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Japan's first case regarding compulsory license based on public interest is finally settled

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On May 30, 2024, the JPO announced that the request for a decision of granting a compulsory non-exclusive license based on public interest under Article 93 of the Patent Act, which was filed by Vision Care and VC Cell Therapy (the "Claimants") on July 13, 2021, was withdrawn upon settlement. It took more than two and a half years from the filing of the request to the conclusion of the case. It was reported as the first case in Japan in which the JPO set up a special committee within the Industrial Property Council, and the committee substantially discussed whether the requested compulsory non-exclusive license should be granted or not.

The patent at issue was directed to a method of producing retinal pigment epithelium (RPE) cells by culturing iPS cells, which was jointly invented and co-owned by Helios, RIKEN and the Osaka University. Helios, which was scheduled to be granted an exclusive license from the co-owners with a right to sublicense, chose Sumitomo Pharma as its collaboration partner to develop RPE cells derived from iPS cells. Sumitomo Pharma was agreed to be an exclusive sublicensee of the subject patent in Japan.

There was one inventor from each co-owner (total of three inventors), and the inventor for RIKEN was Dr. Masayo Takahashi. She was a project leader of RIKEN and had been initially collaborating with Helios, but later left RIKEN and set up new companies, which were the Claimants. Dr. Takahashi, as representative director of the Claimants, demanded a license of the patent, and filed the request for a compulsory license for public interest claiming that they could develop the best treatment for the patients suffering from RPE deficiency such as age-related macular degeneration. On the other hand, when the request was filed, Helios and Sumitomo Pharma were already jointly developing RPE cells derived from allogeneic iPS cells and were even preparing for a clinical trial in Japan. While the case went on, the two companies continued such joint development and Sumitomo Pharma initiated the phase 1/2 clinical trial with patients.

There has been no case in Japan in which a compulsory license based on public interest was granted and it was believed to be a last resort. However, according to the press release, the committee formed a tentative opinion and told the parties that there was a possibility to grant a compulsory license based on public interest to the Claimants, solely for their production of RPE cells derived from autologous iPS cells for treatment not covered by health insurance. The committee's chairman encouraged the parties to settle upon discussion based on such tentative opinion. According to the settlement agreement, which is also disclosed in the press release, the patentees of the subject patent agreed not to enforce the subject patent against the Claimants up to

30 cases of such treatment using RPE cells derived from autologous iPS cells, and the parties also agreed to not interfere with each other's businesses. The JPO emphasized in its announcement that it was desirable to resolve the matter based on the parties' voluntary discussions and reaching an agreement upon discussion matches the legislative purpose of Article 93 of the Patent Act.

According to the press release, committee meetings were held 22 times for the case. The Claimants and the respondent Helios each filed a number of opinions and submitted a vast amount of documentary evidence. However, meeting minutes of the committee and the records of the case are not open to public. This case has left a big question as to how a compulsory license should be determined by maintaining an adequate balance between a patentee's right and the public interest, and what procedures should be taken for transparency.

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