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ETHICAL BOUNDARIES OF GENETIC ENGINEERING PATENTS IN INDONESIA AND MALAYSIA

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Abstract

Genetic engineering increasingly pushes the boundaries of science, technology, and ethics by raising difficult questions about the acceptable limits of human intervention in living organisms. Its relationship with intellectual property law is particularly complex because patent protection is intended to reward innovation and encourage scientific development, while also being constrained by ethical limits expressed through ordre public and morality principles. This study examines how Indonesian and Malaysian intellectual property law regulate patent protection for genetic engineering inventions, particularly in relation to ethical safeguards. Using doctrinal legal research with a comparative approach, this study analyses the relevant patent statutes, legal concepts, and regulatory structures in both jurisdictions. The findings show that Indonesia provides a relatively stronger legal basis than Malaysia, mainly because its patent framework contains more developed definitions concerning invention, technology, and scientific methods. These definitions create broader conceptual space for recognising genetic engineering as a patentable field while also allowing ethical considerations to be developed through implementing regulations. However, Indonesia still lacks concrete examination standards and operational mechanisms for assessing ethical risks in genetic engineering patents. Malaysia, by contrast, recognises ordre public and morality clauses only at a general level and primarily uses them as grounds for refusing patent applications. Its legal framework also provides only limited acknowledgement of the patentability of genetic engineering inventions, especially in relation to microorganisms, without establishing a clear ethical review mechanism. This study argues that both jurisdictions require stronger normative and institutional safeguards to ensure that patent protection for genetic engineering does not undermine public morality, human dignity, environmental integrity, or broader public interest. Indonesia should develop implementing regulations and patent-examination guidelines that translate its broader amended patent definitions into concrete ethical safeguards. Malaysia should amend the Patents Act 1983 to provide an explicit ethical review mechanism for genetic-engineering-derived microorganism patents and clearer standards for applying ordre public and morality exclusions.

Keywords: Genetic Engineering; Patent Law; Ethical Safeguards; Ordre Public and Morality; Indonesia and Malaysia.

A. Introduction

Genetic engineering is among the most advanced scientific developments of the modern era (Davis & Yeddula, 2024), combining multiple scientific fields to develop methods to modify the genetic makeup of many organisms (Demirer et al., 2021). This scientific development has been used to solve many problems in different fields, from agriculture to medicine (Adli, 2018).

However, aside from pushing the boundaries of what science can understand, genetic engineering also actively pushes the boundaries of ethics (Coller, 2019), as modification to genetic makeup can directly influence the characteristics and functioning of living organisms, including humans (Sparrow, 2019). From the legal standpoint, this causes a cascade of legal implications that are highly complex and often not understood (Charo, 2019). Consequently, this situation creates legal gaps that may be exploited, while simultaneously risking violations of fundamental ethical boundaries with potentially adverse consequences for society as a whole (Greely, 2019). Understanding this legal topic in all of its depths is important in ensuring that the current regulatory landscape is capable of protecting ethical boundaries while also supporting the development of advanced science.

The legal implications of genetic engineering are highly complex due to its intersections with ethics (Nwakoby et al., 2025b), which are often manifested in many forms and domains of law (Heled et al., 2024). This highly complex connection with ethics also connects genetic engineering to the domain of Intellectual Property (IP) Law (Sherkow, 2017b). IP Law is a distinct, often highly individual, domain of law that governs the protection of rights over many forms of intellectual property, through many regimes of Intellectual Property Rights (IPR) (Samuelson, 2017). In the context of genetic engineering, IPR helps ensure the protection of genetic engineering as a form of innovation, to reward those behind it with many economic incentives (Panagopoulos & Sideri, 2021). This represents a key function of IPR, which is driving scientific development through the incentivization of innovation and creativity (Sherkow, 2017a). Comprehensively understanding the interplay between these intersections of ethics and law, particularly through the analysis of the IPR legal landscape, can help ensure the balance between ethics and scientific development (Demir & Stamhuis, 2023).

Relevant data have shown the growing importance of ensuring that the regulations around genetic engineering. In Indonesia, this urgency is substantiated by the rapid expansion of commercial planting. In 2025, Indonesia approved 10 varieties of genetically engineered (GE) crops for cultivation, with GE corn covering an estimated 420,000 hectares across the territory (Rahayu, 2025). From Malaysia, the data shows a stark divide between domestic cultivation and market reality. Although the country has no approved commercial cultivation of genetically modified crops, 61 GE products were approved for import and market release. The livestock feed sector depends on imported GE corn and soybeans, including nearly 3.6 million, 640,000, and 1.3 million metric tons of corn, soybeans, and soybean meal, respectively, imported in 2023 (Foreign Agricultural Service, 2024). From the broader ASEAN perspective, AgbioInvestor's Global GM Crop Area Review identifies four Southeast Asian countries with commercial GM crop cultivation in 2025, namely the Philippines, Vietnam, Myanmar, and Indonesia. These countries were identified in a wider Asia-Pacific GM crop area of 22.1 million hectares and a global GM crop area of 216.0 million hectares (AgbioInvestor, 2026). The data show the urgency of ensuring a comprehensive understanding of this form of innovation. Within the context of intellectual property rights, the understanding is particularly important because legal protection provides incentives that can drive further innovation.

The increasing urgency must be met with a comprehensive understanding of the legal landscape of genetic engineering, particularly through the lens of ethics. In the context of IP Law, the focus of ethics is even more important than ever, due to the current speed of development in the relevant scientific fields that use genetic engineering (Nordberg et al., 2018), as it is significantly affected by the economic incentives and protection provided by the relevant IPR regimes (Matthews et al., 2022). Through this lens, the quest for a comprehensive understanding of the highly specific legal topic is connected to the need to ensure that IPR enforcement is consistent with the ethical boundaries. This is particularly important in the context of genetic engineering, which is pushing the edges of scientific developments. Considering the growing relevance and potential impacts of genetic engineering, a holistic perspective is required in this

legal discourse. Relevant regulatory frameworks are not only comprehensively understood but also critically examined to ensure legal certainty and alignment with the broader public interest.

The scholarship around many issues of IP Law and genetic engineering is extensive, as it has been developing rapidly. Specifically about IP Law, Pila (2020) argues that patents should be treated as social contracts and that the granting can be considered a regulatory intervention. This angle is based on the premise that the grant of a patent follows a process of negotiation between the office, representing the public, and the inventor, where morality and other relevant values in society are considered. In the context of genetic engineering, Feeney et al. (2021) argued that genetic engineering should be equipped with a regulation tied to enforceable international regulation. Due to the inherent ethical risks associated with it, the method of ethical licensing was suggested to be considered. However, the study recognized that this could lead to the privatization of morality, particularly with the lack of transparency. Regarding ethical license, Guerrini et al. (2017) extensively explained the development and impacts of ethical licensing as a distinct legal response to accommodate the ethical challenges of genetic engineering. However, the study acknowledged substantial barriers to this method, showing that ethical restrictions could decrease the commercial value of licenses, representing the lack of balance between ethics and commercial interests.

The balance of these aspects has been addressed in a study conducted by Matthews et al. (2022). This study focused on patent law, showing how the IPR regime is instrumental in setting up limits on how genetic engineering can be used, particularly when it includes editing human genes. The study crucially shows the lack of defined standards of examination, but interestingly argues for a case-by-case method, which demands a distinct method than what the study considers "nuanced". On the other hand, Van Beers (2020) makes an even stronger case for ethical boundaries around genetic engineering by directly engaging with the core concepts of morality and human dignity. However, this perspective warns that the emerging consensus for a 'regulatory pathway' rests on an impoverished, one-dimensional understanding of human rights, which marginalizes the collective dimension of dignity in favor of scientific self-regulation. Building on the same foundation, a study carried out by Zanatta Tocchetto (2021) also showed the importance of morality and ethics, but to address the level of complexity of the implications of genetic engineering.

Despite these extensive developments of the literature, the lack of analysis on genetic engineering through the lens of ethics in IP Law, particularly in the specific context of Indonesian and Malaysian legal systems, represents a significant study gap that needs to be explored. The two jurisdictions have adopted different regulatory positions, with Indonesia approving numerous GE-derived products while Malaysia has approved none. This divergence provides a distinct and novel analytical perspective for understanding how both jurisdictions address the ethical boundaries of genetic engineering through intellectual property law. This study is conducted with two core objectives, namely (1) identifying the intersection of ethical and legal implications, and (2) assessing the relevant IPR regimes in Indonesia and Malaysia. However, this study is inherently limited to doctrinal analysis and normative assessment of the relevant laws and regulations, without the use of primary empirical evidence. The results can provide key insights into policymakers on the surrounding legal issues that stem from the ethical boundaries of genetic engineering, particularly through the lens of IP Law.

B. Method

A doctrinal legal study method was adopted in facilitating the analysis of certain legal norms from the relevant regulatory frameworks (Disemadi, 2022). This method enabled Black Letter Law analysis of key legal norms through the use of secondary data in the form of primary law sources (Tan, 2021). The objective of analyzing the legal implications and assessing the adequacy of the relevant laws and regulations made this method suitable for the study, as it viewed the legal topic

through the lens of the normative structure (Taekema, 2018). This study also used a comparative method, which, when combined with the doctrinal legal method, enabled the analysis of multiple legal systems to identify common denominators and differences between those systems. The combination also helped show patterns of legal development, as reported by Negara (2023).

The secondary data in the form of primary law sources used in this study consisted of Indonesian, Malaysian, and international patent-law instruments relevant to the patentability of GE microorganisms. In Indonesia, the study analyzed Law Number 13 of 2016 on Patents, as amended by Law Number 65 of 2024 concerning the Third Amendment to Law Number 13 of 2016 on Patents. For Malaysia, the study used the Patents Act 1983 (Act 291), including the amendments introduced by the Patents (Amendment) Act 2022 (Act A1649). These national instruments were assessed in light of two international legal instruments, namely (1) the Agreement on Trade-Related Aspects of Intellectual Property Rights and (2) the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for Patent Procedure 1977. This study used secondary data in the form of case law, namely the Diamond v. Chakrabarty, 447 U.S. 303 (1980), along with the reference of 35 U.S.C. § 101, serving as the foundation for legal developments around IP Law and genetic engineering.

C. Results and Discussion

1. Ethical Boundaries of Genetic Engineering and its Intersection with IPR

The interplay between ethical boundaries in genetic engineering and the domain of intellectual property law requires establishing a clear foundation of what ethics are and how ethics actively shape the design, implementation, and evaluation of laws (Sipe, 2019). Ethics can be defined as a system of moral principles that defines what is good for individuals and society, based on a set of standards regarding right and wrong that prescribe what people need to do to protect public interests, while focusing on fairness or specific virtues (Kambhampati et al., 2023). Ethics are applied through numerous social interactions and the dynamics around those interactions, affecting virtually all aspects of societal development, including science (Bajwa & Ng, 2025). The importance of ethics in science lies in ensuring that scientific development balances public interest with scientific pursuits (Legault et al., 2017). This is particularly important in advanced and multidisciplinary fields such as genetic engineering (Ebrahim, 2025). Ethics in genetic engineering ensures that all related scientific advances are done through ethical clinical trials, with increasing focus on transparency (Riva & Petrini, 2019). Ethical principles also ensure that the purpose of such advancements does not contradict the core values of society and the broader public interest.

The boundaries of ethics are often tested in the field of genetic engineering due to its complex set of objectives behind the development and even more complex set of implications (Aliyev & Eyvazova, 2025). Genetic engineering is ideally carried out for the purpose of solving problems in the genetic makeup of living organisms, including humans (Doudna, 2020). This is carried out for various objectives, such as productivity in crops, along with curing diseases in livestock and humans (Ansori et al., 2023). However, the implications of the results can be dangerous for genetically modified living organisms, along with other living organisms that are connected in the relevant ecosystems (Boëte, 2025). The potential disruption causes severe or even irreversible damage to naturally developed ecosystems for thousands or even millions of years (Macfarlane et al., 2022), which could lead to catastrophic environmental consequences (Courtier-Orgogozo, 2025).

In contrast to ethics, laws represent a binding codification of social contracts, and violations of the laws carry legal consequences. Although inherently affected by the core ideals behind the relevant ethics, laws have a much more direct function in society, particularly in ensuring that many activities are carried out without damaging the public interest (Dagger, 2018). In particular, IP Law is a legal field that aims to protect the private interests of authors and inventors, while

treading the lines of public interests (Bodimeade & Deane, 2023). In the context of genetic engineering, the relevant IPR regimes aim to protect those who are behind the development of certain genetic engineering innovations as a way to incentivize the contribution to the advancement of science, while also balancing competing public interests. This typical legal landscape of IPR is often connected to the double-edged nature of IPR, which is the capacity to drive innovation while also paradoxically stifling it through excessive monopoly (Showalter & Edelson, 2025). The angle of public interest in the context of genetic engineering extends beyond concerns over excessive monopoly, adding greater weight to legal analysis. This is particularly evident when considering potential disruptions to natural ecosystems and other relevant implications (Sinhmar & Purohit, 2025).

Based on the legal standpoint, ethics significantly affect both the design and the enforcement of laws (Baron & Corbin, 2017; LeBaron & Rühmkorf, 2019). Although it is often attributed to the objective of law, which is to maintain order in a civil society (Henham, 2022; Neoh, 2024), ethics are not just abstract moral principles. Operationally, ethics are normative foundations that significantly shape the legitimacy, acceptability, and practical enforceability of legal norms (Hawkins, 2024). This concept significantly determines how a society would react to a certain law. Ethical principles remain influential due to the ability to operate beneath positive law and guide the interpretation, application, and social reception of legal norms (Navin & Attwell, 2023; Sobolev & Voege, 2020). Therefore, ethics is best viewed as the pre-positive normative foundation of law, which determines whether legal rules are perceived as legitimate, morally acceptable, and worthy of compliance (Young, 2019).

The fundamental difference between law and ethics is that law operates from the standpoint of objectivity, often through the foundations set by existing legal norms or precedents made by courts (Burch & Furman, 2019; Clayton Thompson, 2019). Meanwhile, ethics operate from the standpoint of subjectivity, relative to the surrounding living values that exist in a society (Cerar, 2023). This does not imply that the two stand in opposition, but both operate in a complementary manner. Although laws provide the stable, objective framework necessary for social order, ethics act as the dynamic pulse that keeps the law relevant (Rochel, 2023). As societal values continue to evolve alongside scientific, technological, and cultural advancements, the subjective values and implications are often covered by ethics (Kudina & Verbeek, 2019). This is followed by the laws, which crystalize those newfound values to ensure a consistent and widespread enforcement through objective legal norms (Gstrein et al., 2024).

Within the context of IPR, ethics are rooted in the very foundation of IP Law, to ensure proper appropriation and the enjoyment of economic and moral rights for the rightful person behind a creation or an invention. Ethics ensures the keeping of balance between these inherently individualistic interests and the broader interests of the public (Bodimeade & Deane, 2023). This includes public access to knowledge and, from an even more generalized perspective, the upholding of morality in society (Dermawan, 2024). In essence, no creation or invention should be granted intellectual property protection if it contravenes the values held by society. This is specifically relevant in the case of scientific advancement, as it often pushes the boundaries of morality for the sole purpose of advancing human understanding of nature and the universe, or more specifically, to develop inventions that solve real-world problems (Matthews et al., 2022). The relationship can be attributed to the inseparable nature of ethics in regulatory design and enforcement, which positions ethics not as an external limitation imposed on law, but as a normative foundation that determines the legitimacy, interpretation, and social acceptability of legal protection.

IP Law is a legal domain that is significantly affected by ethics, but this interplay is often expressed explicitly in many normative settings. For example, the *ordre public* and morality exceptions rooted in TRIPS Article 27.2 permit WTO Members to exclude inventions from patentability where the commercial exploitation would be contrary to public order or morality,

including for the protection of human, animal, or plant life or health, or to avoid serious prejudice to the environment (Brown, 2018). This normative setting represents the direct manifestation of ethical considerations encoded in the structure of IPR Law, even though the application of it remains discretionary and unevenly enforced across many jurisdictions (Prifti, 2019). Therefore, it is not an exaggeration to consider ethics as a core foundation of IP Law, which is increasingly moving towards better acknowledgement of the broader public interest (Demir & Stamhuis, 2023). Public interest undoubtedly serves as the primary bridge between IP Law and genetic engineering as it is precisely the public interest that both domains are designed to serve, and where the tensions most acutely converge (Capps et al., 2017). The relevance of public health, ecological safety, and social inequality in this study is not to be understood as an empirical claim that every patented GE microorganism will necessarily produce harmful consequences. These are concerns that represent fundamental issues that the domain of IP Law aims to address, particularly around the proprietary effects of patent protection when it is granted over a living organism.

The patent regime does not authorize clinical use, environmental release, and any other utilization of GE organisms, as these can only be governed by the relevant laws around biosafety, public health, environmental protection, and other sectorally relevant regulatory regimes. Despite these conditions, the patent regime is still important to be used as a crucial filter to ensure that an invention meets the requirements needed to be granted exclusive legal protection. This can help guarantee patent integrity and further accentuate the value of the patented invention, which strengthens the commercial position of the patent holder, shapes licensing arrangements, influences downstream study access, and affects how quickly a biotechnology product moves toward wider development and commercialization.

Within the context of GE microorganisms, the subsequent legal effects that ensure the protection of patented GE inventions become ethically significant primarily because the protected subject matter is not an ordinary mechanical or chemical invention (McLennan, 2017). Living organisms or microorganisms patented as GE inventions are capable of interacting, directly and indirectly, with health, agriculture, ecological environments, and food systems (Eckerstorfer et al., 2025). The first affected domain is public health, which may be threatened by changes associated with a GE invention, particularly when linked to medicine, vaccine development, diagnostic tools, food ingredients, agricultural inputs, and other food-related biotechnologies (Kim et al., 2026). However, the issue is often related to the natural state of the environment, where changes to existing ecological systems can occur through reproduction, mutation, persistence, or horizontal gene transfer. These changes may exceed the capacity of ecological systems to respond effectively (Zhang et al., 2024). In practice, exclusive rights restrict access to essential technologies or concentrate control over biological innovation in the hands of a limited number of private actors, which can severely exacerbate existing inequalities in many societies around the world (Feeney et al., 2021).

The ethical boundaries of genetic engineering, in the context of IPR, can be understood as the limits of actions or steps allowed in the pursuit of genetic engineering. Based on an ethical standpoint, the considerations are interrelated to how the practice of genetic engineering intersects with morality, where the drive for scientific advancement must not go against the core values that shape society, while actively preventing potentially irreversible damages to natural ecosystems and preserving fundamental human dignity (Halpern et al., 2019). From the legal standpoint, laws must be able to address these ethical challenges and ensure that public interests are not harmed in the pursuit of scientific developments, such as genetic engineering (Yotova, 2020). From these two perspectives, intersections exist between ethical boundaries and legal structures, which are shaped by the interaction between both fields. Figure 1 shows the mind map explaining the interplay between ethics and IP Law in the context of genetic engineering.

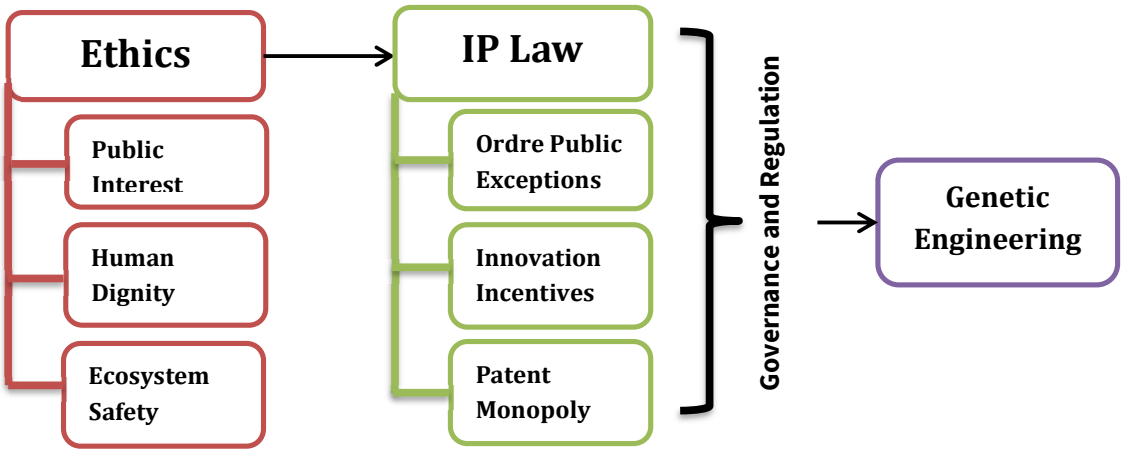

Figure 1. Implications of ethics and IP Law in genetic engineering
Source: Authors' analysis

Figure 1 shows the connection between ethics and law with genetic engineering, having some overlapping elements. The core argument from this figure is that ethics precede law. Therefore, laws should be able to manifest the core values presented by ethics, while also addressing the concerns around them (Floridi, 2018). The core implications of genetic engineering include public interest, human dignity, and ecosystem safety. Public interest was connected to the prevailing norms in society, which covered more of the developmental spectrum in genetic engineering, from studies and trials to how the final product of genetic engineering affected the perception of morality in society (van der Weij et al., 2026). For example, the aggressive commercialization of genetically modified organisms can undermine public trust, particularly when patent monopolies restrict societal access to vital agricultural or medical advancements (Glenna, 2023). The second ethical implication was human dignity, which was specifically important in the case of human genetic engineering, as it risked commodifying human biological materials and altering the germline in ways that could permanently compromise the fundamental rights and autonomy of future generations (van Beers, 2020). Ecosystem safety was the most important, as it affected all living organisms in a particular ecosystem due to potential disruptions. In the context of today's natural ecosystems, the fragility caused by climate change and its impacts has made genetic engineering a potential solution to create climate-resilient organisms, while also paradoxically being a potentially fatal gamble that can lead to irreversible damages.

The progression shown in the figure suggested the role that IP Law had on ensuring that these implications were manifested in the relevant regime. *Ordre public* ensures this function by establishing clear limits that genetic engineering should not cross, including the commercial exploitation of inventions that inherently violate human dignity (Londoño-Lázaro & Córdoba-Marentes, 2021), threaten public health, or cause severe, irreversible degradation to natural ecosystems (Spedicato, 2024). Specifically, human dignity was increasingly connected to the role that humans have in governing the planet, due to the increasing awareness of the responsibility of protecting the natural environment for the future of all living organisms (Sánchez De Jaegher, 2024). This holistic version of human dignity-centred civilization was the single biggest driving force behind the future of planet Earth (Schmidt et al., 2016), despite the planet's 4.5 billion-year history having been shaped by natural forces (Kotzé, 2021). IP law must provide mechanisms to ensure that genetic engineering inventions do not cause irreversible harm to ecological safety and the continuity of ecosystems worldwide. The protection has become increasingly significant as the impacts of climate change continue to intensify.

According to a previous study, human dignity was more understood as a concept that inherently protects the interests of humans (Husovec, 2019), where advanced science, such as

genetic engineering, cannot be utilized in a way that would aggravate socio-economic inequalities (Almeida & Ranisch, 2022). It also created a genetic divide between the poor and the wealthy. The poor faced severe challenges in accessing key necessities, such as healthcare and barriers in vertical social mobility (Gyngell et al., 2019). Based on this standpoint, certain limitations were necessary not only on the rights protected under the relevant intellectual property regime but also on the manner in which GE-derived innovations were utilized in society (Londoño-Lázaro & Córdoba-Marentes, 2021). Therefore, the ethical boundaries articulated through mechanisms must function as binding, enforceable constraints within national patent laws, ensuring that the economic incentivization of genetic engineering does not come at the cost of fundamental human rights, societal equity, and the broader public interest (Matthews et al., 2022).

In the domain of IP Law, innovation incentives and patent monopoly were key aspects of the protection (Gschwindt, 2021), particularly in the context of genetic engineering (O'Brien Laramy, 2024). Although *ordre public* may appear to stand above all other considerations, particularly in the context of the ethical boundaries of genetic engineering, the view is only partially correct and lacks legal precision. When properly invoked, *ordre public* could override individual patent rights. This position is reflected in Article 27.2 of the TRIPS Agreement, which provides that WTO Members "may" rather than "must" exclude inventions from patentability to protect *ordre public*. The provision makes the invocation of *ordre public* discretionary rather than mandatory. In other words, *ordre public* occupies a higher normative position from a legal standpoint, but reliance on this exception requires a rigorous and comprehensive assessment. This assessment shows that granting a patent for a GE-derived product would threaten public peace or social order or would seriously prejudice the environment. The structural conditionality where ethical constraints must be actively and rigorously proven rather than automatically applied is the legal chasm that places GE-derived innovations at risk of outpacing the designed ethical boundaries (Spedicato, 2024).

2. Normative Assessment of the Relevant IPR Regimes in Indonesia and Malaysia

An examination of the relevant intellectual property regimes in Indonesia and Malaysia required recognition that the patent system constituted the primary intellectual property regime for the protection and incentivization of genetic engineering inventions. Theoretically, genetic engineering seemed to be a domain that intersected with other IPR regimes, specifically considering the fact that there were many GE-derived crops that have now become essential to many countries, including Indonesia and Malaysia. This was primarily rooted in the fact that the core subject matter of protection was not merely biological material, but the human-made inventive contribution that produced, modified, isolated, applied, or used that biological material for a specific technical purpose (Hargreaves, 2026). Counterintuitively, within the context of genetically modified microorganisms, the core IPR question did not revolve around authorship, branding, or conventional breeding. It revolved around whether or not a living biological entity altered through human ingenuity could be treated as a patentable invention (Hutukka, 2023).

Understanding the relevance of plant variety (PV) regime requires examination of agricultural applications of genetic engineering, since most practical uses occur in agriculture. Genetically modified crops, plant traits, and seeds have become some of the most important elements of contemporary agricultural practices (Seixas et al., 2022) and have seen serious investments and subsequent developments over the years in science, particularly in the field of biotechnology (Deng et al., 2019). However, this assumption becomes problematic when the legal object and the fundamental building blocks of legal protection are examined closely. PV protection is designed to protect new, distinct, and stable plant varieties, which significantly differ from genetic engineering (Krieger et al., 2020). The field of genetic engineering often revolves around the underlying genetic construct, transformation method, targeted and engineered traits, microorganism, or other technical processes that enable the biological modification behind a new genetically modified version of an organism. This is directly connected to the specific legal

building blocks behind the protection of genetic engineering products, which represents the recognition of human intervention into living biological systems as a technical invention, as opposed to commercial use of the final organism.

The distinction between both countries' intellectual property law regimes remains relevant because Indonesia and Malaysia maintain intellectual property law systems under the international framework established by the TRIPS Agreement (Barizah, 2017). Within the context of genetic engineering, these regimes allow the members to exclude plants and animals from patentability while ensuring that microorganisms and microbiological processes are given legal protection (Barizah, 2019). The primary goal of this study excludes the determination of whether GE crops qualify for plant variety protection. The focus shifts to the adequacy of ethical safeguards in patent regimes in Indonesia and Malaysia regarding the recognition of patentability of microorganisms and microbiological inventions. Therefore, the analysis rests on the premise that patent law functions as the primary regime for protection of GE derived microorganisms, including incentivization, disclosure, and monopoly rights. Scope limitation reduces broader questions beyond this focus (Jacobs, 2025). The limitation also requires analysis grounded in a precise doctrinal basis, particularly patentability exclusions, microorganism-related subject matter, and accommodation of *ordre public*, alongside other ethical safeguards embedded within patent regimes.

PV regime was developed and recognized by the TRIPS Agreement as a *sui generis* intellectual property regime under Article 27.3(b), specifically designed as an alternative to protect the rights of plant breeders over new and phenotypically distinct varieties. This regime operated primarily through a framework conceptually rooted in the UPOV Convention (Wu, 2024). The normative elements connected to PV regime conceptualization include breeder's exemption, which mandates open access to protected varieties for further breeding (Hervouet & Langinier, 2018). Farmer privilege permits farmers to retain and replant harvested seeds without the rights holder's consent (Lawson, 2023). DUS (Distinctness, Uniformity, and Stability) criteria assess protectability based on observable phenotypic characteristics (Zanella et al., 2026). These elements create legal conflict with the proprietary and genotype-driven nature of genetic engineering as an innovation form, where protection attaches to the underlying genetic construct rather than external phenotypic traits. Strict commercial exclusivity for GE-derived innovations was also considered structurally necessary to recoup the substantial research and development investments that define the highly advanced field of science (Lukasiewicz et al., 2024).

The establishment of the patent regime as the primary IP Law that governs the protection of genetic engineering product can be traced back to the landmark United States Supreme Court ruling in Diamond v. Chakrabarty, 447 U.S. 303 (1980). In this case, the Court held that a GE microorganism constituted patentable subject matter under 35 U.S.C. § 101. A core argument in this landmark case was that the biological nature of an invention was irrelevant to patentability. What was determinative was whether the invention resulted from human ingenuity rather than a product of nature, as the Court reasoned that Congress intended patentable subject matter to include human-made inventions (Rahman, 2021). This reference was used across many jurisdictions worldwide in GE-related case law and legal drafting, strengthening the position of the patent regime as the most relevant legal framework for protection of GE-derived innovations (Hutukka, 2023), but also as increasingly relevant now, the balancing of this protection with the broader implications of it.

Focus on the patent regime as the core normative lens for this legal topic received justification, particularly given that patents directly address core characteristics of genetic engineering innovations, including high research and development costs and commercial complexity. Patents also advance public knowledge through mandatory disclosure requirements embedded in the patent application process. From the ethical standpoint, the concept of patentability itself requires a far more complex set of due processes than just the invention as a product (Demir & Stamhuis,

2023). Inventors are typically required to prove inventive steps and methods utilized to create the invention, to ensure that the inventions are truly beneficial to solve a certain problem while also supporting the advancement of scientific knowledge.

The patent regime in Indonesia is enshrined in Law No. 13 of 2016 on Patents, which has been revised twice through the Job Creation Law and, most recently, through Law No. 65 of 2024 on Second Amendment of Law No. 13 of 2016 on Patents (Sujatmiko et al., 2025). The definition of 'patent' has undergone subtle but significant change, along with the surrounding definitions. The 2024 amendment removed the component "result" from the definition, leaving "invention" as a broader term, further supported by the same-year amendment in Article 1, number 2, which added "systems, methods, and uses" to the definition of "invention". This regulatory update technically opened up more room for ethical considerations. The change affected Article 9(a), which, through the 2024 amendment, also received the additional elements of "systems, methods, and uses", to ensure a consistent normative logic. Article 19(1) echoed this change to ensure meaningful application and enforceability of Article 1, number 2.

Although Article 9 generally represented a structurally adequate normative basis for ethical boundaries in genetic engineering, its exceptions for microorganisms in subsection (d) were ethically problematic. Despite the widespread legal practice of allowing the patentability of microorganisms, as required under the TRIPS Agreement in conjunction with the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for Patent Procedure (1977) (Fasa & Hendrix, 2022). This practice remained widely accepted in international intellectual property law. The problem was associated with TRIPS Agreement Article 27.3(b), which made the patenting of microorganisms compulsory for WTO members, but with terms such as "microorganism" and "invention" undefined, leading to the fragmentation of global standards. Fundamentally, microorganisms are living organisms that exist alongside humans, animals, and plants, although the cellular structures are far simpler.

Dissenting scholars have argued, particularly following the landmark United States case *Diamond v. Chakrabarty*, that the classification of a microorganism as a "manufacture" on the basis of human engineering overlooks its ontological status as a living entity capable of reproduction, mutation, and independent evolution (Peukert, 2021). This provision could potentially cause a wide ethical breach. Based on a legal and economic perspective, the provision caused the incentives to practice patent thickets, where companies behind certain GE-derived microorganisms registered a significant amount of patents to excessively create a monopoly and block scientific developments with countless legal barriers (Nwakoby et al., 2025a). Regarding morality, the patentability of microorganisms conflicted with the two branches of human dignity, namely, impacts and responsibility for ecological safety. It also creates a monopoly on medicine (Mali, 2020) and biopiracy (Sinhmar & Purohit, 2025), along with causing irreversible ecological damage through uncontrolled genetic spread (Eckerstorfer et al., 2025).

The core legal gap in this issue was not in the patentability of microorganisms, which was consistent with key international instruments, but in the absence of adequate ethical safeguard mechanisms. Although international instruments and prevailing global practices remained important in doctrinal frameworks, these concepts should not be regarded as comprehensive or final solutions that require no further refinement. The broad guidance provided by the instruments should be treated as a normative foundation for further development, particularly in relation to the ethical regulation of GE microorganisms. Despite the ethical risks identified, Indonesian patent regime lacked sufficient safeguards to ensure that patented microorganisms were compatible with *ordre public*.

Malaysian framework for the protection of genetic engineering through intellectual property was primarily governed by the Patents Act 1983 (Act 291), as amended by Act A1649 in 2023. Different from Indonesian statute, Malaysian Act did not undertake a recent conceptual recalibration of "invention" to explicitly extend it to "systems, methods, and uses." It maintained

a more classical structure in which Section 11 provided that an invention was patentable when it was new, included an inventive step, and was industrially applicable. Meanwhile, Section 12 defined an invention as an idea that, in practice, solves a specific problem in the field of technology and relates to a product or process. Ethical considerations were addressed in Malaysian patent regime through Section 13(1)(b), which excluded plant or animal varieties and essentially biological processes for the production of plants or animals from patentability. This exclusion was qualified by an exception for "man-made living microorganisms, microbiological processes and the products," reflecting a TRIPS-compliant normative framework similar to Indonesian patent regime. When interpreted alongside the statutory definition of "microorganism" in Section 3, this formulation showed that Malaysia was prepared to treat ontologically living, self-reproducing entities as patentable subject matter when derived from human ingenuity.

The core normative gap regarding the ethical boundaries of genetic engineering in Malaysian patent regime was mostly similar to Indonesia, which was the lack of ethical safeguards around the patentability of microorganisms. Although Section 31 did not provide a general *ordre public* and morality ground for refusing a patent, this provision was drafted as a general, discretionary filter rather than a targeted constraint on the specific and well-documented risks of GE microorganism patents. The draft left Malaysian patent regime structurally inadequate in ensuring that the strong proprietary protection it extended to GE-derived microorganisms did not come at the cost of the public interest, human dignity, and ecological safety. Moreover, the classical definition of patents and surrounding elements also structurally limited the extent to which ethical considerations could be incorporated into the legal mechanisms of patentability. This was reflected in this study's decision to exclude the country's Patent Regulation from the normative analysis, as the regulation primarily functioned to operationalize the norms and boundaries established by the principal act. The interpretation was further supported by the absence of any relevant provisions in the regulation that could either show additional gaps or substantiate the gaps already identified in the principal act.

3. Recommendations for Potential Legal Reforms

Based on the problems identified, there needs to be a set of adequate legislative responses to fill the legal gaps currently present in Indonesian and Malaysian legal systems. This is even more important as both countries actively aim to expand the agricultural sector and the relevant subsectors (Xu et al., 2020), particularly in the time of climate uncertainty (Hultgren et al., 2025; Ortiz-Bobea et al., 2021). The core problem regarding the lack of ethical safeguards in genetic engineering is not purely legal in nature, as such concerns are better understood as multidimensional, including various aspects of public interest (Meyer & Vergnaud, 2021; Rueda et al., 2025). However, this is precisely the problem that the legal system must promptly address, to prevent exploitation of patent protection purely for profits while issues that concern the public interests are actively ignored (Bastidas Venegas, 2022; Disemadi et al., 2025). In some cases, this problem can include irreversible damage, particularly in the field of public health and ecological safety (Ren & Zhao, 2025; Tanaka et al., 2017).

Both Indonesia and Malaysia are bound by the broader international standard of patent-law structure that permits, and in certain instances expects, the protection of microorganisms and microbiological processes (Barizah, 2017). This study devised a plan through the pragmatic standpoint, acknowledging that the rejection of patentability of GE-derived microorganisms would be doctrinally unrealistic, considering the potential in solving many agricultural, food systems, and climate issues today. More specifically, the core question that the set of recommendations aimed to address was whether the patentability of the inventions was accompanied by adequate safeguards that were normatively concrete and doctrinally valid. In this case, the clear path of enforceability could help translate ethical concerns into a concrete and consistent standard of patent-examination criteria.

The patent regimes of both countries remain central, as analyses conducted in this study have shown that Indonesia and Malaysia did not provide sufficient and specific standards, as well as concrete mechanisms, to assess *ordre public* and address broader ethical concerns in genetic engineering, including public health, ecological safety, human dignity, and social equity. This remained the case despite both countries' recognition of microorganism-related patentability. However, the recognition was important for subsequent recommendations, as it served as a key normative foundation within the broader constellation of legal norms in the patent regimes of Indonesia and Malaysia.

The comparative results show that Indonesia and Malaysia require different reform pathways because the nature and depth of their regulatory gaps are not identical. Indonesia has a stronger statutory starting point because its amended Patent Law provides a broader and more flexible definition of invention by recognising not only products and processes, but also systems, methods, and uses. This formulation creates a more open doctrinal foundation for accommodating genetic engineering inventions, including those involving modified microorganisms, gene-based methods, and biotechnological applications whose legal character may not fit neatly into older patent categories. More importantly, this broader definition allows ethical safeguards to be developed without necessarily requiring immediate statutory amendment. Indonesia can build upon its existing patent structure through implementing regulations, patent-examination guidelines, interpretive rules, or technical standards issued by the relevant patent authority. These instruments could clarify how patent examiners should assess inventions that raise ordre public, morality, public health, environmental, or human dignity concerns. In this sense, Indonesia's main weakness does not lie in the absence of a basic legal foundation, but in the lack of operational mechanisms that translate broad statutory language into concrete ethical review practices. The amended Patent Law already provides conceptual space for such development; what remains underdeveloped is the institutional method for determining when a genetic engineering invention should be protected, limited, or excluded from patentability on ethical grounds.

Malaysia, by contrast, is characterised by a more classical statutory structure. Its Patents Act 1983 frames invention primarily around product and process categories, which reflects a more conventional understanding of patentable subject matter. This structure is not necessarily incapable of accommodating genetic engineering inventions, but it provides less conceptual flexibility than the Indonesian framework. The ordre public and morality clause in Malaysian law is positioned mainly as a general ground for refusing patent applications, rather than as part of a more developed ethical assessment framework. As a result, the clause functions more as a formal exclusionary rule than as a substantive mechanism for evaluating the ethical implications of genetic engineering. This creates uncertainty, particularly in relation to genetically engineered microorganisms, because the law acknowledges the possibility of patent protection but does not clearly explain how ethical risks should be assessed, who should assess them, or what standards should guide that assessment. Nevertheless, this gap does not mean that Malaysia is significantly behind Indonesia in terms of the legal foundation for reform. Both jurisdictions possess basic legal entry points for integrating ethical safeguards, although they require different methods of development. Indonesia can move forward primarily through regulatory elaboration and examination practice, while Malaysia may need a more explicit reform strategy through amendments to the Patents Act 1983 or the issuance of specific examination guidelines governing the application of Section 31 to genetic engineering inventions. Such guidelines would help clarify the meaning of ordre public and morality in the context of biotechnology, distinguish between ethically acceptable and unacceptable forms of genetic engineering, and ensure that patent protection does not operate merely as an incentive for innovation, but also as a legally responsible mechanism aligned with public interest and ethical accountability.

In theory, legal reforms are required when there is a pressing need to address legal problems that have already produced negative effects on civil order across multiple dimensions and domains

(Albanesi & Teasdale, 2025). Another justification for legal reforms can come from the lack of acknowledgement of the danger acknowledged scientifically, or could potentially injure the values in a society (Tamanaha, 2020). A danger that could potentially injure the values in a society, while often framed around the pretext of prevention, is not built on hypotheticals. It includes actualized harm, direct causation, and measurable social or ecological damage, elements that are hard to prove before the relevant risks materialize. However, the angle of prevention can be based on foreseeable risk, scientific plausibility, moral seriousness, and the potential irreversibility of harm, specifically when the subsequent impacts are acknowledged scientifically and morally. This is the case with the justification for legal reforms concerning patent protection for GE-derived inventions. It includes the grant of exclusive rights over living or biologically active subject matter whose downstream effects may implicate public health, ecological safety, human dignity, and social equity (Guida, 2021).

The devised set of recommendations for legal reforms below is constructed as implementable patent-law mechanisms, moving away from abstract ethical aspirations currently present in international instruments and in the existing patent laws in Indonesia and Malaysia. However, these recommendations are not aimed at replacing the crucial biosafety, environmental, food-safety, or public-health safeguards that exist from other relevant regulations. This is because the set of recommendations requires relevant patent offices to fundamentally recognize how the granting of exclusive rights over GE microorganisms produces legal consequences affecting downstream access, commercialization, licensing, and study control. The primary objective of this reform is to develop a structured bridge between patentability assessment and ethical review, as well as to ensure that a concrete standard can be consistently applied in any genetic engineering invention.

Table 1.
Designed recommendations for legal reforms

Recommended reform	Indonesia	Malaysia	Doctrinal function
Dedicated ethical safeguard test for GE microorganism patents	Develop an implementing regulation or patent-examination guideline under the Patent Law to clarify how Article 9 and the amended definitions of patent and invention apply to GE-derived microorganisms.	Amend or supplement the Patents Act 1983, especially Section 31, with specific criteria for applying ordre public and morality to GE-derived microorganisms.	Converts broad ethical concepts into concrete patentability criteria.
Risk-based patent review system	Require applicants for GE microorganism patents to submit an ethical and biosafety relevance statement addressing public health, ecological interaction, reproduction, mutation, persistence, and social equity implications.	Require similar disclosure through MyIPO examination practice, with higher scrutiny for inventions involving environmental release, medical use, food systems, or agricultural biotechnology.	Allows patent examiners to classify applications according to low, moderate, or high ethical-risk categories.
Inter-agency ethical review mechanism	Establish a consultative mechanism between the patent authority and relevant bodies responsible for biosafety, food safety, health, agriculture, and environmental protection.	Establish a consultative mechanism between MyIPO, the National Biosafety Board, the Genetic Modification Advisory Committee, the Ministry of Health, and relevant environmental or agricultural authorities.	Prevents patentability review from being isolated from technical and sectoral regulatory expertise.
Ethical licensing and access safeguards	Encourage or require licensing commitments for GE microorganism patents that	Introduce public-interest licensing guidance for GE microorganism patents where	Balances exclusive rights with public-health, ecological,

Recommended reform	Indonesia	Malaysia	Doctrinal function
	include essential medical, agricultural, food-security, or environmental technologies.	exclusive control may restrict access to socially important biotechnology.	and social-equity concerns.
Post-grant monitoring linkages	Link granted GE microorganism patents to subsequent regulatory developments where later evidence reveals serious risks to public health, biodiversity, or environmental safety.	Create a post-grant referral system allowing relevant agencies to notify MyIPO when a patented GE microorganism raises serious sectoral regulatory concerns.	Ensures ethical safeguards do not end at the moment of patent grant.

Source: Authors' analysis

The first recommendation is the creation of a dedicated ethical safeguard test for GE microorganism patents. This test should be specifically anchored to the core purpose of ensuring *ordre public*, morality, public interest, and patentability consistency, instead of an ambiguous moral inquiry that is detached from the relevant patent law. In the context of Indonesian legal system, this is carried out by implementing examination guidelines to further support the recent developments made around Patent Law, specifically building on the amended definition of invention as a doctrinal basis for assessing methods, systems, and uses. For Malaysia, the reform focuses on ensuring explicitness of the legal norms, particularly because the Patents Act does not provide the same level of conceptual flexibility. This can be accommodated by statutory amendment, focusing on changing the status of *ordre public* and morality as grounds for refusal to a legitimate legal basis for a mandatory ethical review.

The second recommendation is the adoption of a risk-based patent review system, which would ensure that GE microorganism patent applications are not treated as equally sensitive. Under this framework, low-risk applications, such as contained laboratory tools or non-environmental study methods, could proceed without disproportionate procedural requirements, including extensive disclosure obligations. Moderate-risk applications may also require further explanation of containment, public interest implications, or non-environmental study methods, followed by a more complex disclosure standard. The risk-based patent review system must incorporate the high-risk level of assessment, particularly for GE inventions that include environmental release, food systems, medical applications, agricultural inputs, or organisms capable of persistence and horizontal gene transfer. This should include the highest level of scrutiny for all the previously mentioned assessments, with an even more complex disclosure standard. The mechanism serves the gatekeeping function without replacing any biosafety authority, and can be applied equally in both Indonesia and Malaysia.

The third recommendation represents the crucial glue that binds the previous recommendations, as it facilitates inter-agency ethical review mechanisms. This is carried out to close the gap in authority and technical capability of the patent office, ensuring that the ethical review is bound strictly by the latest scientific and ecological understanding, to fully grasp the picture of ethical implications against public health, agriculture, food, or any relevant environmental sector. The establishment of a consultative mechanism between the patent authority and agencies responsible for biosafety, food safety, and other areas related to the ethical concerns identified earlier could support the implementation of this recommendation in Indonesia. This mechanism should be accompanied by mandatory reporting requirements. For Malaysia, this can be carried out by adopting a similar model through the utilization of MyIPO, establishing the connection with National Biosafety Board, Genetic Modification Advisory Committee, Ministry of Health, and other relevant sectoral authorities. This recommendation ensures that the patent office does not extend beyond the intended scale of authority, while ensuring fair and accurate assessments regarding the ethical implications of GE inventions.

The fourth recommendation represents the final and concrete result of the ethical review process, and a safeguard to help legal risk management of the patent holder. This can function as a distinct incentive that can further motivate other stakeholders to innovate. The review process takes the form of ethical licensing, which can technically grant a patent holder a better market positioning, treating the license as a direct, legal acknowledgement that the GE invention is indeed safe for the broader public interest. This license can be used for licensing, commercialization, study access, and market control. Furthermore, it ensures that GE inventions connected to essential medicines, vaccines, diagnostics, food ingredients, agriculture inputs, and other relevant areas are not used to prevent access to socially important biotechnology. Safeguards for both Indonesia and Malaysia include public interest licensing commitments and expectations of non-exclusive licensing for essential technologies. These safeguards may also include explicit obligations connecting patent rights to compulsory licensing mechanisms in situations where public interest considerations must be seriously considered. The process is followed by post-grant monitoring, which facilitates the gathering of regulatory enforcement data around the enforcement protection based on the norms available on the relevant patent regulations, and most importantly, around the ethical implications of the licensing. With these reforms, this study hopes to develop a more complete ethical safeguard framework that rewards innovation and ensures *ordre public*, while also supporting the advancement of the genetic engineering subfield of science.

D. Conclusion

The analyses show that the patent regime should become the primary focus of doctrinal inquiry because it is the legal field most conceptually consistent with the nature of genetic engineering and the practical need to protect technological innovation. Genetic engineering produces inventions that are not merely scientific discoveries, but may also take the form of modified microorganisms, microbiological processes, genetic methods, technical applications, and products derived from human intervention in living organisms. These characteristics place genetic engineering within the core concerns of patent law, namely the recognition, protection, and regulation of inventions that are novel, useful, and technically applicable. However, the findings also show that both Indonesia and Malaysia still lack sufficiently developed legal norms capable of functioning as ethical safeguards in determining the patentability of genetic engineering inventions.

Indonesia provides a relatively stronger doctrinal foundation because its amended patent framework expands the definition of patentable invention by acknowledging systems, methods, and uses. This broader formulation creates greater legal flexibility for incorporating ethical considerations into patent examination, especially in cases involving genetic engineering technologies that may raise concerns relating to ordre public, morality, public health, environmental protection, biodiversity, and human dignity. Nevertheless, this broader statutory language has not yet been translated into concrete implementing rules or examination standards. As a result, Indonesia has a promising legal basis, but still lacks an operational mechanism for determining when a genetic engineering invention should be granted patent protection and when it should be limited or refused on ethical grounds. Malaysia, by contrast, has a narrower statutory structure because its patent system remains more closely tied to the traditional categories of product and process. Even so, Malaysian law acknowledges the patentability of man-made living microorganisms, microbiological processes, and products derived from such processes under the Patents Act 1983. This recognition confirms that genetic engineering inventions are not entirely excluded from patent protection. The main problem lies in the way the Malaysian framework treats ordre public and morality, which are framed primarily as general grounds for refusal rather than as part of a more developed ethical review mechanism.

In light of these findings, legal reform in both jurisdictions should aim to preserve the patentability of microorganism-based genetic engineering inventions while ensuring that patent

protection does not operate without ethical boundaries. Indonesia should build on its broader amended patent definitions by developing implementing regulations, technical guidelines, and patent-examination standards that translate ethical principles into concrete assessment criteria. Malaysia, meanwhile, should introduce more explicit amendments to the Patents Act 1983 or develop specific examination guidelines clarifying the application of ordre public and morality clauses to genetic engineering inventions. Such reforms would strengthen the balance between innovation incentives and ethical accountability. They would also contribute to the growing literature on the relationship between intellectual property law and genetic engineering, particularly in jurisdictions where biotechnology is developing more rapidly than the legal frameworks designed to govern it. Future research should examine empirical evidence on patent examination, institutional practice, and ethical disputes in genetic engineering to further substantiate the legal gaps identified in Indonesia and Malaysia.

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