VACCINES AND INTELLECTUAL PROPERTY RIGHTS:

CURRENT OBSERVATIONS

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ABSTRACT

'Intellectual property' indicates creations of the mind which usually entitle the creator an exclusive right, intellectual property right (IPR), over the use of the creation for a certain period of time. Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO) requires all Members of the WTO to enact national laws conferring minimum standards of intellectual property protection, with a purpose to stimulate innovation. In this background, the provisions in the Doha Declaration ensure that governments may issue compulsory licenses on patents for medicines, or take other steps to protect public health. There is a concern that international laws on IPRs could impede new manufacturers from entering the market with competing vaccines. This could have important impact on prices and affordability of the vaccines, which are important in protecting the health of people, including those in the developing countries. A fine balance is necessary between the protection of IPRs and the protection of health of people. The current paper examines these concerns and how the global community has been dealing with the issue.

INTRODUCTION

'Intellectual property' (IP) refers to creations of the mind: inventions; literary and artistic works; and symbols, names and images used in commerce.[2] Intellectual property rights (IPRs) are the rights given to persons over the creations of their minds. They potentially give the maker a right directly over the utilization of his/her creation for a specific timeframe. These rights are bestowed upon the inventor by Governments, conferring the protection from unauthorized use of the IP. Vaccines are among the established tools to protect health and wellbeing of individuals and populations. Employing IPRs to vaccines needs a judicious consideration between the rights of the inventors and rights to life and health of the public.

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[2] World Intellectual Property Organization. WIPO. What is Intellectual Property? [Last accessed on 2019 Feb 04]. Available from: https://www.wipo.int/publications/en/details.jsp?id=99&plang=EN.

TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) AGREEMENT

The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement of the World Trade Organization (WTO), which became effective ~~on~~ from 1 January 1995, has been a wide-ranging accord among the members of the WTO.

The TRIPS agreement addresses right related to the following: copyright and related rights; trademarks; geographical indications; industrial designs; patents; the layout-designs of integrated circuits; and undisclosed issues like trade secrets and facts of the tests. Copyrights, licences, and trademarks apply to a variety of creations. Thus they are addressed in different ways. For protection as an IP, patents, industrial designs, integrated circuit designs, geographical indications and trademarks must be registered, which requires a description of what is being protected. This description is accessible to public. Copyright and trade secrets get protection even without registration, as per indicated conditions. Other aspects, like the length of time that each type of protection is conferred, may also vary.

TRIPS AGREEMENT AND PUBLIC HEALTH: DOHA DECLARATION

The WTO's Fourth Ministerial Conference was held in Doha, Qatar on 9-13 November 2001.Through Paragraphs 4 to 6 of the Doha Declaration[3] (November 14, 2001) on the TRIPS Agreement and Public Health, the WTO concurred that:

"4. The TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

> In this connection, we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.

[3] World Trade Organization. Declaration on the TRIPS Agreement and Public Health. [Last accessed on 2019 Feb 08]. Available from: https://www.who.int/medicines/areas/policy/tripshealth.pdf?ua=1

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002."

Thus, Doha Declaration safeguards that governments may take appropriate steps to protect public health. This includes issuing, when necessary, compulsory licenses on patents for medicines.

On 30 August 2003, the WTO members came to a compromise over IPRs and public health. They concurred on legal changes that could result in easy import, by less developed countries, of cheaper generics produced with compulsory licencing.

The 2005 Ministerial Declaration[4] expressed:

> "We reaffirm the importance we attach to the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, and to an amendment to the TRIPS Agreement replacing its provisions. In this regard, we welcome the work that has taken place in the Council for TRIPS and the Decision of the General Council of 6 December 2005 on an Amendment of the TRIPS Agreement."

On 6 December 2005, WTO approved changes to the TRIPS agreement that stabilised a resolution on patents and public health first adopted in 2003. This was formally integrated with the TRIPS Agreement after consent to the Protocol modifying the TRIPS Agreement by two thirds of the members of WTO. The amendment came into force from 23 January 2017 and substituted the 2003 waiver for the member counties who have assented to the changes. India acceded to the amendment on 26 March 2007. Members who are yet to accept the amendment currently, may do so by 31 December 2019.

National Intellectual Property Rights Policy was affirmed by the Indian cabinet on 12 May 2016 to conform to the Doha Development Round and TRIPS Agreement. The Policy has 7 goals and aims for a "Creative India; Innovative India".

WTO permits the least-developed country (LDC) members to maintain maximum flexibility with respect to patenting pharmaceuticals, including vaccines, till 2033.

EFFECT OF TRIPS ON DEVELOPMENT OF AND ACCESS TO VACCINES

As per the TRIPS agreement, countries with vaccine manufacturing capabilities need to provide patent protection for pharmaceutical and biological products. Further, Doha Declaration approved flexibility of TRIPS member states with respect to patent rights for improved

[4] World Trade Organization. Ministerial Declaration. [Last accessed on 2019 Feb 08]. Available from: https://www.wto.org/english/thewto_e/minist_e/min05_e/final_text_e.htm#public_health

availability of necessary medications. The Declaration affirmed that supporting availability of essential medicines should be central to the interpretation of the agreement.

The discussion on the relative importance IPRs and rights to life and health has been fascinating and delicate. Vaccines are whole or portions of microorganisms or toxoids that are given to humans or animals to prevent an infectious disease; a toxoid is a bacterial toxin modified to be nontoxic but is capable of inducing immunity against the toxin. Recently, the term "vaccine" is also being used for immunologic agents administered against different tumour antigens with the objective of inducing an endogenous response against the tumour. As a result of effective and safe vaccines smallpox has been eradicated and polio is near eradication, in the world. Vaccines induce active acquired immunity (in contrast to passive acquired immunity induced by immunoglobulins given from outside), and are well proven medical measures to protect individual-health and public-health. They are known to protect people's incomes and savings, and promote economic growth.

The following deliberation explores the observations on the effect of IPRs on the development of and access to vaccines.

Discussions on IPRs and vaccines should engage issues of multiple IP rights applicable to a vaccine - such as patent, copyright, trademarks, plant breeders' rights and trade secrets concerning various forms and aspects of vaccines - in a way that the development and supply of the vaccines is sustained.

The supporters of Agreement on TRIPS had felt that the global support for IPRs would encourage innovation. However, in reality, the ensuing period saw a reduction in the number of new medicines being approved annually, after the Agreement came into effect. With globalisation various forces, that includes the widespread implementation of TRIPS agreement, have affected various aspects of public health, including vaccine-preventable diseases.

Disease burden is considered a quantitative measure for setting priorities for new vaccine development and usage. But funds are not always assigned in proportion. For example, to control the spread of HIV infection in resource-poor countries an AIDS vaccine has long been considered to be the only practical solution, it has been difficult to persuade vaccine manufacturers to invest their resources in the absence of an obvious financial advantage.There

are high costs involved in developing safe and effective vaccines and in protecting the IPRs involved. Addressing the concerns of the pharmaceutical companies (who form important role-players in the development of new vaccines), including the IPRs, is a crucial factor that affects the pace with which the vaccines are assimilated into vaccination programs.

In the year 2000, Global Alliance for Vaccines and Immunization (GAVI) was created to tie the public and private sectors with the common objective of fair access to new and underutilised vaccines for children in poorest of the nations. At present, GAVI's provider base for new and underutilized vaccines is somewhat limited. After TRIPS agreement, there has been unease that entry of new manufacturers (who could supply GAVI)with competing vaccines is hindered because, vigorous patenting potentially dampens new manufacturers. Measures like better clarity regarding patenting of vaccines, stringent norms for patenting as fit for local requirements and supporting IPRs management skills as applicable, may help counter this dampening effect and ensure economical suppliers for vaccines. It is relevant to mention here that the pneumococcal conjugate vaccine (PCV) has been introduced into the Universal Immunization Program (UIP) of India with support from GAVI. Indiahas the largest number of sub-optimally vaccinated children in the world and is the largest GAVI-supported country. At the same time, the patent applied by Pfizer on its 13-valent pneumococcal conjugate vaccine (PCV-13 vaccine) has claimed to have added more serotypes to PCV. But this is based on obvious technologies that were known to vaccine producers, and granting of patent to Pfizer is mentioned as an illustration of new generation vaccines being disposed to patent-evergreening. This issue has been disputed in the jurisdictions of India, South Korea, US and Europe. If granted without legal analysis, in effect, sweeping patents like this could hinder subsequent manufacturers from introducing new forms of PCV-13.

Specifically in India, Médecins Sans Frontières (MSF) or Doctors Without Borders - a Paris-based humanitarian aid organisation - through its local unit MSF India, has officially challenged the U.S. company Pfizer Inc.'s request for an Indian patent on Prevenar-13 (Pfizer's PCV-13, produced by adding more serotypes to an already-established 7-valent vaccine), with a view that it could deprive many developing nations of cheaper copies of the drug. In August 2017, Indian patent office granted the patent to Pfizer for its Prevenar 13, preventing other manufacturers from producing less expensive versions of PCV-13 and permitting Pfizer the exclusive right to

market it in India until 2026. While Panacea Biotec, another vaccine producer, filed a review petition with the patent office for cancellation of the patent given to Pfizer, MSF India moved Delhi high court against the patent. The MSF opined that the patent was a major blow to the expectations of a access to a less expensive PCV that could protect public from pneumonia. It alleged that the patent supports ever greening, because simple adding of serotypes to the already-established 7-valent vaccine does not involve a technical advancement but is a way to maintain Pfizer's domination till 2026. MSF asserts that nearly a third of the world's countries today, are unable to introduce PCV chiefly due to huge costs; countries that have introduced the vaccine in their immunisation schedules are struggling. For example, South Africa spends more than half of its immunisation expenditures only on procuring PCV-13. If patent hurdles are not removed, this would last till 2026.

It is interesting to observe that in India, under the Section 3 (that deals with 'What are not inventions') of The Patents Act, 1970, the clause (i) states that "any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products" is, among other things, not an invention, and therefore not patentable.

But then, in the developing countries, there is a sluggish progress in the development of new vaccines that could fulfil their needs. It has been pointed that the regulatory-process-driven vaccine research and development shows importance of IP management and that IPRs are of value for the investors and the public as well, because currently the public sector does not have the ability to carry out the role that the private sector is now playing, in the developing countries.

Access to vaccines across the world is lop-sided and disturbing, given its well-recognised association with higher morbidity and mortality in poorer countries.

It is interesting to note that the existing vaccines for the respiratory viruses are for influenza alone, despite other respiratory viruses also having been troubling the people globally. So far, producing vaccines against other respiratory viruses using usual methods has not been pragmatic. Reverse genetics is a different method that may be helpful for the preparation of such vaccines. Here again, resolving the issues related to the IPRs for reverse genetics could facilitate sufficient

vaccine supply to satisfy worldwide demand. In addition, it is suggested that the research on possible vaccines useful against pandemics (‘pandemic’ is a disease occurrence that is geographically widespread; occurring throughout a region or even throughout the world), helping many countries, must involve all vaccine manufacturers, requiring worldwide coordination.

The following factors determine the ability to offer medicinal measures in public health emergencies: development of medicinal processes, establishing capacity, and ensuring access. In viral pandemics, vaccine development will be affected by the patents on the genomic sequences or proteins of the causative agent, as well as on new methods for vaccine making, the vaccine itself or the adjuvant (‘adjuvant’ is an additive that enhances the effectiveness of vaccines) knowhow. All of these are important to enable the production of a functioning vaccine on a quick demand. Patent rights could regulate capacity, which in turn may affect access. Thus, with regard to pandemic planning, how patenting can influence development, capacity and access to medicinal interventions must be considered. Patents may facilitate or inhibit the availability of medicinal measures in pandemics.

Interestingly, a number of establishments had applied for patent involving the genomic sequence of the severe acute respiratory syndrome (SARS) coronavirus. Such situations result in a potential for fragmentation of IPRs. This in turn may adversely affect the development vaccines. In such a context, keeping these patents in a ‘patent pool’, to be licensed on a non-exclusive basis, may help overcome patent-related barriers to making generic vaccines. ‘Patent pool’ refers to the collection of IPRs that can be cross-licensed. These processes can function either through direct transfer or through an entity set up to administer the patent pool. US Justice Department has already issued guidelines of on this. It is heartening to note that the Medicines Patent Pool (MPP), a United Nations supported public health organisation, has been established with the support of Unitaid; it is working to increase access to, and facilitate the development of life-saving medicines for poorer countries. The MPP aids the providing of licenses to all patents required to produce a given final product in a package to several generic producers on a nonexclusive basis; royalties are given to patent holders. The condition that the licenses shall be used only in poorer countries prevents undue entry into the key target markets of brand-name manufacturers.

The purpose of IP protection is to stimulate innovation. Opponents of the TRIPS agreement are anxious that the condition by the Agreement, that all members of the WTO to enact national laws conferring minimum standards of intellectual property protection, is inconsistent with ensuring access to medicines in the developing world. A World Health Organization (WHO) meeting on IPRs and vaccines in developing countries found no evidence that TRIPS has stirred innovation in vaccine development or that protection of IPRs has had a negative effect on access to vaccines. That apart, following TRIPS could mean access to forthcoming vaccines in the developing world might be tougher. It has been suggested that the managing these apprehensions necessitates: all countries adhering to the Doha Declaration and the safeties ('flexibilities') it assured, vigilance on TRIPS-plus components of free trade agreements, creating structures for licensing and technology transfer, and supporting new vaccine development in developing countries. In addition, to ensure proper access to essential new vaccines for the developing countries, the role of global establishments may be crucial in defining best practices, propagation of information, and checking on the effect of TRIPS.[5]

Imploring 'flexibilities' in TRIPS conferred by Doha Declaration could improve affordability and accessibility of medicines (including vaccines) countering such barriers to access as the overall lack of interest by the pharma-industry in discovering new medicines and vaccines for diseases of the poor due to very limited market in developing countries and global IPR protection systems.[6] These flexibilities include: compulsory licenses, governmental use for non-commercial purposes, non-exclusive protection of test data and parallel imports.[7]

As mentioned above, another potential threat to access to medicines and vaccines to be considered are the "TRIPS plus" clauses - the pacts contained within bilateral and regional free-trade agreements - that may contain provisions that allow patent life more than TRIPS minimum

[5]Milstien J, Kaddar M. Managing the effect of TRIPS on availability of priority vaccines. Bull World Health Organ. 2006 May;84(5):360-5. Epub 2006 May 17.
[6]Satyanarayana K, Srivastava S. Poverty, health & intellectual property rights with special reference to India. Indian J Med Res. 2007 Oct;126(4):390-406.
[7]Correa CM. Flexibilities provided by the Agreement on Trade-Related Aspects of Intellectual Property Rights. Bull World Health Organ. 2018 Mar 1; 96(3): 148.

of 20-years, limit compulsory licensing in ways not mandated by TRIPS, and limit exceptions that enable rapid induction of generics.[8]

Further, it has been observed that the global access to cutting-edge vaccine technologies is confronted by IP management approaches - along with technology transfer (legal and technical) capabilities and the capacity needed for hastening research and development, marketing and supply of vaccines. It is suggested that the assembly, organization and analysis of patent landscapes, to identify the amount of patenting, ownership (assignees) and fields of technology covered, might help worldwide vaccine access.[9]

With this background, it is of concern that IP fault lines were noted in the WHO with a continuing disappointment in properly addressing questions of justice and development.[10]

With regard to adjuvants for vaccines, in the light of the limitations due to IPRs, it is commendable that the WHO has promoted the establishment of the Vaccine Formulation Laboratory at the University of Lausanne in Switzerland that formed a platform for access to adjuvants. The laboratory transfers adjuvants and formulation technology free of IPRs to academic institutes, small biotechnology establishments and vaccine producers in developing countries.[11]

International governmental risk pools to fund research and development of infectious disease medicines and vaccines can be used to reduce disease outbreaks. A proposal to prevent epidemics from recurring has been to have the WHO and its technical partners assess which of its member nations are at high risk for a disease and facilitate the creation of international governmental risk pools of those member nations. Risk pools would offer open-indexed grant contracts to fund vaccine and drug development for a specific disease. Pharma-companies could look the index to request for these grants. If the risk-pool nations and a certain company sign an agreement, a jointly accepted quantity of the vaccine or drug would be manufactured at an

[8]World Health Organization. Globalization, TRIPS and access to pharmaceuticals. WHO Policy Perspectives on Medicines No 3, March 2001. Geneva: WHO: 2001.
[9]Clark K, Cavicchi J, Jensen K, Fitzgerald R, Bennett A, Kowalski SP. Patent data mining: a tool for accelerating HIV vaccine innovation. Vaccine. 2011 May 31;29(24):4086-93.
[10]Lawson C. Who shall live when not all can live? Intellectual property in accessing and benefit-sharing influenza viruses through the World Health Organisation. J Law Med. 2011 Mar;18(3):554-76.
[11]Collin N1, Dubois PM. The Vaccine Formulation Laboratory: a platform for access to adjuvants. Vaccine. 2011 Jul 1;29Suppl 1:A37-9.

economical procurement price for those nations. In return, the company would keep any patents or IPRs for the developed vaccines or drugs. Risk-pool countries that did not use their vaccine or drug could resell that supply on secondary markets to other countries outside of the risk pool. This arrangement will increase the supply of tested drug and vaccine entrants accessible for fighting unpredicted future epidemics of any earlier discovered major infectious disease.[12]

An 'IPTK bank' - an entity established to group all relevant *Intellectual Property, Technology, and Knowhow* – has been suggested as a strategy to create a structure capable of facilitating access to new vaccines. It would bond the necessary IPRs, manufacturing process information, know-how, and regulatory expertise into one platform that could be licensed as a bundle with related training components; it could also support in vaccine registration with respective governments.[13]

CONCLUSIONS

The agreement on TRIPS necessitates all members of the WTO to enact national laws conferring minimum standards of IPRs. Such action has been condemned to be inconsistent with ensuring access to medicines in the developing world and potentially has important impact on prices and affordability of the vaccines. However, the provisions in the Doha Declaration ensure that to protect public health, governments may take steps ('flexibilities') – including compulsory licenses, government use for non-commercial purposes, non-exclusive protection of test data and parallel imports – to lessen the negative effect of the agreement's provisions on market dynamics and access to medicines, including vaccines. Managing the threats by theTRIPS agreement requires adherence of all countries to the Doha Declaration and the safeguards it guaranteed, attention on TRIPS-plus components of free trade agreements, forming guidelines for licensing and technology transfer, and promoting innovative vaccine development in developing countries. The role of international establishments is crucial to ensure adequate access to important new vaccines for the developing world.

[12]Erfe JM. Reducing outbreaks: using international governmental risk pools to fund research and development of infectious disease medicines and vaccines. Yale J Biol Med. 2014 Dec 12;87(4):473-9.
[13]Sara Eve Crager, "Improving Global Access to New Vaccines: Intellectual Property, Technology Transfer, and Regulatory Pathways", American Journal of Public Health 104, no. 11 (November 1, 2014): pp. e85-e91.