Biodiversity and Biotechnology

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Increasing alarm at potentially irreversible damage to the world's ecosystems has amplified the call for a worldwide solution to the problems that have led to the current environmental predicament. To an outsider, the United Nations Conference on Environment and Development, or Earth Summit, in Rio de Janeiro in May 1992 was a forum in which the world's political leaders convened to formulate policies addressing urgent environmental questions. The anticipated outcome of the summit would compel the international community to recognize that environmental solutions are in everybody's best interests and within everybody's purview and jurisdiction.

But as the summit drew to a close and the Convention on Biological Diversity (the Biodiversity Treaty) was being finalized, things began to go drastically wrong. Although 98 countries adopted the treaty, the United States announced that it would refuse to sign. To date, the United States has not yielded to international pressures and remains a noncontracting party, although recent statements by President Clinton indicate a willingness to sign the treaty as now constituted.

Much of the popular coverage of the matter focused on the Bush Administration's failure to sign an international accord purportedly aimed at protecting threatened ecosystems. However, among the previous administration's reasons for not signing the treaty is that provisions of the treaty would undermine the protection afforded by patent laws to the domestic biotechnology industry. These protections, sometimes referred to as patent monopolies, provide the principal incentive for the biotechnology industry to invest in product research and development.

The U.S. biotechnology and pharmaceutical industries uniformly applauded the Bush Administration's position. In an open letter dated 11 June 1992, Richard D. Godown, president of the Industrial Biotechnology Association, wrote that the treaty would be counterproductive to achieving the goals of the summit and that negotiations should focus on "conserving biological diversity, including developing suitable measures for promoting the fair and equitable transfer of conservation technology to the owners of the resources to be conserved." Gerald J. Mossinghoff, president of the Pharmaceutical Manufacturers Association, wrote to President Bush that "[t]he proposed Convention on Biological Diversity would undermine the great progress your Administration has made in encouraging other countries . . . to strengthen their patent laws."

Were the provisions of the treaty restricted to promoting and preserving biological diversity, the stance of the Bush Administration might indeed be open to question, and the new stance of the Clinton Administration might seem wholly admirable. President Clinton has suggested that objectionable provisions of the treaty might be favorably amended after the United States became signatory. However, this is by no means the first international treaty addressing world resource allocation that has gone unsigned by the United States. The United States has rejected previous treaties, such as the Law of the Sea Treaty, governing use of seabed resources, and the Moon Treaty, governing use of outer space resources, because these treaties contained provisions that were perceived as attempts by developing nations to misappropriate the benefits of technological investment by developed nations (*1*, *2*).

The Biodiversity Treaty appears cut from the same cloth as previous unsigned resource treaties. Its present label is more than a little misleading: Rather than the "Convention on Biological Diversity," the treaty might just as appropriately have been designated the "Convention on Biotechnology Transfer." Major portions of the treaty, and certainly many of its key provisions, mandate that the signatory nations facilitate the transfer of technology among themselves and, particularly, from developed nations to less developed nations.

Article 16 of the treaty provides that technology transfer "shall be provided and/or facilitated under fair and most favorable terms, including on concessional and preferential terms. . . ." Sections 4 and 5 single out intellectual property rights for transfer, providing that signatory nations (i) "take legislative, administrative or policy measures, as appropriate, with the aim that the private sector facilitates access to, joint development and transfer of technology . . . for the benefit of both governmental institutions and the private sector of developing countries . . ." and (ii) "recognizing that patents and other intellectual property may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to [the treaty's] objectives."

Article 19, section 2, specifically targets biotechnology for preferential transfer when the starting materials for research are found within the borders of developing nations:

> Each Contracting Party shall take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties.

Such language in the treaty prompted alarm in the U.S. biotechnology industry because it appears to presage an attempt to co-opt a technology in which U.S. firms now possess clear world leadership. Admittedly, the scope and meaning of many of the treaty's terms are vague. This, however, simply constitutes an invitation to interpret the treaty broadly, and uncertainty over the breadth of the treaty's effects encourages further alarm. For example, the treaty defines "genetic resources" broadly as "any genetic material of actual or potential value." Does this include macaques taken from a developing nation and used as test animals for AIDS vaccines? Would pharmaceuticals developed as a result of testing in these animals fall within the scope of the treaty's mandates?

The treaty is similarly unclear as to the basis for claiming an interest in the results of biotechnology research. The claims of developing countries to biotechnology results that use those countries' native species as starting materials are framed in terms of a "right" based on the "sovereign rights of States over their natural resources. . . ." Certainly such sovereignty would permit excluding biotechnology researchers from obtaining native materials in the first instance, but it is less clear what might be the basis for extending ownership or control to biotechnology products developed from those native materials once they are removed from their original milieu.

The recent case of *Moore* v. *Regents of the University of California* (*3*) reflects in miniature the ownership issues raised by the Biodiversity Treaty. The plaintiff in the *Moore* case alleged that biomedical researchers, including his physician, had misappropriated his bodily tissues to develop a commercially valuable cell line. The Supreme Court of California declined to allow such a law suit for conversion, holding that the plaintiff could assert a right to be informed by his physician before the tissue's removal of the use to which it might be put but that the plaintiff retained no ownership

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interest in the tissue once it was removed. The court reasoned that the valuable cell line was legally and factually distinct from the tissue initially found in the plaintiff's body because the cell line was the product of inventive effort, and not simply a naturally occurring discovery.

As does the *Moore* case, the Biodiversity Treaty raises the question of whether the original possessors of naturally occurring materials can assert an interest in derivative materials after allowing them to leave their possession. The ownership analysis in *Moore* reflects the concerns that will permeate the international debate over biotechnology transfer. For example, a bedrock provision for determining ownership has been the labor theory of property first attributed to the natural rights concepts of John Locke. Locke theorized that ownership of property properly belonged to those who through their labor extracted materials from their natural setting, and so added value to those materials (*4*).

Other considerations of ownership law that were clearly of concern to the *Moore* court were those derived from the utilitarian philosophies of Bentham and Hume. The modern descendant of these theories, the so-called "law and economics" movement, attempts to evaluate law in terms of economic efficiency. Under such an approach, ownership rules maximize total social welfare. This economic perspective on ownership is particularly important in assessing the impact of intellectual property rules on technology development.

New technology may be exceptionally costly to develop yet relatively cheap to duplicate or reverse-engineer once it becomes available. In such cases, no opportunity exists to recover development costs: Competitors can free ride off the technology developer's investment by appropriating the new technology. Because these competitors do not incur the developer's costs, they can sell at a lower price than the developer, possibly even driving the developer out of business. Free riding removes the incentives to invest in the development of technology.

Intellectual property law is generally held to help alleviate the free rider problem. Laws such as the patent statutes create a period of time during which the developer of new technology can legally exclude competitors from free riding on the developer's invention. Instead, during the 17-year patent monopoly, the patent holder can recoup development costs and begin to make a profit on his investment. Thus, intellectual property provisions foster the creation and development of new technology.

This incentive is likely to vanish with regard to developing nations if the Biodiversity Treaty as now constituted takes force. The language of the treaty appears to allow developing nations to force the developers of biotechnology products to allow use of their technology—a so-called compulsory license. Historically, the nations that were primarily responsible for drafting the Biodiversity Treaty have long sought compulsory licensing for the distribution of patented products in their countries. At the same time, these developing countries have declined to provide intellectual property protection for food and pharmaceutical products and have provided only limited protection for chemical products. Their rationale is that because of their poverty, their populace requires the opportunity to freely use the technological advances of more developed nations.

However, a lack of strong intellectual property protection has generally deterred chemical, pharmaceutical, and other firms from entering manufacturing or research ventures in underdeveloped nations, thus contributing to their lack of development. This trend is likely to be exacerbated by the technology transfer provisions in the Biodiversity Treaty. Here again, the current international situation bears an uncanny resemblance to the issues decided in the *Moore* case, albeit now greatly expanded in scope. The question of economic disincentives was of prime concern in *Moore*, where the court denied the plaintiff's claim in part because such a precedent might result in restricting access to the materials necessary for biomedical research.

According to the court in *Moore*, allowing the donors of biotechnology research materials a claim over derivative products threatened to destroy the economic incentive to pursue important research. Additionally, the court noted that were it to recognize the plaintiff's claim, "with every cell sample, a researcher purchases a ticket in a litigation lottery." Similarly, recognizing the claims of developing nations through the present language of the Biodiversity Treaty is likely to destroy the economic incentive to pursue research in developing nations: With each specimen collected there, biotechnology companies might be purchasing a ticket in a compulsory license lottery.

Thus, the irony of the biodiversity treaty is its potential to deter the very technology transfer that it seeks to facilitate. One result, intended or unintended, of the treaty may be to circumvent other international negotiations concerning intellectual property protection, such as the Uruguay Round of the General Agreement on Tariffs and Trade, or negotiations on world patent harmonization. A focus of these other international negotiations has been to provide strong intellectual property protection in developing countries. Once such protection is in place, regular market forces would be expected to foster biotechnology development and licensing agreements in those nations.

U.S. companies such as Merck appear willing to negotiate royalty agreements with developing nations in return for the right to search for commercially promising native species (*5*). If viable intellectual property laws assure such companies that they can receive a return on their investment, such agreements can be expected to become more common, allowing developing nations to share in the profits of commercial biotechnology. But, as in the *Moore* case, this participation should arise not from an extended right to compel the transfer of technology that another has developed; rather, it should arise from the right to make an informed decision regarding the use of native materials before they are removed from their original milieu. Thus the present administration should consider whether its proposed actions may lend legitimacy to an uncertain compulsory licensing scheme that appears likely to defeat its own purposes.

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