



Paris central division maintains Edwards patent in amended form

Meril Italy Srl and two other Meril entities v Edwards Lifesciences Corporation

(revocation action UPC_CFI_255/2023 and counterclaims for revocation
UPC_CFI_15/2023)

Decision of 19 July 2024 ([ORD_598365/2023](#))

The Court (Paris central division) issued a single decision in these consolidated proceedings maintaining EP 3 646 825 (EP'825) based on Auxiliary Request 2.

Background

EP'825 relates to prosthetic heart valves having a sealing mechanism to prevent or minimize perivalvular leakage.

This UPC action has previously attracted commentary due to Meril's tactic of launching a revocation action at the central division through a subsidiary (Meril Italy Srl) while an infringement action against two Meril Group entities (Meril GmbH and Meril Life Sciences Pvt Ltd) was already pending before the Munich local division. Edwards' preliminary objection challenging the competence of the central division under Article 33 (2) of the Unified Patent Court Agreement (UPCA) was rejected as the Meril entity bringing the revocation action before the central division was not considered to be the same party as those sued before the Munich local division.

When considering consolidation, the Court weighed up the interest in issuing expeditious decisions, significant time difference between the decisions of the involved divisions and

the similarity of grounds for invalidity in both proceedings. Consolidation of proceedings before the local division was rejected in view of Article 33(4) UPCA giving primacy to competence of the central division. The Munich local division's suggestion that Rule 34 of the Rules of Procedure (RoP) should be interpreted to require a joint hearing for the revocation proceedings before a panel comprising all judges from both the central and local divisions was also rejected. Hence the Court decided to join the revocation action and the counterclaims for revocation noting that these claims retain their distinct legal identities and must be adjudicated independently, even if a single decision is ultimately issued.

The most interesting aspects of this decision are discussed below:

Admissibility of amendments

With its initial statement of defence, Edwards included a conditional application to amend the patent and 84 auxiliary requests which were argued by Meril to be inadmissible for not meeting the structure and content requirements of an application to amend a patent as set by Rules 30 (1) and 50 (2) of the RoP. Edwards filed a second request to amend the patent, consisting of 41 auxiliary requests and finally, after the closure of the written procedure and following the interim conference, a third request to amend the patent was filed proposing one unconditional amendment and six auxiliary requests.

The claims as granted were found to add matter and the Court, therefore, was required to decide the issue of admissibility of the amendments.

The Court reiterated that Patentees can amend provided that an application to amend is included in the statement of defence and contains the information referred to in Rule 30 (1) (a) (c) RoP. This includes the language of the application, an indication of whether the amendments are conditional or unconditional, and an explanation of how the amendments comply with Articles 84 and 123 (2) and (3) EPC, and why the proposed amended claims are valid. Rule 30 (2) RoP also allows for a subsequent request to amend the patent, provided that such request is admitted into the proceedings with the permission of the Court. The term 'subsequent' must be interpreted as referring to a request which follows a previous one, so the subsequent request amends the original application to amend the patent.

The Court noted that **if an initial application to amend the patent is found to be inadmissible, any subsequent request to amend the patent must also be considered inadmissible**. This is because a subsequent request inherently presupposes that a previous request was validly submitted. Amending an invalid previous request could be

seen as an inadmissible circumvention of the procedural provisions for amending the patent.

In this case, Edwards submitted a timely application to amend the patent, included in its defence to revocation, and the Court considered its content meets the requirements set forth in RoP for admissibility. The Court held that **while a complete lack of explanation in an amendment request can render it inadmissible, an insufficient explanation does not necessarily have the same effect**. In the latter case, the application may be unsubstantiated but not inadmissible. This unsubstantiated nature would not prevent the defendant from filing a subsequent, compliant request to amend the patent.

The Court considered the number of the amendments originally filed (84 auxiliary request) to be extremely high, potentially hindering the efficiency of proceedings and the goal of delivering expeditious decisions. However, **it did not consider the number 'unreasonable', considering the extreme complexity of the case** (in particular, the number of grounds of invalidity raised), the importance of the patent at issue and the interrelationship with other proceedings concerning related patents of the same family. **The Court noted that lack of a consistent interpretation of the expression 'reasonable in number' also suggests a less strict interpretation of this relevant provision**. Hence, the initial application to amend the patent was considered admissible and Edwards could file a subsequent request to amend the patent.

Claim Interpretation

The Court reiterated a principle set out in a previous UPC decision that even though a patent claim is decisive basis for determining the protective scope of the European patent; the interpretation of a patent claim does not depend solely on the strict, literal meaning of the wording used, as the description and the drawings must always be used as explanatory aids for the interpretation of the patent claim, but this does not mean that the patent claim serves only as a guideline and that its subject-matter may extend to what, from a consideration of the description and drawings, the patent proprietor has contemplated (see order of Court of Appeal issued on 26 February 2024, case UPC_CoA_335/2023).

This issue of using description and drawing to interpret claims is also live at the EPO with pending EPO Enlarged Board of Appeal referral G1/24. It will be interesting to see if the EPO's position will be clarified in a similar direction to UPC case law as opposed to some EPO Technical Board of Appeal case law which has held that description and drawings should only be consulted if claim terms are unclear.

Priority: Rebuttable Presumption

The right to claim priority was challenged on the basis that priority was being claimed by a party other than the applicant of the initial application or their successor in title. The court noted the established position that the priority right is distinct from the right to the subsequent patent application. However, it was also acknowledged that agreements under which title to the subsequent application is acquired usually fail to distinguish between the two rights and, under normal circumstances, any party transferring the right to a subsequent application intends for the subsequent applicant to benefit from the priority right. Furthermore, in most European national legislation formal requirements for transferring priority rights do not exist. The facts established a rebuttable presumption of the entitlement to priority (as set out by the EPO Enlarged Board of Appeal in G1/22 and G2/22) in favour of Edwards and Meril had not provided any evidence to rebut the presumption, such as showing that the priority rights were the subject of a separate dispositive act in favour of third parties.

Priority was however, lost as some of the features present in claim 1 of auxiliary request 2 were not considered to be disclosed in the priority document

Inventive Step

The Court held that the prior art did not suggest that modifying the geometry of the heart valve frame as claimed in claim 1 of auxiliary request 2 would be an obvious approach.

EP '825 stated that the 'honeycomb' / 'hexagonal' structure of the frame "reduces the crimping profile of the valve" and provides stability, radial strength etc. Meril argued that the combination of features in claim 1 of auxiliary request 2 does not offer any discernible technical effect vis-à-vis the prior art and therefore is a mere obvious alternative. They submitted expert declarations stating that the mere fact of having a frame entirely made up of hexagonal cells, as recited in claim 1, was not sufficient to achieve the technical effects mentioned in the patent.

Interestingly, the Court considered that “the ordinary distribution of the burden of proof” would mean that Meril must present evidence for the alleged lack of a technical effect as the party asserting the invalidity of the patent must prove the relevant constituent facts to rebut the presumption of validity accorded to the granted patent. Edwards did not bear the burden of proving that the technical effect was linked to the distinguishing feature in the claim or that such effect was achieved across the scope of the claim. The Court was not convinced that Meril had met its burden and also stated that the fact that a feature is not sufficient for achieving a specific technical effect does not mean that this feature is not relevant.

Meril argued that using a frame geometry exclusively made of hexagonal cells would have been an obvious alternative based on the established prior art demonstrating that hexagonal cells had already been used in heart valves. Frames of heart valves that comprise hexagonal cells were disclosed in the prior art but were only used in combination with (intermediate) rhombic cells. However, the Court held that the mere use of hexagonal cells in the frame of heart valves does not lead to the conclusion that for the person skilled in the art it would be obvious to employ a frame entirely made of hexagonal cells to address the problem of reducing the crimping profile of a prosthetic heart valve. The main prior art addressing the same problem of reducing the crimping profile of the frame of a heart valve was indicating a different solution so replacing the rhombic cells with hexagonal cells in that document would not be consistent with its teaching according to the Court.

Finally, the Court noted that the EPO applies the ‘problem-solution approach’ to assess inventive step and that this test is not explicitly provided for in the ‘EPC’ and, therefore, does not appear to be mandatory. Regardless, applying the “problem-solution approach” to the present proceedings would not lead to a different conclusion in the Court’s view.

Conclusion

This decision provides some useful guidance regarding submission of auxiliary requests, and it is interesting to note that an initial submission of 84 auxiliary requests from the Patentee (the final set of auxiliary requests being limited to 6) was not considered to be unreasonable in view of the highly complex nature of the matter. The line of reasoning here seems familiar to that in EPO Oppositions. It is worth noting that if that initial set of auxiliary requests had been considered inadmissible, the admissibility of Patentee’s later reduced set of requests would have been problematic too. Hence, Patentees need to be careful to ensure that the initial request to amend meets all the requirements for

admissibility.

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It is also interesting to see the UPC apply the recent EPO Enlarged Board decision G1/22 and G2/22 on rebuttable presumption regarding applicant for subsequent application having the right to claim priority from an earlier application.