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Amgen v. Sanofi and Regeneron: Japan IP High Court overrules its own decision on validity of Amgen patent

Mami Hino, Naho Ebata (Abe, Ikubo & Katayama) · Monday, May 15th, 2023

On January 26, 2023, Regeneron Pharmaceuticals, Inc., who sought to invalidate Amgen Inc.'s Japanese patent (JP5705288) covering an isolated monoclonal antibody used as cholesterol medication, won an appeal case in the IP High Court (Case No. 2021 (Gyo-ke) 10093). What was surprising in this case was that the IP High Court's invalidity conclusion was the opposite of its own ruling which was made 4 years ago.

Regarding the same patent, Amgen had already won a battle with Sanofi, a manufacturer of the cholesterol medication "Praluent®" (alirocumab) which Amgen alleged was infringing its patent. Two cases were fought between Amgen and Sanofi, the first one being an invalidity case (Case No. 2017 (Gyo-ke) 10225) and the second one being an infringement case (Case No. 2019 (Ne) 10014). The IP High Court held Amgen's patent valid on December 27, 2018 in the invalidity case, and then found Sanofi's manufacture and sale of Praluent® as infringing Amgen's patent, which was reaffirmed to be valid, on October 30, 2019. Sanofi appealed the decisions to the Supreme Court, but the appeals were rejected on April 24, 2020, and Sanofi was forced to stop its sale of Praluent® entirely in Japan.

However, this was not the end of the battle for Amgen. Regeneron, who co-developed Praluent® with Sanofi, filed an invalidation action with the Japan Patent Office (JPO) against the same Amgen patent on February 12, 2020. In this case, as expected the JPO ruled in favor of the patentee, Amgen, and Regeneron appealed, but this time, as mentioned above, the IP High Court decided that the patent was invalid.

In the Regeneron case, the main issue in the IP High Court was whether the support requirement was met. The claim of Amgen's patent (JP5705288) functionally defines the isolated monoclonal antibody by claiming that the antibody (i) is capable of neutralizing the binding of PCSK9 to LDLR, and (ii) competes with the 21B12 antibody. The court considered the technical significance of the invention to be the finding that "any antibody that competes with the 21B12 antibody in relation to PCSK9 would function as a neutralizing antibody that neutralizes the binding of PCSK9 to LDLR in the same mechanism as the 21B12 antibody." The patent specification disclosed screening methods to obtain antibodies that compete with the 21B12 antibody in relation to PCSK9, but only specified and disclosed several groups of such antibodies that would have the neutralizing function. The court found that the claim would broadly include antibodies which compete with the 21B12 antibody in a manner that sterically hinders the binding of PCSK9 to LDLR as well as antibodies which hinder the binding of PCSK9 to LDLR by recognizing the same

or overlapping binding site as the 21B12 antibody when binding on PCSK9. Since there was no disclosure in the specification showing a mechanism of how an antibody sterically hindering the binding of the PCSK9 to LDLR would have a neutralizing function, the court concluded that the specification does not support that “any” antibody that competes with the 21B12 antibody would function as a neutralizing antibody. Amgen argued that antibodies that do not have the neutralizing function are literally excluded from the scope of the claim, but the court rejected this argument, saying that such understanding would open the door for claims too broad with no justifiable reason.

The IP High Court also made a remark on why the conclusion is different from the Sanofi case. They said that in the Sanofi case, the IP High Court had decided the case based on the premise and understanding that “any” antibody that competes with the 21B12 antibody would bind to almost the same binding site as the 21B12 antibody and would function like the 21B12 antibody. In the Regeneron case, such premise was put in doubt based on new arguments and evidence (such as expert declarations and experiments) filed by Regeneron, which led the IP High Court to decide the case differently.

Amgen has appealed to the Supreme Court.

Amgen is also fighting with Sanofi and Regeneron in the US and in Europe. In the US, Amgen’s patent was invalidated in the lower courts, but Amgen took the case to the Supreme Court and on March 27, 2023, the Supreme Court heard oral arguments from Amgen and Sanofi. The claims of Amgen’s US patent are different from the claims of the Japanese patent in that it specifies amino acids on PCSK9 to which the isolated monoclonal antibody binds, and the issues being addressed are also different in the US and Japanese courts, but the US Supreme Court decision might have some kind of influence on the Regeneron case in Japan, or how functionally claimed antibody inventions are to be handled in Japan.

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