INDIA'S FIRST MAGAZINE ON LEGAL AND CORPORATE AFFAIRS

LEX WITNESS

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Gearing Up for A Fresh Start?

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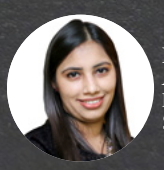

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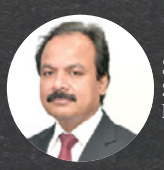

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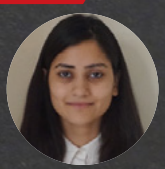

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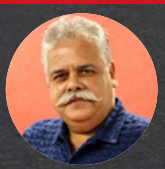

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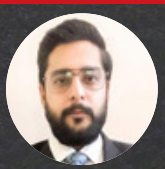

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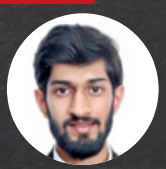

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Gearing Up for A Fresh Start?

Pertinence of Patents in Thwarting the Pandemic (COVID-19)

Surbhi Singh

The horrific tale of novel corona virus (COVID-19) has become our new reality which has disrupted the lives of masses across the globe. In fact, the transmission rate of the COVID-19 virus is so glaring that the same has been declared as a pandemic by the World Health Organisation (WHO). The pandemic is estimated to have affected least 177 countries[1] and unfortunately, is tenaciously emerging, leading to a surge in the number of deaths around the world. As on May 03, 2020 there are around 40263confirmed case and at least 1306 have died due to the outbreak of Corona virus in India[2]. Consequently, with an aim to inhibit further dissemination of the virus, the government has implemented precautionary measures such as travel bans, nationwide lock down, embargo on sale of non-essential items, community surveillance, sanitisation of public places, etc. However, implementation of these measure comes with a cost in form of market slumps and crippled economies. Moreover, considering the pace and magnitude at which the virus is spreading, it is apparent that these initiatives will not be adequate to combat the present crises and the only way to put an end to this ordeal would be to device an effective cure for COVID-19.

Meanwhile, the mankind is grappling to adapt to the 'new reality', the uncertainty with respect to the development of an effective treatment has ushered panic, anxiety and tension amongst the masses. This growing concerns over the widespread of COVID-19 and the ambiguity with respect to a promising cure has triggered the race amongst the pharmaceutical companies, government agencies and health organisations, to hunt for a vaccine, which could fight the virus. Further due to the persisting circumstance, the controversial debate over proprietary rights vs public health, has also resurfaced.

The amount of investment and effort that goes into developing a therapeutic medication or a vaccine for such novel virus, it seems inevitable for the research organisations or the companies, to seek monopoly rights over such potential treatment of COVID-19. The rationale behind granting patents rights is to exclude others from commercially exploiting the patented invention, without the authorisation of the proprietor. Apparently, these exclusionary privileges boosts research

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and innovation, which thereafter, can be put to social utility. Moreover, it precludes the researcher from holding on to the knowledge and expertise which may be crucial for further development and innovation. To sum up, the patent regime is based on the underlined principles, that monopolised privileges incentivises generation and commercialisation of inventions and also, stimulates the dissemination of actionable knowledge and information to the benefit of mankind. Therefore, indisputably, it can be stated that the patent regime plays a crucial role inincubating effective and efficient innovations within a limited time frameand evenin the present case such incentive is likely to accelerate the developmentlifesaving drugs and vaccines to fight COVID-19. However, if left unfettered, the patent practice may become a threat to the well-being of the public, as it fosters innovation by restricting use[3].

The present pandemic situation cannot be translated into an opportune for the pharma companies or large corporations to make fortune out of the vulnerability of the patients.Given the scale of the present health crises, it is not only incumbent for the government authorities to ensure deft development of the crucial medicinesbut also to guarantee accessibility and affordability of such medicines to the public at large. In the present scenario, the government agencies should endeavour to strike a balance between the rights of the proprietors and the right to public health, for common good.

DESPERATE TIME CALL FOR DESPERATE MEASURES-

According to the warning issued by World Health Organisation the outbreak

of COVID-19 need to be contained in an expeditious manner and the failure to do so would 'wreak global havoc'[4]. Further, it has been highlighted that the present crises not only raises public health concern but have also caused economic, political and social upheavals and therefore, it is extremely crucial that an effective cure for the virus is contrived in an unprecedented time bound manner, since time is of the essence[5]. Consequently, even the researchers at present are primarily focusing their clinical trials on existing treatments/ drugs/ vaccines, which would comparatively have less testing requirements, since they have already been tested for other similar viruses or diseases and would be easy to manufacture. Researchers with an intent to save time are primarily emphasising on repurposing or repositioning of the already existing anti-viral drugs[6]. In fact, to aid the efforts of researchers the WHO has released details of therapeutics, which could potentially remedy the effect of COVID-19[7].

Some of the prospective therapeutic drugs that are being tested in clinical trials are Hydroxychloroquine/ Chloroquine which is used to treat malaria, favipiravir sold under the brand Avigan, is used as a medication for influenza, and combination of Lopinavir and ritonavir sold under the brand name Kaletra, isused for HIV/Aids treatment and Remdesivir is a medicine developed for curing Ebola by an American biopharmaceutical company Gilead Sciences. Most of the afore-mentioned drugs are patent protected and are being used by the researchers only for clinical tests purposes[8].

Wuhan Institute of Virology, a Chinese research institute recently filed its patent applications claiming rights over 'the use' of Gilead's experimental antiviral drug viz. Remdesivir, in combating COVID-19. Remdesivir was originally tested against Ebola virus disease, however, the same did not prove to effective as expected. Nevertheless, subsequent studies and clinical trials have shown that the said drug can be

used to treat SARS and MERS as well, two other respiratory illnesses brought on by coronavirus infections[9].This encouraged the Chinese institute to test Remdesivir, as a potential cure for COVID-19. Pertinent to note, that thepatent was claimed by the Chinese institute for an 'unproven' use of the drug inasmuch as the institute had applied for patents prior to the commencement of the trial and experimentation of the said drug. In fact, it was pursuant to the filing of patent application, the institute around early February, 2020,had observed in an publication that a combination of remdesivir and Chloroquine could potentially inhibit COVID-19[10] and followed by the said publication, earliest phase 3 studies of remdesivir for curing COVID-19, was commenced by the institute[11].This pre-emptive move of Wuhan Institute of Virology to seek patent during the persisting crises invited the attention of the critics. Although, in response to the criticism the institute later clarified that the patent was soughtin the interest of the nation and that it will not be enforcing its rights, provided the right holder of the existing drug viz. Gilead, agrees to collaborate with the institute in testing the remdesivir drug and conceiving a cure for COVID-19[12].

Though commencement of clinical trial of promising therapeutic drugs, assures us that we are at the advent of inventing the cure for the COVID-19, however the said fact does not necessarily guarantee easy accessibility of vital drugs to the needful. some pharmaceutical companies despite the distress and apprehension of back lash from the public, have shown an adamant approach in pursuing their patent claim over their inventions. Patents undeniably carry out a role of a catalyst in innovation and development, however, it cannot be allowed to outweigh the lives of the patients and therefore, in the persisting circumstance, it is pertinent that appropriate measures be adopted to curtail the exclusive rightswarranted by patents, to save the mankind from the tragedy of COVID-19.In fact, patent laws of some jurisdictions such as India, forbids monopoly rights over second use of the existing drugs[13]. This may provide some laxity to the state agencies in accessing and adopting existing drugs in the current fight against the COVID-19 virus. However, considering the urgency of the situation, the state agencies would prefer to explore range of alternatives which would comparatively save time, effort and most importantly, avert unnecessary litigation.

FEW EFFICACIOUS METHOD AND PRACTICES ENDURING THE CAPABILITY TO CURTAIL THE MONOPOLISTIC PRIVILEGES GUARANTEED BY PATENT PROTECTION, ARE AS FOLLOWS-

I. Compulsory Licensing

Compulsory licenses are granted in public interest or national emergencies by the governments to the generic companies thereby allowing them produce patented product or process, without the consent of the right holders. Various pharmaceutical companies and governments of developed nations have casted strong criticism with respect to the enforcement of compulsory licensing, due to which countries often experience cold feet in implementing the said mechanism. However, in the given situation the government authorities cannot not be oblivion to the promising role of compulsory licences in ousting the menaces of patent exclusivity. The present situation demands immediate and affordable access to the medicines and treatments and therefore, there can be no qualms on the aspect of imposing limitation on the exclusive rights of the Patent holders by virtue of executing compulsory licenses.

In fact, keeping the paramountcy of public health, several countries, have already initiated the bold step of issuing compulsory license. For instance, Israel has issued a compulsory licence

in relation to AbbVie's Kaletra, due to inadequacy in supply of the said drug. As a consequence of the aforesaid, AbbVie was induced to drop its patents rights over Kaletra worldwide[14]. The Chilean parliament and Ecuador's National Assembly have also adopted resolutions supporting the issuance of compulsory licences to tackle the coronavirus outbreak. In addition to the aforesaid, the German as well as the Canadian government have amended their patent laws in order to enable the government agencies in the said jurisdictions to grant compulsory licenses and even brazil is planning to adopt a similar scheme.[15]

It is pertinent to mention that a rationalised and well strategized patenting and licensing policies are likely to encourage innovations which are crucial in combating COVID-19. It further ensures that prospective researches and discoveries don't circumscribe to the laboratory notebook, instead they are brought to utilisation at the medical front.[16]

II. Monetary Reward

Devising a cure or a vaccine for a pandemic such as COVID-19, is extremely risky, time consuming, involves massive investments and efforts. Once the cure for treating COVID-19, is developed, entities are likely to exploit their patents and profiteer off the vulnerability of the pandemic, which would perhaps cause hike in the prices and scarcity of vital medicines. As a counter measure, the Government organisations can carefully strategies and structure a cash prize or monetary reward system for the entities that have developed a promising cure for COVID-19[17]. These monetary rewards are likely to incentivise and eliminate the need of the right holder to exert their exclusionary privileges. Moreover,

pursuant to the reward being allocated to the innovators, the inventions can be placed in the public domain[18]. This will enable the generic companies to manufacture the lifesaving drugs at cheaper price and also satisfy the growing demands these drugs. In addition to the aforesaid, this would also promote the research institutes to further development or innovate on the existing drugs.

However, it is imperative to highlight, that the object of this scheme is not to alienate the obligations of government agencies, which require them to fund research through grants and are essential for germinating and sustaining research and development. Instead, the said program is manifested as an alternative to the incentivising function that a patent guarantee by providing exclusionary rights to the inventor.[19]

III. Costa Rica's proposal for Emergency Technology Intellectual Property Pool - keeping in view the global of outbreak of COVID-19, government officials of Costa Rica have suggested the WHO to set up a voluntary mechanism, whereby various companies, universities, governments and non-profit organisations can pool their intellectual property including patents.

The objective of IP pool mechanism is to enable wide access and licensing of IPs on reasonable and affordable terms to the member countries for the purpose of developing drugs, vaccine and diagnostics. The mechanism also seeks to addresses the mounting concern of non-accessibility and affordability of the medicines amongst the weaker section of the society.[20]

Moreover, IP pools can be a propitious substitute to government licenses/ the compulsory licences. In fact, the breadth of coverage under IP pool is wider as compared to the government licenses or the compulsory licences, as it encompasses technologies and inventions contributed by large number of organisations. The WHO has welcomed the proposal and the same has also been supported by Netherland, UK government

and various other organisations, including UNITAID which has pledged to finance it.[21]

According to the proposal, the WHO should primarily set out a memorandum of intent to pool IP, which has to be signed by the right holders as well as the government authorities, pursuant to which the parties can negotiate and execute licence or assignment agreement, per there requirement.

IV. The rise of open innovation (Open COVID Pledge)-

In the battle against the COVID-19 virus, various organisations have collaborated and have launched the Open COVID Pledge, which is essentially a platform where the right-holders can openly grant licence in their IP to facilitate the research and development of medicines, vaccines and other discoveries which may be pivotal in combating COVID-19, thereby ensuring that there is no hindrance in dissemination of the knowledge pertaining to the inventions that could save lives and limit the suffering.

Per the terms of Open COVID Licenses- the pledgor can grants a "non-exclusive, royalty-free, worldwide, fully paid-up license (without the right to sublicense)" to exploit the IP (other than trademarks or trade secrets) in products, services and other articles of manufacture in order to fight out the COVID-19. It further provides that the license shall be effective until one year after WHO declares the end of the pandemic. Further, it elucidates that the pledgor "will not assert any regulatory exclusivity against any entity for use of the Licensed IP" in accordance with the license grant, and agrees to not seek injunctive or regulatory relief to prevent any entity from using the licensed IP, however the license can be suspended if the license threatens or initiates any legal proceeding against the pledgor.[22]

METAMORPHOSING THE PATENT REGIME TO FUNCTION AS A COUNTER MEASURE IN COMBATING THE PANDEMIC- AN OPPORTUNITY RATHER THAN AN OCCLUSION:

The pandemic has exacerbated concerns pertaining to the implications of patents on supply of therapeutic drugs and therighteousness of the drug-makers profiteering out of the drug development. The government is already facing several challenge in resolving the Corona Conundrum and instead of creating an obstacle by enforcing the exclusive rights in such crucial times, innovators and researchers are expected to collaborate to ensure innovation and rapid development of the cure.

Several pharmaceutical companies and research organisation, themselves have stepped up to support the cause, pledging suspension of their IP rights in event they succeed in finding the cure, at least till the time the pandemic subsist.[23] While, few still advocate in support of the protectionist approach, despite experiencing the backlash and the criticism, being morally and ethically inappropriate. Nevertheless, in the persisting circumstances, it is suggested that emphasis should be placed on voluntary arrangements, as the same seems to be an imperative instrument in mitigating the present crises and moreover, effectuation of such socially conscious measure erodes the need of the Government agencies to take corrective measure and interfere with the rights of the IP holders through issuance of compulsory licenses. Moreover, such act of benevolence by the corporates may help them garner goodwill and reputation, which would overall be beneficial for their brand.

Notwithstanding the aforesaid, it is reiterated that exclusionary rights cannot be validated at the expense of the public health, the state agencies should not be reluctant in adopting force measure, in the event the innovators are unwilling to cooperate and share the knowledge, particularly, when facing the pandemic.

As emphasised in the preceding paragraphs, extraordinary circumstances require extra ordinary measure and therefore, implementations of measures such as issuance ofcompulsory licence at times are necessitated to ensure adequate supply and affordability of essential drugs. Moreover, such force measures enable the government entities to persuade and motivate companies to voluntarily suspend their patents with an aim to save lives at the time of crises.

The state agencies need to be mindful while structuring the patent regime and occasionally, should consider to prioritise ethical and moral concerns over the financial interest of the right holders, specially while encountering unprecedented global health emergencies. Though, patent protection is imperative for the innovators as it incentivise the development of therapeutic medicines and treatments, however, the same cannot be considered to be impeccable and henceforth, with change in circumstance may require considerable reforms to meet overarching public interests.[24]

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[24]*Supra note 11*

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