

Seagen Gets PGR Nixed Under Fintiv In Rehearing Decision

By **Britain Eakin**

Law360 (July 18, 2022, 5:17 PM EDT) -- Seagen Inc. has persuaded the Patent Trial and Appeal Board on rehearing to deny a challenge from Daiichi Sankyo Inc. and AstraZeneca Pharmaceuticals LP to its cancer antibody patent, with the board saying the post-grant review is no longer warranted under the controversial Fintiv precedent.

The PTAB ruling, which was handed down Friday, marked the second time the board has granted a rehearing request in the case and reversed an earlier institution decision. This time it decided against.

The decision helps cement Seagen's \$41.8 million jury win in parallel Texas litigation in April, and it came the same day a federal judge further solidified that win by rejecting the last of Daiichi Sankyo's invalidity defenses.

Daiichi Sankyo and AstraZeneca lodged the PTAB challenge after Seagen filed the Texas suit in 2020, and the board initially denied it under the Fintiv precedent, which allows it to deny patent challenges when pending litigation is at an advanced stage. The board had cited a trial date in the Texas case that preceded the deadline for the board's final decision by four months as reason to deny the post-grant review.

But it reversed that decision in April after Daiichi Sankyo and AstraZeneca sought rehearing, with the board saying the strong merits of the petition and its decision to grant review of a related petition challenging different claims in the same patent actually favored review in this case. The patent at issue was the only patent asserted in the Texas suit.

Now the board says the circumstances have changed again, and so review is no longer warranted under Fintiv. It pointed primarily to the April jury verdict in the Texas case, which rejected all of Daiichi Sankyo's invalidity defenses, including its argument that skilled artisans wouldn't be able to carry out the invention and therefore the patent isn't enabled.

The jury found that Daiichi Sankyo owes \$41.8 million in damages because a breast cancer treatment medication it markets under the brand name Enhertu infringes Seagen's patent, which covers the delivery of a drug called Adcetris.

The board gave a nod to guidance U.S. Patent and Trademark Office director Kathi Vidal issued last month on the Fintiv precedent. Among the directives in the guidance, she said the board should not deny patent reviews when it determines the merits of a petitioner's unpatentability arguments are

deemed strong. The board had initially determined that the petition was strong on the merits, but said in its decision Friday that shouldn't control here.

"The district court already has substantially completed its review of the enablement issue, and a jury has determined that the claims do not lack enablement. Given this new information, we cannot conclude that petitioner's enablement case is compelling," the rehearing decision said.

The board also noted that Seagen has disclaimed several claims that were dropped from the district court trial, and has requested adverse judgment in the other PTAB case, which had challenged only the claims it disclaimed. That also favored denial, the board said.

The PTAB's decision coincided with an opinion from U.S. District Judge Rodney Gilstrap in the parallel Texas suit. On Friday he rejected an argument that a 15-year delay in the patent's prosecution should have sunk Seagen's jury win.

Seagen filed the Texas suit against Daiichi Sankyo in October 2020 around the same time the USPTO granted the patent, claiming that Daiichi Sankyo's drug, which has allegedly earned the Japanese pharmaceutical giant \$70 million in sales, infringed the patent.

Seagen's complaint alleged that Enhertu uses technology it developed in the field of antibody-drug conjugates, which are used to treat patients with cancer. ADCs are used as "linkers" that connect chemotherapeutic drugs to antibodies, which then target receptors on the surface of cancer cells, according to the complaint.

Counsel for Seagen declined to comment, while counsel for Daiichi Sankyo and AstraZeneca did not immediately return a request for comment Monday.

The patent-in-suit is U.S. Patent No. 10,808,039.

Daiichi Sankyo is represented by Preston K. Ratliff II, Naveen Modi, Ashley N. Mays-Williams and Jeffrey A. Pade of Paul Hastings LLP, Deron R. Dacus of The Dacus Firm PC, and J. Mark Mann of Mann Tindel & Thompson.

AstraZeneca is represented by David Berl, Thomas Fletcher, Jessamyn Berniker, Jessica L. Pahl, Kathryn Kayali, Kevin Hoagland-Hanson and Angela X. Gao of Williams & Connolly LLP, and Jennifer Parker Ainsworth of Wilson Robertson & Cornelius PC.

Seagen is represented by Michael Jacobs, Matthew Chivvis, Bryan Wilson, Matthew Kreeger, Parisa Jorjani, Sumaiya Sharmeen, Karl Johnston, Chris Han and Evelyn Chang of Morrison & Foerster LLP, and Johnny Ward, Wesley Hill and Andrea Fair of Ward Smith & Hill.

The cases are Daiichi Sankyo Inc. et al. v. Seagen Inc., case number PGR2021-00030, at the Patent Trial and Appeal Board, and Seagen Inc. v. Daiichi Sankyo Co. Ltd. et al., case number 2:20-cv-00337, in the U.S. District Court for the Eastern District of Texas.

--Additional reporting by Andrew Karpan. Editing by Adam LoBelia.