



Central Division (Section Munich)

UPC_CFI_80/2023 Order of the Court of First Instance of the Unified Patent Court delivered on 20/11/2023

HEADNOTES:

The Court has discretion to stay proceedings awaiting any relevant decision from the EPO, provided such decision is expected rapidly. There should be a concrete expectation (i.e. a known date in time) for a decision which date should be in the near future such that it is clearly expected to be delivered before an expected decision by the UPC. In exercising Court's discretionary power on the basis of Article 33(10) UPCA in connection with Rule 295 sub a RoP, the Court has to assess the relevant facts and circumstances and has to take into account the interests of both parties. Where the interests of the parties do not align, the Court has to weigh up the interests upon deciding a request to stay proceedings.

KEYWORDS:

Article 33(10) UPCA. Rule 295 sub a RoP. Stay of proceedings (no). Parallel EPO proceedings. Rapid decision. Discretion.

REFERENCE CODE ECLI: Not provided

CLAIMANT (RESPONDENT REQUEST TO STAY)

- 1) **ASTELLAS INSTITUTE FOR REGENERATIVE MEDICINE** Represented by David Carling
9 Technology Drive - MA 01581 - Westborough
– US

DEFENDANTS (APPLICANTS REQUEST TO STAY)

- 1) **Healios K.K** Represented by James Nicholls
7-1, Yuraku-cho 1-chome Chiyoda-ku - 100-0006 - Tokyo - JP

2) **Osaka University**
1-1 Yamadaoka Suita-shi - 565-0871 - Osaka -
JP

Represented by James Nicholls

PATENT AT ISSUE

<i>Patent no.</i>	<i>Proprietor/s</i>
EP3056564	Healios K.K, Osaka University

PANEL/DIVISION

Panel 1 of the Central Division (Section Munich).

DECIDING JUDGES

This Order is issued by Ulrike Voß (presiding judge), András Kupecz (judge-rapporteur) and Paolo Gerli (technically qualified judge).

LANGUAGE OF PROCEEDINGS:

English.

SUBJECT-MATTER OF THE PROCEEDINGS

Revocation action. Request to stay proceedings.

STATEMENT OF THE FORMS OF ORDER SOUGHT BY THE PARTIES

The requesting parties, defendants in the main proceedings (herein referred to as 'Defendants'), are requesting:

1. A stay of the proceedings pending the conclusion of the corresponding opposition proceedings at the European Patent Office.
2. Costs.

The respondent, claimant in the main proceedings (herein referred to as 'Claimant'), is requesting:

1. Dismissal of the Defendants' application for stay of the present proceedings.
2. Costs, in accordance with Article 69 of the UPCA.¹

¹ Agreement on a Unified Patent Court.

SUMMARY OF THE FACTS AND POINTS AT ISSUE

Claimant in the revocation action with number ACT_465342/2023 UPC_CFI_80/2023 has brought a revocation action against European patent 3 056 564 ('the Patent') before the Central Division (Section Munich) of the Unified Patent Court (hereinafter referred to as 'main proceedings', 'CD Munich' and 'UPC', respectively). In the main proceedings, Claimant, inter alia, request a declaration that the Patent has at all material times been invalid and an order that the Patent be revoked in its entirety. Claimant is developing a RPE cell product, ASP7317 (hereafter referred to as 'the Product'). The Product is currently in clinical trials.

In the main proceedings, in the Defence to Revocation ('DR'), submitted on 13 September 2023, the Defendants request, inter alia, an order that the revocation action is dismissed and EP 3 056 564 B1 is maintained on the basis of the Main Request, or failing that on the basis of one of Auxiliary Requests 1 to 6. The DR further included a "Request for stay in view of European Patent Office opposition proceedings" (par. 25-29, 172 under 1 DR).

On 29 September 2023, Defendants made a separate procedural Application via the CMS (App_577540/2023) requesting a stay of proceedings pending the outcome of EPO opposition proceedings ('Request to Stay') on identical grounds. On 25 October 2023, the Claimant submitted a response to the Defendants' Request to Stay. On 1 November 2023, the Defendants submitted a reply to the Claimant's response to Request to Stay. On 6 November 2023, the Claimant submitted a rebuttal to Defendants' reply to the Claimant's response to the Request to Stay.

Opposition against the Patent was filed on behalf of Strawman Limited on 20 April 2022 by the Claimant's representative. Oral proceedings in relation to the patent in dispute before the Opposition Division ('OD') of the European Patent Office ('EPO') are scheduled for 4 March 2024.

Between the parties to the present revocation action (and one additional defendant) proceedings are pending at the UPC in relation to EP 3 056 563 (ACT_464985/2023). The Court has issued similar RoP 28 orders in both actions, with a (provisional) date for an interim conference on 14 March 2024 in both actions and an oral hearing in the same week, with the first hearing date on 25 June 2024.

In its Request to Stay, Defendants brought forward that the patent is subject to pending opposition proceedings at the EPO. According to the Defendant, the Statement of Revocation filed at the UPC is substantively identical to the EPO opposition filed by Strawman limited (by the Claimant's representative). The decision of the opposition division is expected to be announced at the end of the oral proceedings on 4 March 2024. The decision of the opposition division will be appealable. A final decision of the EPO would be expected by mid-2028. Given that it will take an estimated 13 years for the Claimant to complete clinical trials for the Product, a stay of the UPC revocation action pending the outcome of the EPO opposition would be procedurally efficient for all parties concerned. The expenses of the parties and the court time and resources involved at this early stage are small compared with the costs of the hearings that are yet to take place.

Claimant opposes the requested stay. It states that it initiated proceedings before the Court to obtain a swifter decision as to the validity of the Patent and, in turn, to obtain clarity as to its freedom to operate as far as possible in advance of the launch of the Product; and because it wished for the issue of validity of the Patent to be determined in a judge-led forum, which allows

for rigorous examination of both detailed legal arguments and technical issues, supported by expert evidence, in a way that is distinct from the approach adopted at the EPO.

Further facts and arguments as brought forward by the parties will, where relevant, be discussed in the below.

GROUNDS FOR THE ORDER

Legal framework stay of UPC proceedings in case of parallel EPO proceedings

According to Article 33(10) UPCA the Court may stay its proceedings when a rapid decision may be expected from the European Patent Office. Article 33(10) UPCA is implemented in Rule 295 sub a RoP, according to which the Court may stay proceedings where it is seized of an action relating to a patent which is also the subject of opposition proceedings or limitation proceedings (including subsequent appeal proceedings) before the European Patent Office or a national authority where a decision in such proceedings may be expected to be given rapidly.

Bases on the above provisions, the Court has discretion to stay proceedings (“*may stay*”) pending the outcome of parallel EPO proceedings when a *rapid decision* is expected. The UPCA nor the RoP define what is meant by “*rapid*” or what is to be considered as a “*decision*” in this context.

In the absence of any guidance in the UPCA and RoP, what is to be considered “*rapid*” has to be determined based on the facts and circumstances of every case. The use of the word “*rapid*” (“*rasch*” in the German version, “*rapide*” in French) as an adjective to “*decision*” suggests that there should be a concrete expectation (i.e. a known date in time) for a decision which date should be in the near future such that it is clearly expected to be delivered before an expected decision by the UPC.

The Claimant has argued that a “*meaningful decision*” can only be expected to be given by the Board of Appeal by mid-2028, thus the first instance OD decision, as the Court understands it, would not qualify as an “*expected rapid decision*” in the sense of UPCA Article 33(10) (12, 27 Response to the Defendants’ Request for Stay of Proceedings). The Court does not interpret the provisions on staying proceedings as being limited to *final* decisions of the EPO. There is no basis for such a limitation in the wording of the provisions. Such a categorical limitation can also not be based on the object and purpose of the UPCA. Therefore, in the view of the Court, the UPC may stay proceedings awaiting any relevant decision from the EPO, provided such decision is expected rapidly.

The circumstance that a first instance EPO decision is likely to be appealed and that such an appeal is likely to take considerable time is a nevertheless a factor that may be taken into account by the Court when exercising its discretion to stay proceedings (see further below).

In exercising Court’s discretionary power on the basis of Article 33(10) UPCA in connection with Rule 295 sub a RoP, the Court has to assess the relevant facts and circumstances and has to take into account the interests of both parties. Where the interests of the parties do not align, the Court has to weigh up the interests upon deciding a request to stay proceedings. It is for the party requesting a stay to bring forward reasons why staying proceedings is appropriate in a specific case. Nevertheless, especially where it comes to weighing the interests of parties, it is up to all the parties to bring forward why a stay of proceedings would or would not be in their interest. Furthermore, in exercising its discretionary power the UPC must observe the principles

of proportionality, flexibility, fairness and equity (Preamble 2, 4 and 5 RoP, also see Order in Preliminary Objection App_572915/2023, case ACT_551308/2023, CD Paris Seat, dated 13 November 2023, par. 80).

The request to stay proceedings in the present case: discretion

In the present case, a decision from the EPO opposition division is expected to be given at the end of the oral proceedings scheduled for 4 March 2024. The written decision is expected to be notified to the parties a few months after the oral proceedings. This decision will be appealable within two months of notification of the written decision.

It is in the view of the Court doubtful whether a decision that - at the time of issuing the present order - is expected in just over three months with notification of the decision and the grounds expected some months thereafter can be considered as a “rapid decision” for the purposes of Art. 33 (10) UPCA. However, this does not need to be clarified conclusively. Even if this is assumed in favour of the Defendants, who are requesting the stay, in the present case the interests of the Claimant in continuing the proceedings currently outweigh the interests of the Defendants in a stay, as discussed below.

Parties are in agreement that a final decision from the EPO is not to be expected before mid-2028. If the proceedings were to be stayed as requested by the Defendants until the conclusion of the opposition proceedings, the duration of the stay would be at least approximately five years. Defendants argued that it is “not inevitable” that an appeal would be filed after the opposition division decision so that said decision may become final. Whilst indeed the filing of an appeal may not be inevitable, the Court in the context of a request to stay proceedings has to decide based on the most likely and realistic scenario. Given the technology at stake and in view of the fact that the Defendants are defending the Patent both in the EPO and the UPC and absent any indications to the contrary, it seems likely in this case that the unsuccessful party will appeal. Moreover, the Defendants have not provided any undertaking that they will not appeal a first instance decision from the EPO opposition division. In the absence of such an undertaking, the Court assumes that an appeal is highly likely to follow a first instance decision.

The Claimant has reasoned that it brought the present revocation action wishing to obtain clarity as to its freedom to operate as far as possible in advance of the launch of the Product. The Claimant anticipates that European market approval for the Product will be obtained, and product launch will be achieved, significantly ahead of the expiry of the Patent in 2034. In response, Defendants state that the Claimant has not asserted that its anticipated product launch date is before mid-2028. The Defendants also state that they do not follow why the investment in the clinical development programme necessitates obtaining clarity as soon as possible as the Claimant already incurred tens of millions of Euros in development costs and it seems that the product research would continue even if the patent is upheld by the UPC in which case the Claimant would need to seek a license.

The Court finds that the Claimant has credibly established that it has a legitimate interest in pursuing this revocation action with the aim of obtaining (at least some degree of) commercial certainty in view of the Patent. In general, and in particular where a product is being developed that requires significant and increasing investments over time, such as (undisputed) the Product in the present case, there is an interest to obtain such commercial certainty as early as possible. The assertion from the Defendants that the Claimant’s research would continue nonetheless, possibly with the Claimant having to seek a license from the Defendants in the view of the Court

only confirms the Claimant's legitimate interest in attempting to seek clarity at this stage of its product development timeline.

Defendants' interests to (potentially) save litigation costs does not weigh up to the legitimate interest of the Claimant in pursuing this revocation action. In this context, the Court takes into account that by establishing the UPC, the Member States, inter alia, wished to "improve the enforcement of patents and the defence against unfounded claims and patents which should be revoked and to enhance legal certainty..." and to "ensure expeditious and high quality decisions". The UPCA Member States, all of which are also EPC Member States, furthermore established the UPC knowing of and accepting the possibility of parallel proceedings (also see e.g. Article 33(8) UPCA and the very reference to "rapid decision" in the provisions on staying proceedings).

Staying the proceedings will have as an effect that time shall cease to run for the purposes of procedural periods (Rule 296.3 RoP). To order a stay now would unduly and disproportionately hinder the Claimant's access to this Court against its legitimate interests in pursuing this action.

On the other hand, the Court recognises that proceeding with both cases in parallel may result in conflicting decisions by the EPO and the UPC. This risk should generally be avoided where possible. Likewise, parties' and judicial resources should be allocated as effectively as possible. In this regard, the Court agrees with the Defendants that it should be avoided that the UPC will have a hearing on a patent that stands revoked. This situation could indeed arise if the OD revokes the patent on March 4 2024, at least until an appeal is filed against that decision (which has suspensive effect, Article 106(1) EPC, last sentence). However, staying the proceedings already at this stage, as requested by the Defendants, not yet knowing if that situation will arise, is not deemed proportional to that aim.

Instead, the Court considers it more appropriate to continue with the revocation action at least until the interim conference which is to be held on 14 March 2024, which is confirmed by way of this order. This will ensure that the written procedure is finalised and the interim conference proceeds in this action as planned. At the interim conference, parties will have the opportunity to discuss the outcome of EPO proceedings and the consequences thereof for the timetable of these proceedings, whereby a potential stay of proceedings may be discussed again. Should a stay be deemed expedient by the Court at that stage, the case will in any event be (close to) ready for the oral hearing for when the stay of proceedings comes to an end.

In view of the foregoing, the Court takes this opportunity to (in a non-binding way) inform the parties of the following. In the interest of avoiding the undesirable situation described above and to at least mitigate the risk of conflicting decisions, the Court is currently inclined to, after hearing the parties at the interim conference, either postpone the oral hearing and/or stay proceedings in this revocation action in the event that the patent is revoked in its entirety by the OD on March 4 2024, at least until it is known whether the OD decision is final (i.e. appealed) or not. Regardless of the outcome of the oral proceedings at the OD, so also when the Patent is upheld (in amended form), the Court would like to make sure that the written grounds of the OD are available to the parties and the Court well in advance of the oral hearing. To this end, the Court will contact the EPO OD to explore if it would be feasible for the OD to render the written decision before 24 May 2024 (which is almost three months after the oral proceedings and still more than one month before the oral hearing in the revocation action). Should this not be feasible, the Court will consider postponing the oral hearing and/or staying the proceedings until the written decision is available.

By proceeding in this way, the Court is of the opinion that the interests of both the Defendants and the Claimant are sufficiently and fairly taken into account. The Defendants have not brought forward that there would otherwise be disproportional consequences of proceeding with this action without staying.

Conclusion of assessment of the relevant facts and circumstances and weighing the interests of both parties

Having heard the parties, based on the facts and circumstances as set out above and weighing the interests of both parties, the Court comes to the conclusion that the interests of the Claimant in proceeding with the present revocation action currently outweigh the interests as brought forward by the Defendants in staying the action. The Court concludes that it will not (at present) use its discretion to stay proceedings. The Request to Stay made by the Defendants is therefore rejected.

Both sides have asked for a cost award. These requests will be dealt with in the main proceedings as part of the overall cost assessment.

Leave to appeal is granted as this is the first order deciding on a request to stay proceedings and the Court shall endeavour to ensure consistent application and interpretation of these Rules (Preamble RoP, 8).

ORDER

For these grounds, having heard the parties on all aspects of relevance for the following order, the Court:

- Rejects the request to stay proceedings.
- Confirms that an interim conference will be held on 14 March 2024.
- Postpones any other decision to the main proceedings, particularly on costs.
- Grants leave to appeal this Order.

Issued on 20 November 2023

VOB
Presiding judge

KUPECZ
Judge-rapporteur

GERLI
Technically Qualified Judge

ORDER DETAILS

Order no. 579547 in ACTION NUMBER: ACT_465342/2023
UPC number: UPC_CFI_80/2023
Action type: Revocation Action
Related proceeding no. Application No.: 577540/2023
Application Type: Generic procedural Application (Stay)

INFORMATION ABOUT APPEAL

Leave to appeal is granted. The present Order may be appealed within 15 days of service of this Order which shall be regarded as the Court's decision to that effect (Art. 73(2)(b)(ii) UPCA, Rule 220.2, 224.1(b) RoP).