TRADITIONAL MEDICINE AND INTELLECTUAL PROPERTY RIGHTS

GELENEKSEL TIP ve FİKİR MÜLKİYET HAKLARI

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ABSTRACT

Ethnopharmacological information is an important component in both traditional health systems and for future medicine development. Biodiversity-rich countries, indigenous cultures with their knowledge of the use of biosources as medicines and companies that seek to discover new therapeutics through medicinal plants and traditional knowledge are on the way sharing common interests. The value of plants for medicines is more widely recognized and the “intellectual property rights” (IPR) connected with their use have been debated worldwide. “Convention on Biological Diversity” (CBD) which was signed in Rio in 1992, enforces protection of the rights of local people and local knowledge as well as conservation of the biological resources which forms the basic of all those health systems. Thus, conservation of local and indigenous peoples’ rights over their knowledge and resources are an important element of all contemporary conservation approaches. Generally, the intellectual property rights are protected under the patent systems in many countries, whereas access to such legal procedures are not easily available for most of the indigenous communities. Present and future perspectives on the subject are discussed in this article.

KeyWords: Traditional Medicine; Medicinal Plants, Intellectual Property Rights
ÖZET


Anahtar Kelimeler: Geleneksel Tip, Tibbi Bitkiler, Fikri Mülkiyet Hakları

“Folklore belongs, in the first instance, to the cultural heritage.”

African Intellectual Property Organization Bangui, 1977

INTRODUCTION

The World Health Organization (WHO) estimates that the majority of the population of most non-industrial countries still relies on traditional forms of medicine for everyday health care. In many countries up to 80-90 % of the population are in this category.

Traditional medicine has been defined as “the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illnesses” (1).

Another definition relevant for traditional communities is the “traditional ecological knowledge (TEK)”. As a holistic concept, as the science of ecology TEK includes the set of traditional knowledge, innovations and practices and plays an important role in traditional medicine and health systems (2). Different than the western knowledge transmission systems TEK in traditional communities are done by “collective memory” (3).

Human kind faced an explosion of accumulation of information about the universe he lives in. The revolution in science had started with the Renaissance and increasingly developed itself and
accumulation of knowledge accelerated with time. 20th century was the age of incredible change in every aspect of life mainly caused by the innovations in science and technology. Although each invention’s root is based on the previous, basic motor of this western originated knowledge accumulation is the “individual innovation”. Discovery of antibiotics or invention of diesel motors are at the different fields of science but both are sharing the same way of thinking and research methodology. Being “inventive” found great support from the society and it ultimately invented methods to protect itself. “Patent” is the basic mechanism for the protection of innovation. Every year thousands of new patents are applied in the world. In the scientific invention history, actors of invention sometimes chosen to share their invention without any economic expectation or they get benefit from patents. Currently globalized economy favors patenting and patenting has a positive feedback effect on invention. However, with the increase in extent and accessibility of global economy to every part and field of the planet some other problems arise which cannot be easily solved by conventional private rights approach. Intellectual Property Right (IPR) is a form of patenting in the field of intellectual invention. The intellectual property includes copyright, trademark, industrial design but in this article patents related only with traditional medicine are discussed.

When innovations are considered, basically, results of western science is recalled. However, set of inventions that were the fruitful results for thousands of years of knowledge accumulation based on experiences of the traditional societies are also real inventions and are subject to IPR. Cure of a disease which is unknown for modern medicine is a field which has one of the most interest and research has been made on and new problems arise about the IPR of the local people. Conceptual framework on the domains and relations of property and related rights presents a variety of perception to the issue (4-6). Biopiracy or simply using information without giving any benefit for the owner of the entity or information is a threat for future but also a fact at the moment and has many legal consequences (7).

IPR have become a metaphor to describe indigenous ownership of total traditional knowledge also, generating options for contractual mechanisms to ensure benefits return to source cultures and countries. The IPR debates illuminates the vitality of biodiversity for human health. From ancient to modern times, plants have been the cornerstone of pharmacy. But, as time passes, the extinction rate of species and cultures continues to accelerate and human health further deteriorates from diseases for which no cure yet exist. Thus, the value of plants for medicines is more widely recognized and the IPR connected with their use have been debated worldwide (8).
Traditional Medicinal Plants and Its Market

Products derived from traditional knowledge (TK) have benefited the pharmaceutical companies greatly, and indigenous knowledge of plants has played a significant role. These companies are interested because of the cost of screening. Out of 10,000 molecules only one will emerge as a new drug. It nearly needs 15 years to be experienced and also very expensive as it costs $800 million for a single drug to be developed. Globally, almost 121 prescription drugs are made from plants almost half come from tropical lands. Tropical countries are valuable for the richness of their biological and chemical diversity, due, in part, the climatic conditions. In temperate climates, winter kills many plant predators. But since tropical species have minimal seasonal respite from predators, many have evolved chemical protection from countless predators. The plant chemicals that have evolved to increase plants resistance may also provide protection and be therapeutically useful for human health (8,9). In the past, companies from the more developed north have taken the knowledge of the indigenous peoples of the less developed, but biologically diverse tropical countries and converted medicinal herbs into pharmaceutical products without providing any payment to the providers of the knowledge.

The global market for plant based drugs has been estimated at $43 billion. There is an increasing trend for the use of herbal medicines globally (10). Traditional medicine has a dual meaning in Third World and civilized modern -mainly western- countries. Traditional medicine in the developing countries and especially in the third world is not an alternative but is an essential component of their health systems because of its cost and easy access. “When dealing with traditional medicine, one is dealing with issues related to biodiversity conservation, protection, preservation and promotion of cultural heritage and technology transfer” (11). Traditional medicines represent an alternative, an option, for people in modern countries. As well as forming the basis of modern medicine, in Europe, North America and Asia there is a growing need (8-15% annually) for the popular and efficient herbal species (12). But main reason in choice lies in the cultural differences such as, in an enquiry only 3 percent of people form USA claimed that they used traditional medicine in the previous years (13). However, in Germany which has a strong traditional herbal medicine use, this figure was 31 percent and they used phyto-pharmaceutical (herbal medicine) preparations sold as over-the-counter (14).

Agreement on Trade Related Intellectual Property Systems (TRIPS)

Since its inception, the Agreement on Trade Related Intellectual Property Systems (TRIPS), which imposes uniform standards for intellectual property protection, has raised considerable
controversy, due to fears that its implementation may entail price increases for pharmaceuticals, which would reduce peoples’s access to the medicines they need, notably in developing countries. So far, much of the discussion has focussed on modern medicines. From a developing country’s perspective, when looking into the issue of IPR for modern medicines, the objectives are clear, and the strategies that can be used to achieve those objectives are known, though their implementation may be difficult. The same cannot be said with regard to traditional medicine. TRIPS makes no reference to the protection of traditional knowledge; does not acknowledge or distinguish between indigenous, community-based knowledge and that of industry. Traditional medicine is intertwined with access to biological and genetic resources, and with the knowledge of local and indigenous communities regarding their therapeutic properties. Thus, at the national level, a careful assessment of the objectives and possible implications of IPR protection of traditional medicine should be made (15).

**Traditional Medicine and Intellectual Property Rights**

Contribution of the traditional and indigenous peoples to the conservation of the world’s biodiversity and related traditional medicinal information is immense. Everyday ethnobotanical and related surveys and researches provide new information about the cure of various diseases, body improvement and skin care remedies, natural oils and other health care objects. Globalised economy is trying to find more “explorations” about today's diseases from traditional and indigenous communities and during these challenges new and complex problems are arising. Sharing and access to world’s biodiversity resources are seen as a basic human right but this conflicts with the property rights of the “inventor” traditional or indigenous groups. Trade is using all available material for commodification including materials, traditional methods and ideas for medicine and in most of the times without any benefit to the country and community of origin. One notorious example is the derivation of vinblastine and vincristine from the Madagascar rosy periwinkle (Vinca sp.); the drugs have earned the firm around $100 million per year, but neither the shamans that gave the knowledge to the researchers nor the government of Madagascar have received any compensation for their contribution. Commodification of what are collective resources—often a secret or sacred nature—is not only an expression of disrespect for local culture, but a violation of human rights.

IPR are inadequate and inappropriate for protection of traditional ecological knowledge and community resources because they:

- recognize individual, not collective rights;
-require a specific act of “invention”;
-simplify ownership regimes;
-stimulate commercialization;
-recognize only market values;
-are subject to economic powers and manipulation;
-are difficult to monitor and enforce;
-are expensive, complicated, time-consuming (3).

**Convention on Biological Diversity (CBD) and IPR**

It should also be noted that many medicinal plants face extinction. Overexploitation of such plants in order to satisfy industrial and/or export demands can increase the risk (10,16). It is also a historical issue as it was experienced in Ancient Mediterranean World. The plant *Silphium*, well known from contraceptive properties, provided a great wealth for ancient people of Cyrene (a coastal city in ancient Libya), however unsustainable harvest of the plant caused its extinction and loss of further economic gain from the plant (17). Hence, trade in medicinal plants should be regulated, preferably within a broader policy framework dealing with conservation and sustainable use of biological resources.

Conservation is an essential partner in this issue and a vital counterpart in the sustainability of the traditional medicine in biodiversity rich countries. The Convention on Biological Diversity (CBD) is the only major international convention that assigns ownership of biodiversity to indigenous communities and asserts their right to protect this knowledge but it competes for influence with the far more powerful TRIPS (18). The following articles of the Convention are deserved to be mentioned in this review:

**Article 8 (j):** State parties required to “respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional life styles relevant for the conservation and sustainable use of biological diversity and promote the wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices.

**Article 18.4:** Contracting parties should “encourage and develop models of cooperation for the development and use of technologies, including traditional and indigenous technologies.”
Insufficient and even non-existent protection of indigenous and traditional peoples rights in many of the countries make it difficult to create a balance between the possibilities of access posed by CBD and protection of those people’s rights. In the absence of strong national intellectual property legislation and vigorous implementation, the existence of such agreements does little to protect countries from exploitation of their medicinal plants and knowledge. Increasing number of publications will make contribution to the solution (18,19).

Sound collaborations should be formed between CBD–WHO and WTO (World Trade Organization) and groups such as IUCN (The World Conservation Union)/SSC (Species Survival Commission). Medicinal and Aromatic Plants Group under the IUCN /SSC can play important roles in finding solutions. The conservation and sustainable development of biodiversity require a diversity of approaches.

Main Discussions About IPR Related with Traditional Medicine

-Countries like India or China which is rich in traditional medicine innovations can benefit from IPR applications whereas others which are not innovators but the users of medicines will get harm. Insufficient documentation of the traditional medicine is against the lately documented areas since they loose the priority in IPR

-IPR consequences related with indigenous people cannot be separated from the problems of indigenous communities. Many communities became completely disappeared or assimilated as becoming “modernized”. Many of the traditions and applications will become a history soon.

-Introduction of money within traditional production-consuming relations is a threat to traditional life. The will to earn more in less time forces the young ones to go to the big cities and this creates a break point for the flow of information from the elder to the younger: This loss of interest creates a discontinuity to traditional medicinal systems (5, 20, 21).

-Encounters of populations shaped in the hands of different evolutions caused many catastrophic results during the history of colonization and invasions. Western economic enterprises which are highly competitive are behaving like invasive species in indigenous and traditional communities which are stabilized with rich biodiversity.

-Organizational and related insufficiencies in developing countries and their deficiency in competition against global economy are the negative points.
Since interrelations between Individual - Community – Innovator – Ethnobotanist – Commercial companies are based on short term benefits, creating long term and fair interrelations is difficult.

Without keeping traditional systems alive, IPR will not work for traditional medicine and it cannot be thought without conserving biodiversity.

Although CBD aims to protect rich biodiversity may aid in protection of access and sharing of the rich and powerful to the sources.

Until now people suffering from poverty, which are inhabiting biodiversity rich areas couldn’t be successfully incorporated into legal mechanisms of IPR which can be a successful tool for keeping inventive and novel indigenous knowledge while making a difference in economically poor communities, nations and individuals (4).

**Role of Ethnobotany and ethnobotanist**

Although science of ethnobotany is a tool to share traditional and indigenous knowledge with human society it has a risk to serve to global trade for exploitation of the indigenous and traditional medicinal information and sources. Ethnobotanist has the role of “explorer” and indigenous traditional medicine practitioners are playing the role of “inventor”. Ethnobotanist as a collector of information from the local people has a great responsibility to share this information with the great collection of human knowledge. Scientific publication and formation of database systems are crucial in forming a connection between science of ethnobotany and protection of property rights in traditional medicine.

Behavior of ethnobotanists as to how ethically approach their work and results with the indigenous may have serious concerns. One should think first and foremost of the people he wish to consult. What are their priorities? What will they get from this work together? A successful, mutually beneficial and reciprocal working relationship should be established.

**Actions Could and Should Be Taken**

- Countries should ratify and nationally implement the CBD if they have not already done so.

- National and international enforcement mechanisms in the IPR that ensure legal access to genetic resources and traditional knowledge should be fully developed and used.

- The TRIPS Agreement and national legislation should be clarified to avoid granting patents over naturally occurring genetic resources and biological discoveries.
-Political and legal flexibility in the existing international arrangements and negotiations to design and implement defensive and positive national *sui generis* (specially generated) systems to protect traditional medicinal knowledge should be maintained and enhanced.

- Broad and effective participation of indigenous and other local communities in all United Nations (UN) discussions and negotiations on genetic resources and traditional knowledge should be supported and ensured, and permanent mechanisms for participation created (22).

**Successful Case Stories**

- There are very good Indian experiences related with the subject and they can be used as a model for other countries. The emergence of “Honey Bee Network” in 1988-89 signified a point of departure in thinking about the way that should deal with people's creativity, knowledge systems and conservation ethics. The growth of the Honey Bee Network required an institutional support and it was felt that an independent support structure was much needed which could help to sustain Honey Bee newsletter and it's associated activities. SRISTI (Society for Research and Initiatives for Sustainable Technology and Institutions) and its research programmes were the results of that realization (23).

- In Cameroon, the need to ensure adequate protection of medicinal plants in an agreement with the US National Cancer Institute (NCI) led to the inclusion of access and benefit-sharing provisions for genetic resources in the new 1994 Forestry Law (24,25).

- In Peru, the know-how licensing regime adopted by the International Cooperative Biodiversity Groups (ICBG) project strongly influenced the preparation of a draft law for the protection of indigenous collective property rights (26). While marking a significant step towards the generation of *sui generis* legislation to protect traditional knowledge rights, the Peruvian process has highlighted conflicts of perspective, legal vision and interests that must be overcome in order to prepare measures that respond to indigenous and local community priorities rather than serving the interests of the commercial sector and national elites (27).

- The root of the turmeric plant (*Curcuma longa*) has long been used in Asian societies in cooking, cosmetics, and medicine. In traditional Indian Ayurvedic Medicine it is used to treat anemia, asthma, burns, conjunctivitis, dental problems, diabetes, diarrhea, pain, and many other ailments. In recent years, turmeric has attracted the attention of mainstream medical community as well. In 1995, two Indian scientists at an American university received a U.S. patent for a method of using turmeric to treat wounds. In response to a challenge filed by an Indian research
organization, the patent was overturned in 1997. This event is frequently billed as the first case of successfully reversing a biopiracy patent (28).

-In India, the turmeric case eventually opened up the path to the creation of Traditional Knowledge Digital Library (TKDL), namely, an electronic database of traditional knowledge in the field of medicinal plants. It aims to prevent the patenting of existing knowledge. Such a database would enable the patent officers all over the world to search and examine any prevalent use and thereby prevent incorrect grant of patent based on knowledge in public domain. The international acceptance of the TKDL project is also promising (29).

-In 2002, an important precedent was set when the San nation, one of the South Africa’s oldest tribes, reached an agreement with the Council for Scientific and Industrial Research (CSIR) of South Africa, a government body, and signed a pact that acknowledged the San were holders of traditional knowledge. For centuries the San have chewed Hoodia \((Hoodia pilifera)\), a cactus plant, to stave off hunger and thirst during hunting trips in the desert. The theft of intellectual property rights of the San began in 1996 when researchers at CSIR were able to isolate the hunger-suppressing component of the Hoodia plant. The newly identified component was named P57 and patented. The next year CSIR, which retained ownership of the patent, brought in company to further develop P57, in turn, licensed one of the giant pharmaceutical companies to develop and market the compound. The San had shared their knowledge of Hoodia with CSIR, but they were not party to share of a product that could be worth billions of dollars as a natural appetite suppressant. After three years of negotiations, the San and the CSIR have agreed to share the profits from developing an antiobesity drug (28,30).

-In 1991, a contract was signed between Merck and Costa Rica’s Instituto Nacional de Biodiversidad (INBio), a nonprofit organization. In terms of this agreement, over a two-year period, Merck received some 10,000 plant samples. Merck was supplied with information about their traditional use. Merck paid a reported $1.35 million to INBio for these samples and has agreed to pay a royalty of between 2 percent and 3 percent. If one of the samples becomes a billion-dollar drug, Merck has agreed to pay INBio between $20 million and $30 million in royalties (28).

-The Coordinating Body of Indigenous Organisations of the Amazon Basin (COICA), which represents more than 400 indigenous tribes in the Amazon region, along with others, protested about a wrong patent that was given on a plant species native to the Amazon Rainforest, called \(Banisteriopsis caapi\) and its traditional medicinal uses through an indigenous product called

-The neem tree (*Azadiractha indica*) is mentioned in Indian texts written more than 2000 years ago. Products made from it have many uses, including for human and veterinary medicines, cosmetics, insect repellent, and fungicide. Indian farmers traditionally soaked neem seeds in water and then sprayed the emulsion on their plants. Western businessmen were attracted to neem because, unlike most chemical pesticides, it has few damaging side effects. There are many patents on neem products, in India and as well as in the United States and Europe. In 1993, P.J. Margo Private Ltd. began producing and marketing neem biopesticides in India. Public demonstrations broke out against this venture, and a collection advocacy groups joined together in 1995 to challenge the European and U.S. patents on the grounds that the product/process was not novel, Indians had been using neem products in the same fashion for centuries. The European Patent Office revoked the patent in Europe, but the U.S. patent remains valid (28).

-Shaman Pharmaceuticals, founded in 1990, uses ethnobotany as a cornerstone of its drug development process. A pioneer in its approach, Shaman is active in 30 countries throughout South America, Africa and Asia. In each region, it conducts local studies of epidemiology, traditional medicine, culture and ecology of the people and their environment. It focuses on plants that are used by the indigenous people to treat viral and fungal infections, central nervous system disorders, and diabetic conditions. Targeting plants through ethnobotany saves time and money. Within 24 months of Shaman’s launch, two products were ready for clinical trials: one for the treatment of respiratory viral infections and another for the treatment of herpes.

To ensure a long-term supply of plant material for its products, Shaman is developing business relationships with indigenous groups. In Peru, for example, Shaman negotiated with Consejo Aguaruna y Huambisa, an indigenous federation representing 30 000 people, to harvest and supply plant material on a sustainable basis. Shaman recognizes that such a sustainable harvest provides a source of income for indigenous people and contributes to the protection of biological and cultural diversity.

Shaman offers other reciprocal benefits for indigenous communities. Up to 15% of a research expedition budget is used to meet the immediate needs of local communities, which identify their own priorities. Over the longer term, when products begin going to market, Shaman plans to return a portion of the profits realized from its pharmaceutical products to the governments and indigenous organizations in the countries where it works. These revenues will be distributed
through the “Healing Forest Conservancy”, a nonprofit organization established by Shaman Pharmaceuticals (32).

- The Kani community comprises around 18 000 people spread across 30 settlements and villages in the forests of the Agasthiyar Hills of Western Ghats in Kerala, India. Traditionally, Kanis have consumed a dried fruit of *Trichopus zeylanicus* to reduce fatigue. The “discovery” of the therapeutic properties of the herb by a team of Indian scientists visiting the region in 1987, laid the foundation for the Kani Model of Benefit Sharing (KMBS). On the basis of this discovery, Tropical Botanical Garden and Research Institute in Kerala standardized a herbal as a tonic to bolster the immune system and provide energy formulated with *T. zeylanicus* in combination with three other medicinal plants. In 1996, the production technology was transferred to an Indian pharmaceutical company which agreed to share the licence fee and royalty with Kani community on a 1:1 basis. The amount due to the Kanis was transferred to the Kerala Kani Community Welfare Trust which first registered with members from the Kani tribe, with the understanding that the share of the licence fee and royalty would be in the form of a fixed asset of the trust used for welfare enhancing activities of the Kanis (33).

What do these cases tell us about channelling benefits from commercialization of traditional knowledge back to the originating communities? One might categorize solutions as follows:

1. **Harmonize IPR laws.** The “TRIPS Solution” is to harmonize legal protections across countries, which implies introducing rich country IPR regimes into poor countries. From this point of view, uneven IPR protection generates uneven commercialization.

2. **Reform rich country IPRs.** An alternative view is that IPR regimes in rich countries are the problem, and therefore all governments should eliminate patentability of plants (“no patents on life”) and require disclosure of traditional knowledge used.

3. **Place ethnobotanical knowledge in the public domain.** Much traditional knowledge is oral tradition, it must be documented and published. This strives to ensure that nobody will commercialize traditional knowledge.

4. **Create knowledge-sharing contracts.** Introduction of contracting mechanisms and creation of tollgates on the transfer of knowledge are obligatory.

5. **Promote indigenous commercialization.** Commercialization at home must be realized, irrespective of industrial country property rights.
Generally it is known that; traditional medicines are made for traditional uses, not for future sale in distant locations. The challenge facing developing countries is to unpack knowledge from traditional products and repackage it for commercial markets. The existence of IPRs is insufficient to meet this challenge (28).

CONCLUSION

Production of intellectual property, giving a value to it, its protection and use has an increasing importance in the world. Traditional and indigenous life and its properties are annihilating to tremendously changing world of today. These biodiversity and value rich societies are unfortunately among the poorest of all nations and communities. People richest in nature and indigenous knowledge is poorest in capital, technology, infrastructure and access to legal mechanisms. Basic conflict is the incompatibility of standardized uniform commercial systems of developed capitalist countries with traditional health systems which includes traditional knowledge and property protection systems. Main duty is at United Nations, national governments and trade related organizations for the fair trade but Third World Countries and especially the NGOs (Non-governmental Organizations) should be aware and be careful about the current and future trends of the concept. Spirit of initiations such as “Mataatua Declaration on Cultural and Intellectual Property Rights of Indigenous Peoples” should be replicated in other parts of the world (34).

Another disadvantage is the difference in the community structure in every country. Benefit sharing mechanisms of IPR should also be. There cannot be a magic solution for every situation. Deciding whether patenting or legalizing the plants will help the less favorable indigenous people. *Sui generis* systems are good alternatives for the improvement of TRIPS and sometimes mentioned as TRIPS plus. Third world needs a modified form of TRIPS (35,36). However there is scepticism that this *sui generis* option will be adequate to provide any significant alternatives to existing IPRS (37). Change in way of thinking is very important and economical entities should base on cooperation rather than competition. Pharmaceutical companies should be positive towards traditional people during their quest for new phyto-pharmaceuticals and case of Shaman Pharmaceuticals should be discussed as a primary model for such companies (38,39).

Linking IPR with Convention of Biodiversity is very important. Extinction will annihilate plants and traditions and indigenous life will also take its toll. Tsunami of globalization destroys everything or changes to money. Adaptation lived by local people to capitalist systems are against the spirit of traditional medicine and CBD. The basic dilemma is if one thing has no value in
money it may disappear, if it has value it will be used by the most powerful player which has the biggest capital and infrastructure. In both cases traditional people may suffer.

Ethnobotanist should not be just collectors of information basically for their scientific purposes or should not become simply as the traders of knowledge. Publications, meetings and decisions pass the responsibility from scientists to application bodies but not the ultimate solution without action. Ethnobotanists cannot escape from responsibility after a publication or anything else. They should be keeper of both the information gathered and the rights of the people which the knowledge originated. Ethnobotanical information should accumulate both in scientific media and digital libraries specially formed for this subject. Combining the Traditional Knowledge Digital Library with the International Patent System through an International Traditional Knowledge Resource Classification System will be a very important improvement towards future of the situation.

Last but not the least, adaptation of the healer which is doing this action for a mission and not for money into the commerce is difficult. Although as a tool for exchange in the beginning, money has its own value today and makes us not to see other values in life.

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