The Future for Frankenstein Foods

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Abstract.

Economic outcomes in the "plant breeding industry" are being driven by interactions between advances in scientific knowledge, changes in the legal framework for intellectual property rights, and competitive forces in the market. While extended property rights have created the foundation for new markets, the opportunities arising from scientific discoveries have provided powerful incentives for firms to enter these markets and invest in biotechnology. The competitive forces unleashed by these developments are likely to transform the production of new plant varieties.

Scientific discoveries in molecular biology are the bedrock of the biotechnology revolution, and have created the potential for much vaunted gains in agricultural productivity and for new products. There are at least two broad classes of molecular technologies that are relevant to an economic analysis of crop breeding. One group improves the efficiency of all plant breeding, including conventional plant breeding, and includes techniques such as double haploidy and marker assisted selection. The other and much more controversial group are the transgenic technologies used to produce GMO's.

To justify the huge wave of private investment in intellectual property that has fuelled the biotechnology revolution to date, as well as to ensure continued investment in further development of the technology, two necessary conditions must be satisfied. Consumers must purchase the final product, and companies must be able to appropriate enough of the potential value embodied in improved crop varieties to realise a profitable return on their investment.

Concerns about inadequate incentives to invest in further development of GMO's and/or plant breeding include the following issues:

- consumer resistance to GMO's and the consequent lack of a viable sized market for the end product of GM food;
- unanticipated costs of monitoring compliance and enforcing intellectual property rights in enabling proprietary molecular technology as well as in improved crop varieties.
- developments in patent law creating excessive transaction costs, possible patent gridlock, and the "tragedy of the anti-commons",
- *freedom to operate* problems for public research and plant breeding programmes,

Consumer resistance to GMO's poses the most immediate threat to the return on past investments in biotechnology, but may prove relatively transitory. Less widely recognised threats to future investment relate to possible breakdowns in the functioning of the patent system, and/or to difficulties in appropriating realised benefits from biotechnology when embodied in self-pollinated broadacre field crops. Recent extensions to the scope of intellectual property rights in plant genetic resources merely provide a mechanism for private appropriation of some or all of the benefits from molecular technologies, but do not guarantee the emergence of efficient markets in intellectual property rights. Nor do they necessarily overcome high costs of monitoring compliance and enforcing rights in intellectual property in biotechnology. Such difficulties are most unlikely to be resolved by additional government funding of what traditionally has been a public sector activity.

1) Introduction.

The scope of this paper is limited to plant biotechnology, and more particularly to the application of plant biotechnology to breeding improved cultivars of self-pollinated broadacre field crops. The scope of biotechnology is much much broader, and includes other applications to plant breeding and production, animal biotechnology, remediation of environmental damage, and the huge field of medical biotechnology. Nevertheless, at least some of the issues discussed in this paper also are relevant to the future development of other branches of biotechnology.

The Simple Economics of Plant Biotechnology.

Scientific discoveries, including those in plant biotechnology, are a form of intellectual property (IP) which may or may not initially be embodied in some physical form. As a generalisation, plant biotechnologies are processes rather than products, and need delivery systems to bring them to market if they are to create value. In most cases, the obvious delivery system is germplasm for agricultural production. For those molecular technologies that are of economic value in the production of self-pollinated broad acre field crops, the IP is effectively embodied in improved cultivars. Similarly the creative component of plant breeding produces IP by the discovery or development of combinations of improved characteristics or traits that likewise are embodied in improved crop cultivars.

During the past decade or so, this reality was recognised by most biotechnology companies, sooner by some, later by others[1]. Monsanto and Mycogen were among the first to pursue a strategy of assembling four key assets: biotechnologies, patents covering core technologies, germplasm, and a seed distribution system. In order for biotechnology research and crop development to be financially self-sustaining, investors must be able to capture enough of the value embodied in improved crop varieties to realise a profitable return on their investment. Hence the drive by biotechnology companies to vertically integrate into plant breeding and marketing seed.

Plant breeding can be conceptualised as an investment that develops improved varieties with the potential to generate future benefits in the form of improved crop productivity, reduced costs of production, and/or higher returns. Potential value from improved cultivars will be realised only if and when farmers adopt these cultivars in their cropping systems, AND when consumers willingly purchase the food or other crop products in a competitive market. Growers will only adopt these new varieties if they provide real financial benefits that exceed the costs of adoption, including any additional costs of acquiring the improved variety. Similarly, consumers will only knowingly purchase food from these new varieties if by so doing they derive a net benefit in the form of enhanced attributes and/or lower prices relative to available alternatives. In common with other forms of investment, the rate of return will depend on the discounted value of the flow of future benefits net of present value of all costs necessary to generate such benefits.

Traditional Plant Breeding.

Traditional plant breeding involves crossing two plants to obtain progeny that contain a random blend of characteristics from both parents. Breeders then select a few progeny; based on phenotypes (i.e. sets of physical characteristics of the plant) to develop new improved varieties. This conventional field based approach was both expensive and painstakingly slow.

[1] The case of Mycogen, which was one of the first to pursue this vision, has been documented by (Kalaitzandonakes, 1997)

Historically, most plant breeding has been publicly financed, as has the supporting research in agronomy, plant pathology, entomology, biometry, plant nutrition, plant physiology, and other cognate disciplines. Improved varieties have been freely released to producers at nominal costs that at best only partially recover the costs of breeding let alone supporting research.

A New Era for Plant Breeding.

In the new era for plant breeding, all this is changing. Muddy boots methods for plant breeding are being transformed by new molecular technologies such as DNA isolation, double haploidy, marker assisted selection, and above all else by genetic engineering in the laboratory whereby "foreign" genes are transferred into commercially grown crops. The rate of growth of scientific knowledge continues to accelerate as genomes are deciphered, new genes detected, the structure of proteins deconstructed, and the basis for plant function and form are linked to one or more genes. Champions of biotechnology promise that application of this new knowledge will increase yields, decrease pesticide use, and increase tolerance to environmental stress as well as conferring novel traits that would never have been possible using conventional plant breeding techniques.

Using these techniques of biotechnology, scientists can now breed according to the plant's genotype, its collection of genes. Molecular technology allows scientists to analyze the set of genes that the plant contains, and to pinpoint and track a specific region on a plant's chromosome that confers a desirable trait to be during the breeding process. Rather than rely on a plant's phenotype, which may be a poor guide to genotype, it is increasingly possible to identify the genetic basis for the most desirable traits, and to make sure that these traits are successfully transferred. Molecular marker technology that identifies the location of the genetic code on a chromosome that confers a beneficial trait on a plant can be difficult to develop, but thereafter can be used fairly routinely to greatly speed up the crop breeding process.

Public Plant Breeding.

Until recently, exceptions to the dominance of public plant breeding programs, such as hybrid corn, were few and far between. This also is changing rapidly. Many public systems are rapidly being overshadowed by private alternatives[2] in which both new enabling technologies and improved cultivars are routinely protected by intellectual property rights.

Concurrently, many governments are reducing funding to public plant breeding programs, often drastically. Whatever else eventuates, this trend is most unlikely to be reversed. Clearly the future for biotechnology lies mainly with the private sector, although there may be a modified role for "public" institutions that operate in a semi-commercial manner. In either case, incentives for further development of biotechnology need to be sufficiently great to ensure continued investment. Realised value creation is a necessary condition for high social rates of return. Appropriation of at least some of this created value by the investor in biotechnology is a further necessary condition for high private rates of return. Returns on investment will fall if the benefits of the technology fall short of expectations, and/or if investors cannot capture enough of the value embodied in improved crop varieties to realise a profitable return on their investment.

[2] See (Anonymous) for an account of the recent privatisation of the Canadian Canola breeding industry.

Molecular Breeding Technologies.

The molecular technologies that are the bedrock of the biotechnology revolution can be grouped into at least two broad classes that are relevant to an economic analysis of crop breeding. One group improves the efficiency of all plant breeding, including both conventional and transgenic plant breeding. This group, hereafter referred to as molecular breeding technologies, includes techniques such as double haploidy, plant regeneration systems, molecular based hybrid technologies, and marker assisted selection. Potentially beneficial outcomes from the application of these technologies to plant breeding include one or more of the following:

- cheaper development of equivalent[3] improved crop varieties.
- faster/earlier development of equivalent improved crop varieties.
- development of superior[4] improved crop varieties, such as hybrids, that are higher yielding or otherwise more productive.

Use of these techniques in conventional plant breeding is already reducing the time lags from initial crosses to release of new varieties. Few if any concerns have been expressed that demand side issues will impede value creation. In particular, there is no evident consumer opposition to eating food from improved crop varieties developed using these technologies.

Transgenic Technologies.

The other and much more controversial group of molecular technologies are the transgenic technologies used to produce GMO's. These transgenic technologies include genome sequencing and the detection of gene location, the identification of traits associated with these genes, DNA cloning, control of gene expression, and methods for transforming plants by insertion of "foreign" DNA. Potentially beneficial outcomes from transgenic technologies include:

- development of improved crop cultivars with novel[5] agronomic/input traits that enable lower average costs of production.
- development of improved crop cultivars with novel quality-enhanced traits for which consumers are willing to pay a price premium.

Transgenic technologies create value only if consumers purchase the products (GMO's) from the latter two outcomes above. Consumer concerns about GMO's, and the possible lack of a viable sized market for the end product of transgenic technologies, threaten the realisation of substantial value creation from these technologies. This demand side issue is discussed in section 3 below.

Arguably the greater threat to long run value creation from transgenic technologies will come from legal disputes over intellectual property rights that block widespread utilisation and/or further development of the technology. Concerns have been expressed about possible patent gridlock, excessive secrecy and duplication of inventive effort, excessive transaction costs to license patented technology, prisoner dilemma type impasses, and/or the "tragedy of the anti-commons". Such supply side problems might tie up the technology in the courts and block commercial implementation for years, if not decades.

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[3] i.e. varieties with equivalent characteristics to those currently being produced by conventional plant breeding methods.

[4] i.e. In this context, these are varieties that have superior performance to those that economically could be bred by conventional plant breeding methods.

[5] i.e. traits that economically could not have been incorporated into improved varieties by conventional plant breeding methods.

The considerable monopoly power that the large life science companies possess over key proprietary transgenic technologies is another threat to continued development of the technology, and particularly to the *freedom to operate* for public and local industry research and plant breeding programmes. Pricing practices by these large life science companies also might threaten future competitiveness of sectors of the farming industry, as well as limiting widespread value creation.

However the degree to which investors in the creation and development of both groups of technologies can capture the value created is a moot point which will be discussed in section four of this paper. Potential problems of monitoring compliance and enforcing intellectual property rights in enabling proprietary molecular technology, as well as in improved crop varieties, may diminish the incentive for further investment in "breeding" improved crop varieties. First though, the extremely rapid uptake, at least until now, of transgenic crops by North American farmers and others is briefly described in the next section.

2) GMO's – A Transgenic Juggernaut?

Genetically engineered crops that are already being grown commercially include tobacco, cotton, soybean, corn/maize, canola/rapeseed, tomato and potato. GM tobacco was planted commercially in China in the early 1990's, but the first sale of GM food was the delayed ripening tomato[6] in the United States in 1994. In a recent review, (Anonymous1998) noted that seven transgenic crops were grown commercially by 1996 on approximately 2.8 million hectares, mostly in the United States and Canada. Between 1996 and 1998, there was a further increase in the global area of transgenic crops to 27.8 million hectares. Adoption rates have been some of the highest ever for new agricultural technologies, and reflect grower satisfaction with significant benefits ranging from more flexible crop management, higher productivity and a safer environment through decreased use of conventional pesticides.

Almost all of the first generation of GM foods that were grown prior to 1999 provided no direct benefit to the consumer. The principal transgenic traits in 1998 were herbicide tolerance, insect and viral resistance, and hybrid technology. These "input traits" lower average costs of production[7] through some combination of reduced costs of control of, and/or smaller losses from weed, pest, and disease infestation, and through increased yields. Because these novel traits can be introduced into elite germplasm without disturbing the rest of the plants' genetic code, the resulting varieties are potentially much more profitable for growers. Realised profitability will fall short of potential profitability to the extent that a product price discount applies to the GM crop, and/or to the extent that growers have to pay a premium to grow the GM crop relative to comparable "conventional" crop varieties.

Second generation or quality enhanced GM crops, most of which are still under development, incorporate crop attributes that do provide direct benefits to the consumer, or in some cases to intermediate producers. Delayed ripening tomatoes, oilseed rape with modified fatty acid, high oleic acid soybean, and carnations with extended shelf life and modified colour are examples of second generation crops that are already in commercial production.

[6] Marketed by Calgene as the Flavr-Savr™ tomato.

[7] Hybrid technology also provides in-built genetic copy protection, of which more later.

Future examples in the product development pipeline include rice with higher vitamin A content, maize with enhanced essential amino acid levels, corn with improved oil levels, and low allergen rice. Some companies are betting that the third generation of GM crops will be nutraceuticals. Nutraceuticals are foods that prevent or treat diseases or otherwise provide medical or health benefits, and GMO's that include genes coding for pharmaceutical drugs are touted as GM crops of the future.

In contrast to first generation GM crops, these quality-enhanced crops have not been rapidly or widely adopted so far. In 1998, they accounted for less than 0.5 per cent of the total area planted to transgenic crops. Nevertheless, many proponents of GMO's argue that the "problem" of consumer resistance will disappear once production of second-generation GM crops becomes widespread. If consumers value the quality trait for any of these quality-enhanced crops, then the GMO's should command a price premium at retail level. Whether there will also be a price premium at the farm gate is less clear, and will depend, inter alia, on the cost of maintaining an IPPM system.

3) The Demand Side – Food for Thought.

The potential benefits from biotechnology will only be realised if consumers purchase products produced using molecular technology. With the exception of genetically modified (GM) food, most consumers to date appear either ignorant or unconcerned about final products produced using the techniques of biotechnology. For instance, GM products, including some antibiotics, insulin, and growth hormone are widely used in the medical arena, and enzymes produced by GMO's are used in the production of many cheese products, as well as in other areas of food production. In fact, genetically modified materials (i.e. genetically modified organisms and their products) already play an important part in everyday life.

However, consumer resistance to GMO's poses an obvious and immediate threat to expected returns on past and future investments in biotechnology. Alerted by activists, consumers are increasingly aware of public health concerns about GMO's. Within the scientific community, there also are worries about the long-term effects on human health and the environment from widespread use of genetically engineered crops. Other concerns about GM crops include potential damage to the environment, loss of biodiversity from agricultural monocultures; the influence of multinational seed companies on countries' economies; and the possible demise of the small-scale farmer. While various special interest groups share these concerns, it is a growing reluctance to eat GM food by the general public that is limiting the size of the market for GMO's, and even threatening the financial viability of some life science companies.

The most general and popular basis for this opposition seems to be a view that the introduction of (arguably) "foreign" genetic code into a plant just might alter that crop's metabolic pathways, and thereby possibly threaten the health of anyone, or perhaps just someone who eats it. How genetically different GMO's really are from other foods produced from "conventional" breeding methods is still debated by some sectors of the scientific community. For instance, it is argued that crops produced using wide-cross hybrids also contain "foreign" genetic code, but nevertheless are generally accepted and not viewed with the same concern.

Despite these arguments, many people are uneasy with the idea of tinkering with the genetic basis of nature. Such concerns about public health consequences are not limited to ill informed consumers or misinformed activists. One serious concern with transgenic crops is the possibility of accidentally transferring allergy-causing compounds. A recent case in point was fears by Pioneer Hi-Bred that some very small fraction of consumers might have an allergenic reaction to a nutritionally enriched transgenic soybean using a gene from Brazil nuts. As a result, the company discontinued its research, and cancelled further development of that particular GMO. The FDA in the US now warns companies involved in genetic engineering to be cautious when transferring genes from certain genera.

Another source of concern to some scientists are the types of selectable marker genes used in GMO's. When scientists attempt to genetically engineer a crop, they need to be able to determine whether the transformation process has been successful. They achieve this by linking the desired transgene in the construct with a "marker" gene. Genes coding for antibiotic or herbicide resistance have been widely used for this purpose. To test if a cell has been transformed, it is dosed with the antibiotic or herbicide. If it survives, then it also includes the transgene that becomes part of the genetic code of the transformed plant. Other scientists dismiss such concerns, arguing that kanamycin is very rarely prescribed for human use, and that the resistance gene probably wouldn't inactivate the antibiotic in the gastric environment of anyone who ate the transformed plant.

When scientific logic fails to prevail, advocates for GMO's argue that stringent regulatory systems ensure that the dangers to public health are negligible, if not totally risk free. With the aid of molecular technologies, it is relatively straightforward to detect whether an organism has been transformed by the insertion of "foreign" genetic material. As a result of widely held concerns about "foreign" genetic code in food, experimental and commercial production of GMO's in Australia, and in most if not all other countries, is subject to additional and more onerous regulatory regimes than for traditional crop varieties. Note though that these regulatory requirements only apply to crops grown in Australia, and do not apply to GM food grown elsewhere and imported into Australia.

To the general public, these arguments are not compellingly persuasive. GMO's are clearly viewed as both different and more risky to eat than crops bred by more conventional means. Such a response is not irrational. Few members of the public are well enough informed to discriminate between those "experts" claiming that GMO's are totally safe to eat, and those "experts" who assert the contrary. Hence any logical risk assessment has to assign a non-zero probability to the health risk associated with eating GM food.

Consider the consumer's choice from a decision-theoretic point of view. For first generation GM crops[8], purchase of GM food is stochastically dominated by purchase of the non-GM alternative so long as there is no price difference between the two. Alternatively, from the perspective of Lancaster's demand model, the two alternative consumption bundles differ only with respect to one characteristic (i.e. the input trait) which unambiguously is a *bad* characteristic[9]. Hence widespread rejection by consumers of GM foods that only contain input traits is entirely rational so long as there is no difference in price vis-à-vis non-GM foods.

In fact, what is surprising is the number of consumers who buy these GM foods. A topic for empirical research would be to investigate the reasons for doing so. Possible explanations would include a price discount for GM foods; a perceived lack of non-GM alternatives; and a lack of labelling or other reasons for not knowing that the food contained GMO's. Other hypotheses could include irrational behaviour, or a preference for taking risks.

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[8] i.e. crops containing a transgene that only codes for an input trait of no direct benefit the consumer.

[9] In the technical sense that it reduces utility.

For the biotechnology industry, there is a clear lesson about how to solve the consumer "problem" and current lack of demand for GMO's. Trying to allay consumer concerns about the health risk from eating GMO's by relying on scientific argument has not, and will not succeed. Consumers want to be assured about the origins of their food, and ways must be found to allow them to knowingly choose between GM and non-GM foods. Moreover, GMO's from first generation GM crops will have to sell at a discount relative to the GM free equivalents (GMF's) to induce significant numbers of consumers to opt for the former alternative. A credible and reliable system of labelling underpinned by identity preserved production and marketing systems (IPPM) are necessary conditions for consumer sovereignty, and for market forces to reveal the required price discount for first generation GM crops.

To date, many parts of industry have opposed the introduction of IPPM on the ground that it is unnecessarily or prohibitively expensive. However, the spread of the consumer revolt to the USA and Canada, where some supermarkets are moving to ban all GMO's, would seem to make the case for an IPPM system irresistible even to the most aggressive biotechnology firms. Moreover, arguments that the cost of IPPM would be prohibitive are difficult to sustain given the current widespread practice of segregating different grades of non-GM crops to separate higher added value products from other commodities in order to exploit niche markets. A particularly apposite case is marketing systems for organic food.

A number of issues remain. Design of a cost effective IPPM system is one. Allan Buckwell, author of a recently published study "*Economics of Identity Preservation for Genetically Modified Crops*" estimated that the increased cost of segregating GM products could range between 5-15% of the usual farm gate price. He is reported as concluding that paying this cost could have benefits both to consumers and to farmers as long as consumers are willing to pay the added cost of separating GM from non-GM crops from 'plow to plate'[10]. The magnitude and cost structure of an IPPM system will determine, *inter alia*, the market determined equilibrium level of the price differential between GM and non-GM foods at farm gate, and at retail level.

As (Caswell, 1998)notes, government choice of labelling policy for GMO's have markedly different implications for market development. The main policy options for government are:

- Allow no labelling regarding the use or nonuse of GMOs.
- Require mandatory labelling of products that use GMOs.
- Allow voluntary labelling of products that do or do not use GMOs.
- Allow voluntary labelling of products that do not use GMO's.

For reasons discussed above, no labelling is no longer a viable option. The cost of the second option of mandatory labelling will depend very much on the detail of the government regulations. According to Buckwell, a key factor will be the willingness of lawmakers to allow certain tolerances of non-GM products. For instance, the EU is considering a 1% tolerance allowance for GM contamination in food that would carry a GM-free label. However, if governments insist on guaranteeing a 100% GM-free product, Buckwell found that mandatory labelling in an IPPM system could increase the cost of raw materials by 150% (Anonymous1999).

[10] Press Release issued by the Food Biotech Communication Initiative (FBCI), "Unique study on Segregation of GMOs and Non-GMOs shows 'Identity Preservation' is feasible and already being applied but inevitably involves extra costs". February 12, 1999.

Industry could adopt the option of voluntary labelling without government regulation, thus facilitating choice by consumers of food products that align with their preferences. Moreover, because it is the absence of genetic engineering in food that is the key *"attribute"* being demanded, only non-transgenic food would need to be segregated in the marketing chain, labelled and subject to some form of verification. Voluntary labelling is likely to be the most efficient alternative[11] because market forces would determine the acceptance of the new technology. While most people demand food that is GM free, the advantage of voluntary labelling may be minimal, and arguably even unnecessarily expensive if IPPM costs exceed cost savings from growing first generation GM crops. If and when demand for non-transgenic food declines in the longer run to the point where it becomes a specialty product, then requiring compulsory labelling of GMO's is likely to prove unduly costly.

Another question that needs to be studied is the ultimate incidence of the cost of an IPPM system. Many farmers seem to believe that they will bear the entire cost, and some are questioning whether they can bear the expense.[12] On the other hand, Singer, an agricultural economist with the Chicago Federal Reserve Bank predicts that food costs could increase to the consumer because of the costs of harvesting, segregating, testing and labelling GM crops[13].

This question will not be investigated in any detail in this paper. The following simple, and simplistic analysis, suffices to demonstrate some plausible scenarios for future prices for non-transgenic food and GMO's at both retail and farm gate. Clearly the distributional impacts of GMO's are not as straightforward as some commentators have portrayed.

Consider first Figure 1, which illustrates the derivation of what will be called the *relative demand curve* for non-transgenic food (NTF). This demand curve shows the relationship between the price premium for NTF **relative to GMO's from first generation GM crops[14]**. Although not explicit in Figure 1, it makes sense to initially define such a demand curve at retail level, as it is conceivable that there will be no price premium at farm gate. The key assumption is that non-transgenic food and GMO's are close substitutes in consumption, so that the cross price elasticity of demand is positive. In the top half of the diagram, the lines S0 and D_N(P0) represent market demand and supply for NTF prior to the advent of GMO's. P0 and Q0 are benchmark market clearing levels of price and quantity traded for the counter-factual scenario of no GMO's. Although not explicit in Figure 1, the supply curve will be interpreted in subsequent diagrams as supply at farm gate prices.

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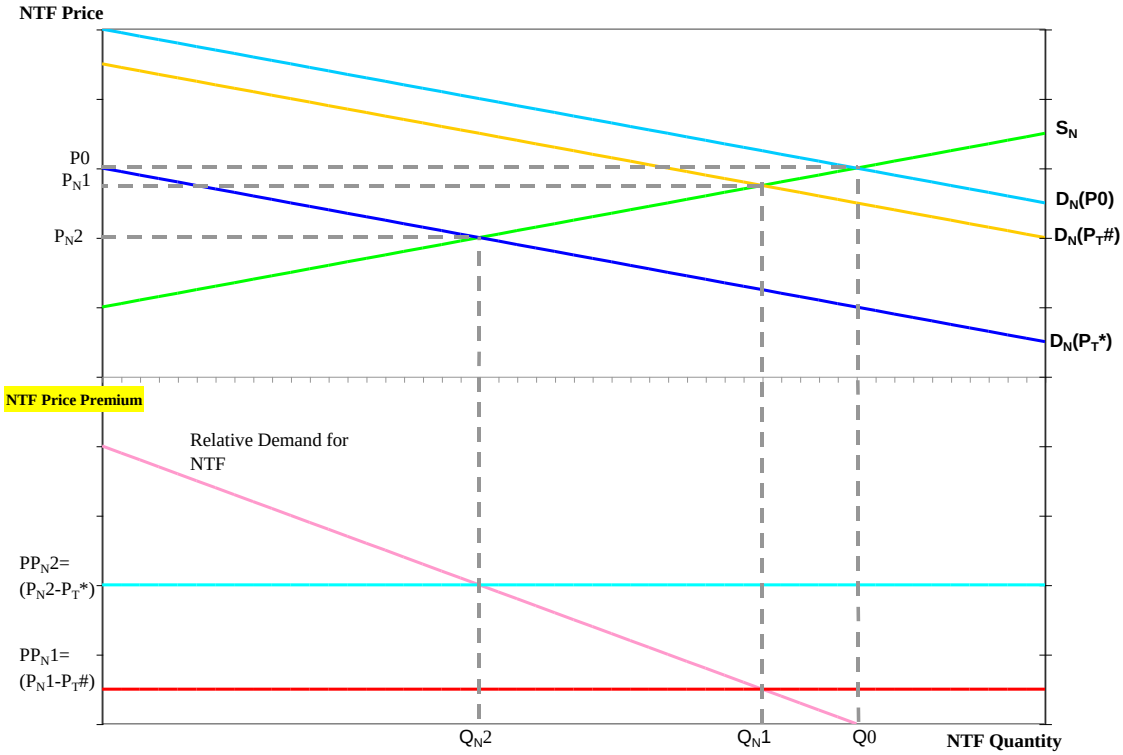
[11] It is assumed that the foregone cost savings from the option of banning GMO's forever would exceed any costs of maintaining an IPPM system.

[12] American Corn Growers Association press release, CORN GROWERS STATE THAT FARMERS SHOULD NOT BE BLAMED FOR HIGHER FOOD COSTS ATTRIBUTED TO GMO's, AGNET, Dec. 29/99.

[13] Ibid.

[14] As noted above, such GMO's offer consumers no advantage relative to non-transgenic foods apart from the possibility of lower prices. For GMO's from second-generation crops, the analysis would need to be modified somewhat to allow for the fact these GMO's have both positive and negative attributes.

FIGURE 1: RELATIVE DEMAND for NON-TRANSGENIC FOOD (NTF)



Three alternative scenarios, where the price for GMO's falls from P0 to P_T#, and then to P_T*, are depicted in the top half of Figure 1 by demand curves for NTF denoted $D_N(P_T0)$, $D_N(P_T\#)$, $D_N(P_T*)$, respectively. As the price of GMO's is decreased, the demand curve for NTF shifts down, and market clearing NTF prices also decrease, albeit not by the same amount as the fall in prices of GMO's. In the bottom half of Figure 1, the relative demand curve for non-transgenic food depicts these outcomes as price premiums for non-transgenic food in relation to consumption (and production) of NTF. The evident range of consumer attitudes to GMO's is represented by a partly elastic relative demand curve [15].

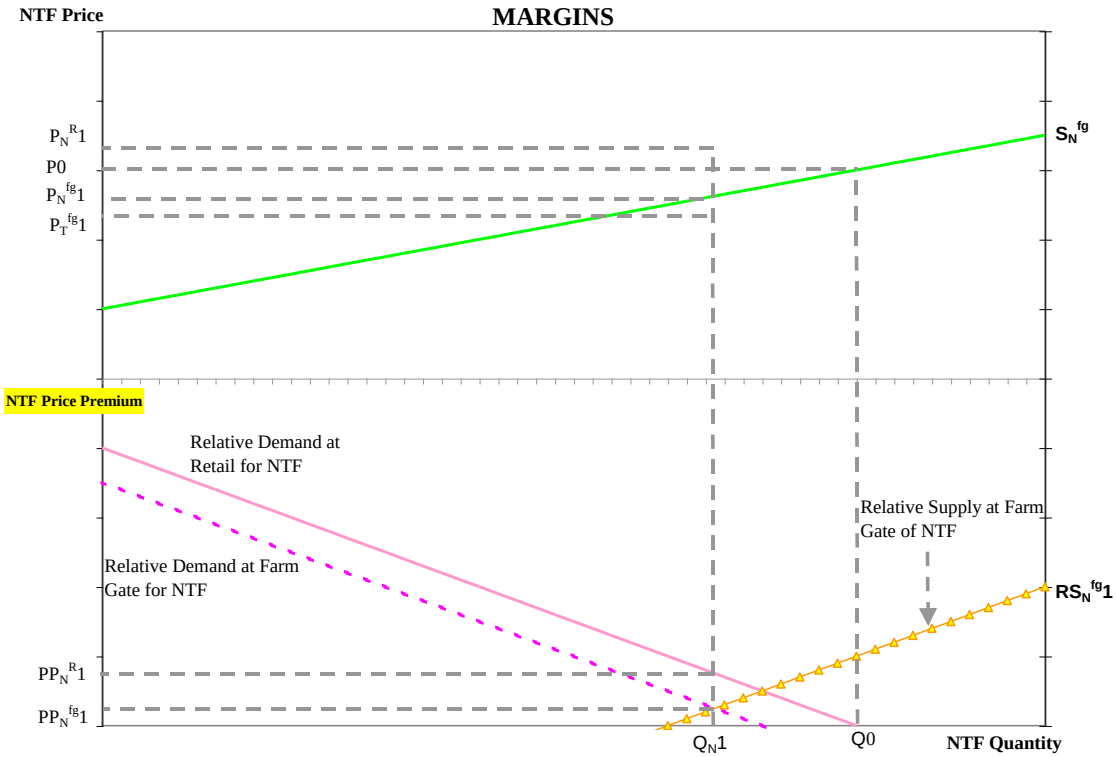
A relative supply curve for NTF can be derived in an analogous manner to that used to generate the relative demand curve for NTF. Such a curve depicts the relationship between the quantity of non-transgenic food supplied, and a price premium for NTF relative to GMO's paid at farm gate. In the absence of first generation GM crops, this supply curve would be perfectly elastic at a price premium of zero at farm gate. If first generation GM crop technology were partly adopted, relative supply from those regions where the new technology did not lower average costs of production would still be perfectly elastic at a price premium of zero. However there also would be a partly elastic zone for other regions where average costs of production are lower due to the new technology[16], so that farmers would need to be paid a premium to be induced to grow NTF.

[15] This relative demand curve may become totally inelastic at low levels of consumption of non-transgenic food.

[16] Sufficient empirical evidence already exists to know that there are significant inter-farm differences in the profitability of transgenic technology. It follows that the relative supply curve will include a less than perfectly elastic zone.

Such a relative supply curve at farm gate, denoted by $RS_N^{fg}1$, is shown in the bottom half of Figure 2 to depict the early stages of adoption of first generation GM crops. As the transgenic technology develops and spreads in the longer term, the somewhat inelastic portion of this relative supply curve will shift back to the left. Also shown in the bottom half of Figure 2 is the relative demand at retail for NTF, and the corresponding but lower relative demand at farm gate to allow for the costs of an IPPM[17].

FIGURE 2: SHORT TERM OUTLOOK for NTF and GMO PRICES and MARGINS



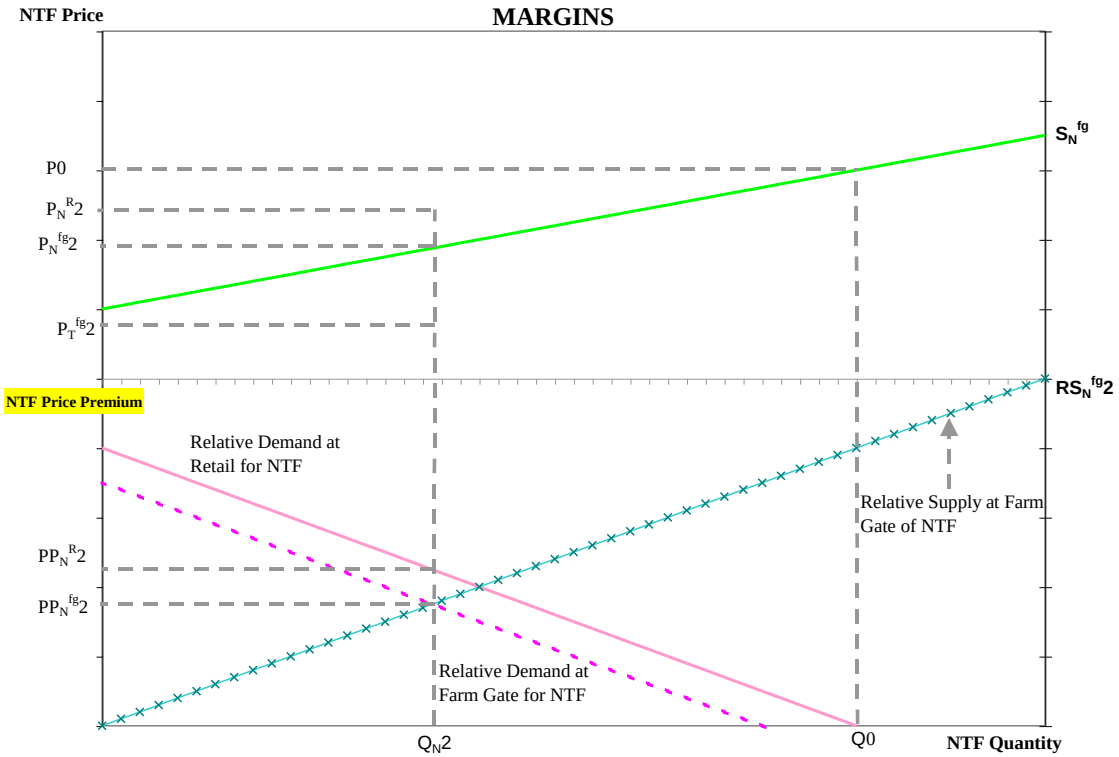
Equilibrium supply of NTF is determined by the intersection of the farm gate relative demand and supply curves at Q_N1. Production and consumption levels of GMO's cannot be shown on this diagram. If there were no income effects associated with the introduction of first generation GM crops, then consumption of GMO's would equal (Q_N1- Q_N0).

The price premium at farm gate for producing Q_N1 of non-transgenic food is $PP_N^{fg}1$, and the corresponding price premium at retail is PP_N^R1. In the top half of the diagram, it can be seen that an absolute price at farm gate of $P_N^{fg}1$is needed to induce farmers to supply Q_N1 of NTF. The farm gate price for first generation GM crops will be $P_T^{fg}1$ (N.B. < $P_N^{fg}1$), and as shown the retail price for NTF is PP_N^R1, which is greater than the benchmark price of P0.

In Figure 3, the likely longer term outcome is depicted once the transgenic technology is more mature and more widely adopted. In particular, it is assumed that the technology is applicable to a much greater proportion of production, and that the cost advantages of growing first generation GM crops vis-à-vis conventional crops also is greater. This scenario is represented by the relative supply curve, $RS_N^{fg}2$. Otherwise the assumptions are equivalent to those in Figure 2. Note that in this case, all prices at both retail and farm gate are unambiguously lower than the benchmark price, P0.

[17] To maintain the validity of the benchmark values for price and quantity, P0 and Q0, it is assumed that the ONLY marketing costs separating retail from farm gate are the costs of the IPPM. This assumption could be relaxed without changing the nature of the results.

FIGURE 3: LONG TERM OUTLOOK for NTF and GMO PRICES and MARGINS



Note that the price for non-transgenic food would fall from P0 to P1'. Consumers of GMO's would pay the lower price, P1, which is the price that producers of GMO's would receive. Under this scenario, all producers would be no worse of, nor any better of as a result of the introduction of transgenic technology.

Initially, it is likely that the price discount will induce relatively few consumers to knowingly consume GMO's. However, if this case follows the pattern of diffusion for other innovations, then over time "learning by looking" will cause most consumer concerns about genetically modified foods to dissipate, although not disappear entirely. For this reason, lack of demand for GMO's may prove to be a relatively short-lived phenomenon.

For quality enhanced GMO's that provide direct benefit to the consumer, analysis of the incidence of IPPM is simpler, and especially so if it can be assumed that these second generation GM crops are otherwise equally costly to produce. IPPM costs will be shared between consumer and producer according to the relative magnitudes of the elasticity of supply and demand.

4) The Supply Side – Intellectual Property Rights and the "Incentive to Create".

Development of a substantial and sustainable market for GMO's is a necessary, but not a sufficient condition for agricultural biotechnology to eventually fulfill its early promise. For the transgenic revolution to continue, not only must value be created, but private investors must have the incentive to continue to invest in further technology development. In the longer run, the key question might not be whether value will be created, but whether private investors can appropriate enough of the value created to make continued investment in technology development profitable. There are many possible answers to this question that could be explored. For instance, it is possible that new developments in molecular biology, of which the now notorious "terminator technology" is the first, but only the first example, may make a discussion of intellectual property rights redundant. However, for now intellectual property rights seem to be the key to capturing value.

Unexpected costs of detecting infringement and enforcing intellectual property rights, both for enabling proprietary molecular technology as well as for improved crop varieties, may eat into returns from investment in plant biotechnology. Another threat to long run value creation from transgenic technologies is the possibility that excessive transaction costs to negotiate license for patented technology will result in patent gridlock. Legal disputes over intellectual property rights also might tie up the technology in the courts and block commercial implementation for years, if not decades. Hence the rest of this paper will concentrate on intellectual property rights issues and consequential supply side problems. A review of the economics of intellectual property rights as they apply to plant genetic resources is the starting point.

The Simple Economics of Knowledge Creation.

While scientific discoveries have created the opportunities for new markets based on biotechnology, it is extensions to the legal framework for intellectual property rights that have made possible private capture of more of the value created by the application of plant biotechnology to plant breeding. Specifically, it is the exclusive legal right to commercially exploit the results of biotechnology research that provides the incentive for firms to invest in the development of this technology. Consequently this section will be devoted to a discussion of the economics of intellectual property rights as it applies to plant biotechnology and plant breeding.

"Intellectual property" can be defined to include most products of intellectual activity and creative endeavour, and other products of the mind that create value. Examples include economically valuable confidential information, inventions in all fields of human endeavour; scientific discoveries; industrial designs; trade marks, service marks, and commercial names and designations. Also included are creative works, such as scholarly, literary, artistic and scientific works; performances of performing artists, phonograms and broadcasts. While sometimes embodied in material matter, intellectual property is of itself intangible. Importantly from an economic perspective, IP is non-rival in use. In contrast, "real" or physical property is a private good that typically is tangible, and is rival in use.

Intellectual property has one of the two characteristics of a classic public good, namely being non-rival in consumption. As a result, users of IP and/or competitors normally can copy, imitate, or otherwise reproduce and use the innovation much more cheaply than the original cost of discovery. True public goods also are not price excludable, so unlike private goods, users who do not pay the asking price cannot be excluded from using them. (Arrow, 1962)recognized that because of this capacity for beneficiaries to "free ride", there will be underinvestment in the production of knowledge in a free market because potential providers will be unable to appropriate all of the benefits derived by users. In the absence of intellectual property rights, most knowledge is a true public good unless it is kept secret. Consequently, the inventor will be unable to appropriate all of the benefits realised by all users of the innovation, and the private rate of return on the original investment will be lower than the social rate of return to the community at large.

Intellectual property embodied in plant genetic resources is a particular case in point. Because it is normally both simple and inexpensive to regenerate plants, the costs to third parties of copying the intellectual property embodied in plant genetic resources is trivial compared to the original costs of generating the knowledge. Hence the incentive to invest in plant breeding traditionally has been too low to induce much private activity because inventions embodied in plants or other living matter have an in-built capacity for self regeneration can be copied very cheaply. Furthermore, the costs of monitoring compliance, detecting infringement, and enforcing rights to property rights in plant genetic resources are commonly greater than for other embodied knowledge where the capacity for self regeneration does not exist. A notable exception has been hybrid corn, which has inbuilt copy protection because the yield advantage from hybrid vigour is lost in farmer saved seed. Hence farmers need to buy seed from the "breeder" each time they grow a new crop.

Intellectual property rights are legal forms of ownership of intellectual property that grant exclusive legal right to commercially exploit the intellectual property, and thus effectively convert non-price excludable public goods into potentially price excludable public goods. Because these rights grant the legal right of price excludability to creators of intellectual property, they facilitate at least partial appropriation of the benefits derived by knowledge users. Note though that intellectual property rights leave unaltered the characteristic of intellectual property being non-rival in use. Hence their establishment involves a trade-off between the potential gains from greater investment in creation of intellectual property versus the dead-weight losses from underutilisation of IP that is actually created.

Typically the creation of intellectual property is a cumulative process, so new knowledge is both the product of creative effort, and subsequently an input into the creation of further knowledge. Hence intellectual property rights that make knowledge price excludable have two contradictory effects on the incentive to create knowledge. On the one hand, they improve the capacity of any individual investor in knowledge creation to appropriate more of the returns from exploitation of "produced" knowledge. Simultaneously though, the cost of further knowledge creation is increased by the need to pay for access to proprietary technology.

If creative talent is widely distributed and difficult to recognise *ex ante*, then it is unlikely that these costs can be internalised within a single corporate entity. On the other hand, the significant transaction costs involved in licensing proprietary technology may inhibit widespread use, and consequently impede the rate of development of derivative technology. As there are a large number of plant biotechnologies that might be used at some stage or other in the plant breeding chain from laboratory to paddock, there is a real risk of blocking future technological progress. In an ongoing context, the balance between these two opposing effects is crucial to the welfare impacts of intellectual property rights, and the dynamic incentive for privately financed inventive activity. The key policy issue from a social welfare perspective is the dynamic incentive to create economically beneficial knowledge.

There is an extensive literature on intellectual property rights[18], particularly with regard to legal issues. The scope of the following discussion is limited to an outline of the broad framework of intellectual property rights, supplemented by greater detail on aspects that have economic consequences.

[18] (Anonymous1998; Anonymous1997; Godden, 1998)

Appropriable Returns on Investment in Biotechnology.

For any individual investor, the expected present value of the net revenue stream accruing to the holder of an intellectual property right will provide a measure of this incentive at a given point in time. The main determinants of this net present value include:

- the costs of acquiring the property right,
- the temporal distribution of costs and benefits,
- total potential value created by utilisation of the intellectual property,
- the proportion of these benefits that can be appropriated as private profit, and
- the costs of enforcing the property right.

(Arrow, 1962) recognised that attempts to appropriate benefits from technology adoption by charging an uniform price inevitably must deny access to some potential beneficiaries who are unwilling or unable to pay the asking price. Since IP is non-rival in use, the social opportunity cost of adoption by an additional user is zero. Thus rationing use by price may limit the amount of value creation. Note though that perfect price discrimination does not exclude any potential user. If perfect price discrimination were feasible, then total value created would be maximised, and the owner of the intellectual property right would appropriate all of it. In practice, perfect price discrimination is unlikely to be feasible, but some forms of intellectual property right might facilitate a higher degree of price discrimination than others.

The proportion of benefits that can be appropriated as private profit will depend, *inter alia*, on characteristics of the intellectual property right. Important characteristics include the term of the intellectual property right (e.g. patent life), its breadth of coverage (e.g. patent scope), and on the processes for detection, prosecution, and redress of infringement that determine the capacity for price exclusion as well as for price discrimination.

Most forms of intellectual property right have a finite term during which the holder has the legal right to exclude others from exploiting the IP. Where the duration of benefits generated by the technology exceed the length of this legally defined period, the latter will limit the proportion of benefits that can be appropriated as private profit. Other characteristics of intellectual property rights, such as filing requirements and examination delays for patents, also can affect the temporal distribution of benefits that can be appropriated by a private investor.

Similarly, the scope of the intellectual property right defines the breadth of technological territory to which the inventor lays claim. Thus an intellectual property right of broad scope will support monopoly power by limiting the opportunities for competitors to invent around the original invention. Furthermore, the broader the scope granted by the intellectual property right, the greater the range of potential uses of the technology that the creator may be able to lay claim and appropriate some or all of the value created. In some cases, the potential uses that can be partially appropriated might include research to develop technology that is an improvement on the original. As noted above, while broad scope will improve the private rate return on investment in the early stages of the development of new areas of technology, it may inhibit further investment in derivative technology, and so stall the dynamics of ongoing technological progress.

Arguably the most fundamental factor is the extent to which the intellectual property right confers the ability to exclude potential users from utilizing those bits of produced knowledge for which they do not pay. Less widely recognised is the ability of the knowledge producer to exercise price discrimination. As noted above, privatising the production of public goods would not involve any efficiency losses if the producer was able to practice first degree price discrimination, **and** able to exclude from use all those unwilling to pay the asking price.

As a general rule, the greater the degree of price discrimination, the higher the proportion of total benefits that can be appropriated as private benefit. In practice, there are limits to the ability of the IP producer to segment potential users into separate markets, and to prevent arbitrage between these market segments. One way in which intellectual property rights might differ is the extent to which they either help or hinder the process of arbitrage. A most prospective area for future research is an analysis of the ways in which differences between IP that are recognised and legitimised by intellectual property rights legislation affect the extent of arbitrage.

Price excludability depends on the ability of the holder of the property right to defend and enforce it against illegal infringement by competitors and/or users. For most types of intellectual property right, the law merely grants the owner the right to exclude others from using the invention unless licensed to do so. To enforce this right, the onus is on the holder to monitor compliance by licensees with the conditions of the license, and to detect and prove infringement by competitors as well as by unauthorised users. Where infringement is alleged to have taken place, the holder must subsequently seek to prove that his/her rights have been infringed by providing acceptable evidence of infringement in the courts, and seeking legally mandated recompense. The considerable costs of monitoring compliance, detecting infringement, and enforcing intellectual property rights against imitation and copying have to be born by the property right holder, and reduce the realised rate of return on investment in IP.

While intellectual property rights provide protection against all illegal use of IP, there are limited exemptions for some types of intellectual property right that legally sanction limited uses with out permission of the right holder. Subject to this caveat, the holder of the right can in theory exclude all potential users unwilling to pay the asking price.

In practice, there is a significant level of infringement, and the processes that determine it can be treated as a problem in game theory. Competitive forces as well as ambiguities in the legal framework for intellectual property rights result in a certain level of infringement for which it is uneconomic to detect, prosecute and seek redress. As a result, there is a dynamic game "played" between potential infringers and property right holders that will determine the actual level of infringement on the one hand, and the optimal level of monitoring and enforcement activity on the other. The magnitude of the costs of imitation by competitors, the costs of detection of that imitation, and once detected, the costs of enforcement against imitators, and the degree of redress and recompense for proven infringement; all will influence the outcome of this dynamic game. Therefore these factors also will have a significant effect on the proportion of appropriable value that is actually captured by a private investor.

Three Key Intellectual Property Rights.

For plant biotechnology, the most important intellectual property rights are trade secrets, Plant Breeder's Rights[19], and patents[20]. All three types of intellectual property right share some common features. For instance, all three provide a mechanism for private appropriation of some or all of the benefits from the application of molecular technologies to plant breeding, but none guarantee the emergence of efficient markets in intellectual property rights.

[19] Or their equivalent in other countries, such as PVPA certificates in the USA.

[20] In the USA, in addition to utility patents which may be granted on most life forms, there is a separate category of Plant Patent for asexually reproducing plants. See (Evenson, 1999).

Each form of intellectual property right also differs from the others in a number of respects. In particular, there are significant differences with respect to the economic incentive to invest in the creation of new IP that can be embodied in improved germplasm.
For biotechnologies embodied in self-pollinated broadacre field crops, copying is both simple and cheap because of the ability of plants to reproduce naturally. Consequently, successful appropriation of returns from these technologies depends critically on reliable and reasonably cheap methods of proving infringement, and on a strong legal basis for intellectual property protection. In most cases to date, transgenic technologies can be patented, and once detected, their use in improved crop varieties can be proven reliably and cheaply. Monitoring compliance and detecting infringement may prove to be more difficult and costly.

The use of enabling molecular breeding technologies in developing improved crop varieties are typically much more difficult to detect, and to prove in a court of law. While these technologies often can be patented, problems in detecting and proving infringement might render patent protection ineffective. Instead it may be necessary to rely on Plant Breeder's Rights, or on trade secrets supplemented by contractual arrangements such as closed-loop marketing schemes, to capture value at the point of seed sale. As the legal protection afforded by these forms of intellectual property rights are weaker than for patents, appropriating realised benefits from these biotechnologies may prove to be quite difficult, costly, and only partly successful.

Trade Secrets.

Any information that has independent economic value, AND is held in private possession is eligible subject matter for a trade secret so long as the company takes all reasonable measures to maintain it as a secret, and prevent it from becoming public knowledge. In some senses maintaining secrecy of the intellectual property is the equivalent of maintaining exclusive possession of a physical good that is rival in use as the basis for protection.

As a form of intellectual property right, trade secrets protect the proprietary information useful to a firm from disclosure to competitors, but in most cases severely limit the options for commercialisation. The nub of the problem is how to simultaneously maintain secrecy, yet fully exploit the intellectual property when the process of commercialisation involves relinquishing sole possession of physical material that embodies the intellectual property. In many cases, the only solution is for the firm to either commercialise the IP by itself, or bring in a few close partners who are sworn to secrecy. Such strategies allow at least some of the benefits of the IP to be appropriated even in the absence of any other legal property rights, but limit the degree of value creation from utilisation of the innovation. Recent attempts to appropriate value from improved crop varieties by charging seed or end point royalties has relied on trade secrets buttressed by contract law in the form of material transfer agreements (MTAs) and "Closed Loop Marketing Agreements" to prevent leakage of the IP into the public domain, as well as on Plant Breeder's Rights.

For certain process innovations, it is possible to maintain the secret while marketing the product. For instance, where the nature of the process innovation can not be deduced nor copied from the product, or where it is embodied in products that cannot be reverse engineered, trade secrets might provide suitable protection. The use of molecular markers in plant breeding programs is an example of the former type of innovation. While some molecular markers are eligible subject matter for patenting, the problems of detecting and proving infringement can make protection by trade secrets an attractive alternative in some cases.

Trade secrets do not protect against independent discovery of the invention. So while in theory the duration of this type of intellectual property right is as long as the owner can maintain the secret, in practice it is as short as the time needed for independent discovery by a competitor. Unlike patents, trade secrets positively encourage, and virtually guarantee duplication of inventive effort.

Another problem with trade secrets is that enforcement is particularly problematic. Effectively the right is only enforceable against persons who can be proved to have “stolen” the IP, and recompense for damages can only be sought from such persons. It can be extremely difficult to detect and prove theft, as it is necessary to rule out independent discovery or public release. Moreover, there are no grounds for action against “innocent” recipients of the IP.

Plant Breeder’s Rights.

The Australian Plant Breeder’s Rights Act 1994 provides protection to plant breeders for the development of improved crop varieties. Equivalent forms of traditional intellectual property protection for plants have been codified in most developed countries, albeit often with different names. For instance, in the US equivalent coverage is provided by the Plant Patent Act of 1930 for asexually reproduced plants, and by the Plant Variety Protection Act of 1970 (Plant Variety Protection Certificates) for sexually reproduced plants. These forms of intellectual property rights are based on the agreed principles in the International Convention for the Protection of New Varieties of Plants 1991(UPOV), which was concerned with protecting the results of conventional biological plant breeding.

Eligibility is determined, and protection granted in Australia by the PBR Office[21] upon receipt of an application, and after a comparison of the breeder’s description of the variety with descriptive records of varieties of the same species. In general, the criteria for eligible subject matter, as well as many other conditions, are much less onerous than for patentability.

After issuance, the applicant must provide a detailed description that is to be made public, and more importantly, there also is a requirement to deposit propagating material for the variety with an approved genetic resource centre and to supply a specimen plant to an official herbarium. Furthermore, the breeder is required to provide 'reasonable public access' to protected plant varieties, something which is satisfied by making propagating material available free, or at a reasonable price and in sufficient quantities to meet demand.

While there are differences between countries in the implementation of PBRs, in most cases they provide protection to varieties that are “new”, "distinct", "uniform", and "stable". Under the Australian Plant Breeder’s Rights Act, the variety must be new in the sense of not previously being known. It must be distinct in the sense that it is clearly distinguishable from previous varieties by genotype characteristics as expressed by the plant. In addition, it must be uniform, breed true to type in the sense that the plant must be able to be propagated unchanged, and have not previously been sold. Note that in common with most countries, there is no requirement for the plant variety or the method of producing it to be genuinely novel, inventive, or even to be useful.

Applications are given a priority date, normally the date of acceptance of the application, and the rights conferred by the Act subsist for 20 years[22] from that date. The issued certificate grants an exclusive right to carry out, or license others to carry out production, reproduction, and marketing of the variety. In Australia and in some other countries, coverage extends to products of the variety, as well as to certain 'dependent varieties'. As explained below, it may also extend to 'essentially derived varieties'.

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[21] Or an equivalent governmental agency in other countries.

[22] The term of PBR is 25 years in the case of trees or vines.

However, there are important limits in the Plant Breeder's Rights Act 1994 to the rights granted by a PBR certificate. The most significant exemptions are the "breeders' exemption" and the "farmers' privilege". Both also are common in equivalent legislation in many developed countries.

So called breeders' rights refers to a provision in the Australian legislation that permits protected plant varieties to be used to breed other varieties without infringing the right of the prior breeder. Moreover, subject to certain caveats discussed below, any bred variety that was "new", "distinct", "uniform", and "stable" could be commercially exploited without risk of infringement, and also would be eligible for issue of a PBR certificate. Since the requirements for eligible subject matter are based on measuring differences in phenotypic expression that have almost infinite variety that are readily manipulated, the scope of protection afforded by Plant Breeder's Rights is potentially extremely narrow.

To broaden the scope of protection, the Plant Breeder's Rights Act 1994 provides for "essentially derived" varieties. While breeding such a variety does not amount to infringement, it may not be commercially exploited without authorization from the breeder(s) holding PBR in the variety from which was 'essentially derived'. Nor can PBR protection be sought for it without such authorization. Clearly the definition of an "essentially derived" variety is critical to the effectiveness of this provision in broadening the scope of protection. The definition in the 1994 Act is far from clear cut, and is relies on terms such as "predominantly derived" and "essential characteristics" that themselves are not precisely defined. The practical meaning of essential derivation will be left to administrative discretion and interpretation in the first instance, possibly supplemented by subsequent court rulings.

A second limit to the rights granted by a PBR certificate is the "farmers' privilege", by which farmers are allowed to save and use, but not sell seed from the protected variety. As indicated by the name "farmers' privilege," under UPOV the farmers' use of seed is a privilege rather than a right convention. Most countries grant this privilege. In Australia, the "farm-saved seed exemption" allows farmers to harvest and use legitimately obtained seed, although there is provision to exempt some taxons from this exemption. (Godden, 1998) believes that these farm-saved seed provisions are likely to begin to disappear as a result of recommendations by the Advisory Committee, and eventually disappear for all varieties. Only time will reveal whether this perspicacity of this prediction

A third exemption to breeders' rights in Australia permits propagating material, presumably including grain, to be used as a food, food ingredient or fuel, or for any other purpose that does not involve production or reproduction of the material. The legal interpretation of this provision is yet to be tested in the courts, but in conjunction with the "farm-saved seed exemption" it would appear to render infeasible plans to collect end point royalties on sales of grain produced using protected varieties.

These three exemptions outlined above to Plant Breeder's Rights would seem to so narrow and weaken the scope of protection provided by PBR certificates as to make redundant further discussion of options for enforcement of rights, and for redress for infringement. For the record, PBR is personal property, and the breeder may commence action for infringement of PBR in the Federal Court. Where infringement is established, relief may include an injunction, and either damages or recompense for foregone profits.

As (Godden, 1998) points out, in addition to this option for redress in the civil courts, infringement of PBR may be prosecuted by the state under the Commonwealth's Crimes Act. He regards this criminalisation of PBR infringements and the substantial penalties for proved infringement, which under rules relating fines to imprisonment are equivalent to eight-and-a-half years' imprisonment, as totally unjustified and unjustifiable. In his words, the net effect "has three dimensions: (i) the coercive power of the State becomes involved in the detection and prosecution of breaches of the Act, and thus breeders' costs in defending their property rights are substantially reduced; (ii) a 'double jeopardy' is created because alleged infringers of PVR become liable for both statutory and civil sanctions; and (iii) an uneven legal playing field is created with respect to defending other intellectual property rights." (Godden, 1998)

In relation to the topic of this paper, the key question is whether Plant Breeder's Rights, even if buttressed by trade secrets and the common law of contract, would provide sufficient legal protection of IP for private industry to continue to invest in development of plant biotechnology for crop improvement. The primary options for capturing value created by proprietary molecular technologies, and embodied in improved crop varieties, are seed royalties, end point royalties, or "Closed Loop Marketing Agreements". So long as the exemption for "farm-saved seed" remains, it is doubtful whether the proportion of value that can be appropriated by way of seed royalties will provide an adequate return on investment. Some state government agencies are using common law contracts to try and negate the impact of the "farm-saved seed exemption", but such arrangements still have to be enforced. End point royalties based solely on Plant Breeder's Rights do not seem to be legally defensible unless the legislation is amended.

Detecting infringement and enforcing breeders' rights are likely to be difficult and expensive, and extremely so if the state does not vigorously exercise the extraordinary powers outlined above. Government agencies already experience considerable problems monitoring and controlling outbreaks of crop pests and diseases in broadacre farming. However, they seem slight compared to the problems of identifying which crops are protected by the rapidly expanding number of PBR certificates, and identifying and proving which ones were grown using an illegal source of seed. By comparison, the undoubted expense of litigation may seem less daunting, although the damage to public relations from initiating lawsuits against growers is still likely to intimidate electorally sensitive governments. Godden's gloomy prophecy about the evolution of Plant Breeder's Rights is founded on an assumption that the vested interests of the breeding industry will determine the outcome. Whether these vested interests will prevail over the farm lobby remains to be seen.

Unlike patents, there is no direct equivalent to the disclosure requirement that is intended to enable continued technological progress. In particular, the pedigree of many PBR varieties may remain concealed[23]. In conjunction with the breeders' exemption, it can be argued that Plant Breeder's Rights provide weak protection to the holder of the property right, and a strong foundation for others to build on the original IP. In addition, because the requirements for Plant Breeder's Rights do not include an inventive step, nor a utility principle, it should be possible to get PBR on a variety that is of little or no benefit to growers, but which nevertheless may serve a firm's marketing interests.

[23] (Alston and Venner, 1999), p.3

This raises the spectre that the seed market will be swamped by varieties with similar genotypes, and that the ability of a plant breeder to appropriate rents from a new variety will soon be dissipated by further releases of many new varieties[24]. Evidence from the canola industry in Canada, where the effective lifespan of a new cultivar protected by PBR is about three years[25], supports this point of view.

"Prior to enactment of PVR in Australia, it was predicted that such legislation would not create plant property rights that were sufficiently effective to promote significantly greater plant breeding investment." (Godden, 1998) Despite several attempts to strengthen protection provided by Plant Breeder's Rights, this prediction still rings true. Further support is provided by the fact that whenever possible, the life science companies are relying on patent protection rather than Plant Breeder's Rights as the legal basis for capturing value from their investment in plant biotechnology.

Patents.

Introduction.

A patent is the intellectual property right of choice for protecting eligible subject matter, commonly referred to as inventions. It offers significantly stronger protection than Plant Breeder's Rights because there are no "breeders' rights" nor rights for farmer saved seed. Patents also can protect a wider range of material than PBR, including proteins, nucleic acids and genes; living organisms including yeasts and bacteria; seeds and other plant parts; hybrids; methods for plant breeding, recombinant DNA, regulating gene expression and plant regeneration; and other biotechnology processes and products. In addition, cultivars and whole plants are eligible subject matter for both patents and PBR.

A patent for an invention is a grant of property by government to the inventor that confers a monopoly right of exclusivity over an invention for a specified period, and to benefit from it without having it copied or imitated. More specifically, a patent confers the right to exclude others from making, using, selling, or importing the invention into the country granting the right, for as long as the patent lasts. To enforce this right, a patentee is entitled to take legal action against anyone who, without permission, makes or uses the invention on a commercial basis, or who sells it.

These rights conferred by patents extend only throughout the country that awarded the grant. As every country in the world has a patent system that is strictly national, a patent granted in Australia has no effect in the jurisdiction of other countries, and *vice versa*. Furthermore, while developments in one country are often subsequently mirrored in comparable developments in other countries, as (Anonymous1998)make clear, the international scene is best characterised as one of great diversity and inconsistencies. Nevertheless, these discrepancies between national systems for intellectual property rights cannot be disregarded, because the laws of other countries can impact on domestic producers when products are exported. For instance, while a patent is only enforceable in the country that issues it, products produced in "non-patent" countries will still infringe the patent if sold in the country where the invention is protected.

[24] (Alston and Venner, 1999)

[25] (Anonymous)

For most internationally traded commodities, it follows that patent legislation in foreign markets will be as important, if not more important than domestic legislation. In particular, the patent system in the jurisdictions of major markets such as the US and the EU may be as important as domestic law in determining the possibility of infringement of patents on proprietary molecular technologies. In addition, with regard to future private investment in the development of the agricultural biotechnology industry, US patent law has been, and is likely to continue to be particularly influential simply because of the preponderance of patents filed for biotechnology inventions in that country.

The following discussion of patents, patent law, and patenting problems uses the U.S. patent as a model, and focusses mainly on US patent office practice, and judicial rulings. In part, this is because of its well-laid out form, and because its format is similar to patents in Australian and other major jurisdictions. There also is the need to ensure that any use of agricultural biotechnology does not infringe US patents for the reasons given above. Finally, if problems of patent gridlock and other intellectual property right blockages to biotechnology development are to arise, then they are more likely to first become evident in the USA.

Eligible subject matter and Enablement.

To get a patent, an application must be lodged that has two main parts[26] of economic import. 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 that specifically define the features of an invention that are protected, the technological territory to which the inventor lays claim. Each part serves different functions, and is examined accordingly.

To be patentable under US law, the specification of an invention must satisfy the requirements for novelty (it must differ in a material way from what is known in the "prior art"), utility (it must have a useful purpose by being industrially applicable), and non-obviousness (it must satisfy the requirements for an inventive step). The latter requirement ensures that the invention is not only novel with regard to public knowledge, but also would not have been obvious to a "person of ordinary skill in the art". Generally speaking, the prior art includes information that is publicly available prior to the filing date of a patent application.

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 both the US and in Australia, so long as these key requirements are met, virtually any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof can be patented without differentiation as to the field of technology. However, most patent laws, including those in Australia, do not allow 'discoveries' to be patented. Only 'inventions' involving a 'manner of new manufacture' are eligible for patent protection, and mere discoveries are ineligible unless they can be applied to some useful end.

[26] Technically, a patent has the following three main sections: (i) a cover page which presents bibliographic information, (ii) a specification, which describes the invention, and (iii) claims, which define the metes and bounds of the patentee's rig which describes the invention, and (iii) claims, which define the metes and bounds of the patentee's rights. A fourth section contains the drawings. (Taken in part from the CAMBIA Web site; http://cambia.org.au/main/index.htm).

Furthermore, claims to human beings, including embryos, are generally not allowable. In Australia, claims to "human beings and biological processes for their generation" are explicitly excluded by the Patents Act 1990. The European Patent Convention also excludes plant and animal varieties, other than new plants and animals produced using a microbiological process. However, plant varieties can be protected via Plant Variety Rights. Apart from such exceptions, most major industrialised countries now grant patents for most living organisms. Courts in the US and Australian have very broadly construed the scope of eligible subject matter to include plants and animals that are the result of human intervention.

Initially a Patent Examiner reviews the application to determine whether the "invention" is patentable. *Inter alia*, this involves a search of the scientific literature to compare the invention with information already available in order to determine whether the requirements for novelty, utility, and non-obviousness are satisfied.

The patent specification must "contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to **enable** a person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention"[27]. In the case of inventions involving a living organism, a deposit of a sample of that organism can supplement the specification. This disclosure requirement ensures that all the information necessary to make and use the invention is in the public domain once the patent issues, and so that the invention can be freely used by others once the patent has expired.

A second purpose is to provide the courts with grounds to determine whether the specification sufficiently discloses the invention to satisfy the enablement doctrine. The doctrine of enablement requires an individual who is "skilled in the relevant art" (i.e. has skill in the relevant technology such as molecular biology) to be able *without undue experimentation* to understand, make, and use the invention as intended by relying on the specification disclosed in the patent application. This doctrine is a key test of whether subsequent inventions infringe the patent. An imitation of, or improvement on an invention that did not requiring *undue* e*xperimentation* would provide grounds for the patent holder to bring a case for infringement.

Patent Claims and the Scope of Protection.

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 all 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 should not extend to inventions that are not *enabled* by the disclosure of the invention in the specification section of the application.

[27] (App 1, Util Pat. §112, first para.). Note that in Australia and the USA, the best method of carrying out the invention known to the applicant at the time of filing must be described.

In evaluating a patent application, the examiner will consider whether the claimed scope is overbroad. Interpretation of the scope of the claim must be done in relation to the written specification description in the patent application. A key consideration is whether the method of invention disclosed in the patent specification would 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.

Most patents involve improvements on previous inventions. These new but derivative inventions also are patentable, subject to meeting the normal requirements for eligible subject matter and adequate disclosure. However, any invention that is an improvement must fall within the scope of at least one prior patent, and in many cases will fall within the scope of many such prior patents. Unless these prior patents have all expired, the holder of the patented improvement must first obtain permission from holders of any and all such preceding patents in order to practice the new invention.

Thus it is common, indeed almost inevitable, for a patentee to have to negotiate licence(s) with earlier patentee(s) in order to be able to use the improved invention. Likewise, the earlier patentee could negotiate to utilise the improvement. This highlights the importance of the issue of technology licensing, and of ensuring that there is an efficiently operating market to license new technologies. Clearly there are going to be transaction costs, and possibly other problems as well, in negotiating required licenses.

It has become common to refer to this need to obtain permission from prior patent holders to practice a new invention as the problem of *freedom to operate.* In some countries, including Australia, patent legislation includes provision for compulsory licensing in an attempt to balance the exclusionary rights of the prior patent holder with the social benefit from maximising value creation and ensuring that ongoing development of the technology is not impeded. How effective this provision is in facilitating *freedom to operate* is debatable. To date there have been no successful cases for compulsory licensing in Australia, and it is estimated that to bring a case would cost between $1 to 2 million. Because there is no provision in US legislation for compulsory licensing, so it is not a solution for most tradeable commodities.

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 at the time when a potential competitor challenges the validity of the scope of claims for a patent, or when the patent holder brings a claim for infringement against an alleged imitator. 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 and Nelson, 1990) discuss the various doctrines of infringement in considerable detail, and readers who desire more detail are referred to that paper. Despite such checks and balances, in the first instance the scope of exclusionary protection is defined by the patent claim, and is generally more expansive than for alternative forms of intellectual property rights.

The extent to which the above features of the patent system might give rise to potential problems for the supply of agricultural biotechnologies is explored in section 5 below.

Duration of protection.

The term of a patent in Australia is 20 years from the earliest claimed priority date provided that the annual renewal fees are paid. Patent terms used to vary widely between countries, but under the TRIPS agreement, the period is being harmonised to 20 years in all countries that are members of the WTO[28]. In Australia, the earliest claimed priority date is the application filing date, but in the US it is the date of invention. Once the patent expires or lapses, anybody is entitled to use the invention without restriction.

In practice, the duration of effective protection provided by a patent might be considerably shorter, and to some extent is an offset to the scope of exclusionary protection afforded by overbroad claims. To give just one example, a patent on a transgenic plant needs to be obtained before seeking regulatory approval, as prior public disclosure would render the invention ineligible for patent protection. If it is necessary to seek approval for field trials as well as for commercial release, then up to half of the available term of patent protection could expire before the firm has any opportunity to commercially exploit the invention and so appropriate some of the value created.

Infringement, Monitoring Compliance, and Enforcement against Imitation and Copying

Inter alia, copying and/or imitation an invention by competitors and/or users infringes the rights of the inventor granted in a patent. As the right conferred by the patent merely grants the holder the right to exclude others from using the invention unless licensed to do so, the owner must assert these rights against any party that infringes the patent. Thus the patent owner has the initial burden of proving that the accused party infringed one or more of the patent claims by unauthorised use, sale, or importation of an invention, or of a product produced using the invention. To enforce this right, the onus is on the holder of the patent to monitor that licensees comply with the conditions of the license, and to detect and prove infringement by competitors as well as by unauthorised users.

Where infringement is alleged to have taken place, the patent holder must subsequently seek to prove that his/her rights have been infringed by providing acceptable evidence of infringement in the courts, and seeking legally mandated recompense. An accused party can mount various defenses. One avenue of defense is to assert that the patent does not cover the accused product or process. Another possible defense would be to dispute the validity of the patent claims, or to argue that that the patent as a whole is unenforceable. Failure to promptly enforce rights once an infringement is discovered can limit remedies awarded by a court, or may even preclude enforcement against that party.

The burden of detecting and proving infringement can be very substantial. Two factors will significantly increase the costs of detecting unlicensed use. One is widespread deployment of a licensed invention, such as a proprietary transgenic technology that is embodied in an improved crop variety, and marketed to farmers. The second involves only process inventions used to produce products that are indistinguishable from products produced by other means that do not infringe the patent.

[28] In the U.S., until 1995 the patent term was 17 years from the date of issuance.

Since the considerable costs of monitoring compliance, detecting infringement, and enforcing intellectual property rights against imitation and copying have to be born by the patent holder, the magnitude of these costs have a significant impact on the incentive for inventive effort that in theory is protected by patent law. Moreover remedies awarded by a court for proven infringement may not fully compensate the patentee for the inability to fully appropriate all of the benefits from the invention that patent law theoretically makes possible. Nor need it compensate for all costs incurred to ensure compliance with patent rights, or for losses from proven and unproven infringement. For instance, the remedy might simply involve an injunction requiring the defendant to desist from further infringing activity, or it might only amount to compensation for proven lost profits. In some cases, it may include damages.

5) Patents, Patent Law, and Patenting Problems– Enclosures of the Mind.

The principal threat to future development of agricultural biotechnology from use of patents to protect inventions can be summarised as follows. Technology development in a science-based field such as biotechnology is cumulative by nature. Virtually every new invention is an improvement on previous inventions, and most build on, and rely on inventions that embody more fundamental and basic scientific principles. The patents for these prior inventions typically have claims of progressively broader scope. While there are many exceptions, in general the earlier the prior date of a patent in the chronology of technological development, the broader are the scope of its claims.

The consequence is a proliferation of patents on a rapidly growing number of inventions that often have conflicting and overlapping claims of broad scope. Eventually, some of these conflicting claims are resolved in the courts, but in the interim there is no system to ensure that claims lodged in different patent applications are mutually consistent. In fact, to the jaundiced observer, it often seems that patent claims are deliberately written to maximise the potential for conflict with claims for other inventions. In any case, the outcome is a multitude of claims of varying scope for related aspects of an invention that overlap at a range of levels. Firms can respond to this situation either by seeking to resolve the conflicts, or they can ignore them and run the risk of an action for infringement.

In theory, it should not be a problem to resolve the conflict. The rights to use all required proprietary molecular technologies could be purchased, or more realistically licensed, from the patentees. In practice, transaction costs, as well as other possible negotiation problems, might make this difficult or impossible to achieve. Such problems would be especially worrisome and inhibiting if each case had to be negotiated *de novo*. A scenario where these problems prove insurmountable, and where patents are more often used to block technological progress rather than to sustain it, has been termed patent gridlock, or the "tragedy of the anti-commons".

In other industries, solutions to patent licensing problems have involved patent pooling, cross licensing, and/or a consolidation of competing firms, and ownership of proprietary technology, to internalise the costs and problems of license negotiation. The downside of the latter solution could be that one or a few firms would establish a dominant industry position, and use the resulting monopoly power to capture most of the value created by the technology[29]. A greater concern is the threat to continued rapid technological development posed by such a scenario. Technological development has stalled in other industries, such as the incandescent light industry, when it came to be controlled by the holder of a dominant patent. Anecdotal evidence is that most of the ideas and even key proprietary molecular technologies that currently are controlled by the large life science companies originated either in universities and other public research agencies, or in small start up companies founded by individuals. Arguably the strengths of the large companies have been in acquiring the rights to these technologies, in commercialising them, and in marketing the resulting products.

Another solution to a proliferation of "blocking patents" has been to establish a technology licensing market along the lines of the market to license copyright to broadcast musical compositions. This would ensure an efficient level of value creation as well as providing a mechanism for patent holders to capture much of this value, and earn a return on their investment.

In the agricultural biotechnology industry, the development of efficient market based technology licensing solutions has so far been inhibited for unknown reasons. Instead, companies have resorted either to court action or to mergers and acquisitions to resolve problems of conflicting patent claims. This paper offers no predictions about the likelihood of the above problems eventually being resolved. Nor does it offer solutions to solve them if they do arise. It merely discusses selected developments that might influence the eventual challenge that would need to be met in the event of market (and legal) failure.

Freedom to Operate.

The large number of proprietary molecular technologies required for their development of GMO's exacerbates the difficulty of separately negotiating all of the licenses required to secure *freedom to operate*. According to (Shimoda, 1995), the ability of companies to commercialize new agbiotech products depends on securing 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 virus resistance, herbicide tolerance, and ripening control.
- **Enabling technologies**, including:
  (a) <u>transformation technology</u> by which a gene which codes for a specific characteristic is inserted into plant cells;
  (b) <u>promoter(s)</u> which are used to control expression of the gene in plants;
  (c) <u>selectable markers</u> which are genes used to determine which plant cells have been successfully transformed to show the desired characteristic; and
  d) <u>gene silencing or regulating technologies</u>, 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.

[29] This concern was addressed in a previous paper. See Lindner, 1999.

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.

Thus 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. Depending on the complexity of the transgenic product, there could be 15 to 40 identifiable tangible components involved. Furthermore, each of these component technologies is likely to comprise subject matter of a kind likely to be claimed in not just one patent application, but in a number of patents held by many different companies.

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 some of the required set of component technologies;
- considerable uncertainty exists 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).

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 free to use and breed with organisms containing the gene naturally." (Barton, 1998) (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 be replicated almost in its entirety in other public varieties. 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 Breeder's Rights laws.

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 is 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.

Freedom to operate is an especially critical issue 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 more 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 other territories, any action for alleged infringement of proprietary transgenic technology by production of internationally traded commodities is likely to be bought in a US court, 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. In the interim though, 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 situations are not without precedent. Nor are the feared outcomes certain to eventuate. (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. It is instructive to briefly summarise some of their findings.

The history of Edison’s single primary patent of broad scope covering the use of a carbon filament as a source of light is especially illuminating. For 12 years after issue of the patent, its validity was contested in the courts. During this period, both competition and technological progress flourished, and lamp prices declined steadily. Despite Edison’s head start, most of the rapid rate of technical advance in the industry increasingly was coming from GE competitors.

After courts eventually upheld the patent, it gave General Electric a dominant position in the industry. This legal monopoly was fully exploited by obtaining injunctions to shut down numerous competitors. (M&N p885). As a result, the share of the market held by GE grew from 40% to 75%, the rate of progress slowed drastically, and the steady downward trend in lamp prices slowed until the patent expired.

The lesson to be learnt from this case is a cautionary one; namely that broad patents can have a significant impact on the pace of technology development. It is not a general argument against patents of broad scope, as there are many other cases that prove that dominant patents of broad scope need not stifle continued technology development.

The contrary story of the development of arc lighting is a case that illustrates what can happen in the absence of a dominant patent as a result of the claim to broad scope being invalidated. In this case, there was a veritable “gold rush” to enter the industry, and any rents to invention that the company might have captured as a return on its investment were dissipated.

A famous case of a pioneer patent comes from the early days of the automobile industry. The key claim of the pioneering Selden patent was to the use of a lightweight gasoline powered internal combustion engine. This single primary patent of broad scope was upheld by the courts, and covered a myriad of possible embodiments. Nevertheless, a wide variety of firms were licensed to use the technology, and arguably the patent did not hinder technological progress. The key to this “happy” outcome was a procedure developed in the industry for automatic cross licensing of patents, a practice that continues in the industry. Other cases of multiple blocking patents impeding process are the aircraft industry and the radio industry. In both cases, multiple licensing arrangements proved extremely difficult to organise, and for aeroplanes had to be imposed by the Navy during World War I.

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) (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 are 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 SAVR 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.

Many of these court findings encourage the adoption of an optimistic viewpoint. 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.

6) Conclusion

A year ago, the future for GMO's looked bright. Plantings of transgenic soybean, corn, cotton, and canola by North American farmers set new benchmarks for the rate of adoption of a new agricultural technology. The only cloud on the horizon was widespread consumer resistance to eating GMO's in Europe, but industry assumed that this was only a temporary problem that could be overcome by more information about the safety of GMO's.

One year later, the outlook has changed. Not only has consumer resistance to GMO's intensified rather than waned in Europe, it has now spread widely in many other countries as well. Even in Canada and the US, there are press reports of supermarket chains declaring that their shelves will be GMO free in future. Not surprisingly, some of the largest food marketing companies are reacting by either refusing to buy GMO's from farmers, or are discounting the farm gate prices that they are willing to pay for GMO's. Lastly, the share prices of some of the life science companies that have gambled most heavily on selling GMO's to the world food markets have been slashed. All of this casts doubt yet again on whether the value created from the agricultural biotechnology "revolution" will be revolutionary.

Despite all the current gloom and doom, there are lessons to be learnt from studies of innovation adoption. First, an innovation will only be adopted for the long term if it delivers meaningful benefits to potential adopters. To date, the overwhelming majority of GMO's in the food chain are the products of first generation GM crops. They deliver lower costs of production to farmers, but no benefits to consumers unless some of the lower production costs are passed on as lower retail prices. In fact, because there is a virtually universal **perception** of some risk to health from eating GMO's, well informed rational consumers will not purchase GMO's unless the price is lower than the non-transgenic alternative. To deliver a price premium for non-transgenic food, industry must provide voluntary verifiable labelling and maintain credible identity preserved production and marketing systems. Second, the most persuasive source of information for potential adopters about an innovation is direct observation of the experience of "early adopters". Thus most consumers will only be persuaded that GMO's are safe to eat after they have observed other consumers eating GMO's on a long-term basis without any ill effects. Again, this is an argument for deep discounts in the retail price for GMO's for an initial period that will be measured in years, if not decades.

In the long run, supply side threats to future development of the agricultural biotechnology "industry" may prove to be less tractable than the demand side threat described above. Investment in ongoing development will only be maintained if it proves possible for investors to capture enough of the value created by agricultural biotechnology to earn a satisfactory return on their investment. A sanitised version of the terminator technology may provide a technical fix. If not, the answer will depend on the efficacy of applicable intellectual property rights.

For plant biotechnologies that end up embodied in improved varieties for broadacre field crops, the most important intellectual property rights are trade secrets, Plant Breeder's Rights, and patents. All three provide a mechanism for private appropriation of some or all of the benefits from the application of molecular technologies to plant breeding, but none guarantee the emergence of efficient markets in intellectual property rights. The costs of detecting and proving infringement, and of enforcing the property right, are likely to diminish potential returns to investment for all three types, but are likely to be more of a problem for the first two. For patents, the greater threat may prove to be patent gridlock. Most technology-based industries have found ways to avoid this problem, but some have not. Only time will tell whether the agricultural biotechnology industry can find a suitable solution.

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