



## Legal and Regulatory Studies for the Downstream of Manufacturing of Walking Aids for the Blind

Paulus Sukapto<sup>1</sup>, Bagus Fauzan<sup>2\*</sup>

<sup>1</sup> Center for Ergonomics, Department of Industrial Engineering, Faculty of Engineering Technology, Parahyangan Catholic University. Email [paulus@unpar.ac.id](mailto:paulus@unpar.ac.id)

<sup>2</sup> Faculty of Law, Parahyangan Catholic University, West Java, Indonesia. Email [bagusfauzan@unpar.ac.id](mailto:bagusfauzan@unpar.ac.id)

Corresponding Author. E-mail [bagusfauzan@unpar.ac.id](mailto:bagusfauzan@unpar.ac.id)

### Abstract

**Background.** The Indonesian government, through President Joko Widodo, has been promoting downstream for Indonesian industries since 2020. Starting from mineral and mineral products, video games to medical devices. This research discusses specifically for medical devices, namely, the downstream development of road aids for people with visual disabilities based on sensor technology, which is an important innovation in supporting user mobility, safety, and independence. In fact, the success of the downstream of these innovations is not only determined by technical and functional aspects, but also depends on legal readiness and compliance with applicable regulations in accordance with the mandate of article 1 paragraph (3) of the 1945 Constitution, that '.. Indonesia is a State of Law..'

**Purpose.** This article aims to comprehensively examine the legal and regulatory frameworks governing the manufacturing system to ensure compliance with applicable laws and regulations for the downstream production of road aids for people with visual disabilities in Indonesia. Some of the aspects studied include intellectual property rights, technical and commercial licensing, quality standards and certifications, and the mapping of legal risks in the downstream process of innovation.

**Method.** The research method used is socio-legal, where the analysis techniques are a mix of qualitative and quantitative through legal literature studies, field observations, multidisciplinary focus group discussions (FGDs), market surveys, and in-depth interviews with key stakeholders. Data were analyzed to assess the level of legal readiness and identify potential legal barriers that could affect the mass production and distribution of blind disability walkers.

**Results.** The results of the study show that although there has been an initial foundation in the form of a patent certificate as a basis for judicial protection, various legal loopholes and risks are still found, including the lack of trademark registration, the inconsistency of the legality of business entities and business classification, the incomplete licensing of the distribution of medical devices, and the lack of optimal fulfillment of quality standards and legal documentation. This condition may hinder commercialization and downstream funding if not addressed comprehensively.

**Conclusion.** This study recommends preparing an integrated legal and regulatory roadmap as a prerequisite for downstreaming the innovation of blind-disabled road aids.

**Implementation.** A comprehensive socio-legal approach is expected to provide certainty and legal protection for inventors and partners, while ensuring the safety and rights of people with visual disabilities as consumers.

**Keywords:** blindness walkers; medical device regulation; intellectual property rights; downstream innovation; legal risks



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## INTRODUCTION

Persons with disabilities are an integral part of Indonesian citizens and have the same position, rights, and obligations in the life of society, nation, and state. The Constitution of the Republic of Indonesia expressly guarantees the principle of equal rights and protection for vulnerable groups, including persons with disabilities, as part of the fulfillment of human rights. In this context, the state has an obligation to ensure the availability of policies, services, and facilities that allow persons with disabilities to live independently, with dignity, and equality in accordance with the mandate of the 1945 Constitution, Law no. 39 of 1999 on Human Rights, Law No. 19 of 2011 on the Ratification of the Convention on the Rights of Persons with Disabilities and Law No. 8 of 2016 on Persons with Disabilities which guarantees for persons with disabilities disability to get access to justice and equality. (Aida Ardini and Dinda Sukma Melati, 2025)

One of the groups of people with disabilities who face significant challenges in daily activities is people with visual disabilities. Limited vision has a direct impact on mobility, safety, and access to public spaces. (Scott, A, 2016) Walking aids, especially smart canes based on sensor technology, are important tools for supporting the independence and safety of blind people, thereby promoting equal participation in society. The development of manufacturing and sensory technologies has created opportunities to innovate walkers that are more ergonomic, adaptive, and responsive to the surrounding environment. (Dewi, U. P, 2013)

The development of manufacturing is also supported by the Government, at a time when President Jokowi continues to promote the downstreaming of Indonesia's resources to support an independent economy. (tempo.com, 2024) Downstreaming refers to the process of transforming raw materials or natural resources into finished products with higher added value. However, the development and downstream use of road aids for the visually impaired cannot be separated from the legal dimension, which is essential to ensuring protection and safety for all parties, especially consumers. (Salim, N. Y. A, 2021)

Walking aids for the blind that use sensor technology and electronic systems may be classified as medical devices, subject to various licensing requirements, quality standards, certifications, and legal obligations related to health.

The concept of legal protection in manufacturing itself has many aspects, ranging from the legality requirements of business entities, aspects of intellectual property rights (IPR), aspects of agreements between stakeholders, and compliance with regulations that have an impact on the public such as taxation and consumer protection, because they are crucial factors in ensuring the sustainability and legal security from the production process to product distribution. (Pudyatmoko, Y. S, 2015)

In practice, many innovations in disability aid face obstacles at the downstream stage due to suboptimal regulatory and legal risk mapping. The absence of a licensing roadmap, lack of understanding of the importance of IPR status, and weak readiness of legal documents often lead to delayed commercialization, increased risk of legal disputes, and even failure of investment funding. This condition shows that juridical studies are not only complementary but are fundamental (empirical) prerequisites in the development of a manufacturing system for the visually impaired. (Nursyamsi, F., Arifianti, E. D., Aziz, M. F., Bilqish, P., & Marutama, A, 2015)

Against this background, this article aims to comprehensively examine the legal construction of due diligence governing the manufacturing system for road aids for people with visual disabilities in Indonesia. This study focuses on identifying relevant regulations; analyzing technical and commercial licensing; assessing the status and risks of IPR; examining quality standards and certifications; and mapping legal risks and their mitigation strategies. The study's results are expected to serve as a practical reference for inventors, universities, industry partners, and policymakers to encourage safe, legal, and sustainable innovation in visual aids for the visually impaired.

The review of downstream road aids for visually impaired users in Indonesia to date can be grouped into three perspectives. First, a normative study of human rights, which focuses on the fulfillment of the rights of persons with disabilities through constitutional instruments, laws, and international conventions. Studies in this cluster generally address equal rights, the accessibility of public services, and state obligations to protect vulnerable groups. The focus remains primarily on the political, legal, and social protection aspects rather than on specific technological products. (Mukrimah, H., Widyastuti, Y., & Indriyany, I. A, 2018)

Second, technical research and design of blind disability walkers, focusing on technological innovations such as ultrasonic sensors, vibration, sound, cane ergonomics, and user-participatory approaches. This type of research has resulted in functional, user-adaptive

prototypes, but most stop at the design stage, technical testing, and improved tool comfort. (Martiningsih, D, 2023)

Third, a partial sectoral normative study that discusses certain regulations separately, from business entity legality and consumer protection to intellectual property rights and licensing standards for production (e.g., Indonesian National Standards and Domestic Component Levels) to distribution. This study has not integrated the entire innovation cycle, from research and manufacturing through licensing and distribution to legal risk mitigation.

Thus, *the state of the art* indicates that there has been no comprehensive study that systematically integrates legal, regulatory, IPR, licensing, and legal risks, based on technical and fundamental processes, in the context of downstream technology-based blind disability road aids.

## LITERATURE REVIEW

### **Regulations and Legal Status Related to Persons with Blind Disabilities in Indonesia**

The 1945 Constitution of the Republic of Indonesia stipulates in Article 27 that every citizen has the same legal status and is entitled to a decent livelihood. Furthermore, Article 28H paragraph (2) states that everyone has the right to convenience and special treatment to obtain equal opportunities and benefits in order to achieve equality and justice. This is in line with the International Convention on the Rights of Persons with Disabilities and the Optional Protocol to the Convention (UN Resolution No. 61/1061 of 13 December 2006) and has been ratified as Law No. 19 of 2011 concerning the Ratification of the Convention on the Rights of Persons with Disabilities which states that the purpose of this convention is to promote, protect and guarantee the full and equal enjoyment of all human rights persons with disabilities and fundamental freedoms and to enhance respect for the dignity inherent to them, with regard to the economic, social and cultural rights of each State Party is obliged to take measures to the maximum extent possible using available resources as well as within the framework of international cooperation when necessary with a view to achieving the full realization of those rights progressively without prejudice to the obligations listed in this Convention which must be immediately implemented under international law (Widhi and Pudyatmoko, 2015).

The position of persons with visual disabilities in the Indonesian legal system has undergone a paradigm transformation from a *charity-based approach* to a rights-based approach. Constitutionally, the 1945 Constitution guarantees the equal position of every citizen before the law (Article 27, paragraph (1)), as well as the rights to live a decent life, obtain

education, and enjoy social welfare (Articles 28 and 31). (Rahmawati, D, 2022) This constitutional norm emphasizes that people with visual disabilities are full legal subjects who have the right to protection and fulfillment of rights without discrimination. (Aida Ardini and Dinda Sukma Melati, 2025)

The principle is further strengthened by Law No. 39 of 1999 on Human Rights, which obliges the state to respect, protect, and fulfill human rights for all individuals, including vulnerable groups. In this context, people with visual disabilities have the right to special treatment to ensure substantive equality. Equality is not defined solely by formal definitions; it is also shaped by the provision of facilities and accessibility that enable effective social participation. (Firmansah, A, 2024)

Indonesia's commitment is further strengthened through the ratification of Law No. 19 of 2011 concerning the Convention on the Rights of Persons with Disabilities (CRPD). The Convention emphasizes the principles of non-discrimination, accessibility, and respect for human dignity. Within the framework of the CRPD, assistive technology is recognized as an important tool for removing barriers to social participation and enhancing the independence of people with disabilities. (Alfitriensi, 2023)

Further implementation is realized through Law No. 8 of 2016 concerning Persons with Disabilities, which explicitly regulates the rights to accessibility, mobility, technology, and assistive devices. This law emphasizes that the state is obliged to provide and facilitate tools that meet the needs of persons with disabilities. Thus, the use of smart technology in road aids is not merely an industrial innovation but also part of fulfilling constitutional obligations and human rights.

Various studies on *smart canes* based on ultrasonic sensors show that technological innovations can increase the effectiveness of obstacle detection compared with conventional canes. The prototype is designed to warn users of obstacles in front of them via a responsive sensory system, thereby improving the safety and independence of mobility for people with visual disabilities. These findings indicate that the development of assistive technology is directly relevant to the right to safe mobility and environmental accessibility, as guaranteed by Law No. 8 of 2016. (Mardiana, S., & Pratama, R, 2025)

### **Walking Aid Technology For Blind Persons**

Humans have vision, which enables them to perceive objects around them; however, people with visual disabilities have visual impairments that limit their ability to perceive

objects. This will hinder daily activities, including walking, due to fear or worry about hitting an obstacle in front of him. In addition, the range of a stick is very limited. (Riyadi, E, 2020) This study aims to design and make a visual disability aid that is suitable for the average Asian body part with a partial approach using materials that are comfortable to wear, and using ultrasonic transducer technology to be able to detect obstacles, so as to make it easier for users to find out the distance of obstacles. The resulting stick can detect objects up to a maximum distance of 3 meters, producing output in the form of sound and vibration. This will enhance the vigilance and mobility of blind individuals in carrying out their activities. By designing the stick using the participatory method, a new result was obtained that was designed more ergonomically on the handle made of wood, and the material used was lighter, namely stainless steel, so that later the stick user would not feel burdened when using it, the short length of the stick that could be adjusted could make it easier for users who have a tall or short posture to remain comfortable in its use (Rizaldi, 2013).

The integration of technology into road aids also demonstrates the downstream dimension of manufacturing within an inclusion-based national development policy. By independently producing smart canes within the domestic industry, the state not only fulfills the rights of people with disabilities but also encourages innovation, job creation, and national technological independence. From a development law perspective, this policy reflects the harmonization between human rights protection and technology-based industrialization strategies. (Sharma, A., & Gupta, P, 2024)

The existence of assistive technology, such as a smart cane, strengthens the argument that the fulfillment of the rights of people with visual disabilities requires a multidisciplinary approach between law and technological engineering. The right to mobility, security, and social participation cannot be separated from the availability of tools that are adaptable to contemporary conditions. Therefore, the downstream manufacturing of smart technology-based road aids constitutes a concrete means of implementing Indonesian constitutional norms, laws, and regulations to ensure the position and rights of people with visual disabilities in a sustainable manner.

## **RESEARCH METHODS**

The method used in this research is socio-legal, in which identifying legal facts requires fundamental or empirical analysis due to their technical nature. However, in the analysis stage, it is necessary to adopt a normative juridical approach grounded in the applicable laws and

regulations of Indonesia. The analysis method is also a mixture of qualitative and quantitative methods, with the following stages:

1. Literature Study and Field Observation (October 2025): Collecting secondary data from scientific journals, research reports, government publications (BPS, Ministry of Health), and news articles related to the technology of Walking Aids for the Visually Impaired.
2. Field Observation: Visits and discussions with tool inventors at UMY, discussions with partners who make road aids for the visually impaired, visits to several Special Schools (SLB) and blind disability foundations in the Special Region of Yogyakarta (DIY) to understand the needs of users and the environment of using Walking Aids for the Visually Disabled.
3. Multidisciplinary Focus Group Discussion (FGD) (November 2025): Involving 20–30 participants consisting of people with visual disabilities, SLB representatives, Social Services, Pertuni, technology experts, and business practitioners. It was held in a *hybrid* format (online via Zoom for participants outside the city, offline on the UMY/Unpar campus for local participants). Objective: To explore perceptions, needs, feedback on prototypes, as well as potential adoption and business models.
4. Market Survey and In-Depth Interview (November 2025): Online Survey: Distributed an online questionnaire (via Google Forms) to 100 potential respondents (blind and family disabled, SLB managers, social institutions) to collect data on feature preferences, willingness *to pay*, and potential demand. In-depth Interview: Interviews with 10 key opinion leaders, such as representatives of the Ministry of Social Affairs, the Directorate General of Intellectual Property, associations of persons with disabilities (Pertuni), and business experts, to gain an in-depth perspective on regulations, markets, and downstream strategies.
5. Data Analysis (December 2025): Legal & Regulation Aspects: The Legal and regulatory aspects in this proposal have the function of identifying legal and regulatory problems for the initial audit of the applicable laws and regulations in Indonesia in order to provide a sense of security for the recipients of the Smart Stick Grant funds. From a legal perspective, several steps are needed to protect inventors from the problems and legal risks that will arise when this road aid is mass-produced. Starting from IPR Status, Technical and Commercial Licensing and Quality Standards and Certification.

## **Legal Aspects to Support the Downstream Manufacturing of Road Aids for the Blind in Indonesia**

### **A. Status of IPR and Technology License**

1. In the status of IPR, Tongkat Pintar already has a Patent certificate with a registration number IDS000007472, since 2021.
2. That in October, Tongkat Pintar was still in the process of discussing brand ownership for the registration application process.
3. That in October, the UMY team was identifying the computer program that was created for the Copyright registration process.

### **B. Technical and Commercial Licensing**

1. Based on Law No. 6 of 2023 Jo, Government Regulation 5 of 2021 concerning Business Licensing, legal entities that produce Smart Sticks must have a special KBLI for the Production of Medical Devices, the Electromedical Equipment Industry, and Trade. Proven by including the Business Identification Number.
2. That based on Law No. 17 of 2023 concerning Health Jo. Permenkes No. 26 of 2018 on Integrated Business Licensing Services, for the distribution of Smart Wabs, a Medical Device Distribution Permit is required.
3. Based on the Minister of Health Regulation No. 14 of 2021 concerning business activity standards, medical device distribution entities must have a Medical Device Distributor Permit (PAK).

### **C. Quality Standards and Certifications**

1. That, based on Government Regulation No. 72 of 1998 concerning the security of pharmaceutical preparations and medical devices, Jo. Permenkes No. 62 of 2017 concerning distribution permits for medical devices, a medical device product must undergo a quality test by an accredited laboratory.
2. That based on Permenkes No. 62 of 2017 concerning the distribution permit of medical devices, a medical device product must have a sensor function test, wheel test and an accredited laboratory battery test.

**Table of Legal Aspects along with scores as indicators of the Downstream Roadmap**

From a juridical perspective, several risks have been identified in the production process of this Smart Stick. Among them are regulations related to Taxes, including Income Tax (PPH), Value-Added Tax (VAT), and Import VAT (for imported materials), in accordance with Law No. 42 of 2009.

1. That the patent from the Smart Stick will be used by other parties. A legal basis must be prepared related to the incentive to use Patents. (Law No. 13 of 2016)
2. If Smart Sticks have been mass-produced, they must pay attention to the legal norms for their marketing, and there are consequences suffered by consumers, and how to deal with them must be considered. (Law No. 8 of 1999).
3. That every stakeholder (whether UMY, Mitra, or other entities) must be prepared for its legality. (Government Regulation No. 5 of 2021).
4. That every stakeholder (whether UMY, Mitra, or other entities) must show the basis of the right to be able to participate in the production activities of Tongkat Pintar, both in the form of a decree or an Agreement. In order not to harm the recipients of downstream grants.

Yes	Criteria	Purpose	Key Questions	Score (1-5)	Guidance Notes for Teams
1	Regulatory Inventory	Conducting binding norm mapping on the business it runs	Have the regulations related to the business process been identified and analyzed in their entirety?	3	Please write down what regulations have been found to be used for the production of road aids: Legal basis for the creation of a business entity Medical Equipment Production Business License Similarity and quality test Test the function of sensors, wheels and batteries SNI (if there is a mandatory regulation) Product Technical Document (Manual Book) Domestic component level (TKDN) Taxes Medical Equipment Distributor License Marketing HKI
2	Stake Mapping	Ensure the identification of key stakeholders in the business and the overall impact	Are the stakeholders mapped appropriate and influential?	3	There must be a legal basis for the position of stakeholders of this activity (inventor = SK from DIKTI or SK from PT) Team=SK from PT UMY= SK as what Producer Partner = company legality

3	HKI	Checking for potential IPR infringements	Is the work being produced safe	4	Show proof of existing IPR ownership, try to have everything
4	Cooperation Scheme	Determining cooperation options with third parties	Does the cooperation option support the feasibility of the project?	3	Gather all agreements with stakeholders Determine the type of agreement (license), spin-off, Joint Venture, Joint Operation.
5	Licensing and Standardization	Identify all required permits and standards and how the process flows	Are there potential obstacles to the licensing flow	3	Medical Equipment Business Entity Medical Equipment Business License Medical Equipment Coating Permit SNI
6	Tax and Intensive	Analyze potential cost burdens on taxes and identify acceptable intensive potentials	Has the tax object been identified in detail and are there any incentives that can be applied for relief?	2	Tax identification (Corporate Income Tax, VAT, Import Duty and Regional Tax) Identification of Intensive potential (either from the Government or even from Universities)
7	Legal Risks, Registers and Mitigation	Identify legal risks for the business plan to be implemented	Have legal risks been fully identified and mitigated?	2	IPR → Ownership claims, lawsuits for infringement of defective products (liability), UUPK compensation Domestic Component Levels Contract → Wan performance against partners Mitigation → Dispute resolution must be determined.

**Table 1 Legal Aspects**

Every production must comply with regulations applicable to the Domestic Component Level if the financial source is from the State. (Presidential Decree No. 16 of 2018)

## Map of Regulations & Downstream Agencies for the Manufacture of Blind Disabled Walking Aids



Figure 1. Visualization of Regulatory + Agency Map

### Feasibility Analysis and Recommendations

Of the 7 parameters of feasibility of legal aspects that must be met for downstream funding, several shortcomings were found, including the following:

1. The eligibility of IPR & Freedom to Operate already has a patent certificate, but does not yet have a registered Trademark.  
**Risk:** brand claims from third parties
2. Legality of Entity & Business Scope does not meet the OSS system according to KBLI  
**Risk:** Lack of a legal entity and the right scope, the permit may fail
3. Cooperation Agreement + P. Confidentiality with stakeholders (Colleges & Partners)  
**Risk:** rights and obligations are ambiguous, disputes cannot be resolved wisely and Information Leaks
4. Business & Technical Licensing Products such as NIB, Distribution Permit  
**Risk:** products cannot be circulated without permission, and the risk of product recall

is high

5. Proof of Quality, safety, and compliance standards from the Laboratory

**Risk:** Ensuring consumer safety and reducing litigation disputes

6. Operational Compliance (environmental & K3 documents) such as Operational Procedure Standards

**Risk:** Risk of administrative sanctions and work accidents

7. Labeling/Claims + Audit readiness (legal documentation)

**Risk:** for downstreaming, the legal requirements are very important; if not met, it can be thwarting the funding process

Recommendations to inventors and downstream actors should focus more on coordinating with stakeholders (colleges & partners) who will be involved in this program, as legal documents are required to establish the security and legal protection of inventors and grantors.

The legal parameters that need to be accommodated are:

1. Other IPR registrations such as Trademarks and/or Industrial designs;
2. Need for a final Deed of Incorporation & Amendment from the Partner (producer and trader);
3. Making Work Agreements with stakeholders (Perguturan Tinggi as IPR holder, Partner as producer, and Partner as distributor/trader);
4. Immediately take care of the Distribution Permit so that the downstream goals are achieved;
5. Carry out laboratory tests to avoid problems with consumers.
6. Requesting environmental documents/k3 from partners (the easiest SOP of the manufacturer);
7. Creating *a manual* of use to avoid legal disputes from the Consumer.

Table 2. Legal Aspect Score Criteria

Yes	Criteria	Score 1	Score 2	Score 3	Score 4	Score 5
1	Regulatory inventory	No list of relevant regulations	Partial list without a norm level source	The complete list has not yet been identified with relevant norms	Complete list, but related norms partially identified	A complete list, a completely identified relevant norm with a supporting analysis
2	Stakeholder Mapping	Key stakeholders have not been identified	The list exists, without the creeper/role	Maps of influence and early issues are available	Impact maps, priority issues are recorded	Impact maps, recorded priority issues, and stakeholder

						engagement strategies
3	IPR Ownership	Have not conducted a search for similar IPR	Have searched 1 type of IPR	Have searched for several types of IPR	Have searched for several types of IPR that have the potential to be registered	Have searched several types of IPR that have the potential to be registered, along with a list of requirements and analysis
4	Cooperation Scheme	There is no cooperation scheme yet	There is a discussion of a cooperation scheme, but it is not yet clear	There is a discussion of the cooperation scheme, along with the pros and cons	There are priority Cooperation schemes along with pros and cons, but there is no risk analysis yet	There are priority Cooperation schemes along with pros and cons, but there is a risk analysis
5	Licensing and standardization	Has not conducted an analysis of licensing needs and standards	Conducting a partial licensing and standard needs analysis	Have identified licensing needs and standards	There is already a mapping of the licensing flow, but the prerequisites do not yet exist	Checklist of standard permissions & prerequisites is available, and identification points.
5	Tax & Intensive	Not yet analyzed	There has been a listing as a potential tax	There has been a listing of potential taxes	There has been a listing of potential taxes and an analysis of some types of taxes	Successfully identify taxes and conduct simulations
6	Risk of Hukum, Registration & Mitigation	No register risk	List of partial risks without score	Risk Register with impact score	Register Risks and Part of Tencana Mitigation	Register Risks and Legal Mitigation Measures

The main novelty of this article lies in the integrative-aspectual approach, namely:

1. Combining the study of disability law with the legal regime of medical devices, so that blind disabled walkers are clearly positioned as legal objects subject to licensing, quality standards, and certification of medical devices.
2. Prepare a comprehensive legal roadmap that includes the status of IPR, legality of business entities, KBLI classification, distribution permits, distributor licenses, quality standards, taxes, and TKDN.
3. Develop a score- and risk-based legal aspect feasibility assessment instrument, which is rarely found in purely normative law research.
4. Placing the legal aspect as a prerequisite for downstream innovation, not just an administrative complement, so that it is relevant for inventors, universities, and industry partners.

Thus, this article is not only descriptive but also applicable and strategic in bridging technological innovation by adhering to the foundations of legal certainty.

## Research Gap

Based on the *state-of-the-art mapping*, there are several research gaps that this article has successfully filled:

1. Absence of a holistic study. Previous research has not examined visual aids from a comprehensive legal perspective, from upstream to downstream (Research & Development extends to production, distribution, and consumer aspects).
2. Lack of downstream legal risk analysis. Most research stops at the technical and social aspects, without mapping legal risks such as IPR claims, distribution permit failures, consumer disputes, and administrative sanctions.
3. There is no legal readiness evaluation model. No indicators and a score-based legal readiness assessment model were found to support downstream funding and commercialization of disability assistance innovations.
4. The gap between technological innovation and practice regulation. Many innovations failed to enter the market due to legal unpreparedness; This gap has not been widely studied academically and practically. (Lianingsih, N., & Yuningsih, R, 2025).

This article fills this research gap by offering a legal evaluation framework and operational strategic recommendations, thus contributing directly to the development of applied research and inclusive innovation policies.

## CONCLUSION

This study shows that the development and downstream use of road aids for people with visual disabilities do not depend solely on technological innovation; they are highly determined by readiness and compliance with applicable legal and regulatory frameworks in Indonesia. Sensory and electronic technology-based road aids are classified as medical devices, so they must comply with business licensing requirements, distribution permits, quality standards, and technical certifications stipulated by law and regulation.

The results of the analysis of the legal aspect reveal that in general, there has been a fairly strong initial foundation, especially in the ownership of intellectual property rights in the form of patents. However, there remain several significant legal loopholes and risks, including the absence of trademark registration; non-compliance with legal requirements for business

entities and business classification (KBLI); inadequate cooperation agreements among stakeholders; and incomplete technical licensing and quality-test evidence from accredited laboratories. This condition can hinder mass production, distribution, and downstream funding if it is not addressed systematically and promptly.

In addition, this study emphasizes the importance of mapping legal risks from the early stages, including IPR risks, consumer protection, taxation, and the obligations inherent in state-based funding for the Domestic Component Level (TKDN). Without adequate legal mitigation, road-aid innovations risk legal disputes, administrative sanctions, and product withdrawal from circulation.

Therefore, this study recommends preparing an integrated legal and regulatory roadmap to improve IPR registration, clarify the legality and scope of business, strengthen cooperation agreements, expedite the management of distribution permits, and ensure compliance with product quality and safety standards. A comprehensive legal approach is expected to not only provide legal protection for inventors and security for potential investors and partners, but also ensure the safety, comfort, and rights of people with visual disabilities as end users. Thus, road aid innovations can be implemented sustainably and have a meaningful social impact.

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#### **Internet resources**

<https://www.tempo.co/ekonomi/mengenal-apa-itu-hilirisasi-contoh-manfaat-dan-dampaknya-85210>

#### **Laws and Regulations**

Constitution of the Republic of Indonesia in 1945.

Civil Code

Law Number 39 of 1999 concerning Human Rights. Statute Book of the Republic of Indonesia No. 165 of 1999.

Law Number 19 of 2011 concerning the Ratification of the Convention on the Rights of Persons with Disabilities. Statute Book of the Republic of Indonesia Year 2011 Number 107.

Law Number 13 of 2016 concerning Patents. Statute Book of the Republic of Indonesia 2016 number 176. Jo. Law Number 65 of 2024 concerning Patents.

Law No. 20 of 2016 concerning Trademarks. Statute of the Republic of Indonesia in 2016 Number 252.

Law Number 8 of 2016 concerning Persons with Disabilities. Statute Book of the Republic of Indonesia Year 2016 Number 69.

Law Number 6 of 2023 concerning Job Creation.

Regulation of the Minister of Health Number 14 of 2021 Juncto Regulation of the Minister of Health Number 17 of 2024 concerning Standards of Business Activities and Products in the Implementation of Risk-Based Business Licensing in the Health Sector

Regulation of the Minister of Law and Human Rights Number 17 of 2018 concerning Business Entity Registration.

Government Regulation Number 5 of 2021 concerning Business Licensing based on Business Activities.

Regulation of the Minister of Health Number 62 of 2017 concerning Distribution Permits for Medical Devices

*Convention on the Rights of Persons with Disabilities. United Nations*