The John M. Rezendes Ethics Essay Competition

MAPPING THE MORAL GEOGRAPHY: INDIGENOUS RIGHTS AND PHARMACEUTICAL EXPLORATION

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The importance of natural products in the development of new pharmaceutical compounds cannot be overstated. Researchers, such as Tyler (1994), Laird and Wynberg (2008), and Firn (2002), point to low corporate R&D expenditures for bioprospecting – the practice of searching for new bioactive compounds in natural sources (see Firn 2002) – and conclude that synthetic techniques have eclipsed nature as a source for new drugs. Nonetheless, 50% of all new small-molecule (i.e., non-peptide) drugs licensed between 1998 and 2002 were developed from natural sources (Newman et al. 2008: 117). In fact, many drugs, such as pilocarpine, an anti-glaucoma treatment; and paclitaxel, an anti-cancer drug, are still too complicated to be generated by modern synthetic chemistry and thus must be harvested from nature either wholly or as precursors (ibid., Susman 2000).

Critics nonetheless rightly point out the low degrees of success apparently endemic to bioprospecting ventures. Firn (2002) cites the National Cancer Institute's (NCI) natural products screening program: of 18,000 extracts screened for anticancer activity, only 1% produced a positive result. In order to increase this success rate, pharmaceutical companies and academic researchers turn to people who have long dwelt in areas of high biodiversity and who have developed medicinal uses for a wide range of species. The practice of using this so-called "traditional knowledge" or TK (see Sheridan 2005, Greer and Harvey 2004) to advance Western medicine is hardly new; it stretches back to the "discovery" of quinine by Spanish missionaries (Newman et al. 2008: 124) and has lately led to the development of influential drugs such as pilocarpine, developed from the Brazilian plant *Pilocarpus jaborandi* (Newman et al. 2008: 127); the drugs albuterol, salmeterol, and isoproterenol, all derived from the plant genus *Ephedra*, a staple of Chinese traditional medicine (Chivian and Bernstein 2008); and prostratin, a new weapon against HIV sourced originally from Samoa (Millum 2010).

Using traditional knowledge can improve the success rate of a bioprospecting venture enormously, which translates into much lower costs for the pharmaceutical company, presumably the reason for Firn's (2002) confusion. Farnsworth (1994) estimates that, on average, 1 in every 10,000 synthetic molecules tested against a molecular target (i.e., a chemical marker specific to a disease agent) will eventually become a drug, and that sampling plants randomly will lower that ratio to approximately 1 success in 8000. But in Crouch et al.'s (2006: 356) survey of 300 ethnomedicinal plant taxa for anti-malarial activity, an astounding 49% showed promise, with the intent to produce one to two new drugs.

Often samples are gathered and new drugs developed without considering the rights or interests of the indigenous communities who open their lands and cultures to foreign bioprospectors. Although currently ethical and legal standards for the treatment of indigenous cultures in the development of new products conflict, there still exist multiple lines of inquiry that can guide a company's researches in indigenous societies. In this essay, I establish indigenous cultures as legitimate interests in the process of drug development through the creation of a framework that incorporates elements of their own moral and ethical systems. Furthermore, I show how biopiracy – the result of violating that ethical framework – fails to adhere to our own ethical standards, refuting Jim Chen's (2006) assertion that “there is no such thing as biopiracy, and it's a good thing, too” (see publication title).

Although Chen (2006) proposes his definition of biopiracy flippantly, calling it a “script,” even his critics, such as Robinson (2010) accept it. As Chen (2006: 2-3) would have it, biopiracy is when:

> <Large northern corporation> <seeks / is developing> a highly sophisticated <plant variety / pharmaceutical product> and sends researchers to <exotic place>. After interviewing local <farmers / foragers>, the company's researchers identify a <species / variety / breed> of <life form> that seems responsible for <desirable trait>. The researchers collect a few [specimens] and collate their interviews. The samples and

> the local lore inspire a successful program of <cross-breeding / genetic engineering / pharmaceutical development>, which saves the company thousands of hours and enables it to eclipse its competition. The company never shares its profits, however, with the local community from which it derived genetic resources and traditional knowledge.

However, while the question of compensation is undoubtedly what drives the biopiracy debate, I reject this definition as excessively narrow. Instead, the question of who has the right to exploit genetic and biological resources should be defined in terms of the concerns of two parties: those who possess the biotechnology capable of making such resources marketable, and those for whom the biological material constitutes a component of what Mathewson (2004) termed a "moral geography." As he describes it, a moral geography is "both the actual and symbolic terrain upon which traditional societies elaborate their customary livelihood and belief systems, and the cognate spaces in which they defend these practices and perceptions" (11-12). This concept provides the basis for understanding and applying indigenous systems of ethics for the treatment of that biological resource.

One well documented indigenous moral geography is that of the Māori of New Zealand. Any plant or other biological resource that the Māori use is classified as *taonga*, or treasure (Lord 2010). *Taonga* is not simply important physically ("this plant is part of my livelihood"), but, as Māori researcher Aroha Mead (1994) explains, it is also important metaphysically ("this plant is part of my way of life and is sacred to me"). Thus, the concept of *taonga* enfolds three things: the physical organism or material derived from the organism itself, the cultural significance of the organism, and the knowledge of that organism's properties and applications. This importance has already been recognized in international law: the 1840 Treaty of Waitangi, signed between Great Britain and a coalition of Māori *iwi* (tribes) establishes a precedent relating to the proper disposition of *taonga*: in exchange for becoming British subjects, the Māori received affirmation of their right to sovereignty over

their traditional lands and, in the Māori version of the document, their *taonga* (Lord 2010). As a consequence, modern researchers interested in studying Māori *taonga*, such as flax (*Phormium* spp.), must receive permission from the local *iwi* and are often apprenticed a member of that *iwi* who has responsibility for that *taonga*, such as a flax weaver (ibid.).

Although it would be just as dangerous to generalize using this example as it would be to use our own ethical assumptions, in practice, many disputes over biopiracy involve an indigenous perspective that resembles that of the Māori – they view the appropriation of their sacred plants and medicinal knowledge as the theft of real property. For example, in the Amazon, a British biochemist spent years among the Wapishana people studying their use of *cunani*, a plant that possesses chemicals lethal to fish but harmless to humans in addition to other ethnomedicinal plant species (Greer and Harvey 2004). He returned home and embarked on a drug exploration program which resulted in multiple patents, outraging the Wapishana:

> When Wapishana chiefs heard what the biochemist had done, they accused him of stealing the knowledge of their ancestors and elders in order to sell it to pharmaceutical companies. As one Wapishana woman put it, 'This knowledge has always been with the Wapishana. It's part of our heritage and now it is being taken from us without any payment.' (Greer and Harvey 2004: 103)

This incident contains elements of Chen's (2006) "script," namely the transfer of knowledge and resources from an indigenous people to a foreign researcher who successfully develops a medicinal product, but the metaphysical element present in this case is completely absent from the "script."

Cunani exists as a component of the Wapishana cultural knowledge and identity, and thus the transgression (from the Wapishana point of view) also occurred on a spiritual level. This spiritual space is one in which an indigenous culture may reject the commercialization of a medical substance as a misuse of their heritage, either due to the lack of compensation or

because the pharmaceutical companies apply the medicine in a way that fails to observe the proper traditions. Following the commercialization of the entheogen ayahuasca, long used in the Amazon as a component of rituals and healing ceremonies, a group of Colombian "shamanic healers" (Tupper 2009: 126) released a critical statement that echoes that of the Wapishana:

> Non-indigenous people are finally acknowledging the importance of our wisdom and the value of our medicinal and sacred plants. Many of them profane our culture and our territories by commercializing yagé [the source of ayahuasca] and other plants. (ibid.)

Critics would argue that these mores are against the Western standards of plants and other biological material as a commodity that may be bought, sold, or traded however the owners may wish. However, Millum (2010) refutes this assertion by noting ethnomedicinal knowledge can only be sold once. When the structures and potential uses of novel compounds enter the scientific literature, the ability of an indigenous culture to control that information truly ceases. Thus, the transfer of communal knowledge is not the province of the individual, as it affects the entire the community. Furthermore, an indigenous person who sells a plant does not realize that he is also selling the metaphysical aspect of the plant as well, for he does not think such information can be bought and sold. As Mead (1994) explained, for many indigenous peoples, the practice of "commodifying … knowledge" is "too [bizarre] to even comment on" (6).

Any attempt to reject indigenous mores as incompatible with the ethical or legal standards of developed nations denies the large body of law that attempts to come to terms with indigenous concepts of ownership. The legal basis for protection of indigenous knowledge grows out of the concept of Westphalian sovereignty, which states that a sovereign nation ultimately has control over the disposition of its resources, which constitute

communal property (Brody 2010). This concept has been enshrined by the United Nations Convention on Biological Diversity (CBD) (ibid.). In addition to reaffirming the rights of individual states to regulate access to their biological resources, article 8j of the CBD extends Westphalian sovereignty to indigenous cultures by requiring that bioprospecting on indigenous lands or which makes use of indigenous knowledge requires prior informed consent and establishment of a benefit-sharing agreement (BSA) with the indigenous peoples in question, subject to national legislation (ibid.).

Biopiracy, however, continues to occur due to the difficulties of enforcing national standards internationally, especially in the face of the United States's refusal to ratify the CBD, the only major country to have not done so (ibid.). Instead, the U.S. sponsored the Trade-Related Aspects of Intellectual Property (TRIPS) agreement, which is currently binding for all WTO nations, despite the fact that it clashes with the CBD on multiple fronts, including the patenting of biological products (GRAIN 1998). Furthermore, the United States does not recognize foreign prior art as justification for the rejection of patents on ethnobiological products (Chen 2006, GRAIN 1998), despite the fact that it has been used to reject patents on ethnomedicines by foreign courts; two examples are the rejection of a patent on cosmetic uses of extracts of the Thai vine *kwao krua* that have long been practiced by indigenous healers (Robinson 2010) and the rejection of a fungicide based on the *neem* tree, native to India, where its anti-fungal properties are well known, by a European court (Sheridan 2005). Because patents granted in the United States are enforced internationally under the TRIPS, the U.S. acts as a "patent haven" that allows companies to circumvent more restrictive patent standards abroad (Chen 2006, GRAIN 1998).

Although the CBD is seen as a faithful attempt to recognize the rights that indigenous peoples have long claimed (see Brody 2010, GRAIN 1998, Dhillion et al. 2002), both it and

the TRIPS, unlike the Treaty of Waitangi, represent a unilateral imposition of the developed world's mores upon the developing world and its indigneous cultures. The CBD is less egregious in this respect than the TRIPS, as it was ratified by those countries (Brody 2010), but the fact remains that the CBD has been ineffective in protecting the moral geography: even those occasions when the CBD is thought to function as intended, there is opportunity for criticism. Such a case is the widely-hailed Merck-INBio agreement, considered by many (see Robinson 2010, Brody 2010, Dhillion et al. 2002) to honor both the letter and the spirit of the CBD. In the agreement, Merck gave USD 1 million in up-front costs and an additional USD 135,000 in equipment for the preparation of samples to INBio, an NGO closely affiliated with the Costa Rican government (Brody 2010: 59). In exchange, INBio provided a specific number of samples and Merck was granted patent rights on all new discoveries, with some royalties returning to Costa Rica for conservation (ibid., Dhillion et al. 2002). However, despite this apparent success, where a developing nation was, in addition to revenue, given the means to produce developments of its own, Dhillion et al. (2002) criticized INBio for its environmentally-insensitive collection practices, and Posey (1996) observed that INBio sampled on tribal lands without consent and that those tribes will not benefit from the original agreement between Merck and INBio.

The TRIPS, on the other hand, makes no attempt to reflect the interests of indigenous cultures, only those of pharmaceutical companies, and it was imposed unilaterally by the United States on the rest of the world:

> [T]he TRIPS Agreement's standards amounted to a veritable revolution in international
> intellectual property law from which the research-based pharmaceutical industry emerged as one of the biggest winners. Faced with a "take it or leave it decision," all developing-country Members of the WTO … agreed to respect relatively stringent world-wide norms of patent protection no later than 2005. (Reichman 2009: 247).

Thus, both agreements are a violation of the sovereignty rights of indigenous cultures that nation-states expect for themselves, limiting what they can do with their own resources. The acts have, not undeservedly, brought accusations of a "new wave of [colonization]" (Mead 1994) from critics.

To defend their actions, biopiracy apologists often appeal to ethical reasoning. However, upon examination, these explanations lack internal consistency. In her essay "The Universal Principles of Business Ethics," Elaine Sternberg (1999) creates a set of principles that she argues are universal because in their absence, a business could not continue to function. Among those principles is the right to property:

> The key features of the ethical infrastructure of business are property rights and the rule of law. Property rights must be well-defined and secure. They include not just clear title to property, but the ability to exploit that property, exclude others from using it, and to transfer it, all without fear of being overridden. (29)

By taking medicinal substances from a cultural territory without the permission of its occupants researchers deny the fundamental right of ownership and control over resources on private lands on which the entire modern economy depends in order to function stably and sustainably. Thus, defenders of biopiracy argue that traditional knowledge does not constitute private property. As Chen (2006) writes, "[e]thnobiological knowledge already lies in a public domain of sorts, albeit perhaps a very small public consisting of the members of an indigenous tribe whose culture itself is endangered" (10). As a component of the public domain, an indigenous people's "clear title" to their intellectual property would cease to exist. But Chen's (2006) claim is false: not only is a knowledge interculturally restricted, the domain of a small group of people that may have little contact with the outside world; but it is also intraculturally restricted: "in [some ethnomedicinal] practices, the apprentice system is [practiced], whereby information is passed on from person to person, father to son...

frequently the information is considered highly secretive and is not documented in writing" (Farnsworth 1994: 44). While there are certainly instances where ethnomedicinal knowledge is a clear component of the public domain (such as the uses of *kwao krua*, which are documented in Thai religious literature [Robinson 2010]), courts have a long history of siding with indigenous peoples when patents are challenged, as mentioned above, indicating that the developed world is capable of recognizing when an ethnomedicinal knowledge resides in the public domain. On the other hand, in instances where the use is not clearly documented by Western researchers, redress is much less guaranteed. The Wapishana were able to overturn the patent on *cunani*, but another, on the *tipir* nut, also a component of their moral geography, was allowed to stand (Greer and Harvey 2004), indicating that this TK is not as freely available as Chen (2006) thinks.

Biopiracy apologists also fall back on utilitarian arguments as justification for the theft of TK. As Chen (2006: 11) himself says, "[a] utilitarian attitude toward intellectual property dictates a very simple answer: 'From an economic perspective, the more people who can use information, the better.'" Thus, according to Chen, biopiracy is justifiable because it brings benefit to us without imposing significant costs on the indigenous peoples from whose knowledge those drugs are derived. As Chen (2006) notes later in his paper, the patenting of a drug in the first world does not *ostensibly* prevent indigenous cultures from continuing to enjoy the traditional applications of the biological compound in question, and, therefore, no harm is done. However, in addition to the immaterial consequences of the invasion and appropriation of the moral geography, there are clear material consequences to biopiracy: the costly litigation to ensure that an indigenous tribe is treated according to international law, lost royalties, and the severe risk that a new drug will lead, either directly or indirectly, to environmental degradation.

Patents made without proper benefit-sharing arrangements bring demonstrable harm in the form of both lost profits for indigenous cultures that are due them, and direct competition with indigenous healers who participate in the global marketplace. An example of the former case is that of *Hoodia gordonii*, long used by the San people of sub-Saharan Africa as an appetite suppressant. It was only after extensive litigation that the San were recognized on a patent made on "P57," an extract of *H. gordonii* and promised royalties from any future development of a P57-based product (Laird and Wynberg 2008). The high cost of such action, though, has discouraged other indigenous peoples from challenging unfair patents (Independent 1999). In Thailand, the patents on *kwao krua* – some of which were still extant at Robinson's (2010) time of writing – if enforced locally, would prevent Thai healers from selling their preparations, and, if enforced abroad, would prevent their export. Again, as Robinson (2010) notes, the *kwao krua* patents clearly mirror descriptions of the plant's uses in Thai religious literature and shouldn't have been granted, but the courts needed – and continue to wait for – a legal challenge in order to overturn them.

Furthermore, by publicizing the beneficial effects of a new compound, drug companies ask indigenous cultures to assume significant risk to the population of the medicine's source. Drug companies often require a steady supply of material because, as noted above, many natural drugs are still too complicated for artificial synthesis and may overharvest source populations. This is a risk that indigenous cultures who are contacted by the West are often forced to take without their consent or the realization of the dangers contact might bring. Harvesting of *Pilocarpus jaborandi* leaves by Merck, for example, directly resulted in its widespread decline and endangerment (Newman 2008). Chen (2006) addressed this by pointing to the CBD's acknowledgment of states' rights to protect native species: "if [*Pilocarpus jaborandi*] bushes are indeed being overharvested for their

pharmacologically active leaves, the depletion should not be blamed on Merck & Company," but the government of Brazil (6), as though a drug company is not responsible for maintaining the sources of its own product: in 1997, Merck employed over 25,000 harvesters to gather *P. jaborandi* in the wild, collecting 1,200 tons of leaves for use in manufacturing pilocarpine for the American market (Newman 2008: 127). If anything, this is a persuasive argument as to why the state sovereignty approach of CBD enforcement is largely a failure: it requires relatively poor states, like Brazil, who for its part, can afford to employ a mere five people to safeguard the entire Brazilian Amazon (Greer and Harvey 2004: 108) to reserve its biological resources for exploitation by developed nations who have the biotechnological capabilities to do so. Protecting biodiversity is more difficult for an economically stressed nation, and perpetuating asymmetric arrangements of the sort Chen (2006) advocates, where source countries are unable to benefit from their own resources, will not ameliorate the situation.

Researchers who attempt to justify biopiracy use a similar utilitarian argument. After a scientist was criticized for going into the Amazon to search for new anti-cancer compounds without the informed consent of indigenous societies, he defended himself by saying,

> While we continue to talk and worry about biopiracy, fewer people are out there actually studying the Amazon, which is a serious form of scientific neglect. Of course biopiracy happens, but we have to balance this against not researching the rainforest at all. Ultimately that is much more damaging to mankind. (Veash 2000 in Greer and Harvey 2004)

The same utilitarian argument emerges from this statement: either we can continue to advance science and human health in first world by causing (minimal) harm to people in the third world, or we can allow those in the first world to continue to suffer. A utilitarian would naturally conclude that the best solution would be to continue to go into the Amazon. But this argument presents a false dichotomy: biopiracy is not an unavoidable side-effect of

scientific research. A royalty-sharing agreement would benefit all parties involved – the consumers of the drug would receive its benefits, the drug manufacturers would receive compensation commensurate with their investment, and the indigenous societies, many of which are impoverished (Laird and Wynberg 2008), would benefit from compensation commensurate with their contributions. The idea that royalty-sharing in and of itself is somehow inhibitory to the research environment is completely belied by the practices of those who recognize an indigenous culture's claim to their moral geography. For example, the scientist who discovered prostratin established a benefit-sharing scheme to ensure that royalties from the licensing of the patent would return to Samoa and the village where natives had helped him make his discovery (Millum 2010). The cosmetics company Natura used ethnobotanical knowledge to develop a line of products that are sourced sustainably and collected using paid indigenous labor (Laird and Wynberg 2008: 78). A portion of net sales is also allocated to community development (ibid.).

Natura's practices are evidence of a truly utilitarian business model. As Sternberg (1999) explains, a business is ethically obligated to "maximize owner value" (15), because it is this maximization that is not only the business's *raison d'etre*, but that which makes businesses distinct from other human organization. However, Sternberg (1999) includes the key stipulation that this maximization must occur over the long-term. Thus, when making an ethical decision, a business or researcher must ensure that there are no (or relatively few) long-term consequences of this act that make it harder to conduct business or research in the future. As a result of biopiracy, the opposite is now occurring: not only are harvests of Merck and other pharmaceutical companies actively destroying populations of medicinal plants, but indigenous communities are restricting the ability of additional traditional knowledge to truly enter the public domain. This phenomenon, which Greer and Harvey (2004) term "research

chill," is well documented.

As a result of the biochemist's patents on extracts from *cunani* and *tipir*, one Wapishana chief forbid future access to all researchers for any reason (Greer and Harvey 2004: 83). Similarly, following an instance in which a novel painkiller was developed from the venom of cone snails without any of the substantial benefits returning to the Philippines, where the snails were purchased from local fishermen, the national government passed legislation restricting the access of future researchers to its genetic resources:

> Now [a researcher studying cone snails] can only obtain the material under the authorization of the CRA [the Filipino bioprospecting regulations] with all its lengthy delays and complications … Common suspicions that commercial research may be cloaked under the guise of academic research add to the confusion. … [I]ndigenous communities are reluctant to sign forms [granting access to their knowledge and resources] because experience has taught them that signing documents means giving up rights. (Greer and Harvey 2004: 171)

Acting in a manner where the legitimate collection of information quickly crosses the line into a commercial profit creates an atmosphere of uncertainty that is corrected through the adoption of restrictive legislation. Crouch et al. (2006), in their search for new anti-malarial agents, lamented the time and expense it took to create over 300 legally-mandated benefit-sharing arrangements with local peoples, of which only one or two is expected to produce income. By committing biopiracy, pharmaceutical manufacturers harm their own long-term abilities to secure new drugs. Oppositely, by acting responsibly and maximizing benefits not simply for the shareholders but for the indigenous peoples who were instrumental in developing the product, a company can ensure a long-lasting, productive relationship beneficial for both natives and the bottom line.

The crux of the biopiracy debate is the vast gulf that exists between theory and practice. In theory, states have sovereignty over their biological and genetic resources, and, where applicable, that sovereignty is extended to indigenous communities. In practice, areas

of high biodiversity often occur in the poorest countries, leaving them without the resources to enforce these rules. In theory, the knowledge of indigenous communities should be gathered, with their cooperation, by scientists for the advancement of human knowledge and the human condition as a whole. In practice, these scientists, regardless of their original motives, are pressured to find commercial applications for this knowledge, and the line between public good and private profit is thin and blurry. In theory, comprehension of the vast therapeutic potential harbored by the planet's rich diversity of plants and animals should encourage conservation. In practice, the high demand for pharmaceuticals in developed countries damages the biodiversity on which indigenous peoples rely.

In order for a truly equitable solution to be found, these gaps must be sealed shut, a process that will not happen within the current porous legal framework. Although Chen (2006) proposes that "it may simply be enough to ensure that alleged acts of biopiracy do not form the basis of patents under existing intellectual property laws" (13), he oversimplifies an exceedingly complex situation. As Bartfai and Lees (2006) argue, patents are granted to drug companies in part to allow them to recoup the costs associated with research and development and clinical trials without having to worry about being undercut by competitors only liable for the cost of manufacture. Thus, a sensible amount of patent protection is necessary to help bridge the divide between a natural product and a pharmaceutical. It then follows that if drug companies must be able to shield their knowledge from their competitors, it stands to reason that indigenous peoples must likewise be able to protect theirs from the drug companies. But this must occur under the auspices of a *sui generis* system, not an extension of American laws and ideas, because forcing another people into the regulatory vehicle of a social contract of which it did not elect to join is the grossest coercive act one cultural entity can perform on another. The pharmaceutical patent is a tool tailored to fit a

specific problem, a regulatory check on a system that would turn on and devour itself in its absence. Indigenous protections must, in their turn, recognize the "complex cultural and spiritual connections" (Robinson 2010: 52) between an indigenous tribe and its biological resources. Adapting our current laws in the manner proposed would prevent legitimately developed knowledge from becoming a pharmaceutical product, because all indigenous knowledge would be considered, according to Chen (2006), part of the public domain and therefore not eligible for protection. This would destroy the already-tenuous connections between indigenous cultures and pharmaceutical companies, which, if managed equitably, has the potential to bring enormous benefits to both sides.

Achieving a balanced management scheme necessitates an internationally binding and internationally enforceable codification of the indigenous moral geography created by negotiating with the indigenous tribes themselves, treating them as valued partners rather than research subjects. The signing of the Mataatua Declaration by 150 representatives of indigenous groups provides a start for negotiations on the terms of those who had been slighted by the current legal atmosphere (Mead 1995). Mead (1995) summarizes the four key aspects of the Declaration as: "recognition that indigenous peoples are exclusive guardians of their knowledge... that they must be the first beneficiaries of it, must be respected for their right to create new knowledge..." and "must be the ones to decide whether to protect, promote, or develop their knowledge" (7). Researchers who commit biopiracy abnegate the possibility of rich ecological systems in which humans have been functioning in and learning about for thousands of years while remaining largely unknown to the Western world and its developments. Approaching these systems in a way that violates our own standards is at best hypocritical and at worst a return to the abuses of the colonial era.

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