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Outer Space, Alien Life and Intellectual Property Protocols: An Opportunity to Rethink Life Patents

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INTRODUCTION

Intellectual property (IP) policies associated with patenting organisms, their products and processes often conflict and generate a range of economic, political and social issues. Current life-seeking missions in outer space provide an opportunity to reconsider those issues relatively free of special interests that have made IP complex and uneven. Because extraterrestrial life has yet to be discovered, it has no current economic value, cultural significance or territorial connection, allowing for more equitable IP treatment. But from the moment of discovery forward there are predictable political and social pressures that would likely fragment attempts at implementing uniform policy regarding extraterrestrial discoveries. This chapter reviews standards and practices for life patents and international agreements regarding bioprospecting in global commons. The deep seabed, Antarctica and outer space are discussed as applicable models framing the concept of the Common Heritage of Humankind as expressed in the International Law of the Sea and the Outer Space Treaty. Who owns extraterrestrial life, and are the concepts of common heritage appropriate? In conclusion, the chapter offers recommendations for structuring IP regarding extraterrestrial life with the goal of generating interest and debate among the international IP and outer space exploration communities.

Legal and customary rights to the ownership of life have existed for millennia. During the last century, however, debates regarding questions of policies related to patenting living organisms, their parts, products and processes have dramatically intensified in parallel with advances in the technologies facilitating their discovery and use. Globalization of research, commercial production and marketing have increasingly shifted life patenting from a predominantly Western perspective to an international one. Disputes rooted in conflicting bioethical interpretations and cultural traditions of ownership and exploitation of life have exacerbated an already complex process. As the rate of new scientific and engineering discoveries in biology and biotechnology continues to accelerate, the number of life patent applications worldwide will predictably increase. The range of what bioscience and related fields may contribute to medical practice and pharmaceuticals, agriculture, robotics, information technologies, industrial processes, military applications

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and other areas over coming decades may be well beyond any capacity for prediction (Thieman and Palladino, 2004; Kurzweil, 2005). These elements combine to create a thicket of often conflicting intellectual property protocols and regulations.

Resolving such complex issues can be aided by creating thought experiments. These are hypothetical situations stripped of complexity to clarify analyses without the confusion and inconsistencies that often accompany lengthy histories of special cases and precedents. While the first formal documentation of the process of thought experimentation in the West comes from the early 19th century, the technique has likely existed in all cultures since humans gained the capacity of using language to speculate (Mach and Hiebert, 1976). In more modern use, such experiments generally follow the scientific method of proposing and then testing a hypothesis under an array of potential conditions. But whereas scientific hypothesis testing generally involves physical or mathematical testing, thought experiments are tested through reason, conjecture, deduction and, often, dialogue with others. As such, the experiments are primarily mental exercises and no physical manipulations are required. Most frequently, such experiments are impossible to actually perform outside of thought, and implementation is neither intended nor required for them to be beneficial in exploring potential consequences and benefits and evaluating possible outcomes and solutions. When successful, insights gained through the process can be imported from the hypothetical to the actual.

The 1967 Treaty on the Principles Governing the Activities of States in the Exploration and Use of Outer Space, Including the Moon and Other Celestial Bodies (the Outer Space Treaty, or OST) does not address intellectual property rights derived from any living system that may be encountered. There is no commonly accepted protocol for how to assign 'ownership' to any biological resource found in the ultimate commons, outer space.

Considering issues related to how life patents might be addressed in an extraterrestrial context may help in clarifying more mundane applications on Earth. Should extraterrestrial life be discovered on Mars, how might we structure a more efficient, equitable and consistent system for patenting that life and its potential products and processes? Such a circumstance may be less hypothetical than generally believed. Research regarding the potential for extraterrestrial life is a priority among NASA's missions (Bertka et al., 2007). The Viking investigations on Mars in the 1970s and the 2012 Mars Science Laboratory have both contributed to the search for life on that planet, and the Kepler telescope's planet-finding mission is assessing and cataloging planets in our galaxy that may have temperatures favorable for life as we know it. Other government-sponsored space organizations (such as the European Space Agency) share the search for life along with a growing number of private commercial ventures (such as Virgin Galactic and Odyssey Moon). Imagining the discovery of life on Mars provides a scenario that is especially applicable to a discussion of IP.

Should extraterrestrial life (defined throughout this chapter to exclude sapient life, those organisms such as humans and great apes that are capable of self-reflection) be discovered, many argue that existing IP restrictions and liberties regulating Earth's life are sufficient; life and its derivative products and processes will be patentable if other requirements for patenting are met, such as novelty (that the invention has not been patented previously), lack of obviousness to others, and utility. That assumption may be reassuring to some, but begs the question, '*which* IP restrictions and liberties?' There are many national and international regulatory protocols, and many conflict. Regardless, the issue remains largely unaddressed, as evidenced by the paucity of publications addressing IP in this context. Either it has not yet been identified or it has been recognized but not considered a foreseeable regulatory problem. Given the potential range of contentious questions that would evolve from someone's filing an extraterrestrial life patent application, the issue may become ensnarled for years awaiting resolution.

The search for extraterrestrial life provides an excellent opportunity to redefine IP practices related to life patents through thought experimentation. First, outer space offers a venue relatively free of the biases and traditions that have made such patents and the patenting process uneven and, at times, both unjust and counterproductive to invention. Second, while the existence of such life is currently hypothetical, it is possible and, arguably, probable (Bennett and Shostak, 2007). Finally, the OST is clear that outer space represents a commons. There are existing models of regulations and agreements regarding IP derived from commons areas here on Earth (such as the deep ocean floor and Antarctica) that provide starting points for crafting regulations for extraterrestrial IP. The successes and failures of such agreements as the Law of the Sea and the Antarctic Treaty System in addressing IP issues provide valuable lessons guiding future protocols for space. If issues of life patents can be resolved to any degree regarding space life, solutions may be applicable to the problems faced in regulating IP back here on Earth.

This chapter: (1) describes a few of the more pervasive problems with the current regulation of life patents; (2) summarizes several international agreements and regulations that address issues of regulating life patents, especially in international commons; and (3) proposes that the ongoing search for extraterrestrial life provides an opportunity for a thought experiment that may aid in structuring new approaches to the ownership of life, its products and processes. The chapter concludes with recommendations for regulating the exploitation of extraterrestrial life.

PROBLEMS AND INCONSISTENCIES IN LIFE PATENTS

The legal and regulatory mechanism for intellectual property ownership has become increasingly complex over the past century. Like policies regulating taxation, it can be influenced by special-interest politics and used as a tool to benefit some to the disadvantage of others. When IP is related to living organisms, regulatory biases and inconsistencies may be amplified by conflicting cultural traditions and even theological perspectives. This section briefly describes three problem areas in regulating life patents: the nature of biotechnological research and application, the lack of globally uniform and consistent law and application, and issues of indigenous claims of prior knowledge and commonly-held resources, such as those of the global commons.

Issues Regarding the Nature of Patenting Biotechnological Research

As with many other regulatory sectors, policies governing IP related to life must constantly strive to adapt to the novelty of the biotechnology that drives it, making consistent and predictable policy challenging. IP can be especially problematic when applied to rapidly evolving biotechnologies such as genomics and transgenetics, nanomedicine and sub-cellular chemistry and metabolism. Here, where the science is both new and complex, reliance on IP precedents becomes especially difficult. It may fall to the courts to not only interpret policy but to make policy. For example, in the US, patenting unaltered segments of human DNA was generally allowable until reversed by the US Supreme Court in June 2013. In that case, the Court disallowed Myriad Genetics' existing patents for isolated human genes associated with breast cancer (mutations of BRCA1 and BRCA2) by concluding that the genes were a product of nature and thus ineligible for patenting (DeVogue, 2013; US Supreme Court, 2013). However, some have speculated that the highly complex nature of the technology involved may be beyond the technical knowledge of the judges (Koerth-Baker, 2013). This points to an emerging problem that whereas biologists with the US Patent and Trademark Office (USPTO) are scientifically qualified to vet the technical quality of patent applications, the regulatory policies and legal precedents that rule their decisions are frequently outdated and difficult to apply to emerging technologies. The courts, however, while likely experts in policy, regulation and precedent, may lack the scientific expertise to adequately appreciate the technological implications of their decisions, especially as they apply to rapidly evolving fields. The resulting instability and uncertainty decrease the ability for industries to plan efficiently and generate frustration among the affected public.

The patenting process may also be counterproductive by promoting secrecy among competing researchers rather than facilitating the free exchange of information. This retards productivity and inhibits the creative benefit of collaboration. As provided in Albright (2004: 25), the *Journal of the American Medical Association* reported in 1997 that one-third of life science researchers surveyed had been denied access to research results from organizations and facilities other than their own. In 2002, the fraction had risen to nearly one half. This lack of access to data inhibits the ability to confirm the validity of published research. Publications can be held back awaiting patent filing, slowing the overall flow of information. This is problematic in a very competitive industry that measures progress in terms of a few months or even weeks. While there are arguments demonstrating the adverse impacts of patenting on creativity, many maintain that life patents encourage research cooperation (Bugos and Kevles, 1992). As with most such issues, a balance between the two is likely preferable.

Issues Regarding Conflicting Protocols and Regulations in Life Patents

The first US patent for a biological product was issued to Louis Pasteur in 1873 for his culture of yeast that was free of contamination. The yeast was not modified biologically in any way. Rather, Pasteur's invested work was purification, separating the desired yeast organism from its natural environment of contaminating bacteria and other non-target yeast strains. A later case that reinforced judicial opinion regarding the classes of living and life-produced products as patentable was adrenaline. Although a US patent was issued for the compound, the decision was challenged in court in 1911 on the grounds that adrenaline was discovered, not invented. The court upheld the patent and explained:

> Takamine (the patent holder) was the first to make (adrenaline) available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. (Dutfield, 2003: 115)

Precedent was set that an extracted, naturally occurring compound could be patentable if it was purified and had the requisite utility and novelty.

The scope of life patents expanded greatly in 1980 with the landmark *Diamond v. Chakrabarty* decision. Here, the US Supreme Court upheld a patent on a genetically modified bacterium designed to break down the chemical structure of hydrocarbons found in petroleum oils through the bacterium's altered metabolic processes. The Court ruled that the resulting bacterium was not a 'product of nature' and was, therefore, an invention and thus patentable. In the majority decision, Chief Justice Warren E. Berger wrote, 'We have cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed', and that 'in choosing such expansive terms as "manufacture" and "composition of matter", modified by the comprehensive "any", Congress plainly contemplated that the patent laws would be given wide scope' (Justia, 1980). Dissenting Justices, however, opined that Congressional intent was clear in not permitting the patenting of bacteria, citing the 1930 Plant Patent Act (the first American protection for new varieties of plants, essentially

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those created through cuttings and grafts rather than through selective sexual breeding) and the 1970 Plant Variety Protection Act (7 USC §§ 2321–2582), which provides patent protection for the seeds of hybridized plants (Lumelsky, 2004). Congress, whatever its intent, did not expressly forbid patents for living organisms of any kind.

The USPTO maintains that while a patent on a gene covers the isolated and purified gene it does not apply to the gene as it occurs in nature. As such, for example, naturally occurring genes in the human could not be patented *in vivo*, inside the human. However, if extracted and purified or biochemically altered in such a way as to make that gene useful to some other purpose, say, disease research, it could be patented. It follows that the altered gene could be re-inserted back into the original donor who would then contain a mix of both patented and unpatented genes that originated from their body. 'By examining these legal precedents, it becomes clear that the difference between a discovery and an invention is a difference in degree rather than in kind, and when the human and material resources inserted in research reach a certain level, the product of such research is protected under patent law' (Mathur and Dua, 2005: pages unnumbered).

In stating its defense in the *Diamond* case, the US government cautioned the Court that allowing Diamond to patent a bacterium would open the door to patenting genetically engineered human life, a 'prospect sounding dangerously close to slavery' (Banner, 2011: 253). The Court was clear that humans were excluded from any patenting, but parts of humans such as genome segments were patentable. However, any organism other than humans may generally be patentable if it does not occur in nature and if it meets other patenting criteria (such as novelty and utility). In this context, 'organism' includes bacteria, plants, animals and other forms of life. However, hybrid humans are not addressed. For example, insertion of a human gene into a fish is allowable. The question avoided, however, was at what point does the percentage of human genes employed in such a creation violate prohibitions on patenting humans? While a mouse might be engineered through the addition of less than one-tenth of 1 percent of a human genome (as was done with the human Foxp2 gene for speech), would the same rules allowing patenting be permitted if 10 percent of a human genome were engineered and inserted to form a transgenetic chimpanzee egg (Enard et al., 2009)? Eighty percent? Although a US patent application filed by Jeremy Rifkin and Stuart Newman in 1997 for a human-chimpanzee chimera was rejected (they wished to secure a patent on the process of creating a chimpanzee that was genetically up to 50 per cent human to block others from pursuing such transgenic research), these kinds of questions will have to be left to future courts or a legislature bold enough to tackle them (Magnani 1999). But they demonstrate that IP law is open to broad interpretation when technology progresses at a quicker pace than regulation.

The US is certainly not alone in adapting IP policy to emerging biotechnology. India's Patents Act of 1970, section 3(j), stipulates that 'plants and animals in whole or in part thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals' are not patentable. India's patent law is in accord with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) at 27(3)(b) which sets a minimum standard by stating that members may exclude from patentability all species of plants and animals except microorganisms. This creates a continuing source of confusion, however, for neither the Patent Act and its subsequent iterations nor TRIPS clearly defines 'microorganism'. The definition of microorganism is vague in other nations' statutes as well. In the vernacular, microorganism simply means any uni- or multicellular living thing that is small enough that it is not easily seen without the aid of magnification. While all bacteria are too small to be seen with the unaided eye, under favorable conditions many microorganisms, such as larger protozoans, can easily be seen without technological assistance. Most existing laws are clear that any genetically modified microorganism (for example, a modified bacterium) is patentable, but the regulatory reliance on size alone to determine what may be patented (whether genetically modified or not) may be entirely irrelevant should an application for patenting microscopic extraterrestrial life be filed. As addressed later in this chapter, such Earth-centric concepts as size may have little to do with the nature or complexity of any life discovered.

Significant confusion results from differing patenting regulations between states. The Indian position, for example, agrees with the USPTO regarding microorganisms, that plants and non-human animals are patentable if removed from their wild condition and genetically modified. However, in opposition to the USPTO, India maintains that any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or similar such process for treatment in animals are not patentable. For example, a technique for growing a replacement human organ *in vitro* would generally be patentable in the US but not in India (Gabriel, 2012). The European Patent Office adds additional ethical caveats to patenting living organisms. Applications for patenting genetically-engineered animals there are denied where the animal would suffer as a result of such engineering in excess of the potential benefit of its use for humans. The European standard arose as a result of the 1985 application to patent the 'Harvard Mouse', genetically engineered to develop cancers to assist cancer researchers. While the application was originally rejected as immoral in Europe because of trauma to the mouse, it was granted 18 years later after further consideration of the degree of suffering in comparison to its potential research and human health benefits. The mouse was granted a patent in the US in 1988, representing the first higher form of life to be patented. In the US, genetically modified organisms are generally patentable because they do not exist in nature (so are novel creations), are certainly not obvious and, where the patent is goal oriented, have credible utility. The variations between the US, India and Europe represent a small sample of the unresolved issues over the kinds of life that can and cannot be patented, conflicting intra- and international jurisdictions, cultural and ethical perspectives and related questions.

Issues Regarding Indigenous Claims and Benefit Sharing

Bioprospecting, the practice of purposefully collecting natural biological materials in foreign areas and then transporting them back to one's home, 'is as old a concept as medicine itself' (Shankar, 2008: 1). In the modern context, however, and seen in its most favorable light, bioprospecting is the process of: (1) searching for, collecting, and subsequently analyzing naturally occurring biological organisms and/or their products to determine their agricultural or biochemical properties for either direct use by humans or synthesizing and mass-producing target compounds; and/or (2) gathering indigenous knowledge or practices regarding the processes that enable the target organism, its processes or products to be used or enhanced (Pan, 2006: iv). Most often, products are subsequently used as pharmaceuticals or cosmetics, as crops and crop-related agricultural materials and in industrial and manufacturing processes. Frequently, bioprospecting is initiated by industrialized or otherwise technologically advanced nations in countries that have little or none of the technology required to fully capitalize on this process.

Here, the term bioprospecting is generally limited to the two actions listed above where the goal is securing a patent. Generally excluded are expeditions and similar activities that sample the biological environment and organisms for educational or purely scientific purposes, for vouchering, determining environmental components, tracking environmental trends and similar actions.

Regardless of motive, however, the process of bioprospecting may culminate in patenting a compound and/or process in the home nation of the prospector or employer, whether commercial, academic, research or other.

While there is no country that permits patents for a naturally occurring higher organism (whether it has been previously described or not), in the US and many other countries patents on specific chemicals isolated or purified from organisms regardless of taxonomic status can be awarded where such uses or processes are novel (for example, the isolation of insulin from dogs in 1922). In most cases, even though the effects of a biological source (such as chewing willow bark to relieve a headache), methods to increase efficacy and extraction methods may have been known by indigenous peoples for centuries, the metabolic pathways, enzymatic activities and biochemical properties of such compounds are not part of that knowledge. As such, those are generally patentable. The willow bark compound used by many cultures for centuries was patented as aspirin by Bayer in 1900.

Issues Regarding Colonizing Perspectives and Biopiracy

The concept of *terra nullius* (unclaimed land – land belonging to no one) is a fixture in Western law dating from Roman times. Until the mid-20th century, however, it was liberally applied not only to clearly uninhabited and unclaimed lands, such as Antarctica, but also to lands inhabited by those determined by Western colonizers as not having sovereign status. For example, Australia was determined by Britain to be *terra nullius* in the 19th century even though it was clearly populated by indigenous peoples. The 1835 proclamation by Governor Bourke legally established that the land belonged to no one prior to the arrival of the British (Fry, 1946). Aboriginal populations were entirely discounted. A fuller definition of the term *terra nullius*, therefore, would continue that the land is not owned or claimed by any sovereign as territory and that the definition of the legitimacy of such a sovereign is to be determined by the potential settler or colonizer.

A similar concept is also applied to knowledge that is held by non-Westerners, knowledge that may not be recognized as real or legitimate until blessed with a Western patent or other form of cultural possession. This, then, provides justification (and a legal remedy) for market control, a *fait accompli* in favor of Western commercial and political interests. Prior to the September 2012 effective date of pertinent portions of the America Invents Act of 2011 (AIA), language demonstrating the colonizing aspects of US patent law was provided in the US Patent Act of 1952, 35 United States Code Section 102, regarding the definition of prior art in the US and in foreign publications:

> A Person shall be entitled to a patent unless: A. The invention was known or used by others in this country or patented or described in a publication in this or a foreign country before the invention thereof by the applicant for patent, or; B. The invention was patented or described in a trade publication in this or a foreign country or in public use or on sale in this country more than one year prior to the date of the application for patent in the United States.

Enactment of the AIA modified that portion of the Patent Act to read:

> A person shall be entitled to a patent unless, (1) the claimed invention was patented, described in a printed publication, *or in public use, on sale, or otherwise available to the public* before the effective filing date of the claimed invention; or (2) the claimed invention was described in a patent issued under section 151, or in an application for patent published or deemed published under section 122(b), in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invation (emphasis added).

Prior to these modifications, it followed that if prior knowledge was held in another country but not published, it would generally have been patentable, able to be claimed as property by the patent applicant. Traditional knowledge (TK) that was not published and not known in the US was analogous to the aboriginal peoples of Australia under British rule; they do not exist for consideration in a legal framework that would compete with colonization. Patent law clearly provided a tool for colonization of information similar to the way that subjugation of indigenous populations is a tool for territorial colonization. US policy is not immune to this potentially paternalistic and condescending perspective. In 2011, the USPTO's Copyright and Intellectual Property Services' Copyright and IP Officer, Kathy Moore, defended IP and challenged the accusation that it was a form of theft.

> Just because products and technologies based on TK have been collectively held for a long time, does not mean they cannot be treated as an IP. The publication of illustrated, traditional folk stories is a simple example which is always popular with children. If indigenous people don't find some way of protecting their cultural heritage, it could disappear altogether. (*Fiji Times* 2011: online)

Unethical bioprospecting has fostered the concept of biopiracy, '(i) the theft, misappropriation of, or unfair free-riding on, genetic resources and/or traditional knowledge through the patent system; and (ii) the unauthorized and uncompensated collection for commercial ends of genetic resources and/or traditional knowledge' (Dutfield, 2004: 2). 'Biopiracy rejects the legitimacy of bioprospecting in its entirety. (In) its extreme it holds that all knowledge is public and free' (Pan, 2006: 3). Also included in the derogatory context of the term is patenting without respect to novelty demonstrated by previous use and TK (Smith, 2004). Combining bioprospecting and biopiracy as one and the same, some claim that both are representative of 'an initiative of the North to globalize the control, management, and biological diversity of resources which lie primarily in the Third World' and represents, therefore, an extension of the inertia of colonialism (Shiva, 1997, as quoted in Pan, 2006: 3). Further, Shiva states:

> The IPR (intellectual property rights) regimes in a digital age carry the mask of earlier times, when patents were licenses to plunder and pirate. The primary difference between patents in a digital age and patents in the gunboat age is that the new technologies can colonize life itself, while the older technologies could only colonize land. But patents and IPRs in the digital age share the earlier history of patents as instruments of conquest, which deny prior rights and erase prior histories of cultures. (Shiva, 2000: 501)

The discussion of bioprospecting brings us back to how we might move forward into outer space. As space becomes accessible to mainly Western countries, how might extraterrestrial life be approached in an equitable manner, given the history of commercial colonization through IP?

Issues Regarding Taking from the Global Commons

Garrett Hardin's remarkable 1968 paper 'The tragedy of the commons' commented on the futility of attempts to avoid the problems associated with human overpopulation. He noted 27 years later that the debate had generally shifted from population to economics and the environment, but that the core of his original conclusion still held – any consumptive use of the resources of the commons must be regulated if they are to be maintained (Hardin, 1995). However, the answer to the question he posed in 1968, 'How do you legislate temperance?' in taking from a commons remains as elusive as ever.

Humans have been able to significantly affect ecosystems and the life they support for millennia. It has only been with the advent of more modern technologies, however, that dramatic impacts on global commons areas such as the oceans have been realized (Kurlansky, 1997). As a result, international agreements and similar protocols regulating the conservation and exploitation of biological and mineral resources in these areas have been implemented.

The Convention on Biological Diversity (CBD) was a product of the world conference convened in Rio de Janeiro in 1992 (the 'Earth

Summit') to address, in part, the widely recognized need for international cooperation to foster the conservation of biological diversity as stated in the Preamble of the Convention (Convention on Biological Diversity, 1992). As part of the United Nations Environment Programme (UNEP), the CBD pledges that maintaining such diversity is a common human concern and an integral part of the development process that is of interest to the UNEP and other UN programs. To accomplish that objective, it strives to implement policy to conserve biological diversity, sustain the function of ecosystem components (through principles of multiple and sustained use) and foster the fair and equitable sharing of benefits arising from genetic resources. This final goal is most pertinent to the regulation of bioprospecting and profiting though extraction of global (and perhaps extraterrestrial) commons' resources.

While the CBD addresses bioprospecting within a state's political jurisdiction, it does not provide guidance related to actions within global commons. The International Union for the Conservation of Nature (IUCN) defines the global commons as 'those parts of the Earth's surface beyond national jurisdictions – notably the open ocean and the living resources found there – or held in common – notably the atmosphere. The only landmass that may be regarded as part of the global commons is Antarctica' (IUCN, 1980: Chapter 18–1, pages unnumbered). In the modern sense, global commons areas generally were not claimed either because they were inaccessible or because they offered no tangible asset worth the effort and cost of settlement or exploitation. International waters and their floors (managed under the UN Law of the Sea Treaty and the International Seabed Authority) as well as Antarctica (governed under the Antarctic Treaty System) provide two significant examples of how international treaties have been charged to manage biological resources and bioprospecting within these international commons. They provide useful models for crafting policies regarding bioprospecting in outer space, the ultimate commons.

Still, the basic tenets of the Convention are not new. The concept had been proposed by the IUCN a decade earlier and other aspects of the CBD had their origins in other UN agreements and protocols. The Convention was unique among previous conservation-goaled documents in that it was legally binding on signatories; parties were obliged to implement its provisions. As of 2013, the CBD had been ratified by all countries in the world except for the US (which has signed, but not ratified), Andorra, and the Holy See. It is likely the US withheld support due to concerns within its own borders regarding perceived overextension of federal control of private lands rather than as a reaction against maintenance of biodiversity (Sovereignty International, 1998). The US supports the CBD's emphasis on programmatic ecosystem approaches to integrated management, conservation and sustainable use (Blaustein, 2006).

Recognizing the economic potential of bioprospecting to unfairly exploit the resources of the commons, Article 1 of the CBD urges the promotion of 'fair and equitable sharing of benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources' (CBD, 1992: 3). While statements incorporated in the various documents imposed obligations on signatories regarding access to biological materials and directed that countries address the benefits of profit sharing through royalties and other instruments, few states have implemented the protocols. However, as described by Laird et al. (2007), where CBD-negotiated benefits packages are designed they typically include monetary benefits based on a per sample basis, periodic milestone payments, and royalties on net sales and licensing agreements in addition to nonmonetary benefits such as training, capacity-building, research exchanges, equipment, technology transfer and joint publications.

> Groups with the most experience in benefit-sharing generally emphasize the importance of non-monetary benefits and 'front-loading' benefit-sharing packages. Front-loading benefit-sharing packages ensures that provider countries receive a stream of benefits through the discovery and development phases, given the small odds of any one partnership yielding a commercial product and

> the fact that all products will not necessarily be billion-dollar 'blockbusters' generating large royalties, or that in most industries products rarely, if ever, achieve this status. (Laird et al., 2007: 118)

International discussions on the protection of TK, access and benefit sharing in relation to genetic resources continue, with work being conducted by the World Intellectual Property Organization (WIPO) and the World Trade Organization (WTO) in the context of the 1994 TRIPS and Article 10 of the 2001 International Treaty on Plant Genetic Resources for Food and Agriculture. As their mission statement provides, WIPO was created by the UN to 'promote innovation and creativity for the economic, social and cultural development of all countries, through a balanced and effective international intellectual property system' among their 185 member states (WIPO, 2012). WIPO generally supports both defensive and positive protection approaches to aid in directing derived benefits to TK holders, thus avoiding having them diverted elsewhere within government.

CBD protocols also have the potential to hinder scientific research and resulting publications. For example, should a researcher enter an area to study a plant and subsequently publish notes regarding the location, ecology, biochemical details, ethnobotanical uses or other data regarding that species, there may be no immediate or traceable financial IP-related profit from that publication. However, where subsequent development of patentable products is enabled in whole or part by the publication of that research, no mechanism exists for garnering royalties. 'But as indigenous peoples' groups, governments, and others seek greater control over their knowledge and resources, there is increasing pressure to limit or restrict publication of certain types of data, or at the very least [to require] informed consent before doing so' (Blaustein, 2006: 563, quoting Sarah Laird of 'People and Plants International'). CBD protocols are insufficient to resolve this conflict between the researcher's desire to publish scientific information and the potential for that publication to lead to future profit-generating IP. Once published, access to and use of research data are outside most researchers' control, and such control is counter to the purpose of publication, where the widest possible dissemination is sought. To require a researcher to gain the consent of indigenous populations prior to publication of findings would likely be unmanageable in addition to slowing subsequent research.

Most pertinent to bioprospecting and property rights, however, is that CBD aids in securing rights to control access to *genetic* resources for the countries in which those resources are located. This allows less developed countries to better benefit from their resources and TK. Where genetic resources are at issue, CBD stipulates that bioprospectors must obtain informed consent from the destination's government prior to gaining access and must share the products of their work with that country. However, CBD has no legal enforcement capacity. That is left to the legislatures of individual national and local governments.

There are weaknesses in IP related to biological resources both within and outside global commons. Existing patenting regulations conflict and the various treaties and agreements that have attempted to implement fair use have generally failed:

- Categorization of life into patentable and unpatentable entities based on factors such as size and perceived ethical or moral status are flawed;
- Protocols differ from one state to another, making uniform application under current patenting regimes very difficult;
- Indigenous claims of ownership are difficult to document and may retard research; and
- The relationship between life patents and the biological resources of the Earth's global commons is unclear.

SEEKING SOLUTIONS – OUTER SPACE AS AN INTELLECTUAL PROPERTY THOUGHT EXPERIMENT

The Outer Space Treaty does not address intellectual property rights derived from any extraterrestrial living organism that may be encountered and there is no commonly accepted protocol for how to assign 'ownership' to any biological resources that might be discovered in this ultimate commons. It has been argued that should such life be discovered, legal treatments available for their exploitation will seamlessly mirror the restrictions and liberties found on Earth, and that derivative products and processes will be patentable if other requirements are met. But as previously described, the regulation of patents regarding biological resources here on Earth is strongly associated with several of the most significant problems faced by IP:

- How can regulations governing life patents adapt to the rapidly emerging issues of biotechnology and the uniqueness of their potentials?
- How can the inefficiencies of multiple, overlapping IP jurisdictions be resolved?
- How might resources of the global commons (here, expanded to include the extraterrestrial commons) be more equitably addressed under a concept of 'common heritage of humankind?'

The Biological Nature of Extraterrestrial Life

Whilst it is possible that any extraterrestrial life may share some of the same biochemical and structural properties as life on Earth, given the significantly different environments of Mars or any other known place in our solar system it is unlikely that any organism discovered will be identical to anything found on Earth. Whatever may be discovered will represent a new organism. As a result, it may be extremely difficult to taxonomically classify potential life within any existing phylogenetic system. The specific IP definitions of what kinds of organisms can generally be patented (for example, a purified strain of yeast) and those that cannot (unaltered 'higher' organisms) will, therefore, not likely apply.

What remains is that current IP statutes generally hold that 'microbes' can be considered for patenting where other qualifying criteria are met. Taken at its obvious meaning, microbes are organisms that either cannot generally be seen without technological enhancement, such as a microscope, or can be seen when concentrated in great numbers, such as in a bacterial colony. 'Microbe' is not a taxonomic classification and has little scientific meaning. It follows, then, that what can be patentable and what cannot is a matter of size. On Earth, size is important in describing our ethical and evolutionary relationship to other organisms; in space, it may be totally irrelevant. An organism's size is an evolutionary adaptation responding to varied environments and is undoubtedly influenced by gravity unless it is aquatic or otherwise suspended. The qualifier 'microbe' loses its IP rationale in the extraterrestrial context.

Similarly, as evidenced by the European reluctance to patent the 'Harvard Mouse', patentability is influenced by the perceived ability of the organism in question to be sentient, to experience physical pain or emotional distress as part of the process of making it a commodity. As with size and microbes, our perception of sentience is a product of our experience with Earth's organisms. Ethical sentiments vary widely, changing with culture and time. Like size, assessing degrees of sentience would not be applicable for extraterrestrial IP.

Considering the challenges that will emerge upon encountering extraterrestrial organisms provides an opportunity to redefine life in the context of IP and reconsider the conflicting restrictions and allowances we apply on Earth. As a result, we may have a broader but more consistent and permanent definition, less encumbered by taxonomic and cultural histories and biases.

Prior Discovery, Traditional Knowledge and Utility

Extraterrestrial life's place within the context of our cultures has not been established, so there is no possibility of conflicting issues of prior discovery or TK. We share no history with extraterrestrial lifeforms; they are neither heroes nor villains in our cultures, not even in the context of a bacterial pathogen.

Value

Any extraterrestrial life will have evolved to adapt to an environment where temperatures, radiation type and intensity, gravity, pressure, atmospheric composition and other factors may imbue it with structural, genetic or biochemical properties of considerable commercial potential. Especially for private space ventures, there would be an expectation of financial profit from such a find, given the considerable expense and liability of successfully launching a vessel, finding life and capitalizing on that find. But there is no guarantee of commercial success. This provides a unique situation for our hypothetical thought experiment. Although concerted efforts are underway to find it, the property in question does not currently exist and may never exist; if found, it may have considerable commercial value or almost none. There is also the chance that it may pose a liability to other activities. These unknowns foster the crafting of policies that may be more equitable in the sharing of profits, risks and liabilities.

Territorial Real Property Claims

In developing the hypothetical scenario, issues of life as IP must consider ownership or control of real property, as well. Generally, the entity that claims the land owns the resources it contains, whether living or mineral. Presently, spacefaring nations concur that outer space and the planets, moons and asteroids it contains represent a form of commons similar to the Antarctic or the seabeds in international waters. As stated in Article II of the 1967 OST, 'Outer space, including the moon and other celestial bodies, is not subject to national appropriation by claim of sovereignty, by means of use or occupation, or by any other means'. However, others interpret the Treaty as silent regarding private ownership of real property and argue that it specifically prohibits sovereign claims only; private acquisition is not blocked (Hearsey, 2008; Reynolds, 2008; Wasser and Jobes, 2008; Pop 2009). A third position is that it permits 'functional' real property distinguishable from deeded real property. Here, a sovereign may control, but does not own, the land on which it builds or lands within a defined occupied and used compound. This would not infer territorial sovereignty in any form in that no title would be provided, but would allow for management of the land (Dalton, 2010). As we move from state-sponsored to private space ventures and commercialization, resolution of property issues becomes critical. Ownership of personal property, such as mined ores, is of great concern to private industries looking to space and the costs and liabilities it incurs. Legal and policy ambiguities can certainly be a disincentive to private investment (Cooper, 2003; Hertzfeld and von der Dunk, 2005). A fourth perspective is that extraterrestrial real property be placed within trusteeships that exist apart from government or private control.

Compounding the issue of real property is the second of the two overarching international space treaties, the 1979 Agreement Governing the Activities of States on the Moon and Other Celestial Bodies (the Moon Treaty). It applies not only to Earth's Moon but to all bodies in our Solar System except the Earth itself. Set in its final form a decade after humans first landed on the Moon, Article 11 of the Moon Treaty closely mirrors the OST in stating, 'The Moon is not subject to national appropriation by any claim of sovereignty, by means of use or occupation, or by any other means'. But it continues, 'Neither the surface nor the subsurface of the Moon, nor any part thereof or natural resources in place, shall become property of any State, international intergovernmental or non-governmental organization, national organization or non-governmental entity or of any natural person'. The intent here is clear, that the land itself shall not become property. Inclusion of the phrase regarding natural resources 'in place' may be open to legal interpretation. Once removed from 'place,' however, the status of the resources (ostensibly including living resources) becomes less clear. But while OST was ratified by 100 nations, including all spacefaring nations, the Moon Treaty has been ratified by only 17, none of which are spacefaring, making it less consequential from a regulatory standpoint. It is considered by many to be a failed international law that will have little relevance to space activities until tested in court by an attempt at a property claim (Listner, 2012).

Both treaties are clear that extraterrestrial real estate cannot be claimed as sovereign property by any nation. However, whether outer space belongs to *no one* or *everyone* is another issue.

Common Heritage of Humankind

Where novel biological resources are discovered in uninhabited regions of the global commons (such as Antarctica or deep seabeds under international waters), questions of TK and novelty are generally unchallengeable and patenting may be nearly guaranteed. In such circumstances and where supported by regulation, a portion of the profits generated by the resulting patent may be required to be used for conserving that environment based on benefit-sharing or royalty formulas. Although such arrangements have not been overwhelmingly successful due to conflicting bureaucracies, similar financial arrangements may be appropriate for extraterrestrial finds. Existing protocols governing bioprospecting in the global commons may provide insights for extraterrestrial application.

Concepts pertaining specifically to the 'Common Heritage of Mankind' (CHM) (synonymous with the more recent and gender neutral 'common heritage of humankind') in relation to exploitation of resources within commons are present in the 1967 OST. They were strengthened when drafted into the 1979 Moon Treaty and the subsequent 1982 United Nations Convention on the Law of the Sea (LOS) regarding seabed resources. However, its definition remains vague and somewhat contentious. The term is not defined in a legal context and was likely inserted to represent aspirations for future policies and legislation (Viikari, 2002: 21). When applied to redistribution of wealth, CHM tends to be highly politicized, as evident in Jennifer Frakes' assessment that 'the manner in which the CHM principle will be used will depend on differing perceptions of reality' (2003: 409).

In general, developed states hold that areas where CHM applies are available for common use within the context of traditional freedom of the high seas and that conservation and management may be required to guarantee the continued availability of renewable resources for future generations. Less developed states (typically those without the access, technology or means to exploit Earth's CHM resources to a significant degree) understandably prefer that CHM be applied in a way that prevents exploiters from monopolizing resources. In general, they wish the option to actively participate in management and ensure that they benefit from any profits earned by exploited resources through benefit sharing (Viikari, 2002; Frakes, 2003).There is little question as to why there are conflicting interpretations of CHM considering non-treaty states', treaty parties', interest groups' and others' (as Frakes states) differing perceptions of reality.

A significant commonality among both developed and developing states is that they ultimately wish to see a degree of exploitation. Without exploitation, neither benefit; with exploitation, developed states likely will benefit and developing states may. It is the disposition of exploitation's profits and the nature of its sharing that are largely in dispute. While all interpretations hold that CHM requires common management to ensure resource conservation for the use and benefit of future generations and non-appropriation as real property or territory, if or how CHM is to be applied in the context of outer-space-derived

IP remains vague. What is clear, however, is that although access to the sea floor resources is limited only by possession of a floating dredge affordable to most of the poorest of states, commercial access to Mars is well beyond their means. When the commons of outer space is only accessible to a very few, it is more difficult to regulate as a commons.

Notably, the common heritage principle regarding resources was first formally introduced to the UN in 1967 (the same year as the OST) regarding ocean resources in UN Document A/6695 (Payoyo, 1997). It was presented as a request to the UN General Assembly, 22nd Session, on 18 August of that year to add as an agenda item: 'Declaration and treaty concerning the reservation exclusively for peaceful purposes of the sea-bed and the ocean floor, underlying the seas beyond the limits of present national jurisdiction, and the use of their resources in the interests of mankind'. When similar common heritage language was added to the OST regarding extraterrestrial resources its only support initially came from a small number of nations (including the United Kingdom and the US). It was recognized, however, that it would be extremely difficult to determine profits in consideration of the diverse sources of expenses and liabilities incurred in identifying, extracting, transporting and refining the resource. In addition, designation of a depository for royalties to be paid by those reaping commercial profits from space exploitation and methods for disbursement has never been determined. It may have seemed premature to focus on addressing these OST details in 1967 because of the likely perception that commercial exploitation may be many decades away, well beyond practical political horizons. With the Apollo Moon landing only two years later in 1969, the possibility of space exploitation may have seemed more of a near-future reality. The more stringent and restrictive language of the 1979 Moon Treaty may have been viewed as a significant threat impeding space development and so was largely avoided by potential signatories (Christol, 1999). Politically, it is more palatable to agree to broad concepts such as CHM when details of the consequences, such as those of benefit sharing, are decades away. When greater detail was provided in the Moon Treaty and especially LOS, the consequences were more palpable and immediate.

Although the Antarctic Treaty (AT) does not mention CHM specifically, it does include language reflecting its spirit that may be applicable to outer space IP:

- Sovereign states and private actors are blocked from establishing territories or otherwise procuring real property
- There is freedom of scientific investigation that is not geographically confined by sovereign boundaries
- Information flow is encouraged both within and outside the scientific community that contributes to achieving a degree of benefit sharing
- Mineral extraction for any but scientific purposes is prohibited
- Conservation requirements serve to acknowledge preservation of Antarctic resources for future generations.

Inclusion of these requirements, prohibitions and intents has not prevented developing states from having additional CHM concerns. Many still view the AT as the government and management of a globally-shared resource by a minority of mostly developed states (Frakes 2003).

Despite its often conflicting definitions and applications, however, CHM's intent is clear: the benefits provided to some through exploitation of the resources of the commons, whether from seabeds, Antarctica or potentially Mars, should be shared with non-participating states. Methods include disbursing monetary royalties collected from profits or providing other forms of assistance, such as access, technical expertise, equipment or training.

In the context of IP and extraterrestrial discoveries, the vagueness of CHM allows for creativity in drafting details for its implementation. As with other factors addressed in this chapter, these details should be addressed prior to any discovery, before valuation of the find or knowledge of what state or corporation is sponsoring the discovery. This allows for a greater degree of justice less affected by special interest influences.

Patent Pools

Limited physical access to outer space may create a patenting environment prone to monopolization of resources. The problem may be exacerbated by the nature of the new technologies of space exploration and may contribute to the anticommons effect of repressing, rather than stimulating, invention. But past problems of access to emerging technologies have been successfully mitigated and provide options that may help in the outer space context.

When the US entered the First World War they had fewer than 100 aircraft; France had over 2,000 and Germany had 1,000. Although the Wrights had patented a mechanism for controlling pitch, roll and yaw in 1906, the following decade was fraught with patent infringement suits brought against those who attempted to use 'their' designs (Albright, 2004: 145). Their patent served to impede, not stimulate, the advancement of both the technology and industry (Porter, 2012). The US government broke the logjam with the creation of the Manufacturers Aircraft Association (MAA), creating a patent 'pool' (Dykman, 1964). Aircraft manufacturers paid royalties into the pool and shared patents, a critical compromise enabling the development of American air power. However, this also resulted in the creation of a quasi-monopoly and blocked non-members from experimenting with aircraft of their own design that employed patented technology. The problem was remedied, in part, by placing the MAA under the US Department of Commerce. Although now regulated, information was more easily shared among a wider user group. Federalizing also facilitated substantial federal funding for the industry, and the federal government was by far the industry's primary customer. Lastly, as aircraft tend to fail in dramatic ways, liabilities were shared, in part, by the federal government. The MAA provided a model for similar developments in space exploration in the 1950s with the creation of NASA. This model of shared patents and liabilities provides some guidance for approaching the problem of patenting extraterrestrial life.

RECOMMENDATIONS FOR INTELLECTUAL PROPERTY REGARDING EXTRATERRESTRIAL LIFE

Given the limitations of current national and international regulations in equitably and efficiently addressing foreseeable patenting issues related to the discovery of extraterrestrial life, how might these problems be addressed and resolved? The novelty and hypothetical nature of the situation lends itself well to creative solutions.

Leave Taxonomy Out of IP Regulation

Taxonomic classifications are impermanent, and even for well-described species with millennia-old relationships with humans, hierarchies are constantly challenged. As the ability to detect and recognize novel life forms is improved by advancing technology and as our reach to new environments expands not only to remote areas of the Earth but to Mars and beyond, regulations, treaties and similar instruments should remain as adaptive as possible to the biological novelty we may discover. Any IP or similar policy should not attempt to classify new life for differential treatment. Terms such as microbial or even sentient, for example, may be meaningless in an extraterrestrial legal context.

Withhold Applications for Patents for Alien Life (At Least Initially)

On Earth, patents have been awarded for products resulting from exploitation of deep seabed organisms. Concerns have been expressed to and by CBD that unrestricted use will decrease biodiversity and, importantly, result in unequal sharing of benefits derived from a common resource. Such patents may have a significant anticommons effect on innovation and research. 'Some resources are too important, in terms of the present and future public benefit, to be subject to strong intellectual property protection' (Oldham and South, 2004: 39). While many in the space development industry do not question their ability to patent any life they may discover as they would microbes on Earth, these are assumptions. Prohibiting the patenting of extraterrestrial life outright, at least initially, is worthy of strong consideration.

The first organism discovered will be extremely rare regardless of whether it represents the only one of its kind in the universe or shares its world with trillions of identical others. If the latter, at first recognition we would not know of its numbers or distribution. Regardless, the first will be of immense potential worth. As diverse as life on Earth is, all forms here have basic biochemical processes in common. For example, all life employs DNA and RNA, all are carbon-based, use only five of over twenty nucleotides in DNA and RNA and follow the same base-pairing rules. It is very possible that new life discovered may employ novel metabolic pathways, enzymatic processes, energy storage mechanisms or other biological functions never described previously. To allow the patenting of any of these from that initial find may confer a *de facto* patent on those similar processes exhibited by all other life on that planet. The incredible power of such a patent would be counterproductive to subsequent research.

Hence, the argument runs, prohibit any immediate patenting of discoveries. Later, after the natural status of the organism has been determined, prohibitions could be reconsidered and, if warranted, modified. But the initial collection should not be eligible for patenting.

Place Restrictions on any Patents Granted

Should patents be granted, limit their scope or duration. For example, consider patents that allow some commercial exploitation but free access to the organism by any qualified party for scientific research. Or, limit the kinds of commercial uses that would be protected by the patent. For example, permit the patenting of a metabolic process that allows an organism to rapidly repair cellular damage done by radiation, but disallow patenting of the gene sequence (assuming the organism has genes!) that allows that metabolic process. Make basic physiological and biochemical data derived from the find, such as a DNA sequence, widely and freely available.

Require Specimen Vouchering with Broad Accessibility

The 1977 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure established a system of International Depositary Authorities (IDAs) for vouchering. Prior to applying for a patent for an organism such as a bacterium, a voucher specimen may be sent to IDA. However, the collection is not a public facility. Specimens generally remain under the legal control of the depositor, and others wishing to use the specimen must have their permission. This favors the patent seeker by aiding in establishing that they were the first to record the find, but it also sequesters the find. While it may be argued that the extraordinary effort required for, say, a private enterprise to venture into space, collect the specimen and return it to Earth justifies singular control of the specimen, it can also be argued that decades of public sponsorship of space research enabled the private investor's accomplishment.

As developed by the WIPO's Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, any living entity or biological material collected is required to be publicly vouchered and deposited in a public institution, such as a museum collection or public research facility. This does not imply free public access, but does require that the specimen or material be available for bona fide scientific research as opposed to sequestration at a private facility. This seems an efficient, equitable, and totally appropriate requirement for extraterrestrial materials as well.

Grant International Patents Only

While most models of intellectual property rights applied to Earth's global commons appear to be fraught with contradictions and lack clarity, the burden of hundreds of years of conflicting geopolitical approaches need not be perpetuated. The issue of overlapping and conflicting legal systems may be avoided if there is one over-arching international administrative system. Such a system would be aided by existing prohibitions in the OST on establishing territorial claims. Limiting the number of regulatory bodies seems essential to uniformity and efficiency (Scuderi, 1989; Balsano, 1995). An international umbrella, such as the OST or its equivalent, should maintain a position of dominance in a hierarchy of other specialized agreements, similar to the Antarctic Treaty's tiered relationship to the Antarctic Treaty System. Should calls for the harmonization of laws, procedures and guiding regulations for space-related IP prove successful, they could be applied to terrestrial issues as well.

Patent Pools

Consider the creation of international patent pools as a remedy for potential monopolization of extraterrestrial life IP.

Expand the Definition of Common Heritage of Mankind

When applied to outer space resources, expand the concept of Common Heritage of Mankind to include extraterrestrial life. As with CHM on Earth where portions of profits made from certain patents are used for the conservation of affected species and their habitats, portions of profits derived from extraterrestrial life patents could be placed in trust for the conservation of extraterrestrial habitats for the benefit of native organisms.

Provide for Developing Countries' Participation in Space Exploration and Exploitation

The International Space Station includes crew from non-spacefaring states. Protocols for providing access to extraterrestrial resources to less developed nations and subsidizing their participation should be considered in the spirit of a shared commons.

CONCLUSION

It is likely that issues of ownership, private profits and intellectual property regarding discovery of extraterrestrial life are not currently of great administrative concern to those in national and international policy positions because there is little anticipation that such discoveries will be made. It may seem so remote that it is not worth the political capital to negotiate compromises. However, that would change rapidly should, for example, the Mars Space Laboratory report signs of endemic life there. At that moment, a clamor for international protocols for ownership and plans for the disbursement of potential profits will predictably move the issue to the top of political, research and commercial agendas.

As stated previously, every problem at one time did not exist. With extraterrestrial IP, the situation could change tomorrow. It may be extremely productive if representatives of spacefaring nations, involved private industry sectors, academic institutions with research interests, the UN, less developed states without direct involvement in space exploration and others formally approached the IP and extraterrestrial life issue as a hypothetical thought experiment. What protocols might they propose that would best address the concerns of all involved? The chances for crafting a fair and equitable resolution are at their greatest now, prior to any such discovery.

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