Chapter 6

Control of and access to genetic modification technologies

Control of and access to genetic modification technologies

6.1 Over the past 15 years, the expansion of the interests of the private sector in agriculture, particularly in the areas of GM crops and seed production, has resulted in much of the technology and germplasm being under commercial control. Universities in developed countries, encouraged by governments, have also increasingly sought patents to protect their inventions in this area.[1] As a consequence, many discoveries and important technologies in plant biotechnology are no longer treated as *public goods*.[2] Rather, they tend to be patented and licensed, often exclusively, to private companies working on major crops such as maize, soybean and cotton. The development of GM crops relevant to agriculture in the developing world will also require the negotiation of intellectual property rights (IPRs).

6.2 In making our recommendations in the 1999 Report, we recognised the potential of IPRs to constrain the development and commercial growing of crops important in developing countries. In particular we recommended that owners of patented technology should be encouraged to license their technology non-exclusively, that patent offices should avoid the granting of overly broad patents, and that the impact of patents on access to germplasm should be monitored (see paragraphs 3.47, 3.56 and 3.61 of the 1999 Report). In this chapter, we consider whether recent developments in IPRs demonstrate that the concerns underlying these recommendations were well-founded. We give particular attention to three aspects of IPRs which are crucial to the development of GM crops: use of Material Transfer Agreements (MTAs), licensing of patented technology, and access to germplasm.

Material Transfer Agreements

6.3 MTAs are widely used as a means of transferring tangible property, such as isolated DNA sequences and plasmids, between research laboratories. An MTA is a binding private contract between the provider of the technology and the recipient. In essence, it limits the right of the recipient to work with the materials except under terms agreed by both parties. Commercial use usually requires a licence agreement. An MTA can be a powerful tool for controlling novel technologies in plant biotechnology, and access to germplasm. For example, an MTA can be used by the provider to exercise a right of refusal to negotiate a non-exclusive licence with the recipient for patents incorporating materials or data provided under the MTA. In the case of GM crops, MTAs may also impose *reach through* rights to products developed by the recipient. The development of the majority of new crop varieties will often involve MTAs.

6.4 The perception that the recent proliferation of MTAs is not necessarily in the public interest is widespread. Researchers in the public sector often view the use of MTAs in research as burdensome in that they tend to make unwelcome demands on their time and resources. The fact that many research materials can no longer be shared freely but must be the subject of a private contract, irrespective of their potential value, is a trend which runs counter to the ethos of scientific research in the public sector. Nor is the use of MTAs confined to transfers between researchers in the public and private sectors. Researchers in the public sector now routinely exchange materials using MTAs. Despite these concerns, there are as yet few

[1] In the US, the Bayh-Dole Act (1998) gave universities and other public research institutions the rights to patent inventions funded by government research grants. Similar legislation is being applied in a number of industrialised countries.

[2] Toenniessen G and Herdt R (2001) Intellectual property rights and food security. Available: http://www.genomics.cornell.edu/gmo/toenniessenpaper.html. Accessed on: 18 May 2003.

documented examples where MTAs have had a negative impact on the development and application of research. We note however that in the case of Golden Rice, difficulties over access to an MTA owned by a private company delayed progress in development by about twelve months.[3]

Licensing of patented GM technologies

6.5 Five major industrial groups of large agricultural biotechnology companies control between them most of the technology which is needed to undertake commercial research in the area of GM crops.[4] They have achieved this position by licensing, strategic mergers and acquisitions. Several of these companies have used their proprietary technologies effectively to develop new varieties of major crops that enhance farm productivity and reduce agricultural impacts on the environment, both in the US and elsewhere.[5] However, work on crops of less commercial interest has progressed slowly, highlighting the need for greater involvement of the public sector in these cases of market failure. The power and advantage that these companies may choose to exercise in respect of licensing patent rights has attracted much negative comment. We concluded in our 1999 Report that the development of GM crops relevant to the developing world would depend in part upon availability of low cost licences or the waiving of fees for patented technologies. As with MTAs, the development of Golden Rice (case study 4) is illustrative in this respect. It shows that while patented technologies may delay the development of new crops, they are not necessarily a barrier.

6.6 Golden Rice is intended for use by farmers and traders whose profit is below US$10,000 per year. These farmers are predominantly subsistence farmers. In view of their vulnerable position it is desirable that seed can be supplied at low or no cost and without restrictions. Once research was complete it appeared that commercialisation would require licences covering 70 patents belonging to 32 different owners.[6] In the event only six licences were required and licence fees were waived. This example suggests that requests for waivers of licence fees to allow the use of patented technologies for the development of crops suitable for subsistence farmers may be received sympathetically in future. However, a more systematic mechanism may be needed if large numbers of patents are involved, and if seed is to be made available to farmers at the low prices that they can afford.

6.7 The shift towards exclusive control of agricultural technologies by the private sector has been aided by organisations in the public sector.[7] Universities, especially those in the US, have licensed many of their innovations, including important technologies in plant biotechnology, exclusively to companies. Consequently, three quarters of new agricultural biotechnology products, including those funded by the public sector, are controlled by the private sector. This trend of increasing investment in universities by industry is becoming much more

---

3 Personal communication, Professor Potrykus, 21 March 2003.

4 Syngenta, Bayer CropScience, Monsanto, DuPont and Dow AgroSciences. ETC group (2002) Ag Biotech Countdown: vital statistics and GM crops. Available: http://www.etcgroup.org/documents/biotech_countdown_2002.pdf. Accessed on: 2 June 2003.

5 Huang J *et al*. (2002) Plant biotechnology in China, *Science* **295**: 674–6; Phipps RH and Park JR (2002) Environmental benefits of genetically modified crops: Global and European perspectives on their ability to reduce pesticide use, *J Anim Feed Sci* **11**: 1–18.

6 Potrykus I (2001) Golden rice and beyond, *Plant Physiol* **125**: 1157–61.

7 Conway G (2003) Biotechnology and the War on Poverty, in *Biotechnology and Sustainable Development: Voices of the South and North*, Serageldin I and Persley GJ, Editors (CAB).

common in the life sciences. It has led to concerns that the current levels of academic-industry collaboration are resulting in university research being increasingly influenced by corporate interests.[8]

6.8 The growth of IPRs has been attributed to the intense competition and low profit margins which exist in the seed industry. These conditions, it has been suggested, encourage companies to accumulate intellectual property to render technologies inaccessible to competitors despite the fact that they may have low market potential. The increasing number and complexity of IPRs which need to be licensed tends to limit their availability to researchers from the public sector. Indeed some take the view that only large companies currently have the capacity to assemble the complex mix of IPRs necessary to enable the efficient development of new technologies and products.[9]

Germplasm

6.9 Germplasm in the form of seeds is the starting point for a plant breeding programme. Some germplasm is publicly available in national and international collections. The 16 International Agricultural Research Centres (IARCs) of the CGIAR (Consultative Group on International Agricultural Research, see Box 6.1) hold over 500,000 accessions of landraces and improved varieties of the world's major crops. These *ex situ* collections are held in trust on behalf of the international community by the IARCs. Companies engaged in plant breeding also hold large collections of germplasm, which they use for breeding and improvement of the crop varieties in which they specialise. They may seek access to national collections and to those of the CGIAR, to improve their own elite strains of germplasm that have resulted from their breeding programmes. The *International Treaty on Plant Genetic Resources for Food and Agriculture* will require a standardised MTA to be used by institutions holding these collections (see paragraphs 6.3-6.4). We welcome this Treaty which, once ratified, will regulate the fair exchange of germplasm for 33 important crops (see paragraphs 5.11-5.15).

6.10 Plant breeders have used plant variety rights (PVR) to protect new crop varieties. These rights are a form of intellectual property and allow the breeder some protection for his new variety. The plant breeders' exemption allows breeders to use varieties protected by PVRs for the purpose of developing new varieties. Genetic modification has provided the breeder with new tools to create novel varieties and stronger rights in the form of patents have been granted to protect them. The collections of germplasm held by the IARCs cannot be patented 'in the form received'. However, once a modification has been introduced, they may then be eligible for patenting. Patent protection for plants or seeds is frequently obtained by securing a broad patent which claims rights over the gene or gene carrier (vector), and may cover a number of varieties or even crops incorporating the gene. In effect, this may have the same outcome as patenting the whole plant because the patent extends to 'all material … in which the product is incorporated'.[10] The holder of a patented variety may be able to prevent others from using it for breeding purposes.

8 For a discussion of how the increasing trend to acquire IPRs may also affect the direction of academic research see Royal Society (2003) *Keeping Science Open: the effects of intellectual property policy on the conduct of science* (London: Royal Society).

9 Conway G (2003) *From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century.* Speech at the Woodrow Wilson International Center for Scholars Director's Forum. 12 March 2003. Available: http://www.rockfound.org/documents/566/Conway.pdf. Accessed on: 10 Oct 2003.

10 *Directive 98/44/EC* Article 9

6.11 Under patent law in the UK, it appears that a plant breeder does not have the clear right to use a patented GM plant variety for breeding purposes. To avoid possible litigation, he can either refrain from using the variety or apply for a licence from the patent owner. Such requests may be refused or granted on less than favourable terms.[11] Nor does the provision of compulsory licensing necessarily offer a further option. UK regulations require the existence of a significantly improved variety to justify a compulsory licence. Such a variety must have been tested in the field and would require prior use of the patented variety. As we noted in our 1999 Report, this potential locking up of genetic variation would be contrary to the spirit and intent of plant variety rights. We consider that there is a strong case for the principle of the breeders' research exemption established for PVRs to be applied to patented varieties. **We reaffirm our recommendation from that Report that the World Intellectual Property Organization (WIPO), the European Commission (EC), the Union for the Protection of the New Varieties of Plants (UPOV), the Consultative Group on International Agricultural Research (CGIAR) and the International Plant Genetic Resources Institute (IPGRI) together closely monitor the impact of patents on the availability of germplasm to plant breeders (paragraph 3.61 of the 1999 Report).**

Box 6.1: **Consultative Group on International Agricultural Research (CGIAR)**

The CGIAR, created in 1971, is an association of public and private members supporting research in a system of 16 centres that are active in more than 100 countries. The CGIAR aims to contribute to food security and the reduction of poverty in developing countries through research, strengthening of local expertise, and support for policy through environmentally sound practices. The CGIAR's research agenda has five main priorities: increasing agricultural productivity, protecting the environment, conserving biodiversity, improving policies which influence the spread of new technologies, as well as the management and use of natural resources, and strengthening networks for national research. The CGIAR holds one of the world's largest *ex situ* collections of plant genetic resources in trust for the global community. It contains over 500,000 accessions of more than 3,000 crop, forage, and agroforestry species. The germplasm within the collections is made available without restriction to researchers around the world, on the understanding that no intellectual property protection is to be applied to the material as such.

Conclusion

6.12 We observed in the 1999 Report that the agrochemical and seed industries were tightly consolidated around a small number of multinational companies. We noted that further consolidation might not be in the public interest and we recommended that the relevant competition authorities keep the sector under close review. Since then, AstraZeneca and Novartis have merged to form Syngenta and Aventis CropScience has merged with Bayer to form Bayer CropScience. With regard to markets in developing countries, Monsanto has, for example, increased its share of the Brazilian maize market from zero to 60% in just two years. Only one Brazilian company remains, which has a 5% share of the market.[12] In anticipation of such developments, we emphasised in our 1999 Report that farmers in developing countries should retain the capacity to choose between growing either new

11 Submission of the British Society of Plant Breeders (BSPB) to the Intellectual Property Advisory Committee (IPAC) concerning Research Exemptions under Patent Law, 17 Oct 2003.

12 Commission on Intellectual Property Rights (2002) *Integrating Intellectual Property Rights and Development Policy* (London: CIPR).

improved seed from the companies or improved seed from national breeding programmes or the CGIAR centres.

6.13 It has been argued that the growth of patent claims in both the public and private sectors could have an inhibiting effect on research. The challenge for the public sector, especially where research is directed at agriculture in developing countries, is how to access GM technologies without infringing IPRs. In addition, they must decide on the way in which their own technologies will be made available.

6.14 New initiatives which recognise the potential of these constraints to inhibit research into crops relevant to developing countries are therefore particularly welcome. Several US universities are now finding that the exclusive licensing of their technologies has deprived them of access to their own inventions. The Public Intellectual Property Resource for Agriculture (PIPRA) is a recent initiative which aims to promote licensing strategies in US universities that encourage retention of rights to their own technologies.[13] These rights can be exercised for non-profit purposes or for the development of crops especially suited to the needs of developing countries.

6.15 The recent establishment of the African Agricultural Technology Foundation (AATF) also seeks to address IP issues in agriculture, relevant to the needs of developing countries.[14] Together with similar activities organised by the ISAAA, the AATF will create partnerships with existing organisations. It will transfer materials and knowledge associated with advanced agricultural technologies that are privately owned by companies and other research institutions, on a royalty-free basis.[15] The AATF will focus on improvements that can be achieved by genetic modification of crops relevant to small-scale African farmers. These include cowpeas, chickpeas, cassava, sweet potatoes, bananas and maize. It has secured support from four of the leading multinational agrochemical companies which have agreed to share patent rights, seed varieties and expertise with African researchers.[16] The AATF also intends to negotiate with other companies for support as well as for licences to important patents.[17]

6.16 As we have noted, the majority of successful applications of GM crops have been developed by industry for commercial agriculture in developed countries (see paragraphs 3.21-3.25 and 3.27). In contrast, most research on GM crops that may have potential for developing countries continues to be undertaken by publicly-funded organisations. A major concern which we expressed in our 1999 Report was the neglect of a serious issue: the risk that gains from GM crops will not be brought to bear on the needs of poor people in developing countries. We also concluded that GM crop technology was unduly concentrated on the crops and farm systems of industrialised countries. The role of the CGIAR in research on GM crops is strategically important. But funding for the CGIAR has fallen in real terms since 1990. Although it spends about US$360 million per year, less than 10% is directed to research on the genetic modification of crops. **We therefore affirm the recommendation made in our 1999 Report that genuinely additional resources be committed by**

---

13 See http://www.pipra.org/.

14 See http://www.aftechfound.org/index.php.

15 Conway G (2003) *From the Green Revolution to the Biotechnology Revolution: Food for Poor People in the 21st Century.* Speech at the Woodrow Wilson International Center for Scholars Director's Forum. 12 March 2003. Available: http://www.rockfound.org/documents/566/Conway.pdf. Accessed on: 10 Oct 2003; see also: ISAAA The Papaya Biotechnology Network of Southeast Asia, http://www.isaaa.org/Projects/SEAsia/transfer.htm. Accessed on: 31 Oct 2003.

16 Monsanto, DuPont, Syngenta and Dow AgroSciences.

17 Gillis J (2003) To feed hungry Africans, firms plant seeds of science, *Washington Post* 11 March 2003.

governments, the European Commission and others, to fund a major expansion of GM-related research into tropical and sub-tropical staple foods.

6.17 Furthermore, as one respondent to our Consultation observed:

> 'The priorities for the development of GM crops seem to be set by institution and/or organisations outside of Africa that may not necessarily address on-farm constraints of major importance. And currently very few countries outside of South Africa have the capacity to develop GM crops. Africa at least needs to develop an inventory of intractable constraints of major food and commercial crops that need urgent attention. Regional bodies such as FARA, CORAF, ASARECA and SADC/FANR[18] might best draw up a list of such constraints and seek funding to develop the capacity necessary for the evaluation of GM crops in Africa.'
> *Dr Kanayo F Nwanze, Director General, WARDA - The Africa Rice Centre*

We endorse this suggestion and recommend that those sponsoring research, in determining which traits in which crops should be developed, be proactive in consulting with national and regional bodies in developing countries to determine priorities for research.

18 FARA – Forum for Agricultural Research in Africa, CORAF – West and Central African Council for Agricultural Research and Development, ASARECA – Association for Strengthening Agricultural Research in Eastern and Central Africa, SADC – South African Development Community and FANR – Food, Agriculture and Natural Resources Development Unit in Harare, Zimbabwe.