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A Socio-Legal Analysis of the Commodification of Indigenous Peoples' Knowledge in the Era of the 'Psychedelic Renaissance'

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Abstract

Western biomedicine is currently witnessing the peak of the second wave of psychedelic science. Due to the re-establishment of system-supported experimentation, increased state and private funding, legislative momentum, and cultural normalisation, this new phenomenon has gained itself a name reflecting its notable comeback – the psychedelic renaissance. But much like the historical Renaissance did not happen in a vacuum, neither does the contemporary one. Although academic and legal debates extensively address clinical trials from the biomedical perspective, they largely neglect the socio-legal consequences that this commercialisation imposes on Indigenous peoples who possess centuries-old wisdom regarding practices involving psychedelic plants. The following study aims to identify the extent to which the commercialisation of psychedelic-assisted therapies exploits the regulatory gaps between international access and benefit-sharing (ABS) frameworks and intellectual property law. Additionally, this thesis examines what the economic, social, and cultural implications of said commercialisation are for Indigenous communities' self-determination. For this purpose, the thesis employs a qualitative, socio-legal lens that combines a doctrinal analysis of legal instruments with a critical evaluation of policy documents and Indigenous position papers. The study concludes that due to the highly imbalanced intellectual property regime and the administration-oriented, passive ABS mechanisms, the economic, social, and cultural self-determination of Indigenous peoples is weakened. The thesis also provides concrete policy proposals regarding the expected decriminalisation of psychedelic substances and the unfolding of the 'psychedelic renaissance'.

Key words: *Indigenous knowledge, Indigenous rights, psychedelic renaissance, intellectual property rights, patent law, access and benefit sharing, biotechnology*

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Table of Abbreviations

ABS	Access and Benefit-Sharing
BfN	*Bundesamt für Naturschutz* (Germany's Federal Agency for Nature Conservation)
CBD	Convention on Biological Diversity
COP	Conference of the Parties (e.g. COP16, COP17)
DSI	Digital Sequence Information
DMT	N,N-dimethyltryptamine (naturally occurring psychedelic compound)
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EPC	European Patent Convention
EPO	European Patent Office
EU ABS	European Union Access and Benefit-Sharing (referring to Regulation 511/2014)
FDA	Food and Drug Administration (US federal agency)
GRATK Treaty	Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge
IP / IPR	Intellectual Property / Intellectual Property Rights
IPLCs	Indigenous Peoples and Local Communities
LSD	Lysergic Acid Diethylamide (synthetic psychedelic drug)
MAT	Mutually Agreed Terms
MDMA	3,4-methylenedioxymethamphetamine (synthetic psychedelic drug)
PIC	Prior Informed Consent
PTSD	Post-Traumatic Stress Disorder
R&D	Research and Development

SSRIs	Selective Serotonin Reuptake Inhibitors
TRIPS	Trade-Related Aspects of Intellectual Property Rights
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

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1. INTRODUCTION

On the 18th of April 2026, a Reuters headline documented a significant shift in contemporary drug policy: 'Trump signs order to accelerate access to psychedelic drug treatments'.[1] This executive order, titled 'Accelerating Medical Treatments for Serious Mental Illness',[2] seeks to fast-track the medicalisation of substances that were once labelled public enemies.[3] The President's declaration that psychedelics are 'not taboo anymore' marks an interesting reversal of the USA's 'War on Drugs' dogma since 1970s.[4] This statement is supported by 50 million dollars of federal funding and the Right to Try Act, which allows terminally ill patients to access treatments that have not officially been approved by the Food and Drug Administration (FDA) yet.[5] Structurally, this political pivot introduces the central human rights dilemma of this thesis: the highest levels of Western political power are now presiding over the rapid commercialisation of the very traditions they spent half a century attempting to suppress.

The growing Western interest towards psychedelics emerges as an urgent response to a worsening mental health crisis. The twenty-first century has witnessed not only an alarming rise in depression and anxiety but also a full-scale crisis of, what George et al. call, 'deaths of despair'.[6] The term refers to 'excess mortality and morbidity from suicide, drug overdose, and alcoholism'.[7] These kind of deaths are estimated to account for 150 thousand fatalities annually in the United States.[8] When distal factors such as the prevalence of handguns and lethal synthetic opioids like fentanyl come into the picture, these statistics form the longest sustained decline of life expectancy (from 2015 to 2017) since the era of the First World War.[9] This crisis also mirrors a broader trend across the Global North: the United

[1] 'Trump Signs Order to Accelerate Access to Psychedelic Drug Treatments' *Reuters* (18 April 2026) <https://www.reuters.com/world/trump-announces-reforms-accelerate-access-psychedelic-drug-treatments-2026-04-18/> accessed 24 April 2026.
[2] Exec Order No 14192, 'Accelerating Medical Treatments for Serious Mental Illness' <https://www.whitehouse.gov/presidential-actions/2026/04/accelerating-medical-treatments-for-serious-mental-illness/> accessed 29 April 2026.
[3] Cindy Brooks Dollar, 'Considerations on the Construction, Timing, and Consequences of the Psychedelic Renaissance' (2025) 53 Contemporary Drug Problems 1 <https://doi.org/10.1177/00914509251344637> accessed 16 March 2026.
[4] 'Trump Signs Order to Accelerate Access to Psychedelic Drug Treatments' (n 1).
[5] Exec Order No 14192 (n 2).
[6] Daniel R George and others, 'Ancient Roots of Today's Emerging Renaissance in Psychedelic Medicine' (2022) 46 Culture, Medicine, and Psychiatry 890, 892 <https://doi.org/10.1007/s11013-021-09749-y> accessed 10 April 2026.
[7] ibid.
[8] George and others (n 6).
[9] ibid.

Kingdom, Canada, and Australia have all reported comparable shifts in mental health morbidity.[10] In the EU, more than one in six is affected by mental health conditions.[11]

In response to these alarming statistics, different governing bodies have approved clinical trials on a number of psychoactive substances. This is not the West's first encounter with these compounds. During the first psychedelic wave, substances like lysergic acid diethylamide (LSD) were widely studied in Western psychiatry.[12] However, the subsequent moral panic and global 'war on drugs' criminalised psychedelic substances and halted clinical research.[13] Today, this suppressed field is experiencing an institutional revival. Approved trials now include 3,4-methylenedioxymethamphetamine (MDMA), ketamine, LSD, psilocybin, and N,N-dimethyltryptamine (DMT), the latter two of which have strong links to ancient indigenous traditions.[14] Numerous frameworks have tried to explain the healing potential of psychedelics: psychodynamic theories suggest hallucinogens weaken ego boundaries to access the unconscious, while cognitive-behavioural models argue they facilitate the emotional engagement necessary for effective exposure therapy.[15] Patient reports often mirror these views, describing the acceleration of emotional processing in psychedelic-assisted therapy.[16] Empirical evidence similarly supports these claims: a landmark study by Gukasyan et al. in 2022 demonstrated that psilocybin-assisted therapy could relieve major depressive symptoms for up to a year.[17] Similarly, research into MDMA-assisted psychotherapy found that 83% of participants with treatment-resistant post-traumatic stress disorder (PTSD) who received the therapy no longer met clinical criteria for the disorder, with positive outcomes remaining stable for at least 3.5 years.[18] In addition to depression and PTSD, clinical studies have also been done to investigate the

[10] ibid.
[11] European Parliament, 'Mental Health in the EU' <https://www.europarl.europa.eu/RegData/etudes/BRIE/2023/751416/EPRS_BRI(2023)751416_EN.pdf> accessed 25 April 2026.
[12] Dollar (n 3).
[13] ibid.
[14] George and others (n 6).
[15] Jamilah R George and others, 'The Psychedelic Renaissance and the Limitations of a White-Dominant Medical Framework: A Call for Indigenous and Ethnic Minority Inclusion' (2019) 4 Journal of Psychedelic Studies 4 <https://doi.org/10.1556/2054.2019.015> accessed 24 March 2026.
[16] ibid.
[17] Natalie Gukasyan and others, 'Efficacy and Safety of Psilocybin-Assisted Treatment for Major Depressive Disorder: Prospective 12-Month Follow-Up' (2022) 36 Journal of Psychopharmacology 151 <https://doi.org/10.1177/02698811211073759> accessed 24 March 2026.
[18] Erwin Krediet and others, 'Reviewing the Potential of Psychedelics for the Treatment of PTSD' (2020) 23 International Journal of Neuropsychopharmacology 385 <https://doi.org/10.1093/ijnp/pyaa018> accessed 24 March 2026.

effectiveness for treating anxiety disorders, obsessive compulsive disorder, cluster headaches, and substance use disorder.[19]

In addition to clinical interests, the capitalist market plays a vital role in rebranding psychedelics and accelerating their legal path. Truly, the financial potential is significant: the legal psychedelic market is estimated to grow by 15% annually, reaching a value of 12.89 billion USD by 2035.[20] By 2027, the psychedelic market is even expected to surpass the size of the legal cannabis market in the US.[21] This trend is directly tied to the decriminalisation of psychedelics. Following the precedent set by cannabis legalisation, most states are expected to enact psychedelic reform legislation earliest in 2033 and latest by 2037.[22] Europe is walking a similar path to the United States. In 2025, Germany joined Switzerland and Canada in allowing the 'compassionate use' of psilocybin, becoming the first country in the European Union to permit treatment for 'life-threatening, long-lasting or seriously debilitating illnesses, which cannot be treated satisfactorily with any currently authorised medicine'.[23]

This renewed Western interest has been widely characterised by the mass media as a 'psychedelic renaissance'.[24] While the term itself implies a scientific rebirth of the mid-century research, it is perhaps more accurately defined by four converging pillars that push these substances from the underground back into the institutional mainstream:

1. Clinical legitimacy: The re-establishment of system-supported experimentation has enabled 'breakthrough therapies' and provided the scientific credibility that is necessary to dismantle decades of stigma.[25]
2. Commercialisation: This clinical legitimacy is increasingly harnessed to attract state and private funding, as well as venture capital. These investments fuel the development of patented

[19] Dollar (n 3) 5.
[20] Roots Analysis: Business Research and Consulting, 'Global Psychedelic Drugs Market Size & Share Report [2035]' (April 2026) <https://www.rootsanalysis.com/reports/global-psychedelic-therapeutics-market.html> accessed 25 April 2026.
[21] Leora Karoll, 'The Psychedelic Surge and Its Threats to Native American Communities' (2024) 11 Brandeis University Law Journal 167 <https://journals.library.brandeis.edu/index.php/blj/article/view/2305> accessed 24 March 2026.
[22] Joshua S Siegel and others, 'Psychedelic Drug Legislative Reform and Legalization in the US' (2023) 80 JAMA Psychiatry 77 <https://doi.org/10.1001/jamapsychiatry.2022.4101> accessed 24 March 2026.
[23] European Medicines Agency (EMA), 'Compassionate Use' <https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compassionate-use> accessed 5 July 2026; 'Germany Establishes EU's First Psilocybin Compassionate Access Program' (*Psychedelic Alpha*, 31 July 2025) <https://psychedelicalpha.com/news/germany-establishes-eus-first-psilocybin-compassionate-access-program/> accessed 5 July 2026.
[24] Dollar (n 3) 1.
[25] ibid.

treatments and branded pharmaceutical products, which guide therapeutic potential towards the stock market.[26]

3. Legislative momentum: The simultaneous gradual easing of previous restrictions has created a regulatory opening for both medical and commercial expansion.[27]
4. Cultural normalisation: Beyond institutional factors, the 'renaissance' also reflects a shift in public opinion, which can be seen in the rise of recreational use,[28] the growth of 'retreat tourism',[29] and consistently positive media portrayals.[30]

This 'new period of acceptance', as Karoll labels it, illustrates an interesting alignment between government policy, medical science, and public opinion in favour of legalising psychedelics.[31]

Crucially, it is widely argued that what is now branded as a 'renaissance' is less of an achievement of Western science and more a Western 'discovery' of ancient wisdom.[32] Psychedelic use has flourished for centuries within traditional and Indigenous societies, where it remains a cornerstone of ritual healing.[33] These spiritual quests involve the sacramental use of plants like psilocybin, peyote, and ayahuasca (containing DMT).[34] Therefore, rather than being an isolated scientific advancement, the current renaissance represents a collision between Western interests and ancient Indigenous knowledge.

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[26] Karoll (n 21); Dollar (n 3).
[27] Dollar (n 3).
[28] T Le Forsonney and others, 'Guidance for Coalitions Informing the Standardisation and Implementation of Psychedelic Therapies in Europe' <https://palliativeprojects.eu/psypal/wp-content/uploads/sites/12/2026/03/PsyPal-Guidance-Paper-V5-2026-03-26-Copyright-Consortium.pdf> accessed 29 April 2026.
[29] Juan Scuro, 'God Hasn't Died, It Has Merely Been Encapsulated – Psilocybin and Ayahuasca in the Psychedelic Renaissance: Intersections between Religion, Indigenous Cosmologies, Spirituality, and Science' (2024) 71 Social Compass 707 <https://doi.org/10.1177/00377686241301923> accessed 22 March 2026.
[30] David A Bender and others, 'Trends in the Psychedelic Renaissance: Applying Artificial Intelligence to Measure Media Portrayal of Psychedelic Drugs in the 21st Century' (2026) 12 BJPsych Open e63 <https://doi.org/10.1192/bjo.2025.10974> accessed 31 March 2026; Dollar (n 3).
[31] Karoll (n 21) 169.
[32] Keith Williams and others, 'Indigenous Philosophies and the "Psychedelic Renaissance"' (2022) 33 Anthropology of Consciousness 506 <https://doi.org/10.1111/anoc.12161> accessed 7 October 2025; Karoll (n 21); Emilia Sanabria, 'Science's "Savage Slot": The Appropriation and Erasure of Indigenous Science in the Psychedelic Renaissance' (2025) 2 Psychedelics 100003 <https://doi.org/10.1016/j.psyche.2025.100003> accessed 16 March 2026; Andrea Ens, 'Silencing Indigenous Pasts: Critical Indigenous Theory and the History of Psychedelics' (2021) 34 International Journal of Qualitative Studies in Education 904 <https://doi.org/10.1080/09518398.2021.1942297> accessed 23 March 2026; Evgenia Fotiou, 'The Role of Indigenous Knowledges in Psychedelic Science' (2019) 4 Journal of Psychedelic Studies 16 <https://doi.org/10.1556/2054.2019.031> accessed 17 March 2026; Dollar (n 3).
[33] Dollar (n 3).
[34] ibid.

1.1. Relevance of the thesis

There is a notable power imbalance in the legal structures meant to protect Indigenous knowledge and generate fair benefit sharing. The West's reliance on Indigenous knowledge is illustratable through the following example: as early as 2001, a report supported by the World Health Organization Traditional Medicine Program (WHO TRM) determined that 80% of the 122 drug compounds used in Western medicine were employed for the same or related purposes as their original traditional medicine use.[35] This suggests that the 'renaissance' is not just discovering brand-new pathways but significantly owes to ancestral expertise. Despite this reliance, Indigenous traditional medicine remains unprotected by law. As of 2022, only the constitutions of Bolivia (art. 42) and Ecuador (art. 57) include regulations specifically safeguarding Indigenous traditional medicine.[36] Even within these pioneering frameworks, there is a lack of language addressing the rapid commodification and commercialisation of these practices as they transition into Western psychedelic sectors.[37]

From the Indigenous perspective, this is not only about economic fairness, but also about cultural survival. The preservation of both tangible material property and intangible assets, such as ceremonies, traditions, and intellectual property, is fundamental for the transmission of cultural identity.[38] Because the economic value of the psychedelic market is heavily dependent on legalisation across several jurisdictions, it is critical to engage with this rapidly evolving biomedicinal field where emerging ethical and legal standards can still be shaped. This thesis conducts a cross-analysis of competing legal frameworks: the intellectual property patent regime, the access and benefit-sharing (ABS) mechanism for equitable distribution, and the most recent WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge ('GRATK Treaty') which tries to combine the IP law with the transparency goals of the ABS regime. By examining these frameworks alongside the newly proposed EU Biotech Act and Pharma Package, this study aims to map out the contemporary regulatory landscape balancing between traditional IP structures with indigenous knowledge systems.

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[35] DS Fabricant and NR Farnsworth, 'The Value of Plants Used in Traditional Medicine for Drug Discovery.' (2001) 109 Environmental Health Perspectives 69 <https://doi.org/10.1289/ehp.01109s169> accessed 25 April 2026.
[36] Constitution of the Republic of Ecuador 2008; Bolivia (Plurinational State of) 2009 Constitution.
[37] Yuria Celidwen and others, 'Ethical Principles of Traditional Indigenous Medicine to Guide Western Psychedelic Research and Practice' (2023) 18 The Lancet Regional Health - Americas 100410 <https://doi.org/10.1016/j.lana.2022.100410> accessed 17 March 2026.
[38] ibid.

1.2. Purpose and scope of the thesis: Research question & sub-questions

Research question 1: To what extent does the commercialisation of psychedelics and/or psychedelic-assisted therapies exploit the regulatory gaps between international ABS frameworks (Nagoya / EU 511/2014) and European Patent Law (EPC)?

Sub-questions:

- How do the patentability criteria under the European Patent Convention (EPC) interface with traditional knowledge regarding psychedelic plants?
- How does the EPC's definiton of prior art exclude orally transmitted Indigenous knowledge?
- Why do synthetic derivatives, like synthetic psilocybin, fall outside the EU ABS Regulation?
- How do the newest WIPO GRATK Treaty and EU Biotech Act change the protection of traditional knowledge?

Research question 2: What are the economic and cultural implications of said commercialisation to Indigenous communities' self-determination?

Sub-questions:

- What alternative regulatory models or policy reforms could reconcile intellectual property enforcement with the principles of distributive justice and benefit-sharing?

1.3. Methodology

This thesis employs a qualitative, socio-legal methodology that combines a doctrinal analysis of legal instruments with a critical evaluation of policy documents and Indigenous position papers. The choice of a socio-legal approach ensures that key regulations are not only evaluated textually, but analysed and synthesised to identify structural regulatory gaps, as well as the broader cultural and ethical implications of commodification. The study relies on desk research, incorporating academic literature, legal frameworks, and grey literature. The literature review in Chapter 2 establishes the conceptual

framework by elevating Indigenous voices, epistemologies, and critiques of capitalist commodification. This conceptual foundation then serves as the analytical lens through which the primary legal instruments outlined in Chapter 3 (such as the EPC, EU Regulations, and the WIPO 2024 GRATK Treaty) are critically evaluated. This socio-legal approach connects legal analysis with cultural context to expose regulatory gaps and address the human rights dilemmas in the psychedelic renaissance

The data collection focused primarily on peer-reviewed academic literature published within the past ten years. Some sources may have an older publication date due to being seminal works, news articles demonstrating media trends, or articles explaining Indigenous cosmologies. Languages included English, Spanish, and German. Primary searches were conducted via Google Scholar using targeted keywords, including ‘psychedelic renaissance’, ‘indigenous knowledge’, ‘intellectual property rights’, ‘patent law’, ‘biopiracy’, ‘commodification’, and ‘sui generis’. This baseline was complemented by snowball sampling, where relevant citations from the retrieved literature were manually traced. Additionally, specialised legal literature and commentary addressing German law were retrieved via the Beck-online database. Some foundational texts were also included at the thesis supervisor’s recommendation.

Geographically, the analytical focus centres on Europe and the European Union. Europe’s strong commitment to fundamental rights makes it an ideal focal point. Having already established global benchmarks in fields like data privacy, Europe provides an ideal environment for pioneering new mechanisms in intellectual property and benefit-sharing, as well. Through the mechanism of the Brussels effect, the high standards developed within the EU have the potential to shape regulatory frameworks globally. The selected legal instruments establish the analytical baseline for the thesis and illustrate the legal evolution over the past decade: the European Patent Convention (EPC) is utilised to establish the core framework for intellectual property rights (IPR) in Europe, under the global mandate of the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereafter ‘TRIPS’). Access and benefit-sharing (ABS) dynamics are evaluated through the Nagoya Protocol, as implemented and enforced by EU Regulation 511/2014. The thesis focuses particularly on the enforcement in Germany due to its leading pharmaceutical industry. Furthermore, EU Regulation 2015/2283 on Novel Foods is incorporated to briefly discuss the other avenues for the regulation of psychedelic-containing products in the Union. Finally, the study analyses the most recent global milestones: the WIPO 2024 GRATK Treaty, EU Pharma Reform 2026, and the proposed EU Biotech Act 2025.

The main text was reviewed by an AI tool, Gemini 3.5 Flash. This was done to get feedback on textual outputs, and the prompt often used was 'In what ways could I enhance the delivery of this text to ensure clarity and fluency?' All answers have been manually reviewed. Parts of the suggestions have been included in the final text, while some were disregarded. The author takes responsibility for all outputs of the used tool. All core arguments, research, and analysis remain entirely the author's own.

1.4. Structure

Following the introduction, the thesis is divided into three main parts: literature review, doctrinal analysis, and discussion. The literature review is further divided into two main chapters, the first of which explores the evolution of the intellectual property regime in the West and the second explores the onto-epistemological tensions between the Western and Indigenous knowledge systems.

The second main part, doctrinal analysis, walks through the main IP framework in Europe (the European Patent Convention), the main access and benefit sharing framework (Regulation 511/2014) and other relevant frameworks (Regulation 2015/2283, Pharma Package 2026, Biotech Act 2025) within the EU, as well as the most relevant recent development (GRATK Treaty).

The doctrinal analysis is followed by a discussion which is divided into three main sub-chapters: first, it synthesises the legal frameworks analysed in the previous chapter and identifies the most crucial regulatory gaps; second, it outlines the main implications of these gaps for Indigenous peoples' right to self-determination; and last, offers four concrete policy proposals.

The thesis concludes with a final 'conclusions' chapter.

2. LITERATURE REVIEW

The term 'psychedelic' encompasses an array of substances with different origins. It includes psychoactive plants embedded in Indigenous sacred traditions, such as DMT in Amazonian ayahuasca, mescaline in North American peyote and psilocybin mushrooms used in Mesoamerica.[39] Later, the Western psychedelic science movement expanded this definition to include synthetic compounds, such as LSD and MDMA. These hallucinogenic substances carry a very distinct historical path between Indigenous millennia-long use of psychoactive plants and a Western discovery-oriented catalyst much later in the 1950s.[40] This literature review outlines the often clashing, scientific systems between the Western standardised science and Indigenous communal, context-specific knowledge. To do so, the review is divided into two sub-chapter which, first, review the legal and capitalist developments of the intellectual property regime in the West, and second, contrasts this with Indigenous position papers to illustrate the deep onto-epistemological clashes and the secularisation of Indigenous sacred practices.

2.1. The Evolution of Intellectual Property Regime in the West

This subchapter walks through the developments of the Western psychedelic scene, drawing particular attention to the early discoveries of psychedelic plants and the concept of biopiracy, then, to the legal evolution of IP law allowing the privatisation of such substances, and lastly, to the capitalist expansion of the newly created market niche.

2.1.1. Patterns of biopiracy in the first wave of psychedelics

Until the early 20th century, the Global North[41] had minimal, if any, access to psychoactive substances due to a combination of physical distance and colonial socio-political framing, which cast these substances as dangerous and socially destabilising.[42] This regulatory exclusion created a vacuum of

[39] Williams and others (n 32).
[40] Scuro (n 29).
[41] Nour Dados and Raewyn Connell, 'The Global South' (2012) 11 Contexts 12 <https://doi.org/10.1177/1536504212436479> accessed 3 July 2026. Aligning with the definition provided in the article, this thesis treats the concepts of 'Global South' and 'Global North' as 'geopolitical power relations', referring to the structural socio-economic and political divide between the regions. The Global North comprises historically privileged, industrialised countries in North America, Europe, parts of East Asia and Oceania. The Global South, in contrast, comprises developing nations in Latin America, Africa and parts of Asia.
[42] Dollar (n 3).

knowledge in the West, which was only filled when ethnobotanical expeditions began to explore and extract these biological resources in the mid-20th century. The portrayal of white scientists 'discovering' mind-altering plants tended to emphasise the legacy of people like Wall Street banker Gordon Wasson while erasing the transfer of knowledge from Indigenous communities.[43] In a pivotal yet controversial encounter, Wasson was introduced to the sacred *velada*, a healing ritual involving psilocybin-containing mushrooms, by the Mazatec *sabia* (wise woman) Maria Sabina in the village of Huautla de Jiménez. Despite the confidential nature of the ceremony, Wasson ignored Sabina's wishes and published a detailed report of his experience in the Life Magazine in 1957.[44] By revealing both her name and the village's location, he triggered an unprecedented influx of spiritual seekers and scholars into the secluded community.[45] This exposure had severe consequences: Maria Sabina was harassed by local authorities, her home was burned down, and she was eventually ostracised by her community for betraying their traditional secrets.[46] While Sabina died in extreme poverty – an ironic contrast to the massive capital currently raised by Western firms based on her community's knowledge – her sacrifice provided the scientific breaking point for Western science.[47] That is, shortly after Wasson's article was published, Albert Hofmann successfully synthesised psilocybin, making the entry of Indigenous medicine into Western clinical research irreversible.[48]

This irreversible entry and the subsequent extraction of knowledge operate within heavily imbalanced dynamics between the Global North and South: The concept of 'biopiracy' – defined by Vandana Shiva as 'the use of intellectual property systems to legitimise the exclusive ownership and control over biological resources and biological products and processes that have been used over centuries in non-industrialised cultures'[49] – did not keep law and policy makers up at night. Instead, the West relied on

[43] Keith Williams and others, 'Indigenous Philosophies and the "Psychedelic Renaissance"' (2022) 33 Anthropology of Consciousness 506 <https://doi.org/10.1111/anoc.12161> accessed 17 March 2026.
[44] ibid.
[45] ibid.
[46] ibid.
[47] ibid.
[48] Scuro (n 29).
[49] Vandana Shiva, *Protect or Plunder? Understanding Intellectual Property Rights* (Zed Books ; University Press ; White Lotus Co ; Fernwood Pub ; D Philip : Distributed in the USA exclusively by Palgrave 2001) 49 <https://syllabus.pirate.care/library/Vandana%20Shiva/Protect%20or%20Plunder__%20Understanding%20Intellectual%20Property%20Rights%20(630)/Protect%20or%20Plunder__%20Understanding%20Intelle%20-%20Vandana%20Shiva.pdf> accessed 11 June 2026.

the concept of 'common heritage of mankind' over biological resources.[50] According to Morgera et al., this legal concept resulted in an 'almost free flow of genetic resources across boundaries' during times that lacked any logic of benefit-sharing or mutually agreed terms.[51] Consequently, these examples of 'discovery' of psychedelics by Western scientists visiting Indigenous communities also gave legitimacy and credibility to white scientists – for example, Wasson, who is considered by many the 'father of ethnomycology'.[52] Meanwhile, the Indigenous expertise that provided the groundwork for their discoveries was ignored.[53]

These new discoveries of mind-altering substances eventually collided with a shifting Western political landscape. Despite the aura of clinical progress surrounding Hofmann's 1943 other famous synthesis, his 'problem child' LSD,[54] the first wave of psychedelic research operated through poor methodological standards and unethical research practices.[55] By the mid-1960s, a media-driven panic began framing hallucinogens as threats to personal and economic stability.[56] For instance, in 1966, the Life Magazine published a landmark cover story titled 'LSD: The Exploding Threat of the Mind Drug that Got out of Control'.[57] Eventually this 'textbook moral panic'[58] led to the criminalisation of psychedelics as Schedule I drugs (1971 Controlled Substance Act) which classified them as substances of high potential for abuse and no medical value.[59] This development followed the global trend set by the United Nations' Convention on Psychotropic Substances.[60]

Following this legal ban, several decades passed in relative silence, which eventually unfolded into the second wave of psychedelic science. Unlike the first wave, which was characterised by discoveries – or

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[50] Elisa Morgera, Elsa Tsioumani and Matthias Buck, *Unraveling the Nagoya Protocol: A Commentary on the Nagoya Protocol on Access and Benefit-Sharing to the Convention on Biological Diversity*, vol 2 (Brill | Nijhoff 2014) 6 <https://doi.org/10.1163/9789004217188> accessed 30 April 2026.
[51] ibid.
[52] George and others (n 15) 10.
[53] Ens (n 32).
[54] Albert Hofmann, *LSD, My Problem Child* (McGraw-Hill 1980).
[55] Dollar (n 3).
[56] ibid 3.
[57] Life Magazine, 'LSD: The Exploding Threat of the Mind Drug that Got out of Control' (1966) 60 <https://www.trippingly.net/lsd-studies/life-magazine-march-25-1966> accessed 30 March 2026.
[58] Stephen Siff, *Acid Hype: American News Media and the Psychedelic Experience* (University of Illinois press 2015) para abstract <https://www.jstor.org/stable/10.5406/j.ctt14jxvrz> accessed 12 March 2026.
[59] Dollar (n 3) 3.
[60] Convention on Psychotropic Substances 1971 (1019 UNTS 175).

better, a number of biopiracy cases – the second wave has been establishing the legal prerequisites for the transformation of sacred traditions into industrial, private property.

2.1.2. TRIPS agreement at the dawn of the 'psychedelic renaissance'

The transition from the legal prohibition of the 1970s to the modern 'psychedelic renaissance' was facilitated by a global homogenisation of intellectual property standards. In 1994, the WTO's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) fundamentally altered the legal landscape by requiring all member states – currently 166 members representing approximately 85% of sovereign states – to provide patent protection for inventions 'in all fields of technology', including biotechnology.[61] In more detail, although article 27.3(b) excluded plants and animals from patentability, it mandated protection for micro-organisms and non-biological processes.[62] This created a structural opening for the surging psychedelic renaissance, which made capital investment less risky by allowing pharmaceutical companies to claim 'novelty', 'inventive step' (i.e. non-obvious), and 'industrial applicability' (i.e. useful) – as required by article 27.1 – by synthesising or altering specific molecules and patenting them as new innovations.[63] By imposing a global 'floor' for IP protection, the WTO practically forced developing nations to adapt to Western standards that were fundamentally contradictory and unbeneficial to their own collective knowledge systems.[64] In practice this meant paying monopoly prices for medicines that were derived from their own resources and cultural heritage.[65] This structural exclusion is reinforced by the fact that the patent system only recognises an individual or corporate inventor, rather than the collective ownership of knowledge (article 29(1), TRIPS).[66] The contemporary patent distribution similarly reflects these conditions. For instance, WIPO

[61] 'Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)' art 27.1 <https://www.wto.org/english/docs_e/legal_e/27-trips.pdf> accessed 6 May 2026.
[62] ibid 27.3(b).
[63] Chidi Oguamanam, 'The WIPO Treaty on Genetic Resources and Associated Traditional Knowledge: A Negotiating, Contextual and Conceptual Appraisal' [2025] International Law Journal <https://www.bu.edu/ilj/files/2025/09/Oguamanam-Final-Formatted-43.2.pdf> accessed 28 April 2026.
[64] ibid.
[65] Keith E Maskus, 'Globalization and the Economics of Intellectual Property Rights: Dancing the Dual Distortion' *Intellectual Property Rights in the Global Economy* (Institute for International Economics 2000) <https://www.piie.com/publications/chapters_preview/99/3iie2822.pdf> accessed 5 June 2026.
[66] TRIPS art 29(1).

data from 2024 reveals that the combined share of patent applications for Africa, Latin America, and Oceania was just 3%, whereas Northern America, Europe, and Asia held the remaining 97%.[67]

This imbalanced legal regime showcased its true colours during the HIV and AIDS pandemic in the 1990s, particularly affecting Sub-Saharan Africa. TRIPS article 31(b) allows some leeway to its patent laws 'in situations of national emergency or other circumstances of extreme urgency'.[68] TRIPS was, therefore, face to face with its first ethical dilemma: prioritising human health over corporate profit. The treaty's flexibility provisions failed in practice: In 1998, the Pharmaceutical Manufacturers' Association of South Africa and 40 international drug companies sued the South African government, arguing that the legislative amendments that allowed parallel medicine imports and bypassed standard protection to secure affordable HIV/AIDS medication violated their TRIPS-mandated patent rights.[69] Even though the coalition of international drug companies eventually had to withdraw the case due to public backlash, this case of pharmaceutical industry giants suing a state attempting to stop a full-scale pandemic 'shocked the world's conscience'.[70] The case illustrated the treaty's inflexibility, or rather, unwillingness to consider public health over corporate profit, due to Western political pressure at the time.

This political pressure was, as Oguamanam observes, largely driven by powerful pharmaceutical companies focused on building a legal wall around expensive brand-name drugs to keep out cheap, generic versions.[71] Consequently, the US sought to 'rein in' developing nations and Indigenous Peoples and Local Communities (IPLCs), accusing them of 'free riding' on the intellectual labour of Western corporations.[72] However, OseiTutu counters this narrative, arguing that TRIPS' protectionist architecture has allowed 'intellectual property generating countries [to benefit] far more

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[67] World Intellectual Property Organization, 'World Intellectual Property Indicators 2025: Highlights - Patents Highlights' (2025) <https://www.wipo.int/web-publications/world-intellectual-property-indicators-2025-highlights/en/patents-highlights.html> accessed 29 April 2026.
[68] TRIPS art 31(b).
[69] Emily L Saslow, 'Compulsory Licensing and the AIDS Epidemic in South Africa' (1999) 13 AIDS Patient Care and STDs 577 <https://doi.org/10.1089/apc.1999.13.577> accessed 16 June 2026; *Pharmaceutical Manufacturers' Association of South Africa v President of the Republic of South Africa (Notice of Motion)* [1998] High Court of South Africa (Transvaal Provincial Division) Case No 4183/98.
[70] Ellen 'T Hoen and others, 'Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All' (2011) 14 Journal of the International AIDS Society 15, para 20 <https://doi.org/10.1186/1758-2652-14-15> accessed 3 July 2026.
[71] Oguamanam (n 63).
[72] ibid 328.

than developing countries'.[73] The clearest example of this hypocrisy is the fact that using Indigenous medicinal plants increases the success rate of drug development by over 70%.[74] This saves years of laboratory time and hundreds of millions in research and development (R&D) costs.[75] Consequently, the world market for medicinal plants discovered by Indigenous communities is valued at up to 43 billion USD.[76] In reality, the well-deserved sharing of benefits does not, however, materialise most of the time. An illustration of this is the jeevani or arogya pacha case. For generations, the Kani tribe of Kerala used the jeevani plant to combat fatigue and stress.[77] This lead the Tropical Botanical Garden and Research Institute develop a drug that is now being sold for 1 billion USD. Kani community received only 12 thousand USD.[78] Therefore, if 'free-riding' refers to benefitting from someone's knowledge or skills without adequately acknowledging it, it can be argued that the primary beneficiaries of this imbalance are Western pharmaceutical firms that use Indigenous leads to bypass the high costs and risks of random plant screening.

The underlying design of TRIPS reflects Western objectives to disregard traditional knowledge[79] and push it into the 'public domain' – practically, anything that cannot be protected with IP rights – where it is free for all to use. Shiva discusses this phenomenon and links the concept of 'terra nullius' to the concept of 'creations of the mind': because traditional knowledge remains mostly absent from Western written documents, the modern IP system treats this information as 'empty' and therefore, patentable for private ownership – just as Indigenous land was deemed 'empty' to justify its seizure. The link between land and Indigenous knowledge is evident when looking into the distribution of 'megadiverse' nations (see figure 1) that collectively host over 70% of the world's biological diversity, mostly in the Global South. This concentration of biological resources puts these countries at the centre of global debates over biopiracy and intellectual property enclosure.[80] Firstly, while the Global South is rich in

[73] J Janewa OseiTutu, 'A Sui Generis Regime for Traditional Knowledge: The Cultural Divide in Intellectual Property Law' (2010) 15 Marquette Intellectual Property Law Review <https://ssrn.com/abstract=1574996> accessed 28 April 2026.
[74] Oguamanam (n 63).
[75] Karoll (n 21).
[76] ibid.
[77] Vandana Shiva, 'Bioprospecting as Sophisticated Biopiracy' (2007) 32 Signs: Journal of Women in Culture and Society 307 <https://doi.org/10.1086/508502> accessed 27 April 2026.
[78] ibid.
[79] WIPO defines Traditional Knowledge as 'knowledge, know-how, skills and practices that are developed, sustained and passed on from generation to generation within a community, often forming part of its cultural or spiritual identity', 'Traditional Knowledge' (*WIPO*) para 1 <https://www.wipo.int/en/web/traditional-knowledge/tk/index> accessed 11 June 2026.
[80] Morgera, Tsioumani and Buck (n 50).

resources, it often remains technologically poor, lacking the infrastructure to research or commercialise its own biological assets.[81] There is also disparity in specialised legal expertise. Resource-rich nations frequently lack the bargaining power to secure equitable ABS agreements and reclaim profits from their own genetic material.[82] In short, while the Global South provides the raw material, the Global North utilises its technological dominance to claim 'innovations' and secure IPRs. Consequently, a biodiverse nation may find itself paying royalties to buy back an 'improved' version of its own native resources.[83]

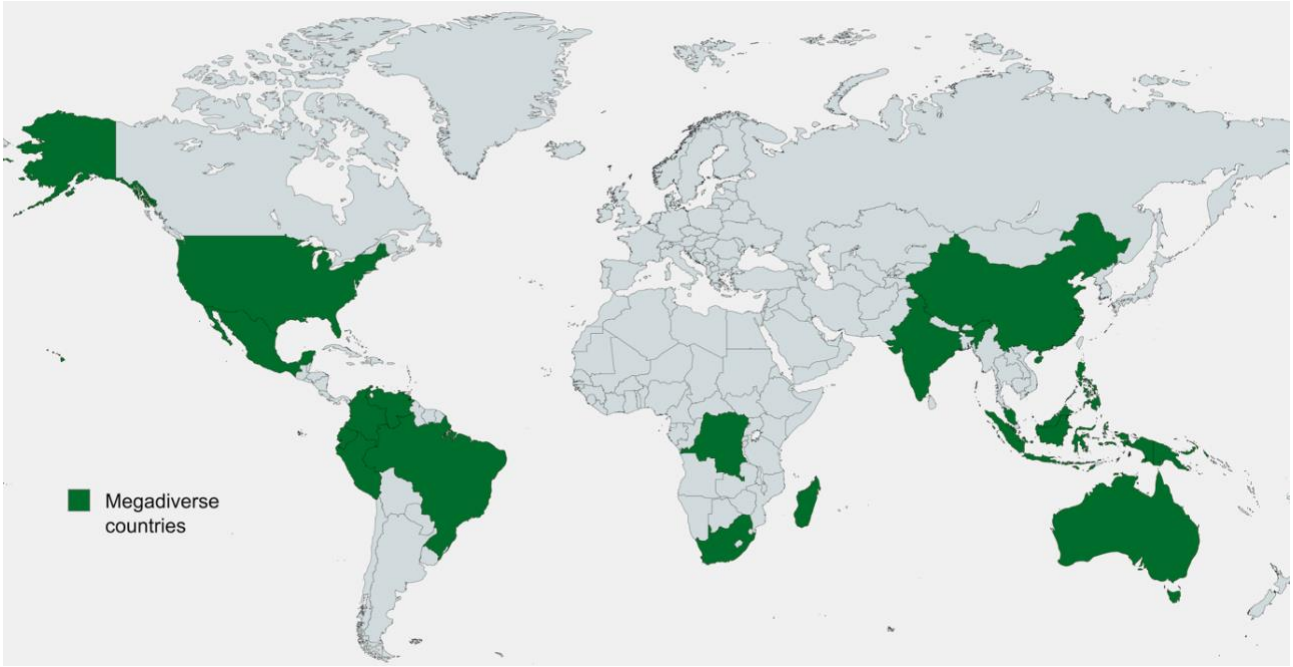

Figure 1: the distribution of megadiverse countries (created with mapchart.net)

A landmark instance of this struggle involved the Amazonian vine *Banisteriopsis caapi*, which is a primary psychoactive ingredient in ayahuasca.[84] In a classic case of biopiracy, American citizen Loren Miller obtained a US plant patent for a new variety of the *Banisteriopsis caapi* (ayahuasca) vine, which he named 'Da Vine'.[85] Although Indigenous organisations from the Amazon Basin successfully

[81] ibid.
[82] ibid.
[83] Maskus (n 65).
[84] Scuro (n 29).
[85] Shiva (n 77).

challenged and overturned the patent in 1999, the case underscored the burden of proof placed on Indigenous communities to defend their ancestral knowledge against claims of 'novelty'.[86] This legal fragility pushed for the creation of the Like-minded Mega-diverse Countries (LMMC), which seeks to institutionalise protections within international frameworks like the Nagoya Protocol on the use of genetic resources and benefit sharing.[87]

To conclude, claims of novel scientific discoveries, enabled by advanced technologies and IP protection favouring the West, distance the second wave of Western psychedelic science from the Indigenous mysticism that has long provided valuable insights into psychoactive plants and healing traditions for Western researchers.[88] Biopiracy does not happen through individual thefts anymore, but through unbalanced IP law regime, which allowed the 'psychedelic renaissance' to develop into a pharmaceutical race. This race is driven by science as much as it is by profit. As pharmaceutical companies lose money in other markets (i.e. opioids; elaboration in the next chapter), they are turning to alternative sources of medicine as their next major source of revenue.

2.1.3. 'The almighty dollar': Capitalist expansion

The resurfaced interest in psychedelics in the West is deeply intertwined with economic incentives.[89] As the Western pharmaceutical companies started to consolidate their patent rights through newly established IP rights, the collapse of the opioid market in the 2010s gave them the final catalyst to fill the void and push for new pathways to make financial gains. The current opioid crisis in the US started from the increase in opioid prescriptions that were deemed non-addictive with little risk in the 1990s and 2000s.[90] Opioids, however, had a high potential for abuse, which triggered widespread addiction and a rapid rise in overdose deaths. Between 1999 and 2023, the number of opioid-related overdose deaths increased nearly tenfold.[91] In 2023, out of approximately 105 thousand people who died from a drug overdose, nearly 80 thousand deaths involved opioids (approximately 76%).[92] This epidemic

[86] ibid.
[87] Morgera, Tsioumani and Buck (n 50).
[88] Dollar (n 3).
[89] ibid.
[90] ibid 11.
[91] Matthew Garnett and others, 'Drug Overdose Deaths in the United States, 2003–2023' (National Center for Health Statistics (US) 2024) <https://doi.org/10.15620/cdc/170565> accessed 13 April 2026.
[92] ibid.

caused the government to impose stricter controls on opioid prescriptions, leading pharmaceutical companies to lose major revenues.[93] The second wave of psychedelics in the West falls 'on the heels of the national opioid epidemic'.[94]

Dollar's contribution draws from theories of Marx and Du Bois to illustrate why capitalist perspectives in the context of psychedelics are noteworthy. As Marx's famously theorises, in a capitalist society, the driving factor is profit, even over human well-being.[95] This profit-driven logic would explain why, as Dollar notes, the US tends to shift classification of different substances based on the fluctuating economic needs or government agendas.[96] Consequently, the primary beneficiaries of the contemporary psychedelic research are not necessarily the patients, but rather pharmaceutical companies, healthcare industries, retreat centres, the state, and the broader economic market.[97] To put the incentive into perspective, the market for products built on the back of traditional knowledge generates between 500 billion and 800 billion USD every year.[98] That said, of course when looking into workforce productivity, the primary beneficiaries could also be patients – not for humanitarian reasons, but to maintain a productive, efficient workforce that is not suffering from mentally paralysing disorders and can, thus, contribute to the economy.[99] Du Bois, on the other hand, identified US capitalism as a political economic system that consolidates private economic resources with state power.[100] Together these classical theories may provide an explanation for why the medicalisation and partial legalisation of psychedelics is a sign of capitalist endeavours and corporate-state interest: Marx's theory provides the motive for capitalising on a crisis (i.e. Opioid crisis in the US) and Du Bois explains how this happens through state-sanctioned exclusion. To elaborate on the latter, Dollar identifies that there is a 'medicalisation-criminalisation divide' which, on one hand, grants legitimacy and protection to

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[93] Dollar (n 3) 11.
[94] ibid 9.
[95] Karl Marx, *Capital: A Critique of Political Economy*, vol 1 (Progress Publishers 1887) <https://www.marxists.org/archive/marx/works/download/pdf/Capital-Volume-I.pdf> accessed 16 March 2026; Dollar (n 3).
[96] Dollar (n 3).
[97] Scuro (n 29); Dollar (n 3).
[98] Palpu Pushpangadan and others, 'Biodiversity, Bioprospecting, Traditional Knowledge, Sustainable Development and Value Added Products: A Review' (2018) 07 Journal of Traditional Medicine & Clinical Naturopathy <https://doi.org/10.4172/2573-4555.1000256> accessed 27 April 2026.
[99] Dollar (n 3) 11.
[100] WE Burghardt Du Bois, *Black Reconstruction: An Essay Towards a History of the Part Which Black Folk Played in the Attempt to Reconstruct Democracy in America, 1860-1880* (1st edn, Harcourt, Brace and Company 1935) <https://cominsitu.wordpress.com/wp-content/uploads/2019/02/w-e-b-du-bois-black-reconstruction-an-essay-toward-a-history-of-the-part-which-black-folk-played-in-the-attempt-to-reconstruct-democracy-2.pdf> accessed 13 April 2026.

'clinical' users and, on the other, continues to punish 'self-directed' users, particularly those from marginalised groups.[101]

When looking at the market itself, several psychedelics are going through clinical trials, some being in phase III (large-scale studies to monitor long-term effects).[102] If psychedelics pass legal barriers as accepted treatments, they could generate profit through several channels. These involve pharmaceutical production, therapy models, and patenting, including drug formulations, treatment protocols and delivery methods.[103] Estimates suggests that 'one should expect to pay no less than 5000 USD out-of-pocket expenses for a guided psychedelic experience'.[104] Therefore, it is no wonder the 'almighty dollar' – as the president of Native American Church of North America Jon Brady says – has become one of the primary engines of the 'psychedelic renaissance'.[105] Interestingly, Sanabria points out that 'most of' psychedelic clinical research is funded by Silicon Valley philanthropists.[106] These people include the CEO of PayPal, Peter Thiel; OpenAI co-founder, Sam Altman; and the wealthiest man in the world, Elon Musk.[107] What connects these people together is the ideology of self-optimising and transhumanism. The most notable change is the assumption that, unlike viewed in the 1960s, psychedelics are no longer anti-establishment but are easily co-opted by the profit-driven, tech-oriented society.[108]

To conclude, the resurfacing interest in psychedelics is inseparable from the capitalist frameworks that fund and direct it. Corporate and state actors have co-opted this scientific evolution, which suggests that the 'renaissance' is as much of a product of market necessity as it is of medical advancement.

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[101] Dollar (n 3) 1.
[102] Scuro (n 29).
[103] Dollar (n 3) 11.
[104] ibid 12.
[105] Hallie Golden, 'Inside the Battle to Save the Sacred Peyote Ceremony: "We'Re in Dire Straits"' *The Guardian* (9 December 2022) <https://www.theguardian.com/us-news/2022/dec/09/peyote-native-american-medicine-nacna-federal-protection> accessed 9 April 2026.
[106] Sanabria (n 32) 4.
[107] Sanabria (n 32).
[108] ibid.

2.2. Onto-Epistemological Tensions

The co-option by corporate and state actors does more than just create a new market. For psychedelics to function as commodities in the Western societies, they must be rebranded into the Western biomedicine. This process requires the devaluation of Indigenous ways of knowing as 'cultural' or 'subjective', which creates a fundamental clash between two worldviews: one that sees a patentable resource, and one that sees a sacred relation. At the heart of this process is a Eurocentric narrative that traces the origin of 'true' science exclusively to the 16th-century Scientific Revolution. By analysing these onto-epistemological tensions, this chapter reveals how Western law systematically excludes Indigenous ways of knowing from the realm of 'objective' (Western) science.

First, this section sets the scene by briefly establishing the 'place-based relation ontology' of Indigenous communities, who view psychoactive plants as autonomous beings and teachers. Then, it examines the Eurocentric hierarchy of different knowledge systems and the 'savage slot' in which Indigenous wisdom is placed. The last chapter illustrates the secularisation process of psychedelic-assisted healing rituals required by the market to be validated as objective, patentable products within Western law.

2.2.1. Plant teachers: the ontological status of psychoactive beings

Western claims of the uniqueness and novelty of psychoactive substances may seem a bit out of place when compared to Indigenous thousand-year-old ceremonial traditions with plants and fungi. These traditions form an integral part in, for example, Peruvian culture where the knowledge and traditional uses of ayahuasca practiced by native Amazonian communities has been declared as National Cultural Heritage.[109] Radiocarbon dating at an archaeological site in Texas has shown that peyote – a small mescaline-containing cactus (*Lophophora williamsii*) native to Mexico and the southwestern United States – was used as early as 6000 years ago.[110] Indigenous communities have long used peyote and other psychedelic plants for a range of purposes, including to eliminate illnesses and resolve

[109] Rosa A. Giove, 'El Ritual de La Ayahuasca: Patrimonio Cultural Nacional de Perú' (2022) 27 Cultura y Droga 17 <https://doi.org/10.17151/culdr.2022.27.33.2> accessed 29 April 2026.
[110] Karoll (n 21); George and others (n 15).

conflicts.[111] The Indigenous approach to the psychoactive plants and fungi is, however, very distinct from the Western view.

First, an essential concept to Indigenous worldview is, as Williams et al. defines it, 'place-based relation ontology'.[112] In this view, the foundation of the Indigenous way of knowing consists of topos, place, land, and territory, where continuous interaction of animate and inanimate (by Western definitions) beings produce new information.[113] This profoundly challenges not only the Western idea of who counts as 'persons', but also the way the world is constructed. That is, whereas Western philosophy emphasises the *logos* where meaning is interpreted and articulated through concepts and words, in Indigenous contexts meaning is often experienced and situated.[114] As Tewa scholar Cajete explains, since 'the world of nature is in constant flux', 'native science does not attempt to categorise firmly within the domains of ideas, concepts or laws formed only through an analysis bent on a specific discovery'.[115] Concretely, this means the refusal to separate the mind from matter or the spirit from soil.[116]

When subsuming this to psychedelics, the same linguistic and ontological tension surfaces instantly. As Luna describes, in Indigenous philosophies, these psychoactive plants are 'teachers' with whom one interacts and learns.[117] These plants are understood to possess agency and spirit. For example, psilocybin-containing mushrooms are called 'rain-water children' in Nahuatl *(apipiltzin)*; the Matlazincas refer to these mushrooms as 'little saints' *(santitos)*; and Nahua people call them 'sacred mushroom that paints or describes' *(teotlaquilnanacátl)* or 'food of the Gods' *(teonanacatl)*.[118] The Western conceptualisation of said substances is often, in turn, classified as 'hallucinogens' or 'psychedelics' meaning 'mind-manifesting'.[119] Both Westernised terms frame the plants' effects as

[111] George and others (n 15).
[112] Williams and others (n 43) 513.
[113] Williams and others (n 43).
[114] ibid.
[115] Gregory Cajete, *Native Science: Natural Laws of Interdependence* (1st ed, Clear Light Publishers 2000) 72 <http://static1.1.sqspcdn.com/static/f/1011404/27242032/1555425643517/Cajete.pdf?token=m1tmRQ1jThimDjsu2J4vBNBQ0dk%3D> accessed 1 April 2026.
[116] Williams and others (n 43).
[117] Luis Eduardo Luna, 'The Concept of Plants as Teachers Among Four Mestizo Shamans of Iquitos, Northeastern Peru' (1984) 11 The Journal of Ethnopharmacology 135 <https://www.samorini.it/doc1/alt_aut/lr/luna.pdf> accessed 31 March 2026.
[118] Williams and others (n 43) 513.
[119] Sanabria (n 32).

neurochemical phenomena emphasising mind and consciousness and, in doing so, only focus on the chemical properties rather than living beings with whom one can enter into a meaningful relationship and acquire knowledge.[120] Another example is the classification of ayahuasca between Western and Indigenous science: the former, classifies ayahuasca as one species – *Banisteriopsis caapi* – whereas the latter identifies multiple kinds based on both plant morphology and the effects when people ingest the vine.[121]

Second, if plants are person and teacher, then the purpose of engaging with them is also different. Waldram notes that Western biomedicine tends to measure its efficacy through curing (i.e. elimination of disease) rather than healing (i.e. alleviation of suffering) which is, in turn, emphasised in traditional medicine.[122] This distinction becomes relevant when considering the notion of efficacy. As Fotiou notes, the current design of scientific protocols, such as the use of placebos, insists on measuring effectiveness and finding new breakthrough treatments in curing a variety of diseases. However, as Fotiou further notes, healing can happen without curing a disease, an example being using psilocybin to decrease depression and anxiety in cancer patients.[123] Still, the current psychedelic research seemingly focuses mostly on cures for what biomedicine has failed to cure earlier.[124] However, in Indigenous knowledge, the causation of physical sickness is often attributed to spiritual, rather than material forces, making the healing process a more holistic experience in which psychoactive rituals bring humans closer to the spirits.[125] In practice, ceremonies like the Peruvian ayahuasca ritual incorporate both physical and psychological elements, which are essential for entering the spirit world and facilitating healing. Concretely, in addition to drinking the ayahuasca brew, spiritual leaders incorporate elements of singing *(icaros)*, rustling leaf fans *(chacapas)* and blowing smoke from Peruvian tobacco *(mapacho)* to protect the physical and spiritual space.[126] Ayahuasca helps identify illnesses, and some Amazonian tribes also use it for artistic inspiration, storytelling, and resolving conflicts. Similarly, Aztec healers utilised psilocybin fungi to access knowledge from 'the world beyond' for the community.[127] In

[120] Scuro (n 29).
[121] Fotiou (n 32).
[122] James B Waldram, 'The Efficacy of Traditional Medicine: Current Theoretical and Methodological Issues' (2000) 14 Medical Anthropology Quarterly 603 <https://doi.org/10.1525/maq.2000.14.4.603> accessed 2 April 2026.
[123] Roland R Griffiths and others, 'Psilocybin Produces Substantial and Sustained Decreases in Depression and Anxiety in Patients with Life-Threatening Cancer: A Randomized Double-Blind Trial' (2016) 30 Journal of Psychopharmacology 1181 <https://doi.org/10.1177/0269881116675513> accessed 2 April 2026; Fotiou (n 32).
[124] Fotiou (n 32).
[125] George and others (n 15).
[126] ibid.
[127] ibid 5.

conclusion, the current biomedical research coupled with new advanced technologies threatens to massively simplify the holistic experience of traditional medicinal practices and convert them into efficiency-focused curing.

2.2.2. 'The Savage Slot'

The current unfolding of the psychedelic renaissance is not a new phenomenon but follows a familiar path from other revolutions in the West – such as the one of science – which did not happen, and neither is happening now in isolation. The flow of information and ideas travels through global connections, deeply connected to empire and colonialism, which contributes to the development of new innovations.[128] Still, as Sanabria critically points out, there is an epistemic system of mythologising the Scientific Revolution as the foundation that distinguished the West from the rest of the 'pre-rational world'.[129] She argues that it is 'an expedient fiction' that science has been attributed to the 'intellectual contribution of a handful of men in select European enclaves'.[130] Although regions like China and the rest of Asia had very advanced knowledge systems and technological advancements, the persistent Eurocentric notion of the true birthplace of 'real' science plays a hegemonic role even today, and places any other knowledge system in a secondary position. This hierarchy of different knowledge systems is crucial also in the context of psychedelic science.

Despite the existence of many different knowledge systems, modern Western science presents itself as the one universal, superior way of knowing. What Haitian anthropologist Trouillot came to call 'the savage slot' and which Sanabria subsumes to the psychedelics' context, represents a paradox through which Western science gains its 'universal objectivity' in three stages: First, it creates a necessary contrast between the West as rational with experimentally validated facts and the '[Indigenous] savage' with beliefs and traditions.[131] This epistemic separation functions as a proof of the West's superiority. Second, for Western science to claim 'breakthroughs' as a solitary, self-discovered achievement (in this context, the healing potential of psychedelic-assisted therapies), it has to eradicate any other knowledge

[128] Sanabria (n 32).
[129] ibid 2.
[130] ibid.
[131] Michel-Rolph Trouillot, 'Anthropology and the Savage Slot: The Poetics and Politics of Otherness' in Michel-Rolph Trouillot, *Global Transformations* (Palgrave Macmillan US 2003) <https://doi.org/10.1007/978-1-137-04144-9_2> accessed 11 April 2026; Sanabria (n 32).

system that may have played a part. The third phase then creates this 'radically incompatible' scenario in which reimagining the established hierarchy or objective validity of Western science only reinforces the dichotomy it is trying to dismantle.[132] For example, in order for Indigenous practitioners to prove the efficacy of a plant medicine, they are likely forced to use Western standards (i.e. clinical trials, chemical isolation, double-blind), which gives the role of the ultimate judge to Western science and biomedicine. To complicate matters even more, as Cajete points out, Western science's very identity is built on its historical divorce from religion; since the time of Galileo, spirituality has been framed as the antithesis of science.[133] Consequently, because Indigenous ways of knowing often integrate the sacred with the empirical, Western science instinctively places them in the 'savage slot' to protect its own foundational narrative of secular objectivity.[134]

In fact, Trouillot argues that the whole field of anthropology emerged as an empirical tool for post-1492 Europe to define itself against the Indigenous 'other', which requires their silence.[135] In the context of the 'psychedelic renaissance', the process of silencing may appear in many ways, disguised as (performative) inclusion. In this process, Western science often cherry-picks Indigenous insights that translate easily into data or function as a way to fill the gaps. This process tends to ignore the inconveniences to secular science such as different ontological depths and spiritual implications.[136] Fotiou points out that silencing may also happen through selective research. While a considerable number of psychedelic plant-related studies have been conducted, the actual local knowledge systems that come with it are proportionally understudied. This knowledge vacuum allows some persistent stereotypes of the 'noble savage' to still dominate Western discourse.[137] An insidious example of this stereotyping could be an article published by Nature magazine that read: 'Psychedelic treatments are speeding towards approval – but no one knows how they work'.[138] By claiming that 'no one knows' how psychedelics work, Western science reveals its prejudice towards centuries-long Indigenous expertise as non-knowledge. This is why, as Ens notes, a simple increase in Indigenous scholarship would likely not change the current white-dominated input in psychedelic research,[139] an example

[132] Trouillot (n 131); Sanabria (n 32).
[133] Cajete (n 115).
[134] ibid.
[135] Trouillot (n 131).
[136] Sanabria (n 32).
[137] Fotiou (n 32) 18.
[138] Sara Reardon, 'Psychedelic Treatments Are Speeding towards Approval — but No One Knows How They Work' (2023) 623 Nature 22 <https://doi.org/10.1038/d41586-023-03334-6> accessed 12 April 2026.
[139] Ens (n 32).

being the editorial board of the new Journal of Psychedelic Studies being 78% 'male and overwhelmingly white' (2019).[140] 'Deafness' of the coloniser is required to keep Indigenous voices excluded.[141] The inclusion of Indigenous voices is frequently performative and oftentimes valued as long as it does not interfere with the overarching goal of validating psychedelic science.[142]

Although knowledge among Indigenous people is acquired in a completely different way than in Western science, Native American educator Cajete notes that the 'coming-to-know' (an Indigenous framing of science, education or art) process is, nevertheless, extremely systematic and based on accumulated knowledge.[143] Cajete continues that to understand the real essence of things, it is not enough to be only rational; it requires the combination of heart and being with rational perception to reach the deeper truth of one's self.[144] Incorporating these notions into the Western legal, political, and science systems would require transformative changes, ranging from ontological changes[145] to legally recognising multiple, co-existing realities (i.e. granting legal personhood to non-human, by Western standards, entities).[146] At the very least, a growing number of scholars call for validating Indigenous knowledge as science.[147] The only way to do this is by acknowledging the integrity and sovereignty of other knowledge systems without translating them under Western scientific standards or capitalist influences.[148] Still, at their worst, international scientific conferences exclude indigenous voices entirely, like in the European psychedelic conference in 2023.[149] Alternatively they may invite Indigenous representation to condense their entire world view to just 10 minutes, as seen in the second World Ayahuasca Conference in 2016 – ironically held in Rio Branco, Brazil, a former hub of the rubber industry built on stolen land.[150] That said, at their best, as noted by Assis et al, the upcoming World Ayahuasca Forum in Autumn 2026 promises some prominent shifts firstly, by giving Indigenous nations an agenda-setting role and second, reversing 'epistemic hierarchies' by flipping the roles and giving Indigenous-framed processes the agency to invite Euro-American institutions, not the other way

[140] George and others (n 15) 10.
[141] Ens (n 32) 912.
[142] Sanabria (n 32).
[143] Cajete (n 115) 80.
[144] ibid 72.
[145] Williams and others (n 43) 509.
[146] Williams and others (n 43).
[147] Robin Wall Kimmerer and Kyle A Artelle, 'Time to Support Indigenous Science' (2024) 383 Science 243 <https://doi.org/10.1126/science.ado0684> accessed 23 March 2026; Sanabria (n 32); George and others (n 15).
[148] Sanabria (n 32).
[149] ibid.
[150] ibid.

around.[151] The 'Ethical Principles of Traditional Indigenous Medicine', formulated by Indigenous-led global experts, states under the principle of 'Respect': 'Nothing about us, without us'.[152] This summarises the needed shift from tokenistic inclusion to genuine sovereignty, where Indigenous knowledge would have the agency to operate as a legitimate, respected entity, instead of serving as a prop for Western companies to gain legitimacy.

2.2.3. Secularisation and westernisation of Indigenous ceremonial knowledge

As psychedelics expand globally, they are increasingly used in ways that are detached from their original spiritual contexts. This part of the subchapter walks through the secularisation process in the following two ways: scientific standardisation and the process of sanitising Indigenous shamanism to fit Western expectations. The term secularisation is here defined according to Scuro: 'a gradual distancing from traditional cultural contexts of psychedelic use and a progressive shift toward scientific rationality and medicalisation'.[153] Although ayahuasca has expanded through various religions notably in Brazil, this study isolates the secularisation occurring in Western contexts.

First, biomedicine centres around a unique notion that a specific treatment should be developed and applied to specific diseases. In contrast, other medical systems – encompassing traditional ones using psychedelics – incorporate all the senses through a range of elements, which makes it almost impossible to separate the effect of one element from another.[154] This rich sensory engagement is the very purpose. Still, Western science and biomedicine are largely based on strict repeatable procedures, such as randomised controlled trials (RCTs) where 'blinding' plays a crucial part – one part of the group gets the real drug, the other a placebo, and the participants, and in some studies also the researchers, do not know who gets what. This is to measure real effect and to be 'genuinely scientific', as Sanabria points out.[155] For psychedelic research, however, it is rather difficult to follow the golden rules of 'standard science'. The obvious reason being the fact that you cannot really 'blind' the effect of

[151] Glauber Loures de Assis and others, 'From Renaissance to Confluence: A Call for Paradigm Shift in Psychedelic Studies' (2026) 3 Psychedelics 100010, 4 <https://doi.org/10.1016/j.psyche.2026.100010> accessed 13 April 2026.
[152] Celidwen and others (n 37) 4.
[153] Scuro (n 29) 720.
[154] Fotiou (n 32).
[155] Sanabria (n 32).

psychedelics in a human body; the signs are clear if you are on psychoactive substances. Second, these clinical trials are psychedelic-*assisted* (as highlighted by Sanabria), which means that it is not solely the drug's effect that is being measured, but the combination of a psychoactive substance and psychotherapeutic intervention that guide the experience.[156] To fix this incompatibility with Western biomedicine, clinical studies forcefully isolate not only the chemical compounds but also any other variables belonging to the broad spiritual experience, to make it fit into Western repeatable standards.

In addition to fitting the complex sensory experience of psychedelic-assisted therapies into standard science, also linguistic nuances play a role in secularising these substances. One of the most secularised psychoactive substances is psilocybin, as the results in Scuro's bibliometric analysis (2024) indicate.[157] To elaborate, unlike ayahuasca-focused publications that stem mainly from humanities and social sciences, those on psilocybin cover primarily the medical and scientific areas, contributing to the medicalisation of psilocybin research.[158] Illustratively, Albert Hoffman, upon successfully isolating and synthesising psilocybin of Mexican origin, uttered: 'These compounds, whose magical psychic effects made the Indians believe for thousands of years that a god resided in them, could now be synthesised into a test tube' (author's translation).[159] Even the standardised name 'psilocybin' of psilocybin-containing fungi speaks to the despiritualisation and secularisation. Despite its multiple names in indigenous contexts as elaborated in chapter 2.2.1., a purely scientific perspective has been adopted.[160]

On top of scientific standardisation, linguistic choices, and chemical isolation, the process of sanitising Indigenous shamanism to fit Western expectations and the capitalist mindset play a role in secularisation and westernisation of Indigenous knowledge. Particularly, ayahuasca's development is rather complex: while its use remains largely institutionalised within religious and neoshamanic rituals, this very structure has paradoxically driven outsiders toward recreational use. In these contexts, the focus often shifts toward individualistic personal transformation, frequently disregarding the Indigenous emphasis on interconnectedness.[161] Namely, Sanabria notes how Amerindian shamanic

[156] ibid.
[157] Scuro (n 29).
[158] ibid.
[159] Albert Hofmann, 'Historia de Las Investigaciones Químicas Básicas Sobre Los Hongos Sagrados de México' *Teonanácatl hongos enteogénicos de norteamérica* (Jonathan Ott 2009) 51 <https://www.ulises.online/wp-content/uploads/2022/04/Teonanacatl.pdf> accessed 11 June 2026.
[160] Scuro (n 29).
[161] Fotiou (n 32).

traditions are often selectively presented and reshaped to modern audiences. This means downplaying or ignoring some traditional aspects of shamanism, such as ambivalence or even aggression, to fit the romanticised image of the 'peaceful healer'.[162] However, not all journeys with psychoactive plants are purely good, harmonious, and healing. A Shipibo *onanya* ('the one who knows'; Spanish: 'él que sabe') from the Peruvian Amazon explains how ayahuasca ceremonies show 'ancestral and personal traumas' and they do not always lead you connect to 'your personal self' (author's translation).[163] As Sanabria summarises well, these sometimes intense experiences do not go well with the 'romantic stereotypings of Amazonian shamans as 'noble savage' living in benevolent harmony with the natural world'.[164] Put simply, Western lifestyles and scientific frameworks subject psychedelics to a legitimisation process that tends to remove traditional teachings and shift the focus instead toward a romanticised, individualistic psychology of healing.

The commodification of Indigenous knowledge sparks strong opinions among Indigenous peoples. José López Sánchez describes the commercialisation of his culture as 'ayahuascaína'.[165] This term draws a deliberate parallel to the history of cocaine (*cocaína*), illustrating how sacred coca leaves were turned into a product of chemical, white powder. López Sánchez elaborates that this process stems from a fundamental disrespect toward 'plants that have a mother' (all direct quotes in this paragraph are the author's translations from the original Spanish text), meaning that these plants are sentient beings with their own guardian spirits and consciousness.[166] López Sánchez concludes this development in an arresting way: 'There is no more killing' in the physical sense of past centuries, but a new form of destruction has emerged.[167] The arrogance of foreign retreat leaders claiming ownership or superior knowledge of Indigenous traditions, combined with the pressure of Indigenous healers to adapt their ancestral methods into market-friendly performances 'transform [the sacred practice] until there is no more'.[168] For López Sánchez, this cultural appropriation is a modern extinction: 'This is how they are killing us.'[169] These Amazonian voices suggest that the 'ayahuascaína' of their traditions is not only a

[162] Sanabria (n 32) 3.
[163] José López Sánchez, Silvia Mesturini and Emilia Sanabria, *Trabajar Con Las Plantas Que Tienen Madres - Diálogos Con Un Onanya Shipibo* (Fineo Editorial 2024) 54 <https://encounters.cnrs.fr/images/pdf/publications/2024-trabajar-plantas.pdf> accessed 17 March 2026.
[164] Sanabria (n 32) 3.
[165] López Sánchez, Mesturini and Sanabria (n 163) 12, 13.
[166] ibid 13.
[167] ibid 59.
[168] ibid.
[169] ibid 57.

new market brand, but a systemic extractive business that threatens their path to self-determination. By stripping sacred plants of their spiritual agency and packing ancestral wisdom into a market-friendly performance, this modern appropriation represents a new, bloodless form of cultural extinction.

3. REGULATORY FRAMEWORKS

Building on the previous exploration of the evolution of intellectual property, this chapter provides a doctrinal analysis of the international legal regimes relevant to the psychedelic frontier. Since the 1990s, Indigenous peoples have pushed for protections against unauthorised appropriation of traditional knowledge and genetic resources.[170] The scope of the analysis incorporates frameworks with different primary objectives: Some instruments affect Indigenous rights directly, such as the Nagoya Protocol and EU 511/2014 Regulation that regionally implements it. Other frameworks affect Indigenous rights indirectly, for example, by shaping intellectual property boundaries and the commodification of traditional knowledge, or by accelerating biotechnological advancements that allow the extraction and commodification to happen at a faster pace.

First, the chapter examines the European IP regime (under the European Patent Convention, EPC). Because the EPC was comprehensively revised ('EPC 2000') to align with TRIPS, [171] and because its membership nearly universally overlaps with TRIPS, the European framework serves as a fully realised execution of these global standards in practice. Second, the analysis assesses the environmental treaty of Nagoya Protocol on Access and Benefit-Sharing (ABS) and how it is enforced through the EU Regulation 511/2014. The thesis also incorporates EU Regulation 2015/2283 on Novel Foods, because not all psychedelic products fall within the scope of pharmaceutical products. Finally, the analysis investigates the newest developments in the field of biotechnology in the EU through the Biotech Act 2025 and Pharma Reform 2026, and globally though the most recent WIPO GRATK Treaty. By examining the intersection of these environmental, intellectual property, and industrial frameworks, the analysis determines the specific legal safeguards and structural vulnerabilities created for Indigenous intellectual sovereignty.

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[170] Tolulope Anthony Adekola, 'Whose Knowledge, Whose Cure? Traditional Medicine and the Boundaries of WIPO's 2024 Genetic Resources Treaty' [2026] The Journal of World Intellectual Property jwip.70016 <https://doi.org/10.1111/jwip.70016> accessed 3 May 2026.

[171] Stacey J Farmer and Martin Grund, 'Revision of the European Patent Convention & (and) Potential Impact on European Patent Practice' (2008) 36 Aipla Quarterly Journal <https://heinonline-org.uaccess.univie.ac.at/HOL/Page?handle=hein.journals/aiplaqj36&id=427&collection=journals&index=> accessed 9 May 2026.

3.1. European Patent Convention under TRIPS' global mandate

The TRIPS Agreement sets minimum standards for intellectual property regulation, which are currently enforced by the WTO's 166 member states. In its opening paragraph, TRIPS recognises the desire to reduce 'distortions and impediments to international trade' and to harmonise global IP regime through 'effective and adequate protection of intellectual property rights'.[172] The Agreement specifically mentions the 'special need of the least-developed country Members in respect of maximum flexibility in the domestic implementation'.[173] The following analysis examines the provisions of the European Patent Convention (EPC). All EU member states are part of the EPC.[174]

a) Patentability under article 52

Article 52(1) in EPC confirms that patents are granted for inventions that are (1) 'new', involve an (2) 'inventive step' (i.e. non-obvious) and are susceptible of (3) 'industrial application' (i.e. useful). It is also confirmed that this definition applies 'in all fields of technology'.[175] According to article 54(1), an invention is considered new 'if it does not form part of the state of the art' – also called *prior art*.[176] From an Indigenous perspective, the state of art crucially also comprises prior knowledge made available to the public 'by means of a written or oral description' (art. 54(2), EPC).[177] That said, because centuries of Indigenous knowledge regarding these substances and their uses have been passed down orally rather than recorded in Western databases, a documentation gap exists.[178] This increases the risk that the European Patent Office will mistake traditional knowledge for a novel discovery and erroneously grant patents on applications or derivatives that actually lack an inventive step.

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[172] TRIPS 320.
[173] ibid.
[174] European Patent Office, 'Member States of the European Patent Organisation' <https://www.epo.org/en/about-us/foundation/member-states> accessed 11 May 2026.
[175] European Patent Office, 'European Patent Convention' art 52(1) <https://www.epo.org/en/legal/epc/2020/convention.html> accessed 11 May 2026.
[176] European Patent Office, 'European Patent Guide' pt 3(3)(1) <https://www.epo.org/en/legal/guide-epc/2023/index.html> accessed 11 May 2026.
[177] European Patent Office, 'European Patent Convention' (n 175) art 54(2).
[178] World Intellectual Property Organization., *Intellectual Property and Traditional Medical Knowledge: Background Brief No. 6.* (World Intellectual Property Organization, 2023) <https://doi.org/10.34667/TIND.47891> accessed 15 March 2026.

Rule 27 of the Implementing Regulation to EPC deems biological material patentable if it is 'isolated from its natural environment or produced by means of a technical process'.[179] This provision extends patent eligibility to digital sequence information (DSI),[180] such as nucleotide or amino acid sequences, 'even if it previously occurred in nature'.[181] Unlike the voluntary nature of physical origin disclosure, non-compliance with these electronic sequence requirements results in the absolute refusal of the application.[182] From a more political perspective, the different treatment towards disclosing geographical origin of a biological material versus DSI may highlight the commercial ethos of TRIPS Agreement and the value that is placed on each resource. Indeed, for the sake of market predictability, DSIs are diligently regulated to facilitate patenting, whereas the ethical obligation to acknowledge the providing country remains an optional check under the EPC.

b) Exceptions from patentability (Art. 53(b, c))

Naturally occurring psychedelic compounds per se – such as the raw psilocybin mushroom – cannot be patented in their base form (art 53(b)) because they are known discoveries and a 'discovery as such has no technical effect and is therefore not an invention within the meaning of art. 52(1)'.[183] To bypass this provision, modern patent claims typically focus on derivates with a specific, technical know-how or novel therapeutic applications linked to those substances,[184] because 'if […] that property is put to practical use, then this is an invention which may be patentable'.[185] The exact legal avenue utilised by the modern psychedelic pharmaceutical industry relies on a specific provision of article 53: Article 53(c) first sentence explicitly excludes methods for 'treatment of the human body by surgery or

[179] European Patent Office, 'Implementing Regulations' art 27 <https://www.epo.org/en/legal/epc/2020/regulations.html> accessed 20 May 2026.
[180] Digital sequence information on genetic resources or 'DSI' is defined by CBD as the 'digital representation of genetic material such as DNA and RNA sequences, and potentially other linked data like amino acid sequences and molecular structures', Secretariat of the Convention on Biological Diversity, United Nations Environment Programme and United Nations Development Programme, *Guide to the Cali Fund: Sharing the Benefits of Genetic Data from Nature* (Secretariat of the Convention on Biological Diversity 2025) 2 <https://www.cbd.int/dsi-gr/califund.guide.pdf> accessed 9 June 2026.
[181] European Patent Office, 'Implementing Regulations' (n 179) art 30; ibid 27(a).
[182] European Patent Office, 'Implementing Regulations' (n 179) art 30(3).
[183] European Patent Office, 'Guidelines for Examination in the European Patent Office' pt G, ch II, 3.1 Discoveries <https://www.epo.org/en/legal/guidelines-epc/2026/index.html> accessed 28 May 2026.
[184] 'Pipeline | Developing Innovative Mental Health Treatments – AtaiBeckley' (*Creating breakthroughs in mental health – AtaiBeckley*, 2026) <https://www.ataibeckley.com/our-work/pipeline> accessed 15 May 2026; 'About Psilocybin Therapy | Compass Pathways' (*Compass*, 2026) <https://compasspathways.com/our-work/about-psilocybin-therapy-and-treatment/> accessed 15 May 2026.
[185] European Patent Office, 'Guidelines for Examination in the European Patent Office' (n 183) pt G, ch II, 3.1 Discoveries.

therapy' from patentability.[186] This reflects a humanitarian rationale, where a doctor or any other medical practitioner do not have to worry about IP rights when giving treatment. The second sentence of article 53(c) immediately goes on to say that this exclusion does not, however, apply to products or substances used in any of these methods.[187] And this is the structural pathway for big pharma to make profit.[188]

c) Exceptions from article 53(c): further medical use

To operationalise this exception, article 53(c), second sentence on medical substances, must be read in conjunction with articles 54(4) and 54(5) EPC. These provisions create rules that make it legally possible to override standard novelty requirements for known chemical compounds:

Article 54(4) sets the standard for 'first medical use' instances by establishing that if a substance is entirely new to the medical field – even if it is already known in the public domain for an industrial or non-medical purpose – article 54(4) allows the applicant to patent that substance broadly for its first generic medical application.[189] In the context of psychedelics, this means that even if an Indigenous community has used a plant for centuries, if it has never entered the official Western medical prior art, a pharmaceutical company can theoretically use article 54(4) to patent it for its first broad medical application.

Article 54(5) sets the standard for 'second medical use' by establishing that if a substance is already known to possess medical properties, article 54(4) can no longer offer protection.[190] In the context of psychedelics, because molecules like psilocybin are already widely documented in modern clinical literature for their therapeutic properties,[191] their first medical use is not applicable. Instead,

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[186] European Patent Office, 'European Patent Convention' (n 175) art 53(c).
[187] 'Germany Pharmaceutical Market Report by Type (Pharmaceutical Drugs, Biologics), Nature (Organic, Conventional), and Region 2026-2034' (*IMARC*, 2025) art 53(c) <https://www.imarcgroup.com/germany-pharmaceutical-market#> accessed 15 May 2026.
[188] European Patent Office, 'European Patent Convention' (n 175) art 53(c).
[189] European Patent Office, 'European Patent Convention' art 54(4) <https://www.epo.org/en/legal/epc/2020/convention.html> accessed 11 May 2026; European Patent Office, 'Guidelines for Examination in the European Patent Office' <https://www.epo.org/en/legal/guidelines-epc/2026/g_ii_4_1.html> accessed 28 May 2026 pt G, ch VI, 6.1 First or further medical use of known products.
[190] European Patent Office, 'Guidelines for Examination in the European Patent Office' (n 173) pt G, ch VI, 6.1 First or further medical use of known products.
[191] Scuro (n 29).

article 54(5) permits an applicant to secure a patent for any 'specific', subsequent therapeutic indication, given that the precise medical application is novel and inventive.[192]

This legal structure may influence how major psychedelic drug companies build their business. At least two leading European companies, Compass Pathways and Atai Life Sciences, rely heavily on the 'further medical use' protections of article 54(5) (see figures 2 and 3). Compass Pathways bases its entire pipeline on a single compound, a psilocybin formulation called COMP360.[193] Instead of patenting the drug itself, they get separate patents by targeting entirely different conditions, like treatment-resistant depression (TRD), post-traumatic stress disorder (PTSD), and anorexia.[194] Atai Life Sciences utilises the same strategy with known traditional psychedelics, such as DMT (the active component in ayahuasca).[195] Because these base molecules are already in the public domain, they fail the novelty requirement of articles 54(1-3) EPC.[196] To secure market exclusivity, companies must, therefore, rely on article 54(5), which allows them to patent niche, novel clinical indications for which the substances are used.

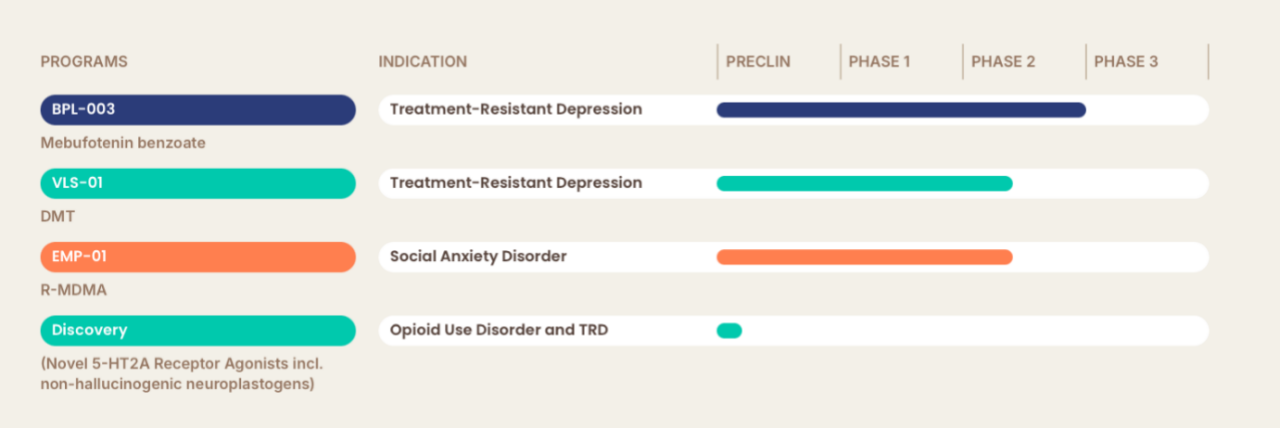

Figure 2: Clinical pipeline of Atai Life Sciences (AtaiBeckley), illustrating the segmentation of known psychedelic compounds (e.g. DMT, 5-MeO-DMT) by specific therapeutic indications [197]

[192] European Patent Office, 'European Patent Convention' (n 175) art 54(5); European Patent Office, 'Guidelines for Examination in the European Patent Office' (n 183) pt G, ch VI, 6.2 Second non-medical use.
[193] Compass Pathways, 'Pipeline Overview' <https://compasspathways.com/our-work/pipeline-overview/> accessed 19 May 2026.
[194] ibid.
[195] 'Pipeline | Developing Innovative Mental Health Treatments – AtaiBeckley' (n 184).
[196] European Patent Office, 'European Patent Convention' (n 175) art 54(1-3).
[197] 'Pipeline | Developing Innovative Mental Health Treatments – AtaiBeckley' (n 184).

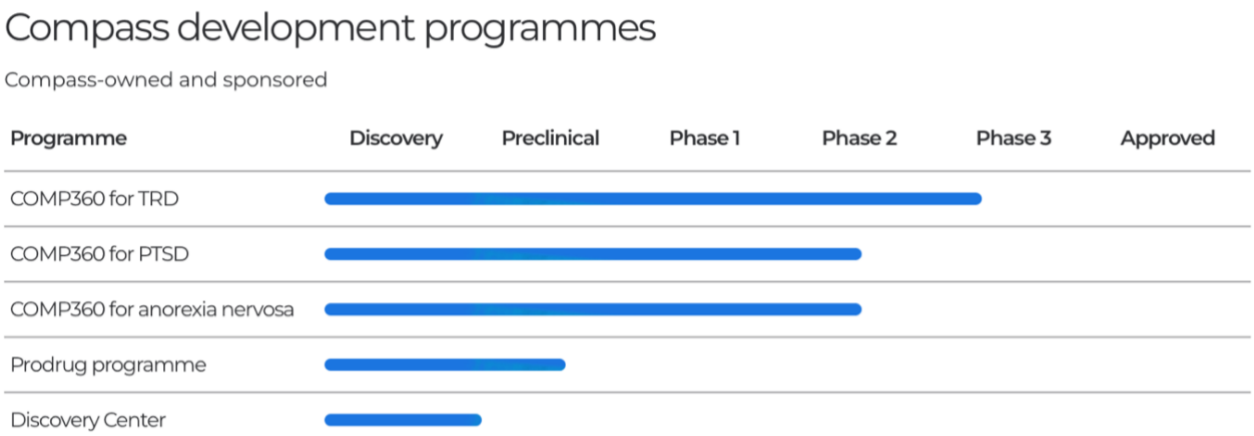

Figure 3: Clinical development pipeline of Compass Pathways, demonstrating the targeted application of a single patented formulation (COMP360) across multiple distinct psychiatric indications [198]

d) Applicant and inventor under articles 58 & 60

Under the European patent system, an application may be filed by 'any natural or legal person' (art 58), but the right to the patent ultimately belongs to the inventor or their successor (art 60(1)).[199] This illustrates individualisation of inventions, which collides with Indigenous collective ownership. The system expects a clear, contemporary invention made by a specific person or group. It is not built for knowledge that evolves over centuries and is passed down by unnamed ancestors.

e) Legal challenges

On top of the challenges regarding patentability (such as further medical use) and the personal scope of protection (the definition of an inventor), this analysis identifies two additional legal gaps within the EPC framework regarding Indigenous intellectual sovereignty.

[198] Compass Pathways (n 193).
[199] European Patent Office, 'European Patent Convention' (n 175) arts 58, 60.

a. Morality clause, article 53(a)

In theory, the morality clause offers an avenue for Indigenous communities to challenge patents involving their sacred genetic resources. However, in practice, its utility is heavily limited. Under article 53(a), the European Patent Office is empowered to reject applications that are contrary to *'ordre public'* or morality.[200] To define a universal morality is, nonetheless, not easy – probably impossible. Indeed, Ann does not explicitly define 'morality' in his article on the *'ordre public'* and morality clause. By contrast, the definition of 'public order' is a well-established legal concept encompassing 'fundamental principles of the legal order'.[201] As Ann notes, these constitute the 'norms that serve to realise and protect values and goods essential to life in the community'.[202] Some of these norms are codified in varying human rights documents such as the ECHR, but they can also incorporate customary law.[203]

The lack of a clear definition of morality may be an indication of an intentionally highly placed legal threshold to prevent subjective evaluations. As Ann notes, socio-economic standards for 'appropriateness' should not form the basis for morality.[204] What he also importantly argues is that there is ultimately a philosophical dilemma at the EPO: how can a centralised system apply a ban based on some pan-European morality, when it is comprised of dozens of different countries and their traditions.[205] Because the burden of investigating each member state's moral landscape, the EPO operates under an assumption that a commercial application of an invention complies with public order in all states. This leaves specific moral objections to be fought later in national invalidity proceedings.[206]

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[200] ibid 53(a).
[201] Christoph Ann, *Patentrecht: Allgemeines* (8th edn, CH Beck 2022) para 10 <http://beck-online.beck.de/Bcid/Y-400-W-AnnLbPatentR-GL-sect15-III-a-aa> accessed 26 May 2026, translated from German using Gemini 3.5 Flash. All subsequent translations from this text are generated by Gemini 3.5 Flash unless otherwise specified.
[202] ibid para 10.
[203] ibid.
[204] ibid para 12.
[205] Christoph Ann, *Patentrecht: Berücksichtigung Im Verfahren Vor Dem EPA* (8th edn, CH Beck 2022) <http://beck-online.beck.de/Bcid/Y-400-W-AnnLbPatentR-GL-sect15-III-a-bb> accessed 26 May 2026, translated from German using Gemini 3.5 Flash. All subsequent translations from this text are generated by Gemini 3.5 Flash unless otherwise specified.
[206] ibid.

So far, case law shows that the basis for patent rejection has mostly been on grounds of tangible bioethical harms such as animal suffering with no human benefit (Onco-mouse case)[207] or modifying the genetic identity of human lineage (human-pig chimeras case).[208] Since the European Patent Office does not even have the legal mandate to determine what is pan-European morality, incorporating another understanding of moral (i.e. that of the Indigenous view) imposes almost an impossible task. Still, for example, the National Council of Native American Churches emphasises 'spiritual respect', arguing that sacred plants should be excluded from secular commodification.[209] If the EPO were to move beyond its narrow, bioethical definitions and adopt a more pluralistic interpretation of morality, article 53(a) could possibly provide a doctrinal basis to invalidate patents on sacred 'living relatives' that violate Indigenous customary laws (see chapter 2.3.1 for elaboration).[210]

A fitting example of this is the Simalikalactone E case (T 2510/18). A patent for an antimalarial drug was challenged under article 53(a) as an act of 'biopiracy' due to its links to Indigenous traditional use.[211] The opposition argued that patenting the invention was fundamentally immoral because researchers had failed to secure prior informed consent.[212] The EPO Board of Appeal, however, dismissed the opposition and maintained the patent. The board ruled that article 53(a) explicitly targets the commercial exploitation of the invention, not the circumstances of its discovery.[213] Even if the researchers acted unethically or illegally, the downstream product itself was highly beneficial to humanity.[214] Therefore, the exploitation of the drug was not immoral, meaning article 53(a) could not be used to punish bad behaviour that happened before the patent was filed. As demonstrated by this case, the purpose of this provision is to, ultimately, prevent patents being granted for inventions which are 'likely to induce riot or public disorder, or to lead to criminal or other generally offensive behaviour',[215] and cannot be used for biopiracy claims nor spiritual reasoning.

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[207] *T 0019/90 (Onco-Mouse)* [1990] EPO Technical Board of Appeal T 0019/90, 1990 OJ EPO (Official Journal of the European Patent Office).
[208] *T 1553/22 (Human-pig chimeras/University of Minnesota)* [2024] EPO Technical Board of Appeal T 1553/22.
[209] From Steven Benally and others, 'Statement from National Council of Native American Churches and the Indigenous Peyote Concervation Iniative Regarding Decriminalization of Sacred Plants Ordinances at the City or Other Jurisdictional Level, as They Pertain to Peyote' (30 March 2020) para 3 <https://chacruna.net/wp-content/uploads/2020/03/DecrimStatementNCIPCIBOD.pdf> accessed 8 April 2026.
[210] Karoll (n 21) 175.
[211] *T 2510/18 (Simalikalactone E)* [2024] EPO Boards of Appeal (Technical Board 3302) T 2510/18 3 Point 2.1 & D54/D55.
[212] ibid Point 2.4.
[213] ibid Point 2.22.
[214] ibid Point 2.9.
[215] European Patent Office, 'Guidelines for Examination in the European Patent Office' (n 183) ch II, 4.1.

All things considered, morality defined through Western standards fail to provide the kind of legal avenue for Indigenous groups to challenge the commodification of their sacred plants on the basis of morality or public order. As far as biopiracy and mutual trust is concerned, they are irrelevant to article 53(a). Even if morality was viewed through a wider lens, article 133 creates a bureaucratical barrier for non-EPC members to challenge patents.

b. Representation under article 133

Even though article 99 technically allows 'any person' to oppose a patent within nine months of the publication,[216] article 133 establishes that persons not having a residence or principal place of business within a contracting state (i.e. anyone who lives outside an EPC member state) must be represented by a 'professional representative and act through him in all proceedings'.[217] In practice, it is possible that this requirement turns a *de jure* right into a *de facto* financial and procedural barrier. Particularly in cases where Indigenous or marginalised communities' rights are violated, this requirement may function as a technical gatekeeper to keep out challengers due to costly proceedings. Indeed, the Simalikalactone E case revealed this very problem. In the end, since Indigenous peoples from the Amazon did not have legal standing before the EPO, the Danielle Mitterrand Foundation acted as the formal appellant-opponent on behalf of the affected community.[218]

3.2. EU Law

Patents are not the only way to protect intellectual property. Alternative pathways include geographical indications (GIs), which protect the reputation and market value of a local resource,[219] and trade

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[216] European Patent Office, 'European Patent Convention' (n 175) art 99.
[217] European Patent Office, 'European Patent Convention' art 133(2) <https://www.epo.org/en/legal/epc/2020/convention.html> accessed 11 May 2026.
[218] Houthoff, 'WIPO Information Sharing Session on Regional, National, and Community Experiences Regarding the Use of Intellectula Property as a Tool to Protect TK and TCEs' (6 March 2026) <https://www.wipo.int/edocs/mdocs/webinars/en/wipo_grtkf_ic_52/wipo_grtkf_ic_52_information_sharing_session_ms_fleur_tuinzing.pdf> accessed 28 May 2026.
[219] World Intellectual Property Organization, 'Protect and Promote Your Culture: A Practical Guide to Intellectual Property for Indigenous Peoples and Local Communities' <https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1048.pdf> accessed 19 May 2026.

secrets, which protect confidential preparation methods or formulas.[220] While organisations like WIPO actively encourage Indigenous communities to use trade secrets to shield traditional remedies (such as ayahuasca recipes) from unauthorised commercialisation,[221] this thesis argues that conventional IP regimes remain, for the most part, unfit for community-owned knowledge. Because standard IP frameworks are inherently geared toward individual or corporate commercial interests, a targeted *sui generis* – unique – system may offer superior protection for Indigenous knowledge.

This subchapter analysing EU law will follow a structure of first, briefly introducing the Nagoya Protocol which the European Union enforces through the EU 511/2014 Regulation. The section introduces core pillars of said Regulation and focuses on national enforcement in the case of Germany. Germany is used as an example as it is the largest pharmaceutical market in Europe.[222] The operational unit of AtaiBeckley, the biggest psychedelic-focused pharmaceutical company in Europe, is also located in Germany.[223] The second part briefly outlines the EU Regulation 2015/2283 on Novel Foods, since not all psychedelic products fall under the category of medicinal products. The last chapter introduces the newest Biotech Act 2025 and Pharma Reform 2026.

3.2.1. EU 511/2014 Regulation on Access and Benefit-Sharing

a) Nagoya Protocol

The Nagoya Protocol addresses the regulatory gaps in the conventional IP regime regarding Access and Benefit-Sharing (ABS). Adopted under the Convention on Biological Diversity (CBD) in 1992 and ratified by 144 parties, the Protocol establishes the first legally binding framework for accessing genetic resources and the 'associated traditional knowledge' held by Indigenous communities.[224] As discussed in the previous section, a classic contemporary example of this intersection is, indeed, found

[220] ibid; TRIPS art 39.
[221] 'Indigenous SMEs and Intellectual Property' (*WIPO*) <https://www.wipo.int/en/web/business/traditional-knowledge> accessed 19 May 2026.
[222] 'Germany Pharmaceutical Market Report by Type (Pharmaceutical Drugs, Biologics), Nature (Organic, Conventional), and Region 2026-2034' (n 187).
[223] 'Psychedelic Company Financing Tracker' (*Psychedelic Alpha*, 2026) <https://psychedelicalpha.com/resources/psychedelic-company-financing-tracker/> accessed 15 May 2026.
[224] Nagoya Protocol on access to genetic resources and the fair and equitable sharing of benefits arising from their utilization to the convention on biological diversity 2010 (3008 UNTS 3) art 5(5) & 7; Morgera, Tsioumani and Buck (n 50).

in psychedelic-assisted therapy forms, which rely heavily on traditional knowledge tied directly to specific genetic resources. By detailing obligations for prior informed consent and fair benefit-sharing, the Protocol creates legal certainty for both providers and users.[225] This link is critical in sectors like pharmaceuticals, where traditional knowledge can increase bioprospecting success by 400%.[226]

The Protocol seeks to balance the economic and non-economic values of biodiversity and integrate fair benefit-sharing (pillar 1) with the conservation (pillar 2) and sustainable use (pillar 3) of biological resources.[227] Article 1 also refers to technology transfer, capacity building, and appropriate funding,[228] which signals an effort to shift the framework from commutative to distributive justice.

Under Article 5(1), the material scope of the Nagoya Protocol comprehensively covers all benefits arising from the utilisation of genetic resources and associated traditional knowledge, extending explicitly to 'subsequent applications and commercialisation', which must be 'shared in a fair and equitable way'.[229] Although patents are not explicitly mentioned in the document, they are captured by the broad language that explicitly targets commercial use.

b) Implementation of the Nagoya Protocol through EU 511/2014

The European Union's approach to the Nagoya Protocol is defined by a shift from regulating the *access* of biological materials to regulating the *compliance* of their users.[230] The EU 511/2014 Regulation serves as the primary regional legal instrument for 'fair and equitable sharing of the benefits arising from the utilisation of genetic resources', recognising that better protection is achieved through a harmonised framework across all member states.[231] Unlike access laws which dictate how a resource is taken from a provider country and which have been left to each member state's own discretion, this

[225] *Nagoya Protocol ch Introduction.*
[226] Morgera, Tsioumani and Buck (n 50).
[227] *Nagoya Protocol; Morgera, Tsioumani and Buck (n 50).*
[228] Nagoya Protocol art 1.
[229] 'Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity' art 5.
[230] Regulation (EU) No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union 2014 (OJ L) art 1; A 'user' is defined as a 'natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources', the EU ABS Regulation art 3(4).
[231] ibid para 35.

Regulation is a compliance law.[232] Its core objective is to ensure that any person or entity utilising genetic resources or associated traditional knowledge within the EU does so in accordance with the Nagoya Protocol's international standards.[233]

a. Material and temporal scope of article 2

The material scope defines which resources are protected. The EU ABS Regulation, article 2, limits the scope to cover 'resources over which states exercise sovereign rights'.[234] It also covers benefits arising from the utilisation of a traditional knowledge, given it was accessed after the 2014 threshold (art 2(1)).[235] Article 3(7) further clarifies that traditional knowledge has to be 'relevant for the utilisation' and written into mutually agreed terms, which is defined as a contract between a provider and a user of genetic resources or associated traditional knowledge.[236] As a result of this requirement, the EU's implementation creates a much narrower material scope than the baseline framework established by the Nagoya Protocol. While the Nagoya Protocol broadly applies to all traditional knowledge associated with genetic resources, the EU Regulation only triggers compliance obligations if that traditional knowledge is already formally bound by an explicit, pre-existing MAT contract.[237] Consequently, the EU framework does not protect or regulate traditional knowledge that is accessed informally or held outside a formalised written agreement. By requiring explicit formalisation as a prerequisite for EU monitoring, this threshold omits bodies of orally transmitted or informally accessed traditional knowledge simply because they were not explicitly written into mutually agreed terms.[238]

The scope in article 2(1) also means that if a scientist collected a sample, say in 2010, these specific EU compliance rules do not apply. This non-retroactive scope may raise issues regarding the use of psychedelic substances that have been in use prior 2014. As, Greiber and Frederichs note, the temporal scope creates a significant timeline gap that creates a structural opening for users to bypass compliance

[232] ibid 2(3).
[233] ibid art 1.
[234] ibid 2.
[235] ibid 2(1).
[236] ibid 3(6, 7).
[237] ibid.
[238] ibid.

by claiming the utilisation of pre-October 2014 samples.[239] Because national competent authorities, such as Germany's Federal Agency for Nature Conservation (BfN), cannot enforce administrative sanctions without first establishing legal jurisdiction, the burden of proof falls onto the national competent authorities to prove or disprove users' timeline claim.[240] In short, while the user (e.g. the company or research institution) holds the procedural obligation to submit due diligence declarations under article 7, the substantive burden of proving the jurisdictional scope is on the competent authority.[241] This is also relevant in case of psychedelic substances since, as discussed in chapter 2, most research on them started already decades ago (e.g. psilocybin).

Article 2(4) establishes that the Regulation only triggers if the resource is subject to the ABS legislation or regulatory requirements of a Party to the Nagoya Protocol.[242] If the provider country is not a party to the Protocol, the EU's due diligence duties do not technically apply under this specific Regulation. Furthermore, as mentioned earlier, the Regulation does not create any new rules for accessing resources within the EU itself; it ensures compliance with other countries' rules on genetic resources.[243]

b. Personal scope, article 3(4)

EU ABS Regulation defines a 'user' as a 'natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources'.[244] All users falling under this definition must follow the duty of due diligence, triggered by the 'utilisation'. This might include commercial users like pharmaceutical companies and biotech startups, and non-commercial users like academic researchers and public research institutes.

[239] Thomas Greiber and Ellen Frederichs, 'First Experiences in the Implementation of the EU ABS Regulation in Germany' in Evanson Chege Kamau (ed), *Global Transformations in the Use of Biodiversity for Research and Development*, vol 95 (Springer International Publishing 2022) <https://doi.org/10.1007/978-3-030-88711-7_19> accessed 5 May 2026.
[240] ibid.
[241] ibid.
[242] the EU ABS Regulation art 2(4).
[243] ibid art 2(3).
[244] ibid art 3(4).

c. *Core duties for users, article 4*

The European Union's Access and Benefit-Sharing (ABS) regime operates primarily as a verification system designed to ensure that users of biological materials have performed the necessary legal checks before commencing research. The core of the Regulation is formed by two duties for users, established in article 4:

1. the general obligation of due diligence (i.e. lawful access; art 4.1) and
2. mutually agreed terms (lawful utilisation; art 4.2) obligations.[245]

Under article 4(1), the due diligence mandate places the burden of proof on users to ascertain compliance with shared objects and find applicable rules of 'any applicable legislation or regulatory requirements'.[246] Once inside the jurisdiction of the ABS Regulations, users must proactively prove that they have followed the duties of lawful access and utilisation. This may include internationally recognised certificates of compliance (recital 21), using recognised best practices developed by users (recital 24) or retrieving samples from a registered collection (recital 28).[247]

d. *Obligations for the member states with the example of Germany: art. 7 & 9*

While Regulation 511/2014 sets the EU-wide standards, article 6 requires each Member State to designate a 'competent authority' to enforce these rules in their jurisdiction.[248] The Federal Agency for Nature Conservation (BfN) remains responsible for implementation of due diligence obligations in Germany.[249] There are two instruments of oversight: formal compliance declarations by users (art. 7) and targeted enforcement checks by competent national authorities (art. 9).[250]

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[245] ibid art 4.
[246] ibid art 4(1).
[247] Regulation (EU) No 511/2014 of the European Parliament and of the Council on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union 2014 (OJ L) recitals 21, 24, 28.
[248] the EU ABS Regulation art 6(1).
[249] Greiber and Frederichs (n 239).
[250] the EU ABS Regulation arts 7, 9.

i. User declarations, article 7

Article 7 establishes the verification system for due diligence at two stages of the research and development chain – 'checkpoint 1' mandates users to file a declaration when a project receives funding (art 7(1)), and 'checkpoint 2' at the final stage of product development (art 7(2)).[251]

The declarations must identify the resource, the country of origin, and provide evidence of PIC, ideally through an Internationally Recognised Certificate of Compliance (IRCC).[252] These certificates are generated when Nagoya Protocol authorities upload the necessary permit information to the ABS Clearing-House, a global platform designed to facilitate information exchange.[253] IRCCs are essential in creating transparency as their content is standardised.[254] Germany has emerged as a European leader in this administrative process by contributing 10 of the first 17 checkpoint communiqués published on the ABS Clearing-House by 2019.[255] Article 4(5) establishes that if there is significant doubt regarding the legality of the access and a user cannot secure the necessary permits, they are legally mandated to discontinue utilisation or face domestic penalties.[256]

To reduce the administrative burden of compliance checks, the Regulation has established two simplifying mechanisms: (1) registered collections and (2) certificates of best practices. First, article 5 introduces 'registered collections'.[257] If a researcher obtains a genetic resource from one of these officially verified repositories, it serves as automatic proof that they have exercised proper due diligence.[258] Germany was the first EU Member State to utilise this system, with the Leibniz Institute DSMZ operating as the only registered collection in the entire Union for several years.[259] Second, article 8 allows industry associations to submit their own tailored sector standards (such as for pharmaceuticals). If the combination of 'procedures, tools or mechanisms' effectively fulfil obligations

[251] ibid art 7.
[252] ibid arts 4(3) & 7(2)(a).
[253] ibid para 26.
[254] Greiber and Frederichs (n 239).
[255] ibid.
[256] ibid 4(5).
[257] ibid 5.
[258] ibid.
[259] Greiber and Frederichs (n 239).

under articles 4 and 7, the European Commission officially recognises them as an approved 'best practice'.[260]

ii. Enforcements check by competent authorities, article 9

Article 9 gives competent authorities, in Germany's case the BfN, the mandate to conduct proactive audits to verify that users fulfil their due diligence obligations.[261] These checks may occur based on two different approaches. First, according to their risk-based plan (i.e. risk-based approach), the BfN has conducted targeted checks on eight main sectors in light of high-risk occurrence of violations based on the utilisation of genetic resources: pharma, cosmetics, biotech, food/feed, biocontrol, plant breeding, animal breeding, and academia.[262]

Second, checks may also occur based on 'substantiated concerns provided by third parties'.[263] These controls have a comparative advantage because they are based on specific evidence rather than a mere risk analysis, which, then, provides more concrete substance for the investigation.[264] For instance, by the end of 2019, the BfN had conducted checks based on substantiated concerns for three companies and one academic institution. In each of these cases, the BfN independently gathered the evidence that triggered the investigation.[265]

c) *Regulatory gaps and other challenges*

The way traditional knowledge is integrated into Western psychedelic science exposes some regulatory loopholes. This chapter identifies the four most notable gaps in the context of regulating psychedelic compounds and balancing benefits arising from their utilisation.

The first gap arises from pure technical aspects. As discussed in the previous chapter, companies like Compass Pathways and Atai Life Sciences do not harvest plants or fungi in their pure form. Instead,

[260] the EU ABS Regulation art 8.
[261] ibid 9(1).
[262] Greiber and Frederichs (n 239).
[263] the EU ABS Regulation art 9(3)(b).
[264] Greiber and Frederichs (n 239).
[265] ibid.

they rely entirely on lab-synthesised molecules for their clinical trials and patent pipelines. This shift to synthetic chemistry bypasses EU biopiracy protections. As section 2.3.4 of European Commission Guidance on Regulation (EU) No 511/2014 states, the definition of derivatives and biological systems 'does not cover material such as synthetic gene segments',[266] which is not explicitly mentioned in the Nagoya Protocol either.[267] Even if these companies utilise a microscopic trace of a natural reference strain to calibrate their testing equipment or benchmark their synthetic molecules, section 2.3.3.2. rules this out of scope as a mere 'testing or reference tool'.[268] The way genetic resources and utilisation is defined in the Regulation leads to a situation where big pharmaceutical companies' core clinical trials and entire drug pipelines are out of scope. This results in a system where the core of the modern psychedelic industry is legally exempt from sharing benefits with the Indigenous communities who preserved these medicines for centuries.

The second technical gap discussed in this chapter is the 'utilisation' trigger. Figure 4, taken from Gerd Winter's article 'The ABS Compliance Regime of the European Union', presents the duties discussed in this chapter in visual form. It identifies the 'basic duties of actors' at each stage of the R&D process. Winter points out that even though article 4(1) obliges users to share benefits fairly, the Regulation does not explicitly define 'subsequent applications and commercialisation' duties (e.g. patenting, marketing, selling products) nor does it explicitly require declarations for the actual act of commercialisation (i.e. not applicable under art 7).[269] The distinction between 'utilisation' and 'subsequent applications and commercialisation' between the EU compliance regime and the Nagoya Protocol is noteworthy. As mentioned in chapter 1.2.1, part a, article 5(1) of the Nagoya Protocol comprehensively covers all benefits arising from the 'utilisation' and, importantly, from 'subsequent applications and commercialisation'.[270] The article 3(5) of the EU Regulation, by contrast, limits

[266] European Commission, 'Guidance Document on the Scope of Application and Core Obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the Compliance Measures for Users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilisation in the Union' (2021) 13 OJ C 1, s 2.3.4 <https://ampeid.org/static/14a22af3d632ecc318a3d30620f25a26/CELEX_52021XC0112(02)_EN_TXT..pdf> accessed 15 May 2026.
[267] Nagoya Protocol.
[268] European Commission, 'European Commission Guidance on Regulation (EU) No 511/2014' (n 266) s 2.3.3.2.
[269] Gerd Winter, 'The ABS Compliance Regime of the European Union' in Evanson Chege Kamau (ed), *Global Transformations in the Use of Biodiversity for Research and Development*, vol 95 (Springer International Publishing 2022) ch 6.1 <https://doi.org/10.1007/978-3-030-88711-7_14> accessed 5 May 2026.
[270] 'Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity' (n 229) art 5.

utilisation strictly to research and development.[271] This legal distinction suggests a deliberate separation between R&D and eventual market commercialisation, which Winter argues, is 'hardly reasonable'.[272] Winter illustrates this through a potential loophole: a MAT agreement might permit product development while strictly forbidding its commercial sale. Because article 3(5) strictly defines 'utilisation' as limited to research and development, an actor who brings such a product to market would not be legally bound by the EU Regulation to respect that specific no-sale condition, which leaves the supervisory authority without the power to intervene under article 7.[273] This vulnerability was independently identified by the Berne Declaration and Natural Justice already in 2015, at the very outset of the Regulation's implementation.[274] The submission warned that declaring obligations only on 'users' without extending it to 'commercialisers' can cause challenges for compliance, particularly if the commercialisers are different from users.[275] Given that the biggest payments (i.e. royalties) usually come from sales rather than the research stage, this gap arguably prevents provider countries from getting a genuine fair share of the profits arising from their genetic resources and, possibly, associated traditional knowledge.[276]

Administrative oversight		Checks		Checks		Checks[a]	Checks[a]
Declarations		Due diligence declaration[b] about		Due diligence declaration[b] about			
		Access	Utilization	Access	Utilization		
Basic duties of actors	Compliance with access conditions	Compliance with		Compliance with utilization conditions		Compliance with conditions for applications and commercialization	Compliance with benefit sharing conditions
		Access conditions	Utilization conditions				
Activities	**Access**	**R&D**		**Final stage of product development**		**Subsequent applications and commercialization**	**Sharing of non-monetary and monetary benefits**
Actors	Researcher, intermediary (collections, brokers)	Researcher and developer		Researcher and developer		Researcher, developer, marketer	Researcher, developer, marketer

Figure 4: 'Basic duties and administrative oversight at various stages of access, utilisation and commercialisation of genetic resources' [277]

[271] the EU ABS Regulation art 3(5).
[272] Winter (n 269) 438.
[273] ibid.
[274] The Berne Declaration and Natural Justice, 'Comments on the Proposed Implementing Act on Regulation (EU) No 511/2014' (2015) <https://www.publiceye.ch/en/news/detail/comments-on-the-proposed-implementing-act-on-regulation-eu-no-511-2014> accessed 21 May 2026.
[275] ibid.
[276] Winter (n 269).
[277] ibid 423.

The third gap identifies a challenge in the enforcement of the Regulation. Statistics from the first five years following the 2014 implementation show that BfN had initiated compliance checks with 54 institutions (see figure 5), 50 of which were triggered by risk-based plan and the remaining 4 by substantiated concerns (see art 9).[278] Already 47 out of 54 cases were dismissed due to R&D activities of particular institutions falling out of the Regulation's jurisdiction.[279] The fact that temporal, material, and geographical criteria must all be satisfied simultaneously creates, as Greiber and Frederichs note, 'a plethora of options for institutions to find their way out of its scope'.[280] For instance, institutions may have declared their R&D activities as simple screening processes (i.e. outside material scope) or claimed that the genetic resources were accessed prior to the October 12, 2014 (i.e. outside temporal scope).[281] Section 3.2. of the EC Guidance further confirms that 'certified evidence of being out of scope of the Regulation will not be required when the authorities carry out checks on user compliance'.[282] As the burden of proof falls on competent authorities,[283] the BfN notes in the Member State Report that 'it is extremely difficult to provide solid evidence of an infringement' since 'most information depend on the willingness of users to cooperate'.[284] Therefore, the effectiveness of user compliance checks is hindered by the complexity of the regulatory scope itself.

N° of cases[a]	Reason for out of scope conclusions
11	Temporal scope (access before 12.10.2014)
5 3 21 6	Material scope – Genetic resource out of scope (human, synthetic, digital sequence information, cut-off) – Derivatives without connectivity – R&D without utilization (e.g. formulation, screening, contract research) – Innovation claimed/assumed but no R&D
5 7	Geographical scope – Not Party to Nagoya Protocol – No ABS legislation in place (or not applicable)

Figure 5: 'Summary of reasons for out-of-scope conclusions'[285]

[278] Greiber and Frederichs (n 239).
[279] ibid.
[280] ibid 534.
[281] ibid.
[282] European Commission, 'European Commission Guidance on Regulation (EU) No 511/2014' (n 266) s 3.2.
[283] Greiber and Frederichs (n 239).
[284] Federal Agency for Nature Conservation (Bundesamt für Naturschutz – BfN), 'Member States' Reporting on the Implementation of the EU ABS Regulation' 11 <https://circabc.europa.eu/ui/group/3f466d71-92a7-49eb-9c63-6cb0fadf29dc/library/25016d15-3664-412f-881e-2d9e93ef58b2/details> accessed 29 May 2026.
[285] Greiber and Frederichs (n 239) 535.

The fourth and final gap relates to a broader crisis of justice within the regulatory framework. As Winter points out, the EU Regulation focuses heavily on administrative compliance and the sustainable use of biological resources, but it ultimately omits the wider objectives explicitly mandated by article 1 of both the CBD and the Nagoya Protocol: technology transfer, capacity building, and appropriate funding.[286] Winter elaborates that the Regulation moves from distributive to commutative justice, which treats ABS as a bilateral business transaction and focuses on the immediate market value of resources.[287] This prioritisation on administrative compliance, however, often omits the distributive justice elements that acknowledge the unequal stage of global development.[288] True distributive justice would direct its focus on sharing science, research results, and long-term support.[289] Instead, the EU's main focus on verifying paperwork (i.e. compliance pillar of due diligence) rather than on access may hinder trust-building between the EU and the Global South. Greiber and Frederichs' observation further strengthens the argument by noting that the systemic focus means that if a provider country possesses weak domestic laws, the EU's due diligence obligations under article 4 may become a technical formality rather than a meaningful benefit-sharing agreement.[290]

3.2.2. EU Regulation 2015/2283 on Novel Foods

While commercial actors actively capitalise on the gaps between ABS frameworks and patent law, their strategies are also shaped by the specific market pathways available to these substances. In the EU, a substance cannot be a 'food' and a 'medicinal product' at the same time; when a product fulfils the criteria for both frameworks, pharmaceutical law takes priority.[291] While most of the commercialisation of psychedelics happen through the medicinal framework aiming for the therapeutic market, some products may also fall within the novel food jurisdiction if aiming for the wellness and supplement market.[292] The increasing prevalence of psychedelic truffles sold as mood-enhancing food supplements

[286] Winter (n 269); Nagoya Protocol art 1; Convention on Biological Diversity: Text and Annexes 2011 art 1.
[287] Winter (n 269).
[288] ibid.
[289] ibid.
[290] Greiber and Frederichs (n 239).
[291] *HLH Warenvertriebs GmbH (C-211/03) and Orthica BV (C-299/03 and C-316/03 to C-318/03) v Bundesrepublik Deutschland* [2005] ECJ Joined cases C-211/03, C-299/03, C-316/03 to C-318/03 [3].
[292] European Union Drugs Agency, 'Frequently Asked Questions (FAQ): Therapeutic Use of Psychedelic Substances' <https://www.euda.europa.eu/sites/default/files/pdf/32077_en.pdf?226163> accessed 3 June 2026; Tom Gallen, 'Psychedelic Truffles Sold As Supplements Under Scrutiny In Europe' (*Consumer Healthcare News & Insights*, 30 August 2024) <https://insights.citeline.com/RS155023/Psychedelic-Truffles-Sold-As-Supplements-Under-Scrutiny-In-Europe/>

is a growing concern to the European Food Safety Authority (EFSA).[293] Although no natural or synthetic psychedelic product has passed the European Medicine Agency (EMA) nor the EFSA,[294] there is an active grey market in Europe for psychedelic microdosing kits and functional mushroom supplements.[295]

According to the EU 2015/2283 Regulation, one of the criteria for a food to be labelled as 'novel' is the 'absence of use for human consumption to a significant degree within the Union' before 1997.[296] The relevant provisions in the context of edible psychedelic supplements are the definitions of 'food consisting of, isolated from or produced from microorganisms, fungi or algae',[297] 'food consisting of, isolated from or produced from cell culture or tissue culture derived from animals, plants, micro-organisms, fungi or algae',[298] and a 'history of safe food use in a third country'. The latter definition requires proof that the food's safety is confirmed from 'continued use for at least 25 years in the customary diet [...] in at least one third country'.[299] Because Indigenous use of psychedelic fungi is sacred and ritualistic rather than a part of an everyday 'customary diet', natural psychedelics face a notable legal wall when trying to enter the EU food market. Only the Netherlands have some legal ways to commercialise psilocybin-containing truffles.[300] Still, it seems that the strict regulation for novel foods pushes commercial actors away from natural resources. Instead, when companies opt for synthetic alternatives, they face way fewer, if any, real restrictions through the ABS regimes or patent law as discussed earlier. Choosing this alternative path and synthesising these compounds makes it much easier for companies to establish an economically reliable business.

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accessed 1 June 2026; Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (Text with EEA relevance) 2015 (OJ L).

[293] Gallen (n 292).

[294] European Union Drugs Agency (n 292).

[295] Gallen (n 292).

[296] Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001 (Text with EEA relevance) 2015 (OJ L) art 3.2(a).

[297] ibid art 3.2(a)(ii).

[298] ibid art 3.2(a)(vi).

[299] ibid art 3.2(b).

[300] Jan van Amsterdam, Antoon Opperhuizen and Wim van den Brink, 'Harm Potential of Magic Mushroom Use: A Review' (2011) 59 Regulatory Toxicology and Pharmacology 423 <https://doi.org/10.1016/j.yrtph.2011.01.006> accessed 3 June 2026.

3.2.3. Newest developments in the EU: Biotech Act 2025 & Pharma Package 2026

The following section discusses the most recent developments regarding biotechnology- and medicine-related legislation in the EU: the Biotech Act and the 2026 Pharma Reform. The combination of these two frameworks is highly relevant for this thesis because, while they are at different legislative stages, together they cover the entire life cycle of pharmaceuticals. The Biotech Act is a sector-specific framework that focuses on biotechnology innovations and dictates how upstream development unfolds through R&D conditions, clinical trials, AI-assisted screening, and market pathways.[301] The Pharma Package, in turn, focuses on the entire lifespan of medicines, including psychedelics, regulating downstream processes such as EMA authorisation, market access, and post-market surveillance within the Union.[302] Any psychedelic-assisted therapy would have to navigate this dual pathway to reach the European public.

To date, the Pharma Package is legally more consolidated than the Biotech Act. The EU Pharma Package has already entered its final adoption stage,[303] while the health-focused Biotech Act is still a proposal and undergoes negotiations between the European Parliament and the Council.[304] That said, according to the European Commission, both frameworks will eventually form a 'complementary' relationship to 'create appropriate conditions for biotechnology from the innovation stage'.[305] This is part of the Commission's broader life sciences strategy.[306] The analysis will first introduce the most relevant amendments of both documents and then synthesise their combined impact relevant to the research of this thesis.

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[301] European Commission, Proposal for a Regulation of the European Parliament and the Council on establishing a framework of measures for strengthening Union's biotechnology and biomanufacturing sectors particularly in the area of health and amending Regulations (EC) No 178/2002, (EC) No 1394/2007, (EU) No 536/2014, (EU) 2019/6, (EU) 2024/795 and (EU) 2024/1938 (European Biotech Act) 2025 (2025/0406 (COD) COM(2025) 1022 final).
[302] European Commission, Proposal for a Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006 2023 (2023/0131(COD) COM(2023) 193 final); European Commission, Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC 2023 [2023/0132(COD) COM(2023) 192 final].
[303] European Parliament, 'Revision of the EU Pharmaceutical Legislation' <https://www.europarl.europa.eu/legislative-train/carriage/revision-of-the-pharmaceutical-legislation/report?sid=10301> accessed 16 June 2026.
[304] European Parliament, 'European Biotech Act I (Health-Focused)' (*Legislative Train Schedule*, 20 April 2026) <https://www.europarl.europa.eu/legislative-train/theme-industry-research-and-energy-itre/file-european-biotech-act-i> accessed 29 May 2026.
[305] European Commission The Biotech Act 2025 (n 301) 7.
[306] ibid.

1. *European Biotech Act*

The biotechnology industry is moving fast, and Europe is no exception. In December 2025, the European Commission released a new proposal for a 'European Biotech Act' to strengthen the EU's biotechnology and biomanufacturing sectors, particularly in the healthcare domain.[307] The Act would, for instance, amend EU Regulation 536/2014 on clinical trials and introduces the concept of a 'high impact health biotechnology strategic project'.[308] The core objective is to maintain the Union's position as a 'biotechnology powerhouse' by boosting competitiveness, strategic autonomy, and economic security.[309] The emphasis on biotechnology is because, over the last decade, this industry has become one of the most economically productive industries with its growth rate being twice as fast as the overall EU economy.[310] Nonetheless, the Commission explicitly acknowledges that the EU underperforms compared to other global regions in commercialising its scientific and innovative outputs.[311]

The core concerns reflected in the new Proposal mirror the realities of the psychedelic business, as well. The two major European psychedelic-focused companies, Atai and Compass, both chose to list on the American stock exchange NASDAQ to access the capital required for large-scale clinical trials and final launch to the US market.[312] This is a reflection of the broader decline of commercially sponsored clinical trials in Europe, which went from 22% to 12% between 2013 and 2023.[313] To stop this development from unfolding any further, the EU has proposed some amendments to its previous Regulations.

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[307] European Commission The Biotech Act 2025 (n 301) see title.
[308] ibid 6, 26.
[309] ibid 1–2.
[310] ibid 1.
[311] ibid.
[312] Atai Life Sciences N.V., 'Form 424B4 Prospectus: Initial Public Offering' <https://www.sec.gov/Archives/edgar/data/1840904/000119312521195060/d39052d424b4.htm> accessed 22 May 2026; COMPASS Pathways plc, 'Form 424B4 Prospectus: Initial Public Offering of American Depositary Shares' (2020) <https://www.sec.gov/Archives/edgar/data/1816590/000162828020013779/compass424b4.htm> accessed 22 May 2026.
[313] European Commission The Biotech Act 2025 (n 301) 3.

a. Relevant legal amendments from the perspective of psychedelic science

This analysis identifies the three most relevant technical amendments of the Biotech Act 2025 in the context of the psychedelic industry. The first major amendment, described in paragraph 80, is the introduction of 'regulatory sandboxes', which serve as safe spaces for products at the early stage of development that do not fall within the scope of existing EU legislative acts in health.[314] This is particularly relevant for innovations that combine a psychoactive drug with psychotherapy and thus, do not directly fit the cell- or gene-based criteria of Advanced Therapy Medicinal Products (ATMPs), nor the structures governing standard small-molecule pharmaceuticals.[315] This amendment on regulatory sandboxes allows creators to explore and assess innovative technologies without major legislative hinderance or financial risk.[316]

Second, the Biotech Act also introduces fast-tracked approval pipelines to lower bureaucratic barriers and speed up commercialisation. The target for clinical trial authorisation is to go from 106 days to as few as 47, provided that there is no additional information needed for the sponsor.[317]

The last point concerns high-impact testing environments and the use of AI. Under article 32, the Biotech Act establishes testing environments specifically designed to leverage AI and advanced computational analytics.[318] Since AI can be used to accelerate drug discovery,[319] this may set the scene for companies to rely on article 54(5) EPC protection and screen for new indications for existing compounds that are already in the public domain, as elaborated previously in chapter 3.1. (c). Similar to the other two legal regimes, the Act does not regulate digital sequence information DSI, which forms the basis for modern psychedelic science. On the contrary, the Act functions as an accelerator to discover new compounds with the help of the newest high-performing AI tools and screening technology.[320]

[314] ibid para 80.
[315] ibid.
[316] ibid.
[317] ibid 27.
[318] ibid 96.
[319] Jerome Sarris and others, 'Artificial Intelligence and Psychedelic Medicine' [2024] Annals of the New York Academy of Sciences nyas.15229 <https://doi.org/10.1111/nyas.15229> accessed 22 May 2026.
[320] European Commission The Biotech Act 2025 (n 301) 96.

Crucially, from the perspective of this thesis, the Biotech Act completely omits any reference to Indigenous intellectual property or Access and Benefit-Sharing (ABS) compliance. By cutting clinical trial authorisation from 106 to 47 days, the time window for competent national authorities to flag non-compliance is cut nearly in half. Since due diligence checks stop at the final stage of product development, fast-tracked processes to minimise time-to-market make compliance checks even more difficult to perform. There is, consequently, a risk that with the new legal amendments, the commercial interest could further complicate ABS compliance.

b. Public interest

Even though the Biotech Act is mainly competition-driven, it simultaneously creates a highly favourable regulatory track for open-science, non-profit initiatives. That is, article 12(4) establishes that a project that is recognised as a 'health biotechnology strategic project' is legally classified as being in the 'public interest' and granted 'the highest national significance'.[321] To get this recognition, a project may have to fulfil the requirements of any of the five functional categories under Article 4(1), including the project being a centre of excellence for advanced therapies or contributing to the development of trusted testing environments for advanced biotechnology innovations.[322]

The recognition of 'strategic protect' status grants priority national funding and allows non-profit, open-science consortia to compete with big pharma. By speeding up approvals, the Act ensures that a group's regulatory speed no longer depends on owning a massive, exclusive patent portfolio.[323] In the traditional IP regime, when investors know that a company owns exclusive rights to a certain compound, they are more likely to invest and secure shares in the commercialisation process. Therefore, the Act weakens this dependency by replacing private venture capital with public funding and guaranteeing fast-track access.[324]

[321] The Biotech Act 2025 ch II, art 12(4).
[322] ibid II, art 4(1).
[323] European Commission, 'Proposal for a Regulation of the European Parliament and of the Council on Establishing a Framework of Measures for Strengthening Union's Biotechnology and Biomanufacturing Sectors (European Biotech Act)' <https://health.ec.europa.eu/document/download/ec1475b7-e3f9-409e-b927-fc7e69306a8c_en?filename=biotech_reg-com2025-1022_act_en.pdf> accessed 29 April 2026.
[324] European Commission The Biotech Act 2025 (n 301).

2. *European Pharma Reform 2026*

The EU 2026 Pharma Package is a 'comprehensive overhaul' of over a 20-year-old pharmaceutical legislation,[325] and is expected to enter into force in 2026.[326] The Package consists of two core frameworks: a Proposal for a Directive on the Union code relating to medicinal products for human use (COM(2023) 192)[327] and a Proposal for a Regulation laying down Union procedures for the authorisation and supervision of medicinal products (COM(2023) 193).[328] The Package forms part of the broader goal of increasing EU competitiveness and placing the EU 'at the forefront of pharmaceutical innovation'.[329] The legislative amendment comes also out of the necessity to ensure that medicines are available to patients regardless of which EU member state they are from.[330]

a) *Relevant legal amendments*

Similar to the Biotech Act, the Pharma Package introduces regulatory sandboxes for testing new approaches and shorter authorisation procedures by EMA, reducing time-to-market process from 210 to 180 days.[331] What is particularly interesting from the point of view of the psychedelic industry is the change in market exclusivity. Numerically, the finalised 2026 reform goes from a non-conditional 8+2(+1) years to a conditional 8+1(+1)+1 years of regulatory data and market protection, which prevents other companies from using the acquired data from R&D or other clinical trials.[332] Practically, what these metrics mean is that the new amendments would reduce the guaranteed baseline monopoly

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[325] European Medicines Agency, 'Reform of the EU Pharmaceutical Legislation' (15 January 2026) s Background <https://www.ema.europa.eu/en/about-us/what-we-do/reform-eu-pharmaceutical-legislation> accessed 16 June 2026.
[326] European Medicines Agency (n 325).
[327] European Commission Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use (n 302).
[328] European Commission Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use (n 302).
[329] European Commission, 'Commission Welcomes Political Agreement on Major Reform of EU Pharmaceutical Rules' (11 December 2025) para 5 <https://ec.europa.eu/commission/presscorner/detail/en/ip_25_3015> accessed 16 June 2026.
[330] European Commission Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use (n 302) s 1.
[331] European Commission. Directorate-General for Health and Food Safety, *Key Elements of the EU Pharmaceutical Reform* (Publications Office of the European Union 2025) <https://doi.org/10.2875/0439635> accessed 16 June 2026.
[332] Council of the European Union, Directive on the Union code relating to medicinal products for human use: Analysis of the final compromise text with a view to agreement 2026 (2023/0132 (COD)) art 81(2); Maarten Meulenbelt Melin Josefine Sommer, Dr Chris Boyle, Anne Robert, Alix Vermulst, Belinda Baum, Anna-Shari, 'EU Pharma Package: Compromise Text Published – Best Efforts Required (Part 2)' (*GoodLifeSci*, 18 May 2026) <https://goodlifesci.sidley.com/2026/05/18/eu-pharma-package-compromise-text-published-best-efforts-required-part-2/> accessed 16 June 2026.

period from the original 10 years, with the possibility to add one more year if significant clinical benefit is demonstrated, to 9 years.[333] These 9 years comprise 8 years of data protection and 1 year of market protection.[334] Any 12-month extension would need to fulfil one of the criteria under article 81(2), including addressing 'an unmet medical need' or conducting clinical trials with a new compound against an evidence-based comparator [rather than a placebo], and proving a 'significant clinical benefit in comparison with existing therapies'.[335]

These new conditions alter the corporate monopoly strategies by linking market protection to proven efficiency of the product. In the case of psychedelics, the condition under article 81(2) of yielding 'significant clinical benefit in comparison with existing therapies' could be highly probable, given the very promising results of these therapies.[336] Similarly, fulfilling the criterion of proving that psychedelic-assisted therapies function better than a 'comparator', like SSRI,[337] might be highly probable for the same reasons.

However, much like the Biotech Act, this pharmaceutical overhaul completely ignores Indigenous IP and ABS rules. This creates a practical problem: under current EU rules (EU Regulation 511/2014), the official check to see if a company ethically sourced its materials happens right when they apply for market approval. By cutting the EMA's review time from 210 down to 180 days, authorities have much less time to run these compliance checks. By prioritising fast market entry over ethical duties, the new rules let companies rush products to market before their origins can even be verified. This makes it incredibly difficult to enforce fair profit-sharing.

[333] Melin (n 332); European Commission Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use (n 302) art 81.
[334] Melin (n 332); European Commission Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use (n 302) art 81.
[335] Council of the European Union Directive on the Union code relating to medicinal products for human use: Analysis of the final compromise text with a view to agreement (n 332) art 81(2).
[336] Gukasyan and others (n 17); Krediet and others (n 18).
[337] Marks Mason and I Glenn Cohen, 'Patents on Psychedelics: The Next Legal Battlefront of Drug Development' (2022) 135 Harvard Law Review Forum 212, 214 <https://ir.law.fsu.edu/articles/736/> accessed 29 April 2026.

3. *Synthesis of Biotech Act and Pharma Reform*

In conclusion, the fact that the most comprehensive pharmaceutical reform in 20 years and a comprehensive biotechnology Act do not address Indigenous IP or ABS compliance in any way is a missed opportunity. Instead, even though both the Biotech Act and the final provisions of the Pharma Package are evolving, together they create pressure to speed up both the upstreaming and downstreaming processes within the EU. One of the clear drivers is boosting competitiveness. While these changes may be beneficial for the EU's standing in the global market, in light of previous analysis of EU 511/2014 Regulation, the deliberate lowering of bureaucratic barriers may exacerbate the backlog of administrative compliance checks. Regulation EU 511/2014 on ABS relies on specific due diligent triggers, one upon receiving research funding and another upon submitting a market authorisation application.

That said, both frameworks, particularly the Biotech Act, also push for cross-border, open-access research within the EU, which serves as a counterbalance to privately funded, for-profit research and development projects. Similarly, the Pharma Reform indicates that holding exclusive market rights has become considerably trickier. To maintain a prolonged corporate monopoly, developers can no longer rely on passive authorised timelines but must actively prove their product's value to the public good by demonstrating significant clinical superiority or addressing unmet medical needs.

3.3. Newest developments globally: WIPO GRATK Treaty 2024

The regulatory gaps identified in the previous frameworks created the urgency to increase legal consistency by aligning intellectual property law with biodiversity law.[338] On the 24th of May 2024, the WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge ('GRATK Treaty') was adapted. By targeting biopiracy concerns through mandatory patent disclosure requirements, the GRATK Treaty marks a 'historic milestone toward a more inclusive IP system'.[339]

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[338] World Intellectual Property Organization, *Intellectual Property and Genetic Resources, Traditional Knowledge and Traditional Cultural Expressions* (World Intellectual Property Organization 2020) 24 <https://www.wipo.int/edocs/pubdocs/en/wipo-pub-933-2020-en-intellectual-property-and-genetic-resources-traditional-knowledge-and-traditional-cultural-expressions.pdf> accessed 14 March 2026.
[339] Adekola (n 170) 3.

To contrast with the TRIPS Agreement which focuses on the rights of the patentee, the WIPO framework aims to focus on the rights of the provider of genetic resources. The core objectives laid down in article 1 are to 'promote efficacy, transparency and quality of the patent system' and 'prevent patent from being granted erroneously' in relation to genetic resources and traditional knowledge associated with genetic resources.[340] The Treaty historically combines the nature of an environmental and IP law regimes. Previously, only a handful of – mostly Global South – countries required such disclosures.[341] What is, however, worth mentioning is that the GRATK Treaty does not explicitly outline the elimination of biopiracy as one of its targets. Instead, it reaffirms the 'mutual advantage' that the IP system does in 'promoting innovation, transfer and dissemination of knowledge and economic development' between providers and users.[342] In this context, a provider country is legally defined as a nation that hosts genetic resources in *in situ* conditions, whereas a 'user country' typically refers to the jurisdiction where the technological or pharmaceutical modification and patenting of those resources take place.[343]

The Treaty requires 15 ratifications to become active. In March 2026, the Treaty had three ratifications from Albania, Malawi, and Uganda, and, therefore, currently serves as a framework rather than a solution.[344] Since the majority of signatories (i.e. 41 out of 44) are from the Global South, [345] the strength of the Treaty might be compromised purely for the lack of legal commitment by the biotechnology-heavy countries from the Global North.[346]

a) Scope: material scope (articles 2 & 3), temporal scope (article 4)

The material scope under article 3 encompasses all patent applications where the invention is claimed to be 'based on genetic resources' or 'based on traditional knowledge associated with genetic resources'.[347] Article 2 defines the requirement to be 'based on' as being 'necessary for the claimed

[340] WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge 2024 art 1.
[341] Adekola (n 170).
[342] GRATK Treaty para preamble.
[343] ibid art 2.
[344] WIPO Treaty on Intellectual Property, Genetic Resources and Associated Traditional Knowledge (Geneva 2024): Status on March 13, 2026 2026.
[345] ibid.
[346] Oguamanam (n 63).
[347] GRATK Treaty art 3(1-2).

invention' and the claimed invention must 'depend on specific properties'.[348] Furthermore, article 4 on non-retroactivity clarifies that the obligations of the Treaty do not apply to patents that have been filed prior to the entry into force of the GRATK Treaty.[349] Practically, this means that at this moment in June 2026, no patents fall within the scope, as the Treaty has not entered into force yet. Still, it provides valuable information about recent developments and possible foresight about patent policies.

b) Legal status and recognition of Indigenous Peoples

Historically, environmental treaties, such as the Nagoya Protocol, almost exclusively used the phrase 'Indigenous and Local Communities' to avoid the specific legal obligations associated with the term 'peoples'.[350] However, the 2024 GRATK Treaty adopts modern international standards by explicitly using 'Indigenous Peoples' and recognising the UN Declaration on the Rights of Indigenous Peoples (UNDRIP).[351] By doing so, the treaty aligns with UNDRIP definitions and recognises these communities as distinct subjects of international law who possess the right to self-determination.

Furthermore, article 10.1(c) establishes the 'effective participation of representatives from Indigenous Peoples and local communities as accredited observers', which signals an acknowledgement of the importance of Indigenous, legally guaranteed participation.[352]

c) Disclosure requirement

The core milestone of the newest Treaty is the obligatory disclosure requirement of inventions that are based on genetic resources and/or their associated traditional knowledge. While under normal circumstances, to obtain a patent, an applicant must explain how the invention works, with the new Treaty, the applicant would also have to disclose from where the genetic resources and/or traditional knowledge were obtained. If the origin is unknown, whatever other available resource must be

[348] ibid 2.
[349] ibid 4.
[350] Grand Council of the Crees (Eeyou Istchee) and others, 'Indigenous Peoples Are "Peoples" Draft COP Decision Violates Treaty Interpretation Rules' (Secretariat of the Convention on Biological Diversity 2014) Joint Submission to the Twelfth Meeting of the COP UNEP/CBD/COP/12/1 <https://quakerservice.ca/wp-content/uploads/2014/09/COP-12-IPs-are-Peoples-Draft-COP-Decision-Violates-Intl-Rules-GCCEI-Joint-Submission-FINAL-Sep-9-14.pdf> accessed 12 June 2026.
[351] Declaration on the Rights of Indigenous Peoples 2007 (UN Doc); GRATK Treaty preamble.
[352] GRATK Treaty art 10.1(c).

provided (such as a gene bank).[353] According to article 1(b), this prevents patents from being 'granted erroneously' for inventions that are not novel.[354]

d) Regulatory gaps and legal challenges

While the GRATK Treaty presents itself as a milestone for the efforts to harmonise environmental and intellectual property regimes, Oguamanam points out that the Treaty's legal strength is diluted by many pragmatic compromises between provider and non-provider countries.[355] This thesis identifies three major gaps.

First, the most notable criticism relates to the ambiguity of the Treaty's language, which, in turn, makes the scope blurry. Since 'traditional knowledge associated with genetic resources' is not precisely defined, patent offices and other enforcing bodies are left with a wide margin of discretion, which might exclude, for example, oral traditions and secret healing practices.[356] Furthermore, the fraught debate over the scope is also seen in the broader sense of the scope: although provider countries insisted that the Treaty covers all IP (e.g. trademarks, trade secrets), the final result was a narrower scope covering only patents.[357] Due to the narrow and unprecise scope, the Treaty seems to aim for an administrative fix in terms of 'erroneous patent grants' instead of reaching a higher social justice.

Second, the question of patent revocation sparked another geopolitical battle between provider and user countries. Indeed, the provider countries strived for a model where patents would get revoked, should an applicant lie about the origin of the source.[358] Ultimately, the final compromise heavily favoured user nations: Article 5.3 of the GRATK Treaty states that 'no Contracting Party shall revoke, invalidate, or render unenforceable the conferred patent rights solely on the basis of an applicant's failure to disclose the information specified in Article 3 of this Treaty'.[359] In other words, once a patent is granted, it cannot be stripped away retrospectively 'solely' because the inventor's failed to disclose

[353] ibid 3.1.
[354] ibid 1(b).
[355] Oguamanam (n 63).
[356] Adekola (n 170).
[357] Oguamanam (n 63).
[358] ibid.
[359] GRATK Treaty art 5.3.

the underlying genetic resource or traditional knowledge.[360] While article 5.4 does provide permit revocation in circumstances where 'fraudulent intent' is proven,[361] Oguamanam notes that defining and sanctioning such intent is bound to trigger an 'interpretative conundrum'.[362] In short, because the Treaty makes it almost impossible to take a patent away, it lacks any real legal teeth to enforce compliance.

Lastly, similar to other environmental and IP treaties, the GRATK Treaty does not explicitly address the issue of digital sequence information (DSI).[363] While article 8 commits to a scope review within four years to evaluate 'derivatives and […] other issues arising from new and emerging technologies',[364] a narrow interpretation of the current text limits the treaty's application strictly to physical biological samples.[365] This illustrates the slow international harmonising between provider and user countries' DSI policies. A megadiverse country, Brazil, for instance, has regulated genetic information 'even if disengaged from the physical sample' since its foundational legal framework on ABS in 2000.[366]

All things considered, while the GRATK Treaty represents a historic attempt to intertwine biodiversity and intellectual property regimes, its practical power is severely compromised. Significant legal gaps combined with a low ratification rate threatens to weaken the overall power to combat non-compliance. Rather than providing an immediate remedy for biopiracy concerns, the Treaty functions, in the words of Native American Rights Fund, as a 'modest but significant step' to ensure longer-term reform.[367]

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[360] Adekola (n 170).
[361] GRATK Treaty art 5.4.
[362] Oguamanam (n 63) 360.
[363] Adekola (n 170).
[364] GRATK Treaty art 8.
[365] Adekola (n 170); GRATK Treaty art 3.1.
[366] Convention on Biological Diversity, 'Compilation of Views and Information on Digital Sequence Information on Genetic Resources Submitted Pursuant to Paragraphs 9 and 10 of Decision 14/20' (2020) CBD/DSI/AHTEG/2020/1/INF/1 <https://ampeid.org/documents/argentina/compilation-of-views-and-information-on-digital-sequence-information-on-genetic-resources/> accessed 3 June 2026.
[367] Chidi Oguamanam, 'WIPO Diplomatic Conference on Genetic Resources and Associated Traditional Knowledge: Delegates Set a Positive Tone in the Early Days' (*CHIDI OGUAMANAM*, 15 May 2024) para 5 <https://www.oguamanam.com/publications/wipo-diplomatic-conference-positive-tone-in-the-early-days> accessed 3 June 2026.

DISCUSSION

The thesis has evaluated the strengths and legal gaps in the context of protecting Indigenous medicinal knowledge in Europe through the European Patent Convention; in the European Union through the EU 511/2014 Regulation under the Nagoya Protocol, the EU 2015/2283 Regulation on Novel Foods, as well as the latest Pharma Reform 2026 and a proposal of the EU Biotech Act 2025, and; globally through the WIPO 2024 GRATK Treaty.

The discussion chapter first, synthesises the discussed legal regimes and identifies the main regulatory gaps in protecting Indigenous intellectual sovereignty. Second, it discusses the implications for Indigenous self-determination and the risk of cultural extinction. Lastly, the thesis offers realistic policy proposals to better protect genetic resources and associated traditional knowledge.

a) Main regulatory gaps in the European and global legal regimes

The evaluation of the different legal regimes has made clear that the legal regimes geared toward the needs of biotech-rich countries do not meet the needs of biodiversity-rich countries. This disparity is evident both in negotiation processes and the 2024 statistical data discussed in Chapter 2, where Northern America, Europe, and Asia accounted for 97% of patent applications, while Africa, Latin America, and Oceania had only 3%.[368] The way patent applications are distributed around the globe demonstrates that the intellectual property regime does not operate on an even, neutral basis. Because of this very disparity, scholars like OseiTutu argue that it is not enough to have a blind IP regime, but distributive justice to prevent economic exclusion of the Global South.[369] Instead of maintaining separate frameworks operating outside the legal regimes of IP and trade, it is necessary to have binding obligations integrated directly into core patent and intellectual property frameworks. The structural separation of these two legal regimes inherently creates systemic gaps that allow corporate incentives to override global health imperatives

This study found that the way Western IP regime operates in the global arena in reality reflects very biased objectives. Under the TRIPS Agreement and its regional siblings like the European Patent

[368] World Intellectual Property Organization, 'World Intellectual Property Indicators 2025' (n 67).
[369] OseiTutu (n 73).

Convention, the patent system is inherently geared to advance individualistic, corporate commercial interests under the guise of reducing 'distortions and impediments to international trade' across 'all fields of technology'.[370] Definitions, such as who can be an inventor, what counts as an invention, what is strictly regulated, and what is in the public domain reflects a Western understanding of inventions being a contemporary one that can be pinpointed on a timeline and that is attributable to an identifiable person.[371] This strict framework is practically incapable to accommodate Indigenous innovation, which is characteristically collective, intergenerational, and evolutionary. This study puts forward that the main commodification process happens through the 'further medical use' under article 54(5) of EPC. Furthermore, there is no ethical obligation to acknowledge the providing country, and even though a moral clause exists, its very strict jurisprudential interpretation practically bars challengers with spiritual or biopiracy claims.[372]

Given this Western inclination to prioritise a predictable and stable global market, the choice of enforcement mechanisms within the EU for the protection of traditional knowledge and genetic resources reflects a broader trend. That is, a common choice, as demonstrated by the EU 511/2014 Regulation, appears to be a series of administrative checks rather than substantive legal changes. While users are technically required to submit due diligence declarations when an R&D project 'utilises' genetic resources and associated traditional knowledge,[373] enforcement relies heavily on corporate self-regulation and voluntary compliance. As the German Federal Agency for Nature Conservation (BfN) notes, the power of the Regulation is structurally undermined because 'there is often not enough public information on users of genetic resources'.[374] Consequently, the Regulation provides an opportunity for ethically minded companies to formalise their compliance, while permitting indifferent actors to operate with relative impunity. In the words of the BfN: 'only institutions compliant with the Regulation will submit a due diligence declaration as otherwise they would reveal their non-compliance themselves'.[375] This basis, accompanied by the fact that the 'subsequent commercialisation' is not explicitly covered, leaves a huge gap in terms of genuine profit-sharing of an invention. Lastly, because

[370] TRIPS 320; European Patent Office, 'European Patent Convention' (n 175) art 52(1).
[371] European Patent Office, 'European Patent Convention' (n 175) art 52(1), 58, 60.
[372] ibid 53(a); *T 2510/18 (Simalikalactone E)* (n 211).
[373] ibid art 4.
[374] Federal Agency for Nature Conservation (Bundesamt für Naturschutz – BfN), 'Member States' Reporting on the Implementation of the EU ABS Regulation (Germany)' 7 <https://circabc.europa.eu/ui/group/3f466d71-92a7-49eb-9c63-6cb0fadf29dc/library/25016d15-3664-412f-881e-2d9e93ef58b2/details> accessed 5 May 2026.
[375] ibid 8.

the Nagoya Protocol failed to mandate explicit patent disclosure mechanisms or link compliance to patent validity,[376] the EU opted for a soft approach on patents. Compliance enforcement is completely separated from the patent-granting process, like the German case illustrates. While national patent offices grant exclusive monopolies with relative autonomy, separate and under-resourced competent authorities, such as the BfN, are left to conduct belated compliance audits.[377] Therefore, the way the EU has decided to enforce the Nagoya Protocol by, for example, delaying compliance checks to the final market-entry phase, enables IP rights protection long before any ethical oversight occurs.[378]

Rather than aiming to rectify some of these asymmetries, recent European legislative trajectories signal the opposite development. The newly proposed Biotech Act 2025 promises an intensification of market-driven deregulation. The Act prioritises industrial competitiveness in biotechnology by fast-tracking pathways to market and explicitly incentivising the deployment of high-performing Artificial Intelligence (AI) screening tools and digital sequencing technologies.[379] Due to the rapid digitalisation and automation of genetic data extraction, this pending framework threatens to outpace the legal protection mechanism for traditional knowledge. The technological speed also highlights why synthetic psilocybin and other synthetic derivatives fall through regulatory gaps. The EU ABS framework is only triggered when a physical biological resource is used. That is why using digital sequence information (DSI) instead allows companies to synthesise the compound and skip any benefit-sharing obligations. The Biotech Act and the Pharma Reform, however, also show indications of a more public-interest-oriented approach: Biotech Act's focus on health introduces high priority categories for national funding if the project, for example, involves cross-border cooperation to 'ensure the integration of research, innovation, and training'.[380] Likewise, the Pharma Package introduces stricter conditions to maintain market monopoly; without proven efficacy of the product – which is measured in, among other criteria, solving unmet medical needs – the baseline protection does not continue. These people-focused provisions do not, however, solve the issue of unregulated DSIs from the point of view of protecting Indigenous intellectual rights.

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[376] World Intellectual Property Organization, 'The Protection of Traditional Knowledge: Updated Draft Gap Analysis (WIPO/GRTKF/IC/47/8)' <https://www.wipo.int/edocs/mdocs/tk/en/wipo_grtkf_ic_47/wipo_grtkf_ic_47_8.pdf> accessed 28 April 2026; Nagoya Protocol.
[377] the EU ABS Regulation; Federal Agency for Nature Conservation (Bundesamt für Naturschutz – BfN) (n 374).
[378] the EU ABS Regulation art 7.
[379] European Commission The Biotech Act 2025 (n 301) 96.
[380] ibid II, art 5(1)(e).

Lastly, on the global stage, the newly concluded WIPO 2024 GRATK Treaty represents a historic diplomatic effort to close some of the most pressing gaps. Yet, it primarily functions to harmonise existing legal baselines rather than introducing any transformative paradigm of absolute protection. Ironically, with the effort to harmonise the global protection mechanism, the WIPO Treaty creates a catch-22 effect on some Global South countries such as India, Brazil, and China as well as progressive Northern nations like Switzerland, that already have passed their own domestic laws and linked patent validity to genetic and traditional knowledge compliance.[381] This dilemma stems directly from the 'no reservations' clause under Article 20 in the GRATK Treaty, meaning that countries with stronger protection mechanisms cannot opt out of Article 5.3 (prohibiting patent revocations). Consequently, these nations are placed in an all-or-nothing situation. On one hand, if they join the Treaty and agree to harmonise their legal system according to the newest standard, they would, practically, have to weaken their own domestic laws by removing the revocation penalty. On the other hand, if they do not join, they may end up in a situation in which they cannot demand other countries respect traditional knowledge and resources in their corresponding national offices.[382] None of the options are particularly favourable.

b) Implications for Indigenous self-determination and the risk of cultural extinction

Current European efforts to protect Indigenous rights fall short. The concern is not only about administrative backlogs or legal technicalities. It is about how the current IP system functions to facilitate the secularisation of Indigenous cultural heritage and weaken their self-determination. According to the International Covenant on Civil and Political Rights (ICCPR) and the International Covenant on Economic, Social and Cultural Rights (ICESCR), self-determination is defined as peoples' right to 'freely pursue their economic, social and cultural development'.[383]

Firstly, when looking at the economic aspect of self-determination, the current IP model is structured to benefit industrialised, biotechnology-rich countries, while forcing developing, biodiverse countries to harmonise their domestic system to align with the global standard.[384] Since 97% of patents are

[381] Oguamanam (n 63).
[382] ibid.
[383] International Covenant on Economic, Social and Cultural Rights 1966 (UNTS) art 1; International Covenant on Civil and Political Rights 1966 (UNTS) art 1.
[384] TRIPS 320.

concentrated to the Global North and parts of Asia,[385] when a developing country strengthens its patent laws, it is effectively ensuring that money flows out of its country in the form of royalties to foreign corporations.[386] Yet, this imbalance is sold as an equal business partnership. By assuming equal footing in the global economy,[387] the EU opts out of any provisions that would guarantee capacity building, technology transfer and funding of biodiversity projects in exchange for accessing genetic resources and associated traditional knowledge.[388] Furthermore, because traditional knowledge is likely classified into the public domain,[389] it is treated as free raw material for Western companies. The resulting biotechnological outputs are, nevertheless, fiercely guarded by Western IP rights. This dynamic illustrates a broader mechanism in which advanced economies use international legal frameworks to consolidate their competitive advantage.

This phenomenon aligns closely with the historical critique identified and described by economists like Friedrich List. His 'infant industry theory', as analysed in Emblemsvåg's article, argues that nascent industries need additional protection in the form of, for example, tariffs, subsidies, and intellectual property rights (e.g. patents), until they are strong enough to compete in the global market.[390] The theory further argues that free trade is only beneficial between states that are at the same industrial level.[391] The double standard arises from industrialised nations' policies to impose the kind of standards on the Global South that they themselves did not fulfil when they were at similar levels of development. This has been captured in a famous phrase by List:

'It is a very common clever device that when anyone has attained the summit of greatness, he kicks away the ladder by which he has climbed up, in order to deprive others of the means of climbing up after him.'[392]

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[385] OseiTutu (n 73).
[386] Maskus (n 65).
[387] Winter (n 269).
[388] ibid; Nagoya Protocol art 1; Convention on Biological Diversity art 1.
[389] OseiTutu (n 73) 191.
[390] Friedrich List, *The National System of Political Economy* (Longmans, Green and CompanyLondon 1885), cited in Jan Emblemsvåg, 'Kicking Away the Ladder: Development Strategy in Historical Perspective' (2005) 13 On the Horizon 186 <https://doi.org/10.1108/10748120510618222> accessed 5 June 2026.
[391] Ibid.
[392] List (n 201), quoted in Emblemsvåg (n 201) 1.

By 'kicking away the ladder', wealthy nations and institutions like the EU create a situation where the legal mechanisms that are required for economic self-determination remain out of reach for Global South countries where a significant number of Indigenous peoples live. Yet, the EU has built its economic strength through the exact same mechanism described in List's theory. Particularly, the creation of the Customs Union in 1958 gradually removed tariffs for European member states, while the Common External Tariff (CET) made sure that countries outside this circle, such as the United States, did not interfere with this collective infant industry project.[393] Currently, the EU has developed into a strong economic power that enforces strict intellectual property rights as well as complex environmental and technical standards.[394] Due to its market power, the EU is able to unilaterally set global regulatory standards – referred to as the 'Brussels effect'.[395]

Admittedly, economic development at the state level in regions like Latin America does not automatically guarantee the economic autonomy of Indigenous communities themselves. However, as long as the current international IP regimes perpetuate these asymmetric power dynamics between the Global North and South, developing nations are structurally restricted from enacting fairer domestic laws that could protect and empower these communities. By enforcing a strict, highly developed Westernised IP model under the guise of an 'equal business partnership', the Global North prevents Indigenous communities and their corresponding states from pursuing their economic development on their own terms, as clearly guaranteed by the ICCPR and ICESCR.[396] Instead of providing capacity building, technology transfer or funding, biodiverse countries are forced onto an uneven playing field where their traditional knowledge is extracted for the most part as a free resource, while the tools to protect it are designed for Western interest. The hypocrisy of, then, calling these countries 'free riders' speaks about the narrative that Western countries have clung onto to justify kicking away the ladder of development. It frames the West's historically protectionist strategy and the subsequent economic dominance as the natural outcome of a free market, while penalising nations in the Global South for trying to do the same.

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[393] Marc Ouin, 'The Establishment of the Customs Union' *American Enterprise in the European Common Market: A Legal Profile*, vol 1 (University of Michigan Law School 1960) <https://repository.law.umich.edu/cgi/viewcontent.cgi?filename=5&article=1002&context=michigan_legal_studies&type=additional> accessed 7 June 2026.
[394] Anu Bradford, *The Brussels Effect*, vol 107 (Northwestern University Law Review 2012) <https://papers.ssrn.com/sol3/Delivery.cfm?abstractid=2770634> accessed 7 June 2026.
[395] ibid.
[396] ICESCR art 1; ICCPR art 1.

Second, the exposure of traditional knowledge to the global marketplace also compromises the second pillar of self-determination: free 'social and cultural development'.[397] Because the EU's due diligence rules are weak and passive, they have created a highly profitable wellness and biomedical market that exploits Indigenous knowledge. The toll of this phenomenon is not only measured in piles of dollar bills. The economic pressure pushes Indigenous communities to compromise on their long-established cultural traditions for economic survival. This internal damage is described by the Union of Indigenous Yagé Doctors of the Colombian Amazon (UMIYAC).[398] In their declaration that condemns the commercialisation of their sacred medicine, they warn that the 'new extractive business' ruins environmental sustainability and creates 'monetary traps reminiscent of the drug trafficking economy'.[399] Just as the commercialisation of sacred coca leaves historically channelled profits to Western corporations while trapping local communities,[400] the commodification of ayahuascaína threatens the right to self-determination from both outside and inside. While Western countries capitalise on a new market niche of psychedelic therapies, local communities face internal pressure to secularise and standardise ancestral practices for commercial consumption. Ultimately, the responsibility lies on the Western business model that enables this process to unfold. The UMIYAC Council goes as far as to urge for individual responsibility as well, stating that when the international public consumes services relating to psychedelics, they unknowingly participate in the appropriation of traditions that 'interfere with [the Indigenous] path to self-determination'.[401]

c) Policy proposals

The last part of the discussion proposes some realistic mechanisms to better protect Indigenous knowledge in the unfolding 'psychedelic renaissance'. This thesis' proposed mechanism is a hybrid model, which includes a reformed patent framework as well as a mandatory sui generis register for traditional medicinal knowledge and a benefit-sharing framework arising from the use of DSI. Lastly, it

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[397] ICESCR art 1; ICCPR art 1.
[398] Tabea Casique Coronado and others, 'Declaration about Cultural Appropriation from the Spiritual Authorities, Representatives and Indigenous Organizations of the Amazon Region' (*UMIYAC*, 1 November 2019) <https://umiyac.org/2019/11/01/declaration-about-cultural-appropriation-from-the-spiritual-authorities-representatives-and-indigenous-organizations-of-the-amazon-region/?lang=en> accessed 9 April 2026.
[399] ibid 7.
[400] Gerald T McLaughlin, 'Cocaine: The History and Regulation of a Dangerous Drug' (1973) 58 Cornell Law Review <https://scholarship.law.cornell.edu/cgi/viewcontent.cgi?article=3892&context=clr> accessed 5 June 2026.
[401] Casique Coronado and others (n 398) para 9.

discusses the 'open access' model to redirect the course of pharmaceutical innovations and private profit.

i) Integration of access and benefit-sharing compliance into patent frameworks

A central systemic gap in the current regime is the separation between compliance on ABS under EU Regulation 511/2014 and the substantive requirements of European patent law under the EPC. To resolve this, the reformed patent framework (i.e. EPC) would directly condition patent eligibility on ABS compliance. The reformed procedure would require that any application involving genetic resources and associated traditional knowledge must include verified Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT). Precedents for such integration already exist within EPC member states. The Swiss national law applies a notably stricter approach to patent law by requiring a formal declaration of source within the patent application itself.[402]

Additionally, this proposed reform would introduce a specific shift in the burden of proof. Instead of requiring national competent authorities to investigate and verify whether an applicant's materials fall within the temporal and material scope of ABS obligations, the applicant would bear the burden of proving either valid compliance or the legal absence of such an obligation. Although the EU cannot impose its own standards on EPC which is a multilateral treaty, the EU member states can draw inspiration from its own environmental frameworks as a reference. Council Regulation (EC) No 338/97 on wildlife trade establishes a permit system where the applicant must actively prove the origin and age of materials before market access is granted.[403] Compared to the passive due-diligence standards of Regulation 511/2014 enforcing the Nagoya Protocol, this model imposes significantly stricter requirements on businesses. By integrating a similar architecture into the patent system, the EPO would set a general ban on genetic resources and associated traditional knowledge, unless the patent includes verified compliance.

[402] World Intellectual Property Organization, *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge* (2nd edn, World Intellectual Property Organization 2020) <https://www.wipo.int/edocs/pubdocs/en/wipo_pub_1047_19.pdf> accessed 27 April 2026.
[403] Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein 1996 (OJ L) 1, art 8.

ii) Database for traditional medicinal products

The other part of the suggested hybrid model is a mandatory sui generis register for medicinal knowledge, which is currently optional under article 6 of the recent GRATK Treaty.[404] The primary advantage of such a register would be the automatic identification of traditional knowledge by patent examiners and the elimination of any reliance on voluntary corporate compliance.[405] This mechanism would be based on whether a patent is truly 'new' (i.e. does not incorporate Indigenous psychedelic use from the public domain) without needing to rely on cumbersome administrative checks of ABS law.[406] Under article 6.2, such databases would be created in direct cooperation with Indigenous Peoples and local communities, and the access to such information system would be subject to authorisation.[407]

This type of sui generis protection is fully operational in India and partially integrated within the European Union. Following a number of biopiracy cases, India started collecting information on over 130 thousand traditional medicinal products and published them in a database.[408] The European Patent Office partnered with India to access this botanical database. The success of this model is exemplified in the neem oil case: although the patent remained valid in the United States, the European Union revoked it due to lack of novelty.[409] In order for biodiverse countries to spare millions of euros fighting biopiracy cases, a comprehensive database of traditional plants and their uses ought to be established. Overall, by 2020, India has successfully revoked 222 patents thanks to the prior art data registry.[410] As Mason and Cohen note, there are also digital libraries, like Porta Sophia, directly dedicated to psychedelic science, assisting innovators and patent examiners by actively identifying psychedelic prior art.[411]

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[404] GRATK Treaty art 6.
[405] Oguamanam (n 63).
[406] World Intellectual Property Organization, *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge* (n 402).
[407] GRATK Treaty art 6.2.
[408] Karoll (n 21).
[409] ibid.
[410] World Intellectual Property Organization, *Key Questions on Patent Disclosure Requirements for Genetic Resources and Traditional Knowledge* (n 402).
[411] Mason and Cohen (n 337); 'Porta Sophia: Psychedelic Prior Art Library' (*Porta Sophia*) <https://www.portasophia.org/> accessed 7 June 2026.

iii) Benefit-sharing arising from the use of digital sequence information (DSI)

As discussed in the previous chapter, one of the most pressing modern challenges in the pharmaceutical field is genetic data used to create new products without requiring a physical sample. According to Global Policy Watch, this phenomenon has become such a critical issue that it is foreseen that a 'new Nagoya Protocol' is looming on the horizon solely for DSI.[412] Therefore, to reflect the realities of modern synthetic biology, this thesis strongly encourages operationalising, alongside a biological registry, a digital sequence information (DSI) registry. A notable milestone was reached in 2024 when COP16 Decision 16/2 established the Cali Fund[413] – a multilateral benefit-sharing tool for the users of nature's genetic data.[414] The agreed contribution would be either 1% of annual profit or 0,1% of annual revenue, independent of direct or indirect use.[415] 'At least 50%' of these funds would go directly to Indigenous Peoples and Local Communities.[416] While COP17 is tasked with detailing the exact implementation mechanism,[417] there are already indicative criteria for the distribution of funds, including biodiversity richness at a national level, the geographical origin of the genetic resources from which the DSI was derived, and a demonstrated need for capacity building for the conservation and sustainable use of biodiversity.[418]

Xu points out that linking the Cali Fund to the most recent WIPO GRATK Treaty remains to be legally and practically difficult.[419] Because the Cali Fund is governed by the CBD and Nagoya Protocol, while the GRATK Treaty operates under WIPO with no authorisation to manage financial assets, there is no

[412] Bart Van Vooren Bertrand Yuliya Gevrenova, Zoé, 'The Nagoya Protocol at Its 10th Anniversary: Lessons Learned and New Challenges from 'Access and Benefit-Sharing'' (*Global Policy Watch*, 16 October 2024) <https://www.globalpolicywatch.com/2024/10/the-nagoya-protocol-at-its-10th-anniversary-lessons-learned-and-new-challenges-from-access-and-benefit-sharing/> accessed 21 May 2026.
[413] Conference of the Parties to the Convention on Biological Diversity, 'Digital Sequence Information on Genetic Resources: Decision / Adopted by the Conference of the Parties to the Convention on Biological Diversity on 1 November 2024' <https://digitallibrary.un.org/record/4079091?v=pdf> accessed 9 June 2026.
[414] Secretariat of the Convention on Biological Diversity, United Nations Environment Programme and United Nations Development Programme, 'Guide to the Cali Fund: Sharing the Benefits of Genetic Data from Nature' (Secretariat of the Convention on Biological Diversity 2025) <https://www.cbd.int/dsi-gr/califund.guide.pdf> accessed 9 June 2026.
[415] Conference of the Parties to the Convention on Biological Diversit, 'Digital Sequence Information on Genetic Resources: Decision / Adopted by the Conference of the Parties to the Convention on Biological Diversity on 1 November 2024' Annex 3 <https://digitallibrary.un.org/record/4079091?v=pdf> accessed 9 June 2026.
[416] Secretariat of the Convention on Biological Diversity, United Nations Environment Programme and United Nations Development Programme (n 414) 5.
[417] Conference of the Parties to the Convention on Biological Diversity (n 413) Annex 4.
[418] ibid Enclosure II.
[419] Shuwen Xu, 'The 2024 WIPO Treaty on Genetic Resources: Dawn of a New Day?' (2026) 62 Stanford Journal of International Law (SJIL) 78 <https://law.stanford.edu/publications/the-2024-wipo-treaty-on-genetic-resources-dawn-of-a-new-day/> accessed 4 May 2026.

legal mechanism to tie disclosures under the GRATK Treaty to benefit-sharing obligations under the Cali Fund.[420] Any alignment between the two frameworks would have to rely on voluntary cooperation or non-binding soft law agreements.[421] Furthermore, IP-heavy countries are already sceptical about contributions to the Cali Fund, making them even less likely to support linking it to an entirely separate treaty.[422]

As an alternative solution, a mechanism similar to the biological registries discussed above could be utilised: the DSI registry could operate in tandem with an updated EU patent system. Under this framework, a mandatory disclosure of origin statement within a patent application would automatically trigger the user's benefit-sharing obligations via the registry.

Ultimately, the aim of this policy proposal is to spark conversation about potential solutions, as the current pace of technological advancement is already outpacing the legal protection of traditional knowledge – particularly where DSI is concerned.

iv) Open science framework

With reference to the HIV/AIDS case and the historical inflexibility of the TRIPS Agreement to adapt to the needs of the wider public,[423] the question arises as to whether patenting potentially life-saving treatments is correct or even moral. Scholars like Mason and Cohen argue that 'strong arguments can be made for prohibiting patents on psychedelics'.[424] This is due to the failure of patents to truly 'incentivise significant innovation' capable of addressing the worsening mental health pandemic.[425] Mason and Cohen argue that it is not only the vast potential of psychedelics to offer solutions to the mental health crisis, but also their deep connection to Indigenous knowledge that makes the case against the monopolisation of such substances much stronger.[426] This notion is also reflected in the latest COP16 Decision, which acknowledges the 'vital role of open access to [DSI] in scientific

[420] ibid.
[421] ibid.
[422] ibid.
[423] *Pharmaceutical Manufacturers' Association* (n 69).
[424] Mason and Cohen (n 337) 234.
[425] ibid.
[426] Marks Mason and I Glenn Cohen, 'Patents on Psychedelics: The Next Legal Battlefront of Drug Development' (2022) 135 Harvard Law Review Forum 212 <https://ir.law.fsu.edu/articles/736/> accessed 29 April 2026.

research and sustainable development',[427] and in the Guide to the Cali Fund, which lays out support for open-access information as a means of 'catalysing scientific research and innovation' due to its 'instrumental [value] in scientific breakthroughs'.[428] Even though a total ban on patents involving psychoactive elements would be an extreme solution, fostering an open, collaborative scientific culture could pave a new way forward, prioritising public health over patent profits.

This public-interest framework is already being operationalised to an extent by pioneering EU-funded initiatives such as the PsyPal Consortium and PSY-NET (COST [European Cooperation in Science & Technology] Action CA24130). The former is the first multi-site clinical study into psychedelic therapy to receive EU research and innovation funds.[429] It outlines six 'work packages' that include, but are not limited to, standardising psilocybin therapy, providing ongoing training, and ensuring that project activities and results are 'widely communicated' by using 'public-facing online platforms'.[430] The latter project, PSY-NET, involves six working groups focusing on, among other objectives, developing new molecules, establishing safety profiles, coordinating multicentre clinical trials and treatment protocols, creating open access platforms and standardising data collection.[431] By operating across multiple EU member states, harmonising clinical and scientific standards, and establishing open-access data-sharing frameworks,[432] these initiatives offer a necessary counterbalance to a purely 'for profit', market-driven mindset. Instead of patenting health-related innovations to enforce market exclusivity, the effect of EU-backed public funding and priority recognition may act as a needed remedy for uneven patient access.[433]

Indeed, the PsyPal Consortium's 2026 guidance paper explicitly warns that because 'companies often serve as key intermediaries between scientific research and regulatory systems', there is a concern that 'EU researchers, funders, and patients may contribute significantly to global clinical development

[427] Conference of the Parties to the Convention on Biological Diversity (n 225).
[428] Secretariat of the Convention on Biological Diversity, United Nations Environment Programme and United Nations Development Programme (n 414) 5.
[429] Le Forsonney and others (n 28).
[430] 'About PsyPal' (*Psypal*, 2026) <https://palliativeprojects.eu/psypal/about-psypal/> accessed 24 May 2026.
[431] 'PSY-NET Action Officially Launched: A New Era for Psychedelic Research in Europe' (*PSY-NET*, 30 October 2025) <https://psy-net.eu/psy-net-action-officially-launched-a-new-era-for-psychedelic-research-in-europe/> accessed 29 April 2026.
[432] 'COST Action CA24130 Psychedelic Renaissance: Turn on, Tune in and Drop in (PSY-NET)' <https://e-services.cost.eu/files/domain_files/CA/Action_CA24130/mou/CA24130-e.pdf> accessed 25 May 2026; 'About PsyPal' (n 430).
[433] Le Forsonney and others (n 28).

without gaining equitable access to resulting therapies'.[434] This 'open science' approach aligns with the third Sustainable Development Goal on the Right to Health,[435] and prioritises the public's right to access affordable medicines over a corporation's right to maximise profit.

[434] ibid 40.
[435] Department of Economic and Social Affairs, 'Goal 3: Ensure Healthy Lives and Propome Well-Being for All at All Ages' <https://sdgs.un.org/goals/goal3> accessed 10 June 2026.

CONCLUSION

This thesis has aimed to investigate the extent to which the commercialisation of psychedelics and psychedelic-assisted therapies in the Western pharmaceutical sector exploits the regulatory gaps between international ABS frameworks (Nagoya / EU 511/2014) and European patent law (EPC). The analysis also covers most recent legal and policy developments in the field, including the WIPO GRATK Treaty, the EU Biotech Act, and the EU Pharma Reform. The second research question aimed to investigate the cultural implications of such commodification in Indigenous communities. The thesis concludes that the current European patent system through EPC provides insufficient protection for Indigenous intellectual sovereignty. Article 54(5) creates the main structural opening for pharmaceutical companies to commodify genetic resources for 'further medical use', largely because Indigenous knowledge is not comprehensively registered in Western databases to demonstrate prior art. Neither does the Convention provide protection under the morality clause 53(a) since it is aimed at extreme bioethical harms, such as human-animal chimeras, and does not cover the circumstances of how the product was discovered.

This legal base coupled with an administration-oriented, passive ABS mechanism through the EU 511/2014 Regulation further erodes the protective base for Indigenous knowledge and benefit sharing. The EU's choice not to explicitly include 'subsequent applications and commercialisation' on the use of genetic material and to place the burden of proof on competent authorities reflects a lenient implementation of the benefit-sharing model. Furthermore, the EU's proposal of the Biotech Act signals high motivation to accelerate biotechnological innovation through high-performing technology. This development places a spotlight on DSI, which are currently underregulated or excluded across relevant frameworks, including the Nagoya Protocol, the EU 511/2014 Regulation, and the WIPO GRATK Treaty. However, rule 27 of the Implementing Regulation to the EPC deems isolated biological material patentable 'even if it previously occurred in nature'.

These regulatory gaps are all part of a broader structural imbalance, exemplified by the high patent filings from the Global North and parts of Asia, compared to minimal activity from Africa, Latin America and Oceania. By forcing a strict, Western-style intellectual property system onto biodiverse nations under the label of an 'equal business partnership', the Global North directly undermines both the sovereign development of these nations and Indigenous peoples' right to self-determination. This

setup completely ignores the actual developmental and capacity-building needs of developing states as well as the rights of Indigenous peoples living within them. Unlike earlier when patents were used by pre-industrialised countries to catch up with technologically more advanced countries, nowadays they are used as instruments to prevent technology transfer. The current IP regime pulls Indigenous communities into economic traps and incentivises them to secularise and standardise their ancestral traditions to fit commercial consumption. While the West sees another market niche for a chemical product, Indigenous peoples experience deep spiritual disrespect. Commercialising these medicines tears them away from their living plant relatives and the interconnected ontological web they belong to.

To alleviate the effect of some the most pressing gaps, this thesis has puts forward the following four proposals. First, following the example of Switzerland, the patent system would be reformed from within by establishing an obligatory disclosure mechanism of genetic resources within the patent application. The reform would also shift the burden of proof to the applicant who would actively need to prove the origin and age of materials – instead of the national competent authority. Second, the thesis proposes a mandatory sui generis register for medicinal knowledge which would function as a defensive mechanism through the collection of Indigenous and traditional medicinal practices and, consequently, the identification of prior art. The third proposal focuses on the issue of the extensive use of DSI without any benefit-sharing. It suggests operationalising the use of the Cali Fund which would establish a fixed contribution for the use of DSI and its subsequent profit. Lastly, this thesis proposed the strengthening of open, collaborative science which would place higher priority on equitable access to resulting therapies and medicines instead of private profit.

The thesis acknowledges the three following limitations. First, with the analytical focus being primarily on the European legislative landscape, this thesis faces clear geographical and jurisdictional limitations. The findings evaluate European frameworks and may not be directly applicable to other major legal systems, such as the United States, or the domestic laws of Latin American nations where many provider communities of psychedelic knowledge are located. Second, regarding the inclusion of Indigenous voices, the scope of this study is textually and regionally bounded. Given the prominent role of Amazonian and Mesoamerican plant medicines in the current commercial psychedelic market, the analysis relies heavily on the perspectives and position papers of Latin American and North American Indigenous communities. Consequently, the findings may not fully reflect the distinct legal, political, and cosmological positions of Indigenous peoples in other regions, such as Africa, Asia or

Oceania. Lastly, the thesis acknowledges a temporal limitation due to the rapidly evolving legal and technological landscape with the example of the ongoing negotiations surrounding the EU Pharma Reform and the proposed Biotech Act 2025. Therefore, the analysis only reflects the regulatory developments up to early 2026, meaning that future legislative shifts may alter the long-term relevance of the results presented in this study. At the same time, since the legal landscape is evolving in real time, this study encourages future researchers to apply a human rights lens to the development and subsequent commercialisation of psychedelic-assisted therapies. Doing so is essential to shift the conversation away from corporate profit and toward a more sustainable, ethically grounded approach to science.

Reforming the intellectual property regime and strengthening benefit-sharing frameworks is vital to ensure that the 'psychedelic renaissance' does not continue on the path of colonial extraction. Protecting traditional knowledge is more than just rectifying historical wrongs or distributing financial gains. To celebrate the past two decades of scientific progress as a 'renaissance' ignores the ladder of Indigenous medicinal know-how that Western medicine climbed to achieve its breakthroughs. It is now the West's turn to return the favour by helping build the economic and legal structures that are needed to safeguard Indigenous intellectual sovereignty and planetary biodiversity. Only when we stop exploiting the very communities that have protected these medicines for centuries, can we truly call this era a renaissance.

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