ENSURING EQUITABLE ACCESS TO VACCINES IN THE GLOBAL SOUTH: ANALYSING THE SCOPE OF THE RIGHT TO HEALTH IN TRIPS WITH SPECIAL REFERENCE TO "THE LESSONS FROM THE PANDEMIC"

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ABSTRACT

Access to quality and affordable healthcare is a human right. However, according to the WHO report 2017, almost half of the population could not obtain essential healthcare. This population primarily constitutes the "global south." While on the one hand, globalization paints a borderless world concomitant to complex interdependencies, on the other hand, through international trade regulations, we have exacerbated the "global health divide."

This health divide was yet again witnessed in the current COVID-19 pandemic. In this paper, we have analyzed how the current Trade Related aspects of Intellectual Property Rights (TRIPS) provisions have become a barrier to equitable health despite the flexibilities provided to least-developed and developing countries. Learning the lessons from the current pandemic, we have provided a way forward to approach the problem of inequitable health access.

Keywords: TRIPS, Essential medicines, Intellectual property, international trade, vaccine equity, global health, pandemic, human rights, patents

Introduction:-

The COVID-19 Pandemic laid bare the colonialism that never ended. In terms of Global public health, it means history repeating itself, millions dying of disease on the one hand and richer countries worrying about rekindling their "economy" on the other. In a nutshell, however, a collective failure! Failure to achieve the "Right to health".

This paper aims to analyse the conflict between IP rights and the right to health. We examine the TRIPS flexibilities and their nuances. We further argue that it is the decolonization of the IP framework that is a lesson for the world to deal with future pandemics.

History of Patent regime and Vaccines: -

The idea obtaining Patents is to gain a monopoly over the manufacture, production, and distribution of the drug. This idea, contrary to present times, was niche in earlier times.

Preceding Trade-Related aspect of Intellectual Property (TRIPS) Paris industrial policy 1883 and World Intellectual Property Organization (WIPO) left the scope of granting patent rights to its members, moreover, the conventions were not binding.

There were even debates about whether vaccines even fall under "invention" and thus to be patented or not. When the Polio vaccine was discovered, the intent was to cure people of the debilitating condition, Jonas Salk himself mentioned that "this vaccine would operate gift to the world"[1].Usually, a vaccine involves the processing of living organisms like a Virus that is to be injected into the human body to fight the disease. It was only after the case of ***Diamond v Chakrabarty***[2] that the creation/processing of living organisms was patentable.

Even after so, the global community, especially the developing and LMICs considered some vaccines falling under the essential medicines category to be too vital to be patented.

[1] Ruby Mellen, *Vaccines have never been distributed equally. A coronavirusvaccine would be no different, historysuggests,* WASH. POST (https://www.washingtonpost.com/world/2020/11/12/vaccine-distribution-history-coronavirus-h1n1-h5n1/)
[2] Diamond v. Chakrabarty, 447 U.S. 303, 100 S. Ct. 2204, 65 L. Ed. 2d 144, 206 U.S.P.Q. (BNA) 193 (U.S. June 16, 1980)

TRIPS and Global health: -

In 1982 some pharma companies of the developed world complained of commercial losses incurred due to a weak patenting system. The "Uruguay Round of negotiations within the General Agreement on Tariffs and Trade (GATT)" lead to the creation of the World Trade Organization (WTO), intending to promote free trade amongst the members of the new organization. Through the last round of Uruguay negotiations agreement on trade related aspects TRIPS came into force.

The aim was to strengthen certain aspects of intellectual property protection at the global level, hence fostering innovation. Unlike the earlier conventions, compliance with TRIPS is not only required of every WTO member is also enforceable through Understanding on Dispute Settlement ('DSU') and Appellate Body to entertain appeals from Panel decisions and sanctions for non-compliance[3].

TRIPS calls for the members member states to grant patents for a minimum of 20 years from the date of filing of the invention. Article 27 further provides that patents shall be available in all fields of technology, so the countries unable to spend on R&D could no longer exclude medicines from patentability to produce the local copies of the patented ones[4].

Indeed, the regime of intellectual property was formalized after the TRIPS. Pandemics and epidemics happened to take the lives of millions. However, the primary reason for the loss of lives of millions in global south was the inaccessibility of vaccines.

Indeed, history repeats! The data of this pandemic reveals that the mortality rate of LMICs due to covid was much more than the birth rate of developed countries. While the global north went on Hoarding the vaccines and getting booster shots, the other side of the globe could not even get a single shot[i]. This phenomenon of global inequity in terms of accessibility of Vaccines is being referred to as ***"Vaccine Apartheid".***

It is thus pertinent to examine what is deferring the world from saving the lives of millions and achieving the goal of the right to healthcare. There happened to be some amends in TRIPS,

[3] Cottier, Thomas. "Working together towards TRIPS." The Making of the TRIPS Agreement (2015): 79.
[4] Article27, Agreements on Trade related aspects of international property,1994,1869 U.N.T.S. 299.

however they need to be sufficiently used/implemented to achieve the goal of ensuring equitable health to all.

Balancing IPR and Right to health: Analysing TRIPS flexibility and its Efficacy: -

The breakthrough event that seemed to balance patent rights and global health was the Doha declaration. It provided something called TRIPS plus and TRIPS Flexibilities.

TRIPS "flexibilities" mean that members can adopt provisions in national legislation that would still meet the minimum standards of TRIPS and hence fully legitimate. EU and US adopted policies like patent linkage, data exclusivity, an extension of patent terms, etc[5]. For low-income and developing countries, it would mean suiting to their standards, defining what "invention" means, importing drugs from the countries where it is available at cheaper rates(parallel imports), compulsory licensing etc.

Compulsory licensing-

Most of the LMICs and developing countries used the TRIPS flexibility of ***Compulsory licensing(CL)*** to efface the growing health burden and end the pandemic. CL was a provision inscribed under article 31 of the TRIPS agreement, CL allows any third party to use the invention without the patent holder's consent and that is not considered an infringement.

Initially, this provision was only available for domestic markets.

E.g., If a generic drug is produced in India by CL, it can only be used by the domestic market of India and not allowed to be exported to other countries this was provided in article 31 (f), and after immense negotiation, this provision was done away with.

Issues with compulsory licensing:-

1. First one is the onus of "adequately remunerating" the patent holders, this leads to a debt later on, and as a result, LMICs are coerced to remain dependent on the global north. LMICs not having Economies of scale again remains an unresolved issue[6].

[5] Correa, C.M., 2022. Interpreting the Flexibilities Under the TRIPS Agreement. *Access to Medicines and Vaccines*, p.1.
[6] Abbas, M.Z., 2021, June. Potential Role of Compulsory Licensing in the Post-COVID Recovery: Contexts, Challenges and Prospects. In *2nd SANEM International Development Conference: COVID-19 Recovery: Contexts and Priorities*.

2. Second, a Member is free to provide a compulsory license for the importation of goods that are patented on its territory, provided that the imported articles meet specific requirements. made in a country where copyright protection does not exist or the protection term does not apply Protection has expired. However, if a potential provider possesses a patent, they have an advantage. country the patent holder may limit shipments to the required countries. medicines. Moreover, since Article 31(f) mandates an obligatory licensee. This limitation would prevent suppliers from supplying the domestic market predominately. providing a needed license solely or mostly for export to a needy country.
3. Another problem about the use of Compulsory licensing is a Power imbalance between developing countries and big MNCs. When developing countries issue a compulsory license, they do at the risk of "disappointing" patent holders. So the patent holders refuse to file patents for other drugs that they produce. This happened in Thailand, wherein the government issued CL for an essential HIV drug Kaletra produced by Abbott, and as a result, Abbott refused to file seven patents in the country[7].

   So essentially, the problem concerning compulsory licensing is a lot more than what could be dealt with by national governments, as, MNCs have immense lobbying power. CL is an "amend" to balance out profit v meeting the needs of healthcare; patents still vest with the holders.
4. Lastly, It's a general attitude of developed countries to use retaliatory measures adopting to sanctions. Eg. The US of the Special Section 301 of the US Trade Act 1974, and in the European Commission Staff Working Document on the protection and enforcement of intellectual property rights in third countries.

An alternative approach to fix the Global health divide: -

This pandemic laid naked the global health divide between the north and south. Some academicians even said "Pandemic laid bare the colonialism that never ended."

As per UNICEF,86% of all doses administered worldwide through March 30 were given to those in high- and upper-middle-income countries, while only 1% went to the world's poorest.

[7] Abbott FM and Reichman JH, 'The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines under the Amended TRIPS Provisions' (2007) 10 JIEL 921, 970.

The charity-based approach of fixing the inequitable access to healthcare, especially in times of crisis is not leading us to the desired destination.

- An example of this "charity-based" approach is the "COVAX" scheme wherein manufacturers would pool voluntarily the procurement to help accessibility of vaccines. This mechanism could not meet the needs of the ongoing demand.There remains a perpetual sense of dependency that is created by these mechanisms. Even after hard negotiations, the creation of a mechanism requires the countries to be grateful to the charity given by the colonizers.
- Further, the TRIPS Flexibilities fail because of the failure to acknowledge that merely "allowing" countries to use provisions does not necessarily mean that it shall be successfully implemented. Factors like power politics need to be taken into consideration.

It is thus argued that the "approach" by which we interpret IP rights vis a vis Global health needs to change. This is required to really achieve the goal of universal healthcare.

Literature review of the proposed Idea:-

Justin Paulfromthe University of Florida, USA remarked that The availability of vaccines is currently crucial. The current predicament has demonstrated that globalization is an unstoppable process. Vaccines are essential to the progression of humanity and the world. A vaccine that does not require a patent could save as debilitating as this one.

What prof Paul has mentioned is an acknowledgment that the pandemic would not end till everyone is vaccinated. There is no rocket science hidden beneath this logic. Indeed, it is the reason diplomacy of India and South Africa did lead to a waiver on IPR protection given to Covid vaccines for a brief period.

However, The Authors as a part of their research called *"decolonizing human rights: how IPR leads to unequal acess of Covid-19 vaccine,"* adopt a different approach.

They argue that The current TRIPS regime focuses on the commercialization of essential medicines, which inherently is a human rights issue and should be looked at from that perspective only. The waiver of patents during Covid-19 and relief packages was not something that was given in Charity but essentially member countries fulfilling their human rights

obligations. Even though the countries are sovereign and attained independence, the current patent regimes coerce them to follow what is profitable for the global north. There is further a problem of "politicization" of essential medicines, during pandemic even global south aimed at providing poorer countries vaccine and covid related help for geopolitical reasons. The commodification of essential medicines needs to really decolonize LDICs[8].

Rochelle C. Dreyfuss in her essay further highlights it's the TRIPS "one size fits all" approach that side-lines heterogeneity of the globe and the problems confronted by the developing nations[9].

Lessons for the future pandemic

There is a need of a change the way we approach interpretation. Acknowledging that TRIPS itself calls for a Human rights centric approach to the way we look at patents is the way forward. There are multiple provisions in the treaty itself which indicate the "intent" behind TRIPS in terms of Trade and equitable access to vaccines.

Preamble of TRIPS itself makes it clear that "measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;"[10]

Similarly, Article 7 indicates subordination of IPR concerning social and economic welfare.

Interpretation of TRIPS from the perspective of the Human right of healthcare reached its peak during AIDS pandemic. In ***Pharma v Mandela 1998***, a suit was filed against the Government of South Africa by multinational (MNC) pharmas of the country, alleging their new amendment to be violative of the norms of the TRIPS agreement. The amendment aimed at providing broader access to cheaper drug through provisions legalizing the substitution of off-patented medicinal drugs, transparency in the pricing of the medicines, and parallel importation of

[8] Sekalala, S., Forman, L., Hodgson, T., Mulumba, M., Namyalo-Ganafa, H. and Meier, B.M., 2021. Decolonising human rights: how intellectual property laws result in unequal access to the COVID-19 vaccine. *BMJ Global Health*, *6*(7), p.e006169.
[9] Nicol, D., Dreyfuss, R.C., Gold, E.R., Li, W., Liddicoat, J. and Van Overwalle, G., 2019. International divergence in gene patenting. *Annual review of genomics and human genetics*, *20*, pp.519-541.
[10] Library, WHO Health Systems(2021), Globalization and Access to Drugs, Health Economics and Drugs Series, No. 007. march. Accessed 2021

patented medicines. The US had threatened to put trade restrictions on South Africa if the amendments were not withdrawn[11].

Why this case is so relevant is because this pointed out the concerns that developing countries were facing because of patent regime. Secondly, patient-led advocacy threw a message of prioritising human right to health over patents.

This needs to be amplified and implemented. Failing to change the way we interpret TRIPS has practical consequences. Like we discussed earlier, when TRIPS flexibilities are used by LMICs. threats are imposed by developed countries. For an instance, India and other countries like Thailand and China were put under the 301 watch list, and in 1992 US excluded India from GSP. This obviously creates hesitancy amongst the global south[12].

Via this Human rights centric approach, there will be an obligation on the developed countries to not to hinder goal of attaining public health.

There's a need for institutions like WHO,WTO ad Human rights council to work together. Further, there is a need to impose an "obligation" for member states to use the "TRIPS flexibilities" rather than mere acknowledgment.

Developed nations must be obligated not to impose sanctions when global south is taking steps to ensure global health especially in times of emergencies/public exigencies. The charitable COVAX project, a model in which altruism is prioritized over rights, is not in line with public health and human right understanding of equitable access to health.

Our approach must berights-centricic" and aimed at decolonizing the current IP framework to eliminate the Global health divide.

It is further contended that there is a need to waive off patents in during pandemics not because of mere moral reasons but also for economies of LMICs and enforcing the right to health, which today remains only a theoretical concept.

[11] Mbali, M. (2013). 'Pharma' v Mandela: South African Moral Capital in a Global Movement, 1998–2001. In: South African AIDS Activism and Global Health Politics. Global Ethics Series. Palgrave Macmillan, London.
[12] Paul C.B. Liu, *U.S. Industry's Influence on Intellectual Property Negotiations and Special 301 Actions*, 13 UCLA PAC. Basin L.J. 87 (1994).

Conclusion

Adequate healthcare is not a privilege that only a minority can afford and access. While it is true that patents are meant to encourage innovation, our current patent system stalls the scope for the same because of various reasons like outnumbering and evergreening of patents etc.

Developing countries have been very assertive that health is not a commodity to be profited from and have emerged as an influential force in reforming the faulty IPR laws both domestically and internationally.

We proposed a "Human rights centric" model to restructure TRIPS. By this mechanism, Sharing of research, process and product patents in times of health emergencies would be something that is an "obligation" on the states.

Our covert deep-rooted colonialism in current IPR regime needs restructuring. This can only happen if we condone the commodification of vaccines and prioritize Human rights over IPR.