

# Merck attacks Wyeth's 'broad' patent claims for Prevnar 13 vaccine



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A showdown between global pharmaceutical giants over the world's best selling vaccine began Monday in Federal Court, with Merck Sharp & Dohme claiming three patents for Prevnar 13 sold by Pfizer's Wyeth are invalid and that its own vaccine offers greater protection against pneumococcal bacteria.

In her opening submission at the start of a two-week trial, Merck barrister Katrina Howard, SC, told Justice Stephen Burley that the claims of Wyeth's patents for Prevnar 13 were "stock standard", lacking novelty and any significant improvement on prior science.

Prevnar 13 generated \$5.6 billion in revenue in 2017 and is used to protect against invasive pneumococcal bacteria, also called streptococcus pneumoniae, an infection that can result in pneumonia, blood infection, middle ear infection, or bacterial meningitis.

Merck's case, filed in August 2017, alleges that Wyeth's two composition patents and one container patent covering the vaccine are invalid. Wyeth's cross-claim, launched in November 2017, alleges Merck infringed the patents with the development of one of its own vaccines, an allegation the company rejects.



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Merck's allegedly infringing vaccine is a 15-valent vaccine, providing protection against 15 serotypes of streptococcus pneumoniae, where a serotype is a subgroup of bacteria with different immune or antibody responses.

Howard told Justice Burley that Wyeth's patents involved a 13-valent vaccine, with its claims covering 13 serotypes – two fewer than Merck's vaccine.

“We say the claims must be construed as being confined to a 13-valent vaccine, in which case the 15-valent vaccine does not infringe the patent,” Howard said.

Wyeth's interpretation of its patent claims were “so broad” as to include vaccines with other combinations of serotypes which would lead to “millions if not billions” of combinations, she said.

“Our friends are patenting a whole area that's still being researched and discovered from now until the patent expires.

Howard also argued that all 13 serotypes, as well as the adjuvant and the buffer specified in Wyeth's vaccine patents, were common knowledge, and that the patents' claims were “basically a survey of the literature and the data” without adding anything new.

The two extra serotypes that Wyeth added to its Prevnar 13 patents, to distinguish the vaccine from prior 11-valent vaccines, were obvious, she said, because they were well known in the scientific community as “the next most important serotypes in terms of prevalence” and their addition had the potential to save a “significant number” of lives.

“The literature showed that there was a very high burden of disease associated with them, they were antibiotic resistant, and cross-protection was limited,” she told the court, listing reasons why it was vital to add these serotypes to the newly developed vaccine.

Merck and Wyeth are locked in patent disputes over the Prevnar 13 vaccine across the globe.

In 2014, the European Patent Office revoked one of Wyeth's patents for Prevnar 13 for lack of inventive step. And in June this year, the US Patent and Trademark Office's Patent Trial and Appeal Board ruled that Wyeth's US formulation patent for Prevnar 13 was invalid, with 21 out of 22 claims unpatentable due to obviousness. Both the European and US decisions are being appealed.

In August 2017, Wyeth was granted a patent for Prevnar 13 by the Indian Patent Office, beating two pre-grant oppositions by Panacea Biotech and Medecins Sans Frontieres. In December 2017, Pfizer retained its Prevnar 13 patent in South Korea, winning a court battle brought against it by SK Chemicals, which wanted to produce its own generic version of the vaccine.

Wyeth is expected to make its opening submissions on Tuesday. [The](#)

[trial will feature](#) testimony from two panels of seven international experts on vaccines, microbiology and immunology.

Wyeth is represented by barristers Tony Bannon SC, Cynthia Cochrane and Rob Clark, instructed by Allens.

Merck is represented by Howard and barrister David Larish, instructed by Corrs Chambers Westgarth.

The case is [Merck Sharp & Dohme Corp. & Anor v Wyeth LLC](#).

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