India’s public health and the looming threat of US pharma giants

More than 1,200 people lost their lives due to floods in India, Bangladesh and Nepal last week. This year’s monsoon season destroyed thousands of homes, schools and hospitals and affected up to 40 million people. The increased rainfall and deadly flooding in South Asia is linked to climate change. In his book *The Great Derangement: Climate Change and the Unthinkable*, Amitav Ghosh offered a chilling account of how climate change is going to wreak havoc in India and elsewhere.

Worse still, the floods caused by climate change have left a trail of water-borne and other diseases. The people who are subjected to these diseases are invariably the poor of India. With more than 1.2 billion people, India, according to several studies and estimates by the World Health Organization, carries the highest disease burden. The country, for example, ranks first among nations in incidence of tuberculosis and pneumonia, malnutrition, and other contagious diseases. That there is an obvious relationship between the social determinants such as water sanitation, nutrition, air pollution, and health is well known. The recent ghastly death of children in Uttar Pradesh is a grim reminder of the deteriorating state of public health in India.

Sadly, the country also remains unprepared to respond to potential outbreaks, including the fast spreading swine flu and meningitis. “Today, countries such as India are more global and mobile than ever before and people can carry infections across the world (in and out of the countries) in hours,” says Unni Krishnan, director of Save the Children, a non-profit that works for child rights. “It is absolutely crucial that pandemic preparedness and response is taken up as a priority, and the disaster management maxim teaches that if you prepare well for one disaster, it helps to prepare for several,” he told *Mint* during the recent World Health Assembly.

Against this disturbing backdrop, the latest decision of the Indian patent office to grant a patent to the US pharmaceutical behemoth Pfizer for pneumococcal conjugate vaccine (PCV) 13, marketed as Prevnar 13, has caused a flutter. Despite the availability of life-saving vaccines, annually around one million children under the age of five years and most of them from the poorest sections of the society, fall victim to pneumonia.

Pfizer’s Prevnar13 and GlaxoSmithKline’s Synflorix (PCV10), which are priced at around $59 per dose (Rs3,800) and three doses are required for vaccination, are an effective treatment for pneumonia globally. These two vaccines protect children from life-threatening infections and lower antimicrobial resistance. Little wonder that the two pharmaceutical behemoths earned more than $40 billion from sales between 2009 and the second quarter of 2017.

Pfizer’s patent, according to a press release issued by Medicines Sans Frontieres (Doctors Without Borders), “involves the method of conjugating (assembling) together serotypes of streptococcus pneumonia into a single carrier.” Obviously, this method of conjugating is essential for PCV developers. The patent secured by Pfizer involves mere addition of serotypes to the already well-established seven-valent pneumococcal conjugate vaccine (PCV7). It does not meet “the inventive step” requirement. In 2014, the European Patent Office revoked Pfizer’s patent on grounds that it does not qualify for the patentability requirement—comprising inventive steps and non-obviousness. “The method Pfizer is trying to patent is too obvious to deserve a patent under India law, and is just a way to guarantee an extended market monopoly for the corporation for many years to come,” said Leena Menghaney, South Asia head for MSF’s Access Campaign.

Significantly, the decision of the Indian patent office has come at a time when the government is reportedly under renewed pressure from the US pharmaceutical lobbies for relaxing the overall standards of patentability. It is well documented, particularly in the annual Special 301 watch list

reports, that the amended Indian Patent Act poses a major barrier for the American pharmaceutical companies, particularly Pfizer, in securing patents for their controversial inventions. The provisions in the Act enable patent authorities to deny the evergreening of patents by powerful pharmaceutical companies to extend the period of patent protection through minor and insignificant changes of compounds.

And ever since the Supreme Court rejected the patent for Novartis's cancer drug Gleevec in 2013, the US trade lobbies and the successive administrations exerted intense pressure on successive Indian governments to allow evergreening practices. Last year, the Indian government issued IPR policy guidelines in the face of renewed pressure from American pharma lobbies.

More important, the Indian patent office's decision has come almost a year after the United Nations high-level panel on access to medicines urged governments to use "flexibilities" accorded to them in the World Trade Organization's TRIPS (trade-related intellectual properties) agreement to ensure that patents for life-saving drugs are only awarded for "genuine innovation."

The TRIPS flexibilities involve "the freedom to determine patentability criteria", including concepts such as "novelty", "inventive step" and "industrial applicability." The UN panel also urged governments, particularly in the developing world, to determine the terms upon which "compulsory licences" are issued to pharma companies for "securing the availability and affordability of health technologies".

India has endorsed the UN panel report and campaigned for its implementation. Yet, media reports continue to circulate that the government gave an assurance to the US business lobbies that it will not use compulsory licences, which are treated as weapons of mass destruction by the US pharmaceutical giants. "And on compulsory licences, I can say that India has not given any assurance to anybody," the commerce and industry minister Nirmala Sitharaman said in an interview on 19 July.

Nevertheless, by granting a patent to Pfizer's Prevnar 13, the Indian patent office has raised new doubts about whether it would properly implement the stringent provisions in the amended patent Act in the days to come.

The Narendra Modi government has an opportunity to squash the criticism of global health pressure groups by issuing a compulsory licence for the pneumonia vaccine. Otherwise, it would be seen as an administration ready to genuflect to the diktats of American lobbies.

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