INTELLECTUAL PROPERTY MANAGEMENT: PUBLIC HEALTH EMERGENCIES; ROLE OF CORPORATIONS AND IMPACT ON THE THIRD WORLD

Anchit Kapoor[*]

ABSTRACT

As the COVID - 19 pandemic is unfolding rapidly across the world resourced organizations and corporations are investing time and money in finding a vaccine for the virus and/or creating rapid testing kits which can produce efficient and effective results in order to contain the virus. Governments across the world have declared strict lockdowns, a result of which is an economic stand still. With economic stimulus packages in order to maintain cash flow in the economy, governments are struggling to find the most effective 'investment' in protecting human kind.

While most concerned citizens and organizations are worried about how the government is going to cap the cost of vaccines and tests among other medical equipment, researchers and innovators are still in process to create such vaccines and medical equipment. Effective measures which include 'incentives' are required to boost research and innovation. Intellectual property plays a very crucial role in such situations.

The cost of creating and successfully testing life-saving drugs and vaccines may run into hundreds of millions of dollars and hence it is important for governments among other authorities to ensure the right incentives for corporations so that indulging in these projects for abled corporations becomes 'viable'. At the same time, the eco-system, which includes governments and multi-national corporations, has to harmonize its facilities

[*] Advocate, BA LLB (Hons), Jindal Global Law School (2020).

in such fashion that the 'equipment' is easily accessible to all and especially the third world nations.

Protecting innovation (PATENTS) acts as a huge incentive for corporations to indulge into R&D and at the same time using the public policy argument, one similar to Article 27 of TRIPS becomes of essence to ensure accessibility to the poor. By ensuring royalty and protection of innovations among WTO members, Patents incentivize corporations to invest money and other resources in the development of vaccines and other life-saving drugs. Applying tools like 'compulsory licensing' serve in the interests of third world nations as it enables them to significantly reduce costs of these drugs/ vaccines in order to ensure accessibility to its people.

This paper aims to explore various provisions of international law and domestic law, from the lens of 'actions' taken by corporations and states in the past to cater to human kind while facing public health emergencies. Further, this paper aims to offer a critical insight into the currently prevailing international mechanism revolving around the development of essential drugs/ vaccines. Along with focusing on IP law as standard, this paper will also look at the possible influence that big corporations and trans-national organizations might exercise over third world nations while entering into negotiations, taking into account their capitalist fundamentals and at the same time, their philanthropic endeavors.

A. BARRIERS TO INNOVATION AND ACCESSIBILITY INCLUDING BUT NOT LIMITED TO INTELLECTUAL PROPERTY, GOVERNMENT POLICY AND CORPORATE FINANCING;

A.1. UNDERSTANDING PANDEMICS AND THE ROLE OF KEY PARTICIPANTS

PANDEMIC has been defined as "*an epidemic occurring worldwide, or over a very wide area, crossing international boundaries and usually affecting a*

large number of people." [294] International coordination and its resultant machinery has been diplomatically created to pose a united front for human kind while engaging with such public health emergencies thereby attaining peaceful diplomatic relations within the settlement of globalisation. There are different participants that operate globally and take up key responsibilities while dealing with public health emergencies, however also, with different interests: Nation states, Multi-National Corporations and Non-Governmental Organizations (NGO's). Each of these participants operate within inherent spectrums which have been defined by their very composition. During a PANDEMIC where there has been an uncontrollable outspread of a life threatening disease, it can be understood that the aim of the nation state is to ensure safety of its citizens and other people within its territory by providing medical aid, drugs, vaccines etc. at the most affordable price; the aim of a multi-national corporation is to ensure financial stability and finding ways to make profit for its shareholders/ investors while at the same time boosting innovation; and the aim of an NGO working globally shall be to ensure maximum coordination among nation states, prevent disputes thereby easing innovation and accessibility.

Multi-National Corporations working in and around the Pharmaceutical Industry play a unique role during public health emergencies. Searching for incentives and working through investment strategies, they have to ensure that production and manufacturing of vaccines and/or life-saving drugs is viable, provided that they are the first ones to create them, and patent them. Since the profits that these MNC's make via royalties and other incentives forms majority of the funding that enables them to further invest in R&D, they have to ensure that they create profitable vaccines. However, expecting

[294] Last JM, editor. A dictionary of epidemiology, 4th edition. New York: Oxford University Press; 2001

profits while addressing health concerns of the third world becomes contradictory in nature. It has been observed that "*in respect of the "most or very neglected" diseases there may be little or no profit incentive at all for private sector firms, even for emerging vaccine suppliers willing to make much lower profit margins than OECD vaccine firms. No possibility of profit very likely means no private sector R&D.* ***The highest international intellectual property standards could be adopted in these countries, or even higher, and still it could not be expected that private sector R&D for these diseases would automatically be stimulated***."[295] As a result of which a "*report of the Global Forum for Health Research drew attention to what has become known as the 10/90 phenomenon, that only 10% of global R&D spending is directed at the health needs of 90% of humanity."* [296]

With high population densities, consistently poor sanitation standards and shortage of medical infrastructure, third world countries, especially the 'least developed countries' require to consume the major chunk of benefits offered by vaccine development or creation of life saving drugs. "*The Mercer Report indicates that year 2000 is up to $750 million. This is of course a good thing but, from the perspective of the developing world, R&D simpliciter is not good enough, it has to be the right sort of R&D, to meet the needs of the developing world."* [297] There is very little that corporations can do other than playing their part in the capitalist machinery, as their survival depends on it. The existence of such a proprietary tool (PATENTS), that incentivizes production of life saving drugs, however also, inevitably reduces access to these drugs by attaching a monetary credit to the cost of such drugs also

[295] Christopher Garrison, 'Intellectual Property Rights and Vaccines in Developing Countries', in Background Paper for WHO Workshop, 2004.
[296] Christopher Garrison, 'Intellectual Property Rights and Vaccines in Developing Countries', in Background Paper for WHO Workshop, 2004.
[297] Christopher Garrison, 'Intellectual Property Rights and Vaccines in Developing Countries', in Background Paper for WHO Workshop, 2004.

known as royalty as is, defeats the point of such inventions. Ideally, innovation is the first step in making access even possible, however at what cost? At the core of any pandemic there are merely two actors: human kind, and the disease acting as a threat to human kind. Modern medical science has proven itself as the only truly effective remedy against disease related public health emergencies. This dilemma arises due to unequal distribution of resources, because of which it becomes impossible to truly unite humanity against the life-threatening disease.

In addition to viability and market strategy, corporations have various other barriers to overcome in order to execute a successful vaccine development project and ensuring that it reaches the needy. Pertaining to the high investments required in such projects, it is apparent that only those with abundant resources take the risk and responsibility of carrying out such developments. "*There are relatively few vaccine manufacturers that meet international standards of quality established by WHO. Many of the individual vaccine markets are monopolies or oligopolies, either by product or presentation*"[298]

With highly trained and experienced personnel along with financial backing available to everyone that takes upon the responsibility, result is a cut throat competition within the pharmaceutical industry. According to a survey on 'Global Vaccine Supply' done by the World Health organisation "*About 80% of global vaccine sales come from five large multi-national corporations (MNC).*" [299] The geographical audience comprising of these 80% sales

[298] Vaccine Markets' (*World Health Organization)* < https://www.who.int/immunization/programmes_systems/procurement/market/global_supply/en/ > Accessed on 19th May 2020.
[299] Vaccine Markets' (*World Health Organization)* < https://www.who.int/immunization/programmes_systems/procurement/market/global_supply/en/ > Accessed on 19th May 2020.

evidently does not extend to the third world. It has been observed "*that the intellectual property rights provided for under the TRIPS Agreement tend to stimulate more R&D for type I diseases than type II diseases, simply because there are more rich people suffering from diseases of type I than type II, and tend to stimulate little if any R&D for type III diseases, because they are only suffered by poor people."* [300]The formulation of international policy has been done in such a manner that MNC's end up competing for the same market i.e the type I disease, which is indicative of the fact that the most abled and well-resourced organizations compete to innovate in the same market for similar products. Branching out of resources is not possible in such a scenario, which would be ideal in order to cater to global needs, thereby excluding the plight of the third world. The competition has not been designed in an ethical manner within the prevailing mechanism as the race is not to "cure" or "save" as many lives as possible however it is to provide to the richest and be the first ones to provide to derive maximum monetary benefit.

In a utopian scenario, resources would back the most abled minds, catering to the most needful public health emergencies, spread across different corners of the globe. In such a scenario, more and more experts will deal with alien challenges forcing them to discover newer threats and allow them to develop probable solutions, and truly serve the needs of mankind. However, within the current mechanism, abled minds and resources are centralised to cater to the needs of those who can re-fund programs of innovation by paying hefty amounts. This seems to be the only possible survival tactic for a pharmaceutical corporation. Efforts are driven to cut costs and increase margins, thereby assuming the place of an ordinary trade or business, usually not responsible for the survival of humanity. "Patent Pools" is one such

[300] Christopher Garrison, 'Intellectual Property Rights and Vaccines in Developing Countries', in Background Paper for WHO Workshop, 2004.

'revolutionary' mechanism, where organisations cross-license/ share each other's patents in order to bring down transactional costs thereby resulting in a more desirable product.[301] Such arrangements are often entered into among competitors, as usually only competitors require each other's patents in their research. For instance, the Medicines Patents Pool was created in 2010[302]. This pool consists of multiple patents related to HIV medicines. Whereas this pool enables all of its contributors to bring down the cost of their medicines, this pool however restricts the scope of the usage of their patents, and concentrates the efforts of 'competitors' within the field of vaccine and pharmaceutical drugs industry around the development of similar products.

As a result of this concentration of efforts and resources a large amount of finances end up getting wasted. As a matter of fact, the quest for innovating a highly demanded vaccine or life- saving drug is like a race. The corporation who innovates first, gets the patent, others have to work around it, make changes etc. in order to legally operate in the market, doing which they spend extra finances just so that they can recoup some of their investment. As a result, 97% patents that are registered are never able to recoup the cost incurred in having them registered (including the cost of production). [303]

In light of the aforementioned arguments, it is important contemplate if the 'incentive' to innovation as provided for under the existing regime, is even

[301] Meir Perez Pugatch, 'Patent Pools and Collaborative Initiatives: Assessing the Efficacy of Alternatives to IP in the Development of New Pharmaceutical Drugs, Especially for Neglected Diseases – An Empirical Analysis', European Journal of Risk Regulation, Vol. 2 No. 4 (2011) pp 566 – 571.

[302] Dr Joe Gamman, Dr Anna Kingsbury , 'Patent Collaboration: Licensing, Patent Pools, Patent Commons, Open Source and Communities of Innovation' < https://core.ac.uk/download/pdf/79181369.pdf > Accessed on 9th June 2020.

[303] A. Samuel Oddi, 'Plagues, Pandemics and Patents: Legality and Morality', < https://www.ipmall.info/sites/default/files/hosted_resources/IDEA/idea-vol51-no1-oddi.pdf > Accessed on 5th June 2020.

enough to secure survival of the corporations? If not this system fails in every way.

A.2. OPERATION OF TRANSNATIONAL AGREEMENTS AND COMPULSORY LICENSING

Trade Related Aspects of Intellectual Property Rights or TRIPS is a transnational agreement among members of the WTO (World Trade Organisation). It was entered into with the intention of laying down general provisions for regulating rights arising out of Intellectual property. With the intention to secure the proprietorship of innovators along with creating mechanisms for widespread access of new technology, the provisions of this agreement have been drafted in such general manner, that no member shall be subjected to compromise on public health, or interests of the nation while complying with any of the other terms laid down. This agreement, lays down universally acceptable terms which shall be followed by each of its members in formulating their respective domestic legislation.

Article 27 of the TRIPS lays down that "*any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application*" [304] shall be patentable subject matter. This broadly phrased statute includes the protection of 'pharmaceutical drugs', which would mean that, with attached royalties, access to modern medical technological advancements would become costlier globally and most of the human population could not be able to afford it. However, Article 27(2) allows members to exclude this protection, if

[304] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

public health, order or morality is at stake.[305] Article 31, further lays down conditions that are to be "respected" by a member while allowing for the use of patented subject matter without authorization of the right holder. [306]In other words, members of the WTO, are permitted, to not extend the protection of certain patents to their right holders, to protect national interests. This provision has been commercially termed as "Compulsory Licensing", where the right holder is forced beyond its will, by a member state, to compulsorily give up its proprietary rights to protect public interest. This provision was added keeping in mind that the members that are capable of investing heavily in technological innovations that could secure the interests of human life, are also the only ones who could pay high royalties to afford them. In order to ensure that these provisions are invoked only by needful members, it was further laid down that any member granting such a compulsory license shall also be the one "predominantly" utilising supply domestically[307]. In other words, nations who are incapable of manufacturing these life-saving drugs, even after being permitted to use the patent protected technology, would not be able to enable access of these drugs to their populous, as other nations who may be able to manufacture the protected products have been prohibited from exporting them.

The aforementioned concern arises because the statute as it is, undermines the very intention of allowing 'Compulsory Licensing' in the first place, hence it was taken up at the Doha WTO Ministerial Conference, 2001 where it was declared that *"We recognize that WTO members with insufficient or no*

[305] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).
[306] TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).
[307] Article 31(f), TRIPS: Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994).

manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.[308]*"* In 2003, as a temporary measure, WTO members agreed to waive the requirement of 'predominant supply' of patented product within the domestic territory of the member invoking 'compulsory license'[309]. In 2005, a proposal to permanently amend the TRIPS Agreement with the aforementioned change was tabled which required sanction from 2/3rd of the WTO Members.[310] Finally, in 2017 a permanent amendment was made to the effect of allowing states exercising the provisions of 'Compulsory Licenses' to export patented products to Least Developed Countries and developing countries dealing with public health emergencies.[311]

In India, Section 84 of The Patents Act, 1970 lays down the grounds for obtaining a 'Compulsory License'. Essentially it revolves around, whether the patented product is not available to the general public in the requisite quantity and at an affordable price.[312] The possibility of getting a Compulsory License arises only after the expiration of three years[313]. This provision essentially takes away the benefit of using compulsory licenses during a Pandemic. The first compulsory license was granted by Indian Authorities in the year 2012, which was disputed by the Patent holder. In the case of *Bayer*

[308] DOHA WTO MINISTERIAL, TRIPS, WT/MIN(01)/DEC/2, 20 November 2001
[309] World Trade Organization, General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,* WT/L/540 and Corr.1 (2003)
[310] World Trade Organization, General Council, *Amendment of the TRIPS Agreement,* WT/L/641 (2005)

[311] WTO, "Press Release", *WTO IP rules amended to ease poor countries' access to affordable medicines* (2017)

[312] The Patents Act, 1970, Section 84 (1).
[313] The Patents Act, 1970, Section 84 (1).

Corporation v. Union of India the rights of a patentee who has used compulsory licensing to produce a product were discussed and naturally minimal royalties were attached with each sale. Further, the patentee was obligated to treat 600 people yearly using the pharma drug, free of cost[314]. Whereas this may seem like a win-win situation, this dispute was eventually settled by the Hon'ble Delhi High Court in 2017 and this course of time, the patent holder did try to bring several stay orders against the licensee and had to eventually sue to the Union of India for exercising its authority under the Patents legislation. Delay in settling these disputes may lead to production/manufacturing lapses and end up depriving the public from reaping up the fruits of public policy.

THE CANADIAN AND RWANDIAN CASE OF COMPULSORY LICENSING[315]:

In 2004, an international humanitarian medical NGO, Médecins Sans Frontières (MSF) sought to obtain a triple combination ARV (zidovudine, lamivudine and nevirapine), and approached a Canadian company for its production. At the time, MSF did not have any specific requests from an importing country. In 2006, the Company applied to obtain marketing approval in Canada, which was granted within six months of its application. However, the product was not covered in the pre-existent Canada's Access to Medicines Regime (CAMR), which implements the Paragraph 6 System, and therefore an amendment of the CAMR process was required. The three prime constituent medicines of the product were each covered by a separate patent,

[314] *Bayer Corporation v. Union of India,* [2017] 238 DLT 701.
[315] World Trade Organization, Promoting Access to Medical Technology and Innovation, *Intersections between Public Health, Intellectual Property and Innovation*, < https://www.wto.org/english/tratop_e/trips_e/who-wipo-wto2013_par6_extract_e.pdf > Accessed 12th June 2020.

that were each held by a separate company. In July 2007, the Company applied to obtain voluntary licenses from the three patent owners but failed.

In the same year, Rwanda expressed its interest in importing the triple combination ARV by sending a brief notification to the WTO, stating that it plans to import 260,000 packs but reserves the right to modify this quantity. It further stated that patent owners would not be permitted to exercise enforcement on the product with respect to any patents that may have been granted within its national territory. Classified as an LDC, Rwanda was free from any other obligation to state anything else, and neither was it required to expressly declare its intention of using the System. Responding to the demand, the Company sought to obtain a compulsory license in Canada in September 2007, which was granted two weeks after the date of application. The license would permit export of 15,600,000 tablets (the equivalent of 260,000 packs) over a period of two years. In October 2007, while the Canadian government notified the WTO that it was using the Paragraph 6 System as an exporting country, the Rwandan Government issued a public tender for the triple combination ARV, suggesting that there were at least four Indian manufacturers who could potentially supply the product at cheaper rates. Canada reported that since these ARVs were not patented in India, the use of the System would not have been required at all, for Rwanda to procure the product from these Indian manufacturers. However, during the tender process, the Company halved the price at which it had originally offered to supply the product - from the original no-profit price of US$ 0.39 per tablet to US$ 0.195 per tablet. The Company went on to win the tender in May 2008.

Complying with the norms of the CAMR and the System itself, the Company ensured that the product version to be shipped to Rwanda, was distinguished in certain ways from the one that was manufactured for the domestic market.

The tablets that were shipped, had an "XCL" mark and were white coloured as opposed to the standard blue. The Canadian government issued an export tracking number which was placed on the product packaging. These distinguishing characteristics, along with the product description detail and shipment detail were posted on the web. The patent holders waived off the royalty that the Company was liable to pay for the right to use the patents.

In the two-year validity period of the compulsory license, the company exported 6,785,000 tablets to Rwanda in September 2008, followed by an additional shipment of 7,628,000 tablets in September 2009.[316]

In the aforementioned case study the nature of cooperation required among nation states and the MNC's (both the manufacturing corporation and the patent holder) to successfully execute a compulsory licensing deal, can be analyzed. "*Developing countries have to pass through maze of rules and procedure to procure drugs from developed countries."* [317] Further, the Canadian Government had to amend its domestic law in order ensure that the said product could be manufactured and exported. The MNC's, the Canadian Authorities were in talks with the government of Rwanda since 2004, and naturally would have had to incur a lot expenses and efforts in order to get the order from Rwanda only to fight a tender eventually in 2007. Even after offering a no profit sale price, the Canadian MNC had to slash its price in half in order to get the deal. The political dynamics of such arrangements make them undesirable. In order to initiate *quid pro quo* among two nations, it is possible that a developed nation may offer such arrangements of compulsory

[316] World Trade Organization, Promoting Access to Medical Technology and Innovation, *Intersections between Public Health, Intellectual Property and Innovation*, < https://www.wto.org/english/tratop_e/trips_e/who-wipo-wto2013_par6_extract_e.pdf > Accessed 12th June 2020.

[317] Raadhika Gupta, 'Compulsory Licensing under TRIPS: How far it Addresses Public Health Concerns in Developing Nations' in Journal of Intellectual Property Rights, Vol. 15, pp. 357-363, (2010)

licensing in order to increase leverage at the negotiating table completely negating the rights of the patent holders. The government in power, naturally exercises a position of influence over large MNC's operating in its territory and such influence can be used for political agendas. "*It is also possible that developed nations use the threat of compulsory licensing to make companies voluntarily take measures to make their drugs accessible, without actually issuing the licence. Some nations have lowered prices while others have offered voluntary, royalty-free licences"* [318] As we have noticed in the aforementioned case study, that the patent holder, "waived off" the royalty that was due under the compulsory license agreement. There is no reason why a corporation would 'decline' to take money that it has rightfully earned, relying on the fact that these corporations majorly fund future research and development projects with the profits they make from existing innovations.

HARMONY OF LAW - MULTINATIONAL CORPORATIONS (CAPITALISM) AND TRANSNATIONAL ORGANIZATIONS (HUMAN RIGHTS);

RESTORATION OF STRUCTURAL DISBALANCE

The abovementioned observations highlight that the individualistic role of corporations, nation state and non-governmental organizations disallows the active protection and recognition of human rights to prevail over the anti-thesis of capitalism. Frequency of these pandemics clearly indicate their inevitability. While holding a conference on "Pandemic Preparedness in the Community", it was held by the European Council that "*The next Pandemic is imminent and we are not prepared. Vaccine availability is not secured. Antiviral stocks do not exist and will not be under the current market forces. In the event of a pandemic millions of people could die, economies will be*

[318] Raadhika Gupta, 'Compulsory Licensing under TRIPS: How far it Addresses Public Health Concerns in Developing Nations' in Journal of Intellectual Property Rights, Vol. 15, pp. 357-363, (2010)

affected and (medical and civil) services could collapse. Members of the public will not excuse authorities, who will be held responsible for not having put in place up-to-date preparedness."[319]

This observation was made by the European Council in 2001, however 19 years later, Europe as a continent is one of the worst hit continents by the novel Coronavirus. It is clear that the ongoing 'preparedness' efforts taken by even the developed nations or the west, or the north, or "the world leaders" are not enough to prevent and/or cope with the outspread of a virus that may cause a pandemic, thereby indicating that a specific mechanism is needed to deal with pandemics.

The current machinery existing in the world which 'ends up' dealing with the pandemic is derived from the pre-existing organizational structure in International relations. Even though there may be exceptions in international regulations specifically created for dealing with Pandemics, there is need for creating specific regulations, parallel to creating international machinery specifically dedicated to surveillance and containment of viruses, along with formulating consistent Research and Development of life saving vaccines and drugs. There is need for a funnel which includes identification of the possible roles that different nation states may play in the process of manufacturing and distribution of vaccines, which may be activated at the earlier stages of a potential Pandemic. The spending of funding in defined tasks by each nation state shall be pre-determined, which may constantly evolve in accordance with judging the potential of contribution that the respective nation states can make. For instance, there are certain specific countries that may be termed as experts in producing/ manufacturing life-saving drugs at lowest cost;

[319] David S. Fedson. "Preparing for Pandemic Vaccination: An International Policy Agenda for Vaccine Development." Journal of Public Health Policy 26, no. 1 (2005): 4-29. Accessed June 14, 2020. www.jstor.org/stable/4498904

similarly, there are MNC's head quartered in certain countries that lead research and development of life saving vaccines and control the majority of pharmaceutical patents required in creating life-saving drugs/ vaccines. It is not necessary that other countries may not come up with the creation of vaccines however it is most probable, that the corporations housed in the countries that have the capacity of spending large funds in R&D, will most likely be the creators of vaccines and others may contribute in the manufacturing and distribution process. Much like the currently prevailing international trade culture in the world, where innovation may take place globally however, majority of technical innovation takes place in the west, whereas the east is utilized for its cheap labor market and manufacturing capabilities, the example of Apple Inc. might be of use here. Apple products are designed in California, while they are assembled majorly in China. However, since the system of international trade has been settled automatically by the operation of capitalism, Apple products are naturally very expensive and cannot be afforded by majority of the people. The current unregulated and free trade machinery for pharmaceutical drugs including life-saving drugs is also therefore, open for manipulation by the operation of capitalism. Different branches, under possible life-threatening viruses among other genetics need to be identified, so that sophisticated hierarchy may be created to efficiently and effectively deal with the related disease. Within this branch, regulatory authorities may be established that work internationally in surveilling possible life-threatening viruses and identifying which viruses may be uncontrollable or may subject as a threat to a global audience. This is to ensure that the production and distribution of vaccines, becomes a last resort, and when that stage comes, the concerned authorities are prepared/ or the most prepared they can be, and no time is wasted in untangling the international mechanism. With prescribed specific roles, and practice, organizations will be able to react promptly and save resources, both financial and human.

NEED FOR PREPAREDNESS

In contrast to the abovementioned suggestions it can be argued, that the cost of setting up specific branches within the pre-existing international infrastructure, will be high and consistently increasing and since Pandemics don't occur every year or within a stipulated time period, much of these funds may go to waste. However, with the increase in the frequency of Pandemics this cost has become inevitable as well. The value that these expenditures bring are similar to many other ventures that are taken by the 'nation state' in order to secure the interests of its populous.

It has to be understood that various nation states, anyway allocate funds to surveillance agencies in order to pre-empt possible threat and save their populous. For instance, the Central Intelligence Agency is funded within the U.S government's budget, the only benefit they derive is security, which might not seem financially viable, however this expenditure is deemed as necessary as it is directly related with the national security of the United States.

In 2004, the U.S government decided to allocate contracts to two American based Pharmaceutical Companies to produce the "monovalent H5N1 "Pandemic Like" Vaccines."[320] Due to a mishap that occurred at their production facilities in the U.K, the United states ended up losing half of their manufactured produce thereby forcing them to rely majorly on their domestic produce for the trivalent vaccine, which would total their supply to 50-60 million doses per year. This production capacity was "not enough to

[320] David S. Fedson. "Preparing for Pandemic Vaccination: An International Policy Agenda for Vaccine Development." Journal of Public Health Policy 26, no. 1 (2005): 4-29. Accessed June 14, 2020. www.jstor.org/stable/4498904

vaccinate even 1/5th of the U.S population" [321]with high doses requirements and the possibility of the occurrence of an outbreak in the recent 2 or 3 years the United States would rely heavily on exports and the global market, where prices would be sky rocketing due to global demand. As a result of which, even in cases where government is funding for research and development along with production of vaccines, they are not able to effectively and efficiently secure all of their interests pertaining to lack of infrastructure and/ production expertise. A better utilization of the governments initial spending would be to secure its interests before-hand by spending money in a pool of resources, which automatically allocates different tasks to most deserving candidates to utilize resources in the most efficient way possible. This will further contribute in bridging the gap between the east and the west and transform the 'Third World Approach to International Law'.

While receiving funding, along with other perks from nation states, Multi-National Corporations should be able to step out of their 'traditional' role during a pandemic. The requirement of generating profit in order to boost R&D during Pandemics is primarily the reason why these vaccines do not often reach the needy. A well contemplated checks and balances system should be legislated internationally in order to ensure that "profit" does not enable the protection of human lives. Much like international funding of Non-Governmental Organizations for instance the United Nations, the plethora of nation states must follow the principles of "common but differentiated responsibility", where the economically stable nations contribute more than Least Developed Nations while keeping the common global benefit in perspective.

[321] David S. Fedson. "Preparing for Pandemic Vaccination: An International Policy Agenda for Vaccine Development." Journal of Public Health Policy 26, no. 1 (2005): 4-29. Accessed June 14, 2020. www.jstor.org/stable/4498904

CONCLUSION:

Transnational organizations, such as the World Health Organization (WHO) ideally, have been designed to formulate smoother mechanisms which result in efficient international cooperation while dealing with a Pandemic or any other Public Health Emergency. By releasing standard guidelines in relation to the process of manufacturing, administering and monitoring life saving drugs the WHO aims to stabilize health care all over the world. As an organization, the WHO is also burdened with the responsibility of collecting data from all over the world pertaining to better ways of creating "pandemic like" vaccines and be up to date with the latest evolutions and innovations in order to prevent harmful/dangerous use of bio technology. The WHO has been trying to generate cooperation among different organizations both, governmental and non-governmental with respect to their Intellectual Property norms in order to boost Pandemic preparedness by consistently suggesting more and more efficient ways of developing 'Pandemic like' vaccines.[322] It has been observed by the WHO that *"the methods for preparing R.G (Reversed Genetics) Engineered viruses are straightforward, the results are predictable, and the process can take as little as 10-20 days. Moreover, when used with avian viruses, the resultant RG Engineered reference strains can be used as seed strains for egg based vaccine production."*[323] Essentially it was agreed upon by vaccines experts that for creating vaccines related to the influenza virus, it is highly beneficial to use the reversed genetics technology as compared to the ordinarily used "Genetic Reassortants" technique.

[322] World Health Organization, *Influenza Pandemic Preparedness Plan.* WHO: Geneva April 1999 <http://www.who.int/csr/disease/infuenza/en/ > Accessed on 13th June 2020.
[323] David S. Fedson. "Preparing for Pandemic Vaccination: An International Policy Agenda for Vaccine Development." Journal of Public Health Policy 26, no. 1 (2005): 4-29. Accessed June 14, 2020. www.jstor.org/stable/4498904

However, the IP rights for the techniques of RG are divided into four portfolios, all of whom are owned by two American Companies, namely MedImmune, Inc. and Mount Sinai Medical Center, in New York City.[324]

Even after identifying, what would be ordinarily termed as an evolution in pandemic preparedness globally, it is impossible for WHO to ensure compliance from the American corporations. Firstly, the WHO has a regulatory status and hence it cannot majorly impose direct sanctions on member states. Further, it is unfair under the existing capitalist regime to force an MNC to completely forgo their IP rights in innovation, as it has been argued in the former section of this paper, their survival depends on it. It is unjust for the world to bank on the innovation efforts and financial efforts put in by two corporations under the existing structure. For one country to invest in the production of vaccines that the entire world is going to benefit from seems unfair, however if the funding of this patent was done by a collective pool regulated by, for instance, WHO, and this pool consisted of funding ventures undertaken by several individual nation states, then apart from credit for innovation, the entire world would have a right in using that technology, which is what is essentially required while dealing with a global public health crisis.

Any one player out of the three namely – Nation State, Non-Governmental Organization, or Multinational Corporation, in the 'Pandemic like' vaccine market is incapable of surviving without complying with the short sighted, pre-existing norms currently in operation, even if they independently indulge into philanthropic endeavors. This industry cannot be looked at as any other ordinary business/ trade, and therefore dependency/ responsibility imposed

[324] Knobler SL, Mack A, Mahmoud A, Lemon SL, *The Threat of Oandemic Influenza, Are we Ready?,* The National Academic Press.

upon Multi-national Corporations for arranging funds and boosting innovation needs to be reduced. A more inclusive pattern needs to be adopted, where nation states each take on differentiated responsibilities according to their capacity, keeping in mind the interests and manufacturing capacity of the third world nations. An auto – trigger machinery needs to be put in place to minimize time lag and maximize action, whenever prompted. Apart from being regulatory bodies, transnational organizations are required to 'police' the pharmaceutical market, with abilities to impose strict sanctions in case of breach, as breaches in such times could possibly affect the quality of human lives.