



## Pandemic, Patents and Public Health

Padmavati Manchikanti<sup>†</sup> and Michelle Dias

Rajiv Gandhi School of IP Law, IIT Kharagpur, Kharagpur – 721 302, West Bengal, India

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The COVID-19 pandemic has compelled a relook at public healthcare and the patent systems. It has brought to halt livelihoods with devastating consequences to people's lives national economies. Global health security is at stake as there is a need to develop and deploy more vaccines, repurpose medicines and increase medical infrastructure support. Collaboration and collective response is imperative at international and national levels. IPR access is crucial in relation to public health. Many countries have issued new policies and enacted laws to make it easier for them to supply medicines to their population during the pandemic. Compulsory licensing has been used as an important mechanism to open up IP without the permission of patent holders. The present study analyses amendments to patent law and IP legislations that are effected from a cross country perspective during the pandemic time. It also examines international cooperation in the context of public health and IP under the TRIPS Agreement in view of the on-going consultation at the WTO. The study reveals differences in approaches to 'governmental use' of patents and access to know-how under the statutory framework. Improving the scope of use of products and process patents, suspension of patent term extension, consolidating the compulsory licensing mechanism, removal of inequity are the predominant aspects that are part of the amendments to patent law in the countries.

Pandemics like COVID-19 need legislative initiatives to secure healthcare system access for all citizens. Healthcare access includes ready availability of basic vaccines, drugs, medical devices and medical infrastructure. There is often a clash between access to healthcare as a fundamental right on one hand and the need to award monopolies in the form of IP rights as an incentive for innovations from the pharmaceutical industry on the other. Hence, obstacles arise in decision-making to balance innovation incentives and ensuring rights to access healthcare. Judicial decision-making and public policy-making have been always at the centre stage in earlier epidemics and now in the current pandemic making it imperative for countries to protect the health interests of their citizens.

**Keywords:** Pandemic, Covid-19, Public Health, Compulsory Licensing, TRIPS Agreement, Patents

The underpinning aspect is the need to consider the inalienable values of universal human rights, constitutional rights and respect ethical norms in public health decision-making. This is paramount to preserve trust in healthcare systems. The Declaration of Alma-Ata, 1978 recognised health as a fundamental right. It established primary health care as the route to accomplish the goal of Health for All.<sup>1</sup> The Declaration mentions the need to use global resources to achieve the target by the year 2000. Combating infectious disease requires coordinated action and it is with ample foresight that the need for international cooperation has been emphasised in those times itself.

International organisations have a crucial role to play in the global response and also carry out essential tasks to ensure coordinated response to meet health targets. At an international level the World Health Organisation (WHO), a specialized body of UN, is responsible for announcing public health measures and monitoring the international scenario in this area. The

announcement of the Public Health Emergency of International Concern (PHEIC) in the case of COVID-19 has opened the implementation of several of the initiatives by WHO and by way of its cooperation. Solutions to COVID19 also are covered by technologies that are patent protected. WHO activated a response for the pooling of patents. In May 2020, the WHO COVID-19 Technology Access Pool (C-TAP), in cooperation with the Government of Costa Rica and forty co-sponsors of the 'Solidarity Call to Action', has called on the global community to take action to exchange information, intellectual property and data required on a voluntary basis with respect to detection, prevention, treatment and response to COVID-19. The aim of C-TAP is also to speed up the scale-up of production and the elimination of access barriers in order to make products globally available.<sup>2</sup> Global health security is a world problem now. International Health Regulations mandate that implementation of public health measures should not be burdened with trade barriers. Alliances such as the Global Alliance on Vaccine Initiative, Measles and Rubella Initiative,

<sup>†</sup>Corresponding author: Email: mpadma@rgsoipl.iitkgp.ac.in

Global Polio Eradication Initiative and several others have provided timely assistance in the access to medical technologies.

The Agreement on Trade Related aspects of Intellectual Property Rights (TRIPS) which entered into force on 1<sup>st</sup> January 1995, establishes an obligation to lay down the requirements for the safeguard and compliance of minimum standards of IPR in member states. Members would need to facilitate efficient and sufficient protection of IPR with a view to remove misrepresentations and barriers to foreign trade. The race for the COVID-19 vaccine and rivalry between vaccine manufacturers has been at the centre of global debate. In October 2020, India and South Africa sent a communication (IP/C/W/669) to the WTO for the TRIPS council to consider the waiving of the enforcement of the provisions in relation to copyright (Section I), industrial designs (Section 4), patents (Section 5) and undisclosed information (Section 7) that would ease out the access to COVID19 related technologies.<sup>3</sup> Such a transitory revocation of intellectual property would also make it possible for non-patent holders to manufacture required medical devices such as ventilators, masks and protective equipment. A temporary waiver would prevent countries to bring trade related challenges under the WTO Dispute settlement forum against countries that grant compulsory licences in response to COVID19. Further consultations have been taken up and different viewpoints emerged. Developing countries argue that there is lock up of technology as part of bilateral understanding, limitation of the COVAX facility due to disproportionate needs in case of developing countries and threat of lawsuits. The IP holders believe that instead of a waiver the voluntary licensing approach is more suitable.<sup>4</sup> Based on the meeting in early May 2021, the revision to the proposal is being considered. It must be understood that a host of non-patent IP are also essential for the development of solutions to combat the pandemic. The UN Secretary General António Guterres call – “*Its time for Science and Solidarity*” has been timely. In its new outreach plan the UN appealed that a coordinated approach involving equity will help solve the current pandemic. This campaign also addresses the aspect of disinformation which negates efforts to solve the pandemic. The UN has also launched a humanitarian response plan together with UNICEF and the WHO.<sup>5</sup> The present study examines the context of public health and patents in the current

pandemic situation. It analyses how health directives influence invoking of patent legislations from the standpoint of how the provisions provide for mandatory or permissive aspects. Further, amendments in patent law related to governmental use and compulsory licensing from a cross country perspective are analysed.

Public health concerns and IP concerns are at cross roads in the current pandemic. Arguments have been put forward for incentivisation and open access of the healthcare technologies alike in the wake of the pandemic. 60% of the emerging diseases are zoonotic in origin. Response of international health regulations, national health systems and local health mechanism has an important bearing of the overall measurement of the efficiency of a healthcare system. Only 30% of the WHO members are compliant with the international health regulations.

#### **Global Collaboration to Deal with Pandemic**

Not only technical guidance is technical guidance that is required during a disease outbreak but also a need for cooperation that is simple and rational. Such a framework of cooperation that exists between nations is an important mode of dealing with mutual health threats. Further, exchanging information and experience on pathogen transmission routes, the illness they cause, and potential solutions speeds up learning and allows for more development. The establishment of rules and principles facilitates knowledge comparability, promotes best practices and the development of common norms. The WHO and its World Health Assembly (WHA) serve as a platform for countries to exchange knowledge, discuss issues and make joint decisions.<sup>6</sup>

The WHO Director General announced the epidemic a Public Health Emergency of International Concern (PHEIC) on 30<sup>th</sup> January 2020, based on the advice and recommendation of the Emergency Committee. From 11<sup>th</sup> to 12<sup>th</sup> February 2020, world experts on COVID-19 convened at the WHO’s Geneva headquarters to determine the existing state of understanding regarding the emerging virus, agree on scientific questions that must be addressed urgently and collaboration opportunities to promote and finance priority research to help contain the epidemic (COVID-19 Public Health Emergency of International Concern (PHEIC) Global Research and Innovation Forum).

Health crisis on global fore can be very challenging to not only manufacture vaccines but also ensure their equitable distribution and further sharing of clinical trial information. International collaboration is also

needed on advice, technical guidance, response research and training. In the absence of an internationally binding agreement on equal access, pharmaceutical companies may prioritize their own interests, favouring more prosperous countries and segments of the population. “Vaccine imperialism” has become a challenge as some countries demand privileged right to vaccinations for their people, while others seek to prioritize economic interests for their pharmaceutical industries.<sup>7</sup> It has been observed that the current pandemic would need innovative legal, operational and financial strategies, compulsory licences, patent pools, advanced business obligations, a multinational buying structure, price caps and mixed financing.<sup>8</sup>

To minimize socio-economic consequences, a concerted response and continued demand for collaboration on global scale is of utmost importance. Multinational organisations such as the WHO are crucial.<sup>9</sup> Through its work closely with influential multi-stakeholder partnerships including the Global Alliance for Vaccines and Immunization (GAVI) and the Coalition for Disease Preparedness Innovation (CEPI) it is coordinating the efforts of the health crisis that countries are grappling in the pandemic.<sup>10</sup> In April 2020, the WHO launched the “Access to COVID-19 Resources (ACT) Accelerator,” a global collaboration that includes the WHO, CEPI, and GAVI, among others, to accelerate the development, manufacturing, and distribution of new COVID-19 therapeutics and vaccines.<sup>11</sup> It also emphasised that for the global supply of the COVID-19 vaccine, coordinated national efforts should be planned.

#### **Evolution of COVAX**

The Access to Covid19 Tools (ACT) Accelerator is a global partnership aimed at accelerating the growth, manufacturing, and equal distribution of COVID-19 studies, therapies and vaccines. GAVI, the CEPI and WHO are leading the COVID19 Vaccine (COVAX) facility. COVAX aims to speed up the growth and production of COVID-19 vaccines while also ensuring equal and balanced access for all countries around the world. This is the world’s largest actively controlled inventory of COVID-19 vaccine candidates. It provides access to a wide variety of vaccine candidates appropriate for a range of circumstances and settings to self-financing members and those qualifying for assistance through the GAVI COVAX Advance Market Commitment.<sup>12</sup> While the opportunity to mobilize vaccination to combat the pandemic is more

important than ever, collaboration to ensure that greater access, information exchange and newer medications and medical infrastructure need to be hastened. It encourages pooling of patents such that the transaction costs could be reduced. This effort is to provide the sharing of data, available knowledge and IP. Such an effort takes into consideration safety only when all are vaccinated and receiving medication as required.<sup>13</sup>

Fully self-financing countries (the high income countries and upper middle income countries representing 53% of the countries) make a direct contribution to this facility by agreeing to buy vaccine doses for the most vulnerable populations. Countries who are funded (the low income countries and low middle income countries which are 47% represent 47% of the countries) have their financial contributions to the facility secured by the process of Official Development Assistance.<sup>14</sup> COVAX announced in January 2021 that it had signed an advance purchasing agreement with Pfizer for up to 40 million doses of the Pfizer-BioNTech vaccine candidate, which has already been approved by the WHO for Emergency Use. The timely and fair distribution of vaccinations is not only a moral but also a strategic and financial imperative. In February 2021, India used the GAVI’s COVAX facility to export Covid-19 vaccines to Africa. The Serum Institute of India had sent the first batch of AstraZeneca/Oxford University-developed vaccine shots for the COVAX global inoculation scheme, demonstrating its contribution to provide COVID-19 vaccines.<sup>15</sup> By supplying the first batch of COVID-19 vaccines to Accra, Ghana, marks a part of an ambitious attempt to produce at least 2 billion doses of COVID-19 vaccines by the end of 2021.<sup>16</sup> COVAX facility has the mechanism of voluntary licensing where COVAX obtains license from the vaccine producers to distribute it to other countries. The 6<sup>th</sup> Access to COVID19 tools (ACT) accelerator facilitation council meeting (on 12 May 2021) emphasised on the need to step up production and increase uptake of COVID19 tools. Over 100 countries are being shipped of medical facilities. As ‘virus variants’ continue to emerge, health sector has been further disrupted. The WHO regulatory updates sign a positive message of increased consultation for global solutions to tackle the new strains. To ensure quality assurance, the COVAX facility has been advised to consider only those products listed by WHO Emergency Use Listing or Prequalification or under exceptional circumstances products that approved by specified stringent

regulatory authorities. In the First meeting of the task force on COVID-19 vaccines, therapeutics and diagnostics for developing countries, the Heads of the World Bank Group, International Monetary Fund, WHO and WTO emphasised on the urgent need to increase supplies of vaccines, therapeutics and diagnostics in developing countries and enhance sharing of information in deployment of COVID-19 vaccines. The current context provides a compelling need to relook at the importance of the public health and IP discussions in relation to the TRIPS Agreement.

### **A relook at Article 31 of TRIPS**

Article 31 of the TRIPS Agreement states, among other things, that the individual or company seeking a license must have made a good effort to procure a voluntary license from the patent holder on equal business terms. Only if this fail a compulsory license be issued, and the patent owner must receive payment. In Article 31(h), there is a mention of “economic value of the authorisation” but no metric is offered for “adequate remuneration” or “economic benefit”. In most cases, acceptable royalties have been determined depending on what the patentee has offered based on past licenses in similar circumstances. It has been observed that such an application is imperfect when dealing with foreign exports, as prices and uncertainties will escalate the price in a huge manner.<sup>17</sup>

The need for catering to domestic manufacturing has been the hallmark of how governments derive the context of opening up of compulsory licensing mechanism. Developing nations concerted efforts to prohibit patent immunity to enable access to life-saving medicines had necessitated the need for a post TRIPS debate on public health resulting in the Doha Declaration.<sup>18</sup>

### **Doha Declaration on Public Health**

A significant number of developing countries, including the African Community, sent a joint request for a special declaration on the TRIPS Agreement and access to medicinal products to the IP/C/W/296 TRIPS meeting, which formed the basis of the Doha Resolution. The developing countries in one voice set the agenda by emphasizing on the flexibility of TRIPS in relation to public health.<sup>19</sup> For the first time on the WTO record, developed country participants, including the European Commission, Japan, Switzerland, and the United States, decided in June

2001 that the TRIPS Agreement provided a number of flexibilities, including compulsory, unconditional licencing. Some countries tried to restrict the scope of the Declaration. In respect to compulsory licences, Article 31 of TRIPS states:

*“Each Member has the right to allow other use of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government, and to determine the grounds upon which such use is allowed”.*

More specifically mentioned in the Doha Declaration Para 6, recognizes the difficulties faced by countries incapable of manufacturing abilities,

*“We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement.”*

Several countries have issued new measures and passed legislation to make it easier for them to provide drugs to their citizens during the pandemic. Compulsory licensing has become a key tool for opening up IP without the consent of patent holders. Agreements such as the TRIPS along with the Doha Declaration have aided the implementation of compulsory licensing. It is amply clear that the scale of requirements is huge to deal with the current pandemic. The need for conditionality and governmental exceptions available under patent legislations of many countries. In the following section, the context of compulsory licensing in light of Article 31 of the TRIPS and the status of the proposals submitted to the WTO for a partial waiver of IP are discussed.

Monopoly in a patent right is conditional in nature. The scope of restrictions depends on patent law of a given country. In certain cases, the government may compel a right holder to sell his patent to a third party in return of adequate royalties. Compulsory license allows governments to use the patented product, or authorize a third party that is willing do so, without the transfer of title. These steps are taken in order to implement public health programs that improve low-income countries access to medicine. Compulsory licensing has the effect of increasing competition, improving medicine access and potentially lowering costs. This has been invoked in the case of pharmaceuticals where public access of the technology

takes precedence over the patent holder's reserved interests and proprietary right to use it. The Doha Declaration reaffirmed governments' absolute right to take steps to protect public health by requiring WTO member countries to issue compulsory licenses to export generic versions of patented medicines to countries with insufficient to no manufacturing capability. COVID-19 vaccine research, approval, and production are moving at a breakneck pace. Many national vaccine programs are being thrown into disarray as a result of setbacks, prompting demands to policymakers and suppliers to work together to boost demand. To improve the availability of potential vaccines, several pharmaceutical firms, including AstraZeneca, have concluded sub-licence agreements with many manufacturers, including the Serum Institute of India. Gilead has already granted its Remdesivir patents to generic manufacturers in India, Pakistan, and Egypt, allowing them to sell the drug in 127 countries.

Compulsory licensing bases public interest central in determining such a grant. In the current situation, where the pandemic has afflicted people from all walks of life, there is an urgent need for medication and/or vaccine to fight COVID 19. It is also reasonable that patentee can be reasonably compensated for the IP in view of the significant investment in development of technology. Voluntary licensing mechanism either on an individual basis or in a coalition form has led to some access of technologies during the pandemic time. But as the world grapples now with 'variants of concern' and a crippling healthcare system there is a compelling need for opening up access to technologies to a greater extent.

#### **WTO Waiver and Opening Up IP to Meet Public Health Requirements**

Countries have refrained from arbitrarily suspending IP rights in their respective jurisdictions. WTO has served as a platform for organizing policies surrounding intellectual property rights (IPRs) to allow greater access to technologies. Under the WTO waiver for IP, countries are discussing the merits of waiving the adoption, operation, or compliance of Sections 1 (copyright), 4 (industrial designs), 5 (patents) and 7 (undisclosed information) of Part II of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) in relation to COVID-19 avoidance, containment, or care for a given duration, in response to a proposal submitted by India and South Africa. India, known as the pharmaceutical hub of the world

because it supplies vaccines to more than seventy countries on a humanitarian and economic basis, is leading the proposal for a temporary TRIPS waiver for IP at the World Trade Organization (WTO). If India is successful in obtaining the planned TRIPS waiver, vaccine costs will be significantly reduced, allowing free flow of drugs and quick technology transition around the world. However, since many western nations are opposed to the decision, having the plan cleared and forming consensus is not going to happen soon enough. Their interests in view of patent linkage in Asia would be also affected.<sup>20</sup> India and South Africa's initiative received an impetus when a coalition of least developed countries (LDCs) recently endorsed it. So far, approximately ninety countries have openly supported this waiver. A revised decision text was published on 25<sup>th</sup> May 2021, which urged the WTO to also consider the emergence of the new variants of the SARS-COV2 virus, effect on children, the need to deploy 'health products and technologies' taking into consideration IP issues. The objectives set forth in Article 7 of the TRIPS Agreement define the essence of how IPRs should be realised i.e., to promote technological innovation, promote dissemination of technology taking to consideration rights and obligation. Further, Article 8 emphasises on the need to formulate and amend laws and regulations to enable protection of public health and nutrition and sectors of vital importance for socio-economic and technological developments. It is amply evident that the joint implementation of both these in the pandemic needs to be considered with the wider approach of securing health technologies access. The need for justifying IPR in relation to these articles should be consistent with the existing realities.

Accessibility, affordability and availability need to continue to be the hallmark of providing health justice in these times of the pandemic. A dedicated effort to improve rights for public is emphasised by WHO and various international collaborations percolating down to the individual countries. Till the time we have a coordinated response under the WTO countries need to depend on domestic measures and existing international cooperation. Compulsory licensing proves to be a quick fix to provide equitable access to medicines and health related drugs during emergencies. The Patents Act, 1970 of India has provisions to implement it when the need arises. Some patent holders freely licence their drugs to generic producers in order to increase access. This is achieved either directly

between patent holders and generic producers or enabled by organisations such as the Medicine Patent Pool. Voluntary licenses, on the other hand, are often used to limit the geographical areas where the licensed commodity can be sold.<sup>21</sup> Compulsory licenses could be an ideal choice for certain countries to increase access to patented medication where there is no provision or jurisdiction to obtain a voluntary license for a particular medicine. Price reduction of patented medicine under compulsory licencing is known and is stipulated to balance interests of the patentee. It is clear that effect of compulsory licencing will rely on the further refinement of procedures to promote its application, growth of technical and manufacturing technologies in developed nations, and the value of life-saving drugs.<sup>22</sup> The usefulness of compulsory licencing threats in agreements with patent holders as a mechanism to lower drug costs is commonly known.<sup>23</sup> Some studies indicate that compulsory licencing has been a successful way for obtaining price increases for patented pharmaceutical products.<sup>24</sup> It has been observed that alternative measures can be more successful than the actual issuing of compulsory licences, such as cost bargaining and voluntary licencing agreements.<sup>25</sup> There are certain limitations in the two methods i.e. compulsory licencing and voluntary licencing. Compulsory licencing is often the only option when patent holder does not reduce price or is not willing to grant a voluntary license.<sup>26</sup> Further, regional or economic restrictions and certain arbitrary licence conditions enforced by pharmaceutical firms reduce the feasibility of voluntary licencing.<sup>27</sup>

The developing countries, most often, are the ones prompt in invoking compulsory licensing as a timely response to solve difficulties faced due to lack of access of a patented product. As a global response, it is desirable that the WTO and WHO open up IP to pool information that would be beneficial globally. The threat of compulsory licensing nevertheless is essential. It makes sense for a country to grant a compulsory license to purchase a prescription drug for a health condition only where there are potential existing generic manufacturers or prospective generic producers. While international cooperation is a requirement for dealing with the existing crisis, national efforts are key to implementation of health mandates. Implementation of national legislative responses to health emergencies not only support domestic measures but also provide opportunities for cooperation in a cross country context.

### **Cross-Country Response during Pandemic**

Pandemic response is multifaceted. Health equity has become the most debated aspect and certainly there are inequalities in this regard. During the pandemic several countries had made amendments to the patent legislation and/or other relevant legislations to enable governments to provide access to patented medicines and medical infrastructure. Cross country analysis of the amendments to patent legislations and other laws provides an important context to understand national policy considerations and preparedness. In the following section, individual country responses are discussed.

On 25<sup>th</sup> March 2020, Canada introduced the “COVID-19 Emergency Response Act” as a legislature enabling a patented technology to be created, marketed, and used by the Canadian state. Under Part 12 and Section 51 amendments have been effected in the Patent Act. Under the current legislation, a manufacturing licence may be granted without first consulting with the holder of the IP or possessing the capacity to manufacture locally, but the patentee must be paid. Under the current Section 19.4 of the Canadian Patent Act, the government may grant compulsory licences to third parties if the Minister of Health confirms a national emergency<sup>28</sup> prior to 30<sup>th</sup> September 2020.

#### **Application by Minister**

*19.4 (1) The Commissioner shall, on the application of the Minister of Health, authorize the Government of Canada and any person specified in the application to make, construct, use and sell a patented invention to the extent necessary to respond to the public health emergency described in the application.*

#### **Contents of application**

*(2) The application must*

- (a) set out the name of the patentee and the number, as recorded in the Patent Office, of the patent issued in respect of the patented invention;*
- (b) include a confirmation that the Chief Public Health Officer, appointed under subsection 6(1) of the Public Health Agency of Canada Act, believes that there is a public health emergency that is a matter of national concern;*
- (c) include a description of the public health emergency; and*
- (d) specify a person, if any, that is to be authorized to make, construct, use and sell*

*the patented invention for the purposes of responding to the public health emergency.*  
(emphasis added)

The Canadian Government has no obligation to negotiate with the patent holder before granting a license to a third party to manufacture a medicine. The patentee would be compensated with the adequate remuneration as determined by the Commissioner taking into the circumstances, economic significance of the authorization and the extent to which the patented invention is produced, built, used, and sold.

In case of France, on 23<sup>rd</sup> March 2020, a new law 'Emergency Law No. 2020-290' was passed that brought in amendments to the Public Health Code. Title 1 deals with State of Health Emergency (Article 1 to 8). Several amendments were effected to improve health protection, health administration and transparency in dealing with the pandemic. Subject to the declaration of the State of health emergency as outlined in Article 1, Article 2 of the Code brings in measures to deal with health threats and deal with crisis. The Prime Minister can exercise price regulation under Article L.3131-15 and take measures for manufacture of drugs to combat the health emergency.

*Article L3131.15. In the territorial districts where the state of health emergency is declared, the Prime Minister may, by regulatory decree taken on the report of the Minister responsible for health, for the sole purpose of guaranteeing public health*

8. *Take temporary measures to control the prices of certain products made necessary to prevent or correct the tensions observed on the market for certain products; the National Consumer Council is informed of the measures taken in this direction;*
9. *As necessary, take any measure allowing the provision of the patients of appropriate drugs for the eradication of the health disaster;*

Article L613-16 and Article L613-17 of the French Intellectual Property Code provide for a compulsory non-exclusive license. Under Article L613-16, the three conditions of no agreement reached with patent holder, patented protecting the invention must be a medical product process of obtaining it and invoking administrative or Court decisions in conditions of high

pricing or insufficient products available must be met.

Some of the advanced countries which have been a hub for manufacturing have also sought to amend their patent law in the wake of the pandemic. In case of Germany, Section 13 of the German Patent Act provides for use of an invention for public welfare.

As per Section 13 of the Act,

- (1) *The patent does not have any effect if the Federal Government orders that the invention be used in the interests of public welfare. Furthermore, it does not extend to a use of the invention that is ordered in the interest of federal security by the competent highest federal authority or on their behalf by a subordinate body.*

The Federal Administrative Court is responsible for dealing with matters related to patent contests by resolving disputes and in conditions of the need for a mandatory licensing ensure appropriate remuneration from the federal government to the patent holder. Germany passed the Prevention and Control of Infectious Diseases in Humans Act on 28<sup>th</sup> March 2020, authorising rolling out of compulsory licensing. Under Section 5(2) of the Epidemic Protection Act, the Federal Ministry of Health is authorised to address the epidemic situation keeping in view national considerations. There is a greater scope of the 'use orders' in view of a parliament-declared nationwide crisis that goes beyond Section 13 of the German Patent Act.

In the case of Israel, under Article Three: Use of Inventions in the Interest of the State, Sections 104 and 105 of Israel's Patents Law 5727-1967 authorise compulsory licences to be granted by the government if the Minister "finds that this is required in the interests of national security or the protection of vital supplies and services".

*Section 104 Right of State to exploit invention-*

104. *The Minister may permit the exploitation of an invention by Government departments or by an enterprise or agency of the State, whether a patent for it has or has not already been granted or has not already been applied for, if he finds that that is necessary in the interests of the National security or of the maintenance of essential supplies and services.*

*Section 105 Right of State to permit exploitation of invention-*

105. *The Minister may, if he finds that that is necessary for the purposes enumerated in section 104, grant a permit under that section to a person who operates under contract with the State, in order to ensure or facilitate the implementation of that contract and for the requirements of the State only.*”(emphasis added)

On 18<sup>th</sup> March 2020, Israel issued a compulsory licence to receive the generic versions of the HIV/AIDS antiretroviral drug Kaletra. This drug is a mixture of AbbVie’s antiviral medications lopinavir and ritonavir. Kaletra's patent expires in Israel only in 2024. This drug is off patent in many countries including India. The issuance of this permit by the Health Ministry provided an opportunity to import generic versions of Kaletra only for treatment of COVID-19. In response to the issuance, AbbVie immediately announced it would not impose its patent rights on Kaletra. In the pandemic time, this is one example of how invoking a compulsory licensing has eased out the use of generics to deal with the potential health crisis.

Chile passed a decree (on 7<sup>th</sup> March, 2020) that was published in the Official Gazette by which the Ministry of Health, Chile declared ESPII, a Sanitary Emergency due to a Public health emergency of International Importance, in view of the outbreak of the SARS COV-2 virus. On 17<sup>th</sup> March, 2020, the Chilean Chamber of Deputies adopted the “Resolution 896 2020”. Part III (2) of the Resolution mandates the Minister of Health to grant non voluntary licenses with respect to medicines and medical infrastructure that is necessary to prevent, diagnose and treat COVID-19.

*Part III. 2. REQUIRE: .....for the granting of non-voluntary licenses provided in Article 51 No. 2 of Industrial Property Law No. 19.039, regarding all patent applications and issued patents related to vaccines, drugs, diagnostics, devices, supplies, and other technologies useful for the surveillance, prevention, detection, diagnosis and treatment of persons infected with the coronavirus SARS-CoV-2, for public health grounds.*

Further, under Part III of the resolution the Minister of Health is further required prepare a report on the existence of patents and other industrial property rights as determined by the National Institute of Industrial Property. The assessment of intellectual property status would help to know whether or not there are restrictions to import or manufacturing in Chile.

It is interesting to note that very early in the pandemic time, Chile has not only recognized the need to open up IP but also emphasized through this Resolution that there is also a need for access to information from the WHO Global Observatory.

4. *TO REQUIRE the Minister of Health to request the World Health Organization (WHO) Global Observatory on Health R&D to collect information on the research and development costs directly associated with vaccines, drugs, diagnostics, devices, supplies, and other technologies useful for the surveillance, prevention, detection, diagnosis and treatment of COVID-19, including the investments made by public sector institutions, private sector institutions, and charities.*

Australia along with other countries submitted a communication (IP/C/W/671) to the proposed discussions on WTO waiver of IP. On 27<sup>th</sup> February, 2020, the Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act 2020 was introduced in Australia that brought in several changes including the phasing out of the innovation patent system. This phase out will begin from 26<sup>th</sup> August, 2021. Further, the scope of the provisions in relation to Crown use and the compulsory licence were expanded.

Intellectual Property Laws Amendment (Productivity Commission Response Part 2 and Other Measures) Act, 2020 introduced Section 160A into Australian Patent Act, 1990:

*160A When an invention is exploited for Crown purposes*

- (1) *An invention is exploited for Crown purposes if:*
- (a) *the invention is exploited for the services of a relevant authority; and*
  - (b) *the exploitation is by:*
    - (i) *the relevant authority; or*
    - (ii) *if a person is authorised, in writing, by the relevant authority for the purposes of this subparagraph—the person for the relevant authority.*

This introduced provision for crown use would allow governments to exploit patented inventions in certain conditions, without infringing patent rights. The Section 163(3) of the Patents Act sets out several conditions. First, the approval of an authorisation for use of a patented invention will be given when efforts have failed to obtain a license. The time period of at



least 14 days would be given by the relevant authority for the exploitation of the invention for crown purposes. The relevant authorities include Commonwealth, State and Territory jurisdictions. Commonwealth and States can utilise 'Crown use' to facilitate the urgent manufacture of medical supplies for use in the treatment or prevention of COVID-19 infection.

Indonesia is one of the countries that is supporting the WTO waiver proposal for opening up of IP for solutions for COVID-19. In the preamble of the patent law, public purpose in relation to patents is indicated as '*that patents are intellectual property granted by the state to inventors for the results of their inventions in the field of technology which have a strategic role in supporting national development and advancing public welfare.*'

Under the Patent Law No. 13 of 2016, Article 1 (15) outlines the context of governmental use of a patent.

*15. Rewards are compensation received by a party entitled to obtain a Patent for an invention produced, in a working relationship or an invention produced by either an employee or a worker who uses the data and/or facilities available in his work even though the agreement does not require him to produce the invention. or the patent holder of an invention produced by an inventor in an official relationship or the patent holder of a compulsory licensee or a patent holder of a patent that is operated by the government.*

In Indonesia, a third party can file an application for a compulsory license pursuant to Article 82 if an invention is not worked within thirty-six months of grant. On 2<sup>th</sup> November 2020, the President of Indonesia passed the Omnibus Law on Job Creation through *Law No.11 of 2020 concerning Job Creation* (called the "Job Creation Law"), which also took effect on the same day. Under Chapter VI, on Ease of doing Business, Article 107 of the Job Creation Law amends certain provisions in the Patent Law No. 13 of 2016. Article 20 of the Patent Law obliged patent holders to manufacture the product or use the process in Indonesia within 3 years of grant date. Under the new regulation, Regulation No. 14 of 2021, patent owners cannot postpone the working of their patent invention under Article 20.

Brazil has been supporting the recent IP waiver proposition at WTO. Three new bills, Bills 1184 of

2020, 1320 of 2020 and 1462 of 2020, were proposed in Brazil for the grant of compulsory licensing during the pandemic. The Bill 1184 of 2020 seeks to allow the compulsory licensing of patents by the Federal Government during the state of health emergency established by Law No. 13.979 of February 6. The Bill 1320 of 2020 seeks to eliminate delays in the grant of compulsory licenses leading to an automatic application under the state of public health emergency. Three conditions that need to be considered in such cases are validity of the license for duration of the public health emergency, remuneration of the patent holder fixed at 1.5% of the sale price to the Government and titleholder of the compulsory licensed patent or patent application will be obliged to provide to the Government all necessary and sufficient information for the effective reproduction of the technologies. The Bill 1462 of 2020 seeks to amend the compulsory licensing provisions of Article 71 of Law No. 9279/1996 of the Industrial Property statute. The objective is to include the option of invoking national or international emergency status.

Article 71 of the Law No. 9279 of May 14, 1996:

*71. In cases of national emergency or of public interest, as declared in an act of the Federal Executive Power, and provided the patent holder or his licensee does not fulfil such need, a temporary and non-exclusive compulsory license for exploiting the patent may be granted, ex officio, without prejudice to the rights of the respective titleholder.*

*Sole Paragraph. The act of granting the license shall establish its term and the possibility of extension.*

From an Indian standpoint, along with S Africa and others it is participating in the consultations on the temporary waiver of IP at the WTO forum. In the recent case<sup>29</sup> of 22<sup>nd</sup> April, 2021 the Delhi High Court ordered the government of the national capital territory of India and others to respond to several aspects on its preparedness to deal with medical oxygen supplies, on the need to invoke compulsory licenses under Section 84, utilise special provisions for compulsory licenses or notification by the Central government under Section 92 and use of inventions for government purpose under Section 100 of the Patents Act, 1970. Subsequent to this, the Supreme Court on its own motion in the case decided<sup>30</sup> by a three judge Bench on April 30<sup>th</sup> 2021 urged the

Central Government to invoke the provisions of the Patents Act 1970 to open up the access to patented medicines and provide an opportunity for generic manufacturers to manufacture the drugs and device needed for dealing with the pandemic. The Court emphasised on the need to make vaccines and essential drugs at affordable prices among other aspects. *NatcoPharma Limited* has filed for a compulsory license under Section 92 (1) read with 92 (3) of the Patents Act 1970. This license is to produce Baricitinib which is under patent protection in India. Incyte Holdings Corporation holds the patent for the same. Unmet needs such as restricted availability and excessive price are the grounds used for invoking compulsory licensing. Natco was given emergency use authorisation by the CDSCO to manufacture Baricitinib for use against COVID-19. Even as the application was pending Eli Lilly entered into a voluntary licensing deal with Natco whereby it provided a royalty-free, non-exclusive voluntary license for manufacturing and commercialisation of the drug. Eventually, Natco withdrew its compulsory license application from the Indian Patent Office.

The analysis of the cross country changes to Patent Law during the pandemic time has implications from the context of public health. In the first quarter of the pandemic many countries enacted legislations that would help governments invoke emergency provisions for use of patents to initiate public health measures. This displayed their preparedness ahead of the pandemic spread. In the second quarter of 2020, coalition on pandemic solutions for pooling technologies and the call for suspension of patent rights gained ground. Voluntary licensing opportunities were opened up on various vaccines and drugs. In the last quarter WTO consultation for IP waiver was initiated. As the pandemic continues to rage across countries with devastating proportions and with variants emerging, there is only consideration that countries need to think – access to technologies and access to information to deal with the pandemic.

### Conclusion

Resolving pandemic crisis has been the primary concern for all those involved in identifying solutions. Institutional competence has been under challenge across the world in dealing with such a situation. Response is the key and time is the essence. The

importance of world fora that directly or indirectly deal with public health is paramount. The development of a collective and coordinated effort for vaccines, medicines, medical infrastructure, sharing know-how and enhancing their availability and accessibility under the WHO is an important development. For more than 10 months the COVAX facility has aided access to medicinal products and test kits to various countries and helped in pooling technologies to deal with the global health crisis. The WHO's leadership is critical in persuading individual nations to provide access to technologies as well as participate in the collaboration and cooperation. Further, the need for information sharing on outcomes is paramount for repositioning COVID19 solutions and approaches. It is time that WHO revisits the International Health Regulations for suitable amendments.

The temporary waiver of IP proposal to WTO initiated by India and S. Africa supported by many countries is a very important development considering the circumstances. Proponents for suspending IP rights and those who advocate for protection of IP rights have their respective arguments. The urgent need for access of technologies is what demands a need to focus on ways to enable IP use for public health. Nations have a combined responsibility. Local scarcity of vaccine and low income countries not having access to vaccine is a serious concern. It is not unreasonable to expect WTO to act in an urgent manner. With new 'variants of concern' of the virus developing, the demand for diversified access to medicines, diagnostics and therapies is increasing by the day. The 'text based negotiations' under the WTO would need to take into consideration the mandates of WHO. The enormous effort of the Doha Declaration on Public Health would become meaningless unless its underpinnings are considered. The 'gestation period' continues on the negotiations. It is time to see whether 'public interest' will be served from the point of view of Article 8 of TRIPS agreement. The World Intellectual Property Organisation (WIPO) needs to take forward the context of 'development dimension' in the context of the pandemic as well. In the recent years, WIPO has enabled access to technologies by negotiating treaties to promote access of IP. It is expected that WIPO play a leading role in promoting discussions on access to IP for public health purposes.

Another important area of focus is national response. As witnessed parallel responses by

countries in the early part of the pandemic is a positive development. There are general conditions as well as specific conditions in patent law that prevent the abuse and undue enrichment of monopoly by the patentee. Analysis of the cross country legislative response indicates to the expansion of the 'governmental use' clause by amendments to patent legislations to take care of public health measures. In certain countries the amendments reflect the scope and coverage of access to not only medicines and vaccines but a whole range of medical infrastructure. Preparedness is the key to remove constraints in implementation of such measures. The amendments are not only to IP legislations but also to the health related laws as well. The role of individual governments measures to deal with pandemic provisioning, need to utilise generics and provide for local decision making is paramount. As urgency is the key, interdependency between countries is necessary to address composite solutions for COVID-19. A significant part of the solutions to the COVID-19 are covered by IP rights. Arguments for reasonable compensation for sharing IP are relevant. Access to IP is an urgent requirement in current circumstances. There cannot be second thoughts about this fact.

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