There are a number of concerns raised by the patenting of living organisms and germ plasm. These range from the metaphysical (what counts as part of nature versus as invention) to practical policy concerns. Among the primary considerations are worries over justice, particularly with respect to "bioprospecting" or "biopiracy"—the development and patenting of material derived from resources and knowledge in less developed nations for the benefit of corporations based in developed nations. I will briefly survey some of the general concerns before focusing on the issue of biopiracy and the justice arguments they present.

The 1930 U.S. law governing plant patents resulted in the patenting of (asexual) plant organisms. The plant variety protection system (PVP) set up in the United States in the early 1970s created a broader system of protection, by including seeds. The 1980 Chakrabarty decision by the U.S. Supreme Court made it possible to patent living organisms (bacteria) and opened the door to the patenting of other organisms, including mammals. Beginning in 1985 (Ex Parte Hibberd), it was possible to obtain utility patents on plants as just another kind of invention. The legitimacy of these plant patents has recently been challenged (JEM Ag Supply v. Pioneer Hi-Bred) on the grounds that the PVP system is meant to handle plant property rights, rather than utility patents. Potentially this could lead to a revisiting of the issues raised in Chakrabarty. (See chapters by Chakrabarty, Wilson, and Seide and Stephens on these issues).

The patenting of organisms and their germ plasm raises a host of broad issues. First, there is the question of the "product of nature doctrine." In case law, it has been established that it is not possible to patent "laws of nature" or
physical phenomena. The question that then arises is how it is possible to patent an organism. How much of a change in an organism needs to be made before it is considered no longer part of nature, but a result of “being touched by the hand of man?” As Wilson’s chapter makes clear, this is a complicated set of issues—engineered organisms seem to represent a middle ground between “naturally occurring” and “manufactured,” between “invention” and “discovery.” Unsurprisingly, when legal and policy issues hinge on the answer to metaphysical questions, controversy ensues. In such a situation, most positions are defensible, either in favor or against the “ownership of life.”

A second objection to agricultural patents is the “common heritage” argument. This objection states that the germ plasm and various organisms (even modified forms) are all essentially a function of the natural world that we all equally inhabit and have inherited. Therefore, we all have a right to share in the benefits of that inheritance. Any intellectual property rights restrict access and use of our shared heritage. In the end, this objection reduces to a version of the previous argument. If a plant variety, a genetically modified organism (GMO), or a gene is a product of nature, it is legitimate to think it is part of our common heritage. If it were truly an innovation or an invention, then it would not really be part of our common heritage. Furthermore, the key justification for a patent system is to promote the general good, through encouragement of both investment (in research and development) and disclosure. Thus, even if plants and other purportedly patentable material were part of our common heritage, there is no reason why patent protection or other intellectual property (IP) regimes could not be enacted as the best means of utilizing that heritage for the general good.

A third general argument against these patents is that they lead to the commodification of life (see essays by Ossorio and Hanson). Patenting of living things requires that we conceive of them in market terms. It implies both ownership and an instrumentalism that is incompatible with many views about the nature of life. This objection has particularly been made from a theological perspective: as a gift from God, life is transformed into an “invention” to be owned and used. It shows a lack of respect and hubris with respect to the world and our relationship to it. This is often expressed in visceral terms as a concern over “playing God.” Though this objection has some weight, it is counterbalanced by arguments about the benefits of utilizing the patent system as a way of encouraging the development of products and even organisms that will be helpful to humanity. Every reli-
igious tradition recognizes the importance of balancing the need to “preserve the garden” with the need to “tend the garden.” The key question is whether patenting of organisms, genes, cells, and the like, pushes the appropriate balance to an excessively instrumentalist view of nature.

These arguments and the legal context in which they take place are well chronicled in earlier chapters of this book. But, they also occur in a changing international context. In the rest of this chapter, I will look at some of the ethical and social issues raised by the “ownership of life” in the agricultural context, particularly with respect to less developed countries (LDCs). Until fairly recently, patenting practices varied widely from country to country and practices that were common in the United States and other Northern nations were often restricted or forbidden in the Southern LDCs. The United States and European Union (EU) were often frustrated in their attempts to enforce intellectual property rights in LDCs. Many of these nations only allowed process patents, not product patents. Therefore, generic companies operating in these countries only had to produce the same pharmaceutical product in a different way to circumvent the patent a company had on a drug. Different countries also recognized patents for varying lengths of time. India, for example, only recognized process patents, and only for a period of five years. Many of the Northern pharmaceutical companies found this a problematic situation for their research and development efforts. Pfizer found that prior to government approval of the antiarthritis drug Feldene, a generic competitor already existed in Argentina, and by the time they went to market, they faced competition from six generic drug companies. Attempts to change the system to make it more uniform across national boundaries met with failure. The World Intellectual Property Organization (WIPO) was set up as a United Nations agency in 1967 to administer international agreements and treaties with respect to IP issues. The Paris Convention of 1883 required that each nation grant the same patent protection to people from other countries that they grant to their citizens. This requirement did nothing to stop countries from having IP systems that differed markedly from the U.S. system, as long as they were consistent. Therefore, Pfizer and other companies began to lobby the WIPO to change the Paris Convention. This effort met with failure. Later, the United States, the EU, and Japan agreed to pursue an alternative. There began to be an increasing connection between IP and trade. This resulted in increasing pressure from the United
States and other Northern nations on the LDCs to comply with their patent protection systems or face trade sanctions. And, because of negotiations over the General Agreement on Tariffs and Trade (GATT), there emerged a “floor” governing IP systems in all GATT nations, through the Trade Related Aspects of Intellectual Property Rights (TRIPS).

The question that the current system raises is whether it is fundamentally unjust. LDCs are systematically disadvantaged relative to the interests of the United States, the EU, and their multinational corporations. The traditional knowledge and the germ plasm of LDCs are mined for their value for industrial interests, often with little or no payback to the original developers of the material. This is sometimes referred to as “biopiracy.” There are at least two different arguments. First, LDCs may be responsible for both the creation and the preservation of valuable germ plasm. These organisms have often resulted from years of agricultural practices (similar in many respects to scientific plant production), and efforts by indigenous groups to preserve valuable and rare resources would seem to entitle the developers to some of the benefits that may accrue as the result of usage of the organisms or genes that they have helped to create and preserve. I will refer to this as “resource biopiracy.” Second, traditional knowledge also involves knowledge of how the raw materials can be harnessed for various purposes: medicinal, agricultural, and so on. The argument that is made here is that IP built on the basis of traditional knowledge should either entitle the communities that created that knowledge with a share of the benefits that ensue, or more typically that the traditional knowledge constitutes prior art and thus invalidates any IP claims. I will refer to this as “knowledge biopiracy.” It is important to recognize that these two arguments may conflict—one is aimed primarily at a share of the benefits of the products that eventually result, while the other attempts to invalidate the legitimacy of the patent claims, leaving development outside of the IP system. I will discuss several examples to illustrate the issues at stake in what are often treated as paradigm cases of biopiracy.

THE BEAN WARS

According to his patent application, in 1994 Larry Proctor purchased a bag of assorted beans in Mexico. He selected the yellow beans and brought
them back to the United States to try growing them in Montrose County, Colorado. He began crossbreeding and selecting and found that he had a plant that had many desirable characteristics: heartier, more moisture resistant pods, and a distinctive yellow color. In 1996 Proctor applied for patent protection and in 1999 received both a utility patent and a U.S. Plant Variety Protection certificate. This patent covers any yellow beans (of a certain shade) from *Phaseolus vulgaris*.

The yellow beans that Proctor found in his “package of dry edible beans” in Mexico were not unique. Mexican breeders have been growing yellow beans for centuries. In recent years, agronomists have been crossing them and producing improved varieties. In 1978 the Mayacoba bean was developed, and has since become quite popular in parts of northern Mexico. There are several other yellow varieties that are also common. In 1994 Rebecca Gilliland began working with a bean cooperative in Los Mochas to arrange to export the Mayacoba to the United States. Exports gradually increased until 1999 when Proctor’s company, Pod-NERS, claimed that Gilliland was infringing on his patent. He demanded six cents per pound (the beans now sell for roughly twenty-seven cents per pound) to license the selling of the beans. Gilliland refused, and she was subsequently served with a patent complaint. She claims that Proctor demanded that U.S. customs agents inspect her produce and bean shipments at the border to prevent yellow beans from being brought into the United States. The result is that the beans are no longer exported, and the farming cooperative has lost out on investments in sorters and Stoneers.

This case has enraged both opponents of the practice of patenting genes and organisms as well as those who advocate better use of the IP system in LDCs. The Mexican government filed a suit to challenge the patent claims, and more recently, the Center for International Tropical Agriculture (ICTA) has also filed a claim against Proctor’s patent. Under terms of the 1994 agreement between the Consultative Group on International Agricultural Research (CGIAR) and the United Nations Food and Agriculture Organization, any germ plasm maintained by the CGIAR is part of the public domain. Intellectual property claims can not be made on any of this material. There are several varieties of yellow beans in the CGIAR’s holdings that would seem to infringe the Proctor patent. There are reports that genetic analysis performed by Mexico’s National Research Institute for Agriculture, Forestry, and Livestock as well as by the ICTA have demonstrated that Proctor’s Enola bean is
genetically identical to plants in the CGIAR holdings (though interestingly, not to the Mayacoba). Further, many geneticists have argued that the two years between 1994 (when the patent claims Proctor found the beans) and 1996 (the time of filing) are not sufficient to truly develop a novel plant variety. In response, Proctor now claims he found the initial yellowish beans in Mexico in 1990, rather than in 1994 as he had earlier claimed.

The case of the Enola bean illustrates beautifully the concept of resource biopiracy. There is no disputing that the raw material for the variety produced by Larry Proctor came from Mexico. It is also clear that the beans that he used (or similar beans) were a product of efforts to both produce and preserve particular varieties, and that ongoing efforts by local farmers and agronomists were underway to produce similar results (similar enough to violate the patent that was issued). Yet those efforts did not result in any IP claims on the part of the developers of the Mayacoba or any of the many other yellow varieties of *Phaseolus vulgaris*. And to answer the claims of Proctor, the CGIAR must undertake expensive litigation. Moreover, success hinges on establishing that the prior art invalidates the claim. In the absence of a native IP culture to protect the interests of local farmers, it is imperative that there be seed banks that can compare older samples with putative new varieties as a way of establishing prior art.

**TURMERIC**

Turmeric has been widely utilized for healing wounds by people in India for centuries. In 1995 two University of Mississippi researchers (of Indian descent), Drs. Soman K. Das and Hari Har P. Cohly, were granted a patent on the use of a certain amount of turmeric as effective for healing wounds. Their patent on “an effective amount of turmeric powder” included both the oral and the topical application of the treatment for surgical wounds and body ulcers. The Council of Scientific and Industrial Research (CSIR) later challenged this patent. A good deal of documentary evidence established the long-standing use of turmeric for precisely these purposes. All told, thirty-two documents were submitted from a large literature on the subject. The patent was canceled in 1997. This case was widely hailed as both a triumph of the existing regulatory system and a demonstration of the inadequacy of the U.S. patent system to prevent biopiracy.
This is a clear example of knowledge biopiracy. As the subsequent challenge clearly demonstrates, the use of turmeric for medical purposes has a very long history. However, it took an expensive legal challenge to successfully overturn the patent. And the key to success was the production of documentary evidence to establish that the use of turmeric for treating of wounds constitutes “prior art.” This means that cultures whose practices are not documented will not be recognized, even if they are quite common and well known locally.

NEEM

The neem tree (a member of the mahogany family) has a variety of uses in India, ranging from medicinal properties to the use of an extract derived from the neem that has proved effective as an insecticide. In addition to its well-established properties as an insecticide, its twigs have been used to clean teeth, its leaves have been used to brew tea to treat a range of ailments, and juice from its leaves has been used to treat skin disorders. The neem tree has been referred to as “the village pharmacy” for all of its uses. Researchers studying many of these properties have attempted to develop products out of the neem. Over thirty patents have been granted on the neem, including one by W. R. Grace of Boca Raton, Florida, on a process for fractionating oils of the neem so that they are more stable and hence can be stored for much longer than the oil extracts that are commonly used as an insecticide. Grace claims the shelf life has been extended from a few days to two years. This patent was granted in 1992, but was challenged by the Foundation on Economic Trends. The challenge was denied, largely due to a failure to offer substantial documentation. Grace holds a number of other patents as well, and at least one them—a fungicide derived from the neem seeds—was finally invalidated (after a lengthy legal and political battle) by the European Patent Office in 2000 on the grounds that the process for which the patent was obtained was actually demonstrably in use for some time. This case has produced a tremendous controversy. Regardless of the substantive legal issues, the neem tree has a social and cultural meaning which makes the prospect of “owning it” far more problematic than any straightforward legal analysis would indicate.

This is in many ways the most complex case. The claim on neem for a pesticide represents both resource and knowledge biopiracy and was over-
turned. More complex is the process patent procured by Grace for developing a more stable variety of the pesticide. This would seem (unlike the previous two examples) to be a fairly straightforward example of the value of bioprospecting. However, it is important to recognize that the material came from India, the basic knowledge of the properties of the neem products and its uses came from India, and there was an indigenous ongoing research program from the 1920s on attempting to derive products from neem including more stable versions of the pesticide. It is unsurprising that developed nations and their corporations would succeed more quickly than the basic research scientists within the LDCs. The current patent system rewards only the conventionally defined “winners” of the race—and this means that the relative latecomers to the research (such as Grace) can build on what has gone before and still procure the patents and de facto win control over future uses of the neem as a pesticide. Thus, the nations that produced the germ plasm and the knowledge that made the developments possible are left without any recognized stake in the eventual rewards that issue from the technology.

The turmeric case is a wonderful example of knowledge biopiracy. Again, the key to the invalidation of the claim was the documentation that established that the usage of turmeric had already been well established prior to the patent issued to the University of Mississippi researchers.

ISSUES RAISED BY THESE CASES

There are several ethical problems with the current IP system as it stands. First, with respect to germ plasm from LDCs, critics have pointed out the disparity between the way genetic resources and other natural resources are treated. Petroleum or mineral resources are the property of the nation within which they reside. Genetic resources, in contrast, “have long been considered a common heritage available to other nations for free.” As the case of the “Bean Wars” indicates, the LDCs often act as stewards of these resources and even utilize scientific methods to develop them. But there is no systematic way of rewarding them for preserving and developing these resources. One solution to this problem has been to create the Convention on Biological Diversity (CBD). This requires that researchers from signatory nations must seek permission prior to utilizing genetic resources from other countries. However, given the extent to which valuable genes and organisms
have already flowed from LDCs to the North, and the additional problems of enforcement, it is not clear that the CBD is a panacea for these problems. Further, it is not clear how to address the conflict between the CBD and the TRIPS. From a moral point of view, the fact that local communities preserve and create genes and organisms would seem to require that ethically they are entitled to some form of benefit sharing in the fruits of future product developments based on their material. The CBD is one mechanism that can help promote benefit sharing, but more needs to be done.

Second, there is the way that the regulatory system seems stacked against LDCs. As the neem and turmeric cases in particular make clear, a U.S. patent can only be invalidated by claims of prior use if there is evidence of use in a form recognizable by the U.S. courts and patent and trademark office examiners. That is, accessible documentation or prior patents are needed to invalidate a claim. If indigenous, traditional knowledge is largely expressed in customs, habits, and oral traditions, they will not be recognized in the patent system. There may even be problems if the documentation is not in English or an easily accessible language. This results in systematically favoring nations with well-established IP systems similar to the one in the United States, and it favors nations that have strong written rather than oral traditions.

In the area of biotech patents, particularly in the United States, there seems to be a great deal of leniency in granting patents by examiners and reliance on the courts and other systems of appeal to overturn patents that are invalid. The problem with this is that it favors nations and corporations with financial resources, which have an incentive to attempt to procure as many patents as possible, whether valid or not, and place the burden on poor LDCs or nongovernment organizations (NGOs) to attempt to invalidate them. Invalidating the turmeric patent cost several hundred thousand dollars, as will the attempt to invalidate the Enola bean patent. It is simply not possible for every one of the many alleged cases of biopiracy to be challenged by the LDCs or the NGO community. It is important to note that the previous argument (which applied to resource biopiracy) leads to a very different conclusion than this argument (which will apply primarily to knowledge biopiracy). This argument challenges the validity of the patents at all, rather than making a case for benefit sharing.

The ramping up of the IP systems in some of the LDCs might be helpful in trying to deal with some of these problems. Peter Drahos has
suggested creating a Global Bio-Collecting Society to better reward the contributions of indigenous groups for their knowledge.\textsuperscript{8}

A third argument against the current system is that the LDCs are arguably deprived of future potential benefits through the opportunity to develop products based on their indigenous genetic resources and/or traditional knowledge. For example, if a company such as W. R. Grace has, in fact, substantially created an innovative process to create a more stable version of the neem pesticide, the current patent system makes them the sole beneficiary. However, it is quite possible that local industries would have eventually produced the same product. Indeed, native neem researchers have conducted most of the research done on the neem tree, beginning in the 1920s. They were ignored for decades. This pits the interests of developed nations, which want products to be developed as quickly as possible, against the interests of the LDCs. Again, this system will favor those nations and institutions (corporations and universities) with the resources to develop products as quickly as possible, building on the genetic resources and traditional knowledge of LDCs.\textsuperscript{9} This is particularly problematic because, in addition to losing future economic opportunities, it may undercut current local businesses as new products undercut existing ones. For example, current neem-based pesticides (with a short shelf life) will presumably lose out in the marketplace in competition with Grace's more stable neem-based product. The loss of traditional industries in competition with superior products could result in food security problems in LDCs.

This argument underscores the importance of developing ways of sharing the benefits with the communities that materially contribute to the development of valuable IP, not just those eventually defined as the "inventors."\textsuperscript{10}

Finally, we need to be concerned about the impact of bioprospecting and biopiracy on the lives of the people in LDCs. When Grace processes twenty tons of neem seed per day in India, it changes the agricultural practices in many ways. It drives up the price of seeds and creates jobs with relatively high wages at the same time that it destroys other jobs. Consideration of these impacts, for better and for worse, must be thought about as part of the consideration of the impact of bioprospecting. If the net harms in a particular case outweigh the benefits (for the LDC), there must be mechanisms that can protect the use of their germ plasm, and their knowledge, so that it does not harm them.

Justice requires attention to more than the technical elements of cur-
rent patent law. It is much more than a technical area of law, and the assessment of what institutions, laws, and practices we should adopt has to involve more than a scientific assessment of the risks and benefits of various IP regimes. Who benefits? Who has a claim on that benefit? Who is exposed to risk? and Who decides the allocation of risk and benefit? are all moral questions that require much more serious attention.

NOTES

1. For more on these and the biopiracy arguments, see Donald Bruce and Ann Bruce, *Engineering Genesis* (London: Earthscan, 1998).

2. Peter Drahos, “Global Property Rights in Information: The Story of TRIPS at the GATT,” *Prometheus* 13 (1995): 6–19 and Copyright 1995 by the president and fellows of Harvard College. Harvard Business School Case 9-392-073. This case was prepared by Michael A. Santoro under the supervision of Professor Lynn Sharp Paine as the basis for class discussion rather than to illustrate either effective or ineffective handling of an administrative situation.


10. Jon Merz, this volume.
Who Owns Life?

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