»Holistic« is the new »problem-solution approach«

CoA of UPC settled comprehensive guidelines on substantial patent law

The Court of Appeal (CoA) of the Unified Patent Court (UPC) recently provided detailed guidelines for assessing several aspects of substantive patent law. These guidelines were eagerly anticipated in view of current uncertainties about whether the Court will apply new standards or whether it will align with existing case law established by other courts and in particular the European Patent Office (EPO). On 25 November 2025, both[1] panels of the CoA issued coordinated decisions in *Amgen vs. Sanofi*[2], relating to antibodies for therapeutic applications, and *Meril vs. Edwards*[3], relating to prosthetic heart valves. Most notably, headnotes concerning the assessment of inventive step largely overlap between the two decisions and elaborate further on the »holistic« approach taken by the CoA in its landmark decision in *Nanostring vs. 10X Genomics*[4] instead of relying on the well-established »problem-solution approach« of the EPO.

Here, we discuss the comprehensive decision in *Amgen vs. Sanofi* that sheds light on the Court's principles for inventive step, claim interpretation, added matter, and sufficiency, summarized in over 20 headnotes. Despite some differences, the basic principles laid down in the decisions indicate further convergence between the UPC and the EPO and mark the next step on the way to a harmonized case law across European jurisdictions.

[1] In October 2025, the UPC announced the establishment of a third panel of the UPC's CoA as of January 2026.
[2] UPC_CoA_528/2024, and UPC_CoA_529/2024
[3] UPC_CoA_464/2024, UPC_CoA_530/2024, UPC_CoA_21/2025, UPC_CoA_457/2024, UPC_CoA_532/2024, UPC_CoA_27/2025, UPC_CoA_458/2024, and UPC_CoA_533/2024
[4] UPC_CoA_335/2023, Order of 26 February 2024

Background

The patent at issue in *Amgen vs. Sanofi* was EP 3 666 797 by Amgen, directed to antigen binding proteins that bind to proprotein convertase subtilisin Kexin type 9 (PCSK9) for use in treating diseases associated with elevated serum cholesterol levels. PCSK9 is a serine protease involved in regulating the levels of the low density lipoprotein receptor (LDLR) protein, a receptor that can lower plasma levels of low-density lipoprotein cholesterol (LDL-C).

A few days after publication of the mention of the grant, Sanofi filed a revocation action against the patent with the Central Division, section Munich (CDM), while on the same day Amgen filed an infringement action with the Local Division Munich against both Sanofi and Regeneron. Regeneron filed a counterclaim for revocation, which was referred to the CDM and, where it was combined with the revocation action lodged by Sanofi and the infringement action was stayed. **The CDM found that Amgen's patent lacks inventive step and revoked the patent. In parallel, Sanofi and Regeneron lodged an opposition against the grant of the patent at the EPO, which opposition was rejected by a decision of 21 May 2025.** Amgen appealed the decision of the CDM, and the oral hearing was postponed allowing the parties to comment on the decision of the Opposition Division of the EPO. **While Amgen's appeal at the UPC was successful, Sanofi's and Regeneron's appeal at the EPO is pending before the Board of Appeal (as T 716/25) with oral proceedings scheduled for 13 to 15 April 2026**.

Inventive step

Introduction

At the heart of the dispute between the parties before the UPC was the question of whether the claimed subject matter involved an inventive step. According to Article 56 EPC, an invention shall be considered as involving an inventive step if it is not obvious to the skilled person having regard to the state of the art.

National and regional courts in Europe have developed several approaches and use different principles when assessing whether an invention involves an inventive step. One approach is the EPO's »problem-solution approach«, wherein inventive step is assessed in an objective and predictable manner in a three-step approach. Said approach comprises the steps of determining the **closest prior art**, which discloses, in one single reference, the combination of features which constitutes the **most promising starting point** for a development leading to the invention, establishing the **objective technical problem** to be solved, and considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been **obvious** to the skilled person. While the EPO's approach is well-established, some jurisdictions such as France, Italy, the Netherlands, and Sweden apply this approach though not necessarily as the only one. In other jurisdictions like Germany and the UK, approaches sometimes referred to as being more »holistic« are commonly applied (Reasons 124 in *Amgen vs. Sanofi* as well as Headnote 5 of *Meril vs. Edwards*).

Thus, a key question has been whether the UPC will follow one of these pre-established approaches, and in particular the EPO's problem-solution approach, or whether the Court will develop its own approach for assessing inventive step.

[5] *Amgen vs. Sanofi*: Headnotes 10 to 22, and Reasons 126 to 138; *Meril vs. Edwards*: Headnotes 4 to 13 and Reasons 128 to 136 with Headnote 13 adding that *»For an inventive step to be present, it is not necessary to show improvement of the technical teaching as defined by the patent claims over the prior art. Inventive step may also be found if the patent claims disclose a non-obvious alternative to solutions known in the prior art.«*

UPC Case Law

First insights into the UPC's framework of assessing inventive step were given by the CoA in *NanoString vs. 10x Genomics* on 26 February 2024. Further guidance is now provided in the two CoA decisions in *Amgen vs. Sanofi* and *Meril vs. Edwards*, wherein the coordinated provision of the UPC's »holistic« approach sets a new hallmark in UPC case law[5]. The decision in Amgen vs. Sanofi additionally elaborates on guidelines concerning the assessment of a reasonable expectation of success, which is a key topic in the life science sector.

In a first step of the holistic approach of the UPC the object of the invention has to be established from the perspective of the skilled person with its common general knowledge at the relevant date, i.e., the **objective problem**. This must be done by establishing what the invention adds to the state of the art based on the claim as a whole in the context of the description and the drawings. Thus, the **inventive concept** underlying the invention (the technical teaching) is also to be considered, which must be based on the technical effect(s) that the skilled person understands is/are achieved with the claimed invention on the basis of the patent* (Headnote 11). Further, the objective problem is formulated, though without any pointers to the claimed solution to avoid hindsight (Headnote 12).

In a second step, it is assessed whether the claimed solution is **obvious** when, at the relevant 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 (Headnote 13). In this regard, it is to be noted that a starting point is realistic if the **teaching** therein would have been **of interest** to the skilled person, e.g., when the relevant piece of prior art discloses several relevant features and/or addresses the same or a similar underlying problem as that of the claimed invention. In case of **more than one realistic starting point**, the claimed invention must be inventive starting from each of them (Headnote 15). As a general rule, a claimed solution is considered not inventive/obvious, when the skilled person **would** take the next step, as a **matter of routine or prompted by motivation or a pointer** in expectation of finding an envisaged solution of the technical problem, and arrive at the claimed invention (Headnote 16). The latter is generally the case when, results of the next step were **clearly predictable** or where there was a **reasonable expectation of success**, with the burden of proof lying on the party asserting invalidity of the patent (Headnotes 17 and 18).

Whether there is a reasonable expectation of success (see page 11 of this issue for a spotlight article) depends on the circumstances of the case and **implies the ability of the skilled person to predict rationally, based on scientific appraisal of the known facts before a research project was started, the successful conclusion of that project within acceptable time limits** (Headnote 19).
For example, the more unexplored a technical field of research, the more difficult it is to make predictions about the project's successful conclusion and the lower the expectation of success (Headnote 20). Further, envisaged practical or technical difficulties as well as costs involved in testing whether the desired result will be obtained when taking the next step may also withhold the skilled person from taking that step. However, the stronger a pointer towards the claimed solution, the lower the threshold for

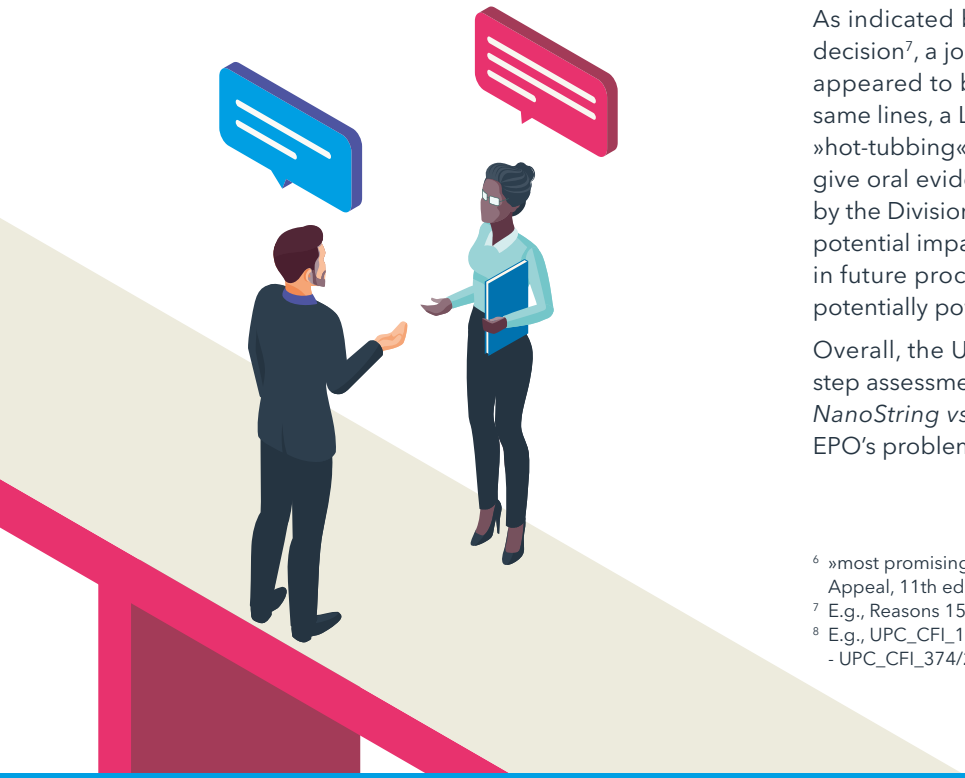
***Update:** The coordinated wording of the two decisions was subsequently amended from »... based on the technical effect(s) that the skilled person on the basis of the application understands is (are) achieved with the claimed invention« to read as »...on the basis of the patent ...« (emphases added). The amendment was apparently inspired by the EPO's Board of Appeal case law in G 2/21 in view of the fact that a court commonly assesses the patent at issue, with any potential deviations from the application as originally filed typically giving rise to added matter.

a reasonable expectation of success (Headnote 20). Also, the fact that other persons or teams were working contemporaneously on the same project does not necessarily imply that there was a reasonable expectation of success. Rather, such a situation may also indicate that it was an interesting area to explore with a mere hope to succeed (Headnote 22). Hence, the decisive question is whether the claimed subject matter follows from the prior art in such a way that the skilled person **would** have found it based on their knowledge and skills at the relevant date.

Discussion

When comparing the UPC's holistic approach with the EPO's problem-solution approach, some relevant differences can be observed.

Most notably, the UPC starts with establishing the objective problem before determining a realistic starting point in the prior art, whereas the EPO first determines the closest prior art and then establishes the objective technical problem based on features distinguishing the claimed subject matter from said closest prior art. Consequently, **the UPC's objective problem is to be formulated based on the contribution of the claimed subject matter, including the inventive concept underlying the invention, to the state of the art** but independent from any specific prior art, whereas the **EPO's objective technical problem is formulated depending on a specific piece of prior art**, with a view to difference(s) between the claimed subject matter and the previously determined closest prior art.



Furthermore, according to the UPC's approach, there can be **several realistic starting points that are of interest** to the skilled person wishing to solve the objective problem, and it is **not necessary to identify the »most promising« starting point**[6] as typically done in the approach taken by the EPO. However, if there are several realistic starting points, the claimed invention must be inventive starting from each of them (Headnote 15).

On the other hand, there are also some common grounds between the two approaches*. For example, the last step both of the two approaches is more or less identical, because in both approaches the decisive question is whether the skilled person **would**, and not only could, have arrived at the claimed solution without any inventive skills and imagination. That is, both approaches **require a pointer or motivation** towards the claimed invention for obviousness.

Nevertheless, the CoA also emphasized that, in the context of reasonable expectation of success, when the patentee brings forward and sufficiently substantiates uncertainties or practical or technical difficulties, the burden of proof that the same would not prevent a skilled person from having a reasonable expectation of success falls on the party alleging obviousness (Headnote 21). This may put a comparatively high burden on the party challenging the patent both when establishing the case and when rebutting the patentee's arguments.

In this context, expert opinions may be of higher relevance before the UPC compared to proceedings before the EPO. As indicated by the citation of expert statements in the decision[7], a joint expert declaration of the parties' experts appeared to be of relevance to the Court. Along the same lines, a Local Division recently suggested a so-called »hot-tubbing« of experts, where experts from both parties give oral evidence in that they answer questions set out by the Division[8]. Hence, parties may wish to consider the potential impact of the UPC's reliance on expert evidence in future proceedings before the UPC as a new, but potentially powerful, procedural facet.

Overall, the UPC appears to prefer a holistic inventive step assessment in line with the earlier CoA decision in *NanoString vs. 10x Genomics* rather than echoing the EPO's problem-solution approach. However, while putting

[6] »most promising springboard«, see the Case Law of the Boards of Appeal, 11th edition, I.D.3.7.2
[7] E.g., Reasons 159, 174, and 187
[8] E.g., UPC_CFI_146/2024 - UPC_CFI_496/2024, UPC_CFI_147/2024 - UPC_CFI_374/2024, UPC_CFI_148/2024 - UPC_CFI_503/2024

more emphasis on the object of the invention and allowing more flexibility in the discussion of possible springboard documents, the assessment of obviousness as laid down by the UPC still appears to be closely related to the EPO's approach. Furthermore, the Court appears to be interested in emphasizing that despite differences in the respective approaches to assessing inventive step, their application should typically lead to identical conclusions (Reasons 124 in *Amgen vs. Sanofi*; also, e.g., Headnote 5 of *Meril vs. Edwards*).

***Note:** Apparently, the main difference between the approach applied by the UPC and the EPO resides in the consideration of the inventive concept as a whole by the UPC, in contrast to the exercise performed according to the EPO's problem-solution approach that includes identifying distinguishing features and their effects before formulating the problem within the boundaries of the plausibility concept as laid down in G 2/21. However, in both cases there is the formulation of a problem, and the remaining considerations are comparable. For example, even in the EPO's approach, situations can arise that require discussing more than one »most promising« starting point.*

Claim interpretation

Previous UPC CoA decisions have established that the interpretation of a patent claim is a matter of law and that the patent claim is not only the starting point, but the decisive basis for determining the protective scope of a European patent[9]. In particular, a patent claim is to be interpreted from the point of view of a skilled person and its interpretation does not depend solely on the strict, literal meaning of the wording used. Rather, the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim and not only to resolve any ambiguities in the patent claim. These basic principles were confirmed in *Amgen vs. Sanofi* (Reasons 39) and appear to be in overall alignment with recent EPO case law[10].

Amgen vs. Sanofi additionally shed light on two more specific questions: first, whether conclusions can be drawn from the subject matter of a dependent claim and its features when interpreting the main claim, and second, on how to interpret medical use claims.

Concerning the first question, it was concluded that the answer depends on the circumstances of the individual case, and the decision generally argues against the possibility of drawing conclusions about the interpretation of the main claim from a dependent claim in cases where the dependent claim only adds an additional feature that does not provide a more specific description of the features of the main claim (Headnote 1 and Reasons 45 and 46).

Importantly for the pharmaceutical and biotech sectors, the Court provided further guidance concerning the second question, namely on the principles for the interpretation of medical use claims. The Court stated that, **where a medical use claim format is used, it is an implicit and inherent feature of a medical use claim that the claimed product must be objectively suitable for the claimed use, i.e., it must be therapeutically effective**. Hence, not any effect

[9] UPC_CoA_768/2024, *Insulet vs. EOFlow*, Headnote 1; UPC_CoA_335/2023, *NanoString vs. 10x Genomics*, Headnote 2

[10] e.g., G 1/24, Headnote *(while the claims are the starting point and the basis for assessing the patentability of an invention, the description and drawings shall always be consulted to interpret the claims, and not only if the skilled person finds a claim to be unclear or ambiguous when read in isolation)*

is sufficient, **but the treatment must be meaningful** (Headnote 2). More specifically, **therapeutically effectiveness requires a noticeable improvement** of the medical condition, **irrespective whether any minimum required effect can be derived from the claim or the description**. Thus, medical use claims do not require any particular threshold regarding the level of therapeutic effect that the claimed product must achieve, as long as it is therapeutically effective in a meaningful way (Headnotes 2 and 3, and Reasons 46 to 49).

Notably, in the latter point, the CoA decision diverges from the previous decision of the CDM that found that *»[i]n view of the teaching of the Patent as a whole, the skilled person would understand the claimed treatment not to be limited to a particular lowering of cholesterol levels as long as there is some (measurable) reduction of cholesterol levels in vivo and provided the therapy is safe«* and when assessing inventive step thus formulated the underlying objective problem as the provision of *»a treatment for hyper-cholesterolemia (or other conditions related to elevated serum cholesterol levels) using PCSK9 as a target«*[11]. In the present decision, the CoA instead formulated the objective problem as the provision of a *»therapeutically effective treatment or prevention of hypercholesterolemia or atherosclerotic disease or other conditions related to elevated serum cholesterol levels«*[12] in line with the underlying problem formulated by the EPO[13].

Added matter

Based on the rationale that patentees shall not be able to claim more than they actually contributed to the state of the art at the priority date, a European patent may be revoked if its subject matter extends beyond the content of the application as filed or, if it was granted based on a divisional application, beyond the content of the earlier application as filed (Articles 123(2) and 76 EPC).

In *Amgen vs. Sanofi*, the Court confirmed that the assessment of whether there is added matter is a question of law to be decided on the basis of the facts brought forward by the parties, namely the relevant claims and the application as filed (Headnote 4 and Reasons 61). The Court summarized that for the assessment of added matter it must be ascertained what the skilled person would derive directly and unambiguously, using its common general knowledge and seen objectively and relative to the date of filing, from the whole of the application as filed. The Court further confirmed that, **as the application is to be considered as a whole, implicitly disclosed subject matter shall also be considered part of its content**. Implicitly disclosed subject matter refers to matter that is a clear and unambiguous consequence of what is explicitly mentioned (Reasons 54).

In *Amgen vs. Sanofi*, the Court also indicated that, in case of a **combination of features, it is neither required that literal support be present in the application nor that at all features of a claim can be found in one paragraph or one example** of the application to comply with Article 138(1)(c) EPC. The provision of alternatives does not mean that the skilled person is required to make an arbitrary selection from various lists **if it is clear to the skilled person which of the alternatives is preferred** (Reason 90).

Given the EPO's well-established »gold standard«[14] and »selection of two lists«[15] approaches, the respective basic principles appear to be aligned between the two institutions. However, while the EPO in many cases appears to require a near literal or verbatim basis in the application as filed, the UPC appears to emphasize consideration of the content of the application as a whole. Hence, it remains to be seen whether the UPC will adopt in practice a comparably strict approach as the EPO when assessing different aspects of added matter.

[11] UPC 1/2023, Reasons 6.30 and 8.27
[12] Reason 38
[13] Opposition Division decision in EP 3 666 797, Reason 10.5.3 *(»provision of a therapeutically effective treatment, prevention or risk-reduction of the conditions related to elevated serum cholesterol levels referred to in the claims«)*
[14] Case Law of the Boards of Appeal, 11th edition, II.E.1.3.1
[15] Case Law of the Boards of Appeal, 11th edition, II.E.1.6.1 and 1.6.2

Sufficiency of disclosure

An invention is to be disclosed in a manner sufficiently clear and complete to be carried out by a person skilled in the art (Article 83 EPC). This requirement is based on the rationale hat the grant of a patent monopoly cannot be justified if the claimed subject matter cannot be achieved by the skilled person on the basis of the patent description. In *Amgen vs. Sanofi*, the CoA summarized the principles for assessing sufficiency of disclosure as applied by the UPC (Headnotes 5 to 9, and Reasons, 103 to 108) as follows:

Sufficiency of disclosure has to be examined on the basis of the patent as a whole from the perspective of the skilled person with its common general knowledge at the filing or priority date. The test to be applied is whether the skilled person is able to reproduce the claimed subject matter on the basis of the patent without any inventive effort and without undue burden. An invention is sufficiently disclosed if the patent specification shows the skilled person at least one way – and in case of functional features: one technical concept – of performing the claimed invention. Where a claim contains one or more **functional features**, it is **not required** that the disclosure includes **specific instructions as to how each and every conceivable embodiment within the functional definition(s) should be obtained**. A fair protection requires that variants of specifically disclosed embodiments that are equally suitable to achieve the same effect, which could not have been envisaged without the invention, should also be protected by the claim. Consequently, any **non-availability of some embodiments** of a functionally defined claim **is immaterial to sufficiency**, as long as the skilled person through the disclosure is able to obtain suitable embodiments within the scope of the claim.

The CoA also indicated that a **reasonable amount of trial and error does not prevent the invention from being enabled** (Reasons 114). As the CoA concluded that **the burden of presentation and proof lies with the party invoking invalidity** of the patent, this may imply a higher hurdle for the party questioning a patent's validity than for the patent holder. For example, in *Amgen vs. Sanofi*, the CoA indicated that the mere fact that a specific method is laborious, time-consuming, and/or challenging does not automatically mean that such method constitutes an undue burden. Furthermore, the CoA found that the overall sufficiency attack failed as the Respondents *»have not shown that the skilled person **would be unable** to obtain further antibodies with the claimed functional properties in a reliable manner with a reasonable amount of trial and error and without undue burden. The Court further stated that the Respondents' complaint that the level of proof required is too high can be dismissed, already for the reason that **no proof of a failed attempt** to obtain suitable antibodies within the scope of the claim was submitted«* (emphases added) (Reasons 114 and 121). Thus, it will be interesting to see how the UPC's approach will develop in the future in this regard.

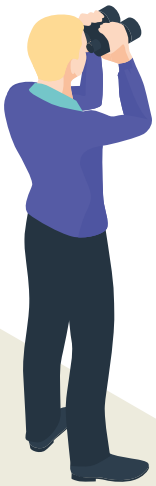
Overall, the principles of assessing sufficiency of disclosure appear to be aligned between UPC and EPO, thus offering an increasing degree of legal certainty. Especially in case of functionally described inventions, as frequently seen, e.g., in case of antibody-based claims, these shared principles may be more patentee-friendly compared to some other jurisdictions that require narrower, structural definitions in such cases, e.g. the US.

Outlook

Overall, the decision *Amgen vs. Sanofi* paves the way for further convergence between case law by the UPC and the EPO. The CoA of the UPC also settled a detailed »holistic« hallmark framework for assessing inventive step in the life science sector in the two separate, though well-coordinated decisions, the clarity of which is certainly highly welcomed by users of the UPC system.

Despite some differences to the EPO's well-established problem-solution approach, the CoA also indicated that currently existing guidelines should generally lead to the same conclusion. Now, it remains to be seen how well outcomes in parallel UPC and EPO proceedings will align.

In *Amgen vs. Sanofi*, the CoA postponed oral proceedings to allow the parties to comment on the decision of the Opposition Division of the EPO, which came to a different conclusion than the CDM had concerning the validity of the patent at issue, and finally declared the patent valid in line with the previous outcome of the EPO's first instance proceedings, overturning the CDM's initial decision. Now, patent practitioners across Europe are eagerly awaiting the outcome of the last chapter of this case to see whether the EPO's Board of Appeal will – or will not – further strengthen the harmonization of case law across European jurisdictions.



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