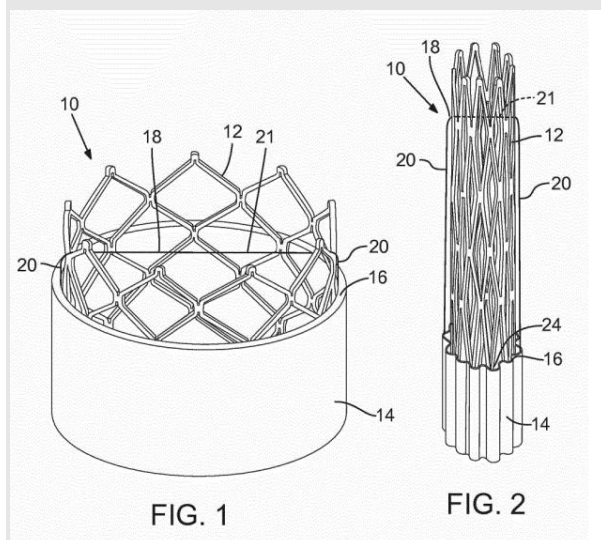


**UPC CFI, Central Division Paris, 30 April 2024,
Meril Italy v Edwards Lifesciences**



*A system comprising a prosthetic valve
and a delivery catheter*

PATENT LAW – PROCEDURAL LAW

Subsequent requests to amend the patent

- may be filed also after the closing of the written procedure with the permission of the Court however, the admission of this subsequent request must not prejudice the other party's right to defence (Rule 30(2) RoP)
- An unconditional amendment and significantly reducing the number of amendments offers a meaningful contribution to the efficiency of the proceedings in term of simplifying the issues which the Court shall address and facilitating a more expeditious decision.
- Claimant is granted a reasonable time period, set in one month, to lodge an additional defence to defendant's new set of amendments

Source: [Unified Patent Court](#)

**UPC Court of First Instance,
Central Division Paris, 30 April 2024**
(Catalozzi)

ORDER

of the Court of First Instance of the Unified Patent Court
Central division (Paris seat)
issued on 30 April 2024
concerning the generic applications Nos.
App_19959/2024 and App_23242/2024
lodged in the proceedings UPC_CFI_255/2023

HEADNOTES: The Court has the discretionary powers to admit an amend of the patent even after a previous application to amend that patent has been submitted and after the closing of the written procedure; however, the

admission of this subsequent request must not prejudice the other party's right to defence.

KEYWORDS: subsequent request to amend the patent; permission of the Court; closing of the written procedure; additional defence

REFERENCE CODE ECLI:

APPLICANT:

Edwards Lifesciences Corporation - 1 Edwards Way, Irvine, 92614 California, USA,
represented by Boris Kreye, Bird & Bird LLP
co-represented by Siddharth Kusumakar and Tessa Waldron, Powell Gilbert (Europe) LLP, and Bernhard Thum, Thum & Partner

RESPONDENT:

Meril Italy srl - Piazza Tre Torri 2 20145 Milano Italy
represented by Emmanuel Larere, Cabinet Gide Loyrette Nouel AARPI

assisted by Raphaëlle Dequiré-Portier, Cabinet Gide Loyrette Nouel AARPI

PATENT AT ISSUE:

European patent n° [EP 3646 825](#)

PANEL:

Panel 2 of the Central Division - Paris Seat

Presiding judge and judge-rapporteur Paolo Catalozzi

Legally qualified judge Tatyana Zhilova

Technically qualified judge Stefan Wilhelm DECIDING

JUDGE: This order is issued by the presiding judge and judge-rapporteur Paolo Catalozzi

SUMMARY OF FACTS AND PARTIES' REQUESTS:

1. On 4 August 2023 Meril Italy s.r.l. lodged a revocation action against patent at issue (EP '825) before this Seat of the Court of First Instance of the Unified Patent Court, registered as No. ACT_551308/2023 UPC_CFI_255/2023.

2. On 16 October 2023, Edwards Lifesciences Corporation, defendant in the revocation action, lodged the statement of defence which included an application to amend the patent, based on 9 conditional amendments and 84 auxiliary requests.

This application has been objected by the claimant, because it disregarded the structure and content requirements set by [Rules 30 \(1\)](#) and [50 \(2\)](#) of the Rules of Procedures ('RoP') and, more generally, by the key principles of European procedural rules and the judge rapporteur stated that issue concerning the admissibility of the request to amend the patent lodged by the defendant could not be addressed during the written procedure but would be dealt in the course of the oral procedure (see, order of 21 December 2023).

3. On 22 January 2024 the defendant lodged its rejoinder to the reply to the defence together with the reply to the defence to the application to amend the patent and with the same pleading it requested to the Court for a leave to amend its case, pursuant to [Rule 263 \(1\) 'RoP'](#) with regard to a new main set of conditional amendments, consisting of 41 auxiliary requests based on 9 individual amendments. The application to amend the case – and the patent – was rejected by the panel as not reasonably justified (see, [order of 28 February 2024](#)).

4. On 12 April 2024 the defendant lodged an application to amend the patent, registered as No. App_19959/2024, proposing one unconditional amendment and six auxiliary requests.

5. On 26 April 2024 the claimant submitted its comment on this application, registered as No. App_23242/2024, leaving to the Court's discretion the decision to grant or not its permission to admit it and, in case of admission, requested that the Court grants the claimant a reasonable time period to file an additional defence to defendant last pleading, without any further reply from the defendant, and to lodge a rejoinder to the defendant reply to claimant's defence of 22 January 2024 lodged on 12 April 2024.

GROUND FOR THE ORDER

Rule 30 (2) 'RoP' and the use of the discretionary powers by the Court.

6. As stated in the previous order issued by this panel on 28 February 2024, [Rules 30 \(1\)](#) and [50 'RoP'](#) allow the patent proprietor to amend the patent concerned, including one or more alternative sets of claims (auxiliary requests), on the conditions that it explains why the amendments satisfy the requirements of [Articles 84](#) and [123 \(2\) \(3\)](#) of the European Patent Convention ('EPC') and why the proposed amended claims are valid and, if applicable, why they are infringed and it indicate whether the proposals are conditional or unconditional and the proposed conditional amendments are reasonable in number in the circumstances of the case.

7. Furthermore, pursuant to [Rule 30 \(2\) 'RoP'](#), the patent proprietor is also allowed to file a 'subsequent request' to amend the patent: this refers to any request to amend the patent which comes after the first one – which may be admitted into the proceedings only with the permission of the Court.

8. The provision grants the Court the discretionary powers to admit an amend of the patent even after a previous application to amend that patent has been submitted and even after the deadline for filing a defence to the revocation action has passed.

9. Since the relevant provisions don't explicitly mention a deadline, this judge-rapporteur considers that a subsequent request to amend the patent may be filed also after the closing of the written procedure; however, the admission of this subsequent request must not prejudice the other party's right to defence.

10. While using these discretionary powers the Unified Patent Court judges have to observe the principles of proportionality, flexibility, fairness and equity, outlined in the preamble 2 and 4 of the Rules of Procedures.

11. With particular regard to the admissibility of a subsequent request to amend the patent, they must balance competing considerations. On one hand, allowing such amendments may lead to a more efficient proceedings, because it narrows the disputed subject-matter and it may expedite the case by simplifying procedural activities. Additionally, it safeguards the patent proprietor's interest in controlling their patent's content, avoiding that a partial invalidation of the patent

leads, as a consequence, to a unintended modification of the claims.

12. On the other hand, admitting subsequent requests to amend the patent may conflict with the purpose of delivering expeditious decisions, forcing an extension of the time of the written procedure in relation to the right of the other parties to prepare corresponding defences, and may undermine the right of defence of these latter parties.

13. In order to enable the Court to strike a fair balance between the opposed interests involved in the request to amend the patent the applicant has to offer a justification of its request, explaining the reasons for modifying the original request to amend the patent.

Reasons for admitting the subsequent request to amend the patent.

14. The defendant argues that the request responds to the judge-rapporteur's suggestion during in the interim conference that the parties should seek to agree to a limited number of auxiliary requests and is justified by the importance of the proceedings. It also argues that admission of the new set of amendments would streamline the current proceedings as it would significantly reduce the number of auxiliary requests, allowing the Court to conduct the proceedings in a most efficient and cost-effective manner.

15. It points out that the admitting the new set of amendments would achieve consistency between the auxiliary requests in this proceedings and those filed in the counterclaim proceedings concerning the same patent now pending before this Seat after Munich Local Division referral and, therefore, to defend the patent in a consistent manner.

16. It adds that that admitting the new set of amendments would not unfairly hinder the claimant, who will only need to address six auxiliary requests and, furthermore, has already filed a defence to these claim amendments.

17. This judge-rapporteur reiterates its position from the [order of 28 February 2024](#) that the interest of the patent holder to align its defence with the one in the counterclaims for revocation is not a reasonable justification for the purpose of addressing the subsequent request to amend the patent. The defendant has not provided any new explanation on why an identical defence is necessary across different challenges. It must be reaffirmed that the risk of conflicting decisions does not arise from defending a patent with different strategies in response to distinct challenges.

18. The judge-rapporteur agrees with the defendant that significantly reducing the number of the amendments and introducing an unconditional offers a meaningful contribution to the efficiency of the proceedings in term of simplifying the issues which the Court shall address and facilitating a more expeditious decision, also with regard to the counterclaims for revocation of the same patent which have been and assigned to this panel.

19. Furthermore, the judge-rapporteur deems that admitting the request to subsequent amend of the patent is consistent with the principle of fairness and equity, as the new set of amendments do not unreasonably hinder

the claimant; indeed, the claimant will face only one unconditional request and six auxiliary requests are filed, as opposed to the 84 auxiliary requests which it otherwise would face.

20. Granting permission to defendant's subsequent request to amend of the patent is also consistent with the principles of proportionality, having in mind the nature and complexity of the current revocation action, and of fairness and equity, as the claimant shall address fewer auxiliary requests and shall be awarded with a sufficient period to exercise its right to defence in an appropriate timeframe.

Claimant's arguments

21. The claimant observes that no agreement between the parties have been reached on the new set of amendments, contrary to the indication of the judge-rapporteur, that a subsequent request to amend the patent may not have the effect of a regularization of procedural errors contained in the previous request and that the admission of a subsequent request may not undermine the right to defence.

22. This judge-rapporteur acknowledges the lack of agreement between the parties on the new set of amendments (although suggested by the judge-rapporteur during the interim conference); nevertheless, this does not prevent the Court from granting permission for the defendant's subsequent amendment request in exercising its discretion.

23. The judge-rapporteur agrees with the claimant that a subsequent request to amend the patent may not have the effect of a regularization of procedural errors contained in the previous request; however, this does not preclude granting the permission requested, as no errors in the previous request has been identified yet.

24. As anticipated in previous para. 20, the consideration of the principle of fairness and equity and, especially, of the right to a fair trial, necessitates granting the claimant a reasonable time period, set in one month, to lodge an additional defence to defendant's new set of amendments; therefore, the relative claimant's request in this regard is granted.

25. At this regard, the judge-rapporteur panel finds it unnecessary to re-open the written procedure, closed on 13 March 2024, for the claimant to file the additional pleading, as this activity is necessary in preparation of the oral hearing and is a consequence of the admission of the amend the patent.

26. Claimant's further request to be awarded with a time period to lodge a rejoinder to the defendant reply to claimant's defence, lodged on 12 April 2024, shall be rejected, as no statutory provision or a Court order authorized the defendant to file such a pleading; therefore, the defendant's reply shall be disregarded and does not require a response from the claimant.

ORDER

For these grounds, the judge-rapporteur:

- grants the defendant's request and, therefore, admits into the proceedings the subsequent request to amend the patent lodged on 12 April 2024;
- grants the claimant a time period of one month, starting from the date of the order's issuance, for submitting an

additional defence to the defendant's subsequent request to amend the patent lodged on 12 April 2024.

Issued on 30 April 2024

The Presiding judge and judge-rapporteur
Paolo Catalozzi
