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COVID-19: An Opportunity to Fix Dysfunctional Biomedical R&D System By Sreenath Namboodiri

Failures of the patent system to meet the public health priorities demand a new approach in research and development (R&D) financing and incentive to pharmaceutical innovations. An R&D model delinking the cost of R&D from the price of the product is the way forward.

As we eagerly await a vaccine for severe acute respiratory syndrome-coronavirus 2 (SARS-CoV-2), we are reminded of 2003 SARS and 2012 Middle East respiratory syndrome (MERS). Even after 17 years of SARS and eight years of MERS, we do not have a vaccine for either. In 2016, Dr. Peter Hotez and his team of scientists at Texas Children's Hospital in Houston, Texas were close to finding one for SARS. They were unable to garner market interest to fund their research and take it forward to clinical trials. It was a missed opportunity that could have saved us from the devastation we face today.

The research in its face value was patentable and patents are supposedly the silver bullet to profit for the pharmaceutical industry. Then, why did the industry neglect the SARS vaccine research in 2016? Is patent protection alone not enough to induce the innovation?

Suboptimality of Patent and Pharmaceutical Innovation

Policy makers justify patent as a tool of innovation. A critical analysis reveals that not all inventions are patented, and only those inventions that fulfill the patentability criteria are patented. The success of innovation, i.e., translating the invention into a product depends on many factors and the patent plays a very little role. Further, the patent indeterminacy creates an insecurity to the commercial value of the innovation, increasing the litigating cost to establish its validity. In the words of John Jewkes, British classical liberal economist, the patent is "a lottery in which it is hardly worthwhile taking out a ticket". Hence, the patent has little role in inducing innovation, and for that matter in protecting investment too. It simply manages competition of a market-successful invention.

Modern invention is a product of many incremental activities. Each step in the process adds onto the piggybank of knowledge, which gradually grows into a new understanding and a

consequential discovery to fuel an invention. Hence, it is not “one decisive self-contained mental operation which can be formulated in a definite claim”. This is particularly a hard reality in the case of the pharmaceutical industry. The presumption of invention to be of a singular inventor and granting a patent is fundamentally illogical. In a utilitarian sense, patent discourages the foundational upstream research, which is the bedrock of all innovations.

Further, the patent-oriented research and development (R&D) system leads to market failure. For instance, there is the case of the Ebola epidemic in West Africa, which claimed more than 11,000 lives. There was no dearth of basic research. In 2009, there were at least seven Ebola vaccines which gave promising results when tested in monkeys. However, only one of these seven candidates was introduced to human trials to test its safety, as the rest of them were abandoned before the West African epidemic. The one in human trials was also later abandoned. None of the vaccines reached the stage for licensure and deployment for the emergency. The case of the SARS vaccine mentioned above is no different. The production cost of vaccines, from the industry’s perspective, could be from US\$ 500 million to US\$ 1 billion, which is exclusive of the cost for building manufacturing plants to make necessary doses. When compounding the profitability, vaccines are predominantly required in the developing and least developed countries (except in rare occasions such as we face today) that have very low purchasing power, limiting high profit in single sales. Thus, patents implicitly discourage any R&D investment towards low-profit segments like infectious diseases, antibiotics, tropical diseases, etc. Further, the monopolistic power of the patent holder leads to higher price and compromises access to innovation. Such failures of the patent system to meet the public health priorities demand a new approach in R&D financing and incentive to pharmaceutical innovations. We should not be blinded by the industry’s inertia to change and risk the quality of life of today and tomorrow.



Photo credit: Delhi Post

The Onus to Remedy

Who has the ‘responsibility to remedy’ the current crisis in the pharmaceutical innovation systems? No business entity could be asked to have a high morale or spend money in R&D and share the R&D result at the cost of their profit. Currently, governments of many developed countries finance R&D, but give away the control of R&D outcome to private monopoly. Therefore, the obligation rests clearly upon the states to spend resources on R&D to meet the public health needs and to also ensure access to R&D outcomes. There is a legal obligation to do so under the International Covenant on Economic, Social and Cultural Rights (ICESCR). ICESCR obligates state parties to ensure the right to health and enjoyment of the benefits of scientific progress (right to science) to their people. The state, therefore, has the single and

whole responsibility to radically change the institution of incentive so as to encourage health equity.

That takes us to the next question; how can we carry out R&D cost-effectively and ensure the twin goals of innovation and access? An R&D model delinking the cost (of R&D) from the price of the product is the way forward. There are various methods of implementing delinking such as prize and grants for innovation, advanced market commitments, etc. However, an open innovation model based on public funding is the best approach for developing medicines and vaccines. An open innovation model brings a democratic form of carrying out R&D through maximum involvement and transparency. Each researcher in an open innovation model shares R&D outcomes on an open platform, which are then peer reviewed to identify the knowledge gaps and collectively ponders for solutions. The contribution, value of contribution and corresponding share of researchers in the output would be determined by the community.

The idea of open innovation is pragmatic and is implementable with certain political will. The advantages are numerous such that it shall outweigh loss, if at all any incurred. It lowers the initial cost of acquiring intellectual property (IP) and the cost of overall research is shared, making it affordable for new entrants and veterans alike. Further, this aids in reducing cost of research by eliminating redundancy, external costs for cross licencing and litigation. The results of open innovation would be ethical and would carry integrity and trust of the scientific community unlike the present system. The open source software movement demonstrated the benefits of this collective approach to innovation in information technology. An example to this model in pharmaceutical innovation is India's Open Source Drug Discovery Project, which is not functioning properly at this stage. COVID-19 provides an opportunity to fix our dysfunctional biomedical R&D system. Choices made today would determine the health equity and global welfare of tomorrow.

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