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Edwards v Meril: 3 insights from the UPC Court of Appeal's decision

With its landmark ruling, the court has delivered guidance for patentees and litigants—including three takeaways for counsel and rightsholders, explain Tobias Wuttke and Axel Berger of Bardehle Pagenberg.

The first-instance decisions by the Central Division (CD) Paris and the Local Division (LD) Munich in the transcatheter heart valve dispute between Edwards and Meril were among the first final decisions in revocation and infringement actions before the UPC (Decisions of July 19 2024, UPC_CFI_255/2023 et al., and November 15, 2024, UPC_CFI_15/2023).

About a year later, the Court of Appeal of the UPC (CoA) has now reviewed these decisions, providing in its appeal ruling three main insights on (1) subsequent applications to amend the patent, (2) the standard for assessing inventive step, and (3) the proportionality of permanent injunctions (Decision of November 25, 2025, UPC_CoA_464/2024 et al.).

The decision was issued on the same day as the decisions in the parallel pharma cases ***Amgen v Sanofi*** and ***Amgen v Regeneron***, which offer further guidance on key patentability issues, including the interpretation of second medical use claims, sufficiency of disclosure, and the concept of 'reasonable expectation of success' in the context of inventive step (Decisions of 25 November 2025, UPC_CoA_528/2024 and UPC_CoA_529/2024).

1. Subsequent applications to amend the patent: towards a more relaxed test?

The Rules of Procedure of the UPC aim to balance the interest of a revocation (counter) claimant in swift legal protection with the patentee's/defendant's right to be heard and the need for effective protection of intellectual property.

This is reflected in the court's discretion to permit late-filed patent amendments (Rules 50.2, 30.2 RoP).

In the present matter, Edwards had filed three applications to amend the patent with the CD Paris:

- a first one with its defence to the statement of revocation on October 16, 2023 (containing 84 auxiliary requests);
- a second one on January 22, 2024 filed after Meril brought a counterclaim for revocation in the infringement proceedings—(containing 41 auxiliary requests), which was rejected as the CD did not accept the coordination of the (then) separate revocation proceedings as a legitimate reason for late filing (order of February 27, 2024); and
- a third one on April 12, 2024, after the counterclaim was referred to the CD, limiting the number of requests to one unconditional amendment and 6 auxiliary requests already part of the second application. This was accepted by the CD Paris, which also granted Meril one month to file a response (order of April 30, 2024).

The CoA accepted the coordination of the (now) joined revocation proceedings as a legitimate interest for subsequent amendments. Contrary to the CD Paris, the CoA held that the admissibility of a prior application to amend the patent is not a prerequisite for admitting a subsequent request.

As a result, it did not have to address the 'reasonable number' of conditional amendments (cf. R. 30.1 lit. c.) RoP) regarding the first and second request. However, the court noted that frustrated expenses of the claimant caused by patentee's subsequent limitation do not affect the admissibility of said limitation but rather could lead to a different allocation of costs.

For now, the CoA's standard on subsequent applications to amend the patent seems more relaxed than the current case law of the Court of First Instance suggested, especially regarding the irrelevance of a prior request's admissibility as long as a legitimate interest is given for a subsequent one.

2. Inventive step—'holistic' over 'differentiating'

As a common court of the Contracting (EU) Member States, the UPC also has to unify the different approaches towards inventive step within them. The CoA opted for the more "holistic" approach (called the "underlying-problem approach" by some, in contrast to [the EPO's "problem-solution approach"](#)), meaning that the objective problem of the invention is to be determined in comparison to the state of the art "not by looking at the individual features of the claim, but by comparing the claim as a whole in the context of the specification and the drawings, thus also considering the inventive concept underlying the invention (the technical teaching)".

Since the second panel of the CoA follows the identical approach (see Decisions of November 25, 2025, UPC_CoA_528/2024 and UPC_CoA_529/2024), this is now the guiding test at the UPC.

While the "problem-solution approach" is arguably more tangible, it is, by its very nature, also more susceptible to hindsight. The "underlying-problem approach" may be able to mitigate this risk and may also be a better representation of the normative character of inventive step.

According to the CoA's assessment, the different approaches should generally produce the same results. However, if applied stringently, there may be categories of cases where this does not necessarily apply (see compilation by Engels and Ackermann in [GRUR 2024, 729](#)).

3. Permanent injunctions—denial as the exception to the rule

Art. 63 (1) UPCA states that the court 'may' grant an injunction, which has sparked debate on whether this entails discretion for the court and to what extent.

The CoA held that the entitled party has a civil law claim under Art. 63 (1) UPCA, meaning that the court—in positive terms—does not have discretion over the grant of a permanent injunction. In negative terms, however, the court may deny the grant based on reasons of proportionality. In doing so, it may also consider the interests of third parties.

If patients are the third parties in question, an exception may be justified if the infringing product is (i) "the sole available treatment method" or (ii) "represents an improvement upon the available treatment methods, resulting in a notable enhancement of patient care".

Based on this standard, the injunction issued by the LD Munich did not cover XL-sized products—for which no alternative exists regarding certain patients—already scheduled for surgery by the time of the LD’s decision. For future cases, the LD Munich considered it sufficient that Edwards had set up a “Medical Request Portal” through which doctors could obtain a “single-use license” for Meril’s XL-sized product if there was no adequate alternative.

The CoA, however, found that the future supply of patients with XL-sized products should not be left to the claimant’s discretion in maintaining or closing said licensing portal. In consequence and upon mutual request by the parties, the CoA established a new explicit exception, which only requires a “notification of intention of use by a physician” and a confirmation “that the XL device is the only available treatment option”.

Edwards v Meril is apparently only the second case where a disproportionality defence against an injunction (preliminary or permanent) was at least partially successful. The first was an exception granted by the LD Duesseldorf in a preliminary injunction case based on the imminent damage for the defendant caused by the injunction (due to contractual claims for damages by a customer) being significantly higher than the damage caused on the applicant’s part (order of October 31, 2024, UPC_CFI_368/2024—***Valeo v Magna***).

Further cases will certainly test the boundaries of proportionality—however, for the time being, arguing disproportionality remains a high hurdle.

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