A HUMAN RIGHTS PERSPECTIVE ON INTELLECTUAL PROPERTY, SCIENTIFIC PROGRESS, AND ACCESS TO THE BENEFITS OF SCIENCE

by

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1. Introduction

Intellectual property regimes seek to balance the moral and economic rights of creators and inventors with the wider interests and needs of the society. A major justification for patents and copyrights is that incentives and rewards to inventors result in benefits for the society. The United States Constitution, written in 1787, for example, vests the Congress with the power "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respectful Writings and Discoveries."[1] Two hundred years later, the World Intellectual Property Organization (WIPO) links the existence of an equitable and modernized patent system to incentives for inventiveness and innovative activity, a willingness to invest in industrial applications, and a favorable climate to the transfer of technology.[2]

A human rights approach to intellectual property takes what is often an implicit balance between the rights of inventors and creators and the interests of the wider society within intellectual property paradigms and makes it far more explicit and exacting. The International Covenant on Economic, Social and Cultural Rights (the ICESCR) is the major international human rights instrument addressing these issues. Article 15 specifies that States Parties, that is the countries that have ratified or acceded to this instrument, "recognize the right of everyone" both "to enjoy the benefits of scientific progress and its applications"[3] and "to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."[4] To achieve these goals, the Covenant mandates that States Parties undertake a series of steps. These include "those necessary for the conservation, the development and the

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[1] Article 1, Paragraph. 8, Section 8, *The Constitution of the United States of America (U.S.A)*, adopted 1787, Washington D.C.: U.S. Government Printing Office, 1985.
[2] *Intellectual Property Reading Material*, (World Intellectual Property Organization (WIPO)), Publication 476E, Sections 4.60 and 4.61, p .59.
[3] Article 15.1. (b), *International Covenant on Economic, Social and Cultural Rights*, henceforth ICESCR, adopted 16 December 1966, 993 U.N.T.S. 3 (entered into force 3 January 1976), G.A. Res. 2200 (XXI), 21 U.N. GAOR Supp. (No. 16), p. 49, U.N. Doc. A/6316 (1966).
[4] Article 15.1 (c), ICESCR.

diffusion of science and culture."[5] More specifically, States Parties "undertake to respect the freedom indispensable for scientific research and creative activity."[6]

Further, States Parties make the commitment to "recognize the benefits to be derived from the encouragement and development of international contacts and cooperation in the scientific and cultural fields."[7]

To be consistent with the norms in the ICESCR, a human rights approach differs in a number of regards from the standards set by intellectual property law. In brief, it requires that the type and level of protection afforded under any intellectual property regime directly facilitate and promote scientific progress and its applications and do so in a manner that will broadly benefit members of society on an individual, as well as collective level. It establishes a higher standard for evaluating patent applications, namely that the proposed invention also be consistent with the inherent dignity of the human person and with central human rights norms. Because a human right is a universal entitlement, its implementation should be measured particularly by the degree to which it benefits those who hitherto have been the most disadvantaged and vulnerable.[8] A right to the benefits of science and technology assumes that both individuals and communities will have easy access. Additionally, a right to the benefits of science and technology cannot be achieved in the absence of careful government policies to determine priorities for investment in and the development of science. The human rights principle that every citizen shall have the right and opportunity to take part in the conduct of public affairs[9] mandates a right of choice for members of society to be able to discuss, assess, and have a role in determining major scientific and technological developments.[10] And finally, a human rights approach entails a right of protection from possible harmful effects of scientific and technological development, again on both individual and collective levels. These considerations go well beyond a simple economic calculus.

Although more than 130 countries have become States Parties to the ICESCR[11] and therefore are legally obligated to comply with these standards, too often, policy makers and legislators do not factor human rights considerations into decision-making on intellectual property regimes, and instead rely primarily on economic considerations. In part this situation reflects intellectual fragmentation of spheres of knowledge and interest.

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[5] Article 15.2, ICESCR.
[6] Article 15.3, ICESCR.
[7] Article 15.4, ICESCR.
[8] A. R. Chapman, "A Human Rights Approach to Health Care Reform," in A. R. Chapman, (Ed.), *Health Care Reform: A Human Rights Approach* (Washington, D.C.: Georgetown University Press), p.153.
[9] Article 25 (a), *International Covenant on Civil and Political Rights*, adopted 16 Dec. 1966, 999 U.N.T.S. 171 (entered into force Mar. 1976), G.A. Res. 2200 (XXI) 21 U.N. GAOR, Supp. (No. 16) at 52, U.N. Doc.A/6316 (1966).
[10] C.G. Weeramantry, "The Problems, the Project, and the Prognosis," in C.G. Weeramantry, (Ed)., *Human Rights and Scientific and Technological Development* (Tokyo: United Nations University Press, 1990), p. 14.
[11] As of 15 January 1998, 137 countries had ratified ICESCR. These numbers have been relatively stable for the past decade. See Paragraph 53, Commission on Human Rights, "Follow-Up to the World Conference on Human Rights: Five Year Review of the Implementation of the Vienna Declaration and Program of Action," Interim report of the United Nations High Commissioner for Human Rights, E/CN.4/1998/104, dated February 20, 1998.

Intellectual property lawyers tend to have little involvement with human rights law, and few human rights specialists deal with science and technology or intellectual property issues. In addition, although many members of the scientific community have become human rights advocates, particularly in societies that do not respect human rights norms, their activities have generally been practical rather than theoretical. Their involvement has sought to bring about fundamental political reforms consistent with a respect for human rights or aimed at protecting colleagues who are being persecuted. Work on broader issues related to the role and nature of science has dealt primarily with the freedom indispensable for scientific research and creative activity and to a lesser extent on the concomitant responsibilities of scientists. Even public interest science advocates concerned with the application of science to promote human welfare generally use the vocabulary of scientific responsibility rather than human rights.[12]

An additional complication is that Article 15 of the ICESCR can be characterized as the most neglected set of provisions within an international human rights instrument whose norms are not well developed. As has been noted by analysts, the implementation and monitoring of the rights articulated in the ICESCR have generally been hampered by various conceptual and methodological difficulties.[13] Much has been written about the lack of intellectual clarity as to the definition and scope of these rights.[14] The provisions in Article 15 share in these problems. Understanding of the full implications of economic, social, and cultural rights is less advanced than is the case with civil and political rights. In contrast with civil and political rights, the rights contained in the ICESCR, with the exception of the labor-related articles, are not grounded in significant bodies of domestic or international jurisprudence. Most of these rights were first articulated and recognized in the Universal Declaration of Human Rights (UDHR)[15] and then given greater specificity in the ICESCR. This is the case with regard to the provisions of Article 15. Although intellectual property claims, cultural life, and scientific advancement were certainly well discussed topics prior to 1948, they were not considered to be human rights. Added to these limitations, the literature conceptualizing the scope of Article 15 and related State Party obligations is even sparser than most of the other rights defined in the ICESCR.

Moreover, economic globalization and increasing privatization and commercialization of science has made it even more difficult to achieve the various balances envisioned in Article 15. These trends have affected the very conduct and nature of science. Because science is one of the most international of all activities, advances in science require freedom of inquiry, the full and open availability of scientific data on an international basis, and open publication of results. Until recently most

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[12] See, e.g., J. T. Edsall, *Scientific Freedom and Responsibility: A Report of the AAAS Committee on Scientific Freedom and Responsibility* (American Association for the Advancement of Science: Washington, D.C., 1975).

[13] See, e.g., A. R. Chapman, "A 'Violations Approach' for Monitoring the International Covenant on Economic, Social and Cultural Rights," *Human Rights Quarterly* 18 (1996):pp. 23-66.

[14] See, e.g., Philip Alston, "Out of the Abyss: The Challenges Confronting the New U.N. Committee on Economic, Social and Cultural Rights," *Human Rights Quarterly* 9 (1987):pp. 332-81.

[15] *Universal Declaration of Human Rights* (UDHR), adopted December 10, 1948, G.A. Res. 217A (III), 3 U.N. G.A.O.R. (Resolutions, part 1), U.N. Doc.A/810 (1948).

developed countries provided extensive public funding for basic scientific research so as to assure widespread availability of and access to the findings.[16] Large government investments in basic research and development made it possible to argue that the conduct of scientific research, including the maintenance and distribution of scientific data, was a public good. Research scientists actively pursued dissemination of research results through publication and often seemed disinclined to patent their discoveries.[17] However, an evolution of government policy, beginning in 1980 with the adoption of the Bayh-Dole Act in the U.S.A., inclined many governments to encourage the private commercial development of publicly funded research. Subsequently many of these countries also began to privatize activities previously delivered by the public sector and to facilitate the generation and distribution of scientific data on a commercial basis. This development, in turn, stimulated pressures for new and broader forms of intellectual property rights to protect economic investments.

The implications of these developments are several. Commercialization has introduced market considerations into the conduct of science. It has eroded the distinction in many areas of scientific research between basic research, where intellectual property rules are primarily concerned with the attribution of ideas and findings, and applied research, where intellectual property and proprietary concerns predominate. This has particularly been the case in computer science and biotechnology.[18] Commercialization has also changed intellectual property from a means to provide incentives to researchers and inventors to a mechanism to encourage investment and protect the resources of investors. Corporate investment in scientific research and development has imposed constraints on science's tradition of open publication. In many scientific fields, particularly the life sciences, some scientists are delaying publication and withholding data so as to secure intellectual property rights.[19] There is widespread concern in the scientific community that privatization, accompanied by legal restrictions and high prices, will restrict scientists' access to data needed for their research.[20] A report by the National Research Council of the U.S. Academy of Sciences comments as follows on these trends:

> Science operates according to a "market" of its own, one that has rules and values different from those of commercial markets. While protection of intellectual property may concern a scientist who is writing a textbook, that same scientist, publishing a paper in a scientific journal, is motivated by the desire to propagate ideas, with the expectation of full and open access to results. To commercial publishers (including many professional societies), protection of intellectual property means protection of the right to reproduce and distribute printed material.

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[16] Committee on Issues in the Transborder Flow of Scientific Data of the National Research Council, *Bits of Power: Issues in Global Access to Scientific Data*, (Washington, D.C.: National Academy Press, 1997), pp. 17, 133.

[17] A. E. Carroll, "A Review of Recent Decisions of the United States Court of Appeals for the Federal Circuit: Comment: Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law," *The American University Law Review* 44 (Summer, 1995): no. 24.

[18] Committee on Issues in the Transborder Flow of Scientific Data, *Bits of Power*, *op. cit*. pp.133-134.

[19] E. Marshall, "Secretiveness Found Widespread in Life Sciences," *Science* 276 (April 25, 1997), p.525.

[20] Committee on Issues in the Transborder Flow of Scientific Data, *Bits of Power*, *op.cit.* p. 111.

> To scientists, protection of intellectual property usually signifies assurance of proper attribution and credit for ideas and achievements. Generally, scientists are more concerned that their work be read and used rather than that it be protected against unauthorized copying. These conflicting viewpoints pose challenging problems for science and the rest of society.[21]

That these trends have occurred within the context of economic globalization has further complicated the situation. Globalization is inimical to human rights considerations in a variety of ways. The first is the values orientation it promotes. A human rights approach is predicated on the centrality of protecting and nurturing human dignity and the common good. It evaluates science according to its ability to promote these goals. In contrast, commercialization and privatization place greatest emphasis on the profitability of science and its contributions to economic competitiveness. Economic globalization also promotes a reliance on the market and translates other values into economic or property discourse. Studies have shown that conceptions and assumptions underlying property discourse tend to influence and crowd out other modes of valuation. The presumption is that all other modes of valuation can and should be translated into market terms.[22]

Additionally, globalization encourages a reconceptualization of the role of the state, reducing its regulatory and redistributive functions and privatizing the performance of many services.[23] This is problematic for the realization of human rights. The recognition of rights confers reciprocal duties and obligations for their realization, and human rights law usually vests these responsibilities in the state. Thus an ambitious human rights agenda, particularly in relationship to the realization of economic, social, and cultural rights, requires a strong and effective state. However, at century's end key elements of the welfare state model are being cast aside and the resources invested in the state are being downsized. In this reorientation, the state is increasingly viewed as a mechanism for establishing the conditions for private actors to fulfill their goals. This often comes at the expense of assuming direct responsibility for social welfare and the common good, as defined by human rights norms. In the process governments are becoming increasingly responsive to the influence of strong economic interests to the detriment of the effectiveness of institutions representing broader constituencies.

This paper will deal with these issues. It is written in three major sections. The first conceptualizes the scope and limitation of the portions of Article 15 of the ICESCR relating to science and technology. The second and third sections of the paper are in the form of case studies of two contested subjects, gene patenting and database protection. Both of these issues have attracted considerable attention in recent years. They are also topics with which the Directorate of Science and Policy Programs of the American Association for the Advancement of Science has been involved.

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[21] *Ibid.*, p 5.

[22] See, e.g., E. R. Gold, *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Washington, D.C.: Georgetown University Press, 1996).

[23] K. Tomasevski, "The impact of globalization on the enjoyment of economic, social and cultural rights in OECD countries," draft paper commissioned by the American Association for the Advancement of Science, 1997.

2. Conceptualizing Article 15 of the ICESCR

(i) Universal Declaration of Human Rights

Article 15 of the ICESCR builds on the text of a parallel article in the Universal Declaration of Human Rights. The first paragraph of Article 27 of the UDHR states that "Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits." The second paragraph of Article 27 adds a second provision: "Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author."

Like other provisions of the UDHR, the context for drafting Article 27 was the widespread reaction to the Nazi genocide and the brutality of World War II. Science and technology had played an important role in the war and served as an instrument of the Holocaust. Therefore it is not surprising that some eminent members of the scientific community took an active part in the public debate after the war regarding the development of a code of universal human rights norms. They included Julian Huxley, the British biologist and writer who served as the first director of the United Nations Educational, Scientific and Cultural Organization (UNESCO), the American chemist W.A. Noyes, and J.M. Burgers, a member of the Royal Netherlands Academy of Science.[24] Additionally, the discussion within the United Nations Commission on Human Rights during the drafting process for the UDHR alluded to the misuse of science and technology by the Hitler regime and the need for safeguards to protect science from being applied for harmful purposes.

Conceptualizing science within a human rights framework, however, required more than just insulating science and technology from potential misuse or even protecting the public from exposure to the harmful effects of science. Like the language in other provisions of the UDHR, Article 27 recognizes a series of rights or claims. All of these rights, including those related to science and culture, are considered to be universal, vested in each person by virtue of their common humanity. The human rights articulated in the UDHR are also held to exist independently of recognition or implementation in the customs or legal systems of particular countries. Human rights are held to comprise important norms that create *prima facie* obligations, particularly on the part of governments, to take positive measures to protect and uphold these rights.[25]

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[24] This discussion of the historical background to the drafting of Article 27 relies on Richard Pierre Claude, "Scientists' Rights and the Right to the Benefits of Scientific Progress." The paper was commissioned by the Science and Human Rights Program of the American Association for the Advancement of Science (Washington, D.C.) and presented at the Hebrew University in 1998. Claude drew on the Official Records of the Third session of the General Assembly, Part I, "Social and Humanitarian Cultural Questions," Third Committee, Summary Records of Meetings, September 21 -December 8, 1948, pp. 619-635.

[25] J. W. Nickel, *Making Sense of Human Rights: Philosophical Reflections on the Universal Declaration of Human Rights* (Berkeley and Los Angeles, University of California Press, 1987), p. 3.

The wording of Article 27 is noteworthy in a number of regards. It goes beyond recognizing a right to benefit from science applications to articulate specifically that everyone has the right "to share in scientific advancement and its benefits." This language emerged from concerns expressed by some members of the drafting committee operating under the aegis of the United Nations Commission on Human Rights that scientific activities, as well as literary activity, were elitist in nature. Paragraph 2 on "the protection of moral and material interests" reflected a variety of interests. One impetus was a desire by some drafters to harmonize the UDHR with the provision on intellectual property in The American Declaration on the Rights and Duties of Man, 1948. Other members of the Committee expressed a desire to use the moral authority of the United Nations (the U.N.) to protect all forms of work, intellectual as well as manual. The provision survived criticisms by some members of the drafting committee that intellectual property needed no special protection beyond that afforded generally by property rights (already in Article 17 of the UDHR), as well as claims that special protection for intellectual property entailed an elitist perspective.

The UDHR was adopted unanimously by the General Assembly on December 10, 1948. As a General Assembly action, the UDHR is aspirational or advisory in nature. It does not legally bind member states of the U.N. to implement it. Over time, however, the UDHR has gradually assumed the status of customary international law. It is considered to be the single most authoritative source of human rights norms. Nevertheless, some provisions, particularly those dealing with basic civil and political rights, have gained more recognition than the provisions dealing with economic, social and cultural rights. Despite a rhetorical commitment to the indivisibility and interdependence of human rights, the international community has consistently treated civil and political rights as more significant than economic, social and cultural rights.

The original plan within the United Nations was to follow the Universal Declaration with the adoption of a series of treaties that would make its provisions more specific and binding on those countries that became States Parties by ratifying or acceding to these instruments. Because of Cold War hostilities, as well as reduced support for human rights treaty-making by the United States, the procedure was delayed. Drafts of two international covenants, one on civil and political rights and the other on economic, social and cultural rights, originally submitted to the General Assembly in 1953, were not approved until 1966. Both came into force in 1976 when the thirty-fifth nation signed these instruments.[26] The ICESCR and the ICCPR, along with the UDHR, are said to constitute the universal bill of human rights. Together they set the minimal standards of decent social and governmental practice.

(ii) Comparing Provisions of the UDHR and Article 15 of the ICESCR

The language in Article 15 of the ICESCR builds on but also differs from the UDHR in a number of ways. Much like the Universal Declaration, the first paragraph recognizes three rights—the right of everyone:

[26] Nickel, *Making Sense of Human Rights*, *op.cit.* pp 5-6.

(a) To take part in cultural life;
(b) To enjoy the benefits of scientific progress and its applications;
(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

It is relevant to note that the intellectual property provision in the UDHR was carried over into the ICESCR despite the fact that the article on the right to property was not. the ICESCR has no equivalent to the Universal Declaration's Article 17.1 language that "Everyone has the right to own property alone as well as in association with others." Nor does it make the commitment found in Article 17.2 that "No one shall be arbitrarily deprived of his property."

Most notably, because the ICESCR has the status of a treaty and as such is legally binding on those nations that become States Parties, the text of Article 15 in the ICESCR articulates a series of responsibilities for States Parties that were absent from the Universal Declaration. It uses the format of "steps to be taken." In doing so, the ICESCR translates the aspirational language of the Universal Declaration into specific legal obligations. These are outlined in Paragraphs 2 through 4:

(2) The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.

(3) The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

(4) The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and cooperation in the scientific and cultural fields.

(iii) Limited Availability of Resources for Conceptualizing the Content of Article 15

As noted above, there have been few efforts to conceptualize the scope of Article 15 and the resultant obligations of States Parties. There is not a body of national or international law on this subject. The United Nations Committee on Economic, Social and Cultural Rights, the treaty monitoring body that oversees compliance with the ICESCR, has not engaged in efforts to interpret this Article. The Committee has not held a day of general discussion on the portions of the article relating to science and technology. Nor has it initiated a process to draft a general comment to clarify its normative content. During the 1970's the Secretary-General of the U.N. and specialized agencies prepared a number of substantive reports on scientific and technological developments and their impact on human rights for presentation to the General Assembly of the U.N. and the Commission on Human Rights, but these studies did not result in standard setting. Also in the mid-1970s socialist countries took the initiative and

developed a "Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind."[27] While this Declaration was approved by the General Assembly, many Western countries decided to abstain because of the references to "liberation movements" in the text, and as an action of the General Assembly it is not legally binding. Moreover, academic literature more often focuses on the potential problems rather than the contributions of science and technology. One of the few sources addressing broader issues of science and technology within a human rights framework is a collection of articles entitled *Human Rights and Scientific and Technological Development.*[28] This publication was sponsored by the United Nations University and edited by C.G. Weeramantry, currently a justice on the International Court in The Hague.

(a) Article 15.1 (b): The right of everyone to enjoy the benefits of scientific progress and its applications

As conceptualized in this paper, the right of everyone to enjoy the benefits of scientific progress and its applications has three central components:

- A right of access to beneficial scientific and technological developments;
- A right of choice in determining priorities and making decisions about major scientific and technological developments;
- A right to be protected from possible harmful effects of scientific and technological development, on both individual and collective levels.

As interpreted through a human rights lens, a right of access at a minimum entails that the freedom and opportunity to benefit from scientific and technical advancement be broadly diffused within a nation "without discrimination of any kind as to race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status."[29] It also requires governments "to ensure the equal right of men and women to the enjoyment"[30] of the benefits. The U.N. Committee on Economic, Social and Cultural Rights interprets these nondiscrimination clauses as requiring States Parties to eliminate both *de jure* and *de facto* forms of discrimination that adversely affect the realization of the rights covered by the Covenant. These obligations have also been interpreted as requiring both negative measures to prevent discrimination and positive "affirmative action" type initiatives to compensate for past discrimination.[31] To fulfill these requirements, the U.N. Committee places considerable emphasis on the realization of the human rights of women, minorities, the poor, and other disadvantaged groups both in their reporting guidelines and in their review of State Party reports.

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[27] "Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind," proclaimed by General Assembly Resolution 3384 (XXX) of November 1975.
[28] Weeramantry, (Ed)., *Human Rights and Scientific and Technological Development, op.cit.*
[29] Article 2.2, ICESCR.
[30] Article 3, ICESCR.
[31] P. Alston, "The International Covenant on Economic, Social and Cultural Rights," in *Manual on Human Rights Reporting*, U.N. Doc. HR/PUB/91/1 (1991), p. 47.

What, then, does this mean for interpreting the right to benefit from scientific advances? It certainly imposes a different standard from the current tendency to favor the interests of large corporations or to promote the abstract principle of scientific competitiveness. A human rights approach establishes a requirement for the state to undertake a very rigorous and desegregated analysis of the likely impact of specific innovations, as well as an evaluation of proposed changes in intellectual property paradigms, and to utilize these data to assure nondiscrimination in the end result. When making choices and decisions, it calls for particular sensitivity to the effect on those groups whose welfare tends to be absent from the calculus of decision-making about intellectual property: the poor, the disadvantaged, racial, ethnic and linguistic minorities, women, rural residents. Consequently, in undertaking these determinations the status of the middle class, the comforts that are likely to accrue to the affluent, or the potential profits to investors count for much less than improving the status of the vulnerable and bringing them up to mainstream standards.

The human rights principle of self-determination enumerated in the ICESCR and the various civil and political rights defined in the ICCPR emphasize the right of all members of society to participate in a meaningful way in deciding on their governance and common future. This translates into a right to societal decision-making on setting priorities for and major decisions regarding the development of science and technology. While this is easy to affirm in principle, it is very difficult to achieve in practice because political institutions have not kept up with technological change. In the early 1980s, C.G. Weeramantry wrote a book entitled *The Slumbering Sentinels* which examines the implications of unfettered technological advance.[32] He commented then that the speed of technological change had left social and political institutions unprepared with the result that technology was leading rather than being shaped by governmental policy.[33] He also identified various power shifts related to technological change, particularly the concentration of power in transnational corporations and these corporations' ability to find a common interest with personnel in government departments at the expense of the democratic process. Further contributing to the inadequacy of political structures in the face of technological changes, Weeramantry pointed out that decisions of major importance involving the use of technology are often taken at the highest legislative and executive levels, to which public interest groups often have little access. The counter-side to inadequate public representation is the growth of the power of lobbyists and their ability to undermine socially beneficial measures.

All of these trends have been further accelerated in the past fifteen years. Weeramantry advocated the need to undertake broad reforms to reorient the political process so as to assure that science and technology policy not be dictated from the top or shaped by a few powerful interests, but this has not taken place. Instead the rapid development of science and technology and the pressures imposed by economic globalization have shifted the balance even further away from citizens' control. A recent

[32] C.G. Weeramantry, *The Slumbering Sentinels: Law and human rights in the wake of technology* (Ringwood, Victoria, Australia and Harmondsworth, Middlesex, England: Penguin Books, 1983).
[33] *Ibid.*, particularly chapter 10.

paper written by the Center for International Environmental Law describes the situation with regard to the formulation of intellectual property law as follows:

> "Intellectual property laws are defined through closed, secretive international negotiations dominated by industry – and are then brought to national legislatures as *faits accomplis*, without democratic deliberation. Combined with the technical, arcane nature of intellectual property legal specialty, this has helped corporate interests to avoid public scrutiny and expand their control over developments in applications such as electronic information, biotechnology or pharmaceuticals. Industrial country governments promote corporate interests in expanded intellectual property rights in the name of maximizing national competitiveness in a global marketplace."[34]

The World Trade Organization's role in standard setting, particularly in light of the closed nature of its proceedings and its lack of concern for democratic procedures or human rights principles, has been of particular concern to many non-governmental organizations, human rights advocates, and environmental groups. Intellectual property is covered by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994 (the TRIPS Agreement). This Agreement, which was a product of the Uruguay Round of trade talks, sets minimum standards for national protection of intellectual property rights and imposes enforcement measures, including the potential for trade sanctions against WTO members who do not comply with WTO rules and procedures. The power of the WTO has been described as "unprecedented in the field of intellectual property protection."[35]

Much has been written about the challenges posed by science and technology to human rights and human dignity. In the thirty years since the publication of Jacques Ellul's pioneering work *The Technological Society*,[36] an increasing number of thinkers have called attention to the potential of technology to diminish human dignity and to erode moral values. According to some analysts, Albert Borgmann among them,[37] modern technology encourages us to treat an expanding range of human relationships as well as things as commodities whose utility we measure and consume. Others, such as Ian Barbour, recognize the subtle danger of extending technological attitudes to all of life until human beings and other creatures are treated as objects to be exploited.[38] Barbour points out that technologies frequently bring an inequitable distribution of costs and benefits: one group benefits while other groups bear the brunt of the risks and indirect costs. According to Barbour, technology, which is both a product and an instrument of social power, also tends to reinforce the concentration of wealth and political power in existing social structures.

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[34] David Downes, "The 1999 WTO Review of Life Patenting Under TRIPS," Revised Discussion Paper, Center for International Environmental Law, Washington, D.C., September 1998, p. 1.
[35] *Ibid.*, p.1.
[36] J. Ellul, *The Technological Society* (New York: Vintage Books, 1964), translated by J. Wikinson.
[37] A. Borgmann, "Communities of Celebration: Technology and Public Life," in Frederick Ferre, Ed., *Research in Philosophy and Technology* 10 (Greenwich, Conn. and London: JAI Press, 1990), 335.
[38] Ian Barbour, *Ethics in an Age of Technology* (San Francisco, Harper Collins Publishers, 1993).

Human rights law confers broad responsibilities on governments to protect against violations. Like civil and political rights, economic, social and cultural rights impose three different types of obligations on states: the obligations to respect, protect and fulfill. According to the Maastricht Guidelines on Violations of Economic, Social and Cultural Rights,[39] the obligation to respect requires states to refrain from interfering with enjoyment of specific rights. The obligation to protect requires states to prevent violations of such rights by third parties. And the obligation to fulfill requires states to take appropriate legislative, administrative, budgetary and other measures towards the realization of these rights.[40]

The 1975 Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind has a number of relevant provisions:

> "All States shall take appropriate measures to prevent the use of scientific and technological developments, particularly by the State organs, to limit or interfere with the enjoyment of the human rights and fundamental freedoms of the individual as enshrined in the Universal Declaration of Human Rights, the International Covenants on Human Rights and other relevant international instruments.[41]
>
> All States shall take measures to extend the benefits of science and technology to all strata of the population and to protect them, both socially and materially, from possible harmful effects of the misuse of scientific and technological developments, including their misuse to infringe upon the rights of the individual or of the group, particularly with regard to respect for privacy and the protection of the human personality and its physical and intellectual integrity.[42]
>
> All States shall take effective measures, including legislative measures, to prevent and preclude the utilization of scientific and technological achievements to the detriment of human rights and fundamental freedoms and the dignity of the human person."[43]

(b) Article 15.1 (c): The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

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[39] The Maastricht Guidelines were drafted by a group of some thirty experts who met in Maastricht from January 22-26, 1997 at the invitation of the International Commission of Jurists (Geneva, Switzerland), the Urban Morgan Institute on Human Rights (Cincinnati, Ohio, USA) and the Center for Human Rights of the Faculty of Law of Maastricht University (The Netherlands). The objective of this meeting was to develop guidelines on the nature and scope of violations of economic, social and cultural rights and appropriate responses and remedies. This author was among the participants. The meeting did not deal specifically with Article 15 of ICESCR.

[40] Paragraph 6, "The Maastricht Guidelines on Violations of Economic, Social and Cultural Rights," reprinted in International Commission of Jurists, *Economic, Social and Cultural Rights: A Compilation of Essential Documents* (Geneva: ICJ, 1997).

[41] Article 2, Declaration on the Use of Scientific and Technological Progress, *op.cit.*.

[42] *Ibid.* Article 6.

[43] *Ibid.* Article 8.

The language in Article 15.1 (c) imposes an obligation on States Parties to protect the moral and material interests of authors and inventors. However, it accords wide latitude regarding the manner in which a particular government confers intellectual property protection. The perspective in this paper is that a human rights framework imposes conditions on the recognition of intellectual property rights. To be consistent with human rights norms, the subject matter considered to be appropriate for patent protection and the paradigm that is adopted would have to meet the following considerations:

- Intellectual property rights must be consistent with the understanding of human dignity in the various international human rights instruments and the norms defined therein;
- Intellectual property rights related to science must promote scientific progress and access to its benefits;
- Intellectual property regimes must respect the freedom indispensable for scientific research and creative activity;
- Intellectual property regimes must encourage the development of international contacts and cooperation in the scientific and cultural fields.

The European Union provides one potential model relevant to the first point. Article 53(a) of the European Patent Convention specifically stipulates that patents should not be granted for inventions "the publication or exploitation of which would be contrary to *'ordre public'* or morality."[44] Several provisions of a recent Directive of the European Parliament and of the Council on the legal protection of biotechnological inventions reiterate this principle. The Directive also excludes inventions from patentability which offend against human dignity and ethical and moral principles recognized in member states.[45] Do these criteria overstep the appropriate role of the state, particularly a liberal state? Philosopher Baruch Brody comments as follows:

> "This European Approach seems perfectly appropriate. Even if the main purpose of the patent system is to promote technological advances, there is no reason why it cannot recognize limitations based upon the need to respect legitimate moral constraints. And even if a liberal state must be neutral and not prohibit behavior merely on the basis of moral constraints, there is no reason why it must promote what it considers to be immoral practices by providing them with intellectual property protection. So neither institutional considerations nor considerations of political policy prohibit the protection of human dignity by the Patent Office."[46]

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[44] Quoted in B. A. Brody, "Protecting Human Dignity and the Patenting of Human Genes," paper prepared for the Gene Patenting Dialogue Group, American Association for the Advancement of Science, May 1997, p. 3. A revised version of this paper appears in A. R. Chapman, (Ed)., *Perspectives on Gene Patenting: Science, Religion, Industry, and Law in Dialogue* (Washington, D.C.: American Association for the Advancement of Science, 1999).

[45] "Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998, Paragraphs. 37-40, on the legal protection of biotechnological inventions," *Official Journal of the European Communities*, 30.7.98, L 213/16.

[46] Brody, "Protecting Human Dignity and the Patenting of Human Genes", *op.cit.*

(iv) Obligations of States Parties

Articles 15.2, 15.3 and 15.4 of the ICESCR impose three sets of obligations on States Parties: to undertake the steps necessary for the conservation, development, and diffusion of science and culture; to respect the freedom indispensable for scientific research and creative activity; and to recognize the benefits to be derived from encouragement and development of international contacts and cooperation in the scientific and cultural fields. To fulfill the first of three mandates, the development and diffusion of science, at the least requires the following:

- Setting priorities for investment in and development of science and technology that weigh both the opportunities for scientific advancement and the potential societal benefits, particularly to poor and disadvantaged groups;
- Developing an adequate process of review to anticipate potential harmful effects of science and technology and inform the public;
- Providing a strong science education program at all levels of the state sponsored school system;
- Offering ongoing public outreach and educational efforts that will better enable individuals to understand the significance of developments and participate in decision-making about priority setting.

Given the enormous influence and impact of science and technology, the responsibility of governments to carefully scrutinize and evaluate science and technology may seem fairly obvious, but it is far from commonplace. Historically, many industrialized countries have allocated research funds through peer review mechanisms that emphasize their potential contribution to scientific knowledge. The assumption that scientific advancement is itself a societal good placed an emphasis on funding pure research without much consideration of its applications. Less developed countries that are primarily recipients, rather than sources of basic scientific research and new technologies, rarely have the infrastructure required to undertake a comprehensive evaluation of incoming products. This is the case whether considering their risks, even when notified by the exporting source of potential problems, or assessing their respective benefits. For this reason, many products that are banned or highly regulated in one country find their way onto the world market, being sold in the very countries whose lack of an educated and technologically sophisticated population makes them even more dangerous to use. Economic globalization has provided incentives to be more strategic about investments in science and technology. However, decisions made to strengthen a country's competitive position or the market advantage of multinational corporations headquartered there cannot be equated with a human rights approach.

A government can best show respect for the freedom indispensable for scientific research and creative activity by adhering to basic human rights norms recognized in the UDHR and the ICCPR. These include effectively protecting the freedom to express and communicate ideas, to travel within and outside of one's country, to assemble and form

professional associations. In addition, the pursuit of science requires an environment that supports the freedom to pursue scientific research in accordance with ethical and professional standards without undue interference. Conversely, the freedom to undertake scientific research and creative activity implies a need for scientific responsibility and self-regulation. Scientific societies in many developed countries have adopted codes of professional ethics in pursuit of these goals. Many of these codes, however, are primarily concerned with the ethics of individual conduct and do not place the scientific enterprise in a broad social context. Moreover, scientific societies, like other professional associations, vary quite considerably in their attitudes toward and capacities for effective self-regulation.

Article 15.4 of the ICESCR mandates that States Parties "recognize the benefits to be derived from the encouragement and development of international contacts and cooperation in the scientific and cultural fields."[47] This requirement should be interpreted in conjunction with other obligations enumerated in the ICESCR, particularly the language of Article 2. This provision directs each State Party to undertake "steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized."[48] Several instruments have tried to spell this out in somewhat greater detail. One section of the 1975 Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind states, for example, that "All states shall cooperate in the establishment, strengthening and development of the scientific and technological capacity of developing countries with a view to accelerating the realization of the social and economic rights of the peoples of those countries."[49]

The most appropriate means to fulfill these goals has been a matter of considerable controversy and conflict between countries in the North and the South, particularly with regard to the role of intellectual property regimes. Most long-industrialized countries have maintained that strong intellectual property provisions promote growth and a strong domestic economy. Developing countries, however, generally do not believe that it is in their present economic interests to implement stronger patent laws. Their opposition is based on three factors: (1) the benefits of an intellectual property system tend to be long-term and tenuous; (2) in the short-term, intellectual property protection increases the cost of development, with the patents awarded and resulting payments for the use of these technologies going primarily to foreign multi-national corporations; and (3) few of these countries have the requisite infrastructure to uphold strong patent systems. Thus developing countries sometimes accuse former colonial countries and multinational corporations of seeking to impose "technological colonialism."[50]

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[47] Article 15. 4, ICESCR.
[48] Article 5, Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind, *op.cit.*
[49] *Ibid.* Article 5.
[50] A. E. Carroll, "A Review of Recent Decisions of the United States Court of Appeals for the Federal Circuit: Comment: Biotechnology and the Global Impact of U.S. Patent Law: Not Always the Best Medicine:," *The American University Law Review* (1995), pp. 2464-2466.

3. Gene Patenting: A Case Study

(i) Background

Prior to 1980, some two hundred years of legal doctrine conceptualized life forms as "products of nature" rather than as a human invention and therefore unable to meet the three criteria for patents established by the U.S.A. Congress and many other countries: novelty, utility, and non-obviousness. These legal standards were overturned in a landmark 1980 U.S.A. Supreme Court decision. In *Diamond v.Chakrabarty,* the Court ruled, in a narrow 5-4 decision, that a genetically modified strain of bacteria capable of degrading components of crude oil and thus useful in cleaning up oil spills was patentable as a new and useful manufacture or composition of matter. While the decision affirmed that phenomena of nature in their natural state are not patentable, the Court identified a major exception: goods that have been transformed from their natural state through human intervention. According to the Court, Congress intended that "anything under the sun that is made by man" to be patentable subject matter.[51] In making this decision the Court was apparently motivated by the goal of stimulating the economy through inventive activity and assumed that the refusal to accord patent rights in genetically engineered organisms would slow down the pace of research in this field. After the 1980 Supreme Court decision, the United States Patent and Trade marks Office (USPTO) began to grant new kinds of biotechnology patents. Utility patents on newly developed plant varieties were soon accepted that went well beyond the limited protection that had previously been available.[52] Some of these patents were so broadly conceived that they covered all seeds and plants of a particular species that were genetically engineered in any manner.[53] A 1987 USPTO announcement then extended patent eligibility to "nonnaturally occurring nonhuman multicellular living organisms, including animals."[54] The following year a Harvard University biologist received a patent for a mouse that had been genetically altered so as to be susceptible to breast cancer and thereby able to serve as an animal model for studying human cancers. Between 1988 and 1996, the USPTO granted at least nine additional patents for genetically engineered animals.[55]

The inception of the Human Genome Project (HGP) in 1988, a major international initiative to decode the human genome, accelerated the pace of genetic discoveries and raised anew the issues related to commercialization of biology. It has been described "as the single most important project in biology and the medical sciences – one that will permanently change biology and medicine."[56] With funding of $200 million per year,

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[51] *Diamond v Chakrabarty* 477 U.S. 303 (1980).

[52] M. Sagoff, "Animals as Inventions: Biotechnology and Intellectual Property Rights," *Philosophy and Public Policy* 16 (Winter 1996), p. 18.

[53] N. Hettinger, "Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics," *Environmental Affairs* 22 (1995), pp. 269-271, 276.

[54] *Ibid.* p. 269.

[55] Sagoff, "Animals as Inventions," *op.cit.*, p. 15.

[56] F. S. Collins, A. Patrinos, E. Jordan, A. Chadravarti, R. Gesteland, L. Walters, and the members of the DOE and NIH planning groups, "New Goals for the U.S. Human Genome Project: 1998-2003," *Science* 282 (October 23, 1998):p. 682.

primarily from the U.S. National Human Genome Research Institute at the National Institutes of Health (NIH), the Office of Biological and Environmental Research at the Department of Energy (DOE), and Wellcome Trust in Britain, scientists are attempting to decipher the structure, positions, and functions of the 50,000 to 100,000 genes in human cells and to identify the approximately 5,000 genes whose defects or mutations are assumed to be the cause of genetically based disease. Public funding is predicated on the belief that the human genome sequence "is such a precious scientific resource that it must be made totally and publicly available to all who want to use it."[57] A second justification is that "only the wide availability of this unique resource will maximally stimulate the research that will eventually improve human health."[58]

In June 1991, well before any of the significant issues regarding intellectual property rights and/or applications of the research and discoveries funded through the Human Genome Project were thoroughly debated, let alone resolved, NIH decided to file a patent application on 350 human gene fragments that had been identified by one of its scientists. Despite strong internal opposition to patenting—specifically by James Watson, a Nobel prize laureate then serving as the director of the Human Genome Project—NIH followed with a second patent application in February 1992, this time on an additional 2,375 gene fragments, and it later submitted a third application for another 4,000. The USPTO turned down the initial NIH patent application on the ground that the gene fragments were neither novel nor useful in themselves. It also found NIH's proposed invention obvious.[59] NIH did not appeal the decision and subsequently a new director issued a statement advocating that its grantees desist from seeking patents on human gene sequences.

The controversy over whether parts of genes can be patented resurfaced in early 1997 when the Deputy PTO Commissioner gave a speech in which he announced that the USPTO was prepared to issue patents on expressed sequence tags (EST), which are gene fragments, without requiring a full description of what the gene does. NIH's chief patent attorney and then the NIH director urged the USPTO not to proceed in this direction because it would discourage scientists from sharing sequencing data.[60] Other credible voices responded by calling on the patent office to classify genetic information as public – that is to rule that they do not constitute inventions. Otherwise, it was argued, a patent holder would be able even to block a scientist's publication of results concerning its gene and/or to demand that any researcher wishing to study the gene must license it.[61]

Thus far the Patent Office has not been responsive to these appeals. Writing in *Science* magazine in May 1998, John Doll, the director of the USPTO section that handles biotechnology patents, sought to provide a clarification of its policy on the patenting of DNA. Two of the points he made are particularly important. To respond to criticisms that the PTO accepted patents on discoveries of naturally occurring sequences

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[57] *Ibid.* p.685.
[58] *Ibid.*
[59] Hettinger, "Patenting Life, Biotechnology, Intellectual property and Environmental Ethics,", *op.cit.* footnote, 24.
[60] "Renewed Fight over Gene Patent Policy," *Science* 276, April 11, 1997, p. 187.
[61] "The Gene Race Quickens," *The Washington Post*, August 22, 1998, A18.

and organisms, Doll distinguished between naturally occurring DNA sequences and sequences that are isolated and purified. According to Doll, the former still does not qualify for patents under U.S. law. However, if a patent application states that the DNA sequences in question are isolated and purified manufactures or compositions of matter or part of a recombinant molecule or part of a vector, it would meet the requirement of being distinguished from its natural state and constitute patentable subject matter. Doll justified the patenting of DNA fragments on the grounds that, even if these gene fragments do not directly identify genes, they may be extremely useful and thus satisfy the utility requirement.[62] This is a much watered down interpretation of the standard of utility.

Patent agencies around the world have been awarding patents based on DNA, including human genetic material and cell lines, for more than fifteen years. By February 1998, the USPTO reported that it has received more than 5000 patent applications based on whole genes since 1980 and granted more than 1500 of them. A study conducted by a science policy group found that the patent offices of the U.S., Europe, and Japan issued 1175 patents on human DNA sequences (partial rather than whole genes) between 1981 and 1995. In mid 1997, there were at least 350 patent applications, covering more than 500,000 gene sequences, pending at the USPTO.[63]

In May 1998, after a ten-year contentious debate and intensive lobbying from the biotechnology industry, the European Parliament approved a Directive that would permit the patenting of genes and genetically modified animals under specific conditions. The European Directive, part of an initiative to harmonize the laws and practice of member states and to place the European biotechnology industry on a more competitive footing, is more restrictive than current U.S. policy. As noted above, the Directive recognizes the need to condition the patentability of living matter on ethical and moral acceptability. In contrast with the USPTO, the Directive puts forward the view that a DNA sequence without indication of a function does not contain any technical information and is therefore not a patentable invention.[64]

(ii) Impact of Gene Patenting on Scientific Advancement

The scientific community has been divided over whether granting patents for DNA sequences will foster or deter research. Attitudes depend to a considerable extent as to whether scientists are in academic or governmental research institutions or working in the private sector. Initial opposition to human gene patenting reflected two concerns. Because the work on which the patent applications were based did not provide knowledge of the function of the relevant gene sequences, patenting of gene fragments was viewed, at best, as premature. The second source of opposition related to the anticipated negative effects that patenting would have on research and therapeutic

[62] J. J. Doll, "The Patenting of DNA," *Science* 280 (May 1, 1998):pp. 689-690.
[63] E. Marshall "Companies Rush to Patent DNA," *Science* 275 (February 7, 1997), pp. 780-781.
[64] "Directive 98/44/EC of the European Parliament," Paragraph 23.

applications of the knowledge generated by the Human Genome Project.[65] The 1991 statement on the patenting of DNA sequences issued by the Human Genome Organization (HUGO), the international research consortium coordinating and enhancing efforts in genome research reflects these concerns. According to the statement, HUGO is concerned that the patenting of partial and uncharacterized cDNA sequences will reward those who make routine discoveries but penalize those who determine biological function or application. Such an outcome would impede the development of diagnostics and therapeutics, which is clearly not in the public interest. HUGO is also dedicated to the early release of genome information, thus accelerating widespread investigation of functional aspects of genes.[66]

Some scientists, particularly those affiliated with the Council for Responsible Genetics, assert that gene patents work against the tradition of shared knowledge in scientific discovery and do not foster science or help people.[67] Currently one pharmaceutical giant, Merck, Sharpe and Dohme, which is the source of funding for a major genomic database at Washington University in St. Louis, argues that genetic sequences should be placed in the public domain and not be subject to patenting. Others in the biotechnology industry, including SmithKline Beecham, the sponsor and owner of another of the three major gene sequencing databases, are seeking patent protection for their discoveries. And even Merck has filed for series of patents on transgenic animals, screening assays, and complementary DNA sequences that have specific therapeutic applications.[68]

Commercialization of genetic science clearly has discouraged data sharing among scientists. One specialist in biotechnology patenting describes the situation as follows: "You no longer have a clearly bounded territory of open noncommercial science…It's like a lottery of sorts, and no one wants to discover they've just parted with a winning lottery ticket. The result…is that "the world of genomics is becoming a place where people are much more reluctant to share."[69] Research data confirm that this is the case. A recent survey indicates that a substantial fraction of researchers in the life sciences have delayed publication or withheld results and materials from colleagues. Of the 2167 scientists surveyed, 410 said they had delayed publication and 181 admitted not sharing data or materials. The reasons given by the researchers were often linked to commercial stakes: 46 percent said they needed time to prepare patent applications and another 33 percent indicated that they were trying to protect intellectual property in some other way.[70] Unsurprisingly, life science faculty with industry support were at least twice as

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[65] L. Roberts, "Genome Patent Fight Erupts," *Science* 254 (1991), pp. 184-186.
[66] The Human Genome Organization, "HUGO Statement on Patenting of DNA Sequences," Bethesda, Maryland, 1995, p. 1.
[67] See, e.g., the special issue of *GENEWATCH*, a bulletin of the Council for Responsible Genetics on "No Patents on Life!" 10 (October 1996).
[68] G. Poste, "The Case for Genomic Patening," *Nature* 378 (December 7, 1995), pp. 535-536.
[69] L. Belkin, "Banking on Genes," *The New York Times Magazine*, August 23, 1998, p.59.
[70] E. Marshall, "Secretiveness Found Widespread in Life Sciences," *op. cit.*, *Science* 276, p.525.

likely as those without to engage in trade secrecy or withhold research results from colleagues.[71]

A 1998 article in *Science* magazine raises yet another issue, namely that the proliferation of gene patents is creating too many concurrent fragments of intellectual property rights by different owners and is thus likely to create serious problems for future product development.[72] The authors, Michael Heller and Rebecca Eisenberg, both faculty members at the University of Michigan Law School, invert Garrett Hardin's well-known metaphor of the "tragedy of the commons" to claim that privatization of biomedical and genetic research is producing a "tragedy of an anticommons." Some thirty years ago Hardin published an article, also in *Science* magazine, the thesis of which was that people often overuse resources they own in common because they have no incentive to conserve them.[73] Hardin's position subsequently served as the intellectual justification for advocates of privatizing commons property. Heller and Eisenberg argue that privatization will result in the tragedy of the underutilization of scarce resources. According to Heller and Eisenberg, the current fragmentation in ownership will require costly future transactions to bundle licenses together before a firm will have the ability to develop new products. Faced with this situation, they anticipate that many firms will choose to invest resources in less promising projects with fewer licensing obstacles and lower initial start-up costs. Because patents matter more to the pharmaceutical and biotechnology industries, they also foresee that firms in these industries will be less willing to participate in mechanisms like patent pools that can help overcome these problems. Additionally, as they point out, some researchers and developers, universities for example, may be ill equipped to handle multiple transactions for acquiring rights to research tools. They therefore conclude that, far from spurring investment and product development, more intellectual property rights may lead to fewer useful products for improving human health.

This already complicated situation became even more so in 1998 when two companies decided to race the NIH-DOE consortium and complete the mapping and sequencing of the human genome ahead of the public venture. By relying on powerful new sequencing machines and taking various shortcuts much criticized by many in the genetics research community, Celera Genomic Corp., the first of these new ventures, anticipated accomplishing the task by 2001, four years ahead of the NIH-DOE target date. This raised the prospect that the fruits of one of the most significant international research projects might be privatized for commercial benefit and not fully accessible to other research scientists. Celera Genomics Corp., for example, plans to enter much of the sequence into GenBank, the Internet directory, once every three months as compared with NIH's daily updates. Nor will every thing the company discovers be made public. Celera will not, for instance, share its interpretation of the data, particularly related to polymorphisms, the genetic differences among human beings. It will also retain the

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[71] S. Krimsky, "Financial Interests Pervasive in Scientific Publications," *GeneWATCH*, 10 (February 1997), p. 8.

[72] M. A. Heller and R. S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research," *Science* 280 (May 1, 1998), pp. 698-701.

[73] G. Hardin, "The Tragedy of the Commons," *Science* 162 (1968), p. 1243.

intellectual property rights to the genes that show particular commercial promise.[74] Spurred by new competition from the private sector and prospects of private control of genetic information, the NIH-DOE consortium decided to accelerate its own schedule. It may have a "working draft" of the human genome as early as 2000 covering about 90 percent of the genome, and a final version by 2002.

(iii) Access to the Benefits of Science

Most of the public support and excitement the Human Genome Project and other genetic research have generated derives from the promise it holds for the diagnosis and eventual development of therapies to treat genetic abnormalities. Human gene therapy has been described as "a symbol of hope in a vast sea of human suffering due to heredity".[75] Thus far the development of gene therapies has been stymied by difficulties in identifying suitable and effective vectors through which to deliver corrected genes to the right location in the cell, but in the future privatization of control over genes may be an increasingly important factor. Many genetic disorders affect relatively small numbers of people, anywhere from a handful to a few thousand people, hardly an inviting commercial prospect. As one gene therapist noted, "The whole concept of gene therapy for genetic diseases doesn't fit the business model."[76] It is therefore not surprising that the focus of gene therapy has shifted from inherited diseases toward other more common and potentially profitable ailments like cancer, AIDS and heart disease. Of the 244 gene therapy trials authorized by NIH since 1989, only 33 are for diseases caused by a defect in a single gene, and half of those were for cystic fibrosis, the most common inherited disease among Caucasians. The figures for the trials registered since the beginning of 1997 are even more unbalanced – 53 for cancer and 8 for hereditary diseases.[77] Just as science is at the frontier of new approaches to gene therapy with considerable promise, the pharmaceutical companies that increasingly control patents on genes, particularly the ones with the relevant expertise, are losing interest because they are unwilling to investment money on treatments that have limited potential for payback.

(iv) Normative and Ethical Concerns Related to the Patenting of Life

The human rights approach defined in the first section of the paper conditioned intellectual property regimes on their conformity with ethical and human rights principles. It is therefore noteworthy that there has been considerable criticism of patents on life on ethical grounds by a wide range of secular ethicists, scientists, and religious groups. Beginning in 1980, when the General Secretaries of the National Council of Churches, the Synagogue Council of America, and the U.S. Catholic Conference wrote to President Carter shortly after the Chakrabarty decision, many groups within the religious

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[74] Belkin, "Banking on Genes,"op.cit. pp. 26-31, 58-61.
[75] J. C. Fletcher and W. French Anderson, "Germ-Line Gene Therapy: A New Stage of Debate," *Law, Medicine, and Health Care* 20 (Spring/Summer 1992), p.31.
[76] A. Pollack, "Gene Therapy's Focus Shifts from Rare Illnesses," *The New York Times*, August 4, 1998, C6.
[77] *Ibid*.

community have expressed concerns about genetic patenting. Rather than expressing an anti-technology position, this opposition reflects a religiously grounded conviction that biological patents constitute a threat to the dignity and sanctity of life.[78] In 1995, the titular leaders of more than 80 religious faiths and denominations in the U.S. - Protestant, Catholic, Jewish, Muslim, Buddhist, and Hindu - held a press conference to announce their opposition to the patenting of genetically engineered animals and human genes, cells, and organs.[79] A similar, albeit not as religious diverse coalition, developed in Europe to present the views of this group of national European Protestant churches on the draft European Community Patenting Directive. The churches, who were organized by the European Ecumenical Commission for Church and Society, made a submission to the European Parliament in 1996 and a presentation to Members of the European Parliament in 1997 to object to the proposed patenting of living organism and genetic material of human origin.

In the period since the 1980 Supreme Court decision much of the debate over the patenting of life has assumed an instrumental frame of reference, but even in a capitalist society there are commodities on which monetary exchanges are blocked, banned, or prohibited. A line of philosophical thinking stresses the moral need to protect certain items from being treated as commodities. Michael Walzer's concept of "blocked exchanges" is useful here. He notes that there are categories of items about which society has determined distribution should be on a noneconomic basis. His list of fourteen such "blocked exchanges" or things which cannot be bought and sold includes human beings; political power and influence; criminal justice; freedom of speech, press, religion, assembly; exemptions from military services, jury duty, or other communally imposed work; political offices; and love and friendship.[80] He does not, however, specifically mention genes, human tissue, or body parts, very likely because the book was published in 1983.

One source of opposition to gene patenting on moral grounds is the intuition that it is not appropriate to grant intellectual property rights over humanity's common heritage. In a 1991 letter to *Science* magazine, Hubert Currien, then the French Minister for Research and Technology, argued that "It would be prejudicial for scientists to adopt a generalized system of patenting knowledge about the human genome. A patent should not be granted for something that is part of our universal heritage."[81] Philosopher Ned Hettinger uses a similar line of reasoning to oppose gene patents. Hettinger claims that proper appreciation for the three and a half billion year story of the development of life on this planet and respect for the processes of evolution and speciation preclude gene patenting. He goes on to observe that:

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[78] For an analysis of the history and bases of the religious opposition, see A. R. Chapman, *Unprecedented Choices: Religious Ethics at the Frontiers of Science*, chapter four (Fortress Press, forthcoming 1999).
[79] "Joint Appeal Against Human and Animal Patenting," text of the press conference announcement made available by the General Board of Church and Society of the United Methodist Church, Washington, D.C., May 17, 1995.
[80] M. Walzer, *Spheres of Justice: A Defense of Pluralism and Equality* (New York: Basic Books, Inc., 1983), pp. 100-103.
[81] H. Currien, "The Human Genome Project and Patents," *Science* 254 (1991), p. 710.

> "Just as it is presumptuous to patent laws of nature, so too it is presumptuous to patent genes, which are equally fundamental to nature. Ideally, gene-types should be treated as a common heritage to be used by all beings who may benefit from them. As previously existing, nonexclusive objects that may be used beneficially by everyone at once, no one should possess the right to monopolize gene-types with patents or to "lock up" genes through any other property arrangements."[82]

More recently an editorial in *The Washington Post* voiced the opinion that "if ever a class of scientific information seemed fundamental to human knowledge and worthy of general access, the basic architecture of our genes is it." The editorial went on to state that "Granters of patents should tread with great care to keep these building blocks of future progress accessible to as much inquiry as possible."[83] Those who are disturbed by the ability of an individual or corporation to claim intellectual property rights over a resource which belongs to the whole of the human community frequently propose some form of public ownership. Advocates of public ownership point out that government funds have frequently played a major role in sponsoring the research that has led to these discoveries, and it is contrary to the public interest to then turn over the fruits to a single owner.[84] Some argue that the human genes, particularly the human germ-line, should be considered as an asset in the common heritage of humankind and propose that it be placed under the same type of international stewardship as the planet's sea-bed.[85] Another variant is the claim that some genes are of sufficient potential public benefit that a commercial monopoly should be prohibited. Examples are the recent calls for compulsory licensing of patents for detection of the hepatitis C virus in the blood and the use of the BRCA-1 gene in breast cancer screening.[86]

The UNESCO Declaration on the Protection of the Human Genome and Human Rights adopted by the UN General Assembly in 1998 recognizes the common heritage principle, at least on a symbolic level. It states that: "The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the common heritage of humanity."[87] Another article opposes commercialization of the human genome: "The human genome in its natural state shall not give rise to financial gains."[88] The Declaration also emphasizes that "benefits from advances in biology, genetics and medicine, concerning the genome, shall be made available to all . . . . "[89]

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[82] Hettinger, "Patenting Life", *op.cit.* p. 286.
[83] "The Gene Race Quickens", *The Washington Post*, August 22, 1998, A18.
[84] A. L. Caplan and J. Merz, "Patenting Gene Sequences: Not in the Best Interests of Science or Society." *British Medical Journal* 312 (April 13, 1996), p. 926.
[85] These positions are cited in E. T. Juengst, "A Global Human Resource?" in E. Agius and S. Busuttil, Eds. *Germ-Line Intervention and our Responsibilities to Future Generations* (Great Britain: Kluwer Academic Publishers, 1998): pp. 86-87.
[86] G. Post, "The Case for Genomic Patenting," *Nature* 378 (December 7, 1995), p. 535.
[87] Article 1, UNESCO (International Bioethics Committee), "Universal Declaration on the Human Genome and Human Rights." <http://www.unesco.org/bc/uk/genome/project/index.h>, downloaded on August 25, 1998.
[88] Article 4, UNESCO, "Universal Declaration on the Human Genome and Human Rights."
[89] *Ibid.* Article 12(a).

Defenders of gene patenting respond to the common heritage argument by claiming that private ownership of genes is no different than most forms of private ownership of property. According to this line of reasoning, all tangible property has some naturally occurring object as its physical basis. Private ownership of genes can be justified in a like manner to all other naturally occurring objectives. They propose providing an experimental use exemption or other special arrangements to compensate for problems resulting from the creation of intellectual property rights over genes.[90] This utilitarian response, however, does not adequately address the ethical issues raised.

(v) Implication of Patents for Respect for Human Dignity

The concept of the inherent dignity of the human person is well established both in U.S. and international law and provides the foundation for the international human rights instruments. The Thirteenth Amendment to the U.S. Constitution also prohibits owning and selling human beings. Some opponents of patenting assume that these protections should extend to human tissue and body parts as well. A draft discussion document written by the Commission of the European Community, for example, concluded that "in the light of the general principle that the ownership of human beings is prohibited, the human body or parts of the human body *per se* must be excluded from patentability."[91] Proponents of patenting, on the other hand, often distinguish between the status of human material in the body and outside of it. Even if they recognize a moral basis for excluding patenting of human material, they claim that it does not extend to patenting *ex vivo* DNA sequences.[92] The European Community statement was only meant to cover parts of the human body as found inside the human body. A recent proposal by Louis Guenin to resolve the patenting controversy also differentiates between the moral status of human property claims on substances within and outside of the body.[93]

Some of those who object to patents on the grounds that intellectual property rights impair human dignity do so because of a commitment to preserve human genetic integrity. They anticipate that DNA sequences, once patented, might be altered either to eliminate flaws or to enhance human potential. Here the opposition to eugenics intersects with the debate about patenting. To respond to the need to preserve human dignity against potential eugenic alteration, the European Community Directive prohibits patenting substances and processes for producing human genetic modifications that do not conform to respect for human dignity.[94]

Does protecting human dignity require treating human biological materials as "blocked exchanges," that is something that cannot be commodified and thereby be owned and sold? It is relevant to note that there is a tradition, supported by philosophical

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[90] OTA, *The Human Genome Project*, pp. 4-11 through 4-15.
[91] Commission of the European Communities, Council of the European Union, "Common Position of the Council Directive on the Legal Protection of Biotechnological Inventions", February 7, 1994 cited in OTA, *The Human Genome Project*, pp. 4-16.
[92] OTA, *The Human Genome Project. op.cit.*
[93] L. M. Guenin, "Norms for Patenting Life Forms", *Theoretical Medicine* 17 (1996), pp. 279-314.
[94] OTA, *The Human Genome Project, op.cit.* pp. 4-22 and 4-23.

and ethical thinking, of moral opposition to the ownership and sale of human parts. Beginning with the collection of blood for transfusions, measures have been taken to protect against the development of a market in human body parts and organs. There is a consensus in the U.S. that human organs required for transplants should be obtained through donation as a gift. It is argued that allowing an organ market to develop would place pressure on poor people to make organs available, as indeed has occurred in some countries, enabling the affluent to exploit poor and vulnerable individuals. Claims are also made that allowing a market to develop in human biological material might undermine social bonds. While individuals are sometimes paid for the collection of blood or semen, such payment, from a legal perspective, is considered to be for services rendered, and not remuneration for the commodity itself.[95]

The question as to whether patenting of human genes is wrong because it diminishes human dignity was the subject of a paper that the philosopher Baruch Brody wrote for the American Association for the Advancement of Science.[96] While Brody acknowledges that it is perfectly appropriate to limit intellectual property rights in human genes when necessary to preserve human dignity, he does not believe that most objections to human gene patenting warrant doing so. After analyzing a variety of concerns that have been put forward, he identifies only two that he considers to offer valid criticisms. Brody recommends that applications to patent an entire set of genes should be rejected, if ever proposed, because of human dignity considerations. He also concludes that protecting against eugenics justifies not allowing the patenting of genetic modifications that are incompatible with human dignity. Otherwise he does not find sound reasons to reject the patenting of a specific human gene on the grounds that it is incompatible with protecting human dignity.

Given the commitment to the value of the human person in western religious tradition, the religious community's concern with the implications of patents for human dignity is understandable. Both Christianity and Judaism conceptualize the human person as the *imago Dei,* a representation of a divine creator. The affirmation of humanity as the image of God appears to play a role in the thinking of at least some of the religious opponents of patenting. Nevertheless, it does not in and of itself provide a clear grounding for opposing patenting of altered human tissue or DNA fragments. One of the complexities in discussions of this issue is that conceptions and interpretations of the phrase image of God have differed dramatically through the centuries, often reflecting the most qualities most valued within a culture. Moreover, it is more appropriately understood metaphorically or relationally rather than having a fixed and defined content.

A related theme in the religious critique is that patenting will demean life by turning life into a commodity whose value will be determined by commercial considerations. This concern is widely shared in the religious community among both supporters and critics of the Joint Appeal. How valid is this criticism? Margaret Jane

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[95] *Ibid.* pp. 4-17 and 4-18.

[96] B. Brody, "Human Dignity and the Patenting of Human Genes," paper written for the American Association for the Advancement of Science Dialogue Group on Genetic Patenting, revised version, May 9, 1997.

Radin, a legal theorist, has examined the social process by which something comes to be understood as an appropriate subject of free market transactions that was previously valued in a noneconomic manner.[97] She distinguishes between literal or narrow and broad or metaphorical senses of commodification. Commodification in the narrow sense describes events in which material goods and economic services are literally bought and sold. According to Radin, commodification also encompasses a worldview that conceives of human attributes as fungible owned objects even where no money literally changes hands.[98] Much like the religious critics of patenting, Radin believes that the way we conceive of things matters to who we are. She concurs that a commodified view of personhood undermines a Kantian conception of the person as an end-in-itself.[99] Nevertheless, Radin recognizes that commodification is not an all or nothing process. She offers the useful concept of incomplete commodification. It refers to a situation in which only one segment of society accepts a commodified understanding.

The question as to whether human gene patenting will promote commodification is an important one, and two legal scholars who recently addressed the topic disagree. E. Richard Gold argues in his book *Body Parts* that making any commodity, including human biological material, subject to property claims will translate its valuation into a market price. Moreover, he claims that market modes of valuation preempt other, more authentic and meaningful forms of valuation, such as considering human DNA, blood, or tissue to be inherently valuable in themselves and as being instrumentally valuable in aiding human health. He supports this thesis through an analysis of legal decisions related to property rights and the ownership of human biological materials. According to Gold, property discourse—that is, the sum of the assumptions, conceptions, and language used by judges, lawyers, and legislators in allocating rights of control over goods—promotes economic modes of valuation because it assumes that proprietary goods are best allocated through the market. He therefore concludes that safeguarding noneconomic values related to the human body requires that human biological materials be treated as nonproprietary goods. To this end, he recommends constructing a method of allocating rights of control over these materials that takes both economic and noneconomic modes of valuation into account, but does not offer the specifics of such a scheme.

However, Radin's proposal about incomplete commodification suggests otherwise. She uses the term incomplete commodification to refer to a situation in which only one segment of society accepts a commodified understanding. She also points out that even individuals sometimes hold both commodified and noncommodified understandings about specific things. Given this situation, Radin believes that it is possible for commodified and noncommodified conceptions to coexist without one necessarily overriding the other.[100] Because neither Gold nor Radin draw on extensive empirical data, it is difficult to evaluate their conclusions.

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[97] M. J. Radin, *Contested Commodities: The Trouble with Trade in Sex, Children, Body Parts and Other Things* (Cambridge, Mass. and London: Harvard University Press, 1996), p. 6
[98] *Ibid*, pp. 12-13.
[99] *Ibid*, p. 92.
[100] *Ibid.* p. 120.

(vi) Impact of Patents on Poor Countries

A 1991 letter from Hubert Currien to *Science* magazine, cited above, anticipated that patenting would have distributive and justice implications because it "would increase costs and penalize low-budget research teams and countries with fragile economies."[101] These concerns mirror the on-going debate on the implications of plant genetic engineering for the South involving questions about life as intellectual property, ownership of seeds, control of plant genomes, and the appropriateness of patenting new plant varieties.[102] In addition to the potential impact of a rigorous system of intellectual property rights in aggravating economic disparities between the North and the South, there are other equity considerations. Organizations like the Canada-based Indigenous People's Biodiversity Network (IPBN) and the Rural Advancement Foundation International (RAFI) have criticized patents as inappropriately conferring benefits on researchers from industrialized countries to the exclusion of the source or owners of the tissue in the Third World. Bioprospecting has been equated with piracy and biocolonialism. These tensions played a role in the decision by NIH to "disclaim" its patent on the human cell line of a Hagahai indigenous person from Papua New Guinea and to discontinue its application on a cell line from an individual from the Solomon Islands.[103] Here the debate on patenting intersects concerns raised by the Human Genome Diversity Project, a proposal to collect and store blood samples from a wide range of ethnic groups to be able to study characteristics of these groups before patterns of migration and intermarriage eliminate differences among them. Public interest groups claim that the Human Genome Diversity Project infringes on the rights and beliefs of many of the targeted groups and by its very nature cannot conform to appropriate procedures for informed consent.[104]

On the other side, proponents of patenting claim that neither developed nor developing countries will benefit from genetic discoveries unless incentives exist to develop commercial products.[105] Others take refuge in market theory claiming that people in developing countries can decide not to purchase patented products if they consider the cost too high. This argument, however, ignores the substantial constraint that poverty imposes.[106] Yet another approach is to try to assure that the source of the material be granted financial benefit from potential profits arising from research on their genetic endowments.[107]

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[101] OTA, *New Developments in Biotechnology, op. cit.,* 14, pp. 137-143.
[102] See for example C. Juma, *The Gene Hunters: Biotechnology and the Scramble for Seeds* (Princeton: Princeton University Press, 1989) and R. Walgate, *Miracle or Menace: Biotechnology and the Third World* (Budapest, London, Paris, Washington: The Panos Institute, 1990) for two different perspectives.
[103] Rural Advancement Foundation International, "Hagahai Cell Line Patent", *GeneWATCH* 10 (February 1997), p. 6.
[104] C. Benjamin, "Indigenous peoples barred from DNA Sampling Conference," GeneWATCH 10 (February 1997): pp. 5, 18
[105] B. Healy, "On Gene Patenting", *New England Journal of Medicine* 327 (1992):pp. 664-668.
[106] OTA, *New Developments in Biotechnology, op.cit.* pp. 4-24.
[107] Sagoff, 1996, "Patenting Genetic Resources", *op.cit.*, p. 17.

(vii) Right of Participation

When making its decision in the Chakrabarty case in 1980, the U.S. Supreme Court refused to deal with the central ethical question of whether life should be the subject of patents. Some of the opponents of Chakrabarty's patent claims, specifically the briefs written for the religious and public interest communities, argued that the Supreme Court should examine the effects that patents on life would have on human dignity, human health, and the environment. However, the Court was unwilling to consider noneconomic values, stating that only Congress was competent to consider such factors or matters of "high policy."[108] Despite the significance of these watershed decisions to patent life—described by one ethicist as "brazen forays into unchartered moral, legal, social, and environmental territory"[109]—there has never been a satisfactory public debate in the U.S. about the appropriateness of this policy. The Supreme Court, which was apparently motivated by concerns about economic competitiveness, did not provide a legal, ethical, or philosophical rationale for its decision. Congress has not wanted to deal with the topic. Until 1997 the United States did not have a functioning national bioethics commission that could serve as an alternative venue for a wider review, and as of mid 1998 the National Bioethics Advisory Commission has not taken up this issue. To date therefore, the limited discussion that has taken place has been within narrow academic and professional circles and focussed primarily on legal precedents, not broader ethical considerations.

The policy process has been somewhat more participatory in Europe, possibly because of the broader political influence of environmental and public interest groups, but it still falls far short of human rights requirements. Moreover, it shows the ability of a relatively small number of powerful companies to influence the political process in their favor. The 1997 proposals defining which biotechnology inventions can be patented were the outcome of a nine year effort by the European Commission to streamline and harmonize Europe's biotechnology patent system so as to make it more competitive with the U.S. and Japan. Draft legislation sent to the European Parliament in 1995 evoked strong opposition from groups opposed to patents on life and was rejected by the Parliament. Two years later when revised proposals were submitted to the European Parliament, Europe's biotech industry mounted a fierce lobbying campaign, aided by patient groups. This lobbying blitz is credited with the dramatic shift in parliamentary support between 1995 and 1997.[110]

4. Intellectual Property Protection for Databases: A Case Study

(i) Background

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[108] E. R. Gold, *Body Parts*, *op.cit.* pp. 82-83.
[109] Hettinger, "Patenting Life, Biotechnology, Intellectual property and Environmental Ethics" *op.cit.* pp. 269.
[110] On this process see Nick, Scott Ram, "Biotechnology Patenting in Europe. The Directive on the Legal Protection of Biotechnological Inventions: Is this the beginning or the end" 2 BSLR (1998) pp. 43-45.

The debate regarding *sui generis* protection of databases provides another example in which narrow economic goals threaten to override less tangible human rights considerations. Databases or "compilations" have been defined as "a work formed by the collection and assembly of preexisting materials or of data . . . "[111] Because databases are usually not novel or non-obvious, but merely sets of data, they are not patentable. Nevertheless, compilations have been protected by copyright in the U.S.A. since 1790 when the first Copyright Act was enacted.[112] A 1991 U.S.A. Supreme Court decision, however, significantly reduced the scope of protection under copyright law. And changing technology has rendered traditional intellectual property regimes less effective in protecting the compilers of computer databases from wholesale copying. In response to these developments, the European Union, the United States, and WIPO have considered various laws and treaties to protect against piracy of databases.[113] Unfortunately, the proposed (and enacted) legislation has put the economic considerations of database producers ahead of the social and cultural rights of the society.

As courts applied copyright law during the nineteenth century, two rationales emerged for protecting compilations. The first, known as "sweat of the brow," focused on the compiler's effort and investment as the justification for copyright protection. The other viewed the creativity and judgment of the compiler in selecting and arranging materials as the basis. Regardless of the theoretical framework adopted to support copyright protection, courts generally gave compilations a broad scope of protection from unauthorized copying. Competitors were required to compile the materials from the original sources.[114] The 1976 U.S.A. Copyright Act tightened the grounds by incorporating a definition of "compilation" that required original selection, coordination or arrangement, but until the 1991 Supreme Court decision courts were divided in their judgments as to the continuing viability of the "sweat of the brow" doctrine.[115]

In 1991, the Supreme Court ruled in *Feist Publication v. Rural Telephone Service Co.* that a telephone directory was not copyrightable. The decision categorically rejected the "sweat of the brow" doctrine and determined that a compilation must evince creativity in its selection, coordination or arrangement to be copyrightable. The Court held that while the selection and arrangement of the facts were copyrightable if original, the facts themselves were not.[116] Subsequent cases in the U.S.A. have generally found the compilations at issue to be copyrightable, but have afforded a narrow scope of protection. Wholesale takings from copyrightable compilations have been permitted

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[111] 17 U.S.C.§ 101.

[112] Register of Copyrights, *Legal Protection for Databases* (Washington, D.C.: U.S. Copyright Office, 1997), p. 3.

[113] The European Union enacted Directive No. 96/9/EC on the legal protection of databases, 1996 O.J. (L 077) 20 [hereinafter European Directive]; the United States House of Representatives passed the Collections of Information Antipiracy Act (H.R. 2652), May 1998, which then became moot because it was not taken up by the Senate; and the Standing Committee on Copyright and Related Rights of the World Intellectual Property Organization recently decided to defer consideration of *sui generis* protection in order to undertake further work and study on the topic (Standing Committee on Copyright and Related Rights, Draft Report, First Session, Geneva, November 2-10, 1998, SCCR/1/9 Prov. 1

[114] Register of Copyrights, *Report on the Legal Protection of Databases*, pp. 3-5.

[115] *Ibid.* pp. 6-7.

[116] *Feist Publications v. Rural Telephone Service Co.* 499 U.S. 340 (1991).

either because the defendant's compilation differed in major ways from the plaintiff's or because the elements of selection, coordination or arrangement that were copied were not considered to constitute creative authorship.[117]

At the same time computer technology and new telecommunications networks are creating new challenges for database compilers. These technological innovations increase the feasibility of collecting, storing, and disseminating huge amounts of data in databases, making them more valuable. At the same time computerization and electronic dissemination of data aggravate the vulnerability of databases to unauthorized extraction. Electronic databases blur the line between collection and application functions by providing users with tools that enable them to tailor-make extractions from the mass of data in the collection. Once compilations are electronically disseminated in databases available to the public, second comers can easily and cheaply copy or manipulate the contents and then market the resulting products to large numbers of people.[118] With the widespread availability of scanning and other conversion equipment, print compilation can also be readily converted to electronic form and manipulated with electronic information tools.[119]

With substantial time and investment no longer a basis for securing intellectual property claims, compilers are turning to other methods to enhance protection.[120] Producers have sought to alter the structure or content of their databases, hoping that adding copyrightable text or making the database more creative will increase meaningful copyright protection. However, databases are most useful when easy to navigate, which often requires mundane arrangement. Secondly, compilers can increase their reliance on contracts to protect their databases. Under a contractual arrangement consumers would agree to utilize the database only for specified uses, excluding, of course, redistribution of the information for profit. However, these contracts are only enforceable between the two parties. If a third party acquires the information, the compiler is not protected. In addition, database producers may use contracts to provide their products on more restrictive terms than under traditional intellectual property laws.[121] Thirdly, compilers may turn to technological safeguards, such as cryptographic software, to prevent unauthorized use. While these are effective to a limited extent, they are still in developmental stages and can be circumvented.[122]

In response to this problem, legislatures have contemplated new and more stringent forms of protection for databases. Beginning in the late 1980's, member states of the European Union sought to harmonize the copyright laws in their various legal systems. The process brought greater awareness of the disparities in the level of protection to compilations in their legal system. To harmonize EU copyright laws, the EU adopted a Database Directive requiring all members to provide a *sui generis* form of intellectual

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[117] Register of Copyrights, *Report on the Legal Protection of Databases*, pp. 10-18.
[118] J. H. Reichman and P. Samuelson, "Intellectual Property Rights in Data?" *Vanderbilt Law Review*, 50 (January 1997), pp. 105-109.
[119] *Ibid.* p. 108-109.
[120] Register of Copyrights, *Report on Legal Protection for Databases*, pp. iii and 71-86.
[121] *Ibid.* p. 81.
[122] Ibid. p. 86.

property protection for database.[123] The Directive provides that database makers who have invested in their product are protected from unauthorized "extraction" or "reutilization" of all or a substantial part, measured qualitatively or quantitatively.[124] The protection lasts 15 years from completion. Substantial changes, including updates, renew the protection for another 15 years.[125] This renewed protection covers the entire database, not just the new matter, and so may allow for perpetual protection for as long as the database is updated.[126] The European Directive grants users the right to extract insubstantial parts of the database.[127] However, there is no general "fair use" provision as there is in copyright. States may make exceptions for noncommercial "extraction for the purposes of illustration for teaching or scientific research."[128] Beginning in 1998, scientists in Europe are bound by these intellectual property protections.

An antipiracy bill was also passed by the U.S.A. House of Representatives in May 1998, but did not become law because it was not approved by the Senate. The proposed Collections of Information Antipiracy Act would have amended federal law so that a person who extracts a substantial portion of a database for an unauthorized commercial use would face civil liability for damages to the owner of the database and in some circumstances would face criminal penalties. To qualify for protection, the database producer must have invested substantial resources or efforts to gather, organize, or maintain the collection. Although the bill would have exempted not-for-profit-educational, scientific, or research users of the database from liability, the exemption would not cover extraction or use of all or a substantial part of a database in a way that could harm the creator's "actual or potential market."[129] The protection was to last for 15 years, and as in the European Directive, it would have been extended to another 15 years when the database is updated. This would have effectively granted perpetual protection.[130] Partly because it did not contain exemptions for research and academic applications, the scientific community strenuously opposed the proposed Act.[131]

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[123] The European Union enacted Directive No. 96/9/EC on the legal protection of databases, 1996 O.J. (L 077) 20 [hereinafter European Directive]; the United State House of Representatives passed the Collections of Information Antipiracy Act (H.R. 2652), May 1998, which has not yet been considered by the Senate; and the World Intellectual Property Organization is considering sui generis protection (CRNR/DC/6, Basic Proposal for the Substantive Provisions of the Treaty on Intellectual Property in Respect of Databases).
[124] European Union, Directive 96/9/EC on the legal protection of databases, 1996 O.J. (L077) 20.
[125] *Ibid.*
[126] Committee on the Issues in the Transborder Flow of Scientific Data, *Bits of Power*, *op.cit.* p. 149.
[127] J. C. Ginsburg, "Copyright, Common Law, and Sui Generis Protection of Databases in the United States and Abroad," *University of Cincinnati Law Review* 66, p. 172.
[128] European Directive, Article 9, quoted in Ginsburg, "Copyright, Common Law, and Sui Generis Protection of Databases", p. 172.
[129] Collections of Information Antipiracy Act, cited in L. R. Raber, "Database Bill Threatens Research", *Chemical & Engineering News* (May 25, 1998) p. 38.
[130] W. Gardner and J. Rosenbaum, "Database Protection and Access to Information," *Science* 281 (1998), pp. 786-787.
[131] Gardner and Rosenbaum, "Database Protection and Access to Information," *op.cit.* p. 786.

WIPO has considered the appropriateness of an international treaty that would provide *sui generis* protection to databases.[132] The EU Database Directive became the basis for an EU proposal for a draft international treaty, and the U.S.A. then submitted an alternative proposal to WIPO. The WIPO Standing Committee on Copyright and Related Rights took up the issue of database protection at its 1998 meeting. At the meeting the Committee decided to defer any initiative on protection of databases due to the lack of agreement on the matter and the seeming inappropriateness of a single solution to bridge the legal gaps. Instead, it recommended that the International Bureau should organize regional consultations and commission a study of the impact of the protection of databases on developing countries.[133]

The primary proponents of increased protection for databases in the United States, which currently holds 75 to 80 percent of the world's database market,[134] are mainly large database producers.[135] They argue as follows: if there is not enough incentive to produce databases, segments of academia and industry that conduct research will suffer, with a net loss to society. In addition, compiling databases is often time and resource intensive, and may merit a recognition of economic rights for the creator. Moreover, while it is expensive to collect and verify large numbers of facts, the evolution of technology with digital and scanning capabilities has made it increasingly simple to copy both online and hard copy databases, and existing law cannot protect against this piracy.[136]

However, others have raised questions as to whether additional legal protection for databases is in fact needed, and even if so, whether the forms of protection that are being proposed are appropriate and cost-effective. Although the traditional theories behind protection for intellectual property may be less compelling in the case of databases, the regimes under consideration are more protective than traditional copyrights and patents. When the U.S.A. Copyright Office held meetings in 1997 with the major groups that had already been vocal in indicating interest, most of the participants from the library and scientific communities, as well as some educational groups, telephone companies and Internet-related businesses, expressed opposition to the proposed U.S.A. legislation. These opponents do not contest the database producers' assertions as to the importance of databases and the changes brought about in their creation, dissemination and use by developments in technology, but they claim that there is not sufficient evidence that a problem exists that requires a legislative solution. Furthermore, they point out that the U.S.A. database industry is thriving under the current legal regime. There is also concern that new protection could result in negative consequences, even if unintended, such as

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[132] CRNR/DC/6, Basic Proposal for the Substantive Provisions of the Treaty on Intellectual Property in Respect of Databases. The protection of databases is scheduled to be discussed at the 2-10 November 1998 meeting of the Standing Committee on Copyright and Related Rights (1st Sess.).
[133] Standing Committee on Copyright and Related Rights, SCCR/1/9, pp. 20-27, 33.
[134] Raber, "Database Bill Threatens Research," p. 39.
[135] Examples include Lexis-Nexis, McGraw-Hill Cos. Inc, Thomson Corp., and Reed-Elsevier. L. Jacobson, "Dueling Over Data," *National Journal* (January 10, 1998) pp. 64, 67.
[136] Register of Copyrights, *Report on Legal Protection for Databases*, pp. 66-68.

accelerating trends toward the commercialization of data, particularly data produced through government funding.[137]

When the USPTO held a second conference in April 1998, the meeting did not produce consensus on any issues, including the fundamental question of whether or not database protection is needed. Nevertheless, the PTO recommended that the administration support a change in the law to provide commercial database developers with protection for their products. It suggested that any database protection regime must carefully define and describe databases and prohibited acts, so as to avoid unintended consequences, including the disruption of non-profit research. Another of the principles the PTO put forward was that databases generated with government funding should not be placed, *de jure* or *de facto*, under the exclusive control of private parties. The report also recommended that any database protection regime should be subject to exceptions largely co-extensive with the fair use provisions of copyright law. The PTO acknowledged that the language that predicated such exemptions on not harming the actual or potential market for the product or service, as in pending legislation, was insufficient, but it did not offer an alternative.[138] Indeed, the report recognized that "there remains at least one place where the interests of database producers and scientists/educators may be in a 'zero sum' conflict: how to handle collections of information specifically prepared and marketed to scientists and educators. . . This is a place where the desire to provide proper incentives for the production of databases runs squarely into the desire to provide as much access to information as possible to researchers and educators."[139] Nevertheless, the PTO still supported consistent application of the incentive rationale and providing commercial firms to have the same protection against educators/researchers as the rest of the market.

(ii) Promoting the Development and Diffusion of Science

Open access to data at an affordable rate is key to the advancement of science. Facts are obviously essential to scientific investigation and have been referred to as the "building blocks of intellectual discourse."[140] Historically, public investments in basic research and development ensured the full and open access to data to the scientific community on favorable economic terms. Federal funding for academic institutions and specialized laboratories in the U.S.A. in response to cold war pressures largely defrayed the costs of collecting and disseminating raw scientific data for much of the past forty years. Analysts have pointed to this strategy as a critical factor in the emergence of the U.S.A. as the world's leading producer of technological goods.[141] Mechanisms for sharing data are even more important in an era in which the investigative model of the

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[137] *Ibid.* pp. 68-69.
[138] US Patent and Trademark Office (USPTO), "Patent and Trademark Office Report on Recommendations from the April 1998 Conference on Database Protection and Access Issues," July 1998, downloaded from http://www.uspto.gov/web/offices/dcp,/olia/dbconf/dbase498.htm.
[139] USPTO, "Patent and Trademark Office Report on Recommendations from the April 1998 Conference", p.16.
[140] Committee on Issues in the Transborder Flow of Scientific Data, *Bits of Power, op.cit.* p. 146.
[141] Reichman and Samuelson, "Intellectual Property Rights in Data?", *op.cit.* p. 99.

solo scientist is increasingly being replaced by the involvement of scientists in large-scale collaborative arrangements.

In recognition of the importance of access to data for research and educational excellence, the scientific community provides strong support for the principle of "full and open exchange of scientific data." This principle, as interpreted within the scientific community, has two requirements. The first is that publicly-generated data be available without charge or for no more than the cost of reproduction and dissemination. The second is that data produced or distributed by non-public sources be accessible for research and education purposes on fair and reasonable terms.[142]

Currently much of the knowledge produced by scientists is collected and distributed through databases. By compiling a vast array of scientific information, databases expedite the sharing of information among scientists and thereby facilitate research and help to make discoveries more rapidly available. Shared databases play a particularly important role in large, complex, interdisciplinary collaborative scientific efforts such as the Human Genome Project, global climate modeling, and AIDS research. Databases are also integral to use of the Internet as a major point of access to research data produced by scientists.[143] Widespread international dissemination of data is key to fostering and maintaining linkages within a global scientific community. Access to data via the Internet may also play a particularly important role in enabling scientists in countries without a significant research infrastructure to have access to recent research findings and to collaborate with colleagues in research generating countries.

Allowing the producers of databases a more extensive monopoly than exists under the copyright regime is likely to undermine these goals. Theoretically, under the proposed new database regimes the facts that a database is composed of would not be protected because they could be gathered from their original sources. However, in practice, this may not be possible. In some cases, the protected database would be the only source of the data. Examples where there is a sole source of data include readings taken at a particular time in the past, government data given to a private producer on an exclusive basis, and information generated by the database compiler itself (such as telephone subscriber information and trading data from financial markets).[144] Under these circumstances, the ability to prevent the extraction of data from the database may in effect be tantamount to ownership of the data itself.[145] Rights would vest in the data itself, leaving no public domain, which is especially dangerous because compulsory licensing is not a component of any of the proposed systems.[146]

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[142] This interpretation appears in American Association for the Advancement of Science, "Statement on Intellectual Property Protection for Databases," adopted by the Board of Directors, October 31, 1997. The American Association for the Advancement of Science is a federation of 235 affiliated science, engineering, and health professional associations and 144,000 members dedicated to improving the effectiveness of science in the promotion of human welfare.

[143] American Association for the Advancement of Science, "Statement on Intellectual Property Protection for Databases."

[144] Register of Copyrights, *Report on Legal Protection for Databases*, p. xvii.

[145] *Ibid.* p. 102.

[146] *Ibid.* p. 89 (also noting that antitrust laws may provide some protection against this outcome).

Therefore it is not surprising that the scientific community has opposed the proposed legislation. The American Association for the Advancement of Science, a federation of 235 science, engineering, and health professional associations, as well as the U.S.A. National Research Council of the National Academy of Sciences, have expressed strong reservations. The statement issued by the Board of Directors of the American Association for the Advancement of Science points out that these new intellectual property protections specifically crafted for databases could impede the sharing of scientific data. It argues that current copyright laws adequately protect databases and contends that the proponents of the new protections have not adequately demonstrated the need for additional restrictions. According to the statement, "Impeding the flow of scientific data would serve neither private interests nor the public good. Everyone loses if scientists are prevented from completing promising research because their access to critical data is denied or too expensive. Intellectual property must never become a disincentive to the full and open exchange of ideas and services." [147]

(iii) Other Human Rights Implications

The important goal of advancing creativity through intellectual property is not directly served by the new database protections under consideration. These initiatives would confer a far broader and stronger monopoly on database developers than is needed to rescue database producers from the threat of appropriations by free-riding competitors. The new laws would also violate the justification for grants of intellectual property rights in terms of the advancement of scientific and technical progress and contributions to artistic and cultural creativity. One assessment of the likely effect of these initiatives is as follows: they would jeopardize basic scientific research, lead to relatively high prices for the use of public goods, vest compilers of databases with an absolute and virtually perpetual protection, and undermine principles embodied in the First Amendment of the U.S.A. Constitution.[148]

The proposed database regimes are particularly problematic from a human rights perspective because of their insensitivity to human welfare and the public interest. As two legal analysts comment, a calculus of net social benefits was never a factor of any importance to either the European Union's Council of Ministers who were responsible for the European Union Directive on the legal protection of databases or the drafter of a similar bill in the United States House of Representatives.[149] Nor was there an explicit analysis of the social or public interest costs for the proposed protection of investment. For these reasons they concluded that the database laws "set a new milestone for mischief by virtually abolishing even the concept of a public domain and by abrogating the public interest components of intellectual property policymaking."[150]

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[147] American Association for the Advancement of Science, "Statement on Intellectual Property Protection for Databases."
[148] Reichman and Samuelson, "Intellectual Property Rights in Data?" *op. cit.* pp. 55-56.
[149] *Ibid.*p.120.
[150] *Ibid.* p.164.

Protection of financial investment has taken a back seat in classical copyright and patent regimes which value novelty, originality, non-obviousness, and usefulness above large investments of time and money. "Most intellectual property laws have been formulated under the myth that they do not protect investment as such. Rather, these laws are supposed to implement the goal of encouraging or rewarding some socially important form of creative contribution of achievement."[151] To the extent that database producers have rights under Article 15.1(c), the claims are not as strong as the claims of creators under traditional copyright and patent regimes. The new database regimes would break with this paradigm by shifting the focus of intellectual property law from non-economic considerations, like the promotion of science and creativity, to protecting investment.[152]

The laws under consideration upset the balance that has existed between the individual and society under copyright law in at least four important ways. They shift the major emphasis from providing incentives and rewards to promote innovation in scientific research and publication to protecting investment. They eliminate the idea/expression distinction, which is the concept that facts are not protectable, only the characteristics of the expression.[153] In addition, the concept of fair use for educational and scientific purposes is severely limited in these proposals. Finally, the protection offered by copyright law is traditionally finite but these proposals are open-ended.[154]

The problem is exacerbated by the limited exceptions for "fair use." Under copyright law, the "fair use" doctrine provides limitations on the creator's rights for certain purposes. The exception generally provides for limited copying to promote criticism, reporting, teaching and research.[155] The exceptions provided for in the proposed legislation are insufficient to allow for scientific research. For example, the exceptions that allow for copying "insubstantial" portions are not useful to scientists who conduct research using a database's entire data set.[156] In the European Directive, States do not have to adopt the exception for "extraction for the purposes of illustration for teaching or scientific research."[157] The end result could be that less information is available to scientists, as well as a general chilling effect on the sharing and use of data. One researcher explained, "[i]n fields like Global Climate change, where many different types of global data are relevant and where a scientist might not know the legacy of a lot of the data, avoiding a breach of the [proposed United States law] could be very

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[151] *Ibid.* p. 163.
[152] Gardner & Rosenbaum, "Database Protection and Access to Information", *op.cit.* p. 787.
[153] For example, under most laws, the basic idea of star-crossed lovers or the scores of a baseball game are not copyrightable. However, the characters, lines and plots of Shakespeare's Romeo and Juliet, and a sports columnist's accounting of the game would be protectable.
[154] Usually the life of the author plus 50 or 75 years.
[155] 17 U.S.C. § 107-108.
[156] Register of Copyrights, *Report on Legal Protection for Databases*, *op.cit*, p. 23.
[157] European Directive. Even if this exception is adopted, "illustration" may not encompass all of the traditional rights under the copyright fair use doctrine.

difficult."[158] The end result is that scientists would have less access to data than under the copyright regime because of the limited scope of fair use.

Similarly, these proposed database instruments would provide more protection than under traditional copyright law because they are potentially protected in perpetuity.[159] Under the legislation as currently proposed, with each substantial update, the database gains renewed protection. Even if only the new portions of the database were protectable, it would be difficult to tell what is protected and what is not within a database that is continuously updated.

The effect of this increased protection could be less availability of data to scientists, and therefore a decrease in everyone's ability to benefit from the advances science can make. The culture among scientists, long based on sharing data, could change as scientists "feel the need to protect their data, either out of a sense of unfairness or simply to have something to trade."[160] Projects that depend on the sharing of data worldwide, such as the Human Genome Project, could "grind to a halt."[161] Scientists may not be able to pay for data, even when the price is determined by a competitive market. For example, when data from the Landsat satellite was privatized in the United States, the price of a single image went from $400 to $4400. Scientists could not afford the data, and research efforts to monitor terrestrial ecosystems through satellite imaging were terminated.[162]

The effects of any increase in the cost of data would be felt especially by scientists in developing countries, interfering with the right of "everyone" to benefit from science.[163] Article 2.1 of the ICESCR, where States Parties agree to "take steps individually *and through international assistance*, especially economic and technical, to the maximum of its available resources, with a view to achieving the full realization of the rights"[164] underscores the global obligation accepted by the signatories. While the Internet promises easy and less expensive access to the latest scientific developments, charging for scientific data that is now freely accessible at minimal or no cost could once again widen the distance between the developed and developing countries.

The States Party to the ICESCR have undertaken to balance the rights of creators with the rights of the society as a whole in Article 15. More than economic considerations are at stake. The proper balance must provide incentive for scientists to create and for scientific tools such as databases to be developed without stifling research by making data available only to wealthier sectors, thereby failing to promote the right of everyone to benefit from science.

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[158] Reichman & Samuelson, "Intellectual Property Rights in Data?", *op.cit.* p. 119 (quoting a letter from Professor S. Alexander).
[159] Gardner and Rosenbaum, "Database Protection and Access to Information", p. 787.
[160] Reichman & Samuelson, "Intellectual Property Rights in Data?", *op.cit.*, p. 113.
[161] Raber, "Database Bill Threatens Research", *op. cit.*, p. 4.
[162] Reichman & Samuelson, "Intellectual Property Rights in Data?", *op.cit.*, p. 121.
[163] ICESCR, Article 15.1.(b).
[164] ICESCR, (emphasis added).

In sum, the current proposals give more weight to the economic interests of investors than under traditional copyright regimes, in spite of the arguably lesser moral interests of database compilers as compared to traditional creators and inventors. In order to adjust the balance, fewer protections should be given to compilers to ensure that scientific research continues to thrive. Fair use protections for scientists, researchers and educators, or providing databases to these groups at the cost of dissemination, as well as finite periods of protection could contribute to fixing the problem.[165] The world's intellectual property lawmakers should strive to fulfill their obligations under the ICESCR by taking human rights as well as economics into consideration.

5. Conclusion

A fundamental thesis of this paper is that a human rights approach to intellectual property takes what is often an implicit balance between the rights of inventors and creators and the interests of the wider society within intellectual property paradigms and makes it far more explicit and exacting. To be consistent with the norms in the ICESCR, a human rights approach requires that the type and level of protection afforded under any intellectual property regime directly facilitate and promote scientific progress and its applications, and do so in a manner that will broadly benefit members of society on an individual, corporate, and international level. It also implies a right of access to the benefits of science, again on both an individual and collective level. Additional components are a right of protection from potential harmful effects of scientific and technological development, and a right of choice in determining priorities and making major decisions. The two case studies examined in this paper on genetic patenting and database protections underscore the additional difficulties imposed by the dynamics of economic globalization on respecting and fulfilling these principles. In both cases, the traditional goal and rationale of intellectual property regimes to provide incentives and rewards to inventors, researchers, and authors have been replaced by a new emphasis on the protection of investment. Simultaneously, commercialization and privatization, accelerated by globalization, are affecting the very conduct and nature of science. These trends have negative implications for the promotion of scientific progress and access to its benefits.

[165] Ginsburg, " Copyright, Common Law, and Sui Generis Protection of Databases", *op.cit.*, p. 151.

BIBLIOGRAPHY

BOOKS AND ARTICLES

Alston, P., "The International Covenant on Economic, Social and Cultural Rights", in *Manual on Human Rights Reporting*, U.N. Doc. HR/PUB/91/1 (1991).

Alston, P., "Out of the Abyss: The Challenges Confronting the New U.N. Committee on Economic, Social and Cultural Rights", *Human Rights Quarterly* 9 (1987): pp. 332-81.

Barbour, I., *Ethics in an Age of Technology* (San Francisco, Harper Collins Publishers, 1993).

Belkin, Lisa, "Banking on Genes", *The New York Times Magazine*, August 23, 1998.

Benjamin, C., "Indigenous peoples barred from DNA Sampling Conference," *GeneWATCH* 10 (February 1997) pp. 5, 18.

Borgmann, A., "Communities of Celebration: Technology and Public Life", in Frederick Ferre, (Ed.), *Research in Philosophy and Technology* 10 (Greenwich, Conn. and London: JAI Press, 1990).

Brody, B., "Human Dignity and the Patenting of Human Genes", paper written for the American Association for the Advancement of Science Dialogue Group on Genetic Patenting, revised version, May 9, 1997.

Caplan, A. L. and Merz, J., "Patenting Gene Sequences: Not in the Best Interests of Science or Society", *British Medical Journal* 312 (April 13, 1996), p. 926.

Carroll, A. E., "A Review of Recent Decisions of the United States Court of Appeals for the Federal Circuit: Comment: Not Always the Best Medicine: Biotechnology and the Global Impact of U.S. Patent Law", *The American University Law Review* 44 (Summer, 1995).

Chapman, A. R., "A Human Rights Approach to Health Care Reform," in A. R. Chapman, (Ed.), *Health Care Reform: A Human Rights Approach* (Washington, D.C.: Georgetown University Press) p.153.

Chapman, A. R., (Ed.), *Perspectives on Gene Patenting: Science, Religion, Industry, and Law in Dialogue*,(Washington, D.C.: American Association for the Advancement of Science, 1999).

Chapman, A. R., *Unprecedented Choices: Religious Ethics at the Frontiers of Science*, chapter 4 (Minneapolis, Fortress Press, forthcoming 1999).

Chapman, A. R., "A 'Violations Approach' for Monitoring the International Covenant on Economic, Social and Cultural Rights," *Human Rights Quarterly,* 18 (1996) pp. 23-66.

Claude, R. P., "Scientists' Rights and the Right to the Benefits of Scientific Progress", draft paper commissioned by the American Association for the Advancement of Science (Washington, D.C.) and presented at the Hebrew University in 1998.

Collections of Information Antipiracy Act, cited in L. R. Raber, "Database Bill Threatens Research", *Chemical & Engineering News*, (May 25, 1998) p. 38.

Collins, F. S., Patrinos, A., Jordan, E., Chadravarti, A., Gesteland, R., Walters, L. and the members of the DOE and NIH planning groups, "New Goals for the U.S. Human Genome Project: 1998-2003," *Science* 282, (October 23), 1998.

Commission of the European Communities, Council of the European Union, "Common Position of the Council Directive on the Legal Protection of Biotechnological Inventions", February 7, 1994 cited in OTA, *The Human Genome Project*, pp. 4-16.

Committee on Issues in the Transborder Flow of Scientific Data of the National Research Council, *Bits of Power: Issues in Global Access to Scientific Data,* (Washington D.C. National Academy Press, 1997).

Basic Proposal for the Substantive Provisions of the Treaty on Intellectual Property in Respect of Databases (WIPO Document, CRNR/DC/6).

Currien, H., "The Human Genome Project and Patents", *Science* 254 (1991), p. 710.

Doll, J. J., "The Patenting of DNA," *Science* 280 (May 1, 1998): pp. 689-690.

Downes, D., "The 1999 WTO Review of Life Patenting Under TRIPS", Revised Discussion Paper, Center for International Environmental Law, Washington, D.C., September 1998.

Edsall, J. T., "Scientific Freedom and Responsibility: A Report of the AAAS Committee on Scientific Freedom and Responsibility" (American Association for the Advancement of Science: Washington, D.C., 1975).

Ellul, J., *The Technological Society* (New York: Vintage Books, 1964), translated by J. Wikinson.

Fletcher, John C. and Anderson, W. French, "Germ-Line Gene Therapy: A New Stage of Debate", *Law, Medicine, and Health Care* 20 (Spring/Summer 1992).

Gardner, W. and Rosenbaum, J.,"Database Protection and Access to Information," *Science* 281 (1998), pp. 786-787.

"The Gene Race Quickens," *The Washington Post*, August 22, 1998, A18.

Ginsburg, J. C., "Copyright, Common Law, and Sui Generis Protection of Databases in the United States and Abroad," *University of Cincinnati Law Review* 66 (Fall 1997): pp. 151-76.

Gold, E. R., *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Washington, D.C.: Georgetown University Press, 1996).

Guenin, Louis M., "Norms for Patenting Life Forms", *Theoretical Medicine* 17 (1996), pp. 279-314.

Hardin, Garrett, "The Tragedy of the Commons", *Science* 162 (1968), p. 1243.

Healy, Bernadine, "On Gene Patenting", *New England Journal of Medicine* 327 (1992), pp. 664-668.

Heller, M. A. and Eisenberg, Rebecca S., "Can Patents Deter Innovation? The Anticommons in Biomedical Research", *Science* 280 (May 1, 1998), pp. 698-701.

Hettinger, Ned, "Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics", *Environmental Affairs* 22 (1995).

The Human Genome Organization, "HUGO Statement on Patenting of DNA Sequences," Bethesda, Maryland, 1995.

Jacobson, Louis, "Dueling Over Data," *National Journal* (January 10, 1998).

"Joint Appeal Against Human and Animal Patenting," text of the press conference announcement made available by the General Board of Church and Society of the United Methodist Church, Washington, D.C., May 17, 1995.

Juengst, Eric T., "A Global Human Resource?", in E. Agius and S. Busuttil, (Eds.) *Germ-Line Intervention and our Responsibilities to Future Generations* (Great Britain: Kluwer Academic Publishers, 1998).

Juma, Calestous, *The Gene Hunters: Biotechnology and the Scramble for Seeds* (Princeton: Princeton University Press, 1989).

Krimsky, Shelon, "Financial Interests Pervasive in Scientific Publications," *GeneWATCH*, 10 (February 1997), p.8.

Marshall, E., "Companies Rush to Patent DNA", *Science* 275 (February 7, 1997): pp. 780-781.

Marshall, E., “Secretiveness Found Widespread in Life Sciences”, *Science* 276 (April 25, 1997), p. 525.

Meyer, P., “The International Bill: A Brief History”, in Paul Williams, Ed., *The International Bill of Human Rights* (Glen Ellen, Illinois: The Free Press, 1981)

Nickel, J. W., *Making Sense of Human Rights: Philosophical Reflections on the Universal Declaration of Human Rights* (Berkeley and Los Angeles, University of California Press, 1987).

The Human Genome Project, (April, 1994).

Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and Cells (Philadelphia: J.B. Lipincott, Co. 1988).*

Pollack, A., “Gene Therapy’s Focus Shifts from Rare Illnesses,” *The New York Times*, August 4, 1998, C6.

Poste, G., “The Case for Genomic Patening”, *Nature* 378 (December 7, 1995).

Radin, M. J., *Contested Commodities: The Trouble with Trade in Sex, Children, Body Parts and Other Things* (Cambridge, Mass. and London: Harvard University Press, 1996).

Register of Copyrights, *Legal Protection for Databases* (Washington, D.C.: U.S. Copyright Office, 1997).

Reichman, J. H. and Samuelson, P., “Intellectual Property Rights in Data?” *Vanderbilt Law Review* 50 (January 1997).

“Renewed Fight over Gene Patent Policy”, *Science* 276, 11 April 1997, p. 187.

Roberts, L., “Genome Patent Fight Erupts”, *Science* 254 (1991), pp. 184-186.

Rural Advancement Foundation International, “Hagahai Cell Line Patent,” *GeneWATCH* 10 (February 1997), p. 6.

Sagoff, Mark, “Animals as Inventions: Biotechnology and Intellectual Property Rights,” *Philosophy and Public Policy* 16 (Winter 1996).

Special issue of *GENEWATCH*, a bulletin of the Council for Responsible Genetics on “No Patents on Life!” 10 (October 1996).

“Statement on Intellectual Property Protection for Databases,” adopted by the American Association for the Advancement of Science Board of Directors, October 31, 1997. The American Association for the Advancement of Science is a federation of 235 affiliated

science, engineering, and health professional associations and 144,000 members dedicated to improving the effectiveness of science in the promotion of human welfare.

Tomasevski, K., "The impact of globalization on the enjoyment of economic, social and cultural rights in OECD countries," draft paper commissioned by the American Association for the Advancement of Science, 1997.

Walgate, R., *Miracle or Menace: Biotechnology and the Third World* (Budapest, London, Paris, Washington: The Panos Institute, 1990).

Walzer, Michael, *Spheres of Justice: A Defense of Pluralism and Equality* (New York: Basic Books, Inc., 1983) pp. 100-103.

Weeramantry, C.G., Ed., *Human Rights and Scientific and Technological Development* (Tokyo: United Nations University Press, 1990).

Weeramantry, C.G., *The Slumbering Sentinels: Law and human rights in the wake of technology* (Ringwood, Victoria, Australia and Harmondsworth, Middlesex, England: Penguin Books, 1983).

World Intellectual Property Organization, *Intellectual Property Reading Material*, Publication no. 476E, Sections 4.60, 4.61.

CASES

Diamond v Chakrabarty 477 U.S. 303 (1980).

Feist Publications v. Rural Telephone Service Co., 499 U.S. 340 (1991).

INTERNATIONAL INSTRUMENTS AND DOCUMENTS

The Constitution of the United States, adopted 1787, Washington D.C.: U.S. Government Printing Office, 1985.

"Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind", proclaimed by General Assembly Resolution 3384 (XXX) of November 10, 1975.

International Covenant on Economic, Social and Cultural Rights, adopted 16 December 1966, 993 U.N.T.S. 3 (entered into force 3 January 1976), G.A. Res. 2200 (XXI), 21 U.N. GAOR Supp. (No. 16), p. 49, U.N. Doc. A/6316 (1966).

"The Maastricht Guidelines on Violations of Economic, Social and Cultural Rights," reprinted in International Commission of Jurists, *Economic, Social and Cultural Rights: A Compilation of Essential Documents* (Geneva: ICJ, 1997).

Universal Declaration of Human Rights, adopted 10 December 1948, G.A. Res. 217A (III), 3 U.N. G.A.O.R. (Resolutions, part 1), U.N. Doc.A/810 (1948).

"Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions", *Official Journal of the European Communities*, 30.7.98, L 213/16.

REPORTS

Commission on Human Rights, "Follow-Up to the World Conference on Human Rights: Five Year Review of the Implementation of the Vienna Declaration and Program of Action", Interim report of the United Nations High Commissioner for Human Rights, E/CN.4/1998/104, dated February 20, 1998.

Official Records of the Third session of the General Assembly, Part I, "Social and Humanitarian Cultural Questions", Third Committee, Summary Records of Meetings, September 21-December 8, 1948.

Standing Committee on Copyright and Related Rights, SCCR/1/9.

UNESCO (International Bioethics Committee), "Universal Declaration on the Human Genome and Human Rights" <http://www.unesco.org/bc/uk/genome/project/index.h>, downloaded on 25 August 1998.

US Patent and Trademark Office, "Patent and Trademark Office Report on Recommendations from the April 1998 Conference on Database Protection and Access Issues", July 1998, downloaded from http://www.uspto.gov/web/offices/dcp,/olia/dbconf/dbase498.htm.