



UPC_CFI_8/2023
Procedural Order
of the Court of First Instance of the Unified Patent Court
delivered on 16/08/2024

APPLICANT/CLAMIMANT

- 1) **Edwards Lifesciences Corporation**
(Applicant) - One Edwards Way - 92614 -
Irvine, California - US

Represented by Magnus Dahlman, Jens Olsson, Siddhartha Kusumakar and Tessa Waldron

RESPONDENT/DEFENDANTS

- 1) **Meril Lifesciences PVT Limited**
(Main proceeding party - Defendant) - Bilakhia House, Survey
No. 135/139, Muktanand Marg, Chala, - 396191 - Vapi, Gujarat
- IN
- 2) **Meril GmbH**
(Main proceeding party - Defendant) - Bornheimer Strasse 135
- 137 - 53119 - Bonn - DE
- 3) **Smis International OÜ**
(Main proceeding party - Defendant) - Harju maakond,
Kesklinna linnaosa, Kaarli pst 9-1a - 10119 - Tallinn - EE
- 4) **Sormedica UAB**
(Main proceeding party - Defendant) - V. Kuzmos str. 28 -
08431 - Vilnius - LT

Represented by Andreas von Falck, Kerstin Jonen, Alexander Klicznik and Beatrice Wilden

PATENT AT ISSUE

Patent no.

Proprietor/s

EP2628464

Edwards Lifesciences Corporation

No

DECIDING JUDGE Kai Härmand

COMPOSITION OF PANEL – FULL PANEL

Presiding judge	Stefan Johansson
Judge-rapporteur	Kai Härmand
Legally qualified judge	Rute Lopes
Technically qualified judge	Elisabetta Papa

LANGUAGE OF PROCEEDINGS: English

SUBJECT-MATTER OF THE PROCEEDINGS

Infringement action & counterclaims for revocation

STATEMENT OF THE FORMS OF ORDER SOUGHT BY THE PARTIES AND SUMMARY OF FACTS

1. The proceedings have been stayed on 9.01.2024 pending the written decision of the Boards of Appeal of the European Patent Office (TBA) in case no. T0308/23-3.2.01. The parties have informed the court that the written decision of the TBA is available. The claimant proposed the timetable for the resumption of the proceedings.

The defendants have proposed another timetable.

2. The decision of the TBA concerns EP 2 628 464 B1 (EP 464). Edwards is the proprietor of EP 464 and the second defendant / counterclaimant (Meril Germany) was the sole opponent in the EPO opposition / appeal proceedings. Oral proceedings before the EPO TBA in T0308/23-3-2.01 took place on 3 June 2024. The written reasons for the EPO's decision were made available on 16 July 2024. The TBA rejected the appeal as inadmissible; the decision under appeal was set aside and the case was remitted to the EPO Opposition Division with the order to maintain EP 464 in amended form according to Auxiliary Request 6", which was filed at the EPO by Edwards with a letter of 24 May 2024 and was the main request at the oral proceedings before the TBA.

Edwards proposed timetable for the orderly resumption of the present UPC proceedings as follows:

- a) Edwards shall lodge an amended statement of claim within 14 days of any further order of the court addressing the requests set out in these submissions;
- b) The defendants / counterclaimants shall file an amended defence and counterclaims for revocation within 28 days of service amended statement of claim; and
- c) Thereafter, the timetable shall proceed in the ordinary course according to the timetable set out in the RoP.

Edwards proposed that the amended pleadings shall not be supplemented or amended in any way, other than to consequentially address the outcome of the TBA Decision.

Edwards' position is that this proposed course of action and accompanying timetable will allow the proceedings to be expeditiously resumed, whilst giving the parties sufficient time to take account of the findings in the TBA Decision. Edwards' proposal will also allow the claims as upheld by the TBA to be introduced into the proceedings in the most efficient way. In particular, R. 30 RoP does not appear to apply in the present circumstances, given that the claims of EP 464 as granted are no longer relevant and the patent will be amended centrally. Edwards further submits that the defendants / counterclaimants will not suffer any prejudice as (a) Meril Germany was the opponent in the EPO opposition / appeal proceedings; (b) Meril India filed an intervention in those proceedings; (c) all of the Defendants are represented by the same legal representatives; (d) the nature of the amendments to EP 464 as granted are relatively minor; and (e) Edwards has proposed

a generous timetable in which no pleading amendments will be due from the Defendants / Counterclaimants for at least two months from the date of the TBA Decision.

3. Defendants are of the opinion that generally the present proceedings are continued in accordance with R. 296.2 RoP. Defendants agree that it makes sense to allow the parties to take into account of the findings in the TBA's decision and to comment in full on the limited version of the patent-in-suit as upheld by the TBA and on the other parties' respective comments. Defendants therefore agree with claimant's proposal to file an amended statement of claim within 14 days of any further order of the court setting the timetable.

Defendants, however, ask for an appropriate deadline to file an amended defence and counterclaim for revocation, namely within 3 months (alternatively 2 months) after service of amended statement of claim, instead of 28 days. Defendants are of the opinion that an amended statement of claim requires a proper statement of defence and a proper preparation of a counterclaim for revocation against the new set of claims of the patent-in-suit. Rules 23 and 25 RoP provide for a deadline of 3 months for that. Such deadline therefore considered Hogan Lovells appropriate by the Rules of Procedure themselves and should also be granted to defendants in the present case. In the alternative, defendants are of the opinion that they should at least be granted a deadline in accordance with / equivalent to Rule 32 RoP (i.e. 2 months) which is provided for a defence to the application to amend the patent. Claimant was in a position to prepare its amended infringement allegations since early June 2024, defendants will see these allegations for the first time after having been served with the amended statement of claim. The timetable proposed by claimant (i.e. 28 days) does not allow for a proper defence against the new infringement allegations. The same is true for the required preparation of an amended counterclaim for revocation. Defendants especially disagree that the limitations to the patent-in-suit are "relatively minor".

Claimant correctly notes under margin no. 10 of its brief dated 25 July 2024 that defendants had challenged the validity of all granted claims with their counterclaim for revocation. However, defendants wish to highlight that the limitations to claim 1 as maintained by the TBA are not based on any of the granted dependent claims. Therefore, the "re-filing" of the existing pleadings in "amended form" is not considered an appropriate reaction to the TBA's decision. Hence, defendants reserve their right to amend and supplement their counterclaim for revocation. Defendants agree that after the filing of the amended statement of claim, the amended statement of defence, and the amended counterclaim for revocation, the timetable should proceed in the ordinary course according to the timetable set out in the RoP.

GROUNDS FOR THE ORDER

According to the 296.3 RoP time shall cease to run for the purposes of procedural period. Time shall begin to run afresh for the purpose of procedural period from the date on which the stay of proceedings come to an end. The procedural rules do not specify the exact further course of the proceedings once the ground for staying the proceedings has ceased to exist.

The exact meaning of the term "to run afresh" is not given in the rules. A traditional distinction is made between suspension and interruption. Suspension of the proceedings means that, if the ground for suspension no longer applies, the proceedings are resumed from where they left off. In the event of a time-limit being interrupted, the procedure starts again from the beginning as soon as the ground for suspension is removed.

The Court considers that the vagueness of the procedural rules is intentional in this context, leaving the court a wide discretion to design the procedure in accordance with the relevant general principles such as procedural economy and flexibility. In the court's view, this is essentially a situation in which the claimant has to bring a new action with clarified circumstances and the defendant has to

put forward new defence accordingly, derived from the TBA decision. The Court is in the position, that the written procedure as such has to be repeated, but with shorter time limits.

Both parties are familiar with the dispute in the EPO and in the court. Defendants who did not participate in the EPO proceedings, are represented and solicited by the representatives who participated in the EPO proceedings and are familiar with the activities in the EPO. Two of the defendants were also parties at the EPO proceedings. Therefore the amendments to the patent-in-suit is not going to be surprising for the defendants.

Therefore, it is not practical to follow the steps and the timeline of the written procedure all over again. There is no need to put forward preliminary objections, application to appoint the technically qualified judge etc. as the court has dealt with these applications already. The parties have to be given additional time to file the statement of claim, the defence and the counterclaim in amended form. The claimant has asked 14 days (two weeks) to file the statement of claim and the defendant agrees with that. The Court finds this to be reasonable deadline.

The claimant has proposed 28 days for the defendant to file the defence and the counterclaim. The defendant has proposed 3 month (alternatively 2 month) to file the defence and the counterclaim. The Court finds it to be reasonable to give the defendants 42 (six weeks) days to file the defence and the counterclaim. After that the proceedings continues according to the rules of written procedure which means that the claimant must lodge a statement of defence to the counterclaim within 2 months from the date of service of the statement of the counterclaim.

The court will rely on resubmitted documents as the positions of the parties in further proceedings, regarding the infringement action and the revocation action.

ORDER

1. The Courts determines the timetable for further proceedings.
2. The Claimant is required to lodge the Amended Statement of Claim within 14 days (30.08.2024).
3. The Defendants are required to file the Amended Defence and Counterclaim for Revocation within 42 days (27.09.2024).
4. The Claimant is required to lodge the Defence to the Counterclaim for Revocation and Reply to Statement of Defence in accordance with R. 29 (a) RoP.

INSTRUCTIONS TO THE PARTIES AND TO THE REGISTRY

The appropriate workflow in the CMS for the amendments is: Application for leave to change claim or amend case/or pleading (RoP 263).

INFORMATION ABOUT APPEAL

Appeal is not possible.

ORDER DETAILS

Order no. ORD_44404/2024 in ACTION NUMBER: ACT_459769/2023 and CC_587594/2023;
CC_587597/2023; CC_587616/2023 and CC_587618/2023

UPC number: UPC_CFI_8/2023

Action type: Infringement Action and counterclaim

Related proceeding no. Application No.: 43606/2024

Application Type: Generic procedural Application