TRIPS Flexibilities for public health in the context of COVID 19

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Introduction

The COVID 19 pandemic has significantly impacted countries in South and South-East Asia. While the first wave of the pandemic had relatively less impact in terms of the extent of populations infected, subsequent waves of the pandemic with the emergence of new variants have led to rapidly increasing rate of infection in most countries in the region. At the same time, access to vaccines has been limited with a relatively small percentage of the population receiving partial or full vaccination. This is primarily due to the limited availability of vaccines because of the lack of mass scale production, which has made all countries dependent on a few pharmaceutical or vaccine manufacturing firms, with production capacities concentrated in a few firms and countries. The WHO coordinated mechanism established to facilitate global supply of vaccines to low and middle income countries – the COVAX Facility – has been unable to supply the minimum doses of vaccines that was expected to be made available to those countries. Developing countries are thus having to compete with rich countries to secure supplies of vaccines for their populations. Enabling mass local production of vaccines through transfer of technology to scale up supply of vaccines for rapid inoculation is urgently needed in all developing countries. Where the vaccines are protected by patents, access to the technology for manufacturing those vaccines will be dependent on both voluntary licensing by the patent holder as well as use of TRIPS flexibilities that can be used for ensuring that exploitation of patent rights do not come in the way of ensuring access to the vaccines. In addition, another possible solution that is currently being discussed in the WTO is a waiver of certain TRIPS obligations to enable access to vaccines, medicines, etc. for responding to COVID-19.

The need for rapidly scaling up manufacturing and supply is not limited to vaccines. This would also be required for therapeutic medicines that are approved for the treatment of COVID-19.

The Emerging Patent Landscape on Vaccines

The development of a number of vaccines for COVID-19 have happened at a historically unprecedented speed, facilitated substantially by massive public investments in their development. Nevertheless, proprietary ownership of these vaccines is determined by a number of patents that have been granted or applied for on the vaccines or their components.

A number of patents relating to technology platforms, lipid compounds, etc. used in making a vaccine have been granted patent protection in some of countries many years before the COVID-19 Pandemic. A 2012 WIPO patent landscape report had identified 11,800 patent families for different components of vaccines to prevent some infectious diseases. A recent study has identified 113 patent families relating to the mRNA technology used by several COVID-19 vaccines producers; many of these patents have been applied for through the Patent Cooperation Treaty with numerous States included, which means that these will enter national phase processing in many developing countries in the next few months or years. Moderna, Inc., the producer of one mRNA based vaccine for COVID-19, is reported to hold "over 270 issued or allowed U.S. and foreign patents protecting mRNA based technology, with over 600 worldwide pending patent applications. The company has identified at least seven granted U.S. patents that it alleges protect its COVID-19 mRNA-1273 vaccine". Moderna has been involved in litigation over three patents held by Arbutus Biopharma. Pfizer and BioNTech have been sued by Allele Biotechnology and Pharmaceuticals, Inc. over the alleged infringement of a patent on a monomeric fluorescent protein used in assays of their COVID-19 vaccine.

In 2021, the US National Institute of Health was granted a patent over a stabilized coronavirus spike protein (i.e., a spike protein that retains its shape in isolation from the virus) which is a key component of both mRNA and adenovirus vector vaccines. This patent.

Table 1 presents an overview of the emerging patent landscape of COVID-19 vaccines. It is possible that many more patent applications on COVID-19 vaccines have been filed after the outbreak of the pandemic through 2020 and 2021 and such applications would be published in the near future. Therefore, the actual number of patent applications may be very substantial.

The existence of multiple patents on COVID-19 vaccines can create challenges for manufacturing vaccines using similar technological approaches in other countries. While some patent holders, e.g., Moderna, have pledged not to enforce the patents during the pandemic, there is no legal restraint against enforcing the patents by any right holder. Moreover, even if a patentee does not enforce the patent, they may decline to voluntarily license the patented technology. For example, so far no vaccine manufacturer has shared their patented technologies in the COVID Technology Access Pool (C-TAP) that has been established by the WHO.

Use of TRIPS Flexibilities

A number of flexibilities are available under the TRIPS Agreement which can be applied by governments to ensure that IP rights do not constrain innovation and availability of health technologies required for responding to COVID-19. These measures include application of rigorous patentability requirements, use of exceptions and limitations including the research and security exceptions, grant of compulsory licenses or government use authorization, use of the transitional waivers for least developed countries (LDCs), parallel importation, and ensuring fair procedures for the enforcement of IP rights.

Specifically in the context of COVID-19, States have pursued the following approaches to respond to ensure patent rights do not impede rapid access to vaccines, diagnostics, therapeutics for COVID-19:

1. Enabling use of compulsory licensing or government use authorization
2. Offering indemnity against infringement proceedings
3. Applying competition law measures
4. Use of sovereign powers

A number of countries have enacted specific laws or issued parliamentary resolutions that authorize or call upon the government to issue compulsory licenses or government use authorization for health products related to COVID-19.

Canada

On 25 March 2020, Canada enacted the COVID19 Emergency Response Act, mandating the Commissioner of Patents to issue grant a government use authorization for any patented invention that is deemed by the Ministry of Health to be necessary to respond to the public health emergency, upon an application for such authorization by the Ministry of Health.

Chile

On 17 March 2020, the parliament of Chile adopted Resolution No. 896 declaring that the global coronavirus outbreak justifies the use of compulsory licensing to facilitate access to vaccines, drugs, diagnostics, devices, supplies, and other technologies useful for the surveillance, prevention, detection, diagnosis and treatment of the coronavirus in Chile.

Germany

On 25 March 2020, Germany adopted the Prevention and Control of Infectious Diseases in Humans Act which authorized the ministry of health to issue government use authorization under the patent law, upon the declaration of a national epidemic by the lower chamber of the German federal legislature. Such an authorization could cover all medical products, their components, medical devices, diagnostics, and personal protective products.

Israel

On 20 March 2020, Israel issued a government use authorization under the Israeli patent law for the importation of generic lopinavir/ritonavir combination for the treatment of COVID-19 patients from an Indian generic company by a local company acting on behalf of the ministry of health.

Immunity against IP Infringement Proceedings

Another approach that countries can take to ensure that IP rights do not impede the use of IP protected technologies for COVID-19 by third parties is to suspend the enforcement of the IP rights and grant indemnity against enforcement actions, including IP infringement lawsuits. It has been argued by some that the recent notice of declaration published by the US Department of Health and Human Services under the Public Readiness & Emergency Preparedness (PREP) Act, conferring immunity from tort litigation for those engaging in acts related to COVID-19 countermeasures, also grants indemnity against patent infringement liability for third parties that use health technologies in relation to COVID-19.

Applying competition law

It is also possible for countries to use measures for anticompetitive use of IP protected technologies in relation to COVID-19. For instance, as noted above, recently the European Commission (EC) launched a preliminary investigation on the abuse of the dominant position in the Dutch market by the multinational pharmaceutical company Roche, on account of its reported refusal to share the secret formula for producing a buffer solution that is necessary for use in testing kits for COVID-19. The EC has also stated that during the pandemic it will also continue to closely and actively monitor relevant market developments to detect instances of undertakings taking advantage of the current situation to breach European Union (EU) competition law, either by engaging in anticompetitive agreements or abusing their dominant position.

Use of sovereign powers

On 23 March 2020, France enacted a new law No. 2020-290 which introduced a new article - L.3131-15 – to the country's public health code, allowing the Prime Minister to

order the seizure of all goods and services necessary to: fight against sanitary disaster; to temporarily control the prices of products; and to take any measures necessary to make relevant medicines available to patients.

Security Exception

Article 73(b) of the TRIPS Agreement states that nothing in the Agreement will be construed as preventing a member from taking any action which it considers necessary for protection of its essential security interests, taken in the time of war or other emergency in international relations. Thus, in furtherance of its health security interests, the TRIPS Agreement allows a country to take measures such as suspending the grant of patent protection (LDC members of the WTO can do so even without using the security exception as they have transitional waivers under article 66.1), and grant indemnity against enforcement actions. In accordance with article 6 of the TRIPS Agreement, a country can also undertake parallel importation of needed products, including from countries where they are produced under compulsory licenses.

Proposal for a TRIPS Waiver

India and South Africa have jointly submitted a proposal to the WTO TRIPS Council requesting, under article IX.3 of the Agreement Establishing the World Trade Organization (hereinafter WTO Agreement), the grant of a waiver from implementation, application and enforcement of intellectual property (IP) rights and their in relation to health technologies for prevention, containment and treatment of COVID-19. The proposal has received the support of more than 100 countries and WTO members have agreed to undertake text negotiations for a decision adopting a waiver.

The proposed waiver would absolve all countries from implementing the referred obligations for a limited time period, extending policy space for governments and extending freedom to operate to parties without risk of infringing such intellectual property rights, while ensuring legal certainty that actions are compliant with WTO international rules on trade related aspects of intellectual property rights. This is essential for WTO members to be able to comply with their human rights obligations. The adoption of this proposal will overcome potential obstacles that some categories of intellectual property rights may create to get timely and unfettered access to technologies and products needed to address the pandemic. It will not affect, however, the enforcement of other categories of rights covered by the TRIPS Agreement, nor its full implementation in relation to matters unrelated to the prevention, containment or treatment of COVID-19. Therefore, the adoption of this proposal could be critical to ensure availability of medical products at affordable price for the prevention, containment and treatment of COVID 19.

However, it is an open question whether the scope of the waiver would be sufficiently broad as proposed, or whether it would be limited to only vaccines, for a short duration and subject to compensation, as some of the developed countries' statements suggest.

Nevertheless, the implementation of the waiver will depend on legislative, administrative and judicial measures that would need to be taken to apply the waiver. The waiver will not be self-executing and will not in itself waive the legal rights under national patent laws. Legislative or administrative measures taken to implement the waiver could also be challenged before the judiciary. In this regard, an important issue to consider would be how to safeguard the domestic implementation of the waiver against legal challenges. Questions of admissibility of such legal challenges, availability of temporary or permanent injunction against a waiver implementing measure, would be relevant issues to consider.

Some Patent Claims on COVID-19 Vaccines

Vaccine Type	No. of patents	Patent Owner/Assignee	Types of claims	Earliest expiry (year)	Latest expiry (year)	Asian Countries (granted/pending)
AstraZeneca (AZD122/ChAdox1 nCOV-19) *Adenovirus vector vaccine*	2	Oxford University Innovation Ltd.	Adenovirus vector derived from chimpanzee adenovirus and isolated nucleic acid molecule used in the vaccine Method for generating recombinant adenovirus with a DNA sequence encoding a gene for use in the vaccine	2032	2039	First claim (term till 2032) has been granted in 19 countries including China, India and Japan in Asia. The second claim (term till 2039) has been filed as an international. (PCT) application designated for national entry in 45 countries including China and India
Covaxin (BBV152) - Bharat Biotech/Indian Institute of Medical Research *Inactivated SARS-COV2 vaccine*	2	University of Kansas Wuhan Institute of Biological Products Co. Ltd.	Pharmaceutical compound including its derivatives and salts for use as adjuvant in composition and preparation of the vaccine (US) Method of preparing inactivated SARS-COV2	2032	2040	The first claim (term till 2032) has been granted only in the US. The second claim has been filed in China (pending) and an international application (designating other countries) or several national applications can be filed by August 2021.

			vaccine (China)			
Zorecimeran (CVnCOV) - CureVac *mRNA*	11	CureVac AG (6) Acuitas Therapeutics Inc. (4) Polymun Scientific Immunbiologische Forschung GmbH (1)	Pharmaceutical composition containing mRNA used in the mRNA platform used to make the vaccine; method of inducing immune response using the platform; nucleic acid molecule for making vaccine for infectious diseases; artificial molecule used for genetic vaccination; specific genetic coding; Markush claims on lipid compounds for composition or preparation of the vaccine; mRNA with lipid nanoparticles, their use in vaccines and process of making such lipid nanoparticles and method of administering to humans.	2022	2040	The various patents have been granted or pending examination in a number of countries, including in China, India, Japan, South Korea and Singapore. Some other patents are in the stage of international applications which could enter for national processing in various countries.

Sputnik V (Gam-COVID-Vac) - Gamaleya *Adenovirus vector vaccine*	5	National Research Center for Epidemiology and Microbiology, Russia	Separate claims on different serotype strains of recombinant human adenovirus, pharmaceutical agents for induction of immunity against SARS-COV2 using specific components of specific serotypes, liquid form of the marketed active ingredients of the vaccine, use for revaccination, and use for vaccination of people above 60 years age.	2040	2041	All patents have been granted in Russia. Separate national applications or international (PCT) applications designating countries for national entry may be filed by specific applicable deadlines in 2022 or 2023 relative to the date of the first filing of the patents in Russia.
Ad26.COV 2-S COVID-19 - J&J *Adenovirus vector vaccine*	21	Brigham and Women's Hospital Inc/NIH, (DHHS) U.S. Government (1) Crucell Holland B.V. (13)	Method of producing virus particle using a specific cell line that is engineered to express adenovirus vectors for use in vaccines; culturing the cell line to used to express adenovirus vectors: claim on cell lines complementin	2023	2040	A number of these patents have been granted in China, India, Japan, South Korea and Singapore (in Asia)

		Jansen Vaccines and preventio n B.V (5) Introgene B.V. (2)	g specific adenovirus serotypes; claim on recombinant adenovirus particle used in genetically modified adenovirus vectors, nucleic acid used in the vector, isolated DNA sequence, use for SARS-COV2, etc.			
mRNA-1273 (Moderna) *mRNA*	17	Trustees of Univ.Penn sylvania assigned to NIH (DHHS), US Govt. (2) Protiva Biotherap eutics/Ar butus Biopharm a (2) Acuitas Therapeu tics (1)	Method of inducing mammalian cell to produce protein using synthesized mRNA; composition of lipid nanoparticles (multiple patents); synthesis of mRNA of the Moderna vaccine; method of expressing polypeptide using isolated mRNA used in making the vaccine; claim on mRNA used in making the vaccine; method of manufacture	2026	2040	International (PCT) applications have been filed. Some have entered national phase in various countries, or would enter in future. Claims pending in China, India, Japan, Singapore, South Korea in Asia.

		Dept. Of Molecular Biosciences, Univ. Of Texas/NIH US (1) Moderna Therapeutics (11)	and optimization of modified mRNA molecules; purified preparation of mRNA; composition of the vaccine; specific lipids; betacoronavirus; method of delivering nucleic acid to humans by lipid nanoparticle.			
NVX-CoV2373/ Covovax (Novavax) *Recombinant nanoparticle vaccine*	5	Novavax Inc. (3) Isconova AB/Novavax AB (2)	Composition of NVX-CoV2373 vaccine, composition of iscom (immunostimulating) particles; method of preparing antigenic composition comprising iscom particle and living microorganism; method of enhancing immune response level and immunomodulating activity by using an adjuvant of specific composition	2023	2036	Patents have entered national phase in many countries and are pending, including in China, India, Japan, South Korea and Singapore in Asia. 2 patents have been granted in Japan.

Tozinameran (BNT162b2) - Pfizer and BioNTech *mRNA*	14	Protiva Biotherapeutics Inc./Arbutus Biopharma Corp. (4) Trustees of Univ. Pennsylvania/NIH (DHHS), US (3) BioNTech (3) Acuitas Therapeutics Inc (4)	Process for producing a lipid vesicle encapsulating a nucleic acid; method of producing lipid vesicle encapsulating a therapeutic product including a nucleic acid; method for inducing a mammalian cell to produce protein using synthesized mRNA; composition of nucleic acid molecule; composition of lipid nanoparticle; method of inducing mammalian cell to produce protein using mRNA used in the composition and preparation of Tozinameran (the vaccine) and its dispersal as injection; purified preparation of mRNA of specific composition, Markush claim	2023	2040	Patents filed and granted in a number of countries, including China and Japan. One patent pending in India.

			of a lipid compound and its derivatives and salts used in preparation of the vaccine; method of delivering nucleic acid to a human by administering lipid nanoparticle.			
BBIBP-CorV (Sinopharm/Beijing Bioinstitute of Biological Products Co. Ltd.) *Inactivated SARS-COV2 vaccine*	1	Wuhan Institute of Biological Products Co.Ltd.	Method for preparing an inactivated vaccine of SARS-CoV-2 virus.	2040	2040	Claim has been filed in China (pending) and an international application (designating other countries) or several national applications can be filed by August 2021.
Coronavac (Sinovac) *Inactivated SARS-COV2 vaccine*	3	Wuhan Institute of Biological Products Co.Ltd. (1) Sinovac Research &	Method for preparing an inactivated vaccine of SARS-CoV-2 virus. Inactivated vaccine for	2040	2040	For the method of preparing inactivated vaccine, claim has been filed in China (pending) and an international application (designating other countries) or several national applications

		Development Co Ltd (2)	SARS-CoV-2 and the preparation thereof			can be filed by August 2021. An international PCT application has also been filed (to be published) on the inactivated vaccine.

Source: Medicines Patent Pool VaxPaL Database

Discussion

What can be the major considerations in case a legal or administrative measure implementing the TRIPS waiver, suspending statutory provisions or regulations in relation to the application, examination, protection and enforcement of patent rights related to health technologies for COVID-19 is subjected to a legal challenge?