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Compulsory Licensing – A Derogation from TRIPS Norms to use in Pandemic Times

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Compulsory licensing is known as a practice that is authorized to a third party by government of a state to make, use, or sell a patented invention without the patentee's consent. This legal definition can be interpreted in a simple language for all such as a compulsory license is an involuntary contract between a willing buyer and an unwilling seller imposed and enforced by the state.

The issuances of compulsory licensing is allowed under some circumstances by the governments of developing countries. Developing WTO Members in particular have a compelling need to use compulsory licensing to improve access to medicines, vaccines and other public health related inventions. In turn, it should be mentioned that the origin of compulsory licenses goes back to the UK Patent Act of 1883 granting licenses as a forfeiture for cases in which the patent was not being worked in the UK, the reasonable requirements of the public were not satisfied, or any person was prevented from working or using an invention. Afterwards, the Paris Convention of 1883 accepted the principle of "working obligation", the forfeiture of the patent would only apply where a compulsory license proved to be ineffective as a means of addressing the non-working of a patent (article 5A), that is, forfeiture became a subsidiary measure only applicable if a compulsory license had failed to remedy non-exploitation.

The Paris Convention recognizes the right of member countries to establish compulsory licenses but with certain limitations under the Convention:

1. Member states may (but are not obliged to) provide for the grant of compulsory licenses to prevent abuses of the exclusive rights conferred by the patent, for example for failure to work.

2. Forfeiture of the patent will not be provided for except where the grant of compulsory licenses is not sufficient to prevent abuses. Forfeiture or revocation of a patent will not be instituted before the expiration of three years from the grant of the first compulsory license.

3. A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of four years from the date of application for the patent, or three years from the date of the grant of the patent whichever period expires last. It shall be refused if the patentee justifies his/her inaction by "legitimate reasons".

4. A compulsory license shall be non-exclusive and shall not be transferable even in the form of the grant of a sub-license except with that part of the enterprise or goodwill which exploits such license.

Further, the concept of compulsory licenses extended from the field of patent to another area of intellectual property rights, namely copyright. Article 80 of the Berne Convention for the Protection of Literary and Artistic Works**,** adopted in 1886, refers to non-exclusive right of performers to forbid the transmission of their works via radio, telephone or other equivalent apparatus or such forms of exploitation but they are entitled to equitable compensation for such uses.

National laws have traditionally identified certain situations in which patents are not to be granted. Many countries, for instance, excluded pharmaceutical products from patentability, a practice that is bound to change with the entry into force of the TRIPs Agreement. Though the TRIPs Agreement has limited the freedom of states to define non-patentable items, WTO Members can exclude from patentability plants and animals, therapeutical, surgical and diagnostic methods, as well as inventions which are contrary to morality or *ordre public*.

Although TRIPs incorporates portions of the Paris Convention, the Berne Convention, the Rome Convention, and the Treaty on Intellectual Property in Respect of Integrated Circuits," the patent provisions are notably new to international intellectual property law.'" Without terming it such, TRIPs allows for compulsory licensing amidst several provisions in Article 31.

Instead, much of their attention has been directed to Article 31, concerning "use without authorization of the right holder" or, in more conventional parlance, compulsory licensing. A "compulsory license" is a license to manufacture the patented product that is granted over the objection of the patent holder. Domestic laws that authorize compulsory licensing are permissible under Article 31 but must satisfy a number of conditions. Among other things, compulsory licensing must be preceded by an effort over a "reasonable period of time" to negotiate a license from the right holder on "reasonable commercial terms." This limitation may be waived by a Member in the event of a "national emergency." [Art. 31(b)] In addition, any such use must be "predominantly for the supply of the domestic market." [Art. 31(f)] Further, "the right holder shall be paid adequate remuneration...taking into account the economic value of the authorization." [Art. 31(h)] These provisions raise a number of interpretive issues. How long must a Member attempt to negotiate a license from the right holder in the face of apparent impasse? When does a "national emergency" exist that allows the prior negotiation to be avoided? What is "adequate remuneration" to the right holder? The developing nations sought favorable "clarification" on these and related issues at the Doha ministerial meeting. Another provision that may afford developing nations an opportunity to lower pharmaceutical prices relates to an important qualification on the exclusive right to import under Article 27. That Article cross-references Article 6 of TRIPs, which provides that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." This obscurely worded provision concerns the question whether a patent holder retains any rights over the resale of a product once it has been introduced into the stream of commerce, or whether the initial sale by the right holder "exhausts" its rights.

The term of compulsory license is not included in Art. 31 of TRIPS, but it is referred under the title of the article "Other Use Without Authorization of the Right Holder", the document firstly clarified the term and included the phenomenon of "compulsory licensing" as a flexibility to TRIPS requirements was the Declaration on the TRIPS Agreement and Public Health (the "Doha Declaration").

With regard to specifics, the Declaration provides:

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

(b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted;

(c) Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those

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relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency;

(d) The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

The shortcomings of TRIPS were obvious and in 2001 at the Ministerial Conference meeting in Doha, WTO Members recognized the gravity of the health problems affecting many developing and least developed countries. The Doha Declaration affirmed that the TRIPS Agreement "can and should be interpreted in a manner supportive of WTO members' right to protect public health and, in particular to promote access to medicines for all." WTO Members could freely grant compulsory licenses and decide on the grounds therefore. In order to provide relief for countries with no production capacity in the pharmaceutical sector, Paragraph 6 of the Doha Declaration instructed the Council for TRIPS to find an expeditious solution before the end of 2002.

An important consideration in determining whether compulsory licenses taken by developing countries will impact innovation is the type of drug licensed. Developing countries care about two categories of drugs, each with its own set of incentives. First, there are "global" drugs that are created for rich markets, but are also useful in developing countries. Examples of these are cancer drugs and AIDS therapeutics. Second, there are drugs specific to developing countries. Examples of these include drugs to treat malaria or tuberculosis, or an AIDS vaccine specific to strains of the virus found primarily in Africa.

Compulsory licensing is far from an easy solution; exploiting it fully requires political will. Based on the past record of licensing, countries that elect to take licenses must demonstrate a willingness to endure lawsuits, pressure, and threats of trade sanctions from the United States. In addition, producing drugs pursuant to a license requires a level of technical and manufacturing capability possessed by few countries. Overreliance on compulsory licensing may also produce unintended negative downstream impacts on social measures other than innovation. In addition, without the ability to import drugs made cheaper by compulsory licensing, many countries will not benefit from compulsory licenses. Still, the credible threat of compulsory licensing may reduce drug prices faster and more efficiently than other voluntary options that have been explored.

It should be noted that ministerial declarations within the WTO are not "legally binding," and in the event of a dispute the language of the treaties as approved by national governments would prevail over any contradictory declaration by the ministers. But the Doha declaration is primarily interpretive of imprecise obligations in TRIPs, and does not appear to contradict any textual provision. As such, it is likely to be persuasive authority in the interpretation of TRIPs in the event of a dispute. It also bears noting that the developing nations did not receive everything on their "wish list" at Doha. Recall that TRIPs Article 31(f) provides that compulsory licensing shall be "predominantly for the supply of the domestic TRIPs Art. 8.1. 10 market." Developing nations nevertheless sought language in the ministerial declaration to the effect that "nothing in the TRIPs Agreement prevents Members from granting compulsory licenses for foreign suppliers to provide medicines in the domestic market," and "nothing in the TRIPs Agreement will prevent Members to grant compulsory licenses to supply foreign markets."34 The importance of this issue is considerable, as some developing nations lack the technical capacity to manufacture pharmaceuticals domestically. Thus, if Article 31(f) is interpreted to allow compulsory licenses

only for domestic manufacturers serving the domestic market, the compulsory licensing option may not be useful in some cases.

Importantly, TRIPS Article 31(f) adds that any use of a compulsory license shall be predominantly for the supply of the domestic market of the member state authorizing such use. Article 31(f) had been read to prohibit the manufacture of generics in third countries for export to those countries experiencing the public health crisis. Thus, countries lacking indigenous pharmaceutical manufacturing capacity could not effectively access medicines in compliance with TRIPS Article 31.

Since the emergence of the SARS-CoV-2 virus in winter 2019, the COVID-19 pandemic has wreaked havoc around the world, costing millions of human lives1 and tens of trillions of dollars in damages. In the intellectual property arena, commentators have advanced different proposals to combat the coronavirus. These proposals range from efforts to maximize the limitations, safeguards, and flexibilities in the intellectual property system, to dramatic adjustments to existing domestic and international intellectual property standards, to creative solutions that lie outside but complement the intellectual property system.

Considering the urgency in finding a global solution to combat COVID-19, especially in view of the continuous emergence of new SARS-CoV-2 variants and the WHO's repeated reminder that "[n]o-one is safe until everyone is safe," it is offered to make a novel proposal that would facilitate the deferral of intellectual property rights in pandemic times. Aiming to "split the difference" between the proponents and opponents of the waiver, the deferral proposal draws support from prior precedents involving temporal adjustments to intellectual property rights.

Although COVID-19 has caused wide devastation and disruption, virologists, public health experts, and other commentators have repeatedly reminded us that a similar global pandemic will likely happen again in the next decade or two. SARS, H1N1, H5N1, Ebola, and Zika, Stefan Elbe has summed up our experience of the twenty-first century so far. Thus, if we are to better prepare for future pandemics, it is important that we take note of the lessons provided by the present pandemic and develop a mechanism that will help address global public health exigencies similar to what we have experienced in the past two years.

From an intellectual property standpoint, it will also be highly beneficial to make significant adjustments to the TRIPS-based intellectual property system by preparing our laws and policies for future pandemics or other global catastrophes. The more ready the intellectual property system is, the fewer urgent or ad hoc adjustments will be needed, and the more robust and resilient that system will become.

References:

1. Gianna Julian-Arnold, INTERNATIONAL COMPULSORY LICENSING: THE RATIONALES AND THE REALITY, PTC Research Foundation of the Franklin Pierce Law Center IDEA: The Journal of Law and Technology 1993. https://ipmall.law.unh.edu/sites/default/files/hosted_resources/IDEA/p349.Arnold.pdf
2. INTELLECTUAL PROPERTY RIGHTS AND THE USE OF COMPULSORY LICENSES: OPTIONS FOR DEVELOPING COUNTRIES, South Centre T.R.A.D.E. Working Papers, P-36,https://www.iatp.org/sites/default/files/Intellectual_Property_Rights_and_the_Use_of_Co.pdf

3. Colleen V. Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovaton?* , 18 BERKELEY TECH. L.J. 853 (2003), Available at: https://digitalcommons.law.scu.edu/facpubs/25
4. Yu, Peter K., Deferring Intellectual Property Rights in Pandemic Times (March 20, 2022). Hastings Law Journal, Vol. 74, 2023, Forthcoming, Available at: SSRN: https://ssrn.com/abstract=4062300 or http://dx.doi.org/10.2139/ssrn.4062300
5. Sykes, Alan, Trips, Pharmaceuticals, Developing Countries, and the Doha 'Solution' (February 2002). Available at SSRN: https://ssrn.com/abstract=300834 or http://dx.doi.org/10.2139/ssrn.300834
6. Abbott, Frederick M., The Doha Declaration on the TRIPS Agreement and Public Health and the Contradictory Trend in Bilateral and Regional Free Trade Agreements (December, 27 2011). Quaker United Nations Office (Geneva) (QUNO), Occasional Paper No. 14, April 2004, Available at SSRN: https://ssrn.com/abstract=1977300
7. Алмосова Ш. Защита прав интеллектуальной собственности по Конституции и государственным программам //Review of law sciences. – 2020. – Т. 2. – №. Спецвыпуск. – С. 72-76.
8. АЛМОСОВА Ш. Трипс битими нормаларини Ўзбекистон Республикаси интеллектуал мулк қонунчилигига имплементация қилиш муаммолари //юрист ахборотномаси. – 2020. – Т. 1. – №. 3. – С. 63-71.
9. Алмосова Ш. С. ТРИПС БИТИМИНИНГ ХИТОЙ ХАЛҚ РЕСПУБЛИКАСИ ИНТЕЛЛЕКТУАЛ МУЛК ҲУҚУҚЛАРИ МУҲОФАЗАСИ АМАЛИЁТИГА ТАТБИҚ ЭТИЛИШИ //ЖУРНАЛ ПРАВОВЫХ ИССЛЕДОВАНИЙ. – 2020. – Т. 5. – №. 11.
10. Yakubova IB (2016) A PERSON'S RIGHT TO HEALTH, AS HIS NON-PROPERTY RIGHTS. ISJ. Theoretical & Applied Science, 12 (44): 124-126.
11. Turdialiev, M. A. (2021). REGULATION OF MNES BY DOMESTIC AND INTERNATIONAL POLICIES. *Збірник наукових праць SCIENTIA*. вилучено із https://ojs.ukrlogos.in.ua/index.php/scientia/article/view/17095.