Court ruled that the former UK approach was unsound and unsustainable in light of settled EPO law.

The UK has now formally adopted the EPO's "any hardware" approach, developed since *Hitachi*.¹³ Under this standard, if at least one element of a claim falls outside the excluded domain (e.g., generic computer hardware), the invention is not excluded from patent protection. This represents a wholesale rewriting of British law on patent eligibility, a move only the Supreme Court had the authority to make.

The impact on UK patent prosecution is immediate and significant. The bar for patent eligibility is now barely more than a formality. If a claim directed to a computer-implemented invention references a computer, network, or other technical means, it avoids exclusion. For example, while the Court in *Emotional Perception* agreed an ANN could be characterized as a computer program, the claim was not excluded because it involved non-program elements in the form of a computer, database, and network.

For years, UK examiners have rejected hardware-inclusive claims under Section 1(2) by arguing the actual contribution was merely software. That argument is now dead. If non-excluded subject-matter exists in the claim, it is legally an invention.

However, passing the eligibility stage does not guarantee a patent. As recognized in *Bentley Systems*, the EPO's lenient eligibility approach only works if the test for obviousness also takes into account whether the invention's contribution to the art lies outside an excluded domain. The battleground has officially shifted from strict eligibility to inventive step.

During proceedings before the Supreme Court, the UKIPO warned that adopting the EPO's eligibility rules without their "problem-and-solution" approach to inventive step would create a mismatched

"Frankenstein monster" of two distinct legal systems. The Supreme Court was not deterred, confirming that while the UK must follow the EPO on eligibility, it can still use the existing British *Pozzoli*¹⁴ framework for assessing inventive step.

To bridge the gap between the low "any hardware" eligibility bar and a rigorous obviousness test, the Supreme Court introduced a new element to the *Pozzoli* framework: the intermediate step.

Acknowledged in *Bentley Systems* and plainly derived from *COMVIK*, this step requires examiners to "filter" claim features before assessing inventive step. Features contributing to the "technical character" of the invention are kept in, while non-technical features (e.g., computer programs, business rules) are disregarded unless they interact with technical subject-matter to solve a technical problem. Crucially, the Court declined to explain exactly how to apply this filtering exercise, leaving UK practitioners to rely heavily on lessons from the EPO's case law.

The EPO's approach prioritizes the technical problem solved and how each feature contributes to that solution. This has been criticized for over-relying on physicality — for instance, *Bentley Systems* excluded improved simulations of technical systems as such from being considered as solving technical problems. Under standard EPO practice, making a better generic ANN or applying it to media recommendations (as in *Emotional Perception*) would likely not be seen as solving a technical problem.

Does this mean the UK has fully surrendered to the EPO? Statutorily, yes. UK examiners will likely mirror the EPO, arguing that software features do not contribute to technical character unless applied to a strictly defined technical problem.

However, British courts are not absolutely bound to follow the EPO. As noted in *Actavis*,¹⁵ if the UK courts believe the EPO "is steering the convoy towards the rocks", they can chart their own course. If the EPO's understanding of what is, and crucially is not, "technical" proves too narrow, British courts therefore retain the freedom to adopt a more moderate, or even more modern, interpretation.

¹² See Mark A.G. Jones, "Emotional AI Is Nothing to Get Excited About, Rules UK Court of Appeal", *Hoffmann Eitle Quarterly*, September 2024, pp. 19-20.

¹³ T 258/03.

¹⁴ [2007] EWCA Civ 588.

¹⁵ [2008] EWCA Civ 444.

The next steps are clear: the war over “contribution” at the eligibility stage is won, and applicants and practitioners must instead focus on the “solution to a technical problem” for the inventive step stage. That is where the new battle lines will be drawn.

Further reflections

While the British Courts in *Emotional Perception* have introduced the filter of the intermediate step, the recent EPO Board of Appeal decision T 558/21 may give those courts some guidance in applying the filter pragmatically. The Board in T 558/21 acknowledged that, in practice, it is often very difficult to exhaustively identify which features contribute to the technical character and which do not. T 558/21 concerned a cryptographic method. Because the mathematical steps of this method, taken together, achieved the technical effect of protecting a cryptographic application against timing attacks, a “presumption” of technical character was established, and it was not necessary to definitively prove that every mathematical detail contributed to that character. This was enough to reject the Opponent’s argument that the only difference with the prior art was mathematical, and so within an excluded domain. Such an approach could reasonably be emulated by the British Courts, although without further judicial guidance the UKIPO may feel itself bound to apply the intermediate step filter strictly, without the procedural shortcuts adopted by the Board in this decision. Such an approach could result in protracted disputes before the UKIPO as to the extent to which each individual feature contributes to an overall technical effect, a significant risk for the British procedure in which each application must be placed in condition for allowance within a relatively short statutory period or otherwise refused.

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CJEU to Clarify the Meaning of “First Marketing Authorisation” and “New Product”

Supplementary protection certificates (SPCs) are granted in the European Economic Area (EEA) to compensate for the loss of effective patent protection for new human and veterinary medicinal products caused by the lengthy regulatory approval process. By extending protection for up to five years after expiry of the patent, the legislator seeks to ensure that the holder of both a patent and an SPC can enjoy an overall maximum of 15 years of exclusivity from the date that the first Market Authorisation (MA) has been obtained for the medicinal product in question.

The determination of this “first” MA under Article 3(d) of Regulation (EC) No. 469/2009 has long been a central point of legal debate.

The recent referral C-15/26 from the German Federal Patent Court (FPC) to the Court of Justice of the European Union (CJEU) aims at clarifying the following question:

Can an SPC be granted on the basis of the first MA for a veterinary medicinal product if an earlier MA exists for a human medicinal product containing the same active ingredient?

1. Legal framework: Article 3(d) and the concept of the “first” MA

Article 3(d) requires that the MA relied upon for an SPC application must be the *first* authorisation to place the product on the market as a medicinal product in the EU.

Article 3(b) clarifies that the relevant authorisation must be issued in accordance with either Directive 2001/83 (human medicinal products) or Directive 2001/82 (veterinary medicinal products), “as appropriate”.

Under Article 1(b) of the SPC Regulation, the “product” is defined as the *active ingredient or combination of active ingredients* of the medicinal product.

2. The new referral C-15/26 (Boehringer Ingelheim v GPTO)

The underlying case concerns Boehringer Ingelheim’s veterinary medicinal product *Aservo® EquiHaler®*, whose active ingredient ciclesonide had previously received authorisation as a *human* medicinal product.

The German Patent Office (GPTO) rejected the SPC application on the ground that Art. 3(b) does not distinguish between an MA for a veterinary medicinal product and an MA for a human medicinal product. Instead, the Patent Office considered the reference to Directive 2001/83 or Directive 2001/82 in this provision as a reference to two equally valid alternatives. Under this interpretation, the earlier human MA bars an SPC based on the later veterinary MA.

However, the authorisation procedures for human and veterinary medicinal products are strictly separated. Therefore, the active ingredient of the first veterinary medicinal product is classified as a “new active substance” (NAS), irrespective of whether an approval exists for an earlier human medicinal product containing the same active ingredient.

Consequently, ciclesonide was classified as a “New Active Substance” in the European Commission decision granting approval for the veterinary medicinal product *Aservo® EquiHaler®* and the authorisation of *Aservo® EquiHaler®* followed the procedure for a first MA in the Community.

This raises the question of whether the distinction between MAs for veterinary medicinal products and human medicinal products in regulatory law should also be applied when interpreting the SPC Regulation.

3. Existing CJEU case law and its relevance

The new referral inevitably invites comparison with **CJEU case C-130/11 – Neurim**, where the Court allowed an SPC based on a human MA even though an earlier veterinary MA for the same active ingredient existed. The Court ruled in favour of granting an SPC based on the reasoning that the scope of the underlying patent did not cover the earlier approved therapeutic application.

The CJEU's *Neurim* ruling did not consider the new active substance status of the active ingredient in question, melatonin, but reasoned that the scope of the patent – which was limited to the treatment of humans – did not cover the therapeutic applications of the earlier approved veterinary medicinal products.

The later decisions **Abraxis (C-443/17)** and **Santen (C-673/18)** significantly limited the scope of *Neurim*. The CJEU clarified that marketing authorisations approving:

- a new formulation (*Abraxis*), or
- a new therapeutic application (*Santen*)

of an active ingredient which has been the subject of an earlier MA cannot serve as the basis for an SPC.

However, neither decision addressed the specific constellation of human vs. veterinary MAs, nor did the Court explicitly overrule *Neurim* in this context. Both of the later judgments were concerned exclusively with human medicinal products. Therefore, the scope of *Neurim* remains uncertain for the human/veterinary scenario that now presents in C-15/26.

4. FPC's position

The FPC considers it plausible that *Neurim* still applies where the earlier and later MAs belong to different regulatory pathways. The Court noted that the objectives of the SPC Regulation support a distinction between human and veterinary MAs. Otherwise, the development of human medicinal products or veterinary medicinal products could be discouraged merely because an earlier authorisation happened to exist for animals or for humans, respectively.

5. Related referral: C-794/25 (Stada v Takeda)

Another recent referral from a Danish court (C-794/25) has put the following question to the CJEU:

Must a derivative, such as lisdexamfetamine, of an active ingredient, such as dexamfetamine [...], be considered to be an independent active ingredient [...] if the derivative in connection with the grant of a marketing authorization is considered to be a new active substance within the meaning of Art. 10(2)(b) of Directive 2001/83/EC [...]?

In that case, the prodrug lisdexamfetamine was classified as a NAS, although the drug dexamfetamine had already been approved. While not directly addressing Article 3(d), the case again involves the interaction between regulatory NAS classifications and SPC definitions.

6. Outlook

Both pending CJEU referrals C-15/26 and C-794/25 highlight an unresolved correlation between regulatory classifications (e.g., NAS status) and the SPC Regulation.

The forthcoming decisions may determine whether regulatory distinctions – human medicinal product vs. veterinary medicinal product, prodrug being classified as NAS over the approved drug – play a role in applying Articles 1(b) and 3(d) of the SPC Regulation. This could have significant implications for future SPC eligibility.

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Two Rights, One Invention – Utility Models and Patents in China and Europe

As a result of recent changes in Chinese practice, applicants who wish to file both a utility model application and an invention application in China for the same “invention-creation” must now make a choice **upon filing** that has ramifications for the claim scopes that may be granted later on. Other jurisdictions, such as France, Germany, Spain, and Italy, apply different rules regarding how “double patenting” is treated between utility models and patent applications – there is no uniform approach.

1. Background

A “dual filing” strategy has been commonly used by applicants in China for some time. Under this strategy, the applicant files both a CN utility model application and a CN invention application on the same day for the same invention-creation. Applicants thereby aim to obtain quick protection in China via the utility model and, later on, to obtain longer-lasting protection when the invention patent is granted. A utility model is granted quickly and does not undergo substantive examination but has a term of only 10 years. The utility model therefore provides protection while the invention application progresses through substantive examination, which can take several years. Eventually, the invention application may be granted as an invention patent, either with amended claims or the original unamended claims. The invention patent then provides longer-lasting protection of up to 20 years.

Under the previous system in China, applicants could choose whether or not to maintain the utility model before grant of the invention application.¹⁶

2. New Regulations in China

Under new regulations that came into force on 1 January 2026, applicants pursuing the “dual filing” strategy now have two options open to them and **must select one of these upon filing the two IP rights**. They can either make a declaration to adopt the “Dual Application for One Invention” system or not.

a) Making the declaration

If the applicant *does* declare adoption of the “Dual Application for One Invention-Creation” system on the date of filing, then the invention application and the utility model application can safely be filed with identical claims. Similar to the old system, the utility model may be granted quickly with the original claims and without substantive examination. The main change in Chinese regulations comes into effect later on, once examination of the invention application is completed. Once the invention application is in order for grant, the utility model must be *expressly abandoned* before the invention patent is granted. This is the case regardless of whether or not any of the claims of the allowed invention patent are identical to any of the claims of the granted utility model.¹⁷

If the applicant has made the declaration to adopt the “Dual Application for One Invention-Creation”, they can only have one granted right active at any given time but these two rights could have the same claim scope.

b) Not making the declaration

If the applicant *does not* declare adoption of the “Dual Application for One Invention-Creation” system on filing, then this has ramifications for the prosecution of the invention application.

¹⁶ Specifically, under the previous system in China, once the invention application was in order for grant, the applicant was invited either to amend claims of the invention application to ensure that none of the invention claims was identical with the granted utility model claims or to declare abandonment of the utility model. If the applicant failed to respond to the invitation, the invention application was deemed to be withdrawn.

¹⁷ Although less likely in practice, the utility model could be the IP right that is retained and the invention application could be abandoned at this stage instead. While this might be rare in practice, this might be the case, for example, if infringement proceedings are in progress based on the utility model at the time that the invention application is in order for grant.

The primary effect is that, in addition to the usual requirements of patentability (novelty, inventiveness etc.), all claims of the invention application must also have different scope from all claims of the granted utility model. Therefore, if the utility model was granted with the same claims as originally filed with the invention application, then the existence of the granted utility model would **prevent** the invention application from being granted with the same claim scope, even if the claims of the invention application were otherwise deemed to be novel and inventive by the Chinese Patent Office.

To avoid this risk, applicants might choose to amend the independent claim(s) of the utility model to be different from the claims of the invention application. This may be done either on filing or within two months of filing the utility model. Typically, the utility model independent claims would be amended to include a feature **from the description** because, in this manner, every claim of the granted utility model would then be different from every claim of the invention application as filed. The utility model may then be granted quickly with its own scope of protection, as usual.

At the end of substantive examination, the invention application can be granted provided all of its claims still differ from all of the claims of the granted utility model. This could mean the invention application is granted with the originally filed claims, provided they meet the usual requirements of patentability (novelty, inventive step etc.). The utility model does not need to be abandoned in this scenario.

If the applicant has not made the declaration on filing, they may have two granted IP rights active at the same time but those must have different scopes for all claims.

3. Situation in some European countries

International practice varies on the subject of double patenting between utility models and invention (patent) applications. We look for example at the legal situation in Germany, France, Italy, and Spain.

a) Germany

German law does not apply any double patenting restrictions between patent applications and utility models, i.e. the rights can co-exist even with the same scope.

b) France

Double patenting between a French utility certificate and a French patent seems to be prohibited in exactly the same way and for the same reasons as it is prohibited between two patents.

c) Italy

Italian law allows the simultaneous filing of a patent application for an invention and a utility model application, but this is not a commonly used strategy. Italian law expressly provides that 'An applicant for an industrial invention patent [...] may simultaneously file an application for a utility model patent, which shall take effect *in the event that the former is refused or granted only in part.*' This means that a complete overlap of the scopes of protection is not allowed in Italy.

d) Spain

Spanish law provides for patents and utility models as distinct national titles conferring exclusive rights in Spain. While there is an express prohibition on double patenting between a Spanish national patent and an EP patent validated in Spain (Art 160), there is no *explicit* prohibition on double patenting between a Spanish patent and a Spanish utility model. However, there may be an implicit prohibition. This *implicit* prohibition relies upon a particular interpretation of several articles of Spanish patent law, taken in conjunction with one another and arguing by analogy.

4. Comparison

China, France, Italy, and Spain each have, unlike Germany, at least some level of prohibition of “double patenting” between a utility model and a patent application. However, the details vary in significant respects between countries.

With the new regulations, China has adopted a particular regulatory approach regarding utility models and corresponding patent applications. By contrast, there is no pan-European harmonisation in this respect. This means there is ample room in Europe for “IP right shopping,” where applicants can select among utility models, national patents, European patents with unitary effect, opted-out classical European patents, and non-opted-out classical European patents. This creates opportunities for optimizing an IP portfolio in many different ways depending on an applicant’s commercial goals.

5. Conclusion

When an applicant has an interest in filing both a utility model application and an invention application in China for the same invention-creation, the applicant now needs to carefully consider the choice of whether to make a declaration *before* filing in China, because any declaration must be submitted by the filing date. In Europe, different jurisdictions may have widely differing practices regarding utility models and corresponding invention patents. This creates opportunities for optimizing an IP portfolio, based on an applicant’s needs and specific commercial interests through careful selection from the wide variety of available IP rights.¹⁸

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¹⁸ With thanks to Marcel Peigné, Irene Martin Badajoz, Gianluca Zanellato, Fabian Hötzel, and Christian Schreiber for their contributions regarding French, Spanish, Italian, and German practice.

Hoffmann Eitle's Significant Contributions to the Development of European Case Law in 2025

Attorneys at Hoffmann Eitle are at the forefront of European intellectual property law. In 2025, we once again contributed to several noteworthy developments in case law through our work on behalf of clients. Below, we highlight several of these cases.

EPO Enlarged Board of Appeal decision G 1/23 removing the reproducibility criterion of G 1/92 from commercially available products as prior art

On July 2, 2025, the landmark decision G 1/23 "Solar Cell" was published by the Enlarged Board of Appeal. Hoffmann Eitle was involved in this case as representative for our long-standing client Mitsui Chemicals, Inc.¹⁹

According to the decision, a product put on the market cannot be excluded from the state of the art solely because its composition or internal structure could not be analysed and reproduced by a skilled person. All technical information about such a product also belongs to the state of the art.

This decision is a major departure from G 1/92, where it was previously held that a product only becomes prior art if it is possible for the skilled person to discover its composition or internal structure and reproduce it. G 1/23 supersedes G 1/92 and states that irrespective of the reproducibility criterion, the product and the technical information about it is prior art if it can be obtained and possessed.

Notably though, the Enlarged Board's decision highlights that even though such products are prior art, this does not mean that such a product is necessarily relevant prior art. Depending on the circumstances, a product may be pertinent with regard to novelty but may not be suitable as a starting point for an inventive

step assessment, as a skilled person's inability to reproduce the product may be relevant information that has to be considered in the selection of the closest prior art.

So far, this aspect has produced mixed results in decisions citing G 1/23. In a related case (T 1719/21), the referring Board considered the non-reproducible product (a specific polymer grade) to represent the closest prior art, as it was in the same technical field and used for the same purpose. The Board rejected the argument that the product would not qualify as closest prior art because it would not be a promising starting point for further developments that require changes to the (unknown) process for preparing the product. Starting from the commercial product, the claimed subject matter was, however, still regarded as inventive.

Another decision of interest in this respect is T 1044/23. Also in this case, the Board considered non-reproducible commercial products (DMDA resins) to form the closest prior art, and the Board was unable to identify a technical effect that is caused by the distinguishing feature (density) over the commercial product. The Board nonetheless considered the claimed subject matter to be inventive, as the Opponent could not show that the skilled person knew how to obtain the claimed material, holding that *"whether the person skilled in the art would be able to identify the measures which would, starting from the DMDA resins, lead to a polyethylene composition that meets the parametric definition of claim 1 without having to resort to an undue amount of experimental work remains a matter of conjecture."*

¹⁹ See also Timo Pruß, G 1/23 – Reproducibility Is Not a Requirement to Make Products Available to the Public in the Sense of Art. 54(2) EPC, Hoffmann Eitle Quarterly, September 2025, pp. 11-14.

In the light of the latter decision, it can be expected that the focus of the arguments will shift from whether the prior art is reproducible to whether the claimed subject matter is (re)producible based on the prior art and common knowledge. Arguments in relation to (re)producibility may thus not fully disappear from opposition proceedings before the EPO.

Insufficient disclosure of a dependent claim combined with late filing of requests deleting this claim leads to revocation at the EPO

The Board of Appeal's decision T 878/23 is a reminder that it is important to make sure that the claims of a European patent are all in line, do not contradict each other, and cannot give rise to issues which could put in question that they can be technically carried out over their entire scope. It also emphasizes the necessity to file all potentially helpful auxiliary requests at the earliest possibility.²⁰

In this case, Hoffmann Eitle objected that dependent claim 4 was insufficient as it defined a composition having a total amino acid content as low as 3.5 wt% when independent claim 1 required at least 10 wt%. Patentee argued that the discrepancy was a simple clarity issue and could thus not be raised during opposition. Patentee argued that the issue was one of an unclear "forbidden area", which typically arises not from a technical impossibility to perform the invention, but from an ambiguity in the claim language. According to the established case law of the Boards of Appeal, such ambiguity comes under the provisions of clarity, rather than sufficiency.

However, the Board of Appeal followed Hoffmann Eitle's arguments that the effect of the dependent claim was not just an unclear boundary. They considered both claims 1 and 4 perfectly clear. Instead, the problem was that the claims were also "mutually exclusive, i.e. incompatible, over a substantial part of their ranges". In view of this contradiction, the Board of Appeal found that "the skilled person cannot technically prepare the composition as defined in [the dependent claim] across substantially the whole breadth claimed".

As all auxiliary requests admitted into the proceedings included the same problematic dependent claim, all auxiliary requests were considered insufficient (Art. 83 EPC). Patentee attempted to fix this by filing new requests deleting this dependent claim in the final stage of appeal proceedings. However, the Board of Appeal held that, as the objection against claim 4 had been raised already in the opposition statement and Patentee could therefore have filed a request addressing this objection at the latest in reply to the Grounds of Appeal, the new requests were not admitted into the proceedings and the patent was revoked.

EPO Board acknowledges further technical use in vehicle body optimization case T 799/24

In T 799/24, Hoffmann Eitle represented JFE Steel Corporation and succeeded in overturning the Board of Appeal's very negative preliminary opinion on inventive step concerning a "method and device for analyzing optimization of vehicle body joint position". The decision provides an important example of a further technical use as discussed in G 1/19 and the possibility of obtaining a patent for inventions in which analysis results are displayed, wherein the final step of applying the analysis results is not explicitly defined in the claims.

The invention relates to an analysis apparatus for optimizing a joint location of an automotive body to improve the performance of an automotive body during driving. Analysis results of an optimization analysis are displayed by the analysis apparatus for automotive body designing. According to the Examining Division during the examination proceedings, the claim merely specified that a model and results of an algorithm were displayed, wherein the presentation of a model was exclusively aimed at the user for subjective evaluation or non-technical decision-making. In the Examining Division's view, this further use of the design did not provide a technical effect.

²⁰ See also Elisabeth Engelhard, T 878/23 – How a Dependent Claim Can Bring Down a European Patent for Insufficient Disclosure, Hoffmann Eitle Quarterly, December 2025, pp. 9-11.

In their preliminary opinion, it seemed that the Board of Appeal would follow the negative position of the Examining Division on inventive step. However, during the oral proceedings, the claimed subject-matter was shown to be inventive. The Board agreed that the formulation in the claim that additional welded points are "to be added" to the automotive body to improve its stiffness during driving at least implicitly specifies a further technical use. At the end of the oral proceedings, the Board decided to remit the case to the Examining Division with the order to grant a patent based on the claims of the main request.

The advantages of a process of manufacturing a product do not necessarily carry over to the product itself when assessing inventive step

The decision in appeal case T 1523/23 confirms that an inventive step of a product cannot be based on a technical effect relating to its manufacturing process.

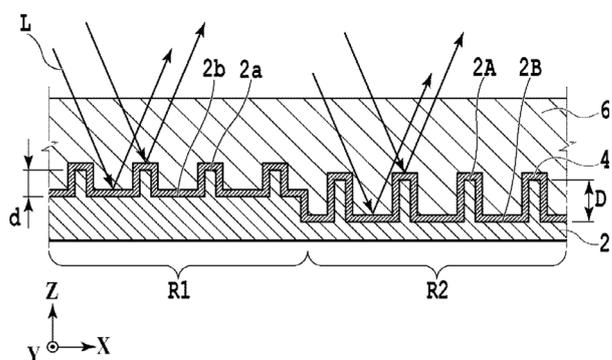


Fig. 2 of EP 3 454 099 B1

The claimed subject-matter is a display comprising an uneven structured layer, provided with two regions (R1 and R2), arranged "so that a reduction of a colour shift with respect to the intended colour of the display is established". In the inventive step discussion, the Board acknowledged that the claimed device differed from the prior art in the configuration of the distances d (from R1) and D (from R2) in the layer, which were chosen to provide specific optical properties to the device (Reasons 3.9).

However, it was questioned whether the last feature of the claimed device, which related to the "reduction of a colour shift" with respect to the intended colour of the display, could support a technical effect.

As such, the legal issue at hand was whether said technical effect could be inferred from the claimed product because it would not be apparent what the "intended colour" was. The feature also expresses that certain, manufacturing-dependent variations in the product only lead to small colour variations. Thus, the effect was to make the manufacturing process easier by allowing some variations, as these would be compensated for in the product.

Case law in the field of chemistry indicates that: "an intermediate intended for the preparation of a known end product is deemed to be inventive if its preparation takes place in connection with inventive preparation or inventive further processing" (T 648/88) and "a chemical compound can involve an inventive step irrespective of whether it itself has an unexpected technical effect, or whether its effect is linked to the improvement in a complete processing" (T 1089/15). This case law was used to argue that the claimed display was inventive based on its preparation or processing.

The Board decided however that the feature in question related solely to the manufacturing process and could not limit the claimed display (Reasons 3.10). The Board further held that "a technical effect achieved by the manufacturing process cannot be relied upon when assessing inventive step of the display of claim 1. Even if the process produces an ensemble of displays whose standard deviation from the mean (target) colour is reduced, for an individual display neither the target colour nor the deviation or reduction thereof is recognizable" (Reasons 3.12). The Board then concluded that in the assessment of inventive step of a device, i.e. a physical artefact, advantages of the manufacturing process do not carry over to the claimed device itself (Catchword).

Defending an inventive step even when the formulated objective problem contains elements of the solution

In *3 Ni 20/23*, Hoffmann Eitle successfully defended a patent against an inventive step objection before the German Federal Patent Court (FPC).

The patent, titled "DIARYLHYDANTOIN COMPOUND", related to prostate cancer treatments. The FPC referred to the problem mentioned in the patent, which identifies a need for a new thiohydantoin compound in such treatments, and consequently formulated the problem as the provision of new compounds having the basic thiohydantoin structure. Notably, the problem was phrased in a way that contained an element of the claimed solution. However, according to the FPC, the patent itself defined the problem in such a way and was hence confined to a thiohydantoin compound. A broader formulation of the problem, which is free of any elements of the solution, would thus not have been justified.

Despite the narrower formulation of the problem, Hoffmann Eitle could defend the "DIARYLHYDANTOIN COMPOUND" patent. The defence nicely illustrates the German inventive step practice, where the technical problem is less relevant than motivations provided by the prior art, which prompt the skilled person to work in a specific area. In the present case, the skilled person would have had to make specific structural modifications to known compounds in order to reach into the scope of the claims. Hoffmann Eitle successfully argued that there was no sufficiently

specific motivation to make such changes. In essence, too many modifications were possible and most were associated with a risk of ending up with a worse performing compound. Thus, the skilled person would have had to resort to inventive skill to end up with the claimed compound.

Thus, even when a German court or office formulates a relatively narrow problem, this does not necessarily have an impact on the inventive step position. Only if it can be shown that the skilled person was motivated by the prior art to work in the claimed area, can an inventive step be denied.

In the meantime, the decision has become *res judicata*.²¹

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²¹ The following attorneys contributed to individual sections of the article: Timo Pruß, Elisabeth Engelhard, Stephanie Rupp, Roland Schieren, Peter Klusmann, Jan Carl Zillies, and Dirk Schüßler-Langeheine.

When No Opt-Out Means No Choice: The Venice Interpretation

The Court of Venice recently issued a decision²² holding that the UPC would have exclusive jurisdiction over classical European patents during the transitional period unless the patent has been opted out, rejecting a widely accepted interpretation of Article 83 UPCA. We look into this decision and its implications.

The transitional period and parallel jurisdiction

The Unified Patent Court Agreement (UPCA) introduced a new judicial framework for litigating European patents. The UPC is intended for rulings on disputes relating to classical European (EP) patents and European patents with unitary effect. However, the UPCA also established a transitional regime starting from 1 June 2023, the date of its entry into force.

Article 83 UPCA provides for a seven-year transitional period, extendable once, during which actions for infringement and revocation²³ relating to European patents and supplementary protection certificates may still be brought before national courts or competent authorities.

At first sight, the provision appears to constitute an exception to Article 32 UPCA, which provides that such actions fall within the UPC's exclusive jurisdiction.

The aim of the transitional period is to mitigate the immediate transfer of competence from national courts to the UPC. To this end, Article 83 UPCA sets out the rules governing that regime: Under Article 83(3) UPCA, proprietors may opt out EP patents from the exclusive competence of the UPC by notifying the Registry. Conversely, under Article 83(4) UPCA, an opt-out may later be withdrawn ("opt-in"), provided that no action has been brought before a national court after the UPCA entered into force.

According to the UPC Court of Appeal's decision UPC_CoA_489/2023,²⁴ this framework results in "parallel jurisdiction" between the UPC and national courts during the transitional period. The prevailing understanding of what constituted a "parallel jurisdiction" was that, unless an opt-out had been registered or an action had already been initiated before the UPC, the proprietor was free to choose where to bring proceedings.

Under this interpretation, the structure of the transitional regime would consist of a concurrent jurisdiction with:

- Choice of forum for EP patents that have not been opted out in case no action involving the concerned patent was brought before the UPC;
- Exclusive national jurisdiction when opt-out was exercised; and
- Exclusive UPC jurisdiction when an action was brought before the UPC first.

The UPC CoA further clarified that such parallel jurisdiction provides for a concurrent competence according to which there is a genuine choice of forum where "the patent holder has the option to initiate infringement proceedings either before the UPC or before a national court" during the transitional period.²⁵

²² Tribunale di Venezia, Sezione Specializzata in Materia di Impresa, sentenza 12 novembre 2025, n. 10432/2024 (Geoplast S.p.A. v. Daliform Group S.r.l. e T.P.S. S.r.l.).

²³ The Court of Appeal later clarified that all actions mentioned in Article 32 UPCA over which the UPC has jurisdiction are encompassed in Article 83 UPCA (Unified Patent Court, Court of Appeal, Order of 12 November 2024, UPC_CoA_489/2023 – AIM v. Supponor).

²⁴ Ibid.

²⁵ Unified Patent Court, Court of Appeal, Order of 2 June 2025, UPC_CoA_156/2025 – XSYS v. ESKO.

Court of Venice decision

Against this background, the Court of Venice delivered a judgment on 12 November 2025, offering a markedly different interpretation of the transitional regime.

Addressing a classical EP patent for which no opt-out had been registered, the Court held that the view that the proprietor is free to choose between national courts and the UPC was incorrect. In the Court's analysis, if no opt-out has been recorded, exclusive jurisdiction rests with the UPC, even during the transitional period.

This interpretation stems from a combined reading of Articles 83 and 32 UPCA. In the Court's view, Article 32 UPCA establishes the UPC's exclusive jurisdiction over actions concerning European patents, and Article 83 UPCA provides for the possibility of the patent proprietor waiving this exclusivity, by means of the opt-out. The transitional period itself (in the absence of an opt-out) does not, according to the Court, preserve the pre-existing national jurisdiction.

Thus, Article 83(3) UPCA becomes the mechanism through which national jurisdiction may arise: only by opting out an EP patent may the proprietor restore competence to the national courts. In the absence of such a waiver, the UPC retains exclusive competence for all actions, even during the transitional period.

Furthermore, the Court rejected the understanding that "parallel jurisdiction" implies a free choice of forum for EP patent proprietors. Instead, it reasoned that allowing such discretion would undermine legal certainty for third parties, such as potential defendants or those who may wish to bring an action concerning an EP patent against the proprietor, who would otherwise be unable to determine which court holds jurisdiction.

In the Court's view, the opt-out mechanism serves precisely to avoid such uncertainty by acting as a transparent and publicly accessible indicator of jurisdiction through the UPC Register.

Following this interpretation, the Court of Venice invoked Article 27 of Regulation 1215/2012 and Article 25 of the Lugano Convention of 30 October 2007. It held that where another court (here, the UPC) has exclusive competence, a national court is required to raise the lack of jurisdiction *ex officio*. As the proprietor had not exercised an opt-out, the Court declared lack of jurisdiction over all claims relating to the European patent involved in the action.

Practical implications

The decision makes new strategic considerations relevant to the transitional regime. If a patent holder intends to litigate before national courts, relying solely on the transitional regime without formally opting out is riskier in jurisdictions that might adopt the Court of Venice's reasoning. A national action filed under the presumption of concurrent jurisdiction could be dismissed for lack of competence, potentially resulting in the loss of valuable months or even years while the claimant is forced to restart the process before the UPC.

This suggests that patent holders wishing to preserve access to national courts should consider filing an opt-out before initiating proceedings, ensuring that national jurisdiction cannot be superseded by a finding of exclusive UPC competence.

For third parties intending to bring a revocation action or an action for declaration of non-infringement, the strategic considerations differ. As the option to file an opt-out on behalf of the proprietor is not available, they cannot prevent a finding of the UPC's exclusive jurisdiction, if a national court follows the Court of Venice's approach. Given the risk, potential challengers may find it safer to initiate proceedings directly before the UPC to avoid jurisdictional rejection and time losses.

The decision therefore inaugurates a new line of jurisprudential thought within the UPCA framework, by departing from the understanding of parallel jurisdiction as a free choice of forum. This interpretation currently represents an isolated national approach. It will be interesting to see whether other courts in UPC Member States will adopt this approach and begin to decline jurisdiction in such cases, or if future UPC case law expressly addresses and clarifies the matter.

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UPC Substantive Law - Comparisons With the EPO and National Courts

This article is a continuation of a series in the *Hoffmann Eitle Quarterly*, in which we compare substantive law at the UPC with that of the EPO and national courts. More details can be found in the [News section](#) of the Hoffmann Eitle website, which is regularly updated.

UPC Court of Appeal has its say on inventive step

In its decision dated 25 November 2025 in case UPC_CoA_464/2024, the Court of Appeal (CoA) set out the approach to inventive step of the UPC, providing a clear test for assessing obviousness. The wording of the test is very similar to that set out in the *Amgen v Sanofi and Regeneron* case, suggesting that it is likely to be consistently applied across all technical fields.

According to the CoA, the “objective problem” must first be determined by comparing the claim as a whole to the state of the art and thus establishing what the invention adds to it. The inventive concept underlying the claim as a whole should also be considered, which is based on the technical effect(s) that the skilled person would understand to be achieved from the disclosure of the application. Similarly to the EPO, the CoA confirmed that the objective problem should not contain pointers to the solution to avoid hindsight.

The claimed solution is then obvious when at the effective date the skilled person, starting from a “realistic starting point” in the state of the art in the relevant field of technology and wishing to solve the objective problem, would (and not only “could”) have arrived at the claimed solution. The relevant field of technology may be the specific field relevant to the objective problem, as well as any other field in which the same or a similar problem arises and of which the skilled person must be expected to be aware.

The above steps reverse the first two steps of the EPO’s problem-solution approach, which first determines the closest prior art before assessing the technical effect of the distinguishing features over that prior art. The first step of the UPC test therefore provides broader framing of the objective problem which is less focussed on

technical effects over specific prior art documents. If anything the “objective problem” might be closer to the EPO “subjective technical problem” (Case Law of the Boards of Appeal of the EPO, I.D.4.4.2).

Notably, the CoA states that a starting point is realistic if the teaching thereof would have been “of interest” to a person skilled in the art who, at the effective date, wishes to solve the objective problem. This may be a document disclosing several claimed features or one which addresses the same or a similar technical problem, and there may be multiple realistic starting points. This approach appears to be broader than the EPO’s approach, which requires the starting document to have a similar purpose or effect as the invention or at least belong to the same or a closely related technical field.

Further, for a finding of obviousness, the skilled person requires a pointer or motivation that, starting from a realistic starting point, directs them to implement a next step in the direction of the claimed invention. A claimed solution must be considered obvious when the person skilled in the art would take the next step, prompted by the pointer or as a matter of routine, and arrive at the claimed invention. This seems quite different to the EPO, which generally looks for teachings that the effect will be achieved with the distinguishing feature. At the UPC, the “pointer” seems to include more general disclosures in the art directing the skilled person to arrive at the invention, even if they do not teach that doing so achieves the effect of the distinguishing feature.

The CoA also made the general point that the burden of proof for invalidity generally lies with the party asserting invalidity. This differs from the EPO where the burden turns on the grounds and the factual circumstances of the case, which may demonstrate the patentee-friendly approach of the UPC.

Prior use infringement defence at the LD Munich: the UPC puts its German hat on

A decision dated 10 October 2025 of the Local Division (LD) Munich in case UPC_CFI_114/2024 confirms that before the UPC the **prior use defence** is not a unitary concept but a country-by-country defence imported from each national law via **Article 28 UPCA**. Outcomes may therefore diverge between UPC states even within a single case.

The court held that Vibrantz's sintering paste literally and directly infringed the patent as amended. Notably, direct infringement was established even though Vibrantz was only distributing the paste, without using it for "solid joining" as required by the claims. This reflects the UPC's relatively broad stance on direct infringement, as discussed [here](#).

Prior use defence as applied by the UPC

Article 28 UPCA provides that any person who would have had a prior use (or possession) right if a national patent had been granted in a Contracting Member State enjoys the same rights before the UPC in that State. However, Article 28 does not define what "prior use" is.

The court treated Article 28 as a "referral rule": the content, conditions, and scope of the prior use defence are entirely determined by the law of the particular state for which the defence is invoked, and the defence only operates territorially in that state.

For Germany, the court applied German prior use principles (mirroring § 12 PatG), requiring that before the priority date the defendant had already begun using the invention or made the necessary preparations for such use in Germany.

The burden of proof lay with Vibrantz, who produced detailed evidence of consistent manufacture and sale of the sintering pastes before the priority date. Ultimately, Vibrantz was entitled to continue those acts in Germany, and the court found that Heraeus had not substantiated actual infringing acts in other UPC states, so no infringement was found.

Working worse is no defence: a recent UPC order reinforces feature-based claim scope

UPC Order UPC_CFI_630/2025 provides guidance on how to define the scope of protection of a device claim in the context of preliminary injunction (PI) proceedings. It also nicely illustrates that the alleged infringer has the burden of establishing invalidity in these proceedings.

While the claim wording remains the decisive reference point, the court expressly relied on the description and drawings to understand the technical meaning and context of the claimed features, including how they are realised in practice (mirroring the interpretative principles of the EPO's G 1/24).

The order illustrates that, when assessing the scope of protection of a device claim, the structural features of the claim are key, not whether the intended technical advantage is fully realised. Specifically, the court held that, if an embodiment incorporates all structural features, the claim's scope extends to that embodiment, even if it performs less effectively than outlined in the description. Using non-optimal embodiments of an invention is not an infringement defence!

It also provides a concrete example of how the burden of proof for patent invalidity rests with the defendant. Where parties submit conflicting translations of prior art documents, the court made clear that the defendant must justify their translation with sufficient detail. If they fail to do so, the court will accept the applicant's version of the translation. This reinforces the strict evidentiary expectations in preliminary measures at the UPC, where there is typically no scope for further fact-finding or expert evidence beyond the parties' written submissions.

LD Munich rejects GXD-Bio's claim against Myriad; EP 3 346 403 revoked

LD Munich dismissed GXD-Bio's infringement action against Myriad and revoked EP 3 346 403 for added matter.²⁶

²⁶ The LD Munich's Decision dated 19 December 2025 (UPC_CFI_437/2024, UPC_CFI_681/2024) is available [here](#). Myriad was represented by Hoffmann Eitle.

Added matter

The LD revoked EP 3 346 403 for added matter. Specifically, the LD found that a claimed feature relating to quantifying an expression level of a target gene in an FFPE (formalin-fixed paraffin-embedded) tissue sample of human breast cancer was not disclosed as belonging to the invention. The LD ruled that *“it is not sufficient that breast cancer tissue samples are disclosed. Rather, they must also be disclosed as belonging directly and unambiguously to the invention. However, this cannot be established as the application teaches the person skilled in the art that the technical problem is to find universal genes which are not limited to use on specific tissue samples.”*

The LD's consideration of a *“disclosure as belonging to the invention”* in the context of added matter is reminiscent of the German case law, e.g. the Federal Court of Justice (BGH) decision X ZR 75/08 – Reifenabdichtmittel. In this decision, the BGH found that the disclosure of a product *containing* certain components does not equally disclose a product *consisting of* these components *as belonging to the invention* in the absence of any indication in the original application text that it is particularly advantageous or otherwise desired that the product exclusively consists of these components.

The LD further held that *“[t]here is no pointer in the application [...] that the FFPE breast cancer tissue samples are particularly preferred”*. The lack of a pointer referred to by the LD is a criterion well-established in the case law of the EPO's Boards of Appeal: a combination of features taken from separate embodiments of the original application is considered to constitute added matter in the absence of a pointer to that particular combination.

Claim 1 further required that OAZ1 is used as a reference gene in the method for quantifying an expression level of a target gene. The LD concluded that OAZ1 was not *singled out* as the reference gene in the claimed method.

Whereas the LD refers to the singling out from the original application, in the terminology applied by the EPO's Boards of Appeal, the expression *“singling out”* usually refers to a claimed feature. In essence, however, it reveals the same underlying concept, namely that singling out a feature in the claim without direct and unambiguous basis in the original application results in added matter, in line with the case law of the EPO's Enlarged Board of Appeal. Using EPO terminology, one could say that the combination of OAZ1 with FFPE breast cancer sample tissues was singled out from different lists, a list of reference genes and a list of FFPE tissue samples, thereby creating new subject matter in line with the EPO's *“two-list principle”*.

Infringement

GXD-Bio's infringement action against Myriad et al. was also dismissed by the LD. A more detailed account thereof can be found [here](#).²⁷

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