Wyeth granted a patent for Prevnar 13, a blockbuster vaccine that helps prevent cases of pneumonia

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Wyeth has been granted a patent for Prevnar 13, a blockbuster vaccine that helps prevent cases of pneumonia, one of the leading causes of deaths of children under five years of age. As per Genetic Engineering and Biotechnology news, GEN, Prevnar was the 10th most bestselling drug with sales in 2016 touching $5.718 billion. Prevenar 13, helps prevent pneumococcal pneumonia and infections caused by 13 strains of streptococcus pneumonia bacteria. Pfizer's patent application for Prevenar 13 has also been challenged in countries like South Korea, USA, Japan, China etc. Its patent in Europe was revoked by the European Patent Office in 2014, and the decision is under Appeal. The Indian Patent office vide decision dated dated 11th August 2017, granted the patent. The decision came after a long battle before the patent office and after dismissal of not only one, but two pre-grant oppositions filed by Panacea Biotech and Medecins Sans Frontieres (MSF). The patent application relates to a 13-valent immunogenic composition for use as a vaccine, comprising polysaccharide-protein conjugates derived from 13 Streptococcus pneumoniae serotypes ((st) 1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F and 23F), each serotype being conjugated to CRM197 carrier protein. The application was opposed on various grounds including novelty, inventive step, composition not being synergistic and therefore not patentable under section 3(e) of the Indian Patents Act. The controller dismissed all the grounds and has granted a patent. The controller held that the vaccine composition claimed is novel as none of the prior arts provide an enabling disclosure to arrive at 13 valent vaccine conjugated to a single carrier CRM197, i.e., the claimed 13 valent cannot be arrived at without undue experimentation from the prior arts and is therefore novel. The controller also held that the composition is inventive as it cannot be achieved with reasonable expectation of success. The addition of serotypes (present invention has 13 of them) was difficult due to interference, epitope load and carrier induced epitopic suppression, antigen competition etc and the applicant arrived at an effective 13 valent overcoming all these. Heavy reliance was placed by the controller on the evidence of the inventor Dr. Paradiso who was was also present at the hearing. The composition was also considered to be synergistic as it provides a range of surprising effects.