PATENTS: PEOPLE OR PROFITS?







The Economics Society, Shri Ram College of Commerce

Review



I complement the students of The Economics Society, SRCC, for bring forward the policy brief on a core issue that will be discussed in the forthcoming 12th WTO Ministerial Conference (MC12,) which will be held in Geneva, Switzerland, from 30 November to 3 December 2021.

In the context of access to vaccines, the paper examines the patent laws, presents the opinion of different stakeholders, identifies the gaps in the TRIPS agreement and makes policy recommendations. The paper is well-researched, and authors have done a detailed literature review. This paper will be useful for policymaker and scholars working on the subject. It will help Indian policymaker as they prepare for the WTO discussions.

- Dr. Arpita Mukherjee, Professor, ICRIER

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INTRODUCTION

witnessed The year 2020 beginning of one of the most devastating events in human history as the unprecedented pandemic brought the global economy to a halt. Imposition of lockdowns led to exorbitant daily losses and the only hope to reduce the effect of the contagious virus was development of a vaccine. While the first vaccine came out in late 2020, and many more have been approved since, inequity in vaccine distribution has hindered the vaccination drive with the developing and third world countries suffering the most.

Even with the huge manufacturing capacities that companies in the era of technology possess, there are many governments who are unable to procure vaccines for their citizens. One of the major roadblocks in the entire vaccine rollout has been the of international provisions protecting agreements intellectual property rights of the vaccine manufacturers. While the formula to beat the virus has been invented, given commercialisation of human intellect, not everyone has the access to it, which fires up the debate on the moral values of modern day capitalism. The developed countries that the international agreements between the members of the World Trade Organisation (WTO) take into consideration such

adverse scenarios wherein human life is to be prioritised as opposed to making. However, sufferings of the countries with no manufacturing capacity to beat the otherwise. prove pharmaceutical companies, in order to protect their bottom line, have often raised their voice against the sharing of industrial secrets that would ideally lead to manufacturing and lower the cost of the drugs for the masses. Considering the amount of investment it takes to research and develop life saving medicines, their arguments present a strong case. However, as the world battles an unforeseen pandemic, do these provisions hold greater significance? Does History provided us with evidence against the same?

In this Policy Report, we dive deeper into the patent laws, understand why were they framed in the first place, their relevance in the scenario and other provisions in place that are allowing these big pharma companies to earn billions out of a pandemic. We also attempt to present arguments on whether the caveats present in those agreements are enough to alleviate the suffering caused by the pandemic. Lastly, we analyse whether the attempt to alternatives presented by those pharmaceutical opposed to companies and international agreements potential have bettering the situation.

IPRS AND PATENTS

In today's knowledge-based economy, physical assets are not the sole source of an organisation or a country's production capabilities. At the core of economic development contemporary world lies innovation, which results from human intellect. Therefore, it is imperative to ensure that ownership of intellectual property is given due recognition via various laws and that those in possession of it stand to gain. The premise for the same is that incentives would further drive innovation.

Intellectual Property (IP) refers to creations of the mind, such as inventions; literary and artistic works; designs; and symbols, names and images used in commerce. The legal rights protecting these creations and inventions are the Intellectual Property Rights. Intellectual Property has the characteristics of a public good i.e. they are non-excludable and nonrivalrous in nature. The consumption of it by one person does not deny someone else from consuming it. Thus, IP Protection is needed for such property holders to derive economic value out of their creation invention. Similar to the foreign of goods and services, a strong IP regime allows for the direct or indirect transfer of technology

in the form of Foreign Direct Investment (FDI).

The World Trade Organisation broadly divides Intellectual Property Rights into two domains:

1. Copyrights and Rights Related to Copyrights:

The main purpose of copyrights is to protect and reward creativity of authors, artists, performers etc.

2. Industrial Property:

Industrial property includes those rights which play a significant role in the domain of business and industrial activity. It consists of two types of rights. First, the protection of distinctive signs in the form of trademarks and geographical indications. These rights help consumers make informed decisions and enable the products of a particular company/ geographical area to be uniquely identified. The second being rights that stimulate innovation and creation of technology. Such rights take the form of patents and trade secrets. The social purpose being the incentive for further research and development activities by giving exclusive rights to holders intellectual property.



Among all the intellectual property rights, patents are the prime drivers of innovation. Coming up with a novel invention requires a great deal of investment in research, which if not rewarded in some way will disincentivize the development of new products and services. A patent is an exclusive right granted for an invention, which is a product or a process that provides, in general, a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application. A patent holder has the right to exclude others from making, using, offering for sale, or selling his or her invention, which is generally valid for a period of 20 years. Such rights are granted by

the government agencies in each country. A substantial amount of research goes into the pharmaceutical industry before the development of a product. Releasing any drug into the market takes several years and therefore Drug Patents play a major role in the growth of this industry and ensure lucrative returns investment. But the morality of patents in the health sector has always been questioned. Patents lead to the monopoly of the companies holding the patent and they would charge a profitable price, which makes the drugs available only to those who can afford them. Therefore it is necessary to formulate patent laws in a manner that puts public health over profits in a crisis situation, such as the COVID-19 pandemic with which the world is grappling.

PATENTS AND INCENTIVES

Patents play a significant role in creating temporary and locality specific exclusive rights that serve as a great incentive for innovation through protection of investments. consequently This results inventions. Patents are not a global asset, they eventually expire. Once they do, the information is freely available to others. Patents are market-based prominent in economies and allow investors to give a fair value to new innovations. Thus, patents play a substantial role in preventing market failure and promoting investment in Research and Development.

However, patent protected drugs do not face any price caps nor any competition for about twenty years, during which they gain market exclusivity. To ensure continuous growth and progress in the health only in terms of sector, not medicines but also in how efficiently they are produced. For this, one requires investment. The financial capital required for this is not small. In the year 2014, the Tufts Center for the Study of Drug Development estimated that it takes about \$2.6 billion and a ten-year long time commitment to develop and license a new drug that can be prescribed.

Without patents, certain pharmaceutical companies would not even invest in research. They would wait for other companies to discover the drugs and license them. Then the companies acquiring the license would price the drug lower to beat the competition. This would lead to market failure, in terms of a positive externality, because companies who did no research would benefit from the information of one company without having to pay for it.

This shows that corporations would not want to invest in something from which they cannot earn profits. Hence, the number of medical innovations would be much less than the socially optimal or required quantity. Patents help in preventing such a situation from arising. Hence, when companies get 20 year patent rights where prices cannot be manipulated by competition or the government, they are motivated to invest and earn a large number of profits.

Similarly, corporations would not invest in research for drugs that treat only a small number of people as the demand would be less.

They would have to invest the same or even more amount of time, money and effort to be able to cater to a very small group of people. This is an important factor as to why drugs to diseases aiming cure 'Tourette's have not been researched much. In the United States, only 2,00,000 suffer from Orphan disease. To stimulate production for drugs the US treating such diseases, government passed the Orphan Drug Act, which gives corporations 7 years of market exclusivity for treating

certain rare conditions. Too much regulation would limit growth but too little can restrict people's access to life saving drugs. For example—Patent protections allowed Martin Shkreli to change the price of Daraprim, a medication used by AIDS patients, from \$13.50 to \$750 per pill in 2015. The inaccessibility of the AIDS treatment drug in Africa and the role of patents in the same has been discussed as a case study in this Policy Report.



UNDERSTANDING THE TRIPS AGREEMENT

International trade plays a significant role in the economic development of nations and also defines the relationship between them. Given the importance of such transactions, multilateral trade agreements are imperative to regulate trade.

first major multilateral agreement was signed in 1947 by 23 countries, which was called the General Agreement on Tariffs and Trade (GATT). From 1948 to 1994, further discussions on international trade on topics such as liberalisation and tariff cuts were done under GATT in the form of 'trade rounds'. The eighth round, known as the Uruguay Round, was the most comprehensive trade discussion to have taken place. It continued from 1886 to 1994 and led to the formation of the World Trade Organisation (WTO) to administer the trade agreements. One such agreement, which was one of the major outcomes of the Uruguay Round, was the TRIPS agreement -The Agreement on Trade-Related Aspects of Intellectual Property Rights. The previous agreements, now dubbed as GATT 1947, GATT 1994, etc. were annexed to the WTO and did not have any separate legal existence.

During the Tokyo Round of trade negotiations, the round that preceded the Uruguay Round, a proposal was put forward to negotiate rules on trade of counterfeit goods, which are inferior quality goods that infringe the trademark, copyright or patent rights of the inventors of those goods. However, it could not materialise by the end of this round and was later re-discussed by trade ministers in the These negotiations were eventually combined with the trade agreements on IP and put under the 'Trade-related aspects intellectual property rights, including trade in counterfeit goods' in the Uruguay Round of trade negotiations. A negotiating group was formed to pursue this mandate which led to the formation of the TRIPS Agreement. This agreement is regulated by the Council for TRIPS, which reports to the WTO General Council.

TRIPS, the most extensive multilateral agreement on Intellectual Property Rights, states the minimum standards of protection and enforcement that intellectual property holders of WTO members should be granted by their respective governments.



CASE STUDY:

INDIA AND AFRICA

In the following few pages, we analyse and trace the trade relations between India and Africa, especially in the context of the medical support that India has provided to Africa since 2001, during the AIDS endemic and recently in 2020, when both countries submitted a joint proposal for a patent waiver.

India got around the TRIPS provisions and provided robust support to Africa during the AIDS endemic. They did so by parallel importing, whose definition has been discussed in detail in later parts. It became the leading manufacturer of generic medicines for AIDS being used in Africa.

Hence, this case study helps us analyse the following-

- The potential of the flexibilities of the TRIPS provisions
- Role of Partial Patent Waiver in providing medicines to the underdeveloped countries
- Potential of a comparatively developed country in helping an underdeveloped country during a healthcare crisis

We also break down the joint proposal submitted by the two countries and try to understand the following-

- The general impact that the proposal may have
- The future of the India-Africa relationship with a special emphasis on the medical development in Africa

CASE STUDY-INTRODUCTION

The legal framework in India has facilitated production of generic medicines, which have been sold at low prices to developing countries. The quality was never compromised and it helped in mass procurement by the needy of these countries. One such example is the help provided to many countries, especially the continent of Africa, during the AIDS Endemic. Indian manufacturers made generic versions of Antiretroviral and exported them on a large scale.

However, such an initiative would bear obstacles with the stricter implementations of The World Trade Organisation Agreement on Trade-Aspects of Intellectual Related Property Rights, and intellectual property measures being discussed as a part of trade agreements in regional and bilateral deals. It is important to analyse whether these measures might have a negative impact on not only India's ability to help developing countries solve the AIDS crisis that remains a prominent health issue in the African region, but also in the provision of medical help developed countries to the rest of the world.

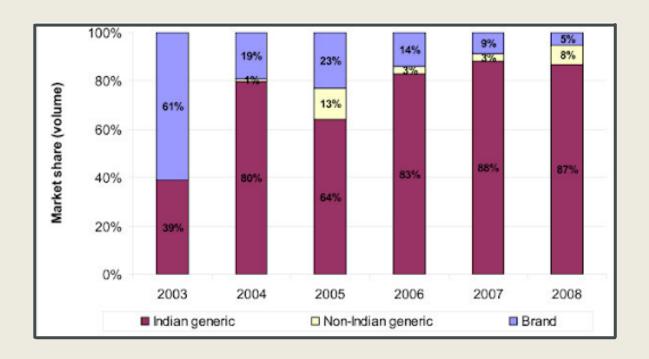


The Indian-African partnership on medicine access has been a long one. It started back in 2001, when large pharmaceutical companies were suing The South African government. The reason behind the same was that the government was trying to import patented AIDS drugs at a cheaper price from willing countries like Brazil and India without permission of the manufacturer (parallel importing). Another reason was the manufacture of such drugs locally without the permission of the manufacturer (compulsory licensing).

However, this, as discussed in detail below, comes under flexibilities provided by the TRIPS agreement. The Giant Indian manufacturer, Cipla, volunteered to sell the generic version at a very low price.

pediatric ARV and adult nucleoside, Indian-produced generics accounted for approximately 91% and 89% respectively, of the global volume purchased in 2008. During 2003 -2008, the number of Indian Generic Manufacturers supplying ARVs

ROLE OF INDIA-AFRICA PARTNERSHIP



This partnership paved the way for the development of a global plan to take actions towards access to medicines. Cipla's decision allowed African nations to take the fight against AIDS. The Indian Generic Manufacturers dominate the ARV market, making up for more than 80% of the volume annually purchased. Among increased from 4 to 10 while the of Indian-manufactured number drugs jumped from 14 to 53. 96 of 100 countries purchased the Generic Indian version in 2008, including the sub-Saharan HIV-burden high African countries. These were used as a first line treatment and were cheaper than the new ones recommended by the World Health Organisation.

A number of Indian versions of Antiretroviral medicines have been patented in developed countries. Indian firms were able to do so because they did not grant patents for pharmaceutical products till 2005, which is a transitional provision of TRIPS. Since the drugs were not patented in India, firms could produce their own versions.

Generic Indian producers supply the majority of ARVs in developing countries and for further scaling up, the **TRIPS** agreement hamper the accessibility. Producers will have to be cautious about the intellectual property obligations through free trade agreements that can prevent them from producing and supplying generic versions of essential drugs. India and its trade partners, with the International organisations and the policy makers of the country, should ensure that there is enough flexibility in the policies and agreements such that Indian pharmaceuticals

continue to produce low-priced, quality-assured generic drugs. India is still the largest supplier of affordable essential drugs to developing countries. Despite the compulsory compliance terms under TRIPS conditions, particularly related to patents of medicines, India has managed to nurture an industry that believes in medicine access.

However, India is constantly under scrutiny for its Intellectual Property Rights practices. The United States and European Union constantly pressure the country to conform to stricter IPR practices. This will hinder the generic medicine industry and cause the prices to rise, leading to a decrease in access to medicines. The recent COVID 19 pandemic is the most recent example that shows that developed countries following stricter IPR norms contribute to vaccine and medicine inequity. This has been discussed in detail in the following sections of the Policy Report.

INDIA PAVING A WAY FORWARD

"India's position continues to be in support of generic drug manufacturing for increased drug access. The Prime Minister's visit to Africa is a clear indication that India values the African market and wants to continue to provide generic medicines at low prices. However, in order to ensure that India can continue to do so with the growing concerns over the IPR norms, India can take an additional step and establish a Make-in-Africa initiative.

India can take advantage of the International IPR exemptions for the least developed countries (LDCs). These were agreed upon by the TRIPS Council. The LDCs have leeway in protecting their IP till 1st July, 2021.

Secondly, this will ensure smooth transition from exporting medicines to producing them in Africa itself. This is because the Indian manufacturers have already established supply chains, and the nuanced understanding of African markets will make setting manufacturing units easier. Thirdly, African countries emulating the Indian IPR model, making the structure very similar to the one that Indian Manufacturers are used to. Lastly and most importantly, Indian companies will be able to expand medicine access regardless of any possible future alterations in India's IPR policy.



CURRENT SITUATION



This year witnessed a stark inequality in the distribution of vaccines, where a large proportion of COVID-19 vaccines had been acquired by the developed countries. The WHO Chief even said that the world verge of a "catastrophic failure." Lack of access to moral COVID-19 vaccines has reflected in the large number of daily deaths in poor countries. India witnessed a shocking number of daily deaths as it grappled to deal with the second wave and faced acute vaccine shortage.

However. the richer countries witnessed a much fewer number of deaths due to vaccine acquisition and distribution. Even in the upper middle income countries, numbers fell. This must help us realise that without ramping up vaccine supply and access through physical and financial assistance, the world cannot recover from this pandemic. In the last 6 months, it has become

increasingly evident that the world's ability to defeat the pandemic will depend a lot on pharmaceutical sector and governments increase accessibility to vaccines. The announcement by the US government in May 2021 to support a joint proposal for vaccine waiver-introduced in October 2020. by India and South Africa before the World Trade Organisation has come a surprise to many experts. However, the fact remains that this may be a necessary step towards achieving vaccine equity. original proposal was meant to cover patents, industrial designs, copyrights and protection of trade secrets across vaccines, medicines and diagnostics. However, The US government has vouched support intellectual property rights vaccines. The Gates Foundation also said that it supports a narrow waiver on intellectual property protections during the pandemic to help vaccine equity.



INDIA'S CONTRIBUTIONS

One trouble with the character of the COVID-19 vaccine scarcity is that victories on paper will now no longer translate into answers in reality quickly enough. Time is of essence, and therefore instead of symbolic ethical victory of waivers, partnerships which are constructed on more than a few voluntary licenses, generation transfer, and consolidation and growth producing potential in growing internationat locations might be more important and appropriate, and thus must run as a parallel goal.

the Changes in regulatory environment and pressure from countries such as India and South Africa must lead to a series of strategic voluntary worldwide and strengthening of the COVID-19 Technology Access Fund (CTAP), which is a WHO initiative to promote technology transfer, discussed in detail in later parts of this Report. Apart from a handful, like the ones involving Serum Institute of India, such partnerships have not been witnessed majorly in the past year.

POSSIBLE EVENTUALITIES



Perhaps, after a series of negotiations, there might arise a narrow exemption for vaccines within the scope of the WTO. This will serve as an incentive for manufacturers and governments to start investing in new medical facilities and develop cold storage.

Until then, more voluntary licenses will be obtained, owing to the transfer of active technology and capacity expansion, which has doubled the global COVID-19 vaccine production.

The developing world in the time of a pandemic does not only need a fair share of vaccines but also a fair share of production rights.

DEEP DIVE INTO TRIPS AND ITS IMPLICATIONS

TRIPS covers, for each IP, the subject matter eligible for protection, the scope of rights to be conferred, permissible exceptions to those rights, and, where applicable, the minimum duration of protection. The TRIPS Agreement states that the member countries may have more extensive laws for IP protection provided they do not contravene the provisions mentioned in the TRIPS Agreement. Under the TRIPS Agreement, patents are granted for inventions provided they meet the standard substantive criteria for patentability - namely, novelty, inventive step and industrial applicability.

Along with these, adequate disclosure of the invention is required to be made to ensure that the public has access to it once the patent term expires. The agreement allows the following exceptions to the rules on the patentable subject matter considering the public health perspective:

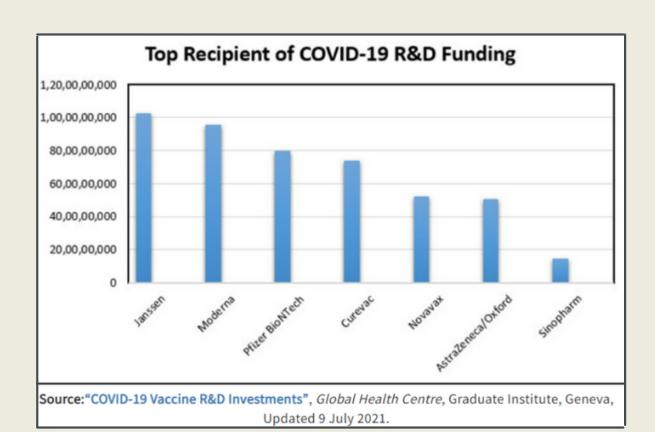
 inventions the prevention of whose commercial exploitation is necessary to protect order or morality, including to protect animal or plant life or health;

- diagnostic, therapeutic and surgical methods for the treatment of humans or animals; and
- certain plant and animal inventions.

The Marrakesh Agreement establishing the WTO, in its Articles IX.3 and IX.4, has provisions wherein the Ministerial Conference may waive off an obligation imposed on WTO member countries 'exceptional circumstances' via a three-fourths majority. Such waivers will be further reviewed by the Ministerial Conference if granted for more than a year and can be extended, modified or terminated on such a review. But battling a devastating pandemic like the coronavirus requires a global effort. This brings into question the efficacy of the provisions of WTO and the TRIPS Agreement in ensuring an equitable access to health related products, central to it being the and distribution production vaccines.

As mentioned above, in October 2020, developing nations, India and South Africa, had submitted their first proposal to the WTO demanding a waiver on the provisions of the TRIPS Agreement for all WTO members for the "prevention, containment and treatment COVID-19". Specifically, were demanded in the proposal for "the obligations of Members to implement or apply Sections 1, 4, 5 and 7 of Part II of the TRIPS Agreement or to enforce these Sections under Part III of the TRIPS Agreement." These sections refer to the stipulations relating to copyright, industrial design, patents, undisclosed information.

The TRIPS Agreement undoubtedly promotes innovation, but when the majority of the research done during a pandemic is publicly funded, its provisions act as a bottleneck to the rights of the public. The developed nations of the world including the likes of United States (US), United Kingdom (UK), the European Union (EU), Australia, Canada, had opposed the proposal on the grounds that the flexibilities provided by the TRIPS Agreement are sufficient to tackle the havoc caused by the pandemic. While the Biden led government did agree to the proposal in May, 2021, it was still opposed by the European Union.



FLEXIBILITIES IN TRIPS

While the TRIPS agreement does a good job in incentivising researchers to innovate and come up with efficient drugs, there are situations wherein public health has to be prioritised, which means giving some leeway to other manufacturers to ramp up drug production.

The TRIPS Agreement does have certain measures which the member countries can take to balance patent rights with public health needs. These measures, called flexibilities, include provisions for granting of compulsory licenses, parallel imports, exceptions to patent rights, and applying a rigorous definition of patentability criteria.

However, in practice, the application of these flexibilities by developing countries were being challenged by multinational pharmaceutical companies and the governments of the developed countries. In this context, the developing countries sought clarity in the relationship between the TRIPS Agreement and public health, which to the Doha Declaration being adopted in the year 2001. It reiterates that the flexibilites mentioned in the TRIPS Agreement should be used by member countries wherever applicable for the protection of public health and promoting access to medicines.



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Flexibilities under the TRIPS Agreement:

1. Compulsory licensing -

One of the flexibilities identified under the Doha Declaration includes the right to grant compulsory licenses. Article 31 of the TRIPS Agreement states that patents can be allowed for "other use without authorization of the right holder". When a government allows any person to produce the patented product or process without taking the approval of the patent owner, it is called compulsory licensing. But this is done based on certain conditions to ensure that the rights of the patent holder are not violated.

According Article to compulsory license may be granted during national emergencies, other circumstances of extreme urgency and anti-competitive practices - but only when some of the regular requirements for the issue of a compulsory license do not apply, such as the need to try for a voluntary license first. Therefore, there must have been an unsuccessful attempt by a person or a company wanting to obtain the license before a compulsory license was granted. Moreover, adequate remuneration should be paid to the patent holder

even if a compulsory license is granted. The agreement gives full freedom to the member countries to decide what qualifies as a national emergency or extreme urgency in order to grant compulsory licenses - the COVID-19 pandemic being one such emergency recognised by governments across the world for granting compulsory licenses.

One of the major drawbacks of the compulsory licensing system was that it allowed its issuance only for domestic purposes, thereby causing difficulties for countries that do not have the required manufacturing capabilities. Thus, paragraph 6 of the Doha Declaration recognised this issue and according to an amendment made in 2003, generic medicines could be manufactured under a compulsory license and exported, under certain conditions, to countries that lack manufacturing capacity. This is known as the Special Compulsory Licensing System, permanently incorporated in Article 31bis of the amended Agreement. It allows granting of special compulsory licenses for the manufacture patented of pharmaceutical products such medicines, vaccines and diagnostics, export to countries with inadequate or low manufacturing

capacity in the pharmaceutical sector. This system was put into place to ensure equitable access to health products such as vaccines in the COVID-19 pandemic. This use of this system may be made by all the members of the WTO and not just the least developed countries.

Example- Bill C-13 amends Canada's Act to empower Commissioner of Patents, on the application of the Minister of Health. to authorise the Government of Canada or another specified person to, in cases of public health emergencies that are matters of national concern, supply inventions that are patented up to the limit necessary. These amendments also include measures protecting the interests of patent-holders; for example, ensuring receipt adequate remuneration by a patent holder for the use of the patent, placing limitations on the duration of the authorisation, providing the patent-owner with notice of the authorization, and ensuring that the patent-owner has recourse to the courts if any person authorized acts outside the scope of the authorisation.

2. Copyright -

In view of larger public interest, for access to medical technology

and innovation, Article 13 of the Agreement allows exceptions to copyrights in special cases as long as it protects the interests of the right holders and does not exploit their work. New research techniques and diagnostics methods such as the usage of text and data mining techniques for mining genetic data have copyrights on them. If there would not exist flexibilities on copyrights, these methods would get restricted to the right holders. It is the application of these flexibilities that allows for a balanced development of innovations.

3. Trademarks -

Similar to the other IP rights, rights conferred by a trademark are not absolute. Limited exceptions to the rights conferred by a trademark is provided by Article 17 of the TRIPS Agreement, taking into account the legitimate interests of the owner of such rights and the third parties.

4. Industrial Designs -

Industrial Designs apply to the ornamental or aesthetic aspects of a product and may be applied on a wide variety of health products.

Exceptions to these rights are allowed under Article 26.2 of the TRIPS Agreement provided they are used for a legitimate purpose such as experimentation or teaching, similar to the flexibilities offered for copyrights and trademarks.

5. Clinical Trial data and Undisclosed Information -

Data collected via clinical research is central to the release of any new drug, especially in the development and marketing of COVID - 19 critical health technologies. Article 39.3 of the TRIPS Agreement requires WTO members to protect such data from unfair commercial use except where it is necessary to protect the public interest.

Similarly the TRIPS Agreement allows for the disclosure of trade secrets for the protection of public interest.

While the TRIPS Agreement was formulated keeping in mind the interests of the owners of Intellectual Property Rights, it does acknowledge situations where the broader public interest should prevail over

commercialisation; therefore making the understanding and application of these flexibilities a prime tool for overcoming adverse situations. In the next section, we seek to analyse if these flexibilities are enough to overcome global health crises like the COVID -19 pandemic.



INSUFFICIENCIES OF TRIPS FLEXIBILITIES



The individuals who go against India and South Africa's proposition for a TRIPS waiver contend that since the TRIPS Agreement contains a few adaptabilities that can be utilised to address general wellbeing exigencies, interest suspend to commitments is superfluous. Indeed, the TRIPS Agreement contains those adaptabilities. One such significant adaptability is compulsory licensing as discussed above, which is directed by Article 31 of the TRIPS Agreement. Under Article 31, public non-business use is conceivable—for example, an administration can approve utilisation of a patent for its motivations. As per an examination, out of 144 cases of the utilisation of TRIPS adaptability measures nations from 2001–2016, 100 cases were of mandatory authorising

or public non-business use to expand creation ofnon-exclusive reasonable prices. medicines at Likewise, the investigation additionally tracked down that an enormous number of LDCs utilised the long change period accessible to them to consent to Article 39 of the TRIPS another Agreement significant TRIPS flexibility. It is wrong to conclude, nonetheless, that these adaptabilities would be adequate in managing all general well-being challenges, particularly one enormous as the current pandemic. utility of similar The TRIPS adaptability, like necessary permits, isn't something very similar for all nations. While nations that have fabricating capacity in the drug area can adequately utilise obligatory licenses, an enormous number of LDCs don't have such ability.

In any event, developing nations that can utilise mandatory licenses to deliver patented drugs consistently under pressures from developed nations to not issue such licenses. For instance, India was exposed to persistent assaults by the US government when it gave a necessary permit in 2012 to create a non-exclusive variant of Bayer's disease drug. As brought up before, for nations that need fabricating capacity, the obligatory permit is anything but a valuable adaptability. Article 31(f) of the TRIPS Agreement expresses that an obligatory permit might be given transcendently for the homegrown market of the country giving the permit.

Consequently, conventional medications delivered under mandatory permit can't be sent out. Subsequently, nations that have restricted assembling capacity in the drug area can not profit from the arrangement on mandatory permitting given in Article 31 of the TRIPS Agreement. This issue was perceived by the WTO in 2001 as clear in section 6 of the Doha presentation on TRIPS and Public Health. It states: "We recognise that WTO individuals with lacking or no assembling limits in the drug area could confront challenges in utilising

mandatory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to track down a speedy answer for this issue and to answer to the General Council before the end of 2002."

In August 2003, the WTO's General Council received a decision that deferred the commitments forced by Articles 31(f) and 31(h) to permit nations to send out drugs produced under mandatory authorisation to nations that did not have the assembling ability. Finally, in 2005, the TRIPS arrangement was revised, which produced results on 23 January 2017, to incorporate Article 31 bis settling on the 2003 choice. The fact that first the waiver followed by the revision of the TRIPS Agreement was required, exhibits that the TRIPS adaptability was not satisfactory in tending to every one of the circumstances of drug shortage.

While this revision has been promoted as having tackled the issue of nations with deficient assembling capacity to get to drugs at reasonable costs, concerns remain about the bulky cycle that nations need to follow to import and fare such medicines. For example, if a nation gives an obligatory permit to send out medications to another country that

needs fabricating ability, the trading nation needs to guarantee that the medications so made are sent out to that country just; the prescriptions ought to be effectively recognisable through various shading, or shape; just the sum important to meet the necessities of the qualified bringing in nation are made; and the importing country needs to inform the WTO's TRIPS council.

These conditions disincentive nonexclusive drug makers from assembling items under mandatory licenses for export. Since the nations that need producing ability are more modest in size, there are fewer economies of scale to be procured to draw in light of a legitimate concern for conventional makers to send out medications such countries. to Indeed, the issue with the economies of scale and the lumbering method obvious the possible in occurrence when this framework was put to use somewhat recently, in Rwanda and Canada. In their proposition, India and South Africa recognised the unfeasible idea of Article 31 bis to address the difficulties presented by COVID-19. Given that an enormous number of areas lack manufacturing capacity in the drug area and that they would require COVID-19 vaccines for populace, the long and bulky systems recorded in Article 31 bis would just

totter their endeavours at general vaccination. Following the systems recorded in Article 31 bis for an enormous number of nations all the while would seriously hinder the fare immunisations, consequently ending up being expensive when nations need these items desperately in the midst of a pandemic. Thus, the sheer size of the issue and epic interest for antibodies from all nations of the world make the TRIPS adaptability unreasonable. There are different adaptations too like willful licensesfor example, licenses given by patent holders to conventional organisations on commonly concurred terms.

The AstraZeneca COVID-19 vaccine, for example, that has been authorized to India's Serum Institute, is an illustration of a deliberate permit. In general, the willful licenses are regularly covered in a mystery where the patent holder controls significant choices, for example, who might be a definitive recipient of the medication and how the outsider merchants are to be chosen. The equivalent can be said about the willful permit given by AstraZeneca to Serum Institute. To support the creation of vaccines to fulfill the immense need, a few different organisations would need to be overhauled, requiring a nonrestrictive arrangement which probably not going to happen.

DISPARITY AND PRIVILEGE

The disparity in availability of COVID-19 vaccines among high and low income nations has become difficult to overlook; as indicated by UNICEF information, 86% of all dosages administered worldwide as of 30th March, 2021 were regulated to those in high and upper-middle income nations, while only 1% have been given to those most vulnerable. The accumulation of vaccines by rich nations, as the pandemic devastates financially impeded countries, has brought the issue of vaccine patents forward.

In the initial proposal, India and South Africa cited an example of such a bottleneck: At the beginning of the pandemic, the United States encountered a shortage of N95 respirators, prompting Kentucky Governor Andy Beshir to request manufacturers to lift their patent.

Supporters of the exemption also pointed out that to support the development of the COVID-19 vaccine, pharmaceutical companies have received generous government funding and believe that the public is entitled to more opportunities, even if it means reduced profits.

The pharma industry has strongly resisted the request since it was documented, demanding that suspending IP rights to vaccines will eliminate the impetus for drug organizations to innovate improve. Biotechnology Innovation Organization president and CEO Michelle McMurry-Heath wrote in The Economist that the proposition subverts the very framework that created the life-saving science, and annihilates the motivation organisations to face challenges to discover answers for the upcoming crisis.



Additionally, for opponents, the exemption is a deviation. While it removes incentives for innovation, it will not help improve global vaccine Pharmaceutical distribution. companies, health experts, and some governments believe that intellectual property rules and their allowed profits have promoted of innovative development technologies such as the COVID-19 vaccine. They also stated that low manufacturing capacity rather than patents is the biggest obstacle to global vaccination efforts. Even if the patent is abandoned, critics believe that without the inventor's technical expertise or access to key ingredients that are already in short supply, many countries will not be able to produce vaccines.

Defenders of the waiver have contended that pharma organisations' restraining infrastructure over antibody creation is unjustifiable given that various COVID-19 immunisations have been openly financed. Essentially 97% of the investigation into the AstraZeneca-Oxford jab has been subsidised with public cash, while

Moderna, Janssen and BioNTech
- the German organization Pfizer
fostered its vaccines with - all
received robust stimulants of
government financing.

It's important to note that the major COVID-19 vaccine manufacturers, just like various nations with an abundance of vaccines, have made arrangements to contribute dosages the worldwide collaboration COVAX. Despite these efforts. rampant vaccine stockpiling, trade restrictions and limited production remain deterrents in the plan's objective to furnish the world's most unfortunate nations with more than two billion portions before the year ends.

Hence, taking these expert views into consideration and the previous analysis of the flexibilities, it is safe to say that they are insufficient. Modifying the flexibilities, implementing policy reforms to allow technology transfer and provide expertise to underdeveloped countries is required for better access and improved medical equity in general.

WILL A WAIVER BE SUFFICIENT?

The TRIPS Agreement recognises the importance of technology transfer through its objective and Article 66.2, which establishes that "developed member countries shall provide incentives companies to institutions in their territories to promote and encourage technology transfer to least developed country members." WHO has established an mRNA technology transfer center to provide a mechanism to promote the exchange of technical knowledge related to the manufacture of mRNA vaccines, but so far no technology holder has participated. In recent history, the most notable attempt was through the WHO **Pandemic** Influenza Preparedness Framework (PIP Framework), where WHO tried to use multilateral access and benefitsharing agreements to negotiate trade technologies in the field of pandemic vaccine manufacturing. Unlike most drugs, vaccines are molecular biologics that require a lot data and technology manufacture: the details of the same won't be disclosed through a simple patent waiver. The initial texts of the waivers proposed by India and South Africa recognise the key role of know-how in vaccine manufacturing capacity. However, unlike patent rights, there is no clear and simple

solution to the proposed exemption, and pharmaceutical companies can vigorously resist this technology transfer. If there is no knowledge transfer, no matter how patent barriers are removed in the TRIPS exemption, it will be difficult for low and middle-income countries to start producing the COVID-19 vaccine.

It is clear, accordingly, that member countries of the WTO need to display a solid obligation to share ability and additionally give monetary incentives to drug organisations based in their regions to effectively participate in the transfer technology for COVID-19 vaccines. so would fulfill Doing commitments mentioned in Article 66 of the TRIPS Agreement and show a commitment to an accessible and impartial vaccine drive for low to middle income countries (LMICs). Much of the research work for COVID-19 vaccines was paid for with public money— either directly by governments, or through open drives, for example, COVAX. This reality alone features the limits of contentions that argue that the TRIPS waiver and related measures annihilate unrestricted economic motivations for R&D speculation.

However, no administration, while consenting to vigorously sponsor the COVID-19 vaccination R&D, tried to negotiate IP possession, or force commitments producers on receiving this financing effectively take part in technology transfer to ensure growth of future manufacturing bases. In a perfect world, access to data and skill should take place through the WHO center point framework (which could be extended past mRNA innovation), as opposed to a bilateral transfer on a

manufacturer to manufacturer premise, to guarantee maximum effectiveness and utility from the exchange.

If one seeks to gain ground on equitable access to the vaccine, the TRIPS waiver should be immediately passed by WTO Members, yet until a solution to ensure technology transfer for vaccine manufacture can be discovered, we remain in a stalemate on equitable access to vaccines.



COVID-19 TECHNOLOGY ACCESS POOL (C-TAP)

COVID-19 Technology Access Pool (C-TAP) is a global one-stop shop developers of COVID-19 vaccines, diagnostics and other therapeutics to share intellectual property, information and data with other manufacturers by nonexclusive and transparent licenses. It was launched on May 29, 2020, by WHO and its partners to facilitate equitable and affordable access to COVID-19 health products by boosting the supply. This was done to scale up the production of COVID-19 health products through multiple manufacturers by sharing technological know-how intellectual property.

The aim was to speed up the development of all technologies needed to fight COVID-19, through open-science research. C-TAP also provides a means to remove barriers to access and makes the availability of products globally possible. Sharing information is a great way to accelerate development and avoid duplication of efforts.

In June 2020, the International Monetary Fund estimated COVID-19 could cost the world economy around \$12 trillion by the end of 2021, which is equivalent to a daily cost of over \$15 billion. In addition, the scale of devastation on the health and livelihood of people could persist for years. This indicates the urgency to bring the pandemic to an end as soon as possible. C-TAP is one way to do this. Reducing the scale of devastation depends on developing vaccines and therapeutics, and making them available globally.

Therefore, sharing data information could substantially advance the speed at which technologies are developed as it avoids the repetition of effort. The efficiency of C-TAP depends on the participation of innovators from all sectors, private, public, academic and philanthropic. It must be in their collective interest to restore the world economy as soon as possible.



Structure of C-TAP:

The operational parts of C-TAP are built around the following existing institutions-

- The Technology Access Partnership was launched by the UN Technology Bank partnership with the United **Nations** Development Programme (UNDP), WHO and United Nations Conference on Trade and Development (UNCTAD). It mainly focuses promoting technology transfer for the production of Personal Protective Equipment (PPE) Kits and medical devices such ventilators. The Technology Access Partnership currently focuses on technology production and transfer to mitigate the immediate effects of COVID-19.
- The Medicines Patent Pool (MPP) facilitates access to medicines by the mechanism of voluntary licensing, so it could play a role in applying IP expertise to patented products and identifying technologies to avail facilities to those who need it the most.
- The Open COVID Pledge (OCP) is a repository for soft and hard technologies for fighting COVID. It is also open to offers from vaccine manufacturers. Through OCP, companies can make available non-exclusive and royalty-free licenses for a fixed time period, until one year after WHO declares the pandemic to be over, or 1 January 2023, whichever is earlier.

- Global Initiative on Sharing All Influenza Data (GISAID) facilitates sharing of genomic and data from COVID cases and therefore enables genomic epidemiology and progress in devising counter measures to new diseases. While the data shared is publically accessible, to the safeguard contributors' interest, those sharing the data still enjoy inherent rights to the data.
- The WHO Global Observatory on Health R&D is a 'one-stop shop' for up to date health R&D information and analysis. It comprehensively includes the resources, processes, outputs and capacity. It consolidates, monitors and analyses information on health R&D, all the while building on existing data. The Observatory, COVID-19, response to continuously updating a list of data tracking and conducting relevant analyses.
- The WHO C-TAP database being the repository for data, is at the core of C-TAP operations.

It acts as a coordination platform and is connected to other databases

where COVID related information is available.

How does C-TAP operate?

C-TAP operates on the basis that there are mutual advantages of sharing data and know-how as it accelerates product development and reduces barriers to access. It would be a huge step towards defeating COVID-19 whether the holders of technology make their contributions for commercial or non-commercial purposes.

WHO establishes a prioritisation process for identifying the products and technologies to be pooled for short term goals, while keeping in mind the more ambitious long term objectives.

C-TAP carries immense potential and can deliver as an emergency operation for faster development of, and equitable global access to, vaccines, therapeutics and diagnostics and necessary medical equipment in a shorter term.

In the medium to long term, C-TAP would help build country capacities to secure a range of knowledge which would help in future epidemics.

CONSTRAINTS TO THE FUNCTIONING OF C-TAP SEEN OVER THE YEAR



Over the past year, C-TAP has not seen much engagement or interest from stakeholders. The high expectations set by C-TAP, to put a halt on the global pandemic, have not been met. What could be the potential obstacles that are stopping C-TAP from operating efficiently?

The reasons can be largely boiled down to the reluctance of the pharmaceutical industry to engage, choosing short term profits over global health.

• Concentration of production within few countries

There are 42 countries that have joined the C-TAP initiative towards global public health. However, none of the countries which possess the technological know-how and

production capacity have signed up, as they are concerned about protecting their trade secrets. These include the EU, the United States and India. Concentration of production in few locations around the world, like the Serum Institute of India, and India's inability to boost up its production capacity, has resulted in miscalculations and delays in the vaccine supply.

According to the WHO Global Vaccine Report 2020, vaccine manufacturing is mainly concentrated with four manufacturers, controlling 90% of the global vaccine supply. In a remark made by AstraZeneca's CEO, he said that AstraZeneca does not have any engineers for assisting technology transfer to WHO.

This shows the pharma companies are reluctant to share their technological assets, thus disregarding the existing capacity in many countries to produce vaccines.

ACT-A vs C-TAP

Access to COVID-19 Tools (ACT) Accelerator is a partnership between WHO and other global health actors, which include the Bill & Melinda Gates Foundation, the Vaccine Alliance, the Global Fund, the Coalition for **Epidemic** Preparedness Innovations (CEPI), Unitaid and Wellcome Trust and other participants from industry and civil society. Its objective is to accelerate development of vaccines and therapeutics, and facilitate equitable allocation of the same.

The idea behind ACT-A is that intellectual property rights must be protected even during the pandemic, and that it is not a hindrance in achieving global access.

Many questions have been raised as to how C-TAP would add to the efforts of ACT-A. Some experts did not understand the use of two different mechanisms to achieve the same goal. An IP expert said that C-TAP challenges ACT-A by

suggesting voluntary approaches towards achieving equitable allocation, as ACT-A is set to protect IP.

WHO pointed out that while ACT-A is mainly focused on development of new tools to fight COVID-19, C-TAP's role is to promote open science. It sees the two initiatives as complementary to one another.

Even so, ACT-A partners, that include Coalition for Epidemic Preparedness Innovations (CEPI) and Gavi, which steer the COVAX facility, have not participated in C-TAP.

There is always nervousness around IP related issues. While ACT-A enjoys the backing of some influential partners, it is not the same for C-TAP.

To maintain monopoly rights, there has been reluctance to share IPRs with low and middle income countries. The ACT-A acted as a shield behind which the pharma companies could enjoy unhindered monopoly. Thus, the ACT-A sabotaged the C-TAP, failing to achieve vaccine equity and global access.



POLICY RECOMMENDATIONS

After taking history into consideration through the case study, analysing the merits and demerits of IPR and examining the limitations of the flexibilities of the TRIPS agreement, we suggest a few policy strategies that can be taken up to help the global medical access.

These Recommendations are divided as:

- General Recommendations
- Recommendations for Low Income Countries
- Suggestions for International Organisations
- Ways to better utilise the flexibilities of the TRIPS agreement

These Policy Recommendations are not exhaustive but some comprehensive suggestions that we as research students find viable.

GENERAL RECOMMENDATIONS

According to the Organisation for Economic Cooperation and Development (OECD), the current discrepancy in the technological capabilities between vaccine producers and an emerging vaccine producers in the developing world is an factor when it comes to the existence of know-how gap. One must analyse the following questions:

• Is there an important know-how gap between developed and developing country vaccine manufacturer? In case it exists, to what does it prevail? What can be done about it? How will impact society in the coming years?

The TRIPS Agreement is unlikely to boost private sector technology transfer for each and every scenario. Even if IP facilitates private sector technology transfer, this does not guarantee that it will occur. The following are some interesting topics to discuss:

- Examine how technology is transferred between, for example, OECD countries and developing countries, and/or between developing countries themselves. Is all of this mediated through a for-profit IP framework? What are the alternatives if not?
- How much 'core' production technology transfer (in terms of, for example, know-how and trade secrets) can realistically be expected, given the friction, in terms of strategic collaboration vs strategic rivalry, between OECD and emerging suppliers?
- What role can the public sector play in the successful transfer of vaccination technology?

Emerging suppliers' know-how deficits can be addressed by contract research, development, and technology transfer based on an MVP-like model.

The Meningitis Vaccine Project (MVP), involving two partners, the WHO and PATH, is a very interesting PPP proposal in terms of IP, where a specific 'know-how' gap of the type discussed above may be sought to be filled through an agreement with a contract research organisation for transfer to an emerging supplier.

The proposal highlights the following details: "We identified four critical components for production of the vaccine: (1) contract manufacture of group A polysaccharide and tetanus toxoid as intermediate components; (2) development of a commercially feasible conjugation chemistry process by experienced scientists; (3) transfer of conjugation process to a vaccine manufacturer in a developing country; and (4) scale-up of production, filling, and freeze drying of antigen, and packaging, storage, and distribution of finished vaccine by this developing country manufacturer."

• Tiered pricing:

Tiered pricing is a well-known strategy for making vaccinations more affordable to underdeveloped countries than to affluent countries. The patent holder, of course, makes the pricing decisions. A donation programme that provides the required product for free to those in need could be considered an extreme example of a pricing decision. When the same vaccines are used in both developed and developing countries, a market with both rich and poor segments develops, and developing countries may be able to benefit from the developed countries' R&D costs.

• Bulk Purchasing/ Procurement:

Bulk purchasing's success is due to the fact that lower prices can usually be offered for larger quantities of the product. In the field of vaccines, as well as, for example, in the field of contraception, bulk purchase techniques play a critical role. In terms of volume, if not dollar worth, UNICEF, PAHO and the WHO account for a significant portion of worldwide vaccine purchasing activity. Vaccines require bulk purchases by their very nature. Given the challenges of vaccine production on a large scale and the need to coordinate production, plans that include accurate disease burden estimation are the need of the hour.

TRANPARENCY OF IPR

Transparency of IPR measures is a part of an existing transparency exercise in which the WTO Secretariat compiles updated reports on trade-facilitation and trade-restricting measures introduced by members of the G20 and WTO members as a whole. The WTO Secretariat has compiled a list of measures regarding trade-related IPRs taken in the context of COVID-19 which is regularly updated and has been verified by the countries as well. This is available on WTO'S COVID 19 webpage. For example, scientists, industry, universities and other stakeholders working to develop technology to combat COVID-19 related health challenges.



WHY TRANSPARENCY MATTERS IN TIMES OF CRISIS

Transparency of IPR information has potential to lead to easy access to patent documents for inventions related to the prevention, identification and treatment of COVID-19. It may promote R&D and the dissemination of knowledge.

An example of this are the government measures and official information issued by national institutions within the scope of their respective authorities as well as sanitary measures that have been adopted because of the emergency declaration in Ecuador. In addition, it provides information generated internationally on COVID-19 contained in dissemination platforms and technological bulletins prepared by international organisations and other national IP offices. The InfoSite is constantly updated with information of interest to users. Article 29.1 of the TRIPS states that an applicant for a patent shall disclose details of the invention sufficiently clearly and the invention should be carried out by a skilled person.

The information given in the patent application may form the basis for a patent document database so that they can facilitate strategic research planning, investments, collaborations, technology transfer, the production of generics and procurement.

Many such IPR Sharing can be seen during the COVID-19 pandemic and these should be followed. In Ecuador, the National Service for Intellectual Rights (SENADI) prepared a resource on technologies used for the prevention and treatment of COVID-19.



The resource contains government measures and official information issued by national institutions within the scope of appropriate authorities as well as the hygiene measures adopted by the country as a result of the emergency declared in Ecuador. In addition, it also discloses information generated internationally on COVID-19 contained in dissemination platforms and technological bulletins prepared by international organisations and other national IP offices. This resource is constantly updated with relevant information. A lot more initiatives are required for spreading essential knowledge.

NATIONAL DRUG POLICY

In order to ensure access to essential medicines, countries need to establish a national drug policy. WHO has released comprehensive guidelines on creating these policies, which would address the access, quality and rational use of these medicines. The WHO draft list on essential medicines can help guide countries in drug selection, although each country should take into account their national priorities and disease challenges. Such a list can increase the use of generics, improve prescribing practices and protect against drug challenges. For example– South Africa had developed a national drug policy with WHO during the 1990s. The Health Minister appointed a Drug Policy committee to develop a pricing plan used both in public and private sectors and to evaluate drug effectiveness. It also focuses on procurement of generics and the distribution of the same in rural areas.



Thus, such lists help -

- 1. Ensure the availability of all drugs to all citizens.
- 2. Regulate the safety and quality of drugs.
- 3. Allow good prescribing practices.
- 4. Promote rational use of drugs by prescribers and users.

MEASURES FOR LOW INCOME COUNTRIES

Low and middle income countries should think about revising their national IPR laws in order to ensure that TRIPS flexibilities specifically geared to promote access to medicines are inculcated into their national laws without any further delay.

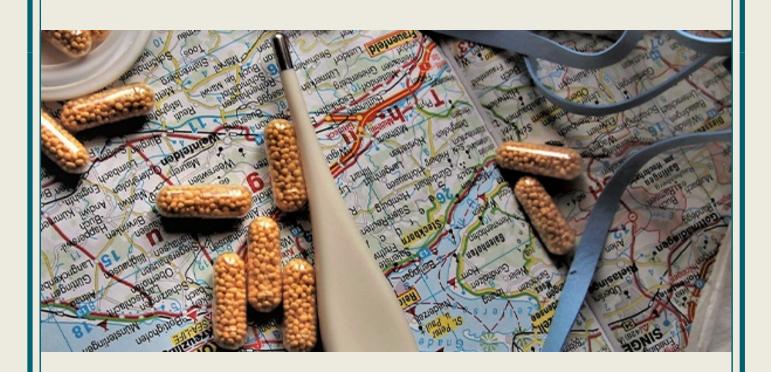
Least developed countries should consider taking the required legislative action, where appropriate, to use the transitional period and not grant pharmaceutical patents till 2021 as provided for in the Doha Declaration.

These countries should encourage cooperation to -

- 1. Develop the national regulatory authorities to ensure quality, safety and efficacy of health products and to allow faster registrations of drugs prequalified by WHO
- 2. Invest in the regional and national production capacity in their own medicine industry to develop local expertise

MEASURES FOR INTERNATIONAL ORGANISATIONS

1. International organisations should support national governments to increase access to treatment by providing technical assistance to implement TRIPS flexibilities in order to promote access to medicines in accordance with their respective mandates. They should address public health concerns in such cross cutting exercises as establishing intellectual property and development strategies or identifying the needs of countries to implement the TRIPS Agreement.



- 2. They should promote the inclusion of flexibilities into legislation and should advocate for the exclusion of legal provisions that could negatively affect access to essential medicines in middle and low income countries.
- 3. Actively monitor the development of intellectual property regulations and their impact on public health, including access to first and second line antiretroviral drugs.
- 4. International organisations should monitor and participate in the debate on alternative models for stimulating innovation relevant to the needs of low and middle income countries.

CONCLUSION

IP rights hold massive importance in today's knowledge-based economy. It has been a controversial subject, frequently mentioned in debates and discussions on political and economical matters. But when we talk about IP rights in the health sector, it is not merely a question of profits and manufacturer benefit. IP rights on the COVID vaccine pose a huge threat towards global access, and therefore towards human life. With new COVID variants being identified, even if the virus is controlled in some isolated areas, it is meaningless until it is controlled globally.

Vaccinating the world would require large-scale transfer of technological know-how to expand the production. Therefore, it is important to ensure that global public health aligns with the incentive-based manufacturing structure. This means having a narrow patent waiver might have huge potential to increase vaccine access in the pandemic.

It is true that there are other bottlenecks to global production and distribution such as lack of required technology, supply chain inefficiencies, trade barriers and scarcity of raw material. These issues also need to be addressed. Hence, the recommendations suggested in the section above tries to tackle these obstacles to health equity in the long-run. However, given the pressing nature of the ongoing COVID-19 pandemic an IP waiver (partial or complete) may act as an immediate short-term method in expanding the global vaccine production capacity.

There is a need for a shared commitment to human health over profits, not just for the current pandemic, but for the longer term.

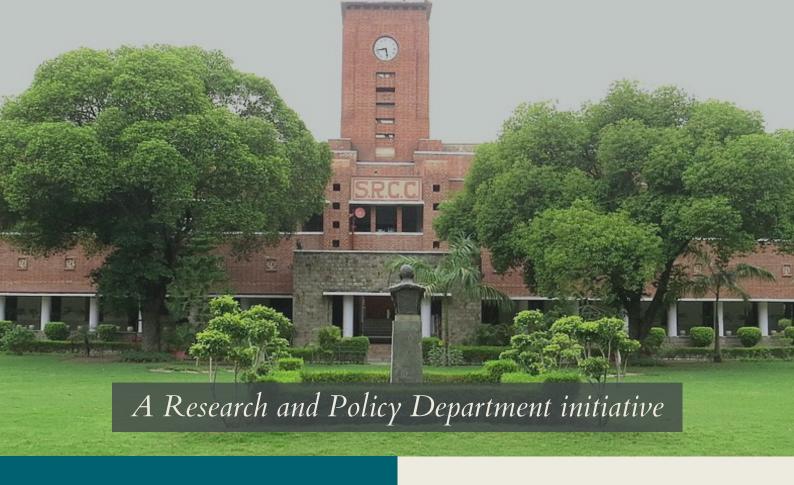
"No one is safe until everyone is safe."



RESOURCES

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