Between Advocacy and Responsibility: The Challenge of Biotechnology for International Law

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Let me begin by saying that I write as a philosopher and ethicist not as an expert in international law. What I argue is that those working in the fields of international law or international legal theory, as it pertains to issues of biotechnology and biodiversity, cannot avoid confronting a range of philosophical and ethical questions. I will frame these issues in terms of "advocacy" and "responsibility." The distinction between "advocacy" and "responsibility" is not meant to imply that advocacy is not a matter of responsibility; rather I will use the term "responsibility" here to refer to those issues and commitments which go beyond the more immediate demands of advocacy. Another way to frame these concepts might be in terms of the distinction between the professional responsibility of advocacy and the larger questions of social responsibility which take us into the domain of ethics.

The fundamental point I pursue is that biotechnology presents special problems for international law. Even though virtually every case is without precedent, the precedents which are now being established will have profound effects in the future. It is this future-orientation which raises profound ethical questions. Given that biotechnology is an incipient technology that will have dramatic, yet unknown, impacts upon the future, the larger questions of social and environmental responsibility cannot be avoided.

While both biotechnology and biodiversity have emerged as important domestic concerns in the United States and Europe, it is in the context of international agreements and international law that we see the real issues emerge. International law is based upon the interpretation of conventions, treaties, and agreements between nations and institutions. Two agreements, crucial to the future of biotechnology, are those signed at the United Nations Conference on Environment and Development (UNCED) and negotiated under the General Agreement on Tariffs and Trade (GATT). What is...
interesting and important for our discussion is that, within these two sets of agreements, we find competing visions for the next century. At the heart of these visions is biotechnology and biodiversity.

UNCED and GATT share much in common. They are the two largest international agreements signed within this generation. Both strive to be holistic and comprehensive in setting an agenda for the present and future world community. Each frames the future in the context of economics, particularly the economics of the relationship between developed and developing countries. Finally, both are concerned about regulating the use and distribution of resources and technologies.

What is disturbing about these crucial documents is what they do not share. There is a fundamental conflict between their respective visions of the future and neither takes into account the other. One way to frame this conflict is to look at the way the future development of biotechnology is viewed in each of these agreements.

Any kind of detailed analysis of these two agreements is beyond the scope of this article; however, it is worth summarizing their basic orientations because these represent the cornerstone of their future. The UNCED process, stretching over many years, attempted to tie two of the most pressing international issues together: the environment and economic development. These competing and related concepts are framed in terms of a balance between the environment, economic development in developed countries, and economic development in the developing world. The phrase, "sustainable development," reflects this set of relationships.

Sustainable development is a new, more holistic, way of framing the problem and not the solution. It recognizes that the issues of the environment and poverty are linked and can only be approached globally and generationally. Sustainable development is first and foremost about the future: preserving resources and a quality of life for future generations while attempting to deal with the problems faced by the present generation. The importance given both to future generations and to developing economies within the UNCED documents was the source of much hostility from global business interests with biotechnology being an excellent case in point.

The background and history of biotechnology in the UNCED process is crucial to understanding the dialectic process. I say process because one cannot simply look at what occurred at the final meetings of UNCED in Rio de Janiero held from June 1-12, 1992. One must begin the study with the first Preparatory Conference in Nairobi in August 1990, wherein biotechnology was slated to have been the subject of one of the conventions.  

1. See THE EARTH SUMMIT: THE UNITED NATIONS CONFERENCE ON ENVIRONMENT (Stanley Johnson ed., 1993) [hereinafter Johnson]. The documents from the Preparatory Conferences used here were obtained through Internet. The final UNCED documents are available at The United Nations Environmental Programme, Intergovernmental Negotiating Committee.
Conventions are the most powerful documents negotiated in the UNCED process. Two conventions were signed in Nairobi, Kenya: the Convention on Biological Diversity and the Convention on Climate Change. The history of biotechnology in the UNCED process is the history of its elimination. At the first Preparatory conference in Nairobi, pressures exerted primarily by the United States, with support from Japan, and Germany, resulted in biotechnology being downgraded from the status of "convention" to that of an issue connected with biodiversity. This pressure was maintained throughout Preparatory Conferences 2, 3, and 4, as well as in the final negotiations in Rio, until biotechnology was taken up as an issue only in Articles 15 and 19. It was addressed indirectly as an issue in Articles 16-18 of the Convention on Biological Diversity, and Chapter 16 of Agenda 21.

The U.S. concern throughout the process was the elimination of anything that would regulate the growth of this new industry. It was relatively easy to do this because UNCED was dealing with a vast range of complex issues, many with more immediate impact upon the developing nations. Biotechnology was either lost in the mix or became a negotiating chip used to get concessions on other issues. Non-governmental organizations, which have never had any well-defined position on biotechnology, did little to press for greater attention to biotechnology. Thus, the fact that UNCED was establishing certain fundamental principles and definitions, or neglecting issues which will have direct and potentially dramatic effects upon the environment was missed by most countries. Only those countries which

2. Id. at 81-102.
3. Id. at 57-80.
4. See Johnson, supra note 1. PreCom II was Held in Geneva March/April, 1991. PreCom III was held in Geneva August, 1991. PreCom IV was held in New York March, 1992.
5. See Johnson, supra note 1, at 88-90.
6. Id. at 89-90.
7. Id. at 293-304.
8. See infra note 9. This is also the interpretation of the Non-governmental Organization Biotechnology Task Force.
9. The ad hoc Non-Governmental Organization (NGO) Biotechnology Task Force led by the representatives of the Biotechnology Working Group of the United States, produced a Critique of Chapter 16 and Agenda 21 and a list of thirteen principles concerning biotechnology which attempt to establish some limitations for its development and use as well as for the equitable distribution of profits and technology transfer.
presently control or seek to continue to control the regulation (or lack thereof) on biotechnology well understood that biotechnology was a major issue.\textsuperscript{10}

By the "Earth Summit,"\textsuperscript{11} most of the issues and questions representing the interests of the developing countries and environmentalists had been eliminated. The issues that remained came suspiciously close to mirroring the biotechnology's own positions and interests. We can find those interests expressed in documents supplied to the UNCED negotiators by the International Bioindustry Forum (IBF).\textsuperscript{12} The IBF is an umbrella organization representing the views of its member organizations: The Senior Biotechnology Advisory Group (Europe), the Japan Bioindustry Association, the Industrial Biotechnology Association (the United States), and the Industrial Biotechnology Association of Canada.

One such document entitled, "Policies for Sustainable Development: The Role of Biotechnology," expresses an uncritical view of the social and environmental impacts of biotechnology.\textsuperscript{13} The following statements are drawn from that document and reflect this view:

New technologies and their applications are essential for human welfare, for worldwide sustainable growth, social development and our natural environment.... The application of new technologies will aid all countries of the world.... Based on experience to date, the benefits of modern biotechnology far outweigh conjectural concerns and therefore must have appropriate support.... Modern biotechnology will help to maintain biodiversity and to ensure genetic diversity.... Biotechnology will (provide) extensive environmental benefits for sustainable growth.\textsuperscript{14}

The document further maintains that genetically manipulated organisms are "natural" (not artificial) and that they are "improvements" upon

\textsuperscript{10} This conclusion is based upon personal observations of the negotiations, as well as interviews with other non-governmental groups.

\textsuperscript{11} Earth Summit refers to The United Nation Conference on Environment and Development held June 1-12 in Rio de Janiero, Brazil.

\textsuperscript{12} See infra note 14, POLICIES FOR SUSTAINABLE DEVELOPMENT.

\textsuperscript{13} See infra note 14, POLICIES FOR SUSTAINABLE DEVELOPMENT.

\textsuperscript{14} INTERNATIONAL BIOINDUSTRY FORUM (IBF), POLICIES FOR SUSTAINABLE DEVELOPMENT: THE ROLE OF BIOTECHNOLOGY, 3-10 (1992)(document was obtained from the NGO Biotechnology Task Force in Rio).
unmodified organisms because of their increased "efficiency." It characterizes those voices which have raised cautionary or critical concerns about biotechnology as "unfounded" and "conjectural" while listing all of the future benefits of biotechnology as if they were facts.

It is reasonable for the bioindustry to vigorously defend its own position. However, when we compare the IBF document to Chapter 16 of Agenda 21, entitled Environmentally Sound Management of Biotechnology, we find the same uncritical perspective. The UNCED document goes to great lengths to present biotechnology as a solution to the world's social and environmental problems. The "Introduction" begins by telling us that biotechnology "promises to make a significant contribution in enabling the development..." of several areas, such as health care, affording food security via sustainable agricultural practice, improving supplies of drinkable water, increasing the efficiency of the industrial development processes for transforming raw materials, and working toward the detoxification of hazardous waste. It proceeds that "biotechnology also offers new opportunities for global partnerships..." especially between countries of the South which are "rich in biological resources [including genetic resources]," and countries of the North which have the technological expertise "to transform biological resources so that they serve the needs of sustainable development." It also seeks to "engender public trust and confidence" in biotechnology. Throughout the document it refers to the use of biotechnology to "improve" or "enhance" life forms.

Sections 16.2-16.31, which comprise the bulk of the document, provide a relatively conclusive list of sustainable ways in which biotechnology might be used. However, only Sections 16.32-16.42 address the issues of

15. Id. at 8.
16. Id. at 9.
19. JOHNSON supra note 1, at 294.
20. JOHNSON supra note 1, at 294.
"enhancing safety and developing international mechanisms for cooperation." These sections are weak and neglect the establishment of legal codes and regulations. Instead, they speak rather vaguely about risk assessment and risk management. They also make reference to "internationally agreed principles" without providing definitions. The sections on cooperations focus on, without providing any specifics, about seeking to "promote the development and application of biotechnologies, with special emphasis upon developing countries."

No mention is made, nor are any mechanisms established, concerning the need to "recognize and protect the traditional methods and knowledge of indigenous people and their communities and ensure their participation in the economic and commercial benefits arising from developments in biotechnology."

Also lacking are specific mechanisms and regulatory structures to deal with issues such as the release of genetically modified materials and transfer of technology. Finally, the sections concerning financial assistance are limited and vague. After reading these provisions, one feels that biotechnology is a solution to many of the social and environmental problems, and it is relatively uncomplicated in terms of its impacts.

What is interesting is that, as vague as the language is, it was still too extreme for the Bush administration. One of the principal reasons cited for the Administration's refusal to sign the Convention on Biological Diversity and its refusal to support Agenda 21 was its feeling that commitment to these agreements would hinder biotechnical growth. The long-term commitments of the Administration to biotechnology are crucial to the internationalization of this new technology. The attitude is that this incipient technology and the industry built around it must be protected at all costs. The stakes are huge. The belief is that the long-term economic recovery of the United States is tied directly or indirectly to the success of biotechnology. This thinking is based on the recognition that the United States will never again be a leader in heavy

22. JOHNSON passim, §16.1 at 293.
23. JOHNSON passim, §16.53(c) at 302.
24. JOHNSON passim, §16.45(a) at 304.
25. JOHNSON passim, §16.45(a)(vi at 304.
26. JOHNSON passim, §§ 15.45-16.52 at 304-06.
27. The Convention was signed by the United States on June 4, 1993; see, for prior objections United Nations Environmental Programme, Intergovernmental Negotiating Committee for a Convention. See also Johnson passim, supplement on statements filed at signing, June 11, 1993.
industry, which has all gone "South." Nor will it lead the world in the production of consumer or high-end electronics; most of which has gone to the "Pacific Rim." The belief that the United States would survive as a "service economy" has not fulfilled its promise. Thus, in terms of the current technologies and industries on the horizon, biotechnology (and information age technologies in general) becomes the primary hope for the future. The Bush administration estimated that by the turn of the century, biotechnology will be a fifty billion dollar per year business in the United States. There have been estimates that by the middle of the next century, as much as fifty to seventy percent of the GNP of the United States will be directly or indirectly tied to biotechnology. The United States is presently the world leader in biotechnology followed by Japan, Germany and Canada. None of these centers of biotechnology want to see regulations, domestic or international, hinder their growth.

We find evidence of that same commitment by the Clinton administration. Given Vice-President Al Gore's statements that the bioindustry amounted to "selling the tree of life," it was unexpected that this administration would take such an uncritical view of the development of this technology. When the Clinton administration finally signed the Convention on Biological Diversity, it did so with the stipulation that it be allowed to file an "interpretive statement" along with its signature. That statement was a guarded secret in Washington circles because it reveals the current administration's position on biotechnology is, in essence, no different than that of the previous administration. The Administration's main thrust is that the U.S. will not be bound by anything which might threaten the development of biotechnology. Its principal concern is to protect the ability to claim and enforce intellectual property rights, i.e., the ability to patent genetic material, and to have unrestricted access to the genetic resources. It is clear that the new administration sees biotechnology as one of the linchpins in its high-tech approach to the economic future of the United States.


29. In fact, even the "forestry initiative" put forward by the United States as what many called a "peace offering" could be seen as an attempt to bolster biotechnology. The money which the Bush Administration committed to forestry was primarily for "research" and "inventory." For the U.S. to inventory the biodiversity of the remaining forests of the world would perform a vital service for biotechnology by providing it with a list of the potential genetic resources available.


32. See supra note 27.
For all of the problems with UNCED, it is still the case that the orientation of the UNCED agreements is one which sees biological diversity as having value in and of itself as well as having an economic value. That intrinsic value confers upon biological diversity certain rights, including the right to exist. The approach taken by the Biodiversity Convention is one that calls for the preservation of habitat (more on this below) and, to some degree, the preservation of the rights of indigenous peoples. Implicit in its vision of the future is a balancing of the preservation of traditions, cultures and heritages of various peoples. Social, ethical, and religious concerns must play a role in the questions of biotechnology and biodiversity. These additional "value" questions prompted the bioindustry's feeling that UNCED was not the appropriate context to establish the long-term regulations and ground rules for the future of biotechnology. It saw GATT as the more appropriate context.

The GATT is, above all, about opening global markets, and creating a "level playing field" for all those who want to participate in the world's market. It recognizes that ours is an international economy, therefore, a definite need exists for a set of internationally recognized regulations according to which international (and to some degree national) business will be conducted. Three significant points exist. First, within the GATT, there is no commitment to sustainable development. Second, where much of the perspective in the UNCED agreements comes from the developing countries (although, as I have argued, this is not the case when it comes to biotechnology), the perspective in the GATT is from the developed countries and the transnational corporations. Third, where biotechnology and intellectual property rights were minimized in the UNCED agreements, they are among the most important issues negotiated in the GATT. As far as the bioindustry was concerned, the GATT was the right context within which regulations should be established because the GATT views all of the issues purely as trade related issues.\footnote{Initial hopes by many that this would change under the Clinton Administration, which has sought to negotiate "side agreements" in the NAFTA, have not thus far proven to be the case.}

The GATT takes the complex social, ethical and cultural issues which are behind the UNCED documents and reduces them exclusively to the trade issue of Intellectual Property Rights (IPR) as Trade Related Intellectual Property Rights (TRIPS). The interests of the GATT do not extend into other areas of biotechnology. The World Trade Organization (WTO), which has now been established for the post-GATT negotiations on such issues as the environment, has shown strong resistance on the part of many of the parties to deal with these issues. They contend that market issues and environmental issues need to be separated. This attitude is diametrically opposed to UNCED and further demonstrates the lack of coordination of these agreements.
The real power behind the GATT, transnational corporations, are also the big winners with the GATT. How one judges whether or not the United States, or any nation in particular, will benefit from the GATT is a matter of the degree to which one is convinced that the economic destiny of the nation is tied to the economic destiny of the transnationals. Once again, the stakes are huge. The transnationals, such as Bristol Meyers, Squibb, Johnson and Johnson, Monsanto, Proctor and Gamble, Dupont, Hewlett-Packard, Time-Warner, and Roche, have all played active roles in "advising" the negotiations. They recognize that they have much to gain from the worldwide standardization of patent and copyrights, and the international recognition of the patenting of life forms.

One way to understand the importance of IPR is to contextualize it within a fundamental restructuring of society and property within the emerging information age. For this new age, new lexicons are being established. The term lexicon is appropriate here even though it basically refers to a word list. The "lex" portion refers to a certain legal standing of those words which are on the official list. Thus, in addition to a list, the definitions of the terms in the lexicon are circumscribed. The key term, as far as biotechnology and biodiversity are concerned, is "information." It is not just the information super-highway which is fundamental to the information age, but biotechnology as well. The reference to "information" here does not mean more information is available, rather a wholesale new description of the world as "information" and "information systems." The emergence of this new cybernetic and biotechnical model for understanding the world ties together two of the great modern-day developments: the computer and biotechnology. The dominant characteristic of both is the reduction and reorganization of the world as "information."

The term cybernetics derives from the Greek, "kybernetes" and means "steersman." Cybernetics was popularized as a term by Norbert Wiener, a mathematician at the Massachusetts Institute of Technology. He spoke of cybernetics as being concerned with information and information systems. Information is "the name for the content of what is exchanged with the outer world as we adjust to it, and make our adjustment felt upon it. The process of receiving and of using information is the process of our adjusting to the contingencies of the outer

34. I say "legal" standing in the sense that lexicons are often specialized word lists with agreed upon definitions. See James Buchanan, The Information Age and its New Lexicon: Biotechnology as a Case in Point, 16 TECH. SOC'Y 4 (1994).
environment, and of our living effectively within that environment."\(^{35}\)

The crucial elements of cybernetics are information and feedback. Wiener believes that information "belongs among the great concepts of science such as matter, energy and electric charge."\(^{36}\) Wiener concludes that "society can only be understood through a study of the messages and the communications facilities which belong to it."\(^{37}\) Information becomes a new mode of understanding the world theoretically; however, it also becomes a new mode of organizing the world practically.

Cybernetics is not concerned with "what a thing is, but how it behaves."\(^{38}\) Cybernetics describes being-as-relation but reduces the complexity of relation to one key concept: "information" and its exchange. This is easy to understand when speaking of computers. However, here the computer increasingly becomes our model not only for understanding and organizing society, but it represents the dominant biological model as well. This was Wiener's intention from the beginning. It is a paradigm shift in the science of biology. Marjorie Grene tells us that there is a new way of thinking in the biological sciences which "says in effect: look to engineering, to blueprints and operational principles for the sources of your theoretical models in biology."\(^{39}\) The key to the forms of engineering that Grene is talking about concerns information systems. W. H. Thorpe describes living organisms as things which "absorb and store information, change their behaviour as a result of that information, and have special organs for detecting, sorting and organizing this information. . . . The most important biological discovery of recent years is the discovery that the processes of life are directed by programmes."\(^{40}\) Programmes are the structures which process and store data; data is information.

Models of understanding become models of organization. It is here that international convention and law play a role. They will determine the

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36. Id. at 27-28.
37. Id. at 25.
lexicons or the way in which we will define and legally circumscribe "information" for the future. In an information age, information becomes a principle locus of power and fiduciary exchange. Information becomes not only the new way of understanding the world, but of organizing it as well. Not only does computer logic become a model for modes of cognitive development and organizational structures, but more importantly, information becomes the newest commodity in the world marketplace. Mark Poster, in a book which is full of insights into this new model of organization, entitled The Mode of Information: Poststructuralism and Social Context, gives us the first key in understanding this change in the world marketplace.

In the era of industrial capitalism social and natural resources essential to the production of material goods came under the control of self-interested private individuals. In the era of the mode of information the process is at work again. We are now being convinced that "information" is first a commodity and second that it is properly controlled by market forces.41

The key issue of concern is how "information" is defined. Information is the newest and, arguably, the most important commodity to emerge on the world's market. It is "information" which is owned as intellectual property; whether that information is a trade secret or whether it is a genetic code. The point is, once it is established that information can be owned (in principle) by means of the recognition of IPR, the next and crucial step is to limit what will and will not count as "information." Turning back to GATT we can see that principles are being established which work towards that end.

Section 5, Article 27, entitled "Patentable Subject Matter"42 states:

1) Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65 and paragraph 3 of the Article, patents shall be available

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42. This is taken from the so-called "Dunkel Draft." Since the GATT is still being negotiated, things may yet be added or retracted from this section, though indications are that it will remain substantially as is.
and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.43

The parts of this section concerning "new," "involve[ing] an "inventive" step," and [being] "capable of industrial application" are crucial. One of the issues that has been raised in opposition concerns the status of "traditional knowledge of indigenous peoples."44 There are many plant breeders who, through generations of trial and error, have developed certain specialized plant varieties. Such plant varieties would not be patentable under these regimes because they do not meet the stipulations "new" and "involving an inventive step." But if a scientist obtains some of these seeds and identifies those special characteristics, it is genetically transformed into "information" and is thus patentable. Such cases already exist. For example, in West Africa the local farmers grow a cowpea which is insect resistant. A scientist at the University of Durban, Angharad Gatehouse, on a trip to West Africa, obtained some of these seeds.45 Using biotechnical techniques he discovered the genetic mechanism which causes them to be insect resistant. He promptly left the university and joined Agricultural Genetic Company of Cambridge and they proceeded to apply for a patent for their "invention." The point is that it was only after the scientists had identified the characteristic genetically that it became "information" and thus could be owned. It could not be owned in its traditional form.46 The inscription of "information" within the new lexicon is limited by terms such as "new" and "inventive step" in order to benefit only the expertise in genetic science and not the expertise in plant breeding.

A further example of the way in which these lexicons are manipulated is seen in connection with the Human Genome Project.47 The National Institutes of Health (NIH) have filed for thousands of patents on genetic sequences and partial sequences. The US Patent Office has thus far refused

43. All citations taken from the on-line version of GATT, received via internet. References will be made by section and article rather than page.

44. This has been a major concern of organizations such as Genetic Resources Action International (GRAIN) and the Rural Advancement Fund International (RAFI).


46. Id. at 9.

patents based upon the lack of "novelty." The NIH has reapplied claiming that the "novel" step is showing what the genetic sequence "expresses." Nothing new has been added. All that has happened is that a new minimalist definition of "information" is being employed which says that identification is information, and thus, patentable. Time will tell whether or not the Patent Office will accept this new interpretation.

Section 5 of the GATT continues:

2) Parties may exclude from patentability inventions, the prevention within their territory of commercial exploitation of which is necessary to protect the order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not merely because exploitation is prohibited by domestic law.

3) Parties may also exclude from patentability:
   a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals.
   b) plants and animals other than microorganisms and essentially biological processes for the production of plants or animals other than non-biological and micro-biological processes. However, parties shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. This provision shall be reviewed four years after the entry into force of this agreement.

These paragraphs are ostensively about what can be excluded from patentability. The most striking thing about them are those things which are excluded from exclusion. In fact, the section opens the door for the recognition of the patentability of life forms. In so doing, the GATT becomes the first full-scale international agreement to recognize that life forms are patentable. It does this in an ambiguous and subtle fashion. The key term is "microorganisms." First, the term itself is very ambiguous. There are no clear legal definitions as to what are and are not to count as "microorganisms." After all, who cares about microorganisms? A very important principle is being established here: life forms are patentable. Section 5(3) does not stop there. It goes on to exclude from the exclusions "non-biological and micro-
biological processes." Again, this is very ambiguous. What is included under "non-biological" processes is never specified. On the other hand, the reference to "micro-biological" process is not mysterious. Interpreted in its most simple terms "micro-biological" would include genetic engineering, and if the process is patentable then the product that the process creates can be owned.

The rest of the paragraph is even more ambiguous. It states that "parties shall provide for the protection of plant varieties . . . by *sui generis* systems." But this has to be read in the light of paragraph 1, which limits criteria of "new" and the involvement of an "inventive step." It is not at all clear what is and is not being protected here. The same can be said of the stipulation concerning *sui generis* modes of protection. What these might be and what might happen if and when they conflict with the GATT is not made clear. What is clear is that, given the GATT, there would have to be real limits to how far such local or regional instruments could go. This raises questions as to what happens when the intent and specifics of UNCED or local/regional/national priorities and GATT come into conflict. Again, it is to the institutional sites that we must look for our clues. One of the mechanisms which the GATT proposes is that when such conflicts exist, those conflicts shall be adjudicated by means of GATT tribunals.

The final sentence about the review of the process four years from inception is again key for the bioindustry. If its strategy is an incremental one which begins with the recognition of the patentability of microorganisms and microbiological processes, then moves to plants, then to animals and finally to human beings, then a review of the policy after only relatively few years is crucial.

Most of what we find in GATT (and NAFTA) is not new. We already have recognition of the patentability of life forms in the United States and Europe. The importance of GATT is threefold: first, it sets the context and the terms of the discourse as being exclusively the marketplace; second, it

48. See supra note 44, § 5, Art. 27, ¶ 3(b) of the Dunkel Draft.

49. The first case involved scientist Ananda Chakrabarty who filed for the first patent on a biotechnological invention in 1972. His application was based upon two points of requested ownership: (1) the tangible microorganism and (2) its possible uses. *See Diamond v. Chakrabarty*, 447 U.S. 303, 65 L. Ed.2d 144 (1980). The patent was finally granted in 1981. In 1988 two scientists at Harvard "invented" and patented the Oncomouse which entailed the insertion of an oncogene into a mouse so that it would develop cancerous tumors. U.S. Patent, Patent Number: 4,736,866, April 12, 1988. See 1989 OFF. TECH. ASSESSMENT NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE, SPECIAL REP., OTA-BA-370. The Supreme Court of the U.S. has stated that anything which results from human activity (inventions) is patentable, including superior life forms. *Diamond v. Chakrabarty*, 447 U.S. 303. The European Patent Office has also granted a patent on the Oncomouse. *EUR. PARL. REP. BIOETHICS IN EUROPE* (Scientific and Technological Options Assessment (STOA)) (1992).
seeks to establish uniform patent regimes for all of those who would participate in those global markets; and third, it establishes a well-defined regime of retributive responses for failure to comply with these regulations.

One of the many challenges facing the international lawyer will be in cases where UNCED (or even local/regional/national environmental standards) and GATT are in conflict. Such cases are inevitable and while GATT is highly ambiguous when it comes to the definitions of such things as microorganisms, it becomes very specific when it comes to the retributive mechanisms for those who do not follow its dictates. On the other hand, mechanisms of enforcement are the weakest part of UNCED. One of the crucial questions for the future of both UNCED and GATT is the establishment of mechanisms of adjudication which strike some balance between the demands and needs of sustainable development and those of open markets. The GATT (or WTO) believe that this should remain within its administrative purview, while others believe that something like a World Environmental Court needs to be established.

What we see emerging here is a totally new theory of property appropriate to the new age. The new legal battlefields upon which the new theories of property and property rights will be shaped, are Intellectual Property Rights (IPR) and Trade Related Intellectual Property Rights (TRIPS). IPR covers a wide range of issues, including copyrights, trademarks, encrypted satellite signals, sound and video recordings, layout designs of semiconductor integrated circuits, trade secrets, industrial designs and patents. I want to focus the discussion here by concentrating upon patents, particularly as they pertain to biotechnology, as it is here that we can see the radical previous notions of property and property rights. It could be argued that the colonization and exploitation of the undeveloped world was carried out because the West or North had a theory of property and ownership long before those other countries did. By the time they awakened to the importance of property and to what they had given away, it was too late. The new mode of property is "information," and, once again, those who are on the cutting edge and in control of the technologies are defining and delimiting what will and will not count as informational property well in advance of those who lack the development to see the long-term implications. Biotechnology exposes a legal quagmire as well as a moral one. The bioindustry is seeking legal protection in the form of intellectual property rights and the patenting of life forms in order to control the financial return from the products which they make from re-engineered DNA. As would be expected, the arguments which emerge from the bioindustry are economic arguments and again, the stakes are high. The bioindustry estimates that it requires on the order of $200,000,000 United States dollars to develop and bring to market a single genetically engineered product. Given the difficulty for companies which have invested such huge sums to control the distribution and reproduction of their products, it is not unexpected that they want patent protection which require the end
user to pay a "royalty" to the company for each new replication. How such "information" can be controlled, royalties computed, and to what degree this information becomes part of the public domain are indeed very complicated problems. Patents are presently the principal legal mechanism for ownership of intellectual property and biotechnical information. But new, complicated issues concerning the differences in process patents versus product patents, novelty issues (one of the precedent criteria for patentability), and reproducibility (which also involves the relationships between developing and developed countries), are raising questions as to whether or not patents (as a mechanism) are able to accommodate the new forms and issues involved here.

The key to assessment goes beyond confronting the question of the notion of property (which is both a legal as well as an ethical issue) which is being employed or developed within biotechnology. In order to begin this process, I want to return to what I have called the new lexicons. How those lexicons are set up is the crucial issue. As I have said, the issue is that these new lexicons will determine what will count as information (and thus be able to be owned) and what will not. As an example, note the previously cited case of the plant breeders in West Africa who cannot "own" the "information" which has come to them through generations of plant breeding (as it is not "property"); contrast that with the genetic scientist who can determine the genetic characteristics (the information codes) of that breeding process and can be granted a patent. The lexicon is established to the advantage of those who possess the higher technology, and this is obviously the developed countries.

Again my point is not to vilify the bioindustry, but simply to point out the forces that are constituting the terms of the discussion of biotechnology in some of the most important institutional sites. By determining the definitions of "information" in the new lexicon at the outset, the bioindustry gains control over the marketplace of information. By establishing the criteria which will determine what is and is not able to be owned, it creates a structured marketplace in which participation is dependent upon technical competencies and their associated criteria. We can hardly blame them for operating out of self-interest, but we should blame ourselves and our institutions which are supposed to safeguard public welfare and which have not raised the kind of questions which need to asked about the distributions of power in this emerging new age.

Likewise, there exists concerns for the preservation of species and biodiversity. There are various strategies for the maintenance of biodiversity

50. In fact, we are entering a new era of bio-politics; new and disturbing forms of knowledge/power configurations which decenter the meaning of terms which have been relatively stable in the past such as "nature" and "species." Taking the last of these first, biotechnology renders the traditional uses of terms such as nature and species meaningless. Nature has always been a limit concept. It has provided us with a set of categories and a ground which more than
and the preservation of species. One view on the preservation of species and the maintenance of biodiversity is holistic in nature. To preserve a species demands that the entire ecosystem within which it cohabits be maintained.

Ontologically, a species is seen in terms of that set of relationships which it maintains with the other participants of that ecosystem. It is this strategy which is pursued by the UNCED Biodiversity Convention. Within what might be called the "mechanistic worldview," we find that a species is viewed in terms of a substance ontology. Preservation is accomplished if a few examples of the species are maintained in holding facilities. These facilities may be limited attempts to preserve or duplicate ecosystems or they may be zoos or animal theme parks. The animal is discursively construed as substance. This means that as long as one material example is preserved somewhere the species is not extinct.

Within a cybernetic/biotechnical worldview, the preservation of a species can be accomplished by preserving its genetic code in a gene bank. Ontologically, a species is reduced to that information encoded in its DNA; wholly apart from its relationship within an ecosystem and even apart from the need to preserve a living example. It should be noted that gene banks are presently being established all over the world, and that one of the primary claims they make to legitimate their existence is the preservation of species.

Above all of this hangs the profound philosophical question of whether a species has a right to exist, and whether this should have some type of international legal standing. Do we preserve species only because they are genetic resources for us or do they have value in themselves? One argument made on behalf of biotechnology is that it will help in the preservation of species through bio-prospecting. Since global genetic diversity is its resource pool, it is obviously to its advantage to conserve it. Thus bio-prospecting is an argument for preservation. However, at some point it becomes necessary to ask whether we want to establish an international legal principle which says we preserve useful species, and allow those which are deemed not useful to become extinct. Granted, this is a harsh statement of the issue, nevertheless, I would argue that it is one which those working in the area cannot avoid.

Finally, there is the claim by the bioindustry that it will add to biodiversity both by working to maintain the present biodiversity (because it is the industry's resource base) and by adding to biodiversity through the

any other concept has been transcultural and transhistorical. Likewise for the term species, with the exception for the rapid disappearance of species due to ecological devastation in the modern period, the concept of species has represented a relatively stable limit to thought and practice. Within the new discursive regime of biotechnology both terms become virtually meaningless as limit concepts. Transgenic organisms do not exist in nature. The slow evolutionary process by which nature introduced new species and new organisms has now been irrevocably altered. The number of new species which might be introduced is limited only by the genetic resource base and human imagination.
introduction of new organisms and species. Foucault’s ideas of knowledge/power regime are thus taken, in some scenarios, to nightmarish proportions. With the introduction of new and more efficiently designed organisms into already overstressed ecosystems, survival of the fittest becomes a game fixed in favor of the laboratory produced contestants. Furthermore, under the protection of the patenting of these life forms, corporations will not just own an animal, plant or organism, but an entire genetic line. It becomes possible to genetically "own" an entire species. This leads one to imagine a future in which the biodiversity remaining on the planet comes primarily from the laboratories. When one adds to this the fact that the industry is now seeking to be able to patent anything it discovers, we are left in a world where the biodiversity of the planet is entirely owned by various patent holders.

Nor is this scenario limited to the nonhuman. There are already cases involving the patenting of human life forms which add disturbing new chapters to what Foucault has called the "political technologies" of control of the body. The case of John Moore’s spleen is just one example. Moore had his cancerous spleen removed at UCLA. It was subsequently determined that his spleen had certain genetic characteristics which made it useful for developing a "cell line." That cell line was sold to a biotech firm, which in turn sold part of it to the giant Swiss concern, Sandoz. Moore went to court to demand a portion of the profits which had been derived from his spleen. The lower court found in his favor but the California Supreme Court found that the companies had no fiduciary responsibility to Moore. (It did, however, allow him to sue his doctors for not informing him of what they were doing.) Moore’s spleen (or, more specifically the cell line developed from it) had become the "intellectual property" of those who had identified its information and use-value. John Moore’s body had become a piece of intellectual property over which he has lost "ownership" rights.

There is also the recent patent application by the Secretary of Commerce of the United States for a cell line developed from the genetic structure of the


54. Mooney, supra note 45, at 217.
Guaymi Indians of Panama (U.S. Patent Application 9108455). This was done without the knowledge of the Guaymi Indians (although the patent application reads "Human T-Lymphotroic Virus Type 2 From Guaymi Indians in Panama" and without any intention of compensation for the use of their genetic structure as an economic resource. This patent application must be seen in the context of a much broader project called the Human Genome Diversity Project which is gathering genetic materials from indigenous peoples all over the planet. When added to the thousands of patents applied for by the National Institutes of Health in connection with the Human Genome Diversity Project we begin to see the dimensions of this new age.

What does it mean to "own" the genetic structure of a person, of a tribe of people or of humanity? What kind of rights do we have over our own genetic structure? Is property to be defined based purely on techno/scientific superiority? How should equitable distribution of profits be structured in such cases? And the basic question behind all of this: should the patenting of life forms be allowed at all? What is clear is that there is a range of profound cultural, social, ethical even religious questions which go beyond the legal issues when it comes to biotechnology.

Finally, there is the international issue of the release of genetically modified organisms (GMO's) into the environment. Not only is this an issue which can be raised with regard to laboratory construction (an international rather than a domestic issue) but also with regard to the experimental release of GMOs. While there are regulations in the United States limiting experimental release of GMOs and the type of testing of genetically created life forms, most developing countries have no such regulations pertaining to either laboratory construction or to experimental releases. This has led critics of the bioindustry to fear that developing countries will become experimental dumping grounds. The long term effects of this scenario upon the indigenous biodiversity cannot be known.

I would argue that all of these issues move us beyond the legal and into the ethical. It is often argued that the larger cultural, ethical, and environmental issues would seem more appropriate for the government official, the professional ethicist or even the futurologists. This is due to the fact that the lawyer's responsibility is advocacy: the representation of the client's


56. This information comes from Pat Mooney at the Rural Advancement Foundation International and will be published in a forthcoming article in DEVELOPMENT DIALOGUE. While it appears that the controversy surrounding this patent application has caused the government to withdraw, it is only a matter of time before such patent applications are commonplace.
interests, whatever may be those interests. But with respect to biotechnology and its future impacts upon biodiversity and society, a greater responsibility is at play here. Given that these long-term impacts are potentially so dramatic, it would be surprising if the lawyer did not find him or herself caught between the short-term demands for profits, markets, etc. and the long-term responsibilities to future generations.

While it is easy to place this greater responsibility aside in the name of advocacy, the question remains as to whom the responsibility belongs. It cannot be argued that it is the responsibility of policy makers as the disposition of biotechnology for the future will clearly not be determined as a matter of definitive policy. Rather, it will be determined in terms of contracts between parties which will test the limits of the interpretive possibilities of the very general principles established in GATT or UNCED. Again, the point is that virtually everything that the international lawyer does with regard to biotechnology and biodiversity will be precedent-setting. The cumulation of these precedents will establish overall trajectory of where we will take this dramatic new technology.

As I have argued, options exist in terms of the principles to which appeals can be made in choosing these directions. The challenge is to strike a balance between responsibility as an advocate of the client’s short-term interests and responsibility to the longer-term interests of sustainability. Finding this balance is likely to require new forms of cooperation with those both inside and outside of the client’s organization and a good deal of creative thinking on the part of the lawyer and those with whom she or he works. What is unacceptable is to ignore or place in abeyance the questions of the long-term effects of biotechnology and of the precedents which are established in the present.

We can all agree that the long-term effects of the last great technological revolution of the Industrial Revolution have not been good when it comes to the environment and biodiversity. Hopefully as we enter this new biotechnological revolution, we will do so in a more conscious and conscientious fashion than we did the first time. It would seem to be undeniable that the long-term potential of biotechnology for both good and bad is unprecedented. For all of the failures of the UNCED process, it does represent a new level of global self-awareness and a commitment to consider the future as part of current decisions. It mandates this responsibility to future generations as part of everyone’s professional responsibility. Sustainability does not need to be a bad or threatening word for business or government. It is one which requires that new solutions be sought which take into account this new awareness of the future. The challenge is to find ways to wed the visions of sustainability to those of open markets. As we move into this new age characterized by information and internationalization, the international lawyer is uniquely positioned to impact the course we chart for the twenty-first century. But in order to do so, he or she must be willing to engage in these
broader questions. For it is through engagement, at this level, that guidance for the crucial legal directions will emerge.