EXEMPTING COVID-19 VACCINES FROM INTELLECTUAL PROPERTY RIGHTS WILL IMPROVE GLOBAL ACCESS AND EQUITY

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India is globally well recognized for its generic drug manufacturing market on which innumerable nations depend for the supply of affordable and cheap drugs. India ranks 3rd in terms of pharmaceutical production by volume and 14th by value world-wide.[i]India is not only acknowledged for drug manufacturing but it is additionally one of the largest vaccine producers in the world. It supplies 62% of the global requirement for vaccines[ii]. The country is now also recognized as the "Pharmacy of the world". In spite of this the country is experiencing scarcity of Covid-19 vaccine and in consequence of this it is the need of the moment to have recourse to provisions like compulsory licensing.

The provisions for such a measure, called compulsory licensing, are enshrined under chapter 16 of the Indian Patents Act 1970 and under section 31 of the Trade Related Aspects of Intellectual Property (IP) Rights.[iii] Many nations including Canada,[iv] Ecuador,[v]Chile[vi] and Israel[vii] have enacted laws or employed resolutions for the reason of compulsory licensing of Covid-related medicines.

Currently, immunization suggests to be the surest and most favorable exit out of Covid-19. Despite a vaccine or vaccines had been developed, still no pharmaceutical company alone have the capacity to manufacture enough vaccine to meet global demand. One would require manufacturing of around five billion doses to vaccinate the world population, for a single-dose vaccine, in addition to ten billion for a two-dose vaccine.[viii] This would need cross-border licensing, and contract manufacturing and technology transfer deals to be struck by vaccine developers at a range and pace beforehand.

A patent comprises a bundle of "exclusive rights" granted by a State for a limited period of time for the exploitation of an invention by the inventor in exchange for the sufficient disclosure of the invention.[ix] Alike other vaccines, those developed to tackle COVID-19 are produced in reasonably a smaller number of countries. Likewise, ingredients of these vaccines and, to a large extent, the medical kit needed to tackle COVID-19 are also manufactured in reasonably few countries. In addition to this public health essential, the faster the vaccines are administered globally the quicker the world economy can nail claw back lost output.

Currently, the Central Drugs Standard Control Organization (CDSCO) which is India's drug regulator has given assent to three vaccines for use Sputnik V Covishield and Covaxin.[x] The technology has been allowed to the Panacea Biotec Limited for manufacture of Sputnik V vaccine by RDIF of Russia by its affiliate company that is "LLC Human Vaccines" of Russia. According to the terms of Agreement there is transfer of technology also.[xi]

As far as the case of Covishield is concerned, Covishield has been mutually developed by University of Oxford, AstraZeneca and SII manufactures.[xii] Covishield in India is on a license with AstraZeneca.

Nevertheless, as respect to Covaxin is concerned, it is a domestically developed vaccine, however, there is uncertainty as to who possess the Intellectual Property rights for Covaxin. According to some news articles, the IP rights for Covaxin are mutually owned by Bharat Biotech and ICMR. As per the memorandum of understanding entered between Bharat Biotech and ICMR it provides for a royalty sharing clause mutually between the two entities.[xiii] Therefore, in this way the Government of India is the owner of Intellectual Property Rights of the "Bharat ka vaccine" that is Covaxin. Thus, it is necessary to put our heads together to the various provisions under the Patents Act, 1970, which the Indian Government can invoke in order to speed-up production of Covaxin in order to tackle the need of the masses.

The origination of patents on drugs has aroused a serious concern in a number of developing countries where availability to medicines is already extremely low. There were many reports about IP rights provisions which hamper timely provisioning of desirable medical products to patients.

In India, the patent regime is controlled by the Patents Act, 1970, Section 92 of the Patents Act [xiv] which is also uniform to Article 31 of The Agreement on Trade-Related Aspects of

Intellectual Property Rights (TRIPS)[xv] Agreement can be invoked of which conceives the grant of a compulsory license, among other things, upon happening of national emergency and extreme urgency. According to these two articles as soon as the declaration of national emergency is made, and the relevant patents notified, any person who is interested in manufacturing the drug can give an application to the Controller General of Patents who can then issue a compulsory license. Now the important question arises in case of pandemic like Covid-19 would meet the requirements for invocation of the provisions for grant of compulsory licenses? The answer for this solution lies in Doha Declaration[xvi] on the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement and Public Health. Clause 5(*c*)[xvii] says that: "public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics" can constitute "a national emergency or other circumstances of extreme urgency".

Therefore, it can be concluded that the Central Government is very well inside its power to issue a declaration for permit of compulsory license for Covid-19 vaccine to other pharmaceutical companies who are desirous and have the technological capability to manufacture the Covid-19 vaccine to speed up the production. As mentioned above as soon as a declaration of national emergency is declared, and the relevant patents are notified, any person who are willing to manufacture the drug can give an application to the Controller General of Patents who can then issue a compulsory license. The patentee would be in return will be paid a reasonable royalty as determined by the Controller General of Patents. Additionally, under Section 100[xviii] of the Patents Act, the Central Government can authorize certain companies to use any patents for the "purpose of the government". So, Indian companies can start manufacturing the drugs while negotiating the royalties with the patentees. Another alternative is for the Central Government to acquire the patents under Section 102 from the patentees.[xix] If the Central Government and the patentee is not able to reach an agreement on the price of the patents, it is up to the High Court to fix the royalty the reasonable royalty that is to be paid to the patentee.

Further, under Section 66 of the Patents Act,[xx] the Central Government is also empowered to quash a patent in the public interest.

There is sufficient legal remedy to make the "public interest" chief of the fundamental principle of patent law. The governing principles to justify the invocation of "public interest" shall be

non-discriminatory accessibility, equal availability and equitable affordability. The global pandemic has come as a reminder that innovation should not only set profiteering as an aim, but it should also deliver humanity. Besides, the longer the delay to invoke public interest to secure the availability of the vaccine, the human race will be rendering a higher cost with the never-ending battle against the pandemic. There is a growing and urgent demand to invoke the provisions pertinent to compulsory licensing and waiver of the patent rights at the international forum.[xxi]

The role that IPRs could play a role in helping to solve these difficult situations should be looked upon. The report of the WHO Commission on Macroeconomics and Health (CMH)[xxii] has also concluded that there is need of large of more public funds into health services, infrastructure and research was also needed to address the health demands of developing countries. As far as access to medicines, it recommended coordinated action to base a mechanism of differential pricing in favor of developing countries backed up, if required, by the more comprehensive use of compulsory licensing.[xxiii]

Nevertheless, one must keep in mind that mere grant of compulsory license is not going to decode the issue of production, but grant of compulsory license can be a starting point in the direction to speed up the production.

ENDNOTES

[i] Pharma Industry in India: Pharma Sector Overview, Market Size, Analysis...| IBEF Ibef.org, (Jul 10, 2021; 10:05PM) https://www.ibef.org/industry/pharmaceutical-india.aspx

[ii] "Invest India" website. (Jul 10, 2021; 10:45 PM) https://www.investindia.gov.in/sector/pharmaceuticals

[iii]Indian Patents Act 1970 and under section 31 TRIPS Article 31 is entitled "[O]there use without authorization of the right holder".

[iv] COVID-19 Emergency Response Act, S.C. 2020, C-13 (Can.)

[v] Resolution for Compulsory Licensing of Patents Relating to Coronavirus, Comisión Especializada Permanente de Educación, Cultura y Ciencia y Tecnología de la Asamblea Nacional [Education, Culture, Science and Technology Commission of the National Assembly], Mar 20, 2020 (Ecuador).

[vi] Proyecto de Resolución N° 896, Resolution for Involuntary Licensing of Patents Relating to Coronavirus, Cámara de Diputadas y Diputados [Chamber of Deputies], Mar. 17, 2020 (Chile).

[vii] Kass D. Israel Defies AbbVie IP to Import Generic Drugs For COVID-19. (Jul 10, 2021; 11:15PM) https://www.law360.com/articles/1255079?scroll=1&related=1.

[viii]Pharma Industry in India: Invest in Indian Pharma Sector (Jul 11, 2021; 12:02AM) http://www.gatesnotes.com/About-Bill-Gates/Year-in-Review-2020?WT.mc_id=20201222100000_YIR2020_BG-TW_&WT.tsrc=BGTW

[ix] See, Philip Grubb & Peter Thomsen, Patents for Chemicals, Pharmaceuticals and Biotechnology (New York: Oxford University Press, 5th Ed, 2010) at p. 3; Lionel Bently & Brad Sherman, Intellectual Property Law (New York: Oxford University Press, 4th Ed. 2014) at p. 335.

[x] https://www.cowin.gov.in/ (Jul 11, 2021; 6:30PM)
[xi] Union of India v Panacea Biotec Limited 2019 SCC OnLine Bom 5316
[xii] AstraZeneca & Serum Institute of India sign licensing deal for 1 billion doses of Oxford vaccine (Jul 12, 2021; 7:30PM)) https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/astrazeneca-serum-institute-of-india-sign-licensing-deal-for-1-billion-doses-of-oxford-vaccine/articleshow/76202016.cms?utm_source=contentofinterest&utm_medium=text&utm_campaign=cppst
[xiii] Scroll Staff, Covaxin's IP rights shared between ICMR and Bharat Biotech, says research body chief Scroll.in (2021), (Jul 12, 2021:4:45PM). https://scroll.in/latest/994052/covaxins-intellectual-property-rights-shared-between-icmr-and-bharat-biotech-says-balram-bhargava
[xiv] Patents Act, 1970, § 92.
[xv] TRIPS Article 31 is entitled "[O]there use without authorization of the right holder".
[xvi] Doha Declaration on TRIPS and Public Health
[xvii] World Trade Organization. Fact Sheet: TRIPS and Pharmaceutical Patents. (Jul 12, 2021:8:56PM) https://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.
[xviii] Patents Act, 1970, § 100.
[xix] Patents Act, 1970, § 102.
[xx] Patents Act, 1970, § 66.
[xxi] Natco has filed a compulsory licence application for Covid drug Baricitinib under Section 92 of the Patents Act, 1970 and India pushing for waiver of IP rights at WTO.
[xxii]Michael Bailey, Priced Out of Reach: How WTO Patent Policies Will Reduce Access To Medicines in The Developing World, Oxfam Briefing Papers, Oxfam International (Jul 13, 2021;3:30PM) http://policy-practice.oxfam.org.uk/publications/priced-out-of-reach-how-wto-patent-policies-will-reduce-access-to-medicines-in-114571.
[xxiii] Id