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PART SIX: Public/Private Sector Relationships

31. Prospects for Public Plant Breeding in a Small Country

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Chapter 31

Prospects for Public Plant Breeding in a Small Country

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Introduction

In an earlier paper I suggested that "the forthcoming biotechnology revolution is not just the product of a scientific watershed flowing from the discovery of the double helix, but also the culmination of a more gradual evolutionary process over the past century involving revision of intellectual property rights to biological research. … the delineation of these property rights (is) an important determinant of the respective roles of the public and private sectors in agricultural biotechnology research" (Lindner, 1992).

Since then, it has become increasingly evident that the biotechnology revolution is being fuelled by the convergence of an explosion of knowledge about molecular biology on the one hand, and by legal and policy developments on the other that have dramatically expanded the scope of intellectual property rights in plant genetic resources.

Recent extensions to the definition of intellectual property rights in plant genetic resources have created the basis for the evolution for new markets, and set in train competitive forces that are likely to transform the respective roles of public and private sector plant breeding. As a result of a series of landmark court decisions in the USA, it is now possible to seek patent protection for genetically engineered life forms, from micro-organisms to plants and animals, as well as to many of the "building blocks" needed to engineer transgenic organisms. New property rights create the basis for new markets, and new commercial biotechnology companies have proliferated rapidly during the last twenty years.

If extended property rights create the foundation for new markets, the opportunities arising from rapid technical change provide powerful incentives for firms to enter these markets. For biotechnology, the competitive forces unleashed by concurrent scientific discoveries threaten to transform the production of new plant varieties. Much of the ownership of intellectual property rights in plant genetic resources is now concentrated in the hands of a small number of very large life sciences companies, and they are investing huge sums in research and development. Some commentators believe that public sector plant breeding and research organisations will be overwhelmed in the process.

The potential implications for the generation and commercialisation of new technology in plant genetic resources and for the evolution of agriculture in small countries like Australia are poorly appreciated. Some of the questions that need to be addressed include the following:

Will owners of intellectual property rights in key molecular technologies make them available to public plant breeding programs in small countries, and if so on what terms?

Will private sector plant breeding "crowd out" public plant breeding R&D?

How serious are compliance and enforcement issues for alternative appropriation mechanisms, such as seed royalties, technology fees, end-point royalties, and "Closed Loop Marketing Agreements"?

Convergent Trends

During the second half of the twentieth century, the explosion of knowledge flowing from the field of molecular biology has transformed the biological sciences, and in particular our understanding of "life processes" and our capacity to intervene in nature. During the last twenty-five years or so, there has been a parallel revolution in the legal framework relating to the assignment of intellectual property rights to plant genetic resources. This has occurred within nations through decisions made by courts and by conscious introduction of policy, and between nations via international agreements, undertakings, and conventions. Finally, after many unfulfilled promises and false starts, the consequent economic revolution has started. This convergence of scientific, technological, legal, policy and commercial developments will have a major impact on the way in which knowledge is generated and commercialised, and on the evolution of agriculture and our food system.

Scientific Trends: Key Elements of Molecular Biology and Genetic Engineering

Our understanding of the intricate and complex functioning of living organisms at the molecular and cellular levels is the outcome of the development of new scientific techniques and tools in the field of recombinant DNA technology. These developments also have accelerated the accumulation of knowledge in such traditional disciplines of biology as genetics, plant physiology, and biochemistry.

A long time advocate in Australia of genetic engineering has described the potential benefits in the following terms (Peacock, 1992, pp. 311-12):

> "as from now, it would also be unthinkable to mount a programme in agricultural research without considering the opportunity for recombinant DNA technology to be used. This is especially true in the production of improved cultivars. … We are now able to consider either the addition or subtraction of particular genes in the genetic make-up of a plant. We are

> also able to modulate the level of expression of genes, thus influencing the amount of a particular product being made. In the not too distant future, we will be able to consider gene replacement, so that we can upgrade the existing genetic software by replacing one version of a gene with a newer, improved version for a more desirable product. These manipulations will close the gap between yield and potential yield. They will provide plants with more robust resistance to pests and disease. They will enable the production of high performance hybrid seed in many crop species and will allow us to construct plants whose seasonal requirements are complementary to each other in agricultural production systems. As well as providing a more flexible and valuable entry of plant products to the food production sector, genetic engineering will enable agricultural production to have a greater impact in the pharmaceutical and industrial business sectors. … Basically genetic engineering is the precise manipulation of the genetic makeup of a plant, where the manipulation involves the addition of a known gene construct."

A number of these predictions have subsequently come to pass, or are close to realisation. Transformation processes have been developed for many broad-leafed plants, and more recently considerable advances have been made in the ability to transform major cereal plants such as wheat and barley.

According to (Peacock, 1992, p. 312), three key advances have made genetic engineering possible. They are the development of technologies to allow isolation and mass production of DNA segments, of systems to transfer specific gene constructs into recipient plants, and the means to introduce new genetic material into a single cell and then recover a whole, transgenic, plant from that single cell. Another major factor was the discovery that a gene has two major components; a product-coding region that dictates the specific amino-acid sequence of the gene product, and a control region that determines the expression (use) of the coding segment.

Traits already incorporated into transgenic plants that have been released, or are close to commercial release include:

- pest control traits such as insect resistance, viral resistance, nematode resistance, and herbicide tolerance;
- post-harvest traits such as delayed ripening of tomatoes, melons, raspberries, and other spoilage prone fruits;
- agronomic traits such as nitrogen fixation and utilisation, restricted branching, environmental stress tolerance;
- male and/or seed sterility for hybrid systems or other forms of genetic copy protection;
- output traits such as blue carnations, high-stearate and other specialty oils from rape or soybean, low-phytate corn, fatty-acid-enriched vegetable oils, coloured cotton, high-carotenoid canola, and functional foods or neutriceuticals.

Production of transgenic plants requires the use of a number of enabling technologies. An example of a pervasive enabling molecular technology is the Gus gene, which is used worldwide in molecular biology laboratories to test which cells have been successfully transformed. Many of these technologies are proprietary, although holders of the intellectual property rights commonly make them available for research purposes without charge.

More recently, genomics has emerged as an upstream enabling technology with the potential to further transform the field of biotechnology. Genomics involves the mapping, sequencing and analysis of genomes to determine the structure and function of every gene in an organism. James (1998) lists the following components of genomics research:

Structural genomics - the structure and organization of genomes
Functional genomics - relating genome structure and organization to plant function
Application genomics – use of genomic knowledge in the development of improved plants.

The most striking result to emerge from the study of comparative genomics is the discovery that an abundance of genes are shared among all life forms. Consequently, the breadth of complementary technologies is far greater than previously thought, and some of the barriers between the health sciences and other branches of biology have been crumbling. James (1998) notes that as consolidation continues in the agbiotech industry, all of the leading companies have made significant investments in plant genomics. In 1998, the USA launched a publicly funded National Plant Genome Initiative with international links to other programs such as the Japanese Rice Genome Program.

Genomic information provides a more efficient base for genetic engineering to improve useful plant traits, as well as to provide a sustainable source of renewable energy and a safer and healthier environment. It not only allows genetic material to be studied, but also to be designed and efficiently produced due to advances in robotics, nanotechnology, high-throughput screening, photolithography, spectroscopy, combinatorial chemistry, transgenics, and bioinformatics (Enriquez, 1998). These technologies have enabled the development of products that can analyze hundreds of thousands of compounds simultaneously rather than a few genes at a time.

National and International Legal Trends in Intellectual Property Rights

The concept of intellectual property as it applies to plant genetic resources has expanded considerably during the past two to three decades. In the United States, a series of landmark legal decisions now provide complete patent protection for genetically-engineered life forms, from microorganisms to plants and animals. Perhaps more importantly, it is now also possible to patent parts of plants and other living organisms, including key elements of the genetic constructs necessary to produce transgenic plants. Many other countries have followed the precedents set by US courts, and others are now under severe pressure to do so as a result of international agreements, most notably TRIPS (Trade Related Intellectual Property Protection).

These developments have been crucial in providing the private sector with the means to capture a financial return on investment in genetic engineering and plant breeding. As a result, corporate interest in patenting has increased markedly to cash in on the possibility of more rapid development of a wide variety of new proprietary products flowing from the new biotechnologies.

For the USA, Wright (1996, pp. 564-5) has summarised the legal measures relevant to the protection of intellectual property in agricultural genetic resources as follows:

Seed and Breed Certification

"Certification guarantees the nature and the genetic background of the seed or breed. It does not prevent sale of similar uncertified products by competitors. Thus it is more like a trademark than a patent".

Trade Secrets

Trade secrets "can protect the proprietary information useful to a firm from disclosure to competitors."

Plant Patents

"In the United States, asexually reproduced plants … may be patented … under the Plant Patent Act of 1930."

Plant Variety Protection Certificates

PVPC's "protect varieties that are genetically uniform, distinct from other known varieties and breed true. … farmers are allowed to re-use their own seed, and despite recent revision of the 1970 Act, the leakage to other farmers is difficult to police."

Utility Patents

In 1980, the US Supreme Court ruled that the patent system covered living things.

In 1982, a subsequent ruling confirmed that seeds, plants and tissue culture could be patented, and patents have subsequently been awarded over the "discovery" of genes. This extension of patent protection to life forms has now spread to most other OECD countries, including Australia, and even to many developing countries.

Most other countries do not have Plant Patents as a separate category of intellectual property rights. Australia, and maybe others do allow "new" plants to be patented as an invention provided that they satisfy all of the requirements for invention under the (normal) patent Act. A number of countries have the equivalent of Plant Variety Protection Certificates, although they often have different names. In Australia, the corresponding form of intellectual property rights are Plant Breeder's Rights.

Recently, the thrust to extend property rights to plant genetic resources was strengthened dramatically by annex 1c of the agreement on Trade Related Intellectual Property Protection (TRIPS). This agreement was one outcome of the Uruguay Round of trade negotiations, and established the World Trade Organization. It also requires all signatory countries to introduce, in most cases before 2000, patenting or some equivalent form of intellectual property protection for plants.

However, there are several international agreements relating to intellectual property rights, and/or access to, and utilisation of plant genetic resources and plant breeding. The following brief overview of the key international agreements, and their main features, has been taken from Bragdon, S. H. and Downes, D. R. (1998) *Recent policy trends and developments related to the conservation, use and development of genetic resources,* Issues in Genetic Resources No. 7, IPGRI, Rome.

The International Undertaking on Plant Genetic Resources (IU)

First adopted in 1983 to promote the conservation, exchange, and use of plant genetic resources for food and agriculture. It is currently being renegotiated to bring it into harmony with the CBD.

The International Union for the Protection of New Varieties of Plants (UPOV)

UPOV aims to maximise plant-breeding efforts, and provides a model for securing protection for plant breeders' rights for plant varieties.

The Convention on Biological Diversity (CBD)

The objectives of the CBD are:
Conservation of biodiversity
Sustainable use of its components
Fair and equitable sharing of the benefits arising from use of genetic resources

The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

The *raison d'être* of the World Trade Organisation (WTO) and related agreements is trade liberalisation. The TRIPS Agreement requires all parties to meet certain minimum standards for protecting intellectual property rights. In particular, parties are required to protect plant varieties either by patents or by an "effective *sui generis* system or by any combination thereof." Many countries, including Australia, delayed signing TRIPS because of concerns about its consequences.

The 1994 FAO/CGIAR Agreements and 1998 External Review of CGIAR

Agreements between CGIAR and FAO placed designated material in CG collections under the auspices of FAO and in trust for the world community. The agreement will be reviewed in the light of the IU negotiations.

The World Intellectual Property Rights Organisation (WIPO)

WIPO was established in 1967 to promote the protection of intellectual property worldwide. From 1998, it will address biodiversity, human rights and indigenous rights.

Evolving Market Structure in the "Life Sciences Industry"

Beginning in 1976 with the founding of Genetech, the first wave of the biotechnology boom saw the rapid proliferation of upstart commercial biotechnology companies. By the 1990s, over a thousand companies existed worldwide, and a substantial number were involved in agriculture. In the second wave, large multinational chemical and pharmaceutical corporations have invested significantly in molecular biology research and development, and have merged with or taken over multinational agribusiness firms.

It is impossible to present a completely up to date account of the state of the life sciences industry. Mergers, takeovers, and deals with private and publicly funded partners are being done and undone at such a pace that anything written on the topic is practically out of date before it can be published. Most of the following excerpts have been taken from Enriquez (1998).

One measure of the impact of advances in genomics is the number of patent applications for nucleic acid sequences to the U.S. Patent and Trademark Office (USPTO), which received 4000 requests in 1991 and 500,000 in 1996. This flood of information with proprietary potential is changing significant portions of the world's economy as biotech, chemical, pharmaceutical, and agribusiness companies seek to lock in patents and licensing agreements to protect their investments in molecular technologies by megamergers, takeovers, and outright acquisitions. Ciba-Geigy and Sandoz recently merged to create Novartis, valued at over $100 billion, and the largest pharmaceutical conglomerate to that date. Alone, it has enough money and breadth of R&D to compete not just in health care, but also in nutrition and agri-business.

> "The genomics-driven metamorphosis of chemical companies is even greater than that which is occurring in pharmaceuticals. Monsanto, a traditional chemical company, reinvented itself as a life science company. Starting in 1985, it began spinning off many of its core businesses. Since 1997, Monsanto has invested $6.6 billion in biotech and genomics. This strategy assumes that molecular research in plants and animals will be applicable in the short term to agribusiness. In May 1998, Monsanto bought DeKalb Genetics and Delta & Pine Land for $4.2 billion and created a joint venture with Cargill, one of the world's largest private companies, to process and package genetically engineered foods." Enriquez (1998, pp. 925-6).

Other chemical companies and major food processors also are restructuring and creating joint ventures to vertically integrate the production, distribution, and processing of genetically engineered crops. Dow Chemical intends to become a life science company, and spent $900 million to buy Eli Lilly's 40% share of a joint venture to modify crops and foods. Hoechst formed an agribusiness venture with Schering-AgrEvo, and bought Plant Genetic Systems for $600 million. This is creating a new industrial sector, agriceuticals.

Certain implications of the ongoing changes in business structure are discussed in more detail later in this paper.

Portents for "Public Plant Breeding" in a "Small Country"

Plant breeding in Australia has traditionally been conducted in "public" research organisations which historically received most of their funding from consolidated revenue. While industry derived funding has gradually been substituting for government funding over the past two decades, plant breeding has continued to be conducted mainly in state government Departments of Agriculture, with selected universities and CSIRO also playing a role in some areas.

In this paper, the term public plant breeding is used in a fairly loose sense to include any plant breeding program that is not conducted on a "for profit" basis. In essence, it excludes only plant breeding by profit making firms who sell seed, or otherwise appropriate some or all of the net benefits generated from growing improved varieties. Public plant breeding includes most other types of program, including publicly funded plant breeding conducted by universities or government agencies, or even contracted out to private institutions. It also includes plant breeding programs funded collectively by industry.

A key characteristic of such programs has been that new cultivars from the breeding program were released as "public varieties" available to all farmers, and that no price premium was charged for the intellectual capital embodied in these varieties. Implicit in such a non-commercial approach has been the presumption that decisions about the level of investment in plant breeding should be based on the principle of maximising social welfare, or at least maximising industry welfare.

Of course, the description above does not recognise that publicly funded rural research has been under pressure for at least the last two decades. Government now demands greater accountability at the same time that it reduces funding for agricultural research and extension. As a result, many "public" institutions are under pressure to become at least partially self-funding, and are starting to charge for selected goods and services. Public research institutions also seek to patent and/or commercialise discoveries made in the course of government funded research, or pursue opportunities to license technologies to the private sector.

Public plant breeding programs have not been immune to government pressure to generate revenue from their activities. Like private business, their capacity to capture a high proportion of the net benefits of new varieties depend on:

- a legal basis to establish ownership of the intellectual property embodied in the variety,
- the capacity to exclude potential users who are not willing to pay the nominated price,
- the costs of monitoring and enforcing compliance,
- the capacity for price discrimination.

In Australia, charging for the products of plant breeding programs is now feasible given the introduction of Plant Breeder's Rights legislation, and the ability to protect plant genetic resources as well as plants *per se* with patents. As a result, seed royalties, Technology User Agreements (TUA), end point royalties (EPR), and "Closed Loop Marketing Agreements" (CLMA) are high on the agenda. Pricing practice by public institutions are still evolving. If they start charging significant fees at levels approaching full cost recovery, and exclude farmers unwilling to pay these fees from access to new varieties, then they cease to be public plant breeding organisations within the meaning of the term in this paper.

The development of hybrid corn provided the first foretaste of the way that genetic copy protection could allow private plant breeders to appropriate much of the benefit of improved germplasm, and so create the incentive for private investment in plant breeding to "crowd out" public plant breeding. However, for many years the difficulty of developing hybrid technology for most other major crops made hybrid corn seem to be the exception that proved the rule that plant breeding would remain predominantly a public sector activity.

More recently, the extremely rapid spread of transgenic crops, almost all of which has been the result of private plant breeding programs, highlights the possibility of private plant breeding of other crops. In a recent global review of commercialized transgenic crops, James (1998) summarised the situation as follows:

> "Between 1996 and 1998, eight countries, 5 industrial and 3 developing, have contributed to more than a fifteen fold increase in the global area of transgenic crops. Adoption rates for transgenic crops are some of the highest for new technologies by agricultural industry standards. High adoption rates reflect grower satisfaction with the products that offer significant benefits ranging from more flexible crop management, higher productivity and a safer environment through decreased use of conventional pesticides, which collectively contribute to a more sustainable agriculture. In 1998, the global area of transgenic crops increased by 16.8 million hectares to 27.8 million hectares, from 11.0 million hectares in 1997. Five principal transgenic crops were grown in eight countries in 1998, three of which, Spain, France and South Africa, grew transgenic crops for the first time in 1998."

The area of transgenic crop in the USA in 1998 was 20.5 million hectares representing 74% of the global area. Other countries with significant areas were Argentina with 4.3 million hectares; Canada with 2.8 million hectares; Australia with 0.1 million hectares; and Mexico, Spain, France and South Africa each with <0.1 million hectares. Industrial countries accounted for about 84 of the total area planted to transgenic crops, which was approximately the same as 1997.

The five principal transgenic crops grown in 1998 were soybean, corn/maize, cotton, canola/rapeseed, and potato. In 1998, transgenic soybean and corn accounted for 52% and 30% of global transgenic area respectively, while cotton and canola each occupied 9% of global area. Principal transgenic traits in 1997 and 1998 were herbicide tolerance, increasing from 63% in 1997 to 71% in 1998, and insect resistant crops, which decreased from 36% in 1997 to 28% in 1998. Stacked genes for insect resistance and herbicide tolerance increased from <0.1 hectares in 1997 to 0.3 million hectares in 1998. Quality traits occupied less than 0.1 million hectares in both 1997 and 1998.

The rapid privatisation of canola breeding in Canada provides a further indicator of the possible future for other public plant breeding programs, and has been comprehensively documented and analysed by Phillips (1999). The following brief overview of selected highlights was summarised from his recent report.

As recently as 1982, there were only six canola cultivars actively grown in the world, all bred by public sector institutions in Canada. The plant breeding program used largely non-proprietary technologies, and all seeds produced and sold were in the public domain. The rate of development of new varieties was also relatively slow, with an average of one new variety every two years, and the average lifespan of a cultivar was about 10 years.

In the mid 1980's, four key factors led to the infusion of private money. First, health research and market development efforts throughout the 1980s opened the market for expanded production. Second, breakthroughs in breeding methodologies improved the economics of private sector breeding. Third, financial deregulation in the early 1980s in North America led to a large pool of capital seeking new investment opportunities, which coincided with the budget crunch in universities and public institutes and new pressures to commercialize new technologies for profit. The fourth and perhaps most crucial factor was the introduction of intellectual property rights for biological inventions.

Between 1982 and 1997, a number of new proprietary technologies replaced the publicly developed breeding methods and more than 125 new varieties were introduced. By 1996, private companies developed more than 75% of the new varieties, while public institutions only developed about one quarter of the seed sold in Canada. The average active lifespan of a cultivar declined to about three years by 1997.

Privatisation of plant breeding is not necessarily a bad thing, particularly for a large country. For instance, private seed companies have dominated plant breeding for decades in one of the most highly productive agricultural industries in the world, namely the corn industry in the US. In this predominantly private system, the rate of investment and variety development have arguably been greater than for the counterfactual of a solely public system. Part of the extra potential net benefit has been dissipated due to price exclusion, and part has been appropriated by seed companies. On balance it is arguable whether the farm sector has benefited from retaining a smaller proportion of a larger cake. From a national perspective though, the Pareto potential gain from privatisation has almost certainly been positive. However, for a small country, there are no transfers to domestic IP owners to compensate for the payments made by farmers as rents to intellectual property. Instead, intellectual property rents are exported in the form of seed company profits.

The term "small country" is used in an equivalently loose way in this paper to the term "public plant breeding". Above all else, it differentiates between "large countries" such as the USA and the EU whose companies control most of the intellectual property rights in plant genetic resources, and "small countries" comprising most of the rest of the world. By definition then, a small country is any country with a minority stake in ownership of plant related intellectual property rights.

It is different from the definition used in the international trade literature, but it has overtones of that meaning. Because of the dominant role of the USA and the EU in world trade, any firm exporting its products has to ensure that they do not infringe patents or other intellectual property rights granted under the jurisdiction of those "large countries". Hence small countries effectively are "policy takers" when it comes to intellectual property rights policies, because even if they could buck the trend toward standardisation of such policies, it is the policies of "large countries" which prevail when it comes to trade in intellectual property.[3]

Partly for this reason, welfare of "small countries" is likely to be of less concern to the multinational life science companies. "Large countries" effectively set the intellectual property rules by which life science companies operate, so they need to be particularly sensitive to the internal politics of these countries. Conversely, there is less incentive to be sensitive to the politics of "small countries". "Large countries" also comprise the largest markets for agribusiness, so “small countries” are more likely to suffer from what is known as the “orphan commodity” problem. Crops that are grown on relatively small areas on a world scale, and/or are grown primarily by poor farmers with very limited capacity to pay for improved productivity, are of little or no interest to large life science companies, and for this reason have been dubbed “orphan commodities”. Bananas, sweet potatoes, cassava, and yams, and lentils and lupins, are examples of “orphan commodities”.

Early evidence supporting this hypothesis of an asymmetry in sensitivity to domestic policy concerns in large countries vis-à-vis small countries comes from the commercialisation of Bt cotton by Monsanto in the USA and in Australia. Bt cotton was one of the first transgenic crops, and was commercially introduced in the USA in early 1996, and later the same year in Australia in time for the 1996/97 growing season. The plant was genetically engineered to express a biological insecticide, the Bt endotoxin from the bacterium, *Bacillus thuringiensis*. This new biotechnology has the potential to increase yields and/or decrease applications of herbicide, and so increase grower profits. It also has the potential to reduce offsite externalities associated with chemical pest control.

Monsanto Corporation is the patent holder for the Bt technology, and effectively commissioned Delta and Pine Land in the USA, and an Australian seed company, Cotton Seed Distributors as well as Delta and Pine Land in Australia, to help it develop transgenic cotton varieties. Although the Bt gene was introgressed into different germplasm in the USA from that in Australia, Monsanto kept close control of the commercialisation process in both countries.

According to Marra, Hubbell, and Carlson (1999), enough Bt cotton seed was available in the USA in 1996 to plant 1.8 million acres nationwide. Monsanto Corporation sought to appropriate the benefits generated by its intellectual property through a technology fee charged at a rate of US $32/ acre (about US $80/ha). While the price charged by Delta and Pine Land for Bt cotton seed was about US $1.50/acre above conventional cotton seed, most if not all of this premium could be attributed to the extra seed production costs for transgenic cotton. In addition, adopters of Bt cotton had to agree to set aside some of their acreage to be used to manage potential insect resistance build-up to the Bt strain. Despite these relatively high adoption costs and restrictions, experimental results were promising, and interest in Bt cotton in early 1996 was widespread.

Based on a farmer survey, Carlson, Marra, and Hubbell (1998) found that on average yields for Bt cotton were 11.4 percent higher than for non-Bt cotton, insecticide applications were 72% lower, and net profits before paying technology fees and extra seed costs were greater by US $233.45/ha. Estimated total extra costs for the Bt technology (license fee and seed cost) was US $91.79/ha, so on average Monsanto was appropriating about 40% of value added by the Bt technology. It needs to be stressed that these average figures conceal very considerable regional, as well as inter-farm variation. Some sense of this variation can be gained from the fact that adoption rates for Bt cotton in Alabama in 1996 were exceptionally high for the first year of release (74%), but as low as 6% in North Carolina (Traxler, 1999). Further evidence that benefits were greater in southern regions than northern regions is provided by the fact that in 1997 Monsanto offered a discount on the technology fee of $10/acre (US $24.80/ha) for the first 50 acres per farm for new adopters in the Carolinas. Even so, although Bt cottonseed was available for planting 7.5 million acres in 1997, only 5.5 million acres were actually planted (Hubbell, Marra, and Carlson 1998).

The pricing arrangements in Australia for the commercialisation of what was called INGARD® cotton were generally similar, only the levels were different. Initially Monsanto set the technology fee at A $245/ha, which at current exchange rates translated to about US $70/acre or approximately double the level set in the USA. Under some pressure from the domestic industry, Monsanto subsequently agreed to what was called a value guarantee program. When the farmer's technology fee exceeded his reduction in insecticide costs on INGARD® cotton vis-à-vis conventional cotton, this scheme compensated him for the difference in cost. Monsanto has refused to release data on payouts under this scheme, although they acknowledge that they have been substantial. The company retained the scheme (in slightly modified form) for the second growing season, but grower exploitation of moral hazard opportunities forced the company to drop it before the third growing season.

In the second growing season, the technology fee was retained at the same level, but an audit rebate of A $35/ha was introduced for farmers who complied with a government mandated insecticide resistance management scheme. As compliance with the audit requirement was effectively 100%, this represented a reduction of A $35/ha in the technology fee. For the third growing season, Monsanto has reduced the technology fee to A $185/ha, and the audit rebate to A $30/ha, thus reducing the effective technology fee to A $155/ha. However, for 1999, the technology fee in the USA has been reduced to US $20/acre, or about A $76/ha.

Despite these high costs, growers planted the maximum area permitted by the national regulatory authority. In 1996, the maximum permitted area was 30,000 ha, which was increased to 65,000 ha and then 75,000 ha in the second and third growing seasons respectively. In most areas, the maximum area permitted to be planted to Bt cotton has been about 20% of total area, so it has not been difficult for growers to comply with requirements for refuges as part of integrated pest management schemes.

For the first two years of commercial release of Bt cotton, inter-country comparisons are complicated by the operation of the value guarantee program. Estimates made from surveys by cotton consultants for the first two years of commercial plantings of Bt cotton in Australia suggest that a majority of cotton farmers incurred a net financial loss from growing and paying for INGARD® cotton in these years (Hancock, Harrison, and O'Brien, 1999). On the one hand, this could be viewed simply as a case where most cotton growers picked Monsanto's pocket. On the other hand, it could be viewed as an attempt by Monsanto to practice almost perfect price discrimination because the net price paid for Bt technology by each grower was equal to the technology fee minus any repayment under the value guarantee program. For the majority of growers, the technology fee was greater than the saving in insecticide cost, so the net price appropriated 100% of the net benefit of growing INGARD® cotton.

From an Australian perspective, there are several concerns with this scenario. First, the practice of inter-country price discrimination by Monsanto puts Australian cotton growers at a cost disadvantage in competing with their American counterparts. Second, the practice of setting a higher price for the technology in Australia limits the level of adoption of the technology. Third, the pricing practice by Monsanto in Australia seems designed to appropriate almost all of the benefit from the technology, and to leave almost none of the benefit with growers. If Monsanto was an Australian company, this would simply be a distributive issue, but given that Monsanto profits are repatriated offshore, it also affects national social welfare.

However, it is the difficulty of securing *freedom to operate* that arguably poses the most ominous threat to public plant breeding in a small country. The experience of an Australian organisation, CLIMA, when it sought to commercialise a transgenic lupin variety, provides an example of the problem. When it commenced research on transformation of lupins, CLIMA sought and obtained permission from AgrEvo/PGS to use the *bar* gene that provides tolerance to the herbicide, glufosinate. After this research was successful, CLIMA sought to negotiate a license to release a transgenic lupin variety containing the *bar* gene, but AgrEvo/PGS refused to negotiate a license. Without permission of the owner of a patent to use a proprietary molecular technology embodied in the transgenic variety, CLIMA could not proceed with plans to commercialise this variety. This threat to public plant breeding can be characterised as "shutting out" rather than "crowding out".

Future Prospects

Plant Breeding at the Crossroads

Plant breeding is at a pivotal point in its evolution. Transgenic crops have reached farmers' fields, and have been adopted at record rates by farmers. Subject to one or two caveats, transgenic crops seem certain to become pervasive in commercial agriculture, at least in developed countries. Consumer acceptance is of course the biggest question mark hanging over the future of transgenic technology, but the possibility of widespread and continued rejection of GMO's is a separate issue in its own right, and will not be considered further in this paper.

For the foreseeable future, new traits already in the technology pipeline that can be introduced into crops using recombinant DNA techniques promise to deliver greater productivity gains on average than traditional plant breeding methods. Even where significant progress does result from traditional methods, as for instance with new breeding lines from the CIMMYT wheat program, the increasing ease with which desirable transgenic traits can be introgressed into most elite germplasm means that transgenic varieties will ultimately dominate non-transgenic varieties.

From an economic standpoint, it is just as significant that patents can be used to protect the molecular technologies incorporated into transgenic crops. Patents are the strongest form of intellectual property protection available to inventors, but very few countries allow plants to be patented. Where it is possible to patent plants, it is not easy for plant breeders to satisfy the requirements for a patent to be issued. In most countries, it is not possible to protect plants *per se* by patents, and therefore not possible to obtain patent protection for varieties bred by conventional means. Therefore plant breeders using conventional means have to rely on other forms of intellectual property rights to protect new varieties from their breeding program. The fact that transgenic crops can be protected by patents, while only weaker forms of intellectual property rights are available to protect varieties bred by conventional methods, merely reinforces the tendency toward an emerging dominance of transgenic technology in plant breeding programs.

Given this fundamental shift in breeding methodology, an attempt is made below to discern future prospects for plant breeding by discussing some of the key factors likely to influence the future evolution of the industry. The starting premise is that further advances in fundamental scientific knowledge will be less important for future evolution of the industry than the extent of market power stemming from control over intellectual property rights in key technologies based on the current stock of scientific knowledge.

In the short run, considerations likely to shape industry development include the following:

- the degree of concentration of ownership of intellectual property rights,
- the commitment by governments to continue to fund public plant breeding programs,
- the commitment by industry to collectively fund plant breeding programs from compulsory levies, and
- the capacity of private and public organisations to capture enough of the benefits from commercialising proprietary technologies.

In the longer run, the degree to which the market remains contestable will be pivotal. In turn, contestability is the key to continued investment in biotechnology, technological progress in plant breeding, and growth in agricultural production.

The way in which patent law operates for biotechnology inventions will shape and influence the resolution of at least some of the issues above. This is an evolving and highly specialised area of law requiring detailed knowledge both of the relevant areas of science as well as the legal basis for intellectual property protection. Discussion of possible scenarios necessarily involves consideration of scientific as well as legal questions. Selected aspects of each are outlined below as a precursor to discussion of the above issues.

The US Patent System

The operation of the patent system within any given country is a complex topic demanding specialised knowledge and expertise. Further complicating the situation in many small countries is the fact that patent law in other jurisdictions may be as important as domestic law in determining the possibility of infringement of patents on proprietary molecular technologies. For reasons outlined elsewhere, the US system is pivotal. The following brief discussion of the US system is based on *ad hoc* sampling from expert sources, but without any legal expertise whatsoever for the interpretation.

According to Merges and Nelson (1990), a patent application has two main parts. One part is the specification of the invention describing the problem, and a precise characterisation of the 'best mode' of solving the problem. The second part is a set of claims defining the technological territory to which the inventor lays claim. Each part serves different functions, and is examined accordingly.

The Patent Office examiner reviews the application to determine whether the "invention" is patentable. *Inter alia*, the specification in America must satisfy the requirements for novelty, utility, and non-obviousness. The equivalent conditions which must be satisfied for an Australian patent to be issued are that it is a 'manner of manufacture, and novel, and inventive, and useful, and has not been the subject of secret use. In addition, the invention must be described in sufficient detail so that it satisfies the enablement doctrine. For any invention, enablement is satisfied when, by reading the patent application, an individual who is "skilled in the relevant art" (i.e. has skill in the relevant technology, such as molecular biology) would have been able to make and use the invention as intended *without undue experimentation*. Imitation of the invention *without undue experimentation* provides grounds for the patent holder to bring a case for infringement of the patent.

In the second part, the scope of the claim details the territory over which control is sought. Patent scope is deliberately not limited to the specific embodiment of the invention described in the specification, and can be as broad as the principle on which the invention is based. This approach is justified on the ground that an inventor who has discovered a new principle that *enables* a broad new range of applications should be entitled to appropriate at least part of the consequential benefits. Otherwise it would be far too easy for imitators to "invent around" a patent, and the protection provided by the patent would in most cases be virtually worthless. However, the scope of the claim cannot extend to inventions that are not *enabled* by the disclosure of the specification of the invention in the patent application.

In evaluating a patent application, the examiner will consider whether the claimed scope is overbroad, in the sense that the method of invention disclosed in the patent specification would not enable manufacture of all potential inventions within the scope of the patent claims. Where the application is judged to have not met this doctrine of enablement, it will be rejected.

However, given the intrinsic speculative nature of predicting future possible inventions based on a disclosed broad principle, it would seem prudent for patent examiners to give the benefit of the doubt to claimants when evaluating the scope of claims against the enablement doctrine. Several experienced observers of the patent process in the US suggest that this is in fact how examiners operate. Recent statements by the USPTO also suggest that examiners subscribe to this or a similar philosophy.

Thus the courts provide the main checks and balances on a natural tendency by applicants to make claims that are overbroad in scope. This can occur either when a potential imitator challenges the validity of the scope of claims for a patent, or when the patent holder brings a claim for infringement against a competitor. In either case, any rulings by the courts based on the doctrine of enablement set the standards for future patent applications. When a case for infringement is being adjudicated, the standards for patent scope for particular technologies may be further elaborated by court rulings based on the doctrines of infringement, including literal infringement, the interpretation of equivalents, and reverse equivalents. Merges & Nelson (1990) discuss the various doctrines of infringement in considerable detail, and readers who desire more detail are referred to that paper.

Proprietary Transgenic Technology for Plants

Successfully managing a product development process for transgenic plants involves scientific and legal considerations, each of which is more complex than might at first be apparent. For instance, many different technologies in addition to the gene expressing the desired trait are required to produce a transgenic plant, and most if not all are likely to be proprietary.

First the gene, or genes, coding for the trait(s) in question need to be identified and cloned. At least some of the methods for doing so may be proprietary. While genes that code for specific trait(s) are the primary genetic 'ingredients' for the transgenic plant, they are just one element of the "cassette" that makes up the required technology profile. Functional genetic units will include at least a promoter sequence, the structural coding sequence (i.e. the 'gene'), and the terminator region. Apart from the gene itself, the promoter that controls expression of the gene is a key element. In some cases, more than one regulatory sequence will be used to control gene expression. The functional genetic units also may include other elements, such as an enhancer, any transit peptide, and any introns.

In addition to one or more functional genetic units for agronomic and/or product traits, at least one or more extra functional genetic units will be required for the selectable marker(s). The core of a selectable marker unit is a gene that enables the identification of cell lines with stable integrated foreign DNA, but at a minimum it also will include its own promoter and terminator sequence. One or more selectable markers may be used, and the individual components for each selectable marker may or may not be proprietary. Even where the individual components are not protected, a patent may protect use of the combination as a selectable marker.

The transformation system is another essential molecular technology that typically is proprietary. Once the transformed cells are identified, they are grown into full plants for seed production, testing, multiplication and/or breeding purposes. Required technologies, such as tissue culture, regeneration, propagation, and analytical assays, are generally not proprietary, but there are exceptions.

Increasing use also is being made of proprietary molecular technologies to produce hybrid varieties in crops where previously it was infeasible and/or uneconomic to do so. As previously noted, hybrids provide a form of genetic copy protection that enhances and complements legal means to protect intellectual property rights.

Depending on the complexity of the transgenic product, there could be 15 to 40 identifiable tangible components involved, each comprising subject matter of a kind likely to be claimed in a patent or patent application. Thus to successfully commercialize a new transgenic crop, a plant breeder must strategically develop legal access to all enabling technologies in order to have the "*freedom to operate*". The devil is in the detail because the *freedom to operate* is limited by several factors, including:

- the large number of technologies used in developing a single product;
- the fact that many of these technologies are patented;
- many different patent holders typically control the set of required technologies;
- considerable uncertainty about ownership of many of these technologies; (due to the number of pending patent applications, and to overlapping claims which are subject to litigation even after the patents are issued).

As a result, plant breeders face formidable transaction costs in negotiating with multiple patent holders over availability and terms for licensing with different degrees of exclusivity and other attributes. In theory, these transaction costs can be reduced to manageable levels by creating industry-wide institutional conventions that foster markets for trading and leasing intellectual property rights. The market for leasing copyright to musical scores is an example where transaction costs for trading in intellectual property rights have been minimised. Presumably necessary conditions for the evolution of such a desirable outcome are a degree of maturity in the application of the scientific technology to industry, and a degree of certainty about the application of patent law to the technology in question. It would seem that neither necessary condition is currently being met for the application of biotechnology to plant breeding. Consequently the evolution of market power in a framework of legal uncertainty is a matter for conjecture.

Concentration of Ownership of Core Intellectual Property

As noted above, the first phase of the biotechnology boom was characterised by large numbers of small startup companies. In the second phase, Lesser (1998), Enriquez (1998), and others have documented and commented on a shift to consolidation through mergers acquisitions and joint venture arrangements. By the time of writing in early

1999, six large multinational chemical and pharmaceutical corporations dominated the industry. Based on a variety of sources, Table 1 lists these six conglomerates and at least some of the companies that have been subsumed by them during the past few years.

It is widely believed that this small group of large life science companies controls somewhere between 60% and 85% of the intellectual property rights over the key proprietary molecular technologies applicable to plant breeding. However, it is impossible to establish the precise extent to which they monopolise control of this IP. Much of the required data is commercially sensitive, or is not in the public domain for other reasons. Patent databases record original ownership, but not subsequent transfers of ownership. Licensing agreements or other commercial transactions that influence the extent to which key companies dominate an industry also are not a matter of public record. Moreover, even if all of the above information were available, it would be difficult to keep track of because the situation changes from day to day.

While it is difficult to establish the situation for all technologies, the trait of insect resistance conferred by transgenic Bt plant technology is a topical and illuminating example. As a case study, it also illustrates how scientific and legal considerations interact to influence economic outcomes. In addition, a lot of information about Bt transgenic technology is publicly available. For instance, in a recent paper Krattiger (1997) documents, *inter alia,* the degree of concentration of ownership of intellectual property rights for Bt technology. His analysis of Bt-related patents issued in OECD countries over the last 11 years revealed some 410 patents, of which approximately one third relate to Bt biopesticides rather than novel Bt genes. Abbott-Laboratories (27), Ecogen (19), Toa (25), and several other Japanese corporations hold most of these patents relating to Bt biopesticides.

Large life science companies dominate holdings of gene based patents related to Bt transgenic technology. The six major company groups hold about 60% of these patents, with Dow (81), Novartis (33), Aventis (22) and Monsanto (20) the largest holders. Ownership of the remainder is widely dispersed. Apart from other companies, universities and public research agencies also have been working on identifying and patenting novel Bt genes. With very few exceptions, these other organisations do not hold more than four patents. In aggregate, the number of patents held by these other organisations is significant, and the widely dispersed ownership, particularly by public institutions (see Table 2 and appended footnote below), would seem to satisfy necessary conditions for this market to be contestable.

However, merely looking at the total number of patents for Bt transgenic technology gives a misleading picture of the degree of market power exerted by the large life science companies for several reasons. First, as Krattiger(1997) explains, Bt transgenic technology is a generic technology covering many different specific applications. Thus only a small proportion of the total number of the patents discussed above will be applicable to a specific application. In fact there are many different strains of the bacterium *Bacillus thuringiensis* that produce a large number of similar but different endotoxins, or Cry proteins. Moreover, each endotoxin has a slightly different mode of action,

TABLE 1 Life Science Groups and Companies Subsumed by Merger and Acquisition

Parent Company	Subsumed Companies
Aventis*	(Rhone-Poulenc
	(Agrevo* (previously Hoeschst + Schering)
	Fisons
	Gene Logic
	Applied Immune Sciences
	Biogemma
	Marion Merrell Dow
	Plant Genetic Systems
	Roussel Uclaf
	Nunherns (Sunned)
	Sun Seeds
	Cargill Seeds North America*
	Cotton Seed International**
Dow	Mycogen Seeds
	Dow AgroSciences (ex Dow Elanco)
	Eli Lilly
	Agrigenetics
	Agriseeds
	Dinamilho
	Carol Products Agricolas
	Buna Sow Leuna Olefinverbund
	Morgan Seeds
	Sentrachem
	Illinois Foundation Seeds
DuPont	Protein Technologies International
	Pioneer H-Bred International*
	Herbert's (coatings)
	Griffin** (crop protection)
Monsanto	Calgene
	Kelco
	Agracetus
	Asgrow Agronomics & Seeds
	DeKalb Genetics
	Holden's Foundation Seeds
	Corn States Hybrid Service
	Delta and Pine Land
	Suregrow
	Plant Breeding International Cambridge
	Sementes Agroceres
	Cargill Seeds International
Novartis	Sandoz,
	Ciba-Geigy and Ciba Seeds
	Northrup-King Seeds
Advanta	Zeneca**
	Royal Vanderhave**
	Mogen

*Not yet finalised, and may not proceed. ** Joint Venture.

and consequentially is only effective against a very limited number of the estimated 67,000 pests that plague agricultural crops worldwide. At least 50 Cry proteins have been identified, and genes coding for 28 proteins that are active against insects have been described in detail and isolated from 14 different Bt subspecies. Research on the manipulation of the cry genes also is leading to the discovery of new binding sites.

TABLE 2 Identifiable Public Institutions Holding Two or More Bt-Related Patents

(Patents issued from 1986 to December 1996)

Institution	Country	Total
Agency for Industrial Science	Japan	2
Agrartudomanyi-Egetem	Hungary	2
Australian National University	Australia	3
CSIRO	Australia	3
Drexel University	USA	2
Institut Pasteur	France	11
Kamenek L K	Russia	2
National Research Council	Canada	2
National Environmental Research Council (NERC)	UK	2
State Research Institutes	Russia	18
University of California	USA	4
University of Wyoming	USA	2
USDA	USA	2
Wageningen University	Netherlands	2
Washington Research Foundation	USA	3
TOTAL		**60**

Compiled from patent offices of various countries by Krattiger (1997). Joint applications of two organizations are listed under the first applicant only and the table does not take into account purchases of patents nor licenses, except those through the purchase of or merger with companies.

Other organizations which are probably **public,** and who hold one patent each are:

Alko, USA; Beijing University of Agriculture, China; Berd-Chem Works, Russia; Berdsk-Fact. Biol. Prep., Russia; Biotechnology Applications, Italy; Boyce-Thompson Institute, USA; Canadian Patent Development, Canada; Cantacuzino-Inst., Romania; Cornell University, USA; CRC, Italy; Finnish National Public Health Institute, Finland; Harvard College, USA; INRA, France; INRS, Canada; Institute of Zoology, Khazakhstan; Lim. Technol. Lab., USA; Michigan State University, USA; Min. Coord. Iniziative, Italy; National University of Singapore, Singapore; Plant Cell Research Institute, USA; Rural Development Administration, Korea; Salk Institute of Biological Studies, USA; Serres R A, USA; Silmaran-Tanabal, Japan; Stanford University, USA; Treetech

Management, USA; University of Georgia, USA; University of Houston, USA; University of Laval, Canada; University of Memphis, USA; University of Western Ontario, Canada.

As a corollary, only a small fraction of the patents referred to above will cover the gene(s) applicable to the control of a particular pest in a specific crop. For instance, according to Krattiger (1997), most current development of transgenic crops utilises only the following Bt genes:

TABLE 3 Corporations Developing Bt Technology by Bt Gene and Target Insect Pests*

Companies	**Gene**	**Origin** (Bt subspecies)	**Major Target Insects**
Monsanto	cryIA(a)	*kurstaki*	Silk worm, Tobacco horn worm, European corn borer
Aventis, DuPont, Monsanto, Novartis, Hunt Wesson, Rohm & Haas	cryIA(b)	*berlineri*	Tobacco horn worm, Cabbage worm, Mosquito
American Cyanamid, DowElanco, Miles, Monsanto	cryIA(c)	*kurstaki*	Tobacco budworm, Cabbage lopper, Cotton bollworm
Frito Lay, Monsanto	cryIIIA(a)	*tenebrionis*	Colorado potato beetle
Cargill, Genetic Enterprises, Monsanto	CBI-Bt**	Not known	Not known

*Adapted from Krattiger (1997).
**Confidential Business Information.

Furthermore, this only gives a partial picture of the dominance of the large life science companies, as many have entered collaborative arrangements for the development of crops protected against insects. For instance, Monsanto is developing crops using some of the 10,000 or more Bt accessions of Ecogen, and Mycogen and Pioneer Hi-Bred International also have a collaboration agreement to develop transgenic crops. Krattiger (1997) concludes that the major players with their own technologies in transgenic Bt plant technology are Monsanto, Novartis, Mycogen (Dow), and AgrEvo (Aventis).

Of these four companies, the first three already have several Bt products on the market and many more in the pipeline. The potential extent of market dominance that these companies currently enjoy through the concentration of ownership or control of intellectual property rights in proprietary molecular technology is even more apparent from the following table, which lists the companies controlling commercial releases of transgenic crops by country for 1995 to 1997.

TABLE 4 Companies Releasing Transgenic Crops by Crop, Country, & Bt Gene Used*

			Bt Gene		
Crop	**Country**	**cryIA(a)**	**cryIA(b)**	**cryIA(c)**	**cryIIIA(a)**
Corn	Argentina, USA, Japan, EU, Canada		Monsanto, Novartis Novartis Monsanto, Mycogen, Novartis		
Cotto n	Australia Mexico Sth. Africa USA	 Monsanto		Monsanto Monsanto Monsanto Monsanto	
Potato	Canada Japan Mexico USA				Monsanto Monsanto Monsanto Monsanto

*Adapted from Krattiger (1997)

The degree of market dominance depicted in Table 4 is likely to be short lived, as other companies will enter these markets by one means or another. In some cases, companies have entered licensing agreements with the patent holders to enable commercial use of the technology, while in other cases firms are seeking to develop alternative technologies that will not infringe current patents. Attempts to "invent around" existing patents range from:

- research to obtain better expression from currently used Bt genes,
- research to discover other Bt genes that are effective for the same insect species,
- research to modify existing Bt genes that code for endotoxins with slightly different modes of action (i.e. binding sites in the insect gut), and
- research on entirely different methods of introducing transgenic insect resistance in crops. For instance, the discovery of a different class of insecticidal toxins produced by *Photorhabdus luminescens* has recently been announced. In addition to insect toxins, other methods under investigation include those based on morpological barriers to insects, production of repellent proteins by the plant,and novel approaches such as exploiting programmed cell death in plants.

Apart from attempting to "invent around" existing Bt transgenic technology patents, most of the major companies also are mounting court challenges to the legality of patents held by business rivals. The issues in these court challenges are essentially legal rather than scientific, and will be discussed briefly in the subsequent section.

The degree of concentration of ownership of intellectual property over genes coding for a particular trait is just one aspect determining market dominance by the large life science companies. According to Shimoda (1995), the ability of companies to commercialize new agbiotech products depends on strategically developing the "freedom to operate". A necessary, but not sufficient condition for a competitive market position is legal access to a number of required pieces of intellectual property, the most important of which are:

- **Trait specific genes**, which control specific characteristics, such as tolerance of abiotic stress, insect, fungal or viral resistance, herbicides tolerance, and ripening control.

- **Enabling technologies**, including:

  (a) transformation technology by which a gene which codes for a specific characteristic is inserted into plant cells;
  (b) promoter(s) which are used to control expression of the gene in plants;
  (c) selectable markers which are genes used to determine which plant cells have been successfully transformed to show the desired characteristic; and
  (d) gene silencing or regulating technologies, such as anti-sense and sense, which can be used to suppress or modify gene expression in plants.

- **Method patents**, which control broad techniques used in the genetic engineering of plants, such as the molecular method for transforming specific crops.

Many scientists are more concerned about monopolisation of enabling technologies than they are about monopoly control of trait specific genes. The mere belief that there may be a bottleneck in enabling technology is stimulating a lot of research. No doubt some of it is motivated by the potential financial returns to be gained by controlling the intellectual property rights to a transgenic technology with such widespread applicability. For other research groups, the motivation is to ensure that disadvantaged countries and peoples are not shut out from the potential benefits of this technology. Whatever the motivation, the key issue is whether such research is likely to be successful.

As illustrated by the discussion of genes for insect resistance discussed above, usually there are a number of alternative means by which science can achieve a given end. While it may be difficult to discover scientific substitutes for some traits, such as the production of specialty oils, even in these cases there typically are end-product alternatives which limit the degree of market power conferred by control over the intellectual property rights to a gene for a particular trait.

Whether there are an equivalently wide range of scientific alternatives for some or all of the enabling technologies is a moot point. To date, the two most widely used methods for transforming plants either involve the use of *Agrobacterium tumefaciens* to "infect" the target cells with a plasmid incorporating the gene for the desired trait, or the biolistic approach, whereby a modified gun is used to shoot DNA particles into cells. Other methods have been developed, but to date have not achieved high enough success rates to be used economically in the commercial development of transgenic crops. Some scientists are concerned that lack of alternative transformation technologies will prove to be a major bottleneck in the development of transgenic crops. However, growing experience with the above two techniques has resulted in continuing improvements in success rates as people experiment with and discover improved variations on the basic methods. Drawing an analogy with cookery might be unfair, but the record to date does give grounds for hope that it is simply a matter of time before a number of successful recipes are discovered. If all else fails, it may be necessary to wait the remaining years until the technology comes "off patent".

A promoter sequence that causes expression in the desired manner also is an essential ingredient for producing transgenic crops. Patents protect virtually all known promoters, so getting *freedom to operate* has to include securing legal access to intellectual property rights to an effective promoter sequence. Promoters differ widely in function and effectiveness in specific situations. Different types of promoter may cause expression in all plant tissues (constitutive), in specific tissues, or in response to a specific stimulus (inducible). The appropriate type will depend on the requirements of the particular transgenic technology being developed.

To date, one of the mostly widely used promoters has been CaMV 35S, both because it is a constitutive promoter, and because higher levels of expression have been achieved with it than with other available alternatives. Monsanto holds the principal patent, but has quite freely approved use for "research purposes". It also has licensed several other companies to use it in commercial releases of transgenic crops. However, some public institutions have had difficulty in obtaining permission to use it in transgenic crops for commercial release.

Pending the outcome of further genomic and related research, it is difficult to know how many promoters exist in nature. Even if the absolute number is large, there may be few naturally occurring alternatives for a specific application. If this proves to be the case, ensuring contestability may depend on the ingenuity of scientists in "manufacturing" synthetic promoters.

Patents over selectable marker genes and functional genetic units are another area of concern about monopoly control of enabling transgenic technology. Commonly used marker genes confer resistance to antibiotics (e.g. the nptII gene confers resistance to kanamycin, neomycin, and G-418), or to herbicides (e.g. the so-called *bar* gene confers resistance to glufosinate), or express certain chemicals for visual identification of transformed cells (e.g. *-glucoronidase or GUS). Even if these genes are not proprietary, their use in a functional genetic unit may be protected. For instance, one plant cell selection technique that has been used commercially is the kanR selectable marker. This marker is based on the *nptII* gene that encodes an enzyme that confers resistance to the antibiotic kanamycin. The functional genetic unit also includes a generic promoter and terminator. While all the three constituent components are generic and not patented, Monsanto has a patent on the combination of the three components. Anecdotal evidence suggests that this rather bizarre situation has stimulated more than enough research to lead to the likely development of a variety of alternative selectable markers in the near future.

The last category in Shimoda's list of enabling technologies is gene silencing or regulating technologies. Patenting this type of technology, as well as other more generic and "upstream" technologies such as genomic information, involves legal issues. These include patent scope and cognate matters more closely related to those of concern about method patents that control broad techniques used in the transgenic technology.

Problems of Patent Scope and Potential Gridlock

According to Barton (1998), the possibilities for patenting plant genetic resources in the USA are among the most broad anywhere, and include obtaining a patent on:

- a gene and its application in a plant,
- on the plant itself, and
- on basic biological processes and inventions.

In the first group, patents covering a gene, and transformed plants using the gene, are often written with multiple claims. "These may cover, for example, an isolated or purified protein, the isolated nucleic acids having a sequence that codes for the protein, plasmids and transformation vectors containing the gene sequence, plants (or seeds for such plants) transformed with such vectors and containing the gene sequence, and the progeny (or seeds) of such plants. This claim structure protects the patent holder against use of the gene by another biotechnologist, but leaves anyone fee to use and breed with organisms containing the gene naturally." (Barton, 1998, p. 85)

Writing the claims in this manner is intended to obtain effective business control of the proprietary gene, and to keep other parties from inserting the gene into other varieties. This may not be contentious so long as the scope of the patent is limited to insertion of the gene into varieties of the same species using established technology. However, some commentators have expressed concern when the scope of the patent extends to cover transformation of other species, and when the method to do so was developed AFTER filing of the patent, and when the development of the post patent technology required significant additional inventive effort.

The second group of patents provides coverage for finished plants. If TRIPS is implemented as currently planned, all signatory countries to the WTO must adopt some form of intellectual property rights to provide coverage for finished plants. The US practice of extending the coverage of utility patents to finished plants has led to certain practices that have attracted criticism. For instance, there are concerns that claims to a specific hybrid variety identified by a deposit might be used to prevent access by other breeders to germplasm in that variety. This is despite the fact that genomic research suggests that the overwhelming majority of genetic code in any given species is not unique to that species. Hence the germplasm in the deposited variety will duplicate that in other public varieties almost entirely. In the opinion of Barton (1998), this use of the patent system is unlikely to be accepted in other countries, not least because it effectively prevents use of the protected variety both for breeding purposes and for reuse by farmers, actions which are explicitly permitted under plant variety protection laws.

For reasons to be discussed in some detail below, the granting of patents that claim coverage over broad groups of transgenic plants, such as the Agracetus patents on *all* transgenic cotton and *all* transgenic soybean plants, has been the subject of even more severe criticism (p.86). This not just an US issue, as initially the European Patent Office (EPO) also granted Agracetus a broad patent covering genetically engineered soybean, although the validity of this patent was subsequently challenged.

Companies holding such patents would seem ideally placed to monopolise production of an entire crop, but the matter is not quite so simple. Other conditions necessary for Monsanto to be able to translate this potential monopoly position into actual market domination include:

- effective business control of the gene(s) needed to produce transgenic crops with "*killer traits*" (i.e. traits that reduce farmers' costs and/or create product price premiums that farmers regard as essential for business survival);
- for each agro-ecological zone in the industry, access to suitably adapted elite germplasm into which "*killer trait*" genes can be inserted;
- <u>undisputed</u> ownership of the enabling proprietary molecular technologies for these traits.

Satisfying the first condition is quite straightforward. Conceivably the second condition could be achieved through strategic alliances with existing breeding programs and seed companies, although the logistical difficulty of doing so should not be underestimated. However, no company has, or conceivably could have <u>undisputed</u> ownership of all enabling proprietary molecular technologies. Hence there can be no *freedom to operate* without resolution of patent rights.

This problem of *freedom to operate* is especially critical because of the third pattern of agbiotech patents identified by Barton (1998). Applications for such patents involve ambitious attempts to protect basic processes and inventions that are critical enabling technologies for further research, as well as for an extremely broad range of opportunities to commercialise more specific "inventions". Examples of such "inventions" that are covered by the many important patents in this class include transformation processes, constitutive promoters, generalised methods of conferring virus resistance, and antisense technology. The variety and scope of claims made in this class of patents are so broad that there is a danger of patent gridlock developing where it is virtually impossible to develop new transgenic plants without infringing one or other of these patents.

Apprehension about patent gridlock has stimulated debate about the scope of claims being allowed by the USPTO when patent applications are examined. While patent coverage is less broad in most other territories, any action for alleged infringement of proprietary transgenic technology by production of internationally traded commodities is likely to be bought in a court under US jurisdiction, and tried on the basis of US patent law (Parker, 1997). It is always possible that the scope of claims made in the patent application might be disallowed, or at least restricted by subsequent court decisions, but in the interim potential competitors must operate at best in a climate of extreme uncertainty, and at worst in a climate of outright intimidation.

One scenario portrayed by Heller and Eisenberg (1998) is the so called tragedy of the "anticommons" in which people underuse scarce resources because too many owners have conflicting claims to the common resource, and can block each others attempts to exploit the resource. They argue that granting patents on outcomes of upstream research, such as on gene fragments, to many different owners, and with overlapping claims, is likely to block further research that needs access to multiple patented inputs to create a single useful product. Each upstream patent on enabling technology allows its owner to seek to license it for product development, thus adding to the cost and slowing the pace of downstream innovation.

Such outcomes are not without precedent. Merges and Nelson (1990) cite early development in electrical lighting, automobiles, airplanes, radio, semiconductors and computers as examples of cumulative technologies where patents of wide scope on basic inventions were granted, and where the potential for patent blockages to impede technological progress existed. In some cases, institutionalised cross licensing arrangement emerged sooner than later, but in other cases progress languished until basic patent(s) expired. Whether this scenario will unfold for the life sciences industry is a topic of intense debate at present.

Litigation over patent infringement, and in particular over alleged infringement of rights to enabling technology, does seem to be a hallmark of the life sciences industry at its current state of evolution. Barton (1998) chronicles some 47 separate cases of litigation over plant agbiotechnology, many of which involve more than two parties. Based on a study of these cases, he suggests that there are two kinds of dispute. In the first set, the key issue involves infringement of a relatively narrow patent, such as one on a specific strain of *Bacillus thuringiensis,* and litigation seeks to enforce the exclusive right to market combinations of novel genes and traditional background material to farmers where the value adding is realised. "This also is the way that patent system is currently working in the pharmaceutical area, where the typical current patent license dispute is between several firms engaged in a race to develop the same product." (Barton, 1998, p. 92).

In most of the other cases, the actions involve alleged infringement of patents where firms are asserting broad rights over basic enabling technology in an apparent attempt to create a position of dominant market power. For instance, in disclosures dating between 1983 and 1990, several firms, including Mycogen, Plant Genetic Systems, Novartis, and DeKalb, sought broad rights over the use of Bt in crop plants. In this and other examples cited by Barton (1998), the filing of patent applications follows a sequence from abstract conception to concrete implementation. From an economic perspective, the key question posed by this and similar cases is where in the sequence should the rights be assigned?

Such questions are up to the courts to resolve, and recent court decisions may have already resolved much of the initial uncertainty over this issue. For instance, Parker (1997) claims that some clear trends on a wide variety of biotechnology patent issues, such as prior art considerations, enablement, inventorship, and infringement, are now evident from decisions by the Federal Circuit over the past decade. He argues that an overriding theme in these rulings is that biotechnology inventions deal with subject matter that is inherently “unpredictable,” and thus are being held to a strict disclosure standard, both for patentability and for infringement purposes. In several cases, biotech patent claims have been invalidated on the basis of "overbreadth" of the claims, and even where claims are found to be enabled, they have sometimes been interpreted narrowly for literal infringement purposes.

The 1991 case of Amgen, Inc. v. Chugai Pharmaceutical Co. Ltd. is cited as an example of the courts' strict treatment of biotechnology patents in terms of enablement. The court ruled that Amgen's broad claims were generic in scope, yet the specification contained little enabling disclosure of how to make particular analogs. This finding by the Federal Circuit that the general principle of overbreadth is a basis for invalidity has established a precedent for almost all subsequent biotech cases. For instance, in a recent case alleging infringement by Calgene's FLAVR SAVRJ tomatoes of a patent by Enzo Biochem Inc., the District of Delaware held that broad claims to antisense technology in general were invalid. The grounds were that the Enzo patents demonstrated the use of the technique only in the context of the bacterium E. coli, and that “undue experimentation” would have had to be practiced to achieve antisense in plant cells. The cases of the Regents of the University of California v. Eli Lilly & Co., and Genentech, Inc. v. Novo-Nordisk, are other examples cited by Parker (1997) of courts being similarly strict with respect to the enablement issue.

More recently, there have been similar findings relating to broad patents for Bt transgenic technology. In February 1998, the Delaware U.S. District Court found that Monsanto, Delta & Pine Land, and DeKalb had not infringed Mycogen’s two patents claiming methods for making synthetic Bt genes, and using them to develop insect resistant plants and seeds, by marketing genetically engineered cotton, potatoes, and corn. Four months later, the same court excused proven infringement of Monsanto’s patent claiming methods of modifying Bt toxin genes to achieve higher levels of expression in transgenic plants, which effectively neutralized the patent. Finally, a Delaware federal jury decided that a Novartis Seeds’ patent claiming coverage of all insect-resistant corn produced with Bt technology was invalid.

However, many questions about the application of patent law to biotechnology cases remain, not least including the debate currently raging over whether DNA sequences can be patented. The process of resolving these matters through court processes will take many years to settle. Business cannot afford to wait so long to exploit valuable proprietary technologies that have a finite life, and by one means or another the life science companies have moved to bypass the uncertainty surrounding patent issues. For instance, even while firms engage in litigation in the courts, they have simultaneously reached explicit or tacit agreement on many cross-licensing arrangements to ensure *freedom to operate.* In other cases where transaction costs have been too high, and/or where expectations have been too disparate to allow such agreements to be reached, firms have resorted to mergers, takeovers, and joint ventures that internalise patent disputes and similar impediments to commercial progress. Judging by the number of mergers and takeovers in the industry in recent years, it would seem that the costs of reaching licensing agreements have been prohibitively high in many cases.

Private/Public Alliances

While business has maintained *freedom to operate* by these means, such devices are not commonly available to public plant breeding organisations. Moreover, as noted by (Barton, 1998), the intellectual property strategies which firms adopt to preserve their own *freedom to operate* include the acquisition of broad and fundamental patents that other firms are likely to infringe. Such strategies also create perverse incentives to more vigorously litigate against infringement by “outsiders”, including public organisations, than to sue other existing major participants in the industry who could respond in kind.

In some cases, public research and plant breeding organisations have sought to avoid the above problems by forming alliances with one or more of the major players in the life sciences industry. Last year, in an unprecedented move the University of California-Berkeley negotiated an agreement with Novartis, reportedly for $50 million in financial support plus access to genomic technology. Under the terms of the deal, Novartis will be able to observe the work of 31 faculty members and nearly 200 graduate students and postdoctoral fellows. Novartis also will have the first opportunity to negotiate the rights to take a proportion of the department's discoveries to market.

In June 1998, AgrEvo and CSIRO announced a five-year strategic alliance to collaborate in specific areas of agricultural biotechnology research. The agreement gives CSIRO ownership of intellectual property associated with the research projects, while AgrEvo will obtain licenses for a range of crops, including cereals, vegetables, oilseeds and cotton. Another development is the partnership formed between Monsanto and the Victorian Department of Natural Resources and Environment to breed “Roundup Ready” canola for Australian agriculture. However, such arrangements are unlikely to be an option for most universities or public plant breeding programs.

Money Matters

Business developments in the so-called life sciences industry are receiving a lot of publicity at the moment, but at the end of the day the huge investments in intellectual property must be converted into products which consumers will demand. Current market valuations of life science companies are very high, and some commercial blockbuster products will have to be created quickly to meet market expectations. As already noted, much of this investment has been made to exploit advances in knowledge of molecular biology, and especially in the relatively new field of genomics. Most companies are seeking to exploit this common scientific knowledge base in a range of "end product" markets spanning several industries, of which agriculture is only one.

This section of the paper is limited to the commercialisation of proprietary molecular technologies by "breeding" transgenic varieties for broadacre crops. Their potential value will depend primarily on how quickly varieties can be developed which either lower production costs, or return higher product prices, or both. The second significant challenges facing life sciences companies is how to appropriate enough of the potential value embodied in these transgenic crops to realise a profitable return on their investment.

Public plant breeding agencies also need to capture a commercial return on their efforts, albeit for somewhat different reasons, including declining public funding. In Australia, most of the debate in recent years has been based on the premise that the Plant Breeders' Rights Act 1994 would provide the necessary intellectual property protection to commercialise varieties produced by breeding programs. This is now in doubt. Partly this is due to legal challenges to the validity of the Plant Breeders' Rights Act 1994, and partly due to growing appreciation of the difficulty of relying on the provisions of the Act to enforce intellectual property rights. In part, it also reflects an emerging understanding of the significance of intellectual property protection for other forms of plant genetic resources.

Thus the capacity to appropriate the benefits of intellectual property ownership is an issue for both the private and public sectors. The ability to appropriate benefits has at least two aspects. One is the ability to exclude potential users from utilizing those bits of produced knowledge for which they do not pay. The second is the ability of the knowledge producer to exercise price discrimination.

In practice, there are limits both to the ability of the producer to exclude all potential users from all units of knowledge for which they do not pay, and to practice perfect price discrimination. Limits on the capacity for price exclusion are likely to depend on the costs of imitation by competitors, the costs of detection of imitation, and the costs of enforcing property rights against imitators, once detected. The fact that patents and Plant Breeder's Rights both have a finite term of 20 years further limits the capacity for price exclusion. Even after allowing for more efficient breeding programs, it is likely to take at least five years to get a new cultivar to market. Hence an upper bound on the effective period for price exclusion will be 15 years, and often the actual period will be substantially shorter. To ensure that the latest technological advances are taken up rapidly by seed producers, many conglomerates have bought up seed companies. DuPont, for example, has mounted a takeover for Pioneer Hi-Bred International to speed up the discovery, development and delivery of new crops.

Intellectual property rights may be infringed by imitation by business rivals, and/or by "piracy" by potential customers. For improved varieties bred by conventional means, both imitation by other breeders and non-compliance by farmers may be difficult and costly to detect. Wright (1996, p. 573) notes that "In a decentralised competitive farming sector, policing of replanting by farmers seems to be a challenge. Private wheat seed markets are reported to thrive only in parts of the United States where farmers have no on-farm storage." This may explain, at least in part, why both public and private sectors are making extensive use of contract law and Material Transfer Agreements (MTA) to commercialise cultivars protected by Plant Breeder's Rights.

Detecting imitation by other breeders is likely to be fairly straightforward for transgenic crops, but the costs of detecting piracy and enforcing property rights by farmers is far from straightforward. If the early experience of Monsanto is any guide, this aspect of intellectual property rights in plant genetic resources has not received the attention it deserves. To defend its intellectual property rights in several transgenic crops, Monsanto requires farmers to sign a Technology User Agreement that gives it the right to take plant samples from fields for three years after last purchase of seeds. Apart from any administration costs, this measure alone has a significant cost in customer goodwill. For transgenic canola in Canada, other reported[4] measures include a toll free tip line, radio advertisements in which Monsanto names farmers who have been caught saving seed; and hiring full-time Pinkerton investigators to deal with a growing workload (as at February 1999) of 525 cases of suspected infringement. About half of these cases have been settled already, and many involved payment to Monsanto of tens and even hundreds of thousands of dollars each. Monsanto predicts that cases still to be settled could involve settlements in excess of a million dollars. Nevertheless, the costs of enforcement are expected to far outweigh payments for settlement of proven infringement.[5]

In general, restrictive trade practices legislation will limit the scope for firms to practice first degree price discrimination between customers, but lower order forms of price discrimination might be feasible. Internationally there are fewer constraints. An example of price discrimination between the US and Australia cotton growers for Bt transgenic technology has been documented. Usage charges via some form of licensing arrangement also may provide opportunities for price discrimination, but the feasibility of doing so is likely to be limited to upstream technologies. Where licensing agreements are used, a wide range of alternative pricing practices are possible in theory, although practical considerations of monitoring use, and ensuring compliance with the terms of the contract may well preclude some or all options.

At the farm level, most intellectual property in plant genetic resources is embodied in new plant varieties. In many cases, the complexity of discriminating between users on the basis of degree of utilization of technology, and/or practical problems in preventing arbitrage precludes charging different prices to different users. However, if the benefits from use of intellectual property are appropriated via a seed price premium, then the amount of benefit appropriated from each user will be approximately proportional to their level of technology use. Relative to charging the same price to each farmer, this is one way of introducing an element of price discrimination. However, it distorts factor price ratios, thus leading to efficiency losses similar to those caused by selective taxes on factor use. End point royalties involving a technology user fee set as a proportion of crop returns avoids this efficiency loss. It also provides a closer approximation to perfect price discrimination, as well as sharing production and product price risks between the owner of the intellectual property rights and the farmer. However, there are likely to be substantial problems with monitoring compliance and ensuring enforcement.

"Freedom to Operate" in a "Small Country"

The term "crowding out" is used to characterise situations where the two sectors potentially could compete for the same market, but one is dominant because of a competitive advantage of one form or another. For instance, it can be argued that in Australia, "public" extension services "crowded out" private agricultural technology and farm management advisory services for many years because the former were subsidised. Conversely, in the US private hybrid corn breeders have largely "crowded out" public corn breeders, presumably because private firms have an advantage in the prosecution of commerce that more than offsets any subsidy to public agencies. In essence, "crowding out" is the outcome of competitive processes.

An alternative to "crowding out" can occur where one sector uses monopoly control of the rights to certain essential inputs to deny access to the other sector. This has been termed "shutting out" to distinguish it from cases where dominance is achieved by competition in the market place rather than in the courts. In the context of this paper, there have been cases where life science companies have effectively "shut out" public agencies from breeding transgenic crops by denying them access to key proprietary technologies. One example is the case of CLIMA described above. Another case involving development of genetically engineered tomatoes in California is described in Wright (1998). Anecdotally, there are accounts of other cases of "shutting out" of public agencies in other countries. Life science companies have confirmed that they may deny public institutions access to proprietary molecular technologies even though the same technologies have been licensed to other companies. Conceptually "shutting out" is fundamentally anti-competitive.

On the face of it, such behaviour is difficult to explain by conventional economic theory. While the firm may perceive that there are costs associated with sub-licensing, they should still be willing to license the technology on reasonable commercial terms. In the absence of explanations from the life science companies, it is only possible to speculate about possible reasons for such behaviour.

There are formidable costs in bringing transgenic crops to market. Apart from the initial research and subsequent commercial development costs, other costs include those of seeking and defending intellectual property rights over key technologies as well as gaining regulatory approval. Monsanto has estimated that it takes up to 10 years and a total of (US)$300 million to commercialise a new technology[6] Estimates to adapt and introduce an established technology to a "small country" range from $2 million to $5 million for further research and development, plus similar amounts for patenting and to gain regulatory approval. These estimates are based on the pathbreaking experience with the first transgenic crops. Costs are likely to fall as scientists become more proficient with transformation processes and achieving desired levels of expression of genes, as companies gain experience in commercialising transgenic crops, and as regulatory authorities develop standardised procedures and protocols for approving release of genetically modified organisms.

Firms also are acutely conscious of the contingent costs deriving from the commercial risks of development. In the context of contracting to license intellectual property, prior to any license being granted, the holder of the IP has the ability to manage risks associated with commercialisation of the technology. Granting a non-exclusive license reduces this capacity for risk management. Moreover, the more non-exclusive licenses that are granted, the greater the risks to the company of an action on the grounds of product liability.

The potential for so called hold-up problems is now generally recognised in the literature. It is described by Milgrom and Roberts (1992, p. 136) as

> "the general business problem in which each party to a contract worries about being forced to accept disadvantageous terms later, after it has sunk an investment, or worries that its investment may be devalued by the actions of others"

Once an IP holder grants a non-exclusive license to any party, it forgoes the opportunity for an exclusive license with any other party. Since only large firms are likely to have the capacity to fully exploit an exclusive license, the value of such a license will typically exceed by several orders of magnitude the value of any possible non-exclusive license. Where the non-exclusive licensee is a small or public organisation, the opportunity cost of such a license may be prohibitive.

The magnitude of any or all of the above costs is not sufficient explanation *per se* for a firm to deny public plant breeding programs access to key technologies; although it could be used to justify license fees that public organisations would find prohibitive.

"Shutting out" on the ground that the crop is an orphan commodity is a closely related justification that also does not bear close scrutiny. For the major companies in the seed business, there are a few "core crops", defined mainly by the actual or potential value of the market for seed. These "core crops" include maize, rice, wheat, soybeans, canola, cotton, sugar beet, and tomatoes. Other crops that, on a world scale, are grown on relatively small areas, and/or are grown primarily by poor farmers with very limited capacity to pay for improved productivity, are of no interest to big life science companies. Such crops have been dubbed "orphan commodities", and include bananas, sweet potatoes, cassava, yams, lentils, and lupins. While development of transgenic varieties for these crops may be commercially unattractive to multinational companies, again this does not justify "shutting out" public plant breeding programs willing to undertake development for non-commercial reasons.

Where ownership of intellectual property rights to primary and/or enabling technologies is widely distributed, the transaction costs of negotiating *freedom to operate* will be significant. The recent spate of mergers in the life sciences industry provides supporting evidence for this proposition. A perception that the transaction costs of negotiating licensing agreements with public organisations are higher than those with profit maximising businesses, together with concerns about allegations of discriminatory pricing in licensing arrangements, could conceivably explain why firms "shut out" public plant breeding programs. Decision-making processes in many public organisations give this explanation some credibility. In addition, the fact that firms often cross-license rights to proprietary technologies to each other lends further indirect support to this hypothesis.

However, perhaps the simplest explanation is the best. A rival company "shut out" by a competitor most probably would sue on the grounds of anti-competitive behaviour. A public organisation faced with the same circumstance most probably would not.

In the Long Run

This paper has focused on short run rather than long run issues. Clearly the latter also are important, maybe more so. One key long run issue is the degree to which markets in intellectual property rights to proprietary molecular technology are contestable. *Inter alia*, this will depend on future changes to the legal and institutional framework for intellectual property rights, and above all else on how evolving industry structure will impact on the supply of new entrants to the industry.

To give just one example of the former possibility, it was reported in The Wall Street Journal of 3 March 1999 that a Federal Appeals Court has agreed to rule on a challenge to the patentability of modified plants. Apparently an Iowa seed merchant, who is being sued by Pioneer Hi-Bred International for unauthorised sale of seed covered by plant patents, is arguing in defense that the U.S. Patent and Trademark erred in granting patents on modifications to plants. While the U.S. District judge rejected the request for the case to be dismissed, he considered the contention to be serious enough to warrant the attention of a higher court. The federal appeals court in Washington that specialises in patent law has decided to hear argument on the patent legality issue.

Perhaps the latter possibility deserves greater attention. At this stage in the evolution of the life sciences industry, the dominant multinational companies have bought most of the small agbiotech firms. On the basis of past evidence, the advantage of large companies is in late-stage research and product development, in commercialisation and marketing of new technologies, and in marshalling the necessary financial resources.

They are inferior to new small biotechnology companies in providing the basic creative research and innovations necessary to open up new areas of technology for commercial exploitation. If the large life science companies use blocking patents and similar means under their control by virtue of ownership of most enabling technologies to prevent entry by new start-up companies, then there is the prospect of a future vacuum in the technology pipeline.

From a public sector perspective, there is growing recognition that they hold just two primary assets with which to bargain with the business sector for access to key enabling technologies. One is germplasm, and in particular elite breeding lines, The other is an established capacity for field based selection and evaluation activities. Of these two assets, the capacity for field based plant breeding activities is highly contestable, so the life science companies can only be expected to value it at replacement cost. This puts a limit on the amount and type of proprietary technologies which can be leveraged on the basis of this asset.

Under some circumstances, germplasm might be more valuable. The key issue is the ability to assert and maintain ownership of germplasm, and in particular to exclude those parties unwilling to meet stipulated conditions for access. The first problem in asserting, let alone maintaining property rights to most of the world's germplasm, is that it has already been released as "public varieties" that are not protected by any form of intellectual property rights. The second problem is that it was developed by public plant breeders who freely exchanged it among themselves, as well as with private sector plant breeders. Consequently, there is no basis for ownership of this germplasm apart from physical possession of the material held by a particular agency. As the private sector also is in legal possession of, or at least has ready access to the overwhelming bulk of extant germplasm, it is legally free to use it in whatever way it wishes, including the development of transgenic crops. Thus it is only recently developed germplasm which might be protected in some manner. Of course, such material is potentially the most valuable, but this value can only be captured if legal rights to the intellectual property it embodies can be successfully established and defended.

In many countries, one option is to register such a variety under an intellectual property right regime variously known as plant variety protection, plant breeders' rights, or similar terms. As noted above, this form of intellectual property protection is generally weaker than that afforded by a patent. Protecting a variety in this way may facilitate charging farmers for the right to grow it, but even this property right is severely attenuated when, as is commonly the case, there is an exemption for farmer saved seed. However, typically there is a further exemption commonly termed breeders' rights. This exemption normally renders Plant Breeder's Rights ineffective as a basis for excluding private (or other public) breeders from utilising the material for the production of transgenic (or conventional) varieties. The only caveat is that the transgenic variety falls outside the definition of an essentially derived variety. In those few countries that allow plants to be protected by patents, including Australia and the USA, it might be possible to avoid this problem of breeders' rights by applying for a patent on newly developed germplasm. However, for most varieties, it is likely to prove difficult if not impossible to satisfy the requirements for a 'patentable' invention, and in particular the requirement for *inventiveness* in Australia, and for *non-obviousness* in the USA.

Hence for most varieties in most countries, the options for protecting newly derived varieties reduce to ownership by virtue of physical possession of the germplasm, supplemented by protecting the IP embodied in the germplasm by trade secrets. Where it is necessary to pass possession of some of the germplasm to other parties, trade secrets can be protected under contract law by using MTA's to impose obligations on recipients. The effectiveness of such an approach in protecting intellectual property remains to be seen, but it seems inevitable that one consequence of the impetus to such measures will be to choke off the intra-national and international flow of germplasm. The long run impact on the relative competitive position of private vis-à-vis public plant breeding is a moot point which only time will resolve.

Conclusion

In conclusion, intellectual property protection cuts two ways for plant breeders. It facilitates the appropriation of benefits derived by farmers from growing new cultivars. However, it also protects the rights of the owners of protected technologies that are inputs to plant breeding. In particular, there is a threat that public agencies will be "shut out" from access to pivotal technologies that either confer overwhelming superiority to new cultivars, or are essential to efficient breeding of competitive cultivars.

Endnotes

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[2]The material for this paper has been collected from published sources, and by interviewing a range of experts in various fields. Individuals interviewed included scientists specialising in molecular biology, academic lawyers specialising in intellectual property rights, representatives of farmer organisations, staff in University technology transfer offices, and present and previous employees of private biotechnology and seed companies involved in research and/or plant breeding, staff in International Agricultural Research Centres, and fellow economists with cognate interests but more expertise in this topic. Given the commercial sensitivity of specific matters in this area, some individuals were bound by confidentiality agreements that precluded them from discussing particular projects. Nevertheless, many individuals in this position were able and willing to respond to many questions in general terms, and thus to provide valuable insights into topics which are intrinsically difficult to conduct empirical research.

[3]Parker (1997) cites a recent case involving the overseas practice of a biotech process where the US Federal Circuit issued an opinion on the scope of infringement under the so-called "product-by-process" provisions of the Patent Statutes. (U.S.C. 271(g)). Under this statute, process patents are given product coverage over products that are made by the patented process, to the extent that such products are not materially changed by subsequent processes. The Federal Circuit construed the "product-by-process" provisions broadly, and found infringement based upon the importation of a subsequent product not directly set forth in the claim.

[4]The Washington Post, February 3, 1999, pp. A1, A6.

[5]Anon, pers comm.

[6]The Washington Post, February 3, 1999, pp. A1, A6.

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