Agricultural microbial resources: private property or global commons?

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Agricultural microbes have become an attractive target for patenting, but the lack of a consistent global patent regime and increasingly heated debates over microbial ownership rights are barriers to the development of this resource.

Microorganisms are an increasingly important source of innovation for global agricultural systems[1]. As one of the last commercially unexploited agricultural frontiers, microbes have emerged in the global research agenda as a low-input way to increase agricultural productivity and crop yields[2,3]. The potential for microbes to increase nutrient availability, enhance crop growth, increase decomposition of organic matter, and protect against pathogens and pests has garnered the attention of both large and small producers[4–8]. In 2007–2008, the global microbial biopesticides market was valued at \$396 million[9].

The functional benefits of agricultural microbes makes them attractive targets for patenting[4,10,11]. Microbes represent an enormous untapped pool for genetic and biochemical diversity for bioprospecting. For example, *Beauvaria bassiana*, a fungus native to Brazil, has been patented as a means to control fire ants, a pest responsible for billions of dollars in damage to US crops. A claim has been made on the Costa Rican bacterium *Streptomyces dicklowii* as a biopesticide to treat and prevent nematode infections in crop plants, which cause an estimated \$80 billion in worldwide crop damage. High revenues associated with the crop protection industry drive a keen interest in developing new microbial control agents for the growing agriculture sector[5,10,12].

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Status of microbial patents

The United States has granted patents on microorganisms for over 30 years, and the European Union offers broad patent protection to any genetic material capable of reproduction. Most industrialized countries recognize patents on naturally occurring substances if (i) their existence was previously unknown and (ii) they were isolated or purified in a laboratory[13]. Legally, isolated microorganisms are not a product of nature but a human invention[14]. International agreements make it difficult for individual countries to enact their own microbial patent laws. For instance, Article 27.3(b) of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement under the General Agreements on Tariffs and Trade (GATT) does not allow member states to exclude microorganisms from patents. However, TRIPS specifically allows countries to exclude patenting of plants and animals, raising the question of whether the distinction is political rather than scientific.

As the race to patent microbial-based products heats up, it is increasingly important to define what is legally patentable. As with other types of patents, novelty and reproducibility are the key criteria for establishing a microbial patent. In plant and animal patents, novelty is typically met by human interventions such as addition of a gene or a trait. However, the degree of novelty required for microoganism patenting varies across countries. In the United States, the isolation of a microbe is sufficient to satisfy the legal novelty requirement, and reproducibility of the process is satisfied by placing the microorganism in a depository[15]. In contrast, Indian patent law makes a clear distinction between a discovery and an invention; the isolation of a microorganism from nature is considered a discovery and cannot be patented, unless a human intervention adds an inventive step[16]. A modification in the microbe's DNA would qualify it for patent protection. As a result, an isolated but otherwise unmodified microbe of Indian origin could not be patented in India, but would be subject to patent protection in the United States.

Parallels between the development of crop and microbial germplasm

Global inconsistencies in patent laws have driven a heated debate over microbial ownership rights[11]. Profits from bioprospecting are predicted to keep rising. Who should share in these profits? The country of origin? The community from which the microbe was isolated? The scientist that isolated and deposited the microbe in a collection? One of the best illustrations of potential conflicts inherent in microbial patent rights is the case of microbes derived from agricultural fields.

Potentially valuable agricultural microbes have developed as a result of hundreds of years of farm management practices[17]. Indigenous communities have long been recognized for their role in manipulating soil and plant biodiversity to increase agricultural output[18–20]. Long-term studies have established that farm management practices, such as crop selection, tillage, rotation and fertilizer regimes drive the evolution of specific consortia of agricultural microbes[21–26]. These management regimes have the potential to select for microbial genotypes that can increase agricultural productivity, for example, by enhancing protection against pathogens, increasing nutrient cycling, or increasing nutrient uptake by crop hosts[7,17,27–29]. These traits have made agricultural microbes a major target for bioprospecting.

Should farmers benefit from the commercialization of microbes isolated from their fields? Microbial selection processes are roughly analogous to the evolution and development of crop varieties, driven by farmers as a result of years of selection. Although a legal framework to recognize farmers' contributions to crop genetic resources is currently in development, no such framework exists to recognize farmers' contribution to the development of microbial germplasm. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) acknowledges the contributions made by indigenous communities in developing crop varieties and formally introduced the concept of farmers' rights[30]. Although farmers' rights have yet to be given an official definition within ITPGRFA, the concept is based on recognizing and rewarding farmers (by means of benefit-sharing programs) for their contributions to the global pool of genetic resources[31,32] (**Fig. 1**).

In both the development of crop and microbial resources, farmers act as selection agents to increase the reproductive success (that is, fitness) of particular genotypes. A major difference is that microbial selection in agriculture may be less directed, or even unconscious. However, unconscious selection has also been identified as a fundamental component of crop variety development[33]. In both cases, the end result is useful germplasm developed by farmers in a mediated selection process.

However, unlike with crop selection, no formal recognition of farmers' rights or potential benefit-sharing programs has been proposed with respect to the microbial resources that evolved or developed from farming regimes (**Fig. 1**). This situation is more worrisome because, as noted previously, states cannot exclude microorganisms from TRIPS patenting regimes and TRIPS does not place any burden on the holder of a patent to share benefits with the individual or community from which the microorganism was isolated and purified. Further, there is currently no international instrument to grant intellectual property rights (IPR) to communities for their knowledge or development of microbes[14,34]. It can also be difficult to identify microbe origin[35], and as a result bioprospectors are more likely to avoid benefit-sharing costs with microorganisms than with crop organisms[36,37].

One of the biggest dangers of the current patenting trend is resource underutilization due to the development of an anti-commons granting exclusive patent rights to one party[38,39]. For example, the *sui generis* option of TRIPS 27.3, which allows states some flexibility in plant and animal protection approaches, motivated states like India to enact stricter legislations restricting access to these resources. Access procedures are now more complicated, typically lack transparency, and can lead to delays in obtaining genetic materials[40]. These restrictions have also resulted in backlash and recriminations between scientists and regulators. For instance, when authorities in India prosecuted and convicted two Czech entomologists under the Indian Biodiversity Act of 2004—aimed at protecting national biological resources from patenting threats—the Act became a focal point for criticism because it presented new barriers to scientific research[41].

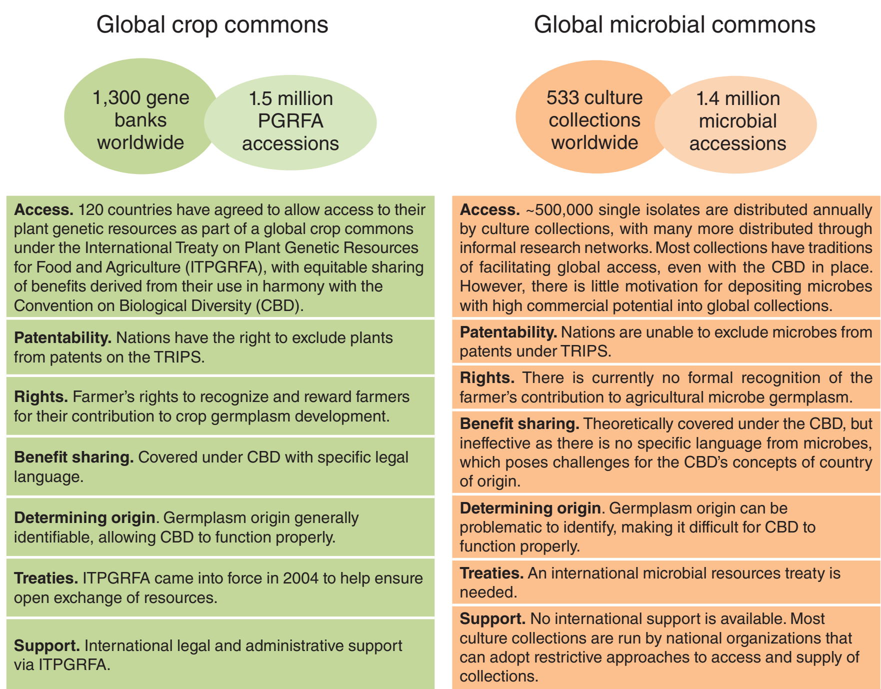

Figure 1 Distribution framework for crop and microbial resources. Although nations have rights to exclude plants and animals from patents, they are unable to exclude microbes. Microbes are covered under CBD, but there is currently no framework to recognize farmers' contributions to the development of agricultural microbe resources.

Potential solutions

How can profits arising from microbial resources be shared equitably? In the case of agricultural microbes, one idea is that farmers or the community from which the strain was isolated enter into a specific benefit-sharing agreement with the industry developer.

The United Nations Convention on Biological Diversity (CBD), which covers microbial germplasm, requires that parties ensure equitable benefits arising from sharing of genetic resources (**Fig. 1**). However, asymmetries of information and power can make it difficult for communities to negotiate equitable benefit sharing[13,42]. A further complication is that the CBD was formulated with the recognition that microbial genetic resources need special consideration, but no specific recommendations have been made for benefit-sharing regimes[43]. Because TRIPS does not require patent applications to be compliant with CBD principles, prior informed consent from communities of origin and proof that benefits are fairly and equitably shared are not required[44]. Moreover, patents have been issued for organisms that allegedly lack adequate inventive steps or novelty, raising concerns of resource misappropriation[44].

In 2010, a CBD meeting called for a review of patent trends for microbial genetic resources, including the impacts of property rights on small-scale farmers in developing countries[34]. Working groups have called for leaving space in international protocols for agricultural microbes, but no specific terms have been proposed for enacting benefit-sharing programs with farmers or communities[34]. IPR systems are geared toward protecting the rights of a single creator, and have thus far proved to have difficulties in accommodating contributions of communities[31,45,46].

On the other end of the benefit-sharing continuum, some have called for the creation of a global microbial commons based on intergovernmental recognition[47,48]. There are currently 533 microbial culture collections—all members of the World Federation of Culture Collections (WFCC)—to facilitate access to global microbial germplasm[48]. However, there is no global consistency among collection protocols. Whereas some culture collections like the American Type Culture Collection (ATCC) assert ownership of their collections, other collections assign ownership rights to the country of origin. Regional entities such as the European Culture Collections' Organization have sought to devise harmonizing guidelines to meet CBD compliance, facilitating exchanges between entities operating in different legal systems[11]. A 'virtual' common pool of agricultural microbes, with pre-agreed terms and conditions, has been proposed to create an open network of microbial collections operating on consistent legal terms[34]. This approach would bring the microbial commons closer in line with the legal frameworks developed for plant genetic resources collections[47].

However, collections oriented toward a 'commons' paradigm appear to be faltering as microbe patenting increases[48]. Collections of nitrogen-fixing rhizobial strains are a case in point. Despite the existence of various databases and collections (e.g., ATCC, German Collection of Microorganisms and Cell Cultures (DSMZ), Laboratory of Microbial Gene Technology (LMG)), IPR and other obstacles are restricting strain exchange[8]. For example, although rhizobial strains for taxonomic studies are widely available, commercially promising inoculant strains are often not listed in databases. Instead, they are generally maintained by companies or research institutes with restricted exchange accessibility[8]. A 'commons' approach is a potential solution, but there is little motivation for depositing microbes with high commercial potential into a commons-oriented collection[34].

A third solution, which falls between direct farmer and/or community profit sharing and a global microbial commons, is a state-administered system that collects revenue from microbial commercialization and steers it toward programs benefiting agricultural communities. In Uruguay, nearly 100% of farmers employ commercial rhizobial inoculum. This high adoption rate has been possible because of a state-supported strategy developed among public research, private industry and farmers to maximize the dissemination of nitrogen-fixing microbes[8]. Industry profits from wide distribution of products, and at the same time farmers benefit from development and access to new microbial technologies. Under this approach, individual states would have a stronger role in governing microbial rights.

Nevertheless, there are dangers in concentrating ownership rights in the state[32], and this approach does not guarantee equal access for all. In some cases, state monopoly has facilitated the transfer of resources to private enterprises at a cost to the general public[42,49,50]. State programs should include transparent benefit-sharing regimes focused on specified public investment. In the case of agricultural microbes, the most appropriate beneficiaries are agricultural development schemes in the communities of origin.

Conclusions

Should farmers or communities have rights to the microbial resources derived from their fields? There is no clear answer, but the question is becoming more and more important as investment in agricultural microbe technology increases. At the very least, the concept of farmers' rights, originally developed to recognize farmers' contributions to crop germplasm development, should be extended to acknowledge the farmers' role in the development of agricultural microbes. The implication is that farmers should benefit (directly or indirectly) from any bioprospecting profits derived from agricultural microbes. Although enacting a benefit-sharing program that recognizes individual farmers or communities from which microbes are derived is unlikely, programs should be established in which profits from bioprospecting are used for further agricultural development. The key objective is to facilitate rapid, regular and low-cost exchanges of microbial resources for use in research and breeding. IPR laws are effective, but to be legitimate they must be adapted to diverse situations[14].

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