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The commercialization of biotechnology: The politics

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University of Hawaii, 1989

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THE COMMERCIALIZATION OF BIOTECHNOLOGY: THE POLITICS

A DISSERTATION SUBMITTED TO THE GRADUATE DIVISION OF THE
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OF THE REQUIREMENTS FOR THE DEGREE OF

DOCTOR OF PHILOSOPHY

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ABSTRACT

The dissertation explores the commercialization of biotechnology by examining the different types of power used to exploit and control biological diversity and related genetic information. For example, the expansion of intellectual property law is essential to the private ownership of genetic resources. What results is a biotechnological hegemony that has parallels with military-industrial complex.

Review of the history and policy-making process raises two fundamental questions. First, how is it possible that the hegemonic process driving the development of biotechnology is able to depoliticize key political issues, and second, what is the role of ideology in the depoliticization process. The commercialization of biotechnology is shown to be linked to the ideology of high technologies.

Descriptive information informs the reader about six political issues: (1) sovereignty of seeds, (2) species extinction, (3) crop vulnerability, (4) deliberate release of bioinnovations into the environment, (5) gene exploitation and (6) the shift in the value of genetic resources. A common theme is the argument that depoliticization is successful in keeping important issues of financial, health and environmental risk from being
articulated, and these risks are expanded to the population at large and transferred from the private to the public sector.

The dissertation speaks to the political issue of mass species extinction and argues the need for a biologically-compatible imperative, which would help establish biological diversity as a common resource and as an component of society's collective memory.
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CHAPTER I

DISCUSSION OF THE DISSERTATION'S DESCRIPTIVE CONTENT,
ANALYTICAL AND THEORETICAL APPROACHES

The dissertation interprets the science, historical events, and the political framing that have resulted in further monopoly control of genetic resources during the basic research phase and early commercialization of biotechnology. Prior to the advances in molecular genetics, genetic resources were largely controlled by those with breeding infrastructures for plant, animals, and microorganisms. These infrastructures controlled the criteria for breeding programs and "field" tests. Advances in the precision of moving genes among organisms have changed the ways genetic improvements are undertaken and who controls the breeding goals.

What is meant by monopoly control? Monopoly control is used in a broader sense than the control of the biotechnology market, which is largely limited to a determination of supply and demand with respect to bio-commodity pricing. Monopoly control, in this case, implies the broad control of a biological technostructure that has been established by narrow private interests for the purpose of exploiting biological knowledge and diversity. The dissertation argues that this control involves not only monopolization
of genetic engineering tools, but also the exclusive con-
trol over, and in some cases the private ownership of, 
related resources, processes, practices, and policies. For 
instance, the Cohen-Boyer patents—which are broad biotech-
nology process patents involving plasmids—require 
licensees to pay Stanford University an annual fee of 
$10,000. Furthermore, the license is not exclusive and 
royalties (up to 50%) are owed from future bioproducts. I 
argue that what results is a biotechnological hegemony that 
has parallels to the political and economic hegemony of the 
military-industrial complex. The structural aggrandizement 
of the military-industrial complex involves a myriad of 
factors which include: secrecy of information, environment-
al risks, rapid growth, self-fulfilling strategies, global 
expansion, national security, and extensive government 
funding. These attributes are to be found in the emerging 
biotechnology industrial complex, which, in turn, is 
central to the establishment of a biotechnology hegemony. 

The dissertation examines the notion that political 
power is essential to the achievement of control. Political 
power is examined by exploring the power relationships 
among social agents, institutions, corporations, and govern-
ment agencies. In this specific case, hegemony is a system 
of control ("unity") of the competitive factions of interests 
centered on genetic resources. Those interests in control
have a preponderant influence over the exploitation of genetic resources.

Through an understanding of the formation of hegemonic power, it may be possible to construct a counter-hegemonic process that speaks to the dismantling of monopoly control. How is the argumentation constructed?

The descriptive material of the dissertation has been selected around specific political issues, such as, for example, the degree to which the United States should allow field testing of novel bioinnovations prior to basic scientific knowledge about the possible spread of genes in the environment. The political issue here is about who wins and loses should a biological accident occur. Through an understanding of political issues, such as these, it is then possible to speak from political theory about the underlying power relationships and the consequences of continuing along the path of greater private ownership of genetic resources. The dissertation, in part, through the formation of a scenario, attempts to project into the future.

The descriptive information informs the reader about six political issues. They are: sovereignty of seeds, species extinction, crop vulnerability, deliberate release of genetically engineered organisms, gene exploitation, and
the shift in value of genetic resources. Examination of these issues addresses two central questions.

The first question asks: How is it possible that the hegemonic process driving the development of biotechnology is able to depoliticize key political issues? The second question asks: What is the role of ideology in the depoliticization process?

The discussion of the role of ideology is centered on the notion that biotechnology is discussed in language that positions it within a broader ideology which is associated with the rationalization and justification of high technologies. This permits manipulation of the various agendas and infrastructures that guide basic biotechnology research, promote capitalization of gene-splicing firms, allow private ownership of germplasm and purchase of genetic engineers. This manipulation operates across the different levels defined by local, state, national, and international jurisdictions. Key to the process is the expansion of intellectual property laws. The patentability of lifeforms, the copyright of computer programs, and the worldwide standards for plant breeders' rights are all examples of the current broadening of intellectual property laws. Hence, redefining of the legal structures is one example of how it is possible to achieve greater control over private ownership of genetic resources.
A common theme unifying the political issues (the discursive chapters) is the expansion of risks to the population at large and the transferal of these risks from the private to the public sector. This theme not only helps to define the power relationships, but defines what is at stake.

For example, the deliberate release of bioinnovations in the environment, framed by the federal regulatory process, shifts the environmental risks from private companies to state and local municipalities. The dissertation argues that depolitization of the political issues surrounding biotechnology is fundamentally a problem of masking the environmental, health, and financial risks borne by the population at large.

Furthermore, the dissertation argues that monopoly control is powerful enough to succeed in narrowing the scope of public debate, manipulating public perception, and limiting scientific debate of important political issues surrounding the development and commercialization of biotechnology. Monopoly control is also responsible for greater exploitation of genetic resources.

The dissertation also speaks against the traditional approach of policy analysis that yields policy recommendations. The dissertation argues that such a traditional approach supports the status quo. For this reason, what
are called "alternative policies," within conventional policy frames, would work against a counter-hegemonic process oriented toward public preservation and equitable use of biological diversity.

It is the author's view that even if non-conventional policy alternatives existed to current biotechnology practices, it would be politically unwise to expose specific measures in a dissertation. The notion of "academic or political freedom" denies the existence of harsh political realities in the United States, wherein those who raise critical questions are often denied access to information, employment, and political power.

However, political philosophy is one dimension of a counter-hegemonic process that gives insight into ways that the consciousness of the social agent and the polis could change. The dissertation discusses the need for a biologically-compatible imperative, which would help establish philosophical and ethical groundings that would go beyond the limited view of genetic resources as commodities. It speaks to the consequences of mass species extinction. Such a positioning speaks to the possibility of a dialectic process that can overcome the many polarities and contradictions of capitalism. One contradiction of capitalism is to pursue systematic exploitation of genetic
resources to the point of resource depletion and destruction.

Furthermore, the dissertation speaks to the need to expose the risks in the exploitation of biodiversity, to infuse broader public and scientific debate about biotechnology, and to fight the expansion in intellectual property laws which in their proposed form would contribute to furthering biotechnical hegemony.

An understanding of the power relations, structures, and hierarchies that comprise monopoly control over genetic resources may permit a reinterpretation of the biotechnology story. The universality of the genetic code challenges the power of a reductionistic ideology that accepts worldwide ecological degradation. The reformulation of biological diversity as common resource—linking human beings to other living organisms within the biosphere—permits a vision of the future that incorporates a moral imperative to maintain biological diversity. Such a vision questions the legitimacy of the current hegemonic process that accepts the rapid expansion in genetic vulnerability of the world's major crops, that denies the links between germplasm ownership and national security, and the continual blurring of public-private boundaries. A counter-hegemonic process delegitimizes the power of monopoly control, questions the contradictions inherent in
profiteering, and begins a dialogue for national and international restructuring.
CHAPTER II
HOW THE POLICY PROCESS AND THE ROLE OF IDEOLOGY MASK IMPORTANT POLITICAL ISSUES FOR BIOTECHNOLOGY

This chapter will examine the premise that the policy process "masks" important political issues for biotechnology, and that through an understanding of this process, it may be possible to delegitimize ("unmask") the current commercialization of biotechnology. A key component of the masking process has been the fostering of a "high technology ideology" that works to depoliticize many of the central political and social issues of biotechnology.

The establishment of a high technology ideology has been accompanied by the formation of broad public policy myths concerning biotechnology. Over the past decade, the construction of publicly-believed myths has been essential to the marketing of biotechnology as a leading high technology.

Of the several myths presented to the general public central is the idea that high technologies result in high paying jobs and that individuals and state governments or municipalities will receive high rates of return on their investments. Such technologies are often presented as compatible with the environment and defended on grounds that issues of risk have been adequately debated by the
"experts." Less easily seen is the package of attributes which accompanies highly automated technologies, which includes the fact that skilled labor undergoes a classical division of labor; huge tax breaks are given to the technology companies; these technologies are polluting; environmental risks, should they occur, will be costly and, perhaps, irreversible; and finally, basic scientific knowledge about technology effects is lacking and experts disagree among themselves on key aspects of the technology.

Furthermore, government reports and the media not only support the hype to sell the notion of biotechnology as a high technology, but such efforts legitimize, without much public scrutiny, the expenditure of public funds to support research and development. As a result, for example, fundamental questions about environmental risk or the public's right of access to genetic information are difficult to raise within status quo policy forums. These policy forums are largely focused on issues of profitability and the development of economic and legal infrastructures which support the commercialization of biotechnology. As stated earlier, it is the premise of this chapter that the policy process masks important public policy issues, and an understanding of this masking phenomenon can help empower counter-hegemonic efforts. This chapter will explore the following phenomena.
The first phenomenon is the acceptance of a biological fix to improve and sustain production systems. The second is the notion of duality which excludes important political considerations in the process of creating conceptual dichotomies. Third, although public policy is believed to be strongly influenced by public opinion, it is often the case that policy shapes public opinion and thorough policy analysis is often stymied. Last, ideology as political quiescence is argued to play a major role in the masking process.

If an issue is defined narrowly as "just" a technical problem, then technical solutions will be sought and corresponding policies will not be broad enough to deal with many of the underlying political issues. Many of the "equity" issues will remain undefined and unchallenged. For instance, questions of equity for sharing in both the wealth and responsibility of genetic resource management are seen as technical problems, not political problems. As a result, resources are spent trying to discover new technologies for storing genetic material for longer periods of time, instead of being used to restructure the international system for the preservation and use of germplasm. For a further discussion see "Equalizing the Flow: Institutional Restructuring of Germplasm Exchange" by the author as published by Duke University Press in Seeds and Sovereignty,
In summation, the notion and acceptance of a biological fix to improve and sustain production systems, "masks" the institutional arrangements and the intrinsic power relationships which operate in this political arena.

The second major argument is based on the assertion that the status quo policy process masks important political issues by a phenomenon that creates broad conceptual dualities. These bifurcations separate critique, discussion and debate through the creation of polarities. Often only one of the "poles" is given consideration, while the other is ignored, or, perhaps, aspects of reality reflected in a conceptual continuum are discounted. Well-established dualities in political science include the following: economic versus political, public versus private and corporate versus individual. Such reductionism can lead to serious masking of important issues to such a degree that, over time, entire discourses are "forgotten." It is possible that the language of a particular discourse is "lost" to a majority of the population. At this stage of political atrophy the loss is de facto, and the masking is inherent in the structures of the status quo and is a consequence of political ideology.

Not only has the policy process in the United States led to the historical separation of the economic from the
political (Dolbeare and Dolbeare, 1971), but there has been a corresponding separation of policy processes into public and private. Often, analyses of U.S. policy making have been focused on the processes of government (descriptions of institutions and their functions), but they have failed to incorporate the way in which power is exercised within a framework of who wins and who loses (Froman, 1984:4-5).

Creel Froman's *The Two American Political Systems* (1984) is centered on the duality between corporate and individual political systems, which helps explain how a discussion about economic matters as democratic rights (e.g., one's right to accumulate wealth) can exclude the political questions and relationships of "persons" to property. Froman argues that with a separation of the economic from the political, politics then tends to describe what institutions are and how they function, without having to deal with the fundamental aspects of political power. He states:

One of the consequences of the democratic ideology is that economics and politics are rarely studied together. Politics is seen as a democratic process, as an independent force unconnected to any dominant content, let alone to property. (p. 194)

The dichotomization is an important aspect of capitalist ideology, and the underlying questions of who benefits and who loses from specific policies are then ignored.
For the sake of argument, the following question will be examined: "How does the regulatory responsibility of the federal, state, and local governments for the deliberate release of genetically engineered organisms affect further commercialization of biotechnology?"

It is clearly evident that accepting that this is the question to ask (from all the other possible questions) limits the potential discourse and masks many important questions about risk and the commercialization of biotechnology. The roles and responsibilities of the private sector are ignored by framing the question within "public" institutions. Furthermore, the semantics of the question imply that further commercialization is an agreed upon norm (public policy objective). What is at issue is how regulation is likely to speed up or slow down commercial developments?

Following this logic, systematic answering of the question may lead to recommendations on how to reorganize levels of responsibilities among the different levels of government to maximize commercialization. Whether levels of safety are sufficient, whether there is sufficient enforcement, or whether ethical or moral questions are overshadowed by economic questions are not easily discussed within the boundaries set by the question. In summation,
many issues are masked through the bounding of questions undertaken within the rubric of policy analysis.

Although public policy is believed to be strongly influenced by public opinion, it is often the case that policy shapes public opinion (Dye, 1984:320). Such shaping of public opinion is strongly linked to the overall process of legitimation and the formation of group interests.

For example, the Office of Technology Assessment's Background Paper #2 titled, New Developments in Biotechnology (May 1987), deals with public perceptions of biotechnology. The report details the results of a nationwide survey of public knowledge and opinion about issues concerning biotechnology, especially those related to the willingness of Americans to accept biohazards in return for benefits of scientific innovation. In the executive summary, the report claims that 62 percent of the public feels that the benefits of biotechnology outweigh the risks. However, closer examination of the survey questions reveals narrowness in the framing of the risk questions. For instance, those questions of public reaction to genetic engineering in one's own community were limited to those that have "no direct risk to humans and a very remote potential risk to the local environment."

Exploring problems of policy analysis further helps to better understand this element of masking phenomenon.
Lindblom, in The Policy-Making Process (1986) lists four areas that stymie thorough policy analysis. Lindblom argues that it is difficult to define the policy problem, to gather adequate information, to organize goals and values, and to overcome the resistance by individuals or institutions to policy analysis. These are substantial barriers to studying power relations, which are important to policy analysis. Direct access to communications is difficult and costly. Capitalist ideology determines what issues are important and that this ideology "takes certain beliefs out of the gunfire of criticism" or "throws up some argument to defend them." Lindblom states:

These beliefs, verification of which would require impossible feats of fact-gathering and analysis, can therefore be introduced into policy analysis as though they were settled fact. . . . If the ideology is far enough from fact, however, it can cripple policy analysis. It may generate agreed-on policies that nevertheless do not work—as, for example, our budget-balancing policies at the onset of the Great Depression of the thirties. Ideologically correct, they prolonged the Depression rather than shortened it. (p. 23)

Much of the data needed to study the corporate political system is kept hidden, for example, through trade secrets, and much of the data within governments is inaccessible. In addition, emphasis on policy implementation instead of policy formation can "limit" which policy issues gets analyzed.
THE ROLE OF IDEOLOGY IN THE MASKING PROCESS

It is important to link the notion of ideology to political quietism and hegemonic power. Ideology will be discussed as having the following two elements: theoretical representation and symbolic language. These elements function to serve as "ideal" types of political representation by individuals and groups. Such representations operate as "world views," whereby, beliefs, values and context of thinking limit political action and consciousness. Ideology, in this sense, plays a major role.

Insight into the notion of a "world view" will be explored through the writings of Edelman, Giddens, and Rifkin; insight into the notion of symbolic language will be explored through Edelman's thoughts on the use of symbols to achieve political "remoteness."

Jeremy Rifkin in Algeny (1983) sees how the current world view based on Darwinism masks important questions concerning genetic engineering. Rifkin states:

The new temporal theory of evolution replaces the idea of life as mere machinery with the idea of life as mere information. By resolving structure into function and reducing function to information flows, the new cosmology all but eliminates any remaining sense of species identification. Living things are no longer perceived as carrots and peas, foxes and hens, but as bundles of information . . . How can any living thing be deemed sacred when it is just a pattern of information? (p. 228)
Rifkin sees genetic engineering—the ability to control the blueprint of living things—as the "ultimate intellectual deception." In a rapidly advancing field such as biotechnology, questions raised before a breakthrough are deemed "purely hypothetical" and those after the fact "irrelevant."

Anthony Giddens in *Central Problems in Social Theory* (1979) expands the discussion of ideology by examining the interrelationship between ideology and domination. Giddens believes ideology can mask issues of domination.

For example, sectorial interests can be expressed as universal needs, social laws can be reified as natural laws (e.g., Social Darwinism) and communication can be manipulated to mask the asymmetrical distribution of resources. For Giddens, ideology involves "symbol-systems." The use of symbols and the manipulation of language can be used to create a pseudo-crisis as a means to frame the political agenda and exclude policy issues.

Murray Edelman in *The Symbolic Uses of Politics* (1967) adds a dimension by exploring political forms and symbols. Edelman identifies "the key function of remoteness" as a major influence upon symbolic meaning. Edelman concludes: "Unless an appropriate political setting has been created, legitimizing a set of values and a mode of access, a group interest cannot be expressed in policy no matter how strong
or widespread it may be" (p. 105). Political forms not only deliver power and services to certain groups, they also symbolize what people need to believe about the state. Such abstraction from reality, for Edelman, is one reason for political quiescence.

Symbols, especially condensation symbols such as the American flag, help create rituals which promote conformity and joy in conforming. Collective symbols become political forms, which in turn, come to "symbolize what large masses of men need to believe about the state to reassure themselves." Such shaping of class interests is strongly linked to the overall process of legitimation. In this sense, patriotism can be a strong force in binding interest groups together that is effective in keeping critical questions from being raised.

"SUCCESSFUL" UNMASKING OF IMPORTANT POLICY ISSUES

It is important to unmask technical language to reveal the ambiguities of its content. Many aspects of biotechnology are highly technical and interdisciplinary. For example, understanding the use of vectors to incorporate novel genes into a host requires knowledge about microorganisms, pathology, molecular genetic and cell biology. The need to reveal ambiguities may be true for legal language (Edelman, 1967), and for specialized scientific
language. Hence, it is important to "translate" or demystify terms and concepts to make knowledge available to the general public. Being able to explain scientific terminology in a way that is accessible to the general public should help unmask self-serving policies so that conflicts of interest can be raised as policy issues.

With respect to the commercialization of biotechnology, an ability to talk about the specifics of the technology to the general public will help develop a framework to understand the recent historical shift between the public and private roles for breeding, expose the fallacies of ideology driving U.S. agriculture, elucidate the expansion in intellectual property laws for monopolization of genetic resources, and show how the burden of proof is being shifted to the public sector through deregulation. Such efforts could unmask the hidden power relations that are being expanded through the commercialization of biotechnology.

Such successful unmasking, when it occurs, is linked to a shift in fundamental power relationships. The shift can come about through a dialectic process that involves a change in consciousness, a change in the laws that govern society, or through a restructuring of political power. Such changes involve a shift in who controls.
Giddens' notion of the dialectic of control, which he developed in *Nation-State and Violence* (1985), speaks to such a shifting in power relationships.

No matter how great the scope or intensity of control superordinates possess, since their power presumes the active compliance of others, those others can bring to bear strategies of their own, and apply specific types of sanctions. . . . All forms of rule have their "openings" that can be utilized by those in subordinate positions to influence the activities of those who hold power over them. One consequence of this is that technologies of power—in other words, formalized procedures of rule—rarely if ever work with the "fixity" which on the face of things they might seem to possess. The more a social system is one in which the control exercised by superordinates depends upon a considerable scope of power over subordinates, the more shifting and potentially volatile its organization is likely to be. (p. 10)

His notion of "dialectic of control" is similar to Hegel's "master-slave" relationship, where through a process of rejection and confirmation, there is achievement of self-autonomy through a shift in conceptual states ("passing over" through negation).

**CONCLUSION**

This chapter explores the interrelationship between the policy process and the masking of political issues. Such an understanding increases the potential to unmask important issues surrounding the commercialization of biotechnology. The separation of the policy process into a public-private dichotomy is an important factor in the
historical separation of economic from political issues. Such a separation keeps important questions of who benefits and who loses from being articulated. The policy process also shapes public opinion, coalesces interest groups, and drives the process of legitimation. Ideology plays a key role in the masking process.

The lack of information, the cost of obtaining information, and the resistance to political analysis are substantial barriers. The status quo policy process is linked to monopoly control of information and resources, which include modes of censorship and procedures of exclusion. The notions of ideology and social domination are intrinsically linked.

An important component of ideology is its symbolic dimension. Under capitalism, ideology is interwoven with the means of production. Ideology is reproduced. Ideological formations are successful in depoliticizing policy issues. However, there is a relationship between the process of masking and the opposite process of unmasking. The dialectic process is one avenue for successful unmasking.

The dialectic process can be used to raise one's level of consciousness. There is a shift in conceptual states through an interplay of inherent opposites. Through dialectic thought, the underlying contradictions and asymmetrical distributions of power and resources can be
exposed. In addition, technical language can be made unambiguous through demystification and renaming. Hidden relationships and agendas can be exposed.

The dialectic process, proper documentation, exposure of symbols, and demystification of language can be used to understand the masking phenomena and to unmask the pertinent issues for biotechnology. Such an unmasking allows for critique of economic structures that are driving the national and international commercialization of biotechnology at the expense of health and environmental safety.
CHAPTER III
THE SHIFT IN VALUE OF GENETIC RESOURCES AND THE
PHENOMENON OF MASS EXTINCTION

This chapter will explore the issues surrounding the shift in the value of genetic resources as a result of the commercialization and the related global phenomenon of mass species extinction. The reductionism inherent in monopoly control of genetic resources is partly responsible for the lack of an ethical imperative to preserve the world's biodiversity. The chapter supports the premise that biological diversity should be linked to a broad notion of collective memory.

THE DICHOTOMY SURROUNDING THE UTILITARIAN VALUE OF GENETIC RESOURCES

One of the central dichotomies surrounding the utilitarian value of genetic information is that genetic resources are "priceless" in their role to sustain and enhance production systems, but in their raw state, they are virtually without market value. Market value is largely captured through the "enhancement" process, which traditionally has shifted useful genetic information (genes) into commercial crops and livestock through breeding programs. This dichotomy in value has been maintained for
over a hundred years, and it has been the principal justification for collecting raw genetic resources as a "free" resource. This dichotomy highlights the principal structure that has allowed exploitation of genetic resources by economically developed countries which are wholly dependent upon them to sustain their agricultural systems.

The capitalist mode of production is able to gain monopoly control, because it determines when and where value is permitted. To a large extent, value is permitted at points where it can be captured through commodification. Value (as determined by price) is intrinsically linked to the control of genetic information. As breakthroughs in biotechnology speed up the process, the control of genetic information (including databases and genetic probes) is essential to the maintenance of hegemony over the production of such goods as new crops, pharmaceuticals and pesticides.

One way of approaching a more comprehensive valuation system is to reverse the following question: How do current structures and infrastructures give value to genetic resources? The question would then become: How do genetic resources give value to current structures and infrastructures?

Partial answers can be found in the linkages that are formed between specific genetic traits and commodities.
Genetic information is incorporated into the value of the commodity itself. Such a narrow instrumental formulation of value is central to monoploy control of genetic resources. As value is linked to a specific commodity, the intrinsic and future values of genetic information are largely nullified.

Such valuation also leads to infrastructures—such as production systems based on hybrids—which override the self-replicating nature of traditional varieties. As a result, farmers cannot save their own seed, but must purchase it. Therefore, any genetic improvements made to the variety must also be purchased every growing season.

It took less than five years for biotechnology to shift from a basic research phase to one of rapid commercialization. Recent breakthroughs, such as the construction of artificial chromosomes, allow the transfer of larger quantities of genes (in comparison to the use of plasmids and viruses as vectors) between diverse organisms. Such tools of the trade bypass the previously known breeding barriers. Now, in theory, the genes from any species can be inserted and expressed in another. The wealth of the world’s biota becomes a single gene pool for exploitation. The barriers to those involved in genetic engineering are now in indentifying desired traits.
One could draw a simple analogy to a library with millions of volumes randomly shelved in closed stacks without any indexing to a catalogue system. These books would not be of much value until a catalogue could be established to locate desired volumes. This situation parallels the current level of knowledge about biological diversity: the location of the chromosome and the gene sequence are not known from most proteins. The ability to use biological diversity and its value is intimately linked to indexing-type considerations. However, with the advancements in genetic probes (restriction fragment polymorphisms), gene synthesizers and communication technologies—for the first time—a gene catalogue for the human genome and other selected organisms is moving closer to reality. This breakthrough in knowledge will affect tremendously the value of genetic resources and related information. A major shift in value will also profoundly affect the continuum between public and private ownership of biological diversity. As the "raw" resources take on greater value, because of increasing ease to integrate desired traits into production systems, biological diversity is likely to become a commodity for private ownership and exploitation.

As will be discussed in more detail with an analysis of intellectual property laws, genetic information can be
argued to be a common resource that should be managed collectively as public information. Such a reconceptualization would shift the infrastructures toward broader, more egalitarian valuation approaches. The creation of public evaluation/descriptor databases (including genetic probes) would begin to break some of the monopoly control over genetic information.

One of the likely contradictions of capitalism is that in the rush to privately own and control the information surrounding the commercialization of biotechnology, insufficient resources will be given to protect the wealth of biological diversity that is rapidly diminishing.

Estimates on the current loss of biological diversity are based primarily on the probable loss of forests in the tropics and through an interpretation of fossil records. Even though the predictive power of these forecasting tools is limited (due to the difficulty in establishing a net extinction rate), ecologists estimate that between 3 to 257 species will be lost per day by the year 2000. If the worse case predictions turn out to be correct, then the loss of thousands of species per year could be catastrophic to the biosphere.

This mass extinction--likely to take place over the next few decades--shall occur rapidly and probably prior to the gathering of data to verify its occurrence. As a
comparison, geological evidence suggests that earlier periods of mass species extinction happened over thousands or even millions of years. Hence, should the underlying assumptions prove correct the timetable for resolution is extremely limited. Still, arguments are presented to dispute the sense of urgency.

Scientific evidence suggests that 99 percent of all species that ever existed are now extinct. This evidence is used to argue that extinction is necessary and part of a "rebalancing of nature" (cosmic ontological theory). Others argue that mass extinction is divine punishment for the fallibility of humankind (apocalypse theory). Conservative economists, Simon and Wildavasky (1984) claim that the estimates of some 40,000 species lost per year by the year 2000 are nothing but exaggerations. They conclude that the loss of biological diversity is not a priority to which resources should be allocated, and that the task to evaluate genetic resources "approaches, or surpasses, the limits of any existing human knowledge." Without good time-series data on tropical forest lost with evidence to directly linking this deforestation with extinction, Simon and Wildavasky stick to their criticisms. Nonetheless, ecologists and biologists, such as, Myers, the Ehrlichs, Gould, Lovejoy, Simberloff, Morain, Prance, and Raven would disagree.
Ecologists and biologists have been struck by the rapid deforestation that is taking place in Latin America, Africa, and Asia. This deforestation, in their opinion, is linked to an increased population's efforts to meet their basic needs such as need for basic firewood for cooking or land for subsistence farming. Estimates suggest that some 25 percent of all species are found in the Amazon and in the tropical forests of Africa and Asia. Insects and plants are expected to have the largest number of extinctions. Most of these are likely to go extinct prior to their ever having been identified by field scientists. What makes these projections worrisome is the close dependency among species. For example, Myers (1984:172) contends that "when one plant species disappears, it is likely to take with it between 10 and 30 associated animal species that depend on it." Ecologists also argue that an event leading to an extinction is quite independent of the organism's previous history. Furthermore, although the ecology of tropical forests is extremely complex, these specialized ecosystems are vulnerable to disruptions. Finally, at what point the loss of biological diversity will result in the irreparable degradation of the biosphere is unknown.

Various scientists and social scientists are calling for an ethical responsibility for survival based on a broad
notion of ecological homeostasis. Fritjof Capra in, *The Turning Point* (1982), calls for a change in perception that breaks the stranglehold of anthropomorphism. His new sense of vision includes:

The new vision of reality is an ecological vision in a sense which goes far beyond the immediate concerns with environmental protection. To emphasize this deeper meaning of ecology, philosophers and scientists have begun to make the distinction between "deep ecology" and "shallow environmentalism." Whereas shallow environmentalism is concerned with more efficient control and management of the natural environment for the benefit of "man," the deep ecology movement recognizes that ecological balance will require profound changes in our perception of the role of human beings in the planetary ecosystem. In short, it will require a new philosophical and religious base. (p. 411)

Yet, it is likely that any new vision will need to incorporate an understanding of the mass extinction process. A "race against the biological clock" is one component of the ethical responsibility; one dimension is time and another is magnitude. Vision, with responsibility, is continuity with the future. Perhaps one element of the catastrophe is the difficulty for the human mind to comprehend the occurrence of mass death, even the mass extermination of humans that has taken place, for example, in the death camps of the Holocaust.

Edith Wyschogrod in, *Spirit in Ashes: Hegel, Heidegger, and Man-Made Mass Death*, (1985) explores the notion of a mythical structure that reveals a lack of
coherence in the logic of mass death. She writes:

... the death event reflects efforts to restore wholeness to a fragmented spiritual and material cosmos by remythologizing the broken totality. Like genuine cosmogonic myths, these myths of negation try to order and systematize relations and connections by articulating the particulars to be annihilated. Thus it should come as no surprise that a peculiar pattern of logical relations inheres in the death event. But this structure cannot impose coherence upon that which inherently cannot be thought, namely nonbeing. Thus the logic of the death event must be one of paradox. (p. 35-36)

Interestingly, Wyschogrod sets the historical articulation of the paradox with the pre-Socratic philosopher, Zeno of Elea. The paradox reflects a relationship between infinity and finity. Zeno's assertion that there is infinite divisibility (an infinite subdivision between any two parts) presupposes an infinite "supply of parts." Wyschogrod argues that this structure of thought is unconsciously applied to human societies, even to the extreme conclusion that there is an infinite supply of humans. Perhaps, unconsciously, there is a corresponding tendency to see an infinite supply of species in the diverse flora and fauna of the world, such that the elimination of thousands of species is non-problematic. How is this possible? What are the scope, temporality and definition of Wyschogrod's concept of the death-world?

Central to her discussion is the notion of the authenticity paradigm for death. Death can be linked in a
necessary relationship to the process of life itself, or it can be alienated from it. The death of Socrates is used as an example, but the conceptual shift from the past to the current situation of mass death is expressed in the quotes below.

Before mass death cast its shadow over contemporary existence, the most significant meaning structure which governs individual dying and attains consensus in Western culture is the assumption that a good death, even if not free of pain, is the measure of a good life. (p. 2)

Dying acceptably is only possible if death has become an ingredient in life itself long before life is extinguished. Life in turn can be lived with integrity only if death is already accepted as inseparable from it. (p. 2)

The incongruities and paradoxes generated by the phenomenon of contemporary extermination challenge our understanding of finitude as set forth in the authenticity paradigm (p. 14)

Hence, the mass death event destroys the meaning of death in Western culture by polarizing the thought structures for life and death. Reinterpretation of mass death negates this sense of opposition. Language is needed that allows the extinction process to be problematized.

The "deathworld" that Wychogrod is talking about makes it difficult to problematize mass extinction because meaning structures are destroyed. This negation of meaning, the telos of the deathworld, renders mass extinction possible. In part, interpretation of the future becomes more difficult, and the qualitative loss that results
from the extinction of diverse species is in itself a
blinding paradox: simple reductionism allows a lack of
continuity in the memory system of humankind. The loss of
the Other (diverse biota) is seen as expendable. The
language of technique allows a loss of meaning through the
transformation of quality into quantity. The difference
between quality and utility is also lost. Wyschogrod makes
the link between technological society and the instruments
of death.

It is not difficult to see the difference between the
pregiven horizon of utility and meaning on the one
hand and the world of science as a manifold of mathe­
matized constructs together with the sociocultural
institutions which borrow their criteria from it on
the other. But what of the deathworld? It is far
less easy to see the difference between technological
society and the deathworld--for without the spiritual
and material apparatus of technological society, how
would the deathworld have come into being? The pro­
cedures and instruments of death which depend upon
the quantification of the qualified world are innova­
tions deriving from technological society and, to
that extent, extend its point of view. (p. 25)

One aspect of the power of genetic engineering is the
ability to reduce the quality of an entire living organism
to quantifiable sequences of genes that express specific
proteins. Once these sequences are cut from the genome
with enzymes, they are then separated and treated as
commodities that have an infinite potential for recombi­

tation. This procedure "rejects the unity of being." This
rejection shifts structures of meaning through alterations in the historical experience of humankind.

These shifts in epistemology—one's understanding of nature and grounds of knowledge—alter the concept of time horizons and fundamental spatial relationships. In this sense the mass extinction of species cannot be separated from the biotechnologies that are transforming the meaning of a species. The relationship between extinction and advances in molecular genetics is being established primarily through the narrow criteria of utilitarian value: useful genes and non-useful genes. Genetic engineering, coupled with mass extinction of species, is an acceleration of evolution that appears to be in the control of humanity. Accepting the challenge of managing evolution requires a tremendous leap in knowledge and understanding of many natures: human nature, ecosystem complexities and the telos of life. This epistemological shift was expressed by Jeremy Rifkin in *Algeny* (1983). Rifkin questions the reduction of life to mere information.

For the algenist, species boundaries are just convenient labels for identifying a familiar biological condition or relationship, but are in no way regarded as impenetrable walls separating various plants and animals . . . all living things are reducible to a base biological material, DNA, which can be extracted, manipulated, organized, combined, and programmed into an infinite number of combinations by a series of elaborate laboratory procedures. (p. 15)
How are the changes in the way we think as a result of the advancements in genetic modification related to the mass extinction process?

The technological advancements, for example, the ability to move genes between any two species, cause a fundamental shift in the signification of meaning through a further distancing of humankind from other lifeforms. The utilitarian value of the genetic code introduces a state of separation that causes further polarization. Through the bifurcation between oneself and other species, humankind loses sight of the vast intricate relationships among species. For this reason, the current period of mass extinction is largely invisible, and when seen, in part, is accepted as a "natural" process of readjustment of the biosphere. In other words, the rapid expansion in technologies that exploit the genetic code are intrinsically linked to the masking and acceptance of the mass extinction process. As a result, much of the institutional response to slow the onslaught is symbolic and misdirected.

For example, the U.S. government spends less than $20 million annually to run the National Germplasm System. This level of funding is grossly inadequate and emphasis is given almost entirely to domestic crops.

Collective memory, that which is defined through language, culture, theory, philosophy, and so forth, is the
engine that drives the meaning of relationships. Collective memory shapes one's understanding of the universal. One avenue to comprehend the extinction process is a better understanding of the deathworld, which has been expanded to include the mass extinction of species. Understanding the contradictions inherent in the coming about of the deathworld allows for a negation of a process that is in itself a negation of life. Continuity might be restored in the collective memory that allows for political imperatives.

This is not to argue that all species should be saved from extinction, yet there needs to be a realization of what is being lost--the magnitude of loss of relationships and knowledge--through mass species extinction.

CONCLUSION

There is a need to reconceptualize the problem that "drives" the development and use of this powerful technology. The ability to cross species breeding barriers, raises ethical and metaphysical questions. A broader ethical and philosophical understanding might break the stranglehold of monopoly capital, which defines issues of political control, environmental uncertainties, and cultural risks within a narrow framework of private ownership. At issue, too, is the demand that basic
research into biotechnology be intelligently regulated and applied. The power of the technology, if understood, calls for an ethics of responsibility that speaks to the vulnerabilities of knowledge and fragilities of the biological world. What is the context in which the vulnerabilities could be seen?

On the one hand, the technological breakthroughs greatly speed up aspects of the evolutionary process, because there are no longer firm notions of "breeding barriers" and "species uniqueness." Genes from any species may be exchanged. The current limit is governed not by taxonomic differences, but by the number of genes which can be transported into a host cell by its vector, and by the number of genes that can be "controlled" once introduced (factors of genetic stability and expression). There is no certainty about what impact the cumulative use of genetic engineering will have on the evolutionary process.

Metaphysically, the technological breakthroughs speak to a notion of interconnectiveness: one's relationship with other species and the environment. More importantly, the breakthroughs disrupt one's self-conception, because the distinction between humans and other organisms is less clear with the exchange of genes among species. Now that the human genes for insulin have been transformed and expressed into bacteria, there is less distance between the
two species: there is less certainty about what it means to be human.

The technological breakthroughs also speak about greater vulnerability, responsibility for the direction of evolution, and for the maintenance of ecological stability. The vulnerabilities are threefold. First, the use of bioinnovations are likely to increase the dependence on elite production-types, thereby increasing crop vulnerability. Second, the expansion in power over the genetic makeup of species may increase one's sense of self-vulnerability. Coming to terms with this sense of self-vulnerability should be part of the political responsibility that is less anthropomorphic and homocentric.

The third vulnerability/responsibility issue speaks to the need for the perpetuation of ecological stability. There is not only a need to maintain biological diversity as a critical component of ecological stability, but there is also a need to recognize the possibility that ecological stability may "unravel" with an exponential acceleration. In other words, a mass extinction of species may result in a rapid acceleration of a loss in ecological stability. Although it is impossible to predict an exact timing and location for such an ecological disaster to occur, enough is known about the biological interrelativeness of species
to suggest that the timetable for decision making may be short in comparison to other eras of extinction. It is also possible to suggest, that until a certain point in time, humankind has opportunities for stopping the processes that are leading to biological degradation. Not acting is a decision that will hasten the extinction process that has already begun. Action will, however, require dealing with issues of power.

Hans Jonas in the *The Imperative of Responsibility* (1985), implores the reader to rethink his or her ethical responsibility toward a global future. Jonas establishes a cause-and-effect relationship between the change in nature of human action and the nature of politics. He calls for a new theory of responsibility that includes an expansion of power, which is accompanied by a contraction of "man's image" (one's self-conception and being). It is a fundamental question of legitimate power over illegitimate power. The question of which force to use and how much is, for Jonas, a question of political philosophy. Jonas states:

This raises to an ultimate pitch the old question of power of the wise, or the force of ideas not allied to self-interest, in the body politic. What force shall represent the future in the present? ... That is: before the question of what force comes the question of what insight or value-knowledge will represent the future in the present. (Emphasized in original test on p. 22)
Questions of vulnerability and magnitude of irreversibility delineate Jonas' notion of what needs to be avoided at all costs. His philosophical outlook unfolds as he speaks metaphorically about a knowledge "looking glass" that gives insight into that which threatens and that which should be preserved.

... it is an anticipated distortion of man that helps us to detect that in the normative conception of man which is to be preserved from it. And we need the threat to the image of man--and rather specific kinds of threats--to assure ourselves of this true image by the very recoil from these threats. As long as the danger is unknown, we do not know what to preserve and why. Knowledge of this comes, against all logic and method, from the perception of what to avoid ... We know the thing at stake only when we know that it is at stake. (Emphasized in original text, on pp. 26-27.)

Not only does Jonas feel that technology has destroyed our normative foundation, but that modern technology has destroyed our concept of species. Power over power would help develop a Role of Stewardship based on new ethics that would give nature rights. The duties of an ethic of the future would require visualizing the long-range effects of the biotechnological enterprise that would incorporate an obligation to posterity that would defeat "purposelessness." The need to preserve genetic diversity is stressed by Francois Jocob in The Possible and the Actual (1982). He states:
Diversity is one of the great rules in the biological game. All along generations, the genes that constitute the inheritance of the species unite and dissociate to produce those ever fleeting and ever different combinations: the individuals. And this endless combinatorial system which generates diversity and makes each of us unique cannot be overestimated. It gives the species all its wealth, all its versatility, all its possibilities. Diversity is a way of coping with the possible. It acts as a kind of insurance for the future. (p. 66)

Both Jonas and Jacob might extend their reasoning to make a metaphysical argument for the imperative that a species diverse world ought to exist. The idea of humanness has coevolved with the presence of diverse flora and fauna.

One such dimension involves the expansion of society's collective memory to include genetic memory. Genetic memory would include knowledge about important relationships, such as coevolutinary factors. Regardless of whether or not there are etiological forces driving the larger evolutionary process, stored genetic information can be viewed as a powerhouse, not only for evolutionary change, but also as a resource to buffer global uncertainties.

An expansion of collective memory to include genetic memory may also allow for new dimensions to replace the current paradigm surrounding species uniqueness. The notion that species are genetically unique is being dismantled by the crossing of species barriers with powerful gene-modifying technologies. Linking genetic
information to a larger social memory may help shape a social imperative that spurs proactive policies.

Expansion of philosophically- or metaphysically-based imperatives, may allow for the reconciliation of tensions inherent in the struggle over the ownership and reproduction of genetic resources. Such positioning could help break current structures of domination and exploitation of genetic resources. Development of genetic memory as a dimension of our collective memory could lead to a dialectic process that can overcome, or at least expose, inherent contradictions in the production and reproduction of genetic knowledge.
CHAPTER IV
THE HISTORY, SCIENCE AND POLITICS OF THE PROBLEM

HISTORY OF THE PROBLEM

The commercialization of the new genetic technologies—for example, genetic engineering, protoplast fusion, microinjection of DNA, and monoclonal antibodies—has taken place almost entirely over the last twenty years. The Boyer-Cohen patent for the basic genetic engineering process (using a plasmid to insert recombined DNA) was awarded in December 1980. Since that time, several hundred U.S. companies have either formed or shifted funding toward the exploitation of biological diversity and bio-techniques which move desired genes into microorganisms, plants, and animals. Since 1983, the U.S. patent office has received nearly 24,000 biotechnology patent applications. The new bioproducts include bacterial-produced human hormones, bacterial pesticides for agriculture, new vaccines, diagnostic agents, and cancer drugs. The door for legal patenting of bioproducts, in addition to bioprocesses, opened in the 1980 Diamond vs. Chakrabarty decision by the Supreme Court, which allowed for an expansion of intellectual property laws into the arena of biological innovations.
This rapid commercialization is built on earlier scientific breakthroughs in this century, which include, for example, Jacques Monod and François Jacob's work on the functioning and dimensionality of proteins, Linus Pauling's work on crystal structures (alpha helix), and James Watson and Francis Crick's breaking of the genetic code with their model of the double helix (1953). In the early 1960's, scientists learned how genes are moved from one bacterium to another. By the late 1970's, further research with bacteria yielded the isolation of many different restriction enzymes. Through the use of such enzymes, specific genes are "cut and joined" during genetic modifications. By the early 1980's, molecular scientists were introducing novel genetic material into the cells of higher plants and animals.

Institutionally, the Rockefeller Foundation, the National Science Foundation, and the National Institutes of Health have been instrumental, through their funding of medical and biological research, in transforming the basic sciences of biochemistry and molecular biology into a $1 billion per year industry (Kenney, 1986). Instrumental to the commercialization has been the regulatory debate over the basic research and the release of genetically engineered organisms into the environment. This is so, because many of the basic research agenda have determined
the breakthroughs for medicine, e.g., diagnostic probes and non-medical bioproducts have been agriculturally-based.

The birth of the recombinant DNA debate came with the 1973 Gordon Conference on Nucleic Acids (Krimsky, 1982:13). The conference raised concerns over the possible harm that could come from novel hybridizations. One focus of debate was Paul Berg's proposed SV4-lambda phage experiment, which raised concern about the possibility of introducing a monkey cancer-causing virus into the human population. Biohazards conferences in 1973 and 1975 at the Asilomar Conference Center in Pacific Grove, California, expanded the scientific debate over the safety of this new powerful technology. The debate culminated in a scientist-imposed voluntary moratorium, which later became the National Institutes of Health (NIH) Guidelines; the Guidelines were promulgated in 1976. The Guidelines were slowly reduced, over the next eight years, amid some controversy and continued debate. As will be discussed later, the NIH Guidelines were conceptually and historically linked to the formulation of the Coordinated Framework (1986), which serves as the regulatory vehicle for the deliberate release of genetically modified organisms. These were the two essential documents around which the national debate over risk and the control of biotechnology revolved. The underlying risks and debate over ownership of this powerful and
profitable technology were central to the interest group formations.

The discussion of interest group formation is fundamental to an understanding of the history and the politics of biotechnology. Clearly, the most visible group is the scientists who have become biotech entrepreneurs. Not only is the issue of control over the research agenda important, but also the structural conditions that will promote commercialization. Favorable structural conditions include minimal regulatory hindrances of basic research and field testing, grant support, and policies to protect intellectual property and patents within internationally competitive markets. The positioning of the university-based interest group has been most visible at the interface between universities and private biotechnology companies in the dichotomy between their researchers' roles as faculty members and as partners in a biotechnology company. The rapid commercialization of biotechnology has created new structural elements to the traditional relationship between industry and university. The relationship is characterized by the proximity of biotechnology centers to universities that have strong molecular genetics programs.

In addition, universities such as Stanford have launched licensing and patenting offices to capitalize on bioinnovations developed within their laboratories. With
such approaches have come lucrative incentives and salaries for faculty working with biotechnologies, as well as a juggling of for-profit and nonprofit centers. At this structural level it is hard to differentiate private biotechnology companies from quasi-public university ventures. As will be discussed later, the shift between the public and the private sectors for plant breeding has also been blurred. The biotechnology industry has become formalized in its own right as an interest group through newsletters, such as "Genetic Engineering News," and Washington D.C.-based lobby groups. Lobbying efforts have been effective in controlling important aspects of public policy formulation and debate.

The visible areas of lobbying effectiveness have been the reduction of NIH Guidelines and the lack of clear Congressional legislation to regulate the biotechnology industry. The biotech industry has always argued that it can be self-regulating, and that needed "regulation" can be achieved through administrative rules and regulations. This balance is extremely subtle, and it is effective in its ability to focus attention at the national level to such a degree that statewide attention, laws, and regulations have been minimal for basic research and even less so for issues surrounding the deliberate release of genetically engineered organisms. Individuals within such
prestigious federal government offices such as the National Science Foundation, the Office of Science and Technology Policy, and the Office of Technology Assessment have been responsible for orchestrating much of the so-called scientific debate surrounding the political issues.

To be specific, the Office of Technology Assessment has pushed, since 1984, the need to speed up U.S. commercialization of biotechnology to defend its "leading technological edge." Manipulation of public policy was most noticeable in a 1987 background paper titled, "New Developments in Biotechnology: Public Perceptions of Biotechnology."

In another specific case, Dr. Kingsbury of the National Science Foundation at a 1985 joint OTA/NSF workshop on deliberate release attempted to orchestrate, with the help of future grant money, a "generic" concept of review of deliberate release proposals that would permit major exemptions and reduced levels of environmental review. Scientists have been adamant that deliberate releases should continue to be reviewed on a case by case basis. It is interesting to note that Dr. Kingsbury was investigated for conflict of interest as a proxy voting board member of a biotechnology company.

The personal stakes are high, and the potential for huge profits is a strong motivating factor. As will be
discussed later, such structural arrangements, which incorporate strong ideological stances, have been one factor that has kept important questions of risk undiscussed.

An important aspect of the biotechnology story has been the debate over environmental risks. The debate over the guidelines for basic research and later over the framework for review of deliberate release bioinnovations has fostered some environmental interest group formation.

A number of prominent scientists such as Ethan Singer and Jonathan King from MIT have helped foster a broader public debate. Roy Curtis, with a background in bacteriology, was outspoken about the limitations of the NIH Guidelines and the performance of the NIH Recombinant DNA Committee (better known as the RAC), of which he was a member. Jeremy Rifkin, a well known critic of genetic engineering, has raised both environmental and philosophical questions. Dr. Richard Lewontin from Harvard has been outspoken about the monopoly control of genetic resources and breeding approaches based on hybrids. Sheldon Krimsky from Tufts has been outspoken about the lack of clear public input into the key policy issues (Krimsky, 1982).

As Krimsky documented in Genetic Alchemy (1982), the public input came, for the most part, after the decisions
had been made by a small group of leading scientists. The extent, nature, and timing of public input have always been in question. The issue, other than assurance that the development of biotechnology should be done safely, was to assure that the general public not control or regulate basic scientific research for recombinant DNA. Issues of "burden of proof" and "public interest" became the windows for organized critique by public groups. The major avenue of "acceptable" public involvement was peer review committees that were formalized into Institutional Biohazard Committees, which were later renamed to Institutional Biosafety Committees (IBCs). Even the change in names of the peer committees suggests limits to public involvement. Still, several public interventions were successful in "rocking the biotechnology boat."

Although the first debate over recombinant DNA research goes back to 1974 at the University of Michigan, the best-known example was the debate in Cambridge, Massachusetts, which lasted a number of years and involved the university communities of Harvard and MIT; most debates took place at Cambridge City Council hearings. Cambridge's mayor at the time, Alfred Vellucci, encouraged a broad forum on the issues, which led to the formation of the Cambridge Experimental Review Board (CERB).
The CERB held more than 100 hours of hearings and meetings. The debate, during the summer of 1976, received worldwide press coverage. At issue was the building of P3-level containment laboratories and the acceptance of the newly generated NIH Guidelines. Although the Cambridge City Council voted a moratorium on recombinant DNA research, and the debate did influence other cities and states to pass legislation, the focus shifted from local ordinances to national legislation (Krimsky, 1982).

More recent examples of local debate came with the proposed field testing of the "ice-minus" strain in California. In November 1985, the Environmental Protection Agency (EPA) had given first approval for field testing to Advanced Genetic Sciences (AGS), Inc., by granting an experimental use permit for a genetically modified strain of *Pseudomonas* (OTA, 1988). The bioinnovation known as "Frostban" (deletion of the ice-nucleation protein gene) could potentially reduce frost damage on strawberry plants, but it might also interfere with rainfall. Being the first field test of the new biotechnologies, it received national coverage.

Debate centered, in early 1986, at the Monterey County Board of Supervisors' hearings, at which time an ordinance was passed banning experiments in Monterey County for 45 days. The field test was never conducted in Salinas.
Valley, in part due to AGS' unauthorized release of the test bacteria on the rooftop of its main building, which resulted in the suspension of its permit and a reduced fine of $13,000. The EPA permit was reissued, and the field test was carried out in Contra Costa County outside of the small town of Brentwood on April 24, 1987. It should be noted that Judge John Sirica issued an injunction against the field testing of another genetically altered Pseudomonas strain in 1984 that had been planned to be tested in Tulelake, California. It took three years to overcome the local opposition, and, coincidentally, that test by the University of California took place only three days later on April 27, 1987. OTA concluded their review of these cases in the quote below:

The Tulelake scenario is similar to that of Monterey County. Both experiments involved proposed releases of P. syringae, both followed similar regulatory approval processes, and both were linked together in many media stories. While both experiments elicited opposition in their respective communities, in Tulelake it focused to a significant degree on a fear that locally grown crops would be boycotted by buyers, damaging the local economy. Although opponents of the Monterey County and Tulelake field tests went to county authorities to stop the experiments, opponents of the Tulelake field test also relied on State environmental law as the basis for their suit in Sacramento County Superior Court. In both instances, experimental plants were vandalized. (p. 52)

A number of conclusions can be reached about public participation in the debate over the risks of recombinant
DNA research and the deliberate release of genetically engineered bioinnovations.

The level of public participation at the local, state, and national levels has been modest. It was successful in troubling both scientists and entrepreneurs about the possibility of local regulation of biotechnology activities. Kenney, (1986) concluded from analysis of the events of the Cambridge City Council over genetic engineering research that:

The lack of national legal uniformity implied that researchers at some universities would have a comparative advantage over others, that is, strict regulations would be more costly to comply with and might slow down research progress--an important consideration in the bitter competition for grants. (p. 25)

Although the public debates in university towns such as Cambridge or Ann Arbor may have succeeded in forcing federal agencies to take more oversight responsibility, it neither coalesced long-term debate around the lingering environmental questions nor around the deficiencies of the NIH Guidelines or the Coordinated Framework. In fact, proponents of rapid biotechnology commercialization were successful in using the "fear of local regulation" to defend the need for the NIH Guidelines, which was then used as a justification to stifle proposed Congressional legislation to mandate safety procedures for both public and private companies. Debate in Congress, in 1977, over
Senator Kennedy's bill (S1217), saw intense lobbying by both scientists and university administrators to kill the bill and to keep private industry adherence to the Guidelines voluntary.

The lack of sustained debate over the risks and the direction of basic and applied research are fundamental to an understanding of the politics of the problem. But the debate over risk has been largely defined by questions about whether enough is known about the underlying science to assure adequate control. It is interesting to note that much of the excitement of biotechnology arose out of a belief that the technology could accelerate the United States toward an economy based on "renewable" resources. Not only would organisms provide the needed information, but they would often become the industrial "powerhouses" that would produce the desired bioproduct such as interferon, human insulin, and plant pesticides. Such a position of environmental compatibility helps to diffuse other issues of environmental risk.

The rapid commercialization of biotechnology greatly renewed interest of the industrial societies in the control of genetic resources. Hence, the second major historical dimension of the dissertation involves the exploitation of the genetic resources themselves.
The world's biotic diversity "houses" tremendous amounts of information within its cells. If compared to a library, the human genome would contain some 3,000 volumes of 1,000 pages each, with each page representing one gene specified by 1,000 letters (OTA, 1984:33). Many of the thousands of genes in a living organism produce highly specific proteins that can be of immense commercial value once they have been identified. Genetically modified organisms can be used, for example, in bioprocesses in the production of such metabolites or cell components as lactic acid, or enzymes. Biotechnologies can be applied to fermentation technologies, and the pharmaceutical, chemical, agricultural, and food processing industries.

The expansion in the ability to use genes from diverse species is a radical change from the limitations of traditional or mutation breeding. In addition, some steps of the breeding process can be greatly enhanced, thereby reducing the timetable for gene integration and selection. But what has been the history of genetic resource accumulation and control?

Lucile Brockway in, Science and Colonial Expansion: The Role of the British Royal Botanic Gardens (1979), explored the degree of genetic accumulation and dependency during the colonialism of the nineteenth century. In particular, she examined the role of Kew Gardens in England
and the colonial botanic gardens in transferring plant germplasm, which became the cornerstone of plantation crops such as rubber, cinchona, and sisal. She concluded (from Kloppenburg, 1988):

I further suggest that the Royal Botanic Gardens at Kew, directed and staffed by eminent figures in the British scientific establishment, served as a control center which regulated the flow of botanical information from the metropolis to the colonial satellites and disseminated information emanating from them. Much of this botanical information was of great commercial importance, especially in regard to the tropical plantation crops, one of the main sources of wealth of the empire. Decisions taken at Kew Gardens or implemented with the help of Kew Gardens had farreaching effects on colonial expansion: if the botanists could suggest where to find a plant that would fill a current demand; how to improve this plant through species selection, hybridization, and new methods of cultivation; where to cultivate this plant with cheap colonial labor; and how to process this product for the world market; then botanists may be said to have had a major role in making a colony a viable and profitable part of the empire. (p. 50)

Nineteenth-century European colonial expansion was characterized by both competition and cooperation among the powers. The Dutch from their botanic garden on java engaged in parallel activities of plant transfer and development . . . The French copied British and Dutch plantations methods in their rubber industry in Indochina . . . Europe was achieving global dominance, extracting and mobilizing the energy of the world for its own purposes. (p. 51)

Brockway establishes that the transfer of plant germplasm was vital to western hegemony in the nineteenth and twentieth centuries. The importance of plant germplasm was to be witnessed again in this century as the expansion of
monocultured crops through high yielding varieties (HYVs) required specific genetic breeding breakthroughs and the constant influx of genes to counter the ever-changing populations of pests and diseases. It was not until the early 1980's that Third World countries challenged the "mining" of this "raw" material from their countries. The issue of gene exploitation and domination surfaced at the 1981 U.N. Food and Agricultural Organization's Conference.

As will be discussed later in more detail, the debate centered over the control of plant genetic resources, which not only included the subject of international collection, but also the control of breeding techniques, training of personnel to manage genebanks, the legality of patents and plant breeders' rights, and the issue of sovereignty over seeds. In short, the politics and technical competence of the entire global system of collection, management, and preservation came into question. Furthermore, between the years 1981 and 1985, in part through the formation of the FAO Commission on Plant Genetic Resources, important conceptual linkages were established between the commercialization of biotechnology and greater hegemonic control and exploitation of genetic resources.

Two publications by Pat Roy Mooney, Seeds of the Earth (1979) and The Law of the Seed (1983), were instrumental in raising international awareness of the economic and
political issues of monopoly control of plant genetic resources. Political pressure built around the FAO initiative, better known as the "FAO Undertaking," which calls for a legally binding International Convention on the exchange of plant genetic resources and the creation of an FAO-controlled worldwide genebank system. To date, there has been little restructuring of international germplasm preservation institutions. But also missing from the discussion is any debate over the consequences of mass extinction of the world's biological diversity. What are the key arguments surrounding mass extinction?

The estimates of species extinction for the next few decades by prominent ecologists (a loss of 3 to 257 species per day in the year 2000) even if they are only modestly correct, forecast a rate of species loss that is vastly greater than any previous period of mass extinction as suggested by fossil records. This level of extinction would be very different from the "historical" evolutionary process that incorporates a "background" level of extinction into its dynamics. This magnitude of loss would create an imbalance between speciation and extinction, which is likely not only to alter fundamental biological cycles and increase the level of genetic vulnerability, but also change the nature of the evolutionary process. The timescale of this projected extinction is such that it is
likely to become serious, if not catastrophic, before the basic research data about the problem are gathered.

The counter-arguments by critics, especially those from the field of economics, disclaim the 40,000 species lost per year or some 100 per day, on grounds that there is no good time-series data on tropical forest lost or the link between the loss of individual tropical forests and the extinction of species. Critics claim that there is little information known for other species besides birds and mammals, which comprise only a small percentage of the world's biota. Furthermore, some claim that species extinction is a natural process, divine punishment (apocalypse theory) or a precondition to the spawning of new or "better" lifeforms. Rejection of the estimates then permits the argument that it would be more sensible to fund other human priorities instead of costly biological diversity preservation projects. The above arguments and counter-arguments are based on assumptions and notions about the value of biological diversity.

Ecologists claim that biological diversity is essential to the maintenance of ecological balances: that a level of biological diversity is needed for ecosystems to be resilient and to function. This assumption is based, to a large degree, upon the existence of coevolutionary factors and interrelationships among species. For example,
the loss of one plant species is likely to lead to the extinction of 10 to 30 associated animal species (Myers, 1984). Correspondingly, it is assumed that the loss of many species is likely to undermine the stability of a given biological community such that basic biological cycles, e.g., water, energy, or nitrogen are also disrupted. Once basic genetically-based resilience is lost, then a chain reaction leads to spirals of degradation. Included in this degradation is the depletion of gene pools (genetic variability) through the loss of races and populations of species. Hence genetic degradation not only affects the quality of the environment, but it also diminishes the ability of biological systems to respond to future disasters or to maintain a composition of species that maintains an "equilibrium." The above arguments speak to a moral imperative to save the world's diversity for future generations. Economists have suggested the notion of a safe minimum standard (SMS) (Randall, 1985) level of genetic diversity preservation to assure ecosystem survival. In theory, public policy commitment to some SMS standard would shift the "burden of proof" arguments over "how much diversity is enough."

The arguments also refute economic determinism based on the maximization of social utility through the functioning of a laissez-faire biological diversity market.
Critics argue that biological diversity should not be reduced to being a "commodity." The economic notion of equilibrium is determined on supply-and-demand factors (surplus and scarcity functions) that determine market prices. Critics claim that although economic theory can project into the future, determination of future use values is ex ante and subject to all the difficulties of forecasting and determination of probability (Thompson, 1980). Market theory works best for homogenous commodities traded in truly competitive markets, and biological diversity does not translate well into either category. This is especially true because the large majority of biological diversity has never been scientifically described, and in its "raw" form (unlinked to desired traits), genetic variation has no direct utilitarian value (Berlan and Lewontin, 1985).

Furthermore, value determination of biological diversity solely through market forces is likely to hasten the degradation of the world's biological diversity, because only a small fraction of the genes will ever be commercially exploited. Those in support of broad biological diversity preservation programs justify expenditures based on the belief that genetic diversity has immense intrinsic value. Arguments accepting intrinsic
value can be philosophically or ethically based and defined by broad notions of social good and responsibility.

It is argued (Wyschogrod, 1985; Jonas, 1984) that the probable mass extinction of species ought to be part of an interpretation of the future. Part of the interpretation of technological change demands an ethics that includes issues of equity about the benefits and the risks surrounding the exploitation of genetic diversity. In addition, without fundamental changes in epistemology relevant to advances in biotechnology, the rapid expansion in the exploitation of the genetic code is intrinsically linked to the masking and acceptance of the beginning of the mass extinction phenomenon. The discourse over the extinction of biological diversity speaks to the problem of biological diversity preservation.

The issues of preservation—as linked to U.S. international development aid—were dealt with during a 1981 "U.S. Strategy Conference on Biological Diversity," which was sponsored by the Department of State and the U.S. Agency for International Development. This conference helped to spur a 1985 interagency task force report to Congress on "U.S. Strategy on Conservation of Biological Diversity." There was strong consensus that many of the biological diverse ecosystems found in developing countries are deteriorating, and that "provisions for conserving biological
diversity must be incorporated into development planning."
The U.S. Congress received a major report on Technologies to Maintain Biological Diversity (OTA, 1987a). None of the reports openly dealt with the underlying structural and political issues that had been raised during the earlier FAO debates. The OTA report was blatantly biased in its decision to examine only the technologies to maintain biological diversity. Such a framing of the problem ignored the more fundamental questions of ownership, control, and use of biological diversity, which, by necessity, would have shifted the focus to institutional and political questions. As a result, the assessment was "technology-driven" (with the major focus on the performance of the technologies themselves), instead of examining the social problems that arise from technological change. Furthermore, such "limited" framing of government reports is very much a part of the history of the problem.

To give another specific example, the project manager rejected the inclusion of a Hawaiian case study that compared the extinction problem in the islands to that found in Third World countries with similar extinction and related politically-driven land use problems. The case study exposed the fact the United States is doing little to protect endangered species in its own states, but its policies were demanding that Third World countries be
responsible for protecting genetic resources within their respective boundaries. In addition, the denial of such a comparison also rejected the notion that land use and ownership questions are intrinsically linked to the extinction problems in gene-rich areas. The narrow framing of issues is achieved by "hiding" behind a mask of policies and policy formation that is technology-driven.

This fundamental "masking" of important social issues by scientific issues will be discussed later in more detail. Still, it is vital to understand the underlying science of the problem and the scientific interrelationships among the erosion of biological diversity, species extinction, and environmental risk from the release of genetically engineered organisms.

THE SCIENCE OF THE PROBLEM

As discussed above, there are two major underlying scientific areas that frame the problem. First, there is the loss of biological diversity, and second, there are potential environmental and health risks from the commercialization of biotechnology. How should the loss of biological diversity be defined?

Genetic diversity is a highly complex biological concept that is based upon evolutionary theory, taxonomic
categories, and the interrelationships among species, populations, and communities in given ecosystems. Loss of genetic diversity can take place at any different level within this conceptual hierarchy. Irreversible loss takes place when species go extinct, and biological theory suggests that serious degradation of ecosystems will affect the stability—including the level of diversity—of the organisms within them. Extinction, therefore, is intrinsically linked to biological diversity and biological stability.

The current estimates of species extinction rates are based on the projected loss of tropical forests, which may contain up to 40 percent of the world's biota (with the entire tropical regions containing some 70-80 percent). A number of unanswered scientific questions complicate the estimates.

First, only about 1 percent of the world's species are well-documented, and biological literature suggests a range in species from three million to perhaps as large as ten million. Second, the role of extinction is not well understood; it has been estimated that 99 percent of all species have fallen to extinction. Third, most of the concern about the rapid degradation of ecosystems and tropical forests has come from anecdotal information gathered during repeated trips into these areas for collection and basic
research by biologists. Fourth, discussion of genetic
diversity loss based on species may be misleading, because
losses of diversity in populations may be more significant
to ecosystem stability. Fifth, the rate of speciation
(the evolution of new species) and the effect of widespread
extinction on this process are unknown. As a result of the
unanswered questions, biologists disagree about these
dimensions and nature of the problem. These uncertainties
introduce a fundamental "burden of proof" issue about the
nature and magnitude of the current mega-extinction
phenomenon and ecosystem degradation problems. At issue is
the degree to which biological diversity is linked to the
resilience and sustainability of the planet's biological
cycles. This interface is an important juncture between
the macro- and micro-worlds. Knowledge of how the
technologies perform gives a better understanding of the
micro-world within the cell, which is expressed
(phenotypically) in a given environment.

The coding process that builds proteins is the same
for all living organisms; hence, all living organisms are
related through the universality of the genetic code. The
new genetic technologies allow for more precise movement of
genes across diverse species, control over their expres-
sion, and techniques for identifying and isolating specific
genes. In the recombinant DNA process, a vector is used to
transport genes from one organism into another. The donor DNA is cut into fragments by highly specific restriction enzymes and then inserted into the vector. Often a bacterial plasmid (a circular, self-replicating strand of DNA introduced by the process of transformation) is the "shuttle" used to transport "novel" genes. Viruses are also used. Specially constructed probes are then used to find the few cells which contain the desired genes. This process is powerful in a number of respects in comparison to the natural processes (sexual and asexual) for gene exchange.

The techniques described above bypass the biological barriers that limit, to a large degree, the exchange of genes among similar species. The recombinant DNA technology allows, for example, the introduction and expression of the human gene for insulin to be incorporated into bacterial cells. This type of sharing of genes is not possible in nature. The techniques also can be performed in a small laboratory, which is an advantage over traditional breeding of crops, where trial plots would have to be established. The use of tissue culture techniques can save months, if not years, over some selective breeding programs used to enhance commercial breeds. The advantage of saved time in conjunction with the power to move specific genes (instead of entire chromosomes) makes the application of genetic
engineering almost unlimited, because the wealth of genetic
diversity "opened up" by the technological advancements is
immense. But it is precisely this "opening up" that raises
many questions about health and environmental risks.

Such concerns have generated a "new" science for bio­
technology risk assessment. Risk assessment considers such
factors as the harm that the genes could cause, the degree
to which the genes may spread in the environment, the scale
on which the technology will be used, and the knowledge
needed to use it properly. Biotechnology risk assessment
was also needed because of a lack of understanding about
how such "novel" creations would behave once released into
the environment. The questions of biological uniqueness
brought unique questions. One of the most difficult ques­
tions, still unanswered, is the degree of environmental
damage that could occur as the result of the technological
breakthroughs that allow the exchange of genes between
higher and lower lifeforms (e.g., between microorganisms
and plants). Not only could such changes introduce new
diseases, but such genetic engineering could result in
significant changes in evolutionary patterns. It was also
known--because bioinnovations are self-replicating--that
once introduced into the environment there was no assurance
that these bioinnovations could be recalled. What are some
of the characteristics of biotechnology risk assessment?
Generally, risk is defined as the potential (possibility and probability of occurrence) for adverse consequences. For bioinnovations, risk assessment could include, for example, "worse case" scenarios for human pathogens, estimates of persistence of the organism or the engineered genes in the environment, and ecosystem structural and functional analysis. In short, those involved in risk assessment frequently ask the question: "What if this happens?" As will be discussed later when examining questions of risk for crop vulnerability and deliberate release, the bounding of questions of risk is central to the politics of the problem. Still, a lack of knowledge about the biological behavior of bioinnovations raises many questions about the legitimacy of the science of biotechnology risk assessment.

POLITICS OF THE PROBLEM

Clearly, the most visible politics emanating from the science of biotechnology emerged and continues to come from issues concerning risk. Very closely tied to the debate over risk are the politics over who controls the basic and applied research agendas, which ultimately decides how the technology will be used and who benefits. The politics of the science of biotechnology have several important interlocking dimensions.
Fundamental to the dissertation is the notion that this politics of the science determines how, for example, questions of risk are framed. The framing, therefore, determines which questions of risk are legitimate and who bears the burden of proof. Correlated with questions about the burden of proof about the possible risks are questions about who will bear the harm should an accident occur.

Without clear evidence of harm, risk is debated by so-called experts using technical arguments and counterarguments. The shift in these arguments over time reveals many political elements of the problem, because the underlying assumptions reflect the positions of the principal stakeholders. Often, concepts are redefined, or hierarchies of risk assessment are constructed to manage the politics of both the science and the emerging industry. The construction of risk ideology and the choice of language to speak about the risks and uncertainties are fundamental to this process. It should be noted that many of the risks for the novel bioproducts may not appear or be able to be measured for decades.

The two main frameworks for risk--through the NIH Guidelines (NIH, 1976) and the Coordinated Framework (Federal Register, 1986)--were based around the notion that some new genetic combinations, especially those involving intergeneric transfer, were novel and could therefore pose
unique risks. Those who thought there was little or no difference between genetic engineering and other traditional breeding approaches argued that changes of a few genes did not substantially change an organism. From such reasoning, they argued that structuring of risk assessment based on "novelty" was slowing down the commercialization of biotechnology. This distinction is of even greater importance for deliberate release, because there is a much lesser degree of physical or biological containment possible, in comparison with laboratory-based research. For example, high-risk experiments must take place in a facility that has biological safety cabinets and special filters, but such barriers are not possible during field testing. The frameworks, in part, through definitions, determine which organisms need review, if at all, and what level of review by which agency. The issue of responsible "agency" is critical to the discussion of the politics of biotechnology.

At one level the distinction of whether primary review is carried out by the Environmental Protection Agency or the U.S. Department of Agriculture could result in different types and thoroughness of review. However, this distinction misses a major political decision: the orchestration of review at the federal level removes the individual states from direct involvement in the review and
regulatory process. The focus of review at the federal level allows greater control for the commercialization of the basic science, even though the local communities and state governments will bear the burden of risk should an unforeseen event or accident occur. This process of shifting many of the environmental and economic risks from the private to the public (federal, state, and local) sectors will be explored in later chapters. Such shifting of risk is fundamental to the politics of the science of biotechnology. An analysis of the shifting of risk, helps to reveal the organizational politics of biotechnology as science. The structure surrounding the funding of basic research through corporate research contracts is exemplary.

One examination of the funding arrangements of biotechnology research was undertaken by Martin Kenney in Biotechnology: The University-Industrial Complex (1986). In an examination of large university-industry research grants over the period of 1974 until 1983, Kenney documented more than $132 million for biotechnology-related research from corporations to universities, medical schools, and independent research laboratories. Areas of research included nitrogen fixation, monoclonal antibodies, and plant molecular genetics. Kenney argues that such funding legitimizes new relationships.
One important ingredient of the new partnerships was the negotiation of licensing agreements for inventions and discoveries. Kenney argues that the particular 1974 agreement between Harvard University and Monsanto for cancer tumor research ($23 million over 12 years) was instrumental in changing Harvard's patent policy. Kenney also argues that this endowment was allocated without any peer review process, and that it raised questions of whether such contracts undermine the notion of academic freedom for setting research priorities. Furthermore, he claims that: "The Harvard-Monsanto agreement was the first of a new type of corporate-university relation in which large sums were directed to specific researchers who continued their work while remaining at the university" (p. 59). Such relations also raise ethical questions about the "sharing" of laboratory facilities and graduate students. Research grants are a significant window into the political economy of the biotechnology industry.

A discussion of the political economy of biotechnology necessitates an examination of the nature of biotechnology as an industry. Biotechnology is no different from other industrial processes in its production of commodities to be sold in the marketplace. Many biotechnology products may be new, but they may compete with similar products from
natural plant sources, e.g., indigo dye or those produced through chemical synthesis.

Biotechnologies may offer the following advantages over conventional processes:

1) Greater specificity of catalytic reaction;
2) Milder temperatures and pressures for reactions, resulting in reduced energy costs and space;
3) Lower labor costs through computer-controlled processing using microorganisms;
4) Factories are free from geographical constraints;
5) The "raw" genetic diversity may be collected "freely" as common heritage;
6) Intellectual property rights have been granted to both biological innovations and biotechnology processes, in addition to traditional plant variety protection rights.

Because of these advantages, biotechnology as an industrial approach offers unique elements of control over the relations of production (including the bioprocesses and bioproducts). The revolutions in computers, data storage, genetic engineering, and industrial engineering are brought together under the rubric of biotechnology. Biotechnology as an industrial approach, as will be discussed later, is intrinsically linked to the needs of venture capital and to the larger needs of the U.S. economy to capture
international markets and to reindustrialize. The underlying fostering of a national, high-technology ideology is very much linked to the politics of the biotechnology economy. Biotechnology is another important phase in the development of monopoly capital that aims to create a universal market with an increased share of bioproducts as major commodities. The continued masking of important regulatory issues impacts on Third World economies and food security, impacts on the U.S. labor force, shifting of risks to the public sector are all consequences of the continued industrial development under monopoly control. The advancement of monopoly control of biotechnology will now be discussed.

To understand the basis of monopoly control of biotechnology, it is important to conceptualize the structure of the industry and the potential to exploit the power of genetic resources. As identified earlier, the wealth of genetic diversity is a tremendous source of coded information. The technological breakthroughs of the last decade opened up this resource in unique and powerful ways. The avenues of domination involve not only control over the technology (gene-splicing know-how), control over the raw resources and cell lines, but also control over the evaluation data and descriptor information which links the gene
sequences to commercially-valuable biological substances. Each of these control nodes involves mechanisms to protect the underlying interests inherent in monopoly control. Orchestration of these mechanisms, for example, occurs through the promulgation of protective state and federal laws, through the development of new relations of production that promote secrecy, and the fostering of division of labor practices that reduce the cost of technical labor skills. All of these mechanisms, specifically constructed for the biotechnology industry, have begun to appear.

With respect to new relations of production between the university-corporate sectors, the Pajaro Dunes Conference in 1982, was instrumental in setting benchmark "guidelines" for the process of policy formation. The meeting on university/industrial relations, financed by the Henry J. Kaiser Family Foundation, included presidents from Stanford, Harvard, California Institute of Technology, and the University of California. Representatives from industry included Beckman Instruments, Inc., Syntex Corp., Cetus Corp., Gillette Corp, Eli Lilly and Co., E.I. du Pont de Nemours, and Genentech Corp.

There was consensus that universities could accept proprietary information and should file for patent coverage, even though such steps could cause delays in
publication of information. In an effort to uphold the traditional view of the role of the university with respect to the progress of "open" science, it was agreed that contractual agreements should be made public and intellectual property matters should be handled on a case-by-case basis. Documentation from the conference suggests some consensus on the acceptance that "exclusive licenses" could be granted to the corporation which funded the research, as long as there is diligence in developing the patents (OTA, 1984:579). It is clear that such an approach offers a new level of protection of information and knowledge among select universities and corporations. The following chapter explores further the role of intellectual property laws in furthering monopoly control of biotechnology.

As will be discussed further, two levels of biotechnology's division of labor are occurring. First, many of the technical steps, involving gene manipulation, sequencing, and selection are being mechanised, as is the case with gene synthesizers, or are being "divided" into specific tasks that can be performed by a lab technician instead of a costly Ph.D. scientist. At the international level, the testing of bioproducts is just beginning to spur an international division of labor, in part, to avoid stiffer environmental regulations, and, perhaps, to reduce labor and land costs. Chapter VII discusses these issues more fully.
CHAPTER V

THE DEBATE OVER THE ROLE OF INTELLECTUAL PROPERTY: ONE OF THE IMPORTANT APPARATUSES OF THE CORPORATE STATE TO FURTHER MONOPOLY CONTROL

The first U.S. copyright and patents laws were enacted in 1790. Such laws were based on the Constitution, which empowers the U.S. Congress to "promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive rights to their respective writings and discoveries" (Benko, 1987:7). Copyright protection extends over the life of the individual (plus fifty years), whereas, patents allow an inventor rights for seventeen years. In addition to the two mentioned above, intellectual property rights also include trademarks, trade secrets, confidential business information, and plant breeders' rights.

One assumed argument from economic theory by proponents of patents is that these property rights are essential to the stimulation of innovation. Economic and philosophical arguments in the nineteenth century were largely responsible for the extension of personal property rights to intellectual property rights by allowing, for example, legal protection over products and processes. In other words, intellectual property rights secures ownership
not over "things" but over what is "embodied in things."
For example, personal property rights give protection for
the fruit on a tree in one's yard, but intellectual
property law would give protection for the rights to the
process of engineering the gene for faster ripening
varieties. However, the granting of broad ownership
rights through intellectual property law has raised
questions.

For example, some opponents claim that such protection
leads to monopoly control that disadvantages individuals,
companies, and nations (especially lesser economically
developed countries). A strong international movement
against patents took place during the mid-1800's, but it
was insufficient to stem the expansion of intellectual
property laws. Further discussion of monopoly will be
discussed later in this chapter.

Generally, international treaties do not specify
rules but attempt to bring differing laws into conver-
gence. Intellectual property laws are country-specific,
and patents need to be applied for, to a large degree, on a
country-by-country basis. There are at least twelve major
agreements governed by WIPO (World Intellectual Property
Organization). WIPO was established as a specialized
agency of the United Nations in 1974. The United States
does not belong to many of these agreement because of
conflicts of laws or national interest (Benko, 1987:5). Nonetheless, the United States has taken an active role in protecting biotech products and processes through intellectual property law channels.

Any discussion of intellectual property for biotechnology must not only consider the impacts of current laws; future impacts must also be examined. Broad consideration should be given to the inherent properties of the genetic code, the applicability of the new gene-splicing tools, and future bioproducts. It is certain that attempts to broaden intellectual property laws to be "coherent" with advancements in biotechnology will affect not only the innovation process, but who benefits. Besides the trade-offs tied to rewards and incentives, there is the underlying debate whether this technology and related genetic resources should be in the public or private domain.

With advances in biotechnology some renewed debate over the legitimacy of patents and other forms of legal protection for living organisms, their processes and products has occurred.

One major aspect of the new debate is focused not on whether intellectual property laws serve the public interest but deals with the establishment of international agreements that will facilitate enforcement and standards in international markets for bioproducts. The violations
of intellectual property laws become national issues: American companies, for instance, complain of heavy losses and disincentives to innovation, whereas a lesser economically developed country protests monopoly control by foreign and transnational companies. The commercialization of biotechnology has brought a new wave of concern over the role of intellectual property laws and raises issues of who benefits and who loses. Some of these issues are being debated at WIPO.

It is also questionable whether there is adequate legal justification for allowing the information contained in the genetic code (as a self-executing, embodied algorithm) to be copyrighted. The legal boundaries—distinguishing what one owns from what another owns—are more difficult for intangible objects. For intellectual property law there is a legal distinction made between idea and expression.

Ideas cannot be copyrighted or patented, but they are considered part of the "public domain." But for new technologies such as biotechnology the distinction is difficult to draw with certainty. Part of the difficulty comes because, at the genetic level, the biological code is similar, as a work of function, to other types of information-based products. The functional DNA nucleotide sequence has many parallels to semiconductor chips or
computer algorithms, neither of which have copyright protection in the United States.

A striking analogy exists between the genetic code and a computer program: similarities between bits and nucleotides or between programs and geneotypes. Both are information embodied by a code that regulates a process when "read" by a machine or a living organism. Proteins can be made in different ways just as a particular computer-based algorithm can driven by various programs. Because of these similarities, legal arguments can be made to support the position that the genetic code should be left in the public domain. However, the Supreme Court decided in 1980 that recombinant DNA products and processes were patentable. At issue was a strain of bacteria "constructed" by developing a "novel" strain, which gave the organism in question the new ability to degrade one of the components of crude oil.

In 1972, the researcher, Ananada M. Chakrabarty, was working for General Electric Company on a new bacterium to help break up an oil spill. Knowing that anyone could isolate the bacterium from the environment once introduced, he applied for a patent as a means of protection. The U.S. Patent and Trademark Office granted a patent for the process of recombining the plasmids but refused to grant one for the organism itself on grounds that current law did not apply to living organisms. The Court of Customs and Patent
Appeals overturned the decision on grounds that if the bio-invention met patent requirements, e.g., that the invention constituted a "manufacture" that was novel and had utility, a patent could not be withheld solely because the invention was a living organism. The nation's highest court agreed.

The Supreme Court found the government's position—that the Plant Variety Protection Act of 1930 and the 1970 Plant Variety Protection Act both excluded bacteria— unpersuasive. Dissenting justices felt that the majority decision (5-4) extended the scope of patent law and ignored Congressional intent.

The U.S. Supreme Court in Diamond v. Chakrabarty, 447 U.S. 303 (1980) set the precedent for the patenting of genetically modified organisms under categories of composition of matter and process of U.S. Code 101, even though the decision concerned only a particular bacterial type. The fact that the genetic information incorporated already existed in nature was not at issue in the majority position. However, the case did raise an issue over where to draw the line on what living organisms (known as the "slippery slope" argument) could be patented, and the narrow opinion suggested that Congress should deal with the questions. Nonetheless, the links among information, wealth, and international affairs were recognized.
The Office of Technology Assessment's *Intellectual Property Rights* (1986:14) touched upon the important linkages and questioned the policymaking role of the Supreme Court in this area.

... intellectual property policy can no longer be separated from other policy concerns. Because information is, in fact, central to most activities, decisions about intellectual property law may be decisions about the distribution of wealth and social status. Furthermore, given the scope of the new technologies and the trade in information-based products and services, U.S. intellectual property policy is now inextricably tied to international affairs.

In light of the Supreme Court's consistent signals to Congress that the judiciary should not serve as a policymaking forum for patent and copyright law, resort to the courts to resolve many of these technological issues may be tantamount to a delegation of Congress's policymaking authority. Even if the judiciary acts with restraint with respect to policymaking, the application of obsolete law to novel circumstances may end up skewing the policy objectives that the statute seeks to promote.

As was the case of the NIH Guidelines for genetic engineering, legal or regulatory precedent set in the United States is often adopted as the guidelines for other countries. Worldwide legal homogeneity for intellectual property law is essential to the expansion of biotechnology. Plant variety protection underwent an earlier expansion of protection within the United States and among International Union for the Protection of Plant varieties (UPOV) members. Member countries have intensive agricultural systems that
require highly developed plant breeding sectors. A major aim of UPOV is to foster international agricultural trade.

In 1979, debate in Congress over plant variety protection centered around testimony on H.B. 999 heard by the House Agriculture Subcommittee on Department Investigations, Oversight and Research. The bill proposed amendments to the 1967 Plant Variety Protection Act; the 1967 Act expanded protection of the 1930 Plant Patent Law. One of the amendments extended protection from 17 to 18 years, bringing the United States into alignment with the intellectual property agreements of UPOV, thereby facilitating its entry into the organization. The international system for breeders’ rights was created in 1961 at the International Convention for the Protection of New Varieties of Plants. It should be noted, however, that the European Patent Convention and Japanese law prohibit plant and animal varieties, but that there is greater legal similarity with U.S. intellectual property laws for the protection of microbial strains (OTA, 1981).

It is interesting to note that the Plant Variety Protection Act of 1967 and the Plant Patent Act of 1930 were used as arguments (both for and against) the 1980 Supreme Court decision to allow patents on bacterial strains. The issue of whether living organisms should be patentable is still under debate, although the recent
decision to allow patents on other higher organisms seems to give the "green light" to everything living except humans. Opponents of patents raise moral, ethical, and religious arguments against the issuance of patents for living organisms.

Other opponents have argued that the enforcement of plant breeders' rights in Europe results in extinction of varieties. This claim is made on the fact that UPOV issues a "Common Catalog" of "legal" (protected) seed which can be sold. As companies delete "illegal" seed from their catalogues, the survival of those seed-types is unlikely. Dr. Erma Bennett of the Crop Ecology and Genetic Resources Unit of the United Nations Food and Agricultural Organization estimates that by 1991 only one-fourth of all European vegetable varieties will have survived the enforcement of plant patent law (Fowler, 1979). Hence, the expansion of intellectual property laws is linked to the loss of genetic diversity. This trade-off should be measured against the economic incentives offered to breeders on the creation of new varieties. Another important social trade-off involves the issues surrounding confidential business information in applications seeking approval at the federal and state levels for the deliberate release of genetically modified organisms.
In short, confidential business information is a key intellectual property avenue for biotechnology companies to protect their business interests, while complying with requirements for federal and, in some cases, state review of applications of bioproducts for field testing. Information that would be protected from disclosure under the Freedom of Information Act [5 U.S.C. 552 (b) (4)] includes trade secrets, commercial and financial information. Trade secrets will be discussed in more detail later in this chapter. Companies or persons wanting this protection must show that substantial competitive harm would occur should, for instance, environmental, safety, potency or data be disclosed. At issue are the parameters determining a "public document or record" for public inspection, confidential information protection, and the government's right to review such information for harm to humans, crops or livestock, and the environment.

A specific example concerning confidential business information will be presented below to allow a more detailed discussion of how such protection works and the underlying issues. The example will explore the deliberate release of genetically-engineered tomatoes into the Hawaiian environment. The role of federal agencies, in this case the U.S. Animal and Plant Health Inspection
Service (APHIS), in the review process will be discussed vis-a-vis the State of Hawaii's role and laws.

CONFIDENTIAL BUSINESS INFORMATION: HAWAII CASE

The U.S. Animal and Plant Health Inspection Service (APHIS) is responsible for review of applications for deliberate release into the environment of genetically engineered organisms which involve, for example, plant pests. Rules about confidential business information are partly defined in "APHIS Policy Statement on the Protection of Privileged or Confidential Business Information" (50 FR, 38561-38563). APHIS will only make disclosure, for instance, to the State of Hawaii if there is parallel state legislation to protect business information. Such information is important for the State of Hawaii to assess whether or not the deliberate release poses a threat to health, agriculture, or the environment.

As is currently practiced, a company sending material to APHIS sends two documents: one with confidential business information (CBI) included and the other with CBI deleted. Full documentation will be available only to persons outside APHIS if the request is deemed a proper official purpose (with proper security procedures), and APHIS will also afford the submitter the opportunity to object to disclosure (even to a state department of
agriculture). This framework was tested during the fall of 1988, when Hawaii's Department of Agriculture was asked to review a request by Calgene (a biotechnology company based in Davis, California), to field test genetically-engineered tomato plants on Molokai.

On October 28, 1988, the State Department of Agriculture's Advisory Sub-Committees on Microorganisms and on Plants met at the Quarantine Office in Honolulu to discuss the Calgene request. The Department was asked to review the CBI-deleted document only (some 38 percent of the total document had been deleted). Federal law requires that a permit is needed prior to the release into the environment of a regulated article such as an agricultural pest. Calgene had used the plasmid of the plant pest, Agrobacterium tumefaciens, to genetically engineer a gene (polygalacturonase antisense gene) into a commercial tomato variety. APHIS rules require state notification and a 30 day period for review of these applications. Applications are reviewed to determine if there is any significant risk involving such factors as the escape of the plant (or the engineered genetic material) into the surrounding environment.

In a Department of Agriculture memorandum dated November 10, 1988, the department concluded that A. tumefaciens was not associated with the tomato plants in
question, but it acknowledged that "Hawaii's environmental conditions do differ from other parts of the country and, therefore, Hawaii's plant regulations need to be reviewed to determine if genetically-engineered plants should be regulated" (DOA, 1988).

What is obvious from the description above is the conflict of interest between the protection of confidential business information (CBI) and the review of information by a state agency as a legitimate government function. Information held confidentially, and therefore restricted from the right-of-review, may be that which is necessary to determine whether it is safe to proceed with the release of a new organism into the environment.

At issue is whether existing state statutes contain a provision regarding public access to or exemption of disclosure of CBI which is comparable to the provision under the federal FOIA, and whether state law (Act 160, sec. 2, 1988 Haw. Sess. Laws 286) mandates that the State Department of Health receive applications for the release of genetically-modified organisms which contain CBI information. Principally, at issue is whether or not the State of Hawaii can undertake a legitimate review of applications with confidential business information deleted. In a nonformal opinion, the Director of the Office of Information Practices of the Department of the Attorney
General found that the "State must review all information related to an application in order to make informed decisions about the application to protect the public's interest." Subsequently at issue is whether such information should be exempt from the State's Uniform Information Practices Act (Act 262, sec. 1, 1988 Haw. Sess. Laws 473). It should be noted that the Office of Information Practices will be drafting model rules relating to state security procedures of CBI documents that can be modified to meet the requirement of individual departments. It should also be noted that disclosure of CBI, in any manner, would be a state misdemeanor, and federal employees (under the Trade Secrets Act) can be fined up to $1,000 and/or imprisoned for up to one year for unauthorized disclosure.

The above discussion also raises political and public policy issues for intellectual property laws, of which protection of confidential business information (CBI) is an important legal instrument for the biotechnology industry.

The Hawaii review of Calgene's application to APHIS clearly shows that the review by the State of Hawaii is fragmented and the adequacy of current law and further amendments (by Act 262, 1988 to be effective July 1, 1989) are uncertain. The issue of access to documents (containing CBI information) in all cases by the public is
contradictory to the public interest in having the right-of-review of all information related to the release of genetically modified organisms, because it severely limits the degree of access and restricts the release of such information. Furthermore, the protection of CBI (protection of a company's competitive standing) outweighs the legitimate state government function to review applications for possible significant harm, as well as public access to the review process and proprietary information.

The system as defined above is complex. The punishments for unauthorized disclosure--perhaps, even for disclosure of general environmental concerns in the press--are substantial, and business has the right to object to CBI disclosure even to state governments where the field testing is to be conducted.

With respect to the further commercialization of biotechnology, it is likely that CBI approaches will be used broadly not only to maintain a company's competitive edge, but also to frustrate the release of information to the public concerning the risks of field testing and to diminish the role of state agencies in the review process. For example, parallel legislation at the state level to the Freedom of Information Act and rules protecting CBI are needed before confidential information will be released. It is likely that the biotechnology lobby may be strong
enough, in the near future, to keep such legislation from passing at the state level. The testimony against House Bill 2201, 1988 (see Hawaii Case Study in Chapter VIII), is a clear example of the biotechnology industry's attempts to stifle state regulation.

Furthermore, more discussion is needed--from a public interest viewpoint--on the merits of such broad CBI protection for an industry that has the potential for irreversible environmental/health risks. Finally, it should be noted that the above example, involving an agricultural pest, is the only known example where federal rules require that there is state review (30 days) of an application to APHIS. Unless there are state laws requiring a review of all applications, it is likely that most states will not be directly involved in the review process.

MONOPOLY CONTROL THROUGH THE IMPLEMENTATION OF INTELLECTUAL PROPERTY LAWS

Monopoly control, through the implementation of intellectual property laws, involves a number of avenues. David Noble in America by Design (1977), discusses the ability of corporate power to monopolize knowledge and products through patent law. Noble argues that corporations which control the primary patents for a given industry also can control future patentable innovations.
Furthermore, corporations are able to control not only the patents on a given product but also the patents on the process for the production of a given product. Corporations, as a result of legal changes, also secured the patent rights of the inventions of their employees. Other methods of control, identified by Noble, include: (1) incomplete disclosure of information and delays in patent applications, (2) the use of trademarks, and (3) coordinated agreements among companies. Trade secrets are another avenue for control.

Trade secrets are an alternative approach to patents and copyrights. The first significant trade secret case was heard in 1837 (Kintner and Lahr, 1975:119), and such protection is based on whether there is a "secret" and whether disclosure would cause economic harm. Industrial processes and chemical formula are well-known examples of subject matter of trade secrets. A trade secret must have three legal elements: novelty, secrecy, and value. The legal requirements for novelty for trade secrets are lower than for patent prerequisites. Total secrecy is not required, but confidentiality must be maintained. Trade secrets are essential to the control of products for high technology companies. In The Trade Secrets Handbook: Strategies and Techniques for Safeguarding Corporate
Information (1985), Dennis Unkovic claims that "trade secrets play a linchpin role for high-tech companies."

All companies, regardless of size or business activity, possess commercially valuable trade secrets, but technology is generally a less critical element for companies in mature industries. Capital requirements and access to assured sources of supply frequently outweigh trade secrets in importance for mature industrial concerns. This story is far different for the high-tech company. Trade secrets play a linchpin role for high-tech companies.

Unkovic then argues several key factors that make trade secrets critically important to the high technology industry. They are: (1) the highly competitive nature of so-called high technologies; (2) confusion over intellectual property laws; (3) that small high-tech companies may lose secrets through present or former employees; (4) the dependence on multisuppliers and contractors for production and marketing of high-tech products; and (5) the reality of trade secret espionage. For the reasons mentioned above, signed secrecy agreements are often requirements for employees and nonemployees (e.g., consultants, bankers). Broad secrecy agreements cover all company knowledge and information.

Negative consequences to the public interest can arise frequently. Trade secrets can stifle competition, the release of products may be delayed to hinder discovery by reverse engineering, and exclusive licensing agreements
can hinder the transfer of technology. Furthermore, all of the above can lead to monopoly control.

In 1890 the Sherman Antitrust Act was passed. The Act prohibits "monopolization" and "attempts to monopolize." Attempts to extend patents, for example, beyond their scope, can be questioned. From previous litigation history, any company that has 85-90 percent of market shares has monopoly power over a given commodity (Kintner and Lahr, 1975:99). Although there are limits to patent monopoly, litigation of abuses is difficult and costly.

CONCLUSION

This chapter presents a brief overview of intellectual property laws--patents, copyright, trade secrets, and other confidential business information--in relation to the current commercialization of biotechnology. Confidential business information was explored specifically for biotechnology considerations through the examination of Calgene's application to field test genetically-engineered tomatoes on the Island of Molokai.

Because of the structure of high technologies, biotechnology being a key industry in this classification, intellectual property law is essential to control by the private sector. Intellectual property law is also a major factor in the private sector being able to capture greater
monopoly control. The expansion in these laws is diminishing public efforts that were previously responsible for serving broader interests.

Due to the fact that patents are determined largely on a country-by-country basis, that trade secrets in the United States are determined by state law, and that many bioinnovations do not fit into patent or copyright law, there is still uncertainty over boundaries, applicability, and enforcement of intellectual property laws at the state, federal, and international levels. However, the rapid privatization of genetic resources, genetic information, processes, and products is raising serious questions about the current expansion in intellectual property laws. Not only is the patentability of lifeforms still questionable, but the issues of public interest should be reevaluated in light of the recent technological breakthroughs and business trends for biotechnology. In particular, the debate over the link between an expansion in intellectual property laws and greater monopoly control should be examined specifically for biotechnology.

Issues of monopoly power also extend beyond legal matters and national borders. For example, many Third World countries raise ethical concerns about the private ownership of genetic resources and the expansion of plant variety protection laws and patents. They claim that poor
countries are unable to purchase the needed protected agricultural bioproducts (e.g., commercial seed). Without the breeding infrastructure, even free access to new varieties for basic research is meaningless. Their sense of urgency stems from very real concerns surrounding food security. Without access to the technology, there will also be a widening gap with nations who do have access. Control of basic research is a form of monopoly control.

Knowledge of the genetic code for desired genes, biotechnology processes or evaluation data are power and the control of germplasm for economic species is wealth. There is no doubt that whoever controls the information embodied in the genetic code will control many facets of the biotechnology market estimated to be worth billions of dollars.

Intellectual property laws are the "linchpins" for the private commercialization of biotechnology. Unless there is continued debate about whose interests the expansion in intellectual property laws serve, then it is likely that few aspects of commercialization will be controlled by the public sector. Public sector involvement in the United States could be essential to broad use of the immense power inherent in the biotechnologies, to the establishment of public databases, and to public access to gene sequence information (genetic probes) that are essential to breeding
programs. Public sector involvement could also be essential to a more equitable use of biotechnology in lesser economically developed countries to sustain their production systems.
CHAPTER VI

GENETIC RISKS: DEVELOPMENT OF A FRAMEWORK TO CRITIQUE THE EXPANSION OF RISK FROM THE PRIVATE TO THE PUBLIC SECTOR

The purpose of this chapter is to develop a framework to explore the relationship between the exploitation of genetic resources and the transfer of risk from the private to the public sector. Analysis will focus on two examples.

The first involves an examination of structural changes of U.S. agriculture and the shift in plant breeding responsibilities from the public to the private sector. Both the structural changes and the breeding shifts are linked to the increased levels of crop vulnerability. It is argued that such vulnerabilities translate into direct risks, which are being increasingly carried by the public sector.

The second example examines the environmental risks surrounding the deliberate release of genetically modified organisms. The discussion of risk also includes a critique of the regulatory framework for biotechnology, which argues a historical shifting of risk (in this case, the redefinition of the "burden of proof") from the private to the public sector. Both examples help further define the relationship between power and the exploitation of genetic resources and information.
The exploitation of genetic resources can be linked, in part, to how the technological advancements in molecular genetics have altered the modes of identifying desired traits, breeding, and seed multiplication.

Biotechnology as a "new" breeding approach is dependent on the identification, extraction, and integration of desired genes; the power source is the wealth of genetic diversity harnessed with the molecular and cellular tools that facilitate highly specific transformations. Genetic engineering tools accelerate all phases of the breeding continuum, which is often referred to as the "breeding pipeline." This truncation in the creation of new varieties is an important element of control that allows for a more rapid exploitation of genetic resources. With shorter research and development periods, it is now possible for the private sector to take a broader role in the breeding process. To help conceptualize these developments, the structure of U.S. agriculture and the public-private crop breeding dichotomy will be discussed.

HOW THE INTERRELATIONSHIP BETWEEN CHANGES IN THE STRUCTURE OF U.S. AGRICULTURE AND CROP BREEDING ARE SHIFTING RISKS THROUGH INCREASED CROP VULNERABILITY

The U.S. agricultural industry is characterized by its long history of cooperation between public funding of
breeding new varieties within the Land Grant System and the private seed industry. This interrelationship has been termed the "breeding-pipeline" consisting of a seven phase continuum (see Table 1), which incorporates desired traits into commercial varieties.

Table 1

| Phase I: Collecting, documenting and distributing "raw" germplasm for ex-situ storage and introduction into breeding programs. |
| Phase II: Understanding the genetic variability and geographic distribution of cultivated and cytological related species. |
| Phase III: Screening and locating desired traits. |
| Phase IV: Studying the genetic mechanisms of inheritance of the desired genes. |
| Phase V: Developmental breeding of desired genes into improved strains. |
| Phase VI: Breeding for commercial seed stock. |
| Phase VII: Producing commercial seed for sales distribution. |

Historically, this has created a division of labor between the public and private sectors such that the public sector has been concerned with phases 1-5, while the private sector has been primarily concerned with phases 6
and 7. However, the advancements in biotechnology, in part, because they greatly reduce the time needed to accomplish several of the first five phases, have been a factor in shifting many of the public sector breeding activities into the private sector.

The seven-phase continuum is a complex and costly series of events that can take as long as twenty years. In the United States, the maintenance and preservation of genetic resources are intimately linked to breeding goal priorities, and those breeding goals are, in turn, linked to how and where crops are produced. There is, therefore, an important relationship between the maintenance and preservation of germplasm and the structure of agriculture. Industrialized countries are dependent on genetic diversity in the development of "standardized" varieties, (e.g., consistency in height and maturity for mechanical harvesting or food processing and for resistance genes to crops pests).

The structure of American agriculture has changed dramatically during this century. Although farming is often thought to be a "family" business, this changed with the loss of millions of farms over the last four decades. The number of farms peaked at 7 million in the 1930's and steadily dropped to below 2.7 million in the 1980's (USDA, 1981). With the loss of many farms of small acreage, U.S.
agriculture has lost much of its distinctiveness. More importantly, with the industrialization of farming, there have been corresponding increases in crop vulnerability.

Much of what is known about crop vulnerability has been learned from studies of crop epidemics. During crop failures, like the Irish potato famine, a large percentage of the yield is lost. Bad weather adds to the demise of the crop, but levels of genetic homogeneity are linked to lowered resistance. The issues of genetic crop vulnerability have been documented by the National Academy of Sciences (1972, 1978) and were discussed by the U.S. Congress during hearings on the proposed amendments to the Plant Variety Protection Act (P.L. 577, S.B. 23, and H.B. 999), which were held on July 19, 1979, and April 22, 1980.

One year later, the GAO issued to the U.S. Congress the report titled, "The Department of Agriculture Can Minimize the Risk of Potential Crop Failures," which focused on crop vulnerability and the link to the National Plant Germplasm System. The 1981 GAO report concluded:

The present system does not comprehensively address the real risks of genetic vulnerability. Potential crop failures are a national and international concern, and the regional efforts have not added up to an effective national program. Critical policy questions have not been addressed, indications are that germplasm protection and preservation mechanisms are inadequate, and comprehensive plans have not been made to cope with present and future problems. The system's organizational structure cannot sufficiently address these problems, and the Department's recent
As the above mentioned reports indicate, the problem of genetic vulnerability is strongly linked to the structure of agriculture. Crop vulnerability can be increased as the result of, for example, breeding methodologies, method of field cultivation, and dependence on elite varieties with a high degree of genetic homogeneity. The U.S. corn blight in the early 1970's illustrates how crop vulnerability is increased from a dependence on elite lines.

In the case of the corn blight, the epidemic occurred, in part, as a direct result of breeding methodologies, which used male sterile lines to reduce the cost of producing hybrid seed. So, by the late 1960's, some 90 percent of all corn grown in the United States had a common genetic link (probably a trait located on the mitochondrial genome), which in unfavorable weather became the "weak link." At this point, it is important to relate what happened to cause the epidemic to the issue of why the structure of American agriculture increases the risk for the use of new biological innovations in intensive, monocropped systems.

Advances in molecular genetics are increasing these trends toward "weak links" by developing elite varieties that have been improved for specific traits. The attempt
to engineer nitrogen-fixing (nif) genes into the chloroplasts of cereal crops is exemplary, because if the approach works, the same nif genes could be integrated into the genome of all major crops. Therefore, crop vulnerability leading to crop failure can be greatly increased by the rapid commercialization of bioproducts.

The question of crop vulnerability is much broader than the potential loss of a specific crop. The issue of crop vulnerability across the entire production system of a country involves other questions. In this broad sense, crop vulnerability is a social question of how much risk society is willing to take, who bears the burden of that risk, and who reaps the benefits. One approach, which helps to understand who bears the risks, examines the different types of risk and how the risks are being shifted over time.

The above discussion has concentrated on one type of risk: the risk system-wide crop failure that is increased or decreased depending on the level of genetic homogeneity used within a given farming system. When crops fail, for example, there is the ultimate risk of starvation for the subsistence farmer, the loss of the family farm, loss of profits for the corporate business, and higher food prices for the consumer. In the United States, the federal government has mitigated these risks through deficiency
payments, crop insurance and grain reserve programs, basic research funds for pest and disease resistance, and management of the National Germplasm System.

With the shift of breeding responsibilities toward the private sector, there has been a privatization of germplasm and genetic information that had been freely circulated among public institutions, e.g., the Land Grant System, and often between private seed and other agricultural input companies. However, with the recent option to patent biological innovations, much of the information is now proprietary, innovations are delayed in the patent process, and the focus of breeding is more narrow and short-term (with respect to pest and disease resistance breeding, which often requires years of basic research). These changes--grouped together--greatly increase the long-term risks.

From the analysis above, it is clear that the commercialization of biotechnology has had an impact on major shifts in the responsibility for crop breeding. Not only do these shifts increase the likelihood of epidemics and crop failures, but the ability to respond to them is also destabilized.
SHifting of the burden of proof from the private to the public sector: deliberate release of genetically modified organisms

The commercialization of biotechnology involves the deliberate release of genetically modified organisms into the environment. The intentional release of genetically modified organisms raises different questions about risks than previously raised during the 1970's about the risks related to recombinant-DNA research. The NIH Guidelines established socially acceptable levels of physical and biological containment based on assumed hierarchies of risk, whereas, the intentional release of bioproducts bypasses the concept of containment. These types of risks must be viewed in a broader social and political framework involving regulation.

The regulatory framework

The current regulatory framework emerged from the National Institutes of Health (NIH) Guidelines (adopted in 1976), which assigned risk categories and levels of containment to recombinant DNA experiments. The NIH Recombinant DNA Committee maintained oversight of recombinant DNA research until the promulgation of the
Coordinated Framework by the Office of Science and Technology Policy on June 26, 1986.

The principal function of the Coordinated Framework was to allocate the approval responsibilities (regulatory policies), among FDA, EPA, OSHA, and the USDA, and to define the research policy responsibilities among NIH, NSF, EPA, and the USDA. Federal statutes used by regulatory agencies include the Toxic Substances Control Act (TSCA), the Federal Insecticide and Rodenticide Act (FIFRA), Plant Quarantine Act, and the Federal Noxious Weed Act.

As a result of nonspecific legislation for living organisms, regulation is dependent on laws passed in the 1970's, e.g., FIFRA in 1972, and TOSCA in 1976, which are largely applicable to conventional chemicals. Many bioproducts ready for release are different from conventional chemicals in their ability to self-replicate or transfer their "novel" genes to other species.

The lack of clear legislative intent has added to the difficulties in deciding which agency has jurisdiction. For example, a genetically-engineered microorganism to be used as an agricultural pesticide would be reviewed by both EPA and the Animal and Plant Health Inspection Services of the USDA. Companies are already attempting to "exploit" the jurisdictional discrepancies by "shopping around" for the agency that would be most lenient in their review.
The Coordinated Framework is still undergoing scientific scrutiny and debate over important definitions involving "pathogenicity," "intergeneric transfer," and "release into the environment." These definitions are important because they set the parameters which determine which innovations need review and which are exempt (e.g., gene deletions). Another area of dispute is whether or not sufficient scientific knowledge exists to assess field testing and widespread use of bioinnovations, which demands an understanding of the potential risks.

At the center of this debate is a regulatory dilemma: there is insufficient experience with genetically engineered organisms in the environment on which to base most risk assessments or to perform adequate environmental risk assessments. Although there has been much insight gained from 15 years of laboratory research, there is little correlation between such facilities and the environment. This gap in knowledge has been legally challenged but not well understood by the judicial system.

On November 4, 1985, the Washington Post reported that the Environmental Protection Agency (EPA) had cleared the first release of a genetically-engineered microbe into the environment. Although it is unlikely that the new Pseudomonas strain will cause environmental damage, there is some uncertainty.
The Foundation on Economic Trends announced that it will restart litigation against EPA on grounds that an environmental impact assessment—required by National Environmental Policy Act (NEPA)—had not been performed. There appears to be no assurance of genetic "recall" once an engineered organism is released into the environment.

Ecological assessment is less well developed than epidemiological studies for human health, although there have been applications of similar studies for specific agricultural systems. Proliferation of genetic information in ecosystems is difficult to measure because of numerous "feedback loops"; for example, changes in the environment can accelerate establishment or transfer of "novel" genes to other organisms. Generally, ecosystem interactions are both difficult to describe and to predict. The exchange of novel genes, especially among microorganisms in the soil, may also greatly enhance persistence of pathogens. The key to risk assessment is prediction and, logically, the vast permutations of information that are constantly changing makes comprehensive assessment questionable.

On November 21 and 22, 1985, OTA hosted a joint workshop with NSF to explore the horizontal transfer and genetic stability associated with the deliberate release of genetically engineered organisms. Included in this effort was a discussion on ways to reduce the frequency of...
horizontal transfer through modifications of vectors, conditional lethal genes, and marker genes. Such approaches would require experiments that can detect such transfer in the field. To date, needed methodology is limited or non-existent.

There was no consensus on the way to approach this issue of deliberate release of genetically-engineered organisms that would yield generic rules for distinguishing between high and low frequency of horizontal transfer of genetic information. How can one predict what the secondary transfer of genes is likely to be, when only 10 percent of microorganisms are known? What do we know about cryptic genes, especially those maintained through infectious transfer? What are the mechanisms which maintain the integrity of species? How much free DNA survives on clay particles and for how long? These were some of the unanswered technical questions. Also at issue is the lack of provision for direct state involvement in the regulatory process.

The Coordinated Framework makes no direct provision for state involvement in the regulatory process. It is assumed that there will be voluntary public and private peer review of proposed research and deliberate release of genetically-engineered organisms. Peer review is largely conducted by Institutional Biosafety Committees (IBC's).
The General Accounting Office (1987) in "Biotechnology. The Role of Institutional Biosafety Committees," found from the analysis of 261 chairpersons of IBC's, that gaps existed on the various committees in areas of physical containment, ecology, epidemiology and also large-scale fermentation technology. Their composition is "heavily weighted" with those having recombinant DNA backgrounds. It can be assumed that many on such committees are also members of private, for-profit biotechnology companies. In interviews with officials at the Agricultural Research Service, the Environmental Protection Agency, and the National Institutes of Health, GAO found that "biosafety committees probably or definitely lack the capability to assess environmental release proposals at the present time" (p. 18).

Peer review is important at the local level because of the need to consider differences in environmental conditions that are state-based. A rule set forth by the USDA (52 Fed. Reg. 22891) mandates state notification and review of permits for bioinnovations involving plant pests (OTA, 1988:62). States are beginning to legislate "right to know" statues that require simultaneous notification when applications are sent to federal agencies for initial review.
In January, 1988, the Wisconsin legislature considered action that would require a state permit prior to release, and Texas introduced legislation in its 1987 session requiring state notification of deliberate releases. Hawaii, through H.B. 2201, may be the only state to have actually passed such legislation. (See Hawaii Case Study presented in Chapter VIII.)

It could be argued that an a priori perception is held by public officials and the general public that since state governments are actively involved in the promotion of biotechnology, there has been equal "investment" in oversight and monitoring of public, quasi-public, and private enterprises. Evidence suggests this perception is false.

In Hawaii, for example, although the Legislature has appropriated funding of genetic engineering at the Nitrogen Fixation by Tropical Agricultural Legumes (NifTAL) station, the Pacific International Center for High Technology Research (PICHTR), and the Cancer Research Center, there has been no direct funding to assure safety of laboratory workers, the environment, or the public at large. In fact, there is no expert (as of September 1989) in the State Department of Health, who has the authority to respond should a biological accident occur.

Organisms (#3) found that "in the long term (10 to 50 years), unforeseen ecological consequences of using recombinant organisms in agriculture are not only likely, they are probably inevitable" (p. 87-8). Not only are there liability issues as the result of direct state subsidy of biotechnology, but there are concerns about who will bear the burden to "clean up" after these unforeseen ecological consequences.

Small biotech companies are likely to file for bankruptcy at the beginning of ecological disasters, leaving states to carry the burden. Furthermore, even if Hawaii's Department of Health is never directly involved in any "clean up" efforts, state agencies will need to share responsibility for effective monitoring and to prepare for an effective response, should one be necessary. It was clear from the 1989 Exxon oil spill in Alaska that contingency plans for a such a disaster were totally inadequate. Such uncertainties demand further understanding of the "burden of proof" debate and who bears the probable risks and costs to respond should a major accident occur.

Initial concerns over the use of genetic engineering techniques came when researchers in the 1970's suggested splicing DNA of the Simian virus (SV 40) with a bacterium found in the human gut (Eschericia coli). Scientists feared that the genetic combination would establish a new
dissemination route for the virus (OTA, 1981:197); the
virus could then potentially cause cancer in human cells.
Such uncertainties raise questions concerning the
possibility and probability of harm and its magnitude.

Public policy is often not specific about who bears
the responsibility for the burden of proof about evidence
of risk and safety. In other words, should a company show
proof that the release of a genetically-engineered organism
is safe, or should the public have to prove that such a
release will cause harm? Such questions are in the balance
of the burden of proof issues and interest group formation.
In fact, the issues of "burden of proof" have been central
to the formulation of the regulatory framework, risk
assessment, and risk management. A historical review of
regulatory policy formation clearly shows a shifting of the
burden of proof (for potential harm) from scientists and
private companies to the general public. Furthermore, it
establishes conflict of interest between promotion of the
technology and the burden of proof over safety by federal
agencies.

CONFLICT OF INTEREST WITHIN FEDERAL AGENCIES BETWEEN THEIR
ROLE AS PROMOTORS AND REGULATORS OF BIOTECHNOLOGY

The General Accounting Office issued a briefing report
to the Chairman of the House of Representative's Committee
The great majority of the USDA scientists involved in the recombinant DNA experiments (see Table 2), felt that there was little risk involved in the deliberate release of their products and that correction of a problem would be either self-correcting or controlled with little effort. The GAO report did not analyze the significance of these findings, but they raise a number of questions, especially as there have been few test cases to gain empirical data about the release of genetically-engineered organisms into the environment. The questions asked by the GAO study deal with the perceptions of USDA scientists. It is likely that these specific perceptions about potential "problems" and "efforts to correct any problems" were influenced by the predominant high technology ideology (which includes
Table 2

Scientists' Responses to Problematic Releases

<table>
<thead>
<tr>
<th>Problem Level</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>No problem</td>
<td>75</td>
</tr>
<tr>
<td>Very minor problem</td>
<td>09</td>
</tr>
<tr>
<td>Minor problem</td>
<td>0</td>
</tr>
<tr>
<td>Moderate problem</td>
<td>0</td>
</tr>
<tr>
<td>Major problem</td>
<td>0</td>
</tr>
<tr>
<td>Very major problem</td>
<td>0</td>
</tr>
<tr>
<td>Do not know</td>
<td>3</td>
</tr>
</tbody>
</table>

What effort would it take to correct any problems that might arise?

<table>
<thead>
<tr>
<th>Effort Level</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self-controlling</td>
<td>68</td>
</tr>
<tr>
<td>Little effort</td>
<td>13</td>
</tr>
<tr>
<td>Some effort</td>
<td>2</td>
</tr>
<tr>
<td>Moderate effort</td>
<td>3</td>
</tr>
<tr>
<td>Great effort</td>
<td>0</td>
</tr>
<tr>
<td>Very great effort</td>
<td>0</td>
</tr>
<tr>
<td>Uncontrollable</td>
<td>1</td>
</tr>
</tbody>
</table>

biotechnology) in the United States. What does political theory on the role of ideology suggest to explain this?

Chapter II on the masking of biotechnology issues argues that ideology plays a key role in creating public policy irrationalities and incompatibilities. Biotechnology is one of the so-called high technologies that is supported by this ideology.

Creel Froman in Two American Political Systems: Society, Economics and Politics (1984:84) argues:

One of the functions of an ideology, however, is to encourage people to believe something without looking very closely at the data, as though it were already demonstrated that what the ideology says is true, and perhaps as though it were already proven or somehow unnecessary to prove.

Taking Froman's thoughts further, biotechnology research at the USDA has become a "self-serving" activity, thereby allowing a separation between how the research (with inherent risks) is justified and explained," and this separation is explained as a function of ideology (Froman, 1984:86).

One of the functions of an ideology, however, is to encourage people to believe something without looking very closely at the data, as though it were already demonstrated that what the ideology says is true, and perhaps as though it were already proven or somehow unnecessary to prove.

Inference is required to understand the power relationships. Economic power relations are important to the commercialization of biotechnology. Such relationships are evident in the expansion in intellectual property
rights that apply to many in public institutions, the economic incentives govern the political relationships driving the perceptions of risk.

Theodore Lowi in The Politics of Disorder (1971) would argue that the "masking" of potential risks by the USDA scientists is a symptom of "political quiescence" that is grounded in the prevailing ideology of "interest group liberalism." Not only would their individual self-interest prevail, but the affinity with other molecular biologists outside the USDA system would hamper their willingness to examine the gaps in knowledge about deliberate release (enumerated in the discussion above). The data call into question USDA's regulatory role.

It is questionable whether the USDA will even be able to self-regulate its own experiments and products. This was recently the case with USDA's sale of the genetically-engineered "Omnivac-PRC" used as a vaccine for immunity to a pseudo-rabies virus. The USDA had licensed Biologics Corporation to put the vaccine on the market, but halted sales after the Foundation on Economic Trends filed a petition with the USDA to suspend the license because the Department had failed to undertake an environmental impact assessment. The USDA justified the lack of environmental assessment on grounds that the product was not significantly different from other marketed products.
The issue of which federal agency regulates which bioproducts and the correlative issue of conflict of interest (both a promoter and regulator of the technology) exist for not only the USDA, but also for the National Science Foundation, the National Institutes of Health, the Departments of Defense and Energy. In addition to environmental risks, there are also hundreds of millions of dollars of public monies at risk, which have been "gambled" in federal grant support of R & D activities for biotechnology.

But government grants (estimated to have been $510.9 million in FY 1982 & FY 1983) are only part of the government subsidy, because other tax incentives, for example, limited tax partnerships (see Table) and other financial arrangements have been substantial.

Just as the environmental questions are uncertain, so too are the economic winners and losers. Nonetheless, questions of who benefits and who loses are essential to the overall discussion of the shifts in risk--from the private to the public sector--that have occurred during the commercialization of biotechnology over the last decade.
<table>
<thead>
<tr>
<th>New Biotechnology Firm</th>
<th>Partnership Date</th>
<th>$ in millions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agrigenetics</td>
<td>1981</td>
<td>$55.0</td>
</tr>
<tr>
<td>Genetic Systems</td>
<td>1982</td>
<td>3.4</td>
</tr>
<tr>
<td>Cetus</td>
<td>1982</td>
<td>80.0</td>
</tr>
<tr>
<td>Cal. Biotechnology</td>
<td>1982</td>
<td>27.5</td>
</tr>
<tr>
<td>Genentech</td>
<td>1982</td>
<td>55.0</td>
</tr>
<tr>
<td>Molecular Genetics</td>
<td>1982</td>
<td>11.2</td>
</tr>
<tr>
<td>Neogen</td>
<td>1982</td>
<td>.9</td>
</tr>
<tr>
<td>Hybritech</td>
<td>1982</td>
<td>7.5</td>
</tr>
<tr>
<td>Cetus</td>
<td>1983</td>
<td>78.0</td>
</tr>
<tr>
<td>Genetech</td>
<td>1983</td>
<td>34.0</td>
</tr>
<tr>
<td>Genetics Institute</td>
<td>1983</td>
<td>25.0</td>
</tr>
<tr>
<td>Serono Labs</td>
<td>1983</td>
<td>29.0</td>
</tr>
</tbody>
</table>

Total........................................$405.4

CONCLUSION

Arguments and evidence have been put forth to establish the different types of risks that directly relate to the commercialization of biotechnology. These risks include: crop vulnerability, environmental damage from the release of genetically-engineered organisms, regulatory conflicts of interest, a shifting of the "burden of proof" and economic risks. It has also been established that the shifting of these risks has been primarily from the private sector to the public sectors. Furthermore, it has been established that the shifting of risks involves fundamental structural changes.

For example, the increased risk with respect to crop vulnerability is associated with a fundamental change in how new varieties are bred, who owns the biological innovations and who controls the inherent "wealth" of information contained within the genetic code of plants, animals, and microorganisms used in agricultural systems. These structural changes establish the relationships between power and the exploitation of genetic resources. Through the transferal of risks, the private sector also controls the reproduction of the means and the relations of production for biotechnology. The world's biological diversity has become a commodity to be privately owned and exploited.
Such commodification is linked, in part, to the shifts in utilitarian value of biological diversity as a direct result of scientific breakthroughs. More importantly the change in value reflects a deepening gap between gene-rich and gene-poor countries.
CHAPTER VII
INTERNATIONAL CRISIS: A WIDENING GAP BETWEEN GENE-RICH AND GENE-POOR NATIONS

This chapter will explore, through a three-part approach, the international context that is driving the exploitation and control over genetic resources. Emphasis will be given to plant genetic resources.

Part I explores two aspects of biotechnology's commercialization. The first explores the link between industrialized nations' efforts to reindustrialize their economies, and the second introduces the notion of an initial division of labor that has international dimensions. These dimensions are likely to hasten and exacerbate the various gaps between the "gene-rich" economically developing countries and the "gene-poor" industrialized nations (a North-South dichotomy).

Part II details one major gap area: the lack of skilled personnel, biotechnology expertise, and breeding infrastructures in most "gene-rich" economically developing countries. The major focus is a critique of the international training efforts for plant genetic resources during 1969-1983 by the International Board for Plant Genetic Resources. Examination of the training programs gives some insight into the specific "hidden" policies for greater
monopoly control by countries which support the Consultative Group on International Agricultural Research. Part III examines the issue of "equity" over access to and control of plant genetic resources. This broader international issue initially surfaced in 1981 at the 21st Conference of the Food and Agricultural Organization of the United Nations. Since then, there has been heated debate among member nations concerning the proposal for a new international system that would shift control to Third World countries. This initiative is more commonly known as the FAO Undertaking. In addition to a Commission on Plant Genetic Resources, the Undertaking calls for an International Gene Bank separate from the current system which is directly controlled by the interests of industrialized nations.

The three parts tell an emerging story about who currently controls genetic resources and how they are controlled nationally and internationally. What is clear, is that the advancements in biotechnology--in conjunction with private ownership, commodification and state-supported commercialization--are likely to hasten the technological and human resource gaps between those countries that have the majority of the world's biological diversity and those that have the capital and technological expertise. A better understanding of this dichotomy is essential to a
restructuring of the international system that would be more equitable to the countries who could most benefit.

PART 1: BIOTECHNOLOGY'S LINK TO INDUSTRIALIZATION AND AN INTERNATIONAL DIVISION OF LABOR

During periods of economic recession, industrialized nations have renewed interest in reindustrialization to maintain their competitiveness (profit margins) in world markets. Although it is true that new projects are screened by venture capitalists for those which will generate large markets and acceptable rates of return under all economic conditions, the screening for biotechnology is both national and international in scope. This parallels, for example, developments that took place in the electronics industry. Cheaper, non-unionized labor is a major driving factor. Biotechnology has its own unique geographical preferences for new biotechnology firms.

Biotechnology suits venture capital investment (highly mobile capital) because the industry has few geographical restrictions. Many biotechnology endeavors, especially those involving gene-splicing, can be extremely small-scale. Biotechnology is linked to other technological and economic revolutions, such as computer technology. As recognized by Bluestone and Harrison in The
Deindustrialization of America (1982), these are "permissive" technologies.

Permissive technologies provide inherent technological and structural means for expansion which link them intrinsically to the economic forces of capital concentration. Bluestone and Harrison claim:

The period under discussion is characterized by almost breath-taking changes in technologies that permit managers to shift capital (and products) across long distances, and to operate far-reaching networks of production facilities. Of course, it is hardly a new development for business to want to be able to move as far as possible at the cheapest cost. But until recently, the prevailing technologies of transportation, communication, and production sharply constrained such free-wheeling mobility. (p. 115)

This posture recognizes the ways in which the technology can be geared to reduce a company's dependency on costly labor. For example, fermentation-based biotechnology industries can be as automated as breweries. As corporate capital is under pressure to expand its market share both nationally and internationally, division of labor is already occurring within the biotechnology industry.

At the national level, many routine laboratory operations are now being performed by technicians instead of Ph D scientists. As is suggested in the Hawaii Case Study (see Chapter VIII), state legislators are willing to fund vocational schools, community colleges, and state universities to meet the employment demands of high-tech
companies, which would include laboratory technicians for biotechnology. In addition, gene synthesizers and other sophisticated tools are mechanizing important aspects of the industry. Such investments in the commercialization of biotechnology are linked to larger industrializational patterns.

Bluestone and Harrison in *The Deindustrialization of America* (1982) link high technology investments to the larger systematic disinvestment in the U.S. industrial base. They established five key social problems for local communities with high-tech investment activities. The problems were: (1) wage levels for new high-tech jobs can be lower than other industrial labor, (2) unequal income distribution levels in high-tech regions, (3) increased instability of employment, (4) the high-tech industry is subject to boom and bust cycles, and (5) those high-tech industries that do succeed will continue to undergo geographical dislocations. The need for high return on investments to cover the cost of venture capital will force many companies to shift facilities or capital at faster rates. During such major shifts, the state plays a role in the industrialization process.

The state during such times of economic mobilization joins the private sector by helping to "underwrite" the risks and expand control over the division of knowledge,
labor, and power. For biotechnology, the relations of production are also shifted because organisms are used as "labor" (the "powerhouses") for production.

The knowledge-labor-power relationship is fostered to such an extent that a level of ideological legitimization is achieved in the name of industrialization. This is demonstrated through the tremendous wealth of information contained in the genetic code, that can be privately owned and controlled through patents by a small number of individuals, corporations, or universities. The important role of intellectual property laws in the expansion of jurisdical-political apparatuses was discussed earlier in Chapter V. As established in Chapter II, the commercialization of biotechnology, through the notion of the "need" for industrialization, is linked to the ideology of high technologies.

Theory suggests that with the technological shifts come changes, too, in the role of the Third World in the worldwide expansion of corporate capitalism. These changes are just beginning, but the changes are likely to come more rapidly with further internationalization of biotechnology. Such shifts can be seen in the notion of "peripheral state" within the international division of labor (Carnoy, 1984; Frobel, et al., 1978; Frank, 1978).
Martin Carnoy, in *The State and Political Theory* (1984) develops the relationship between the metropoles of the capitalist nation-state and the periphery (e.g., Third World nations). He states:

... the imperialist metropoles are the ones that develop this international division of labor and accumulate capital from it. As technological changes and changes in the organization of capitalist expansion (the transnationals, for example) take place, changing tasks are assigned to the underdeveloped countries in that division of labor and in the process of capital accumulation. (p. 187)

Frobel, et al. (1978) examine the preconditions for the worldwide expansion and accumulation of capital. They include (1) a world-wide "reservoir" labor force, (2) the development of technology that allows industrialization to be less dependent on geographical distances, and (3) the division of labor. They conclude: "... however much the transnational expansion and accumulation of capital takes advantage of national disparities... the extension and deepening of transnational reproduction nonetheless requires certain elements of an international superstructure." The role of the state is critical for expansion.

Furthermore, the state is linked to the creation and reproduction of an ideology compatible with capital expansion. Ideology plays a central role in the "masking" of questions about policy, economic development, and
structural changes. One important structural component is the role of the peripheral state.

Petras (1984) sees the promotion of industrialism as a key feature of the peripheral state. The notion of peripheral state is relevant because Third World countries do not have environmental regulations concerning the development or testing of new bioinnovations. Regulatory constraints in the United States are likely to drive field testing of bioproducts overseas. For instance, Honolulu-based Hawaii Biotechnolog Group initially planned for overseas testing of their recombinant-DNA Mediterranean fruit fly (sterility project) as a way to avoid federal regulations. Just as Third World countries became the "dumping ground" for restricted agricultural pesticides, it may also become the "testing ground" for biotechnology companies. It is interesting to note, with respect to the issues surrounding a biotechnology international division of labor, that U.S. based biotechnology companies have argued for deregulation within the United States to assure that the companies, themselves, are not "driven" overseas.

Another issue involving the peripheral state has to do with barriers to the transfer of technology and knowledge to developing countries and the eventual exploitation of cheap labor overseas by biotechnology companies. Thus, the agenda-setting for R & D will become another form
of technological dominance. It is unlikely that many underdeveloped countries will be able, over the next few decades, to master the technology and provide necessary training to meet their internal basic needs.

PART II: CRITIQUE OF IBPGR TRAINING FOR PLANT GENETIC RESOURCES

A key component to the structural inequity between "gene" rich and "gene" poor nations is the disparity in the number of adequately trained personnel who have the knowledge and skills to preserve biological diversity and to use the new biological techniques for the improvement of crop yields and livestock production. Most of the nations with an indigenous supply of biological diversity have limited capacity for gene bank management and biotechnology-based crop/livestock improvement programs.

The North-South conflict is rapidly expanding the gaps in the technological and management skills needed to maintain and use biological diversity. The underlying disparity--the inequities surrounding genetic resources--results from and is continued through the establishment and reproduction of international hierarchies (for monopoly control) within key institutions such as the Food and Agricultural Organization of the United Nations. International training related to plant genetic resources
is a key component of the hierarchy for the control over this vital international resource.

The key institution for international training is the International Board for Plant Genetic Resources, which is better known by the IBPGR acronym. Analysis of the Board's training activities during the years 1969-1983 exposes the elements of the hierarchy that exist within the international centers for agricultural research. This is particularly true for the Consultative Group on International Agricultural Research (CGIAR).

The IBPGR is one of the international centers of the CGIAR. It is an unusual center because of its standing as a trust fund within the Food and Agricultural Organization at its headquarters at Rome. The IBPGR has spent several million dollars over the last decade on international training for plant genetic resources. The Board's activities have supported efforts by industrialized nations to maintain monopoly control over the resource base.

The Board, because of its limited staff, and with no full-time person responsible for training, has had a limited involvement in the planning of training course agendas, teaching or evaluation of the courses it has sponsored. The Board has had some involvement with the selection of participants, usually by asking governments
and institute directors to nominate candidates and then screening them. Because there has been (1) little evaluation of the courses (until 1983), (2) infrequent involvement from IBPGR regional officers, (3) no up-to-date training lists, (4) often poor coordination with the hosting institution, (5) a policy to teach at the regional level, and (6) a majority of the courses have been taught in English, the IBPGR's commitment to training quality is questionable. It is only recently, since 1982, that there has been much attention given to the training of specific skills, such as gene bank documentation, plant tissue culture techniques or measurement of seed viability (see Table 4).

Training courses have been sponsored at 22 institutes and centers around the world since 1977 for 886 participants from 108 countries. Training courses, sponsored by the IBPGR within the CGIAR system, have been limited to CIAT, IITA, and ICARDA; however, CIP has run its own training courses on potato germplasm, and on-the-job training has also been sponsored at IRRI and ICRISAT (see Table 5) for listing of these international centers). There has been a strong concentration of training in Asia (44.4 percent), with the highest number coming from Indonesia, the Philippines, India, and Thailand (see Table 6).
Table 4

IBPGR Supported Training Courses

<table>
<thead>
<tr>
<th>Postgraduate Course</th>
<th>Individuals</th>
</tr>
</thead>
<tbody>
<tr>
<td>M.Sc. Degree Support</td>
<td>182</td>
</tr>
<tr>
<td>Postgraduate Training Courses</td>
<td>58</td>
</tr>
<tr>
<td><strong>General Genetic Resource Training Courses</strong></td>
<td></td>
</tr>
<tr>
<td>Exploration, Characterization, Conservation, Evaluation and Utilization</td>
<td>272</td>
</tr>
<tr>
<td><strong>Specialized Training Courses</strong></td>
<td></td>
</tr>
<tr>
<td>Specific Crops: (maize, legumes, barley, Aroid, root &amp; tuber)</td>
<td>123</td>
</tr>
<tr>
<td>Seed Physiology/Technology</td>
<td>78</td>
</tr>
<tr>
<td>Documentation /Information Systems</td>
<td>74</td>
</tr>
<tr>
<td>Gene bank Management</td>
<td>18</td>
</tr>
<tr>
<td>Plant Tissue Culture</td>
<td>22</td>
</tr>
<tr>
<td>Extension Work</td>
<td>20</td>
</tr>
<tr>
<td><strong>Study Tours</strong></td>
<td>39</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td>886</td>
</tr>
</tbody>
</table>

137
Table 5

International Agricultural Centers of the CGIAR

(Center, Location and Date of Initiation)

<table>
<thead>
<tr>
<th>Center</th>
<th>Description</th>
<th>Location</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>IRRI</td>
<td>International Rice Research Institute;</td>
<td>Los Banos, Philippines</td>
<td>1959</td>
</tr>
<tr>
<td>CIMMYT</td>
<td>International Maize and Wheat Improvement Center;</td>
<td>Palmira, Colombia</td>
<td>1964</td>
</tr>
<tr>
<td>IITA</td>
<td>International Institute of Tropical Agriculture;</td>
<td>Ibadan, Nigeria</td>
<td>1965</td>
</tr>
<tr>
<td>CIP</td>
<td>International Potato Center;</td>
<td>Lima, Peru</td>
<td>1972</td>
</tr>
<tr>
<td>ICRISAT</td>
<td>International Crops Research Institute for the Semi-Arid Tropics</td>
<td>Hyderabad, India</td>
<td>1972</td>
</tr>
<tr>
<td>WARDA</td>
<td>West African Rice Development Association;</td>
<td>Monrovia, Liberia</td>
<td>1971</td>
</tr>
<tr>
<td>ICARDA</td>
<td>International Centre for Agricultural Research in Dry Areas</td>
<td>Lebanon.</td>
<td></td>
</tr>
<tr>
<td>IBPGR</td>
<td>International Board for Plant Genetic Resources;</td>
<td>Rome, Italy</td>
<td>1973</td>
</tr>
</tbody>
</table>
Table 6

Number of Training Positions Supported by IBPGR
Training Courses, Study Tours and Fellowships for 108 Countries by Region for 1969-1983

<table>
<thead>
<tr>
<th>Regions</th>
<th>Total</th>
<th>% Of Worldwide Training</th>
</tr>
</thead>
<tbody>
<tr>
<td>Africa</td>
<td>125</td>
<td>14.1</td>
</tr>
<tr>
<td>Asia</td>
<td>393</td>
<td>44.4</td>
</tr>
<tr>
<td>C. &amp; S. America</td>
<td>159</td>
<td>17.9</td>
</tr>
<tr>
<td>W. European</td>
<td>98</td>
<td>11.1</td>
</tr>
<tr>
<td>E. European</td>
<td>13</td>
<td>1.5</td>
</tr>
<tr>
<td>Mediterranean</td>
<td>60</td>
<td>6.7</td>
</tr>
<tr>
<td>Pacific Islands</td>
<td>20</td>
<td>2.3</td>
</tr>
<tr>
<td>Other</td>
<td>18</td>
<td>2.0</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td>886</td>
<td><strong>100.0%</strong></td>
</tr>
</tbody>
</table>
IBPGR training efforts to date have not served well the specific needs of economically-developing countries (many of which are gene-rich), but have been designed partially to identify individuals to assist with IBPGR's collecting objectives; training goals and objectives have been linked closely to collecting policy. The IBPGR has systematically "mined" gene-rich countries to extract resources into gene banks located for the most part in the economically developed countries and other CGIAR centers such as the International Rice Research Institute (IRRI). The IBPGR defends itself by claiming that it leaves duplicate samples in the host country, but a majority have no proper storage facilities to house the material, thus it is quickly lost. Furthermore, without the infrastructure to integrate desired genes into production systems, the "raw" germplasm is of little value unless it is integrated into local production systems. The IBPGR is the CGIAR's key actor in the exploitation of genetic resources. In conclusion, it is no longer a matter of speculation that the CGIAR has spent millions of dollars in forming a "network" for collection.

The need for good quality international training is essential to more equitable exchange and use of germplasm and genetic information. The constraints are political. Optimistically, education could be a point for convergence
for a counter-hegemonic project for Third World countries. Education is the key to empowerment. The "breeding pipeline," the continuum from collection to final breeding (see Chapter VI for further details), is complex and involves many diverse skills. Analysis of international training gives insight into other international issues.

The broader international issues surrounding plant genetic resources surfaced at FAO's 21st Conference, which took place in November of 1981 (Mooney, 1983:25). The focus of the debate took shape in FAO Resolution 6/81, which came out of an initiative from southern countries (with leadership from Mexico) to formulate a strategy to regain control over plant genetic resources.

Earlier in the spring of 1981, the Mexican government had suggested the idea of creating an International Gene Bank separate from the U.S. National Germplasm System and the repositories of the CGIAR system. This argument was based in part on estimates at the time which showed that as much as 92 percent of plant seeds stored in gene banks were under the political control of the North, with the U.S. government repositories holding almost one fourth (Mooney, 1983:25-29). The 6/81 resolution survived intense diplomatic pressure by the United States and Canada to crush it. The resolution called for a drafting of a legal international convention to explore the feasibility of an
International Gene Bank. These were the earlier events which led to the birth of a highly controversial document that was coined the "Undertaking." It was officially adopted in November of 1983 by the 22nd Conference of the Food and Agricultural Organization of the United Nations.

PART III: THE CONTROVERSY OVER THE FAO UNDERTAKING

The Undertaking requested that the FAO's Director General examine and prepare a draft for an international convention with legal provisions to ensure that global plant genetic resources are fully and freely available. The Undertaking was based on the belief, held by most, that there is currently no international agreement for ensuring the conservation, maintenance, and free exchange of genetic resources from existing germplasm banks. The Director General (FAO, 1983:6) concluded in his report to the assembly that:

Whether or not restriction on the availability of plant genetic resources are more widespread than has so far become apparent, the fact remains that there has been no general commitment on the part of the governments or relevant institutions to apply the principle of free exchange and to ensure that this principle is adequately reflected in basic legal texts.

Some at the conference went as far as saying that the current system is not working (just from technical criteria alone), and that it does not function as a coherent
international network, but only serves the interests of the developed countries in general and the Consultative Group on International Agricultural Research (CGIAR) in particular.

Critics of the International Board on Plant Genetic Resources (IBPGR) claim that it has been biased toward priorities which inherently serve the *ex-situ* interests of the CGIAR. Regardless of limits in scope, any broader institutional program will need more than the IBPGR's annual budget of some $4 million. Fundamental to a successful restructuring will be enhanced germplasm integration and accessibility. Yet, access is meaningless unless the material can be used in a successful enhancement program. Still, countries without their own gene banks could take advantage of an international system which coordinates worldwide breeding, seed bulking, and distribution efforts.

Foremost at issue during the debate was the question of who will control genetic resources in the future? To a large extent, this is a political question; it is a political question full of deep emotion. Delegates from lesser economically developed countries felt strongly that genetic resources are intrinsically linked to their concerns over food production and security. In addition, some countries, for instance, Mexico and Spain, held the position that the developing world has supplied the "raw" genetic resources
to the developed countries without compensation, and too often these same countries have been unable to buy back expensive commercial seed. This has been a source of "inequity" that has spurred the international debate. The United States Government, during these initial debates on the Undertaking, took a strong stand against the Undertaking and the establishment of a FAO Commission on plant genetic resources.

The U.S. was one of a few countries to completely oppose the Undertaking and has justified its position by saying, "If it ain't broke don't fix it" (direct reference to IBPGR). The U.S. Department of State and the Office of International Cooperation and Development (OICD) of the USDA have taken the lead role in "depoliticizing" the issues of genetic resource ownership, the impacts of patents, and the biased policies of the IBPGR. It is vital to examine the dimensions of the efforts to depoliticize the issues.

CONCLUSION

It is a key element of the hegemonic process to keep the issues of equality and the politics of corporate monopoly of agricultural inputs and outputs depoliticized. The main "tactic" is to discount the thousands of years of breeding work that went into the production of traditional
varieties. At the same time, economically developed nation-states and transnational corporation (TNC's) claim that the "raw" germplasm (also including wild plants) is common property, which should be freely accessible worldwide. Under this practice, germplasm only begins to take on commercial value once it has been enhanced through, for example, breeding programs or genetic engineering.

It is essential that a historical perspective is maintained that gives intrinsic value to "raw" genetic resources. Such a historical perspective would also include a total restructuring of future goals for the management and use of germplasm. Such a perspective would also expose the repeated need for industrialized nations to expand their markets overseas, to locate a cheaper international labor supply, and to find foreign areas to test their products that have potential risk to human health, livestock or the environment. As biotechnology continues to further commodify genetic resources toward monopoly control, a classic division of labor (both national and international) is already visible and likely to intensify.

Related to the issues of inequity over access, ownership and control of genetic resources is the lack by most gene-rich countries of skilled personnel, biotechnology expertise, and breeding infrastructure. Examination of the
IBPGR training policies and practices leads to the conclusion that for more than a decade it has not served well those countries that are gene-rich but economically underdeveloped. Evidence suggests that the IBPGR has been instrumental in developing policies to extract key germplasm from strategic countries for the continued stability of monocultured crops in industrialized countries. The Board's collaboration with other international centers calls the entire CGIAR system into question. Furthermore, it is not surprising that the United States has chosen to fight vigorously the initial Undertaking, the functioning of the FAO Commission on Plant Genetic Resources, and the establishment of a new international system.

Sadly, the long-term objectives and the inherent objectives of the Undertaking have not been adequately addressed. Unless the United States and other economically developed nation-states change their worldviews, their continued efforts to depoliticize the issues will only fuel the controversy. In addition, the emergence of biotechnology as an avenue to maintain the corporate competitive edge in world markets, the subsequent need for private control of genetic inputs and processes, and strong lobby interests (e.g., the American Seed Trade Association) are factors that mitigate against a compromise.
However, by better understanding the structural elements, contradictions, and political hierarchies behind the controversy it may be possible to move more quickly on innovative ways to restructure the international germplasm community.

The position maintained by the block of Third and Second World countries (with support from some European nations) contains a major contradiction. The initial 6/81 resolution was based largely on the premise that plant germplasm should be considered a "common heritage," thereby ensuring "full and "free" access to all varieties and plant breeding lines. The North has always considered the "raw" genetic resources and traditional varieties to be "common heritage." The confusion over the "common heritage" issue--as it was linked to commercial varieties--kept some key structural issues from being addressed. A broader discourse would have further exposed the significance of biotechnology developments and the expansion in intellectual property laws beyond plant breeders' rights. Access to germplasm as seeds is only a small dimension of biological diversity's wealth as information. Questions of equity and policy formation can be advanced by a discourse that speaks to the inherent power relationships, modes of domination, and structures of control.
CHAPTER VIII
HAWAII CASE STUDY

INTRODUCTION

The purpose of this chapter is to examine the preconditions and developments in Hawaii, since the early 1980's, that have affected and continue to affect the research, development, and commercialization phases of biotechnology. In part, this chapter is an extension of the theoretical arguments made in earlier chapters, because of the relationships established between the ideological developments of high technology and those specific to biotechnology. For this reason, aspects of high technology developments are discussed that set the preconditions for biotechnology. Descriptive material and historical information is used to support the key assumption of this chapter: that biotechnology is being "sold" in the State of Hawaii as one of the so-called high technologies.

Hawaii is an excellent location to study these developments because the industrial scale of high technology, including biotechnology, is still small, thereby allowing easy access to key people, information, and meetings. Hundreds of hours were spent during the dissertation process attending meetings, related to high
technology developments in general and biotechnology specifically, sponsored by private companies, state executive agencies, the legislature, and the University of Hawaii. These meetings and materials generated from them were the main source of information for this chapter. Methodologically, the chapter argues that through an understanding of the historical/descriptive context it is possible to better understand the power relations that emerge with the commercialization of a technology. Inferences about power, once understood at the state level, are assumed to be applicable to other states or to the larger national and international developments for biotechnology. This chapter will only focus on events in Hawaii, and it is further assumed that the chapter will be read in the larger context of the entire dissertation.

The chapter highlights common themes that reinforce the major arguments of the dissertation: (1) that the State (including the State of Hawaii) plays a major role in the shifting of risks from the private to the public sector as a precondition to the commercialization of biotechnology, (2) that intellectual property laws are reinterpreted to accommodate this commercialization (in this case, the expansion of confidential business information), (3) that biotechnology will undergo divisions of labor as it commercializes, and (4) greater hegemony is established
that is likely to accelerate the extinction of species and cause other environmental damage as the result of deliberate release of genetically-modified organisms.

Furthermore, "gene-rich" countries that are lesser economically developed (the notion of periphery as developed in preceding chapter) have similarities to the Hawaiian case, because much of the land in these areas is controlled by a small number of landowners, and they share the probable phenomenon of mass extinction of species. It is likely, too, that the underlying political issues are analogous.

The chapter explores the future activities and companies moving into the high technology parks and incubation centers, the legislative arena that helped shape some of these developments, and Hawaii's fledging biotechnology industry.

Specific questions are raised in this chapter. Some include: What kind of companies are likely to move into the high technology parks that are constructed or planned? What role will the community colleges play in developing a labor pool to fill the needs of high tech companies? What Hawaii Revised Statutes will be revised or what new laws will be passed to accommodate high technology developments in the State? To what degree will the U.S. military dominate so-called high technology expansion in Hawaii? To
what extent will the commercialization of biotechnology further accelerate the extinction of unique species in Hawaii? Questions such as these are asked and examined in this chapter.

BACKGROUND INFORMATION

Since the early 1980's the State of Hawaii has attempted to support the development of high technologies. The State executive and legislative branches have played a key role in creating a "high tech environment," in hopes of attracting high technology companies to Hawaii. This environment includes changes to tax laws, starting new educational programs, building high-technology parks and innovation centers. This environment also includes a tremendously biologically unique and geographically isolated island system.

In addition to such infrastructural considerations, the State of Hawaii, through initial seed money, has accepted much of the legal liability under current tort laws. In other words, the State of Hawaii has underwritten the risk for capitalist expansion of so-called high technologies in Hawaii. The acclaimed benefits to the state--more better paying jobs, environmentally-compatible industries, and state revenues--are still questionable at this time, even when evaluated within the narrow confines
of cost-benefit analysis. Evidence suggests that the State of Hawaii, in close association with venture capitalists, has supported the notion of a high-technology ideology for the commercialization of biotechnology in Hawaii.

The concept of high technology was defined as a new class of business ventures that would bring jobs to Hawaii and help to diversify Hawaii's economy. Hawaii was sold as having a special niche: potential future space-port, ocean resources, tropical agriculture, telecommunications, and an educational focus for Asia and the Pacific.

Certain companies such as Intellect, Inc., were highlighted as model companies. Such catalytic efforts would then attract companies to fill the high technology parks under design and construction. To help attract companies, infrastructural changes were begun. They included changing tax laws, stepping up State appropriations for quasi-public institutions, e.g., PICHTR, and gearing educational programs to fit the needs of future high technology workforces. The concept of high technology must be questioned.

The "lumping together" of diverse technologies, for example, space, computer, telecommunications, biotechnology, into the generic category of high technology limits the scrutiny of each of these endeavors. As previously discussed in Chapter II in greater detail, this
type of conceptualization poses major economic development projects as technological advancement goals. High Tech Parks are sold to the community on the assumption that these technological advancements are needed to keep pace with such states as California and Massachusetts. The separation of possible disparate economic impacts or environmental harm, for example, from the issues of technological progress by advocates of the high tech package makes it more difficult to critique the advantages and disadvantages of rapid commercialization of biotechnology in Hawaii.

Selling of the high tech concept can be used to create the conditions for venture capital and federal-military funds moving into the State. Already, millions of state tax dollars have been spent to pay for high technology infrastructure. This includes a degree of social acceptance by the public, legislators, the President of the University of Hawaii and the Chancellor of the community colleges. When sold in this fashion, the risks underwritten by the State of Hawaii, are not discussed. Three different categories of potential risk will be discussed: (1) damage to the unique Hawaiian environment, (2) weakening of unionized labor, and (3) the loss of university professors to private industry.
The single greatest risk involves the vulnerability of the State of Hawaii to be hit by "deep pocket" liability suits (under tort law) should accidents occur that cause harm. This may be especially true when state employees are involved in the research or testing phase of high technology projects. At this time, there are no formal mechanisms in Hawaii for reviewing experiments involving genetic engineering of plants or microorganisms. It will not be long before field testing will be conducted in Hawaii; Calgene, in the fall of 1988, asked for a permit to conduct field testing of genetically engineered tomatoes (expressing polygalacturonase antisense gene) on the Island of Molokai. Deliberate release is likely to focus on bioproducts that need to be tested in a "tropical" ecosystem. The financial and environmental magnitudes of these risks are still largely undetermined.

Gearing-up of high technology industries in Hawaii will be a major force in the furtherance of a labor pool that is non-unionized. The creation of a high-tech industry that replaces the agricultural labor force will be significant in diminishing the power of labor unions in Hawaii. It is unlikely that there will be a high-tech labor union formed, in the near future, to bring together the different types of industries such as electrical engineering, space, biotechnology, and communications.
Further high-tech advances will impact the structure of basic research in Hawaii. The division between public and private will diminish as university professors and graduate students enter into high-tech ventures. Even though guidelines are being established at the university to reduce the degree of conflict-of-interest, such a trend will not reduce the decision-making process toward projects that will return a high rate of profit. The profit motive—as the principal criterion—will direct the use of technology breakthroughs. Furthermore, some of the best molecular biologists are likely to be less involved with teaching. Hence, a shift toward massive support of high-tech on campus will impact the quality of classroom education. It is likely, too, that some professors will start private companies to do military research that would otherwise not be done on campus. The contract for remote sensing research awarded to SETS (a private company) by a defense agency is one example: the historical relationship between SETS and the Planetary Geosciences Division of the Hawaii Institute of Geophysics' laboratory facilities, faculty, and graduate students highlights such questionable linkages.

But perhaps, more importantly, the changes in land use, tax laws, and legal changes will set the course for
overall economic development in Hawaii that will continue to degrade its fragile ecosystem.

HAWAII'S GENETIC DIVERSITY AND PRESERVATION PROGRAMS

Hawaii is estimated to have some 2,600 endemic species, but the State also has more recorded endangered and extinct species than any other island or country. The Committee on Research Priorities in Tropical Biology (NAS, 1980) of the National Research Council of the National Academy of Sciences recognized this problem:

The destruction of the Hawaiian environment is proceeding with great rapidity, and consideration has for some time now been given to schemes to replace native forests with plantations of such trees as Mexican ash and Australian Eucalyptus so that the state could be spared the necessity of importing lumber and pulp from the mainland. Such exotic animals as pigs and goats are ravaging the vegetation, even within the national parks and supposedly conserved areas. The Hawaiian Islands are one of the greatest natural laboratories of evolution in the world, and government agencies (federal and state) should work to conserve the biota and provide adequate funds to study it.

The degradation of Hawaii's environment shows clearly the inherent conflicts over land use. For example, Mouflon sheep were introduced to the Island of Hawaii in the 1960's to genetically "upgrade" the stock of wild sheep for hunting. Without an eradication program on Mauna Kea, it is likely that the honeycreeper will go extinct. Conservationists have been fighting the hunters in federal court.
since 1978. It has been estimated (Ramsey, 1983) from Fish and Wildlife surveys that 60 percent of Hawaii's original bird species have become extinct since humans arrived on the islands, and an additional 20 percent are endangered. Extinction pressure on species dates back to the Hawaiian civilization when royal garments used colorful feathers from forest birds. Later, in the nineteenth century, scented sandalwood was endangered by foreign demand.

Although Hawaii is a small state, it has a diversity of ecosystems. Not only are species threatened, but entire ecosystems are also under pressure. A number of programs have been established to conserve species and their natural environments. The USDA-Forest Service's Hawaii Forestry Support Program, the Department of Commerce/State of Hawaii's Estuarine Sanctuary Program, Hawaii's Marine Life Conservation District, Bishop Museum activities, and The Nature Conservancy (TNC) are among those better known.

The TNC began its program in 1968 with the goal to conserve the full biological diversity of the islands. In its initial five year plan, fourteen potential preserves were identified. In 1979, TNC launched its $3 million Endangered Hawaiian Forest Bird Project as a comprehensive conservation program and in 1983, initiated an in-house inventory based on the "natural heritage program" of Hawaii's flora and fauna. The National Research Council
(NAS, 1980) noted that the "last complete flora of the islands was published in 1888, and no comprehensive guide to the native and introduced plants is available."

The first decade of activities was marked by "failure" (Little, 1982). It proved difficult to establish well-protected preserves in Hawaii, in part, because of the cost and difficulty in obtaining land. Once established, there continued to be problems with feral animals. For example, the invasion of pigs resulted in further degradation of the 5,500 acre Kipahulu Valley Reserve. The future success of TNC may well depend not only on its ability to raise funds, but also on its ability to work with large public and private land owners.

Once familiar with the Hawaiian case, one is left with this staggering question: If the United States, with all its resources, has failed and continues to fail in any major effort to preserve the genetic diversity of the Hawaiian Islands, what can the United States expect from other countries that have fewer resources and greater pressures to exploit the biological systems that harbor the wealth of biological diversity?
WHAT KINDS OF COMPANIES ARE LIKELY TO MOVE INTO THE HIGH TECHNOLOGY PARKS?

It could be argued that companies will be attracted because Hawaii has some comparative advantages over other U.S. states or nations. Does Hawaii offer any specific advantages?

Hawaii's most evident advantage is its location in the subtropics. This may attract enterprises involved with field testing genetically engineered bioproducts for tropical land- and ocean-based cultural production systems. Hawaii's wealth of diverse endemic species and ecosystems offers an array of unexploited genes and environments for basic and applied research. Hawaii has a number of pests, for example, the Mediterranean fruit fly, the presence of which allows for the testing of sterilization research that cannot be conducted on the U.S. continent. Hawaii's geographical isolation also offers a "barrier" for testing products that might spread in the environment. This might allow for development of biological weapons by the military or the testing of horizontal transfer of recombinant DNA products. Other political issues will influence what kinds of high technology companies might relocate to Hawaii.

It is likely that major foreign policy issues will play a key role in the establishment of a high technology
industry in Hawaii. For example, balance of trade deficits and quota negotiations between the United States and Japan have influenced Japanese donations to basic research grants for high tech ventures in Hawaii. On May 26, 1987, Governor Waihee accepted a check for $1 million from the government of Japan to support the Pacific International Center for High Technology Research (PICHTR); this was the first foreign gift to PICHTR. U.S. Senator Spark Matsunaga said: "Japan's contribution today to PICHTR, based in Hawaii, represents the first visible move toward a cooperative U.S. and Japan venture into high technology research, agreed to by President Reagan and Prime Minister Nakasone in May 1986" (PICHTR, 1987). Key to the May 1986 discussions between President Reagan and Prime Minister Nakasone were balance of trade deficits and quotas. Macro-political issues--such as the number of Japanese automobiles that can be imported into the United States--are likely to continue to influence the role and involvement of governments such as Japan and Taiwan in Hawaii's high technology developments. But within U.S. borders, the U.S. military is likely to be the single greatest influence.

Stated more strongly, the U.S. military-industrial complex is likely to dominate high technology developments in Hawaii. The Reagan Administration's Strategic Defense
Initiative (SDI) will shift millions of dollars into Hawaii. For instance, a "Star Wars" laser was tested from the summit of Haleakala on Maui in 1983 by the U.S. Air Force. The laser was fired from the Optical Station in conjunction with the launching of a modified Terrier-Malemute rocket from the Pacific Missile Range facility on Kauai. Future laser testing facilities are being constructed on the island of Hawaii (Addison, 1986). In a 1983 study by Maui consultant, John Decker, about 55 percent of the 142 organizations and individuals involved in high technology activities at that time were military related. With current military reorganization within Hawaii and future development of a "space port" on Hawaii, military high-technology developments are likely to continue to escalate throughout the State. It is likely that some high technology companies that will move into the planned high tech parks will assemble electronic hardware for military communications equipment.

HAWAII'S FUTURE HIGH TECH PARKS AND INCUBATION CENTERS

An MPI Marketing Research study concluded (HTDC, 1984:33) that by the end of the century, Oahu could accommodate two 300 acre high technology parks, but HTDC recommended at the time that the State of Hawaii "seek to
develop at least one high technology park on each major island." However, due to the impact of large parks on the environment, a number of smaller sites have also been considered. A major criterion is the presence of a trained and dependable workforce suitable to the various high technology companies.

The first high technology park site to be developed was the 256 acre Mililani Town, Oahu site owned by Castle & Cooke and marketed by Oceanic Properties under the direction of Kent Keith (former head of the State Department of Planning and Economic Development). Constructions costs were estimated (1984) to be $22 million dollars to provide water, utilities, and roads. Permitted site uses will include administrative offices, manufacturing and assembly, marketing, and product testing. A number of companies, for example, SETS and Inteleton, have moved their operations to the high tech park. Also on Oahu, the second major project has been the conceptualization of the Manoa Innovation Center (MIC) for which the Hawaii Legislature appropriated $60,000 for design in 1987 and more than $6 million in 1988 for construction of the 42,000 square foot facility.

The MIC is being built around the notion that it can help to incubate new business ventures by subsidizing rents and allowing access to university facilities, faculty, and graduate students. In addition, it is believed that
innovation centers allow for centralized management assistance and facilitate the sharing of ideas and experience among entrepreneurs. Such support, theoretically, increases the chances of financial success during the initial years of product development and competition. The MIC has been slated to be the home for PICHTR, the Research Corporation of the University of Hawaii (RCUH), and facilities operated by the Hawaii Institute for Electronics Research (HIER).

The feasibility analysis and development plan funded by the Hawaii State Legislature for the development of the MIC was prepared by the Washington, D.C.-based company, Pryde, Roberts and Company (December, 1986). Major anticipated benefits highlighted in the plan include the creation of 100 to 150 new jobs (at any given time) with a total of 500 to 700 jobs over a 20-year period (assuming that successful firms move out into the community after a 4-year incubation period). It is hoped that MIC will help diversify and expand the economic base of Hawaii.

Analysts contacted 21 firms to survey their interest in occupying space in the incubator facility; only nine expressed an interest. Disadvantages to doing business in Hawaii included shipping and communication costs, labor and workmen's compensation costs, and isolation from markets. As the report clearly establishes, the University of Hawaii
will play a special role in the success of the innovation center. This will be achieved through the establishment of interrelationships between the University of Hawaii and MIC.

General business consulting is likely to be the main interrelationship. Faculty consulting would likely be coordinated through the Pacific Business Center Program, and hiring/use of graduate students would probably be handled on an *ad hoc* basis. Engineering design and prototype development were two identified areas. Technology transfer and access to information were two other major components of the collaboration. The University is currently reviewing state conflict-of-interest laws and patent/copyright policies (Simone, 1987) to make it easier to benefit from commercial applications. University of Hawaii president, Dr. Albert Simone, is involved in developing guidelines and standards for faculty. However, for-profit efforts will be encouraged where faculty or the university can take partial equity shares in new high technology enterprises. Even if there is agreement over what the ethical standards should be, the new institutional arrangements will set the course for many high technology goals, many of which will be determined purely by cost benefit analysis and profit objectives. The University of Hawaii has an annual budget of $350 million.
The report did not examine the legal and social implications of the MIC, other than its impact on property taxes/values and on traffic on the surrounding neighborhood. Conflict-of-interest and intellectual property matters are central to the debate over the development of the MIC. In addition, the Biotechnology Division of PICTHR is likely to be housed in the future MIC facilities. Under that assumption, it is likely that laboratory space will be used for genetic engineering. Currently, for example, PICHTR-sponsored research is involved with developing genetic engineering techniques for genetic sexing of the melon fly, *Dacus cucubitae*. However, any genetic engineering work requires adequate biological and containment approaches. Projected equipment costs for the facility are insufficient to establish containment laboratories. Such oversights raise questions about what the facility can and should be used for once constructed. Perhaps, genetic engineering, regardless of containment levels, should not be conducted in a residential neighborhood (see previous discussion on the risks for the recombinant DNA research and the deliberate release of genetically engineered organisms).

Although sites are being considered for neighbor islands, the Maui Economic Development Board has moved quickly on the 300 acre site at Kihei. The site had a land use
designation changed from agricultural to urban. On the island of Hawaii, high tech developers see an Ocean Science Park being developed in conjunction with the National Energy Laboratory of Hawaii (NELH) at Keahole Point. This is the site of the Ocean Thermal Energy Conversion (OTEC) project, which yields nutrient-rich ocean waters for aquaculture projects. Other possible sites include the University of Hawaii Hilo campus, and several sites on Kauai. Although there has been some coordination through the HTDC, there has been tension between developments on Oahu and those on Maui.

The reality is that the two sites may be competing for limited high technology companies that are willing to move to the State. Developments on Oahu are primarily being guided by State organizations, whereas the Maui site is being spearheaded by county-business groups. For this reason, there is likely to be continued tension between the two approaches.

HIGH TECHNOLOGY DEVELOPMENTS: THE LEGISLATIVE ARENA

The Hawaii State Legislature introduced 27 bills related to high technology developments in 1983 and 1984. The bills introduced covered a broad spectrum of economic areas such as: special purpose revenue bonds, increases in the Capital Loan Program, appropriations for high
technology entities, e.g., PICHTR and HTDC, changes in investment tax credit and excise tax, and measures to increase the flow of venture capital into the State. Even the establishment of a high technology high school and changes to curriculum were considered at the University of Hawaii Manoa and Hilo campuses. In addition, H.C.R. 138, H.D. 1 of the Twelfth Legislature asked that HTDC streamline land permit and development procedures for high technology developments and to propose business and financial incentives to attract high technology companies.

The HTDC in its Statewide Strategy for High Technology Growth (1984) found three main constraints to high technology development in the State of Hawaii. They are: (1) the Use Tax, (2) Manufacturing and Excise Tax on goods sold for out-of-state use, and (3) zoning procedures. The report also suggested a 5-10 percent corporate tax exemption for firms moving to Hawaii.

What is evident in these financial shifts is an active State involvement in the lowering the financial risks for companies to move to Hawaii and begin high technology ventures. The period 1985-1988 was also a busy time for introducing bills to promote the high technology developments.

Some important bills supporting the commercialization of high technologies were signed into law by the Governor
during this period. For example, House Bill 221 (Act 112, 1985) requires that the High Technology Development Corporation establish policies and procedures to ensure that industrial parks comply with development rules and establish fines. Senate Bill 1855 (Act 190, 1986) authorized the issuance of special purpose revenue bonds to assist the Cyanotech Corporation to finance biotechnology activities at the National Energy Laboratory at Keahole Point on the Island of Hawaii. House Bill 1227 (Act 244, 1987) appropriates funds to the Department of Planning and Economic Development for a feasibility study of establishing a major space technology industry in Hawaii. The bill also provides support to the University's Hawaii Natural Energy Institute to assure that hydrogen fuel will be available for spaceport development. House Bill 1500 (Act 241, 1987) establishes a "new industry training program" for local residents to work with businesses relocating to or expanding in Hawaii. Most of the businesses which qualify are those in the class of high technologies, e.g., space, biotechnology, and electronics. Senate Resolution 131, SD1, 1987, requested the Honolulu Community College to conduct a study of job training needs for mid-level personnel for high technology employers.

The Fourteenth Legislature saw a better balanced package of legislation regarding the continuum between
promotion and protection for biotechnology. This effort began with the adoption of H.R. 193, H.D.1, in 1987, which requested the Department of Health to form an interagency task force to plan a strategy for appropriate monitoring of R & D activities for deliberate release of genetically-engineered organisms. It further asked that lines of authority and procedures be developed as a safeguard in case of a biological accident. The Department of Health submitted its interim report in December 1987, but it failed to address the legislative intent of the resolution.

The first meeting of the interagency Ad Hoc Committee on Genetically Engineered Organisms (CGEO) took place on November 6, 1987. The committee agreed that it was the appropriate time to establish state policies (DOH, 1987). Although the CGEC was unable to complete its report to the Legislature it did, however, set a number of objectives.

The report included the following objectives: (1) review national biotechnology R & D activities and their potential health and environmental impacts, (2) review Hawaii's biotechnology R & D activities and their potential health and environmental impacts, (3) assess the adequacy of federal and state guidelines, regulations, and programs to address potential adverse health and environmental impacts from biotechnology in Hawaii, (4) develop conclusions and recommendations regarding the adequacy of
existing guidelines, regulations, and programs to prevent adverse health and environmental impacts from biotechnology in Hawaii, and (5) record and distribute committee findings and recommendations. The final DOH report in response to H.R. 192-87 was submitted to the Legislature in early 1989.

Because of the inability of the CGEC to make progress in 1987, the 1988 Legislature adopted S.C.R. 117, H.D. 1, to urge the committee to include environmental concerns, state agency responsibilities, and proposed legislation in its final report. It resolved that the CGEO consider which state agencies or departments should be involved in the review of proposed testing or commercialization of bioproducts, project information gathering and personnel costs, and develop additional legislation. In addition to the two resolutions related to the Ad Hoc Committee, there were hearings on H.B. 2201.

The original purpose of H.B. 2201 when introduced was to require any applicant to a federal agency for a permit or approval of any bioproduct to submit (at the same time) one copy to the Department of Health. In addition, genetically modified organisms were added as being subject to health rules for public health and safety. In the course of hearings, the bill was amended in two substantial ways.

First, "basic research relating to genetically-modified organisms" was deleted, as a necessary area for
which copies of applications must be sent to the Department of Health. Secondly, "genetically modified organisms" was deleted as a subject area for rules. The amendments clearly show interest group pressure to lessen the regulatory nature of the bill. The need for a State of Hawaii regulatory role was dismissed by the biotechnology interest groups.

The bill was first heard jointly before the House Committees on Health and Planning, Energy, and Environmental Protection, and then by House Judiciary and finally by Senate Health. Testimony was heard from the Hawaiian Sugar Planters' Association, College of Tropical Agriculture and Human Resources, Hawaii Biotechnology Group, Hawaii Democratic Movement, Sierra Club, and the Departments of Health, Agriculture, and Business and Economic Development. The transition in testimony by the Department of Health (DOH) shows most clearly the pressures by the business community to weaken or kill the bill.

In all hearings, DOH testified in support of the bill's intent on grounds that, if enacted, the measure would alert DOH to the development and use of genetically modified organisms. Their first testimony stated that the department would be alerted "without placing a burden upon these important scientific and economic activities." This language was dropped in the Senate, along with the
additional language that "the Department of Health is not in a position to adopt rules at this time." In short, due to pressure, the department backed off its earlier position that would have included rule-making authority. The issue of rule making authority was most strongly questioned by the Department of Business and Economic Development (DBED).

DBED attacked the bill on grounds that it was premature and that the language, "genetically modified organisms" was inappropriate. DBED's testimony argued that the Ad Hoc Committee had yet to adequately address the various issues, such that regulation should be deferred until submittal of the final report to the 1989 Legislature. DBED testimony stated:

Hawaii's biotechnology industry is small but promises great potential by increasing agricultural productivity, eradicating fruitflies, and generating new advances in biomedicine. Premature regulation could stifle this new industry which we wish to promote.

Fear of any regulation was sufficient for the bill's amendments. Pressure on DOH was sufficient for its posturing. Such an outcome raises a number of issues and questions.

First, should DOH have rules over a technology as powerful as genetic engineering? Under Section 321-11, Hawaii Revised Statues, the department may adopt rules as it deems necessary for the public health and safety for such areas as laundries, hospitals, laboratories, milk,
resturants or theatres. Should it not have the authority to make rules over a technology that involves the genetic transformation of agricultural products, pesticides or therapeutic drugs? Not only is the safety of these products at issue, but also the direct and secondary impacts of these products on the environment. A discussion of environmental concerns must also take into account the current limitations for institutional arrangements here in Hawaii.

For example, the current "Hazardous Materials Storage and Handling Guidelines" (MTP, 1988) developed for Mililani Technology Park do not apply to infectious waste management or to containment of biologicals that have been genetically-modified. These are significant gaps in the guidelines that were originally designed to prevent hazardous materials from getting into the ground water or being released into the atmosphere. Furthermore, although park occupants shall notify the Department of Health of having submitted a hazardous materials management plan to the Mililani Park Design Committee, there is no procedure for the department to review them. In this case, especially where genetically-engineered organisms are involved, notification without outside review is insufficient.
Besides environmental issues, there are also issues of liability, because the State of Hawaii seeded much of the initial basic research, development, and commercialization activities. The disbanding of the U.H. Institutional Biosafety Committee in the early 1980's leaves the state legally vulnerable. Since that time, there has been no formal peer review of biotechnology research on campus. Right of review threatens many biotechnologists' sense of doing business. Testimony on H.B. 2201 by the Hawaii Biotechnology Group showed such posturing.

The idea of genetic engineering can provoke an emotional response, conjuring images of white-frocked scientists playing God and placing the world at peril. In fact, genetic engineering is not a radical departure from other scientific techniques. It should be viewed as an alternative to the traditional animal, plant and microbial breeding methods that have given us high-lysine corn, stunning orchids and beefaloes.

Institutional arrangements must also be critiqued at the national level.

The promulgation of the federal "Coordinated Framework" (1986) and the 1987 NAS position paper ("Introduction of Recombinant DNA-Engineered Organisms into the Environment: Key Issues") are two excellent examples. Such documents become the gospel of industry that there is enough regulation and that the industry can now go full steam ahead. These so-called "blue-ribbon" efforts become the platform from which it is stated that there is "evidence" that no
unique risks exist, that the risks are acceptable, and that there is adequate scientific knowledge. However, gaps in our knowledge are substantial, and there are strong justifications for the State of Hawaii to know what biotechnology activities are ongoing and planned.

The above mentioned federal "Coordinate Framework" is structured to eliminate any oversight and regulatory authority at the state level. For environmental review, this approach assumes *a priori* that risks can be adequately considered in Washington for all geographic locations throughout the United States. This assumption should be strongly questioned. Bioinnovations released into the Midwest may have different ecological consequences in Hawaii. The fragility of the Hawaiian ecosystem, the high rate of species extinction, and the lack of knowledge about Hawaiian ecological niches all suggest that some level of review and additional regulation are needed for the deliberate release of genetically engineered organisms into Hawaii. The current regulation of exotic species by the Department of Agriculture, also, strongly argues in favor of state-based scrutiny.

Although the Hawaii Plant Quarantine Law (Chapter 150A, HRS) and administrative rules and policies deal with importation and release of plant and animal species originating outside Hawaii, there are no state statutes or rules
to regulate the deliberate release of genetically-altered species in Hawaii. Some control by state agencies is warranted because even single gene changes can alter a host's pathogenicity. At the state level, public policy should demand reasonable levels of review and discussion of "burden of proof" and liability issues. Hawaii's emerging biotechnology industry raises these fundamental concerns.

HAWAII'S BIOTECHNOLOGY INDUSTRY

The Hawaii Biotechnology Group (HBG), the Pacific Biomedical Research Center (PBRC), and the Nitrogen Fixation by Tropical Agricultural Legumes (NifTAL) are leading Hawaii's biotechnology research. Initially, HBG has focused on a project to control the Mediterranean fruit fly through the development of a male sterilization program.

The HGB, in an effort to engineer male sterile Mediterranean fruit flies, raised roughly $2 million through a research and development Limited Partnership. The Partnership had 50 percent of investors from Hawaii, with $50,000 coming from the Hawaii State Department of Planning and Economic Development. Because of the debate over the release of genetically engineered organisms, HBG planned to conduct tests outside the United States. It is
hoped that the use of a single lethal gene will facilitate selection of only sterile males, thereby reducing the cost (perhaps up to 50 percent) of raising the fruit flies. Labs using the procedure will pay a licensing fee equal to 10 percent of their total annual costs. In 1986, there were 12 laboratories in the world—a $6 million market—that produced sterile fruit flies. In a second project, HBG is planning to use the Hawaiian spear poison as a "magic bullet" (in conjunction with monoclonal antibodies) as chemotherapy against cancers.

NifTAL on Maui, using a grant from USAID, is attempting to genetically engineer a "super" strain of Rhizobium for higher rates of nitrogen fixation and persistence in tropical soils. The Oceanic Institute is working on the modification of Spirulina aimed at improving its nutritional quality. Other efforts by PITCHR's Biotechnology Division include the development of serological detection systems for bacterial diseases of Hawaiian and other tropical crops. In Fiscal Year 1987, PICHTR budgeted $93,326 for biotechnology activities.

There are two structural characteristics of Hawaii's biotechnology industry. First, the industry is clustered around small, well-identified groups. Second, there is no clear demarcation between the public and the private sectors.
Since biotechnology developments are and will be fostered by small groups, there will be no resources available from these enterprises to respond, should there be ecological or health problems. Private or quasi-private companies would probably declare bankruptcy, thereby leaving the State of Hawaii largely responsible. As ecological disasters may be irreversible, the outcomes could be staggering. For this reason, varying amounts of liability insurance could be carried by Hawaii-based biotechnology companies. Furthermore, it should not be forgotten that state appropriations have been instrumental in fostering the institutional arrangements.

Another issue raised during testimony on H.B. 2201, involved the debate over proprietary rights. Companies fear that oversight will undermine the proprietary nature of their research and development for bioinnovations. Such a stance was even present, to some degree, in the testimony by Dean Kefford from the UH College of Tropical Agriculture and Human Resources. Kefford argued that university applications should be reviewed by its own Institutional Biosafety Committee, which would then send an abstract to the Department of Health. Reducing the flow of information to an abstract would keep proposal details within university circles. Even if the maintenance of proprietary information is essential to the commercialization of
biotechnology, steps can be taken to provide confidential review. It can be argued that proper review can boost public awareness when prudent and objective reviews are conducted.

The laws, testimonies, and structural arrangements discussed above have affected the number and type of biotechnology ventures. Understanding the biotechnology developments at the state level may give insight into what is likely to happen in the future not only for Hawaii but for other areas in the United States.

CONCLUSION

The Hawaii case study shows that the concept of high technology is ideologically defined as a "positive" commodity for the state. Millions of state tax dollars have been invested without investigation of financial or environmental risks that may come with future developments. This is especially true with the commercialization of biotechnology. The state High Technology Development Corporation (HTDC) and the former Department of Economic Planning and Development (DPED) have been instrumental in underwriting risk for private companies to relocate to Hawaii. Such efforts have included changes in taxes and educational infrastructures.
Instrumentally, the University of Hawaii will play a key role in developing the link between the public and private sectors. This role will continue to raise conflict-of-interest questions as faculty and graduate students enter the high technology consulting business.

If current trends continue, over 50 percent of all high-tech endeavors may continue to be military- and space-related. Furthermore, large financial grants from foreign countries, Japan and Taiwan for example, will be linked to macro-political issues such as balance-of-trade relations.

High-tech, including biotechnology, jobs will continue to go through classic division-of-labor changes, which will result in a corresponding reduction in wages. These and other commercial high technology efforts are likely to result in lowering the number of laborers in unions.

With recent applications by biotechnology companies from the U.S. mainland to field test in Hawaii, it is likely that this trend will continue. Also, local biotechnology companies are close to field testing bioproducts that are in the research and development phase. The State of Hawaii, as of July 1989, has yet to formalize an inter-agency committee to review such applications. The potential for profound environmental damage exists, and as has been established, there is the need to review applications for their impact on local environments.
For the reasons listed above, political scientists in Hawaii should continue to question and critique high-tech developments in the State.
CHAPTER IX
SCENARIO: A LOOK TOWARD THE FUTURE

INTRODUCTION

The formation of a future view as a scenario should not be considered an attempt to forecast or to predict. The scenario is a tool to help understand possible future interactions over time, and to see the current issues in a new light. Furthermore, one failing of status quo technology assessment is its usual tendency to concentrate analysis on the state-of-the-art to such an extent that political issues are buried under layers of techniques and descriptions. For example, in genetic engineering a futures scenario for cryopreservation might predict a reduction in the fixed costs for long-term seed storage, but overlook the equally important issue of equity in ownership of and control over genetic resources. This scenario, by contrast, is structured to explore the social and political issues that will also be interactive with technological innovations.
WILL THE HELIX BE UNWOUND BY ILL-TIMING?

Looking back, the 1980's were a time of rapid commercialization of biotechnology and of efforts to "sell" major federal and state undertakings to the American taxpayer. The "hype" employed was similar to the selling of the space program in the 1960's. Biotechnology was sold as the new scientific frontier. One report after another was commissioned to study the problem.

In the fall of 1981, some 300 policymakers attended the U.S. Strategy Conference on Biological Diversity to review domestic and international policies and programs, and to recommend initiatives and promote public awareness. In 1985, there was an Interagency Task Force Report to Congress titled "U.S. Strategy on the Conservation of Biological Diversity" as a follow-up report to Congress. Participants in these government studies were influenced by two events that took place in the 1970's: the Stockholm Conference on the Human Environment and the start of the Man and the Biosphere Program.

In a further contribution to this developing climate, the Congressional Office of Technology Assessment released a series of reports on the future of genetic technologies. The Impacts of Applied Genetics. Microorganisms, Plants and Animals was published in 1981; The Role of Genetic Testing
in the Prevention of Occupational Disease was released in 1983; a background paper on "Human Gene Therapy" was issued in 1984; the year 1987 saw Technologies to Maintain Biological Diversity, and "Field-Testing Engineered Organism: Genetic and Ecological Issues" and "U.S. Investment in Biotechnology" were released in 1988. Reports dealing with animal, plant, and microbial germplasm were stacked higher and higher during the latter years of the decade. Yet, some were heard to ask, "Is there really a problem of losing thousands of species and degrading the world's biota? Or, is it just another problem of supply and demand among gene resource rich and gene resource poor countries and companies?"

These two questions fueled an unfortunate bureaucratic tension that was to last through most of the 1990's. Officials were unable to legislate much additional funding, because no long-term trend data on species loss were available. At the same time, strong lobbying pressure by biotechnology companies was successful in having political authorities reduce environmental barriers to the further commercialization of biotechnology. Internationally, the issues were depoliticized through the fostering of a high technology ideology.

Through the last decade of the century, efforts to gain international cooperation to control biotechnology
were haphazard, despite the fact that advances in molecular genetics were even more rapid than during the breakthroughs of the 1980's. These commercialized breakthroughs did have a direct impact on the exploitation of genetic resources.

At the moment, it is hard to discern the pattern in the midst of such breakthroughs. Unfortunately, it is easier in retrospect.

The advancements--from the end of the 1980's and through the 1990's--in cellular and molecular genetics were instrumental in extending the long-term storage of the seed for commercially-important crops, for identification of desired genes, their cloning and integration into commercial varieties or types, and in reducing barriers to international transportation of genetic resources. In short, these developments led to worldwide markets for biological innovations.

The technical breakthroughs, for instance, advancements in immunologic tests, allowed for a reduction of quarantine periods, which in the 1980's could take as long as five years; these delays were a major constraint to the utilization of genetic resources. As a result of faster and more specific testing capabilities, protection of crops and livestock was maintained while quarantine times, by 1992, were only a matter of a few weeks. The identification of desired traits advanced much faster than
had been anticipated. The truncation of breeding activities completely altered the structure of U.S. seed companies and other major farm supply companies. The major effect was the practice of selling complete biological "packages," which included seeds or livestock that had been biologically-engineered to fit machinery and pesticide needs for specific production systems.

Historians of science remember the initial excitement over the use of restriction fragment polymorphisms (RFP's) in 1985, which offered many advantages over conventional genetic markers and isozymes. The broad application of this technology allowed for the construction of gene-probe libraries. These libraries facilitated a faster identification of desired traits and gave better "prediction" for engineered-breeding. It was the Supreme Court decision in 1993, which ruled that gene probes/clones could not be considered proprietary, patented, or copyrighted, that led to the formation of a National Probe/Clonal Library. This decision set a precedent for reversing earlier intellectual property laws that had led to greater monopoly control of genetic resources in the 1980's. To some degree, it set some parameters for ownership of and control over germplasm.

In this sense, the decision reversed the broad interpretation of the earlier landmark 5 to 4 decision (Diamond
v. Chakrabarty, June 16, 1980), wherein the Supreme Court had ruled that a man-made microorganism was patentable. That ruling was gradually extended to include all organisms except humans within a space of a few years.

Furthermore, the 1993 decision was largely responsible for keeping information about gene sequences in the public domain. This decision was vital to international efforts to maintain biological diversity. At the time, the decision was strongly criticized by private biotechnology companies as a threat to destroy "private incentives" and the competitive edge of multinational biotechnology companies in bio-tech initiative. The U.S. Supreme Court decision provided the influence for a world treaty on genetic resources, as well as establishing a standard for most national laws worldwide.

By the end of the century, the battle over the use of recombinant DNA was no longer a single issue, because advancements in other techniques that facilitated gene transfer expanded the cellular and molecular tools for "gene-splicing" and chromosome transfer. The larger issue of the sufficiency of genetic diversity in production systems became the issue after the failure of rice, corn, and wheat crops in the year 2005. But we are jumping ahead in the narrative. It is important to look more closely at
the major innovation trends that led up to worldwide crop failure.

Advocates had hoped that cryopreservation techniques could be applied across-the-board to plant, animal, and microbial species, and that preservation could last indefinitely (for hundreds of years), thereby insuring that biological diversity would exist in perpetuity. However, research in the late 1980's and early 1990's proved that "problems of genetic stability" continued to force research to overcome the barriers for long-term storage on a species-by-species basis. As a result, there were only sufficient funds for preservation research for major crops and related species.

Interestingly, the logical conclusion--that emphasis should be shifted to in-situ approaches--was not recognized politically by industrialized countries. Emphasis on in-situ approaches was not politically acceptable to countries that were dependent on imported germplasm to maintain the stability of their production systems. Instead, emphasis was given to approaches, such as gene banks, that could be controlled by nations that were deficient in genetic diversity. Although the genetic repositories facilities were upgraded, their capacity was only sightly increased as a result of advances in preservation technologies.
At the same time, the advancements in monoclonal antibodies and other genetic probes allowed for greater detection of virus and bacterial pathogens in seeds, vegetative propagules, and animal embryos; this led to a worldwide reduction in quarantine procedures, facilitating the shipment of all forms of germplasm for basic research and product development.

Research into the genetics of plant and animal pathogens had an additional spin off: new pseudo-pathogens were used as vectors to transport genes into cells which were more efficient gene-shuttles than the previously used tumor producing plasmid of the Agrobacterium tumefaciens or the cauliflower mosaic virus (CaMV).

It was the overdependence on a few vectors for many transformations, in conjunction with increased genetic homogeneity across crops that led to the "Great Blight" in 2005 by expanding the range of disease vulnerability. But at the time, these uses of new vectors were viewed as just another technical breakthrough, with the advancements in genetic probes and clones greatly reducing the time needed for breeding, selection, and multiplication of varieties.

By the end of the 1990's the Land Grant System, established at the public agricultural stations and colleges for breeding new varieties for major crops, "collapsed" to the wave
of biotechnology-based breeders. These bio-breeders offered complete biological-engineered farming approaches.

The first biologically-engineered approach was for hybrid corn. It contained a new "seeder" which "germinated" the hybrid seed within its primary tank, and the emerging embryos ("artificial seed") were then coated with a cultured nutrient-resin containing biological pesticides and "super" nitrogen-fixers. The hybrid seedling had been genetically modified to be resistant to herbicides and some leaf-applied pesticides. The tanks of the "fermentation-seeder" could then be removed for the harvesting module. Even the harvesting times were genetically controlled to stagger the season so that the machinery could handle some 30 production sites.

In short, the advances in cellular and molecular genetics allowed for tremendous differences in how, where, and which crops/varieties could be grown. The concentration of control over production resulted in an even greater concentration in the number of elite varieties used. Unfortunately, the biological advancements also gave a false conception about genetic diversity as a whole: policymakers could not distinguish between the relatively small amount of new genes being introduced into varieties versus the vastly greater concentration of genes being used in intensive production systems.

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CONCENTRATION OF NEW GENES USED IN BREEDING INCREASES CROP VULNERABILITY

Secondary impacts are a recurrent problem with technological innovation. In this case, although the advancements in the biological sciences "opened" (e.g., bypassed species breeding barriers) the gene pool to exploitation, the traits that were first exploited were a small number of genes that fit production objectives. Hence, although it was true that new genes were introduced into production systems, the small percentage of gene change was much less than the concentration of genes through the dependence on monocropping and elite varieties.

The resultant effect was an escalation of overall genetic uniformity and a further degradation of the gene pool. In fact, during the 1990's biotechnological tools gave policymakers a greater and false confidence in the ability to manage national gene banks, variety development, and use of genetic diversity. Unfortunately their confidence masked their inability to perceive how these biological innovations were being used as a result of vertical integration and control over genetic resources that the private sector was able to mobilize through biological packages. In addition, another important biological factor had also been overlooked.
BETTER UNDERSTANDING OF COEVOLUTION

Even now in the twenty-first century, the forces of coevolution are still not well understood, but they are better respected than in earlier decades. This is not surprising, as the breaking of the gentic code and the advancement in gene tools "shifted" emphasis to the microbiological level for macro-commercial applications that could be supported by the marketplace and away from global ecology. It was a powerful, but myopic vision for the future. Enterpreneurs asked: "How can we be concerned about all the interactions of an ecosystem, when we can't even follow or predict the horizontal transfer of genes in the environment?" Little concern was given to the need for introducing biological innovations with coevolutionary concerns in mind.

The prevailing attitude appeared to be: "Go forward until some accident happens." Only some years later did investigators come to appreciate that as higher organisms had evolved always in conjunction with lower organisms (baceteria, viruses, viroids and so forth), elements from the procaryotes had not only been incorporated into the cells of higher organisms as mitrochondria and chloroplasts, but many of the so-called redundant genes had come from such frequent occurrence of bacterial and virus
infection. These complicated balances between host-pest resistance and virulence had developed gradually, slowly over millions of years. How, then, were coevolutionary factors linked to the cause of the "Great Blight" of 2005?

The 1990's witnessed further advances in the transfer of the nitrogen-fixing genes to major cereal crops. However, it was soon discovered that additional photosynthetic energy to drive the fixation process (to split the triple bond of the nitrogen molecule) was needed. One option seemed to solve the energy requirements by creating a structural change in the chloroplast itself which would free and recycle energy within the leaf. This approach worked, and nitrogen fixing and chloroplast-modifying genes were genetically-engineered into all major cereal crops. This was to become the genetic weak link as the plants engineered with the "nif-photo" genes proved to be highly sensitive to the leaf blight (Biotech infestans).

The year 2005 was a particularly wet year; weather conditions were one of the major epidemiological factors in producing and then spreading the blight. The blight was quickly spread by the massive level of international travel and shipping at the time.

Almost one half of the world's grain crops was lost from the pathogen or destroyed to hinder the epidemic. It appears that although the World National Academy was
tracking the homogeneity of genes in crop nuclei, no information had to be kept for organelles in the cytoplasm. Some scientists had warned of a worldwide blight, but others had countered that the probability of a pathogen attacking more than one crop was too small to halt the spread of biological innovations.

**FAMINE'S IMPACT ON THE MANAGEMENT OF GENETIC RESOURCES**

The "Great Famine" resulting from the blight had a major impact on the future management of world genetic resources. Until then, the genetic vulnerability of crops had provided no demonstration of the importance of the management of genetic resources to overall food production. The famine affected millions of people throughout the world. With hundreds of thousands dying of starvation in Africa and Asia, the issue of food security was strongly linked to genetic vulnerability and diversity.

Ironically, earlier that year, the National Germplasm Storage Facility (NGSF)--which had been built in 1991 to house the long-term storage of plant, animal and microbial germplasm--was destroyed by fire. Some 80 percent of its collections were lost. In addition, only about 40 percent of duplicated material (in backup shorter-term repositories) was "viable." It appears now that the USDA
had never followed through on advisory precautions mandated by Congress in 1989.

These events were the major catalysts in the reassessment of germplasm management. However, changes began at the end of the 1980's with the creation of the FAO Commission on Plant Genetic Resources and the broad realization by some scientists that in-situ conservation was the key to better management of the world's biota.

The need for better in-situ approaches had been recognized by IUCN/UNEP/WWF in its World Conservation Strategy (1980), but government officials overwhelmed with the costs of buying and managing large diverse habitats, hesitated to act. They managed to reassure themselves that even in the face of high extinction rates, the world still contained a "wealth" of biological diversity. Many officials apparently believed that the resiliency of tropical forests had been understated and the fragility of ecosystems overstated by ecologists.

The advances in biotechnology, reported in the newspapers and weekly magazines, enhanced a general feeling that necessary genetic diversity could be "created" on demand by the new technologies. To many it appeared logical to assume that extinction was no more than a normal aspect of the evolutionary process. Some argued further that too much diversity might even be harmful. In the face
of confusing arguments and counterarguments, which seemed to cancel each other, status quo policies were continued, even though it was evident that classical conservation techniques up until the late 1980's had largely failed to maintain biological diversity.

For example, billions of dollars had been spent on maintaining species in zoos, which accomplished little in protecting gene pools and ecosystems. Private, not for profit, groups were deluded that their fund raising activities oriented to the protection of "cute-looking" mammals was an effective conservationist strategy. In time emphasis shifted to the management of populations in the 1990's and subsequently to management of ecosystems by the year 2000.

An increased understanding of gene homology and heterology led to a more precise understanding of genetic uniqueness. However, the most important conceptual change in overall conservational thinking had to do with the better understanding of the "generation time" concept. In other words, species with long intervals between succeeding generations had to be maintained differently than species with short intervals. For example, bacteria can reproduce in minutes whereas sea turtles may take up to 40 years.

Such differences were strategic to the development of minimum viable population (MVP) recommendations that would
maintain a high percentage of the genetic diversity found in populations. It was realized by scientists that a timescale of several hundred years was needed to make management decisions. However, initial advances in captive breeding techniques for animals that were developed in the 1980's (artificial insemination, embryo transfer, hormone-releasing hormones, superovulation, chimeric blastocysts and interspecific and intergeneric hybridization) allowed for a reduction of generation times for mammals in the wild by the year 2010. In-situ approaches became the major focus for the World System for Genetic Resources that was formalized five years earlier.

The concept for a world system dates back to political struggles that emerged over the creation of a United Nation's Commission on Plant Genetic Resources at the Food and Agricultural Organization (FAO). The major project of the Commission, begun in 1983, was known as the FAO Undertaking.

HISTORIANS SEE FAO UNDERTAKING AS A PIVOT POINT FOR CHANGE

Historians look back to the birth of FAO's Undertaking (1983) as the pivot point in the debate over the control and ownership of genetic resources. As some may remember, the U.S. Government led the partial dismantlement of the United Nations through a withdrawal of funding, first from
UNESCO, followed by a delay in funding to or a cut in specific budgets controlled by FAO.

The U.S. politically attacked FAO's attempt to keep germplasm and related information within the public domain. The industrialized world realized how strategic the diverse biota was to the ever-expanding biotechnology industry. Besides continuing to expand legislation for intellectual property rights (e.g., plant breeders' rights, patents, and copyright) to protect the ownership of the resources, the United States discouraged the transfer of skills to nations where the diversity was indigenous.

Economically developing countries, attempting to supply basic human needs, agreed in principle to the closing of the "gene frontier" at the end of 1991, in the treaty on "Laws Governing the Mining of Germplasm" held in Mexico. In response, the United States refused to give financial support to the International Commission Genetic Resources established by the Mexico treaty and signed by more than 80 countries. Mobilization came four years later with the financial backing from oil-producing countries.

The political battle over the control of the genetic resource base was a "no win situation" for both industrialized and non-economically advanced countries. However, increased news coverage of the issues did spur a broader range of grassroots activities that focused on collecting
native varieties, introducing low cost storage techniques, and starting localized in-situ repositories. Many of these programs grew out of a greater coordination between nations in the Middle East and South America or between Japan and Asian countries. Millions of petro-dollars on the one hand, and trade-dollars on the other were shifted to stabilize the tropical forests which contained the majority of the Earth's biota. By the early 1990's the Middle East and Japan had become the world leaders in genetic resource management.

Although the FAO Undertaking and Commission had never gotten to the point of implementation on a world scale, it had, nonetheless, fostered the idea of a world system which became formalized in 1995 as the World System for Genetic Resources. Besides providing oversight of protected lands, the System controlled the advances in information technologies that linked new characterization and evaluation techniques with World Gene Banks, Data Centers and Gene Clone Libraries.

It had been the breakthroughs in characterization of large genetic sequences that allowed for a greater rationalization of the entire system. The old Linnaean system of taxonomy (based largely on breeding and morphology guidelines) did not hold for genetic homology across the plant kingdom. Once genetic homology patterns (based on
cytological and genetic studies) were uncovered, it became possible to maintain a much broader amount of genetic diversity in smaller populations of species.

Fortunately, by 1995 enough of the world's biota remained in national and world parks and preserves to support a long-term protection and use strategy for genetic resources. The world recession of 1992 (caused by the collapse of the lending system) ironically saved many of the major ecological zones from destruction. Nonetheless, the assumption by ecologists that the disappearance of one species would, probably, "take with them" other species to extinction unfortunately turned out to be correct.

SPECIES EXTINCTION EXCEEDS 50,000

Although estimates on species extinction are still disputed, 50,000 species are known to have fallen to extinction between 1986 and 2005 and, perhaps, an equal number of extinctions could not be documented. During the same period, the size of estimated worldwide protected zones dropped from some 4 to 2.3 million square kilometers, with a corresponding loss of 25 biogeographic provinces. Fortunately, the shift from domestic crops and stock species to wild population preservation and ecosystem management kept the loss from destroying the total ecosystem balance.
Advancements in computer programs facilitated better management of the International Biosphere Reserves and other natural areas by allowing better environmental impact assessment and screening for genetic diversity. If it had not been for the World System for Genetic Resources (WSGR) and the innumerable public and private efforts, the loss of genetic diversity likely would have been catastrophic. What were some of these key efforts undertaken by the WSGR?

Even with efforts to reduce the bioeconomic gap between biotechnology rich and poor countries, some 50 countries are still considered LBA's (lesser biologically advanced). The Genetic Equity Payment Treaty adopted in 1995 was successful in shifting capital to countries which housed the majority of biological diversity. A "Seed-Dollar" currency was first introduced in 1996 to buffer the fluctuations in other international currencies. This transfer of funds was successful in providing immediate assistance for the creation and preservation of effective national park lands in the LBA nations.

The United States was the only country not to initially sign the treaty; the EEC signed but with some reservations. After the "Great Blight" which destroyed much of the grain crops and the gene bank fire of 2005, the United States did sign.
The future outlook for 2020 and beyond holds some possibility that pressures on biological diversity will finally begin to taper off over the subsequent decade. At that time, extinction and speciation rates could reach equilibrium. Insight gained from the study of coevolutionary factors and corresponding genetic linkages over the past two decades has allowed for much improved management of biosphere parks and reserves; management proficiency should continue to improve into the future. Continued improvements in "biological resolution" of scanners/lasers housed in satellites should continue to assist in finding and describing new species. This information will be relayed directly to specialized databases.

At the molecular level, the breaking of the "electropluse" of the genetic code should allow for the complete mapping of genes along entire chromosomes or plasmids by the end of next year. The concept of genetic "uniqueness" should be defined for at least 1,000 coevolutionary factors and for a majority of genetic materials housed in repositories by the year 2025.

It had been hoped for several decades that biotechnologies would yield the key to a much broader ability to synthesize lifeforms. Although a few commercially important polygenic traits have been completely synthesized (they cannot be found in nature), the gene synthesizers
have been only routinely useful once desired genes have been "translated" and mapped.

The political battle over the ownership and control of genetic resources finally ended in 2010, with the signing of the World Gene Treaty (which greatly expanded the earlier treaty of 1990 for payment for access to genetic resources and information). Greater efforts to keep the level of genetic homogeneity to safe levels (e.g., limiting the transfer of embryos from genetically related stock) appears to have reduced the need for national or private collections; greater support for the World System for Genetic Resources has and should continue to stabilize the genetic resources of the biosphere.

Looking back over the last 50 years, or so, it is hard to believe that it took so long for the international system of germplasm preservation to gain acceptance, for the advantages, disadvantages, or complementarities of in-situ and ex-situ systems to be understood over an extended timetable, and for problems of mass extinction and production vulnerability to be reduced to socially and ecologically acceptable levels. Perhaps, if time travel becomes a reality, as some scientists are predicting by the year 2050, then our future mistakes can be corrected more easily than trying to learn from those of the past.
CHAPTER X
CONCLUSION

Earlier chapters argue that the commercialization of biotechnology generates environmental and economic risks that are being largely "underwritten" by the public sector, and that greater monopoly control is being achieved through private ownership of genetic resources and related information. Furthermore, the biotechnological enterprise is likely to hasten the extinction of the world's flora and fauna and increase the genetic vulnerability of major production systems.

Biotechnology is not a single industry or scientific discipline; it is a collection of novel genetic techniques and processes that use living organisms and their byproducts for production of biologically-manufactured commodities. The end products could be, for example, monoclonal antibodies, biological weapons, or novel crops that are resistant to pesticides. Genetic diversity is the "power" source fueling this new production approach.

Biological diversity is a living resource that self-replicates and evolves. It can be extracted and stored in gene banks or repositories. Knowledge of gene sequences and information about specific genetic traits can be stored on computer databases. Using the concepts of gene
function, genome, and gene pools genetic resources can be examined at both the micro- and macro-levels.

Biological diversity in its broadest sense is fundamental to the stability of ecosystems, biological cycles, and production systems. Biological diversity is a unique resource. The power of the technology, if understood, calls for an ethics of responsibility that speaks to the vulnerabilities of knowledge and fragilities of the biosphere.

Its utilitarian value changes through incorporation into improved varieties, stocks, and strains. Understanding the integration and control of genetic resources is key to the analysis of biotechnology's commercialization.

An analysis of the commercialization process requires not only an understanding of the technology, but also an understanding of where the wealth of diversity is located, the current institutions that manage the resources, and the power relationships. A discourse is needed that speaks to genetic resources as a power and exposes the dangers of private ownership and articulates a political position that fosters a counter-hegemonic process.

A counter-hegemonic process must expose the contradictions and the ideology of the so-called "high-technologies." The contradictions can be unmasked through an understanding of the relations of bioproduction. A
counter-hegemonic process based can contribute to some resolution of the tendency toward seeing the problem in terms of dichotomies and to raising ethical and policy challenges. There is a need to reconceptualize what the problem is that "drives" the development and use of this powerful technology. At issue, too, is a counter-hegemonic process that demands that basic research into biotechnology is intelligently regulated and applied.

The technological breakthroughs necessitate greater responsibility for the direction of evolution and for the maintenance of ecological stability. The use of bioinnovations is likely to increase the dependence on elite production-types, thereby raising the percentage of production systems based on monocultures. As argued in Chapter IX, the parallel use of "biological packages" will increase the overall level of genetic vulnerability of the world's production systems.

The dissertation argues that the issues, contradictions, and dichotomies must be unmasked before there can be sufficient knowledge of the problems to see them politically.

One of the more easily visible dichotomies is the split between the two fundamental approaches of germplasm preservation. The dichotomy can be defined as in-situ and ex-situ preservation approaches. Other dichotomies for
biological diversity include "common heritage" vs. private ownership, "gene-rich" countries vs. "gene-poor" countries, and extinction vs. speciation. Using dialectic thought helps not only to redefine the problem caused by the bifurcation itself, but it also allows for institutional restructuring that has been defined by the duality.

The breaking of these fundamental dichotomies is essential to creation of new potential for social change, policy formation and greater consciousness for the scope of biological diversity activities. Such an outlook may, in fact, help break a major paradox: the scientific knowledge needed to guide the decision-making process is likely not to be available until the level of ecological degradation has already reached the "point of no return." In this sense, the dialectic process may help to break the dependency on experts for decision making, and allow philosophical and ethical knowledge to guide decisions into the future.

As developed above, exploring the relationships inherent in the dichotomies of biological diversity helps to identify where power is located and to better understand the relations of bioproduction. Exploration of the policy process gives insight into the various economic, political, and ideological structures and infrastructures that result in greater monopoly control of genetic resources.
As discussed earlier in Chapter V dealing with intellectual property law, the continual expansion of these boundaries determines what bioinnovations can be patented, what information can be held proprietarily, and what protection can be captured through plant breeders' rights. These instruments further the privatization of genetic information and resources. The expansion of intellectual property laws, as an instrument of financial and information control, determines not only who benefits, but also sets what modes of accumulation are legal or whether the public has the right to review pending business proposals for risk to the environment or public health.

As previously discussed, the 1980 Supreme Court decision, which allowed the patenting of bacteria, also called on the U.S. Congress to consider legislative needs in the area of biotechnology. The 1980 Supreme Court acknowledged the need for more comprehensive statutes for the regulation of biotechnology, as the Diamond v. Chakrabarty, 100 S. Ct. 2204, 2207 (1980), was a narrow decision. The issues are not a matter of technicalities over whether an engineered organism is a "discovered" invention not found in nature, or whether the legal "enablement" requirement can be met. Such issues do not expose the infrastructures designed to exploit genetic resources. A counter-hegemonic process speaks to the need of unmasking the broad consequences of
biological diversity exploitation. It also speaks, simultaneously, to the concerns of food security, environmental quality, and cultural and biological heritage.

More importantly, the contradictions created in the current mode of genetic resource production and reproduction must expose the magnitude of risk inherent in the commercialization of biotechnology. It is precisely the interrelationship between risk and the underlying contradictions, that exposes the exploitative nature of the current status quo power relations. These power relations are involved not only with the immediate exploitation, but also with the long-term control of genetic resources and knowledge. Ownership is one key to control.

Central to a counter-hegemonic project is the further linkage of the exploitation of genetic resources to the extinction process. Reductionistic exploitation assumes an unlimited supply of genetic information, but more importantly, macro-political questions of sovereignty over genetic resources and food security are structurally linked to genetic resource loss and misuse. These structural links go beyond arguments for fair compensation or for access to valuable genetic resources. The process of reproduction of genetic information within the capitalist mode of production is an important structural element driving the exploitation of genetic resources.
Exploitation, as experienced through the commercialization of biotechnology in the United States, is linked to the loss of species worldwide.

The United States will play a critical role in the international commercialization of biotechnology and the control of genetic resources; the two are intrinsically related. Because the wealth of biological diversity in Hawaii, the state is likely to play a key role in educating policy makers about the consequences of mass extinction and of the issues surrounding biological diversity preservation in the "gene-rich" areas. What is certain is that billions of dollars, the balance between public and private ownership of genetic resources and food security are at stake.

Economic pressures—the need for high rate of return on venture capital, international competition and the need for industrialization—are driving the commercialization of biotechnology toward more narrow interests. The pressures will also hasten the rapid release of genetically modified organisms into the environment. The biotechnology lobby will continue, if unchecked, to restructure both state and federal regulatory roles and legislative statutes toward their private interests. At the international level, the commercialization of biotechnology is likely to add to the degradation of biological resources and to fuel North-South tensions.
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