WYETH GRANTED A PATENT FOR PREVNAR 13, A BLOCKBUSTER VACCINE THAT HELPS PREVENT CASES OF PNEUMONIA

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The first battleground of any patent application is the patent office of any country; they help shape the future course of legal proceedings thereof and hence the arguments and orders at this stage become pivotal to a patent's future. Wyeth's application, 8081/DELNP/2007 (now granted as IN 286321 for Prevnar13®), was prosecuted by Anand and Anand at The Indian Patent Office and the Office vide its decision at the end of 2017, granted the patent. The ride to a favourable decision wasn't a smooth one; it came after a long battle before the patent office and after the dismissal of not one, but two pre-grant oppositions filed by Panacea Biotech and Médecins Sans Frontières (MSF). The patent relates to a 13-valent immunogenic composition (Prevnar13®) 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. Prevnar13® is a blockbuster vaccine that helps prevent cases of pneumonia, one of the leading causes of deaths in children under five years of age of which India accounts for approximately 20%. The application was opposed on various grounds including novelty, inventive step, and its composition not being synergistic and therefore not patentable under section 3(e) of the Indian Patents Act. The Controller, eventually, in a well-reasoned order dismissed all the grounds and granted a patent. The order, after a rigorous contention by the Agent for the Applicant, brought in its wake not only various legal grounds, like inadmissibility of the belated filed document/rejoinder, the inadmissibility of an unverified translation of a non-English document filed by the Opponent but also clarified in detail on technical grounds raised by the Opponents. The Controller, in this instance, upholding the principles of natural justice, accepted the belated filing of documents and submissions of the Opponent and the Applicant respectively; however, alongside also discouraged such late filings especially when they are of a technical nature in contentious proceedings. The Controller also held that the vaccine composition claimed is novel as none of the prior arts provides an enabling disclosure to arrive at a 13 valent vaccine conjugated to a single carrier CRM197. The Controller also held that the composition is inventive as it cannot be achieved with a reasonable expectation of success. The composition was also considered to provide a range of surprising effects and was therefore held to be synergistic. The battle, however for Prevnar13®, is not over and is pending at various fora in the country. Panacea Biotech Ltd. has filed a review of the pre-grant opposition decision of the Controller and post-grant opposition. Further, MSF has filed a writ against the order of the Controller challenging the grant of the patent. **Significance**: Highly contested Prosecution of blockbuster vaccine, overcame two major pre-grant oppositions. The granted patent still facing challenges. **Team Anand and Anand**: Archana Shanker, Arpita Kulshreshtha and Gitika Suri.

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