



GRANTING OF COMPULSORY LICENSE TO INDIAN PHARMACEUTICAL COMPANIES- A MOONSHOT TO CURE INDIA'S COVID VACCINE WOES

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INTRODUCTION-

We live in a globalized world – where supply and demand are not only limited to a nation's borders but span across multiple countries and even continents; however, no matter how globalized a nation's economy is, it may still fall prey to what former US Defense Secretary Donald Rumsfeld termed as “the known unknown”¹ which could be conveyed as “we know, what we do not know”. It must be stated that although the term is contrarian in nature – yet it holds true, and the said principle has been used in the context of project management and strategic planning.

Mankind has faced some “known unknown” over the ages, and is still coming to terms with the latest “known unknown” i.e., Covid-19 pandemic, the first case of the same was detected in

December 2019 in Wuhan, China according to the WHO³ yet there have been media reports which state that the first case of Covid-19 occurred in October 2019⁴ in China.

Mankind through recorded history has been witness to many outbreaks which have cost numerous lives such as the Black Death which ravaged Europe in 14th Century, to the Spanish Flu (1918-1920) and is coming to terms with Covid-19 pandemic. Covid 19- has affected every corner of the world and still continues to remain an active threat to the world with it going through numerous mutations and exhibition of new symptoms.

On the question of origin of COVID -19 one proposition has been that the disease was zoonotic in origin and the reservoir for SARS-CoV-2 was a bat probably- a “Chinese Horseshoe Bat (*Rhinolophus sinicus*)” or an “Intermediate Horseshoe Bat (*Rhinolophus affinis*)”⁵, however it must be noted there are claims on the record that the origin of COVID - 19 were far more nefarious in nature-that the COVID-19 disease pandemic was designed by Chinese lab researchers as a biological weapon⁶ or that the pandemic

¹ Michael Shermer, Rumsfeld's Wisdom, SCIENTIFIC AMERICAN (Sept 1, 2005) <https://www.scientificamerican.com/article/rumsfeld-s-wisdom/>

² Hugh Courtney, Jane Kirkland, Patrick Viguier, Strategy under Uncertainty, Harvard Business Review (Nov. 1997), <https://hbr.org/1997/11/strategy-under-uncertainty>

³ Archived: WHO Timeline - COVID-19, <https://www.who.int/news/item/27-04-2020-who-timeline---covid-19> (last visit July 5, 2021)

⁴ Deepali Sharma, *First Covid-19 case emerged in China in October 2019: Study*, Hindustan Times

(June 25,2021 08:07am) <https://www.hindustantimes.com/world-news/first-covid-19-case-emerged-in-china-in-october-2019-study-101624585897030.html>

⁵ Andersen, K.G., Rambaut, A., Lipkin (2020), W.I. et al. The proximal origin of SARS-CoV-2. *Nat Med* 26, 450–452. <https://doi.org/10.1038/s41591-020-0820-9> Andersen, K.G., Rambaut, A., Lipkin, The proximal origin of SARS-CoV-2. *Nat Med* 26 (2020) 450–452

⁶ Cleo Paskal, ‘China turned Covid-19 into biological weapon, committed mass murder’, The Sunday Guardian (May 22, 2021,11:04pm),



was caused due to a leak or mishap-intentionally or unintentionally at the Wuhan Institute of Virology⁷.

There have been as estimated 18.4 crore cases of Covid-19 worldwide and this has resulted in approximately 39.7 lakh deaths⁸. A blog by the Brooking Institute has termed Covid-19 as “developing countries pandemic”⁹ and has stated that the share of mortality rates resulting from Covid 19 in developing countries in terms of excess mortality could be as high as 86%. Also, the blog makes light of figures that mortality rates in developed countries (High Income countries) is decreasing on account of increasing vaccine usage, but developing countries have not seen decrease in respect to mortalities on account of lack of vaccine availability and crumbling health infrastructure as well as higher prevalence of co-morbidities amongst the population of developing countries.

COVID SITUATION IN INDIA

<https://www.sundayguardianlive.com/news/china-turned-covid-19-biological-weapon-committed-mass-murder>

⁷ PTI, *Covid-19: Why lab-leak theory is back despite little new evidence*, Business Standard (June 22, 2021 12:57pm), https://www.business-standard.com/article/current-affairs/covid-19-why-lab-leak-theory-is-back-despite-little-new-evidence-121062200519_1.html

⁸ COVID-19 Coronavirus Pandemic, <https://www.worldometers.info/coronavirus/> (last visited 5th July 2021)

⁹ Indermit Gill, Phillip Schellekens, *Covid-19 is a Developing Country Pandemic*, BROOKINGS INSTITUTE (last visited July 5, 2021) <https://www.brookings.edu/blog/future-development/2021/05/27/covid-19-is-a-developing-country-pandemic/>

¹⁰ India Covid, <https://www.worldometers.info/coronavirus/country/india/> (last visited 5 July 2021)

As of 5th July 2021, India has had the highest number of confirmed cases of COVID-19 after the United States of America, with the number of confirmed cases being 30,581,578, the resulting deaths from Covid-19 were 402,708¹⁰. The first case in India occurred in Thrissur, Kerala on 30th January 2020.¹¹ The first death caused due to Covid-19 in India occurred on 12th March 2020¹² in Karnataka. A national lockdown of 21 days was announced on 24th March 2020 under Section 6 and 10 of the Disaster Management Act, 2005.¹³ Accordingly with increasing number of infections another phase of lockdown followed on 14th April 2020 which was to end on 3rd May 2020 and was later extended till 31st May 2020.

The ramifications of the Covid crisis were rampant during the first wave – they led to mass migration of labourers from cities to their native village, economic growth in the country contracted by 23.9%¹⁴ in April-

¹¹ Bindu Shajan Perapaddan, *India's first coronavirus infection confirmed in Kerala*, The Hindu (Jan 21, 2020 07:36am),

<https://www.thehindu.com/news/national/indias-first-coronavirus-infection-confirmed-in-kerala/article30691004.ece>

¹² AFP, *Karnataka announces India's first coronavirus death*, The Economic Times (Mar 13 2020 08:33am),

<https://health.economictimes.indiatimes.com/news/industry/state-minister-announces-indias-first-coronavirus-death/74604253>

¹³ Nistula Hebbar, *PM Modi announces 21-day lockdown as COVID-10 toll touches 12*, The Hindu (Mar 24, 2020 11:14pm),

<https://www.thehindu.com/news/national/pm-announces-21-day-lockdown-as-covid-19-toll-touches-10/article31156691.ece>

¹⁴ Scroll Staff, *India's GDP falls by 23.9% in April June quarter in worst ever contraction*, The Scroll (Aug 31, 2020 5:49pm),



June of 2020 first wave of Covid-19 cases, unemployment significantly increased,¹⁵ collapse of Indian tourism industry,¹⁶ also on the educational front schools were forced to adopt to digital mode of teaching, and exams scheduled were postponed indefinitely or alternative methods of evaluation were enforced in regards to school as well as college students. The Covid 19 crisis also put tremendous pressure on the crumbling medical infrastructure of India- many people were not afforded hospital beds and there was lack of oxygen supply and many patients succumbed due to this, there were many incidents of hoarding of essential medical supplies and equipment, many families were put on the path of financial ruin due to treatment cost associated with Covid 19

treatment.¹⁷ More than 500 doctors succumbed to Covid 19 according to the Indian Medical Association since March 2021 till May 2021 and at least 748 doctors died in 2020 during the first wave of Covid-19 in India.¹⁸

THE CURRENT STATE OF VACCINATION IN INDIA-

Vaccination for all age groups have been opened after many policy reversals of the Government of India,¹⁹ but there are various hurdles in effective vaccination of the entire populace of India , many factors are responsible for the present state of vaccination ranging from- absence of a clear plan of vaccination,²⁰ lack of advance procurement of vaccines,²¹ lack of cold chain,²² vaccine hesitancy,²³ to lack of

<https://scroll.in/latest/971809/indias-gdp-falls-by-record-23-9-in-april-june-quarter>

¹⁵ BusinessToday.In, *India's unemployment in 2020 at worst level in 29 years, shows study*, BusinessToday.In (May 28, 2021 06:51pm), <https://www.businesstoday.in/jobs/story/india-unemployment-in-2020-at-worst-level-in-29-years-shows-study-297195-2021-05-28>

¹⁶ Prajakta Patil, Vandana, *Charting the step-by-step collapse of India, SEA's travel and tourism*, The Ken (May 20,2020), <https://the-ken.com/story/india-sea-travel-data/>

¹⁷ Kaushik Deka, *India's Covid collapse, part 3: Lack of health infrastructure exacerbates the situation*, IndiaToday (May 17,2021 09:12pm), <https://www.indiatoday.in/magazine/cover-story/story/20210517-india-s-covid-collapse-part-3-lack-of-health-infrastructure-exacerbates-the-situation-1800977-2021-05-10>

¹⁸ Pamela Constable, Tanya Dutta, *India's covid surge has killed more than 500 doctors and sickened hundreds of others since March, stretching staffs thin*, The Washington Post (May 8,2021 05:16am), https://www.washingtonpost.com/world/asia_pacific/india-coronavirus-health-workers/2021/05/27/a9e31d7c-bd79-11eb-922a-c40c9774bc48_story.html

¹⁹ "Reuters, *India's Covid Vaccine Policy flip-flops explained*, The Economic Times (Jun 8, 2021 09:33am),

<https://economictimes.indiatimes.com/news/india/indias-covid-19-vaccine-policy-flip-flops-explained/articleshow/83319213.cms?from=mdr>

²⁰ "Associated Press, *COVID-19 vaccine: Poor planning, production glitches likely behind shortage in 'world's pharmacy' India*, Firstpost (May 22, 2021 9:51pm) <https://www.firstpost.com/india/covid-19-vaccine-poor-planning-production-glitches-likely-behind-shortage-in-worlds-pharmacy-india-9646621.html/>

²¹ "Financial Express Online, *Covid-19: Why India is facing vaccine shortage*, Financial Express (May 10 2021, 9:07am)

<https://www.financialexpress.com/lifestyle/health/covid-19-why-india-is-facing-vaccine-shortage/2248748/>

²² "Press Trust of India, *Lack of Cold Chain India's Biggest Challenge in Covid Vaccine Distribution: Report*, NDTV (Dec. 09, 2020, 9:32 pm) <https://www.ndtv.com/india-news/lack-of-cold-chain-indias-biggest-challenge-in-covid-vaccine-distribution-report-233646>

²³ "Associated Press, *Vaccine hesitancy put India's gains against coronavirus at risk*, Mint (Jun 21 2021, 10:50 am),



supply of raw material for manufacture of vaccines,²⁴ wastage of vaccines²⁵ but the biggest factor in lack of effective vaccination has been the limited vaccines which have been made available to states.²⁶ It must be noted that as of this moment there are majorly 3 vaccines available in regards to Covid-19 i.e., Covaxin vaccine which has been developed and manufactured by Indian biotechnology company “Bharat Biotech” in consultation with “Indian Council of Medical Research (ICMR),”²⁷ Covishield vaccine which is being manufactured by Serum Institute of India (SII)²⁸ and “Sputnik V” vaccine which has been developed by the “Gamaleya Research Institute of Epidemiology and Microbiology” in Russia²⁹ and which is to be manufactured in India by Dr. Reddy’s Laboratories. Although the efficacy reports of the vaccines are noted to be satisfactory it must

be noted that far better candidates in terms of efficacy have been widely developed and deployed in the West to combat Covid-19 i.e., the vaccines developed by Pfizer/BioNTech and Moderna which were majorly funded Government of the United States of America under the auspices of Operation Warp Speed³⁰ which are sold under the brand name Comirnaty and Spikevax respectively.³¹ It must be noted that the vaccines developed and manufactured in India namely Covaxin which is an inactivated viral vaccine and Covishield which is a viral vector vaccine.³² The major vaccines which have been developed and adopted for use are mRNA-based vaccines. mRNA vaccines are based on the principle of introduction mRNA which would allow the target immune system to create a harmless protein similar to the actual spike protein, which would then help the body fight off

<https://www.livemint.com/news/india/vaccine-hesitancy-puts-india-s-gains-against-coronavirus-at-risk-11624252466615.html>”

²⁴ “Reuters, *India’s vaccination fall from peak, raw material shortage hits output targets*, The Economic Times (Apr 16, 2021, 03:41 pm), <https://economictimes.indiatimes.com/news/india/indias-vaccinations-fall-from-peak-as-infections-hit-record/articleshow/82100440.cms?from=mdr>”

²⁵ “Prabhjote Gill, *4.6 million doses of COVID-19 vaccine were wasted in India — enough to vaccinate half of Bangalore*, Hindustan Times (Apr 20, 2021, 07:33 pm), <https://www.businessinsider.in/science/health/news/4-6-million-doses-of-covid-19-vaccine-were-wasted-in-india-enough-to-vaccinate-half-of-bangalore/articleshow/82165181.cm>”

²⁶ “Neha Arora, Manas Mishra, *India’s coronavirus infections ebb but states struggle for vaccines*, Reuters (May 25, 2021 9:54 am), <https://www.reuters.com/world/india/india-posts-lowest-rise-daily-covid-19-cases-since-april-14-2021-05-25/>”

²⁷ “COVAXIN® - India’s First Indigenous COVID-19 Vaccine,

<https://www.bharatbiotech.com/covaxin.html> (last visited July 5, 2021)”

²⁸ “ChAdOx1 nCoV- 19 Corona Virus Vaccine (Recombinant) COVISHIELD, SERUM INSTITUTE OF INDIA PVT. LTD, https://www.seruminstitute.com/product_covishield.php (last visited 5 July 2021)”

²⁹ About us, SPUTNIK V, <https://sputnikvaccine.com/about-us/> (last visited 5 July 2021)

³⁰ “Coronavirus: Operation Warp Speed, US DEPARTMENT OF DEFENSE, <https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/> (last visited 5 July 2021)”

³¹ “Kathy Katella, *Comparing the Covid-19 Vaccines, how are They Different*, YALE MEDICINE <https://www.yalemedicine.org/news/covid-19-vaccine-comparison> (last visited July 5 2021)”

³² “Covaxin vs Covishield – A Detailed Comparison – Efficacy, Side effects, <https://pharomeasy.in/blog/covaxin-vs-covishield-a-detailed-comparison/>(last visited 5 July 2021)”



any future infection and thus are more effective than traditional vaccines.³³

As of 5th July 2021 35,12,21,306 doses of vaccine have been administered,³⁴ but there runs a risk that fake vaccines could be administered³⁵ and such events have occurred to testify in regards to the same, also many vaccination drives also run the possibility of fudging up the numbers of vaccinations done in order to meet the quota³⁶ irregularities of these nature are bound to occur in a massive exercise such as this; regardless of this it has been documented that many State Governments have complained to the Central Government as they have run out of vaccine doses.³⁷ It is quite clear from the situation on the ground, that more has to be done in regards to rectify the vaccine situation in India. Also the major manufacturers of vaccines in India- “Bharat Biotech” and “Serum Institute of India” have entered into agreements to supply vaccines to other nations as well, so it must be stated that not all vaccines manufactured in India are to meet the

needs of every Indian and also the manufacturing capabilities of Bharat Biotech and Serum Institute of India are limited, therefore there lies an inherent conflict on part of Indian manufacturers to meet their commitment to foreign nations or the motherland.

Vaccine manufacturers such as Pfizer/BioNTech and Moderna have been in talks with Government of India but at the present juncture it seems that the talks have reached a stalemate on over the issue of liability of the vaccine manufacture in event of deaths caused by the said vaccine manufactured by same.³⁸

Therefore accordingly due to prevalent circumstances in regard to vaccinations it would be well served if the Government of India would act and permit the development and manufacturing of Covid vaccines under the aegis of compulsory license as envisioned in The Patents Act, 1970 and in international instruments to which India is a party to such as “TRIPS Agreement (The Agreement on Trade-Related Aspects of Intellectual Property

³³ “Why are mRNA vaccines so exciting, HARVARD HEALTH BLOG, <https://www.health.harvard.edu/blog/why-are-mrna-vaccines-so-exciting-2020121021599>(last visited 5 July 2021)”

³⁴ “Ministry of Health and Family Welfare, Govt of India <https://www.mohfw.gov.in/> (last visited 5 July 2021)

³⁵ TIMES NOW, *Mumbai fake vaccination scam: 11 FIRs filed so far, first in Navi Mumbai*, The Economic Times (Jul 5 2021 10:39am) <https://economictimes.indiatimes.com/news/india/mumbai-fake-vaccination-scam-11-firs-filed-so-far-first-in-navi-mumbai/videoshow/84133114.cms>”

³⁶ Rajesh Kumar Thakur, *Bihar vaccination numbers don't add up*, The New India Express (May 18, 2021 09:53am), <https://www.newindianexpress.com/nation/2021/may>

[/18/bihar-vaccination-numbers-dont-add-up-2304019.html](https://www.newindianexpress.com/nation/2021/may/18/bihar-vaccination-numbers-dont-add-up-2304019.html)

³⁷ “BusinessToday.in, *COVID-19 phase 3 vaccination for 18+ starts today but states don't have vaccine stock*, BusinessToday (May 01, 2021 08:03am), <https://www.businesstoday.in/latest/economy-politics/story/covid-19-phase-3-vaccination-for-18-starts-today-but-states-dont-have-vaccine-stock-294826-2021-05-01>”

³⁸ “Teena Thacker, *Pfizer, Moderna may want indemnity cover before launching vaccine in India*, The Economic Times (Apr 16, 2021 12:15pm) <https://economictimes.indiatimes.com/industry/healthcare/biotech/pharmaceuticals/pfizer-moderna-may-want-indemnity-cover-before-launching-vax-in-india/articleshow/82091162.cms?from=mdr>”



Right)” by virtue of being a member of World Trade Organisations (WTO).

COMPULSORY LICENSING UNDER THE TRIPS AGREEMENT AND THE PATENTS ACT, 1970

The World Intellectual Property Organisation (WIPO) has defined patent as an exclusive right that is conferred upon an invention that could be a product or a process which provides a new alternative method of doing something or something which provides a solution to a problem.³⁹ Patent can be elucidated to include “legal right of an inventor to exclude others from making or using a particular invention”⁴⁰ within its realm of meaning. Patents create a monopoly right.

Compulsory licensing is conveyed as “involuntary contracts between a willing buyer and an unwilling seller imposed or enforced by the state”.⁴¹ Compulsory licensing can envision as an authorisation allowing production of a product that is patented without the express approval or consent of the said patent holder provided that the patent holder is paid a set fees for the license, thus they override the monopoly rights of a patent holder. Granting of compulsory licenses in regards to pharmaceutical product usually results in drastic decrease in prices⁴². Compulsory

licensing thus when granted could lead to drugs being priced affordably and also their production and supply is greatly enhanced.⁴³ There are numerous provisions in “TRIPS Agreement and the Patents Act, 1970” in relation to compulsory licensing,

COMPULSORY LICENSING UNDER THE TRIPS AGREEMENT-

The TRIPS (The Agreement on Trade-Related Aspects of Intellectual Property Rights) Agreement covers the following areas broadly-

- “Relation between multilateral trading system and international intellectual property
- Standards of protection that should be afforded in regards to intellectual property rights
- Procedure that should be prescribed by member states in relation to intellectual property rights
- Resolution of Disputes arising in relation to intellectual property amongst members of World Trade Organisation (WTO)
- Special transitional arrangements for the implementation of TRIPS provisions”⁴⁴.

The TRIPS Agreement has been viewed as a bridge in reconciling trade priorities of countries-developed or not⁴⁵ however

³⁹ Patents, <https://www.wipo.int/patents/en/> (last visited July 5, 2021)”

⁴⁰ “Hall, Bronwyn (2007), Patents and Patent Policy. Oxford Review of Economic Policy 23: 568-587”.

⁴¹ “Julian-Arnold G. (1993), International compulsory licensing: The rationales and the reality, IDEA: The Journal of Law and Technology, 33 (2): 349”.

⁴² “AIDS Drugs Policy: Ce Africa Policy Information Center. (1999). AIDS Drugs Policy: APIC)”

⁴³ “Ansh Singh Luthra, *Politics, pharma, patent, profit or the people of India? A case for compulsory licensing*, Bar & Bench (May 1, 2021 1:11pm) <https://www.barandbench.com/columns/patents-covid-19-drugs-case-for-compulsory-licensing>”

⁴⁴ “Intellectual Property: Protection and Enforcement, https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited July 5, 2021)”

⁴⁵ “Doern, G. Bruce 1998 Global Change and Intellectual Property Agencies: An Institutional



TRIPS Agreement has also been accused by developing countries of ignoring “local needs, national interests, technological capabilities, institutional capacities, and public health conditions”.⁴⁶

Patentability can be withheld in accordance of Article 27(2) of the TRIPS Agreement in context of public order and morality.⁴⁷ Preceding passage of the TRIPS Agreement a few nations had refused patent protections specifically for pharmaceutical products, leading to manufacturing and exportation of low-cost copies of medicines to other countries without the implicit permission of

the rights holders.⁴⁸ Article 27(1)⁴⁹ has thus led to the curbing of such practice. Article 8 permits countries to take steps accordingly in view of public health and nutrition⁵⁰ in synergy with the TRIPS Agreement. Article 30 allows for exception in relation to rights conferred in relation to patents subject to conditions.⁵¹ Article 31 allows the adoption of compulsory licenses under the head “other use”; such “other use” has to be considered on the basis of individual merits of each case,⁵² they may be granted without the authorisation of the right holder in cases of a national emergency,⁵³ public non-

Perspective (Science, Technology, and The International Political Economy), Routledge Publications”

⁴⁶ “Yu, Peter K. (2007) The International Enclosure Movement, IND. L.J. 82: 827-828”

⁴⁷ “TRIPS Article 27(2)” “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law

⁴⁸ “Boulet, P., Perriens, J., Renaud-Théry, F., & Velasquez, G. 2000. Pharmaceuticals and the WTO TRIPS Agreement: Questions and Answers. UNAIDS/WHO.

[http://apps.who.int/medicinedocs/pdf/whozip18e/whozip18e.pdf.](http://apps.who.int/medicinedocs/pdf/whozip18e/whozip18e.pdf)”

⁴⁹ “TRIPS Article 27(1)” “Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.5 Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”

⁵⁰ “TRIPS Article 8”- “(1) Members may, in formulating or amending their laws and regulations,

adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. (2) Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”

⁵¹ “TRIPS Article 30”- “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties”

⁵² “TRIPS Article 31(a)”- “authorization of such use shall be considered on its individual merits

⁵³ “TRIPS Article 31(b)”- “such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably



commercial use⁵⁴ or anti-competitive practices.⁵⁵ Article 30 has provisions which states that “usage may be non-exclusive”,⁵⁶ it also further states that authorisation is bound to reviewed by a judicial authority⁵⁷ and also that the authorisation may be terminated if the conditions contingent for promulgation of said authorisation are no longer in force.⁵⁸ Article 31(f) states that “compulsory license shall be authorised if motive of authorisation is for usage in domestic markets of member making such authorization”.⁵⁹

A reading of Article 31(f) leads to a conclusion- that there is restriction on exports of medicines to countries which lack manufacturing capabilities, given that Article 31(f) states that usage under compulsory license is to be redirected in the member’s own domestic market, The Doha Declaration recognised this conundrum and expressly sought to resolve the issue of

compulsory licensing in regards to exportation of drugs to developing countries as expressly stated in Paragraph 6⁶⁰ of the Declaration.⁶¹ In 2003, the World Trade Organisation (WTO) sought to implement Paragraph 6, this culminated in the passage of Article 31*bis* which has come into effect since January 23, 2017 which waives the obligation under Article 31(f), Article 31*bis* permits compulsory licenses and exportation of products that are deemed to be pharmaceutical in nature to eligible importing members.⁶²

Thus, it is clear that there are adequate provisions in TRIPS Agreement, which permit for the granting of compulsory licenses under a set of given circumstances,⁶³ however for developing countries practical difficulties still persist in context of compulsory licensing, as developed countries are known to use pressure tactics against developing

practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly”

⁵⁴ *Ibid.*

⁵⁵ “TRIPS Article 31(c)”- “the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive”

⁵⁶ “TRIPS Article 31(d)”- “such use shall be non-exclusive”

⁵⁷ “TRIPS Article 31(i)”- “the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member”

⁵⁸ “TRIPS Article 31(g)”- “authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led

to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances”

⁵⁹ “TRIPS Article 31(f)”- “any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use”

⁶⁰ “Decision dated 30 August 2003, of the General Council on ‘Implementation of paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health’ (the Decision)”.

⁶¹ “The Doha Declaration, Explained, https://www.wto.org/english/tratop_e/dda_e/dohaexplained_e.htm(last visited July 5, 2021)”

⁶² “Article 31*bis*, <https://www.ippt.eu/legal-texts/trips/trips-73> (last visited July 5 2021)”

⁶³ “Compulsory licensing of pharmaceuticals and TRIPS, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm(last visited July 5 2021)”



countries in order to dissuade them from taking any action accorded them under the aegis of 'compulsory license', as the said granting of 'compulsory license' could have economic ramifications for the developed countries.⁶⁴

COMPULSORY LICENSING UNDER The PATENTS ACT, 1970-

Provisions in regards to compulsory licensing is given in "Chapter XVI" of The Patents Act. Reference is made to Section 84 and 92 of the Act, which lays down the circumstances compulsory licenses may be employed. Section 84⁶⁵ states that a compulsory license can be granted after the expiry of 3 years from the date of grant of patent, the act prescribes the requirements to be complied with when involving a question of granting of said license-

- "Reasonable requirements of the public have not been satisfied in regards to the patented invention
- Patented Invention is not available to the public due to it being out of the realm of affordability
- Patent Invention has not worked in the territory of India"

Section 92 of The Patents Act 1970 however also creates an alternative path in the granting of compulsory license, by mandating that the Controller may grant compulsory license at any time after the finality of the patent in event of the following circumstances-

- "national emergency

- extreme urgency
- public non-commercial use"

The Controller may further grant 'compulsory license' in event of any epidemic as mandated under Section 92 of the Act, in such circumstance he is also not bound to follow the procedure as mandated under Section 87 of The Patents Act, 1970 which accords due process to be afforded to the patent holder and the applicant for compulsory license.⁶⁶

A STUDY OF GRANT OF COMPULSORY LICENSE IN INDIA

In India, only one compulsory license has been granted and that is in the case of Bayer Corporation vs. Union of India⁶⁷

FACTS- The petitioner (Bayer Corporation) was granted a patent in regards to a drug called "Sorafenib Tosylate" on 3rd March 2008. The said drug was to be used in the treatment of kidney cancer and was sold under the brand name "NEXAVAR". An Indian drug company 'NATCO' approached the petitioner in 2011 after 3 years of sealing of the patent and sought a voluntary license to manufacture the said drug. 'NATCO' through a licensing deal sought to sell the drug under its own brand name and sought to sell the drug at a drastically low price in the market than the petitioner. Petitioner rejected 'NATCO's offer. 'NATCO' approached the Patent Office under Section 84(1) and sought a compulsory license to

⁶⁴ "Saha S. (2009), Patent law and TRIPS: Compulsory licensing of patents and pharmaceuticals, Journal of the Patent and Trademark Office Society, 91 (2009) 364-37"

⁶⁵ "The Patents Act, 1970 § 84, No. 30, Acts of Parliament, 1970 (India)"

⁶⁶ "The Patents Act, 1970 § 92, No. 30, Acts of Parliament, 1970 (India)"

⁶⁷ 2014 SCC Online Bom 183



manufacture 'NEXAVAR'. In 2012, the appropriate authority (Controller General of Patents) granted a compulsory license to 'NATCO' to manufacture 'NEXAVAR' and also directed them to pay a royalty of 6% of net sales to petitioner till the expiry of the patent. Aggrieved by the order of the Controller, petitioner approached the Intellectual Property Appellate Board which affirmed the order of the Controller. The petitioner then moved to the Bombay High Court and sought that granting of license be cancelled.

HELD- The Hon'ble Bombay High Court upheld the "granting of license and stated that the petitioner was not selling the drug at an affordable price, it had failed to meet the reasonable requirement of the public in respect of the patented drug". The Hon'ble Court stated that "the proceedings under Section 84 of the Act were in the public interest as the entire basis of the grant of the compulsory license is based on the objective that patented article is made available to the public at large and is priced at an affordable rate".

CONCLUSION-

Thus, it is clear from the various provisions contained in TRIPS Agreement and The Patents Act, 1970, that granting of compulsory license is acceptable in situation of emergencies. India is in the midst of a second wave of Covid-19 disease pandemic, a majority of the country is still waiting to be

inoculated against Covid-19. It is high time that the Government of India grant compulsory license to Indian pharmaceutical companies that have the facility and the resources to manufacture vaccines. The Government of India has refused to allow the granting of compulsory licenses in regards to the manufacturing of vaccines, stating that it not an attractive deal⁶⁸ despite repeated suggestions to the contrary by the Hon'ble Supreme Court of India.⁶⁹ It must be remembered that the basic principle behind compulsory licensing is to make "those things affordable, which are not affordable", the time is now to take steps as accorded under Section 92 of the Patents Act, 1970 and Article 3 of TRIPS Agreement to grant compulsory license to potential vaccine manufacturers. Drastic measures such as compulsory licensing is the only moon-shot to transform India from a vaccine deficient state to a vaccine surplus state and bring about vaccine equity and save countless lives from a potential third wave of Covid-19.

⁶⁸ "TNN, *Compulsory licence not attractive: Government*, The Times of India (May 28, 2021, 06:52am), <https://timesofindia.indiatimes.com/business/india-business/compulsory-licence-not-attractive-government/articleshow/83024491.cms>"

⁶⁹ "LiveLawNewsNetwork, *Why Centre Not Considering Compulsory Licensing For COVID Drugs Like Remdesivir, Tocilizumab? Supreme Court Asks*, LiveLaw (Apr 30, 2021 08:02pm), <https://www.livelaw.in/top-stories/why-centre-compulsory-licensing-covid-remdesivir-tocilizumab-supreme-court-asks-173413>"