Open Source Drug Discovery – redefining IPR through open source innovations

*Geetha Sugumaran**

Owing to its research-intensive nature, Intellectual Property Rights (IPR) is known to play a vital role in fostering innovations in pharmaceutical and biotechnological industries. But the dry drug discovery pipeline for neglected tropical diseases like tuberculosis and malaria over the years, despite the existence of patents has led to the realization that manufacturing interest of pharma companies is largely governed by purchasing capacity and demand of the consumer population. Lack of market incentives discourages the discovery and development of novel drugs, especially in the case of neglected tropical diseases prevalent in the developing countries with poor purchasing power. This necessitates the development of a new business model that along with fostering innovation can provide an affordable healthcare. The Open Source Drug Discovery (OSDD) Project of the Council of Scientific and Industrial Research presents one such cognizant and effective model that is a unique blend of the principles of IPR and distributed co-creation in open-source mode. This article explains how OSDD promotes discovery of new drugs in open-source mode while enabling and encouraging patenting. It also explores OSDD view on patents and how it assesses the role that patents can play other than establishing market monopoly and ensuring social returns.

Keywords: Drug discovery, innovations, open source, tropical diseases.

THE monopolization of knowledge as an individual property has always been a much debated issue. The pros and cons of patent technology and award of Intellectual Property Rights (IPR) has been a debate dating back to 1421, when the world's first patent was arguably granted to Filippo Brunelleschi for an improved method of transporting goods up and down the River Arno in Florence, Italy[1]. And with the most recent reforms in the patent acts across the world after agreement on trade-related aspects of IPR by the US Government, the debate still continues. With the emergence of open source as a trend in technological innovations, the question of the possibility of co-existence of patent rights and technological innovations, in open-source mode cropped up giving way to further debates and discussions. Patents and open-source products have been conceived to be fundamentally incompatible, and there have been numerous efforts towards the development of models that bring together copyright and community co-creation resulting in the development of open-source licenses like GPL[2].

Geetha Sugumaran is in the Open Source Drug Discovery Project, Council of Scientific and Industrial Research, Anusandhan Bhawan, No 2, Rafi Marg, New Delhi 110 001, India.
*e-mail: geethasugumaran@gmail.com

Patents and pharmaceutical industry

Owing to its research-intensive nature, patenting is known to play a crucial role in the development of new products in pharmaceutical and biotechnological industries. Patents are the means to establish market monopoly and ensure social returns. British economists Taylor and Silberston, based on a survey of UK R&D managers, suggest that pharmaceutical R&D expenditures would be reduced by 64% in the absence of patent protection[3]. While patents play a vital role in governing market monopoly, and have been instrumental in motivating pharmaceutical innovations, the manufacturing interest in itself is largely governed by purchasing capacity and demand of the consumer population. This mechanism is quiet evident when one compares the existing markets for so-called new-age diseases like cancer and diabetes and diseases that afflict the invisible population of the developing countries like tuberculosis (TB) and malaria, two prominent, neglected diseases that contribute the maximum to global disease burden. It is interesting to note that patents fail to play the role as a driver of innovation in the pharma industry in case of these neglected tropical diseases (Figure 1). Lack of profitable market incentives has discouraged the effort of manufacturing drugs for neglected diseases that affect the poor population of the developing world[4] (Figure 2).

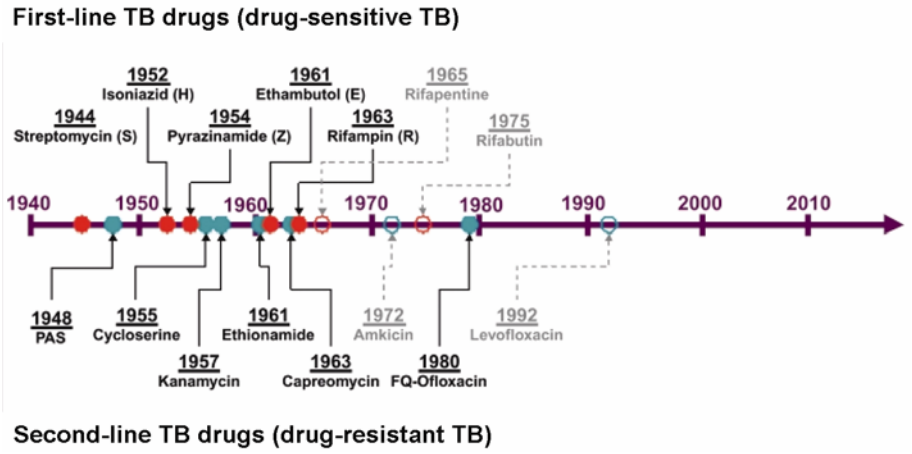

Figure 1. Discovery timeline of currently available TB drugs. Dotted lines indicate that these drugs are not first in class (source: Ginsberg, 2008).

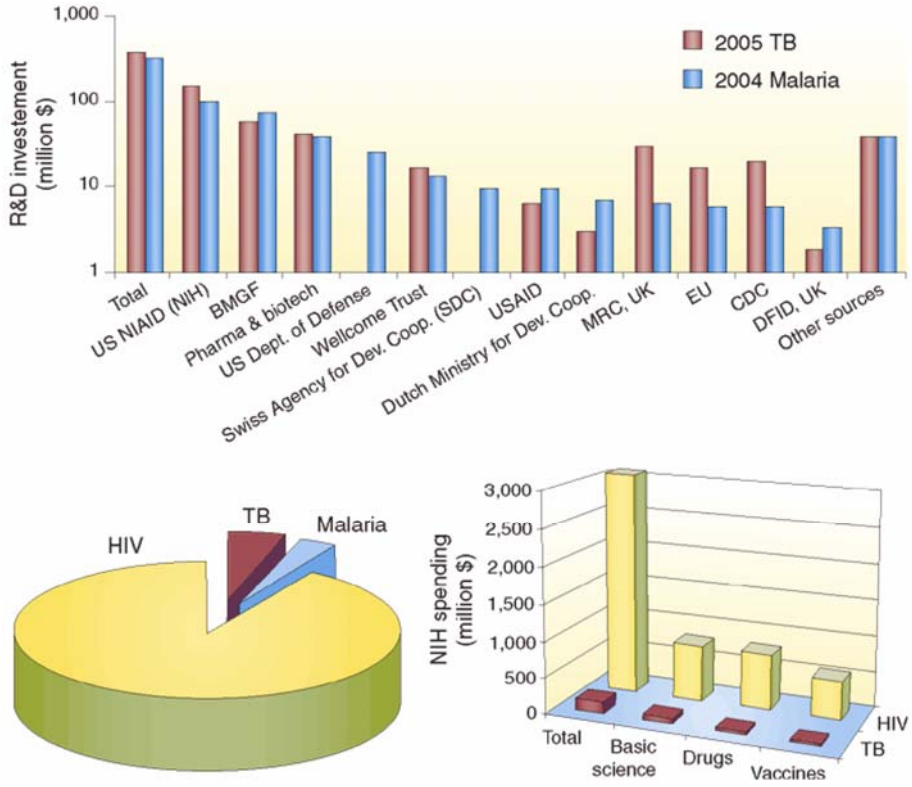

Figure 2. Funding situation for TB (source: ref. 7).

Open Source Drug Discovery: converging patents and open-source innovations

Open Source Drug Discovery (OSDD) is a multifaceted drug discovery project that offers a cognizant and practical model which aims at converging patents and open-source innovations. It is a common assumption that open-source innovations and patent systems are far from co-existence. OSDD, in its quest to discover drugs in an open-source mode is an initiative towards viewing the current patent systems with a fresh perspective. The current status of the dry drug pipeline for neglected tropical diseases like TB, along with the understanding that in the absence of a market size that attracts the interests of the pharmaceutical industry, IPR as a legal system has a limited role to play in fostering innovation, is the key motivation behind OSDD.

OSDD is proving that an IP neutral approach towards drug discovery and development is in fact the best way to ensure affordability and accessibility of drugs in the market. This approach is quite contrary to the popular perception of patents as a legal system to exercise control and as

a means of monetary gain. The OSDD model is a unique amalgamation of open source and patenting principles. Along with mandating adherence to principles of open sharing of data by the participants of the community, OSDD encourages patenting and contribution of patented information for ensuring attribution to the inventors and for proving the non-obviousness of the research. OSDD has a unique view on patents and the instances where inventions are covered by patents; it is to fulfil the following objectives:

(1) Affordability and accessibility: Most of the pharmaceutical companies do not undertake drug discovery for neglected diseases and this task has been undertaken by OSDD. But along with discovery of new potent drugs, it is also crucial to ensure the affordability and accessibility of the drugs. Patented inventions of OSDD are to ensure that the drugs are licensed non-exclusively, as generic drugs, utilizing open competition in the market, removing the monopolistic nature of IP for access in the developing countries.

(2) Quality control: The second objective of patenting in OSDD is to ensure quality control of downstream drug manufacturing, by licensing to only those entities who employ quality processes during drug manufacturing.

(3) Ensure attribution: According to A. H. Cottrell[5], the reward of science is attribution. OSDD aspires to use patents as a tool for attribution rather than a means of revenue-generation. The patented data submitted to OSDD are used by the on-line virtual collaboration system to track individual contributions – a mechanism called 'micro-attribution'.

(4) OSDD supports patenting based on general public licence that ensures that the subsequent innovations which follow on the existing patent remain openly accessible through the OSDD community through its viral clauses[6].

OSDD is thus emerging as a unique healthcare model that blends together the policies of patenting and innovative open-source research to make drugs for neglected diseases prevalent in developing countries easily accessible and affordable without price monopolies. It is indeed the need of the hour that we develop a balanced view towards health as a right and health as a business (quoting Samir K. Brahmachari[6]). Models like OSDD which can assimilate together the concepts of patents and open-source research are required to bring out more innovative breakthroughs that can change the lives of the underprivileged population across the globe.

1. http://newdelhi.usembassy.gov/iprpatents.html
2. http://www.free-soft.org/gpl_history
3. Taylor, C. T. and Silberston, Z. A., The *Economic Impact of the Patent System: A Study on the British Experience*, Cambridge University Press, Cambridge, UK, 1973, A. xiii, p. 408.
4. Trouiller, P., Olliaro, P., Torreele, E., Orbinski, J., Laing, R. and Ford, N., Drug development for neglected diseases: a deficient market and a public-health policy failure. *Lancet*, 2002, **359**, 2188–2194.
5. Cottrell, A. H., *Sociology of Science*, Free Press of Glencoe, Barber & Hirsch, 1962, pp. 388–393.
6. Open Source Drug Discovery; www.osdd.net
7. Kaufmann, S. H. E. and Parida, S. K., Changing funding patterns in tuberculosis. *Nat. Med.*, 2007, **13**, 299–303.

ACKNOWLEDGEMENT. I thank the OSDD Consortium and specially Mr Zakir Thomas, the Project Director for valuable support and guidance.

Received 30 March 2012; accepted 17 April 2012