COVID-19 AND THE ROLE OF TRANSNATIONAL INTELLECTUAL PROPERTY: A REQUIRED PAUSE ON INNOVATION AND COMPETITION FOR VACCINE EQUITY

Dr. Ana Penteado
Adjunct Associate Professor
The University of Notre Dame, Australia

This is a working paper because developing global awareness of international law and domestic law limitations are of urgent public interest. High mortality has been recorded in less developing countries and developing countries with a deadly virus and mutations in circulation. Four COVID-19 variants are ravaging our society at the moment. With a choice of granted vaccines developed in the northern hemisphere, we had an opportunity to eradicate or at least control SARS-COV-2 disease. Despite that, we are still locked in international trade and competition issues to make the vaccines available globally. There are plenty of arguments regarding manufacturing, distribution, lack of talent pool locally, and the World Health Organisation initiative that depends on vaccine donations to supply developing and less developed countries. Nonetheless, with the variations of the original virus rapidly evolving, this window of opportunity is becoming smaller by the day. This working paper intends to present some historical background for legal actions and public policies in situations like this pandemic where economics are not the priority.

This working paper is organised by historical references to mRNA technologies, addressing manufacturing and distribution arguments, a brief explanation of clinical trials, a look into drug projects and the incentive for funding, a study on the incentive for patenting subject-matter already funded by taxpayers via collaborations and contracts, and the connection of all these elements with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs) an international treaty that abides all member-States including on article 27 (2). This working paper does not intend to find a solution but to show alternatives to start looking into resolving regulatory issues and legal gaps that are in place.

I. Concerning vaccine manufacturing and distribution, a step before vaccines grant

The argument of shortage of raw materials is a deceptive one. There was no shortage of raw materials for vaccines production but a sustainable and massive investment to monopolise these raw materials to few sources in selected countries. For instance, the supply chain for *Pfizer*® was duly impacted by a lack of quality of raw materials, with a culmination

of high demand for these organic matter allied to the delays in clinical trials.[1] On December 21st, 2020, the European Medicines Agency (EMA) approved a conditional marketing authorisation for *COMINARTY* produced by *Pfizer*® and *BioNTech SE*.[2] Ten days prior to that date, *Pfizer/BioNTech* had been approved by the Food and Drug Administration (FDA) for individuals over 16 years of age for emergency use only. The situation was fluid in the United States until the pandemic spread throughout the whole country when an emergency was identified.[3]

The argument of insufficient production capacity is a result of a myriad of clinical trials, devoid of satisfactory evidence-based medicine, that slowed down global management for vaccine distribution.[4] Clinical trials are part of the drug patent process and a mandatory risk enterprise for pharmaceutical production. The main goal of a well-designed, diversified clinical trial is to attest efficacy and safety in adverse conditions of drugs used in humans, in this case, the SARS-COV-2 or COVID-19 vaccines. A well-conducted clinical trial contributes to a better decision-making process for healthcare professionals, such as doctors, nurses, researchers and scientists, in advising governments. Educating the public and bringing broad awareness of the possible side effects in the life of drug development is a must. Clinical trial results are of global concern because the results may change the rules and procedures to access drugs, nationally and internationally, affecting local healthcare systems and future innovation to manage a problem like a pandemic.

The argument of the highly complex manufacturing process is partially acceptable. One of the reasons for this argument to be acceptable, in terms, is that it avoids the fact that since the 1970s, there are experiments with genetic engineering, gene-splicing techniques and gene transfer vectors.[5] The mRNA technique is not novel many scientists around the globe have been exposed to the concept. Basically, it delivers a synthetic ribonucleic acid (RNA) as a messenger that teaches the human body the knowledge to produce almost any protein or antibodies inside and outside cells.[6]

[1] See, The Wall Street Journal, available at https://www.wsj.com/articles/pfizer-slashed-its-covid-19-vaccine-rollout-target-after-facing-supply-chain-obstacles-11607027787

[2] See, European Medicines Agency, available at https://www.ema.europa.eu/en/news/ema-recommends-first-covid-19-vaccine-authorisation-eu

[3] Educational websites have been the major source for the public at large to be educated at light speed. See, https://www.precisionvaccinations.com/vaccines/biontech-pfizer-covid-19-vaccine. But compare with Pfizer website for COVID- 19 vaccine available at https://www.cvdvaccine.com/ and https://www.pfizer.com/products/product-detail/pfizer-biontech-covid-19-vaccine

[4] See Nature, Editorial, Evidence-based medicine: how COVID can drive positive change, available at https://www.nature.com/articles/d41586-021-01255-w

[5] See, Fritjof Capra, The Hidden Connections, (First Anchor Books, 2002), page 158-159.

[6] See, Karikó K, Buckstein M, Ni H, Weissman D. Suppression of RNA recognition by Toll-like receptors:

It has been a prior art since 1989, with studies on the RNA correlation to oncogenicity well publicised in the scientific community.[7]

II. mRNA technique, a quick historical background

Drew Weissman's interest in the human immune response to pathogens allied to the pioneering Kathlin Karibó research resulted in a paper entitled "Suppression of RNA recognition by toll-receptors: the impact nucleoside modification and the evolutionary origin of RNA".[8] Therefore, the highly complex manufacturing process has been well-known and used in selected projects since some time ago, according to Weissman and Karibó.[9] However, the use of mRNA technology to develop future vaccines, not necessarily for COVID-19 only, was always a possibility. Therefore, sharing the mRNA know-how was a question of business strategy. For example, management strategies should consider logistic infrastructure globally or choosing a partner for large-scale vaccine manufacturing outside of Europe for rapid transportation and distribution to countries in the southern hemisphere. After all, SARS-COV-2 or COVID-19 spread it from South to North.

One must bear in mind that mRNA technology was not the only vaccine in the race for an effective solution. Other vaccines using traditional methods were also in the pipeline for the World Health Organisation (WHO) approval process, namely the vaccine pre-qualification (PQ), such as Janssen – Cilag International,[10] Oxford-AstraZeneca[11], COVIDSHIELD[12], BIBP/Sinopharm[13], and

---

the impact of nucleoside modification and the evolutionary origin of RNA. Immunity. 2005 Aug;23(2):165-75. doi: 10.1016/j.immuni.2005.06.008. PMID: 16111635. https://pubmed.ncbi.nlm.nih.gov/16111635/
See also, Jackson, N.A.C., Kester, K.E., Casimiro, D. *et al.* The promise of mRNA vaccines: a biotech and industrial perspective. *npj Vaccines* **5,** 11 (2020). https://doi.org/10.1038/s41541-020-0159-8

[7] See, Raymond V, Atwater JA, Verma IM. Removal of an mRNA destabilizing element correlates with the increased oncogenicity of proto-oncogene fos. Oncogene Res. 1989;5(1):1-12. PMID: 2506502, available at <https://pubmed.ncbi.nlm.nih.gov/2506502/>

[8] See, Karikó K, Buckstein M, Ni H, Weissman D. Suppression of RNA recognition by Toll-like receptors: the impact of nucleoside modification and the evolutionary origin of RNA. Immunity. 2005 Aug;23(2):165-75. doi: 10.1016/j.immuni.2005.06.008. PMID: 16111635, available at Karikó K, Buckstein M, Ni H, Weissman D. Suppression of RNA recognition by Toll-like receptors: the impact of nucleoside modification and the evolutionary origin of RNA. Immunity. 2005 Aug;23(2):165-75, available at <https://pubmed.ncbi.nlm.nih.gov/16111635/ >

[9] See, Damian Garde and Donald Saltzman, The story of mRNA: from a loose idea to a tool that may help curb Covid" November 10, 2020, available at< https://www.statnews.com/2020/11/10/the-story-of-mrna-how-a-once-dismissed-idea-became-a-leading-technology-in-the-covid-vaccine-race/>

[10] See, The World Health Organisation, Pre-Qualification of Medical Products, available at https://extranet.who.int/pqweb/vaccines/who-recommendation-janssen-cilag-international-nv-belgium-covid-19-vaccine-ad26cov2-s

[11] See, The World Health Organisation, Pre-Qualification of Medical Products, available at https://extranet.who.int/pqweb/vaccines/covid-19-vaccine-chadox1-s-recombinant

[12] See, The World Health organisation, Pre-Qualification of Medical Products, available at https://extranet.who.int/pqweb/vaccines/covid-19-vaccine-chadox1-s-recombinant-covishield

[13] See, The World Health Organisation, Pre-Qualification of Medical Products, available at

Sinovac/CoronaVac.[14] Pre-qualification vaccine participation in the WHO assessment includes any manufacturer that has met the mandatory suitability (PSPQ) and has also received marketing authorisation from the national regulatory authority (NRA) of the country of manufacture for compliance with the local regulatory authority, which must be included in the World Health Organisation list.[15] Options to contain this virus were available.

In clinical trials, mRNA technology was more effective and safer against SARS-COV-2 or COVID-19. Therefore, there is tremendous public interest and an abundance of peer-reviewed literature on mRNA technology. One cannot forget that a cycle for approval of any medicine prior to COVID-19 would be measured in years. Consequently, it is a remarkable event that we have so many vaccines approved through four phases of clinical trials in two of the most conservative agencies for therapeutics safety in the world, namely the Food and Drug Administration and European Medicines Agency, in less than a year.[16]

III. IP Rights for Collaboration and contracts

Generally, an investment for a drug development is high and uncertain. There are so many stages of approval that the risk is part of the drug process. This is due to the marketing approval stage for new drugs approval, which could be delayed in years or show a failed project. The investment for a new drug in the United States is around U$ 2 billion dollars.[17] As the emergency in the United States took shape, *Operation Warp Speed* focused on COVID-19 vaccines or effective treatment, with a budget approved by the U.S. Congress of U$ 19 billion dollars.[18] Five of the seven major private pharmaceutical manufacturers established in the United States accepted this advanced funding for research and clinical trials.[19]

https://extranet.who.int/pqweb/vaccines/covid-19-vaccine-chadox1-s-recombinant

[14] See, The World Health Organisation, Pre-Qualification of Medical Products, available at https://extranet.who.int/pqweb/vaccines/who-recommendation-sinovac-covid-19-vaccine-vero-cell-inactivated-coronavac

[15] See, the World Health Organisation, Pre-Qualification of Medical Products, Vaccines, available at https://extranet.who.int/pqweb/vaccines/procedures-fees-who-prequalification

[16] See, Centers for Disease Control and Prevention, COVID-19, Science Brie: COVID-19 Vaccines and Vaccination, Summary of Recent Changes, available at https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/fully-vaccinated-people.html

And European Medicines Agency, available at https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/covid-19-latest-updates

[17] See, Congressional Budget Office, Non-Partisan Analysis for the U.S.Congress, Research and Development in the Pharmaceutical Industry, April 2021, available at https://www.cbo.gov/publication/57126

[18] See, Congressional Budget Office, Research and Development in the Pharmaceutical Industry, April 2021, https://www.cbo.gov/publication/57126

[19] See, Congressional Budget Office, Research and Development in the Pharmaceutical Industry, April 2021, https://www.cbo.gov/publication/57126

With this substantial financial support, COVID-19 manufacturers and biotechnology companies will not require more financial advancement to cope with risk and high investment. Nonetheless, the most in need are those perishing by a lack of vaccine equality because the distribution of these vaccines is unsatisfactory. Regardless of the politics of this matter, health is still a high moral compass that we all aim to reach by having compassion for others, in short, solidarity. A highly infectious disease can spread anywhere in a globalised world because it is airborne and human transmissible. Again, it is convenient to remember that the COVID-19 mutates very rapidly. Four variants are in circulation as the latest notice, so governments should donate extra vaccine doses and advocate solid support for the Covid-19 Vaccines Global Access COVAX initiative[20] to protect those fully vaccinated. If not for the protection of others, at least consider their own population that is at risk of being re-infected.

If all are not safe, no jurisdiction will be safe. This human and financial investment of unprecedented collaboration to get a vaccine granted in a record time would be a stroke of misfortune if a new wave of this virus, re-invigorated by mutations, contaminate and take more lives. Thus, it seems natural to advocate for a global vaccination rapidly and effectively.

Again, a swiftly licensing pool would hardly be a hurdle for patentees' profit because the funding has been advanced in a lump sum. Therefore, to raise an argument of a profitable outcome when such an amount of money has been at the industry's disposal may appear insensitive. Besides, the argument of lack of skilled talent to repurpose facilities seems hardly acceptable as a scientific fact but rather as a business strategy for convenience to keep vaccine manufacturing under control.

As we have noted, mRNA technology is not new. For instance, Australia can produce locally with the Monash Institute of Pharmaceutical Sciences (MIPS). The leading investigator, Professor Colin Pouton and his team have produced mRNA, and their project is active with a fund incentive recently apportioned to the leading research facility from the Victoria government.[21] MIPS has produced three mRNA candidates in Australia, which potentially could be distributed to the whole region of Australasian

[20] See, The World Health Organisation, COVAX, available at https://www.who.int/initiatives/act-accelerator/covax

[21] See, Monash University, Pharmacy and Pharmaceutical Sciences, Colin Pouton, available at https://research.monash.edu/en/persons/colin-pouton and see also https://research.monash.edu/en/projects/a-safe-effective-and-rapidly-tuneable-sars-cov-2-vaccine. See also, Yarra Murray Atfield, Victoria announces 50 m to fund mRNA COVID vaccine production in Australia, available at https://www.abc.net.au/news/2021-04-21/victoria-to-develop-mrna-covid19-vaccine-facilities/100083372

and South Asia. Hypothetically, that part of the mRNA production would support the logistics of manufacturing and distributing COVID-19 vaccines by India in a record time than organising vaccine distribution based in the northern hemisphere. A fast approach is necessary, otherwise, a resurgence of this virus will be inevitable.[22]

IV. Waiving IP rights will not scale or speed up vaccine manufacturing and distribution

Waiving IP rights is necessary to bring all stakeholders to the table to collaborate on the standstill on technology transfer and capacity building. Waiving IP rights is not a solution to the problem. It is a strategy to solve a problem created by patenting these life-saving vaccines in the first place. Moreover, it is an opportunity to show support for our global community since vaccine nationalism created segregation through access to vaccines and medical therapy. For instance, two of the world most significant producers of generics, India and South Africa, were left outside of this innovative and competitive group of countries. There are political issues of concern, as well.

Economist Jayati Ghosh called out her government for a series of missteps in the vaccine distribution. However, she notes that raw materials prohibition to be exported to India delayed vaccine production for other countries that depended on Indian vaccine production.[23] As a result, it becomes a policy of vaccine apartheid, in which Ghosh suggests that without a global chain of resources being produced around the world to speed up distribution, all countries will be affected by the recession due to the virus.

Economic indicators may convince countries with advanced technology to think about global health as an asset to avoid an economic crisis for all, including their own. Countries and regions that have applied a strict foreign policy of monopolising raw materials such as the European Union and the United States to support a stock-piling vaccine policy may be under mercantilism policy advice, which worked in the past with colonialism. European countries used mercantilist policies in the past for the exploitation of metals, such as Portugal and Spain. We live in modern times, and such policy has no room to survive in pandemic times.

Having a monopolistic approach to life-saving therapies and vaccines proves to be an inefficient health access strategy. Indeed, it

[22] See, World Health Organisation, Regional Office from Africa, available at https://www.afro.who.int/news/vaccine-supply-crunch-adds-risk-covid-19-resurgence

[23] See, Jayati Ghosh, at Covid-19 in India, profits before people, available at https://www.socialeurope.eu/covid-19-in-india-profits-before-people
See also, DW documentary, Does a vaccine spell the end of the coronavirus pandemic? Available at https://youtu.be/ExcB9ISbccg

implies not saving lives by choice. One does not need a human rights advocate to understand that this policy is unfair and unjust. In the past, such policy was tested for HIV therapies, resulting in an immoral profit for drug companies from the access to HIV life-saving medicines.

A recent paper authored by John Aubrey Douglass[24] explores the influence of the Bayh-Dole Act on federal funded therapies in the United States against price control, plus a positive reform after the 1980s that produced a legislation pro-patent policy inside universities. Douglass says:

"At the same time, the emergence of "vaccine nationalism", in which nations and drug makers prioritize control of IP and production of vaccines for their own populations, is testing the ability of the world to effectively respond to the virus as it mutates."[25]

V. Patent Policy, the untouchables

Anyone who espouses the idea of patent untouchability or playing with patents is playing with fire is counting on our ignorance to have forgotten what an incentive the Bayh-Dole Act, 1980 was for patents. It was enacted to foster collaboration between basic research and advanced the American universities' role in negotiating licensing strategies with pharmaceutic companies and biotechnology enterprises. In addition, science as a component of the economic cycle in the United States was incorporated under a conservative government as an economic asset. Not to mention the tax credits for the private sector to invest in basic research, so taxpayers would have the best of two worlds – cutting edge technology and competitive access to these products.[26]

Humbolt philosophy of access to science to all and protection from private interests gave the Reagan administration a profit-orientated university-private sector alliance. The Bayh-Dole Act produced legislative variations worldwide in the United Kingdom, Japan, France, Germany, Austria, Denmark, Norway, Portugal, Spain, and Finland.[27] Douglass called our attention to the Lisbon Strategy establishing the European Research Area and the Horizon Europe program, a funding program spearheaded by the European Commission.[28] The Horizon Europe program has a budget of € 95.5. billion dollars for four main missions, including health and innovation, so there is no surprise that some research institutes in Europe are eager to get their share of this magnificent apport of

[24] See, The University of California at Berkeley, Goldman School of Public Policy, Center for Studies in High Education, John Aubrey Douglass, available at https://cshe.berkeley.edu/publications/federally-funded-research-bayh-dole-act-and-covid-vaccine-race-john-aubrey-douglass

[25] See, The European Commission, Horizon Europe, Strategic Plan, page 4 available at

[26] See, ibid.

[27] See, ibid.

[28] See, ibid.

money. In case there is doubt that this strategy applies to healthcare, the Horizon Europe 2021-2024 stated that:

"Horizon Europe will act as a synergetic force across the EU funding programmes.5 Through the programme, special attention will be given to ensuring vibrant cooperation between **universities, scientific communities and industry, including small and medium enterprises**, and citizens and their representatives, in order to bridge gaps between territories, generations and regional cultures, especially caring for the needs of the young in shaping Europe's future."[29]

In other words, Horizon Europe is the copycat of the Bayh-Dole Act on steroids. Now European pharmaceutical, biotechnology industries and universities are partners, in which research centres will act as a one-stop brain talent repository for both sectors, which erodes the walls between basic research and applied research, although some may be unconvinced:

"CLUSTER 1 (Health) will increase Europe's autonomy in delivering health care by contributing to safer, trusted, more effective and efficient, affordable and cost-effective tools, technologies and digital solutions for improved (personalised) health promotion and disease prevention, diagnosis, treatment and monitoring for better health outcomes and well-being, **by integrating people in the design and decision-making, based on expected health outcomes and potential risks involved.** It will also contribute to a health-related industry in the EU that is more competitive and sustainable, ensuring European leadership in breakthrough health technologies and open strategic autonomy in essential medical supplies and digital technologies, contributing to job creation and economic growth, in particular Small and Medium-sized Enterprises (SMEs)." [30]

It is rather challenging to see technology transfer from any technology cluster in Europe for manufacturing purposes to less developed or developing countries to occur in a time frame to save lives. However, the whole point of deploying *integration of health policies,* as a European Union plan, may impact every aspect of technology transfer outside of the EU. Because individual European Union countries in their policy strategy will have limited incentive to export raw materials (like reagents for mRNA vaccines) to non-European countries or to

[29] See, The European Commission, Horizon Europe, Strategic Plan, page 7 available at https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/ec_rtd_horizon-europe-strategic-plan-2021-24.pdf

[30] See, The European Commission, Horizon Europe, Strategic Plan, pages 10, 17, 19, 34, 37, 38, 41, 42, 53, 64, 66 (valorisation of intellectual property), 75, available at https://ec.europa.eu/info/sites/default/files/research_and_innovation/funding/documents/ec_rtd_horizon-europe-strategic-plan-2021-24.pdf

have an incentive to promote technology transfer to countries in need outside of the European Union bloc.

No economic incentive means, in short, loss of lives.

VI. PATENT OFFICES, and TRIPS article 27 (2) exclusion of patentability

It is expected that basic research is conducted to support and improve public policies for the common good of our society so that an informed government may influence stakeholders in the economic sector to produce commercial research for global consumers. Governments should be monitoring prices for medicine, especially the ones that are life-saving drugs.

We should not think about entrepreneurship and competition or profit from high prices for licenses to manufacture life-saving therapies worldwide in the current situation.

One would expect more vaccine diplomacy in times of pandemic, not, conversely, less. At the global level, these economic elements of innovation, technology transfer, and competition are enshrined in the multilateral agreement, The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). But why is an absence of advocacy for TRIPS, article 27 (2), to be used in situations such as the SARS-COV-2 pandemic? Why TRIPs article 27 (2) sits idle in times like this?

The TRIPs, article 27 (2) states that:

"Section 5: patents

Article27

Patentable Subject Matter

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

3. Members may **also exclude** from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement."

Since most jurisdictions have ratified TRIPs, article 27 (2) should have been operational and meaningful. Nonetheless, the truth is far from it. Article 27 (2) has been not useful for the HIV outbreak, and there were no efforts to articulate a specific meaning attributed to *ordre public* or public policy. For instance, SARS-CoV was contained relatively fast after its discovery in 2002, so *ordre public* was not applicable, or at least it would be controversial to restrict the scope and use of IPRs for a contained virus.[31] However, this is not the case with this current pandemic. There is no guarantee that this airborne infection will not return to re-infect populations with many mutations and variables. So, in protecting the *ordre public* or morality to save human lives, this article 27 (2) is a piece of useless knowledge if not used with urgency now. There is an argument to be made that TRIPs does not offer any operational means to permit article 27 (2) to work for States that ratified the agreement. In The United Nations Compendium of International Agreements on Transfer of Technology: Selected Instruments (UNCTAD 2001), or *Compendium,* this management gap is stated as:

"Though the TRIPS Agreement expressly refers to transfer of technology, concerns have been expressed **about the lack of mechanisms in the Agreement to operationalize it**, and the need to develop this concept further in future negotiations has been indicated."[32]

If we have a general meaning for the *ordre public*, it is a flexible interpretation of the principle applicable by choice of the member-States, or in other others, its application is subjective. Subjective means here an unclear set of rules to attribute the circumstances in which it will be operational. For that matter, the *ordre public* lacks purpose for a situation that requires utmost urgency in the COVID-19 case.

COVID-19 virus is an excellent example of a circumstance to be included in Article 27 (2). An airborne disease with a rapid mutation that has decimated individuals regardless of their gender, citizenship, or age would be eligible for such use in the last two years. People are dying of this disease for no access to vaccines because vaccine diplomacy is not working to full effectiveness. Regarding vaccine diplomacy, one does not consider the efficacy standard of the many available vaccines but just access to any vaccine.

A question of public policy or *ordre public* must involve the patentability of subject-matter. Whether the subject-matter is eligible

[31] See, Center for Control Disease Prevention, SARS-CoV available at https://www.cdc.gov/sars/index.html

[32] See, UNCTAD, Compendium, 2001 available at <https://unctad.org/system/files/official-document/psiteipcm5.en.pdf> Cross-reference to Correa, footnote 3.

for an incentive such as to have a grant as a patent or not is the issue for public policy in our treaties and international instruments. In this case, whether it is good public policy to have incentive for basic research via patentability of life-threatening diseases in our public universities and institutes or to re-think incentives for an invention such as a vaccine that saves lives should be the preoccupation of any global, regional, or domestic policymaker.

One would say that implementing a definition of public policy applicable for TRIPs article 27 (2) will help member-States define their economic risks of offering patentability to any biotechnology subject-matter. Including a situation such as a COVID-19 pandemic would be a logical circumstance to avoid patentability instead of an opportunity for pure commercialisation of products. It seems a no-brainer.

We are not witnessing a first-time event for a race for patent exclusivity in an innovative environment such as the biotechnology industry. In 2000, the Human Genomic project and the private-owned Celera Genomics agreed to publish the human genomic map for science and future research instead of working on opposite sides: one side for commercialisation and the other for the public release of the results the future of the human genomic map research.[33]

Patent eligibility is a major problem for patent examiners and patent offices around the world. As patent attorneys specialised in therapeutics and biotechnology medicine recognise, building a strategy for biotechnology clients depends on domestic patent law and international patent law. Shopping for friendly jurisdictions with broad patent eligibility for patent applicants is one of the strategies, so there is a pressing need to have domestic law, including jurisprudence to consider the eligibility and limits for patentable subject-matter. However, with a flexible scope for patent applications domestically and TRIPs article 27 (2) with no specific meaning for the *ordre public,* there is no incentive for domestic patent law to review the scope and patent breadth. Considering this reality, patent examiners have little room to interpret the law in a restrictive sense, but rather the examination process must follow what is available within their domestic jurisdiction.

One of the busiest patent offices in the world has one of the broadest acceptance for interpretation of patent claims, which results

[33] See, Nature, How Diplomacy helped to end the race to sequence the human genome, Editorial, available at <https://www.nature.com/articles/d41586-020-01849-w >. Understanding how we have got to this biotechnology competition to patent biotechnology technologies, one must go back to 1975 Asilomar Conference, see a detailed account on biotechlogy history on Fritjof Capra, The Hidden Connections, (Anchor Books, 2002), pages 158-162.

in a friendly acceptance of claimed subject-matter. However, for the European Patent Office (EPO), the interpretation of a patent claim depends on the wording used in the written claims described for the invention, according to article 53 on Exceptions of Patentability,[34] which the patent examiner must interpret with cross-reference to other Rules and EPO articles and with the limitations on EPO international search.[35]

Coincidentally, the EPO, article 53, refers generally to *ordre public* stated at the TRIPs, article 27 (2). Nonetheless, with no attribution to the meaning of *ordre public*, there is no clear guidance for patent examiners but the domestic law, free to create a novel meaning according to the economics of the moment.

VII. Conclusion

Legal tools are available to improve access to information, technology transfer, changing patent policy, and activating supply chains globally. Moreover, using an international agreement as TRIPs for forging trust among States in situations such as a pandemic allows a more significant collaborative effort among many stakeholders disenfranchised from technology clusters. Transparency and trust are of utmost emergency to avoid theories of insufficient evidence and chaotic vaccine hesitance in our communities. With TRIPs, an agreement of binding nature, we have an excellent instrument to put to the test on article 27 (2). If SARS-COV-2 and its mutations are not controlled at a reasonable pace, it will get worse before it gets better.

With no generics availability for high-end medicines, especially vaccines, patentability for life-saving therapeutics sends a message of mistrust to those who have no access to it and a great deal of lack of morality and a deficient bioethics protocol in our patent system. Thus, becoming more of an intention to achieve vaccine diplomacy but no real intention to act upon it. Moreover, in these times of digital inclusion, communications are instantaneous. Therefore, witnessing deaths in less and

[34] See, the European Patent Office, article 53, available at < https://www.epo.org/law-practice/legal-texts/html/epc/2020/e/ar53.html >

[35] To understand the complexity of the European Patent Office patent application rules for therapeutic use, one has to read the parameters of EPO international search. See, "2. Subject-matter which the ISA is not required to search and examine Art. 17(2)(a)(i) and Art. 34(4)(a)(i) together with Rules 39 and 67.1 are the equivalents of Art. 52(2), (3) and 53(b), (c) EPC concerning the exclusion from patentability of non-technical inventions, programs for computers, methods of doing business, medical methods and the exception to patentability for plant or animal varieties or essentially biological processes for the production of plants and animals, respectively. Since the PCT procedure does not lead to a grant, subject-matter which would be excluded from patentability under the EPC is identified as subject-matter for which the ISA and/or the IPEA is not required to carry out search and international preliminary examination. The criteria applied for the decision not to perform an international search are the same as for the European procedure. This means that the discretion of an ISA not to search subject-matter set forth in Rule 39.1 is exercised by the EPO as ISA only to the extent that such subject-matter is not searched under the provisions of the EPC. For subject-matter which the ISA is not required to search under Art. 17(2)(a)(i) and where, as a consequence, an incomplete search report will be issued, the restriction."

developing countries daily for a lethal virus with a vaccine available is appalling.

It negates the very first principles of the Charter of The United Nations, which advocates for security and peace for all States. To achieve peace and security, we need global health, not by elective priority to nationals, but for all. It shows a lack of justice to withhold nations from therapies regardless of the economic bracket. It is to our mutual benefit to quell SARS-COV-2 variations before they spread out to more populations everywhere. Sitting comfortably in front of any digital media, watching others in despair, and waiting for vaccine diplomacy to come from somewhere else, is not an option. It is time to revert economics as a sole leading component for public health policy in life-saving therapies and re-assess broad patentability eligibility to include proper bioethics principles in our patent laws. TRIPs agreement is a tool, for that matter. That will be a welcome support to re-open negotiations for international agreements such as TRIPs and discuss our options on patentability issues.