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Critical Legal Analysis on Medicine or Vaccine License for Strengthening Access to Justice in Indonesia: A Case of Corona Vaccine Licensing

Agung Sujatmiko[1], Ghansham Anand[2], Mochamad Kevin Romadhona[3]
[1]Faculty of Law, Universitas Airlangga, Indonesia, email: agung.sujatmiko@fh.unair.ac.id
[2]Faculty of Law, Universitas Airlangga, Indonesia, email: ghansam@fh.unair.ac.id
[3]Faculty of Social and Political Sciences, Universitas Airlangga, Indonesia, email: kevin.romadhona@staf.unair.ac.id

Abstract

This study examines the issue of voluntary licensing for COVID-19 vaccines as a case study to understand the interaction between patent protection, contractual obligations, and accountability mechanisms during a public health emergency. Although the debate on vaccine import and export is no longer central in 2025, analyzing voluntary licensing practices from the pandemic period remains relevant for evaluating the legal and governance frameworks applied at that time. The research focuses on the licensing agreement between PT Bio Farma (Persero) and Sinovac Biotech Co., which played a crucial role in Indonesia's vaccine procurement and production. The analysis explores how the patent regime regulated under Law Number 13 of 2016 on Patents structured the rights and obligations of the parties, including risk allocation, liability provisions, and the licensor's responsibilities regarding the safety and performance of the vaccine. Using a statutory and conceptual approach, this study argues that voluntary licensing during the pandemic was not merely a technical mechanism for transferring patent rights but also a process intertwined with transparency requirements, risk mitigation, and legal protection for the state and end-users. The findings aim to contribute to the body of knowledge on health governance, patent licensing in emergencies, and the development of more accountable vaccine procurement models for future health crises.

Keywords: *Health; Immunity; License Agreement; Sinovac.*

1. INTRODUCTION

The COVID-19 pandemic has exposed profound structural inequalities in global and national health governance, particularly concerning access to essential medicines and vaccines[1]. In Indonesia, the legal framework governing medicine and vaccine licensing became a critical determinant of whether citizens could effectively enjoy their constitutional right to health during a public health emergency. The unprecedented demand for COVID-19 vaccines, combined with limited domestic production capacity and strong intellectual property protections. It raised fundamental questions regarding access to justice, state responsibility, and the balance between public interest and private pharmaceutical rights[2].

[1] Annamarie Bindenagel Šehović and Kaymarlin Govender, "Addressing COVID-19 Vulnerabilities: How Do We Achieve Global Health Security in an Inequitable World," *Global Public Health* 16, nos. 8–9 (September 2021): 1198–208, https://doi.org/10.1080/17441692.2021.1916056.
[2] Lawrence O Gostin, *Public Health Law: Power, Duty, Restraint*, vol. 3 (Univ of California Press, 2000).

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Indonesia's Constitution explicitly recognizes health as a fundamental human right. Article 28H paragraph (1) of the 1945 Constitution guarantees every person the right to obtain health services[3], while Article 34 paragraph (3) obliges the state to provide adequate health care facilities and public service facilities[4]. These constitutional mandates are further operationalized through statutory instruments such as Law No. 36 of 2009 on Health and Law No. 6 of 2018 on Health Quarantine. However, during the COVID-19 crisis, the effectiveness of these legal guarantees was heavily shaped by regulatory mechanisms governing vaccine authorization, licensing, procurement, and distribution. This situation reveals a tension between formal legal norms and their practical realization, positioning the vaccine licensing regime as a crucial site for critical legal inquiry. From a global perspective, vaccine licensing is deeply embedded within the international intellectual property regime, particularly the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). While TRIPS provides flexibilities such as compulsory licensing and government use in situations of national emergency, many developing countries, including Indonesia, have faced political, economic, and administrative barriers that limit the effective invocation of these mechanisms[5]. The COVID-19 pandemic thus reinvigorated debates on whether existing international and domestic legal frameworks sufficiently accommodate public health imperatives or instead perpetuate structural inequities in access to life-saving technologies.

In Indonesia, the emergency use authorization (EUA) and vaccine licensing process for COVID-19 vaccines, administered primarily by the National Agency of Drug and Food Control (BPOM), was designed to accelerate access while maintaining safety and efficacy standards[6]. Nevertheless, the centralized and technocratic nature of this process raises concerns regarding transparency, accountability, and public participation. Critical legal scholars argue that such regulatory frameworks often prioritize procedural legality and expert authority over substantive justice, potentially marginalizing vulnerable populations and limiting meaningful access to remedies[7][8]. In this context, access to justice, in this context, extends beyond the availability of courts or formal legal remedies. It encompasses the ability of individuals and communities to benefit equitably from health-related legal regimes, including timely and affordable access to vaccines. A critical legal analysis reveals that vaccine licensing laws do not operate in a social vacuum but are shaped by power relations among the state, multinational pharmaceutical corporations, international institutions, and the public. Consequently, the legal architecture surrounding vaccine licensing may inadvertently reinforce inequality by privileging commercial interests and global supply chains over distributive

[3] Achmad Hariri et al., "State Responsibility for the Fulfillment of the Right to Indonesian Citizen Health Constitutional Perspective," Atlantis Press, 2021, 163–68.

[4] Ardiansah Ardiansah, "Responbility Of Public Health Service Based On The Constitution Of Indonesia," *Jurnal Diponegoro Law Review* 5, no. 1 (2020): 51–66.

[5] Carlos M Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed books, 2000).

[6] Ranti F. Mayana and Tisni Santika, "The Social Function of Intellectual Property and Government Intervention in Mitigating the Pandemic: A Perspective from Indonesia," *The Journal of World Intellectual Property* 25, no. 3 (November 2022): 694–713, https://doi.org/10.1111/jwip.12252.

[7] Roberto Mangabeira Unger, *The Critical Legal Studies Movement: Another Time, a Greater Task* (Verso Books, 2015).

[8] Boaventura de Sousa Santos and Boaventura de Sousa Santos, *Toward a New Legal Common Sense* (Cambridge University Press, 2002).

justice and public welfare[9]. This article employs a critical legal analysis to examine Indonesia's COVID-19 vaccine licensing framework as a case study to assess whether existing legal mechanisms strengthen or hinder access to justice. By interrogating the assumptions, power structures, and normative priorities embedded in vaccine licensing laws and policies, this study seeks to contribute to broader debates on health justice, legal reform, and the role of law in responding to public health emergencies. Ultimately, the Indonesian experience offers important lessons for rethinking medicine and vaccine licensing regimes in ways that better align legal certainty with social justice and constitutional obligations.

2. ANALYSIS AND DISCUSSION

2.1 Legal Framework on Medicine and Vaccine Licensing in Indonesia

The legal framework governing medicine and vaccine licensing in Indonesia is grounded in public health law, pharmaceutical regulation, and intellectual property law, which together define the state's authority and obligations in ensuring access to essential medicines. The primary statutory foundation is Law No. 36 of 2009 on Health[10], which establishes health as a fundamental human right and imposes a constitutional duty on the state to ensure the availability, accessibility, and affordability of safe and effective medicines and vaccines. Article 5 of the Health Law explicitly recognizes every person's right to health services[11], while Article 98 mandates state control over pharmaceutical preparations to safeguard public interests and safety[12]. Pharmaceutical licensing and market authorization are further regulated under Law No. 17 of 2023 on Health[13], which consolidates and updates Indonesia's health governance framework, including provisions on drug and vaccine regulation. This law reinforces the regulatory authority of administrative bodies while emphasizing efficiency and responsiveness in licensing processes, particularly in strategic health sectors. At the administrative level, licensing procedures for medicines and vaccines are implemented through regulations issued by the National Agency of Drug and Food Control (BPOM)[14], which exercises quasi-regulatory and quasi-judicial powers in assessing safety, efficacy, and quality prior to market approval. From the perspective of an intellectual property perspective, Law No. 13 of 2016 on Patents also plays a decisive role in vaccine licensing, particularly with respect to the protection of pharmaceutical inventions. While patent protection grants exclusive rights to patent holders, the patent law also recognizes the social function of intellectual property. Articles 109–120 provide legal bases for compulsory licensing and government use of patents in situations of national emergency or public interest, including public health crises. This normative tension between private exclusivity and

[9] Upendra Baxi, *The Future of Human Rights* (Oxford University Press, 2007).

[10] Yodi Mahendradhata et al., *The Republic of Indonesia Health System Review*, vol. 7, no. 1 (WHO Regional Office for South-East Asia, 2017).

[11] Muhammad Yunus Idy and Handar Subhandi Bakhtiar, "The Function of the State in Providing Health Services: Indonesia Perspective.," *Indian Journal of Forensic Medicine & Toxicology* 15, no. 4 (2021).

[12] Lidya Shery Muis et al., "State Responsibility for Access and Availability of Patented Drugs for Public Health," *Yuridika* 38, no. 2 (2023): 219–42.

[13] World Health Organization, *Joint External Evaluation of the International Health Regulations (2005) Core Capacities of Indonesia: Mission Report, 16-20 October 2023* (World Health Organization, 2024).

[14] Deasy Silvya Sari et al., "Strategic Health Diplomacy: An Indonesia's Approach in Securing COVID-19 Booster Vaccine Supplies," *Jurnal Hubungan Internasional* 13, no. 1 (June 2024): 17–30, https://doi.org/10.18196/jhi.v13i1.17829.

collective welfare becomes particularly pronounced in the context of vaccine access during pandemics, where patent-based market structures may constrain the timely and equitable distribution of life-saving. In addition to domestic law, Indonesia's regulatory framework is shaped by international legal obligations, particularly the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the International Covenant on Economic, Social, and Cultural Rights (ICESCR). Indonesia ratified the ICESCR through Law No. 11 of 2005, thereby undertaking a legal commitment to the progressive realization of the right to health, including access to essential medicines. These international norms provide a legal and moral justification for state intervention in pharmaceutical licensing when market mechanisms fail to ensure equitable access.

2.2 Emergency Powers and Regulatory Flexibility during COVID-19

The COVID-19 pandemic prompted the Indonesian government to activate emergency legal instruments that significantly altered ordinary regulatory procedures for medicine and vaccine licensing[15]. The designation of COVID-19 as a national disaster through Presidential Decree No. 12 of 2020 established a legal basis for extraordinary executive action, thereby enabling regulatory flexibility in public health governance[16]. This emergency framework justified accelerated approval mechanisms, procurement strategies, and exceptional administrative discretion in vaccine licensing. One of the most consequential regulatory adaptations was the introduction of Emergency Use Authorization (EUA) by BPOM, which allowed vaccines to be authorized on the basis of limited clinical data under urgent public health conditions. While this EUA mechanism facilitated rapid access to COVID-19 vaccines, it simultaneously generated concerns regarding transparency, accountability, and public participation in administrative decision-making. The legal rationale for EUA reflects a shift from precautionary regulatory logic toward risk-management grounded in utilitarian considerations, in which regulatory speed is prioritized over procedural completeness. Emergency regulations further enabled the centralization of vaccine procurement and licensing through executive instruments, including presidential regulations and ministerial decrees. Although this concentration of authority reduced procedural barriers, it also attenuated conventional checks and balances within the administrative law framework. From an access to justice perspective, the limited availability of judicial review and public oversight mechanisms during emergency licensing processes constrained opportunities for affected communities to challenge or scrutinize licensing decisions. Moreover, although Indonesia's patent law provides mechanisms for compulsory licensing during national emergencies, these provisions were not fully utilized during the COVID-19 pandemic. Instead, the state relied predominantly on voluntary licensing arrangements and international partnerships, reflecting a cautious posture toward directly confronting global pharmaceutical patent regimes. This regulatory choice underscores the structural constraints imposed by international political and economic pressures, even where expansive emergency powers are formally available to the state.

[15] Ahmad M. Ramli, Tasya S. Ramli, and Gabriela M. Hutauruk, "Patent Waiver on COVID-19 Vaccine: Indonesian Law Perspective," *The Journal of World Intellectual Property* 25, no. 1 (March 2022): 174–85, https://doi.org/10.1111/jwip.12214.

[16] Syamsuddin Radjab and Muhammad Ikram Nur Fuady, "The Indonesian Government's Inconsistency in Handling the Covid-19 Pandemic," *Yuridika* 36, no. 3 (2021): 745–58.

2.3 Voluntary and Compulsory Patent Licensing Under Indonesia Patent Law.

Patent Law Number 13 of 2016 regulates mandatory and voluntary licensing regimes[17]. Under this framework, voluntary licenses, which are non-exclusive in nature, meaning that the licensor retains the right to continue producing the licensed medicine or vaccine, including COVID-19 vaccines. In voluntary licensing, the licensor and the licensee have equal rights and obligations that reflect each party's responsibilities. Subsequently, the license agreements are not standardized instruments but are negotiated arrangements due to their mutual interests and equal position[18]. Each party has the right to regulate the agreement's contents appropriately to the existing principles of contractual freedom. Although not a standard agreement, clauses often contradict the norms of contract law in the Civil Code, meaning the agreement cannot work as expected. According to Rahmi Jened, there are three types of licenses, each distinguished by its legal basis and the mechanism through which it is granted. Voluntary licensing arises from the principle of freedom of contract, meaning its implementation depends entirely on the parties' mutual agreement. In contrast, non-voluntary licensing is issued through a court decision when there is a conflict between antitrust law and intellectual property law, particularly in situations where the intellectual property holder engages in anti-competitive behavior. Meanwhile, compulsory licensing is mandatory in nature because it is established directly by statute for the public interest, while still ensuring that the rights holder receives appropriate compensation.[19]

Voluntary licenses are divided into the following two main variants, as follows:[20]

a. Exclusive Licensing

   Only the licensor agrees not to grant other licensees the same rights in exclusive licensing. It may include competition, granting of a sub-licensee, performance requirements to be met, or time limitations.

   The licensor is willing not to grant another license to another party in the same scope or field. This may lead to competition from other licensees or the licensors, granting of sub-licenses, performance requirements to be met, and time limits.

b. Non-Exclusive Licensing

   In non-exclusive licensing, equal rights to intellectual property are granted to several licensees within the same scope or field consecutively and simultaneously. This implies a license with equal rights in Intellectual Property Rights is granted to several licensees sequentially and simultaneously.

Article 79, paragraph 1 of Patent Law Number 13 of 2016 states that the licensees are required to register their license agreement with the Directorate General of Intellectual Property. The registration ensures that the agreement does not conflict with existing legal provisions, including provisions that prohibit practices hindering technological progress and economic development. In this case, technology is expected to be transferred from developed to developing countries with the licensing agreement. The state, as represented

[17] Alina Wernick, "Compulsory Licenses in Patent Law," in *Mechanisms to Enable Follow-On Innovation: Liability Rules vs. Open Innovation Models* (Springer, 2021), 205–55.

[18] Agung Sujatmiko, *Perjanjian Lisensi Merek* (Qiara Media, 2020).

[19] Rahmi Jened, "Konflik Yurisdiksi Dan Penegakan Hukum Kekayaan Intelektual Dalam Rangka Pasar Tunggal," *Mimbar Hukum-Fakultas Hukum Universitas Gadjah Mada* 28, no. 2 (2016): 201–14.

[20] Rahmi Jened, *Hak Kekayaan Intelektual: Penyalahgunaan Hak Eksklusif* (Surabaya: Pusat Penerbitan dan percetakan Unair, 2010).

by the Directorate General of Intellectual Property, should refuse to register a license if the agreement hinders technological progress and undermines the national economy. The refusal aims to promote a more effective technology transfer process[21]. This is appropriate to the mandate in the Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreement as adopted and implemented by Indonesia. According to AM Ramli, developing countries rarely experience effective technology transfers, particularly in relation to vaccines[22].

One principle used in the patent license agreement is the principle of freedom of contract. In this case, the parties are free to formulate the contents of the agreement according to their wishes, including provisions on royalties, payment timing, dispute resolution, and the expiry of the agreement. The parties are expected to obtain anticipated benefits based on the freedom of contract principle. As the licensor, patent owners may receive significant economic benefits, similar to those obtained by the licensee. The freedom of contract primarily supports the interests of economic actors[23]. This statement was inspired by Atiyah's opinion that the contents of contracts are generally oriented toward economic exchange[24]. Furthermore, contract law regulates such exchanges and provides legal protection for the injured party[25].

According to Taryana Soenandar, as reflected in the Principles of International Commercial Contracts (UNIDROIT), the principle of freedom of contract embodies the parties' autonomy in shaping their legal relationship. This principle allows the parties to freely determine the content and substance of their agreement, as well as to choose the form in which the contract is concluded. Once formed, the contract becomes binding and acquires the force of law for the parties who enter into it. Although this freedom is fundamental, it is not absolute, as mandatory rules may serve as exceptions that limit the parties' autonomy. Furthermore, in interpreting contracts, it is essential to consider the international character and objectives of the UNIDROIT Principles in order to ensure consistency and coherence within the broader framework of international commercial practice.

These views reflect the underlying spirit of freedom in contract formation. This spirit is manifested when the parties are positioned in a relatively balanced manner with respect to their rights, obligations, and bargaining position. When such a balance is absent, the formation of an agreement becomes more difficult in practice. The principle of freedom of contract is implemented in the agreement's content, involving royalty payments, the validity period, and dispute resolution[26].

Another principle is good faith, which demands that a license agreement be implemented in a manner that enables the parties to obtain maximum benefits. The principle of good faith occupies a central position in contract law. It applies not only at the implementation and signing stages, but also before the closing of a contract[27]. There

[21] Agung Sujatmiko, "Penyelesaian Sengketa Merek Menurut Undang-Undang Nomor 15 Tahun 2001," *AD-HAPER: Jurnal Hukum Acara Perdata* 2, no. 1 (2016): 169–91.

[22] Ahmad M Ramli, Tasya S Ramli, and Gabriela M Hutauruk, "Patent Waiver on COVID-19 Vaccine: Indonesian Law Perspective," *The Journal of World Intellectual Property* 25, no. 1 (2022): 174–85.

[23] Yohanes Sogar Simamora, "Prinsip Hukum Kontrak Dalam Pengadaan Barang Dan Jasa Oleh Pemerintah" (UNIVERSITAS AIRLANGGA, 2005).

[24] Simamora.

[25] Simamora.

[26] Russell Parr, *Royalty Rates for Licensing Intellectual Property* (John Wiley & Sons, 2012).

[27] Simamora, "Prinsip Hukum Kontrak Dalam Pengadaan Barang Dan Jasa Oleh Pemerintah."

are two meanings of good faith. The first meaning relates to contract implementation as specified in Article 1338 paragraph (3) BW. In this regard, good faith or bona fides is proper behavior between the two parties (*redelijkheid en bilijkheid*). Testing whether a behavior is appropriate and fair is based on unwritten objective norms. Second, good faith is also a state of not recognizing a defect, such as payment in good faith, as regulated in Article 1386 BW[28].

The principle of good faith is essential in implementing an agreement. Disputes arising from an agreement often stem from the absence or violation of good faith, as stated in Article 1338 paragraph (3) BW. This provision shows that the parties are expected to act honestly, thereby making good faith a fundamental requirement in both the formation and implementation of an agreement. The liability of Sinovac vaccine producers under the licensing agreement includes the obligation to compensate the consumer through monetary compensation and measures health recovery. This obligation should constitute a primary concern of Sinovac Life Sciences Co., Ltd. and PT. Bio Farma (*Persero*) is a vaccine producer. A dispute between the producer and user could be resolved arbitrarily or in court. Resolution through arbitration could be taken because there was a business transaction between Sinovac Life Sciences Co., Ltd., and PT. Bio Farma (*Persero*). In contrast, the dispute between Sinovac Life Sciences Co., Ltd. and users could be resolved in court.

2.4 Patent Licensing of the Sinovac COVID-19 Vaccine in Indonesia

The patent license agreement between Sinovac Life Science Co., Ltd. and PT. Bio Farma (*Persero*) has several rights and obligations as a consequence of the contract[29]. The rights and obligations of the parties in the Sinovac vaccine patent license agreement are as follows:[30]

Licensor Rights:

a. Receive royalty payments appropriate to the agreement;
b. Entitled to use their patents;
c. Demand the cancellation of the patent license when the licensee acts contrary to the agreement.

Licensor's Obligations:

a. Guarantee the use of patents from legal defects or lawsuits from third parties;
b. Guide and supervise vaccine quality;
c. Request the licensee's approval when the licensor asks for patent removal.

Licensee's Rights:

a. Using the patent appropriate to the promised period;
b. Demand repayment of the royalty portion paid to the owner of the canceled patent;
c. Grant further licenses to third parties appropriate to the agreement.

Licensure's Obligations:

a. Pay royalties appropriate to the agreement;

[28] Simamora.

[29] Vania Lutfi Safira Erlangga et al., "Patent Suspension on the COVID-19 Vaccine in Indonesian Patent Law Perspective," *Cogent Social Sciences* 9, no. 1 (December 2023): 2202936, https://doi.org/10.1080/23311886.2023.2202936.

[30] Muhammad Reza Syariffudin Zaki and Muhammad Farhan Akmal, "Covid-19 Vaccine Legal Protection Through Patent For Public Interest," *Transnational Business Law Journal* 2, no. 1 (February 2021): 50–67, https://doi.org/10.23920/transbuslj.v2i1.694.

b. Request the recording of the license agreement to the Directorate General of Intellectual Property Rights.
c. Maintain vaccine quality;
d. Implement the agreement properly.

The licensor's obligation guarantees that the licensed vaccine is safe from hidden defects and third-party legal claims. This means that Sinovac Life Sciences Co., Ltd. must exercise due care in implementing its licensing agreements. It bears responsibility when the licensed vaccine contains hidden defects that are detrimental to the user. The licensor's liability is to compensate the licensee and the user when they suffer losses. This implies that the principal obligation lies in ensuring that the licensed rights are beneficial and usable by the licensee. These rights relate to licensed objects that must be used safely and be free from legal problems[31]. The obligation is attached to the Sinovac vaccine's licensor because users suffer side effects. However, pharmaceutical companies do not provide much liability protection in an emergency situation. This can be observed in the cases of the Pfizer and Moderna vaccines from the United States, where licensors are not held directly responsible for vaccine recipients. As a result, the public is generally unable to bring claims against theCOVID-19 vaccine manufacturers for severe side effects arising from vaccination. Additionally, government compensation is not automatically available to affected individuals. When a follow-up event or side effect occurs after vaccination, the Health Service facility or department records, reports, and investigates beforehand. This is based on Article 35 of the Decree of the Health Minister Number 10 of 2021 concerning the Implementation of Vaccination in the Context of Overcoming the COVID-19 Virus Pandemic. The Regional Committee for the Assessment and Management of Post-Immunization Adverse Events conducted a field etiology study. The National Committee for the Assessment and Management of Post-Immunization Adverse Events also conducted a causality study. The results relate to the COVID-19 Vaccine product; the Food and Drug Supervisory Agency conducts sampling and testing. Furthermore, the government finances health services for the vaccine recipient concerned when the post-vaccination follow-up event requires treatment and care.

Article 36, paragraph 2 of the Health Minister Regulation Number 10 of 2021 states that health services provided in accordance with medical indications and treatment protocols are financed by the active national health insurance program participants through the national health insurance mechanism for class III health services. For non-active participants, the national health insurance program is funded by the state budget of revenues and expenditures following state finance legislation. In accordance with Article 37 of the Health Minister Regulation Number 10 of 2021, the government provides guarantees when a post-vaccination adverse event causes the recipient to experience disability or death. In such cases, the government provides disability or death compensation. Disability is divided into severe, moderate, and mild categories. Furthermore, Article 38 paragraph (3) outlines several categories of severe disabilities. These include conditions such as the loss or paralysis of the lower limbs, as well as the loss or paralysis of the upper limbs. Severe disability also encompasses situations

[31] Dewi Astutty Mochtar, *Perjanjian Lisensi Alih Teknologi Dalam Pengembangan Teknologi Indonesia* (Alumni, 2001).

in which an individual experiences paralysis or loss of both one lower and one upper limb. In addition, total loss of vision in both eyes is categorized as a severe disability. The provision further includes individuals who are mute and deaf, those suffering from permanent severe mental illness, and persons with extensive impairments affecting vital bodily systems, including the nervous, respiratory, cardiovascular, digestive, or urogenital systems.

The criteria for disabilities, as regulated in Article 38 paragraph (4), describe various physical and mental conditions that may affect an individual's functional abilities. These include circumstances in which a person experiences the loss or paralysis of one lower limb or, similarly, the loss or paralysis of one upper limb. The regulation also acknowledges sensory impairments, such as the loss of vision in one eye, as well as communication-related disabilities, including muteness and deafness. In addition, it recognizes moderate mental illness as a form of disability that may affect cognitive or emotional functioning. The criteria further extend to more specific physical impairments, such as the loss of an index finger or thumb on the right hand, or the loss of two or more fingers on the same hand. Furthermore, they encompass partial defects affecting vital bodily systems, including the nervous, respiratory, cardiovascular, digestive, or urogenital systems, which may impact a person's overall health and the capacity to carry out daily activities.

Defects classified as mild criteria, as regulated in Article 38 paragraph (5), include several conditions that are considered less severe in nature. Mild psychiatric disorders fall into this category, reflecting mental health issues that do not substantially impair daily functioning. This classification also includes the loss of a finger or toe, which, although physically limiting, is regarded as a minor impairment when compared to more severe forms of disability. Additionally, reduced eye function is included, referring to a decline in visual ability that does not reach the level of total or near-total blindness. The loss of an earlobe is also categorized as a mild defect, provided the individual can still hear normally. Lastly, this provision encompasses changes in the classification or function of organs that result in diminished value or capacity compared to the pre-existing condition, yet do not significantly affect overall bodily function.

Vaccine recipients who experience health problems may receive compensation by submitting an application letter containing their identity and a description of the case suffered. The amount of compensation is not specified in detail in the health minister's regulation. The regulation merely provides that the Minister of Health decides the compensation after obtaining approval from the Minister of Finance.[32] Vaccine recipients are entitled to appropriate compensation based on Government Regulation 3 of 2002 concerning Compensation, Restitution, and Rehabilitation of Serious Human Rights Violations. The compensation should be given quickly and accurately. This is because the recipients should receive treatment at a fast and appropriate time.[33]

Based on existing Government Regulation, the vaccine recipients' right to obtain adequate health care is inherent to the individual and cannot be contested. This is

[32] Muhmmad Zainuddin and Siti Nur Umariyah Febriyanti, "Perlindungan Hukum Terhadap Relawan Uji Klinis Vaksin Covid-19," *Jurnal Ilmiah Dunia Hukum*, 2021, 134–42.

[33] Andi Koswara, "Tanggung Jawab Pemerintah Dalam Pemberian Dan Pengajuan Kompensasi Dan Restitusi Terhadap Korban Pelanggaran Ham Berat Berdasarkan Peraturan Pemerintah Nomor 3 Tahun 2002 Dan PP Nomor 44 Tahun 2008," *Doctrinal* 6, no. 1 (2021): 1–10.

because the right to have good health is a human right that the state is obligated to guarantee. Law Number 39 of 1999 states that human rights are inherent in humans as creatures of God and as gifts that should be respected, upheld, and protected by the state. The state has a responsibility to provide recovery measures and appropriate medical treatment to individuals who experience health problems due to the COVID-19 vaccine. The right to health is also regulated in international law, contained in:

a. The Universal Declaration of Human Rights (UDHR) was ratified in 1948. The right to health is regulated in Article 25, which stipulates that everyone has the right to a standard of living adequate for the health and well-being of themselves and their families. These include the right to food, clothing, housing, and social security, particularly in situations of unemployment, illness, disability, abandonment, or old age. Additionally, these rights apply to other circumstances beyond individual control that cause a decline in a person's standard of living of others[34].
b. International Convention on Economic, Social, and Cultural Rights (ICESCR). According to Article 12 of the ICESCR, States parties recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
d. International Convention on the Elimination of All Forms of Racial Discrimination (ICERD). Article 5 points iv states that everyone has the right to public health, medical care, social security, and social services.

Some of these regulations should be implemented in the practice of the state and social life. Several principles should be met in realizing state obligations to implement the right to health. These include the availability of health services, acceptability, and quality[35]. The right to health gives rise to the principle of patient autonomy. According to Article 5, paragraph (3) of Law Number 36 of 2009, patients have the right to determine the steps taken against them related to their health. Since the Nuremberg Code of 1947, patient autonomy has given birth to a moral principle for patients to determine their destiny[36]. The doctor-patient relationship is based on the right to information and the right to determine one's destiny[37].

The government assumes responsibility and liability when the vaccine recipient experiences health problems. The state's responsibility is to guarantee people's right to health as an inseparable part of human rights. The mechanism for vaccine users and recipients to exercise their rights as citizens is regulated by the statutory laws. In this case, vaccine users may not receive satisfactory health services from the state. This means they may file a mass lawsuit as regulated in Article 46 of Law Number 8 of 1999 concerning consumer protection. The law states that a mass lawsuit filed by consumers who share similar interests and suffer harm may be legally proven. Class action lawsuits are classified within civil law and are filed as claims asserting rights containing disputes. The disputing party may be an individual or a legal entity, such as the state. The claim filed by the plaintiff is usually in the form of compensation, including monetary

[34] Muh Alwy Arifin, A Rizki Amelia, and Leilani Ismaniar, *Hukum Dan Bioetik Dalam Perspektif Etika Dan Hukum Kesehatan* (Deepublish, 2019).
[35] Zainul Hakim and Yayah Nurasiah, "Moderasi Beragama Berbasis Masjid," *HAWARI: Jurnal Pendidikan Agama Dan Keagamaan Islam* 3, no. 2 (2022).
[36] Pitono Soeparto, *Etik Dan Hukum Di Bidang Kesehatan: Edisi 2* (Airlangga University Press, 2006).
[37] S H Prof. Hermien Hadiati Koeswadji, *Hukum Kedokteran* (Citra Aditya Bakti, 2018).

compensation. Losses experienced by group representatives and members must arise from similar facts and legal basis for the lawsuit to be considered a class action[38].

In Indonesia, patent law does not operate in isolation but interacts closely with consumer protection, product liability, and mechanisms of state compensation. Indonesian Patent Law, primarily governed by Law No. 13 of 2016 on Patents, grants patent holders exclusive rights to exploit their inventions or technological innovations for a certain period. These exclusive rights enable patent holders to control the production, distribution, and use of patented products, thereby preventing unauthorized exploitation by third parties. However, such exclusive rights are not absolute and must be balanced against public interest, particularly consumers' right to safe, reliable, and high-quality products. The interaction between patent law and consumer protection becomes evident when a patented product poses potential risks to consumers. For instance, if a patented product is defective or fails to meet safety standards, consumers are entitled to legal protection. In this context, Law No. 8 of 1999 on Consumer Protection functions as a crucial legal instrument for safeguarding consumers from losses caused by defective products, regardless of their patented status. This demonstrates that holding a patent does not exempt a producer or patent holder from the legal obligation to ensure the safety and quality of their products.

Patent law also intersects directly with product liability. Even though a patent holder has exclusive rights to produce or license a product, they can still be held accountable if the product causes harm due to design defects, manufacturing flaws, or insufficient instructions for use. This underscores the principle that patent protection is not absolute; legal responsibility for consumer safety remains a fundamental duty of the patent holder. Furthermore, the relationship between patent law and state compensation becomes relevant when patents are linked to public interest. In cases where patent infringement or misuse leads to consumer or societal harm, the state may play a role in facilitating compensation or in resolving claims for damages. Additionally, Indonesian law allows for the state to exercise compulsory licensing under certain conditions, enabling the use of a patented invention without the patent holder's consent, particularly where the product is essential for public welfare, such as life-saving medicines or critical technologies. This mechanism illustrates a balance between exclusive patent rights and public interest, ensuring that access to essential products remains possible and affordable. Overall, the interaction of patent law, consumer protection, product liability, and state compensation emphasizes the need to balance the exclusive rights of patent holders with their responsibilities for safety, quality, and public interest. While patents function as an incentive for innovation, they do not absolve patent holders of legal accountability when their products cause harm to consumers. Simultaneously, the state operates as both regulator and facilitator, ensuring that consumer rights are protected, losses arising from defective products are compensated, and public access to critical technologies is preserved. This interconnected legal framework thus creates a system in which patent rights, consumer protection, product liability, and state compensation reinforce one another, while maintaining an equilibrium between private interests and collective welfare.

[38] Emerson Yuntho, *Class Action Sebuah Pengantar: Seri Bahan Bacaan Kursus HAM Untuk Pengacara X* (Jakarta: Lembaga Studi dan Advokasi Masyarakat, 2005).

The mass lawsuits are intended to resolve problems when the vaccine recipients suffer losses, although such claims may be rejected by the court based on its assessment of the facts presented. Therefore, the claimant's professionalism should be taken into account, as it relates to the technical requirements involved in preparing a lawsuit. The plaintiff may appoint a specialized attorney with professional expertise in drafting a well-structured lawsuit. Moreover, judicial neutrality is essential, as judges resolvers who are expected to render decisions fairly and wisely. As God's representatives in decision-making, judges should act neutrally and professionally without harming either party. This should be emphasized because the plaintiff rarely wins a mass lawsuit. The decisions often defend the defendant or the state in most disputes with mass lawsuits.

A complaint may be filed with the Ombudsman when the plaintiff obtains unsatisfactory results. The Ombudsman was formed to respond to public complaints regarding state services, such as vaccinating people. Based on Article 1, point 1 of Law Number 37 of 2008 concerning the Ombudsman, the institution oversees the implementation of public services organized by state and government officials. These services include those provided by State-Owned and Regional-Owned Enterprises, as well as private entities or individuals assigned to carry out certain public services funded by the state or regional revenue and expenditure budget.

The Ombudsman was established to promote a democratic, just, and prosperous legal state and to encourage effective and efficient state and government administration. It was intended to support governance that is honest, transparent, clean, and free from corruption, collusion, and nepotism. The institution was intended to improve the quality of state services to ensure citizens gain justice, security, and better welfare. Moreover, the Ombudsman helps create and enhance legal efforts to eradicate and prevent maladministration, discrimination, collusion, corruption, and nepotism. It improves national legal culture, public legal awareness, and the rule of law based on truth and justice. In exercising its authority, the Ombudsman listens to both parties and does not receive compensation from the complainant or the reported party. Additionally, it is not concerned with legal protection, but it examines actions against appropriate norms[39].

Mass lawsuits and reports to the Ombudsman have not occurred regarding vaccinations in Indonesia. This means there are no lawsuits filed by vaccine recipients related to health problems. Recipients do not bring up the problem through mass lawsuits or by reporting to the Ombudsman. This means that the vaccination has run relatively smoothly, indicating that the licensor of the Sinovac vaccine, the recipient, and the implementer have acted correctly and could be accounted for medically and legally. A successful vaccination should be continued to the third or booster stage. This ensures the achievement of good immunity and prevents further COVID-19 development because the virus is mutative.

3. CONCLUSION

The analysis of Indonesia's patent licensing framework regarding the Sinovac COVID-19 vaccine highlights the balance between intellectual property rights, public health objectives, and consumer protection. Patent Law No. 13 of 2016 provides

[39] Philipus M Hadjon, Sri Soemantri Martosoewignjo, and Sjachran Basah, *Pengantar Hukum Administrasi Indonesia* (Gadjah Mada University Press, 2005).

mechanisms for both voluntary and compulsory licenses as instruments to balance patent exclusivity withnational and public interests. The licensing arrangement between Sinovac Life Sciences and PT Bio Farma demonstrates this balance, emphasizing principles of contract law such as freedom of contract and good faith. These principles are crucial for determining the enforceability of licensing agreements, particularly during public health emergencies, which complicate liability and obligations. The findings show that most Sinovac vaccine recipients experienced mild side effects, while severe adverse reactions were relatively rare, confirming the vaccine's overall safety profile. Indonesia's regulatory framework further ensures that vaccine recipients are entitled to medical treatment and compensation, reinforcing the state's obligations under national and international human rights provisions. The intersection of patent law and consumer protection highlights that patent rights do not exempt producers from legal accountability, with the state assuming a vital role in managing adverse events and compensation mechanisms. Although the absence of legal actions suggests that the licensing and implementation process has functioned effectively, the Sinovac experience underscores the importance of a patent licensing framework that aligns intellectual property rights with public health imperatives and human rights standards.

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