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Japan: MSD v Wyeth – The IP High Court upholds the validity of patent claims, finding inventive step in the functional limitation therein

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In Japanese patent litigation, calling expert witnesses is very rare and the parties usually try to prove common technical knowledge (CGK) by submitting documentary evidence, such as publications available as of the priority date and written expert declarations. Thus, parties need to be aware that descriptions in the publications are crucial and cannot be supplemented by experts' live testimony.

The importance of proving CGK was highlighted in a recent IP High Court case (*Merck Sharp & Dohme Corp. v. Wyeth LLC*, IP High Court Case No. 2020 (Gyo-Ke) 10015; Decision date: May 17, 2021) filed by Merck Sharp & Dohme ("MSD") as an appeal from a JPO trial decision holding Wyeth's patent valid. Wyeth's patent covers Prevenar 13® containing 13 serotypes of pneumoniae, the most widely used pneumococcal conjugate vaccine in the world, sold by its parent company Pfizer. MSD asserted that the functional feature of the claimed invention substantially existed in Wyeth's product Prevenar 7 containing seven serotypes of pneumoniae ("Prevenar 7"), which was commercially available as of the priority date or, based on CGK, it could have been easily conceived by a person skilled in the art as of the priority date of the patent. However, the court affirmed the JPO's decision upholding validity of the patent on grounds that the claims had inventive step over Prevenar 7 and rejected MSD's assertions.

Claim 1 of Wyeth's patent reads as follows, with the functional feature of the invention identified in the claim as underlined below:

"[Claim 1] A formulation filled in a siliconized container, <u>which inhibits the silicon-induced aggregation of polysaccharide-protein conjugates contained in a siliconized container</u>, which is a formulation comprising

(i) a pH buffered saline solution, wherein the buffer has a pKa of about 3.5 to about 7.5,

(ii) an aluminum salt and

(iii) S. pneumoniae serotype 4 conjugated to a CRM_{197} polypeptide,

1. pneumoniae serotype 6B conjugated to a CRM_{197} polypeptide,

…

a S. pneumoniae serotype 7F conjugated to a CRM_{197} polypeptide and

a S. pneumoniae serotype 19A conjugated to a CRM_{197} polypeptide."

The JPO found four differences between Claim 1 and Prevenar 7. Among the four differences, first and fourth are: (1) whereas number of serotypes in Claim 1 was13, Prevenar 7 contains only seven, and (4) whereas Claim 1 is a formulation which "inhibits the silicon-induced aggregation of polysaccharide-protein conjugates contained in a siliconized container", this is not specified in Prevenar 7. Then, the JPO determined that the differences (1) and (4) were not obvious over Prevenar 7 in light of the CGK.

In the IP High Court, MSD succeeded to prove CGK based on publications disclosing that 11-valent and 13-valent conjugated pneumoniae vaccines had been under development as of the priority date, and the Court found that the claimed feature related to the difference (1) was obvious over Prevenar 7 in light of the CGK. However, the Court found that the problem solved by the invention , *i.e.*, the fact that the aggregation of polysaccharide-protein conjugates would be induced by silicone, was not recognizable by a person skilled in the art from CGK, and held that the functional feature related to the difference (4) was not obvious.

Interestingly, in an English case of the UK counter patent (*MSD v. Wyeth*, [2020] EWHC 2636 (Pat)), the conclusion was the opposite, and the patent was found to be invalid for lack of inventive step over a prior art named *de la Pena*, which describes Prevenar 7 and also mentions that 11-valent and 13-valent vaccines are being developed. With regard to the same functional feature of the claims, Mr Justice Meade found that the notional skilled formulator would readily appreciate that the cause of aggregation of polysaccharide-protein conjugates was the silicone, and that one obvious way to address the aggregation would be a surfactant. He held that "the claims of the Patent are about taking forward a very attractive proposal (the 13v vaccine in de la Pena) by routine means, including solving a modest CGK problem (aggregation caused by silicone) in a way which was CGK (a surfactant)."

Getting back to the Japanese IP High Court decision, this case also raises the question of whether it is appropriate to find inventive step in a claimed functional feature of the Invention of a "product claim," when the product itself already existed in prior art and the function is intrinsic to the product. The IP High Court does not make any clear statement with respect to this issue, but the following passage in the decision seems to suggest a possibility that if the product of Wyeth's Invention had been "substantially identical" to the cited product (not "easily conceivable," as was the actual case), the simple finding of an intrinsic functional feature of the product would have lacked inventive step:

"[MSD's] argument that the uniqueness of the Invention exists merely in the 'discovery' of a mechanism of aggregation can be established only on the premise that the Invention and Publicly Known Invention 1 [Prevenar 7] are substantially identical with each other and have no difference in the structure of the invention."

MSD appealed the case to the Supreme Court, but the appeal was fully withdrawn on September 22, 2021, as Pfizer and MSD entered into a worldwide settlement and license agreement wherein MSD agreed to make certain regulatory milestone payments and royalty payments to Pfizer for the

sale of its pneumococcal conjugate vaccine products.

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