

## Enclosing the Global Plant Genetic Commons

Robert W. Herdt

### Abstract

Property rights are assured by the collective standing behind one's claim to the benefits stream generated by property. Changing technology and institutions have interacted throughout history to create property rights from what had previously been public goods. The discovery of knowledge about DNA and the useful products that can be created through applications of that knowledge has generated conditions that have led to intellectual private property claims on many new processes and products. Large multinational life sciences companies seeking to capitalize on these developments have purchased many heretofore independent seed companies, leading to a high level of concentration in the seed industry. These issues are treated differently in various countries and many developing countries have limited capacity to deal with them. Policies to address the challenges created by this set of events are outlined.

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## Enclosing the Global Plant Genetic Commons<sup>1</sup>

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*“Though all the fruits [the earth] naturally produces, and beasts it feeds, belong to mankind in common, as they are produced by the spontaneous hand of Nature, and nobody has originally a private dominion exclusive of the rest of mankind in any of them, as they are thus in their natural state, yet being given for the use of men, there must of necessity be a means to appropriate them some way or other before they can be of any use, or at all beneficial, to any particular men.”*

John Locke, Concerning the True, Original, Extent, and End of Civil Government.

Property can be defined as assets that generate a benefit stream. Property rights in turn, can be defined as “the capacity to call upon the collective to stand behind one’s claim to a benefit stream.”<sup>3</sup> We generally think of property as land, buildings and financial instruments, but since the eighteenth century, technology has probably created property of far greater value than all existing real estate. Compare, for example, a technology-based corporation like Microsoft with a physical asset-based one like General Motors. In late December, 1998, Microsoft corporation was valued by the stock market at \$353 bill while General Motors was valued at \$48 bill. Microsoft had annual sales of \$16 bill while GM had annual sales of \$150 bill.<sup>4</sup> The huge asset represented by Microsoft was generated simply through technology as embodied in software (and market power), while land, building and machinery are an insignificant part of the total.

A second example provides further illustration. Prior to the development of the telegraph in 1837, the electromagnetic spectrum existed but had no economic value. Visible light from the sun was the primary member of the electromagnetic spectrum that provided services recognized by humanity. Sunlight stands as one of the few remaining examples of a public goods – its use by one person does not compete with or rival its use by another, and no person can exclude other persons from its use (although blockage of natural light in cities is changing this, and physical constraints like imprisonment can deny individuals access to sunlight). In economics jargon, sunlight is a pure public good because its consumption is non-rival and non-excludable.

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<sup>3</sup> Bromley, D.W. *Environment and Economy: Property Rights and Public Policy*, Cambridge, Mass., Basil Blackwell, Inc. 1991.

<sup>4</sup> <http://www.marketguide.com/mig/>

Technological developments have transformed other members of the electromagnetic spectrum from unrecognized public goods to private assets of immense value. Radio waves were unknown in the eighteenth century. They certainly were not private property. Since then the world has seen their conversion from unknown phenomena, into public goods and then into private goods through the application of science to create technologies and then the creation of laws and other social institutions by which to appropriate that property and allocate the income streams generated therefrom. Further, the nature of electromagnetic waves – their ability to travel infinite distances through space, and the applications invented for their use – long distance communications -- means that to be effective, the laws or agreements about their use must cover large distances. Electromagnetic waves quickly became the subject of international agreements.

As the telegraph spread, it became apparent that without some standards and regulations its use would be limited. In 1865 the International Telegraph Union was created with the adoption of the first Convention by twenty countries.<sup>5</sup> The invention of the telephone in 1876 was followed by agreements on its use in 1885; the first voice radio transmission in 1902 was followed in 1906 by the Berlin International Radiotelegraph Conference; the first broadcast radio in 1920 by international agreements on its use in 1927; and so forth through television, the launching of Sputnik, communications satellites, cable TV, and cellular telephone.<sup>6</sup> The Iridium system, which claims the ability to provide instant voice and data communications from any spot on the globe however remote, to any other, is the latest step in this series of technological developments. With each innovation, regulations allocated the relevant electromagnetic waves. In the beginning, allocations had little value, but as the value of communications for advertising became apparent, broadcast licenses became important assets. The transformation of the ether from a valueless, ephemeral, universal presence into private property, through interrelated innovations in technology and institutions, is complete.

As might be expected, the creation of this wealth has generated conflict, with different individuals and groups each seeking to maximize their own benefits. The nature of the conflict is not always obvious. In 1963, the Hat Creek radio telescope of the University of California detected unexpectedly strong transmissions from deep space that were discovered to be the “first known natural maser, an intense blast of laserlike, organized radio waves unleashed by molecules excited by cosmic radiation.”<sup>7</sup> This unusually strong signal, localized at 1612 megahertz (MHz), has led to an important scientific tool that enables astronomers to estimate the diameter of stars and their distance from earth. But while this particular signal is quite distinct and localized, other signals close to 1612 MHz can interfere with the scientific applications. For the past forty years astronomers have sought to protect the area around 1612 MHz from radio signals. In 1992, the International Telecommunications Union awarded radio astronomers primary rights to the spectrum from 1610 to 1613.5 MHz to protect them from harmful interference. However, the Iridium system has rights to an adjacent band, from 1616 to 1626.5, and

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<sup>5</sup> [http://www.itu.int/itudoc/about/itu/history/landmrks\\_e\\_5517.txt](http://www.itu.int/itudoc/about/itu/history/landmrks_e_5517.txt).

<sup>6</sup> *ibid.*

<sup>7</sup> David Malakoff, “Iridium Accelerates Squeeze on the Spectrum,” *Science* 282, p. 34-5, October 2, 1998.

stray radiation from Iridium is claimed to degrade the quality of the astronomers' signals.<sup>8</sup> Technological and regulatory solutions to the conflict are being explored.

Similarly to the electromagnetic spectrum, which has existed from the beginning of time, DNA has existed from the beginning of life as we know it, providing the essential service of transmitting all biological traits from one generation to the next. It was generating great value, but was not an asset. It was like sunlight, a part of nature whose use was non-rival and non-excludable. The discovery of DNA and the invention of ways to visualize it, characterize it, map it and move it from one organism to another has generated a new class of asset whose ownership is now being contested by multi-billion dollar companies. What was a global genetic commons is being enclosed. The pace is rapid, and at the end of the Twentieth Century intellectual property rights over plant genomic information is being concentrated in the hands of a few highly capitalized companies. "Monsanto along with a handful of other major corporations now holds most of the primary biotechnology-related assets needed for doing business in the agricultural sector."<sup>9</sup> The potential implication of these developments for the public interest is the focus of this paper.

### **Property Rights in Crop Plants**

Varieties of vegetatively propagated plants have been patentable in the United States since 1930, and sexually propagated plants (i.e. those reproduced through ordinary seeds), have been eligible for intellectual property protection under the Plant Variety Protection Act since 1970. But there was little public attention to the issue of intellectual property in plants. The seed industry consisted of hundreds of small companies producing seeds for relatively local conditions. Plant breeders in universities and government agencies continued to be the main creators of new varieties, which were provided to seed companies at little or no cost. The technical nature of seed was unchanged, despite the legal ability to claim patent protection.

Open-pollinated seeds (i.e., seeds other than hybrids), reproduce the traits of their parents with high fidelity, so once a farmer has even a small quantity of seed of a particular variety, she can obtain additional seed simply by growing the crop and harvesting the grain, which is seed for the next planting. The seeds of desirable crop varieties have historically spread quickly from farmer to farmer. In the low-income countries of Asia this is how the "Green Revolution," spread, and notwithstanding many reports to the contrary, spread quickly and widely to farmers of all sizes and characteristics.<sup>10</sup> Not only do seeds self-reproduce, but it is difficult or impossible to distinguish varieties by looking at their seeds (sometimes even by looking at the growing plant because appearance is inevitably affected by growing conditions). Thus, farmers could easily reproduce seeds of new varieties and companies would have no way of proving the seed was their variety. The incentive for private companies to invest in developing new plant varieties was

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<sup>8</sup> *Ibid.*

<sup>9</sup> Jeffrey L. Fox, "Monsanto unaffected by merger halt? Nature Biotechnology 16 December 1998 p. 1307.

<sup>10</sup> See for example, "Who Benefits from the New technology? Ch 10, The Rice Economy of Asia, Randolph Barker, Robert W. Herdt with Beth Rose, Resources for the Future, Washington D.C. 1985

limited because open-pollinated seeds are like a public good -- once they exist it is difficult to prevent any farmer from using them (non-excludable), and because they self-reproduce, their use by one farmer does not compete with their use by another (non-rival).

Hybrids provide the contrasting example and were the primary driver of private investment in the seed business before the 1990s. Hybrids are produced by crossing two distinctly different parental lines. Planting the seed harvested from a hybrid crop typically gives a range of different-looking, different-quality, different-maturity offspring. Farmers who want to grow the original hybrid have to obtain new seed for each planting. Companies that were able to keep the identity of the parental lines secret were able to prevent others from producing their hybrids, thereby generating continuing sales potential. By creating hybrids with improved production traits that were attractive to farmers, companies built businesses based on hybrid seeds beginning in the 1940s. Hybrid seeds are not public goods because it is possible for companies to exclude farmers from producing their seed. But of all the major crops, only corn was well-suited to hybrid seed production.

The development of DNA-based techniques, generally known as biotechnology, and their application to plants opened new possibilities for seed businesses. These techniques permit one to routinely distinguish any individual living organism from any other, regardless of how similar they may look. This makes it possible to identify the ancestors of any plant variety and hence the developers of a variety with near certainty, just as in the animal world a sample of DNA can be matched to any individual with near certainty. That certainty provides a way to exercise property rights over seed varieties because now one can prove who created the original variety. DNA techniques also promise to make possible the development of a wide range of new plant traits that will increase the economic value of plants.

On the institutional side, the 1980 *Diamond vs. Chakrabarty* Supreme Court decision permitted patenting of biological organisms, traits and genes set off an explosion of gene-related investment, with a significant amount focused on plant genes.<sup>11</sup> Still, as recently as 1989, it was unclear “whether widespread patenting of agriculturally important genes is a likely prospect,” partly because broader property claims based on a variety or trait rather than genes were also possible.<sup>12</sup>

Most new non-hybrid varieties were produced by plant breeders working for land grant universities in the United States or public institutions in other countries. But that is changing. It is estimated that in 1994, private companies accounted for 66% of the approximately 2241 scientist years devoted to plant breeding in the United States, up from 63% in 1990.<sup>13</sup> Carl Pray reports that now in the United States “more food and agricultural research is conducted in the private sector than in the public sector...public

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<sup>11</sup> (C.O. Qualset, E.C.A. Runge, J.J. Mortvedt, Foreword, Intellectual Property Rights Associates with Plants, ASA Special Publication Number 52, Crop Science Society of America, Inc., American Society of Agronomy, Inc., Soil Science Society of America, Inc., Madison Wisconsin, USA, 1989)

<sup>12</sup> Stephen A. Bent “Patenting Genes that Encode Agriculturally Important Traits,” *bid.*, p. 118

sector research is expenditure is increasing more rapidly than public expenditure...and “private research is particularly strong in some of the fastest growing and most important areas of applied agricultural research such as biotechnology, plant and animal breeding, precision agriculture, and animal health.”<sup>14</sup>

The full consequences of the DNA revolution are still to be played out, but a number of trends of interest have emerged:

1. Intellectual property rights are being rapidly extended to plants and their smallest genomic components in the industrialized countries.
2. Intellectual property rights in plants are being pressed on developing countries through international agreements.
3. A few companies have acquired most of the world’s seed production capacity.
4. Agribusiness, pharmaceutical and chemicals companies are merging to create a new, highly concentrated, life sciences industry.
5. These new companies are providing unprecedented levels of funding to public research universities.

*Extension of Intellectual Property Rights.* Until recently, intellectual property rights (IPRs) were of limited relevance to plant breeding. In both industrialized and developing countries public-sector plant breeding programs were the chief producers of improved crop varieties which were created by freely sharing genetic resources and research findings across regions and countries. Public sector plant breeders took discoveries from the academic world, combine them with local knowledge and genetic resources and distribute the resulting varieties through local seed production systems. The success of such collaborative research depends on a willingness to share discoveries and materials for the common good. In the genetic improvement of plants, each enhancement (whether through breeding or genetic engineering) is built on preceding generations so the process of adding value requires physical use of the earlier plant material itself.

Taking advantage of the technical capability made possible by DNA, companies have applied for and been granted patent rights to plants and animals as well as biotechnology research methods and cloned genes. Intellectual property rights extend not only to plant traits and genes but also to the smallest fragments of genetic material. In the United States DNA constructs that meet “all the conditions for patentability (such as statutory subject matter utility, enablement, written description, novelty, and non-obviousness)” can be patented, although “in order for DNA sequences to be distinguished from their naturally occurring counterparts, which cannot be patented, the patent application must state that the invention has been purified or isolated or is part of a recombinant molecule or is now part of a vector.”<sup>15</sup> In particular, short fragments of DNA used as genome

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<sup>13</sup> Frey, K.J., National Plant Breeding Study-I: Human and Financial resources devoted to Plant Breeding and Development in the United States in 1994. Iowa Agricultural and Home Economics Experiment Station, Iowa State University, Ames, Iowa.

<sup>14</sup> Carl E. Pray, Role of the Private Sector in Linking the U.S. Agricultural Scientific and Technological Community with the Global Scientific and Technological Community, unpublished paper, March 30, 1999.

<sup>15</sup> John J. Doll, The Patenting of DNA, *Science*, v.280, 1 may 1998, p. 689-90.

markers like expressed sequence tags (ESTs) and single nucleotide polymorphisms (SNPs), although they may not directly identify genes, “may still be extremely useful and thus satisfy the utility requirement,” and hence be patentable.

The extension of patents to such short sequences of DNA raises some scientific and intellectual issues which are illustrated by Gelbart’s analogy between an instruction book and the genome. He points out that if every set of information needed to deploy a given protein or polypeptide in the correct set of cells at the proper developmental times and in the requisite quantities were “analogous to one sentence in the instruction manual that we call the genome, a reasonable current assessment is that we have partial but still quite incomplete knowledge of how to identify and read certain nouns (the structures of the nascent polypeptides and protein-coding exons of mRNAs). Our ability to identify the verbs and adjectives and other components of these genomic sentences is vanishing low. Further, we do not understand the grammar at all – how to read a sentence, how to weave the different sentences together to form sensible paragraphs describing how to build multi-component proteins and other complexes.”<sup>16</sup>

In such an instruction book, is it appropriate that all elements – nouns, verbs, adjectives, grammar, phrases, sentences, paragraphs, sections, and the whole – be subjected to intellectual property rights? Is there not a distinction between the basic elements of DNA and their combination something like the distinction between ideas and the expression of ideas in copyright of conventional books, or like the distinction between words and particular sequences of words?

Might it be preferable for much DNA information to be placed in the public domain by its inventor and remain there? It is certainly possible, for if a sequence or “invention has been described in a patent or printed publication anywhere in the world, or if it has been in public use or on sale in the United States for more than 1 year before the date on which an application for patent is filed in the United States, a patent cannot be obtained. Thus any SNPs or ESTs that have been available in a public database for more than one year prior to the filing date of the application cannot be patented.”<sup>17</sup> Placing basic DNA information and materials in the public domain would allow property rights enforcement to focus on traits of utility to farmers, which is after all where value is generated in agriculture.

*Extending Intellectual Property Rights to Developing Countries.* The principles of sharing germplasm and research results among participants were at the center of the plant breeding work of the centers supported by the CGIAR and were enshrined in an International Undertaking of the Food and Agriculture Organization of the United Nations.<sup>18</sup> But this tradition of sharing conflicts with several other international agreements. The Convention on Biological Diversity (CBD) which emerged from the 1992 UN Conference on Environment and Development established national sovereign

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<sup>16</sup> William M. Gelbart, Databases in Genomic Research, *Science*, v. 282, 23 October, 1998.

<sup>17</sup> *Ibid.*

<sup>18</sup> See the documents reproduced in Genetic Resources, Biotechnology and Intellectual Property Rights, International Potato Center, Lima, Peru, June 1998.

rights over indigenous germplasm. While it was motivated by a desire to protect germplasm that might have pharmaceutical value, it applies to crop germplasm as well.<sup>19</sup> A third international agreement, the Trade-Related Aspects of Intellectual Property Rights, which forms part of the World Trade Organization apparatus, is requiring many developing countries to establish intellectual property rights for plants if they wish to participate on an equal basis in international trade in any products.

Although some believe that patents and other IPR may raise costs or discourage innovations in the developing world, or shift power unfairly to industrialized country firms away from developing country organizations, it appears that the momentum behind the international agreements will make the introduction of intellectual property rights in developing countries inevitable. These initiatives, driven by industrial intellectual property concerns have engulfed agricultural interests with a speed and intensity that has caught many in the developing world unaware and unable to deal with intellectual property rights.

*Consolidation of the Seed Industry.* The consolidation of seed producers into a few mega-seed companies has proceeded at an astounding rate over the past 15 years. In 1982 Monsanto, now the second largest seed seller in the world, was a pure chemical company until about 1982 when it entered the seed business by acquiring DeKalb's wheat research program. In the '90s they increased their seed business by obtaining AgriCetus, Britian's Plant Breeding Institute, Cargill's seed operations in Africa, Asia, Central and Latin America and Europe, and others. They purchased Calgene Inc, a leader in plant biotechnology in 1995 and Asgrow Agronomics, a leader in soybean and corn seeds, in 1996. In May, 1998 Monsanto announced that it had reached agreements to acquire two seed companies – DeKalb Genetics Corporation and Delta & Pine Land Company,<sup>20</sup> and in mid-year announced a merger with American Home Products. The merger, however, was abandoned, and in November Monsanto announced plans to cut its workforce by 2500, possibly to help cover the \$4.2 bill cost of DeKalb and Delta Pine.<sup>21</sup>

DuPont, another traditional chemical company, in 1997 established a \$400 million joint venture with Pioneer Hi-Bred, the world's largest seed company. The venture aimed at producing feedgrains designed to optimize weight gains in livestock, and other products tailored to meet specific markets. Subsequently, DuPont acquired controlling ownership of Pioneer. Novartis, the third largest seed company, was created through a combination of Ciba-Geigy and Sandoz. It owns Northrup King, Funk Seeds, Rogers Seed Company, and six other seed companies and has sales of almost \$1 bill annually.

Thus, Monsanto, along with a handful of other giant corporations – Pioneer/DuPont, Novartis, AgrEvo, Zeneca, and Dow – are coming to dominate the world seed industry. The ten largest firms have 30% of global seed sales and have attracted the attention and

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<sup>19</sup> Frisvold, George B. The Convention on Biological Diversity and Agriculture: Implications and Unresolved Debates. *World Development* V. 26 (4), p. 551-70, 1998.

<sup>20</sup> <http://www.monsanto.com/ag/articles/98-05-11acquireDeltaPine.htm>

<sup>21</sup> Ed Schafer, Associated Press, November 12, 1998



opposition of groups that claim to represent farmers.<sup>22</sup> The business plans of the mega-seed companies seem straightforward: control everything from genetic engineering of seeds to the selling of seeds to farmers, to marketing plant-grown drugs, modified foods, and industrial products. They aggressively employ patents to claim intellectual property and defend those claims equally aggressively, as illustrated by the case among Monsanto, Novartis and Mycogen over rights to corn with “built-in insect resistance.”<sup>23</sup> They are developing new technologies to protect intellectual property technically, such as a gene that makes the seed produced by their varieties sterile. Within the next few years many, if not most, of the potentially valuable genes from major crops are likely to be the intellectual property of these corporations. They can be expected to seek profits from new high-quality seeds for farmers who are capable of paying a premium price. But they have little incentive for producing crops that are important to the poor and disadvantaged farmers who primarily save their own seeds.

*The Life Sciences Industry.* DNA contains all the information that distinguishes a living organism and many believe it holds the key to creating all kinds of biologically active materials that can cure or prevent diseases in humans, animals and plants. This makes DNA technology of great interest to pharmaceutical companies which have reached out to acquire biotechnology capacity even as they were acquiring seed companies. At the same time, because many chemicals are used to affect biological processes such as pest control in agriculture, chemical companies are interested in them. The possibility of modifying the biochemical properties of grains and oilseeds used as inputs in processed foods has attracted the attention of food companies, who envision the possibility of lowering input costs or creating foods with properties highly desired by consumers. The demonstrated possibility of producing pharmaceuticals through genetically engineered plants and animals reinforces the interests of drug companies in agricultural biotechnology.

A new life sciences industry is emerging from the combinations of chemical, agricultural and pharmaceutical companies. Dealing with such masses of data and making sense of them requires big computers and outstanding scientists. It is estimated that the maize genome contains about 30,000 genes and about 3 billion base pairs, “which makes it comparable in size to the human genome.”<sup>24</sup> Companies are becoming ever bigger to secure as much of the talent and information as possible and are aggressively patenting processes, traits, and sequences. The US Patent and Trademark Office received 4000 patent requests for nucleic acid sequences in 1991 and 500,000 in 1996.<sup>25</sup>

Mergers and acquisitions across pharmaceuticals, chemicals, and agribusiness has created a few mega-companies like Novartis, valued at over \$100 billion.<sup>26</sup> Monsanto began its biotechnology work in 1981 before it bought its first seed company. Its biggest

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<sup>22</sup> Data assembled by Rural Advancement Foundation International, <http://www.rafi.ca>

<sup>23</sup> <http://www.monsanto.com/monsanto/media/current/980630-btpatent.html>

<sup>24</sup> Jon Cohen, Please Pass the Data, *Science* V. 276, 27 June, 1997, p.1961.

<sup>25</sup> US Patent and Trademark Office, Hearing and Request for Comments on Issues Relating to Patent Protection for Nucleic Acid Sequences,” University of California, San Diego, April 16, 1996.

<sup>26</sup> Enriquez, Juan, Genomics and the World Economy, *Science*, V. 128, 14 August, 1998, p. 925.

agricultural venture has been the creation of crops engineered to be resistant to its Roundup herbicide. Selling seeds of such crops through its subsidiary companies or licensing the Roundup Ready gene has been the primary reason why herbicide resistant crops are planted on nearly 20 million hectares of land in 1998.<sup>27</sup> In 1997 Monsanto took a major step in transforming itself into a DNA-based company by splitting into biotech and chemical divisions and then selling off its chemical division.<sup>28</sup> DuPont, another traditional chemical company, in early 1998 split its life sciences work into one of three business units and shortly thereafter announced plans to sell off its energy company in order to invest the proceeds in life sciences.<sup>29</sup> Hoechst sold its basic chemicals divisions and invested in AgrEvo, an agribusiness biotechnology venture with Schering, bought Plant Genetic Systems for \$600 million, acquired Cargill's North American seed business for \$650 million and recently announced a merger of their agricultural, pharmaceuticals and veterinary medicine activities with Rhone-Poulenc.<sup>30</sup>

Dow was a chemical company until 1989 when it absorbed Eli Lilly as a wholly-owned subsidiary and changed its name to DowElanco. In December, 1996 the company expanded its access to biotechnology when it became a majority shareholder in Mycogen, a diversified biotechnology company with technology for insect-resistant crops. In April, 1998 the company acquired a cotton seed breeding program located in the Chaco province of Argentina and a Brazilian hybrid maize seed company. In July, 1998 Mycogen and Rhône-Poulenc Agro, the crop protection subsidiary of Rhône-Poulenc SA, signed a letter of intent to pool plant biotechnology assets to develop and market genetically modified plants and seed products containing multiple traits, initially focusing on modifying cotton and sugarcane with Mycogen's insect resistance gene derived from the natural insecticide *Bacillus thuringiensis* (Bt) and Rhône-Poulenc Agro's gene sequences which provide tolerance to various herbicides.<sup>31</sup>

*Research Investments in Public Sector Organizations.* At the same time as the life sciences industry has been consolidating small seed companies into mega-seed companies, they have been investing huge sums in research, not only in their own laboratories but in new ventures with public sector organizations. In July of 1998, a new private-public consortium announced the creation of a \$145 million basic plant research center in St Louis. With a staff of 80 and an annual budget of \$15 million, the new center will be run as a not-for-profit organization. The sponsors include the Danforth Foundation, Washington University, the Missouri Botanical Garden, the University of Missouri, the Monsanto Fund and Monsanto itself. The center will receive its own patents and any income from licensing. Monsanto will benefit through close association with the center, but the center is intended to operate independently from its backers.<sup>32</sup>

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<sup>27</sup> James, Clive, Global review of Commercialized Transgenic Crops: 1998. ISAAA Briefs No. 8-1998, Ithaca, NY.

<sup>28</sup> <http://www.monsanto.com/Monsanto/About/Past/default.htm>

<sup>29</sup> Enriquez, *op. cite.*

<sup>30</sup> John Hodgson, *Nature Biotechnology* v. 17 January 1999, p. 15.

<sup>31</sup> <http://www.seedquest.com/News/Companies/Mycogen.htm>

<sup>32</sup> Kaiser, Jocelyn, *Plant Biologists Score Two New Major Facilities*, *Science*, V. 281, 17 July 1998, p. 317.

In July of 1998, Novartis announced the planned investment of \$600 million to fund initiatives in plant biology. The first step was the creation of the Novartis Agricultural Discovery Institute (NADI), to be located in San Diego, California with about 180 researchers.<sup>33</sup> In November 1998 the University of California at Berkeley announced a \$25 million deal with NADI for the support of basic research in agricultural genetics in return for first rights to negotiate for the findings. The basics of the deal provide \$5 million a year, two-thirds for direct support of projects selected on a competitive basis and one-third for overhead and infrastructure costs to the University. NADI may also “supply proprietary tools, technology or tangible research materials under appropriate confidentiality and/or material transfer agreements. As it becomes developed, a database of NADI genomics bioinformation may also be made available to program participants who choose to access a NADI facility (under a separate “access” agreement) where a suite of workstations will be available.” A six member Advisory Committee is responsible for the relationship between the University and Novartis while a five member Research Committee selects and oversees projects.<sup>34</sup>

There is little doubt that more deals like this between major public sector institutions and the big private companies will be struck in the future. Other initiatives will also be generated, in part as reactions to such deals. Recently, the Director of the Cornell University Agricultural Experiment Station promulgated a “Statement of Intent to Form the Consortium for Genomics Research in the Public Sector.” The national public sector plant research organizations of Brazil, China, India, and the United States, as well as five of the CGIAR research centers (IRRI, ICARDA, CIMMYT, ICRISAT, CIAT) have indicated their willingness to subscribe to the consortium,<sup>35</sup> which seeks to serve the world community through the development, application and dissemination of genomics and computer technology relevant to world germplasm resources in plants. Cornell University has established an Institute for Genomic Diversity devoted to developing and applying genomic technologies and computational tools to the conservation, evaluation and utilization of plant genomic resources worldwide and intends to support the consortium through information resources, knowledge, and training.

### **What are the Challenges?**

The speed and economic muscle behind recent developments in private company plant genetics are viewed with pride and hope by some and with apprehension by others. The mega-seed companies’ views are reflected in their aggressive corporate advertising campaigns and high-tech home pages on the World Wide Web.<sup>36</sup> Financial market forces have generated immense investment and shareholder value. But the trends also raise a number of concerns of public interest. With such power directed at applications, what will happen to basic science and who will teach the next generation of plant biologists? With market forces directing priorities, how will the needs of those without market power

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<sup>33</sup> <http://www.prenewswire.com/cgi-bin>

<sup>34</sup> [http://www.urel.berkeley.edu/urel\\_1/CampusNews/PressReleases/releases/Agreement.html](http://www.urel.berkeley.edu/urel_1/CampusNews/PressReleases/releases/Agreement.html)

<sup>35</sup> W. Ronnie Coffman, “Future of Plant Breeding in Public Institutions,” a paper presented to the American Seed Trade Association, December, 1998.

<sup>36</sup> <http://www.monsanto.com/monsanto/index4.html>

be met? How will developing countries adjust to the rapidly changing plant germplasm realities? With such a great degree of market concentration, how will abuses of power be avoided?

*Basic Research and Education.* Basic research is conducted with little or no thought of a product other than increase of knowledge; it encourage researchers to simply learn as much as they can about whatever they care to investigate. Scientists employed by private companies are sharply focused on products. The more money companies pour into research, the greater the proportion of work directed toward technology development and the less toward basic research for knowledge building. “But technological progress cannot continue without the input of basic research and the conceptual breakthroughs it makes possible...Apart from a handful of exceptions, the new technological companies in the Silicon Valley mold do not invest in long-term research.”<sup>37</sup> Basic research has no role in corporate research or in educational programs driven by sharply defined end-products.

Considerably more knowledge is needed to achieve the promises of biotechnology. We still know very little about how to make use of DNA sequence information. The task of matching data with function or with means of affecting the function is huge. Even with the full DNA sequence of an organism, “with regard to understanding how to make sense of the A’s, T’s, G’s, and C’s of genomic sequence, by and large we are functional illiterates...For now the genomic sequence of an organism is written in a language we barely comprehend. However, through the work of the scientific community, we can attach biological meaning to limited regions of the sequence.”<sup>38</sup> Scientists working toward highly applied goals will not generate this kind of more basic knowledge. It is short sighted to believe that simply because the life sciences industry is making large investments in plant biotechnology that the knowledge base for the next fundamental breakthrough beyond DNA will be built.

A related problem will occur with educating the next generation of plant biologists. If the most talented scientists are employed in companies and not in universities, the quality of education will suffer, graduating scientists will know more technology specifics but be less able to build new knowledge. Likewise, because training in biology so much a hands-on matter, unless students can use the latest processes, tools and materials, which may be restricted if produced in corporate labs, knowledge will be restrained.

In most cases owners of intellectual property permit its use for teaching and research, but simply obtaining appropriate permissions takes time and resources, thereby slowing the process. Recognition of these concerns may be one of the factors motivating the funding of university biology departments by Novartis and Monsanto. The unrestricted nature of the research conducted under Monsanto’s funding to the Danforth lab and of Novartis’ funding to Berkeley suggests this may be the case. Of course, Novartis has members on both the Advisory Committee and the Research Committee that are responsible for the

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<sup>37</sup> Nathan Myhrvold, Supporting Science, Essays on Science and Society, Science, v. 282, 23 October, 1998.

<sup>38</sup> William M. Gelbart, Databases in Genomic Research, Science v. 282, 23 October, 1998,p. 659-61.

Berkeley grant, so skeptics may claim that enables sufficient direction by the company. Still, the funding does provide some recognition of the value of undirected research.

*Needs Poorly Expressed in the Market.* According to Evenson, “Clearly there is an economic role for the public sector even when the private sector is actively inventing new usable technology. The standard public good argument applies to plant germplasm.”<sup>39</sup> While this is possibly an overstatement, as plant germplasm may not be a pure public good, he identifies three elements in the case for public sector investment in crop germplasm variety development:

1. Clear identification of the problems and limitations of existing technology in order that germplasm can be tailored to overcome these problems may not be done completely by market-driven mechanisms,
2. The need to provide technology for markets too small to interest the existing firms,
3. When public sector investment is needed to ensure technological competition.

Small markets exist for many minor crops in the United States where the opportunity for profit is limited. This may include crops that (1) are cultivated on a limited acreage, (2) provide relatively limited gross revenue, (3) for which there is no existing plant breeding base. “A National Plan for Promoting Breeding Programs for Minor Crops in the U.S. has been developed by a coalition of private and public plant breeders (the “Buckwheat Coalition”).<sup>40</sup>

Two mitigating factors suggest some of these concerns may be overdrawn for industrialized countries. As the plant breeding activities of the big companies expand to fully meet the needs for the major crops there seems no obvious reasons why they would not turn to the minor crops. Second, according to the theory of “synteny” there is great similarity among genes and where they lie in relation to one another along the chromosomes, at least within families of plants. To the extent that this holds, research on one plant will have great value in addressing the challenges in other plants.<sup>41</sup> These mitigating factors do not, however, offset major concerns of developing countries.

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<sup>39</sup> Evenson, R.E. Intellectual property Rights and Agribusiness Research and development: Implications for the Public Agricultural Research System. *American Journal of Agricultural Economics*, 65 (5) December 1983.

<sup>40</sup> W.R. Coffman, *op. cite*.

<sup>41</sup> Gale, M.D. and K.M. Devos, Plant comparative genetics after 10 years, *Science* v. 282 23 October, 1997, p. 656-8.

*Developing Countries Concerns.* Crop productivity is determined by genetics and environment and by their interactions, so plant biotechnology addressing plant production challenges of the industrialized North have limited relevance to the tropics. If the genes that control a plant's reactions to elements of tropical production environments are not identified, the gains from synteny will be limited. Further, because over half the investment in plant biotechnology is directed toward herbicide resistance or product quality,<sup>42</sup> which may not be the highest priority for developing countries, the potential for spillover is limited.

Developing country crop variety development systems are poorly equipped to deal with the rapid changes that are occurring because they have depended so extensively on international free exchange of germplasm. As plant research in the industrialized world has come to be dominated by private companies this process has slowed. But public-sector plant breeders don't know how to respond, and when they try are handicapped by the huge disparity in resources and negotiating power between themselves and the companies.

Among the most important assets accumulated by previous public investments are the plant germplasm collections of developing countries and the CGIAR. These logically should form the basis for variety development efforts for those markets. It is now possible for a company to take an existing variety, insert a few genes, take out a patent, and try to sell the seeds wherever they are adapted. Of course, the value of any variety is determined by the combinations of genes that determine height, leaf density, drought tolerance, disease resistance, grain type, maturation period, and so forth. The addition of one or two traits adds value, but clearly there was value in the preexisting line or variety. Without IPR on that preexisting line any compensation to plant breeders or institutions who developed the previous variety is unlikely. All varieties are built on preexisting varieties, and as recently as 50 to 100 years ago, all seeds were selections by farmers of the most attractive plants in their fields. These so-called landraces underlie all plant breeding.

The argument is made that the public interest demands some compensation by private companies who add a few genes to existing varieties. One possibility is market segmentation to allow the poorest developing-country farmers to obtain improved varieties at minimum cost while imposing higher charges to others. To ensure this is at least a possibility, public-sector plant breeding organizations must gain the capability to deal with IPRs and negotiate with private companies to preserve the public interest in assets accumulated with public funding.

*Company Power and Freedom to Operate.* The ownership of a large fraction of seed production capacity by a few firms is beginning to attract public attention. One only need recall how domination of the American automobile industry by the Big Three allowed them to set prices and determine product characteristics. Only when foreign firms introduced new ideas was price and quality competition regained. The current court case

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<sup>42</sup> As reflected in the proportion of field tests of genetically engineered crops in the United States. See Clive James, *Global Status of Transgenic Crops in 1997*, ISAAA Brief No. 5-1997, Ithaca, NY.

against Microsoft is providing many claims about the anticompetitive nature of a highly concentrated market.

Given the existing intellectual property rights on the tools, processes, materials, and cloned genes that are inherent components of plant biotechnology, a company has rights to products made using those components. However, there are disputes about how far rights should “reach through” to subsequent discoveries. For example, Cre-loxP is a tool used to create research animals to study the function of certain genes. A gene has been identified that appears to play a role in a particular disease. Further research has identified a molecule that serves as a drug target. Drug development and screening is pursued without use of the Cre-loxP. Can the drug developer enter into licenses for the drug’s production and sale without involving the company that owns the IPR on Cre-loxP, the original tool?

Some commentators claim the company is leveraging “its proprietary position in upstream research tools into a broad veto right over downstream research and product development,” while representatives of the company that owns the tool claim they “reserve neither right in our license agreements with academic and other not-for-profit institutions.”<sup>43</sup> Subsequently representatives of another academic institution report having approached the holders of IPR on proprietary research tools such as promoters and transformation systems for discussions on commercializing applications of the technology in crop plants. They report with “surprise and dismay” that “the holders of these proprietary “upstream” technologies “have effective veto power over whom universities can and cannot approach with their technologies for commercial development.”<sup>44</sup>

Examples of power plays by companies are making the rounds of the academic plant biology community, and they extend to the developing world. A developing country research institution working with a CGIAR research center using public support seeks agreement to use a proprietary gene in the development of technology to address a major problem confronting smallholder farmers in Africa. The company holding the IPR agrees to license the gene only if it and it alone can determine how commercialization will proceed in the event the research proves successful.<sup>45</sup> Many researchers are discovering that it is easy to get a material transfer agreement or other license to use proprietary technology for research purposes, but when the research turns up a potentially useful technology, some owners of IPR don’t hesitate to use their power to dictate how and even whether commercialization can proceed. The freedom to conduct research is different from the right to negotiate with the owner of IPR when it comes time to apply research results in farmers fields.

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<sup>43</sup> See the exchange of letters between David S. Block and Daniel J. Curran of DuPont Merck and Rebecca S. Eisenberg and Michael Heller of the University of Michigan Law School, *Science v. 282*, 20 November 1998.

<sup>44</sup> Colm Lawler and Fred Erbsich, *From Mice to Maize*, *Science v.283*, 1 January, 1999.

<sup>45</sup> Joe deVries, personal communication.

## Where does the public interest lie?

In a time of rapid change, it is not easy to see where the public interest lies. Most might agree it is in the public interest to promote those socially desirable objectives that may be neglected without deliberate action and to discourage or prohibit socially undesirable results that might occur if deliberate public action is not taken, or that intellectual property “rights should be shared so that the maximum benefit eventually accrues to the maximum number of people.”<sup>46</sup> But these idealistic concepts provide little concrete policy guidance.

The discovery of DNA and the invention of techniques using DNA have made the previously invisible global genetic commons visible. The interaction of technological change and intellectual property rights is allowing the transformation of DNA from a public good whose consumption was non-rival and non-excludable (and perhaps not even recognized) into private property. If one believes that such claims on the global genetic commons are necessary in order to make the “fruits of nature” usable, one may view these developments positively. On the other hand, the privatization of the genetic commons might simply redound to the benefit of some particular persons at the expense of the larger society.

Despite the great wealth creating power of market forces, it is clear they do not resolve all issues in a socially desirable way. Collective social action is needed to set the institutional framework within which market forces operate, and the institutional solutions may differ for industrialized and developing countries. Increasingly, as cross-national flows of capital, information, goods, and people have reached massive proportions, national institutional frameworks are becoming inadequate. Multinational companies can shift operations and funds across national boundaries with ease and impunity, and as a consequence, there is a need to examine plant biotechnology issues not only from national viewpoints, but also from an international perspective.

*Market power:* Markets in which there is a single seller (monopoly) or several sellers (oligopoly) tend to operate in ways that follow from their structure. In order to maximize their profits, sellers in such markets have the incentive to increase prices and reduce quantities relative to prices and quantities that would occur in a competitive market. The concentration of seed production in the hands of a few companies will inevitably lead in those directions. The classical cases of “natural monopoly” that have existed in earlier eras, for example, with public utilities led some countries to establish nationalized monopolies or alternatively to establish regulatory bodies that set prices charged to consumers.<sup>47</sup> Alternative public responses have been dissolution of monopolies. Consolidation of seed producers has reached such an extent that representatives of farmers in the United States are becoming alarmed and are beginning to call for some such remedies.

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<sup>46</sup> See the editorial in *New Scientist*, 17 April 1999 on information and property rights.

<sup>47</sup> In recent years technological developments have undercut the natural monopoly of the telephone company, first with alternative long-distance carriers made possible through cheap fiber optic or high capacity satellite-based service, and more recently through local cellular telephone service.



Many developing countries are at a significant disadvantage in controlling monopolies, having relatively few persons with the knowledge required to regulate monopolies, especially in a relatively esoteric field like plant biotechnology. Many countries have historically provided for a controlled monopoly or a government monopoly in crop research and seed production. The experience has been mixed, however, and in recent years the World Bank has urged borrowing countries to divest themselves of operating companies like those that produce and sell seeds. Typically, such companies are purchased by one of the big multinationals, but the monopoly position is preserved. A more preferable policy would be to allow local production or importation and sales of seeds by any company, subject only to quality standards. In addition, the large multinational seed companies are actively negotiating with developing countries for rights to import and sell their products under special arrangements, which amount to government-blessed monopolies. All monopoly and oligopoly situations should be resisted because competitive markets in seed development, production and sales will generate the greatest public benefit.

*Patents and plant variety protection.* Patents are a special case of monopoly, one endorsed by society for a limited time period and requiring disclosure of the invention. Many argue that patents function to stimulate economic activity by granting exclusive rights to the inventor to economically exploit the invention. However, others argue that for small developing countries, patents raise the costs of new goods and restrict the ability of local, low-capital innovators to improve on existing technology, especially in the plant area.

A key question with implications for building knowledge in plant biotechnology is what shall be patented. The United States Patent Office allows the patenting of SNPs – single nucleotide polymorphisms or single base pair polymorphisms in the DNA of organisms. Companies specializing in the identification of SNPs and other molecular markers anticipate selling that information to others who would commercialize the application of the knowledge. SNPs are, however, essentially existing constructs of nature, discovered but not invented, and it is reasonable to ask where the line should be drawn between public and private ownership of the genome. This is an issue requiring further public debate and, when resolved, perhaps further legislation.

The United States is the only major country to allow the use of patents to protect crop varieties, and U.S.-based companies have pressured the United States government to urge, in international negotiations, that patents be the system of choice for all countries. Ironically, the patenting of varieties is currently being challenged in a case before the United States District Court.<sup>48</sup> There is a chance that in the U.S. patenting of varieties will be disallowed because there exists legislation providing an alternative system of protecting the intellectual property embodied in plant varieties. If the practice of patenting varieties is overturned, intellectual property in crop varieties in the United States would be governed by the plant variety protection (PVP) system, which is similar

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<sup>48</sup> Kilman, Scott, Biotech Industry Shivers at Threat to Seed Patents, Wall Street Journal, March 3, 1999.

to protection provided in many other countries and is internationally recognized under the UPOV treaty.

The plant variety protection system allows farmers to save seed for their own reuse and plant breeders to use them in research designed to produce further varietal improvement. Both these provisions are prohibited by patents but seen to have significant public welfare advantages, certainly for developing country agriculture. Regardless of what happens in the United States, the use of the PVP system, which prevails in most of Europe, is preferable for developing countries. With little competitive loss, the big seed companies could agree to use PVP in developing countries in cooperation with public breeding agencies.

*Biotechnology and IPR capacity in developing countries:* The capacity of governments or the science sectors of many developing countries to understand, deploy and negotiate regarding biotechnology is quite limited. They simply have very few people with the education and experience required to understand these matters. Training to build national capacity in the science and management of biotechnology, intellectual property rights, biosafety, and international negotiations is an overwhelming need. This will require considerable investment by individuals, countries and donors. Life science companies have contributed to building the needed capacity through projects that link specific technologies with training of scientists, such as with the sweet potato in East Africa or potato in Mexico. But these arrangements have involved fewer than 10 scientists. What is needed is a massive effort to create a cadre of national scientists so countries themselves can make determinations about what standards are appropriate and what technology to use.

Companies could establish a fellowship program for training developing country scientists in crop biotechnology, intellectual property and international negotiations. Participating companies could contribute to a fellowship fund administered by a neutral fellowship agency, something like the Fulbright program. Fellows would be chosen on a competitive basis according to criteria that might include national agricultural needs and academic excellence. Training 500 individuals to the PhD level would require about \$75 million. If the fund and the award process is insulated from the companies, fellows would be seen as national resources and would not be obligated to the commercial interests.

*Biotechnology tools and techniques.* To speed the development of biotechnology capacity in developing countries, companies that have intellectual property rights over certain techniques or materials might agree to license these for use in developing countries at no cost. The agrobacterium transformation system is one possible candidate for such treatment. Another candidate might be all the privately held genomic data about a key crop species in which much genomic data is already in the public domain, say rice. Making these key tools available, not just for research, but for commercial applications in developing countries might give a boost to developing country scientists.

Another set of actions would relieve apprehension in the developing world over what they perceive as unreasonable intellectual property rights claims on crop varieties or crop traits of distinct national origin such as South Asian basmati rice or Thailand's Jasmine rice. The U.S. patent on "Basmati rice lines and grains" specifically claims the invention of "novel rice lines with plants that are semi-dwarf in stature, substantially photoperiod insensitive and high yielding, and that produce rice grains having characteristics similar or superior to those of good quality basmati rice grains produced in India and Pakistan."<sup>49</sup> An agreement to share financial rewards from such inventions or grant free licenses to use such lines in breeding programs in the country of origin of the said trait might gain the appreciation of developing country researchers. One might also foresee the possibility of legal actions in the United States and Europe against companies that claim IPR on such traditional crop traits.

*Gene protection systems.* Efforts to induce farmers to purchase all the seeds they need are probably not socially optimal in developing countries because seed production systems are not adequate to supplying all the needed seeds and farmers have limited cash liquidity for such purchases. This can be seen from the experience with hybrids. They provide a certain natural inducement to purchase new seeds each year but in many developing countries farmers choose not to do so but instead to accept the lower yield associated with reusing the grain from hybrid maize as seed. The idea of using in developing countries technologies designed to prevent germination of grain as seed, thereby blocking farmers from saving their own seed (called "terminator" by some), has engendered strong opposition in most quarters. The possible consequences if farmers who are unaware of the characteristics of such seed purchase it and attempt to reuse it are certainly negative and may outweigh any social benefits of the seeds thereby protected. In any case, there is widespread negative public reaction to encouraging poor farmers to use such technology.

An alternative approach to protecting genetic technology might be to develop a "lock and key" gene control system based on the idea that genes would be freely available for incorporation by any breeder, but would be silent until they are turned on by farmers through a deliberate process, say the application of an environmentally friendly, biodegradable "key" compound. All the "base" traits in such seeds would be reproduced when it was saved and replanted unlike with the terminator gene, but only when the key compound is applied would the additional, special traits be expressed.

*Food and environmental safety.* Over the past six months an intense controversy has erupted in Europe, especially in England, about genetically modified organisms (GMOs) in foods that threatens the entire agricultural biotechnology process. One focus of challenge is the safety of GMOs as food. A second challenge is the possible negative environmental effects of the introduction of GMOs into the crop production environment. These issues have been the subject of much scrutiny during the development of genetically engineered crops and a number of procedures have been put in place by national authorities to ensure safety. Another objection is the moral, ethical issue of

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<sup>49</sup> Sarreal et. al. United States Patent 5,663,484, September 2, 1997.

meddling with nature or “playing God.” These issues are being contested, but many believe they could be resolved if genetically engineered foods were labeled.

If instead, policies are implemented in Europe that impose such strict constraints on GMOs as to stop or significantly slow the deployment of GMOs in developing countries, either through regulations or because of spillover of opinion, it could have significant negative consequences on using biotechnology in developing countries and hence on future food supply. Already many countries lag behind with implementing procedures under which such GMOs could be tested and approved for production. Meanwhile, in 1998, over 60 million acres of GMO corn and soybeans were grown, mainly in the United States and Canada.

*Need for a public dialogue.* It is clear that the wide range of suggestions made here will not simply be accepted by companies or governments. In many cases there is no clearly preferable position. In some cases agreement by a single company would disadvantage that company. What is needed is a wide-ranging, broadly inclusive dialogue among all concerned parties -- civil society, governments, companies, scientists, ethicists, and intergovernmental agencies to consider these issues and agree on a framework for their resolution in the future. It is certain they will continue to become ever more complex.

#### **PROS AND CONS OF IPR IN DEVELOPING COUNTRIES**

##### Pros

- Provides incentives to create knowledge
- Encourages greater research and development within the country
- Discloses information other researchers can use to make further advances
- Encourages greater research and development investments in industrialized countries on issues of concern in developing countries
- Encourages transfer of knowledge to developing countries
- Creates a market for knowledge by providing a legal basis for technology sales and licensing

##### Cons

- Increases costs of protected products and may price them beyond the reach of the poor
- Shifts bargaining power toward producers of knowledge rather than users
- Broad patents may discourage follow-on inventions and slow the overall pace of innovation
- The knowledge gap between industrial and developing countries may increase
- Industrial-country firms may take advantage of indigenous knowledge and natural products without compensation to local communities