Inventive Step at the EPO and the UPC

»Reasonable Expectation of Success«, »Try and See«, and Emerging UPC Practice

In life sciences cases before the European Patent Office (EPO), the assessment of obviousness typically turns on whether the skilled person would have proceeded with a »reasonable expectation of success«. Other approaches, such as »try and see«, play a more limited role. Recent UPC case law indicates that a similar hierarchy of tests will apply under the UPC.

Inventive step before the EPO

Pursuant to Article 56 EPC, an invention is considered to involve an inventive step if, having regard to the state of the art, it is not obvious to the person skilled in the art. For assessing inventive step, the EPO uses the so-called problem–solution approach which comprises three steps.

First, the closest prior art is identified. Second, the objective technical problem is formulated on the basis of the technical effect or effects achieved by the features distinguishing the claimed invention from that prior art. Third, it is assessed whether, starting from the closest prior art and confronted with the objective technical problem, the skilled person would have considered the claimed solution obvious.

In biotechnology and pharmaceutical cases, the third step of the problem–solution approach is frequently informed by the question whether the skilled person would have embarked on the claimed course of action with a »reasonable expectation of success«. This test was articulated in the early 1990s and has since become the predominant standard for assessing obviousness in these technical fields.

According to the case law of the EPO Boards of Appeal (CLBA, 11th edition 2025, I.D.7.1), a »reasonable expectation of success« exists where the skilled person can, on the basis of the prior art and common general knowledge at the relevant date, reasonably conclude that the envisaged technical teaching will solve the objective technical problem within acceptable time limits. Predictability or certainty of success is therefore not required for a finding of obviousness (see, e.g., T 149/93, reason 5.2, and T 296/93, reasons 7.4.4.).

Contrary to its present-day perception as an alternative test setting a lower bar for a finding of obviousness, **the »try and see« approach was originally developed within the framework of »reasonable expectation of success«.**

The Boards of Appeal have applied »try and see« in situations where the closest prior art provides a clear pointer towards a limited number of concrete options and where routine experimentation would allow the skilled person to straightforwardly verify whether the envisaged solution works (see, e.g., CLBA, 11th edition 2025, I.D.7.4). In such cases, the Boards held that the skilled person would have had either some expectation of success or, at worst, no particular expectations at all, but merely a »try and see« attitude. Such an attitude, however, was not considered equivalent to an absence of a reasonable expectation of success (see, e.g., T 1045/98, reasons 16 and 17).

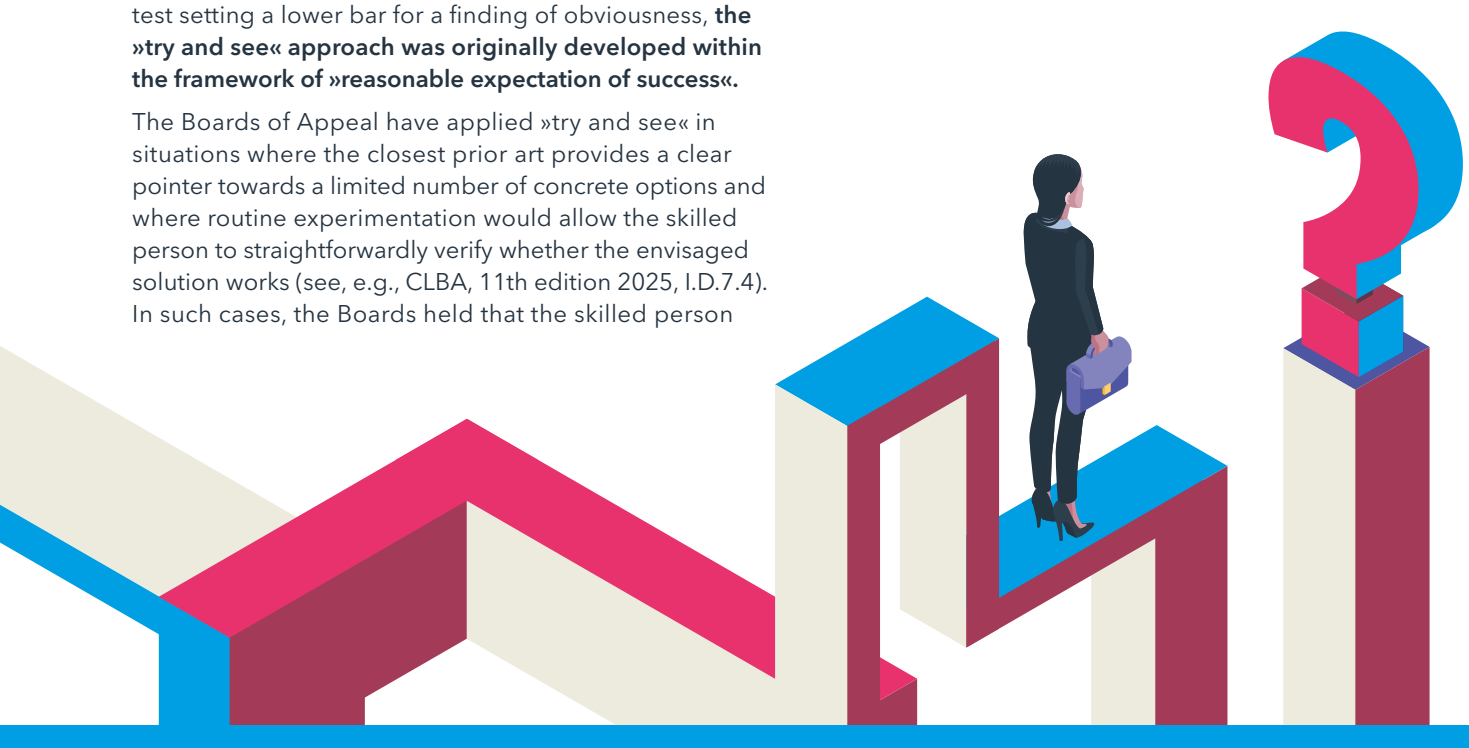
Importantly, the Boards of Appeal have consistently rejected any notion that »try and see« allows the skilled person to explore technical possibilities at will. Its application presupposes a clear direction provided by the prior art and the absence of substantiated technical uncertainties that would deter the skilled person from proceeding.

Nevertheless, the »try and see« approach is often regarded as conceptually separate from, and less effective than, the »reasonable expectation of success« standard when raising objections of obviousness. This perception may reflect an increasing tendency in EPO case law to apply »reasonable expectation of success« in a manner approaching predictability, particularly in inventions directed to therapeutic use in humans.

Presumably for these reasons, the »reasonable expectation of success« test is commonly perceived as being more patentee-friendly than the »try and see« approach.

Inventive step before the UPC

One of the most closely watched questions for the patent community has been how the UPC will assess inventive step in biotechnology and pharmaceutical cases. Recent decisions in the dispute between Amgen and Sanofi concerning PCSK9 inhibitors for the treatment of hypercholesterolaemia provide valuable guidance.



The UPC Central Division

In its decision of 16 July 2024 (UPC Central Division, Munich, UPC_CFI_1/2023, decision of 16 July 2024 (*Amgen v Sanofi*)), the Munich Central Division of the UPC revoked Amgen's PCSK9 antibody patent EP 3 666 797 B1 for lack of inventive step. Starting from prior art suggesting the use of antibodies blocking PCSK9, the court held that the skilled person would have pursued this route as **»a next step«** (see headnote 4).

The Central Division considered it unnecessary to decide whether a reasonable expectation of success was required in circumstances where the prior art provided a clear incentive and where implementation of the suggested route did not appear to involve more than routine experimentation (see reason 8.56).

In doing so, the Central Division treated the »next step« analysis – closely reminiscent of the EPO's »try and see« approach – as conceptually distinct from the »reasonable expectation of success« standard, thereby echoing a prevalent perception in current EPO practice.

The decision thus appeared to signal a shift towards a lower threshold for obviousness before the UPC than that traditionally applied under the EPC, raising concerns that the UPC might develop into a comparatively less patentee-friendly forum.

Against this backdrop, the judgment of the UPC Court of Appeal was awaited with particular anticipation, as it was expected to clarify whether the UPC would chart a divergent course or instead align its approach with established EPO jurisprudence.

The UPC Court of Appeal

In its decision of 25 November 2025 (UPC Court of Appeal, UPC_CoA_528/2024 and UPC_CoA_529/2024, decision of 25 November 2025 (*Amgen vs. Sanofi,* for a general analysis see page 3 of this issue)), the Court of Appeal set aside the first-instance decision and upheld the patent. **The Court articulated a framework for assessing inventive step that closely corresponds to the established EPO jurisprudence on »reasonable expectation of success«** (see headnotes 17 and 19-20).

In this context, the Court held that

a claimed solution is obvious only if the skilled person would have taken the next step in the expectation that it would solve the objective technical problem.

Obviousness may arise where the outcome is clearly predictable or where the skilled person has a reasonable expectation of success. The Court clarified that such an expectation implies the ability of the skilled person to predict rationally, on the basis of a scientific appraisal of the known facts at the outset of a research project, that the project would be successfully concluded within acceptable time limits. **The Court further held that the stronger the pointer towards the claimed solution, the lower the threshold for establishing a reasonable expectation of success** (see headnote 20).

On the facts of the case, the Court of Appeal identified substantial uncertainties at the priority date concerning the relative contribution of extracellular and intracellular PCSK9 pathways. These uncertainties deprived the skilled person of a reasonable expectation that antibody-based inhibition of extracellular PCSK9 would be therapeutically effective in vivo.

Outlook

The UPC Court of Appeal's decision points to convergence, rather than divergence, between UPC and EPO practice in the assessment of inventive step. For the foreseeable future, »reasonable expectation of success« is likely to remain the dominant framework for evaluating obviousness before both venues.

At the same time, the Court recognized that a strong pointer in the prior art may lower the threshold for establishing a reasonable expectation of success, echoing early EPO case law in which »try and see« reasoning developed within that framework. In practice, this may lead to outcomes resembling »try and see« in cases where the closest prior art clearly points in the claimed direction and only routine verification is required.

From a strategic perspective, nullity plaintiffs are therefore best advised to frame such arguments before the UPC as applications of the »reasonable expectation of success« framework. In light of the current perception of »try and see«, opponents before the EPO may wish to adopt a similar approach, making use of the terminology now endorsed by the UPC.

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