THE DEMAND AND SUPPLY OF HUMANITY: ON THE LEGALITY AND JUSTIFICATION OF ADOPTING COMPULSORY LICENSING MEASURES FOR COVID-19 MEDICINES*

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I. INTRODUCTION: THE CORONAVIRUS PANDEMIC

The unprecedented Coronavirus ("COVID-19") pandemic caused a global paradigm shift and ushered in the *new normal*. Due to the virulent spread of COVID-19 and its threats to humanity's survival, the Philippine government has been taking extreme measures to mitigate the effects of the pandemic.

The amount of COVID-19 related expenses has been sharply increasing and will continue to do so for an uncertain period of time while there remains no treatment to prevent or cure the disease. Should the increase in transmission of the COVID-19 virus continue, the government's 600 billion-peso budget[1] will eventually run dry.

This Essay submits that the Philippine government should adopt compulsory licensing measures for COVID-19 medicines.

COVID-19 is an infectious disease caused by a new form of the coronavirus, causing those infected to experience respiratory illness or worse, to suffer death.[2] As of the end of June 2020, the number of COVID-19 confirmed cases has exceeded 10.1 million worldwide,[3] with over half a

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* *Cite as* Julia Therese Pineda, *The Demand and Supply of Humanity: On the Legality and Justification of Adopting Compulsory Licensing Measures for COVID-19 Medicines*, 93 (Special Online Feature) PHIL. L.J. 107, [page cited] (2020).

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[1] Melissa Luz Lopez, *TIMELINE: The COVID-19 response money trail*, CNN PHIL., Apr. 8, 2020, *at* https://www.cnnphilippines.com/news/2020/4/8/COVID-19-response-money-trail.html

[2] World Health Organization ("WHO"), *Coronavirus*, WHO WEBSITE, *at* https://www.who.int/health-topics/coronavirus#tab=tab_1 (last visited June 29, 2020).

[3] Worldometer, *Coronavirus Update*, WORLDOMETER WEBSITE, *at* https://www.worldometers.info/coronavirus (last visited June 29, 2020).

million deaths.[4] Cases in the Philippines alone have exceeded 35,000,[5] with over 1,000 deaths.[6] The rapid spread of the COVID-19 virus has led the World Health Organization ("WHO") to characterize the outbreak as a pandemic.[7]

The crisis is aggravated by the lack of vaccines or curative treatments.[8] Since COVID-19 is transmitted through droplets,[9] its transmission is almost invisible, especially if the source thereof is an asymptomatic person. Thus, a vaccine has been considered as the ultimate weapon against the virus and the best way out of the crisis.[10] A fast-tracked vaccine usually takes at least 12 to 18 months to be developed due to the required research and development, testing, manufacturing, and regulatory compliance.[11] As of April 2020, there are already at least 254 therapies and 95 vaccines being considered as COVID-19 treatment.[12]

In the Philippines, the government has characterized the COVID-19 pandemic as a national emergency. In Republic Act No. 11469 or the "Bayanihan to Heal As One Act," the Philippines declared a State of Public Emergency due to COVID-19:

> In view of the continuing rise of confirmed cases of COVID-19, the serious threat to the health, safety, security, and lives of our countrymen, the long-term adverse effects on their means of livelihood, and the severe disruption of economic activities, a state of national emergency is hereby declared over the entire country.[13]

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[4] *Id.*

[5] Presidential Communications Group, *Laging Handa PH*, COVID-19 DASHBOARD WEBSITE, *at* http://www.covid19.gov.ph (last visited June 29, 2020).

[6] *Id.*

[7] WHO, *WHO Director-General's opening remarks at the media briefing on COVID-19*, WHO WEBSITE, Mar. 11, 2020, *at* https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020. "WHO has been assessing this outbreak around the clock and we are deeply concerned both by the alarming levels of spread and severity, and by the alarming levels of inaction. We have therefore made the assessment that COVID-19 can be characterized as a pandemic."

[8] WHO, *supra* note 2.

[9] *Id.*

[10] Stuart Thompson, *How Long Will a Vaccine Really Take?* THE NEW YORK TIMES, Apr. 30, 2020, *available at* https://www.nytimes.com/interactive/2020/04/30/opinion/coronavirus-covid-vaccine.html

[11] *Id.*

[12] *Id.*

[13] Rep. Act No. 11469 (2020), § 2.

Indeed, the COVID-19 pandemic has had an irreversible impact on the different sectors in the Philippines and disrupted the daily lives of every Filipino. While the government and the private sector have been adopting measures to mitigate the crisis, the health, economic, and social circumstances of the people continue to worsen while there is no vaccine or curative treatment.

The COVID-19 pandemic has united all people of the world, as we commonly face the threat to survival and individually carry the burden of performing our moral obligations (e.g., wearing a face mask, practicing social distancing) to alleviate the universal plight. Given all humans are born equal with the universal right to health, it is the demand of humanity to ensure everyone is saved from the suffering caused by the pandemic through secured access to a cure. Thus, pharmaceutical companies and governments must heed the call to altruism, to supply humanity even at the expense of lost profits or innovation opportunities.

This Essay is a preparatory study for the government's possible response of making COVID-19 medicines accessible to the entire Philippine population. It will justify the adoption of compulsory licensing on the basis of the national emergency affecting public health, and demonstrate how to implement the same while considering the legally protected intellectual property rights of pharmaceutical companies.

II. THE LEGAL PROTECTION OF INTELLECTUAL PROPERTY

Intellectual property ("IP") rights are the rights conferred to persons over creations of their minds, usually endowing the creator exclusive right over the creation for a certain period of time.[14] The World Trade Organization ("WTO"), of which the Philippines is a member State,[15] provides reasons for the protection of IP rights:

1. Encourage and reward creative work
2. Technological innovation
3. Fair competition
4. Consumer protection

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[14] World Trade Organization ("WTO"), Trade-Related Aspects of Intellectual Property Rights, at 24.3 (2008), *available at* https://www.wto.org/english/tratop_e/trips_e/ta_docs_e/8_bgd_trips_89_e.pdf

[15] WTO, *Philippines and the WTO*, WTO WEBSITE, *at* https://www.wto.org/english/thewto_e/countries_e/philippines_e.htm (last visited June 29, 2020).

5. Transfer of technology
6. Balance of rights and obligations[16]

The protection of IP rights provides incentives for innovation activities, for the benefit and development of society as a whole.

Society most especially benefits from patented inventions as these are "[a]ny technical solution of a problem in any field of human activity which is new, involves an inventive step and is industrially applicable[.]"[17] The goal of the patent system is to bring new ideas into the public domain through disclosure, while striking a balance between the interest of the inventor to enjoy his invention and the people who would benefit from its use. Thus, the Supreme Court has recognized the three-fold purpose of the patent system:

> [F]irst, patent law seeks to foster and reward invention; second, it promotes disclosures of inventions to stimulate further innovation and to permit the public to practice the invention once the patent expires; third, the stringent requirements for patent protection seek to ensure that ideas in the public domain remain there for the free use of the public.[18]

IP is protected in the Philippines under Republic Act No. 8293 or the Intellectual Property Code of the Philippines ("IP Code"), and the Trade-Related Aspects of Intellectual Property Rights Agreement ("TRIPS").

TRIPS is an agreement that embodies the commitment of WTO member States, such as the Philippines, to protect IP rights within their territory[19] and is considered part of Philippine domestic law by virtue of the country's ratification[20] of the Marrakesh Agreement Establishing the World Trade Organization in 1994. [21] Following the Philippines' international commitment, the legislative body enacted the IP Code to reflect the requirements of TRIPS.[22]

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[16] WTO, *supra* note 14, *at* 24.3-24.4.

[17] INTELL. PROP. CODE, § 21.

[18] Pearl & Dean (Phil.), Inc. v. Shoemart, Inc., G.R. No. 148222, 409 SCRA 231, Aug. 15, 2003, *citing* Aronson v. Quick Point Pencil Co., 440 U.S. 257, 262 (1979).

[19] Agreement on Trade-Related Aspects of Intellectual Property Rights [hereinafter "TRIPS Agreement"], art. 1, Apr. 15, 1994, *available at* https://www.wto.org/english/docs_e/legal_e/27-trips.pdf

[20] CONST. art. VII, § 21.

[21] WTO, *The Philippines: September 1999*, WTO WEBSITE, *at* https://www.wto.org/english/tratop_e/tpr_e/tp114_e.htm (last visited June 29, 2020).

[22] *Id.*

Under Philippine law, should a patent application meet the requisites of patentability—novelty, inventive step, and industrial application—it is granted a patent by the IP Office.[23] Since they are excluded from the list of non-patentable inventions, medicines are considered patentable, provided they meet the requisites under the IP Code.[24]

Under Section 71 of the IP Code, a patent over a product confers the right "to restrain, prohibit and prevent any unauthorized person or entity from making, using, offering for sale, selling or importing that product[.]" Similarly, under Article 28 of TRIPS, a patent over a product confers the right "to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product[.]"[25] Thus, as recognized by the Supreme Court in *Pearl & Dean, Inc. v. Shoemart Inc.*, pharmaceutical companies that hold patents over their medicines enjoy the exclusive right to make, use, and vend the patented products and prevent others from exercising similar privileges without the patent holder's consent.[26]

To develop medicines, pharmaceutical companies incur significant costs for research and development. On average, to introduce a new medicine to the market, these companies invest hundreds of millions of dollars over many years into research and development.[27] Compared to other forms of patented inventions, the costs of inventing medicine is significantly higher due to the technical, regulatory, and dissemination barriers to entry. [28] A pharmaceutical company undertakes research and development activities, including discovery research, multi-stage testing, and clinical trials. Thereafter, the company engages in regulatory, promotional, and distribution activities.[29]

Recognizing the costs of research and development of new medicine, patents function as an incentive to pharmaceutical companies. More than an incentive, the protection of IP rights is considered essential for recouping

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[23] Rep. Act No. 8293 (1997), § 21.

[24] § 22.

[25] TRIPS Agreement, art. 28. (Citations omitted.)

[26] Pearl & Dean (Phil.), Inc. v. Shoemart, Inc., G.R. No. 148222, 409 SCRA 231, Aug. 15, 2003.

[27] Carmelo Giaccotto, Rexford Santerre & John Vernon, *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, 48 J. L. & ECON. 195, 196 (2005).

[28] Richard Epstein & F. Scott Kieff, *Questioning the Frequency and Wisdom of Compulsory Licensing for Pharmaceutical Patents*, 78 U. CHI. L. REV. 71, 78 (2011).

[29] Giaccotto et al., *supra* note 27.

investment to develop and market drugs globally. [30] Pharmaceutical companies with patents enjoy broad discretion in determining the pricing of their medicines, and set the price of medicines above that which would be optimal in a competitive market.[31]

Without patents, imitation products can drive innovator pharmaceutical companies out of business by forcing market prices down due to negligible costs for research and development.[32] Low standards of IP rights protection reduce expected income streams and the incentive to invest.[33] Thus, patents are needed to allow innovator pharmaceutical companies to price above marginal cost to recoup expenses and to preserve incentives for future research and development.[34]

While the IP Code was enacted to protect the interest of innovators over their IP, the State policy balances the private rights over IP with the social function the use of IP bears. A portion of Section 2 of the IP Code provides:

> The State recognizes that an effective intellectual and industrial property system is vital to the development of domestic and creative activity, facilitates transfer of technology, attracts foreign investments, and ensures market access for our products. It shall *protect and secure the exclusive rights* of scientists, inventors, artists and other gifted citizens to their intellectual property and creations, particularly when beneficial to the people, for such periods as provided in this Act.
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> The use of intellectual property bears a social function. To this end, the State shall promote the diffusion of knowledge and information for the *promotion of national development and progress and the common good.*[35]

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[30] Vanessa Kerry & Kelley Lee, *TRIPS, the Doha declaration and paragraph 6 decision: what are the remaining steps for protecting access to medicines?*, 3 GLOBALIZATION & HEALTH 1 (2007), *available at* https://globalizationandhealth.biomedcentral.com/articles/10.1186/1744-8603-3-3

[31] CARLOS CORREA, IMPLICATIONS OF THE DOHA DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH 7 (2002).

[32] Patricia Danzon & Adrian Towse, *Differential Pricing for Pharmaceuticals: Reconciling Access, R&D and Patents*, 3 INTL J. HEALTH CARE FIN. & ECON. 183, 185 (2003).

[33] Fredrick Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INTL ECON. L. 469, 473 (2002).

[34] Danzon & Towse, *supra* note 32.

[35] Rep. Act No. 8293 (1997), § 2. (Emphasis supplied.)

Following the declaration of State policy, the protection of IP must align with the promotion of national development and progress and the common good.

III. THE ADOPTION OF COMPULSORY LICENSING AS A COVID-19 RESPONSE

A. Accessibility of COVID-19 Medicines Aligns with the Common Good

It is the common good for COVID-19 medicines to be made accessible to all persons to prevent the further transmission of the virus and put an end to the pandemic. The WHO echoed this sentiment: "If countries detect, test, treat, isolate, trace, and mobilize their people in the response, those with a handful of cases can prevent those cases becoming clusters, and those clusters becoming community transmission. Even those countries with community transmission or large clusters can turn the tide on this virus."[36] Considering that the COVID-19 virus is not bound by geographic borders, ethnicity, gender, age, physique, or wealth, but in fact has been indiscriminately infecting any person through contact transmission, widespread efforts are required to put an end to the pandemic.

The COVID-19 pandemic has caused an economic crisis due to the shutdown of the market, as well as the unplanned fiscal spending of governments to address the situation. In the Philippines, COVID-19 treatment reportedly ranges from PHP 43,000.00 to about PHP 800,000.00.[37] The reported ceiling cost is almost four times higher than the average family income of PHP 267,000.00.[38] COVID-19 treatment is not only expensive in the Philippines, but in developed countries as well. In the United States, it was reported that many COVID-19 patients have struggled with the cost of medical treatment.[39]

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[36] WHO, *supra* note 7.

[37] Trishia Billones, Jessica Fenol & Warren de Guzman, *How much does COVID-19 treatment cost, and how much will PhilHealth cover?*, ABS-CBN NEWS, Apr. 15, 2020, *available at* https://news.abs-cbn.com/business/04/13/20/how-much-does-covid-19-treatment-cost-and-how-much-will-philhealth-cover

[38] CEIC Data, *Philippines Average Family Income: Philippines: All Income Classes*, CEIC WEBSITE, *at* https://www.ceicdata.com/en/philippines/family-income-and-expenditure-survey-average-annual-income-by-family-size-and-income-group/average-family-income-philippines-all-income-classes (last visited June 29, 2020).

[39] Hilary Wong, *The case for compulsory licensing during COVID-19*, 10 J. GLOB. HEALTH 1 (2020), *available at* http://www.jogh.org/documents/issue202001/jogh-10-010358.html

To promote the common good, the government must enact measures to ensure the affordability and accessibility of COVID-19 medicines. In an open letter calling on all governments to unite behind a people's vaccine against COVID-19, more than 140 world leaders and experts made this statement:

> Governments and international partners must united around a global guarantee which ensures that, when a safe and effective vaccine is developed, it is produced rapidly at scale and made *available for all people, in all countries, free of charge*. The same applies for all treatments, diagnostics, and other technologies for COVID-19.
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> * * *
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> *Our world will only be safer once everyone can benefit from the science and access a vaccine* – and that is a political challenge.[40]

B. Compulsory Licensing as a Possible Solution

To achieve the common good of accessibility of COVID-19 medicines, it is submitted that the Philippine government should consider enacting legislation for the compulsory licensing of medicines for the prevention or cure of the virus. Compulsory licensing is an exception to the exclusivity of the rights granted to a patent holder. The IP Code authorizes the Director General of the Intellectual Property Office to "grant a license to exploit a patented invention, even without the agreement of the patent owner, in favor of any person who has shown his capability to exploit the invention"[41] under the legally defined circumstances. In effect, the government may legally grant an exception to the exclusive protection of a patent by allowing the use of the patented invention by itself or by a third party, even without the consent of the patent holder and despite the latter's dissent.[42] By manufacturing generic alternatives of the medicines, the government can ensure the affordability thereof since only negligible costs are involved in production and distribution.

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[40] Oxfam International, *OPEN LETTER: Uniting Behind A People's Vaccine Against COVID-19*, MEDIUM, May 14, 2020, *at* https://medium.com/@Oxfam/uniting-behind-a-peoples-vaccine-against-covid-19-87eec640976 (Emphasis supplied.)

[41] Rep. Act No. 8293 (1997), § 93.

[42] Jon Matthews, *Renewing Healthy Competition: Compulsory Licenses and Why Abuses of the TRIPS Article 31 Standards are Most Damaging to the United States Healthcare Industry*, 4 J. BUS. ENTREPRENEURSHIP & L. 119, 124 (2010-2011).

TRIPS allows for compulsory licensing, provided the proposed user has made unsuccessful efforts over a reasonable period of time to obtain the consent of the patent holder on reasonable commercial terms.[43] This requirement may be waived in case of national emergency or other circumstances of extreme urgency.[44]

Under the IP Code, among the grounds for compulsory licensing are national emergency,[45] and where the public interest (including health, in particular) so requires, as determined by the appropriate government agency.[46] Similar to TRIPS, the IP Code requires a prior attempt at negotiation before the grant of a compulsory license, but such requirement does not apply in situations of national emergency or other circumstances of extreme urgency[47] and in cases where the demand for patented drugs and medicines is not being met to an adequate extent and on reasonable terms.[48]

Thus, the IP legal regime recognizes national emergency, such as public health crises, to justify the issuance of a compulsory license, regardless of prior attempts at negotiation with the patent holder, if any.

Because of the pandemic, other countries have recently adopted compulsory licensing measures in relation to COVID-19 treatment. In Israel, the Minister of Health, acting under authority conferred by the Israeli Patents Law, issued a compulsory license for the importation of the Kaletra drug for the sole purpose of medicinal treatment of COVID-19 patients.[49] In France, the emergency law to deal with the COVID-19 pandemic amended the public health code to allow the Prime Minister, when a state of health emergency is declared, "to take all measures to make available to patients appropriate medicines for the eradication of the health disaster."[50] In Germany, the government enacted the Epidemic Protection Act, which included an amendment to restrict German patents covering pharmaceuticals or medical

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[43] TRIPS Agreement, art. 31(b).

[44] Art. 31(b).

[45] Rep. Act No. 8293 (1997), § 93.1.

[46] § 93.2.

[47] § 95.2(b).

[48] § 95.2(d).

[49] Thiru Balasubramaniam, *Israel issues compulsory license to allow the government to import generic versions of Kaletra*, KNOWLEDGE ECOLOGY INTERNATIONAL WEBSITE, Mar. 23, 2020, *at* https://www.keionline.org/32503

[50] Francois Pochart, Mathilde Rauline & Océane de La Verteville, *Compulsory licenses granted by public authorities: an application in the Covid-19 crisis in France? Part 1*, KLUWER PATENT BLOG, Apr. 23, 2020, *at* http://patentblog.kluweriplaw.com/2020/04/23/compulsory-licenses-granted-by-public-authorities-an-application-in-the-covid-19-crisis-in-france-part-1/?doing_wp_cron=1593338428.2446949481964111328125

devices.[51] In Canada, the Emergency Response Act allowed the issuance of a compulsory license in response to the public health emergency, among other emergency measures.[52]

The Philippines should follow suit and prepare for the introduction of COVID-19 medicines to the market in order to ensure that, upon availability, the same remain accessible to all Filipinos for the prevention and cure of COVID-19.

C. Legality of Adopting Compulsory Licensing during the COVID-19 Pandemic

TRIPS embodies the international obligation of the Philippines to protect and uphold IP rights within its jurisdiction. Should the Philippines fail to comply with TRIPS, and upon complaint by a WTO member State, it may be subjected to WTO's dispute settlement mechanism.[53] A violation of an international obligation may also subject the Philippines to responsibility under customary international law.[54]

The legal question must be addressed before the Philippines resorts to compulsory licensing of COVID-19 medicines—whether compulsory licensing measures to address the COVID-19 pandemic are legally permissible.

It is submitted that there exists a clear and justifiable ground for the issuance of compulsory licenses for COVID-19 medicines—a national emergency contemplated under TRIPS. TRIPS did not provide qualifications on what constitutes a national emergency or a circumstance of extreme urgency, but instead gave the task to local courts or administrative authorities to judge when the public interest requires the granting of a compulsory license.[55]

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[51] Jill Tellioglu & Hazal Koepp, *Germany, UK, USA: Are Patent Exceptions the Cure to COVID-19?* MORRISON & FOERSTER WEBSITE, Apr. 14, 2020, *at* https://www.mofo.com/resources/insights/200414-patent-exceptions-cure-covid-19.html

[52] Stephen Selznick & Any Obando, *Canada: COVID-19 Impact: Changes To The Canadian Compulsory Licensing Scheme*, MONDAQ WEBSITE, Apr. 20, 2020, *at* https://www.mondaq.com/canada/operational-impacts-and-strategy/919256/covid-19-impact-changes-to-the-canadian-compulsory-licensing-scheme

[53] WTO, *supra* note 14, at 24.22.

[54] Rainbow Warrior Affair (New Zealand v. France), XX R.I.A.A. 215, 251 (Apr. 30, 1990).

[55] CARLOS CORREA, INTELLECTUAL PROPERTY RIGHTS AND THE USE OF COMPULSORY LICENSES: OPTIONS FOR DEVELOPING COUNTRIES 13 (1999).

To solidify the State's right to grant compulsory licenses and exercise its discretion to determine the existence of grounds therefor, the WTO provided additional guidance through the Declaration on the TRIPS Agreement and Public Health ("Doha Declaration").[56] The Doha Declaration is to be read into the interpretation of TRIPS,[57] following the rules under the Vienna Convention on the Law of Treaties.[58]

In the Doha Declaration, WTO member States recognized both the importance of IP protection for the development of new medicines, as well as the concerns about its effects on prices.[59] As discussed above, the patent system confers patent holders discretion in setting prices to allow them to make a profit.[60] The Doha Declaration tempers this discretion by identifying high prices of medicines caused by patent protection as among the grave problems that afflict developing countries.[61]

To clarify the relation of TRIPS to public health, the Doha Declaration states that:

> We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be *interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.*
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> In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose.[62]

To further strengthen the recognition of a State's right to grant compulsory licenses, the Doha Declaration recognized that the TRIPS'

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[56] Kyung-Bok Son, *Importance of the intellectual property system in attempting compulsory licensing of pharmaceuticals: a cross-sectional analysis*, 15 GLOBALIZATION & HEALTH 1, 2 (2019), *available at* https://globalizationandhealth.biomedcentral.com/articles/10.1186/s12992-019-0485-7

[57] James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J. L. TECH. 291, 306 (2002).

[58] Vienna Convention on the Law of Treaties, art. 31-32, Jan. 27, 1980, *available at* https://legal.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf

[59] Declaration on the TRIPS Agreement and Public Health [hereinafter "Doha Declaration"] ¶ 3, Nov. 14, 2001, *available at* https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[60] *Supra* Part II.

[61] Correa, *supra* note 31.

[62] Doha Declaration, ¶ 4. (Emphasis supplied.)

flexibilities include "the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."[63] Further, public health crises, including epidemics, can represent a national emergency or other circumstances of extreme urgency, as determined by a member State.[64]

The Doha Declaration quelled any doubt as regards a State's sovereign discretion to determine what constitutes a national emergency that would justify resort to compulsory licensing measures. The specific recognition of the primacy of public health indicates that public health-related patents may be treated differently from other patents.[65]

The Doha Declaration's recognition of the primacy of public health over proprietary interests aligns with the universal status of the right to health, thus further supporting the characterization of the COVID-19 pandemic as a national emergency under TRIPS.

Article 12 of the International Covenant on Economic, Social and Cultural Rights provides that "[t]he States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health."[66] Among the essential elements of the right to health are availability and accessibility.[67] Therefore, to uphold the right to health, the State must ensure the said conditions prevail. States have a corollary obligation to ensure access to affordable health care.[68]

The right to health is also enshrined in Section 15, Article II of the Philippine Constitution: "The State shall protect and promote the right to health of the people and instill health consciousness among them."[69] The elements of accessibility and affordability are adopted in Section 11, Article XIII: "The State shall adopt an integrated and comprehensive approach to

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[63] ¶ 5.2.

[64] ¶ 5.3.

[65] Correa, *supra* note 31, at viii.

[66] International Covenant on Economic, Social and Cultural Rights art. 12, Dec. 16, 1966, 993 U.N.T.S. 3, *available at* https://www.ohchr.org/EN/ProfessionalInterest/Pages/CESCR.aspx

[67] United Nations Committee on Economic, Social and Cultural Rights, General Comment No. 14, The Right to the Highest Attainable Standard of Health (Twenty-second session, 2000), at ¶ 12, U.N. Doc. E/C.12/2000/4 (Aug. 11, 2000).

[68] WHO, *Human rights and health*, WHO WEBSITE, Dec. 29, 2017, *at* https://www.who.int/news-room/fact-sheets/detail/human-rights-and-health

[69] CONST. art. II, § 15.

health development which shall endeavor to make essential goods, health and other social services available to all the people at affordable cost."[70]

The right to health deserves such legal distinction because it is considered essential to the enjoyment of other human rights.[71] As such, the right to health has been considered by the United Nations General Assembly as an "investment in human capital and social and economic development, towards the full realization of human potential, and significantly contributes to the promotion and protection of human rights and dignity as well as the empowerment of all people[.]"[72]

However, the right to health does not exist in a vacuum, but in the same legal environment that promotes and protects IP rights. There are apparent conflicts between the IP rights regime and human rights law, since the former does not fully allow the universal enjoyment of the right to health due to the barriers for the use of patented inventions.[73]

As to what should prevail in the international and domestic spheres, it is submitted that the right to health trumps the right to property. Internationally, this view is supported by TRIPS, as it includes in its principles the adoption of measures necessary to protect public health,[74] and it allows the granting of compulsory licensing for matters such as public health.[75] In the Philippines, the Supreme Court has already recognized the secondary nature of the right to property: "based on the hierarchy of constitutionally protected rights, the right to life enjoys precedence over the right to property. The reason is obvious: life is irreplaceable, property is not."[76] The right to health—being essential to the right to life and considering the absence of good health deteriorates or destroys life—also takes precedence over IP rights.

The COVID-19 pandemic is a national emergency in the Philippines, thus justifying compulsory licensing measures. Aside from its positive classification as a national emergency under the Bayanihan to Heal As One

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[70] Art. XIII, § 11.

[71] OFFICE OF THE UNITED NATIONS HIGH COMMISSIONER FOR HUMAN RIGHTS & WORLD HEALTH ORGANIZATION, THE RIGHT TO HEALTH 6 (2008).

[72] United Nations General Assembly, Resolution Adopted by the General Assembly on 10 Oct. 2019 (Seventy-Fourth Session, 2019), at ¶ 8, U.N. Doc. A/RES/74/2 (Oct. 10, 2019).

[73] Haochen Sun, *Reshaping the TRIPs Agreement concerning Public Health: Two Critical Issues*, 37 J. WORLD T. 163 (2003).

[74] TRIPS Agreement, art. 8.

[75] Art. 31; Doha Declaration, ¶ 6.

[76] Social Justice Society v. Atienza, Jr., G.R. No. 156052, 545 SCRA 92, 157, Feb. 13, 2008.

Act,[77] and its qualification as a national emergency under TRIPS interpreted alongside the Doha Declaration, the pandemic's threat to the survival of humanity and the universal enjoyment of the right to health are grave and imminent to necessitate the proposed compulsory licensing measures.

D. Balancing the Consequences of Enacting Compulsory Licensing Measures

While compulsory licensing measures may present itself as the obvious solution to securing access to COVID-19 medicines, it would be hasty to conclude that it is the best option available to the government without considering the consequences thereof.

Compulsory licensing measures are considered to have a serious chilling effect on inventing. Inventions, especially in pharmaceutical companies, require a huge investment that cannot be recuperated without the enjoyment of IP rights.[78] Other consequences of compulsory licensing measures include the potential loss of foreign direct investment and investment opportunities and the reduction of incentives to innovate.[79]

The granting of compulsory licenses can be misused, thereby threatening the security of private property and the promotion of innovation. As such, this measure has been considered akin to the governmental taking of property through expropriation.[80] Given the great impact of compulsory licensing on private property rights, it must be used conscientiously, so as not to hinder innovation and trample upon private rights.

A good warning comes from Brazil's experience with Merck & Co., in which the Brazilian government issued a compulsory license, despite having middle-class income levels, for the sole purpose of lowering the cost of pharmaceutical products. Merck & Co. was dissuaded by Brazil's actions, stating that "[t]his expropriation of intellectual property sends a chilling signal

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[77] Rep. Act No. 11469 (2020), § 2.

[78] Selin Sinem Erciyas, *Compulsory Licensing and 'Inventing' for COVID-19*, INTERNATIONAL BAR ASSOCIATION WEBSITE, June 30, 2020, *at* https://www.ibanet.org/Article/NewDetail.aspx?ArticleUid=486fe1e1-c68b-45a1-9b0c-c4238cc2e2b3

[79] Jerome Reichman, *Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options*, 37 J. LAW MED. ETHICS 247 (2009).

[80] Matthews, *supra* note 42, at 124.

to research-based companies about the attractiveness of undertaking risky research on diseases that affect the developing world[.]"[81]

While making medicines cheap appears to be beneficial in the short term, it risks undermining incentives for future development or distribution of medicines,[82] as learned in the case of Brazil. Aside from the moral disincentive, future research and development may not be financially feasible because compulsory licensing may deprive a pharmaceutical company of expected income streams needed for reinvestment into research and development. This may result in a delay of new medicines or the non-development of medicines for common diseases in countries that enforce compulsory licensing measures.[83]

There is also a moral and legal debate as to who should bear the burden of making medicines accessible to all. This is not the obligation of pharmaceutical companies, but an obligation of the State. Pharmaceutical companies have highlighted how access to medicine is a "problem arising from improper prescribing, irrational use and selection, poor distribution chains, and unsustainable financing."[84] Notwithstanding the fact that pharmaceutical companies do not bear the burden, these companies are aware that their IP rights are subject to the State's sovereign power to issue compulsory licenses when public health necessitates such measures. Thus, under the law, IP rights must yield to State regulation in exceptional circumstances.

The importance of balancing seemingly conflicting rights was emphasized in an article:

> Intellectual property protection should keep a balance between the need to provide incentives to reward and spur innovation and the need to ensure that society benefits from having maximum access to new creations. *Just as too little protection of intellectual property rights can impede innovation and trade, so can too much protection undermine the fundamental human rights.*[85]

Applying a balanced approach to the COVID-19 pandemic in the Philippines, it is clear that the benefits of adopting compulsory licensing outweigh the consequences.

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[81] *Id.* at 135.
[82] Danzon & Towse, *supra* note 32, at 201.
[83] Epstein & Kieff, *supra* note 28, at 80.
[84] Kerry & Lee, *supra* note 30, at 9. (Citations omitted.)
[85] Sun, *supra* note 73. (Emphasis supplied.)

First, there is a need to ensure access to the COVID-19 medicines not only because of the universality of the right to health, but more importantly because of the nature of the virus, which can be transmitted instantly and invisibly. As the WHO emphasized, a whole-of-government and whole-of-society approach is needed to prevent infections, save lives, and minimize the impact of the pandemic.[86]

Second, the COVID-19 pandemic is an unprecedented challenge that governments were unprepared for. Developing countries often have a limited short-term health budget, thus paying for COVID-19 medicines may entail an opportunity cost, such as the discontinuation of other health programs.[87] This has proven to be true as to mass testing in the Philippines. There is limited government capacity to conduct mass testing, causing such to be delegated to the private sector.[88]

Third, given that the average family income in the Philippines is reported at PHP 267,000.00,[89] the average Filipino cannot afford these unforeseen medical expenses. It has been reported that even wealthy countries have citizens struggling to meet medical expenses related to COVID-19.[90] The availability of generic alternatives could substantially reduce the prices of COVID-19 medicines, making the same affordable to a greater number of people.[91]

Fourth, without mass access to COVID-19 medicines, there will be gaps that allow the continued transmission of the COVID-19 virus, thereby weakening the efforts to end the pandemic. Mass treatment is required to prevent transmission, as emphasized by the WHO.[92]

Fifth, global leaders have already called for the "people's vaccine," encouraging COVID-19 treatment to be "made available for all people, in all

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[86] WHO, *supra* note 7.

[87] Joshua Cohen, *Pricing of COVID-19 Treatments and Coronavirus Vaccines*, FORBES, May 11, 2020, *available at* https://www.forbes.com/sites/joshuacohen/2020/05/11/pricing-of-covid-19-treatments-and-coronavirus-vaccines/#690478b42865

[88] Darryl John Esguerra, *Gov't says it's up to private sector to conduct mass tests for COVID-19*, INQUIRER.NET, May 18, 2020, *available at* https://newsinfo.inquirer.net/1276892/amid-limited-covid-19-testing-capacity-govt-to-let-private-sector-conduct-mass-testing

[89] CEIC Data, *supra* note 38.

[90] Wong, *supra* note 39.

[91] Abbott, *supra* note 33, at 472.

[92] *Supra* Part III.A.

countries, free of charge,"[93] and thereby echoing the need to adopt drastic measures to ensure accessibility of COVID-19 medicines.

Sixth, public opinion favors compulsory licensing over the protection of IP rights, and has been effective in influencing pharmaceutical companies to be more altruistic than profit-driven in their response to the pandemic.[94]

Finally, compulsory licensing is not designed to be prejudicial to the patent holder's interest, although it may result in a less than ideal operational setback. TRIPS mitigates the harm to the patent holder by imposing strict requirements for the validity of a compulsory license. Among these requirements are the individual merits for authorization of use,[95] attempt at voluntary licensing negotiation,[96] limited scope and duration of use,[97] non-exclusivity and non-assignment of use,[98] and adequate remuneration in the form of just compensation,[99] among others. In the pharmaceutical industry, royalty rates are around 10% on sales, which take into account the need to recover the money invested in the patented invention.[100] Thus, TRIPS still seeks to protect patent holders by ensuring fair restrictions are imposed upon the use of the compulsory license and requiring the payment of adequate remuneration.

E. Alternative Solutions

The government can impose maximum retail prices for medicines[101] under the Universally Accessible Cheaper and Quality Medicines Act of 2008 or Republic Act No. 9502. However, these ceiling prices may hinder pharmaceutical companies from distributing COVID-19 medicines in the Philippines if it would not be profitable. Price controls are viewed as a barrier for pharmaceutical companies' entry into a foreign market when such controls are too restrictive.[102] Notably, the same law recognizes compulsory licensing

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[93] Oxfam International, *supra* note 40.

[94] Erciyas, *supra* note 78.

[95] TRIPS Agreement, art. 31(a).

[96] Art. 31(b).

[97] Art. 31(c).

[98] Art. 31(d), (e).

[99] Art. 31(h).

[100] Motohiro Yamasaki, *Determining Pharmaceutical Royalties*, LES NOUVELLES, Sept. 1996, at 113, *available at* http://plg-group.com/wp-content/uploads/2014/03/Determining-Pharmaceutical-Royalites-Motohiro-Yamasaki-Les.pdf

[101] Rep. Act No. 9502 (2008), § 22.

[102] Eric Bond & Kamal Saggi, *Compulsory licensing, price controls, and access to patented foreign products*, 109 J. DEVT. ECON. 217, 218 (2014).

as among the measures to achieve accessible, cheaper, and quality medicines.[103]

The government can negotiate for discounted bulk purchase deals[104] or for voluntary licensing. Historically, pharmaceutical companies have offered poor countries discounts for medicines, such as antiretrovirals for the treatment of HIV-AIDS.[105] However, unlike compulsory licensing, these alternatives are dependent on the discretion of the patent holder and not attainable by the mere exercise of sovereign power. Prior experience also shows that pharmaceutical companies cannot match prices offered by successful generic producers.[106]

Parallel importation might be an available measure, wherein COVID-19 medicines lawfully manufactured and marketed in another country would be imported into the Philippines without the consent of the patent holder in the importing country. However, a compulsory license is also required for the importation of patented medicines. Philippine law allows the government to grant a special compulsory license for the importation of patented drugs and medicines primarily for domestic consumption.[107] Moreover, under TRIPS, the Philippines must notify the WTO of its intent to import due to the lack or insufficiency of local manufacturing, since such would entail a waiver of the compulsory licensing requirement of the predominant supply of a domestic market.[108] Notably, there is potential infringement in the country of export even if the importing country has a compulsory license if the patent holder in the country of export did not consent to the export or is not under compulsory licensing.[109] Thus, should the Philippines lack manufacturing capacity for COVID-19 medicines, and there are no countries able to export the same under a compulsory license or exception, there might be no supply of the needed medicines.[110]

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[103] Rep. Act No. 9502 (2008), §§ 10-13.

[104] Epstein & Kieff, *supra* note 28, at 83-84.

[105] International Institute for Sustainable Development, TRIPS and Public Health, (2003), *available at* https://www.iisd.org/sites/default/files/publications/investment_sdc_dec_2003_9.pdf/

[106] *Id.*

[107] Rep. Act No. 8293 (1997), § 21; Rep. Act No. 9502 (2008), § 11.

[108] Lalitha Narayanan, *Doha Declaration and Public Health Issues,* 13 J. INTELL. PROP. RTS. 401, 405-406 (2008).

[109] Abbott, *supra* note 33, at 501.

[110] *Id.* at 499-500.

IV. CONCLUSION

This Essay presented the legal viability of adopting compulsory licensing measures and argued for its necessity and benefit in addressing the public health crisis.

There is a legally recognized justification to strictly uphold the patent rights of pharmaceutical companies. There is private interest in ensuring profitability, as well as public interest in incentivizing innovation. While compulsory licensing will make COVID-19 medicines accessible in the short-term during the heat of the pandemic, the hidden costs of this measure come with long-term consequences on innovation and health treatments.

However, the universal access to COVID-19 medicines is an irreplaceable means for survival, a demand of humanity, and a necessary sacrifice—a supply of humanity from those in the position to give. As demonstrated in this Essay, the COVID-19 pandemic is an unprecedented health crisis threatening the survival of humanity and the collapse of the global economy. Thus, notwithstanding the indirect costs of compulsory licensing, the right to health of all people must take precedence over the IP rights of pharmaceutical companies and must be upheld through compulsory licensing measures that would ensure universal access to COVID-19 medicines.

The WHO has warned: "This is not just a public health crisis, it is a crisis that will touch every sector – so every sector and every individual must be involved in the fight."[111] With these final words, we are reminded that, at this exceptional time of unprecedented crisis, we heal as one through our collective action for the common good, and not by asserting private interests over the needs of humanity.

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[111] WHO, *supra* note 7.