



Reconciling the 2024 WIPO Treaty on Genetic Resources and Associated Traditional Knowledge with the TRIPs Agreement: Administrative Formalities vs. Substantive Patentability Criteria

Lam Luthfiyyah Khairun Nisa¹

¹Faculty of Law, Universitas Sebelas Maret

Corresponding author's email: lamluthfiyyah@uns.ac.id

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Abstract

The adoption of the WIPO Treaty 2024 introduces a disclosure of origin obligation as an effort to enhance transparency within the patent system. However, this integration has sparked debate regarding its compatibility with the TRIPs, particularly in relation to the potential emergence of new substantive requirements that exceed the global patentability criteria. This study aims to analyze the conformity of such disclosure requirements with the international standards set forth in Articles 27.1, 29, and 62 of the TRIPs. Employing a normative legal research method and a textual interpretative approach grounded in the VCLT, this study examines relevant WTO jurisprudence in order to identify the permissible limits of administrative procedures. The findings indicate that Article 27.1 of the TRIPs is of a limiting character, such that disclosure of origin may not be imposed as a substantive requirement capable of defeating an invention. Nevertheless, such an obligation remains internationally valid insofar as it is framed as a "reasonable procedure" under Article 62.1 of the TRIPs. This requires member states to apply administrative sanctions with due caution, particularly in assessing fraudulent intent, so as to preserve legal certainty without distorting the globally agreed minimum standards for patent protection.

I. Introduction

Biopiracy cases have exposed a persistent vulnerability in the global patent system, inventions derived from genetic resources or traditional knowledge can be patented without disclosing their origin, enabling rights holders to benefit from biodiversity while source communities receive nothing. One major concern is preventing patents from being granted or used to exploit traditional knowledge and genetic resources. This can be addressed by requiring patent applicants whose inventions involve such resources to disclose their origin, demonstrate that they have obtained Prior Informed Consent (PIC) from the local communities who own them, and show that they have established benefit-sharing agreements with those communities (de Werra, 2009: 143). The Enola Bean patent where a US company obtained rights over a yellow bean variety long cultivated by Mexican farmers exemplifies how patent offices, operating under the patentability criteria of novelty and inventive step alone, have no mechanism to screen for misappropriation. It was only after a decade of costly litigation that the patent was revoked, underscoring the systemic inadequacy of existing rules (Shashikant, 2009: 1-2). Developing countries, which harbour the majority of the world's genetic resources and host the communities that have custodied traditional knowledge for generations, bear a disproportionate share of this harm.

On 24 May 2024, International efforts to bridge the protection of Intellectual Property (IP) with the utilization of Genetic Resources (GR) and Traditional Knowledge (TK) through the adoption of the Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge in the WIPO Diplomatic Conference (DIPCON-GR TK). This treaty is the result of text-based negotiations conducted by the Intergovernmental Committee (IGC) since 2010 for the purpose of formulating an international legal instrument in this field (Yu, 2024: 278). Under Articles 3 and 5, patent applicants are obliged to disclose the country of origin of any genetic resource or associated traditional knowledge used in their inventions. The treaty's proponents argue that this mechanism will enhance patent quality and deter erroneous grants. Yet the normative relationship between this disclosure obligation and the substantive patentability framework of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement) remains unresolved and this unresolved tension constitutes a critical legal gap in the current literature.

Article 27.1 of TRIPs Agreement obliges Members to make patents available for inventions that satisfy the criteria of novelty, inventive step, and industrial applicability,

and expressly prohibits discrimination by field of technology (Gervais, 2012: 430), although States retain policy space to interpret those standards in accordance with national conditions (Correa, 2022: 263). Disclosure of origin, by contrast, is an administrative procedural requirement that operates independently of those criteria. Whether compliance with, or failure to comply with, this disclosure obligation can lawfully affect patentability. For example, through sanctions such as refusal or revocation without violating TRIPs Agreement has not been systematically examined. This question has practical urgency, patent offices across all contracting states must now determine how to lawfully implement the disclosure obligation, and the answer matters most to biodiversity-rich developing countries where the treaty's protective purpose and TRIPs Agreement compliance obligations are most likely to pull in opposite directions.

This paper therefore addresses the following research question: Is the disclosure of origin requirement under the 2024 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge consistent with the patentability standards and the non-discrimination principle of Article 27.1 of TRIPs Agreement, and under what conditions may administrative sanctions for non-compliance be imposed without breaching TRIPs Agreement's obligations? To answer this question, this paper proceeds in three analytical steps. First, it examines whether disclosure obligations constitute a permissible extension of the invention disclosure framework under Article 29 of TRIPs Agreement. Second, it considers whether such obligations may be characterised as "reasonable procedures" within the meaning of Article 62.1, thereby insulating them from Article 27.1 scrutiny. Third, it analyses the limits of patent authorities' competence in assessing fraudulent intent and imposing sanctions, drawing on the principle of mutual supportiveness articulated in the Convention on Biological Diversity and the Nagoya Protocol. The scholarly contribution of this paper lies in its articulation of an integration pathway, one that allows biodiversity-protecting procedural obligations to operate within the global patent system without distorting its substantive architecture.

II. Analysis of the Compatibility of the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge 2024 Disclosure of Origin Obligation with the TRIPs Patentability Regime

In 2000, WIPO, through its General Assembly, established the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore (IGC) to address intellectual property issues related to genetic resources, traditional knowledge, and traditional cultural expressions. In its initial phase, the IGC

focused on research activities and mapping the issues in that field. Subsequently, since 2010, the IGC has engaged in text-based negotiations to formulate an international legal instrument in this area (Yu, 2024: 278). These negotiations eventually led the WIPO member states to agree to convene a diplomatic conference in July 2022 with the aim of finalizing an International Legal Instrument on Intellectual Property and Genetic Resources, Traditional Knowledge, and Folklore. At its culmination, on 24 May 2024, at the DIPCON-GRTK, the IGC formally adopted the Treaty on Genetic Resources and Traditional Knowledge. Pursuant to the terms of the Treaty, particularly Article 17, it shall enter into force after ratification by at least 15 member states (Oguamanam, 2024: 323-324). According to WIPO Documents 2025, 44 states have signed the Treaty, including Algeria, Australia, Bolivia (Plurinational State of), Bosnia and Herzegovina, Brazil, Burkina Faso, Cabo Verde, Central African Republic, Chile, Colombia, Congo, Côte d'Ivoire, Democratic People's Republic of Korea, Dominican Republic, Ecuador, Eswatini, Gambia, Ghana, Indonesia, Iran, Lesotho, Madagascar, Malawi, Marshall Islands, Morocco, Namibia, Nicaragua, Niger, Nigeria, Niue, Paraguay, Peru, Saint Vincent and the Grenadines, Sao Tome and Principe, Senegal, South Africa, Switzerland, Togo, Uganda, United Republic of Tanzania, Uruguay, Vanuatu, Zambia, and Zimbabwe, and two states have ratified it, namely Malawi and Uganda. If one refers to Article 17 of the Treaty, which provides that, "This Treaty shall enter into force three months after 15 eligible parties referred to in Article 12 have deposited their instruments of ratification or accession," then as of April 2026, the Treaty has not yet entered into force.

The WIPO Treaty on Genetic Resources and Associated Traditional Knowledge 2024 aims to enhance the effectiveness, transparency, and quality of the patent system relating to genetic resources and traditional knowledge, while preventing the erroneous grant of patents for inventions that do not satisfy the elements of novelty or inventive step in connection with the use of such genetic resources and traditional knowledge.

The Treaty establishes a common set of rules intended to improve international legal certainty by encouraging states to align their domestic legislation through the adoption of the same or similar legal standards as specified in the Treaty. The principal rules in the Treaty concern disclosure of origin in patent applications, as set out in Articles 3 and 5. These provisions essentially reflect the understanding of how the disclosure of origin mechanism operates, as already understood prior to the Diplomatic Conference. Given that the Treaty on Genetic Resources and Associated Traditional Knowledge lies at the intersection of IP law and the ABS regime (Morgera, 2024: 63), the parties in the preamble

and the Treaty provisions emphasize the importance of mutual supportiveness with other international instruments relating to genetic resources and traditional knowledge, thereby indirectly promoting lawful genetic resources and traditional knowledge through greater transparency, as well as supporting the creation of a sustainable innovation ecosystem. Such an ecosystem contributes to biodiversity conservation and sustainable use through mechanisms of fair and equitable benefit-sharing arising from the use of genetic resources and traditional knowledge. Through compliance with domestic ABS law, innovators are expected to engage in practices that do not damage or erode the biodiversity from which those genetic resources derive. The Treaty regulates that the disclosure of origin obligation applies only to the state where the resources were accessed. This provision enables the country of origin to verify whether access to its genetic resources has complied with the ABS regime arising from obligations under the Nagoya Protocol.

In the regulation of genetic resources, Article 3.2 of the Treaty also provides that where patent protection is sought for an invention based on traditional knowledge associated with genetic resources, the applicant must disclose the indigenous peoples or local community that provided such knowledge. If such information is unknown to the applicant, the source of the knowledge must be disclosed. The term “source of traditional knowledge associated with genetic resources” includes, among other things, scientific publications, publicly accessible databases, patent applications, patent publications, and various other means through which such knowledge may be obtained, as set out in Article 2. Unlike footnote 2 concerning genetic resources, the Treaty does not specifically regulate cross-border situations involving traditional knowledge, leaving such matters to the parties to address. Article 3.3 states that if the patent applicant does not know either the country of origin or the source of the genetic resources or traditional knowledge, the applicant must submit a declaration stating such lack of knowledge (Callo-Müller *et al.*, 2024: 7).

To support the preventive objective, Article 6 of the Treaty permits States Parties to establish and manage information systems on genetic resources and traditional knowledge, so that national patent authorities may take such information into account when assessing relevant prior art. In addition, Article 6.1 provides that, where relevant, indigenous peoples, local communities, and other stakeholders shall be involved in the development of such information systems. This provision makes possible the development of initiatives such as India’s Traditional Knowledge Digital Library (TKDL), which currently provides its information to sixteen patent offices, including the European Patent Office (EPO) and the United States Patent and Trademark Office (USPTO) (Yu, 2024: 293-295). In the

event of non-compliance with the disclosure of origin obligation, the States Parties agree to establish legal, administrative, and public policy measures to impose sanctions for such violations, as provided in Article 5.1. Nevertheless, Articles 5.2 and 5.2*bis* provide that the parties are required to give the applicant an opportunity to remedy any deficiency in disclosure before sanctions are imposed. Such opportunity is granted only where there is no element of fraud or fraudulent intent on the part of the applicant, given that the Treaty adopts a strict approach to cases involving fraud.

Under Articles 5.2*bis* and 5.4, the parties may refuse to allow the applicant to cure a failure to comply with the disclosure of origin obligation where fraud or fraudulent intent is present, and may even impose sanctions or remedies after the patent has been granted. However, the Treaty does not explain whether the existence of fraud or fraudulent intent must first be determined by an entity other than the national patent authority. This is relevant because Article 3.5 states that the parties are not required to oblige patent offices to verify the authenticity of the disclosed information. The issue that arises is whether the disclosure of origin requirement in the WIPO Treaty on Genetic Resources and Associated Traditional Knowledge 2024, as explained above, is consistent with the standards on patentability established in the TRIPs Agreement. Within that framework, the relevant TRIPs provision to be analyzed is Article 27.1, which governs patentable subject matter. Article 27.1 of the TRIPs Agreement is one of the broadest and most stringent provisions in establishing international patent law standards, and it states:

“27.1 Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”

If interpreted using the method of interpretation codified in the VCLT, particularly as set out in Articles 31 and 32, which emphasize textual interpretation of the provisions of an international treaty (Linderfalk, 2007: 205), the phrase “provided that” in Article 27.1 of the TRIPs Agreement introduces a conditional clause that is complete and exhaustive. Accordingly, the three criteria mentioned in that provision, novelty, inventive step, and industrial applicability are the only requirements determining the availability of patent protection. The structure of the provision does not textually allow the addition of other

substantive requirements beyond those three criteria, so a requirement that patent applicants identify genetic resources and provide proof of PIC as a condition of patentability may potentially conflict with the TRIPs Agreement.

III. The Relevance of Articles 29 and 62 of the TRIPs Agreement as a Procedural Basis for the Legitimacy of the 2024 WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge

A. The Scope of Invention Disclosure under the Standard of Person Skilled in the Art in Article 29 of TRIPs Agreement

Article 29 of the TRIPs Agreement governs disclosure requirements in patent applications. It requires that an invention be disclosed in a manner sufficiently clear and complete so that it may be carried out by a person skilled in the art. In addition, there are several optional additional requirements that may be imposed by WTO Members. One such requirement is the obligation to disclose the best mode, namely the best method known to the inventor for carrying out the invention. Another optional requirement is the obligation for the patent applicant to provide information concerning related patent applications filed in other countries, including patents that have been granted or refused.

The latter requirement is intended to facilitate the patent examination process, particularly in developing countries that often face limitations in human resources and technical capacity when assessing compliance with the substantive requirements of patentability. Even so, the application of such requirements must not disturb the principle of patent independence as established in the Paris Convention and later incorporated into the TRIPs Agreement framework. Article 29 of the TRIPs Agreement reads:

“29.1 Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

29.2 Members may require an applicant for a patent to provide information concerning the applicant’s corresponding foreign applications and grants.”

In this context, the wording of Article 29 of the TRIPs Agreement does not, in principle, provide an appropriate framework for incorporating a disclosure of origin requirement. Information concerning the origin of genetic resources or the circumstances related to their acquisition is generally not necessary for an invention to be carried out by a person skilled in the art (de Carvalho, 2000: 380). Nevertheless, in certain cases,

particularly in biotechnological inventions whose implementation does require the use of such natural resources, knowledge of the place from which those resources were obtained may have practical relevance to the carrying out or use of the invention (de Carvalho, 2000: 381). Another provision of the TRIPs Agreement relevant to requirements that may be imposed on patent applicants under the domestic law of WTO Members is Article 62. That provision encompasses the entirety of Part IV of the Agreement, which governs the acquisition and maintenance of intellectual property rights as regulated in Part II, particularly Sections 2 through 6.

This creates a critical distinction, while Article 29 focuses on the technical sufficiency of the patent ensuring the "bargain" between the inventor and the public Article 62 addresses the procedural formalities necessary to secure that right. If a disclosure requirement is framed purely as an administrative formality under Article 62, it must still satisfy the "reasonableness" test. This means it cannot be used as a veiled mechanism to impose new substantive criteria that would result in the summary rejection of a patent for reasons unrelated to its technical merit. When these natural resources are essential for replication, the origin may serve a technical purpose, however, when used merely to track benefit-sharing compliance, the requirement shifts from a tool of patent quality to a tool of international policy. Consequently, any implementation must be carefully calibrated to ensure that procedural mandates under Article 62 do not collide with the substantive protections of Article 27, thereby maintaining the delicate equilibrium of the global Intellectual Property system.

B. The Justification of Reasonable Procedures and Formalities under Article 62.1 of the TRIPs Agreement

Article 62 confers on Member States the authority to require compliance with reasonable procedures as a precondition for the acquisition and maintenance of patents. Nevertheless, the Agreement provides only a number of general indications that may assist in clarifying what is meant by reasonable procedures, without laying down a precise definition of that concept. Article 62 provides:

“62.1 Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II, compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement.

62.2 Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or

registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

62.3 Article 4 of the Paris Convention (1967) shall apply *mutatis mutandis* to service marks.

62.4 Procedures concerning the acquisition or maintenance of intellectual property rights and, where a Member's law provides for such procedures, administrative revocation and *inter partes* procedures such as opposition, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of Article 41.

62.5 Final administrative decisions in any of the procedures referred to under paragraph 4 shall be subject to review by a judicial or quasi-judicial authority. However, there shall be no obligation to provide an opportunity for such review of decisions in cases of unsuccessful opposition or administrative revocation, provided that the grounds for such procedures can be the subject of invalidation procedures.”

First, Article 62.1 of the TRIPs Agreement provides that the procedures and formalities applied by Member States must be consistent with the provisions of the Agreement. In other words, such procedures and formalities must not only comply with the basic principles of the TRIPs Agreement, such as the NT and MFN principles, but must also conform to other relevant substantive provisions, including Articles 3 and 4 of the Agreement. This indicates a link between procedures considered reasonable, as permitted under Article 62, and the patentability requirements laid down in Part II, Section 5, in particular Articles 27.1 and 29. Second, Article 62.2 emphasizes that procedures applied subject to compliance with the substantive conditions for the acquisition of rights as set out in Article 27.1 must permit the grant of patents within a reasonable period of time. This provision is intended to prevent an unwarranted curtailment of the patent term. Accordingly, procedures considered reasonable are, in essence, procedures that assist patent authorities in assessing whether an invention has met the substantive patentability requirements of novelty, inventive step, and industrial applicability. In addition, the imposition of reasonable fees in that process is also permitted. This understanding is based not only on the interpretation of the text of the TRIPs Agreement itself but is also supported by the negotiating history of the Agreement.

During the negotiations, Members never proposed that requirements unrelated to the characteristics of the invention or to the fees charged by the patent office could be treated

as part of the permissible procedures (de Carvalho, 2000: 382). For example, at an early, unsuccessful stage of the negotiations that later led to the 1988 Montreal Mid-Term Review, a number of GATT parties set out their views on key trade issues relating to intellectual property. The European Communities complained that procedural differences and complexity in certain countries made it more difficult for companies from the Communities to obtain IP protection abroad than for their competitors within the Communities. Similar views were expressed by the Nordic countries Finland, Iceland, Norway, and Sweden which considered that a number of obstacles to IP protection were linked to the complexity of the procedures applied. Switzerland also expressed concern that national procedures which were complex, costly, and time-consuming hindered small and medium-sized enterprises from entering foreign markets (de Carvalho, 2000: 383). Canada, for its part, argued that discriminatory and non-transparent procedures could increase uncertainty in international trade in goods and services.

In brief, even before concrete proposals on the establishment of the TRIPs Agreement were formally tabled, the GATT parties had underscored the importance of procedures that are simple, expeditious, and relatively low-cost. The objective was to enhance legal certainty surrounding the grant and enforcement of patent rights and, at the same time, to reduce the length of administrative processes and procedural burdens in securing such protection. These considerations were subsequently reflected in various proposals submitted within the GATT framework. The first proposal submitted by the European Communities even contained language that was later adopted almost *ipsissimis verbis* or in the very same words, with only minor changes, in the final text of the TRIPS Agreement (Draft Agreement on Trade-Related Aspects of IPRs, Communication from the European Communities, 1990, GATT Doc. MTN.GNG/NG11/W/68).

In the Chairman's report to the negotiating group dated 23 July 1990, a number of proposed requirements relating to patentability included the following. First, requirements such as the filing of an adequate disclosure in the patent application and the payment of reasonable fees were not regarded as inconsistent with the obligation to provide patent protection.

Second, patent holders were required to disclose the invention prior to the grant of the patent in a clear and complete manner, so as to enable a person skilled in the relevant technical field to carry out the invention. In this context, such disclosure also included the obligation to indicate the best mode. The language proposed by the European Communities was ultimately adopted almost *ipsissimis verbis*, that is, with essentially the

same wording, in the provisions that later became part of the TRIPs Agreement (GATT Doc. MTN.GNG/NG11/W/76, 1990). These precedents show that the TRIPS Agreement, in principle, recognizes only three substantive requirements for the patentability of an invention, namely novelty, inventive step, and industrial applicability.

The requirements that may be imposed on patent applicants are, in principle, limited to the obligation to provide information to the patent office in order to demonstrate that these three criteria have been met. The same reasoning applies to the two additional requirements allowed, though not mandated, by Article 29 of the TRIPs Agreement. The best mode requirement essentially relates to the element of industrial applicability of an invention. Meanwhile, the obligation to provide information on patent applications filed in other countries, including patents granted or refused, can help verify findings concerning novelty and inventive step already assessed by patent offices in other jurisdictions. Beyond these requirements, WTO Members are also permitted to apply reasonable procedures as provided in Article 62.1 of the TRIPs Agreement.

According to the negotiating history, the standard of reasonableness of such procedures is determined by the extent to which they bear a direct relationship to the substantive requirements laid down in Article 27.1, namely novelty, inventive step, and industrial applicability and the disclosure conditions set out in Article 29. Apart from the obligation to pay reasonable fees, additional procedures should not be imposed where they do not directly relate to the process of identifying or assessing these three substantive patentability requirements (de Carvalho, 2000: 386-387). This framework creates a "ceiling" for member states, preventing the unilateral introduction of new hurdles that could stifle innovation or create fragmented intellectual property landscapes. Accordingly, the disclosure of origin requirement in the recently finalized WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge, particularly Article 3, must be implemented cautiously. The risk is that such a requirement could be misconstrued as a new substantive requirement capable of invalidating an invention.

Instead, it must remain strictly within the confines of an administrative obligation that does not distort the patentability criteria, which are already limitative under the TRIPs Agreement. To ensure this balance, it is essential to distinguish between the right to a patent and the formalities of the application. If a disclosure requirement is treated as a substantive criterion (a "fourth requirement"), it threatens the stability of the patent system. An invention that is genuinely new and non-obvious could, in theory, be stripped of protection simply due to a procedural oversight regarding the geographical origin of a

genetic resource. Such an outcome would contradict the objective of Article 27, which seeks to provide a predictable environment for technological transfer. The "reasonableness" of Article 62 of TRIPs Agreement further reinforces this, mandating that procedures for the acquisition of Intellectual Property Rights must be fair and equitable, and not unnecessarily burdensome. Furthermore, the implementation of Article 3 of the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge must grapple with the "chilling effect" on research and development. If the consequences of non-compliance include the revocation of patent rights, the resulting legal uncertainty may deter investment in biotechnological fields that rely on genetic resources. To remain "reasonable," enforcement mechanisms should prioritize curative measures allowing applicants to rectify omissions rather than punitive invalidations. Ultimately, the integration of these two legal regimes must be guided by the principle of harmonization. By viewing disclosure of origin as a tool to assist patent examiners in conducting prior art searches (thereby strengthening the application of Article 27.1) rather than a barrier to entry, states can respect the sovereignty of genetic resources without undermining the foundational pillars of international patent law. The goal is a symbiotic relationship where administrative transparency supports, rather than supplants, substantive innovation.

IV. Conclusion

Based on the legal analysis set out above, this study concludes that the disclosure of origin requirement under the WIPO Treaty on Genetic Resources and Associated Traditional Knowledge 2024 is, in principle, not incompatible with the TRIPs Agreement, provided that it is treated as a procedural formality rather than as an additional substantive patentability criterion.

Although Article 27.1 of the TRIPs Agreement establishes a limiting threshold for patentability, namely novelty, inventive step, and industrial applicability, the disclosure obligation finds its juridical basis in Article 62.1 of the TRIPs Agreement as a "reasonable procedure" intended to promote transparency and the effective operation of national patent systems.

Nevertheless, a legal risk arises if Member States impose automatic patent revocation as a sanction for non-disclosure in the absence of fraudulent conduct or intent. Such an approach may be regarded as inconsistent with the TRIPs non-discrimination norm in relation to fields of technology. Accordingly, administrative sanctions and the opportunity to rectify defects in the application should be prioritized in order to preserve legal certainty for innovators.

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