Changing intellectual property regimes: implications for developing country agriculture

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Abstract: The revolutions in biotechnology and intellectual property protection began in the developed world. The USA led the global transformation of intellectual property protection, and has been the leader in commercialisation of biotechnology in agriculture. Now all members of the World Trade Organization are committed to offer intellectual property protections for agriculture. Will the benefits of agricultural biotechnology proliferate globally as a result? Can we now rely on the dynamism and focus of the private sector to exploit the potential of biotechnology to meet the needs of developing nations? In this paper we look forward, drawing some inferences from the record thus far regarding the future relevance of agricultural biotechnology for developing countries.

Keywords: innovation; biotechnology; research investments; freedom to operate; intellectual property.

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1 Introduction

The revolutions in biotechnology and intellectual property protection began in the developed world. As discussed in the companion paper (Wright and Pardey, 2006) the USA led the global transformation of intellectual property protection, and has been the leader in commercialisation of biotechnology in agriculture. Now all members of the World Trade Organization are committed to offer intellectual property protections for agriculture. Will the benefits of agricultural biotechnology proliferate globally as a result? Can we now rely on the dynamism and focus of the private sector to exploit the potential of biotechnology to meet the needs of developing nations? In this paper we look forward, drawing some inferences from the record thus far about the future relevance of agricultural biotechnology for developing countries.

To date, the large and overwhelmingly public agricultural research effort of developing countries has, with a few notable exceptions, made relatively little progress in developing and commercialising agricultural biotechnology innovations. Some applications, such as virus elimination using in vitro propagation, marker-assisted breeding, and use of genetic cultivar identification to improve the efficiency of germplasm conservation, have been used for years in many countries. But here we shall concentrate on the technology that has most captured the interest of farmers, breeders and private firms, the development of new cultivars with transgenic traits.

As in North America, transgenic traits offering tolerance to broad-spectrum herbicides or resistance to insects involving *Bt* genes, have dominated agricultural biotechnology innovations adopted by farmers in other countries. Although contributions from China are becoming increasingly significant in terms of variety of traits and the range of species of transgenic plants and animals under development, achievements in development of new transgenic plant varieties elsewhere have been very modest (Pardey et al., 2005). The overwhelming majority of the value and area of transgenic cultivars adopted globally involve traits developed in North America. Indeed most if not all the transgenic cultivars used widely by farmers in developing countries other than China appear to have been either developed in the USA, or bred from transgenic parents developed there (FAO, 2005; Pardey et al., 2006).[1] The ability to obtain, and if necessary adapt, transgenic cultivars developed in the USA has been crucial for the diffusion of this technology to farmers' fields that has occurred in the developing countries, where the largest adopters by area are Argentina, Brazil, China, Paraguay, India, and South Africa (James, 2004, p.10). Argentina, China and Brazil dominate biotech crop value outside North America, accounting for about one third of the world total of $44 billion in 2003–2004 (Runge and Ryan, 2004, p.v).

Here we address three questions. First, have intellectual property claims held by the developed countries been a major hindrance to biotechnological innovation in the developing world thus far? Second, how are the stronger intellectual property regimes currently being adopted by developing countries likely to affect exploitation of the opportunities offered by agricultural biotechnology in the region? Third, what types of institutional initiatives might improve the effectiveness of agricultural innovation for the developing world in the new global intellectual property environment?

2 Have intellectual property problems been a major hindrance to diffusion of agricultural biotechnology?

In the international agricultural research community, the belief has been widespread that patents have been hindering access to important plant biotechnologies for developing countries. For example, in a survey by Taylor and Cayford (2002), about two thirds of 'stakeholders' with interests in plant breeding, intellectual property, and agricultural development report that US patents adversely affect the ability of researchers to access and use specific gene traits, transformation tools, transformation marker systems and genetically modified germplasm for developing country purposes. The survey included the information that US patents were valid only in that country. Many of the respondents were located in developing countries. It may be that some were confused on this issue, and perhaps others perceived that the USA and other donors use their funding of international aid as a means of de facto extension of patent rights.

Referencing a communication involving the leadership of an international agricultural research centre, Taylor and Cayford (2002, p.40) report the view that that "National agricultural research systems and CGIAR institutions could jeopardize their funding if they systematically violated US patents to develop useful applications of biotechnology". This talk of 'violation' indicates that the reach of US patents rights in the non-profit sector can extend well beyond the geographic bounds of their legal, if not their political, reality, and certainly beyond the scope of protection recognised by well-informed private firms.

Such confusion is encouraged by well-publicised news stories of donations of intellectual property rights for technologies patented in the Europe, the USA and other rich countries, such as 'Golden Rice', and virus-resistant potatoes, sweet potatoes and yams for use by poor farmers in developing countries.[2] The reports often imply that IPRs would otherwise constrain such research and innovation in those developing countries. Thus the Nuffield Council on Bioethics (2004, p.XIX) commented that "… the recent example of Golden Rice shows that patented technologies need not necessarily be a barrier". In fact few or no relevant IPRs existed in most of the developing countries among the top 15 importers or producers of rice (Kryder et al., 2000; Nottenburg et al., 2002). Innovators have generally been either unable or unwilling to file for patent protection in many developing countries. Moreover, the main staples for the poor in such countries are largely consumed domestically; the portion exported to rich countries where imports are subject to relevant domestic patents is typically small (Binenbaum et al., 2003). Finally, modern biotechnology has been applied predominantly at the pre-commercialisation stages of research. Patent holders typically have little or no incentive to constrain this type of activity. Prior to commercialisation, little or no recoverable damages are generated. In fact, patent-holders are often happy to see their technology locked into an innovation, because the investment committed, in time as well as resources, improves the patentee's bargaining position should the innovation proceed to commercialisation.

It is clear that intellectual property claims have not greatly hindered international diffusion of agricultural biotechnology thus far. Some recent papers even suggest that the reverse is true. Kanwar and Evenson (2003) and Lesser (2005) find a positive empirical relationship in the aggregate between intellectual property protection and foreign direct investment, respectively. Though it is difficult to be sure that such aggregate relationships are not unduly influenced by other confounding influences, it is thus possible that applications of biotechnology will increase in developing countries in response to the strengthening of IPR protection under the trade related aspects of intellectual property rights (TRIPS) agreement (TRIPS, 2002). On the other hand, as noted in the companion paper, Lanjouw (2005) finds that lengthening product patent protection can, in fact, delay diffusion of patented pharmaceuticals. Whether a similar effect could occur in agriculture is an important unresolved question.

2.1 Agricultural research support: volumes, intensities and sources

From an economic development perspective, the pre-eminent concern with intellectual property rights is the degree to which their incentive effects impede or enhance investments in agricultural innovation over the long haul. With respect to global research effort, agricultural research expenditures are a special case. Table 1 shows estimates for 2000, the latest year for which data are available. In developed countries, the private-sector share of total agricultural R&D is about 55%, comparable to other areas of rich-country R&D where the private share typically (but not always) accounts for substantially more than half (often more than 60%) of the overall science spending. Moreover, the expenditure share of the developing countries now slightly exceeds the public or private shares of the rich-country group. Agricultural research is globally dispersed, more so than science spending generally, and public and private involvement are both important.

Table 1 Estimated global public and private agricultural R&D investments, 2000

	Agricultural R&D spending (million 2000 intl. dollars)		*Shares in global total (%)*	
	1981	*2000*	*1981*	*2000*
Public				
Asia and Pacific (28)	3,047	7,523	20.0	32.7
Latin America and Caribbean (27)	1,897	2,454	12.5	10.8
Sub-Saharan Africa (44)	1,196	1,461	7.9	6.3
West Asia and North Africa (18)	764	1,382	5.0	6.0
Subtotal, Developing Countries (117)	*6,904*	*12,819*	*45.4*	*55.8*
USA	2,533	3,828	16.7	16.6
Subtotal, High Income Countries (22)	*8,293*	*10,191*	*54.6*	*44.2*
Total (139)	*15,197*	*23,010*	100.0	100.0
Private				
Developing	–	869	–	6.5
High Income	–	12,577	–	93.5
Total	–	13,446	–	100.0
Public and private				
Developing	–	13,688	–	37.5
High Income	–	22,767	–	62.5
Total	–	36,456	–	100.0

Source: Pardey et al. (2005)

The public and private roles in agricultural science have been evolving, reflecting changing economic conditions in the broader economy as well as in agriculture, along with trends in the institutional environment, including intellectual property rights, and in public attitudes and perceptions. While many elements of the changes have been common among countries, reflecting common influences at work, there have been some important differences between countries as well – especially between the richest and the poorest countries.

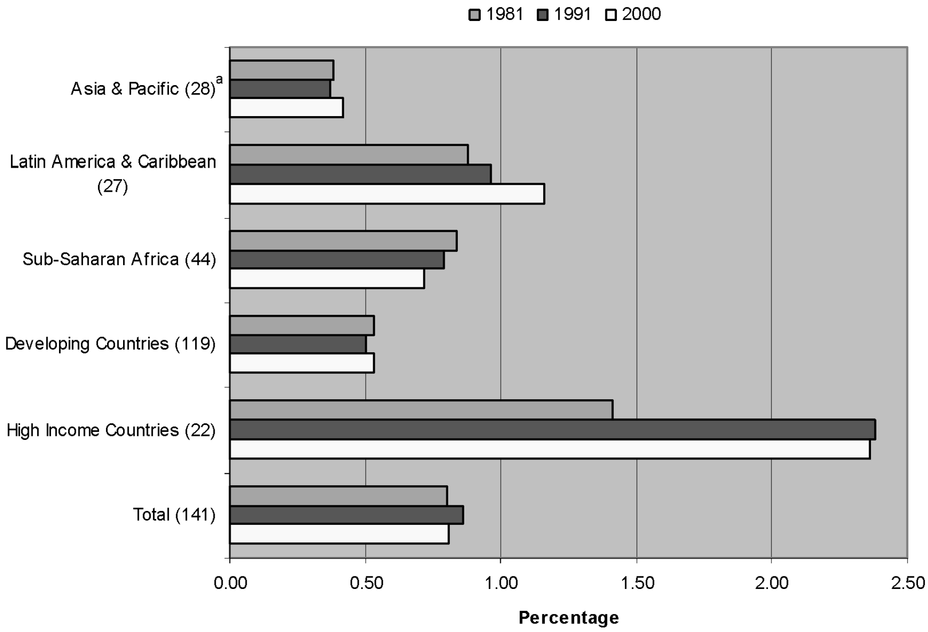
Over the past several decades, worldwide public investments in agricultural research increased by 51%, from an estimated 15.2 billion international dollars (year 2000 prices; see Pardey et al., 1992) in 1981 to $23 billion in 2000 (Table 1).[3] Over this period the developing-country proportion increased, so much so that, during the 1990s, the developing countries as a group undertook more of the world's public agricultural research than either the public or private sectors in the developed countries. Notably, only 6.5% of the estimated global total of $13.4 billion of private agricultural R&D took place in developing countries, and the lion's share of that private research was done in the Asia and Pacific region.

Agricultural R&D in rich countries is dominated by just four countries, and likewise agricultural R&D in the poorer parts of the world is dominated by a small set of countries.[4] Five countries, China, India, Brazil, Thailand and South Africa undertook 53.3% of the developing world's public agricultural research in 2000, up from 40% two decades earlier. Meanwhile, only 6.3% of agricultural R&D worldwide was conducted in 80 other countries, home to some 625 million people in 2000.

Spending by low-income countries, dominated in terms of share of population and spending by India and China, grew rapidly during the 1990s, so that by 2000 these two countries alone accounted for 39% of the developing world's public agricultural R&D, significantly higher than their 22.9% share in 1980. Notably, spending on crop biotech research in China shot up dramatically, from an estimated total of just $17 million in 1986 to $112 million in 1999 (Huang et al., 2002). In stark contrast, Sub-Saharan Africa has continued losing market share, falling from a 17.3% to 11.4% share of the global agricultural R&D total between 1981 and 2000.

In interpreting research expenditure shares, it warrants noting that, in total value of agricultural production, the developing countries are dominant. For developing countries, public agricultural research was only about 0.53% of agricultural GDP in 2000, (and still lower in China), compared with about 2.36% in developed countries as a group (Figure 1). Expenditure per person engaged in agriculture was vastly higher ($11.92 per person in 2000) in developed than developing countries ($2.72 per person). By these 'research intensity' measures, research was a less important contributor to agricultural production in developing countries. There is ample opportunity for conventional agricultural research to contribute more in these countries. A serious concern is that the research intensity is actually falling in Africa (Pardey et al., 2006; Bientema and Stads, 2004), a region in desperate need of more agricultural research, despite evidence of high returns on agricultural research projects (Oehmke and Crawford, 1996; Maredia et al., 2000).

Figure 1 Public agricultural research intensities, regional comparisons, 1981 and 2000



[a]Bracketed figures indicate number of countries in regional averages.

Source: Pardey et al. (2006)

Furthermore research intensities understate the scientific knowledge gaps between different regions. As Pardey and Beintema (2001) emphasised, the total cumulated agricultural research resource stock, at reasonable rates of interest and depreciation, is at least 12 times higher, in proportion to value of agricultural output, in the USA than in Africa (compared with a 3.4-fold difference in their respective research intensity ratios in 2000).

In sum, agricultural research throughout large parts of the developing world is hindered largely by inadequate expenditure intensity. Further, there is no near-term prospect that the private sector will fulfil the biotech innovation role, at least with respect to most staple food crops. Absent support from rich countries – either in kind as part of publicly performed research, or in cash through public or private philanthropy – effective public-private innovation partnerships are unlikely to materialise (Doering, 2005, p.11).[5]

In acquiring applications of a new technology pioneered elsewhere, a natural initial role for developing-country researchers is adaptation of the technology for local conditions. As has long been recognised, this adaptive effort is crucial for efficient dissemination of promising technologies globally (Alston, 2002).[6] For specific well-targeted projects, it is in principle feasible to transfer the application of biotechnology to a country with advanced innovative capacity. For example yams for introduction in Africa have been transformed by Monsanto in the USA, and then the investments necessary for application in Africa have been supported through the Agricultural Technology Foundation and the Danforth Foundation (Kent, 2004). But even with this unusual foreign support, commercialisation of local adaptations of biotech innovations has been blocked or at least delayed by domestic biosafety regulations in Africa.

2.2 Biosafety regulations

Genetically modified organisms including agricultural plants and animals are subject to the Cartagena Protocol on Biosafety adopted in 2000 by parties to the Convention on Biodiversity, and to other domestic regulations in developed and developing countries. Even in the USA, the regulation of genetically modified plants involves insufficiently coordinated responsibilities of different public agencies, and has significant gaps in coverage (Pew Initiative on Food and Biotechnology, 2004). In developing nations the regulatory structure is typically less well established, and the regulations in force might themselves be viewed, in particular cases, as institutional experiments evolving towards feasible implementation.

Compliance, if achievable at all, can be very costly. Redenbaugh and McHughen (2004, p.109) report these costs to be at least $1 million per allele for both horticultural and field crops, if approval is sought solely for the USA. Cohen (2005, p.30) reports estimates of compliance costs of $700,000, $4 million and $2.25 million for transgenic papaya and soybeans in Brazil, and rice in Costa Rica, respectively. He observes that

> "Paradoxically, because they are novel, locally developed products pose unique challenges for institutes seeking regulatory approval … In contrast, GM crops pre-approved in Western markets are more successful in gaining approvals in developing countries." (Cohen, 2005, p.33)

Kent (2004), drawing on his experience with biotechnology transfer to Africa, notes that biosafety regulations

> "… risk stifling the emergence of locally adapted technologies by making it too expensive to take even the first step in moving them out of the lab and into field conditions. This problem affects public researchers even more seriously than companies."[7]

Even if developing countries do not share European concerns with the safety of transgenic foods, and adopt technology already tested and approved in North America, fears of trade disruption by importers citing risk of contamination are another deterrent to approval of adoption of transgenics (Cohen and Paarlberg, 2004). In the long run, this could hinder biotech adoption in export crops. As discussed below, the major food staples are in general likely to be largely unaffected by such concerns. Recent problems in Zambia might constitute the exception that proves the rule.[8]

Regulation of large firms may be easier to implement than regulation of a multitude of domestic farmers. Recent experience with soy in Brazil and cotton in India shows that regulations and laws that delay or prevent importation or domestic commercialisation of transgenic germplasm by large, highly visible plant breeding firms can be ineffectual in preventing smaller breeders or farmers from introducing and adopting transgenic cultivars without any formal approval or regulation. The latter occurred on such a massive scale in both the Brazilian and the Indian cases that there appeared to be a loss of effective public regulatory control.[9] Both examples illustrate that dissemination of transgenic technologies, if sufficiently attractive, can rapidly occur without intellectual property protection, and without sponsorship by public authorities or large firms.

As familiarity with transgenics and their management increases in developing countries, it is possible that, barring the emergence of new, adverse information, the domestic influence of groups with concerns about consumption of transgenics will subside. If so, formal regulations could be relaxed somewhat and administered more efficiently and predictably, at least with respect to staple food and fibre crops which are not intended for export to countries with more entrenched opponents of genetic modification. In that case, under the most optimistic assumptions about research funding in the public sector, the rapidly changing IPR environment might become a prominent influence on development and commercialisation of appropriate agricultural biotechnology. In this context, managing intellectual property rights and related policies will be important for developing countries.

Even under optimistic assumptions, biosafety regulations, intellectual property protection and some components of adaptive research will impose fixed minimum costs on applications of biotechnology such as genetic transformation. Public involvement in these innovations will not be justified in cases where the added social value of the innovative effort is below the fixed costs incurred.

Absence of private interest is not per se justification for public investment. The larger the value of the crop, the more the value of a given improvement. Before the biotechnology revolution, breeders of crops with small markets relied on a narrow germplasm base and made little use of genebanks to explore sources of genetic improvements (see Wright, 1997, and references therein). The costs of doing more exploration of genetic resources could not be justified by the prospective returns.

On the other hand, absence of private interest, even when institutions are well developed and private investment is highly competitive, is not proof positive that research is not justified. In the USA, wheat breeding has not attracted sustained attention of major private crop breeders. Yet the social returns to wheat breeding accruing domestically in the USA, (including prominently domestic adaptation of innovations generated in developing countries), have been high in the USA on a sustained basis (Pardey et al., 1996).

2.3 Freedom to operate for public non-profit researchers

If ownership of the multiple rights necessary to develop new agricultural biotechnologies is diffuse and uncertain, the multilateral bargaining needed to access all of these rights at arms length, and bring a product to market, can become difficult if not impossible. In the private sector, this problem has been solved by bringing key technology ‘in-house’ within oligopolies via merger and acquisition. On the other hand, the facts regarding global agricultural research, reviewed above, indicate that development of agricultural biotechnologies for use by farmers will be largely a public enterprise (particularly for staple foods) over the next few decades at least, especially in developing economies. The same will continue to be true in the developed countries for all but the handful of the most lucrative crops, and for upstream research that is still largely performed by universities and other nonprofits with public funding.

For the public and non-profit sectors, merger with or acquisition by the private sector is not generally an option for obtaining freedom to operate, or to secure crucial complementary assets, although mixing of public and private forms of organisation appears to be a feature of the Chinese environment currently (Fan et al., 2006). Public-private partnerships and research consortia are other options that have been somewhat successful in some cases. (See Fuglie and Schimmelpfennig, 2000 and the chapters therein)

In one controversial case, a partnership between a life-science corporation, Novartis, and the Department of Plant and Molecular Biology in the College of Natural Resources at the University of California, Berkeley, provided substantial funding to the latter (see Rausser, 1999) while offering no intellectual property rights to Novartis beyond rights to first negotiation of patents on a subset of the department's research output. But this relationship proved problematic for the university, and apparently unrewarding for the private partner, who opted not to continue the arrangement beyond the initial five years of the contract. It is unlikely to be used as a model for future university-industry collaboration.[10]

But do non-profits and public-sector research organisations have offsetting advantages in obtaining freedom to operate in agricultural biotech? A priori, it would seem that they should. After all, the applied research interests in cultivar development of non-profits are largely focused on products of no great interest to the private-sector agricultural biotechnology firms, which continue to emphasise soybean, hybrid corn, cotton, canola and some specialty horticultural crops.[11] Furthermore, the more basic research advances, which are likely to be generated as complements to applied public research in this area (Stokes, 1997), can be very valuable to the private sector. Finally, the producers of transgenics currently have a formidable public image problem. Obviously they wish to be seen as 'helping feed the world's poor' by offering key enabling technology to the relevant public/non-profit research agencies working on behalf of the world's poor people, whether that research is done in developed or developing countries.

Do these positive factors ensure that worries about the 'anticommons' are unfounded, and freedom to operate is not, and will not become, a significant problem for non-profit agricultural biotech research? Many well informed observers appear, in casual conversation, to believe that there is in fact no problem worthy of serious attention by policy makers. Evidence on this question from this relatively new, dynamic sector is, not surprisingly, scant and hardly definitive, especially at a time when public acceptance and regulation are overwhelming obstacles to the generation and diffusion of new cultivars produced using transgenic methods.

The available sources relevant to the implications of IPR for freedom to operate in public/non-profit agricultural biotechnology include surveys, econometric analyses of citation behaviour, and case studies. We briefly consider each in turn.

2.4 Surveys

In a survey by Zhen et al. (2006), which focused on researchers in plant biology and related fields at four public land grant institutions (UC Berkeley, UC Davis, UC Riverside and the University of Arizona), with 93 respondents, researchers indicate that when they send research tools to colleagues, whether at other universities or in industry, the interaction is more frequently informal than formal.[12] (Receipts of tools from industry are predominantly formal). Researchers rarely check the IPR status of the tools they use. On the other hand, more than one third of the survey respondents had made invention disclosures, implying more than casual acquaintance with the patent system.

Most of the respondents act as if they had a bona fide research exemption. For them, concern with freedom to operate is focused on lack of easy and quick access to materials held by others. Over the past five years, more than one third of respondents reported delays in obtaining access to research tools, with a mean of 2 delays, and mean duration of over eight months. More than one quarter of the respondents reported one or more cases in which difficulties in obtaining research tools affected their research projects in ways other than causing delays. In one third of these cases, alternative tools of equivalent effectiveness were used, but in about 40% of cases researchers resorted to less effective tools.

More seriously, in about one quarter of the problematic cases a project or line of research that was part of a project had to be abandoned, or not initiated, due to lack of access to research tools.[13] There does not appear to be strong evidence distinguishing academia from industry as the major source of these problems. The majority of all respondents, and of the subset who have made invention disclosures, believe that IPR on research tools is, overall, having a negative effect on research in their area.

The attitudes of the agricultural biotechnologists surveyed are largely consistent with those of scientists actively engaged in genomics, proteomics and related fields surveyed in a study by Walsh et al. (2005), commissioned by the National Academy of Sciences Committee on Intellectual Property Rights in Genomic and Protein Related Innovations, formed at the request of the National Institutes of Health. They are also in line with a key finding of an earlier survey (Walsh et al., 2003): Public sector and non-profit scientists usually ignore intellectual property claims in accessing, making and using their research tools. Scientists continue to consider themselves to have a de facto research exemption. From their viewpoint, they encounter ‘freedom to operate’ as a problem when they cannot get their hands on a research tool, held by another, as quickly and easily as usual. In such cases the problem arises not only from patent-related intellectual property claims, but also from more traditional academic concerns with priority of publication and competition for support.[14]

The reported perceptions of scientists regarding freedom to operate appear quite rational. First, the expected penalties for infringement are the financial damages suffered by the patentee from infringement. When the infringement relates to research usage rather then commercialisation, these will typically be too small to cover the cost of litigation, even if, as is possible in the USA, there is a prospect of an award of triple damages. Use of patented processes to produce innovations marketed much later may be difficult to verify, and, if not embodied in the innovation itself, or revealed in publications or in the course of meeting regulatory requirements, may become subject to a statute of limitations (six years in the USA). On the other hand, the cost of a full freedom-to-operate analysis on each and every technology and material used in the lab would be prohibitive for a public or non-profit researcher. The only feasible way to avoid any risk of infringing others’ patents might well be to cease cutting-edge research.

Patentees rationally wait until a program has succeeded in bringing an innovation close to commercialisation before warning that the technology infringes. Freedom to operate problems materialises in the subset of projects that have survived to this point and show the greatest promise, and they are experienced as constraints on commercialisation. Usually, it is infeasible for the researchers to substitute away from the infringing embodied technology at this late stage.

Comparison of the two surveys conducted in 2005 suggests that the effects on research of lack of access to needed technology have been more serious on average for biotechnologists working on agriculture than for those focused on human health. This might reflect the smaller set of promising technologies in agriculture and the lower level of resources available to help scientists surmount or invent around roadblocks.

2.5 Econometric citation studies

Until recently, many economists and lawyers viewed claims of negative effects of IPR on research as purely ‘anecdotal’. One reason for this is that each case of research problems has its own special features. The standardisation that facilitates quantification is a real challenge. The metrics that have been used are at best only indirectly related to the productivity of the research enterprise, which by its very nature is not standardised.

Two recent papers have used forward citations as an indicator of the effects of patenting on subsequent research in biotechnology. Murray and Stern (2005) consider the 169 peer-reviewed scientific papers published in *Nature Biotechnology* between 1997 and 1999 that could be linked to a US patent. Sampat (2004) analyses the genomic patents assigned to the top 15 recipients of NIH funding over the period 1990–2000, and identifies 499 patent-paper matches. Using different approaches, they find similar overall post-grant declines in citations (between 9% and 17%, and 14%, respectively).[15]

These papers are important, because they find the first quantifiable, econometrically estimated effect of patenting on a relatively standardised metric of the flow of research information. However, the causal links between patent issue, changes in citation behaviour and changes in research require further examination and explanation. Nevertheless, the citation studies do at a minimum indicate that prior patenting appears to affect a quantifiable aspect of the behaviour of other scientists.

2.6 Case studies of public/non-profit agricultural innovation blocked by domestic IPR

As discussed above, in the agricultural research sector, public research institutions have responsibility to see research through to commercialisation in all but the few lucrative markets that attract the bulk of private-sector attention. Public biotechnology research related to health, on the other hand, is (with prominent exceptions such as research complementary with clinical use of diagnostic tools) directed at providing upstream input to private-sector development. Negative effects of IPR on non-profit ‘commercialisation’ of innovations have until now been most apparent in the agricultural sector, and in non-profit institutions such as medical centres where clinical researchers wish to use patented diagnostic tools to treat patients, for a fee, as part of their research program. It is the effect of IPR on the mission of these integrated enterprises, rather than on the environment perceived by the bench scientist, that is the key issue for the prospects for biotechnology innovations for agriculture in developing countries.

For the public and non-profit agricultural research sector, any effects of IPRs on the overall research are difficult to measure objectively. Appeal might be made to the law of large numbers in analysing samples of thousands of citations or hundreds of researcher responses. But thousands of citations might relate, in the end, to only a handful of commercialised products. Moreover, as noted above, surveys of scientists, even those located within an agricultural experiment station, reveal that they generally perceive the effects of IPR in relation to their own laboratory or area of investigation. This no doubt reflects the specialisation necessary for progress in modern research. Most scientists are not directly responsible for development of a commercialised product that could be a target of an infringement suit.

The number of biotechnology innovations that have been developed anywhere near to the point of commercialised actions by public and non-profit agriculture is small. Further, had more been developed, political and social opposition to transgenic products in key export markets would very likely have prevented commercial adoption in many cases. Thus a direct statistical analysis of effects of IPR on agricultural biotechnology innovation through to adoption on farmers' fields is impossible at this time. To discuss the issue further we are forced to resort to case studies, anecdotes and the perception of industry participants.

In the USA and some other developed countries, there is some evidence that university research projects designed to produce new crops with modern biotechnology have been shut down because of refusal of IPR-holders to permit commercialisation of varieties incorporating their intellectual property. In one instructive example, University of California researchers, with financial support from producers, successfully created a tomato variety genetically engineered to express the University's endoglucanase gene to retard softening and improve shelf-life characteristics (Wright, 1998). However, the promoter they used was one for which a patent application surfaced during the development of the new cultivar. The patentee, a life science corporation, refused to negotiate terms for the use of its embodied technology for commercialisation of the cultivar. The research and development effort came to naught, shattering the confidence of the producers, who helped finance the project, in the capacity of the University to successfully breed and commercialise new transgenic cultivars.

In another example, development of a fungus-resistant strawberry at the University of California was blocked by lack of access to the necessary *Agrobacterium* transformation technologies (National Research Council, 1997, p.8). Funding of the research by the Strawberry Commission was discontinued (National Research Council 1997, p.9). In another case, a dead end was encountered when transgenic barley with good herbicide tolerance was developed during a research project. The owner of the relevant herbicide tolerance patent refused to negotiate commercialisation rights, and indeed refused to discuss developing the germplasm itself (Wright, 1998). Reports indicate that similar impediments to commercialisation, in the form of refusal of freedom to operate, have been encountered in development of herbicide tolerant turf grass at the University of Michigan (Erbisch, 2000) and of a herbicide tolerant lupin in Australia (Lindner, 1999). The point of these examples is not that they would all have been commercially successful given freedom to operate, but that freedom to operate was in these cases a serious barrier to a system of non-profit innovation that has responsibility for development to the point where they were made available to farmers in the field.

Why do these roadblocks occur? Economists expect that when there are gains to be made from a trade, the trade will occur. If the parties failed to find a mutually satisfactory solution in the above examples, by an economic tautology, the 'transaction costs' must have been too high. Perhaps the public-sector negotiators had unrealistic expectations regarding private sector largesse. The owner of the key IPR might have been concerned with protecting itself from liability or from damage to its reputation due to misuse beyond its control. In some cases the expected financial gains, given the size of the market, might have been less than the cost in time and money to the IPR owner (public or private) of making and enforcing an agreement. Or perhaps the patent holder saw no reason to help out a potential competitor, for little financial return, in a market that could one day be of financial interest to the patentee.

The examples we have discussed are few, anecdotal, and rather old. But in more recent conversation, scientists who have experience with startups and public-sector development in this area generally strongly support the view that IPR thickets, along with testing costs to meet registration and regulatory requirements, are two serious impediments to development of transgenic cultivars for agriculture and horticulture in the USA, for all but the most lucrative markets. Like-minded research managers, and their potential financial supporters, will avoid the lines of research that could furnish new examples to add to the list, a serious reaction that would likely be even more difficult to quantify.[16]

At present, there is more optimism with respect to genetic engineering for health-related markets. But here, too, there have been problems related to freedom to operate. At the University of California Berkeley, researchers in 2003 developed transgenic wheat lines that were shown to be less allergenic in an animal model. Patents to some of the methods and materials used to develop the new transgenic lines of the California wheat variety, *Yecora Rojo*, were licensed to a firm that did not pursue development of hypoallergenic wheat. Sublicensing of rights back to the university, to allow product development of the hypoallergenic wheat to proceed, was delayed, hampering negotiations for further development with other firms that were potentially interested in this opportunity at that time. Since then, the investment climate has changed, and market and consumer concerns have become the dominant obstacles to further commercial development of hypoallergenic wheat.[17]

Definitive evidence on the effects of IPR on agricultural research will not be available soon, if ever. But the evidence from surveys, citations and case studies constitutes, in aggregate, a strong prima facie case for a significant blocking effect of intellectual property claims in public/non-profit agricultural research that yields commercially attractive results. One commentator has complained that there is no evidence of such a blocking effect on commercialisation of an innovation in a staple in a developing country. This is not surprising, as strong patent protection of agricultural biotechnology innovations is just now being implemented in most developing countries. However, we already have cases in which US patents, later invalidated, have been used to hold up commercialisation of products from developing countries.

Where developing-country producers grow crops for export to the developed-country markets, a US patent of dubious validity can be, and has been, used to disrupt exporters to the USA. For example, a Colorado firm patented a yellow bean, which it named the 'Enola bean', bred from beans purchased in Mexico. The firm had reproduced and selected the yellow beans over several self-pollinated generations. After receiving the patent, the firm proceeded to demand licenses from importers of similar Mexican beans. This patent was challenged in the USA, and after several years was surrendered in 1995 for reissue/re-examination. The patent's long-run status is unclear, although plant variety protection still covers the Enola bean (Nottenburg, 2005).

In another case, an improperly obtained patent on a new and superior variety of pineapple was referenced in a letter from a Vice President of Del Monte Fresh Produce to a Central American researcher. The writer warned him against working on pineapple plant material developed by Del Monte Fresh Produce, which, he added, owned a US Plant Patent.[18] Similar warnings allegedly were sent to potential US competitors, including Dole. It later became clear that the variety in question was not patented, and indeed had been refused a US patent in 1992. The patented variety was another improved variety, a hybrid that was a sibling to the Del Monte Gold variety. That patent was later withdrawn by Del Monte Fresh Produce, which acknowledged pre-patent sales of the patented variety by a competitor.

These examples show that, even before TRIPS has had its full effect, confused perceptions of the geographic scope of patents, combined with confusing use of US patents of dubious validity, have had a plausibly discouraging effect on agricultural research and production in the developing world. After TRIPS has been fully implemented, the potential geographic scope of protection will cover all members of the WTO, and thus could be almost global if applications are submitted in all relevant countries. Furthermore, restrictive actions, or threats thereof, involving dubious patents could be made much more effective by the changes mandated by TRIPS. A dubious US patent could well be used to persuade local patent authorities in the country of the potential competitor to approve a local patent application. The cost of challenging the validity of such patents is likely to be such a heavy burden on less-developed country researchers and producers that competition in major markets might be eliminated, or delayed for years.

These examples are instructive regarding the types of potential threats associated with intellectual property claims that can confront developing-country producers and innovators. They are obviously too few to establish the seriousness of such threats.[19] In any event, it is important to stress that, thus far, the overwhelming reason for lack of adequate agricultural research in developing economies, and in particular in sub-Saharan Africa, has been the lack of sustained, adequate flows of investment in research in this area, noted above. For public and non-profit researchers everywhere, the lack of capacity to make the heavy investment in the testing required for regulatory approval is another major limitation on agricultural biotechnology innovation involving plant transformation.

For the future, the World Intellectual Property Organization is exploring the implications for standardising and centralising certain aspects of patenting worldwide, consistent with at least European levels of protection, via the proposed Substantive Patent Law Treaty. The Treaty could offer very important economies in administering patents worldwide, with evident advantages for small and less developed countries. But it could also result in a further strengthening of global IPR, which might not be in the interests of such countries.

The potential influence of patents (and IPR more generally) on agricultural research in developing countries is changing rapidly, to the degree that countries are achieving effective implementation of TRIPS and subsequent agreements.[20] Public and non-profit researchers in these poorer parts of the world, who will continue to be responsible for the bulk of agricultural research not directed at the most lucrative cash crops, are now increasingly confronting the challenges of obtaining the necessary freedom to operate for bringing new crops, processes and products to market that have already been faced by their counterparts in the developed countries. At present they are very poorly equipped, in terms of funding, information and expertise, to meet this challenge.

3 Institutional initiatives to encourage agricultural biotechnology innovations

For policy makers, the challenges are to get the science done, while avoiding IPR problems that might materialise when commercialising or distributing technology to farmers. Several institutional innovations that have been designed to address these challenges deserve attention. The Public Intellectual Property Resource for Agriculture (PIPRA) initiative has several aims (Atkinson et al., 2003). One is to construct databases with complementary informational services to facilitate, for research planners, preliminary scoping of the freedom to operate problems along a research trajectory. Another is to educate public sector institutions on best-practice licensing that reserves rights for humanitarian purposes. PIPRA also supports development of key enabling technologies, as alternatives to tightly-controlled proprietary technologies, offering freedom to operate for public and non-profit researchers. It also seeks to overcome public-sector fragmentation, encouraging collaboration in bundling technologies and reducing costs of licensing.

The Biological Information for Open Society (BIOS) initiative (Nature, 2004) is a bold attempt, extending achievements originating with CAMBIA in Australia, fostering collaborative open-source development of sets of key enabling technologies for agricultural biotechnology. It intends to develop licensing strategies inspired by the open source movement in software. It also offers a database with information from over 70 patent offices, which is used in supporting IP landscape analyses and other informational services for researchers in agricultural biology as well as other health-related fields.

Another relevant initiative is the African Agricultural Technology Foundation. It is a public/private attempt, supported by the Rockefeller Foundation, to facilitate negotiated, case-by case royalty-free licensing of proprietary technologies owned by firms, to be developed by African institutions for small farmers in a way that reduces risks and transaction costs faced by the donors.

The Specialty Crops Regulatory Initiative launched in November 2004 is a collaborative effort to establish an organisation to facilitate, and reduce the cost of the regulatory approval of biotechnology-derived specialty crops.[21] This initiative seeks to play a role in this area similar to that of the IR-4 Project of the USDA to facilitate approval of pesticides for small crops, and the Orphan Drug Act to encourage the development of new drugs for diseases with small markets.

Economists have developed other proposals that merit serious attention. Masters (2003) is promoting a system of prizes to encourage innovations that offer social value to rural Africans, to reduce the gap between perceived private returns and social value (the ‘consumer surplus’) and provide more incentive for profit-oriented initiatives in the public interest. Kremer and Zwane (2005) propose a related program, with more specific goals. Lanjouw (2003) advocates a change in domestic patent law that encourages holders of key patents that have their largest potential market in developed countries to grant effective freedom to operate in a list of less developed countries, provided production is not exported back to other markets.

Finally, developing countries should be aware of the need for access to expertise in the law, economics and administration of intellectual property protection, in international negotiations and in formulation of domestic policies. Some informed observers believe, for example, that Australian negotiators, expert on trade questions, were outmatched on key intellectual property issues in the recent bilateral negotiations with the USA. Expertise is available on the world market, at a price. Developing countries need to make the educational investments required to establish the domestic capacity to identify the appropriate international sources of expertise, and to use their advice effectively. This is a significant challenge.

4 Implications

Until recently, agricultural research in developing countries, which is predominantly public, has been less constrained by valid intellectual property rights than many international researchers and other observers appear to have believed. As intellectual property rights proliferate in the most important export and consumer markets, the problems of freedom to operate in developing economies will become similar to those encountered by the public and non-profit researchers who account for almost half of agricultural research effort in developed economies.

Experience thus far in countries that are leaders in applications of biotechnology offers important insights for the dozen or so developing countries with substantial near-term potential for the development and application of agricultural biotechnology. First, scientists in the public laboratories have been relatively unconstrained by most intellectual property claims not embodied in materials, because they ignore them. For them, freedom to operate tends to mean ability to get the tools needed to do the project. Conversely, lack of freedom to operate is perceived as lack of timely access to materials physically controlled by others. Material transfers are the intellectual property claims that dominate their attention.

For research policy makers, the situation is quite different (Graff et al., 2004). The private firms who tend to acquire most claims on key technologies originating in the public and private sectors are focused on a handful of crops, but their technologies are much more broadly applicable. Though they cannot, and often have no incentive to, control infringers in the lab, they can prevent the commercialisation of new cultivars and other innovations achieved using their proprietary technology. This is the major freedom to operate problem for the stronger public agricultural researcher programs (as distinct from individual scientists in these programs), in rich and poor countries alike. It can become evident only in that tiny but important subset of lines of research that are successful enough to have been commercialised. (In the survey by Cohen 2005, only seven cases, of 201, had reached the commercialisation stage.)

In the years of time and effort that must be invested in a successful innovation, it is likely that one or more patented technologies will become embodied in the product by scientists oblivious to IPR claims. When this has happened in the course of public-sector transgenic innovations for use in a developing country, failure of the patentee(s) to consent to negotiate seems to have been a more prevalent roadblock than demands for excessive royalties. Concerns with control, reputation and the cost of negotiation seem to outweigh the modest licensing revenues obtainable from crops of no direct interest to the private sector. Even a single 'train wreck' in public sector development can mean frustration, withdrawal of funding sources, and indeed the failure of public research programs.

Nations with strong agricultural research capacity, like China, Brazil, India and Argentina, have shown that they need little or no overseas investment to support rapid diffusion of the most profitable transgenic technologies originating in the USA and elsewhere. Strong domestic intellectual property protection is probably not in their interests, absent the threat of trade sanctions. This might change, if they succeed in developing and patenting new transgenic rice technology, for example, that is attractive to other countries. It may be that they will demonstrate a comparative advantage in transgenic cultivar development for some crops in the medium term. In any event, these countries should give serious attention to initiatives such as PIPRA and BIOS, which also serve the needs of public agricultural research in the rich countries.

Beyond the effects on the choice of programs and their successful completion, the new IPR regime is also changing the perceived mission and funding structure of the stronger public research institutions in developing countries. For example, Koo et al. (2006) report that EMBRAPA, the large Brazilian federal agricultural research organisation, has negotiated contracts with private seed producers that restrict the latter from pursuing further research on the germplasm they receive, in sharp contrast with the traditional notion of the role of public research institutions in fostering private applied research based on their own innovations.

Finally, it is important to recognise that the dominant constraint on agricultural innovation for the majority of developing countries is not at present IPR. It is a lack of sufficient and sustained funding in the face of well-documented high social returns on research using non-transgenic technologies, a problem also observed in developed economies with strong IPR, for all but a handful of crops. Especially in poor countries, another serious constraint at present is strict and costly biosafety regulation.

For many, if not most, developing countries, these problems will not be solved in the near future. For such countries, applications of biotechnology are likely to be concentrated in non-food cash crops, and in particular in corn, soybean, and cotton, often using cultivars developed from transgenic events produced in the rich countries. Where substantial adaptive research or market development investment is required, strong intellectual property rights might be necessary to encourage rapid development and diffusion of imported technology by private seed producers. Where local public sector biotech research capacity continues to be weak, local development of biotech for staple food crops is unlikely to occur, regardless of intellectual property protection.

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Notes

[1]Of 15 GMOs reported as released varieties in FAO (2005, Table 13, p.43), all but one of the non-Chinese varieties appear to be imported, if one includes Bulgarian maize and Indonesian cotton, for which the origin of the transgenic variety is not reported. Pardey et al. (2004) report that all the officially approved Monsanto/DeltaPine bioengineered cotton varieties grown in China are the same varieties grown in the USA. Likewise the transgenic cotton varieties grown in Mexico are from the USA, while in South Africa, *NuCotn 37-B*, a US variety, is widely used.

[2]The donations more typically take the form of grants of physical access to constructs and other crop improvement materials and expertise rather than intellectual property per se.

[3]All these data involved conversions from local currency units to US dollar equivalents using purchasing power parities to account for cross-country price differentials, rather than using market exchange rates. See Pardey *et al.* (1992) for details. These agricultural R&D spending estimates are from Pardey *et al.* (2005).

[4]The USA, Japan, France, and Germany accounted for two-thirds of the public research done by rich countries in 2000, about the same share as two decades earlier.

[5]As Doering (2005, p.11) puts it: "Despite much talk, public-private partnerships in which both sectors make contributions and have a stake in the outcomes are rare in crop development for developing countries." He goes on to illustrate the unrealistic conditions often imposed by international donors on potential partnerships: "Project structure must guarantee the benefits to the poorest farmers and guarantee that benefits to the private sector also create public goods such as rural development, improved agricultural productivity, and seed markets".

[6]Assessing the formal impact evaluation literature, Alston (2002) contends that up to half the local productivity gains in agriculture over the past several decades are attributable to the effects of spill-in technologies developed elsewhere.

[7]See also Pray (2006).

[8]Recently Zambia, during a famine in part of the country, refused food aid in the form of maize from the USA, on the grounds that it contained genetically modified seed. It was reported that the government was concerned with the response of the European Union to Zambian exports, should they become contaminated with transgenic seeds. Some informal reports imply that domestic inter-regional politics influenced policy in this case.

[9]This phenomenon is characteristic of the power of farmers to trump public regulation withholding innovations when the apparent returns are sufficiently attractive. A similar loss of control occurred on two separate occasions with respect to new technologies for biological control of rabbits in Australia.

[10]Much stronger claims were negotiated by DuPont Corporation in 1981, when Dr. Philip Leder was recruited from the corporation by Harvard University Medical School. In return for $6 million to support Leder's research, Harvard gave DuPont exclusive license to any patents that might result from that research. This arrangement led to the development of the 'OncoMouse', the subject of the first patent on a living animal, in 1988. DuPont's license terms for use of the oncomouse as a research tool subsequently generated much controversy (Marshall 2000).

[11]See the papers in California Agriculture (2004).

[12]About 400 surveys were distributed. The response rate reflects the fact that at each institution the entire department was included in the sample. No attempt was made to pre-select those scientists who were engaged in applications of biotechnology to agriculture.

[13]Follow-up interviews made it clear that reports that a project was affected referred to one line of investigation in a larger research enterprise, rather than an entire independently funded project.

[14]The exception is diagnostic tools which are used by universities in revenue-generating treatment of patients, which jointly contributes to ongoing research. Concerns with commercial application have led patentees to vigorously pursue infringers including clinicians involved in research, generating a great deal of controversy.

[15]The 14% refers to the effects found by Sampat of patents on gene sequences. Non-sequence patents ('techniques') showed no such effect. Since techniques, once published, can usually be copied, the latter result is consistent with bench scientists' perception that access means freedom to operate.

[16]Such a chilling effect has been claimed with respect to commodity boards interested in research on minor crops at the University of California (National Research Council, 1997, p.9).

[17]This project was led by Bob B. Buchanan and Peggy G. Lemaux of in the College of Natural Resources, University if California Berkeley, whom we thank for this information.

[18]The letter included the following, as reported in the Consolidate Class Action Complaint (RMB), US District Court, Southern District of New York, In Re Fresh Del Monte Pineapples Antitrust Litigation, 4th August 2004, at 20:

> Fresh Del Monte Produce Company is aware that your company has acquired pineapple plant material and is researching the growth and production of pineapple plants. Del Monte has also learned of an organised effort to steal this planting material from the Del Monte plantation for propagation.
>
> Be advised that Del Monte is the developer of this plant material and intends to protect its interests as necessary. In addition, be advised that Del Monte owns US Patent No. Plant 8,863, dated 16th August 1994.

[19]Many more reports of problems with intellectual property claims by the North are listed on websites of non-governmental organisations, but these tend to be unreliable, or difficult to verify.

[20]Already the commercial seed market has undergone a rapid increase in concentration via acquisitions by multinational corporations (Commission on Intellectual Property Rights, 2002) in Brazil, where Monsanto received permission (currently under legal challenge) to collect royalties on soybeans via a point-of-sale payment, and in Mexico.

[21]For more information on this initiative go to http://www.csrees.usda.gov/nea/biotech/part/biotechnology_part_specialty.html.