

IP POLICY STUDY 2020 – PART ONE

**A COMPREHENSIVE APPROACH FOR  
ADDRESSING A BALANCE BETWEEN PATENT  
AND PUBLIC HEALTH IN THE CONTEXT OF  
COVID-19 PANDEMIC**

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# 1. Introduction:

The unnerving bio-catastrophe of the millennium, the COVID-19 pandemic, throwing out of gears the settled global system in all walks of life of mankind brought to the fore an array of challenges. The containment of the pandemic at any cost prioritising the ‘life’ for ‘living’, gradual shift to phased prioritisation of ‘living’ with ‘no sacrifice of human life’, finding the effective cure for the affected by promoting, supporting, encouraging innovations in the field, global cooperation in ensuring the availability, accessibility and affordability of the health care facilities and a host of challenges are being addressed both at the global level and the national level. The legal instruments guaranteeing the right to health-International & National-, the Nobility of medical profession with Hippocratic oath at the helm, legal regime for approval of the novel effective treatment products & processes, the Intellectual Property regime accommodating the larger public interest in its sweep – paving way for State as well as IP holders to play an active role in facing the challenge – are matters of concern at this juncture.

This paper is an *attempt to examine the Patent system playing a proactive role in addressing the challenges. Instead of inappropriately presenting patent as opposed to public health, this paper attempts to examine the patent system as promoter of public health.* The paper in chapter 2 examines the situation from human rights perspective, right of healthcare for every human being, constitutional guarantee in India, and the Global distributive Justice as a goal. Can there be a legal obligation on the global community or the ‘haves’ in the form of duty of justice?. The third chapter addresses the developments in diagnostics process for the detection of the COVID-19 and the treatment for the same through adopting the existing health care system and at the same time developing newer innovative products and processes. Absence of a vaccine is a bigger challenge and the scientific community’s response has been significantly encouraging. The incentive in Patent system has encouraged innovators to file patent applications. The International Institutional involvement, the response by Nations, the active role of the Industry in making available the products or processes in the patent regime as well, and process for ensuring technology transfer are some of the issues addressed later.

The patent system, while incentivising the innovator, has structured itself to take care of the health emergency of the kind. The paper examines the Indian Patent system that can be utilised at every stage of challenge by the Government to ensure that availability, accessibility and affordability of health care products and processes gets top priority.

In an emergency of this magnitude, can international obligations of enforcement of IPR be suspended by the member state is also addressed by the paper.

## 2. Human Rights, Global Justice, Right to and Access to Healthcare:

The COVID19 scare at global level posing threat to human existence and a challenge to the human ingenuity surfaces the arguments for examining the philosophical outlook of the humanity surpassing the artificial national boundaries. The COVID19, forcing a reflection of non-discrimination, non-north-south dilemma, and vulnerability pressurizes the global community to think alike in a sense of universal love and brotherhood.

This leads us to examine the idea of **cosmopolitanism** that entails that all people, irrespective of their political, legal, economic or social status are entitled to equal respect and consideration. It observes all human beings as members of one single community. It originated from Diogenes of Ancient Greece and since then has found favour with many great philosophers including Kant, Durkheim and Ulrich.

It has strong roots in Indian philosophy, where the cosmopolitanism has been the fundamental block of all the Hindu schools, which have evolved over time. The concept of **VasudaivaKutumbakam**, propounded in Maha Upanishad which means "world is one family" captures the very essence of the cosmopolitanism. Also the concept of Chakravarti in the Indian political theory envisions a world government to take of all its subjects.

The very first notion of right to health was found in the Article 25(1) of the **Universal Declaration of Human Rights**, which sets the universal standard for the right to health and well-being. It states that everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

The scope of the Right to health expanded and explicitly set out in Article 12 of **International Covenant on Economic, Social and Cultural Rights**. It declares that the states should take steps to realise progressively to the maximum available resources the highest attainable standard of health, including the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; the improvement of all aspects of environmental and industrial hygiene; the prevention, treatment and control of epidemic, endemic, occupational and other diseases; and the creation of conditions which would assure to all medical service and medical attention in the event of sickness.

Examining the scenario from the perspective of **Constitution of India**, it is evident that the right to health has become integral part of the right to life. Though not explicitly mentioned in the Part III of the constitution, the Supreme Court has in many cases has held that Right to health is a Fundamental Right. In *Bandhua Mukti Morcha vs. Union of India*<sup>1</sup>, the Supreme Court of India has held that the right to live with human dignity, enshrined in Article 21 of the Constitution of India, includes protection to health. In *State of Punjab and Others vs. Mohinder Singh Chawala*<sup>2</sup> court held that the Government has a constitutional obligation to provide health facilities. In *Paschim Banga Khet Mazdoor Samity vs. State of West Bengal*<sup>3</sup>, Court observed that there is an obligation on the State to safeguard the right to life of every person as preservation of human life is of paramount importance. The state run government hospitals and the medical professionals are duty-bound to provide medical assistance for the preservation of the human life.

Just like the fundamental rights, the **directive principles** enshrined under the constitution also impose a duty upon the state to positively contribute towards the health of its citizens. Article 47 of the constitution provides for the duty of the State to raise the level of nutrition and the standard of living and to improve public health. It states that the State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties and, in particular, the State shall endeavour to bring about prohibition of the consumption, except

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<sup>1</sup> AIR 1984 SC 802

<sup>2</sup> AIR 1997 2 SCC 83.

<sup>3</sup> AIR 1996 SCC (4) 37

for medicinal purposes, of intoxicating drinks and of drugs which are injurious to health.

**India's International obligations under the constitution of India: Article 51**, requires the State to endeavour to promote international peace and security, to maintain just and honourable relations with other nations, to respect international law and treaty obligations and to encourage settlement of international disputes by arbitration. This article imposes duty on the state to have international cooperation. If this article is read along with the fundamental rights and DPSP, which are inspired by the Universal Declaration of Human Rights, it leaves no doubt as regards India's global obligations to respect as well as promote human rights and thereby assist other humans in need. Moreover, for the state to fulfil this duty, **Article 253** provides the Parliament unbridled power to make any law in order to meet its international obligations.

## 2.1 Distributive Justice Concept – Duty of Justice and Humanitarian Assistance.

In the debate regarding justice and right to healthcare one crucial question that is raised is whether there is a duty of universal healthcare and humanitarian assistance. If there is such a duty, then upon whom can such a duty be imposed. All the nations provide some kind of healthcare to their citizens. However, there is a huge gap between the capabilities of the developed and the developing and the least developed nations. So the pertinent issue is that whether the states with advanced healthcare abilities also have the duty to assist those who do not have such capabilities.

From the perspective of **John Rawl's**<sup>4</sup> appeal to the principle assuring fair equality of opportunity it seems plausible to cast such a duty. Moreover, the difference principle<sup>5</sup> propounded by Rawls, entails that the system be arranged in way so that the least advantaged members of society are better off

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<sup>4</sup> John Rawls, A theory of justice 266 (1971).

<sup>5</sup> Samuel Freeman, Rawls on distributive justice and the difference principle, Oxford Handbooks Online (2018)

than they would be in any alternative arrangement. The capability approach forwarded by **Amartya Sen** would also back the same<sup>6</sup>.

However, there are other approaches worth mentioning with respect to the duty of justice. The most critical is the **relationist** vs the **non-relationist** debate. The relationists argue that the duty to assist others is only limited to those with whom one has some relation. Therefore, according to them, the states are under no obligation to assist others. If at all they have some duty to assist it is the minimal basic duty of humanitarian assistance<sup>7</sup>. This argument is in line with the approach of liberal non-relationists such **David Miller**, though the extremist relationists even deny the minimalist duty of assistance.<sup>8</sup>

On the other hand, the non-relationists, argue that there is a universal duty to assist cast upon everyone capable of providing such assistance. They also argue that the global duty to assist is not minimalist. It is in fact egalitarian in nature and therefore the advanced nations are under the duty to provide assistance to less capable ones leading to an equal opportunity for all.

## 2.2 Global justice and duty to assist in the light of COVID-19 crisis

In the light of recent developments related to the COVID-19 pandemic, the relevant question with respect to the relationist vs non relationist debate could be that what is the nature of duty that can be imposed upon the nations with respect to providing medical assistance to others.

As regards the relationist approach, the first argument is that **considering the contagious nature of the Corona virus**, even the relationist approach has to favour the global duty to assist because if there is no such assistance then the virus outbreak in one country will definitely affect the future possible situation in the other country.

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<sup>6</sup> Amartya Sen, *The Idea of Justice* (2009)

<sup>7</sup> Chris Armstrong, *Global distributive justice* 34 (2012).

<sup>8</sup> David Miller. *National Responsibility and Global Justice*(2012)

Therefore, here in this case it can be observed that there is a **merger of relationist and non-relationist approaches**. Or it can be said that assisting everyone is the best way to assist those with whom one has a relationship as the health of each individual in the earth is linked with the health of the other.

After ascertaining that there is in fact a duty to assist everyone, the next issue that is pertinent is about the scope of the duty to assist. This would answer the questions on how much a state can be pressed for providing assistance to the other. Do they have to prioritise the health care of their own nationals and provide minimalist or at best second priority assistance or they have to go all out to assist everyone equally without making any distinction between the geographical, political, or social relationships?

This debate becomes interesting due to the peculiar nature of the COVID pandemic. Generally the nation's worst affected by the diseases and healthcare deficiencies are the developing and the least developed countries. Therefore, the global call to assist in matters of healthcare has generally been in favour of the global south and the assistance has been expected form the developed countries.

However, the current COVID pandemic has affected the developed countries equally if not more than the developing and least developed countries. In such a situation, what is the degree of duty to assistance that can be imposed upon the developed countries. In fact, strangely, it has been observed that in some instances the developed countries have asked for the assistance from the developing countries, be it the case of the US asking India for hydroxychloroquine<sup>9</sup> or Italy buying PPE kits from China<sup>10</sup>.

This answer to this query is also dependent upon the attitude of the nations. Do the nations really consider the fight against the COVID crisis as a universal fight or are they only concerned more about improving their domestic situation. Do the nations think that controlling the COVID

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<sup>9</sup> Hydroxychloroquine consignment from India arrives in US, The Economic Times (2020), <https://economictimes.indiatimes.com/news/politics-and-nation/hydroxychloroquine-consignment-from-india-arrives-in-us/articleshow/75103328.cms?from=mdr> (last visited May 27, 2020).

<sup>10</sup> China sold the PPEs to Italy it got as a donation from them: Report Hindu businessline (2020), <https://www.thehindubusinessline.com/news/world/china-sold-the-ppes-it-got-as-a-donation-from-italy-to-italy-report/article31270033.ece> (last visited May 27, 2020).

domestically is enough to insulate themselves from the COVID situation in the rest of the world?

The COVID pandemic is still in its initial stage. It's trajectory is still evolving and capability to infiltrate is not yet fully estimated<sup>11</sup>. Some time back many state-heads denied the seriousness of a COVID-19<sup>12</sup> but they have now changed their stances and not only they have accepted it as a global calamity but have also taken major steps to contain it. Therefore it can be assumed that in the coming time, soon the nations will find answers to the difficult questions related to their nature of duty to assist and act appropriately in the best interest of the health of their citizens as well as the global community.

With regard to the duty of the medical community in playing the pivotal role during the pandemic takes us back to the **Hippocratic oath** [It is an ethical code contributed by the ancient Greek physician Hippocrates and has been adopted as a guide to conduct in the medical profession.] It has become very important in respect to right to health because it casts a positive duty upon all the medical professionals to act in the best interest of the sick and diseased people. It also casts a negative duty upon the doctors to do no harm to the patients nor be guided by commercial returns.

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<sup>11</sup> This Is the Future of the Pandemic, Nytimes.com (2020), <https://www.nytimes.com/2020/05/08/health/coronavirus-pandemic-curve-scenarios.html> (last visited May 27, 2020).

<sup>12</sup> Uri Friedman, The Coronavirus-Denial Movement Now Has a Leader The Atlantic (2020), <https://www.theatlantic.com/politics/archive/2020/03/bolsonaro-coronavirus-denial-brazil-trump/608926/> (last visited May 27, 2020).

### 3. **Diagnostics and treatment of COVID19 and related Patented products and processes:**

There is a need for Innovations for addressing the current issues related to COVID-19 along with the permanent enduring solution with appropriate Vaccine. Developing a vaccine is a time-consuming process where intensive research is needed followed by the clinical trials.

In the process of treating COVID-19 at different stages, Innovations play a crucial role to address the specific challenges faced at different stages. Along with the existing technologies or innovations, there is a need for the development of new products for addressing the complex issues. For example, at the stage of testing, the accuracy of the results and sampling time is one of the biggest challenges that need to be addressed for timely treatment.

While treating COVID-19, there is a need for different category of the products, like:

- a) Masks
- b) Diagnostic Kits for Screening and testing
- c) Artificial Respiration equipment
- d) Personal Protection equipment
- e) Medical facilities
- f) Sanitizers and disinfectants
- g) Vaccines

Under the Patent regime, globally there is a good number of Patents filed and granted on Masks, Diagnostic kits, Medical equipment, protection kits, sanitizers etc., Patent holders are enjoying a monopoly over their inventions. Responding to the magnitude of the threat and need for speedy action, some of the companies like Amazon, Hewlett Packard Enterprise, IBM, Facebook, Nasa Jpl are making their already existing related patents open freely available to fight COVID-19 under “Open COVID pledge”<sup>13</sup>. Several Japanese Companies

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<sup>13</sup><https://openCOVIDpledge.org/>

and University of kyto also made an open COVID-19 declaration<sup>14</sup> to pledge Patents, design, copyrights to accelerate the developments for COVID-19 related research and make their Patents, designs, utility models freely available to the public to fight and end the COVID-19 pandemic as on May 25-2020, 748,374 patents have been declared open to the public. Still, there is grey an area where new inventions can only be the solutions. The ongoing research resulting in the filing of a patent application can be seen from some recent patent publications on different Screening methods etc., in India.

**Screening/Testing and Identification** are the first and foremost step in fighting COVID-19, as per the reports by ICMR<sup>15</sup> total of 2227642 samples have been tested for COVID-19<sup>16</sup>. Following are the categories of diagnostic kits that are used in India and the same have been validated in regular intervals:

- 1) Diagnosis by Real-Time Polymerase reaction
- 2) Antibody (IgM,IgG) based Rapid tests

Apart from the above, two more testing kits that are used to diagnose TB are also being used for testing COVID-19. They are TrueNat, CB-Naat testing kits. As on 16.05.2020, total 522 (Both private and governmental) labs reporting to ICMR Conducting independent testing<sup>17</sup>.

As on 16.05.2020, 77<sup>18</sup> Real-Time polymerase reaction (RT-PCR) have been validated by ICMR. Among 77 kits 27 kits were reported satisfactory by ICMR. IIT Delhi, HeliniBiomolecules, ADT India Ltd., Biogenomics, and GCC Biotech Pvt ltd., are some of the Indian Companies/ Institutions that developed kits among positive 27kits.

Time for the testing, accuracy in the results, and affordability to the testing devices/ diagnostic kits are the major challenges that need to be addressed, and Innovations are happening globally for the same. Inventors of a few of the Inventions have filed for patent protection in India recently, after the corona outbreak. Some of them are:

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<sup>14</sup><https://www.gckyoto.com/declarers>

<sup>15</sup> ICMR abbreviated as Indian Council of Medical Research

<sup>16</sup> A report released by ICMR Dated 17.05.2020

<sup>17</sup> Indian council of Medical research, department of health research, report dated:16.05.2020

<sup>18</sup> Performance evaluation of commercial kits for detection of SARS-CoV-2 RNA by Real Time PCR, dated 16.05.2020

1. Application number, 202011013176A: A novel and reliable (RT-PCR) based detection method for corona virus (2019) infection”, filled on 26.03.2020, and published in the patent journal of India dated 01.05.2020
2. Application number, 20204101015044 A: Intelligent methods for detecting coronavirus using RNA & share the location using IOT, filled on 06.04.2020, and published in the patent journal of India dated 22.05.2020.

### 3.1 Recent Developments on Testing Kits:

Council of Scientific and Industrial Research, Institute of Genomics and Integrative Biology (CSIR -IGIB) India, developed a paper strip test named “Feluda”. In this test, they are using CSIPR technology. The cost of the strip is Rs. 500, which is highly economical than the existing tests available. CSIR-IGIB claims they have filed for a patent for this technology in India. If this test is successful, then this will be a path changer for quick identification for COVID-19 patients. Agreement Between CSIR-IGIB and Tata sons on licensing “Knowhow” related to developing Feluda Kit has been signed<sup>19</sup>.

ICMR – National Institute of Virology jointly developed Antibody detection for COVID -IgG ELISA tests named as “COVID – KAVACH ELISA”. The advantage of this test is they can test 90 samples at a time in a single rule which will take 2.5 hours, as per the statement made by the Union Health Minister on 11.05.2020.

Apart from the above category, there are few patents published recently in India related in products for handling COVID-19. They are

3. Application number, 202021010543A: Electronic Currency note Sterilizer machine. filled on 05.04.2020, and published in the patent journal of India dated 22.05.2020
4. Application number, 202011012796 A: KAWACH: An IOT Based COVID-19 Precaution and Hygiene Alert Device. filled on 24.03.2020, and published in the patent journal of India dated 01.05.2020
5. Application number, 202011014491 A: Corona umbrella, filled on 01.04.2020, and published in the patent journal of India dated 08.05.2020

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<sup>19</sup> Press Information Bureau, Government of India, Dated 05.05.2020

6. Application number, 202031016741 A: Method for monitoring person for detection of possibility of corona infection, filled on 18.04.2020, and published in the patent journal of India dated 15.05.2020
7. Application number, 202011015433 A: Karna KawachAn ultra-personal protection equipment kit, filled on 08.04.2020, and published in the patent journal of India dated 15.05.2020

Inventions like Corona Umbrella and Electronic Currency note Sterilizing machine shows how unique inventions can handle other COVID-19 related issues. The Patent system always helps in improving innovations and helps in addressing the grey areas where inventions can fit, making solutions available and incentivizing the inventor and motivating others to find solutions.

### 3.2 Developments related to COVID-19 Vaccine:

To date there are no patents granted for any product/process for treating COVID-19. As the vaccine is the only weapon to eradicate COVID-19, Globally lot of Research is happening and to encourage research lot of funding have been invested in Developing COVID-19 Vaccine<sup>20</sup>. Global Collaborations like Access to Covid-19 tools (ACT) Accelerator have been Initiated by the World health organization, the main agenda of this accelerator is to collaborate global institutions to accelerate the vaccines, diagnostics of COVID-19 production.

Global Health actors like WHO, BMGF, CEPI, Gavi, Global Fund, Unitaid, and private sector partners have come together to accelerate vaccine development and make equitable global access to new COVID-19 essential health technologies.

In this regard, CEPI (Coalition for Epidemic Preparedness Innovations) has opened to fund for the rapid development of a vaccine. Any interested institutions or organizations can apply for this fund by signing the contract with CEPI and this is opened till 30<sup>th</sup> of June 2020.

Very pleasing and in tune with the cosmopolitan approach, if one were to look at their Intellectual Property clause: the interesting aspect of this funding for COVID-19 by CEPI is that it will *not claim any Intellectual property right ownership on the Patents* arising from funding projects. But the condition

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<sup>20</sup>Novavax scores \$384M deal, CEPI's largest ever, to fund coronavirus vaccine work

is that supply and sell of vaccines should be at a *fair price*, what is the fair price is an open ended question here, and one more contrasting issue is that CEPI also mentioned that vaccines should be available populations where they are needed to end pandemic, regardless of ability to pay<sup>21</sup>.

One of the Interesting aspects that we need to look at here is that obtaining patents rights in public funding research, where funds were collected and allocated to a particular company for developing vaccines during this pandemic situation. Can they think of inventions to be free from patents for use open to the public? In such a case the inventions will be open to other players enabling improved research, and quick & easy availability of the vaccine. Alternatively, can the company itself secure patent rights and make technology & Know-how open to the public for a certain limited period.

In India, there are many pharmaceutical players and individual organizations working to get a monopoly claim on treating COVID-19, and there are patents published in India recently, claiming to treat COVID-19. Some of them are,

- a. Application number, SARVA JURA KUDINEER, filled on 09.03.2020, and published in the patent journal of India dated 20.03.2020
- b. Application number, 202021010578 A: Composition for Prevention and treatment of Respiratory Virus. filled on 12.03.2020, and published in the patent journal of India dated 22.05.2020

### 3.3 Clinical Trials:

We also need to look into the clinical trial phases happening globally, Clinical trials were happening for undisclosed compositions and there are few known medical components on which clinical trials were happening already known composition and also different undisclosed compositions.

More than 2000 Clinical trials have been in different phases globally<sup>22</sup>. Most importantly as on 15<sup>th</sup> of May 2020, eight candidate vaccines are in clinical evaluation. Following is the list of Vaccines in Clinical Evaluation:

<sup>21</sup>[https://cepi.net/news\\_cepi/cepi-seeks-to-expand-COVID-19-vaccine-portfolio-focusing-on-speed-and-global-manufacturing/](https://cepi.net/news_cepi/cepi-seeks-to-expand-COVID-19-vaccine-portfolio-focusing-on-speed-and-global-manufacturing/)

<sup>22</sup> World health organizations, International Clinical Trials Registry Platform (ICTRP)

S.no	Type of the Vaccine	Developer	Stage in Clinical Trails
01	Adenovirus Type 5 Vector	CanSino Biological Inc./Beijing Institute of Biotechnology	Phase-2
02	LNPencapsulated mRNA	Moderna/NIAID	Phase- 2
03	Inactivated	Wuhan Institute of Biological Products/Sinopharm	Phase -1/2
04	Inactivated	Beijing Institute of Biological Products/Sinopharm	Phase- ½
05	Inactivated + alum	Sinovac	Phase ½
06	ChAdOx1	University of Oxford	Phase – ½
07	3 LNP-mRNAs	BioNTech/Fosun Pharma/Pfizer	Phase- 1/ 2
08	DNA plasmid vaccine with electroporation	Inovio Pharmaceuticals	Phase 1

Apart from the above eight candidate vaccines, 110 candidate vaccines are in Pre-clinical stages that are developed by Institutions and different Pharma/ Biotech Companies.

There is no published data on the patent filings on the above listed trails data.

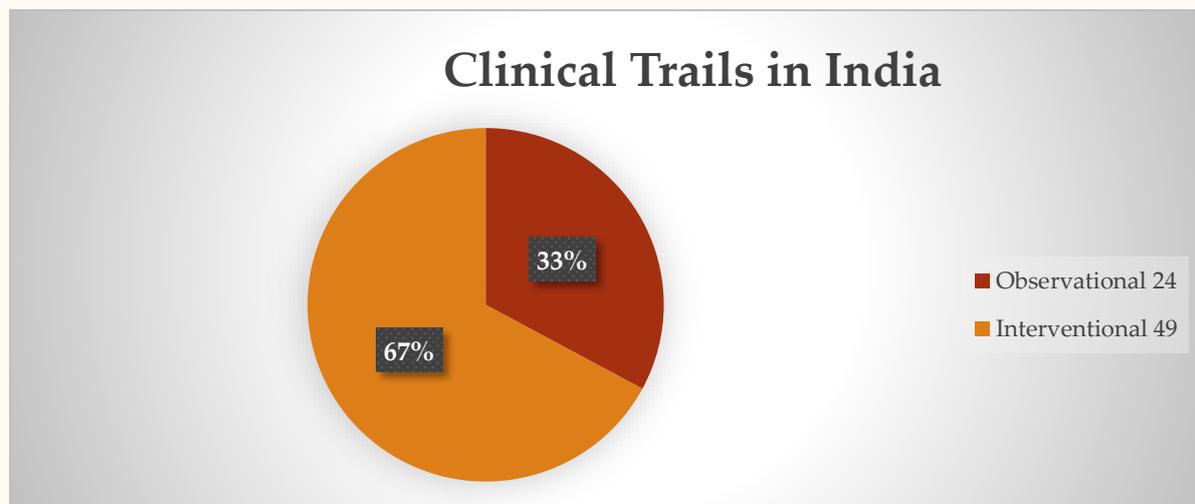
The University of Oxford for its ChAdOx1 vaccine, announced that it made an agreement<sup>23</sup> with Astrazeneca for Production and Distribution of the vaccine once this vaccine is proved effective. For the global distribution of the vaccine, Astrazeneca will work with other global partners. The University of Oxford has entered Phase II/III Clinical trials in humans at 13 different locations

<sup>23</sup><https://www.research.ox.ac.uk/>

in the UK. As per the agreement, both the parties University of oxford & Astrazeneca shall operate on a **not-for-profit basis till pandemic ends.**

### 3.3.1 Clinical Trials in India:

As on 17<sup>th</sup> May 2020, total 73 Clinical Trials with relate COVID-19 were registered in India, among 77 Clinical trials few observational trails also happening along with the Interventional Trails<sup>24</sup>.



Institutions like AIIMS, Aster Malabar Institute of Medical Sciences, KERALA etc., and also few biotech companies, Pharma and the Ministry of Ayush, Government of India are acting as the Source of Monetary/ Material support for conducting these clinical trials in India.

<sup>24</sup> Data collected and compelled from the CTRI (Clinical Trails Registry of India)

Following is the List of Intervention Name that is used in conducting Clinical trials in India; almost all the trails are in Phase-2 Clinical Trials.

S.no	Name of the Intervention Used
01	Hydroxy Chloroquine
02	Imatinib
03	Convalescent plasma (source : International Stem cell Services Ltd)
04	Itolizumab
05	Remdesivir, chloroquine or hydroxychloroquine, Lopinavir with Ritonavir. (Biocon Biologics India Limited)
06	Topical Nasal 0.03% chloroquine eye drops
07	Recombinant BCG vaccine, VPM1002 (Serum Institute of India Pvt. Ltd.)
08	SSV Formulation Tablets
09	(autoclaved)Mycobacterium (Cadila Pharmaceuticals Limited )
10	Novel Artificial Intelligence Algorithm to screen COVID-19 Patients from X-Ray , CT-Scan of Thorax and Voice Sampling through Android App and storage through Cloud.
11	ZingiVir H
12	Ivermectin
13	cadamba drug therapy
14	MyVirttablets (MiLabLifeSciences P Ltd )
15	Ciclesonide, Hydroxychloroquine, Ivermectin
16	Dabur Chyawanprash (Dabur India Ltd,)
17	Niclosamide
18	Favipiravir 200mg Tablets (Glenmark Pharmaceuticals Ltd.)
19	Shanshamani Vati or Sudarshana Ghanavati or Ashwagandha
20	Yashtimadhu tablet
21	Guduchi tablet
22	Five Undisclosed Ayurvedic Preparations
23	Kabasura Kudineer
24	AYUSH 64
25	Arsenicum album 30C
26	Guduchi ghan vati

Still, there is a need for Innovations related to treating COVID-19, and to make it easy for access to the information related to the patent literature and also to look into the advancements that happening globally in the patent regime. WIPO has come up with a unique search option for COVID related inventions known as “Patentscope COVID-19 Index”.

### 3.4 Initiatives taken by IP offices:

#### **3.4.1 United States of America:**

USPTO (United States Patents and Trademarks office) came up with new COVID-19 Prioritized Examination Pilot program<sup>25</sup> for small and micro entities whose patent application either for Product or Process should claim or relate to COVID-19.

USPTO also initiated Platform called “ Patents 4 Partnerships<sup>26</sup>”, this is a IP market Platform where patents can be listed voluntarily for licensing, Inventions related to the Prevention, diagnosis and treatment related to the COVID-19 and related technologies patents have been listed.

#### **3.4.2 Australia:**

IP Australia came up with “centelPede”- A real time information delivered on COVID-19. This is completely related to the unpatented literature published globally.

One more Initiative from the IP Australia is “Patent Analyst Hub” where latest Covis-19 related technologies have been listed separately. <sup>27</sup>

#### **3.4.3 Israel:**

Israel also came up with “Accelerated Examination<sup>28</sup>” of the patent application relevant to the COVID-19 where any of the claims containing method for the treatment of COVID-19 , can be accelerated for the examination report and there will be no special fee for this accelerated examinations.

<sup>25</sup><https://www.federalregister.gov/documents/2020/05/14/2020-10372/COVID-19-prioritized-examination-pilot-program>

<sup>26</sup><https://developer.uspto.gov/ipmarketplace/search/platform>

<sup>27</sup><https://www.ipaustralia.gov.au/tools-resources/patent-analytics-hub>

<sup>28</sup>[https://www.justice.gov.il/Units/RashamHaptentim/news/Pages/COVID19\\_app.aspx](https://www.justice.gov.il/Units/RashamHaptentim/news/Pages/COVID19_app.aspx)

## 4. Access to the [Patented or Non-Patented] Technologies:

Towards addressing the challenge posed by the pandemic of COVID-19 to the mankind, worldwide, it requires a colossal effort at different levels and in such consonance access of many technologies is vital, out of which some be under patent system and some may be patent free. To make those more accessible, different institutional efforts are being made which either may be by making different collaborative efforts including patent pooling, pledging of patents, licensing and cross licensing or at the different governments of the world, or different international organisations including WHO and WIPO.

### 4.1 International Developments:

Since the Novel Corona Virus (later named as COVID-19 by WHO) pandemic did outbreak in China, and later in other parts of the world. There have been various legislative and executive responses at international level in terms of different international institutions and countries. However, the area of such responses has been diverse in nature, as this pandemic is affecting various aspects of common life, but here in accordance of the context of the subject responses which produces direct or indirect effect upon patent rights.

#### 4.1.1 International Institutions:

##### World Intellectual Property Organisation (WIPO)

Towards making information more readily available in this pandemic the WIPO has launched COVID-19 IP Policy Tracker which provides information on measures adopted by different IP offices of different jurisdictions while responding the COVID-19.<sup>29</sup> In an statement WIPO also assured that “WIPO is available to any of its member States that so wish to provide advice and assistance on innovation policies, the targeted use of exceptions and limitations, the appropriate use of flexibilities to ensure access

<sup>29</sup>COVID-19 IP Policy Tracker, WIPO, available at: <https://www.wipo.int/COVID19-policy-tracker/#/COVID19-policy-tracker/voluntary-actions-text>

where there is evidence that IP is a barrier, and the modification of IP rules and regulations to mitigate the damage resulting from the COVID-19 crisis and its economic consequences.”<sup>30</sup>

### **World health organization (WHO)**

The WHO, adopted a proposal of Costa Rica for creating a voluntary patent pool and collecting patent rights, data of tests and trial, and other information for being shared in developing drugs, vaccines, and diagnostics.<sup>31</sup>

### **World Trade Organisation (WTO)**

The WTO being a multilateral organization, cannot take any policy decision unilaterally, but at organizational level it has taken various measures which includes the creation of a dedicated page<sup>32</sup> on the WTO website which provide up-to-date trade-related information considering the impact of this pandemic on exports and imports.

## **4.1.2 RESPONSE BY NATIONS**

As this pandemic started to step out of China in other countries, various swift legislative and executive responses started to come from different countries of the world. Such responses also included in respect to Patent related law and policies of those countries. Some of the countries have exercised and some are in process of exercising special measures such as compulsory licenses towards potentially relevant patented technologies and products in terms of COVID-19 challenge. Many of them are implementing voluntary measures in their jurisdiction to assist and a multitude such technologies and other relevant measures.

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<sup>30</sup>Francis Gurry, Some Considerations on Intellectual Property, Innovation, Access and COVID-19, April 24<sup>th</sup>, (2020), available at: [https://www.wipo.int/about-wipo/en/dgo/news/2020/news\\_0025.html](https://www.wipo.int/about-wipo/en/dgo/news/2020/news_0025.html)

<sup>31</sup>WHO and Costa Rica preview technology pooling initiative to ensure access to COVID-19 health products for all, WHO, available at: <https://www.who.int/news-room/detail/15-05-2020-who-and-costa-rica-preview-technology-pooling-initiative-to-ensure-access-to-COVID-19-health-products-for-all>

<sup>32</sup>COVID-19 and world trade, WTO, available at: [https://www.wto.org/english/tratop\\_e/COVID19\\_e/COVID19\\_e.htm#measures](https://www.wto.org/english/tratop_e/COVID19_e/COVID19_e.htm#measures) (Last access on May, 27<sup>th</sup>, 2020)

**a. Israel**

Israel is the only country, which has granted compulsory license towards COVID-19 treatment.<sup>33</sup> The license was issued under Section 104 of the patent statute, which allows the state to circumvent the law for national defence purposes. On 18th March, by exercising such power the minister of health and attorney general issued a permit allowing the state to import a generic version of AbbVie's Kaletra from India towards the treatment of COVID-19 infected patients. This is the first exercise of such power of compulsory licensing by the Israeli government under Section 104 since the introduction of such provision in 1967.

**b. Canada**

Canada has passed the COVID-19 Emergency Response Act, on 25th March, which apart of other measures and conferring a range of powers to authorities towards addressing the emergency situation by pandemic caused by COVID-19.<sup>34</sup> The Act also specifies that if the Federal Minister of Health considers there to be a public health emergency, the Commissioner of Patents may allow the Canadian state to produce, sell and use a patented invention.<sup>35</sup>

**c. Chile**

The Chamber of Deputies of Chile did pass a resolution asking the government of Chile to declare its support for issuance of compulsory licenses on patented products which are likely to be used towards the treatment of patients of COVID-19.<sup>36</sup> The resolution which passed by lower house by the majority of 127 votes to zero also requests the Minister of Health to direct the government departments to report on the vaccines, drugs, tests and equipment

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<sup>33</sup>AishaniSingh& Arindam Purkayastha, Worldwide: Israel Issuing Compulsory License During The Time Of COVID-19 Pandemic <https://www.mondaq.com/india/operational-impacts-and-strategy/917898/israel-issuing-compulsory-license-during-the-time-of-COVID-19-pandemic> (Last access on May, 27<sup>th</sup>, 2020)

<sup>34</sup>COVID-19 Emergency Response Act, S.C. (2020, c. 5), available at: [https://laws-lois.justice.gc.ca/eng/AnnualStatutes/2020\\_5/page-1.html](https://laws-lois.justice.gc.ca/eng/AnnualStatutes/2020_5/page-1.html) (Last access on May, 27<sup>th</sup>, 2020)

<sup>35</sup> Part 9, Para 12, COVID-19 Emergency Response Act, S.C. 2020 available at: [https://laws-lois.justice.gc.ca/PDF/2020\\_5.pdf](https://laws-lois.justice.gc.ca/PDF/2020_5.pdf) (Last access on May, 27<sup>th</sup>, 2020)

<sup>36</sup>Resolution On Compulsory Licences For Patented Medicines Passes In Chile, 1<sup>st</sup> Feb. (2017). available at: <https://www.ip-watch.org/2017/02/01/resolution-compulsory-licences-patented-medicines-passes-chile/> (Last access on May, 27<sup>th</sup>, 2020)

which may be considered necessary for such purposes. Furthermore, the resolution also has also requested to the Government of Chile to ask the World Health Organization (WHO) to collect information on the R&D costs associated with relevant treatments. However, the referred resolution is not binding upon the government but is surely an influential force regarding policy over such issue.

#### **d. Germany**

In March, the Bundestag- the legislative body of the largest economy of Europe did pass a legislation in relation to the threat of COVID-19, the *Prevention and Control of Infectious Diseases in Humans Act*, which, along with other provisions also conferred power to the Federal Ministry of Health the ability to issue a compulsory license under the existing Section 13(1) of the Patent Act.<sup>37</sup> However, neither such license has earlier been issued by the Germany in past and patent-related orders issued as a result of the new legislation will be automatically revoked if the Bundestag decides that Germany no longer faces an epidemic, or when the law expires.

#### **e. France**

The France through an amendment has enacted a new law on 23rd March introducing a new article L.3131-15<sup>38</sup> in 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. It is being analyzed by experts that by such amendment practically, the Prime Minister will now be allowed to permit the seizure of drugs and/or to direct the launch of generic products on French territory before the expiry of patents/SPCs, whenever he finds it necessary and being

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<sup>37</sup>Dr. Sebastian Fuchs, COVID-19: New German legislation to fight pandemic may affect granted German patents, <https://www.twobirds.com/en/news/articles/2020/germany/COVID-19-new-german-legislation-to-fight-pandemic-may-affect-granted-patents> (Last access on May, 27<sup>th</sup>, 2020)

<sup>38</sup>Décret n° 2020-545 du 11 mai 2020 prescrivant les mesures générales nécessaires pour faire face à l'épidémie de COVID-19 dans le cadre de l'état d'urgence sanitaire, NOR: SSAZ2011567D, available at: <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000041858681&categorieLien=id> (Last access on May, 27<sup>th</sup>, 2020).

considered it goes well beyond the compulsory licensing measures adopted elsewhere.

*f.* **Ecuador**

A resolution was passed by The Education, Culture, Science and Technology Commission of the National Assembly of Ecuador on 20th March requesting the health minister of Ecuador to issue compulsory licenses on products whose availability is significant in regard to the public health response to the pandemic caused due to COVID-19.<sup>39</sup> The commission has also asked the health minister of the country to exercise the power under article 501 of the Código Ingenios, which allows third parties to access and use a patentee's data, including the data of clinical tests and trails.

*g.* **Bangladesh**

Bangladesh Government has issued an emergency decree, exercising which a pharmaceutical company Beximco Pharmaceuticals is able to donate copies of the Gilead Sciences (GILD) medicine- remdesivir, to state-run hospitals free of charge, whereas will sell the intravenous treatment to private hospitals.<sup>40</sup> Reportedly few of Bangladeshi firms have started to manufacture anti-viral drug remdesivir. Few firms including Eskayef Pharmaceuticals and Beximco Pharmaceuticals have already “launched their products for the COVID-19 treatment under brand names, Remivir and Bemsivir respectively”.<sup>41</sup> However, Gilead Sciences has expressed that “Gilead has not provided a license to Beximco Pharma, Eskayef Pharmaceuticals or any other company in Bangladesh to manufacture remdesivir. Gilead cannot comment on or verify

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<sup>39</sup> Resolución para requerir al Gobierno Nacional el establecimiento de licencias obligatorias y otras medidas que permitan garantizar el acceso gratuito y a costos asequibles de los productos farmacéuticos y tecnologías médicas en la Declaratoria de Emergencia Sanitaria por la pandemia del Coronavirus (COVID-19) y demás variaciones, así como los protocolos e instrumentos de bioseguridad para el personal de salud, posgraduados y estudiante del Sistema de salud pública, Comisión de Educación, Cultural Ciencia y Tecnología, March, 20th, (2020). available at: <https://www.keionline.org/wp-content/uploads/ES-Ecuador-CL-resolution.pdf> (Last access on May, 27<sup>th</sup>, 2020).

<sup>40</sup> Ed Silverman, First generic version of Gilead's remdesivir will be sold by a Bangladesh drug maker, May 22nd, (2020), available at: <https://www.statnews.com/pharmalot/2020/05/22/gilead-remdesivir-COVID19-coronavirus-beximco-patent/> (Last access on May, 27<sup>th</sup>, 2020).

<sup>41</sup> Usha Sharma, Remdesivir in India: An unfolding story, Express Pharma, June 12<sup>th</sup>, (2020). available at: <https://www.expresspharma.in/COVID19-updates/remdesivir-in-india-an-unfolding-story/>

the authenticity or effectiveness of this product as it is not manufactured by Gilead or one of our licensed partners.” But arguably Bangladesh being a LDC (Least Developed Country) has such option as LDCs are exempted from implementing Patent Law (TRIPs) up to 2033 under Doha Declaration.<sup>42</sup>

#### 4.1.3 INTER-GOVERNMENTAL COLLABORATIONS:

The corona virus disease is novel and the existing medical drugs and technology is unable to provide remedy, the world is looking at invention of new drugs or vaccine with optimistic eyes. Different countries are taking different approaches, but there’s not a single obvious solution because of lack of strong vision and research strength. While many countries or organizations are researching (some are claiming to found)<sup>43</sup> and trying to invent the drug / vaccine to cure this COVID-19, believing in the saying ‘**Sanghe Shakti Kalyuge**’, there is a need of putting efforts together; like **one world- one disease- one cure**.

#### Technology Transfer: Pre and Post Invention

Technology transfer is the mechanism by which the accumulated knowledge developed by a specific entity is transferred wholly or partially to another one to allow the receiver to benefit from such knowledge. Patent distribution/ Patent citations/ technology transfer or technology spill over has been regarded as a good measurement of technology flows among different countries in the field of technology. [Sending Unit -to- Receiving Unit]

Patenting discoveries made in **government-sponsored research** is the most effective way to promote technology transfer and commercial development of those discoveries in the private sector. The best way to achieve widespread use of the results of government-sponsored research is to make them **freely available** to the public.<sup>44</sup>

<sup>42</sup> Usha Sharma, Remdesivir in India: An unfolding story, Express Pharma, June 12<sup>th</sup>. (2020). available at: <https://www.expresspharma.in/COVID19-updates/remdesivir-in-india-an-unfolding-story/>

<sup>43</sup> <https://www.nationalheraldindia.com/international/antibody-found-to-block-COVID-19-virus-100-in-experiments>

<sup>44</sup> Rebecca S. Eisenberg, Patents: Help or Hindrance to Technology Transfer?, University of Michigan Law School University of Michigan Law School Scholarship

## **Issues related to Technology Transfer:**

The process of transferring technology is multifaceted which influenced by number of factors including political and policy framework, human resources and infrastructure.

Some of the primary issues in technology transfer are e.g. asymmetric information (imbalance of knowledge bank), Market power, Uncertainty regarding the qualities of the innovation and Cost issues.

## **Technology Transfer in TRIPS**

In the objective clause of the TRIPS agreement which says that the protection and enforcement of IPRs should contribute to the promotion of technological innovation and further to the transfer and dissemination of technology.<sup>45</sup>

In the Article 8 of the TRIPS agreement empowers the member country by taking measures which may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices unreasonably restraining trade or adversely affect the international transfer of technology.<sup>46</sup>

Article 66 of the TRIPS mandates that all developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.<sup>47</sup>

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Repository (1996) available at:  
[https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1087&context=book\\_chapters](https://repository.law.umich.edu/cgi/viewcontent.cgi?article=1087&context=book_chapters)

<sup>45</sup> Article 7- Objectives- The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

<sup>46</sup> Article 8(2)-Principles- 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.

<sup>47</sup> Article 66 Least-Developed Country Members- (2)- Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging

## Global Tech Transfer Processes

Global framework is required that supports transfer of technology at the national and international level. A linear, smooth and easy technology transfer process to be adopted globally for quick and authentic development in the procurement of drugs / vaccine for COVID-19.

The importance of transferring technologies for medicines is also recognized in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property Rights of the World Health Organization.<sup>48</sup>

There is no place for Market Competition, as COVID-19 is a global pandemic and efforts are for the wellbeing of Humanity. Time demand not only to find out a correct and authenticated cure by putting efforts together and generating socially useful – rather than merely profitable – pharmaceutical innovation but such innovation should happen in lightening way. Many institutes are setting examples while taking the actions in lightning speed e.g. when a scientist at the University of Dayton Research Institute (UDRI) in Ohio developed software which detects the COVID-19 virus in seconds using an X-ray technology, the tech transfer leaders had licensed it in two and a half days and on the market in just seven without waiting usual months or years to get it to market.<sup>49</sup>

Cost of technology transfer can be covered by all countries on basis of their bearing capacity [mechanism of pooling may be adopted]. Fair and reasonable terms play a vital role to provide a suitable legal framework to address these issues.

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technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base.

<sup>48</sup> World Health Assembly Resolution 61.21 which includes the WHO Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property. An agreed action is - to promote transfer of technology and production of health products in developing countries through identification of best practices, and investment and capacity building provided by developed and developing countries where appropriate. Available at [https://www.who.int/phi/publications/Global\\_Strategy\\_Plan\\_Action.pdf?ua=1](https://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf?ua=1)

<sup>49</sup> <https://techtransfercentral.com/2020/04/22/ttos-respond-to-urgent-pandemic-needs-with-war-time-licensing/>

There are instances where related work theory (Same aim and objectives of research) works to research and provide access to researched vaccine to the public. The twenty five year partnership between Brazil's Oswaldo Cruz Foundation and GSK has resulted in technology and manufacturing agreements that have led to the development of vaccines that were essential to Brazil's universal immunization program.<sup>50</sup>

Transfer of technology is a better mechanism in research and development to find the medicine and further distribution and access of this cure to the general public in case of the development of drugs for COVID-19. **Public private partnership** on the global platform will provide a path to sun of hope to rise rather than researching and developing vaccine by individual country or company.

Defence Research & Development Organization (DRDO) proposes to transfer 'Counter COVID-19 Technologies'<sup>51</sup> to industries through signing of Licensing Agreement for Transfer of Technology (LATOT) between industries and the concerned lab of DRDO at 'Nil' ToT fee and 'Nil' royalty charges (for sales in India) and with minimal royalty charges in case of export.<sup>52</sup>

## 4.2 Industry-Government Response:

### 4.2.1 Response by Industry

The pharma and other related industries which are associated with any elements of the diagnostic and treatment measures of this pandemic also have been responsive and have responded also towards the issue of patent rights.

A UK-based global biopharmaceutical company AstraZeneca is in association with the Oxford Vaccine Group (OVG) of the University of Oxford in developing a vaccine and further making it accessible to the world.<sup>53</sup> Under

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<sup>50</sup>GSK and Brazil's Fiocruz form partnership for new R&D effort and increased vaccine access. Available at <https://www.gsk.com/en-gb/media/press-releases/gsk-and-brazil-s-fiocruz-form-partnership-for-new-rd-effort-and-increased-vaccine-access/>

<sup>51</sup> <https://drdo.gov.in/drdo-developed-counter-COVID-19-technologies>

<sup>52</sup> <https://drdo.gov.in/transfer-technology-tot-drdo-developed-counter-COVID-19-technologies>

<sup>53</sup>Landmark partnership announced for development of COVID-19 vaccine, Oxford Vaccine Group, April, 30, (2020). available at: <https://www.ovg.ox.ac.uk/news/landmark-partnership-announced-for-development-of-COVID-19-vaccine> (Last access on June, 23<sup>rd</sup>, 2020).

an agreement with the Oxford University, AstraZeneca is required to work with global partners towards international distribution of the prospective vaccine, while ensuring the accessibility for low and medium income countries too. The development of such prospective vaccine is being referred is in advanced stage. The Oxford University and AstraZenca both have agreed to work on a not-for-profit basis for the duration of this pandemic, “with only the costs of production and distribution being covered”.<sup>54</sup> The agreement refers that any royalties which is being received by the University “will be reinvested directly back into medical research, including a new Pandemic Preparedness and Vaccine Research Centre”.<sup>55</sup>

“**The Open COVID Pledge**” has been launched on March 30 in USA, whereas this Pledge is a “commitment by holders of intellectual property to share their intellectual property for the purposes of ending and mitigating the COVID-19 Pandemic.”<sup>56</sup> Under this arrangement the implementation of the pledge requires the pledger (company or individual) to publish a license consistent with the pledge.

A similar initiative, the “OPEN COVID-19 DECLARATION”, was launched in Japan on May 7<sup>th</sup>.<sup>57</sup> To participate in the declaration, participating companies are required to “commit not to assert certain intellectual property right against any activities whose [sole] purpose is stopping the spread of COVID-19, including diagnosis, prevention, containment and treatment.” This declaration is a promise of not asserting any IP rights against any individual or other entity during the period starting with the date of the declaration and ending on the date on which the WHO declares that the COVID-19 outbreak no longer constitutes a public health emergency of international concern.

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<sup>54</sup>Landmark partnership announced for development of COVID-19 vaccine, Oxford Vaccine Group, April, 30, (2020). available at:<https://www.ovg.ox.ac.uk/news/landmark-partnership-announced-for-development-of-COVID-19-vaccine> (Last access on June, 23<sup>rd</sup>, 2020).

<sup>55</sup>Landmark partnership announced for development of COVID-19 vaccine, Oxford Vaccine Group, April, 30, (2020). available at:<https://www.ovg.ox.ac.uk/news/landmark-partnership-announced-for-development-of-COVID-19-vaccine> (Last access on June, 23<sup>rd</sup>, 2020).

<sup>56</sup> The Open COVID Pledge, available at: <https://openCOVIDpledge.org/> (Last access on May, 27<sup>th</sup>, 2020).

<sup>57</sup>Twenty Founders Announce OPEN COVID-19 DECLARATION - Pledge Not To Enforce IP Rights, May 27<sup>th</sup>, (2020). available at:[https://www.prweb.com/releases/twenty\\_founders\\_announce\\_open\\_COVID\\_19\\_declaration\\_pledge\\_not\\_to\\_enforce\\_ip\\_rights/prweb17108473.htm](https://www.prweb.com/releases/twenty_founders_announce_open_COVID_19_declaration_pledge_not_to_enforce_ip_rights/prweb17108473.htm)(Last access on May, 27<sup>th</sup>, 2020).

Three major research groups of the world, the Innovative Genomics Institute, Howard Hughes Medical Institute and University of California has offered a “no-fee, royalty-free license” to their work involving the diagnosis and treatment of COVID-19.<sup>58</sup>

After the compulsory license issued by the Israel, AbbVie, the USA based firm in March, declared to stop itself from enforcing its patent anywhere in the world on Kaletra, which is an HIV medicine which is currently being tested for effectiveness in the treatment of COVID-19.<sup>59</sup>

Gilead, the developer of Remdesivir, which had applied for "orphan status" for Remdesivir to US regulators took such application back. It is relevant to note that under US IP law, pharmaceutical companies developing treatments for diseases which affects fewer than 200,000 people can enjoy market exclusivity for seven years.<sup>60</sup>

Roche, the world's leading diagnostic kit maker, which initially was not releasing the chemical formulae for a reagent, buffer used in its polymerase chain reaction-based test for COVID-19, later, agreed to release the recipe for a liquid solution that Dutch laboratories need to run a COVID-19 test.<sup>61</sup>

A device manufacturing company Medtronic Plc has announced to provide the specifications of their ventilator designs, online towards encouraging other manufacturing entities to copy and use for manufacturing.<sup>62</sup> The company has also ramped up production of a newer ventilator model to try to meet demand.

<sup>58</sup> Our Pledge to Share COVID-19 IP, March 29th, 2020 IGI News, COVID-19, available at: <https://innovativegenomics.org/news/our-pledge-to-share-COVID-19-ip/> (Last access on May, 27<sup>th</sup>, 2020).

<sup>59</sup> Financial Times, AbbVie drops patent rights for Kaletra antiviral treatment, available at: <https://www.ft.com/content/5a7a9658-6d1f-11ea-89df-41bea055720b> (Last access on May, 27<sup>th</sup>, 2020).

<sup>60</sup> Katie Thomas, Gilead Withdraws Request for Special Orphan Status on Experimental Virus Treatment The New York Times, March 25, (2020), available at: <https://www.nytimes.com/2020/03/25/health/gilead-coronavirus-orphan-drug.html> (Last access on May, 27<sup>th</sup>, 2020).

<sup>61</sup> Statement from Roche Diagnostics on supply of the SARS, available at: <https://diagnostics.roche.com/be/en/article-listing/Statement-SARS-CoV-2-test-material.html>

<sup>62</sup> Darrell Etherington, Medtronic is sharing its portable ventilator design specifications and code for free to all, available at: <https://techcrunch.com/2020/03/30/medtronic-is-sharing-its-portable-ventilator-design-specifications-and-code-for-free-to-all/> (Last access on May, 27<sup>th</sup>, 2020).

#### 4.2.2 NON-EXCLUSIVE VOLUNTARY Licensing agreement by Gilead:

The FDA has issued an Emergency Use Authorization (EUA) for remdesivir as it is found to be helpful in treatment of COVID 19 patients. Remdesivir also approved by the Japanese Ministry of Health, Labour and Welfare for patients with severe COVID-19 under an exceptional approval pathway.

To ensure large scale availability of remdesivir at affordable rates the Gilead has signed non-exclusive voluntary licensing agreements with nine generic pharmaceutical manufacturers of which seven are based in India and one each in Pakistan and Egypt.

In India the licensees are Cipla Ltd, Dr. Reddy's Laboratories, Hetero Labs Ltd, Jubilant Lifesciences, Mylan, Sygene Ltd and Zydus Cadila Healthcare Ltd. In Pakistan it is Ferozsons Laboratories and in Egypt it is Eva Pharma.

Under the terms of license the Gilead will provide technology transfer for manufacturing process. The licenses will be royalty free until the World Health Organization declares the end of the Public Health Emergency of International Concern regarding COVID-19, or until a pharmaceutical product other than remdesivir or a vaccine is approved to treat or prevent COVID-19, whichever is earlier.

The licensees shall have their own prices. These Companies shall supply to not only their country but also shall manufacture and supply to 127 countries with low and lower-middle income.<sup>63</sup>

**Such licensing arrangement is a sign of cooperation to fight the pandemic where a patent holder is granting royalty free licenses to companies in other countries who have proven capability to manufacture at mass scale at substantially lower costs to manufacture and distribute the vital drug for their own country and 127 other countries with low income.**

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<sup>63</sup> <https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir>

### 4.2.3 Agreement between University of Oxford and Astra Zeneca

Oxford University's landmark partnership with AstraZeneca for the development and potential large-scale distribution of COVID-19 vaccine candidate

Oxford University's Medical Sciences Division is developing a vaccine for COVID 19. The project is being funded by UK Research and Innovation (UKRI) and by the Department of Health and Social Care through the National Institute for Health Research (NIHR). Initial funding being £24.6 million. The Government has further announced new funding of £65.5 million for acceleration of corona vaccine trials. Phase II and Phase III trials have begun with recruitment of humans for trials.

The University of Oxford has entered into an agreement with AstraZeneca a UK-based global biopharmaceutical company for the further development, large-scale manufacture and potential distribution of the COVID-19 vaccine under development.

**The agreement between University of Oxford and Astra Zeneca is to operate on a not-for-profit basis for the duration of the coronavirus pandemic, with only the costs of production and distribution being covered. Oxford University and its spin-out company Vaccitech, who jointly have the rights to the platform technology used to develop the vaccine candidate, will receive no royalties from the vaccine during the pandemic.**

AstraZeneca has entered into an agreement with Europe's Inclusive Vaccines Alliance (IVA), spearheaded by Germany, France, Italy and the Netherlands, to supply up to 400 million doses of the University of Oxford's COVID-19 vaccine, with deliveries starting by the end of 2020. Apart from this the Astra Zeneca has entered into agreement with large global partners to manufacture to and distribute to the low and medium income countries.

AstraZeneca is working on a number of agreements in parallel to ensure broad and equitable supply of the vaccine throughout the world at no profit during the pandemic.<sup>64</sup>

Astra Zeneca is in discussion with international organisations such as the Coalition for Epidemic Preparedness Innovations (CEPI), Gavi the Vaccine Alliance and the World Health Organisation (WHO) and various governments for the fair allocation and distribution of the vaccine around the world. Company is also in discussions with the Serum Institute of India and other potential partners who can produce the vaccine at mass scale and distribute the same.

#### 4.2.4 CSIR IGIB and TATA Sons sign an MoU for licensing KNOWHOW related to development of a kit FELUDA for rapid and accurate diagnosis of COVID-19.

India has very large population. An affordable, reliable and cost effective testing is very vital for containment of COVID 19. CSIR Institute of Genomics and Integrative Biology (CSIR-IGIB) under sickle cell mission and utilizes an indigenously developed cutting edge CRISPR Cas9 technology to specifically recognize COVID-19 sequence in a sample. A combination of CRISPR biology and paper-strip chemistry leads to a visible signal readout on a paper strip that can be rapidly assessed for establishing the presence of viral infection in a sample. It is a completely indigenous scientific invention.

It uses a test protocol that is simple to administer and easy to interpret enabling results to be made available to the medical fraternity in relatively lesser time, as compared to other test protocols. It is not dependent on expensive Q-PCR machines. It is a futuristic technology that can also be configured for detection of multiple other pathogens in the future.<sup>65</sup>

The CSIR has licensed the technology to TATA sons. The license includes transfer of the knowledge for scaling up the knowhow in the form of a kit that can be deployed for COVID-19 testing at the earliest.<sup>66</sup> The partnership is for

<sup>64</sup> <https://www.astrazeneca.com/media-centre/press-releases/2020/astrazeneca-advances-response-to-global-covid-19-challenge-as-it-receives-first-commitments-for-oxfords-potential-new-vaccine.html>

<sup>65</sup> <https://www.csir.res.in/sites/default/files/Press%20Information.pdf>

<sup>66</sup> <https://www.tata.com/newsroom/covid19/icmr-feluda-mou-rapid-test-kit-covid-19>

mass production and quick deployment of testing kit for fighting the menace of COVID-19.

#### 4.2.5 Maruti Suzuki mobilizes production of ventilators, masks and PPE to support India's preparation against COVID-19

Maruti Suzuki India Limited (MSIL) at the request of Govt. of India is assisting in the production of ventilators, masks and other protective equipment. It has entered into arrangement for manufacture of ventilators with AgVa Healthcare, an existing approved manufacturer of ventilators. MSIL has started manufacturing with AgVa Healthcare to rapidly scale up production of ventilators so as to reach a volume of 10,000 units per month.<sup>67</sup>

AgVa Healthcare is responsible for the technology, performance and related matters for all the ventilators produced and sold by them. MSIL will use its experience in manufacturing to use large scale production of ventilators by upgrading systems of productions, have better quality control and also seek the help of its suppliers to supply quality components. Ventilators are critically important to fight COVID 19. The country is having shortage of ventilators. MSIL will help in arranging finance and other approvals and assist in increasing volume of production. MSIL would provide these services free of cost to AgVa Healthcare.

A joint venture of MSIL M/s Krishna Maruti Limited, will be manufacturing 3-ply masks for supply to the Haryana and Central governments.. The Chairman of the company will provide 2 million masks free of cost as his own contribution.

Another joint venture of MSIL M/s Bharat Seats Limited would be manufacturing protective clothing as soon as all approvals are in place.

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<sup>67</sup> <https://www.marutisuzuki.com/corporate/media/press-releases/2020/maruti-suzuki-mobilizes-production-of-ventilators>

## 4.2.6 Certain other contributions by industries in fighting COVID 19

### Tata Consultancy Services

One of the particular challenges of the lockdowns is school and university closures. UNESCO estimates that 1.37 billion children risk having their education interrupted. TCS is applying technology to provide a solution there and have made their proprietary distance learning software platform available for free to educational institutions.<sup>68</sup>

### Mahindra and Mahindra Ltd

M & M Ltd. is developing an Affordable Respirator (Ambu Bag) that is useful at the initial stage of medical intervention. It will cost as little as Rs. 7500 compared to Rs. 5- 10 lakh of traditional ventilator. The production of ventilator will start in a couple of weeks.

Company has also started producing 5000 Face Shields a day which it hopes to ramp up to 50000 a day . These will be given to medical staff free of cost.<sup>69</sup>

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<sup>68</sup> <https://www.tcs.com/company-overview/tcs-response-covid-19>

<sup>69</sup> (Mahindra news room stories)

## 5. The Patent system facilitating the development of innovative technologies and access to those technologies:

The patent system has often been misrepresented as monopolistic and as a furtherance of private interest. During this pandemic, patents have been portrayed as a barrier to access to diagnostic kits and vaccines (existing/when they are available). The issue with this line of thought is that the patent system has inbuilt mechanisms which protects the larger public interest, especially in times of crisis, which have not been taken into account. The author would like to argue that patent system has been designed to facilitate access to innovation and technology, especially in the arena of pharmaceuticals and access to medicines, and therefore would shed light upon the provisions, both in the International and National context as to how this can be achieved.

The international patent law, governed by TRIPS, protects patent rights under Article 27 – Article 34. Under the agreement, member nations are allowed to “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.”<sup>70</sup>

Here the attention needs to drawn to the phrases “*necessary to protect public order/morality including to protect human life....*” A pandemic can definitely be considered to be a situation where it becomes important to protect human life, thereby protecting public order. Any vaccine which is developed can be denied a patent under these regulations. There is another provision, which is important here, members are also allowed to exclude from patentability “diagnostic, therapeutic and surgical methods for the treatment of humans or

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<sup>70</sup> Article 27 (2), Agreement of trade related aspects of Intellectual Property, 1994.

animals.”<sup>71</sup> Any new diagnostic testing kit could be denied a patent arguing upon this provision.

Since these are unprecedented times, the provision would have an application unseen in any previous situation. Then there is the provision of compulsory licensing, within the TRIPS Agreement, which provides for the provision of compulsory license, which provides for grant of non-exclusive licenses based on reasonable rates of royalty<sup>72</sup> This provision has also been adapted into the Indian patent system. The TRIPS agreement posed one particular problem, in the arena of compulsory licenses that the license could only be granted mainly for home production that is *“such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.”*<sup>73</sup>

This problem was addressed in the DOHA DECLARATION. The Doha declaration addressed public health, and patents and access to medicines. The dialogue in Doha Declaration was that the members should not be constrained by TRIPS agreement when there was question of public health<sup>74</sup>, and therefore members would interpret TRIPS agreement in consonance with public health, and access to medicines. Therefore the members would be given freedom to grant compulsory licenses and the terms upon which they would be granted.<sup>75</sup>

The agreement also provides that *“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.”*<sup>76</sup> The argument can be made by each individual country, whether the present pandemic is a national emergency and therefore provisions of compulsory licensing could be determined by the country as per their needs.

The Doha Declaration led to the amendment of the TRIPS agreement which entered into force in 2017. The amendment was the provision of article 31bis, which provides that *“the Article 31(f) shall not apply with respect to the grant*

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<sup>71</sup> Article 27 (3) (a), Agreement of trade related aspects of Intellectual property, 1994.

<sup>72</sup> Article 31, Agreement of trade related aspects of intellectual property, 1994.

<sup>73</sup> Article 31(f), Agreement of trade related aspects of intellectual property, 1994.

<sup>74</sup> Paragraph 4, Doha Declaration, 2001

<sup>75</sup> Para5 (b), Doha Declaration, 2001

<sup>76</sup> Para 5 (c), Doha Declaration, 2001

*by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.*"<sup>77</sup>

The provision essentially means that countries which have lesser access to medicines can be provided access by means of a compulsory license. A country which has the production capability can make use of the provision to export pharmaceutical products to another country in need of medicines. The Doha Declaration was drafted keeping in mind the needs of the least developed countries and their need to access to medicines.<sup>78</sup>

The above provisions at the international level prove that patents are not barriers to any access to medicines/diagnostic kits/ other equipment to be used for the public at affordable rates. There are similar provisions in the Indian Patent act as well. These provisions provide safeguard the public interest over the private one. There are numerous ways in which the government could intervene and if not end/ then restrict the monopoly of the patent holders.

The Indian patent act, envisages patent as an exception, rather as the rule, therefore there is a very expansive section, which rules out a lot of inventions from the scope of patents, that is section 3. Section 3 provides that any invention "*the primary or intended use or commercial exploitation of which could be contrary public order or morality or which causes serious prejudice to human, animal or plant life or health or to the environment.*"<sup>79</sup> This provision is very similar to the one in TRIPS, and provides that any invention which if used commercially, would be against public order cannot be patented. The provision can be expansively interpreted to suggest that in the current times an invention such as drug, if it used for commercial exploitation only, would cause grave prejudice to human life, and therefore should not be patented.

Section 3 (i) further prevents the patenting of a diagnostic method or other methods of treatment<sup>80</sup> for human beings. The section therefore could be used during the present pandemic to disallow patents for any new diagnostic kits and such other methods as may be invented. The present section is exclusionary section, therefore excludes these certain subject matters from the

<sup>77</sup> Article 31*bis* (1), TRIPS Agreement, 2017.

<sup>78</sup> Carlos M Correa, Implications of the Doha Declaration on the TRIPS agreement and public health, World Health Organization [2002]; available at: [https://www.who.int/medicines/areas/policy/WHO\\_EDM\\_PAR\\_2002.3.pdf?ua=1](https://www.who.int/medicines/areas/policy/WHO_EDM_PAR_2002.3.pdf?ua=1)

<sup>79</sup> Section 3(b), Indian Patent Act, 1970

<sup>80</sup> Section 3(i), Indian Patent Act, 1970

fray of patents. Even if the subject matter is patentable, then also there are many inbuilt mechanisms in the public interest.

The first concept is of voluntary license. It has to be remembered that any private institution is a profit making entity, if the companies give out more licenses, then they get more royalty, earn more income, so it would be quite favourable to grant voluntary licenses. Companies holding the patents can be requested to grant voluntary licenses, so that the diagnostic kits and vaccines can be mass produced. The company holding the patent in this case would have ample opportunity of safeguarding their interests as well as providing for accessible and affordable diagnostic kits and medicines. The recent agreement between Gilead and five generic companies of India and Pakistan seems to be a measure in this direction.<sup>81</sup> If circumstances such arise that this option does not seem feasible then also there are a few other options that the central government can utilise.

The first of which is section 47 of the Indian Patent Act, under which the Central government can import a patented drug for its own hospitals and distribution in dispensaries. This subsection empowers the Central government for such scenario where a drug is patented in India but is not currently being manufactured in India.<sup>82</sup> This can be done by a simple notice in the official gazette. Section 47 has been previously invoked in India, in the case of chemtura corp. v Union of India,<sup>83</sup> where the section was invoked by the railways to manufacture a part of a train for which Chemtura corp. held the patent. The court interpreted the railways to be a part of the government and any such use by any department of the government was covered under section 47. The court interpreted the word '*merely for its own use*' to mean use even by agents of the central or state government as long as the result was for the use of the central government. In the present case, the provision would mean that the contract for the manufacture/ importation of the drug/vaccine can be contracted to other parties as long as the end use is by the government.

There is another option for the central government, acquisition of the patent. The sections 99- 103 provide for use by the central government. Section

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<sup>81</sup> COVID-19: Jubilant Life Signs Licensing Agreement With Gilead For Remdesivir, Read more at: <https://www.bloomberquint.com/coronavirus-outbreak/COVID-19-jubilant-life-inks-licensing-agreement-with-gilead-for-remdesivir>

<sup>82</sup> Section 47(4), Indian Patent Act, 1970.

<sup>83</sup> 2009(41) PTC 260(Del)

99 specifies that an invention would be said to be made for the government if it was used, made, vended or exercised for the purposes of the government.<sup>84</sup> This provision plays an important role in reading of section 100, which gives power to the central government to use inventions for the purposes of the government.<sup>85</sup> The section authorises the Central govt to use any invention at any time after it has been filed, or granted with certain conditions attached to it. It lays out the procedure for such acquisition by the government, and gives the government the power to make, use, exercise or vend the invention, import the machine, apparatus or other article or medicine or drug covered by such a patent.<sup>86</sup> There is a distinction in the Sections 47 and Section 100; this was pointed out in the case of *Garware Ropes v AI corp.*<sup>87</sup> The Bombay High Court opined that this section was for the use of the government and by third parties under express contract of licensing by the government, while section 47, which essentially gives the power to the government to use any invention without paying any royalty, is only for its own use, and would not apply to third parties.

There is another option for acquisition by government, this time under section 102, which gives the central government power to acquire a patent for a public purpose. In this case, the patent would be transferred to the government and all the rights shall vest with the government. In both these acquisitions, the patentee shall be given royalty or compensation as may be agreed between them.<sup>88</sup> Section 100 uses the term for “use by the government”, without altering the ownership or the claims of third parties while Section 102 gives the Central government the power to acquire the patent itself. This is however restricted only to public purposes. The current pandemic and the needs of accessible and affordable diagnostic kits and vaccines would most certainly qualify for public purpose. If there is a dispute regarding the nature, then such a dispute can be taken to the High Court.<sup>89</sup>

The next option of Compulsory Licensing is being touted as the solution by many authors and countries<sup>90</sup> across platforms. The compulsory licensing invocation is a powerful and coercive step, which allows the government to

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<sup>84</sup> Section 99, Indian Patent Act, 1970.

<sup>85</sup> Section 100, Indian Patent Act, 1970

<sup>86</sup> Section 100 (3), Indian Patent Act, 1970

<sup>87</sup> (2008) 3 MLJ 599

<sup>88</sup> Section 102, Indian Patent Act, 1970

<sup>89</sup> Section 103, Indian Patent Act, 1970

<sup>90</sup> A statutory cure in the coronavirus era - compulsory licensing of patented drugs, Available at: <https://www.lexology.com/library/detail.aspx?g=84365952-e8c4-477c-ae82-ba16d04ca7a2>

step in, and grant non-exclusive licenses to third parties<sup>91</sup>, to produce the diagnostic kit/ vaccine at a determined rate of royalty till the situation persists. This option is a solution when no other measure to either convince the patent holder is feasible. Section 84 – Section 92 provides for compulsory licensing procedure. A compulsory license as explained earlier is a measure which can be utilised by countries, for manufacture and export of necessary pharmaceuticals. The measure however is used sparingly, and for good reason, that it should be one of the last measures, to force the hand of the government to intervene which can be a private agreement. The compulsory licensing provision has been only used once in India, in the case of Bayer v Natco,<sup>92</sup> for the cancer drug sorafenib tosylate. After that one case, where in public interest Natco, the generic company was given a compulsory license for the cancer drug. The reasoning for the judgement was based on the balance of a public interest and the private right of the patentee. The precedence was given to the public interest. Further it is important to note that in the case of a compulsory license, the application can only be made after three years of the grant of the patent and subject to the fact that the patent has not been sufficiently worked in India at reasonable prices. The evidence of a patent being sufficiently worked can be found via the form 27, through which the patentee has to annually provide information from the patentee as well as all the licensees to what extent the patent has been commercially worked in India. This if not satisfactory, then an applicant can approach for the grant of a compulsory license.

Further Section 92 specifically provides for compulsory license in special cases, such as national emergency, or extreme emergency, or a case of public non-commercial use and includes a public health crisis. Then in this case the non-exclusive license would be granted at such conditions that the articles manufactured are at the lowest possible prices.<sup>93</sup>

The next option within the patent mechanism is the nuclear option which is revocation of the Patent. Patent rights under Article 48 are always granted under certain conditions and are subject to those conditions being fulfilled. If those conditions are not fulfilled the government has a choice to revoke the patent. This power is granted under sections 64 – 66 of the Act. Specifically Section 66, which gives the government the power to revoke the

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<sup>91</sup> Section 84, Indian Patent Act, 1970

<sup>92</sup> Bayer v Natco, Order No. 45/2013 IPAB

<sup>93</sup> Section 92(1)(ii), Indian Patent Act, 1970

patent in public interest. If the government feels that a certain patent is '*mischievous to the state or generally prejudicial to the public*', it can, in public interest, revoke the patent. The patent holder will be duly heard, and a notification will then be issued in the official gazette.

There is the last option that is surrendering of the patent by the patent holder themselves which can also be exercised at this time.<sup>94</sup>

The Patent Act not only gives power to the central government to exercise any of the above options, it also empowers the government to grant compulsory license for the purpose of export to countries which has insufficient or no manufacturing capacity in the pharmaceutical sector for addressing the public health crisis.<sup>95</sup> Therefore India has a provision where it can also help other nations using a compulsory license. The patent act of the country therefore is very suitably prepared to not let patents be a hindrance, rather at this point be of some use to the government. Patents are the balance between public and private interests and at this point the scales tip towards the public interest.

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<sup>94</sup> Section 63, Indian Patent Act, 1970

<sup>95</sup> Section 92A, Indian Patent Act, 1970

## 6. Enforcement of IPR's and Balancing the public Interest:

The fundamental objective of TRIPS is to harmonise international trade by securing certain minimum standards to be followed by Member Countries. The public good principle that is essential to any intellectual property is also recognized by TRIPS. So, whenever there is a need to interpret the provisions of TRIPS, the balance by protecting both public good and the private interest shall be maintained. Article 1 of the TRIPS mandates the member States to adhere to the minimum standards only, it also gives the freedom to have 'more extensive protection than is required by this agreement' but that is up to the discretion of the member states to do so.

Article 1<sup>96</sup> defines the nature and scope of the agreement and the it gives freedom to the member states to adopt the means to implement the provisions in their own jurisdictions. Article 7 and Article 8 of the TRIPS shed more light on the scope by giving us the principle and the objectives of the TRIPS. Article 7 of TRIPS, expands the scope of the public interest balance by instructing that the enforcement of the agreement should lead to the promotion of knowledge and should be "a manner conducive to social and economic welfare"<sup>97</sup>. Article 8 of TRIPS, allows the member states to adopt measures necessary to protect Public health and nutrition, if they are not contradictory to the provisions of the TRIPS agreements.

Now when we are to interpret the provisions of Article 73 of the TRIPS agreement, it should be interpreted in light of the above provisions of TRIPS. In these crucial times of Pandemic, where public health is of paramount importance, relying on to the Article 73, which is a limitation on TRIPS, will further expands the scope of the agreement. The Security Exceptions clause in 73 is a standalone provision and the opening statement of the clause "Nothing in this Agreement shall be construed"<sup>98</sup> excludes the applicability of the foregoing provisions in toto, still, interpreting in light of the scope and

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<sup>96</sup>Article 1, Agreement of trade related aspects of Intellectual Property, 1994.

<sup>97</sup>Article 7, Agreement of trade related aspects of Intellectual Property, 1994.

<sup>98</sup>Article 73, Agreement of trade related aspects of Intellectual Property, 1994.

objectives of the trips will lead to a conclusion that the present crisis is sufficient to invoke the security exceptions clause by the member states, if required.

The Executive Director of the South Centre, Mr. *Carlos Correa*, wrote an open letter to the Director Generals of WHO, WIPO, and WTO emphasizing on the use of the Article 73(b) of the TRIPS agreement if it deemed necessary by the Member States. The letter states “support developing and other countries, as they may need, to make use of article 73(b) of the TRIPS Agreement to suspend the enforcement of any intellectual property right (including patents, designs and trade secrets) that may pose an obstacle to the procurement or local manufacturing of the products and devices necessary to protect their populations.”<sup>99</sup>

## 6.1 Power of Member country to suspend IPR enforcement to protect ‘it’s essential security interests’: Article 73(b) of TRIPs

Article 73 of the TRIP’s agreements sets out few security exceptions as against their commitment to TRIPS. One such exception is provided in favour of the Member States as Article 73 (b) of the agreements to protect “it’s essential security interests”. The Article 73(b) lays down three situations, which acts as a pre-condition for invoking this provision by the member states.

Article 73: Nothing in this Agreement shall be construed:

- (b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;
  - (i) relating to fissionable materials or the materials from which they are derived;

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<sup>99</sup>Open letter from Carlos Correa, Executive Director of the South Centre, COVID-19 PANDEMIC: ACCESS TO PREVENTION AND TREATMENT IS A MATTER OF NATIONAL AND INTERNATIONAL SECURITY, See the full text at <https://www.southcentre.int/COVID-19-open-letter/>.

(ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;

(iii) taken in time of war or other emergency in international relations;  
or

In the present scenario, when the world is struggling to find ways and means to tackle the pandemic, it is of utmost importance to have a clear outline of this provision and the applicability of this provision in the present COVID19 situation.

The only WTO Panel Report<sup>100</sup> discussing the scope of Article XXI(b)(iii) of the GATT 1994 (the mirror provision of Article 73 of TRIPS) suggests that the applicability of the Article 73 is dependent on whether the requirements of the enumerated subparagraphs are met or not and the same shall be objectively be found to meet the requirements in one of the enumerated subparagraphs of that provision.

This leads to the question that, what is the scope of the self-judging nature of the Article 73(b) of the TRIPS, is it self-judging or WTO panel can review the decision of invoking the same? To answer this, we must look into the nature of the mirror provision XXI(b)(iii) of the GATT 1994 and the views of the experts on the same.

First, The terms “which it considers necessary” which Sub-clause (a) and (b) of the article 73 of TRIPS differs from the subclause (c) of the Article, so the deliberate use of the words “it considers” in the first two provisions, reveals the intention of the member countries that these two provisions will be self-judging in nature. Whereas, the sub-clause (c) is subjected to a separate treatment by excluding any such terms in the provision, this reveals the decision of member states to make clause (a) and (b) self-judging is intentional and deliberate, and the same shall be treated as such.

Second, Article 73 of the TRIPS is a mirror provision of Article XXI(b)(iii) of the GATT, and if we look in to the scope of the GATT provision, GATT

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<sup>100</sup>Panel Report, RUSSIA - MEASURES CONCERNING TRAFFIC IN TRANSIT, WTO Doc. WT/DS512/R (adopted Apr. 05, 2019) [hereinafter WTO Panel Report (Russia – Traffic in Transit)]

Article XX sets out “General Exceptions” and none of the subparagraphs use the word ‘which it considers’ to explain the word ‘necessary’ in the provisions, also article XX of the GATT makes it a prerequisite to have a requirement of, non-discrimination to be taken into account before invoking this Claus. No such requirement is there in Article XXI(b)(iii) of the GATT, hence it can be derived that absence of any such requirement, which invites a WTO review, makes it self-judging.

Third, there have been many instances where Member Countries have accepted the expert views on Article XXI(b)(iii) of the GATT and considered it as self-judging.

The resolution of a GATT dispute between the United States and Czechoslovakia (1951) confirms the self-judging nature of GATT Article XXI (b)<sup>101</sup>.

In 1982, the European Communities (“EC”) and its member States, Canada, and Australia, used Article XXI to justify restricting trade in certain imports for non-economic reasons; and the EC representative explained the exercise of these “inherent rights” constitutes a “general exception” that “required neither notification, justification nor approval”<sup>102</sup>.

In 2019, The WTO Panel in the Russia – Traffic in Transit (DS 512) dispute<sup>103</sup>, between Ukraine and the Russian Federation concluded that the Article XXI(b)(iii) of the GATT 1994 is not totally “self-judging” but the power to review is limited to whether the requirements of the enumerated subparagraphs are met or not.

Hence it can be concluded that the Article 73 of the TRIPS can be invoked by a member country if any of the requirements in the subparagraphs are met, and the power to review the decision is limited only to the that extant not beyond.

To find of the applicability of the provision in the current situation we have to discuss, whether the current pandemic can be “other emergency in

<sup>101</sup>Summary Record of the Twenty-Second Meeting, GATT/CP.3/SR.22 (June 8, 1949), at 9.

<sup>102</sup> GATT Council, Minutes of Meeting, C/M/157 (June 22, 1982), at 10.

<sup>103</sup> Para7.102 of Panel Report, RUSSIA - MEASURES CONCERNING TRAFFIC IN TRANSIT, WTO Doc. WT/DS512/R (adopted Apr. 05, 2019)

international relations” within the scope of Article 73(b) (iii) of the TRIPS or not.

First, Even though the provision does not define what constitutes “other emergency in international relations” and whether or not it is limited to situations of armed-conflicts only, a clarification under the para 5(c) of the DOHA Declaration (Declaration on the TRIPS agreement and public health) clearly states that public health crises, including epidemics, can represent a national emergency or other circumstances of extreme urgency. Looking at the magnitude of implications of the present pandemic it can be an emergency, the fallout of which can be felt internationally. Hence, concluding that the present COVID19 can call for being “other emergency in international relations” will not be unfounded.

Second, The WTO panel report on this issue (Russia – Traffic in Transit) in 2019 clarified the obligation of good faith<sup>104</sup> is a general principle of law and a principle of general international law which underlies all treaties, as codified in Article 31(1) of the Vienna Convention which states that, "a treaty shall be interpreted in good faith ..." and Article 26 of the Convention that "every treaty ... must be performed by the parties in good faith". So, the global concern with regards to the pandemic leaves a very little scope in doubting the intention of the member country in invoking the exception the Article 73 of the TRIPS.

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<sup>104</sup>Para 7.132-38102 of Panel Report, RUSSIA - MEASURES CONCERNING TRAFFIC IN TRANSIT, WTO Doc. WT/DS512/R (adopted Apr. 05, 2019)

## 7. Conclusions and way forward:

The present COVID-19 situation has not only brought unprecedented human and humanitarian challenges but also has vastly impacted both the Global health and economy on an unimaginable scale. This pandemic has halted the global trade to the extent that many global institutions has reported negative growth rate for coming future. In such a situation the global community is looking for a solution in a form of a drug or a vaccine which can fight the COVID-19 and be a saviour of the humankind.

To end this pandemic, all the nations should move a hand to hand to handle the issues related to the COVID-19, there are already existing patents available to fight COVID-19, and also there are many inventions coming up to fight COVID-19. Access to the patented literature related to COVID-19 made easy by the initiatives takes by different IP offices and by WIPO as well. On the other hand, Funds have been collected and investing to develop vaccines. Many corporates came up with initiatives like pledging their Intellectual Property to end the COVID-19. When we look at all the developments related to fighting COVID-19 one thing is noticeably clear that we cannot take out the role of Intellectual Property rights to win over COVID-19.

In this paper we have discussed the present legal position at a global level to find out what are the various legal provisions which will come into play if we have a solution to the above problem in the form of a medicine invented by any individual or an organisation. It is the duty of the global communities to come up with a solution in these times and look beyond their own personal gains. Whether it is the idea of “VasudaivaKutumbaka” or global Human Rights instruments like, Universal Declaration of Human Rights or International Covenant on Economic, Social and Cultural Rights, Right to health is well recognised and the same needs to be respected and protected. The global community has responsibility to look further ten their own domestic situation come together to put up a universal fight against the pandemic. There are several efforts made to find out the solution for the COVID-19 in terms of diagnostics and treatment, in which most of them falls into the domain of Patent protection. But mentioning Patents and limiting it only to the protection of the rights of the Patent holder will be a misrepresentation of the Law whose primary objective is the progress of Science and encouragement of creation of

knowledge for the welfare of the people. The same is reiterated by the various initiatives taken up by people across the Globe, be it a collaborative effort to develop a vaccine or making all the literature easily available for use by the researchers to help them in the process of development of medicine. Many States, either by the way of passing a Law or by issuing a notification, has made the situation more conducive for use of existing patented technologies in the efforts of development of new drug to combat the pandemic. Even if we look into the existing Global patent regime, we will find that it supports and facilitates the invention of technologies in the time of pandemic and epidemics. The existing Patent instruments have forecasted a situation similar to this and they already have provisions to support the needs of the people in these times. A thorough analysis the legal provisions both at National and International level proves that Patents are not barriers to access to medicine, rather it Supports the accessibility and affordability by putting appropriate limitations on the rights of the patent holder.