Mr. Rishikesh Singh Faujdar

Prof. S.Z. Amani

Faculty of Law, Jamia Millia Islamai, New Delhi-25

Topic: TRIPs Compliant Patent Law and Access to Medicine: A case Study of India Keys Words: TRIPS, WHO, Patent, Medicines,

The patent system is social policy tool that aims to stimulate innovation. Internationally, patent protection is governed by the World Trade Organization (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement. TRIPS do not establish a uniform international law, but sets out minimum standards of patent protection that must be met by all WTO members. Developed countries have already implemented the agreement, and other countries such as India are implementing it now, in 2005. Least-developed countries are not obliged to do so until 2016. Medicines are expensive when they are protected by patents. The patent holder has a monopoly on the drug for a minimum of 20 years, and uses that period to maximize profit. But as soon as generic competition is possible, prices of medicines plummet: for instance, after the Brazilian government began producing generic AIDS drugs in 2000, prices dropped by 82%.

Findings of thesis

Indian Pharmaceutical Industry needs to invest increasingly to develop new molecular companies in the R&D (R&D) process; R+D benefits can be reaped over the coming years. Good manufacturing practices and increasing investments should also be adopted in the Indian Pharmaceutical industry. GMP-certified production facilities are accepted globally and will greatly increase the sales of companies. Yes, people have a variety of infectious diseases, several new life-style diseases, and so the pharmaceutical industry is a sunshine industry with often new boundaries for growth. The endless search for effective treatment of diseases will always be

Current new pharmaceutical industry prospects. The study of chapters 1 and 2 reveals that the Indian patent system is not only primarily nationalist, but also strongly nationalist. In other words, in the world, there are no uniform or standardized patentability standards or qualifications. The pattern of intense imperialism in patents has been such that it is often difficult to find criteria for granting patents, if not impossible, in realistic terms. The initial Patents Act 1970 was a wise legislation that promoted the growth of industry and adequately protected the public interest. However, in order to emphasize these concepts (a) innovation, (b) innovation and, more specifically, industry application and the preceding requirements for patent grants, the Indian Patent Act was amended from 1999 to 2002 and 2005. It is true that national mechanisms have very few consensus on the adequacy of patent systems. The 2005 amendment, which removed Section 5 from the main law, was the most important step in compliance with TRIPS. In the absence of section 5, a patent for invention promising for a period of 20 years pharmaceutical, food and agricultural products is now valid. Even if the rule India's patent law has been significantly revised in 2005, including the most controversial provision for drug patents in pharmaceutical products. Civil society activists are concerned about the drastic increase in the price of medications and adverse effects of the exposure to prescription medicines. A number of important provisions are included in 2005 legislation to ensure that approved generic versions of the goods are not subject to pressure. It also provides access to available new medicines. Whether such laws would automatically be applied in ways that favor public health remains to be seen. Furthermore, in keeping with Section 84(6) of the main statute, the 2005 Act filtered down one of these litigation hindrances by ensuring that "voluntary agreements" with a patentee should be completed within six months. In relation to drugs where the API is of considerable significance, and in compliance with Section 2(ta) of this statute, the definition "pharmaceuical substance" is not still specific and consistent. While there are some of the lowest worldwide costs, Indian companies are able to supply the world not only with the Indian drugs industry but also with essential medicines. Therefore, firstly, we should use this opportunity to enhance drug manufacturing in India by supporting and streamlining the production of pharmaceuticals through initiatives such as consistent implementation of production personnel movement policies across all the states (including formal notice for all government / local authorities); Droges are acceptable worldwide due to low prices. To USFDA (India has the world's largest number of USFDA plants) reputed for the highest standards, India

will offer high-quality pharmaceutical drugs at low prices. The USFDA has a reputation for quality. Second, for the production of diagnostic sets and other medical devices to develop, the government needs to launch targeted financial incentives to promote the manufacture especially as the raw materials to produce these devices are highly dependent on imports. It also represents an opportunity to return a much larger share of API manufacturing to India, so that it is not dependent on imports of essential inputs. In this context, the decision by the government, through bulk drugs parks and production-related incentives, to promote domestic KSM, intermediate and API manufacturing, is an extremely welcome policy for the industry. The future can further strengthen the independence of India in the pharmaceutical industry by offering incentives / support for the manufacture of API and Intermediates / KSM, for example, for SEZs for bulk medication manufacture. Thirdly, the Indian pharmaceuticals industry is now designing new molecules for the treatment of various medical conditions. In the clinical trials, many Indian companies already have molecules. The development of new drugs costs money and, while holding companies responsible for new medicine for India and the world, the government must ensure the necessary profits for investing in new molecules. Indian prices are currently among the lowest in the world. Research data for 108 molecules from the IIM-Ahmedabad also shows that price management has not increased access and affordability, based on data of 2011-18. Thus, the drug price policies need to be refined to generate adequate surpluses to invent new molecules and to keep prices low, so that affordable healthcare is provided. The government can therefore boost India's pharmaceutical research and development by implementing streamlined and speededed regulatory and test pathways for all medicines, including Covid-19. Increased innovation / R&D can provide Indian pharmaceutical products with a long-term drive. Three recommendated steps in support of R&D expenditure and results, increased R&D funding availability and a closer cooperation process among government institutions such as CSIR labs and NIPERs with private R&D are recommended. Three suggested measures are recommended. During the Covid 19 crisis, the industry already took crucial measures by exporting medicines to several friendly countries. A formal export incentive program for the Indian pharmaceutical industry can be initiated to improve medical supply to global markets far in the medium term. This project would be much wider. The Indian pharmaceutical industry has the ability to play a greater role in ensuring the protection of global drugs supply and the possible financial opportunities will play a major role in this. It, of course, is subject to the fair cost of supplying

essential medicines in India. The Indian pharmaceutical sector is a nation's strategic industry, with a scale advantage (1.5% of GDP contributed directly to \$37 billion in 2019-20, with another 3% coming indirectly). The industry also has international presence and receives more than \$10 billion annually as a net foreign exchange. The tech in the 1990's and 2000's will do for India, Pharma. The back office became India. Let this be the moment at which the trend has been intensified to become 'the world's pharmacy.