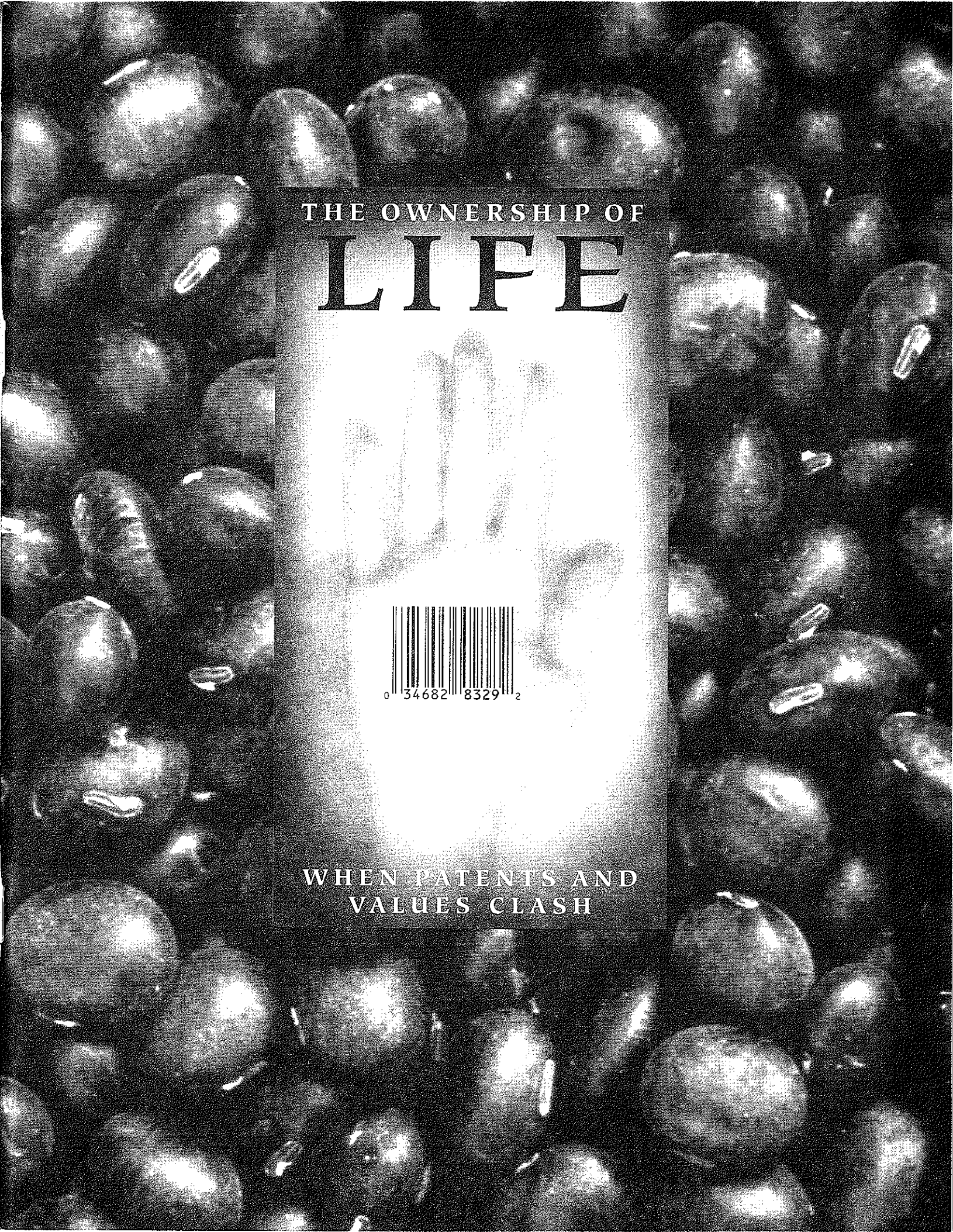

THE OWNERSHIP OF LIFE

WHEN PATENTS AND VALUES CLASH

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...And with the cooperation of colleagues around the world,
for this generation and all of our descendants...

COVER PHOTO BY JIM BONES: "LAMMER'S BLACK" HEIRLOOM SOYBEANS

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TO RACHEL CARSON

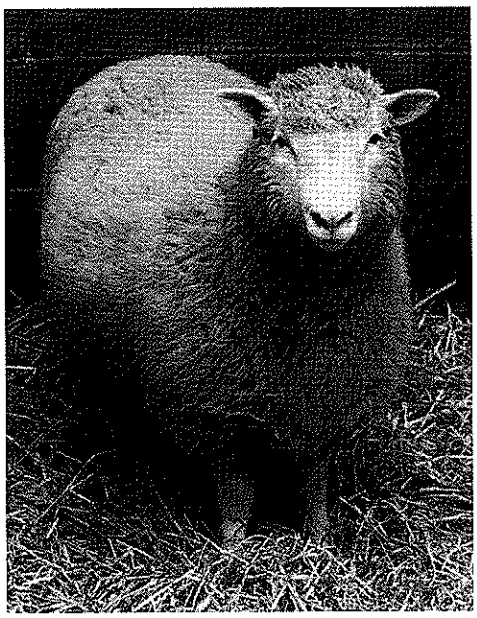
whose scientific acuity, prescience and courage serve and inspire us still

C O N T E N T S

INTRODUCTION

by Bill McKibben, author, The End of Nature

If you wanted to list the most important technological developments of human history, the top two items might well be the discovery of fire, and the emerging ability to manipulate genes. Fire changed the world, made us a new species; we feel the aftershocks of that discovery even today, in the industrialization that marks our age. Now genetic manipulation offers a tool at least as powerful—offers the prospect of change so fundamental we can only begin to guess at the consequences.



AP / WIDEWORLD

Dolly, the cloned sheep.

And yet, oddly, we don't much seem to care. Sure, we can muster a few days of interest for Dolly the doppelganger sheep, but in general we leave this question to the scientists, and to their entrepreneurial colleagues intent on turning research into product. This is one of the few great issues of our time and yet the debate about its potential has barely been engaged, at least in this nation. It's as if we split the atom and no one had cared, no one had stepped forward to carry on the decades-long debate that brought us back from the nuclear brink and yet helped figure out those areas (medicine, for instance) where it made sense to use the atom.

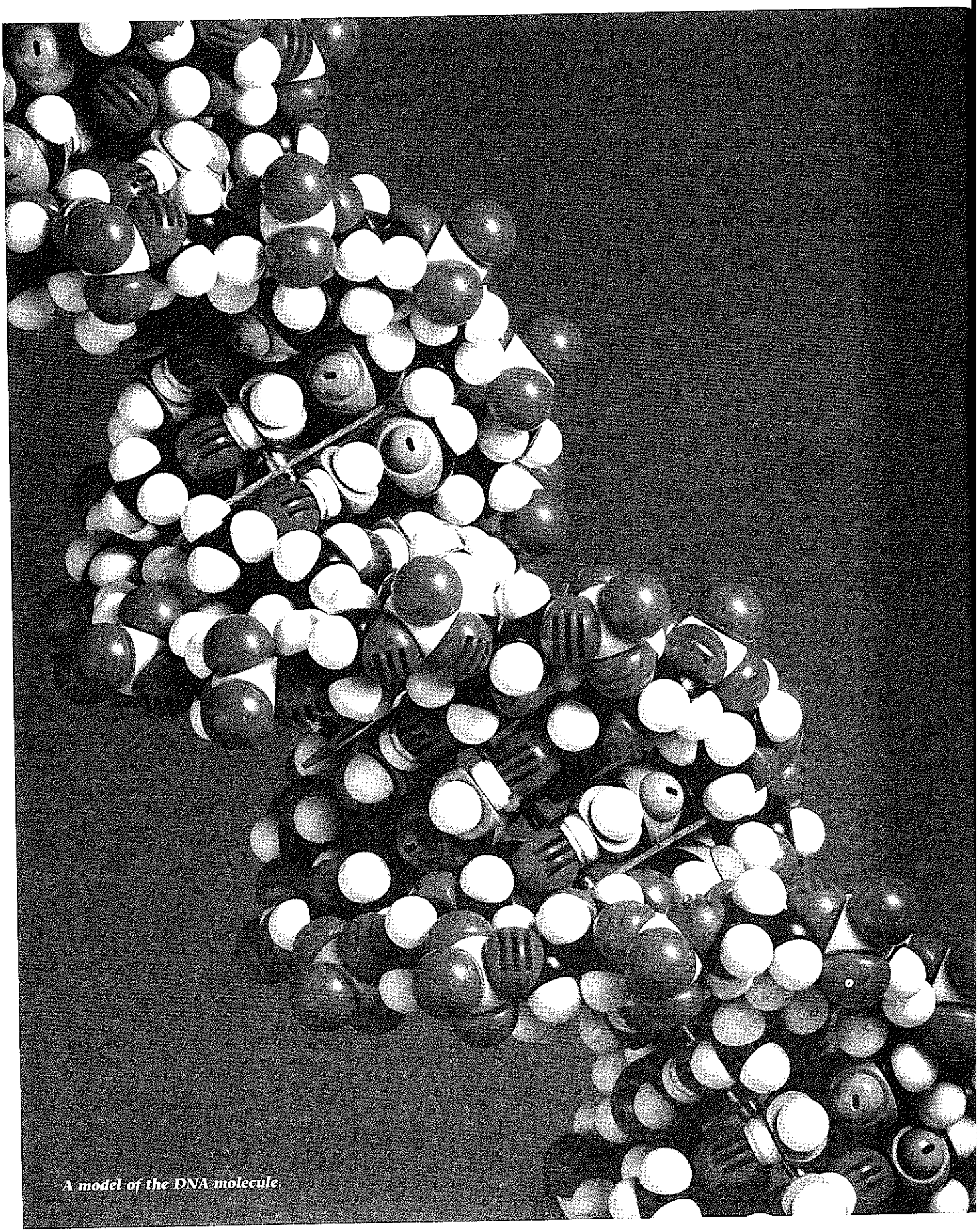
There are two ways to duck this issue, and we are taking both of them. One is to pretend that it's nothing new, just the natural extension of the cross-breeding humans have practiced since the start of agriculture. This is nonsense—nature confined such experimentation to very

strict boundaries. A pea and a pig couldn't mate, nor a person with either of them, so their genes were forever separate. In a way, that was what defined the "nature" of any species. Now, if we choose, there are no such boundaries.

The other way to ignore the implications of this question is to insist that nothing could possibly be done to alter the future development of this technology. That too is nonsense. A great deal of the research, for instance, is driven mainly by economics, dependent on the prospects of huge markets for patented forms of life. The European Parliament has taken steps toward banning patents; were the U.S. and Japan to consider similar restrictions, the chances that we'd be patenting the genetic code of New Guinean tribals would decrease; the future would change. There are many other possible forks in this road as well, just as at one time we could have dealt with the invention of the car in a different, more productive fashion.

The list of reasons to be apprehensive about genetic engineering is long. There are the physical fears about the dangers inherent in monocultures or in manipulated genes crossing to wild populations, the social fears about how this will likely accelerate the differences between the rich and the poor parts of the world, and the moral and spiritual fears about what it means to literally act as gods, creators.

At the moment, though, the greatest danger is that we won't pay attention to this new way of being human, this incredible increase in our power as a species. To ignore this issue is to duck history. ❧



A model of the DNA molecule.

THE OWNERSHIP OF LIFE

WHEN PATENTS AND VALUES CLASH

Each generation has its defining political crisis, its Vietnam or Berlin Wall. In a world of rapid change, each also has its technological revolution, be it the car, atomic bomb or computer. On the eve of a new century, we find ourselves facing what promises to be both, a moment where political crisis and technological change seem destined to collide. The heart of the issue is an effort by a new industry to render life itself a product, bought and sold on a global scale.

Most of us are as yet unaware of this trend, let alone the profound impact it could have on the future. It began with a series of court decisions and trade agreements that gave various biotechnology developers the license to declare life their own private property. Today, these entities are engaged in a furious rush to secure patents on life in all its forms, down to the cellular and genetic levels. Their goal is to gain monopoly control over a wide range of plants, animals, microorganisms and even genes, including ours.

Owning the patent to a living thing is not like owning an individual cow, a dog or a fruit tree. It is a more far-reaching form of ownership. The distinction can be likened to the difference between owning a lake and owning the chemical formula for water. A patent holder for water's chemical formula would have the legal right not only to decide who could have access to a particular lake, but to any water anywhere, and to the use of the chemical formula for any purpose.

If allowed to continue, the trend toward patenting life will have profound consequences. Imagine a world whose entire food supply is

controlled not by the local farmers who grow the crops, but by a few giant corporations driven solely by the narrow logic of quarterly returns. Imagine a world where the legacy of ancient knowledge carried in a single seed can be exploited by absentee "owners." Imagine a world where the sacred texts of life, written in the genes of each organism, become the raw materials of an industrial process, spliced and recombined with little regard for the vast potential dangers—and no reverence at all for the life forms that now exist.

Those who stand to benefit from such a world are currently spending millions to promote it. The so-called life industry's campaign on behalf of life patenting has the power to reshape nearly every aspect of society, including medicine, agriculture, science, law and trade. The environment stands to be profoundly affected as well. The ethical and spiritual dimensions of such radical change are impossible to ignore.

This briefing book is part of our effort to increase awareness now while the trend toward patenting life can still be influenced. We end with a list of resources for those seeking further information.

"The moral goodness of all progress is measured by its benefit to humankind. Do the benefits of patenting outweigh the burdens? Any piece of science is not just science. It also has ethical and political considerations. We need to have an active engagement of the scientists, ethicists and moral theologians."

Bishop William Friend
Consultant on science and human values, National Council of Catholic Bishops

THE EVOLUTION OF LIFE PATENTING

During the 1980s, the U.S. government removed all barriers to the patenting of life. A few key decisions opened the floodgates:

- In 1980, the U.S. Supreme Court ruled that genetically engineered microorganisms were patentable.
- In 1985, the U.S. Patent and Trademark Office, with no further guidance from Congress or the courts, declared that plants and seeds were also patentable.
- In 1987, the Patent Commissioner announced that the license to patent should be understood to encompass animals.

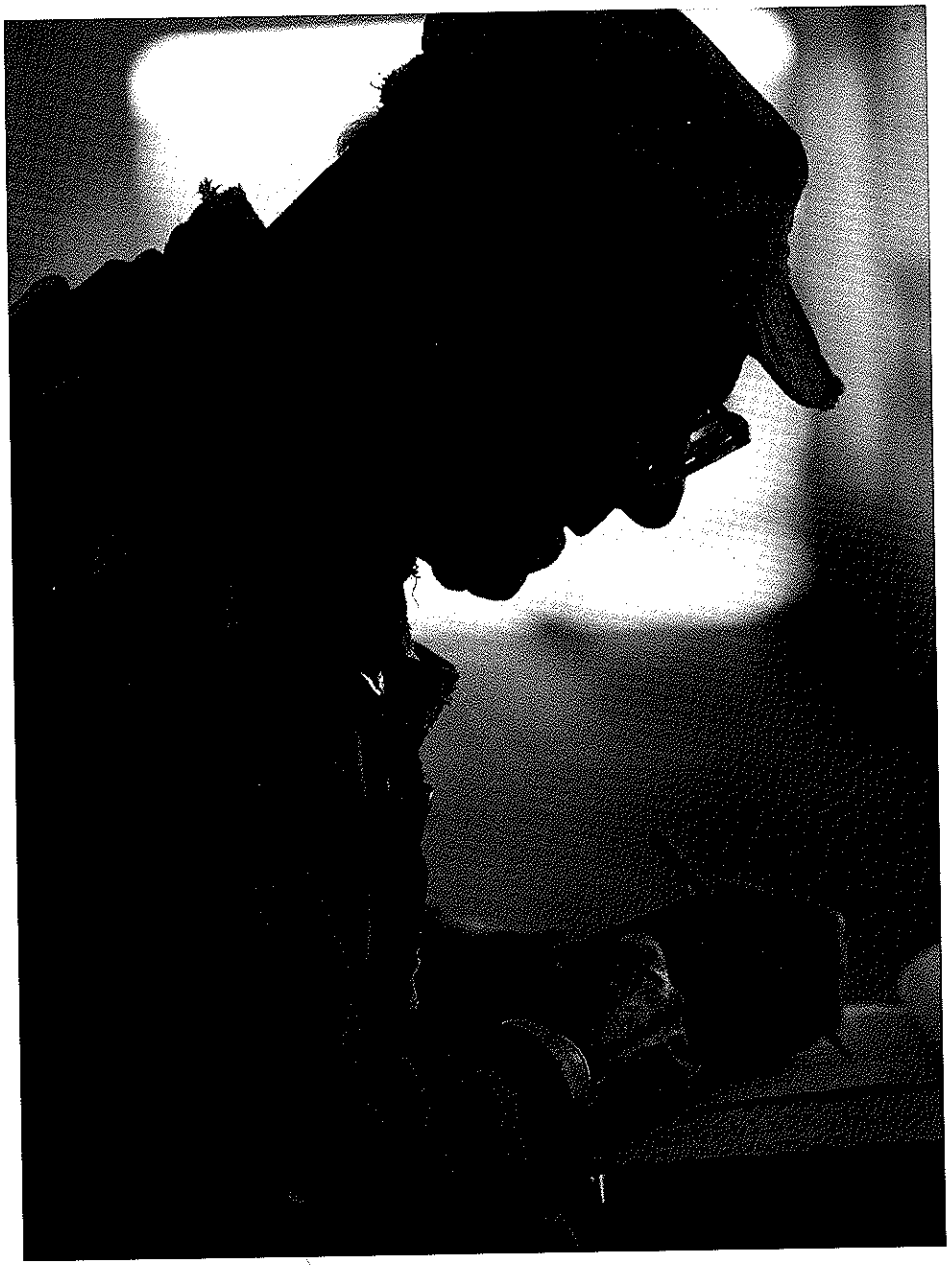
These decisions made it legal in this country to patent virtually all life forms. People were supposedly excluded from patenting, but not the pieces of people. Human cells and genes were soon just as much commodities as other living matter. Small biotech firms sprang up to tap the new market, only to be bought by bigger firms, creating the giants that now dominate the life industry. Today, these corporations are pushing for trade pacts that would give them the same monopoly patents around the world.

How could this have happened? In one sense, the story begins with the U.S. Constitution, whose authors made a point "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries." In the words of Thomas Jefferson, "ingenuity should receive

The Brazilian rain forest. Much of the world's biological diversity remains clustered in the world's equatorial regions—a fact not lost on the biotechnology industry. Companies based in the North are now scouring the South for living resources they can patent.

Their search is not limited to existing plant varieties and animals. Current patent laws also allow for the ownership of specific genes and the traits encoded within them. With genetic material redefined as a patentable technology, those who own it hold an enormous power: the right to control the access to life at its most fundamental level.

Life patenting is one of the forces driving the "industrialization" of modern agriculture. Though bioengineered crops promise short-term gains in yield, they may be costing individual farmers the control over their operations.



a liberal encouragement." This was the birth of U.S. patent law.

Patent laws were intended to serve the public good. Over time, however, a number of social forces conspired to erode this ideal. Among them were the radical changes that modern science and commerce brought to Western agriculture, changes that would eventually turn farming into an industry dominated by the corporate suppliers of chemicals and seeds.

"A gene is not an invention."

Evelyn Gebhardt
German Social Democrat;
Member, European Parliament

A hundred years ago, nearly all U.S. crop varieties were developed by Indigenous Peoples and farmers, based on a wealth of plant diversity carried in seeds from Europe, Asia, Africa and Latin America. The country's institutional plant breeders also relied on farmers' seed. Though seed companies existed in the 1800s, they weren't a major economic factor. As noted by Dr. Cary Fowler, a former senior officer at the United Nations Food and

Agriculture Organization, the chief source of new seeds in the U.S. through much of the 19th century was the federal government, which distributed millions of seed packets in an effort to build a nationwide agricultural base.

The birth of a seed and plant breeding industry led to the first actual steps toward patenting life. By 1930, with passage of the Plant Patent Act, plant varieties were on their way to being recognized as a form of intellectual property, the legal equivalents of books and computer software. Over the next several decades, into the '60s and '70s, this concept would be elaborated, both in the U.S. and throughout the industrialized world. These "Plant Breeders' Rights" awarded seed firms exclusive control over their varieties in the market for up to 25 years.

Thus by the 1980s the way was paved for expanding these concepts yet again. If plants could be intellectual property, why not the rest of life? According to Philip Bereano, a professor of technical communication at the University of Washington, "for 200 years the idea that general patents could cover life forms was viewed as ridiculous." Not anymore.

Today, commercial plant breeding and seed sales are dominated by the huge corporations that form what we now know as the life industry. The life industry controls an ever-growing market share of bio-industrial goods related to food, agriculture and health, including seed, fertilizers, pesticides and drugs. Their markets are worldwide, and so are the biological resources they must mine to supply them.

With the rise of genetically engineered animals and crops, manufacturers are in constant need of new biological and genetic resources. While the life industry is based in the North, 80% of the world's remaining biodiversity lies in the tropical and subtropical regions to the South. Acquiring this natural wealth is crucial to the life industry's growth, and they're currently doing so on a widespread scale.

"As in many other areas of ethics, you find out where the issues are when you trace the money. Of course people who have an economic stake want patent protection to recoup their investment. And we certainly want to endorse healing and curative technologies that will bring about wonderful ends. But there have to be limits. What patenting does is view living things only in terms of market values. We prize living organisms for something besides their market value."

Ben Mitchell
Consultant on biomedical life issues, Christian Life Commission, Southern Baptist Convention

LIFE PATENTING GOES GLOBAL

During the 1990s, the life industry has pushed for new global trade rules that would give them easier access to critical bioresources. To a large degree they've succeeded. Life-patenting laws based on the U.S. model are becoming the global standard, thanks largely to a pair of recent international accords.

• The Convention on Biological Diversity was first adopted by the Rio Earth Summit in 1992. Though the convention acknowledged the need to protect living resources as well as the Indigenous Peoples who often stewarded them, many critics say its real effect has been the

Threshing rice in West Bengal, India. In agrarian communities throughout the world, ancient patterns of existence are now threatened by radical change, much of it driven by outside corporate interests.

HELDUR NETO/CNS - IMPACT VISUALS

opposite. A basic problem, they argue, is that it recognizes intellectual property rights over living material.

• The World Trade Organization (WTO) began operating in 1995, the latest in a series of efforts to oversee and "harmonize" world trade. All member nations, including 84 from the developing world, are required to legalize intellectual property over most forms of life.

Fearing trade sanctions, many countries will now be forced to adopt patent laws that may be unsuited to their levels of development. In the past, such laws were considered the right of each nation to determine. That's no longer so. Trade accords are eroding sovereign rights, even as they hand extraordinary power to the corporations that form the life industry.

"Global trade treaties and property right provisions make the rights of people secondary to the protection of goods, services and knowledge."

Dr. Winston Caroo
Director of Programs,
Agricultural Missions,
National Council of Churches

LIFE PATENTING VERSUS THE INDIVIDUAL

While the modern patent laws have been integral to the life industry's growth, they've done little to protect individual inventors, those they were originally designed to serve. All but a tiny fraction of patents are now awarded to companies and institutions.

Many would argue that the patent laws devised to encourage innovation now actually do the opposite. Even among research scientists, the practice of sharing knowledge has given way to a new secretiveness as collaboration falls victim to the widening concepts of monopoly control. In a world where a single gene can be worth billions of dollars, no one dares give away what could be the next lucrative life commodity.

Most people may find it difficult to care about such changes, but this is shortsighted. As we'll detail later, the corporate control of agriculture poses a serious threat to our food supply. The engineered crops of today are fickle thoroughbreds, honed for short-term performance and profit, not long-term health. The resulting loss of genetic diversity leaves the entire seed supply vulnerable to climate change, pests and disease.

The classic example is Ireland's great potato famine in the 1840s, where a potato crop stripped of its genetic diversity—a monoculture—fell victim to the blight. Famine and disease led to widespread death and emigration, reducing Ireland's population by more than two million in a few years. Many scientists are convinced that genetically uniform crops could lead to a similar but even more massive crisis today.

Farmers were once this country's principle guardians of genetic diversity, but that's no longer true. After a century of assaults on their traditional practices, many are now virtual contract workers on their own land, raising crops that are never really theirs. Most farmers in the U.S. are almost

"In the 'good old days,' scientists couldn't wait to share their findings. The exchange of knowledge is the lifeblood of scientific discovery. Patents help create a cone of silence, with people working on projects they know have to be kept secret. Look at Dolly the sheep—what happened between last summer, when the discovery was made, and March, when it was announced to the world? The scientists were keeping silent in order to protect the patent rights. Over time, a scientific system saturated with patents will become so silent, ingrown and reluctant to communicate results, that it will retard innovation."

Dr. Margaret Mellon
Adjunct Professor, University of Vermont Law School;
Director, Agriculture and Biotechnology, Union of Concerned Scientists
(for identification purposes only)

entirely dependent on "invented" seeds guarded by a legal tangle of Plant Breeders' Rights and patents that make it illegal to save or resell the seeds harvested on their own land.

The farmer's slow descent into corporate servitude may presage our own. As the rush to patent life expands ever outward around the globe—and inward, to the molecular essence of our identities—it's only a matter of time before we ourselves wake up one day as someone else's intellectual property.

In fact, a few already have.

BIOTECH: GOOD PRESS, BAD SCIENCE

Medical miracles are the life industry's glamour events. Hardly a week passes without word in the news of another breakthrough teased out of nature by the gene cutters and bioengineers. The underlying message is always the same: cancer, AIDS and even world hunger can all be cured, if only the public would allow the scientists to do their magic unfettered by our silly qualms and superstitions. They, and the corporations, will handle it.

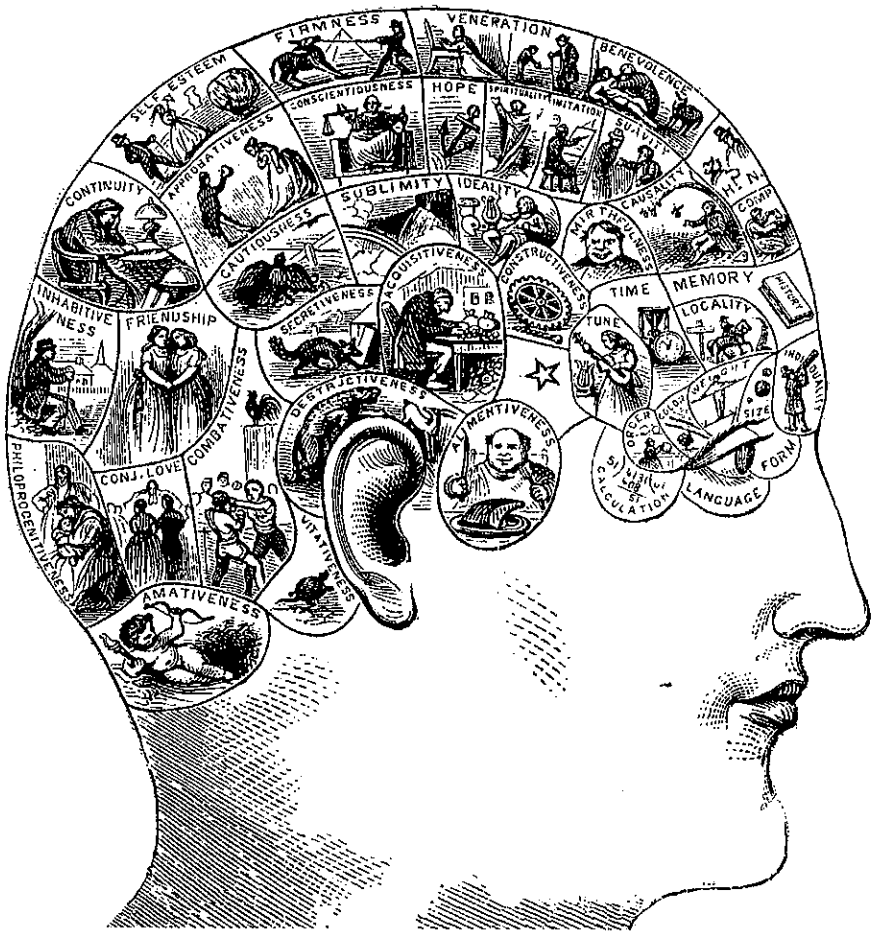
"There's good evidence that the patenting of human life, genes and biochemical processes will artificially increase the prices of delivering health care to people. At the same time it will pervert some very important aspects of the scientific research process. The marketplace is simply not as efficient a winnower of poor science as scientific peer review and the redoing of experiments. That process—though it may not lead to products—protects the public."

Dr. Paul Billings
Clinical Associate Professor of Medicine, Stanford University; Board of Directors, Council for Responsible Genetics

Crucial to their success, they say, are exclusive monopoly rights to the cells and genes with which they're tinkering. Without this control, their investments can never be recouped, they argue, and biomedical research will come to a halt. In other words, profit alone is the engine of new knowledge. As a pharmaceutical company representative bluntly put it, "No patent, no cure."

Nothing compels us more than the promise of less suffering, a promise that underlies the power and mystique of any healer. The would-be shamans of bioengineering know this well and use the popular press to constantly remind us of their prowess. This is especially true of those who are mapping the human genome—the sum of the genetic material, contained in our chromosomes in the form of DNA, that makes us a distinct species. New "disease genes" are constantly being located: the breast cancer gene, the obesity gene, the colon cancer gene, the baldness gene. The assumption is that cures can't be far behind.

The fanfare often disguises a lot of shoddy science. The current scramble to claim ownership of human genes and gene sequences has been compared to a chaotic gold rush. What they're seeking is the biological information contained in our DNA. The genomic companies and researchers are frantically staking claims to whatever they can find there, often prior to knowing what it really is, or does. In 1992, for instance, the National Institutes of Health (NIH) filed for patents on thousands of human gene sequences related to the human brain. The fact that little else



A phrenologist's map of the human mind, 1870. History has seen its share of dubious scientific theories presented as absolute truth. The ruling paradigm today is to attribute most ills to singular genetic causes. Shortcomings in this view, even potentially dangerous ones, may be overlooked in the rush to commercialize new insights.

was known of the genes led one famous genetic researcher, Nobel laureate James Watson, to call the NIH application "sheer lunacy." No matter. The trick is to patent now and ask why later.

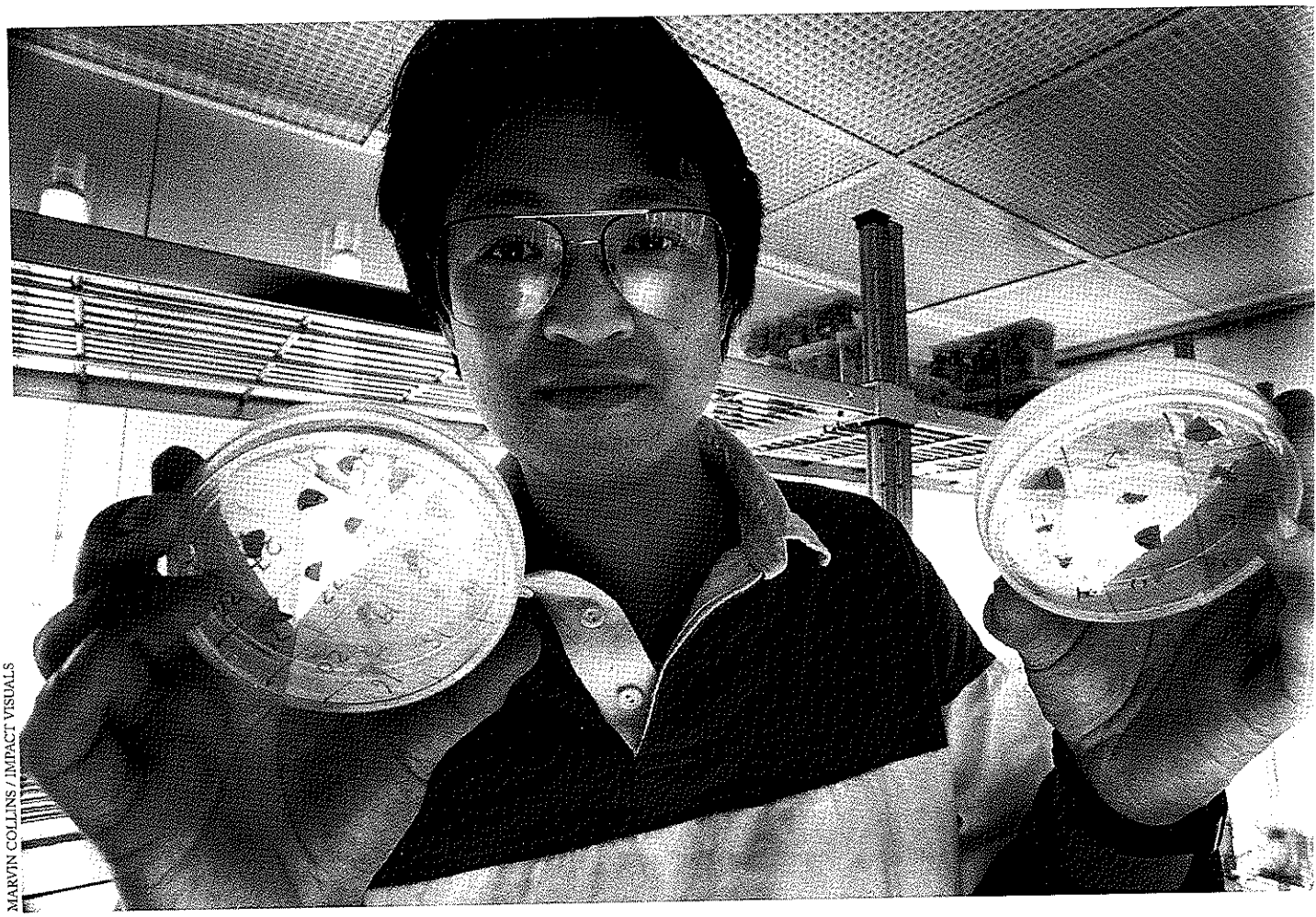
As noted before, this hyper-competitive atmosphere has dramatically altered the relationship among scientists. Science works best when research is shared, when colleagues build on each other's work, when a crucial missing piece of a puzzle can be supplied from the lab across the hall or around the world. What's more, scientists are trained to challenge each other's work, to question new ideas and find their hidden flaws before they're unleashed upon the public.

Today, thanks largely to the trend toward patenting life, peer review has lost much of its impact. Researchers are under great pressure to keep their work in-house. They're often required to apply for patent protection well before they should, at least by former standards. Even the initial research can be warped by the rush to yield patentable results. Scientific conferences have also changed. Once lively forums for the meeting of minds, they're now something less, as papers on preliminary work disappear and former colleagues become tight-lipped rivals.

Lost in the process is any sense of a shared moral code among researchers. Many scientists would like to think their only duty is to the

"Patenting means that only those applications which are owned and patentable are going to be funded for scientific research. Public money and tax dollars are being directed into science fields only elites can benefit from. The problem is that three-quarters of the world's population can't pay their medical bills and suffer from simple diseases that are curable."

Jeannette Armstrong
Okanagan tribal leader, writer and poet



MARVIN COLLINS / IMPACT VISUALS

A scientist at the University of California examines genetically altered tobacco plants in 1990. Bioengineering is a multi-disciplinary pursuit that melds the knowledge of the social and natural sciences with the vast power of the modern computer. Ideally, modern scientists will play a role in weighing the social consequences of their research.

facts, but this is a conceit of the times—and not a flattering one compared to the large-mindedness of most of their predecessors. Take the global fraternity of physicists who cracked the riddles of the atom. From the beginning, many recognized the social consequences of their discoveries, along with the need to discuss them. As the ones who understood the research most deeply, they were also the ones who together could most appreciate its tremendous power to reshape, or destroy, the earth. Only with the outbreak of a world war did they agree to proceed in silence; and even then, they were keenly aware of having chosen between the lesser of two evils.

A similar ethic of secrecy pervades those unraveling the human genome, but to what end? The answer is usually nothing more than the bottom line of the conglomerate for which they soldier. In such a climate, intellectual property isn't a research tool; it's a marketing weapon whose real purpose is to exclude competitors. That's clear in this 1995 statement from Myriad Genetics Inc., a U.S. genome research firm. "The identification and patenting of genes will present significant barriers to entry," they note, "and potentially permit substantial operating margins."

Given the high cost of securing life patents, the system has a built-in bias toward large companies, which often spend huge sums in protecting their ownership claims. According to the American Bar Association, intellectual property law is the country's fastest growing legal field. The costs of filing and enforcing a patent can total millions of dollars over its lifetime. Clearly this money could do more for public health if spent in other ways.

"Industry can say, 'if you don't provide us with patenting, we won't provide you with a cure.' It's blackmail, but it's happening. Genes become currency."

Heltrud Breyer
Green Party;
Member, European Parliament

Legal fees are but one aspect of the price of doing business in the capital-intensive life industry. Research and development are another. Such massive costs make biotech a field reserved for all but those with the deepest pockets. That's troubling enough. Even worse, their profits often derive from technologies originally developed with public money.

In the U.S., taxpayers have contributed millions of dollars to human genome research via government labs, only to see private companies reap the benefits; public policy requires the resulting patents to be turned over to private-sector collaborators. The public ends up paying twice: once to fund the initial R&D, and then again as the consumers of high-tech health care.

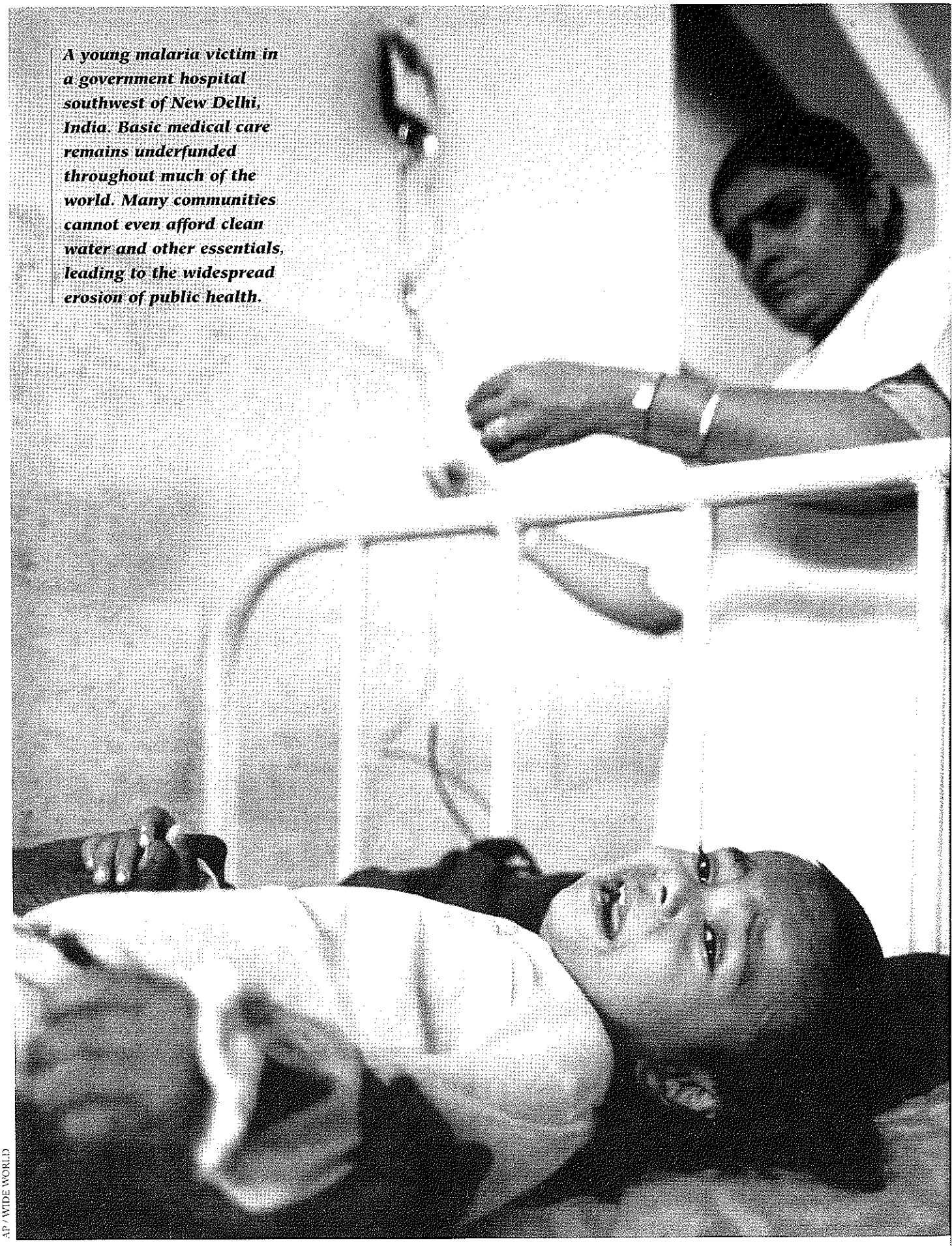
The drain doesn't end there. For example, researchers with the NIH developed a method crucial to "ex-vivo" gene therapy—a way to remove cells from a patient, alter their genetic make-up and return them to the body. After getting a sweeping patent on this procedure, the NIH licensed it to Genetic Therapy Inc., at the time a private U.S. firm. In 1995, the firm's control over this powerful new technology lured Sandoz, the Swiss-based pharmaceutical giant, to buy them for $395 million. Six months later, in a $27 billion merger, Sandoz and another Swiss behemoth, Ciba-Geigy, became Novartis. That's how one of the world's largest life conglomerates gained exclusive access to a genetic therapy funded by U.S. taxpayers.

"Much of the research on cancer doesn't lead to products. But no company under the current patent system is going to do that kind of research—they will only conduct the kind of research that leads to blockbuster products. Wouldn't it be smarter for us to encourage a publicly supported research system?"

Dr. Margaret Mellon

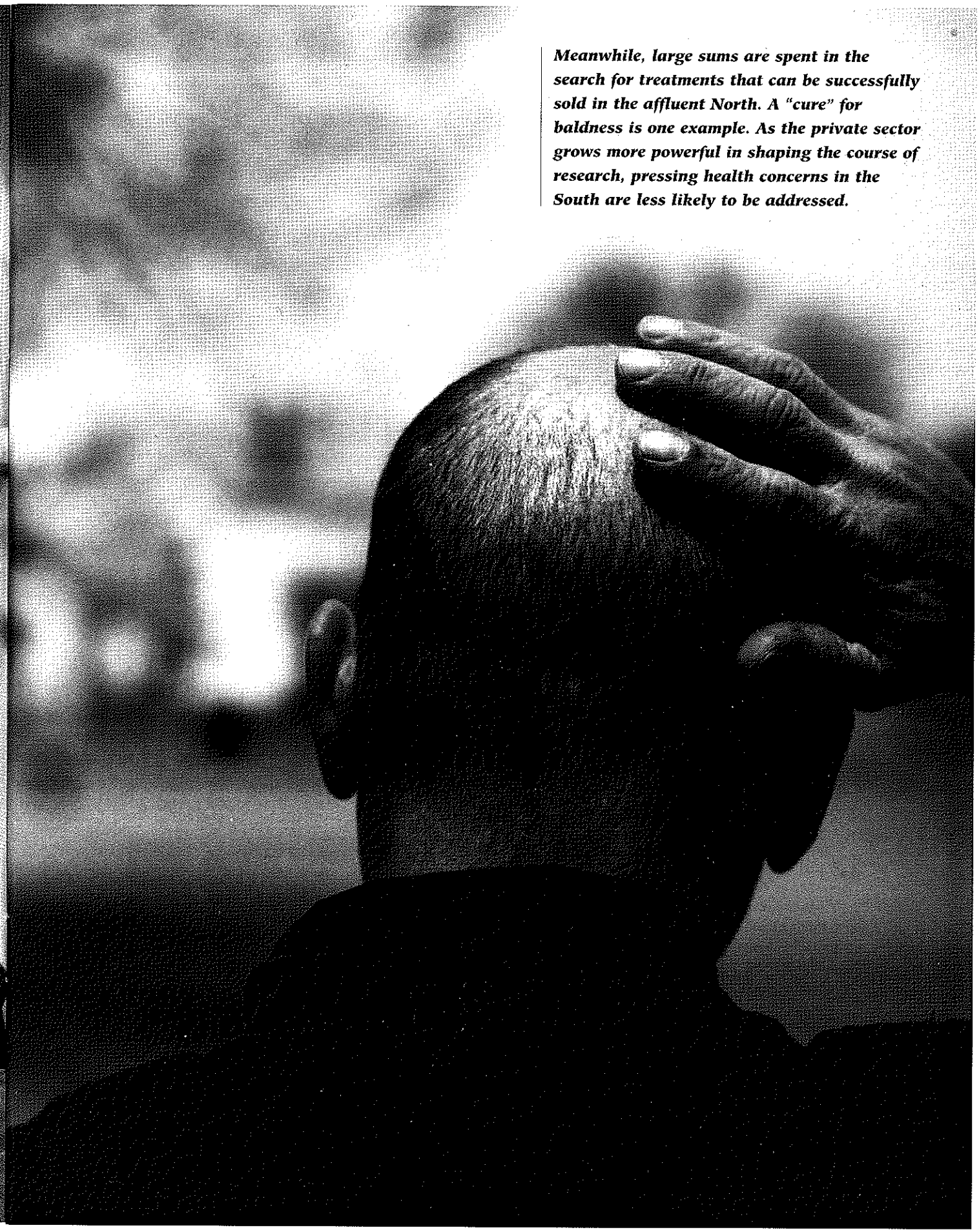
We're led back to the basic question: who are these life patents really helping? And how can we be sure that those who control so much of the world's knowledge will apply it to our most pressing needs? In fact, unless there's money in it, we can be sure they won't. The life industries openly admit that profit is their sole motivation.

No wonder, then, that research tends to address the ills of those who can afford the cures. In 1997, malaria, an age-old tropical scourge, is the world's number-one infectious killer—and probably will remain so. One problem is that its victims are mostly poor: an unpromising market for costly new therapies. Meanwhile, the genomic companies are hotly pursuing treatments for baldness and obesity. When Rockefeller University licensed the patent for the so-called obesity gene to Amgen in 1994, the rights sold for $90 million. Not a bad deal when you consider the poten-



A young malaria victim in a government hospital southwest of New Delhi, India. Basic medical care remains underfunded throughout much of the world. Many communities cannot even afford clean water and other essentials, leading to the widespread erosion of public health.

AP / WIDE WORLD



Meanwhile, large sums are spent in the search for treatments that can be successfully sold in the affluent North. A "cure" for baldness is one example. As the private sector grows more powerful in shaping the course of research, pressing health concerns in the South are less likely to be addressed.

tial demand: Americans spend some $30 billion annually on diet pills, weight-loss programs and related books.

HUMAN LIFE: PATENTS PENDING

What does it feel like to be patented? Here's how John Moore describes what it's like to be known as Patent No. 4,438,032:

> "...Without my knowledge or my consent, I was deprived of right of dominion over my own unique genetic material—I was controlled, deceived, lied to and ultimately violated in an unbelievably arrogant and dehumanizing way."

In 1976, Moore's doctors at UCLA took cancerous cells from his spleen and without his knowledge used them to develop a lucrative series of proteins for fighting bacteria and cancer. The key to this research was the "Mo cell line;" that is, an artificially sustained culture of the cells removed from Moore. A cell line can theoretically live forever, in this case churning out revenue for those who control the patent.

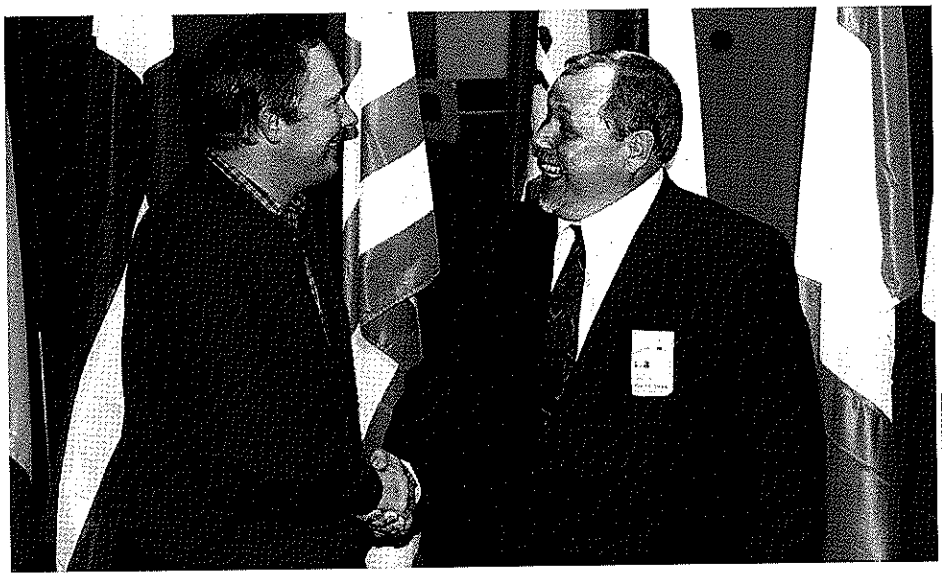
In 1984, after the doctors got a patent for the cell line, the unwitting donor filed suit. Moore based his case for a share of the profits on what most U.S. citizens would consider a self-evident truth: a person's property right to his or her own body.

But in 1990 the California Supreme Court ruled otherwise. Moore could sue his doctors for failing to tell him beforehand of their intent, they said, but he had no basic claim to his tissues once they'd been removed.

Moore's story is part of a much wider trend. The other cases may be more subtle, but they're no less frightening in their implications. The 13th Amendment of the U.S. Constitution clearly states that slavery and all

"According to patent laws in this country, life can now be defined as a human invention. We are in the middle of a legal free-for-all. There are no rules right now: virtually anything living is seen as patentable. Corporations are enclosing the whole living commons."

Andrew Kimbrell
Executive Director, Center for Technology Assessment;
Author, The Human Body Shop: The Engineering and Marketing of Life



EDMONDS INSTITUTE

John Moore (right) with a member of the European Parliament in 1994. The European Parliament has taken steps toward banning patents on life.

other forms of "involuntary servitude" are against the law. The brave new world of biotechnology couldn't care less. Until recently, the public had been told little about the issue and thus was barred from any discourse on its ramifications. The life industries would like to keep it that way.

The threats to personal freedom and dignity, however, are becoming too blatant to ignore. Genetic testing alone has created an array of new abuses. People at risk of genetically based conditions may be denied health and life insurance as well as jobs. The Massachusetts-based Genzyme is developing a technology that can simultaneously analyze DNA from 500 patients for the presence of 106 different mutations on 7 genes. The public has good reason to fear these threats to personal privacy. Many will no doubt decline genetic testing as a result, even in situations where it could be medically useful.

Another U.S. firm, Biocyte, Inc., now has exclusive rights to the umbilical-cord blood cells used in transfusions and surgery, including critical marrow transplants. Even certain members of the medical community believe that's going too far, that such a resource should never be privately held. British doctors have called monopoly control of these human stem cells "immoral and unethical." According to Alejandro Madrigal, director of the Anthony Nolan Bone Marrow Trust, "This is something no one should have the right to patent."

Nevertheless, the rush to patent continues. In November 1996, for instance, the U.S. Patent and Trademark Office announced that it was "drowning" under patent applications for human gene sequences. Overwhelmed with the backlog, the office now restricts the applications for gene sequences to 10 per claim.

The world got a clue as to where all this may be heading with the unveiling of Dolly, the cloned sheep. When Scottish researchers at the Roslin Institute reported their successful cloning experiment last winter, a reproductive technique formerly limited to science fiction suddenly became real. The social and ethical implications were immense, and so was the commercial potential. The researchers were quick to declare that such technology should not be used on humankind—but only after they'd quietly applied for two worldwide patents. Published in March 1997, the patents give the Roslin Institute monopoly rights to the sheep-cloning technique, which then was licensed to PPL Therapeutics, a small biotech company based in the United Kingdom and the United States. The patent protection is not limited to sheep; it covers all animals—and does not exclude humans!

Just one week after word of Dolly, an Oregon primate center announced that it had produced two monkeys from cloned embryos. Realistically speaking, could humans be far behind? Don Wolf, head of the

"There's a belief that is being fostered by biotechnology that science leads ethics—it's out in front, shaping and providing the answers. The argument is that more research will answer the questions, produce a just society, end suffering, end cancer. Well, some of it enhances us, some of it doesn't. The people who built the railroads or invented the electric light bulb or telephone thought they would take care of all your problems. Now, we hear the same thing about the biomedical sciences. This is a train very much spinning out of control. We need to slow up this process and institute some saner balance into the system."

Dr. Paul Billings

"Natural reproduction is slow, random, too unpredictable for companies. If you have genetically engineered animals, you can't risk natural selection."

Andrew Kimbrell

AP PHOTO / JACK SMITH

Two rhesus monkeys cloned from embryos at the Oregon Regional Primate Research Center. The social debate over cloning has not kept up with the rapid scientific advances.

primate research team, noted that some 300 clinics in this country alone already handled human embryos "almost totally without regulation."

Cloning is an issue of profound moral and social importance. Its course should not be decided in the market or behind closed corporate doors, but by informed citizens and governments worldwide. In March 1997, the Council for Responsible Genetics began that dialogue by calling for a global ban on cloning. Their statement equated cloning with slavery, torture, nuclear war and other "behaviors that are counter to the survival...of individuals within civilization." Without public input, the intrusion of commerce into natural life will surely continue.

"Changes in the patent law were made outside of public view. But there are many concerned citizens. If they can create an organized concern, their numbers will rise and bring these issues into the public forum. This has to become a public policy debate—not just a legal matter."

Dr. Jonathan King
Professor of Biology, Massachusetts Institute of Technology;
Board of Directors, Council for Responsible Genetics

That wouldn't surprise John Moore. In late 1994, Moore toured Europe on a crusade to drum up opposition to life patenting among the member states of the European Parliament. A few months later the parliament voted to block such patenting, a decision that reflected widespread resistance in Europe to bioengineered products in general, including hormone-treated meat and milk and genetically altered crops.

But a democratic rejection of such technology is apparently not enough to stop it. The new international trade laws now have more clout than the mere will of a country's people. The World Trade Organization recently declared the European Union's ban on hormonally doctored beef to be "illegal," citing the lack of evidence that it posed a health threat.

In the new courts of international trade, products, not people, are innocent until proven guilty.

ROBBING LIFE'S CRADLE

Until now we've focused mainly on the life industry's assault on the individual. Most people raised in a democratic society naturally oppose such injustice once it is brought to their attention. The next step for those seeking to understand this issue is to realize the fate of a John Moore is but a parable of a much larger process, an erosion of rights that threatens to indenture much of the developing world.

Let's recall a basic fact: the multinational corporations that control the life industry are located in the North, whereas their key resource—biodiversity—lies mainly to the South. All these corporations now have agents wandering the tropics with cheek swabs and sample vials, staking rights to any life form, in whole or part, human and otherwise, that may lead to new bioengineered drugs, foods and crops. Many would say their goal is to rob the tropical zone of its diversity, then turn the region into a vast new market, charging its peoples for what was theirs in the first place.

"If a company goes sampling for genetic materials in an indigenous community, have the people in that community been informed about it? Do they have a full understanding of what they are getting involved in? For those tribes that don't want to participate, the answer is simple: leave them alone. For tribes that do want to get involved, their rights should be protected."

Dr. Frank Dukepoo
Hopi geneticist and Lecturer in Biology, Northern Arizona University

"What we point to with pride as one of the outgrowths of patenting are the huge investments in biomedical science—and the flourishing pharmaceutical industry. Yes, it does help cure some diseases. But we need to ask whether we are putting the right emphasis on market-driven responses to diseases instead of prevention."

Dr. Margaret Mellon

This is the essence of "biopiracy." The biopirates are essentially stealing resources and knowledge from the Indigenous Peoples who have developed them over centuries. The new industrial "owners" might like to call their plunder "strategic raw material," but this ignores a crucial truth. What the biopirates and bioprospectors take back to their labs in the North is often not raw material. In the case of seeds and their genetic complements, they're engineered in their own right, shaped by farmers, in concert with local environments, over more than 200 generations.

To justify their actions, the biopirates may fall back on the zookeeper's rationale: they're helping to save and catalogue life's richness before it disappears. Such reasoning ignores the fact that natural habitats, including sustainable agrarian habitats, are by far the planet's most effective sanctuaries of life. When left to its own devices, life begets life, constantly replenishing its own diversity. This cannot be said of the samples consigned to refrigerated gene banks and cell dishes in the North. Such reasoning also overlooks the damage they themselves are doing to these regions by encouraging their exploitation.

The spread of biopiracy has created new jobs for ethnologists and anthropologists, often with tragic results. Their understanding of indigenous culture has become a tool for prying out the knowledge these peoples hold of their local ecosystems. Such information can be extremely valuable, especially in the search for new medicines. According to the Rural Advancement Foundation International (RAFI), about one-quarter of the world's pharmaceuticals in 1990 were derived from plants, with an annual sales value of $43 billion. Some three-quarters of these drugs were "discovered" through their prior use by indigenous healers.

Like others in the field, the U.S. company Shaman Pharmaceuticals has had great success in searching for useful plant compounds by recruiting the local experts. Thanks to these guides, more than half the company's collected samples show promise as new drugs. Compare that to a random mass screening, where the rate is less than one percent. A woman healer in Samoa led a Western botanist to a tree, *Homolanthus nutans*, that she uses to treat viral illnesses. Back in the lab, a chemical from the tree's bark—prostratin—appeared to protect immune cells from being destroyed by the AIDS virus. In 1995, another U.S. biotechnology company announced that it had identified 32 extracts from traditional Chinese herbal medicines that hold potential for preventing the sexual transmission of AIDS.

Another traditional resource is India's neem tree, *Azadirachta indica.* For centuries, Indian farmers have used neem seeds as a natural insecticide. The tree has been prized for its other properties as well, a source of every-

thing from medicine to shampoo. Drawing on local knowledge, scientists isolated compounds from the neem's oil, seeds, bark and leaves. The neem-derived natural insecticide has proven to be extremely effective, controlling as many as 200 harmful insect species. Unlike most synthetic pesticides, it appears to pose no threat to beneficial insects, birds or mammals.

A botanical drawing of the neem, a tree whose many practical uses have long been known to India's people. Neem is now the subject of U.S. patents.

Since 1985, more than 30 U.S. patents have been issued for various neem-based formulas. Companies both here and in Japan are hoping to capitalize on its useful properties. But as Indian activist Vandana Shiva observes, the growing global demand for neem seed has turned a traditionally free resource into a costly commodity at home. Many of its local users can no longer afford it.

The need to cure AIDS and other diseases may compel us to wave aside such concerns. There's certainly no denying that traditional knowledge holds much value to the health of a wider world. How such knowledge can be fairly shared—or even if it should be—are complex issues. Pharmaceutical corporations profit handsomely from traditional knowledge and remedies, but patents neither recognize nor reward the innovations, knowledge and labor of farmers and Indigenous Peoples.

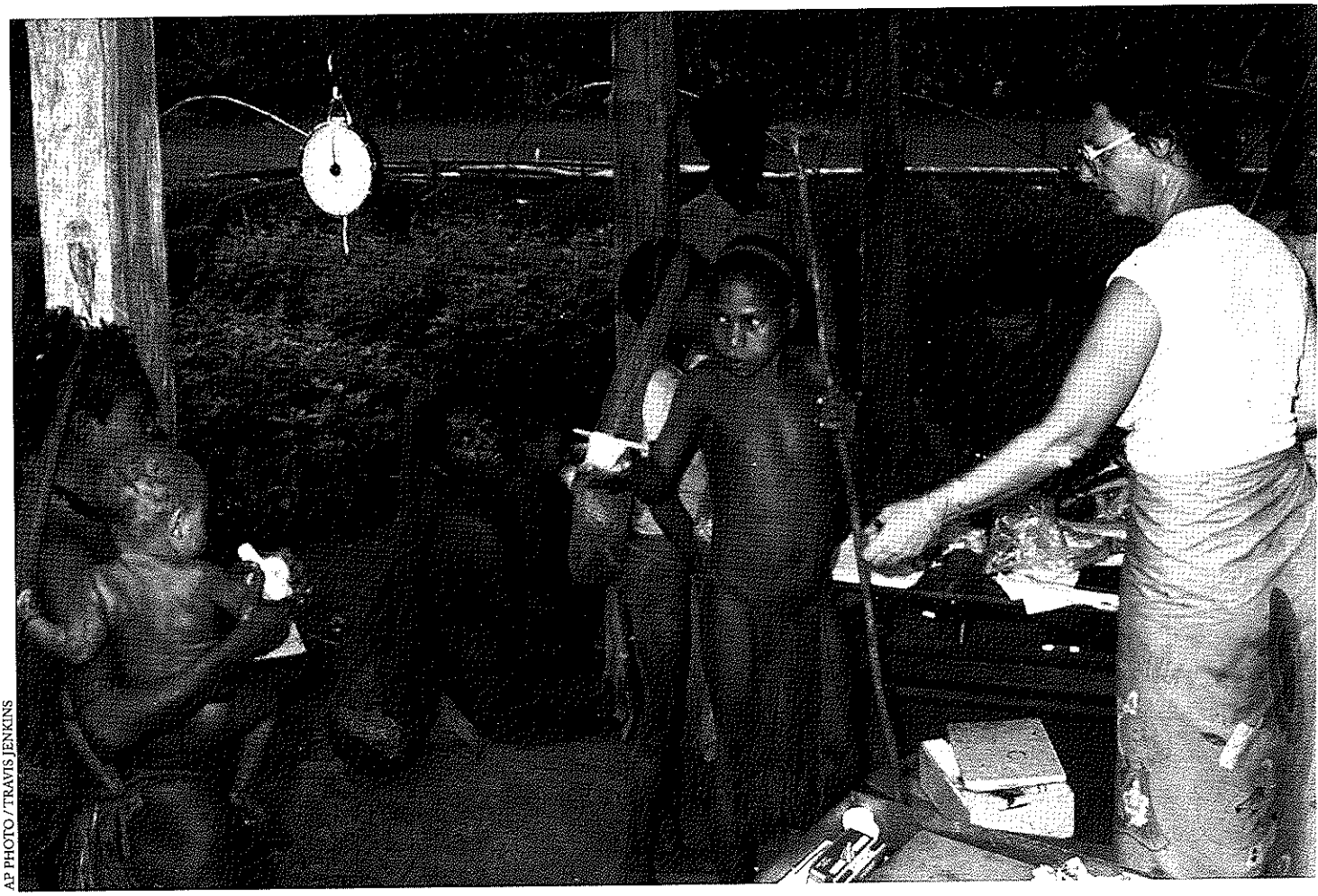
THE HUMAN HARVEST

During the 1990s, several U.S. research agencies sent out medical teams to collect cells and DNA from the world's remote peoples. One of their goals was to find variant strains of lymph cells that might prove useful in treating AIDS and certain cancers. The earliest efforts to patent their findings met with resistance—which U.S. officials dismissed, stating: "Under our laws, as well as those of many other countries, subject matter relating to human cells is patentable and there is no provision for considerations relating to the source of the cells that may be the subject of the patent application."

"In the rush to turn life forms into global commodities, there is no regard for the community-held knowledge, the religious rights or the human rights of Indigenous People."

Jeannette Armstrong

Then, in 1995, the U.S. government gave itself a patent for a cell line drawn from a young man of the Hagahai people of Papua New Guinea. We can imagine the response here if the Hagahai suddenly decided to traffic in unauthorized copies of American software, let alone the cells of an American software writer. As international concern continued to mount, our govern-



AP PHOTO / TRAVIS JENKINS

Members of the Hagahai, a remote people in Papua New Guinea, with a medical anthropologist. An effort by the U.S. government to patent cells from a Hagahai man triggered worldwide protest.

ment quietly dropped its claim on the Hagahai cell line in late 1996.

Unfortunately, the wider trend continues. The corporate gene hunters often target remote and isolated peoples. The search for "disease genes" often leads to individuals or families who carry a unique genetic trait or are affected by a specific disease. What the hunters want is the DNA from distinct carriers of an inherited trait—be it breast cancer, baldness, obesity, asthma or diabetes. Such a trait may become prominent in a small, isolated community over the course of generations. By analyzing the DNA extracted from such individuals, researchers hope to pinpoint the mutant genes that cause their diseases and conditions.

Ideally, this is a possible step toward new therapies and diagnostic tests. In practice, the biotech craze may be encouraging "genetic reductionism," a tendency to see all diseases as genetically induced, thus diverting attention from other causes of poor public health, including malnutrition, pollution, squalor and poverty. Whatever the case, the rush to identify and patent human genes is now a high-stakes scavenger hunt. Consider the following examples:

• Genset, a French company that collects and patents human DNA,

recently made an agreement with the Chinese government that allows them to collect DNA samples from remote villages.

• Canadian researchers traveled to the isolated South Atlantic island of Tristan da Cunha and took blood samples from its inhabitants, who suffer one of the highest asthma rates in the world. The samples were later turned over to California-based Sequana Therapeutics, which has a $70 million deal with a German pharmaceutical corporation to locate asthma genes.

• The Pima Indians of Arizona, who suffer from high rates of diabetes, are now the subject of research seeking a genetic origin for the disease.

• Researchers with ties to the French company Genethon have reportedly discovered a remote island population in the Indian Ocean that may possess genetic immunity to multiple sclerosis, a degenerative disease of the central nervous system.

No international rules exist to protect such people from being commercially exploited. In many cases, they may be giving blood, hair and tissue samples willingly, at least by the standards of "informed consent." But seldom are they told that products and knowledge derived from their DNA may be patented and commercialized in a process totally outside their control.

The potential for abuse is immense. A report by RAFI traces the disturbing flow of human tissues from Indigenous Peoples of Colombia to the labs of the American military. First collected by Colombian university researchers from 1987 to 1992, the samples later found their way to the drug company Hoffmann-LaRoche as well as U.S. government research institutions—without the knowledge of the donors. Given the unregulated flow of human genetic material over borders and from lab to lab, such samples could easily end up being used for, say, biological warfare research or some other purpose the donors would be shocked to learn they had assisted.

"We do not know what fundamental fairness exists between parties like researchers, laboratories, financiers. Within their contracts, is there something that speaks for equal human dignity of all persons? Is there a protection clause? I ask, what will prevent someone from buying a company out, taking their patents and creating an abusive practice?"

Bishop William Friend

LIFE PATENTING AND AGRICULTURE

There's been a vast change over the years not only in how our food is grown, but by whom. Modern agriculture is now an industry. Many farmers have lost the right to control seeds and livestock on their own farms. Today, "bioserfdom" is not just a futuristic concern; it's a reality.

In 1996, for example, the U.S.-based Monsanto Company introduced their "Roundup Ready" soybean, a genetically engineered variety that can tolerate high levels of Roundup, the company's best-selling weed killer. Farmers who wanted to grow the patented seed had to sign a "gene licensing agreement" that barred them from saving it, re-selling it or supplying it to anyone—even for breeding research. The crops could only be treated

"Patenting will drive up food prices. The reason you want a monopoly is to raise prices."

Dr. Jonathan King

with Monsanto's herbicide. Monsanto had the right to ensure compliance by monitoring the farmers' fields for up to three years.

As the life industry gains control over farm management, the once independent farmer becomes merely a "renter of germplasm." More and more, their crops are not generic commodities, but brand-name products, even in the ground. A growing number of large-scale farmers will soon be raising patented varieties tailored to a specific market niche. These crops will often be treated with specified agrochemical packages, thus insuring that herbicide and pesticide sales stay in the corporate family.

As with bioengineered health care, the costs of doing business in this field are driving out all but the biggest players. For instance, one genetically engineered corn variety developed by Pioneer requires access to 38 different patent claims involving 16 separate patent holders. The costs are huge, but Pioneer, the world's largest seed company, can afford them. Millions are also spent on legal battles involving strategic gene ownership. One biotech company, DNA Plant Biotechnology, spent $6.3 million defending its patents on a tomato variety engineered for long shelf-life—and that's not unusual.

"We are witnessing a transformation of farmers as breeders and producers of their own seed supply to farmers as consumers of proprietary seed from the seed industry. It is also a shift from a food economy based on millions of farmers as autonomous producers to a food system controlled by a handful of multinationals that control both output and inputs. This is a recipe for food insecurity, biodiversity erosion and uprooting of farmers from the land."

Dr. Vandana Shiva
Physicist, philosopher and director, Research Foundation for Science, Technology and Ecology, India

These economic pressures have contributed to the consolidation of the seed industry in the U.S. as well as globally. According to Kent Whealy, executive director of the Seed Savers Exchange in Decorah, Iowa, 23% of the mail-order seed companies in the U.S. and Canada (54 out of 230) either went out of business or were taken over between 1984 and 1987. By 1994, just 35 companies controlled 57% of the world's commercial seed market; Pioneer sold more than $1.5 billion worth of seed that year. In 1996, Monsanto bought up several seed companies and gained control over one-third of all the corn seed sold in the United States.

Around the world, large corporations have been buying out the smaller firms, often dropping their regionally adapted collections in preference for standardized varieties that grow reasonably well in all areas, thus assuring the greatest sales in new national (or even international) markets. Irreplaceable genetic resources are being destroyed to maximize short-term profits.

The life-patenting trend is also radically changing the focus of agricultural research. These companies insist they'll develop the technology to feed a hungry world, but what they really seek are patented products suited to the needs of industrial agriculture. Tomatoes with a longer shelf-life, for instance. Or milk from hormonally treated cows. Or crops like the Roundup Ready soybean, engineered to tolerate a particular chemical weed killer. Another new class of crops contains a gene from *Bacillus thuringiensis* (Bt), a soil bacterium that organic farmers have traditionally used as a natural pes-

DAVID RAE MORRIS / IMPACT VISUALS

Protesters in St. Paul, Minnesota, call for the labeling of all milk from cows injected with rBGH, the genetically engineered bovine growth hormone, in 1994.

ticide. These are just a few of such products to appear in the 1990s.

The biotech industry says genetically engineered products are safe; but how reliable is their research, given the industry's obvious bias? At the very least there are potential risks. It's clear, for instance, that herbicide-tolerant varieties encourage the use of herbicides, even as the health problems tied to herbicide-tainted soil and water are coming to light. Once again, we see corporate researchers looking past a real issue—safer alternatives—to the more immediate end of fostering dependence on their products.

A report from the Union of Concerned Scientists describes another possible risk: the jumping of implanted genes to nearby weeds or relat-

Modern industrialized agriculture encourages widespread use of genetically uniform varieties. These "monocultures" may perform well in the short run, but they may also be vulnerable to crop epidemics that could wipe out large portions of the world's food supply.

ed plants. Spontaneous gene flow has already been documented. The questions now are how widely it will occur and what will be the consequences. Transgenic wild plants—"superweeds"—could become serious problems for both farmers and the ecosystem. There's also the threat of "superbugs." Insect pests could develop immunities after adapting to genetically engineered crops like those that carry the Bt gene. At the very least, widespread use of Bt crops could compromise an important natural tool used by small, independent farmers—one more step toward destroying their way of life.

The ecological risks increase as genetically engineered crops are pushed on a global scale. The greatest potential for disaster lies in the biologically rich South, where wild relatives of major crop species are more abundant and thus more likely to take up new genes. Will the biotech firms seeking to penetrate these vast new markets fully weigh such risks? There's reason to doubt it. As a result, many scientists and organizations are calling for a "biosafety protocol," legally binding regulations for the international testing and use of genetically engineered organisms.

Whether or not the risk of a genetically engineered accident is realized any time soon, monopoly control over the crops that feed and sustain humankind is a present danger. In 1992, Agracetus, a small biotech company later bought by Monsanto, received a patent on all genetically engineered cotton varieties—regardless of how they were transformed or what germplasm was used to engineer them. It was the first "species-wide" patent ever granted. But it wasn't the last. In 1994, the same company received a European patent on all genetically engineered soybeans. These patents have a chilling effect on research and pose serious threats to food security. It means a handful of corporations could gain exclusive control over high-tech research for entire segments of the world's food supply. Both the cotton and soybean "species-wide" patents have been challenged on moral and technical grounds, but they remain in effect today.

"We are looking at an exponential increase in biological pollution through the multiplication and mutation of genetically engineered organisms. Once they've been put into a living system you can't recall them."

Andrew Kimbrell

A WORLD AT RISK

The ownership of life has implications for everyone. The erosion of genetic diversity it triggers seems destined to create genetically uniform crops with the potential for catastrophic failure. Meanwhile, industrial agriculture leads to an erosion of social diversity as well. Both are dangerous forces in an increasingly crowded and volatile world.

Biologically speaking, crop and livestock diversity are vital to agriculture's long-term vigor. To maintain pest and disease resistance in major

food crops, for instance, or to increase drought tolerance, plant breeders constantly require fresh genetic infusions from the gene-rich South. The greatest threat to this resource are new, uniform seed varieties and the monocultures they generate. The process isn't new; it's been underway since the Green Revolution brought industrial agriculture to the South in the 1960s. But the growing strength of the life industry threatens to accelerate it.

"The great land masses and oceans, once a shared biological commons, have been systematically enclosed and commercialized, their living inhabitants transformed into private property whose value is measured in purely market terms. In the name of profits, transnational business firms have rapidly gained commercial control over the earth's seeds and animal breeds, guaranteeing them a virtual monopoly over the world's food supply. They have been aided in their efforts by national governments—especially the United States—that have been quick to extend the patent laws to include ownership of microbes, plants and animals."

Jeremy Rifkin
President, Foundation for Economic Trends

With the spread of industrial agriculture, the loss of agricultural biodiversity has accelerated dramatically. We are losing the biological options we need to strengthen food security and perhaps to survive global climate change. The United Nations Food and Agriculture Organization warns that crop genetic resources are disappearing at the rate of 1-2% per year. Domestic livestock breeds are disappearing at an annual rate of 5%, or 6 breeds per month. The simple arithmetic reveals diversity to be an endangered resource. The worst-case result could be famine on an unprecedented scale.

Nevertheless, the push toward genetic uniformity continues. The Forestry Corporation of New Zealand, for example, is planting 200,000 genetically identical "super pine trees" created through a test-tube technique called facile cutting. Unilever, the world's largest food corporation, can mass produce up to a half million high-yielding, genetically uniform oil palm clones annually for its plantations in Asia and South America. The breakthroughs in sheep cloning foretell the day when researchers will manipulate embryonic cells to produce herds of identical livestock.

Socially speaking, the impacts of commercial biotechnology may be even more profound. The immediate threats are to the farmers who play a vital role in protecting genetic diversity. The vast majority of farmers in the South save and exchange seed with their neighbors. But as seed companies turn this region into another market, the commercial crop varieties they introduce will lead to higher seed prices and closer control. Farmers in growing numbers will be forced to buy new seed each year. Lacking conservation programs, the world will lose a resource crucial to the health of its major food crops: the last reservoirs of farmer-maintained genetic diversity.

As for the farmers themselves, their very survival is jeopardized. Throughout the developing world, the destruction of traditional agrarian life has led to the rise of vast urban slums, simmering caldrons of social tension, hopelessness and disease. Observers like Vandana Shiva have argued that what the North refers to as "religious" and "ethnic" strife in the South may actually be traced to this social upheaval—and the external forces that drive it.

JOE FISH / IMPACT VISUALS

The people of Colombia's Cauca region in 1988. Many Indigenous Peoples have begun to organize in their resistance to the outside forces that threaten their livelihoods and communities.

LIFE PATENTING VERSUS THE HUMAN SPIRIT

In the first book of the Old Testament, Adam and Eve are banished from the garden of Eden after partaking of the Tree of Knowledge. As they leave for the East of Eden, they see that an angel has placed a barrier, a flaming sword, in front of the Tree of Life. At the very wellspring of the Christian, Jewish and Islamic traditions, we find a reminder that life flows from a source beyond the human, that life is a force, an essence, with which we are not to interfere.

This ancient story reflects a view shared by many religious and ethical traditions. Whatever our beliefs, most peoples see life itself as something sacred, something above our mundane concerns, including commercial gain. Perhaps that is why people around the world react to the corporate ownership of life with instinctive revulsion. In the light of a creation whose beauty and complexity humbles every thoughtful being, these

entities are inhumanly arrogant. We're offended by the crass presumption that life could be their private property. Above all else, we know that basic human decency forbids it.

In the effort to redirect the trend toward patenting life, those who have experienced it firsthand have much to teach us. The world's Indigenous Peoples have long endured the assault on their personal and cultural integrity that now threatens the larger world. Their traditional knowledge is as crucial to humanity as the genetic information carried in their plants—and it is just as irretrievable once it vanishes. They can teach us the power of resilience in the face of what appears to be the unstoppable march of "progress." But patenting isn't unstoppable; the future is not yet written.

"Independent of the biological, cultural, social or religious differences that distinguish human beings, each individual has a natural right to be what he or she is and to have sole responsibility for his or her genetic heritage."

Bishop William Friend

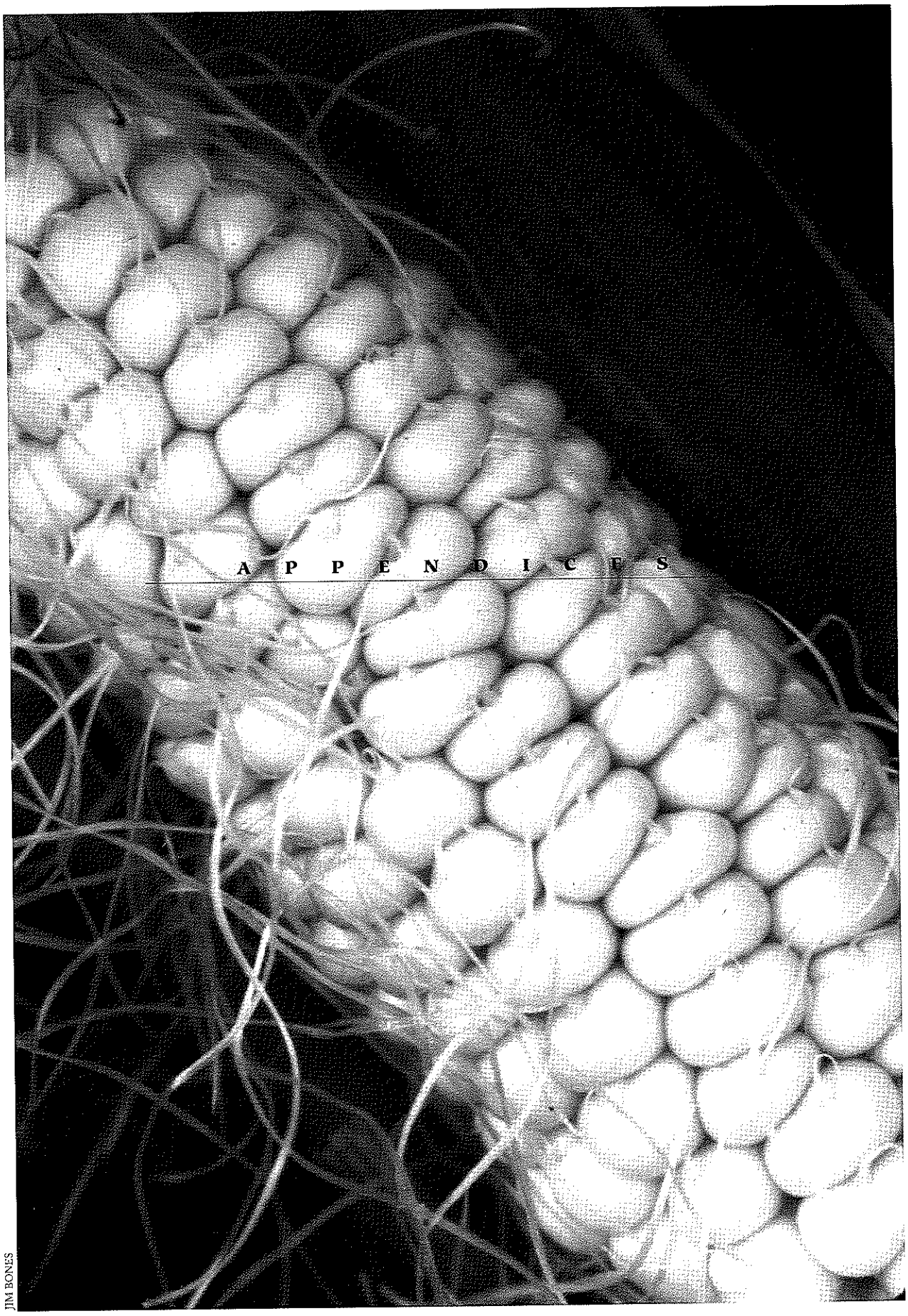
Other potential allies include the scientists themselves. Even if they personally choose not to explore the ethical dimensions of their research, they must acknowledge that such inquiry is integral to real knowledge. Their insights, astounding though they are, must be shared with the wider community engaged in the effort to understand the impact of this new technology. Lastly, they must realize that nothing they do is neutral. If an anthropologist visits a remote people to appropriate their knowledge but does nothing to protect them from disappearing, that is a moral act. Scientists are not exempted from their duty as moral beings.

It's easy to slip into the trap of seeing the life-patenting trend as an inevitable step in social and scientific history. These companies say life patents are required to feed the hungry millions, cure pandemics and develop a global system of trade that will reflect the realities of the next century.

We, like many others, think otherwise. This book attempts to further the process of envisioning a different, more responsible future. We end here by noting that what has been stolen in the rush to patent life can also be reclaimed.

Earlier this year, in response to the demands of Indigenous Peoples, a Colombian genetics institute offered to return thousands of human tissue samples collected from the country's indigenous communities. The Indigenous Peoples' organizations suggested a dialogue to discuss how, through legal means, all parties could establish a protocol for genetic research based on trust and understanding.

Intelligent, informed activism can help build understanding of an issue that truly has global consequences. We too must acknowledge that nothing we do is neutral, that sharing this knowledge, like not sharing it, is a moral act. ❀



APPENDICES

JIM BONES

FUNDING THE PATENT ISSUE

by Dr. Herman Warsh, Trustee, C.S. Fund

The patenting of life is an integral part of the overall trend towards a globalized economy and political system. This trend brings to mind a number of important connections for those of us in the funding world:

For those concerned with the environment, "free trade" has come to mean freedom from oversight or control, thus losing hard-fought environmental gains here in the United States.

For those of us concerned with human rights, globalization means the inability to close our frontiers to products made through a partnership between transnational corporations and brutal, often military-dominated governments which furnish compliant and low-paid work forces who have no legal protection or guarantees.

If you are concerned about the safety of our food supply, anything that reduces our legal right to set standards, or examine and restrict imports, is unacceptable. The loss of biological diversity and the increasing private ownership of seeds and of life itself is untenable.

I am one of the many who insist that we are individuals: I refuse to be treated as a consumer unit. Therefore I must fight against the turning of the living world into a commodity. Many of the environmental and human rights issues I have been working on for decades will be reversed if the biological commons are not maintained open and free.

Dr. Warsh is Vice President of the C.S. Fund. His philanthropic work includes service on the board of the Warsh-Mott Legacy, and formerly on the board of the Ruth Mott Fund and the staff of the Charles Stewart Mott Foundation. Herman Warsh's many years of environmental work include serving as Chair of the Board of Friends of the Earth-U.S. and membership on the boards of many other organizations including the Environmental Policy Institute, the Oceanic Society and High Country News.

PATENTING OF LIFE?

by Hermann Hatzfeldt, Trustee, HKH Foundation

Patents and life are two categories which appear to be at odds. When I first heard of "patents on life" I thought it was a joke. What used to be science fiction is now reality, however. The gene has replaced the atom as the icon of our age. Genetic engineering has become the cutting edge for modern science, the new frontier for big business and a major public concern.

The two mega-technologies have much in common. Both are ideologies with far-reaching repercussions on present and future society. Both are sharing grand aspirations for the advancement of mankind. But they differ in scope and in essence. While nuclear fission was designed for two limited purposes only—building bombs and generating electricity—biotechnology encompasses all forms of life. The focus has changed from the external to the inner spaces of nature. Control over the building bricks of life—genetic information—is now the target. Plants, animals and even humans are no longer taken as god-given; they have become disposables made by humans. This amounts to a radically new vision of the world and man's place in it.

Indeed, biology has become big business. Biotech companies are crawling over each other in prospecting the new biological territory and staking out claims for gene digging. Protection of intellectual property rights has become key in this modern gold-rush.

The first patents on life were given on plants in 1970; on micro-organisms in 1980; on animals (the now famous "oncomouse") in 1986. By now, several thousand such patents have been granted; many more are pending. The latest stage so far in this development is reached with the patent-protected "Dolly," the first successful cloning of an animal. The inevitable next step will be humans.

The original idea of legalizing intellectual ownership rights through patents was to encourage bright individuals, mostly of slender means, in their research by protecting the use of their inventions for a limited time. In the early days, therefore, patents served as a tool of public policy for giving the weak a chance against market concentration of the strong. But the traditional purpose of patents has meanwhile been thoroughly perverted. Today, large biotech corporations are protected by broad patents on well-known processes of discovering, changing and using living matter. What is here encouraged are monopolies, not competition. As a result, a handful of chemical companies and agro-businesses already own a large part of the world's commercially bred plants and animals and will soon control most of our inherited biological resources.

In the old system, patentable inventions had to meet the twin criteria of novelty and usefulness. The new patents on life, however, have little to do with inventing anything new. Genes are of course useful, but they are hardly novel. They have always been there. They cannot be invented or owned or sold. The same holds true for the technical processes by which a gene is isolated, recombined and made usable. Once discovered, the process is the same the world over. Patently, biotech patenting has degenerated into an enormous treasure hunt—who comes in first in the race is allowed to keep and exploit the treasure of life.

There is no justification for patents on life. Whatever one's evaluation of the merits and dangers of genetic engineering may be, exclusive property rights on living organisms and on knowledge of their use are not in the public interest. In my opinion, all forms of biological diversity and the knowledge thereof should be exempted from patenting. (Example: TRIPS Article 27.3 (b) of WTO does not do so, and should.) Here are some of my reasons.

Industry, science and governments have entered into an unholy alliance to speed up biotech R&D. For

this, patents are claimed to be necessary and useful. Necessary and useful for whom? A few biotech companies and a number of scientists and genetic engineers will certainly benefit. But what about the rest of society?

Some well-publicized benefits in health care are usually taken as arguments for patenting being useful and necessary for the development of pharmaceutic preparations, diagnostic tests and therapeutic treatments. But in these specific cases conventional patents on the product of research—the medicine—provide sufficient protection and incentives. There is no need for the current practice of protecting broadly the process of research and its raw material—the gene—as well as future applications. Patenting the gene rather than the medicine gives single companies control over future developments and limits the choice of doctors and patients. This is unethical and detrimental to public health. (Examples: although the breast cancer gene BRCA2 was discovered simultaneously by different research teams, the U.S. firm Myriad got the patent on this gene and its applications, now crowding out its competitors. The same is happening with blood cells from the umbilical cords of newborn babies.)

Agriculture is another example. It is often claimed that biotechnical patents on plants and animals are needed to ensure food security in the future. Nonsense. For centuries farmers have been in charge of conserving and sustainably using biological resources. They, not agribusiness, are the inheritors and guardians of biodiversity. If sustainability in agriculture is endangered, existing socio-political arrangements need to be changed and not yet another technical fix introduced. As a matter of fact, species patents on seeds and crops are about creating artificial scarcity, not about sustaining natural diversity. They deliberately narrow the gene pool and inevitably lead to an erosion of genetic variety and diversity. Thus, they endanger the very resource on which they thrive. There lies the real threat to sustainable food security. (Examples: patents on soybeans by Monsanto or on corn by Ciba-Geigy.)

Such patents also raise grave political and social questions. Whose are the world's biological resources? Are a few corporations entitled to privatize and commercially use what used to belong to the commons? How is this global expropriation of local resources and community knowledge to be justified? Are these companies, whose short term interest is to maximize shareholder value, trustworthy custodians of long term biological diversity? If not, what are the likely consequences? Considering that biological resources are concentrated in the South while patent holders are in the North, what about equity?

For the purpose of this paper, I can merely point out issues like these. None of them had been sufficiently considered before life began to be patented, though all of them should have been. It is the way we deal with biotechnology—whether we want to control or to encourage it—that will make a great difference to the world we are going to inhabit. A balanced public debate on this has yet to begin. I am convinced that private foundations, because they are not part of the unholy alliance, are in a unique position to contribute to starting it.

Hermann Hatzfeldt is a Trustee of the HKH Foundation and of several foundations in Germany. He is a dedicated human rights activist, environmentalist and sustainable forester.

DECISIONMAKING AGENCIES INFLUENCING THE FUTURE OF PATENTS ON LIFE

U.S. DEPARTMENT OF AGRICULTURE (USDA)

Administrator
Animal, Plant, Health Inspection Service (APHIS)
USDA-APHIS
4700 River Road
Riverdale, MD 20737
voice: 301-734-7324
fax: 301-734-8724

Director
Plant, Protection & Quarantine Division (PPQ)
USDA-APHIS-PPQ
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voice: 301-734-7612
fax: 301-734-3643

Director
Biotechnology and Scientific Services Program
USDA-APHIS-PPQ
4700 River Road
Riverdale, MD 20737
voice: 301-734-7612
fax: 301-734-3643

U.S. ENVIRONMENTAL PROTECTION AGENCY (EPA)

Administrator
U.S. Environmental Protection Agency
401 M Street SW
Washington, DC 20460
tel: 202-260-4700
fax: 202-260-0279

Director
Biopesticides and Pollution Prevention Division
Office of Pesticide Programs
EPA
401 M Street SW
Washington, DC 20460
tel: 703-308-8712
fax: 703-308-7026

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Commissioner
Food and Drug Administration (FDA)
5600 Fishers Lane
Rockville, MD 20857
tel: 301-827-2410
fax: 301-443-3100

Director
Center for Food Safety & Applied Nutrition
FDA
200 C Street SW
Washington, DC 20204
tel: 202-205-4850
fax: 202-205-5025

U.S. PATENT AND TRADEMARK OFFICE (PTO) (U.S. DEPARTMENT OF COMMERCE)

Asst. Secretary of Commerce and Commissioner of Patents and Trademarks
U.S. Patent and Trademark Office
Washington, DC 20231
tel: 703-305-8600
fax: 703-305-8664

Deputy Asst. Commissioner for Patents
U.S. Patent and Trademark Office
Washington, DC 20231
tel: 703-305-8800
fax: 703-305-8825

U.S. TRADE REPRESENTATIVE (USTR)

Office of the United States Trade Representative
Executive Office of the President
600 217th Street NW
Washington, DC 20508
tel: 202-395-3230
fax: 202-395-4809

CONVENTION ON BIOLOGICAL DIVERSITY (CBD)

Secretariat
Convention on Biological Diversity (CBD)
World Trade Center
393 St. Jacques Street, Office 300
Montreal, Quebec
Canada H2Y 1N9
tel: 514-288-2220
fax: 514-288-6588
Email: biodiv@mtl.net

EUROPEAN PATENT OFFICE (EPO)

European Patent Office
Erhardtstrasse 27
D-80331 Munich
Germany
tel: 49-89 23-99-0
fax: 49-89 23-99-4465

UNITED NATIONS FOOD AND AGRICULTURE ORGANIZATION (FAO)

Food and Agriculture Program (FAO)
Viale delle Terme de Caracalla
00100 Rome
Italy
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WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO)

WIPO
34, chemin des Colonbettes
P.O. Box 18, CH-1211
Geneva 20
Switzerland
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fax: 41-22 733-4128

U.S. LIAISON OFFICE

2 United Nations Plaza
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WORLD TRADE ORGANIZATION (WTO)

Center William Rappard
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POSITION STATEMENT ON CLONING

by the Council for Responsible Genetics

A call for a worldwide ban on human cloning, and wider public debate about biotechnology:

I. We call upon the nations of the world to prohibit the cloning of human beings, by incorporating such prohibitions into their national laws and statutes.

II. We call upon the United Nations to take the initial steps by constituting an International Tribunal to articulate the concerns arising in different nations, cultures, religions and belief systems, with respect to the potential cloning of humans.

III. We call upon the Congress of the United States to pass legislation to:

1) Prohibit the cloning of humans either through embryo splitting or nuclear transfer.

2) To exclude animals and plants, their organs, tissues, cells or molecules from patenting, whether naturally occurring or cloned.

IV. We call upon the citizens of the world and their institutions, including the media, to promote a vigorous public debate regarding the cloning of animals, and in particular, which practices are acceptable and which are are not.

In the course of human history our species has recognized many behaviors that are counter to the interests of the survival, development and flourishing of individuals within civilization. Among these are involuntary servitude, or slavery; torture, the use of poison gas, the use of biological weapons, and human experimentation without consent. Human societies are working on preventing other destructive practices such as child labor, environmental degradation, nuclear war and global warming.

The cloning of sheep and monkeys opens up the specter of human cloning. The fundamental character of this activity is to transform humans into commodities, to devalue the relationship of humans to each other and to their culture. Just as the 13th Amendment outlawed slavery, and other laws prohibited torture, child labor and other forms of human exploitation, the time has come to prohibit human cloning. We therefore call upon the United States, individual nations and the United Nations to declare the cloning of humans beings an immoral and illegal activity.

"CAN" DOES NOT IMPLY "OUGHT"

Despite the sheep cloners' disclaimer of any intent to apply this technique to humans, mainstream commentators, including "bioethicists," are already peddling the ideas of cloning dying children or 100% compatible human organ donors. (Transplantation of fetal pancreatic and brain tissue is already being used experimentally for treating diabetes and Parkinson's disease in adults.) Scientists are reluctant to aver, for the record, technological or medical scenarios that appear bizarre or avant-garde. We can expect that professional bioethicists and corporate marketing agents will ply their trade to make such new applications culturally palatable.

SOME EXPERIMENTS WILL BE PREVENTED

By banning cloning, some scientific questions will be more difficult to answer. But scientific convenience cannot be used to justify the degradation of the human condition, as occurred in the Nazi concentration camps, or in the Tuskegee syphilis study. The difficulty in obtaining classes of biomedical information is not a sufficient justification for research that exploits and demeans human beings.

DNA IS NOT DESTINY

Clones may share the same DNA, but they can hardly be described as "identical copies." Developmental, environmental and social factors stamp each living creature with the mark of individuality, even in the case of genetically identical twins. To be human is not the simple summation of genetic, biochemical or physiological processes. It involves the learning of language, the transmission of historical knowledge, the generation of new knowledge, the creation and transmission of music, art and other forms of culture. Culture and society exist outside of physiology

and are not transmitted through genes or cells, but through human communication and interaction occurring in organized societies.

HUBRIS OF ENORMOUS MAGNITUDE—IMPROVING ON NATURE

Cloning per se will not be the most likely end point if this technique is attempted in humans. The cell nuclei of a mature individual with known biological characteristics can be used as the raw material for "enhancement" techniques, involving introduction of extra or altered genes. The idea would be that the resulting clones would be "new" improved models, with increased disease resistance, and superior social, intellectual or athletic skills. This highly questionable enterprise, now technically feasible, makes possible a virtually unlimited set of eugenic attempts at "improvement" from a culturally defined and arbitrary starting point.

DANGEROUS LOSS OF DIVERSITY

Even if the cloning technique were entirely confined to nonhuman animals in the foreseeable future, it would still be problematic. The robustness of natural populations, including their flexible response to new conditions and hence resistance to disease, lies to a great extent in their genetic variability. This characteristic would be entirely eliminated in a population of clones. The near total loss of the entire U.S. corn crop in the 1970s as a result of monoculture—overuse of too narrow a genetic base—is a harbinger of what could happen with cloned livestock.

ANIMALS ON THE ASSEMBLY LINE

Proponents suggest that farm animals of the future could be cloned to better maximize agricultural production: sheep cloned for softer wool or cows for higher milk yield. Transgenic animals could be cloned to produce human pharmaceuticals or even organs for human transplantation. But are we prepared to view animals solely as lucrative biofactories, useful only in their capacity to serve human needs? When utility becomes the sole lens through which we view nonhuman animals, we have begun a systematic ethical decline.

EROSION OF RESPECT FOR LIFE

The industrialized production of agricultural animals according to pre-specified standards will inevitably undermine any respectful stance toward animals that may remain in our highly corporatized culture. Our experience undermines any argument that the human realm can be successfully insulated from a basic disrespect for other living organisms. Our history of treating animals as commercial goods, as well as the current trend of dismantling social programs protecting our society's most vulnerable people (children, poor and elderly), are not encouraging in this regard. Historical experience also points to a relationship between increased interest in genetic enhancement and decreased respect for the natural variation in ethnicity and ability in human life.

DEMOCRATIZING TECHNOLOGICAL PRACTICE

Genetic engineering is a technology developed largely with public tax funds. Hence, in fashioning policies for its implementation we should reflect upon citizen concerns. According to a recent *Time*/CNN poll of 1005 adults, conducted February 26-27, 1997, 93% of Americans oppose the cloning of humans, and 66% oppose the cloning of animals. The Council for Responsible Genetics joins the call for a worldwide ban on human cloning and for wide public debate on the wisdom and ethics of animal cloning.

ECOLOGICAL RISKS OF TRANSGENIC CROPS IN A GLOBAL MARKET*

Conclusions and Recommendations of the Union of Concerned Scientists

by Dr. Jane Rissler and Dr. Margaret Mellon

CONCLUSIONS

This report reaches four major conclusions:

1) Commercialization of transgenic crops posses serious environmental risks.

The widespread commercialization of transgenic versions of the full spectrum of food and fiber crops poses serious environmental risks that can be considered in several broad categories. These include the possibilities that:

• Transgenic crops themselves will become weeds. Weeds—a term that will be used broadly in this report to cover plants unwanted in farms, lawns, roadsides and unmanaged ecosystems—are billion-dollar problems. In 1991 alone, farmers and others spent over $4 billion to control weeds in the United States.

• Transgenic crops will serve as a conduit through which new genes move to wild plants, which could then become weeds. Like the crops themselves that become weeds, these plants could require expensive control programs. In addition, the novel transgenes may affect wild ecosystems in ways that are difficult to evaluate.

• Plants engineered to contain virus particles will facilitate the creation of new viruses. New viral pathogens that affect economically important crops could require significant control costs.

• Plants engineered to express potentially toxic substances like drugs and pesticides will present risks to other organisms that are not the intended targets of the new chemicals. For example, drug-producing plants might poison birds feeding in corn fields.

The report also considers the cascading effects that can ripple through an ecosystem as the result of an initial perturbation, and acknowledges the fact that some risks of transgenics may not yet be known.

The environmental risks of transgenic crops are not generic; that is, the plants do not share any one particular trait, such as fast growth or aggressiveness. Instead, their risks depend on the novel combinations of traits that modern gene transfer technologies make possible. Thus, many genetically engineered organisms will not be harmful. At the same time, the overall likelihood of harm will rise as the number and variety of crop releases increase.

The risks are similar in some ways to those of the introductions of nonnative organisms into new environments. Most nonnative organisms die out quickly in new environments. But, occasionally one will take hold, and—in the absence of ecological controls—thrive to cause extensive damage. A recent Office of Technology Assessment (OTA) study has indicated that nonnative species have caused billions of dollars of damage in the United States alone (U.S. Congress, 1993, Harmful Non-Indigenous Species in the United States, OTA-F-566). The OTA report notes that a number of the harmful nonindigenous species were originally intentionally imported for use in agriculture.

2) Commercialization of transgenic crops could threaten global centers of crop diversity.

Among the most challenging risks of transgenic crops is the threat that they might pose to the populations of wild plants and landraces (traditional varieties) that are centers of genetic diversity for crops—both as a result of the competition from the transgenic crops themselves and also by the transfer of the new genes in the crops into the landraces or wild relatives via pollen transfer. These centers of diversity, located primarily in the developing world, are regions that contain the greatest concentration of crop biodiversity.

Together landraces and wild relatives are the richest repositories of crop genetic diversity. They are the natural reservoir for the traits needed to maintain the vitality of modern crops. The genes for important traits like disease resistance—few of which have been identified and isolated —are the natural capital on which both traditional crop breeders and genetic engineers depend.

Crop genetic diversity is already diminishing at a stunning rate, as farmers around the world are persuaded to abandon the numerous landraces of the past in favor of a relatively few modern crop varieties. Expensive transgenic plants, which will generally have to create large markets to recoup research costs, will exacerbate that trend.

Few U.S. crops have centers of diversity in this country. This means that transgenic crops sold and planted in the United States generally pose less of a direct threat to crop biodiversity than they do if they are planted elsewhere

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* *From* Perils Amidst the Promise: Ecological Risks of Transgenic Crops in a Global Market *by Dr. Jane Rissler and Dr. Margaret Mellon, Union of Concerned Scientists, 1993.*

in the world. At the same time, the importance of centers of diversity to the continued vitality of U.S. and world agriculture makes it imperative that the United States understand the vital role of these regions in the future of agriculture.

3) Two aspects of the risks of transgenic crops can be assessed and minimized through a scientifically sound regulatory system.

These are that transgenic crops themselves will become weeds and that novel transgenes will be transferred into wild populations. Weediness potential can be predicted, although imperfectly, on the basis of the comparison of the field behavior of the transgenic plant to its nonengineered parent. The possibility of transgene flow can be assessed primarily on the basis of information about the distribution of sexually compatible wild and weedy relatives in the region where the crop is grown. If no wild and weedy relatives are in the vicinity, for example, there is no risk of gene transfer. Where relatives are found in the region, experiments can be done to determine the degree to which the crops and its relatives interbreed. If the transgenes are transferred to relatives, weediness potential experiments can be done.

4) Other aspects of the risk of transgenic plants are difficult to evaluate.

For example, the likelihood of gene flow is difficult to assess in many places outside the United States because information is unavailable on the distribution of wild plants. This is often true of countries harboring centers of diversity for crops important to world agriculture.

Also, the likelihood that virus-resistant crops will lead to the creation of new viruses is difficult to evaluate due to the lack of established methods to measure virus populations in the field, though there is adequate information to begin to develop such methods.

The long-term, cumulative risks to ecosystems of introducing large numbers of transgenes and transgenic plants are not well enough understood to allow their prediction except in the grossest sense. It is unlikely that ecosystem dynamics will be well enough understood any time in the near future to confidently predict this aspect of environmental impact. Obviously, unknown risks cannot be anticipated or evaluated.

RECOMMENDATIONS

The Union of Concerned Scientists (UCS) calls on the federal government to adopt strong measures to protect against the domestic, and, to the extent possible, the global environmental risks posed by genetically engineered crops.

UCS recommends the following specific actions:

1) The United States should establish a strong federal program to assess and minimize the risks of transgenic crops before they are commercialized. The program should consider the risks to agriculture and wild ecosystems in the United States and elsewhere in the world and should pay particular attention to the protection of centers of diversity for important food and fiber crops.

2) All transgenic crops should be evaluated for at least two aspects of ecological risk—weediness potential and gene flow—before they are approved for commercialization. Effects on centers of diversity within the United States should receive special attention.

3) The federal government should develop standard protocols to assess the risks of creating new viruses, nontarget effects of pesticides and the eco-toxicity of plant pharmaceuticals.

4) The U.S. government should sponsor research that would enable a full assessment of all ecological risks of genetically engineered crops.

5) Congress should direct the National Academy of Sciences to prepare a report on: i) the likelihood that seeds of engineered crops developed in the United States will be dispersed to centers of crop diversity, and ii) the availability of floristic surveys and other information needed to assess the impacts of engineered crops released in countries harboring the centers.

6) All transgenic seeds that are exported from the United States should bear a label stating that approval of the seeds under U.S. law carries no implication of safe use in other countries.

7) No company should be permitted to commercialize a transgenic crop in this country until a strong government program is in place that assures risk assessment and control of all transgenic crops, and gives adequate consideration to centers of crop biodiversity here and elsewhere in the world.

8) The appropriate United Nations organization should develop international biosafety protocols, which are necessary to ensure that developing countries, especially those harboring centers of crop genetic diversity, can protect against the risks of genetically engineered crops.

LEGAL ISSUES IN THE PATENTING OF LIFE FORMS

by Kristin Dawkins

A presentation at the Council for Responsible Genetics' Conference "Resisting the Commercialization of Our Genes," Harvard University, October 26, 1996.

Intellectual property rights grant exclusive rights to monopolize an invention for extended periods of time, usually 17-20 years. Under the new Uruguay Round trade rules, all member countries of the World Trade Organization must apply intellectual property rights to the use of plants, microorganisms, and other life forms. The actual text of the Uruguay Round Agreement on Trade-Related Aspects of Intellectual Property Rights, known as the TRIPs Agreement, states that all members "shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof." (*Sui generis* is a Latin phrase meaning "of their own kind.")

Simultaneously, governments are given the option to exclude from patentability: "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes." In other words, anything that can be genetically manipulated can be patented and monopolized.

Many governments have noted possible legal conflicts between the TRIPs provisions and the objectives of the Convention on Biological Diversity. After all, the Contracting Parties to the biodiversity convention have agreed to cooperate to ensure that intellectual property rights "are supportive of and do not run counter to its objectives"[1]—which are the conservation and sustainable use of biodiversity, and the equitable sharing of its benefits.

Some governments have expressed concern that intellectual property rights for industry, as defined in the TRIPs agreement, will prevail over the traditional rights and rights holders recognized in the Convention on Biological Diversity. Indigenous and local communities, according to the biodiversity convention, should share in the benefits derived from the use of their knowledge, and have the right to approve and be involved in plans to widen the use of their traditional innovations and practices.

The new technologies, meanwhile, bring threats of their own. Genetic engineering is a relatively new science, with many as yet untested impacts on biodiversity, biosafety and food security. A group of scientists at Oregon State University in the U.S., for example, found that a bacteria genetically engineered to more efficiently convert agricultural wastes to ethanol fuel also destroyed much of a fungus essential to the recycling of nitrogen through plant roots.[2] If this product had been commercialized, it could have led to desertification throughout its biological range in the field. Such risks have led governments to begin negotiating a legally binding protocol on "biosafety" as part of the Convention on Biological Diversity.

Other governments have noted a contradiction between the rights of patent holders and the goal of diffusing environmentally friendly technologies, asking whether intellectual property rights could be regulated in order to promote technology transfer. Researchers seeking the enormous financial returns of a patented product are contractually obliged to work in secrecy. Or they may fail to develop products from the patent, waiting to use the engineered gene later to monopolize a "more important" crop.[3] Of course, this disincentive for sharing knowledge applies not only to research in the laboratory, but also to the transfer of technologies across countries.

And some governments have observed that the TRIPs agreement could have negative impacts on the conservation of biodiversity itself.[4] When all possible uses of a patented trait are monopolized, further research and development on the genetics of that trait are stifled—limiting the genetic diversity of plants bred to express such a trait. Furthermore, plant breeding programs are designed to produce genetic uniformity, in order to meet the legal requirements of the Union for the Protection of New Varieties of Plants (UPOV), which grants another form of intellectual property rights—exclusive "Plant Breeders' Rights" (PBRs) over the seeds of new varieties to their developers. Breeding for uniformity means that, over time, distinct varieties will become less and less distinct.[5] And the commercial goal of developing only the most

marketable traits leads to a decline in the pool of genetic diversity preserved in seed banks.

Originally, the 1978 UPOV convention also granted farmers the "privilege" of saving seeds at harvest and informally exchanging them with other farmers, despite PBRs, and likewise granted breeders an "exemption" allowing them to use the genetic material of restricted seeds to develop new varieties without paying royalties or penalties. In 1991, however, UPOV was amended to eliminate both the farmers' privilege and the breeders' exemption—creating new rules limiting farmers' use of their harvested seed and severely limiting breeders' use of genetic material covered by PBRs. This revision also allows governments to grant both PBRs and patents not only to genetic material but to whole crops.

As UPOV has moved away from farmers' privilege, the Food and Agriculture Organization (FAO) of the United Nations has sought to define "Farmers' Rights." In 1989, the FAO endorsed a concept of Farmers' Rights that would recognize farmers' contributions to developing biodiversity and, in fact, to share with them the benefits of their work—the exact opposite of patent protection. This concept, embraced in a legal document called the "International Undertaking on Plant Genetic Resources," is now being revised by negotiators at the FAO. Many advocates of Farmers' Rights hope the revised Undertaking will become a protocol of the Convention on Biological Diversity and thus, an integral part of the debate over the conflict between the convention and the TRIPs agreement.

The TRIPs provisions were so controversial during the Uruguay Round negotiations that the final agreement states that they "shall be reviewed four years after the date of entry into force"—in other words, in 1999. Between now and then, peoples and their governments can strive to organize defensible *sui generis* instruments that preserve the public interest—defining the collective rights of Indigenous Peoples, strengthening the definition of Farmers' Rights with the FAO International Undertaking, building up Farmers' Rights and biosafety protocols under the Convention on Biological Diversity, and insisting that patents *do* run counter to the objectives of the convention.

Over millions of years, the Earth has become populated with a bountiful array of genetic diversity that sustains us all. Suddenly in this—our own generation, we discover that the planet's gene pool is no longer expanding. It is shrinking. It is not impossible that the loss of key species may cause gaps in the cycle of life so great that major portions of the food supply fail. The globalization of plant patenting stimulated by the Uruguay Round TRIPs agreement will accelerate the rate at which market forces already stimulate monocultural cropping with genetically uniform plant varieties[6]—setting up perfect conditions for the massive spread of pests and blight. Karnal bunt, for example, is a fungus that preyed on vast tracts of the U.S. wheat crop in 1996, affecting $4 billion of export production.[7]

Alas, our government is responsible for creating much of this ecological and social disaster. The U.S. Trade Representative's Office, riddled with corporate lobbyists from the giant food conglomerates, has used the Uruguay Round and other trade negotiations to promote draconian intellectual property rights and destructive shifts in agriculture policy all over the world. But there is a silver lining: it means that we citizens of the United States have the means to insist upon change. The next millennium beckons.

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[1] *Convention on Biological Diversity, Article 16.5. 1992.*

[2] *Hill, Richard L. "OSU Study Finds Genetic Altering of Bacterium Upsets Natural Order."* The Oregonian. *August 8, 1994.*

[3] *Day, Peter R. "The Impact of Patents on Plant Breeding Using Technology" in* Genes for the Future: Discovery, Ownership, Access. *NABC Report 7. June Fessenden MacDonald, ed. 1995.*

[4] *Press release. "Relationships Between Environmental Policies and WTO Services and Intellectual Property Agreements Examined." Information and Media Relations Division of the World Trade Organization. Geneva, Switzerland. August 14, 1995.*

[5] *Fowler, Cary and Pat Mooney.* Shattering: Food, Politics and the Loss of Genetic Diversity. *University of Arizona Press. 1990.*

[6] *The Crucible Group.* People, Plants, and Patents: The Impact of Intellectual Property on Biodiversity, Conservation, Trade, and Rural Society. *International Development Research Centre. Ottawa, Canada. 1994.*

[7] *"Karnal Bunt Studies Moved." North Dakota State University Extension Service.* AGWEEK. *October 14, 1996.*

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WE CAN'T DO WITH NATURE AS WE PLEASE

by Peter Montague

It seems as if the entire "developed" world is depending on rapid industrial innovation to pull its chestnuts out of the fire. The people who run the permanent government (they're not elected) seem stuck on the idea that tremendous growth will be required to solve the problems of poverty, well-being and pollution within the U.S. and throughout the world.

Even the Brundtland Commission—the prestigious group that coined the phrase "sustainable development" back in 1987—argued that the world's total economic activity would have to increase five-fold to 10-fold to lift all humans out of poverty. The need for growth has become an axiom of modern industrial/economic/political life.

A corollary to this axiom says that rapid technical innovation is the way to achieve growth. Therefore "sustainable development" requires rapid growth, which in turn requires rapid technical innovation, according to the people who think themselves as managing the planet.

Obviously, this view creates an imperative to deploy new technologies—an imperative that is particularly visible, these days, in the fields of genetic engineering and materials science—the systematic effort to create materials that nature never made, from which to construct next year's automobiles, airplanes, rockets, medical machinery, skyscrapers, foodstuffs, space stations, pesticides, communications and entertainment platforms, armaments and so on.

But in the recent past the mad dashes towards new technologies have usually created serious trouble:

• Our oil-based civilization seemed like it was giving us a wonderful life until it started warming up the planet: in 1995-96, the world's community of meteorologists reached consensus that our devotion to petroleum has ominous implications for the kind of world we will leave to our children.

• For 50 years, new uses of mercury proved to be very productive in scientific instruments, silent light switches, latex paints, pesticides and more. But now we find that the mercury content of the world's atmosphere has nearly doubled and consequently the fish in most of our fresh waters have become poisonous from a build-up of toxic mercury in their tissues.

• Lead is a superb pesticide, gasoline additive, paint supplement and glaze for pottery. But now we find that millions—literally millions—of children in the U.S. and abroad are having their intellectual capacity permanently diminished by lead poisoning.

• The invention of DDT made it possible to control malaria-bearing mosquitoes without understanding the life-cycle of the mosquitoes. DDT made mosquito control so easy that we forgot how to employ knowledge of mosquito ecology to control malaria, relying instead on the heavy hand of DDT. Now that the side-effects of DDT have become apparent—disruption of hormones of wildlife and contaminating humans on a global scale—DDT is being phased out and malaria, the number one killer worldwide, is resurgent. Other infectious diseases are spreading as well, because of environmental dislocations caused by human technologies.

• Learning how to "fix" nitrogen from the atmosphere was a marvelous innovation, leading to artificial fertilizers, increased per-acre agricultural yields and green lawns. But new environmental disruption caused by a planetary overload of nitrogen is emerging as a new global concern*—a triple threat warming the Earth, contributing to the destruction of the ozone layer and diminishing valuable biodiversity.

• Nuclear energy was sold to taxpayers with the promise of electricity "too cheap to meter" and nuclear weapons as so horrific that they would make war unthinkable. Nuclear energy turned out to be expensive, and today war is hardly unthinkable. Furthermore, the U.S. Secretary of Energy declared, "The arms race is over. Our struggle now is to get rid of this sea of plutonium." The world's 700-ton stockpile of plutonium—an element described by its discoverer, Glenn Seaborg, as "fiendishly toxic"—has created what *The New York Times* calls "one of the most intractable problems of the post-Cold-War era."

The list could really be extended, but the point is probably clear.

Caroll Pursell, a technology historian at Case Western Reserve University, says: "Technology should be

about the exercise of prudence. But economic considerations usually push new developments forward."

This is certainly the case with genetic engineering. The genetic engineering industry hit its stride in 1995-96 when U.S. regulators (Food and Drug Administration and Environmental Protection Agency) approved the commercialization of half a dozen new genetically engineered crop species, which are now being dispersed into the environment on a large scale. Soon these species will be sold abroad.

For the first three billions years of life on Earth, genes could only be shared among species that were similar enough to mate and reproduce. There was no way dog genes could get into cats, or corn genes into wheat. The gene pool of the mating species limited the genetic information that any species could contain. Natural genetic variations have always occurred, and those that promote survival may endure and eventually cause a species to evolve. But the process up until now has been glacially slow.

What is new about genetic engineering is that it allows genes to be shared among completely unrelated species. And quickly. Genes from a trout can be put into a tomato, for example, to give the tomato some desirable characteristic that only the trout used to have. Species created in this way are known as "transgenic species" or "living modified organisms" (LMOs). Now, literally for $68 any microbiology graduate student can purchase a gene splicing kit and start transplanting tobacco genes into mosquitoes, or shark genes into lady bugs to see what will happen.

In 1996, the Union of Concerned Scientists (UCS) published a book urging caution as transgenic species are released into the environment. The book basically asks, "What will it mean to have a steady stream of animal and microbial genes entering the gene pools of plants in wild ecosystems?" Based on principles of ecology, principles derived from observing the way nature works, UCS warns of the following scenarios:

• Gene flow, in which new genes from insect-, disease- or herbicide-resistant species flow to wild plant relatives and weeds, causing agricultural and ecological havoc unless effective controls are available and affordable.

• Harms to non-target species arising, for example, from new gene products with toxic qualities being ingested by birds and other feeders in the region where LMOs are cultivated.

• Cascading effects on an ecosystem triggered by the introduction of LMOs, such as pests developing resistance to Bt in transgenic plants or being diverted to other food sources.

• Loss of biological diversity arising when LMOs displace other species, a particularly acute problem in the Third World nations that possess great crop diversity but lack the infrastructure and expertise to prevent losses.

We must ask, why do we create such similar problems again and again?

Why do we never seem to learn?

It is because, most fundamentally, we believe we are the master species, and that the rest of creation exists for our benefit. We are free to do with it as we please. Secondly, we have set up our rules so that the people who perpetrate new technological mistakes profit from them in the short term, leaving the long-term costs to be borne by others.

What could we do differently? We could put the burden of proof on those who want to deploy new technologies, similar to the way we put the burden of proof on people who want to sell new pharmaceutical drugs.

An elegant, conservative scheme for shifting the burden of proof has been proposed by economist Robert Constanza. He calls it the "precautionary polluter pays principle." Basically, it would require technical innovators to post a performance bond up front, to cover the worst-case costs of what they are about to unleash on the world. Would it slow the pace of technical innovation? Surely it would. Do we need such a slowing? Only if we desire a future for humans.

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*Stevens, William K. *"Too Much of a Good Thing Makes Benign Nitrogen a Triple Threat,"* The New York Times, *10/12/96.*

Peter Montague is director of the Environmental Research Foundation in Annapolis, Maryland, and editor of Rachel's Environment & Health Weekly.

Excerpted from SUNS, the South-North Development Monitor *#3917. Penang, Malaysia, February 6, 1997.*

CONSUMERS PAY BILLIONS FOR PATENT EXTENSIONS ON MEDICATIONS

by Dr. Azra Talat Sayeed

If you are one of the tens of millions of Americans who take prescription or over-the-counter-drugs, you are now paying your share of a windfall $1.2 billion that drug-makers are collecting in 1996 and 1997. This windfall profit will grow to $6 billion in coming years, as the pharmaceutical industry in the U.S. enjoys extended terms on patented drugs.

Due to a vote in Congress after the Uruguay Round GATT negotiations on intellectual property rights, the period of patent protection for U.S. brand-name drug manufacturers is now extended from 17 to 20 years. During the extended period, manufacturers that were prepared to distribute generic drugs—with an identical chemical composition to the better known brand-name products—are obliged to withhold the discounted supplies from the drug store shelf.

The difference in price between the patented and generic versions of the identical drug can be as much as 45% in the first year of competition. By the time generic drugs have been in the market for about 3 years, they tend to be 75% cheaper than their trade-marked cousins.

These are the findings of a 1995 study by Professor Stephen W. Schondelmeyer, Endowed Chair in Pharmaceutical Management and Economics at the University of Minnesota and Director of the PRIME Institute. The study examines the economic impact of GATT patent extension on 109 brand-name drugs.

One of the products which gained patent extension is Zantac, the most widely prescribed drug in the world. Zantac tablets, once scheduled to go off patent in December 1995, remain competition-free from an identical generic version until July 1997. The price of a typical month's supply of Zantac, about $90 in 1994, should have dropped this year to only $50—as the patent for the brand-name expires. But the lack of competition for an additional 20 months means Zantac consumers will have paid an extra $1.4 billion over a period of 6 years—the time a competitor will need to break into this monopolized market.

Brand-name or trademarked products are really just those that lack competition because they are still protected by a patent. The ostensible purpose of the patent is to enable the developers of the product to recoup their research investment; yet of the 109 drugs studied, many were near the end of their 17 year exclusive marketing period. The manufacturers of these products had already earned more than their actual investments through highly profitable sales.

Generic manufacturers and consumers both are paying dearly for a health care cost which could have been totally avoided. A few major pharmaceutical companies are the big winners. Consumers should object.

Dr. Talat Sayeed studied Social and Administrative Pharmacy at the University of Minnesota and has now returned to Pakistan where she is working with consumers organizations.

World's Top 10 Pharmaceutical Corporations

COMPANY	1995 SALES (US) MILLIONS	COMMENT
Glaxo Wellcome (UK)	$11,800	Glaxo and Burroughs Wellcome's 1995 merger was worth $14 billion
Merck (USA)	$10,960	
Novartis (Switzerland)	$10,940	Ciba and Sandoz merged in 1996
Hoechst (German)	$9,420	acquired Marion Merrell Dow in 1995 for $7.1 billion
Roche (Switzerland)	$7,820	
Bristol-Myers Squibb (USA)	$7,810	
Pfizer (USA)	$7,070	
SmithKline Beecham (UK)	$6,600	
Johnson & Johnson (USA)	$6,300	
Pharmacia & Upjohn (Sweden)	$6,260	Merged in 1995

Source: RAFI, based on Wall St. Journal, 7 March 1996. Company sales exclude sales of nondrug products.

World's Top 10 Agrochemical Corporations

COMPANY	1995 SALES (US) MILLIONS	COMMENTS
Novartis (Switzerland)	$4,410	combined CibaGeigy and Sandoz
Monsanto (USA)	$2,472	
Bayer (Germany)	$2,373	
Zeneca (UK)	$2,363	
AgrEvo (Germany)	$2,344	formerly Hoechst and Schering
DuPont (USA)	$2,322	
Rhone-Poulenc (France)	$2,068	
DowElanco (USA)	$1,962	
American Home Products/ American Cyanimid (USA)	$1,910	American Home Products acquired American Cyanamid
BASF (Germany)	$1,450	

Source: RAFI, based on AGROW, No. 253, March 29. 1996.

World's Top 10 Food and Beverage Corporations

CORPORATION	1995 SALES (FOOD AND DRINK) MILLIONS	FOOD/DRINK AS % OF TOTAL SALES
Nestle SA (Switzerland)	$46,400	99%
Philip Morris Inc. (USA)	$33,035	50%
Unilever PLC/NV (UK/Netherlands)	$25,300	56%
ConAgra, Inc. (USA)	$20,345	84%
Coca-Cola Co. (USA)	$18,018	100%
PepsiCo Inc. (USA)	$16,123	53%
Mars Inc. (USA)	$13,500	100%
Cargill Inc. (USA)	$12,929	28%
Archer Daniels Midland (USA)	$12,672	100%
Kirin Brewery Co. (Japan)	$12,626	97%

Source: DataMonitor

GLOSSARY

Prepared by the Rural Advancement Foundation International (RAFI) and initially published in Enclosures of the Mind: Intellectual Monopolies, *RAFI 1996.*

Biotechnology
A variety of techniques that involve the use and manipulation of living organisms to make commercial products. These techniques include cell culture, tissue culture, embryo transfer and recombinant DNA technology (genetic engineering).

Biological Diversity or Biodiversity
All living organisms, their genetic material and the ecosystems of which they are a part. It is usually described at three levels: *genetic, species and ecosystem diversity.*

- *Genetic diversity* is the variation of genes between and within species. It is all the genetic information contained in the genes of all individual plants, animals and microorganisms on earth. Genetic diversity within a species permits it to adapt to new pests and diseases, and to changes in environment, climate and agricultural methods.
- *Species diversity* is the total number or variety of species in a given area.
- *Ecosystem diversity* is the total variety of ecosystems or interdependent communities of species and their physical environment. Ecosystems may cover very large or quite small areas. They include such natural systems as grasslands, mangroves, coral reefs, wetlands and tropical forests, as well as agricultural ecosystems that depend on human activity but have characteristic assemblages of plants and animals.

Biopiracy
The use of intellectual property to legitimize the exclusive ownership and control of biological resources and knowledge, without recognition, reward or protection to informal innovators.

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure
An international treaty administered by the World Intellectual Property Organization (WIPO) that has been signed by 32 countries.

Cell Line
Cells removed from humans or animals that are manipulated to sustain continuous, long-term growth in an artificial culture. So-called immortal cell lines have been cultured to live indefinitely under artificial conditions, where temperature and nutrient requirements are strictly controlled. Cell lines provide an inexhaustible supply of the DNA of the organism they are taken from (see Human Genome Diversity Project below).

Centers of Genetic Diversity
The locations where the world's most common food crops are found to have the greatest genetic diversity. Often called the Vavilov Centers after the Russian scientist who identified them in the early 1900s, they tend to be areas where crops have been cultivated longest and most widely, but are not necessarily the centers of origin of crop species.

Compulsory licensing
A legal mechanism that obliges patent holders to make their inventions available at equitable prices if competitors can prove that patents are not being "worked" to the benefit of society or are not accessible within a reasonable price range.

Conference of the Parties (COP) to the Convention of Biological Diversity
All the countries which have ratified the Biodiversity Convention. The COP meets periodically to discuss and shape the implementation of the Convention. Meetings were held in the Bahamas in 1994, in Indonesia in 1995 and in Argentina in 1996.

Consultative Group on International Agricultural Research (CGIAR)
An informal network of 16 International Agricultural Research Centers whose gene banks came under the control of the UN Food and Agriculture Organization in October 1994. The centers are:
CIAT: Centro Internacional de Agricultura Tropical/ International Center for Tropical Agriculture, Colombia

CIFOR: Center for International Forestry Research, Indonesia; **CIMMYT:** Centro Internacional de Mejoramiento de Maíz y Trigo/International Center for the Improvement of Corn and Wheat, Mexico; **CIP:** Centro Internacional de la Papa/International Potato Center, Peru; **ICARDA:** International Center for Agricultural Research in the Dry Areas, Syria; **ICLARM:** International Center for Living Aquatic Resources Management, Philippines; **ICRAF:** International Center for Research in Agro-forestry, Kenya; **ICRISAT:** International Crops Research Institute for the Semi-Arid Tropics, India; **IFPRI:** International Food Policy Research Institute, United States; **ILRI:** International Livestock Research Institute, Kenya; **IIMI:** International Irrigation Management Institute, Sri Lanka; **IITA:** International Institute of Tropical Agriculture, Nigeria; **IPGRI:** International Plant Genetic Resources Institute, Italy; **IRRI:** International Rice Research Institute, Philippines; **ISNAR:** International Service for National Agricultural Research, Netherlands; **WARDA:** West Africa Rice Development Association, Ivory Coast

Convention on Biological Diversity or Biodiversity Convention
A legally binding international agreement for the conservation and sustainable use of biodiversity. Its final text was adopted in Nairobi on May 22, 1992. It was signed by over 150 countries at the UN Conference on Environment and Development in Rio de Janeiro, Brazil, in June 1992 and was ratified by 128 governments as of October 1995. The convention came into force on December 29, 1994. The U.S. had not ratified it as of June 1997.

Copyright
An intellectual property right intended to protect artistic and cultural works, such as books, illustrations, photographs and television programs, from being duplicated or transmitted without the author's permission. Copyrights do not give exclusive right to the ideas in protected material, but rather to the specific format in which they appear.

DNA (Deoxyribonucleic acid)
The molecule in chromosomes that is the repository of genetic information in all organisms (with the exception of a few viruses in which the hereditary material is ribonucleic acid or RNA). The information coded by DNA determines the structure and function of an organism.

***Ex situ* conservation**
Literally, conservation "off-site" or outside an organism's natural habitat. Gene banks and botanical gardens are examples.

Farmers' Rights
In 1985, the UN Food and Agriculture Organization (FAO) Commision on Plant Genetic Resources (now the FAO Commision on Genetic Resources for Food and Agriculture) introduced the principle of Farmers' Rights. The FAO's International Undertaking on Plant Genetic Resources was amended in 1991 to include Farmer's Rights. The amendment recognizes farmers as past, present and future *in situ* agricultural innovators who collectively have conserved and developed agricultural genetic resources around the world. Farmers are recognized as innovators entitled to intellectual integrity and to compensation whenever their innovations are commercialized. Farmers have the right to Germplasm, Information, Funds, Technologies and Farming/Marketing Systems (GIFTS). Compensation was anticipated via a global Gene Fund, paid into by the North for genetic conservation and improvement in the South. Agenda 21, the United Nations' blueprint for sustainable development, and the Biodiversity Convention have also adopted the concept of Farmers' Rights. The government of India is drafting legislation that would establish it in law; other governments are also considering legislative options. The financing and implementation of Farmers' Rights will be addressed by several international agricultural meetings in the coming years.

General Agreement on Tariffs and Trade (GATT)
The GATT was established in 1947 and grew from a club of 23 industrialized nations to an agreement between 115 signatory states. Following the Uruguay Round of negotiations (concluded in 1994), GATT came under the management of the multilateral World Trade Organization on January 1, 1995 (see below). The Uruguay Round included an agreement on intellectual

property as a trade issue, known as Trade Related Intellectual Property Rights or TRIPS (see below).

Gene
The functional unit of heredity. A gene is a section of DNA that codes for a specific biochemical function in a living being. Genes are physically located on chromosomes.

Genetic Engineering
The use of high technology processes to manipulate the DNA of living organisms in order to create new, different organisms in a laboratory.

Genome
All the genetic material in the chromosomes of a particular organism or species.

Gene bank
A form of *ex situ* conservation for plant, seed and animal germplasm. Gene banks are usually humidity- and temperature-controlled facilities where seeds and other reproductive materials are stored for future use in research and breeding programs. Gene banks that stock crop germplasm are also called seed banks. Though very important, they are a poor replacement for the maintenance of crop genetic diversity *in situ* or on-site.

Germplasm
The total genetic variability, represented by germ cells or seeds, available to a particular population of organisms.

Green Revolution
A massive and controversial agricultural research and production strategy which aimed to increase the output of staple grains in the South starting in the 1960s. Initially funded by the Rockefeller Foundation, it was later supported by aid from Northern governments. The Green Revolution was based on the belief that world hunger was basically a technical problem which could be fixed by raising agricultural production through higher-yielding varieties. This assumption and approach have dominated agricultural aid for three decades. The Green Revolution's critics have pointed out the political and economic causes of hunger, the need for land reform, and the need for other structural changes in agriculture and consumption worldwide. At its peak, the Green Revolution produced high-yielding varieties of a few staple crops. Unlike most farmers' varieties, however, these new plants were designed to be highly dependent on expensive and often environmentally unsound chemical inputs. Large-scale, capital-intensive agriculture reaped the benefits while smaller farmers were marginalized, increasing social tensions and working against *in situ* conservation. Many of the agricultural research centers of the Consultative Group for International Agricultural Research (see above) contributed to or were formed as a result of the Green Revolution.

Human Genome Project
An international collaborative endeavour among geneticists to "map the human genome" by using new technologies to describe the chemical composition of an estimated 100,000 genes that control the inherited part of human beings' makeup.

Human Genome Diversity Project (HGDP)
"A collaborative research project...being developed on a global basis under the auspices of the Human Genome Organization." Its goal is "to arrive at a...more precise definition of the origins of different world populations by integrating genetic knowledge...with knowledge of history, anthropology and language." One of its expected uses is to provide information on the role played by genetic factors in the predisposition or resistance to disease. Concretely, the HGDP plans to draw and immortalize human cell lines from hundreds of Indigenous Peoples worldwide.

Human Genome Organization (HUGO)
The international umbrella organization that manages the Human Genome Project. In the U.S. it is primarily funded by the Department of Energy and the National Institutes of Health. In Europe, HUGO is funded by the European Commission.

***In situ* conservation**
Literally, conservation "on site." *In situ* conservation is the conservation of ecosystems and natural habitats, and the maintenance, recovery and development of viable populations of species in their natural surroundings. In the case of domesticated livestock or cultivated crop species, it is their conservation in the surroundings where they have developed their distinctive properties.

Intellectual Property (IP) or Intellectual Property Rights (IPRs)
Laws that grant monopoly rights to those who create ideas or knowledge. They are intended to protect inventors against losing control of their ideas or the creations of their knowledge. There are five major forms of IPRs: patents, Plant Breeders' Rights, copyright, trademarks, and trade secrets. (See other entries in the Glossary for definitions of each.) All IPRs operate by exclusion, granting temporary monopoly rights which prevent others from making or using the creation. IP legislation is national, although most countries adhere to international conventions governing intellectual property.

International Undertaking on Plant Genetic Resources
A multilateral instrument adopted by the United Nations Food and Agriculture Organization in 1983 that is currently being re-negotiated to bring it in line with the Convention on Biological Diversity. It is a voluntary agreement intended to provide an international framework for the collection, conservation, exchange and utilization of plant genetic resources for food and agriculture.

Life industry
An industry that has arisen through mergers and cooperative agreements among corporations to profit from the manipulation and ownership of living organisms. With the development of biotechnology and the increased use of intellectual property systems, these previously discreet agrochemical, seed, pharmaceutical and food industries increasingly depend upon a similar set of technologies and laws which allow the monopoly control of living organisms.

Microorganisms (or microbes)
Tiny living things that are not visible except with a microscope. These include algae, bacteria, fungi (including yeasts), certain protists (one-celled organisms that are not bacteria) and viruses. For the purpose of patent protection, the term microorganism often applies to other types of biological material, including cell lines of plants and animals, and human genetic material. There is considerable uncertainty regarding the scope of the term.

Paris Union on Industrial Property
The principal inter-governmental body established to govern the patent system and determine the ground rules for patents. In recent years its regulatory capacity has been overwhelmed by national patent office decisions in the U.S. and Europe. It is likely to be further undermined by the TRIPS agreement (see below).

Patent
A legal monopoly that covers a wide range of products and processes, including life forms. To be patentable, inventions must meet three basic criteria. They must be: (1) novel, that is, they must not have been known previously to the public; (2) useful, that is, they must do what they claim, though they need not necessarily be practical; and (3) non-obvious, that is, they must have an "inventive step" and constitute some notable extension of what was previously known. Patents provide exclusive legal protection to patent holders, usually for 17 to 20 years. Anyone wishing to use a patented invention must receive permission from the patent holder and often must pay a royalty. In exchange for this monopoly, the patent holder must disclose or describe the invention.

Patent Cooperation Treaty
An effort to create a global patent system to ensure that a patent granted in one country will be adopted in all member countries. It has not yet achieved its goal. The treaty has 77 member states, including all industrialized countries, ten former French colonies in Africa, two countries from the Americas and eight from Asia. It is likely to become less relevant with the adoption of TRIPS under the World Trade Organization (see TRIPS).

Patent Culture Depository
An institution for the deposit of microorganisms subject to patent claims. Twenty six such institutions in 15 countries have been recognized by the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (see above). These institutions contain the living materials (microorganisms, genes, seeds, animal embryos, human and animal cell lines, etc.) that are the basis of virtually all patents on living material.

Plant Breeders' Rights (PBRs)
A form of intellectual property law that grants a plant breeder's certificate to those who breed new plant varieties. Plant Breeders' Rights generally contain breeders' and research exemptions that allow non-commercial use

of protected varieties. In the U.S., recent court decisions have threatened these exemptions. There are currently two international agreements governing PBRs, both of them under UPOV, the International Convention for the Protection of New Plant Varieties (see below).

Sui generis legislation
Literally "of its own kind," that is, in a class alone. This refers to any unique form of intellectual property legislation specifically designed to meet certain needs.

Trade secret
An intellectual property right used when inventors do not wish to patent in order to protect themselves from competitors. Unlike patents, trade secrets do not require inventors to publish and have no time limit. They can be maintained, for example, by contracts with company employees who are legally bound not to disclose the protected information.

Trademark
A form of intellectual property right that provides legal monopoly for a name, or a linguistic or visual symbol.

Transgenic organism
Any organism that has been genetically engineered to contain a gene from another organism, usually from a different species.

Trade Related Intellectual Property Rights (TRIPS)
TRIPS is a GATT agreement, now administered by the World Trade Organization (WTO), stipulating that all signatories must conform to industrial country standards of intellectual property law. TRIPS requires signatories to introduce patent coverage for microorganisms and to have some form of intellectual property coverage for plants. Developing countries have until at least the year 2000 to implement the agreement's intellectual property provisions. Least developed countries have until 2004, with a possible extension. The WTO will review the TRIPS agreement in 1999, and it could be modified as a result.

Union for the Protection of New Varieties of Plants (UPOV)
A Geneva-based organization established in 1961 under the World Intellectual Property Organization to implement Plant Breeders' Rights. There are two operative UPOV Conventions, dated 1978 and 1991. The 1978 Convention allows farmers to save and replant PBR-protected seed from their harvest. The 1991 version restricts the right of farmers to save seed and makes Plant Breeders' Rights more like patents, extending the scope of the monopoly granted to the certificate holder. To date, only the U.S. and Australia have adopted the 1991 Convention. The UPOV Council meets briefly every October, after a series of inter-governmental and government/industry committees that effectively regulate the evolution of the Convention. UPOV had 31 member states, most of them industrialized countries, as of December 1996. However, many countries of the South are preparing to join UPOV.

World Intellectual Property Organization (WIPO)
The Geneva-based organization that houses international intellectual property conventions adopted by significant parts of the world community, including conventions on patents, Plant Breeders' Rights, and the Budapest Treaty on IPRs over biological materials. WIPO had 161 state members as of February 1997, including all industrialized countries and many countries of the South. The annual WIPO Council includes all members and observers. Each convention has its own membership and forum under the WIPO umbrella. The Director General of WIPO is usually the Secretary General of the individual conventions, but day-to-day operations are generally carried out by a specialist secretariat led by a Deputy Secretary General.

World Trade Organization
A body created at the conclusion of the Uruguay Round of GATT in 1994 to monitor the GATT agreement and pursue global trade objectives. It became operational on January 1, 1996. It now has the potential to become the dominant forum for determining the future of intellectual property laws worldwide.

WEB SITES OF INTEREST

ALLIANCE OF GENETIC SUPPORT GROUPS
medhelp.netusa.net/www/agsg.htm

AMERICAN TYPE CULTURE COLLECTION
www.atcc.org

BIODIVERSITY ACTION NETWORK
www.intr.net/esw/bionet.html

BIO ONLINE
cns.bio.com

BIOSPACE
www.biospace.com

BIOTECH
biotech.chem.indiana.edu

BIOTECH LAW WEBSERVER
biotechlaw.ari.net/foley/homepage.html

CULTURAL SURVIVAL
www.cs.org

CULTURAL SURVIVAL CANADA
www.cscanada.org/~csc/home.htm

ENVIRONMENTAL DEFENSE FUND
www.edf.org

ENVIRONMENTAL RESEARCH FOUNDATION
www.monitor.net/rachel

EUROPEAN PATENT OFFICE
www.epo.co.at/epo

GENELETTER
www.geneletter.org

GENOME DATABASE MENU
www.hgmp.mrc.ac.uk/Public/genome-db.html

GREENPEACE BIODIVERSITY CAMPAIGN
www.greenpeace.org/cbio.html

GREGORY AHARONIAN'S INTERNET PATENT NEWS SERVICE
srctran@world.std.com

HELIX-GENLINE
healthlinks.washington.edu/genline

IBM'S PATENT SERVER DATABASE FOR U.S. PATENTS
patent.womplex.ibm.com

INSTITUTE FOR AGRICULTURE AND TRADE POLICY
www.iatp.org/iatp

MOLECULAR GENETICS JUMP STATION
www.ifrn.bbscr.ac.uk/gm/lab/docs/genetics.html

NATIONAL BIOTECHNOLOGY INFORMATION CENTER
www.nal.usda.gov/bic

NATIONAL CENTER FOR BIOTECHNOLOGY
www.ncbi.nlm.nih.gov

NATIONAL CENTER FOR HUMAN GENOME RESEARCH
www.nchgr.nih.gov

NEWS SERVICE
www.prnewswire.com

PESTICIDES ACTION NETWORK
www.panna.org/panna

PURE FOOD CAMPAIGN
www.geocities.com/Athens/1527

RECAP (RECOMBINANT CAPITAL) SIGNALS
www.recap.com

RURAL ADVANCEMENT FOUNDATION INTERNATIONAL (RAFI)
www.rafi.ca

SHADOW PATENT OFFICE
www.spo.eds.com/patent.html

SELECTED SITES RELEVANT TO PLANT GENETIC RESOURCES
web.icppgr.fao.org/Links/links.html

SOCIETY, RELIGION AND TECHNOLOGY PROJECT
webzone.ccacyber.com/www/strproject/geneng2.htm

UNION OF CONCERNED SCIENTISTS
www.ucsusa.org

U.S. PATENT AND TRADEMARK OFFICE
www.uspto.gov

U.S. PATENTS SEARCH DATABASE
patents.cnidr.org

U.S. PLANT VARIETY PROTECTION
probe.nalusda.gov:8000/related/aboutPVP.html

USDA, APHIS, BSS-BIOTECHNOLOGY AND SCIENTIFIC SERVICES
www.aphis.usda.gov/bbep/bp

VIRTUAL LIBRARY ON HUMAN GENOME PROJECT
www.ornl.gov/techresources/humangenome/genetic.html

WORLD INTELLECTUAL PROPERTY ORGANIZATION
www.wipo.org

WORLD TRADE ORGANIZATION
www.wto.org

FROM THE SPONSORS' ROLODEX

A starter list of non-profits working on ownership of life issues and their implications

BIOTECHNOLOGY WORKING GROUP
Phil Bereano
c/o Department of Technology Communication
University of Washington
14 Loew Hall
Box 352195
Seattle, WA 98195
Phone: 206-543-9037
Fax: 206-543-8858
Email:
phil@uwtc.washington.edu

CALIFORNIA BIOTECHNOLOGY ACTION COUNCIL
Doreen Stabinsky
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717 Oak Street
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Phone: 916-757-2975
Fax: 916-278-7582
Email: dfstabinsky@ucdavis.edu

CENTER FOR TECHNOLOGY ASSESSMENT
Andrew Kimbrell
310 D Street NE
Washington, DC 20002
Phone: 202-547-9359
Fax: 202-547-9429
Email: office@icta.org

COUNCIL FOR RESPONSIBLE GENETICS
Wendy McGoodwin
5 Upland Road
Cambridge, MA 02140
Phone: 617-868-0870
Fax: 617-491-5344
Email: wendy@essential.org

EDMONDS INSTITUTE
Beth Burrows
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Email: beb@igc.apc.org

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Fax: 410-263-8944
Email: erf@rachel.clark.net

FARM AID
Carolyn Mugar/Harry Smith
334 Broadway, Suite 5
Cambridge, MA 02139
Phone: 617-354-2922
Fax: 617-354-6992
Email: farmaid1@aol.com

FOUNDATION ON ECONOMIC TRENDS
Jeremy Rifkin
1660 L Street NW
Washington, DC 20036
Phone: 202-466-2823
Fax: 202-429-9602
Email: campaign@igc.apc.org

FRIENDS OF THE EARTH
Brent Blackwelder
1025 Vermont Av NW
Third Floor
Washington DC 20005-6303
Phone: 202-783-7400
Fax: 202-783-0444
Email: foe@foe.org

GENERAL BOARD OF CHURCH & SOCIETY OF THE UNITED METHODIST CHURCH
Jaydee Hansen
100 Maryland Avenue NE
Washington, DC 20002
Phone: 202-488-5650
Fax: 202-488-5639
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shanta_bryant.parti@ecunet.org

GREENPEACE-USA
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Fax: 202-462-4502
Email: greenpeace.usa@
wdc.greenpeace.org

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Email:
debra_harry@together.org

INDIAN LAW RESOURCE CENTER
Robert (Tim) Coulter
602 North Ewing Street
Helena, MT 59601
Phone: 406-449-2006
Fax: 406-449-2031
Email: ilrc@mt.net

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P.O. Box 485
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Fax: 218-751-0561
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On the Importance of Foundations Supporting Work on the Policy Issues Raised by Genetic Screening and Engineering

Dear Harriet,

In response to your question, I think that the policy issues raised by the discoveries of how to cut and splice DNA in the 1970s rank in significance with those that arose with the discovery of nuclear fission in the 1930s.

Some issues have turned out to be less serious than feared at first. These include the dangers of producing an "Andromeda strain" type disease or kudzu-type plant. In other cases, however, serious issues have begun to come into focus as commercial applications emerge.

In my view, the first set of serious issues that have come to maturity stem from the ability to screen human beings for genetic damage. Eventually this capability should be matched by new methods to cure cancer and other genetically influenced diseases. In the short term, however, the result has been the premature commercial promotion of often shoddy genetic screening tests and the acquisition by insurance companies and employers of genetic information which they sometimes use to reject "high-risk" applicants for medical insurance and jobs. One policy issue is therefore the protection of personal information—an issue which has gained urgency with the development of another technology, the Internet. Another related policy issue is the need to change our approach to medical insurance as it becomes increasingly possible to predict individual risks, and the idea of communities sharing individual risks is increasingly made obsolete by the competition for low-risk individuals.

In the longer term, the most significant issue may be the regulation of the genetic engineering of humans. We have already engineered domesticated animals and plants by selective breeding. (Witness the dachshund!) In-vitro fertilization and genetic engineering should soon make it possible to "improve" our children in ways far beyond the limited possibilities provided today by amniocentesis and selective abortion. We already see the

potential demand for such services in the tens of thousands of children who are receiving daily growth-hormone injections over periods of years—not because they are growth-hormone deficient but because their parents would like them to grow taller than they otherwise would. (Despite the cost of tens of thousands of dollars, this may be a good investment. Reportedly, Harvard male MBAs earn on average $10,000 more annually per inch of height.)

Sometimes I think that genetic engineering of humans could be the only hope for eradicating the savagery that manifests itself today in Bosnia, Zaire and in the increasing disregard within the "advanced" countries for the poor and disabled. However, leaving the decisions on how to apply these capabilities to the invisible hand of the market strikes me as similar to Russian roulette.

The silence of the leadership in the molecular-biology community on this subject is deafening. The lesson that they have apparently learned from the reaction to their call in 1974 for a temporary moratorium on certain types of potentially dangerous bacterial-gene splicing experiments is that the public will over-react if you raise a safety concern. I disagree with this conclusion. In fact, the reaction of the public to this first genetic scare was remarkably responsible. There were local hearings in towns and cities where universities proposed to build high-containment laboratories but these projects all ultimately received go-aheads. And the recombinant-DNA Advisory Committee which was set up by the NIH to review genetic experiments quickly de-regulated most types of experiments as it became clear that they posed little hazard.

I had hoped that the molecular biologists would learn from the experience of the nuclear physicists. A few have, but most have not. The U.S. Human Genome Project has set aside a few percent of its funds for research into the "ethical, legal and social implications" of the new technology. However, as one might expect, given the source of the funding, the research is quite "academic" and has done relatively little to inform the public policy debate.

So my answer to your question is: yes, please encourage your colleagues to fund high-quality research and activism in this important policy area, just as they do in the areas of environmental and nuclear-weapons policy.

With very best regards,

Frank von Hippel, Professor of Public and International Policy and
Chairman of the research arm of the Federation of American Scientists