

EIP

Request for a stay

Astellas Institute for Regenerative Medicine v Healios KK and Osaka University (UPC_CFI_80/2023)

Order of 20 November 2023

On 1 June 2023, Astellas Institute for Regenerative Medicine (“Astellas”) applied to Munich central division to revoke EP 3,056,564 for a method of purification of retinal pigment epithelial cells which was granted in joint names of Helios KK and Osaka University (together “Proprietor”). The patent was also under opposition at EPO by Strawman Limited who filed opposition on 20 April 2022. On 10 August 2023 the EPO set the date of oral proceedings to be held on 4 March 2024.

The Proprietor sought a stay of the UPC revocation proceedings pending conclusion of the opposition proceedings and costs. Astellas sought dismissal of that request and its costs. The court set a date for an interim conference on 14 March 2024 and a hearing date of 25 June 2024.

The Proprietor pointed out that the opposition grounds at EPO are substantially identical to the revocation ground at UPC. The opposition was in the name Strawman Limited but the representative was the same as that of Astellas at UPC. As to time scale, the opposition decision would be announced at end for the oral proceedings on 4 March 2023. Any appeal should be concluded by mid-2028. As Astellas is not expected to complete clinical trials for 13 years a stay would be procedurally and cost efficient.

Astellas opposed the stay. It had launched UPC revocation proceedings to get a swifter decision and clarity about freedom to operate at an earlier stage. It also preferred validity to be tested in a judge-led forum with rigorous examination of legal arguments and technical issues supported by expert evidence.

Decision

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Art 33(10) provides that the court may stay its proceedings when a rapid decision may be expected

from the EPO and this is also reflected in Rule 295 RoP.

What is considered to be “rapid” is based on the facts and circumstances of each case. There should be a concrete expectation for a decision to be delivered at a known date in the near future and before an expected decision by UPC. The court considered that this did not have to be a final decision of the EPO. However the time taken to resolve any appeal was a factor to take into account when exercising its discretion.

The court had to take account of the interests of both parties and, where they do not align, weigh them up. It should also observe the principles of proportionality, flexibility, fairness and equity.

Discretion

The court was doubtful whether a decision due from EPO in three months with written grounds expected some months later could be considered “rapid”. But even assuming this in favour of the Proprietor, the balance of interests came down on the side of Astellas.

As a final decision of EPO was not expected until mid-2028, a stay would need to be in place for five years if an appeal was filed, which the court considered highly likely noting that no undertaking had been given by the Proprietor not to appeal.

Astellas has a product in clinical trials and is aiming for European market approval and product launch well ahead of expiry of the patent in 2034. It has a legitimate interest in obtaining commercial certainty as early as possible. The potential saving in litigation costs of a stay do not outweigh this. The UPC was established according to the preamble 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”. To order a stay would unduly and disproportionately hinder Astellas’ access to the court and its legitimate interests.

Future Conduct of Case

The court refused a stay. The revocation proceedings will continue at least until the interim conference on 14 March 2024, thus ensuring the written procedure at UPC is finalised. At this point the outcome of the oral proceedings will be known, and a potential stay can be discussed again. If the opposition division revokes the patent, the court may

postpone the oral hearing and/or stay the revocation proceedings (at least until it is known if that decision is final or will be appealed).

Further, the court will also contact EPO opposition division to explore whether their written decision can be available before 24 May 2024 (three months after oral proceedings at EPO but one month before the scheduled oral hearing at UPC). If this is not possible the court will consider postponing the oral hearing or staying the proceedings until the written decision is available.

Costs will be dealt with in the main proceedings as part of the overall cost assessment. Leave to appeal was granted.

Comment

The court has taken a pragmatic approach in continuing the proceedings until the outcome of the oral proceedings at EPO are known, while leaving open the possibility to revisit potential postponement of the oral hearing or imposition of a stay at the interim hearing once the outcome of the opposition is known.

This decision was delivered on 20 November 2023, around the same time the EPO indicated a change in practice to allow for acceleration of opposition (and appeal) proceedings in light of UPC or national revocation proceedings, as well as in the case of infringement proceedings (subsequently published in November Official Journal). Acceleration, if requested, would significantly reduce the time to a final decision following any appeal compared with the estimate of mid 2028 considered by the court above. This could be another factor to feed into any review by the court at the interim hearing.