PHILIPPINES' EMERGENCY PATENT LAW

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THE PATENT PANDEMIC

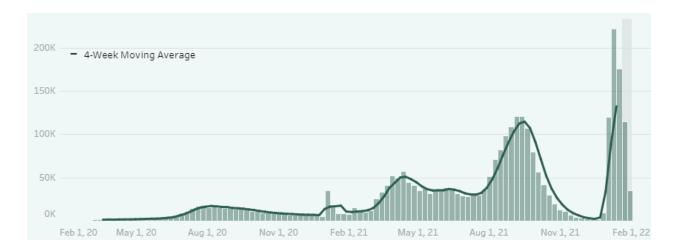
An Analysis of the Philippines' Emergency Patent Laws in the Time of the COVID-19 Pandemic

RAUL GABRIEL M. MANALO¹

INTRODUCTION

The year 2020 began with the Coronavirus disease 2019, commonly known as COVID-19 (hereinafter referred to as COVID), creeping into every nation around the world. By the second quarter of the year, it brought governments to their knees as it affected the global economies and the world was sent into a pandemic situation. Countries scrambled to adjust their policies in containing the spread of the disease through actions such as quarantines, work-from-home setups, and state-financial aid.

In the Philippines, cases spike throughout the duration of the pandemic as shown in the chart below. These include the summer of 2021, 3rd quarter of 2021 and early 2022 where the Omicron variant emerged. In an effort to mitigate the damage of the disease, the Philippine government enacted Republic Act (R.A.) 11494 also known as the Bayanihan Act during the height of the early lockdown. This paved the way to numerous policy changes by government agencies to combat COVID. These policies include financial aid to those employees who lost their jobs due to the pandemic, benefits for frontline workers (e.g. death benefit), and quarantine passes to control movement in high-density areas.



¹ Understudy, UST Law Review (Vol. 66), Juris Doctor Candidate, University of Sto. Tomas Faculty of Civil Law (2024); A.B. European Studies, Ateneo de Manila University

Source: Department of Health (DOH) COVID19 Tracker (https://doh.gov.ph/covid19tracker)

Health care facilities faced inadequacies in terms of equipment, testing, and facilities which resulted in multiple national lockdowns due to rising numbers of cases during the third and fourth quarter of 2020. In a May 2020 study, countries with higher number of hospital beds and nurses show a lower number of fatalities. ²For the Philippines, it faced such public health challenges. A 2021 early COVID-19 response study reported that the country has roughly ten hospital beds and six physicians per ten thousand Filipinos. Health care facilities also face inadequacies in terms of equipment, testing, and facilities which resulted in multiple national lockdowns due to rising numbers of cases during the third and fourth quarter of 2020.³

Governments sought for different solutions in containing the spread of the disease while also developing a cure or some sort of medicine to counteract the disease's symptoms. For the private sector, the pandemic prompted pharmaceutical companies as well as other industries to find remedies to counteract COVID. As of late 2020, vaccines are now being introduced into society to provide protection against the disease's effects. Vaccines are not necessarily distributed equally however as the capital region has a higher vaccinated population (more than 90%) areas in the southern Muslim regions (less than 25%). In early 2022, medicine shortages were reported which resulted in a Joint Memorandum by the Department of Health and the Department of Trade and Industry limiting an individual and household's purchase of certain medicine.

Before and after the release of the vaccines, however, governments have already moved towards technological and innovative solutions particularly on the use of patented inventions to produce a solution to the pandemic. Countries such as Israel and Canada have utilized this approach in tackling COVID in order to produce a medical solution to the crisis. Thus, there is increasing debate on the exception or circumvention of invention rights or intellectual property rights on these inventions as there is a greater need to prevent the loss of human life due to COVID.⁶

² Amit, et. al., <u>Early Response to COVID-19 in the Philippines</u>, Western Pacific Surveillance Response Journal, 56, 2021.

³ Farzanegan, et. al., <u>Globalization and Outbreak of COVID-19: An Empirical Analysis</u>, CESifo Working Papers, 2-20, 2020.

⁴ Yvonne Su and Sivakamy Thayalaan, <u>The Philippines' COVID-19 Response has left the most vulnerable behind</u>, The Diplomat, 11 February 2022, https://thediplomat.com/2022/02/the-philippines-covid-19-response-has-left-the-most-vulnerable-behind.

⁵ Department of Health and Department of Trade and Industry, Joint Memorandum Circular No. 22-01, January 22.

⁶ World Health Organization (WHO), <u>Intellectual Property Protection</u>: <u>Impact on Public Health</u>, WHO Drug Information Vol. 19 (3), 236-238, 2005.

This paper will discuss the Philippines' Patent law particularly on its emergency patents provision (sec. 74 and 93) as well as its implications on the country on socio-political, economic and legal perspectives. The scope of this paper includes Patent law in the pharmaceutical industry. This study will be done using comparative research through jurisprudence and extrapolation of studies and reviews conducted in other countries (e.g. United States of America, Nigeria, South Africa).

PATENT LAW IN THE PHILIPPINES

A. INTELLECTUAL PROPERTY CODE

The Intellectual Property Code of the Philippines⁷ (IPC, RA 8293) is the governing law for matters involving Intellectual Property. It is the state's policy (as provided under section 2 of the Intellectual Property Code) to provide protection and security for intellectual property holders as well as promote technological transfers, encourage innovation, and ensure market access for new inventions. In giving a brief historical context to IP law in the Philippines, prior to the current law, IP law can be traced back to as early as the Spanish Occupation during the early 19th century wherein the Spanish settled controversies for certain inventions during the time.⁸ Decades later, the Patent law of 1888 granted inventors the exclusive right of exploiting their invention including the sale, use, and consumption of such invention but in order to obtain such rights, patent applications of Philippine residents are required to be sent to Spain for its examination and grant.⁹ During the American period, Act No. 666 was enacted and this provided for acquiring ownership of trademarks.¹⁰ When American rule ceased in the Philippines, further laws were enacted to improve Intellectual Property protection such as RA 165 (Old patent law), RA 166 (Trademark law), and Presidential Decree (PD) 49 (Decree of the Protection of Intellectual Property). At the end of the 20th century, the Intellectual Property Code was enacted not only to amend the provisions of the previous IP laws but also to honor the country's commitments on international

⁷An act prescribing the Intellectual Property Code and establishing the Intellectual Property Office, Providing for its powers and functions, and for other purposes, R.A. 8293.

⁸ World Intellectual Property Office (WIPO), <u>Background Reading Material on the Intellectual Property System of the Philippines</u>, WIPO Publication No. 686 / PH(E), 3, 1993.

⁹ WIPO, supra note at 6, 3-4.

¹⁰ Zuneca Pharmaceutical vs. Natrapharm, Inc., G.R. No. 211850, September 8. 2020.

treaties, particularly on the Agreement on Trade Related Aspects of Intellectual Property Rights¹¹ (TRIPS Agreement; to be further discussed later in this study)

The state policy of RA 8293 is provided under sec. 2 of the law; summarily to provide protection and security for intellectual property rights holders as well as promote technological transfers, encourage innovation, and ensure market access for new inventions.

The law has various provisions on the kinds of intellectual property particularly on Patents, Trademarks, and Copyright. This paper, however, will focus on Patent law, specifically on its rights, limitations, compulsory licensing, and government use of Patents.

Suppletorily, for this paper, the Universal Access to Cheaper Drugs law or R.A. 9502¹² shall be referenced and applied as it is the law providing for easier access to cheaper and quality medicine. Its application is mainly to show the legislature's actions in developing a stronger foundation for accessible medicine by amending certain provisions in the IPC. Specifically, excluding certain medical inventions from patent protection, creating limitations on Patent rights pertaining to medicine, and expanding the provisions on compulsory licensing especially in accordance with TRIPS Agreement.

B. PATENT LAW, RIGHTS, AND LIMITATIONS OF A PATENT HOLDER

A patent holder has certain rights as provided for under Section 72 of the IPC they may exercise with respect to their patented property:

- 1. If the patent pertains to a product, the patent holder may prohibit and prevent any unauthorized person from making, using, offering for sale, selling, or importing the patented product;
- 2. If the patent pertains to a process, the patent holder may restrain, prevent, or prohibit any unauthorized person from using the process. This means using the said process for manufacturing, dealing, selling, or importing any product derived from the patented process;

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¹¹ The TRIPS Agreement provides for the minimum standards for enforcing intellectual property law across signatories for all types of intellectual property. According to the WTO's Fact Sheet (2003), the TRIPS agreement attempts to universalize or standardize a level of protection to states through obligations and modes of dispute settlement to protect IPR holders.

¹² An act providing for cheaper and quality medicines, amending for the purpose R.A. 8293, R.A. 6675, and R.A. 5921, and for other purposes, R.A. 9502.

3. Patent owners may also assign or transfer the patent and create licensing contracts to other entities who may wish to use the patent.

In summary, a patent gives protection to patent holders to prevent any abuse of one's inventions. This form of protection will last for a total of 20 years from the time of filing of the application. As stated in *Pearl and Dean vs. Shoemart, Inc.*: "... [t]he goal of a patent system is to bring new designs and technologies into the public domain... On one side of the coin is the public which will benefit from new ideas; on the other are the inventors who must be protected." In the mentioned case, it made reference to the case of *Bauer & Cie vs. O'Donnell*15 which briefly emphasized that the patent system allows for the promotion of new and useful inventions to remain in public for the people's use. Furthermore, the protection of the invention for a number of years while gaining the privilege of reaping the fruits from their invention.

Despite the promotion of intellectual property rights, however, such rights are not absolute. Section 72 of the IPC provides for the exceptions to which a Patent holder may not prevent a user from utilizing his invention/process. These are: (1) when one is using a patented product which is put on the market in the Philippines by the owner of the patented product (or with his express consent to put such product into the market). With regard to drugs, the limitations on patent rights apply after the drug has been introduced in the Philippines or anywhere else in the world by the patent owner or their authorized representative. An additional proviso states that the right to import the drug must be available to any government agency or private third party. (2) When the product/ process is done privately or not on a commercial scale, provided that the use does not significantly prejudice the economic interests of the patent owner. (3) When the product/process is exclusively used for experimental use of the invention or for scientific or educational purposes. (4) For drugs/medicine, if the act is for the purpose of development and submission of information for issuance and approval of government regulatory agencies required by law. (5) When the act is for preparation for cases (medical/pharmaceutical) of medicine in accordance with a medical prescription. (6) Lastly, When the invention is used in any ship, vessel, aircraft, or land vehicle entering the territory of the Philippines temporarily or accidentally provided that such invention is for the needs of the vehicles and not for manufacturing anything to be sold in the Philippines.

¹³ RA 8293, sec. 54.

¹⁴ Pearl and Dean vs. Shoemart, Inc., G.R. No. 148222, August 15. 2003.

¹⁵ Bauer & Cie vs. O' Donnel, 229 US 1; The reference to this case about patent infringement on a drug mainly discusses on the invention benefitting the public while also protecting the inventor's rights to the patent.

EMERGENCY PATENTS

A. EMERGENCY PATENTS

Emergency Patents are not formally and specifically defined by any local or international document but through the Doha declaration¹⁶ and TRIPS agreement, emergency patents can be pinpointed to inventions that are taken for public health purposes or other national emergencies of a State. For simplicity and academic purposes, this paper will use the term "Emergency patents" as an umbrella concept for "those patents exploited or used without the consent of the patent owner for the purpose of dealing with national emergencies and preservation of public interest." This definition shall be limited to the scope of public health and medicine. The reason for this is the limited literature on patent use outside of the field of medicine and public policy.

The critical idea of emergency patents is that these patents are to be exploited by an entity without the permission of the patent holder to mainly and urgently preserve said public health. The research theorizes that there are two kinds of "emergency patents": (1) Government Use and (2) Compulsory Licensing. They are considered emergency patents as they can be an urgent mechanism (particularly during national emergencies) for the use of patented inventions without the consent of the Patent owner.

B. GOVERNMENT USE

Under Sec. 74 of the IPC, the Philippine Government or its authorized entity may exploit a patented invention without any agreement or consent of the patent holder during certain circumstances as follows: (1) When public interest so requires (particularly on matters of national security, health, development, etc.), (2) when a judicial or administrative body deems that the manner of exploitation by the patent owner or his license is anti-competitive, and (3, 4, and 5) for drugs/medicine, there is a national emergency or other circumstances of extreme urgency which would require the use of the patented invention, there is public

¹⁶ The Doha declaration provided for the recognition of health rights and the underlining of public health through intellectual property, particularly on Patents.

non-commercial use of the patent without satisfactory reason, or when the demand the for the patented invention is not being met to an adequate extent and on reasonable terms.

Under sec. 74.2, the execution of sec. 74 provides for the requirements on the usage of emergency patents. On the subject of national emergencies thus, sec. 74.2 (a), (d), (e), (f), and (g) shall apply. The mentioned provisions provide for the notice to the patent holder should their patent be used for national emergencies. They also provide for the scope and limitations to which the emergency patent shall only be used for, the non-exclusivity of the invention, and the rights of the patent holder for remuneration of their patent's exploitation. Lastly, the latter subsection provides for the requirement of the existence of a national emergency or circumstances of extreme urgency to be determined only by the President of the Philippines.

C. COMPULSORY LICENSING

Compulsory licensing under sec. 93 of the IPC is the granting by the government of a license to an individual who has the ability to exploit a patented invention without an agreement with the patent holder. This compulsory license may be granted under the following circumstances: (1) national emergencies or other circumstances of extreme urgency; (2) if circumstances of public interest requires such license (for national security, nutrition, health, economic development); (3) when a judicial or administrative body has determined that the manner of exploitation by the owner of the patent or its licensee is anti-competitive; (4) In cases of public non-commercial use of the invention by the patent holder without satisfactory reason; (5) without satisfactory reason, the patented invention is not being worked in the Philippines on a commercial scale despite being capable of being worked upon²²; and (6) when the demand for a patented drug is not being met as determined by the Department of Health (DOH).

Under RA 9502, a new section, sec. 93-A, amended sec. 93 of RA 8293 as it provides for the issuance of a Special Compulsory license under the TRIPS agreement which the Philippines is a party to. Following the

¹⁷ Sec. 74. 2 (a).

¹⁸ Sec. 74. 2 (d).

¹⁹ Sec. 74. 2 (e).

²⁰ Sec. 74. 2 (f).

²¹ Sec. 74.2 (g)

²² Provided the importation of the patented invention will constitute to be working or using of the patent;

TRIPS agreement, sec. 93-A gives the Director General of the Intellectual Property Office (IPO) the power to grant a special compulsory license for importation of patented drugs and medicine of those who did not opt out of Art. 31bis of the TRIPS agreement. Art. 31bis shall be discussed in the latter parts of this paper but regarding RA 9502, these special compulsory licenses are for ensuring access to quality affordable medicine in the local market. The special license also grants the right of adequate remuneration to the patent holder and such license must provide measures in order to protect the patent holder from any possible abuses to his patent rights.

Furthermore, sec. 93-A is available for the manufacturing and exportation of drugs and medicines to countries having insufficient manufacturing capacity in their pharmaceutical sector to address public health matters. The importing country, however, must grant the compulsory license on their end as well in order for the importation of the drug from the Philippines in compliance with the TRIPS agreement.

The purpose of compulsory licenses is mentioned in the case of *Smith Kline & French Labs. vs. Court of Appeals:* "... the legislative intent in the grant of a compulsory license was not only to afford others an opportunity to provide the public with the quantity of the patented product but also to prevent the growth of monopolies." These compulsory licenses basically allow other capable entities to exploit patented inventions through an application with the Intellectual Property Office of the Philippines. As stated earlier, the capable entity could even exploit the patented invention without the inventor's consent if any of the six mentioned circumstances are present. This would mean that able-minded individuals or organizations could respond fast to events such as the COVID-19 pandemic by utilizing the invention to create better access to medicine or even find a cure to the disease.

D. COMPULSORY LICENSING VS. GOVERNMENT USE

Comparing the taking of patents through compulsory licensing *vis-à-vis* government use, the former is a grant given by the Director-General of the IPO to a private individual whom the government sees as one who has the ability to exploit the patented invention under the circumstances provided. Government use on the other

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²³ Smith Kline & French Labs vs. Court of Appeals, G.R. No. 121867, July 24. 1997.

hand is when a government agency or a government-authorized entity exploits a patented invention even without an agreement with the Patent holder.

As provided under sec. 93 and 94, one of the main differences is that a compulsory license is mainly petitioned or initiated by a private entity who believes that they are capable of utilizing a patented invention using the grounds of sec. 93 as basis for their license application. Plain-text reading shows that only private persons are the ones involved in the grant of a compulsory license, whereas for emergency patents, it allows for the use of the patented invention by government agencies in addition to private entities. The exception is the special compulsory license under the TRIPS agreement initiated by the DOH as they are the ones who recommend to the Director-General the need for such license for importation of a certain patented drug.

This leads to another difference which is the importation and exportation of the patented product. Compulsory licenses allow an individual to exploit a patented invention without the patent owner's consent. As provided by sec. 93-A, the provision not only talks of importation of a foreign patented product but also exportation of a locally patented medicine (provided that the importing foreign country granted the same compulsory license in their jurisdiction). Meanwhile, sec. 74 is silent as to the use of the patented invention for importation and exportation. Overall, this would perhaps mean that the scope of sec. 74 remains on a national level while compulsory licenses are able to transcend said scope to have an international reach on other nations' patents.

Another difference in the essential components to the execution of emergency patents are the grounds. Government use of the patents are determined by the President as stated in sec. 74.2 (g).²⁴ For compulsory licensing, the provisions in the chapter for said subject are silent on who determines a "national emergency". Additionally, one detail different from the government use is the taking into account "vital sectors of the national economy" when it comes to concerns of public interest. The significance of this is that it would also deal not only with actual emergencies declared by the government but also unfamiliar emergencies²⁵ as well. The petition for

²⁴ The President of the Philippines determines the national emergency and the urgency of the need to exploit the patented invention.

²⁵ Unfamiliar meaning these are emergencies that while not as mainstream or commonly broadcasted as certain events, can still be said to become detrimental to national health as it involves some sort of danger if left untreated (e.g. prevalence of known diseases such as Hypertension or HIV/AIDS and incoming unknown diseases into the country).

compulsory licenses may present arguments that could possibly highlight the need to exploit a certain patented invention in order to address matters such as inaccessibility of medicine for certain diseases.

Lastly, there is a difference when it comes to the limitations of patent use (importation, exportation). For government use, the provisions are silent on the "use" including importation or exportation of patented products. Therefore, it is plausible that government use strictly focuses on Patents in the Philippines only whereas compulsory licensing allows for the use of Patents abroad as it involves the importation and even exportation of said patented products.

To briefly show the subtle differences between the two, a table is provided below:

EMERGENCY PATENTS		
	GOVERNMENT USE	COMPULSORY LICENSING
SCOPE & LIMITATIONS	 Local Level; Only local patents can be exploited; Does not involve importation and exportation. 	 International level; Patents abroad can be imported If Patents abroad are to be exploited, foreign country must have the compulsory license for that product as well; May involve importation and exportation
INITIATOR	 Government agency or authorized entity; IPOPHL provides for the implementing rules & regulations for the use of the patent. 	 Private entity; Granted by the Director-General of the IPO; Secretary of DOH may file a petition for a special compulsory license.
GROUNDS	- National emergencies as determined by the President	 Silent on who determines national emergencies; Includes vital sectors of the national economy in consideration.

The importance of differentiating the two emergency patents is mainly to determine who would be initiating the "exploitation" of the patented product and the scope and limitations of the patents to be used for the pandemic/national emergency.

While one can argue that one is deprived of property because of the taking of one's patented invention without some sort of agreement, remuneration is still provided in accordance with the value of the patent authorization as provided. Furthermore, the idea of the government "taking" patented inventions is substantiated through jurisprudence, especially for matters involving public need. In obtaining an invention, the Philippine government's taking can be somewhat akin to its power of eminent domain over the private property.

In this paper, the taking of a patented medical invention is for public purposes and with just compensation. Eminent domain is defined as "... entering upon private property for more than a momentary period, and, under the warrant or color of legal authority, devoting it to a public use, or otherwise informally appropriating or injuriously affecting it in such a way as substantially to oust the owner and deprive him of all beneficial enjoyment thereof". 26 The case of *Vda de Castellvi* stated circumstances for valid eminent domain which are: (1) the entrance and occupation of the private property, (2) such entrance must be more than a momentary period, (3) entry is under the warrant or color of authorities, (4) the entry must be for public purpose, and (5) the utilization results in the deprivation of the owner in enjoying their property. These criteria may not strictly and directly apply to cases of emergency patents but they can perhaps be used as a direction for a more nuanced guideline on the taking of patented inventions without the patent owner's consent. A more in-depth discussion shall be provided later in the implications as local and foreign jurisprudence and laws shall be analyzed.

APPLICATION OF EMERGENCY PATENTS CONCEPT

A. JURISPRUDENCE

In the Philippines, there are only a number of cases reaching the Supreme Court involving compulsory licenses and none which involve government use or the triggering of sec. 74. The jurisprudence mentioned in this research is to create a relationship between the principles being used for emergency patents and national emergencies, i.e. pandemics such as the COVID-19 pandemic. Such principles may then be extrapolated as a

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²⁶ Republic vs. Vda de Castellvi, G.R. No. L-20620, August 15. 1974.

substantiation to socio-political, economic and legal current events involving the said pandemic and future national emergencies.

The case of *Dupont vs. Francisco* is significant because it emphasized the judiciary's power in protecting the public interest in national health, particularly on the Losartan product of the petitioner (Dupont). The patented product deals with hypertension and the Court in this case denied the petition as they deem that public interest is prejudiced if Dupont's patent revival is granted as stated:

"Public interest will be prejudiced if, despite petitioner's inexcusable negligence, its Petition for Revival is granted. Even without a pending patent application and the absence of any exception to extend the period for revival, petitioner was already threatening to pursue legal action against respondent Therapharma, Inc. if it continued to develop and market its losartan product, Lifezar. Once petitioner is granted a patent for its losartan products, Cozaar and Hyzaar, the loss of competition in the market for losartan products may result in higher prices. For the protection of public interest, Philippine Patent Application No. 35526 should be considered a forfeited patent application."

The production of Losartan products by respondent (Therapharma, Inc.) and a number of other pharmaceutical companies produce competition with the retail price and effectiveness of petitioner's.. Analyzing the Court's decision, ruling for the respondent would result in ensuring the economic competition and accessibility of Losartan products. The Supreme Court in this case utilized the fact that hypertension is a pervasive disease and the medicine against it is becoming economically problematic to lower-earning households. The decision is beneficial especially to those afflicted with Hypertension as the case showed facts on how the said disease is very prevalent and deadly in the Philippines. The principles of economic competition and accessibility may be argued and applied as Courts would decide based on what protects the fair competition and accessibility of medical products. Such principle would most likely apply especially during national emergencies where communities may face crisis such as medicine shortages. Today, the idea can be used to rule for compulsory licenses or be a basis for administrative or judicial bodies to use certain patents to combat COVID. The case may be used as reference in

²⁷ As mentioned in the case: "In a study conducted by the Philippine Institute for Development Studies, "affordability of drugs remains a serious problem" in the Philippines. It found that because of the cost of drugs, accessibility to drugs

drugs remains a serious problem" in the Philippines. It found that because of the cost of drugs, accessibility to drugs become prohibitive for the lowest-earning households and are "even more prohibitive for the unemployed and indigent."

preventing future monopoly or anticompetitive behavior in the medical industry and ensure access to medicine that addresses the symptoms of said disease.

A significant case relating to compulsory licenses is the case of *Smith Kline & French Laboratories*, *LTD.* vs. Court of Appeals, et. al. ²⁸ In this case, the product being filed for a compulsory license by the private respondent (Doctors Pharmaceuticals) is the drug, Cimetidine ²⁹. The Court of Appeals decided for the private respondent as it finds that the Director of Patents correctly granted the license. The Director determined that the product is considered useful as it is fundamental for the promotion of public health thus, the grant was a valid exercise of police power. Additionally, the legislative intent of granting compulsory licenses is to provide others the opportunity to supply the public with a quantity of the patented product as well as prevent the growth and possible abuses of companies who have a monopoly on certain products especially on medical products. The Court referenced RA 165 (old Patent law) as basis in deciding for Doctors Pharmaceuticals. To quote the decision of the director of patents from the CA proceedings:

"... liberal treatment in trade relations should be afforded to local industry for as reasoned out by respondent company, it is so difficult to compete with the industrial grants [sic] of the drug industry, among them being the petitioner herein, that it always is necessary that the local drug companies should sell at much lower (than) the prices of said foreign drug entities."

Such quotation is important as it shows the critical involvement of Intellectual Property authorities in providing basis to approving or disapproving compulsory license grants. The Director's decision was also used as basis by the Supreme Court in the reliance of administrative agencies' expertise to decide niche cases such as this. On the issue of property, the Court stated that compulsory licensing of medical products is not considered a deprivation of property. The license still provides the patent owner a monopoly over the product for two years and afterwards, a form of agreement can be made between the compulsory license petitioner and the patent holder for a reasonable royalty.

Lastly, the case of *Barry John Price*, et. al. vs. United Laboratories (UNILAB)³⁰ focuses on the factual findings on the grants for compulsory licenses and the subject of just compensation in the "taking" of the patented

²⁸ Smith Kline, G.R. No. 121867.

²⁹ A vital medicine for heartburns and ulcers

³⁰ Barry John Price, et. al. vs. United Laboratories, G.R. No. 82542, September 29. 2988.

product. The respondent in this case was granted a compulsory license for a pharmaceutical compound, used for making anti-ulcer medicine, which the petitioner opposed. The case was elevated up to the Supreme Court where the essence of the decision focused on the capabilities of the private respondent being a qualified entity to be granted the compulsory license as referenced below from the case:

"The Director's finding that UNILAB has the capability to use the patented compound in the manufacture of an anti-ulcer pharmaceutical preparation is a factual finding which is supported by substantial evidence, hence, the Court of Appeals did not commit a reversible error in affirming it...

Of indubitable relevance to this point is the evidence that UNILAB has been engaged in the business of manufacturing drugs and pharmaceutical products for the past thirty (30) years, that it is the leading drug manufacturer in the country, that it has the necessary equipment and technological expertise for the development of solid dosage forms or for tablet, capsule, and liquid preparations, and that it maintains standards and procedures to ensure the quality of its products...

Even if it were true, as alleged by the patentee (although it is denied by UNILAB), that its capability to use the patented compound was only acquired after the petition for compulsory licensing had been filed, the important thing is that such capability was proven to exist during the hearing of the petition."

On the matter of compensation, the Court answered petitioner's arguments through sec. 36 of RA 165 which states that should there be no agreement on the terms of the license, the Director of Patents can set such terms which he did in this case as the petitioner is provided a reasonable royalty for the Patent use.

The cases of *Dupont, Price*, and *Smith Klein* focus on the issue of capability, public health, and property rights (pertaining to eminent domain and police power). *Dupont* shows the emphasis on the protection of competition and accessibility as a basis for the Supreme Court's decision. The relevance of the latter two cases (*Price* and *Smith Klein*) in application to the COVID-19 pandemic is that they can be used as substantiation for future cases that involve the exploitation of patents without the agreement of the Patent holder. Should some patented medicine be urgently needed to address a pervasive emergency, the arguments of police power and protection of public health can be used. Additionally, any entity able to show their prowess and means to tinker

and utilize medical products may also be granted compulsory licenses that can perhaps aid communities in accessing and obtaining cheaper alternative medicaments. Given that the country is facing another wave of spiking cases³¹ with the emergence of the Omicron variant, perhaps the use of emergency patents could swiftly address the matter at a different pace. Other nations have applied similar principles to their own situations during the current pandemic and past crises as well. An example of this is a Canadian pharmaceutical company, Biolyse, applying for a compulsory license to make a generic version of Johnson & Johnson's (J&J) COVID vaccine. ³² The objective for Biolyse is to supply cheaper vaccines to Bolivia to mitigate the spread of the disease as of mid-2021. In principle, this could be something the Philippines can mimic; capable entities apply for compulsory licenses or a government agency take patented medical inventions. This would enable Filipino companies or the government to produce or obtain cheaper and more accessible medicine. Given that there is a large number of capable local pharmaceutical companies in the Philippines, emergency patents could be one way in addressing the pandemic for the country.

B. FOREIGN JURISPRUDENCE AND CASES

Applying the similar principle of governments use/compulsory licensing of patents without an agreement for national emergencies, some of the significant examples include: the United Kingdom's (UK) *IPCom, GMBH & Co. vs. Vodafone Grp., PLC.,* ³³ Australia's *Stack vs. Brisbane City Council* ³⁴, and United States' Abbot and Merck ³⁵ against the failure of Thailand to enforce intellectual property rights after the latter applied for a compulsory license.

In the case of *IPCOM*, *GMBH*., while not a case involving pharmaceutical inventions, it utilizes the Crown use (state-use) of infrastructure technology. The principle of the case shows the government use of such technology to give access for emergency responders and that the provisions of the UK's Patents Act³⁶ provide for

³¹ Calonzo, Andreo, <u>Philippine Posts Highest Covid Positivity Rate as Cases Spike</u>, Bloomberg Politics, 5 January 2022, https://www.bloomberg.com/news/articles/2022-01-05/philippines-posts-highest-covid-positivity-rate-as-cases-spike.

³² Kerry Cullinan, <u>Company Pushes Canada to Grant Compulsory License for Johnson & Johnson COVID-19 Vaccine</u>, Health Policy Watch, 5 May 2021, https://healthpolicy-watch.news/company-pushes-canada-to-grant-compulsory-license-for-johnson-johnson-covid-19-vaccine/.

³³ IPCOM GMBH & Co. KG vs. Vodafone Group, PLC, EWHC 132 (Pat) paras [184]-[213].

³⁴ Stack vs. Brisbane City Council, FCA 570 [1995].

³⁵ Thomas Fuller, <u>Thailand takes on drug industry, and may be winning</u>, The New York Times, 11 April 2007, https://www.nytimes.com/2007/04/11/world/asia/11iht-pharma.4.5240049.html.

³⁶ Subsections 56 (2) and 59.

the kinds of services that are included for state-use. For the case of *Stack*, it is similar to *IPCOM*'s wherein the Federal Court of Australia used Crown use over a patent on water meters to levy charges on users based on their water consumption for state purposes. Lastly, the case of *Abbot and Merck* involves Thailand's use of compulsory licenses for drugs treating chronic illnesses (e.g. Malaria, Ebola) and the United States placing the former on its IP watch list due to the former's failure in enforcing IP rights. This event's relevance is shown by a "strong arming" perception of a country to a patent holder as the latter has little recourse against the arguments of governments on "national emergencies". Merck, the Patent holder in this case, was forced to argue under Thai law on the case given to them and this resulted in a negative international perception towards the company. The protest from the company is due to the vague wordings of the TRIPS' Art. 31bis particularly on the duration of the use of the patented product together with the definition of a "national emergency".

Many countries have aligned their Intellectual Property laws and policies to Art. 31bis of the TRIPS agreement particularly on emergency patents (i.e. Compulsory licenses and State-use of Patents). Briefly, Art. 31bis of the TRIPS agreement provides for the global minimum standards for the protection and enforcement of intellectual property rights.³⁹ The agreement also provided for the use of compulsory licenses which, as mentioned earlier, allows for a government to license the use of a patented invention to an entity without the consent of the Patent holder; such licenses are also granted especially in times of urgency and national emergency.⁴⁰ The aforementioned foreign cases use the principle stated under Art. 31bis in order to either grant a compulsory license or for the state to utilize a patented invention without the patent owner's consent. Such cases also discuss the extensive reach of the TRIPS agreement pertaining to the provisions of emergency patents. The scope of public health and national emergency is vast to the point that there are various studies arguing against art. 31bis as it contains deficiencies that may prove problematic to patent owners. This will be discussed in the latter parts of the paper but to briefly state, some of them include matters on broad terminologies on the agreement and matters on compensation. In spite of the issues, many countries have continued to adopt their IP

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³⁷ Alexandra Farquhar, <u>Redefining the TRIPS Agreement to Accommodate en masse compulsory licensing of vaccines & other pharmaceuticals for the treatment of COVID-19</u>, North Carolina Journal of Law & Technology vol. 22 (2), 271-272, December 2020.

Darren Schuettler, <u>Angered U.S. firm excludes Thailand from new drugs</u>, Reuters, 14 March 2007, https://www.reuters.com/article/us-thailand-drugs-abbott-idUSBKK27714620070314.

³⁹ WHO, supra note 6 at 238.

⁴⁰ WHO, supra note 6, at 239.

laws in accordance with the TRIPS agreement, providing provisions for the notice, agreement, and compensation for the use of patented medicine.

C. EMERGENCY PATENTS LAW COMPARATIVE ANALYSIS

This portion of the paper provides an overview of some countries' legislative action and their emergency patent response to the COVID-19 pandemic. The inclusion of the provisions and literature could provide a supplement for lawyers, judiciaries, and scholars on creating arguments and decisions pertaining to emergency patents and its use in national emergencies. Such supplements can also be used for substantiation for further IP-policy making and future emergency patent use for nations heavily affected by COVID-19.

South Africa has its South African Patents Act, which provides for patent rights and emergency patent use. Similar to the Philippines', the South African Patents Act also contains the two variations of the emergency patents⁴¹ (i.e. government use and compulsory licensing).⁴² Its Constitution however, explicitly shows the conditions to determine the just compensation of the "taking" of the intellectual property.⁴³ It being: (1) current use of the property, (2) history of the acquisition and use of the property, (3) its market value, (4) extent of direct state investment, beneficial capital investment, and subsidy in the acquisition of the property, and (5) purpose of the expropriation of said property. In comparison with the Philippines' emergency patents provision, such criteria on remuneration for the taking of patented inventions is slightly different. The difference lies on the fourth criterion which is a factor not explicitly taken into account for cases of eminent domain nor the Intellectual Property code's emergency patents. In the IP Code, it only takes into account the economic value of the authorization/grant for government use or compulsory licenses.⁴⁴ This could possibly result in inaccurate valuing of the patented invention if state subsidies and investments onto the invention are not factored in. On a different perspective, the "economic value of the authorization" can be seen as broad and without much detail as to how the valuation is calculated. This could leave patent owners without proper just compensation and due process for the taking of their property.

⁴¹ South African Patents Act 57 of 1978, sec.s 4, 78-80.

⁴² Mikhalien du Bois, <u>State Use Provisions for Patent Law</u>, and <u>Expropriations: Some Comparative law Guidelines for South Africa during the Covid-19 Crisis and Beyond</u>, PER/PELJ 2020, 3, 2020.

⁴³ South African Constitution, Sec. 25 (2) and (3).

⁴⁴ R.A. 8293, sec. 74.2 (f) and 100.6.

For the United Kingdom and Australia, they have the 1977 Patents Act (United Kingdom; Sec. 56-59 for emergency patents) and the 1990 Patents Act (Australia; Sec. 163), respectively. In UK's emergency patent law, anyone authorized in writing to act on the Crown's behalf may act on matters involving emergency patents. Such acts include making, using, and importing a patented medicine but not selling and offering for sale. The provisions for the UK's patent act do not require the state to negotiate with the Patent owner and an entity may obtain the authorization to infringe the patent even after the act has been done (Crown defense will be applied; immunity from infringement). An interesting provision is Section 57A of the UK's Patents Act allows for the determination of the compensation to the patent owner after the commencement of Crown use and courts can even award compensation for lost contracts and reasonable manufacturing profits. ⁴⁵ Comparing UK law with the Philippines', the latter does not provide for compensation on lost contracts and manufacturing profits. Sec. 57A of the UK's Patent Act provides for a detailed procedure on the compensation for the loss of profits on the part of the patent owner. Such detail is somewhat lacking in the IP Code of the Philippines to the extent that the IP code does not specify who shall be remunerating the inventor. Furthermore, the code does not state the consideration of loss of profit from failure to secure contracts or from manufacturing costs.

Australia's crown use, on the other hand, provides for the assurance on immediate access of inventions for the benefit of the services of the respective governments and that infringement only takes place when there is a non-compliance with the terms agreed on in sec. 163 (2) of their Patents act. In 2020, amendments were made requiring prior negotiations with the Patent owner before any use of the invention with the exception of emergency instances. The amendments now explicitly require authorities to have tried for a reasonable period to achieve an agreement with the patent owner before the exploitation of the invention. These amendments are absent to the Philippines' as there is no provision which requires government authorities to obtain an agreement with the owner. For compulsory licenses, it at least requires the petitioner's efforts in obtaining authorization from the patent owner⁴⁶ before they may obtain a license without the latter's permission. Exceptions to this are national emergencies or when the demand for patented drugs is not being met.⁴⁷

For Canada's Patent Act of 1985, it is similar to Australia's Patent act wherein the Canadian government has to negotiate with patent holders before the Patent's usage. Only when there is a failure can the government

⁴⁵ Cornish, et. al., <u>Intellectual Property</u>, Sweet & Maxwell (6th Ed.), 324-325, 1 Jan 2007.

⁴⁶ R.A. 8293, sec. 95.

⁴⁷ R.A. 8293, sec. 95.2 (c) and (d).

apply for the use of the patent without the Patent owner's consent. Again, the exception is a national emergency. In mid-March 2020, Canada legislated the COVID-19 Emergency Response Act making changes to current legislation to respond to the COVID-19 pandemic. The amendment clarified the government use of patents during public health emergencies; it provided limits to the period of the patent use to 30 September 2020⁴⁸. Additionally, the amendment mandates that any application for the use of the Patents must mention the specific patent to be used as well as the person/entity authorized to exploit such invention. ⁴⁹ Lastly, subsection 19.4 (5) clarified the remuneration for the government use of the patented invention by taking into account the economic value of the authorization and the extent to make, construct, use, and sell the patented invention. Comparatively, the significant difference between Canada and the Philippines is the legislation which the former issued to adapt against the pandemic and its specificity on matters such as period of use and remuneration. The Philippines has not adopted any sort of legislation relating to emergency patents and the COVID-19 pandemic which Canada has for its COVID-19 response act. Canada's emergency patent provisions are more specific as it provides a specific duration especially for inventions during the pandemic. An additional detail on their emergency patent provisions is the consideration of the capability of the inventor to produce and sell the patented invention in its remuneration proceedings.

The aforementioned Patent laws of the various countries all show a form of protection and urgency to national emergencies, particularly on the subject of public health and negotiation & remuneration to the Patent owner. In comparing other countries' emergency patents provision against the Philippines', the differences mainly lie on the specificity especially on the matter of remuneration. Nations such as South Africa and Canada protect inventors by laying down in detail the basis of their remuneration. This is to ensure that inventors get compensated properly for their works especially since in the field of medicine, such products are mass produced and distributed to countries that differ in economics. Additionally, it is also notable that nations such as Australia include some sort of negotiations clause in their emergency patents provisions (both Crown use and Compulsory licensing). Particularly, it requires reasonable effort and for a considerable period of time before the actual exploitation of the invention without consent. The mentioned points stress the concept of due process and compensation especially for patented property. The emergency patent laws of each country, while unique on their own, afford inventors a level of negotiation power which is dependent upon their own individual

⁴⁸ COVID-19 Emergency Responses Act, sec. 19.4 (9), 2020.

⁴⁹ Supra note at 48, sec. 19.4 (2)(d), 2020.

circumstances. Applying the comparative analysis to Philippine law, policy makers could possibly improve the due process procedure for patented invention taking through a more detailed provision for negotiations or compensation.

Summarily, the scope of the mentioned laws, cases, and their principles may be applicable to the Philippines. This is because the country experiences national emergencies similar to other countries' that could call for the use of emergency patents. An augmentation in the supply of booster shots (and vaccines) and other medicine through emergency patents may help in the recovery of the Philippines in the socio-political and economic aspects. Furthermore, the idea of the government "taking" patented inventions (particularly medicine) is legally provided by various laws (R.A. 8293, R.A. 9502) and is substantiated through jurisprudence, especially for matters involving public need.

IMPLICATIONS OF EMERGENCY PATENTS DURING THE COVID-19 PANDEMIC

The implications of using emergency patents in the Philippines could be extrapolated from cases mentioned earlier as well as through intellectual property data, current and past events, and studies conducted relating to pharmaceutical patents and compulsory licenses on medicine. While there is limited quantitative data and judicial cases relating to emergency patents in the Philippines, the research attempts to deduce possible implications using the principles of the international data and knowledge obtained from the sources mentioned.

A. SOCIO-POLITICAL

Policy makers must be vigilant in adapting legislation to the current events, especially those that pose risks to public health and safety. In this case, the COVID-19 pandemic. This is so that Filipinos and industries may be able to adapt to the pandemic as well as invoke their rights during emergency situations. Adapting legislation particularly on emergency patents may create a good perception that policy makers are finding more innovative, technological, and medically-oriented solutions to the pandemic.

Unfortunately, in the World Intellectual Property Office's (WIPO) website (as of January 20. 2022), the Philippines has yet to produce any emergency patent issuances that react specifically to the COVID-19 pandemic. There were efforts however to create guidelines on the use of special compulsory licenses through a Joint

Administrative Order by the DOH and IPO Philippines in early 2020. So As of February 2022, the said order has not been released and it was originally only meant to receive comments from the public. Currently, the IPO Philippines has only released issuances on filing matters, intellectual property deadline extensions, and other adjustments pertaining to the pandemic. None of the issuances include a focus on the use of emergency patents nor realize the latter's potential to combat COVID.

In a global survey conducted by in April 2020 by Law Firm Norton Rose Fulbright, ⁵¹ a global law firm, conducted a global survey listing certain nations that have adapted an emergency patents provision as well as their response towards patents and COVID-19. For Canada, as mentioned earlier, it created provisions relating to its Patents Act (sec. 19.4) which allows for the use of a patented invention during public health emergencies and sets an expiration for such use. For France, while it does not directly deal with emergency patents, the country did introduce an emergency law⁵² which authorizes the seizure of goods and services necessary to fight against the disaster (COVID Pandemic). This may arguably pertain to medical patents as one form of seizable goods should the French government deem it necessary. Israel, at the onset of the pandemic, has issued a compulsory license in importing a generic version of an experimental drug to combat COVID which is also an essential drug for treating HIV. Days later, a ripple effect from Israel's government action resulted in the Patent holder of the drug announcing that it would no longer enforce its patents. Such an act progressed the battle against HIV/AIDS as well as the treatment of COVID-19 for it significantly gave access to cheaper versions of the patented drug, ⁵³

The aforementioned examples, on a policy level, show the active prudence of policy makers to adapt and attempt to overcome national emergencies. In the situation of the Philippines, several legislative challenges concerning emergency patents have yet to be addressed. A notable one is the remuneration for the use of the patents which may not be updated to existing global standards.⁵⁴ The prices of medicine may vary depending on

⁵⁰ Editha Hechanova, <u>Philippines: IPOPHL posts proposed guidelines on compulsory licenses</u>, 20 January 2020, https://www.managingip.com/article/b1kblk4tssz7kv/philippines-ipophl-posts-proposed-guidelines-on-compulsory-licenses

⁵¹ Sanft, et. al., <u>Governmental use of patented inventions during a pandemic: a global survey</u>, Norton Rose Fulbright, April 16. 2020.

⁵² Emergency Law No. 2020-290.

⁵³ Perehudoff, et. al., <u>Overriding drug and medical technology patents for pandemic recovery: a legitimate move for high income countries, too, BMJ Global Health Journal, 2, 2021.</u>

⁵⁴ Mario Cerilles Jr. and Harry Fernan, <u>Analyzing the interplay between the right to health and pharmaceutical patent rights in the introduction of a COVID-19 vaccine into the Philippines</u>, Int.l Journal of Human Rights in Healthcare Vol. 14 (3), 240-254, 2021.

the country and the quantity of orders a nation would procure. Philippine jurisprudence provides only the Director of Patents' decision to provide for the adequate compensation for the compulsory license. The jurisprudence did not state any rationale in forming for the rate of compensation given to the patent owner. At the onset of pharmaceutical companies producing massive quantities of medicine, a more detailed and transparent method of compensation should be conducted to show actual just compensation of the patent use. Failure to adequately compensate patent owners for the unconsented use of their inventions discourage inventors and/or give negative perception towards the country for its failure to protect IP rights.

On a non-policy level, the Philippines has challenges in its research and development compared to other developing countries. ⁵⁵ For patents, the IPO Philippines' website records the patent filings growing continuously since 2015 (see tables 1 and 2 below) but a significant number of these are from the Patent Cooperation Treaty (PCT)⁵⁶, which means these are filed by international companies and are not filed by locals. In 2020, Patent applications declined and unusually contradicted the theory of Liu, et. al. ⁵⁷ which stated that there is normally a pattern of patenting activities following a pandemic of human coronavirus. This is proven by figure 3 below taken from Liu et. al. 's study on patents relating to coronaviruses. This theory is corrected as shown by statistics the IPO Philippines reported, stating that intellectual property filings in 2021 have increased by the 3rd quarter of said year. ⁵⁸

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⁵⁵ Zuraida Cabilo, <u>Philippine Intellectual Property Rights under the World Trade Organization</u>, 1995-2005: <u>Implementing the flexibilities under a TRIPS-Plus Commitment</u>, Philippine Journal of Third World Studies 2009 24(1-2), 85, 2009.

⁵⁶ The Patent Cooperation Treaty (PCT) provides for a uniform standard on patent filing applications in order to protect inventions in different countries.

⁵⁷ Liu et. al., <u>Global landscape of patents related to human coronaviruses</u>, International Journal of Biological Sciences vol. 17 (6), 1592-1593, 2021.

⁵⁸ Intellectual Property Office of the Philippines, <u>H1 Intellectual property filings record 20% growth</u>, 30 Aug. 2021, https://www.ipophil.gov.ph/news/h1-intellectual-property-filings-record-20-growth/.

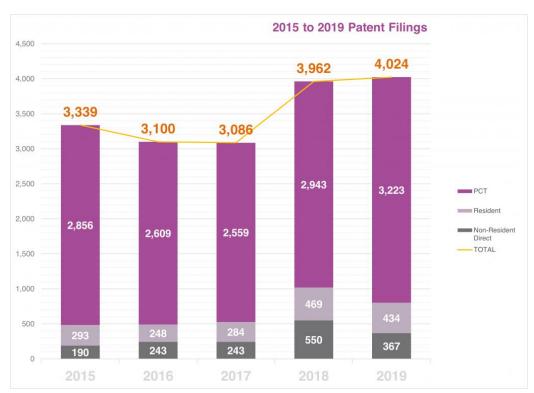


Table 1: Philippines' Patent Filings from 2015 to 2019 (Source: Intellectual Property Office of the Philippines)

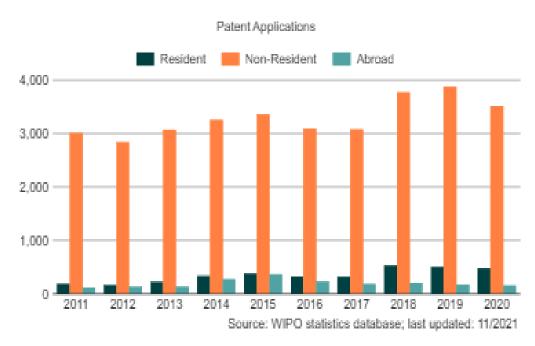


Table 2: Philippines' Patent Applications 2011-2020 (Source: World Intellectual Property Office)

Developing on the research and development subject with regard to Liu, et. al.'s study, emergency patents are available options capable of being catalysts to propel science and technology in the country. By obtaining and accessing inventions from other countries, Filipino scientists and researchers would be able to experiment and possibly concoct new and alternative forms of medicine that may help in combating COVID-19 as well as future variants of the disease and future pandemics. Government agencies and local universities may partner with foreign governments, companies, and universities to enable local scientists and inventors to obtain resources in developing new medicine. In figures 2 and 3 of Liu, et. al.'s study, there are a number of nations near to the Philippines (e.g. China, Japan, India, South Korea)⁵⁹ that are significant contributors to patents with some being universities as well. Figure 1 contains multiple charts showing the constant increase in patents over the decades especially when pandemics ensue as well as the number of publications on patents for coronaviruses. Additionally, charts C and D of figure 1 show the geographic distribution of patented inventions pertaining to coronaviruses with China, Japan, India, and South Korea leading for Asia.

The relevance of these figures and charts is that it shows the near possibilities of establishing relationships with foreign entities to galvanize the use of emergency patents with the hope of developing better, cheaper, and more alternative medicine. With large patent producers neighboring the Philippines, the execution of emergency patents in response to the pandemic may create a ripple effect if a state were to follow Israel's steps. Applications of compulsory licenses and government-use of patented inventions could create access to a wide array of science and technology that would possibly spur some sort of cure for other diseases if not COVID alone. Politically, it would create better relations between nations as it would be publicly seen as a regional and/or continental effort to defeat diseases.

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⁵⁹ China (2,255 patents), Japan (224 patents), India (213 patents), South Korea (191 patents).

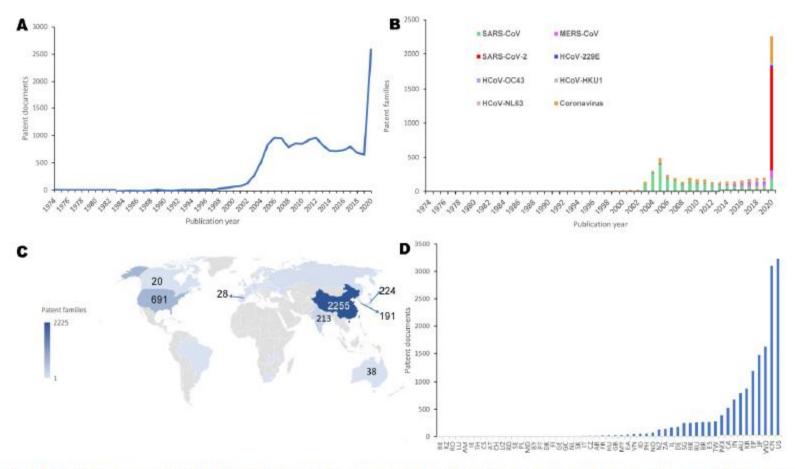


Figure 1. Temporal and geographic distribution of coronavirus patents. a. Publication trend (based on patent documents). b. Annual publication change of seven subtypes of human coronavirus and coronavirus type not announced patent (based on patent families). c. Geographic distribution by nationalities of patent inventors. The color intensity denotes the frequency of patent families. d. Geographic distribution by nationalities of jurisdictions (based on patent documents). The "Two-Letter codes" by full country names are shown in Supplementary Table S2.

Source: Liu, et. al., supra note 57, at 1590

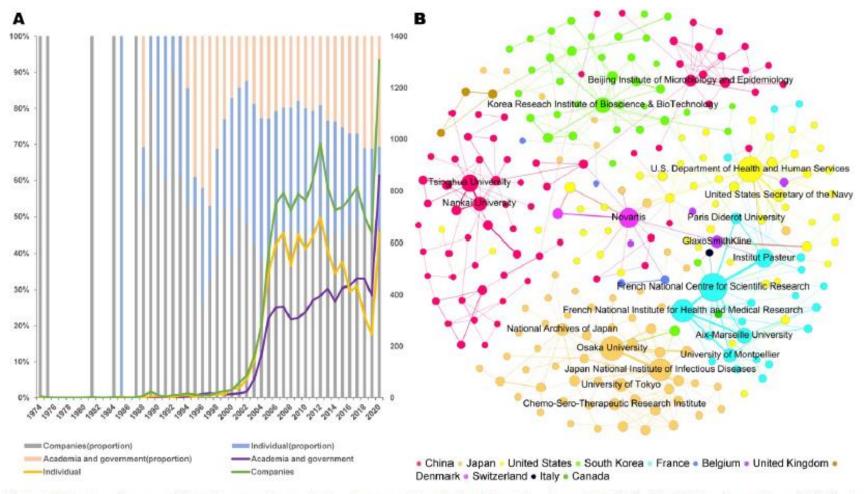


Figure 2. Types and cooperation of coronavirus patent assignees, a. Organizational types (based on patent families). b. Collaboration patterns. Institutional collaboration network, in which nodes denote assignees and edges represent co-assignee relations. The main collaboration relationships and patterns among assignees was extracted by network clusters detected using the Louvain modularity method, and labels names of top 20 active institutions. Node size is scaled to the number of patent families, while the thickness of each edge represents collaboration frequency. Countries mean regions in which assignees are located.

Source: Liu, et. al., supra note 57, at 1591

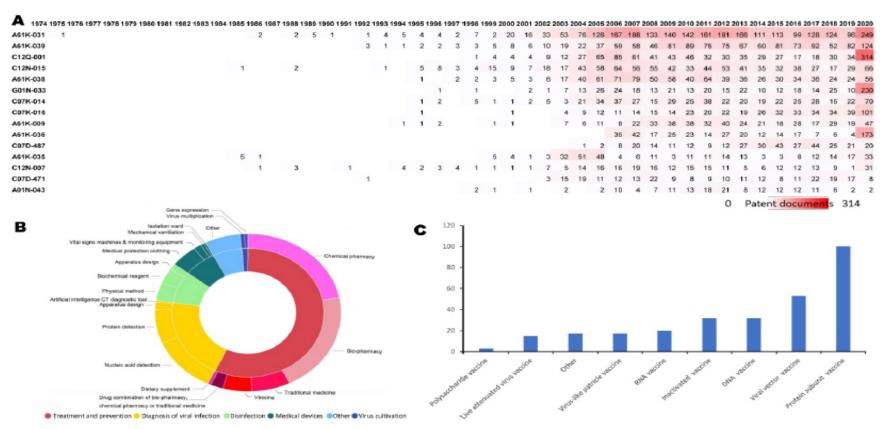


Figure 3. Technological categories of coronavirus patents. a. Annual changes of Top 15 International Patent Classification (IPC) codes based on patent families (for further information on IPC codes, visit https://www.wipo.int/classifications/ipc/en/). A61K-031 (Medicinal preparations containing organic active ingredients), A61K-039 (Medicinal preparations containing antigens or antibodies), C12Q-001(Measuring or testing processes involving enzymes, nucleic acids or microorganisms; compositions therefor; processes of preparing such compositions), C12N-015(Mutation or genetic engineering; DNA or RNA concerning genetic engineering, vectors, e.g. plasmids, or their isolation, preparation or purification; use of hosts therefor), A61K-038 (Medicinal preparations containing peptides), G01N-033(Investigating or analysing materials by specific methods), C07K-014(Peptides having more than 20 amino acids; gastrins; somatostatins; melanotropins; derivatives thereof), C07K-016(Immunoglobulins, e.g. monoclonal or polyclonal antibodies), A61K-009(Medicinal preparations characterised by special physical form), A61K-036(Medicinal preparations of undetermined constitution containing material from algae, lichens, fungi or plants, or derivatives thereof, e.g. traditional herbal medicines), C07D-487(Heterocyclic compounds containing nitrogen atoms as the only ring hetero atoms in the condensed system), A61K-035(Medicinal preparations containing materials or reaction products thereof with undetermined constitution), C12N-007(Viruses, e.g. bacteriophages; compositions thereof; preparation or purification thereof), C07D-471(Heterocyclic compounds containing nitrogen atoms as the only ring hetero atoms in the condensed system, at least one ring being a six-membered ring with one nitrogen atom), A01N-043(Biocides, pest repellants or attractants, or plant growth regulators containing heterocyclic compounds). b. Sunburst chart of technological categories (based on patent families). c. Vaccine categories (based on patent families)

Source: Liu, et. al., supra note 57, at 1593.

B. ECONOMIC

Economically, emergency patents could provide better accessibility to cheaper medicine especially for the financially constrained due to the pandemic. In early 2022, a new variant: the Omicron variant, caused a spike in cases in the Philippines and many other countries as well.⁶⁰ While vaccines have been an immense help in mitigating the effects of COVID, many who contract the disease still experience certain symptoms such as coughs and colds. Thus, a bigger demand for over-the-counter medicine occurred. Due to the spike in demand, reports on overpricing and hoarding have become prevalent, especially when the pandemic was coupled with heavy monsoons in late December 2021.⁶¹

Emergency patents can create access to a supply chain of medicine especially those financially-constrained. A case of using emergency patents to deal with diseases is Remdesivir. It is the first therapy drug authorized for emergency use with patients afflicted with COVID-19. The drug is priced at around 3,000USD and through deals and executions of emergency patents, it resulted in the production of generic medicines of Remdesivir in developing countries. ⁶² The problem however, is the supply that consequently resulted in higher prices of the drug. This resulted in Russia issuing a compulsory license to allow Russian companies to produce a generic Remdesivir drug at a more competitive price (around 600-1000 USD). ⁶³ This is one of many events wherein governments decided to use emergency patents as a means to obtain more affordable medicine for their constituents. Other examples include the U.S. State of Louisiana (2017) exploring its government use provision to lower prices of patented Hepatitis treatments to negotiate for cheaper prices. ⁶⁴ Another is the UK Parliament (2019) debating on the issuance of a compulsory license to purchase generic versions of a drug to treat cystic

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⁶⁰ Sebastian Strangio, <u>Omicron driving COVID-19 Wave to new heights in the Philippines</u>, TheDiplomat, 18 January 2022, https://thediplomat.com/2022/01/omicron-driving-covid-19-wave-to-new-heights-in- the-philippines/.

⁶¹ Mary Sagarino, <u>NBI-7 warns hoarders of flue medicines, sellers of fake meds, Cebu Daily News, 18 January 2022, https://cebudailynews.inquirer.net/420938/nbi-7-warns-hoarders-of-flu-medicines-sellers-of-fake-meds.</u>

⁶² Perehudoff, et. al., Supra note 53, at 3.

⁶³ Meduza, <u>Russian Authorities issue first-ever compulsory license for controversial coronavirus treatments</u>, 14 January 2021, https://meduza.io/en/feature/2021/01/13/uncertain-benefits

⁶⁴ Amy Kapczynski and Aaron Kesselheim, <u>'Government patent use': a legal approach to reducing drug spending.</u> Health Affairs 2016; 35:791, May 2016.

fibrosis. Summarily, access to drugs is dependent on pricing; something that may save or threaten an individual's life. 65

These examples merely show the large possibilities of reducing drug prices and providing wider access to alternative and cheaper yet effective medicine through the use of emergency patents. Emergency patents may either be used directly or simply as a negotiating tool to lower prices. 66 This kind of power however, could be at the expense of the Patent owner and to inventors who would see the government "strong-arming" them and their inventions. Such actions could intimidate many inventors, especially smaller entities, and could possibly discourage them from further inventions. This is significant especially when remuneration of their products is beaten by slow judicial and administrative processes. Furthermore, due process is critical in these government takings as intellectual property rights are still under property rights. Without proper hearings, inventors may be left at the government's whim on deciding what may be deemed just compensation. Thus, procedures on hearing the side of the government and the patent owner are essential to determine the adequate value of the invention for the remuneration of the latter. Governments have to substantiate their valuation over the patented product while patent owners must detail their own version of their invention's valuation (e.g. consider personal circumstances, manufacturing costs, possible contract loss, etc.). Through dialogue and negotiation, the State and the inventor may reach a mutual agreement for compensation on the use of the patented invention.

C. LEGAL

On the legal side of emergency patents, it deals with matters on property vis-à-vis health rights, eminent domain, police power, monopolies, and statutory construction of the TRIPS agreement. The discussion of such legal implications is important to ensure that one knows the extent to which one can argue for emergency patents as well as recognize the limitations of such laws.

For Property vs. Health rights, with the Philippines signing the RA 9502, such law bolsters the already heavy emphasis on public health and affordability of medicine. Foundationally, the mentioned law finds its essence under the provisions of the 1987 Constitution of the Philippines which highlights the protection of life⁶⁷

⁶⁵ Jacob Sherkow and Patricia Zettler, <u>Epipen, Patents, and Life and Death,</u> New York University Law Review, 165, August 2021.

⁶⁶ Perehudoff, et. al., Supra note 53, at 3.

⁶⁷ CONST, art. II, sec. 5.

and health of the people⁶⁸. The right to life trumps the right to property especially during circumstances of urgent national emergency and this would mean access to medicine. Such a right is justifiable as it would be for the interest of the public, public order, and public safety.⁶⁹ It would only be proper to justify the use of utilizing emergency patents given that cases are spiking once more this early 2022. To prevent further social and economic damage, the emergency patents provisions may be triggered by the appropriate entities (i.e. DOH, IPO).

On the matter of monopolies, eminent domain and police power, the cases of *Price, Smith Kline*, and *Du pont* establish the local jurisprudence on emergency patents (more emphasized on compulsory licensing than state-use). For future cases involving such Patents, the Philippine government may use the aforementioned cases as basis for a court or administrative body's decision. To supplement their decisions, the mentioned bodies may also use foreign jurisprudence such as but not limited to the cases mentioned earlier. The application of the cases and its principles could provide the Philippine government with a justification to utilize emergency patents to procure a better supply of medicine and technology in alleviating the impact of the Omicron variant.

Despite the presence of jurisprudence both local and international, the research would point out that the taking done through emergency patents should be nuanced and seen separately from the normal eminent domain. Some of the elements of a valid taking mentioned earlier from the case of *Vda de Castellvi* include: that there is an entrance and occupation of the private property, such entrance is more than a momentary period, and that the utilization results in the deprivation of the owner in the enjoyment of their property. These elements cannot concur properly with the "taking" of patented inventions through compulsory licensing or government use because (1) there is no "entrance/occupation" of the private property; (2) in arguendo that one can argue that there is an "entrance", such entrance is only for a momentary period; and (3) the utilization of the property does not result in the total deprivation of the owner in enjoying the property. The subject property in this study is not some real property that can be "entered" unless one's definition of "enter" is through entering a contract or agreement re. the patented invention. If that would be the case, the momentary period being discussed in the mentioned jurisprudence discusses periods that normally should not be temporary. For emergency patents, its usage only goes insofar as the duration of the national emergency requiring the use of the patented invention. Moreover, the use of the invention by the government or another capable entity does not totally deprive the

⁶⁸ CONST, art. II, sec. 15.

⁶⁹ Adebambo Adewopo, <u>Access to Pharmaceutical Patents in the COVID-19 Emergency: A case for government use in Nigeria</u>, Journal of African Law Vol. 65 (2), 275-276, 2021.

owner of the enjoyment of his property. A patented medicine, while taken and produced by someone else, does not necessarily mean the patent owner is deprived or prevented from the use of their invented medicine.

In this section, the main focus is on the issues of compensation and vague definitions⁷⁰ as those issues apply to the jurisprudence available and to Patent laws of the Philippines. Many studies have been done analyzing the TRIPS agreement, particularly on its art. 31bis as issues are mainly on its vague definitions, abusive use of emergency patents, and ineffective procedures under the said article.⁷¹ For vague definitions, the first two words can somewhat be vague due to the broad dictionary definition, but in countering such argument, perhaps the intent of art. 31 of TRIPS is not to actually define such words or give grounds but to provide leeway or flexibility as mentioned earlier.⁷² This is so that nations can tailor their laws, in this case IP laws, to whatever national issue they are uniquely experiencing.

On the issue of compensation, this topic was discussed in the jurisprudence of *Price* and *Smith Kline* wherein compensation is already considered just when a royalty agreement is agreed upon after the 2-year monopoly of the patent or when the Director of Patents provided an agreement. But, as mentioned earlier, the level of compensation especially for heavily used medicine may not be up to global standards. Thus, the WHO and United Nations' Development Program (UNDP) created a guideline in establishing a royalty system through different approaches.⁷³ The first system states a 4% base royalty rate which is flexible up to 2% depending on certain factors. Another system would be the Canadian's royalty system wherein a royalty rate is set from 0.02% to 4% of the price of the generics made from the patented invention while considering the country's rank in the UNDP Human Development Index. A royalty system is also an option wherein it is based on the patented invention's product price but adjusted to the level of income of the country. Such modifications in the emergency patents provision particularly for just compensation is necessary to satisfactorily protect IP rights of patent holders.

In approaching the topic of compensation with eminent domain proceedings, this research points out the overly broad and vague provisions of the IP code in providing for compensation in exploiting a patent owner's

⁷⁰ Vague definitions: centers on definition issues particularly on "urgency", "national emergency", and "reasonable compensation"

⁷¹ Farquhar, supra note 37, at 268.

⁷² Adewopo, supra note 69, at 281.

⁷³ Daniel Hofileña, <u>Reinforcing the role of Intellectual Property in the Battle against the Pandemic: The Vowel Framework</u>, DLSU Business & Economics Review 30(1) 2020, p.94, 2021.

invention. The provisions on the IP code state that compensation will be valued according to the economic value of the authorization/grant but does not state how the economic value will be measured. If one were to argue that the taking is something within the nature of "eminent domain", there should be guidelines in assessing the value of a property. Guidelines on valuing private property for government taking were provided in the *Vda de Castellvi* case wherein factors such as location and land condition were considered. Thus, in instances where emergency patents are needed, there should be guidelines on how administrative or judicial bodies would value the property. This is to ensure the due process and just compensation that patent owners are duly entitled to.

RECOMMENDATIONS AND CONCLUSION

Emergency patents are large sources of solutions to mitigate the impact of the COVID-19 pandemic. While the end of the pandemic is not yet in sight, every form of solution is needed to address the medical problems in the country. The utilization of emergency patents opens up access to a larger array of medicaments to tackle the ongoing crisis and the act should be done urgently not only to reduce the number of deaths and cases of COVID but also to justify the use of the legal provisions. Government agencies should be taking notice of the worth that emergency patents bring in providing solutions to this pandemic. Therefore, some form of issuance with regards to the Intellectual Property Code should be written and released. Their expertise in their field will be needed as under sec. 74 (a) of the said code, the executive department are the entities responsible to determine if an invention should be exploited for public interest purposes. Applying the principle, departments such as the DOH, Department of Labor & Employment (DOLE), and the Department of Trade and Industry (DTI) are aware of the medical and economic situation of businesses and employees. Thus, if they deem that there is an urgency to provide medical inventions to the private entities, they can easily obtain such through the execution of the emergency patent provisions.

In order to remedy such matters, recommendations include: an updated legislation for an adapted response to the pandemic, an issuance on the utilization of emergency patents, and guidelines or rules on the compensation scheme for the entities who have their inventions exploited due to national emergencies.

Pampanga Sugar mills, and to the flourishing first class town of Floridablanca" (Vda de Castellvi, G.R. No. L-20620).

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⁷⁴ "We cannot disregard the observations of the commissioners regarding the circumstances that make the lands in question suited for residential purposes — their location near the Basa Air Base, just like the lands in Angeles City that are near the Clark Air Base, and the facilities that obtain because of their nearness to the big sugar central of the

Approaching a legislative side on the pandemic, the Philippine Congress should be legislating on other possible means of alleviating the impact of COVID-19. In this case, a law providing for further amendments on the IP code, particularly on the provisions for emergency patents must be created. The content should state the value of emergency patents in creating better access to medicine in response to the pandemic. Furthermore, it should establish protection for the patent owner by specifying their rights as the patent owner of the exploited invention, basis of their invention's valuation/compensation, and the exploitation period of the medical invention. Some considerations for the valuation should include the quantity of the medicine to be exploited, its purpose, the production costs, and even lost contracts. Should Congress legislation be improbable, the participation of executive agencies in involving and adapting IP law would be a sound alternative.

The creation of issuances by administrative bodies also have a large and essential role in the utilization of emergency patents. As provided under the Intellectual Property Code, government use and the special compulsory licenses can be initiated by a government agency (e.g. DOH, DTI, DOLE) in order to answer a national emergency. These government agencies have the most knowledge and experience in their respective fields and therefore, can best argue and justify the use of emergency patents in response to certain national emergencies. Additionally, they may also be more able in producing the guidelines in compensation, duration, etc. as they have the legal expertise and field knowledge especially during the pandemic. With the assistance of the IPOPHL, government agencies can easily craft joint-issuances pertaining to emergency patents and pinpoint valuable inventions to utilize against the pandemic.

In organizing the recommendations, see below a proposed brief outline in amending the emergency patents provision:

EMERGENCY PATENTS:

- Determination of national emergencies
- Government Use
 - Scope and duration of exploitation
 - Who may use the invention
 - Compensation Scheme

- Compulsory Licenses

- Who may use the invention

- Criteria to determine the entity to exploit the invention
- Compensation Scheme
- Rights of the patent owner
- Procedure for applications, appeals, and termination of exploitation

By exempting certain medical inventions for the pursuit of a solution to end the pandemic, a country can encourage the stimulation of innovative ideas and reveal crucial information either about COVID or to any national emergency. Jurisprudence, local and international, are rife with justifications on the use of emergency patents and the use of such only further amplifies the field of science and technology. Academics and legal scholars have written numerous studies on such Patents and its effects are far-reaching. Therefore, it can be safe to say that in socio-political, economic, and legal perspectives, emergency patents may be able to be justified should the right entities act upon it.

⁷⁵ Rachel Halpern, <u>National Emergency Exemption: Patents in the Time of Coronavirus.</u> Columbia Undergraduate Law Review Online Journal, June 20. 2020, https://www.culawreview.org/journal/national-emergency-exemption-patents-in-the-time-of-coronavirus.