

# The Role of Intellectual Property in the Development of Digital Health System Lesson Learned from the Pandemic

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## ABSTRACT

Public Health Surveillance is a highly important undertaking to conduct disease navigation and control by serving an early warning system concerning the health emergency condition to identify public health emergencies and designing public health policy and strategy. This article analyses the utilization of creation protected by intellectual property in supporting the development of the digital health system using the juridical – normative and empirical legal method. The result shows: First, the support of digital tools, creativity, and innovation are critical in the development of a solid and reliable public health system. Second, it's important to address the social function of intellectual property as the protection of creativity and innovation related to the digital health system with public health sensitive approach, and lastly, the successful digital health system formulation requires an integrated strategy, synergy, and collaboration of state holder and stakeholders in formulating intellectual property-based public health protection.

**Keywords:** *Public Health Surveillance, Intellectual Property, Digital Health System.*

## 1. INTRODUCTION

The chaos and panic started in December 2019; hospitals in Wuhan, Hubei Province, China began to report patients with unidentified novel pneumonia cases, and after researchers rapidly analyzed this novel virus known as a novel coronavirus (SARS-Cov-2/Covid-19) [1]. World Health Organization (WHO) has declared Covid-19 as pandemic [2] since Covid - 19 has become a long-lasting global pandemic with high infection, fatality, and mortality rates also incapacitated health systems, to rely on vaccines alone is high risk; thus, the possible approaches for infection prevention are physical distancing, case isolation, quarantine, contact tracing, and the implementation of safety and health protocol.

The approach of existed health services needs some transformation and adaptation with the consideration of risk and benefit during the pandemic. As an attempt to reduce the risk of virus transmission,

health facilities are trying to minimize direct encounters by providing alternative services rely on alternative devices for an example phone application, telemedicine, and other digital platforms to support and promote distance healthcare and administration.

Concerning the nature of the infectious disease, it's highly critical to understand the routes and timings of transmissions, and digital health systems have become reliable tools in providing the data and supportive healthcare material. The study concerning digital intervention for tracking infectious disease was previously conducted by Eysenbach on Flu-Related disease in 2006, and the result shows the number of user-generated data utilizing the internet of things has made assessable what was previously unassessable. [3]

Many countries have shifted their health care method toward digital health systems during the pandemic. Indonesia launched "Peduli-Lindungi/Care-Protect" as online surveillance–mapping tool to conduct early detection of the

infectious risk of Covid-19. Through the Decree of the Ministry of Communication and Informatics Number 171/2020, the "Peduli-Lindungi/Care-Protect" Application has been declared as the official tool in the implementation of Health Surveillance to combat Corona Virus Disease 2019 (Covid-19) using some main strategies: tracing, tracking, warning and fencing and further encouraging patients to seek online services on health consultations rather than direct meeting services. This approach was also implemented in the US, where after the pandemic erupted, the number of online health consultations has massively increased up to 10 times comparing to the recorded data in pre-pandemic times [4]. Similar situations occurred in Australia, Australia's COVIDSafe.app as the part of the digital health system that is based on voluntary uptakes and initiatives, protected by legislation. [5] Further, under the Australian Government's National Health Plan for COVID-19, electronic prescriptions are now being fast-tracked to allow patients to receive vital healthcare services while maintaining physical distancing and isolation; and, to support this, more than 90% of pharmacies are registered, and 94 % of public hospital beds are connected [6]

The pandemic brought both challenges and opportunity for a rapid shift towards digital health in the term of disease prevention, consultation, and health treatment. The use of technology in healthcare has never been more critical. The utilization of digital technology, creativity, and innovation are of paramount importance in combating measures of Covid-19 as a public health emergency, and in this condition, it's important to search for creative, effective, and proactive solutions by optimizing human creativity as endless resources to provide for common interests. Therefore, this article aims to analyze the urgency of the Digital Health system (DHS) by fostering the creation and innovation on the intellectual property platform to serve both the public interest on health emergency conditions as well as ensuring the acknowledgment, protection, and fulfillment of moral and economic rights of the creator and inventor by emphasizing the social function of intellectual property to promote the public literacy and inclusion of intellectual property.

## **2. RESEARCH METHODOLOGY**

The research was conducted by juridical – normative and empirical legal research method with two types of approach: doctrinal and non-doctrinal. The data are collected by literature review then analyzed by conducting deeper analysis. Doctrinal

legal approaches are used to analyze positive legal materials used to address the problem concerning the social function of intellectual property through an inventory of intellectual property legal principles and regulations. This research does not only collate of the materials such as concepts, theories, principles, and regulations of law dealing with the topic but also elaborates the reality of the emergency that requires non – doctrinal legal research concerning relevant phenomena and challenges to analyze the role of intellectual property in the development of digital health system and to find the intersection and balance between legal protection of intellectual property for the creator/inventor and the interest of public health.

## **3. FINDINGS AND DISCUSSIONS**

Disaster and emergency management is a basic function of public health. National emergency plans should establish a national stockpile of essential medicines, healthcare facilities, access to healthcare treatment, vaccines, and medical supplies to manage emergency needs, including public health law that authorizes the government to take such measures as reasonably necessary to prevent and mitigate public health crisis.

Public health systems play a critical and integral role in preparing responses and strategies to mitigate and recover from health crises and emergencies. The public health system is expected to articulate and execute the strategic arrangements and mechanism for the coordination in response to public health emergencies conditions to build Public Health Emergency Preparedness (PHEP) as the capability of the public health and health care systems, communities, and individuals to prevent, protect against, quickly respond to and recover from health emergencies. [7]

During an emergency like a pandemic, health care providers are relied on to prevent excess deaths, facilitate surveillance and mitigate the escalation of infected patients. To perform these tasks, they need to be aware of public health threats and emergency conditions [8]. Public Health Emergency Preparedness (PHEP) also requires legal preparedness concerning broad legal policy concerning public health emergency, legal guidance and implementing regulations in the scope of preparedness, interpretation of existing law and concern about individual and organizational liability also ethical concerns over infringement of individual freedoms and privacy. [9], Moreover, PHEP also requires public awareness and competency to make an effective legal response to all public emergencies. [10]. Public awareness and competency to conduct the right response to a public emergency

require comprehensive and transparent information on a certain level, Conflict of norms concerning confidentiality and privacy arises when it comes to a public health emergency. The principle of medical confidentiality is one of the most venerable obligations of medical ethics. Doctors are bound by the Hippocratic Oath not to use the private or confidential information they acquire in health treatment for any purpose other than the continuing care of the patients and not to reveal it without the consent of the patient to anyone who is not directly involved in that care. [11], however, as the response of high importance of information availability and accessibility for Public Health Emergency Preparedness (PHEP), as currently, there is a common recognition that public interest may on certain occasions (including health emergency) justify an exception in breach of confidentiality principle. This is due to the fact that the better and more well informed the public, health professionals, and policymakers, the bigger it affect the success rate in affecting the awareness, knowledge, awareness, or even clinical outcome and digital media platforms provides the wide-reach and fastest way of information spread.

### ***3.1. The Perspective of Intellectual Property and Public Health***

#### *3.1.1. Justification of Protection and Social Function*

The justification of intellectual property rights lies on the basis that IP encourages creativity; society needs intellectual creation to ensure cultural, economic, and technological improvements in the form of social progress. Based on this premise, the IP regime grants intellectual property to the creators a reward, which enables the creator to gain economic and non-economic benefits by rendering their creation accessible to the public and benefits the community based on the philosophy of enlightenment. [12]

The justification of intellectual property protection as part of property rights lies on the foundation related to human rights. Article 27 of the Universal Declaration of Human Rights stated everyone has the right freely to participate in the cultural life of the community, to enjoy the arts, and to share in scientific advancement and its benefits, and everyone has the right to the protection of the moral and material interest resulting from any scientific, literary or artistic production of which he is the author.

Concerning the broad scope of intellectual property rights and how creativities and innovations embodied as inseparable elements of mankind in their sustainable effort for common interest, Thomas Aquinas conceived

the idea of the social function of the property where he considered private property to be just to the extent that it served the general interest and positive law could not be just and legitimate unless it was directed at the common good. [13]

Thomas Aquinas perceived the general interest as the good of mankind. In this conception, the reference of general interest has to originate from the human interest and is further implemented by legislators. The value of an idea in the intellectual property concept is directly proportional to the benefit and utility of the idea for the common good. Thus social function cannot be separated from the intellectual property concept. Thomas Jefferson argued that a person might have exclusive rights over an idea that comes to his or her mind as long as he can keep the idea for himself without spreading it to others. However, when the idea is revealed and spread to others, automatically, the existence of the idea becomes public property. Jefferson emphasizes the concept of "divine rights" that an idea embodied in a useful work should be allowed to spread for the common benefit in the context of the development of the quality of life and morals. Divine rights are especially implied concerning the essential product, for example, in the field of food, health, and education, to maintain the common sustainability and collective well-being. [14]

#### *3.1.2. The Protection of IP Rights in Digital Health Technologies*

Even before the Covid-19 pandemic, digital health was a rapidly growing business that shifted the approach of the healthcare industry by transforming the interaction of patients and doctors/healthcare providers in a more accessible way. Digital health refers to the use of information and communications technologies in medicine and other health professions to manage illness and health risks and to promote wellness.

Digital health as a system has a broad scope; therefore, there are various technologies and innovations involves in creating digital health products like mobile health, health, and wellness application, telehealth, electronic medical records, medical imaging, diagnostic devices, and other wearable digital health products. This raised the important issue considering the comprehensive yet flexible and cost-effective IP protection to cope with the rapid growth of digital health innovation and technology also the relatively shorter life cycle of digital health products.

Intellectual property protection regarding digital health is widely spread from patents, copyright, trade secret, industrial design, and licensing. [15] Most importantly, when it comes to IP protection of digital health, it's important to consider a new perspective and

approach to be compatible with digital health characteristics of rapid innovation, improvement, and quick turnover that requires digital health businesses to actively develop their IP strategy.

Patent relatively uses to protect several digital health technologies, tools, and mechanical and functional aspects of the devices; however, in some jurisdictions, patent rights took a relatively long time to obtain for several procedural reasons; also, there is much room for improvement of digital health and this result ongoing innovations of technology. These make patent platforms unattractive choices for digital health technology, and some companies have shifted to the protection for utility models to protect innovative tools that cannot be protected by patent for the lack of inventive steps.

An industrial design protects the visual appearance of digital health applications, for example, the design of the device, tools, and the web. These appearances make the product more appealing to the consumers. Design protection should be considered for the appearance of digital health is closely linked to the consumer's decision and driving the sales of the device.

Copyright can use to protect digital health software and algorithm, and further, as data-driven devices, digital health applications can collect and store data for healthcare. Data alone cannot obtain IP Protection, but a collection of data that are arranged systematically or methodically in the form of a database is potentially protected by copyright. Trade secret protection is also increasingly used by digital health companies to protect their data, processes, and innovations. The trade secret protection approach considers being more suitable considering the rapid evolution of technology and the approach of confidentiality perceived to be more compatible with innovative companies.

Digital health as the emerging healthcare industry cannot be separated from product branding; therefore, the implementation of trademark protection becomes essential as product identity and in build product reputation and consumer loyalty. Lastly, for further development and marketing of digital health products, intellectual property licensing platforms serve the functional tools in spreading both technology transfer and the broader production and marketing of the products.

### ***3.2. The Perspective of Social Function and Public Health Emergency***

#### ***3.2.1. Public Health Surveillance and The Urgency of Digital Health System During Pandemic***

Public Health Surveillance defines as the continuous, sustainable, systematic collection, interpretation, and analysis of health-related data required for the planning, execution, and evaluation of public health practice. [16] Surveillance is a highly important undertaking to conduct disease navigation and control by serving as an early warning system by monitoring the epidemiology of a condition to identify public health emergencies to set priorities in designing public health policy and strategy. Along with the technological advancement, much public health surveillance was conducted with the support of electronic and digital devices and led to the formulation and development of Digital Health. Digital health defines as technology that links and enables people and populations to manage wellness and health, supported by accessible and supportive providers integrated with digitally-enabled care environments that strategically utilize digital media, tools, technologies, and services to transform healthcare treatment. [17].

The relevancy of digital health is compelling because the traditional and conventional paper-based method of contact tracing for infectious diseases has been proven to be insufficient during the Ebola outbreak for causing incompleteness in contact identification and delays in contact tracing steps, for example, in alerting of involved contact or suspected case that required isolation. [18]. The utilization of Digital Health have already been developed for other infectious diseases such as Ebola and SARS; however, many governments and health system have been slow in adopting these technologies. [19]. Since the beginning of the COVID-19 outbreaks, many smartphone apps have been developed and utilized in the context of contact tracing as health surveillance measures by public authorities. Contact tracing is the process of identification and investigation of individuals who have been in exposure to positive confirmed Covid-19 patients.

The aim of contact tracing and warning is for public health authorities to rapidly identify as many contacts as possible with a confirmed case of Covid-19, suggest them to self-quarantine in no-symptoms or light symptoms, prioritizing rapid test and isolate them if they developed symptoms. Although contact tracing may look challenging, previous epidemic infectious diseases have been effectively controlled through the initiation to conduct contact tracing and isolation [20];

thus, online surveillance–mapping tools have the potential to improve the early detection of infectious in comparison to traditional and conventional epidemic tools.

In this matter, digital tools serve extra huge contribution to contact tracing efforts by improving the efficiency, speed up the overall process substantially and far less time consuming than contact tracing carried out manually by public health authorities, maintain the accuracy of data management and automated process based on the severity of their condition and enable to provide early access to healthcare and immediately reduce the risk of transmission.

Digital tools also prevent the burden of the data collection process and management conducted by the human resource by allowing electronic self-reporting by cases, location, and contacts, and this is considered to be a great help concerning the nature of the Covid - 19 pandemic where the virus spread through the interaction or contact between people, mainly when an infected person is in close contact with another person, current studies and evidence suggest that the main way the virus spreads is by respiratory droplets.

Numerous countries developed online contact tracing for the surveillance of Covid-19, for example, SORMAS (Surveillance and Outbreak Response Management and Analysis System) that has widely used in Nigeria and Ghana, aligned with the Africa-wide Integrated Disease Surveillance and Response (IDSR) and Digital Health Platforms and as a result the utilization of these digital platforms keep these countries in a good position to keep pace with the emergence of new Covid-19 cases and enhances national health system preparedness and response capabilities [21] SORMAS also widely used in Nepal and Fiji Island [22]

The digital health system potentially plays a huge role in mitigating public health crises; however, there are several challenges in its implementation. First: the access to technology. There are significant proportions of the population who do not have access to technology or internet connectivity. Access to technology and connectivity is of paramount importance in developing digital health systems. A study conducted by researchers at Oxford University Big Data Institute concluded that a minimum of 60% of a country's population would need to be involved in the digital health surveillance approach to be functionally effective [23] and to reach the highest percentage possible of digital network connectivity, government interventions are needed. These interventions not only in providing connectivity and develop tracing devices,

but the government also needs to work with the experts and stakeholders to establish an accessible digital health system while maintaining data protection and security also certain degree of privacy and confidentiality.

### 3.2.2. *Encouraging Social Functions of Intellectual Property: Public Health Concerns and Public Awareness*

There is common recognition of the important role of intellectual property in encouraging health-related research and development (R&D) that may lead to the invention of new medicine and novel healthcare tools with potential use to all countries, but there are price and competition costs to IP, relating to the health sector the lack of affordable access to treatment or medicine can have dangerous and high-risk consequences. The conditions include the unaffordable price and low purchasing power that determine access to medicines are critical matters.

Article 7 of the Agreement on Trade-Related Aspect of Intellectual Property Rights (TRIPs Agreement) obliged the member state to comply with the minimum standards while allowing considerable room to develop national regulations and provisions that ensure a balance between the minimum standards of IP protection and the public good. Moreover, member states can adopt necessary measures and provisions to protect public health, nutrition, and the public interest that vital importance for their socio-economic and technological development.

In protecting public health and the ongoing pandemic situation, public interest should be positioned as the priority by promoting the social function of intellectual property. The concept of social function means that individual/private intellectual property rights are not allowed to harm the public interest. French Constitutional Council adopted a social limitation approach in formulating the limitation of absolute rights were general interest use as the limitation of private property where a (private) property can give way to general interest when needed [24].

Social function is the core principle that is embedded and inherent in Indonesia. There are always portions for social function and public interest as the result of collectivism and kinship principle adopted as one of the most fundamental principles in Pancasila as Indonesian Grand Norm. In this matter, Pancasila shall be perceived not only as a set of moral philosophies of the country but a fundamental norm and the highest

purpose of the state to provide social justice and achieve social welfare.

One's personal and private interests are always balanced by the common goods, subjective rights are exercised due to their social functions, which are accompanied by the principles of deliberation, harmony, peace, and justice to achieve the ultimate goal as a just and prosperous society. Reflecting on the social function of intellectual property rights has become a current necessity in mitigating the crisis that arises from the pandemic that started as a health crisis and uncontrollably led to a multi-dimensional crisis. To reflect and emphasize the social functions, especially during this challenging period, is therefore essential, as it could help the general public to understand the purpose of IP protection and thus to acknowledge, respect, and conduct the protection measures more willingly. Further, it's expected to foster a sense of creativity and innovations from these challenging times with greater strengths.

Digital health is a relatively new industry that is placed at the intersection between healthcare, innovation, technology, medical devices, and pharmaceutical sectors. Most digital health systems heavily rely on the use of data to assist and provide the diagnosis, treatment, prevention, and monitoring of disease. The wide scope of creativity and innovation utilizes in the digital health system urges comprehensive IP Rights protection. On the other hand, the public health emergency requires the wide implementation of the social function to ensure availability, accessibility, and affordability. Take patent as an example; compulsory license provides the implementation of social function as the counter for exclusive rights and monopolistic nature of the patent that possibly create a serious threat to public health for the patent holder have immense power to determine the price, to decide a certain amount of production and to limit the availability and accessibility of product or technology. [25]

TRIPs Agreement as the international framework for intellectual property set out the protection of public health as the implementation of Doha Declaration, which states that TRIPs Agreement should be implemented in a manner supportive of WTO member states to protect public health by providing flexibility and safeguards. [26] There are some TRIPs provisions that are crucial to public health protection: "Bolar Provision," Parallel importation, Compulsory License, and Governmental Use Authorization for the public interest. However, this provision requires the role of the government to appropriately reflect these provisions in national laws. [27]

"Bolar" Provisions creates the condition to allow the generic manufacturers to take preparation steps regarding testing, construction, and registering their products, and this allows the generic medicine companies to start marketing their products immediately after the end of the patent protection period. [28]. The implementation of the "Bolar" provision has a positive impact on sustaining the availability of medical products and ensuring the accessibility to generic medicine, which is more affordable for society.

Parallel importation also plays an important role in ensuring public health, especially concerning the condition of the Covid-19 pandemic that widely and badly affects many countries. Parallel importation allows the importation of patented products from a third country where the product is sold at a lower price. This is highly important to maintain the purchasing power of society and to meet the demands of medicine. This concept is an attractive and viable solution, especially for developing countries and Least-Developed Countries with problematic manufacturing resources to produce their own medicine.[29].

The compulsory license is the authorization given by the competent public authority to use a patented invention without the consent of the patent holder and mostly implemented to ensure the availability, accessibility, and affordability of essential medicine by granted the third party to produce a generic version mainly for the domestic market. [25], [30] The compulsory license can be granted based on various grounds. According to Article 31 of the TRIPs Agreement, member states are allowed to grant a compulsory license on the grounds to be determined by each member state, for example, public health emergency or urgent condition as the result of a natural catastrophe, epidemic, pandemic, or war and to counter anti-competitive practices that create excessive prices and other unfair practices.

Governmental use can be implemented on several grounds similar to a compulsory license, for example, the public interest in the context of national security, providing medicine and healthcare for the poor and marginal society, ensuring the supply of essential nutrition, the development of vital sectors for the national economy and in the case that the invention or the product is unavailable in sufficient quantities or quality or unaffordable prices in the country.[26]

Considering the importance of public health protection, it's critical to expand the social functions of other IPs other than patent; for example, in copyright, there are *fair use doctrine* that covers a certain degree of utilization (mostly) for educational and non-

commercial purposes, meanwhile, in terms of trademark, trade secret and industrial design, it's still quite challenging to formulate social functions related to public health as provided by the patent regime.

Public health concern shall be perceived as a global moral issue that as a concept is covered by article 27.2 of TRIPs Agreement that allows member countries to exclude from patentability such inventions which may offend the morality of public order of its society. Unfortunately, nothing has been clearly stated in the TRIPs with respect as to what comes under "morality." Both "public order" and "morality" are reflective of the prevailing principles, socio-cultural and religious values of member countries. Thus it's quite challenging to provide an objective definition for all, and as a result, the exclusions of "public order" or "morality" from patentability is vary between member states. The applications and implementations of these exclusions largely depend on several things, from political will, legal system, local culture, and practices of the particular states.

The conditions and the demand of public health urge the public health sensitive approach and educational effort to increase public knowledge, and public engagement in the term of the justification and necessity for intellectual property protection and careful consideration should be given to regulations in IP law system that affecting public health to develop a consistent legal framework to build the comprehensive and sustainable IP- based protection of public health.

#### **4. CONCLUSION**

Based on the discussion and findings, public health surveillance is critically important as an early warning system to identify public health emergencies and further design public health policy and strategy with the support of electronic and digital devices in the development of a Digital Health System. Digital tools potentially serve an extra huge contribution and improving the efficiency, maintain accuracy and updating of data in far less time consuming, automating processes to provide early access to healthcare and reduce the risk of transmission.

Besides the huge potentials, there are several challenges in the implementation of Digital Health, for example, access to technology and internet connectivity. A study from Oxford University Big Data Institute concluded a minimum of 60% of a country's population would need to be involved in order digital health system to be functionally effective. Government interventions are needed not only in providing connectivity and develop tracing devices

but also to establish the overall accessible, user-friendly, and trusted digital health system while protecting the data protection, security, and maintaining a certain degree of privacy and confidentiality.

Digital disruption placed digital health as an important support of public health, a rapidly growing businesses and current tendencies in healthcare treatment that widely used several intellectual properties from patent, copyright, trade secret, trademark, industrial design, and licensing, thus regarding the IP protection of digital health it's important to consider unconventional approach and perspective to cover rapid innovation, improvement and quick turnover to provide comprehensive IP protection regulations and the implementation of the social function to ensure the availability, accessibility and affordability, thus its important to reflect and emphasize the social functions especially during this challenging times as it could help the general public to understand the purpose of IP protection and thus to acknowledge, respect and conduct the protection measures more willingly and further it's expected to foster the sense of creativity and innovations from these challenges times with greater strengths. As academic recommendations, public health sensitive approach and careful consideration should be given to the formulation of IP regulations in the IP law system that affecting public health to develop a consistent legal framework to build comprehensive IP-based protection of public health.

The implementation of social functions of IP as a concrete follow-up can be translated from the TRIPs Agreement that set out the protection of public health by providing flexibility and safeguards, for example, "Bolar" Provision, Parallel Importation, Compulsory License, and Governmental Use. Further, considering the importance of public health, it's critical to expand the social functions of other regimes of IP other than patent. In the term of public health as a system, sustainability plays an important role to provide public health measures not only for emergency conditions but also integrated as national IP strategy in supporting the sustained availability, accessibility, and affordability of healthcare and medicines that covers not only curative medicines and treatments but also diagnostic tools and preventive measures and medicines.

Lastly, the formulation of IP-based public health protection system as the policy implications will reach its optimum level of benefits through synergy and collaboration between related elements from state holders and stakeholders to build a solid support system of IP-based public health protection with

significant impact and benefits both the IP holders and society in common.

## AUTHORS' CONTRIBUTIONS

All authors contributed substantially to the design and implementation of the research, to the analysis of the result, and to the writing of the manuscript.

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