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RIGHT TO ACCESS AFFORDABLE AND EFFECTIVE MEDICINES IN THE WORLD OF PATENTS AND PANDEMICS WITH REFERENCE TO INDIA

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ABSTRACT

Pharmaceutical Drug research and development is an expensive, time consuming and uncertain process that may take 8-10 years to complete. Patent watch begins much before a new drug is approved for marketing and significant amount of time can be lost in the review and approval process by regulatory bodies. So to regain the considerable time and resources invested in the drug development and approval process the pharmaceutical companies depend on exclusivity provisions granted by the regulatory bodies. There are several official and unofficial methods to extend term of a patent beyond 20 years, Official methods include provisions by some regulatory bodies such as Data exclusivity, Orphan drug exclusivity, Pediatric exclusivity and the 180-day exclusivity for first generic company after the expiration of patent in American Hatch Waxman Act, 1984 or Supplementary protection certificate given by European Medical Agency. Unsanctioned methods include altering or reformulate the existing compound to obtain a new patent by creating combinations, taking advantage of polymorphism, authorized generics, etc. In the era of big pharmaceuticals dominating and promoting their drugs through international conventions and important national persons, it is very difficult to assume that states really want to promote affordable and effective drugs for patients globally. Despite being there explicitly in Article 25 and Article 27 of Universal Declaration of Human Rights, 1948 and in Article 12 of International Convention on Economic, Social and Cultural Rights, 1966, people have not been able to fully enjoy and exercise their rights regarding health. In fact, the world needs to think seriously about World Health Organization's approach to health crisis globally after their

approach to Corona virus scare globally and their bipartisan attitude towards China. We need to look also weather international law is applicable actually or is it mere paper work exercise. The world needs to make fine balance between research and development of new drugs and their quality and price also. Despite efforts from various organizations from different countries and different people, it has not been achieved fully. We should not forget that it was Hamid Yusuf and his Indian Company Cipla which came into aid of world with 38 cent per day therapy for epidemic called acquired immunodeficiency syndrome (AIDS).

Keywords: *big pharmaceuticals, international conventions, bipartisan, corona virus, scare*

Human Right And Right To Affordable And Effective Drugs

Article 25 of United Development of Human Rights, 1948 says that everyone has the right to a standard of living adequate for the health and wellbeing of himself and of his family including medical care.

Article 27 of United Development of Human Rights, 1948 says that everyone has the right to share in scientific advancement and its benefits.

Article 12 of International Convention on Economic, Social and Cultural Rights, 1966 also says that the states parties to the present convention recognize the right of everyone to enjoyment of the highest attainable standard of physical and mental health. The steps to be taken by the state parties to achieve the full realization of this right shall include those necessary for the reduction of infant mortality and for healthy development of the child and the prevention, treatment and control of epidemic diseases.

Article 31 of Trade Related Intellectual Property Rights (TRIPS)[1] says that State government may be permitted to issue compulsory licenses for public noncommercial use.

Doha Declaration also was the reaction of developing countries against developed world. Some of the key take away of Doha declaration includes:

- Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

[1] Trade Related Intellectual Property Rights

- Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crisis, include those related to HIV/AIDS, Tuberculosis, Malaria and other epidemics can represent national emergency or other circumstances of extreme urgency.

- Setting up a patent system of their own devising is a sovereign right of nations. Countries are given autonomy on this and many other issues.

- Unlike other disputes in World Trade Organization (WTO)[2], a Compulsory license dispute is appealed not in WTO but to Nation's judicial system or Review Board.

- Paragraph 4 of Doha Declaration affirms that the Trade Related Intellectual Property Rights Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating the commitment to the TRIPS Agreement, the nations have agreed that the Agreement can and should be interpreted and implemented in a manner supportive of World Trade Organization members' right to protect public health and, in particular, to promote access to medicines for all.[3] This includes vaccinations also.

International Conventions

The convention on biological diversity was opened for signature at the Earth summit in Rio de Janeiro, Brazil on June 5, 1992 and by the end of July 1993, 165 countries had signed the treaty. It contains three national level obligations; to conserve and sustainably use biological diversity and to share its benefits. All United Nation member states except United States have ratified this treaty. As of 2016, the convention has 196 members that includes 195 countries and European Union.

Arguably, there is room within TRIPS agreement to reshape implementation in a manner that protects traditional knowledge. Article 7 identifies the objectives if the entire TRIPS agreement as to contribute to the promotion of technological innovation and to transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations. This language together with Article 8 which provides that member states may adopt measures necessary to protect public health and to promote the public

[2] World Trade Organization
[3] https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

interest in sectors of vital importance to their socio-economic and technological development was included in the final TRIPS agreement at the behest of developing countries. These provisions have supported people attempting to blunt the force of Article 27.3 TRIPS.

In paragraph 19 of Doha Declaration, negotiators reaffirmed that Art 27.3 needs to be reconsidered in light of the Article 7 and 8 objectives, with regard to traditional knowledge.

According to WTO, "Intellectual property rights are the rights given to people over the creation of their minds". Yet the way TRIPS is structured against indigenous groups to claim any intellectual property rights over the unmediated products of their traditional knowledge. As a result, indigenous and traditional knowledge is consigned to the global commons. This produces a striking imbalance the creations of the mind of modern science are considered property and eligible for the full panoply of TRIPS protections, while the creations of mind of indigenous people are not.

Patent laws and its manipulations

Indian Patent Law after independence was based on the Ayyangar Committee Report.The Ayyangar Committee Report on Patent Law gives us a well thought insight into the regulatory mindset of the Indian State with respect to patent policy in the 1970s. The Report takes stock of patents granted and pending applications to find that ownership of patents is primarily with multinational companies. It recommends that the best response to this situation, 'In the national interest', is to adopt a defensive patent policy which accommodates the drive for the independent, domestic development of the national economy. The Patent Act, 1970 enacted the policy, which denied product patents in pharmaceutical drugs which endured until we signed the Trade Related Intellectual Property Rights Agreement in 1994. It was certainly successful in promoting domestic pharmaceutical companies in developing a low-cost, high-access generics medicines. These firms innovatively developed new product processes and novel formulations and modes of delivery and the technological capacity by reverse engineering in the global market for generics.

However, even the most intense lawyer for this policy would reluctantly agree that this policy failed to discover newer drugs. These firms which exploited the commons of ideas created by the patent policy failed to sustain this commons by reloading it with a tradition of innovation and invention. The reforms in the Indian patent Act, 1970 started in the 1990s, with Patent (amendment) Act, 1999 and Patent (Amendment) Act, 2002 and became TRIPS Compliant with the Patent (Amendment) Act, 2005, though not clearly articulated in a policy document, promises to change these priorities. We are likely to see a significant increase in the patenting of new drugs and molecules by foreign and Indian companies, but there will be natural rise in prices and decreasing access to drugs for consumers. It may be that cutthroat competition or

drug price control policy may contain some of the adverse effects of this turn, but it seems that we are condemned to the eternal play of one imperative at the cost of the other.

Detailed provisions for the grant of compulsory licenses are among the features of the Indian Patents Act, as amended. The Act provides that an application for the grant of compulsory license can be made only after three years from the date of grant of the patent unless exceptional circumstances like national emergency or extreme emergency can be used to justify the grant of a license on an earlier date. Three broad grounds for the grant of the compulsory licenses have been spelt out thus: (a) reasonable requirements of the public with respect to the patented invention have not been satisfied, (b) the patented invention is not available to the public at a reasonably affordable price, and (c) the patented invention is not worked in the territory of India. However, a compulsory license can be granted only when the patentee is paid adequate remuneration taking into account the economic value of the authorization.

Bayh-Doyle Act in USA

The Bayh-Dole Act is a **federal law enacted in 1980** that enables universities, nonprofit research institutions and small businesses to own, patent and commercialize inventions developed under federally funded research programs within their organizations. United States has created this law to incentivize the research and encourage it. India still has to come up with the competent act that encourages invention but we have started Start up programs across universities that encourage invention and new business ideas.

Generic drug companies

Since the generic company has to spend less on Research and Development, they are able to provide drugs at prices manifold lower than branded drugs. Consequently, the generics significantly reduce the market share of the branded drugs, which compels the innovator firms to adopt unethical practices of ever-greening. Generic drug companies play a very important role as cheaper generic versions of the costly branded drugs are the only hope to save lives in underdeveloped and developing countries. Innovator firms exploit the loopholes in the patent laws to acquire additional patents over the parent patent to retain its exclusivity in the market. Thus, these additional patents for minor modifications fortify the parent patent and significantly delay the entry of generic competitors which in turn directly affects public health.

Patent Picketing

Patents picket is a term used when the patent holder practices the patent in certain jurisdictions but refuses to work the patent in others. The idea of patent picketing developed as a result of shift from the representation of the working of an invention physically to mere describing, effectively, the inventions in patent applications. Patent holders picket with their patents and demand higher price, thereby not only preventing others from using the invention but also ensuring that the product is made available in the market. Such behavior can be regarded as the abuse of intellectual property when the non- working of a patent leads to deprivation of another patent locally. The issue of market initiated compulsory license may solve the problems linked with IP abuse arising out of patent picketing.

Human immunodeficiency virus infection and acquired immune deficiency syndrome (HIV/AIDS) and epic response by CIPLA

Initially, when respected drug maker like CIPLA tried to make a cocktail of anti-retroviral drug combination which it was giving $600 to African nations and at $350 to Doctors without Borders, the whole world leaders such as President Bush of USA and Al Gore of UK were against Indian drug maker and African Leader Nelson Mandela who changed patent law in Africa. It was the promise of CIPLA to give ARV drug cocktail combination at $1 per day which caught the eyes of activists working for patients worldwide. With the help of Clinton foundation, these ARV combinations were sent to 30 cents per day. Thus, cheap drugs were made available to African countries which in turn were helpful in less spread of AIDS all over the world. PEPFAR program was later appointed by American President George Bush as he too later supported the cheap drug program.[4]

Corona Virus scare and world's response

Coronavirus has now done what years of United States Government Accountability Office reports, United States Congress and Comptroller and Auditor General in India could not achieve. It has laid open the full perils of United States and India's dependence on an overseas drug supply on active pharmaceutical ingredients. Not only has these pandemic intensified already serious drug shortages, but also has raised questions about quality and reliability of drugs supplied. India is dependent on china for 30% of its Active pharmaceutical ingredients. Major products for which dependent on China: Antibiotics, Cephelosporins, Vitamins, Paracetamol, Meformin, Renitidine, etc. Fermentation based products are a challenge to India. Recently, Indian government has allocated Rs.10000 crore budget and is planning to buy 3 Special Economic Zones to build bulk drugs to reduce

[4] Katherine Eban, "Bottle of Lies", Juggernaut books

dependence from China. The cocktail developed as antibody for protection against the pandemic Covid-19 by Rosche pharmaceuticals and marketed by CIPLA would cost Rs.1,20,000 to people in India.

Patents and Vaccination

India is a land of over 136 crore people. To make everyone immune to pandemic requires humongous efforts on part of the government and it is not possible with the help of people also.

The vaccines available in the market are protected under Patent law as per the Trade Related Intellectual Property Rights Agreement. This makes the right of patent holder of vaccines to manufacture and distribute the vaccines or medicines for the whole term of 20 years. The Developing countries have also acquired raw material used for making the vaccine. So this shortage is detrimental to the vaccination program of India despite the government making huge efforts. In light of these facts, India and South Africa's proposal to remove patent protection by using TRIPS waiver is not arbitrary and too much. All other proposals to pacify the movement are derailing the humanitarian cause of access to affordable and quality medicines in the pandemic situation which is a basic human right.

The Crossroads

The United States Food and Drug Administration (USFDA)[5] has proposed generics to patients as a bargain with no drawbacks, but there are hidden costs that are not being examined. In times of pandemic, the USFDA removes hurdles for Indian companies as they want medicines soon. Sometimes, Indian pharmaceutical industry is criticized for giving fraudulent data for bioequivalence for their generic drug as abbreviated new drug application and subsequently sold in United States of America 6 months earlier than other generic drugs. Patients have often complained about side effects of some generic medicines like Ranbaxy.

CONCLUSION

After the invasion of corona virus and its disastrous effect on people all across the world, certain myths have been broken completely. The veil of World Health Organization as well as United Nations Organization has been lifted and they have become nothing but puppets of super powers. The same applies for international conventions also. It reminds us of Austin's vision that international law is not law. Covax initiative is a welcome step but it is not adequate. In these times, Indian philosophy of "Vasudev Kutumbkum" remains intact. Our

[5] United States Food and Drug Administration

medicinal system is about taking fewer drugs and eating something hygienic so that preventive measures are protecting us. We don't believe in discovering diseases so that we have to eat more and more drugs to prevent and protect us from diseases. The world needs to seriously relook at the western model of Medicines and infuse Indian philosophy of Ayurveda and other herbs related cures and it must also try to stop Biological war fares by bringing and enforcing strict conventions.

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