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Ethical Concerns about Psilocybin Intellectual Property

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ABSTRACT: Since a 1957 exposé in Life Magazine, chemical compounds derived from Psilocybe mushrooms have been the focus of dozens of attempted and successful patents, most recently to treat depression. Regrettably, the Mazatec indigenous communities who stewarded these traditional medicines for millenia are not party to any of these patents, despite a number of international treaties asserting indigenous rights to their intangible cultural heritage.



KEYWORDS: psilocybin; magic mushrooms, indigenous rights, intellectual property, Maria Sabina, Wasson, patents

In 1957, Life magazine published one of the most impactful articles in modern history about psychedelics. "Seeking the magic mushroom" was written by a former J.P. Morgan banker named R. Gordon Wasson. Within two years of the story's publishing, psilocin and psilocybin, the main active compounds in the mushrooms, were isolated, characterized, synthesized and named by Swiss chemist Albert Hofmann at the Sandoz pharmaceutical company. Sandoz quickly patented the extraction procedure and a method for "therapeutic tranquilization", marketing pills under the trade name Indocybin.²

Six decades later, North-American and European businessmen disproportionately reap financial gain from psychedelics. In October 2020, one of the first pharmaceutical companies focused on developing psilocybin for the treatment of depression went public, and has a current market value of approximately \$1.5 billion.³ According to the World Health Organization, depression affects 264 million people worldwide,⁴ and is a leading cause of disability in the 21st century. This constitutes a market which can surpass 200 billion dollars in the USA alone.⁵ Therefore, with a neoliberal lens, developments with psilocybin are considered significant advances involving ethnopharmacology, chemistry, psychopharmacology, toxicology, psychology, and psychiatry.

From an indigenous perspective, psilocybin research and drug development tells a story of extraction, cultural appropriation, bioprospecting, and colonization. In Life Magazine's article, R. Gordon Wasson wrote of his expeditions to Oaxaca, Mexico, seeking the sacred rites and mushrooms of the Mazatec people, and learning from a curandera he initially protected with the pseudonym, Eva Mendez. Eva Mendez guided Wasson on the sacred veladas, in exchange for Wasson's

promise of secrecy, including a promise to never publish photos. However, Wasson ultimately betrayed his promise and revealed his teacher's identity, curandera Maria Sabina, in his second volume: Mushrooms, Russia and History. He also widely published and publicized her photographs, thus constituting further betrayal. After Wasson's visit to Huautla de Jimenez, conflict ensued; Maria Sabina was briefly jailed and her house was set on fire. Details of the story vary according to different accounts, 6-9 but these sacred Mazatec rituals were well hidden for centuries. Many indigenous spiritual practices were brutally persecuted and banned during the Spanish inquisition and conquest; thousands were slaughtered. That these rituals survived the events between the inquisition to Wasson's first visit reveals their strong resilience; for the Mazatec, these mushrooms and traditions are still sacred and the last healing resource as a medicine (Figure 1).

Less than a month after Wasson's article on May 13th, 1957, the Governing Body of the International Labour Office convened in Geneva, on June 5th, 1957, to establish the Indigenous and Tribal Populations Convention No 107. As Mexico adhered on June 01 of 1959, the convention cannot be applied retroactively to the Wasson case. In 1989 this convention was renamed to Indigenous and Tribal Peoples

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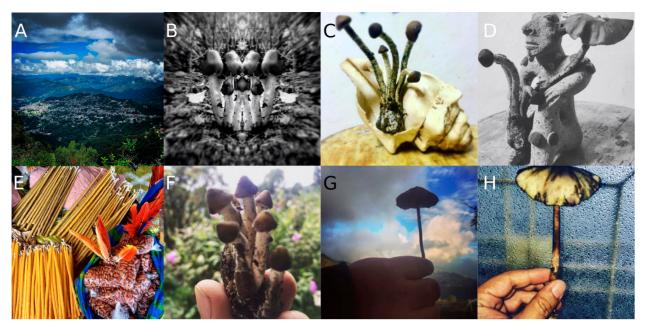


Figure 1. Town of Huautla de Jiménez in Oaxaca and some key cultural elements in the Mazatec mushroom culture. (A) Huautla de Jiménez, Naxin Nanda Tejao. (People of deer, water and eagle). (B) Ndi xijto (little things that sprout, landslides). (C) Ndi xijto (little things that sprout, landslides). (D) Ndi xijto (little things that sprout, landslides). (E) Candles, cacao, and macaw feathers; some elements used in healing Mazatec rituals. (F), (G), and (H) Ndi xijto (little things that sprout, landslides). Photos by Inti Gracia Flores.

Convention of the International Labour Organization 169. According to its preamble: "in many parts of the world these peoples are unable to enjoy their fundamental human rights to the same degree as the rest of the population of the States within which they live, and that their laws, values, customs and perspectives have often been eroded". The same convention determined that "the social, cultural, religious and spiritual values and practices of these peoples shall be recognized and protected" (Article 5a) and that "governments shall consult the peoples concerned, through appropriate procedures and in particular through their representative institutions, whenever consideration is being given to legislative or administrative measures which may affect them directly" (Article 6a).

In 1992, 150 world leaders signed the United Nations Convention for Biological Diversity (CBD) in Rio de Janeiro, which directs the signatory States, through national legislation, to "respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices" (Article 8j). The CBD was followed by other agreements such as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000) and Nagoya Protocol on Access to Genetic Resources (2010).

These developments culminated in the Convention for the Safeguarding of the Intangible Cultural Heritage 2003 of the United Nations Educational, Scientific and Cultural Organization (UNESCO). According to its preamble, it was recognized that "in particular indigenous communities, groups and, in some cases, individuals, play an important role in the production, safeguarding, maintenance and re-creation of the intangible cultural heritage, thus helping to enrich cultural diversity and human creativity". Intangible cultural heritage was defined

as "the practices, representations, expressions, knowledge, skills—as well as the instruments, objects, artefacts and cultural spaces associated therewith—that communities, groups and, in some cases, individuals recognize as part of their cultural heritage" (Article 2.1). In 2007, the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP) was adopted by a majority of 144 states in favor and 4 votes against which were later reversed, establishing that "indigenous peoples have the right to practise and revitalize their cultural traditions and customs", including "the right to maintain, protect and develop the past, present and future manifestations of their cultures, such as archaeological and historical sites, artefacts, designs, ceremonies, technologies and visual and performing arts and literature" (Article 11.1) determining that "States shall provide redress through effective mechanisms, which may include restitution, developed in conjunction with indigenous peoples, with respect to their cultural, intellectual, religious and spiritual property taken without their free, prior and informed consent or in violation of their laws, traditions and customs" (Article 11.2).

These advancements imply that traditional knowledge is not an open access unregulated market. 10 Indigenous people have the right to protect, preserve, and develop their traditional practices and medicinal knowledge, and are entitled to benefit from developments based on their intangible cultural heritage, including their spiritual practices. According to these treaties and regulations, bioprospecting must include previous informed consent of the communities involved. Most laws on the matter were developed as a consequence of the CBD, now one of the international treaties with the highest number of signatories in history. However, there are still a series of important issues pending and ongoing debates on how to best achieve just and fair consultations and agreements, respecting ethical, epistemological, and ecological concerns, and how to properly share the benefits in the case of private properties of pharmaceutical corporations based on cumulative collective knowledge of indigenous peoples. 10,11

Table 1. Past and Current Psilocybin Patents^a

owner/assignee	patent/pub. no.	title	priority date (yyyy-mm-dd)	status	general subject matter
University of Padova, IRB Barcelona	WO2020181194A1	compositions and methods of use comprising substances with neural plasticity actions administered at nonpsychedelic/psychotomimetic dosages and formulations	2019-03-07	published	microdosing with structural analogues of psilocin, norpsilocin, psilocybin, baeocystin, norbaeocystin, DOI, DMT, LSD, and ibogaine
Diamond Therapeu- tics	WO2020157569A1	methods and compositions comprising a 5ht receptor agonist for the treatment of psychological, cognitive, behavioral, and/or mood disorders	2019-01-30	published	treating a neurological condition by administration of a serotonin receptor agonist, including psilocybin
Apollo Neuroscience	US20200215297A1	systems and methods of mitigating negative effects of therapies with transcutaneous vibration	2019-01-04	pending in US	transcutaneous vibratory simulation during psilocybinassisted psychotherapy
Yale University and U.S. Dept. of Veterans Affairs	WO2020041329A1	combination therapy for treating or preventing depression or other mood diseases	2018-08-20	published	treating a mood disorder, by administration of compositions including psilocybin
Robert Petcavich	WO2019246532A1	method of inducing dendritic and synaptic genesis in neurodegenerative chronic diseases	2018-06-21	published	treating neurodegenerative disease by administration of a psychedelic, including psilocybin
VTT Technical Research Centre of Finland	WO2019180309A1	heterologous production of psilocybin	2018-03-19	published	biosynthetic production of psilocybin from host cell
Akili Interactive	WO2019161050A1	cognitive platform including computerized elements coupled with a therapy for mood disorder	2018-02-18	published	computer systems for psychedelic-assisted psychotherapy
CaaMTech	US20190142851A1	compositions comprising a psilocybin derivative and a cannabinoid	2017-11-16	pending in US	purified psilocybin derivatives combined with a cannabinoid
Eleusis	WO2019079742A8	methods and systems for enhancing safety of psychedelic drug therapies	2017-10-19	published	screening a candidate for treatment with psychedelic agent, including psilocybin
Compass Pathways	US20200199161A1	preparation of psilocybin, different polymorphic forms, intermediates, formulations and their use	2017-10-09	pending in US	oral dosage forms of crystalline psilocybin in the form polymorph ${\bf A}$
Compass Pathways	US10519175B2	preparation of psilocybin, different polymorphic forms, intermediates, formulations and their use	2017-10-09	granted 2019-12-31 (ex- pires 2038-10-09)	treating drug resistant depression with crystalline psilocybin in the form polymorph A
Eleusis	US20200147038A1	assessing and treating psychedelic-responsive subjects	2017-04-20	pending in US	improving mental or physical well-being by administration of a psychedelic, including psilocybin
CaaMTech	US20180221396A1	compositions and methods comprising a psilocybin derivative	2017-02-09	pending in US	purified psilocybin derivatives, some together with cannabinoids and terpenes, for treatment of psycho- logical disorders
Procare Beheer	US10729706B2	psilocybin and/or psilocin in combination with cannabinoids and/or terpenes	2017-01-18	granted 2020-08-04	treating a psychological disorder by administration of psilocybin together with a cannabinoid and/or a terpene
Joseph Rustick	US10596378B2	method for treatment of depression using synaptic pathway training	2016-10-18	granted 2020-03-24 (expires 2038-06-07)	treating a neurologic condition by synaptic pathway training, including by administration of psilocybin
Insectergy LLC	US10738268B2	cannabis nanoemulsion methods	2016-08-21	granted 2020-08-11 (ex- pires 2036-11-01)	cannabis oil nanoemulsions with various compounds including psilocybin
Paul Stamets	US20190192498A1	psilocybin compositions	2016-07-23	pending in US	compositions of psilocybin, niacin, and mushroom or cannabis extracts, and their use to treat neurological or mental health disorders
Paul Stamets	US20190105313A1	psilocybin compositions	2016-07-23	pending in US	compositions of psilocybin, niacin, and mushroom or cannabis extracts, and their use to treat neurological or mental health disorders
Paul Stamets	US20180021326A1	compositions and methods for enhancing neuroregeneration and cognition by combining mushroom extracts containing active ingredients psilocin or psilocybin with erinacines or hericenones enhanced with niacin	2016-07-23	abandoned	compositions of psilocybin, niacin, and mushroom or cannabis extracts, and their use to improve neurological health

Table 1. continued

owner/assignee	patent/pub. no.	title	priority date (yyyy-mm-dd)	status	general subject matter
Emory University Galenea Corp	US20120108510A1 US20120159656A1	methods of improving behavioral therapies compositions and methods for evaluating cognitive defects	2010-05-20 2009-04-24	abandoned abandoned	psychedelic-assisted psychotherapy using psilocybin to identify a candidate therapeutic agent for treatment of a cognitive deficit
Koninklijke DSM N. V. (formerly Microbia Inc.)	US7229784B2	modulation of secondary metabolite production by zinc binuclear cluster proteins	2000-09-19	granted 2007-06-12 (ex- pires 2023-06-05)	improving yield of fungal metabolites in bioengineered cells, including psilocybin
Sandoz Sandoz	US3192111A US3183172A	method of inducing therapeutic tranquilization with psilocybin and psilocin obtaining psilocybin and psilocin from fungal material	1959-02-16 1958-02-21	expired expired	using psilocybin and psilocin to induce tranquilization extracting psilocybin and psilocin from fungal material

²Source: https://psilocybinalpha.com/data/psilocybin-patent-tracker. (accessed Oct 14th, 2020)

Researching psilocybin is configuring a bioprospecting project resulting in the pharmaceutical industry pursuing innovation through intellectual property rights with no plans for reciprocity with or compensation for the indigenous communities who have protected these traditional mushroom practices for millennia. Thus, it is critical to reconsider the neoliberal pharmaceutical approach, including basic science to clinical science, and the implications of its stated goals. In the case of psilocybin, for which there are now at least 24 registered patent processes (Table 1), no pharmaceutical psilocybin developers have reached any legitimate or reciprocal agreements with the Mazatecs, or any other indigenous communities.

Some important considerations are warranted, especially regarding the many species of mushrooms now identified in the genus Psilocybe and the issue of spirituality. The mushrooms Wasson brought out of Huautla de Jimenez are the basis of the current commodification of psilocybin; they were identified as Psilocybe mexicana, but hundreds of others are now known, some which can even be cultivated indoors. Yet, despite some of these being native and endemic to Europe, for example, Psilocybe semilanceata, reported centuries ago as intoxicating or poisonous, there is little to no evidence of interest in their medical properties in western scientific literature before Wasson's historical account, thus corroborating the sine qua non role of the Mazatec in all further psilocybin developments. For the Mazatec, the mushrooms are primarily used as medicine, to treat sick people, although in a context and worldview which can be characterized as spiritual by western scholars. And although western science tends to dismiss or disregard spiritual issues in drug development, some of the most important psilocybin studies to date focus exactly on the spirituality domain. Even neuroscientific studies reveal correlations between spiritual or mystical experiences with treatment outcomes in depression. 12

Developments in psilocybin science and research are intimately intertwined with the Mazatec intangible cultural heritage, raising concerns about harms caused by intellectual property regimes. As the biodiversity regime can be applied to patents in the future, but not retroactively to isolated psilocybin patents obtained by Sandoz Ltd. in 1965, the question is how to protect and develop traditional medicine ceremonies in a way that serves indigenous communities? Why is the so-called psychedelic renaissance, including commodification, almost exclusively benefiting nonindigenous Western businessmen? Is there any restitution or reparation to be done in this case?

Raids and extractive activities continue to this day in the Mazatec land. Mycologists, biologists, speleologists, and scientists descend upon the Mazatec community, without asking for permission from or adequately explaining their research to the community. Some researchers claim they received permission and have protocols to specifically work with the indigenous communities, but it is not clear what kind of permission was requested or from whom it was received. Instead, a Mazatec communitary protocol could be developed in order to consent with the researchers on the biocultural heritage. The racialized and colonial western mindset contributes to Westerners' ongoing delegitimization of indigenous community-held knowledge. Westerners consciously or subconsciously racialize and demean the Mazatec as the "noble savage." Western scientists and researchers tell Mazatec chojta chijne (wisdom bearers) that they in fact are

naming the mushrooms incorrectly, and that they do not know the range of their local mushrooms.

Depression is considered a disorder based in a series of social determinants, many of which can be dramatically exacerbated by colonial and extractive enterprises. Notably, studies about depression cite causes including grief, loss of significant personal relationships in communities, loneliness, stress and past history of abuse, physically, mentally, and emotionally. Bioprospecting and biopiracy often cause conflicts, tensions, disconnection, poverty, and suffering in the communities from which the knowledge and tradition originate. This suffering tracks onto our understanding of how one's social and cultural environment can affect mental health. In other words, nonconsensual extractive for-profit ventures based on intellectual property regimes can cause intergenerational distress and suffering in impacted indigenous communities in a way that could actively perpetuate mental illness, while cutting them off from rightful benefits derived from their intangible cultural heritages. As depression both perpetuates and emerges from socio-economic barriers, so the idea of its treatment being extracted from highly traumatized populations to benefit the current healthcare economy indicates an ethical oversight on the part of most western scientists and researchers. The motivations behind a highly profitable business selling psilocybin as a panacea for this century forces us to ask: will this treatment really be affordable to all social stratum, or only for a privileged part of society?

Aiming for justice, the Mazatec must benefit for their centuries-long stewardship of these sacred rituals and knowledge. Since these Mazatec rituals became public in 1957, no one has sought reparation or reciprocity with the communities in a fair manner. This implies extraction in all aspects and meanings, including abuse of the Mazatec people's hospitality.

As the third decade of the 21st century unfolds, the survival of indigenous peoples and our natural world is gravely threatened at an unprecedented level by construction, mining, logging, and energy "development programs" for the benefit of shareholder driven corporations. When the intellectual "property" derived from naturally occurring compounds is the prior art of indigenous people, we are obliged to explore the ethics of shareholders reaping the financial benefit from these compounds. Reflecting on these ethical dilemmas may offer frameworks to understand and solve for the ongoing harm of extractive economics, and perhaps even point the way toward reciprocal and reparative arrangements with indigenous stewards of medicines and molecules around the world.

ASSOCIATED CONTENT

Supporting Information

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This article in the Mazatec language (DOCX)

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K.G., I.G.C., I.A., N.L.G. and E.E.S. wrote the article. A.C.R. contributed to specific points and translated back and forth between English and Spanish to allow participation of I.G.F.

Note

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