Commercialization and the Scientific Research Process: The Example of Plant Breeding

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Abstract

Changes in plant breeding during the past 15 years, driven by discoveries in biology and information technology and by laws allowing the patenting of biological material, have exceeded changes since the discovery of genetics. Expansive patenting may have reduced the free exchange of germplasm and, along with other developments, may limit the future involvement of the public sector in plant breeding. Biology, and the industries (agricultural and medical) that depend on it, are now involved in a revolution comparable to the one that took place in physics at the beginning of this century. Large scale DNA sequencing is revealing the genes required to encode most major life forms, including humans, microbes, plants and animals. The scale of discovery is causing a major shift in the paradigm of biological research from a reductionist approach that focused on individual phenomena, to a highly paralellized approach that integrates the molecular information for whole organisms across biological kingdoms and encompasses entire physiological and behavioral systems. Companies and industries are being restructured in a way that will change the world's economy. The tremendous impact of commercialization on plant breeding research can be traced to the passage of the Bayh-Dole Act in 1980 that led to a rapid increase in the patents granted to U.S. colleges and universities. A faculty panel determined recently that Cornell University could better serve its internal and external responsibilities by placing a greater emphasis on the development and commercialization of university inventions while simultaneously participating in an effort by the Rockefeller Foundation and other leading research universities to establish an IPR clearinghouse and an IPR pool that would facilitate collective licensing of university technology for humanitarian use throughout the developing world. If present trends continue in the patenting of genes it appears that two or three companies will have a major influence on the global food system. The future of plant breeding depends on the policies that we evolve for the management of intellectual property related to crop improvement. Genes may be to plants what words are to books. If words were copyrighted, only the few who owned them could communicate and our society would be harmed. In the end, decisions will probably be made based on what makes economic sense and by answering the question posed recently by Alan Greenspan, "Are all property right inalienable, or must they conform to a reality that conditions them?"

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Introduction

The nature of scientific research has changed rapidly in recent years. Applied biological research, such as plant breeding[2], has changed more in the past 15 years than at any time since the discovery of genetics. Change has been driven by discoveries in the field of biology and information technology and accelerated by laws protecting or patenting biological materials, including plant cultivars, genes, and numerous enabling technologies. Concerns exist that expansive patenting, in terms of number and breadth, may limit the future involvement of the public sector and jeopardize the utilization of our germplasm resources for the welfare of humanity (Barton, 1997; Bragdon and Downes, 1998). Practicing plant breeders are very much aware of a major reduction in the free exchange of germplasm, although it has not been well documented. This paper examines recent trends in the scientific research process using the example of plant breeding, discusses the forces that will shape the future, illustrates the interdependence between the public and private sectors, and concludes with projections about the future, particularly in the public sector.

Recent Trends in Plant Breeding

Frey (1996) conducted a survey of the change in science person years (SYs) devoted to plant breeding research and development (R&D) during the 5-year period 1990-94. He found that the total number of SYs devoted to plant breeding R&D in the United States was 2,241 in 1994, distributed among private companies (1499), state and territorial agricultural experiment stations (SAES) (529), the Agricultural Research Service (ARS) of the United States Department of Agriculture (USDA) (177), and Plant Materials Centers (PMCs) of the USDA (36). Over the 5-year period the net loss of plant breeding SYs in SAESs was estimated to be 12.5, or 2.5 SYs per year. For the same period the growth in private industry SYs was 160, or about 32 SYs per year.

Many of the leading institutions in public sector plant breeding have ceased to produce finished cultivars and are concentrating on methodology development, applying the discoveries of basic biology to crop improvement. Over the past few decades, the Agricultural Research Service of the United States Department of Agriculture (USDA/ARS) has chosen to concentrate on basic science, eliminating or curtailing nearly all the cultivar development programs on minor crops. Today, USDA/ARS devotes only 12 percent of its plant breeding SYs to cultivar development (Frey, 1997). State

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[2] Plant breeding is a relatively unrecognized scientific specialty that is the basis of human civilization. Fewer than 2500 plant breeders practice in the United States – fewer than 7,500 (estimated) worldwide – sustaining a relatively small number of crops that capture solar energy and sustain human existence. Rice, for instance, is the primary staple of half the world's population. The rice genome was first mapped at Cornell (McCouch, et al 1988) Cornell supports the only Department of Plant Breeding in the United States, numbering eleven faculty members.

Agricultural Experiment Stations also reduced their collective human input into plant breeding by 2.5 SY per year during the period 1990-94.

Transgenic crops are rapidly gaining in importance, with the area increasing from 1.7M ha in 1996 to 58.7M ha in 2002 (James, 2002). Transgenic crops are, of course, proprietary and are almost exclusively the product of the private sector in industrialized countries. It seems likely that this is just the beginning of sweeping changes in global food and fiber production based on genetic technologies. On the other hand, we must remember that the future of both public and private sector plant breeding ultimately depends on the perception of consumers worldwide. In “Playing God in the Garden,” a New York Times Magazine article, Michael Pollan (1998) wrote:

> In a dazzling feat of positioning, the industry has succeeded in depicting these plants [transgenics] simultaneously as the linchpins of a biological revolution – part of a “new agricultural paradigm” that will make farming more sustainable, feed the world and improve health and nutrition – and, oddly enough, as the same old stuff, at least so far as those of us at the eating end of the food chain should be concerned.

Pollan termed this a “convenient version of reality” which has thus far been roundly rejected in Europe and ultimately could be rejected in the United States and other parts of the world. The more likely scenario would seem to be that it is just a question of time until these technologies are accepted worldwide, particularly once products with health or quality benefits for consumers become available over the coming decade. However, at this time, the eventual acceptability of bioengineered foods for consumers is unknowable.

Genomics -- Framing the Future

Biology, and the industries (agricultural and medical) that depend on it, are now involved in a revolution comparable to the one which took place in physics at the beginning of this century (Tanksley, 1998). Large scale DNA sequencing is revealing the genes required to encode most major life forms, including humans, microbes, plants and animals. The scale of discovery is causing a major shift in the paradigm of biological research from a reductionist approach that focused on individual phenomena, to a highly paralellized approach that integrates the molecular information for whole organisms across biological kingdoms and encompasses entire physiological and behavioral systems.

The major outcomes of genomics research over the next 10-30 years will be: (1) the association of DNA sequence data with biological function and the determination of how nucleic acid and protein sequences have changed through evolutionary time to create the diversity of life forms that now inhabit this planet, and (2) understanding the flow and regulation of information encoded by the genome and the way genomic information is, in turn, regulated by information from the environment. The ensuing discoveries will revolutionize our understandings of the origins of life and the molecular processes that underlie life. They will also lead to many revolutionary discoveries in engineering, medicine, the environment and agriculture.

As new discoveries in the genomics arena are applied, companies and industries are being restructured in a way that will change the world's economy (Enríquez, 1998). Many of the worlds largest companies have been forced to reinvent themselves as conventional demarcations blur. Initially, they formed what Enríquez termed the life sciences industry. He pointed out that the flow of genomics information is so massive that it threatened to overwhelm existing R&D budgets, labs, and knowledge bases.

Megamergers and dissolutions have been happening as companies attempt to lock in patents and licensing agreements and maximize profits. As investors began to recognize (a) the cost of bringing agricultural biotechnologies to market (in no small part due to regulatory costs), (b) the magnitude of public resistance to bioengineered crops, particularly in Europe, and (c) consequently, the relatively limited returns to investment in agricultural research (people able to pay for food are already consuming more than they need), the vision of a life sciences industry has been abandoned. The highly profitable medical sector of such companies has been separated from the agricultural component, while the latter has reaffirmed its affiliation with the agricultural chemical industry as a source of cash flow for investment.

So far, the public sector has been mostly a spectator in this process. Interactions with the private sector have been largely in training scientists and as grant recipients for specifically defined products. As consolidation approaches its limit in the private sector, this is beginning to change. Large companies are now seeking strategic alliances with public sector institutions to gain access to new ideas. Comprehension of this prospect in the public sector is increasing and the implications, particularly for plant breeding and most other areas of biological research, are extraordinary.

The Bayh-Dole Act

The tremendous impact of commercialization on plant breeding research can be traced to the passage of the Bayh-Dole Act in 1980 ("Bayh-Dole"), a watershed for the licensing of innovative results that flowed from federally sponsored research projects in the United States. Bayh-Dole was the Federal government's response to perception among governmental, industry and academic leaders that few of the results of federally sponsored research projects were being commercialized and hence benefiting U.S. taxpayers. There was a broad sense at the time that the public was not receiving any significant benefit from its support of public research. Moreover, there was pressure at both the Federal level and within many individual states to reduce public budgets, including the public support provided to higher education and its related research activities. Enabling research institutions to license the results of their researchers' work seemed a positive way to cushion the shock of reduced governmental research support, and a way that respected the then emerging "privatizing" atmosphere.

The key provisions of the Act[3] were:

- uniform patent policy established for federally funded research;
- university-industry collaboration encouraged;
- universities and/or for-profit grantees/contractors[4] may elect to retain title to inventions developed through government funding; and
- the government retained a non-exclusive license to practice the invention throughout the world (an option that could only be exercised if statutory protection was sought in foreign jurisdictions).

The Act and subsequent guidelines have led to a dramatic increase in university-industry intellectual property (IP) transfers and, overall, has been considered highly successful in that regard. Three key factors are credited with that success:

1. certainty of title given to inventions;
2. leadership delegated to the inventors (individuals and/or institutions); and
3. uniform IP standard provided for all research conducted with government funds and a predictable patent and licensing procedure.

Because Bayh-Dole permitted research institutions to claim ownership of federally funded research results, this law provided a mechanism for research institutions to commercialize those research results and in this way, it was argued, the public would benefit. The terms of Bayh-Dole provided the incentive for many U.S. universities (and similar U.S. research institutions) to establish or expand their technology licensing activities. Bremer (2001) has shown an increase in patents granted to U.S. colleges and universities following the enactment of the Bayh-Dole (Figure 1).

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3 P.L. 96-517 of 12 December 1980 and subsequent modifications (P.L. 98-620 of 8 November 1984).

4 The for-profit grantee clause was part of an amendment in the form of a Presidential Memorandum on *Government Patent Policy* of 18 February 1983.

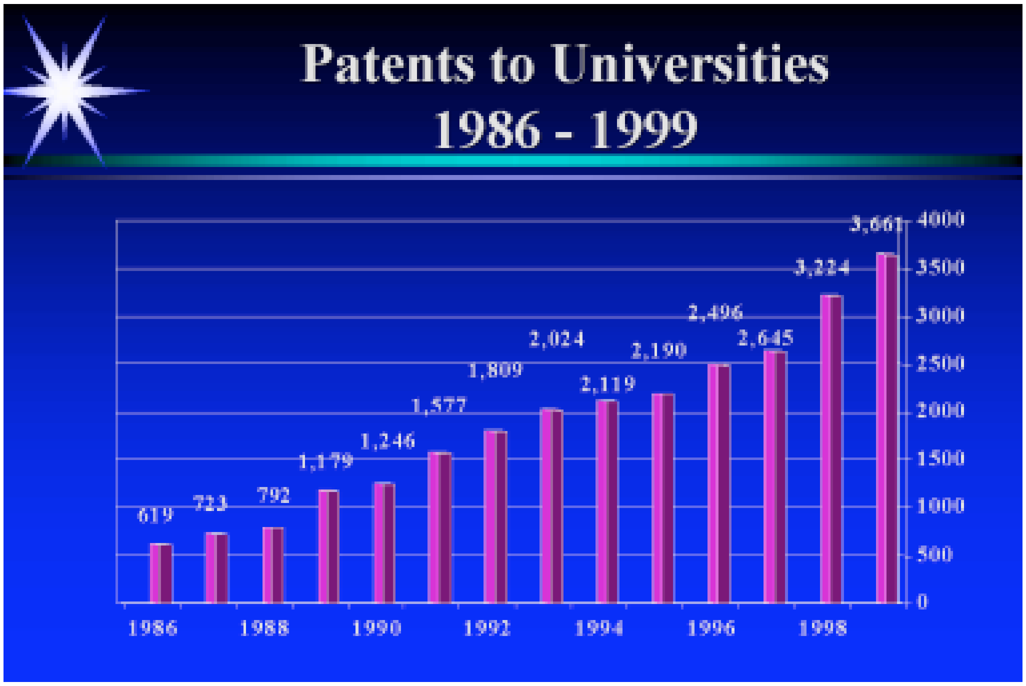

Figure 1. Patents granted to universities following the enactment of Bayh-Dole (Bremer, 2001)

University Policies

The Bayh-Dole Act undoubtedly had a significant impact in the U.S. on the protection and transfer of university inventions. By extension, the impact on federally funded research on university IP policy and management/licensing of inventions strategies was considerable. At present, the U.S. Government is one of a very few major research funders with an explicit IP policy. However, current discussions under several fora are shifting rapidly in the direction of establishing policies. That is, philanthropic foundations and other sponsor agencies are increasingly coordinating their policies to create a unified, level playing field. The objectives of these institutions mainly relate to their missions of ensuring access to research inventions by developing countries for social and humanitarian benefits.

This debate and ensuing policy shifts are expected to lead to new challenges for universities, especially ones with a long history and interest in collaboration with organizations in the developing world. These challenges are related to the difficulty of reconciling IP policies of different research sponsors, and of harmonizing university IP policies with any possible new restrictions imposed.

A complementary development in the international debate relates to finding appropriate mechanisms for reducing the barriers that impede access specifically to agricultural biotechnology for subsistence and minor crops. Among others, what has been proposed is the creation of a clearinghouse to advise researchers, administrators, and technology managers about practical IP management strategies that will result in quicker decisions, lower transaction costs, and ultimately, the development and dissemination of plant varieties using biotechnology that address hunger (subsistence crops) or contribute to more vibrant state economies (minor commercial crops). In addition, endeavors are proceeding towards the creation of a mechanism such as a technology pool derived from many public sector institutions to grant researchers broader access to complementary collections of agricultural biotechnologies, materials and information for specific purposes.

Even with those processes in place, the obstacles to the transfer of modern biotechnologies to resource poor farmers remain numerous. Included are:

- Covering regulatory costs,
- Partitioning markets with both commercial and small farmer applications,
- Developing transformation protocols for non commercial crops like cassava,
- Provision of training,
- Establishing and monitoring oversight, such as may be needed for the delay of resistance development when using *Bt* crops, and
- Managing the tradeoff between costs and the maintenance of genetic diversity when multiple local varieties are being grown.

The question of allowing faculty to start a company (or take employment with a company) that licenses their own inventions from the university raises issues of conflict of interest. These issues are dealt with in the policy statements of many universities, and thus it is implicitly assumed that faculty have the right to such activity, but clear statements to this effect are not always found. Discussions about these matters in email newsgroups address the question of allowing faculty "entrepreneurial leave of absence" to start their own companies, and it seems that faculty members often want to be involved in some way with the commercial development of their own inventions. The conflict of interest (and conflict of commitment) issues need to be considered, but with a system in place to monitor this aspect, most universities allow, and often encourage, faculty to take such external roles. Indeed, the commercialization of technologies often requires the ongoing involvement of the inventors as those most knowledgeable about the potential of the product and the interested firms. In other cases, university technology transfer offices must take an equity position in a product to attract investors, so that the offices' activities move beyond licensing into venture capitalism.

Existing university policies evidence apparent internal conflicts that lead to questions about their overall roles and effectiveness. Some examples include:

- The university or its research foundation has a fiduciary responsibility that may best be exercised with exclusive licenses. Exclusive licenses can sometimes provide a lower public benefit than non-exclusive licenses. The gene gun developed at Cornell is a good example. Conversely, exclusive licenses can be necessary to elicit the amount of additional investment required to bring a product to the commercialization stage.

- Sometimes access to a technology is possible only by cross licensing, involving other university inventions, but when doing that, a research foundation must make decisions about the use of technology that may have been discovered by another inventor(s). How should those conflicts be resolved under patent policies that promise researchers specific benefits following the licensing of their inventions?
- Is it possible and appropriate to identify critical technologies (like the gene gun) and forgo exclusive licensing for greater public benefit? Does exclusive licensing actually provide for greater public benefit by providing adequate corporate incentive to expand the technology's use? These matters need to be studied in more detail and discussed openly so that policy outlines may be established.

Perhaps most significant to the research process though is the possible reduction in the exchange of information caused by property rights and financial benefit issues. Certainly there are adequate anecdotal examples of the chilling effects of property rights on information exchange and publication speed. But anecdotes are not a proper basis for policies. A few surveys have been conducted, particularly in the medicine/human genomics fields that suggest some modest effects on information exchange and speed of publication that can be attributed to property rights practices. In many cases, property rights are claimed under contract law (MTAs) rather than patents so that modification of Intellectual Property Rights legislation, as has been proposed, will be insufficient to correct all the issues that have arisen.

More broadly from a policy point of view, the ongoing debate on policy shifts by other research sponsors, including the possibility for the creation of clearinghouses and patent pools (primarily based on U.S. university IP), is expected to have an impact on the way researchers will do business in the future. However, many key technologies (such as the Monsanto 35S promoter) are controlled by the private sector that may not cooperate fully with the clearinghouses.

A faculty panel (Coffman, et al 2003) determined recently that Cornell University could better serve its internal and external responsibilities by placing a greater emphasis on the development and commercialization of university inventions. While such a change in emphasis would eventually involve many aspects of the university, a starting place was thought to be an increase in incentives for activities leading to and promoting commercialization. The following changes were recommended in university policy:

1. Recognize the issue of a patent on an invention as an academic contribution similar to the publication of a refereed journal article for promotion and tenure purposes;

2. Provide additional and, particularly, more rapid financial (including for research) support for inventors. The present system with a lag of five to eight years between invention and realization of any financial returns provides limited incentives for inventors to develop an invention further, particularly for younger professionals;

3. Modify the university Conflict of Interest policies to allow more joint activity as a university faculty or staff member and officer in a startup firm directed to commercializing the invention.

4. Participate in an effort by the Rockefeller Foundation and other leading research universities to establish an IPR clearinghouse and an IPR pool that will facilitate collective licensing of our technology for humanitarian use throughout the developing world.

The last recommendation recognizes that (1) intellectual property rights (IPR) are here to stay and globalizing; (2) most key inventions will continue to occur in the public sector at research universities; (3) public funding should maximize public benefits and food security is an important public benefit; (4) international agricultural research centers and national agricultural research systems throughout the world need help with access to IPR; (5) the private sector will not serve poor farmers; (6) private companies have IPR that they are willing to donate and pooling IPR creates added value; (7) most university scientists would like to see their work benefit needy people; (8) a portfolio of public IPR supplemented by case-by-case licensing can provide freedom to operate and sharing that will benefit humanity.

However, university inventions are frequently at an early stage of development and require significant additional investment before usable products are available. This additional investment typically comes from the private sector which must be compensated for its expenditures and risk. This is quite a different scenario from what is often involved in these discussions where university inventions are treated as being fully functional right out of the laboratory.

Implications of Proprietary Technology

If present trends continue in the patenting of genes it appears that two or three companies will have a major influence on the global food system. With the advent of proprietary technology, small seed companies will either license technology from private industry suppliers or again look to the public sector for advanced breeding material. But most public sector programs have long since moved to more basic research and the development of source material. Because of the severely limited resources available in public sector programs, the provision of advanced breeding material will be a need (if small seed companies are to survive) but a very limited opportunity. In fact, with most important enabling technologies controlled by large-scale companies in the private sector, it is difficult to see how public sector programs can continue to be relevant in the production of advanced breeding material unless strong partnerships exist between public sector programs and those holding the enabling technologies in the private sector. Research exemptions are generally available but leave the public sector breeder in the very difficult position of developing technology that s/he may not be able to distribute.

Public/Private Interdependence

Education. The public and private sectors of plant breeding research genuinely need each other. The public sector is in the best position to lead in the training of plant breeders, now a lifelong endeavor. Hawk and Smith (1993) stressed that applied corn breeding programs in the public sector will be necessary to develop the human resources essential to future breeding efforts. Industry can be a better partner and supporter of the public sector's education mission. Exploring new teaching techniques with industry involvement is highly desirable (McConnell, 1997). Self-paced learning modules available over the Internet will be an important part of the continuing education of plant breeders. Plant breeding is changing dramatically and we need a new vision and a new curriculum for training tomorrow's plant breeders. This training must consider the revolution in information technology as well as the revolution in molecular genetics. Overall, this situation may not be fundamentally different from other sectors such as electronics that long have been dominated by a few firms with large patent portfolios. The biggest difference is perhaps the lower profit margins in agriculture versus other sectors.

Minor crops. The private sector will not be able to meet the needs in minor crops, due to the limited opportunity for profit, and will continue to look to the public sector to support such crops. Minor crops are defined as crops that (1) are cultivated on a limited acreage, (2) are produced as strains of major crops for niche markets, (3) provide relatively low gross revenues, (4) receive limited or no investment in research by either public or private sectors, and (5) feature plant breeding activities that are diffuse or non-existent. A National Plan for Promoting Breeding Programs for Minor Crops in the U.S. has been developed (Frey, 1997) by a coalition of private and public plant breeders (the "Buckwheat Coalition"). Elements of the plan include (1) establishing an organization to promote breeding of minor crops, the National Coalition for the Improvement and Use of Minor Crops (MCIC), (2) improving economic viability of minor crops, (3) promoting awareness of the significance of minor crops, and (4) securing sustained funding for minor crop breeding.

Some years ago, the pharmaceutical industry faced a similar issue for financing investments for rare diseases, the so-called orphan drugs. The response was the offering by the FDA of exclusive licenses for those products, as well as grants targeted to their development[5]. While the exclusive license provisions in particular have been controversial, the approach does provide possible models for encouraging investment into the breeding of minor crops.

Genepool Enrichment. Genepool enrichment is a common need for all plant breeding programs but cannot be supported extensively by any individual program or company. The same public/private coalition concerned with minor crops has developed a National Plan for Genepool Enrichment of U.S. crops (Frey, 1998). Elements of the plan include (1) establishing an organization to implement a crop genepool enrichment program, the Crop Genepool Enrichment Coalition (CGEC), (2) providing for the timely and orderly enrichment of genepools of U.S. crops, (3) promoting awareness of the significance of crop genepool enrichment to the future viability of U.S. agricultural production, and (4) securing sustained funding for crop genepool enrichment.

At the international level, the 2001 FAO International Treaty on Plant Genetic Resources for Food and Agriculture has established a standardized agreement for accessing genetic resources for designated crops in public genebanks. The initial and essentially derived variety provisions of the 1991 UPOV act are intended to provide incentives for background breeding. The U.S. adopted those provisions in 1994[6], although they have yet to be implemented here or elsewhere.

The Future of Plant Breeding Research

Beginning early in this century and peaking with the Green Revolution, the stream of public research has been of enormous benefit to humanity, particularly the citizens of the United States who have spent an ever diminishing portion of their income on food. The majority of this benefit came from plant breeding (Ruttan, 1982) and was based on an implicit contract that genetic resources were public and available to anyone. Lately, the rules have changed. More and more of the best science is patented. Some scientists believe that any DNA of value will eventually become somebody's property (Herdt, 1999). Others suggest that only discrete sequences of DNA that represent a valuable asset will be patented. In either case, the beneficiaries will be the stockholders and employees of the private sector and consumers who will enjoy lower food prices. Producers are expected to move increasingly to contract production for products developed specifically for specialized markets. Contract production can have mixed effects, from reducing management requirements to shifting some risks onto the contractor. Producers with the poorest soil/water resources can be expected to suffer the most if denied access to cost reducing technologies while crop prices fall as producers elsewhere in more favorable circumstances adopt those same technologies. That is essentially what occurred with past Green Revolution technologies. However, in some

[5] See http://www.fda.gov/orphan/.
[6] Plant Variety Protection Act of 1994, Sec. 111(c).

cases, new technology (drought tolerance, for instance) may allow enhanced use of those resources.

Plant breeding will become integrated fully with agricultural research specifically, and with biological, engineering, and medical research generally. Future plant breeders will rely heavily on computers to an extent that can hardly be imagined today. A plant is a biological entity driven by a piece of code interacting with the biological, physical, and chemical environment. That code will be deciphered at a rapidly increasing rate, along with the code for other organisms in the environment, particularly pest organisms. All useful code eventually may be proprietary. The characterization of production environments will be refined continuously. It is unlikely, in the fullness of time that the public sector will have a role that is independent of the private sector. Indeed, even today, public sector agricultural research would be much diminished but for the access and contracts provided by private firms.

Change is coming quickly in some areas. The major firms in the private sector are interested in partnerships with the public sector that offer a “first look” at new ideas. This became evident when U.S. News and World Report (Petit, 1998) reported that the UC, Berkeley had completed “...an unprecedented deal to sell access to an entire department. For $25 million up-front for new campus laboratories and $25 million in research funds over the next five years, the Swiss-based biotech giant, Novartis[7], gets to observe the work of 32 faculty members and nearly 200 graduate students and postdoctoral fellows in the Department of Plant and Microbial Biology. Novartis also gets first crack at negotiating the rights to take the department’s discoveries to market.”

Can we expect more alliances like this in the future as well as increasing alliances among competitors in the private sector? Low current profits and investor disillusionment with agricultural biotechnology means large upfront payments are unlikely at present. Numerous lawsuits now pending on biotech patents will likely be settled so that such patents are shared between “Haves.” “Have-Nots” will be left to license technology at increasing royalty rates. The public sector may tend to partner with the “Haves” because public sector breeders generally are starved for resources and they need such partnerships to maintain their education programs. The true implications of domination by large firms depends, in no small part, on the rate of the advancement of the science. If it continues at a high rate, then rapid obsolesce means protection is relatively less important than when advances are more paced.

Unification of the public sector may become a significant factor. A group of research university presidents (Science Policy Forum, May, 2003) is attempting to unite public sector institutions to conserve the right to utilize their collective intellectual property for

[7] Subsequent to this agreement, the agricultural component was spun off from Novartis and merged with a similar spin-off to form Syngenta.

humanitarian purposes. They have expressed their intent to form the Public-Sector Intellectual Property Resource for Agriculture (PIPRA) for the purpose of (1) reviewing public-sector licensing practices, (2) creating a collective, public, IP asset database, (3) pooling specific IP to form shared technology packages and (4) inviting broad participation by other public-sector institutions.

The future of plant breeding depends on the policies that we evolve for the management of intellectual property related to crop improvement. Sears (1998) pointed out that the free exchange and utilization of germplasm has been the foundation for all plant improvement efforts since crops were first cultivated over 10,000 years ago. He draws the analogy to a book (which may be copyrighted) and words (which may not be copyrighted). If words were copyrighted, only the few who owned them could communicate and our society would be harmed. Genes are analogous to words in that they allow the creation of new plant cultivars just as words allow the creation of a book. Everyone in society should have the right to use genes. Cultivars (novel genotypes or combinations of genes), not genes, should be eligible for patenting. It is now clear that the current system of patenting genes restricts the playing field so that only two or three companies will have a major influence on the global food system. In a broader context, the debate over the patentability of 'discoveries' such as naturally occurring genes is an age old one. Key interpretations are now being made by the U.S. patent and Trademark Office (Cowley and Makowski, 2003).

In the end, a decision probably will be made based on what makes economic sense. In a recent presentation reported by BBC News (2003), Alan Greenspan mulled the issues of patenting:

> Mr. Greenspan made no judgments over whether the rules designed to cope with real world, concrete property were too tight or too loose to make sure protection for ideas contributed to economic growth. Nor did he comment on the Fed's economic policies or the state of the U.S. economy. But he made it clear that hard decisions and deep thinking were needed to make sure that the balance was right. "Ownership of physical property is capable of being defended by police, the militia, or private mercenaries," he said. "Ownership of ideas is far less easily protected." One ancient example, he commented, was that of calculus, the mathematical tool discovered by Gottfried Leibniz and Sir Isaac Newton in the 17th Century, noting that their discovery was made freely available, triggering massive intellectual advances elsewhere. "Should we have protected their claim in the same way that we do for owners of land?" he asked. " Or should the law make their insights more freely available to those who would build on them, with the aim of maximizing the wealth of the society as a hold. Are all property rights inalienable, or must they conform to a reality that conditions them?"

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