FEASIBILITY STUDY OF INDIA'S STAND ON COMPULSORY LICENSING OF COVID VACCINES UNDER WTO TRIPS REGIME

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ANALYSING THE DICHOTOMY

On "March 30, 2021", many national leaders and humanitarian bodies issued an exceptional unified demand for a new interim agreement on global preventing and responding, stating that there would be more outbreaks and catastrophic medical catastrophes.[i] This danger cannot be addressed by a specific nation or intergovernmental organisation. The issue isn't if it will happen, but how and at what time will it take place.

As the globe grapples with said "coronavirus (COVID-19)" epidemic, the appeal represents the depressing reality of the issues that this outbreak has presented to us, as well as the incapacity of the existing framework to solve them. Although various drug manufacturers have managed to conquer the initial tremendous obstacle of producing a vaccine notwithstanding this coronavirus, and a variety of medicines are already in the process. The next, but another primarily important, challenge is to make the requisite amount of vaccinations and disseminate them evenly and economically over the world. Sometimes this obstacle, on the other hand, has been believed to be a major problem. To protect over 80% of the global total, roughly 15 billion shots are predicted to be necessary. Upwards of 2 billion vaccine units have indeed been delivered worldwide, as per the World Health Organization (WHO), with much more than 80% among those shots given in high- and topmost nations but merely 0.3 percentage in least developed states. It's been suggested that getting individuals at lower earning communities immunised might take decades. As a result, this issue has presented an important topic i.e. In what way can the nations increase the speed with which vaccinations are produced and distributed globally at a reasonable cost?[ii]

A patented invention or a knowledge management centre, on the other hand, are not well adapted to obtaining entry to production of confidential proprietary knowledge and related technical expertise. Quite a method, while novel, can only really succeed if the intellectual proprietors believed in the concept and were prepared to share their proprietary information data displayed with the licensing arrangement. The danger of losing discretion in the procedure is probably too big for many of the manufacturers to willingly engage. Drug manufacturers clearly see proprietary information as highly noteworthy "intellectual property (IP) assets". The "Pandemic Technology Access Pool ('C-TAP')", that was established via the "WHO in May 2020", is a good example of this. "South Africa and India" proposed additional alternative in "Late 2020" for addressing the hurdles to deliverability of inexpensive "COVID-19" essential clinical items. They demanded that perhaps the "World Trade Organisation" relinquish definite regulations of the "Trade-Related Aspects of Intellectual Property Rights ('TRIPS') Agreement" for the preventative measures, therapeutic interventions, or deterrence of the pandemic, which would include intellectual property and unrevealed knowledge about immunisation and associated health innovations, in an amended application made in "May 2021"; such an exemption would be in effect for at least three years from the date of the course of action.[iii]

Although Intellectual waivers or forced licencing of inventions may assist to speed up vaccine development, both strategies provide one major downside. Vaccination are complicated biomaterials, and their production is difficult due to the particular technology and resources necessary, the production structures required, and the professional knowledge and understanding demanded, among other factors. "Patent" and, more significantly, private information is usually used to safeguard such information. This has sparked a heated discussion over whether or not drug manufacturers should disclose their intellectual property-protected knowledge with the parties.

THE FEASIBILITIES AND COMPLICATIONS ALLIED WITH "COMPULSORY LICENSING"

In contrast to the development of a comparatively tiny medication, in which the recipient of a license agreement doesn't even need exposure to specifics of the production system in order to

improve a homogeneous unit, the production of a complicated vaccination requires detailed knowledge of the production cycle. This might be accomplished by obtaining an intellectual property licensing. It's also not essential to recreate a possibly prior art production operation to assure an average accuracy, and third-party licensees can make the intended final outcome using a different technique of production. Vaccination, on the other hand, are complicated special proteins that need a distinct combination of expertise and training, along with a thorough understanding of the fabrication procedure as well as the usage of specialist tools (probably developed through producer themselves). [iv]

Whatever administration that wishes to place a regulatory approval in the control of a license holder first should select a possible operator. That operator must at the very minimum have a facility, apparatus, and several level of knowledge in this field. The operator would be responsible for 'setting up, calibrating, and measuring instruments, as well as training experts to operate it. . The extent of technical assistance, along with the range of coverage needed to manufacture, must be identified in the authorization, and, as the segment on proprietary information licencing clearly explained, much will rely heavily on further additional expertise or "display what" to empower the license holder to make significant application of the innovation.[v]

A “licensing agreement” of proprietary information should mention a certain amount of materials that are similar to components of a “voluntary licensing deal”. A “voluntary IP licensing” often contains the following: designation of the “licensor and licensee”, statement of the assets leased, “kind of licensing” (“limited, partial, or non-exclusive”), constraints placed on the “license holder”, and compensation, which is normally in the form of reimbursement. There can be viewed as safeguards in place to maintain secrecy, as well as promises from both the "licensee and the licensor" about the integrity of the items created, which are often backed up by an indemnification intended to protect the “licensors” against defective produces. Expiration clauses will be included in the agreement.

PROTECTION OF VACCINE TECHNOLOGIES UNDER THE IP REGIME

Vaccines are an essential weapon in the fight against the coronavirus pandemic and works by directing our body's immune system to detect and combat pathogens like bacteria and viruses that target and invade it. Whenever the body is inoculated, it is capable of preventing diseases by battling and exposing the organisms that cause the illness.[vi] Several vaccines, including protein based and inactive vaccines, comprise of dead pathogens or small specks of the contagion promoting entities to induce an immunologic reaction and others, including "adenovirus" as well as "RNA-based vaccines", possess generative traits from the pathogen that causes the creation of "virus proteins" upon inoculation, eliciting an immune reaction. COVID-19 vaccinations are currently available in a variety of forms, that include the "nucleic acid vaccine" i.e., the genetic approach, "live-attenuated vaccine", "inactivated virus", and the "viral vector".[vii] The latter class of vaccine, known as "messenger RNA" or "mRNA", is by far most difficult to manufacture since it is dependent on a totally new technique with very constrained manufacturing capability, as well as a scarcity of knowledge and expertise and critical elements. Vaccines are sophisticated and delicate biological products that require a lengthy and complex manufacturing and quality control process. Though each product's production process is distinct and unique, several phases are identical, such as active component propagation, refinement, formulation, filling and finishing, and inspection and laboratory testing. This manufacturing is difficult for a variety of reasons, including sophisticated procedures, expert knowledge and expertise, and the need for proper production facilities. Furthermore, although conventional pharmaceuticals are made using relatively less complex chemical syntheses, biopharmaceuticals, such as vaccinations, necessitate very particular standards and practices throughout the manufacturing process.[viii]

INTELLECTUAL PROPERTY RIGHTS AND VACCINES

Vaccines are regulated by a wide variety of intellectual property rights. Patents are the most well known Intellectual property right that is applicable to vaccines and innovations related to vaccines. By imposing exclusive rights on the holders, patents authorize pharmaceutical

businesses to manage and secure the outcomes of its scientific research innovation and development. The holder of the patent possesses the right to restrict others from exploiting their innovation, and therefore possesses control over the product's manufacture, marketing, and pricing.[ix] Patents on formulations on vaccines, such as the combining medicinal constituents and vaccine administration equipment, such as an injection delivery mechanism or capsules capable of releasing the product in a specific section of the body, may be protected. Trade secrets are another important intellectual right connected to vaccines. All sorts of knowledge that dispense a competitive edge or economic advancement to its holder since it is not widely known are considered trade secrets. Additionally, despite the fact that test data results, particular unpatented clinical formulas, cell culture, genome details, and many other biologic matters may be secured under trade secrets. Additionally, pharmaceutical establishments perceive clinical testing outcomes to be trade secrets. Regulations relating to data protection protect and regulate this information, that is founded on the principles of Article 39 Clause 3 of the "Agreement on Trade Related Aspects of Intellectual Property Rights" TRIPS, which compels the members of the WTO to safeguard test data given to regulatory agencies from disclosure, unethical marketing and unfair commercial usage.

Compulsory licensing mechanism is one of the widely mentioned approaches for accelerating accessibility to covid-19 vaccinations. Considering the fact that pharmaceutical firms are increasingly patenting the outcomes of their vaccine research, the exclusive privileges and rights to vaccinations of covid-19 may limit or even prevent access to this medication. International norms, on the other hand, have special processes linked to forced licensing and governmental usage for uncommercial activities that allow for the limitation of the patent exclusive rights. A government-issued license known as a compulsory license, authorizes an individual who obtains it to utilize the innovation in the absence of the patent holder's permission. The "TRIPS Agreement" contains this feature.[x] Furthermore, the "Doha Declaration on the TRIPS Agreement and Public Health", announced in the year 2001 and reaffirmed that awarding compulsory licenses is the flexibility of TRIPS, which all the members of the WTO possess the right to employ if needed. This approach has been applied in the most of the jurisdictions throughout the world and can be used to solve issues relating to public health. Governmental usage is a category of compulsory license whereby the government regulates its own utilization of a patented invention by issuing permission to an agency or department of the State or to a private organization. This could be a useful and

effective instrument because the administration would not have to file a "formal request" to the possessor of the patent and can settle public health issues on its own. Governments utilizing this approach, would not have to devote hours obtaining a license, as mandated by “TRIPS” in the case of a standard compulsory license, and may authorize governmental use as required. Compulsory licensing has some drawbacks and limitations. Compulsory licenses are usually provided in connection with existing patents. Patent applications are not covered by the mechanism. Application for patents is now being filed for several innovations relating to covid-19, which will be issued in the future years. As a result, this technique of compulsory licensing will not be available until the patent is granted. As a result, it is really possible that national intellectual property laws will have to be changed to permit compulsory licensing of formal request for patents.

Furthermore, whilst compulsory patent licensing may be beneficial in boosting accessibility to certain drugs, such as "small-molecule medical products", this approach may not be helpful in the case of biologic drugs, including vaccines, since their technology used in manufacturing process can be conceivably secured by law of trade secrets. Despite "small-molecule medications", that are uncomplicated for anyone else to "reverse engineer" as well as duplicate lacking knowledge of specialized manufacturing method, understanding how to manufacture a complicated biological medication, including a vaccine, could be crucial. Some claim that in the domain of vaccines 'a production method is a product'. As a result, a compulsory licensing of patents will be inadequate without any such understanding, and patent holders are under no duty to give any extra information surpassing what would be specified in a patent specification under a compulsory licensing. However, unlike the compulsory licensing technique designed for patents, there is presently no analogous mechanism under Intellectual property laws for compulsory licensing of trade secrets.

PROTECTION BY TRADE SECRET LAWS IS NOT ABSOLUTE PROTECTION

National law governs the trade secrets till the extent they may be subjected for compulsory disclosure or legal use by other parties. The term "public interest" is vague, but it is acknowledged that governments of the nation may override such national trade secret

regulations when the curiosity of the public is in, say, acquiring "life-saving technology" takes major priority over trade secret protection. Other than the two parties, 3rd individual has every right to admittance of specific material because of advertising permission, comprising the figures collected in the clinical trial, in the pharmaceutical industry. However, in absence of an overriding interest of the public, such access is subjective to exception if disclosure would jeopardize person's business interests, including the IP rights along with it. However, neither the EU nor the US have particular provisions in IP law that allows a person with compulsory access to the trade secrets of other person and that to be pooled with contestants or the government. As for which, "while a trade secret may be voluntarily licensed, a request for such a licence may or may not be denied."

"LICENSING OF TRADE SECRETS" IS COMPULSORY BY LAW, AND IT IS BASED ON THE PUBLIC'S INTEREST

Trade secret laws have a significant element of public interest. The English courts have developed a countervailing public interest defence to a breach of confidence action that affirms that if there are any circumstances in which the receiver of the confidential information may very well be able to reveal that information to a relevant authority or, in some cases, to the mainstream press because it is justified in doing so for the public interest. However, that aspect of public interest does not extend to justifying the compelled release of trade secret through a compulsory license agreement. "The public interest in the trade secret law involves an appropriate balance between the best interest of the trade secret holders and the public interest in having to disclose such trade secrets." Such balancing process is normally done while assessing a defence mechanism against an unauthorized disclosure of the trade secrets. In few cases, the courts have been relying on the interest of the public to permit the 3rd parties to gain access over the "trade secrets". In the case of "Detroit Med. Ctr. v. GEAC Computer Sys.", "the court determined that the public's interest in obtaining proper medical care outweighed the public's general interest in the fulfillment of such confidentiality agreements." In the present instance of "licensing" of the "trade secrets" relating to the "COVID-19 vaccines", the present mentality of the public is an underlying interest of the people worldwide that with the disclosure of such "trade secrets" will benefit the people at large. "Public interest disclosure" does not

demand it to be publicly released. But it does necessitate disclosure or transfer of that trade secret to another company, supported by a severe requirement of confidentiality. As a result, such methods are less affecting to the original owner itself than the current legal "public interest defence." It's crucial in the midst of a "global pandemic", which provides an ideal opportunity to pique "public interest".

THE TRIPS AGREEMENT AND COMPULSORY LICENCING OF TRADE SECRETS

The A.39 may be seen as the leading global norm for "the protection of trade secrets under the TRIPS Agreement". It is meant to safeguard consumers from prejudicial rivalry in the global marketplace. It requires the members to safeguard confidential information in order to facilitate "proper protection in cases of unfair competition", as stated in the "A.10 bis of the Paris Convention (1967)". The competition created with unfair means is effectively safeguarded against unfair economic conduct by the system. TRIPS-enshrined trade secret legislation protects us from the misappropriation of "trade secrets", which is unlawful if it was obtained improperly and are either utilized, disclosed, or violate an obligation to maintain secrecy. It is acquired improperly if it was obtained by the way of "theft, bribery, deception, breach or solicitation of a breach of fiduciary duty to maintain secrecy, or espionage, including electronic espionage". The "TRIPS Agreement and the Doha Declaration" establishes key philosophies and purposes for community healthiness protection. "Article 7 of TRIPS" specifically states that "Intellectual Property Rights protection and enforcement should contribute to the development of technical innovation as well as the transfer and diffusion of technology in a way that promotes social and economic well-being." Furthermore, A.8 states that "the members may act in a way necessary to protect public health when drafting or amending their laws and regulations, and that appropriate measures may be required to prevent right holders from abusing intellectual property rights or resorting to practices that harm the international transfer of technology". And there are no particular limitations in the TRIPS Agreement that would bar "compulsory licensing of trade secrets". "TRIPS" includes a mechanism for "compulsory licensing of patents", it specifically excludes "compulsory licensing of trade marks" as it is not permitted as per A.21 of TRIPS. As a result, this could be interpreted as authorizing

governments to grant forced trade secret licensing when necessary, for the protection of health of the public at-large.

IMPENDING FACTORS FOR YIELDING A "COMPULSORY LICENSE OF TRADE SECRETS PROTECTING COVID- 19 VACCINES"

"It is argued that Covid-19 vaccines are new and the efficacy & Internal Technological capabilities of these vaccines demonstrates the potential futility of a compulsory license" Additionally, it is claimed that this explanation is unproductive as "TRIPS" permits for Satisfactory Compensation to be remunerated to the "patent holder under Article 31(h)", nevertheless, fails to describe satisfactorily and the technique of computing payment. "There also exists a risk of retaliation by the pharmaceutical companies which can severely harm the Indigenous Industry". "Like in Thailand, after compulsory licensing of Abbott's HIV drug,

Abbott withdrew and stopped selling several drugs in Thailand"

- "Issuing compulsory licenses would only be feasible if the government has a generic producer ready to manufacture sufficient quantities of generics and is technologically equipped. Another setback can be in the protection of trade secrets"
- "Article 39 of the TRIPS Agreement" entails the affiliates to shield "trade secrets" against prejudicial profitable practice.
- Further, yielding "patent waivers" can dishearten "pharmaceutical corporations" from inoculation novelty as they require to capitalize a lot in the "R & D", Such renunciations afford a shortcut to contestants looking to obtain luxurious knowledge.

"Fearing the hindrance of IP Rights in the timely provisioning of medical products, India and South Africa put forth a proposal seeking waiver of patent obligations before the WTO"

"Advocates of Compulsory Licensing have suggested that it is a good measure to solve the problems relating to the manufacturing of the COVID-19 vaccines and related equipment" "They argue that granting a compulsory license will be a win-win situation for both the stakeholders and the public"

(A) "It will help the stakeholders by not depriving them of any rights that they have substantially invested in"

(B) "further it will safeguard public health with ensured production and supply of vaccines. Another argument raised in the support of a grant of compulsory licenses is the supremacy of the right to health over patent protection"

(C) "In some fields, simply having licenses to the necessary patents is enough to begin manufacturing a product and selling it"

(D) "Often, patents covering the same end product are owned by different companies — the latest 5G wireless telecommunications technology, for example, is covered by patents held by more than a hundred different companies a so-called patent thicket While biotech inventions are often covered by far fewer patents than electronic devices, they still often require licenses from multiple patent owners, and the failure to obtain just one can block the production of a product"

(E) "This may be why, despite the fact that Moderna publicly pledged not to assert its mRNA vaccine patents back in October 2020, nobody has yet reproduced the Moderna vaccine for commercial distribution"

(F) "A broad compulsory license of patents in a country would eliminate the need for multiple bilateral licensing negotiations, speeding up time to market and allowing compensation determinations to follow after products are distributed a so-called liability rule solution, which has previously been proposed in this context".

TRADE SECRETS LICENSING

This section will define trade secrets and explain how they vary from other IP rights in terms of licencing, establishing the framework for the next section's discussion of mandatory trade secret licencing.

Every IP right is created on the basis of a trade secret, or, as the "European Commission" put it in a report on trade secrets, "every intellectual property right starts life as a trade secret." [xi] Because of their secret, an unpatented innovation, a creator's concept for a novel inventive

invention, or the scheme for a fresh movie or book all possess worth. The status of the right transforms whenever the creation takes the formula of a "patent application" or the concept is registered, but its value is predicated on confidentiality until the application is published or the concept is made public.

"Trade secrets", like other "intellectual property rights", are given protection by the rules of the nation where the owner (or controller—see below) resides or where an infringement complaint is being filed.[xii] Unfair competition laws are used in some nations, whereas civil wrongs, contract, and employment laws or codes are used in others. "Municipal rule" is overlapped by a notch of consistency in the "Uniform Trade Secrets Act"[xiii] and "Federal statutes" in the form of the "Economic Espionage Act 1996" and the "Defend Trade Secrets Act 2016", which are both based on state law. The United Kingdom and other nations that trail "English common regulation" rely heavily on precedents and the evolution of the rupture of assurance suit for protection.[xiv]

"LICENSING OF TRADE SECRETS"

A "licence" does not give you ownership of the intellectual property underpinning it. It authorises the licensee to perform something that would be a violation of the licensor's rights if the licence did not exist. There isn't a lot of information on trade secret licencing available.[xv] In many aspects, a trade secret licence is similar to other intellectual property licences. There are, nevertheless, some important alterations. If a "licensor" licences an invention to a licensee who later breaches the licence, the licensor retains ownership of the property and is free to find a new licensee. If, on the other hand, "a trade secret licensor" licences its privileges to a "licensee" who then breaches the license's secrecy obligations by revealing the clandestine information to the "public domain", the licensor is basically left with nothing to market. Because the profitable worth of a "trade secret" is founded on its confidentiality, when that confidentiality is lost, the licensable right's substance is also lost. The licensor may have a strong entitlement for compensations in contradiction of the "criminal licensee", but it may not be enough to compensate for the lost revenue from licencing. As a result, a perilous contrast amid "trade secrets" and other "intellectual property rights" is highlighted. The value of trade secrets is determined by their confidentiality. When the right to privacy is taken away, the

worth of the right is also taken away. As a result, trade secret protection in many nations is predicated on the trust relationship between the 'owner' and the information recipient rather than on property rights.[16]

RECOMMENDED PHRASEOLOGY OF A "COMPULSORY VACCINE TECHNOLOGY TRANSFER"

Although there are some reservations about the introduction of a compulsory license, it is a qualified yes. In the case of Mallinckrodt Ard Inc[1]., the "US Federal Trade Commission imposed a compulsory license on the company for the development and commercialization of a bio therapeutic drug".

The license issued to the defendant technology owner was a perpetual, fully paid-up, assignable, and sub licensable license. It provided for the use of the "licensor's" trademarks and its governing material.

The term "Monitor" refers to an impartial arbitrator designated by the "FTC" to supervise the "licensor's" fulfilment of certain responsibilities vides the license, such as the submission of brochures and the giving of admittance to persons to offer engineering knowledge material. This forced license was awarded in a unique situation involving an antitrust violation. The public interest is at the heart of the awarding of a compulsory license to make COVID 19 vaccination equipment obtainable. However, the community attention must take into justification the securities of the licensor technology proprietor, who may have invested a significant amount of period and currency developing economic value for its proprietary.

"The monitor's role, introduced in the Mallinckrodt case, demonstrates that an independent third party could play a significant role in overseeing access to and protection of the licensor's technology, essentially to ensure fair play in what would be an enforced contractual relationship far removed from the typical commercial technology licencing arrangement between commercial parties. Some of the concerns raised in Section 8 above, particularly those pertaining to the enforcement of cross-border responsibilities, may be addressed by the involvement and supervision of a trusted third-party monitor".

SUPPLEMENTARY CONCERNS WITH "COMPULSORY LICENSING OF TRADE SECRETS"

Some additional problems may occur while granting a vaccine's obligatory licence. When conceding a "compulsory licence" for a drug or "vaccine", one of the hurdles to overcome is data and commercial exclusivity, which safeguards experimental assessment statistics given by the inventor to the suitable authority. This exceptionality is intended to prohibit other pharmacological firms from using such information to get an advertising agreement for their nonspecific or "biosimilar" variety of the maker's product throughout the time of protection. The EU pharmaceutical law, for example, provides for an 8-year data exclusivity term and a 2-year marketplace exclusiveness period throughout which nonspecific businesses can request for publicizing permission (while they are not permitted to advertise such products in the given time frame).[xvi] Small compounds and biological products are both covered by this EU exclusivity rule. After the exclusivity period has expired, generic businesses may depend on on the information supplied to the supervisor by the original manufacturer, eliminating the need to repeat lengthy experimental trials to verify that their nonspecific variety of a brandname medicine is harmless and operative.[xvii] "Common corporations just need to demonstrate that their basic variety is "bioequivalent" to a previously permitted merchandise from an originator. Candidates for "biosimilar medicines" (common organic drugs) can also use the data provided by the original manufacturer. They must 'demonstrate finished all-inclusive comparability lessons with the "orientation" organic medication that: (a) their biotic prescription is strongly comparable to the standard medication, despite erraticism intrinsic to all living pills; and (b) there are no clinically evocative variation in mean of safety, quality, and efficacy among the "biosimilar and the reference medicine".[xviii] This means that a compulsory licensee would be unable to get a marketing authorization for its vaccination if it had exclusivity." Several writers have proposed that such exclusiveness be relaxed to permit "forced licensees" to acquire marketing authorizations before the "licenses" expire.[xix] Furthermore, a biosimilar company is often expected to undertake more challenging and provide more statistics to establish the resemblance of its creation to the authorized innovative biotic medication than a standard common

Pharmaceutical industrialist. This means that a compulsory licensee would be unable to get a marketing authorization for its vaccination if it had exclusivity." Several writers have proposed that such selectness be relaxed to consent "forced licensees" to acquire marketing authorizations before the licences expire.[6]

CONCLUSION

The "COVID-19 pandemic" modelled considerable hurdles to the international public, enlightening the contemporary organization's incapacity to satisfactorily accomplish the contagion's destructive properties on a universal gauge. Accelerated manufacture of COVID19 vaccinations, as well as their equal distribution worldwide, are critical to containing this epidemic. This is a difficult task because there is insufficient manufacturing capacity to yield tremendous amounts of doses required to vaccinate the population globally with no part left in a timely manner. Additionally, there exists another, potentially grave, stumbling block: capacity to access technologies related to vaccine is indispensable to speed up production. Pharmaceutical companies, moreover, own a swing of IP privileges that protect such novelties. Numerous methods, such as "voluntary technology pools", compulsory licencing and "C-TAP" and the "TRIPS waiver", have been projected to eradicate this IP barricade. However, there has been a major fault: the "vaccine" industrial procedure fortified by the "trade secrets" and a lack of a method in place to pressurize and push pharmaceutical businesses to distribute the vaccines.

The article proposes, in order for forced licencing of patents or IP waivers to succeed, a separate system which includes compulsory licencing of intellectual property like trade secrets is essential. The divulgence of proprietary knowledge connected to coronavirus vaccinations is claimed to be in the public's best interests. This scheme will also be in harmony with the "TRIPS Agreement", which, while not definitely barring "forced licencing of trade secrets", demands that its fundamentals are to be construed in a technique that reinforces the privileges of the members of the WTO that aims in safeguarding and protecting the health of public. Lack of such a system, the "TRIPS Agreement's" adaptability in the form of compulsory "patent" licencing, put in place to balance strong private intellectual rights, will be lost. The TRIPS Agreement's flexibilities in the configuration of compulsory licencing of intellectual property

like patents, that were introduced for equilibrating private patent rights would be futile and pointless without this extra mechanism.

Compulsory licencing of trade secrets creates a few unique challenges, and some practical solutions are being considered to bring into equilibrium the interests of the owners of technology with the general interest in increasing vaccination availability. Forced licencing of patents and IP waivers are now being proposed as ways to speed up the manufacture of COVID19 vaccines, but an extra method of compulsory licencing of trade secrets is necessary. A suggestion for an advanced system to compulsorily licence the trade secrets, along with a review and scrutiny of the substance of such licences, the hurdles that will overcome, and phrasing of such a licence is thought to give countries with important advice on how to improve the effectiveness of their compulsory technology transfer mechanisms.

ENDNOTES

[i] "Global leaders unite in urgent call for international pandemic treaty (*WHO press release*, 30 March 2021). Available at https://www.who.int/news/item/30-03-2021-global-leaders-unite-in-urgent-call-for-internationalpandemic-treaty (accessed 20 March 2022)."

[ii] "Aisling Irwin, 'What it Will Take to Vaccinate the World Against COVID-19. A Special Report Outlines the Challenges - From Unleashing the Power of mRNA Vaccines, to the Battle for Temporary Intellectual Property Relief' (*Nature* 25 March 2021). Available at https://www.nature.com/articles/d41586-021-00727-3 (accessed 21 March 2022)."

[iii] "WTO, WIPO, WHO, 'Promoting Access to Medical Technologies and Innovation Intersections between Public Health, Intellectual Property and Trade' (2012), available at https://www.wipo.int/edocs/pubdocs/en/global_challenges/628/wipo_pub_628.pdf (accessed 21 March 2022)"

[iv] "Liz Szabo et al., 'Why Even Presidential Pressure Might Not Get More Vaccine to Market Faster' (KHN, 26 January 2021). Available at https://khn.org/news/article/ramping-up-covid-vaccine-production-could-take-monthseven-with-bidens-best-tool-to-pressure-companies/ (accessed 22 March 2022)."

[v] "Mark Anderson and Victor Warner, *Technology Transfer* (4th edn Bloomsbury Professional 2020) Chapter 2"

[vi] WHO 'How do Vaccines Work?' (8 December 2020). Available at https://www.who.int/news-room/featurestories/detail/how-do-vaccines-work (accessed 21 May 2021).

[vii] Robert Weber, 'Explaining Johnson & Johnson's, AstraZeneca's new COVID-19 Vaccines' (The Ohio State University Wexner Medical Center, 2 March 2021). Available at https://wexnermedical.osu.edu/blog/explainingjohnson-johnson-astrazeneca-vaccines (accessed 21 May 2021).

[viii] Hilde Stevens et al., 'Vaccines: Accelerating Innovation and Access. Global Challenges Report' (WIPO, 2017) 14. Available at https://www.wipo.int/publications/en/details.jsp?id=4224 (accessed 21 May 2021).

[ix] Carlos M Correa, 'Guide for the Granting of Compulsory Licenses and Government Use of Pharmaceutical Patents' (2020) 107 The South Centre Research Paper 13; McMahon (n 23) 322.

[x] Article 31 of the TRIPS Agreement.

[xi] "<European Commission, 'Final Study on Trade Secrets and Confidential Business Information in the Internal Market' (2013). Available at https://file:///C:/Users/olgag/Downloads/130711_final-study_en.pdf (accessed 21 May 2021)."

[xii] "<Trade secret laws differ from country to country and no attempt is made here to provide detailed source material. See Trevor Cook, *Trade Secret Protection: A Global Guide* (Globe Law and Business 2016); also 'Trade Secrets' (WIPO).> Available at https://www.wipo.int/tradesecrets/en/ (accessed 21 May 2021). A good perspective on the area is provided in SK Sandeen and EA Rowe, *Trade Secrets and Undisclosed Information* (Edward Elgar 2014)."

[xiii] Uniform Trade Secrets Act 1979 (amended in 1985).

[xiv] *"Coco v A.N.Clark (Engineering) Ltd* [1969] RPC 41. Generally: Tanya Aplin et al., *Gurry on Breach of Confidence* (2nd edn OUP 2012). The UK has implemented the EU Trade Secrets Directive—see the Trade Secrets (Enforcement etc) Regulations SI 2018/597."

[xv] "Jorda (n 88); Dennis Unkovic, *The Trade Secrets Handbook* (Prentice Hall 1985); John Hull, 'Trade Secret Licensing: the Art of the Possible' (2009) 4 *JIPLP* 203; John Hull, 'The Licensing of Trade Secrets and Know How' in Jacques de Werra (ed) *Research Handbook on Intellectual Property Licensing* (Edward Elgar 2013);

[xvi] "Directive 2004/27/EC on the Community code relating to medicinal products for human use [2004] OJ L136/34. In the USA, the Biosimilar Price Competition and Innovation Act (BPCIA)"

[xvii] See Medicines Law & Policy, 'Data Exclusivity in the European Union: Briefing Document' (2019).

[xviii] EMA, 'Biosimilar medicines: marketing authorisation'.

[xix] "Ellen Hoen et al., 'Data Exclusivity Exceptions and Compulsory Licensing to Promote Generic Medicines in the European Union: A Proposal for Greater Coherence in European Pharmaceutical Legislation' (2017) 10 *Journal of Pharmaceutical Policy and Practice* 19; Correa (n 42)."