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With Pneumococcal Vaccine Patent, Pfizer Wins on Many Counts

BY JACOB PULIYEL ON 25/08/2017 • LEAVE A COMMENT

Not only was Pfizer given a subsidy to 'develop' a drug that already existed, the profits they will make from the inefficient vaccine is much beyond what was originally stipulated.

A company logo is seen through branches at a Pfizer office in Dublin, Ireland November 24, 2015. Credit: Reuters/Cathal McNaughton

New Delhi: Pfizer has been granted an Indian patent for its Prevenar 13 (https://thewire.in/170159/india-pfizer-patent-pneumonia-vaccine/) – a pneumococcal vaccine. The vaccine costs more than Rs 3,000 per dose and the three doses required to immunise a child cost more than Rs 10,000. The decision of the patent office bars other Indian companies from making a cheaper version of the vaccine. Although the vaccine is exorbitantly expensive, it has poor efficacy. Yet one is not surprised by the news of the patent, given the background story, nationally and internationally, of this vaccine. According to the petition by Prashant Bhushan (http://jacob.puliyel.com/paper.php?id=181) in the Delhi high court, this vaccine has the distinction of being recommended even before it was manufactured, let alone tested, by the National Technical Advisory Group on Immunization, which is meant to evaluate and recommend vaccines for introduction in the country.

Vaccine with little efficacy

Pneumococcal bacteria are only one of a very large number of organisms that cause pneumonia.

There are many other bacteria, mycoplasma and viruses that can also cause pneumonia. The pneumococcal bacteria itself has around 100 strains. The vaccine is against only 13 of those pneumococcal bacterial strains. It is clear that this vaccine impacts only a tiny fraction of the causes of pneumonia. Bacterial pneumonia is an eminently treatable condition, responsive to antibiotics with few long-term sequlae.

Before this vaccine against 13 strains was brought to the market, most pneumococcal pneumonia was caused by seven strains of the bacteria, which strains were responsive to inexpensive antibiotic like penicillin. A vaccine against the seven common strains was introduced in the US in 2000. It resulted in the near disappearance of these seven strains but other strains replaced the ones eliminated (http://www.chd.dphe.state.co.us/Resources/cms/dc/Immunization/2010%20Pediatrics%20-%20Kaplan%20-%20Serotype%2019A%20is%20the%20most%20common%20serotype%20causing%20invasive%20pneumococcal%20infections%20in%20children.pdf). The new strains caused more problems like pus collection in the chest and many were resistant to the first line penicillins. In short, the use of the vaccine was making the problem worse. This was followed by the development of a ten-strain vaccine and when that caused further strain shifts, the 13 valent vaccine was brought out. Other countries clearly had the opportunity to learn from these mistakes and grab the option not to introduce a vaccine that aggravates the problem. But such is the clout of the vaccine manufacturers and their international promoters like the WHO and GAVI, that the vaccine is being recommended in the poorest of countries that can ill afford to make such costly mistakes.

The vaccine has very poor efficacy. According to a WHO bulletin (https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2649528/), the vaccine reduces the incidence of pneumonia by 3.6 cases per 1,000 children vaccinated. Preventing these four cases (a generous approximation) of pneumonia by vaccinating 1,000 babies with a vaccine at Rs 10,000 per child will cost a mind boggling Rs 100 lakh, whereas treating four cases of pneumonia with syrup Septran, as advised by the WHO, will cost Rs 40. Even if the vaccine is procured at a tenth of the market price, the vaccine will still cost Rs 10 lakh to reduce four cases of chest infection.

Adverse effects

The vaccine has other problems besides poor efficacy. A study published in the prestigious *New England Journal of Medicine* (http://www.nejm.org/doi/full/10.1056/NEJMoa035060#t=articleResults) shows that the vaccination nearly doubled the incidence of asthma. For every two cases of pneumonia prevented, one child developed asthma. Pneumonia is a one-off transient disease. Asthma, on the other hand, has longoterm implications. One is left to wonder what the trade-off is. In spite of all this evidence, this vaccine is being introduced in India to be given to every child.

The need for introducing this exorbitantly expensive vaccine that perhaps aggravates rather than alleviates respiratory morbidity in children and the need, now, to grant it a patent in India, has left organisations like Medecins Sans Frontiers (MSF) wondering about the clout that the manufacturer wields. We had evidence of this clout ten years ago when it the company hijacked the GAVI Advanced Market Commitment (AMC) funds. Professor Donald W. Light of Stanford University described this (http://www.tandfonline.com/doi/abs/10.4161/hv.7.2.14919) in lurid detail.

A woman walks past a chemist shop in Mumbai, India, on April 28, 2017. Credit: Reuters/Files

AMC hijacked

Pharmaceutical companies in general are keen to make drugs for the rich countries that they can sell at great profit. They have little interest in making vaccines for diseases like malaria that affected poor countries because the countries that needed the vaccine cannot afford their profit margins. In 2005, the Center for Global Development and the Bill and Melinda Gates Foundation came up with an idea to incentivise drug manufacturers to manufacture vaccines for neglected diseases like malaria. Donors made an AMC to make up the loss of revenue to the company that makes a drug for a neglected disease. The MSF estimates that profits for a breakthrough drug is approximately $400 million. The AMC agreed to buy upto a few hundred million doses of the new vaccine at what they called the 'buyout price' that ensured that the manufacturer made the profits it would make if the vaccine had been made for rich countries' market. In turn, the manufacturer would commit to making the drug for low-income countries at $1-2, with no profit. Donors would not pay till the manufacturer came up with the breakthrough vaccine. The company that arrived there first would walk away with all the profits.

After the monies were collected from international donors for setting up the AMC, inexplicably the money was given to Pfizer for the Prevenar 13, which vaccine the company had already developed to replace their blockbuster seven-serovalent pneumococcal vaccine made for the rich market. Also, the buyout price was raised from $5-6 to $10 and the tail price (the no-profits price) was raised to $3.50 from the agreed $1-2. So in fact, no new vaccine for a neglected disease was developed. The company made profits in excess of $600 million, where the normal profits are $400 million according to calculations of the MSF. At the international level, this AMC killed off any interest other manufacturers may have had to make a cheaper vaccine. They could not compete against the huge subsidy given to Pfizer.

The last straw

India does not qualify for GAVI funding as its GDP per capita is in excess of $1,500 a year. It has to pay the full negotiated price for the vaccine. Indian manufacturers therefore had an incentive to make a cheaper vaccine for the local market and for other countries like India that have graduated out of GAVI aid. The present grant of the patent to Pfizer for Prevenar 13 kills that incentive all the way up till 2026.

Of course if the patent were not there, it may have helped the development of a less expensive

vaccine and addressed the cost issue, but it would not alter the facts about the poor efficacy or the problem of asthma caused by the vaccine.

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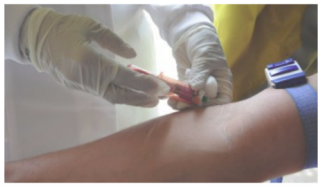

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