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Covid-19 medications and public health – Are patents becoming the whipping boy?

Economy

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The slow roll out of vaccine in the country is not because of any barrier caused by patents rather it is because of raw material shortage, and inadequate manufacturing facility.

India is gripped by a fierce second wave of Covid -19 which has created a major crisis on the public health front. This crisis is becoming more severe because of the non-availability of some medicines used for its treatment and the vaccines to prevent it. This has also triggered debates across the country on the role played by Intellectual Property Rights (IPR) in general and patents in particular. While hearing the matter pertaining to Covid-19 crisis the Supreme Court asked the Government of India why it was not invoking the provisions under the Indian Patents Act 1970 (IPA) to deal with the crisis.

The shortage of the availability of the medicines to treat the disease and slow roll out of vaccines have resulted in lot of misconceptions regarding the role played by patents in this crisis. This writeup will be examining the role played by patents in the present crisis with respect to treatment and vaccine options.

Patents are negative rights which means that they give the patent owners the right to exclude others from making, using, selling or importing that product in India under section 48 of the IPA. In India, the approval to market a drug is given by an organisation called the Central Drugs Standard Control Organisation (CDSCO) under the Ministry of Health and Family Welfare. It is the Drugs and Cosmetic Act 1940 and Drugs and Cosmetic Rules 1945 which regulate the import, manufacture, distribution and sale of drugs and cosmetics. The applicant has to demonstrate the safety and efficacy of the drug for use in humans before the drug can be approved for import or manufacturing. In India, the patent office plays no role in the drug approval process.

When it comes to some of the commonly used treatment options in the case of Covid-19 like Favipiravir, Remdesivir, Dexamethasone, Methylprednisolone and Tocilizumab the role played by patents appear minimal. Amongst these five drugs, Favipiravir and Remdesivir are anti-viral drugs, Dexamethasone and Methylprednisolone are corticosteroids and Tocilizumab is a monoclonal antibody. While the first four are manufactured by chemical processes the last one is synthesised from biological organisms. Favipiravir developed by Japan-based Fujifilm Toyama Chemical corporation may be useful to treat mild to moderate symptoms of Covid-19. With respect to the main compound of Favipiravir there exists no patent in India which means that Indian companies have nothing to worry about any infringement action. Thus, by August 2020 many Indian companies have launched Favipiravir in India and the medicine is available in India without any threat of patent litigation.

With respect to Remdesivir, there is an Indian patent granted to Gilead Inc. for the invention titled “Compounds for treating Filoviridae virus infections” that relates generally to methods and compounds for treating Filoviridae virus infections and particularly to methods and nucleosides for treating Ebola virus, Marburg virus and Cueva virus. Gilead filed its patent application with the Indian patent office in April 2017 and the patent had been granted in February 2020. However, Gilead has voluntarily licensed this patent to about seven Indian companies including Dr. Reddy’s, Cipla, Cadila, Hetero etc. and the drug is available in India from June 2020. The shortage of the drug which has been reported in media is because of the sudden surge in number of Covid 19 cases in April 2021 coupled with scaling down of drug production in the

months of January and February because of the drop in number of Covid-19 patients and consequent fall in demand. The existence of patent in favour of Gilead has not impacted the availability of the drug in India as the launch of the drug happened as early as June 2020 through voluntary licenses issued by Gilead.

In the case of corticosteroids like Dexamethasone and Methylprednisolone, there are no patents as they are old drugs. If these medicines are not available in sufficient quantities patents cannot be blamed and questions should be raised about the adequacy of manufacturing facilities and the robustness of supply chain management practices.

Tocilizumab is a large molecule biologic which is an Interleukin 6 inhibitor used to treat a subset of Covid-19 patients suffering from a hyperimmune response called cytokine storm. This drug has Indian patents and the patent holder, Switzerland-based Roche, has permitted only Cipla to import and sell the drug in India. Thus, Tocilizumab may be a fit case for invoking a compulsory license under the IPA.

However, a compulsory license is not a panacea to all the problems relating to availability of biologics. Compared to small molecule chemicals like Favipiravir it is much more difficult to reverse engineer a biologic like Tocilizumab. Apart from the patent the regulatory approval process for the generic version of a biologic called 'biosimilar' is very stringent. Companies who develop biosimilars through the process of reverse engineering shall prove two things before it is allowed to market the product. Firstly, it should be shown that the biological product is highly similar to the original biologic and secondly there no clinically meaningful differences exist between the biosimilar and the original biologic on parameters of safety, quality and efficacy.

The regulatory approval process for a biosimilar is time consuming process which involves clinical trials. There are news reports that Hyderabad-based Hetero has come up with a biosimilar to Tocilizumab and has applied for clinical trials. If India has to very quickly ramp up Tociluzumab production it should work closely with Roche which can grant voluntary licenses and manufacturing know-how to many other Indian pharma companies. Compulsory licensing at this stage may appear as a coercive measure and non-co-operation by the patent holder on transfer of know-how can do more harm than good if our aim is to ramp up production of the drug manifold in a very short time frame to deal with the pandemic.

Delay in Vaccine Roll Out – Role of Patents

The slow roll out of vaccine in the country is again not because of any barrier caused by patents. The two vaccines which are currently available in the country, Covishield and Covaxin are not granted any patent. Even if the companies have applied for patents, it would take about three years for them to be granted a patent. However, it needs to be seen whether any of the platform technologies used in the manufacturing of theses vaccines are patented in India. In case any of these technologies are protected by patents then efforts should be made to issue compulsory licenses on them.

The main reason which has slowed down vaccine manufacturing is raw material shortage, and inadequate manufacturing facilities. The highly sophisticated manufacturing processes used in the case of viral vector-based vaccines like Covishield increased the gravity of the problem. In the case of Covaxin, the Government of India is a co-owner of all the rights including the right to apply for patents. Nothing stops the Indian government from roping in more pharma /vaccine manufacturers from India and abroad to ramp up the production of vaccine through transfer of technology. Even in the case of Covishield, government can request Astra Zeneca-Oxford/ Serum Institute to rope in more manufacturers on the basis of technology transfer/know-how and ramp up production many times.

Last week a major announcement came from US regarding its support for an IP/ patent waiver regarding COVID-19 vaccines. This proposal is very much in its initial stages and we will have to wait for the final decision of World Trade Organisation to assess the impact. However, it is unlikely to be of much help to us because our slow rollout of vaccines is not caused by any barrier caused by patents on vaccines. Even before this announcement the US company Moderna which made its vaccine based on mRNA platform issued a statement that that it will not enforce its COVID-19 related patents against those making vaccines intended to combat the pandemic and has promised to license its intellectual property for COVID-19 vaccines to companies who want to use its technology.

Concluding Thoughts

It is expected that in the coming days there will be series of steps taken by all stakeholders on the manner in which the poor and needy can access vaccines and drugs in an equitable manner. Similarly, companies that own product patents will need to work with Indian generic companies to reach a viable licensing mechanism that satisfies both sides. However, putting the entire blame on patent system for the current crisis is only going to obfuscate the truth and will not help us in any way to find a solution.

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