ESRC Genomics Forum Workshop Report

Plant Breeding and Intellectual Property

ESRC Genomics Forum, Edinburgh

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Contents

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The contents of this report reflect discussions that took place during the meeting, and may not represent the views of all the meeting participants, the views of the ESRC Genomics Forum or those of NIAB.

Executive Summary

This workshop on plant breeding and intellectual property set out to discuss the following question:

> *Does the current European Intellectual Property Protection regime for plants stimulate or impede investment and innovation?*

Over the course of a lively and productive day, this question was broken down and re-framed in several ways. What emerged was a complicated and context-dependent relationship among innovation, regulation, intellectual property protection and access to germplasm. Innovation in plant breeding cannot be treated as a simple, linear process. It may:

- take place in the public or private sector, through public–private partnerships, and at the level of individual farms and farmers;
- be treated as a fairly closed process, or in a more distributed and participatory manner;
- use well-established breeding and selection methods or draw on the very latest genetic information and technology;
- feed into commercial or informal seed systems.

An obvious consequence is that there is unlikely to be a single property protection framework that will stimulate innovative plant breeding across this range of locations and approaches. The intellectual property regimes of Plant Variety Rights and patents were viewed by the participants as sustaining innovation in the private sector designed for commercial benefit. However, some noted with concern that the current system for certifying new varieties acts as a form of straightjacket, reinforcing and rewarding innovation that is based largely on incremental improvements in plant varieties.

There seems little doubt that advances in the science and technology of plant breeding can enable innovation in plant breeding if it is desired. However, the ability of the current PVR framework to reward innovation that makes use of new types of genetic information and technologies was questioned over the course of this meeting. The speed with which new crop varieties can be developed using genetic information has led to discussion at industry level of changing the breeders' exemption — in effect, introducing a mechanism to restrict access and slow down innovation. Patents, not PVRs, are also increasingly used to protect seed-based innovations that rely on genetic information. Growing alignment of the PVR and patent systems can be observed. However, some participants cautioned that strengthening the PVR system will not necessarily stimulate innovation.

Seeds can be seen as a commercial or tradable product, a source of genetic diversity for further development, or even a part of the common heritage of humankind. These views lead to different perspectives on how one might manage seed flows, and how to derive profit from seed. How should one think about the information contained in seeds? What value is added during the innovation process? Do all breeding techniques and technologies add the same type of value in the same way?

Underlying the central workshop question is a political issue, relating to the challenges facing sustainable agriculture. These include climate change, land and water availability, and population growth. Will an increase in the speed and scale of plant breeding be sufficient to meet these challenges, or might a more fundamental change in the *direction* of innovation be required? Can and should we rely on the commercial/private sector to meet these longer-term, high-risk, public good-oriented goals? There was widespread acknowledgement that public sector plant breeding has atrophied over the past 30 years, as have links between public and private plant breeding institutions. How might more productive relationships be established and sustained across distributed innovation systems? To what extent can regulatory and property protection systems be (re-)designed with such goals in mind?

In conclusion, it seems that there might be a case for re-thinking aspects of the IP framework for plant breeding. The current system reinforces an approach that is perhaps not suited to emerging challenges or the needs of different players in the innovation system. However, moves to strengthen, weaken or fundamentally alter the existing frameworks should be thought through in the context of the dynamic relationship between regulation, innovation, investment and public goods.

Workshop Presentations

Wayne Powell — Advances in the science & technology of plant breeding

Wayne Powell from NIAB spoke about advances in molecular genetics for plant breeding, and questioned whether the intellectual property protection regime for plants has kept pace with these developments. He described two principal routes for the development of new plant varieties using molecular genetics: one relying on gene discovery for the development of transgenic varieties, and the other based on genetic diversity screening for the purposes of improving germplasm via non-transgenic methods. Approaches including QTL mapping, association mapping, and selection screening have successfully been used to identify genes controlling traits such as senescence in wheat, oil content in maize, and genes involved in crop domestication.

Wayne also placed these advances in science and technology in a broader context relating to funding, innovation and challenges for plant breeding. The challenges facing sustainable agriculture are significant, including climate change, land and water availability, and population growth. The range of genetic diversity currently exploited in plant breeding is small — for example, about 10 varieties of wheat account for 90–100% of the variability in the wheat gene pool. Increased exploitation of genetic diversity, coupled with the growing efficiency and predictability of modern genetic technologies, certainly provide opportunities to re-invigorate plant breeding and help address global challenges. But does the UPOV framework for protecting new plant varieties encourage and reward step-changes in the development of new plant varieties? Or does it promote incremental improvements to the same base germplasm? Wayne argued the latter.

Steve Hughes — Innovation systems in plant breeding

Steve Hughes from the Egenis Centre in Exeter explored the relationship between intellectual property and innovation. He began with the view that strengthening the IP framework for plants will not necessarily stimulate innovation. This is in part owing to where the main 'bottlenecks' in the innovation process are found — Steve identified access to and exploitation of genetic variation as a key 'log jam' for innovation in plant breeding. Through a 'back-of-the-envelope' sketch, he suggested that the innovation process in plant breeding companies restricts access to (genetic) knowledge by other groups — a final, tested variety emerges, but everything else remains inaccessible. Would a more networked, decentralized and participatory system that allowed access and exchange at several points during the innovation process result in better exploitation of genetic diversity in plant breeding in both industry and the public sector?

Striking an appropriate balance between access and proprietary rights for the purposes of innovation is not straightforward, particularly as knowledge is intimately tied up with seeds. Underlying much of Steve's talk was the acknowledgement that seeds and seed systems are thought of in many different ways. Some would say they are part of the common heritage of mankind (and thereby common property accessible to all), in some cases they are treated as national sovereign property (for example, in the Convention on Biological Diversity), and in other instances they are protected as private and exclusive property, and thus tradable commodities.

Mike Adcock — Developments in European Plant Intellectual Property

Mike Adcock from the University of Durham provided a very helpful overview of Plant Variety Rights (PVRs), patents, and the interface between these two intellectual property regimes. The PVR system is a *sui generis* system, designed by plant breeders to protect new varieties. The main instrument is the 1961 International Convention on the Protection of New Varieties of Plants (UPOV), revised in both 1978 and 1991. Key derogations include a research exemption and that for farm saved seed, although both have been limited to some degree through UPOV 1991. European Community PVRs are granted for varieties that are distinct, uniform, stable (DUS), new, and have value for cultivation and use (VCU) — 2,616 Community PVRs were granted in 2007.

Patents are a negative right over production or use. The two main sources of patent law in Europe are the European Patent Convention (EPC, 1973) and the EC Directive on the Legal Protection of Biotechnological Inventions. Article 53(b) of EPC specifically excludes plant varieties from patenting, as does Article 4 of the Biotech Directive. However, the 'Novartis ruling' from 2000 permits the patenting of plants in Europe provided that a *technical invention* can be shown, and that plant varieties are not claimed specifically.

There is reasonable overlap between these two IP regimes, and some of the revisions to UPOV strengthen the IP protection and bring it closer to patent-like protection. Farm Saved Seed applies equally to PVR or patent-protected plants, and compulsory licensing is similar. However, there are fundamental differences in the breeders' / research exemption between the patent and PVR system, with patents able to restrict research on plant varieties to a greater degree than PVRs (citing potential commercial applications).

Bernard Le Buanec — Protection of plant-related innovations: Current debates

Bernard Le Buanec from the International Seed Federation (ISF) highlighted some current concerns and debates within the seed industry regarding the protection of plant-related innovations. One area of active debate relates to the exploitation of an 'essentially derived variety' (edv). An edv is a variety that is predominantly derived from an initial protected variety, and conforms to that initial variety in the expression of its essential characteristics. This definition is ambiguous with respect to what the threshold or cut-off should be for declaring a new variety as 'predominantly' derived. The ISF has developed its own calibration protocols, using genotype similarity thresholds as 'trigger points' for discussion/arbitration regarding phenotypic similarity. There is also an unresolved question about whether the use of genetic information (for example, with 'reverse breeding' approaches) might be thought of in terms of 'predominant derivation'.

This issue ties in with a broader debate about whether the breeders' exemption (regarding access to plant varieties for further breeding) should be modified in light of new technologies that have dramatically increased the speed with which new varieties can be developed (including genetic technologies such as molecular breeding). In order to provide a minimum time for breeders to benefit from new varieties, there is discussion (but no consensus as yet) about phasing-in access to new plant varieties, with an initial restricted period. A final debate highlighted by Bernard concerns the coexistence of patents and PBRs, particularly with regards to transgenic varieties containing patented elements. The current position of the ISF, so as not to restrict breeders' rights, is to consider that "a commercially available variety protected only by Breeder's Rights and containing patented elements should remain freely available for further breeding." Provided that any new varieties are not edv, they should be freely exploitable by the developer. However, if they fall within the scope of the patent's claims, negotiation will be required.

Open session: Participant contributions

Chittur Srinivasan has been using econometric modelling to determine the incentives for innovation provided by the Plant Variety Rights system. Although it is difficult to isolate exact levels of economic return attributable to PVRs, he suggests that in practice they offer very limited protection. Moreover, the distribution of rewards is highly skewed, meaning that most crops earn very little indeed.

Niels Louwaars placed the issue of IP protection in a more international context, and identified pressures linked to harmonization for the purposes of international trade. Describing intellectual property rights as a contract between innovators and society, he suggested that the workshop question might be re-framed as 'How do countries assess what is the optimal level of intellectual property protection for them?' For example, weak IP rights might be more appropriate for local seed systems, with stronger rights necessary for commercial / export crops. Could we come up with a system that assesses relative needs in this way? Such a framework would help to take into account development issues relating to IP.

Bram de Jonge suggested that public research institutes occupy an interesting position in this debate. They face increasing pressure to protect their research findings and develop IP policies, in part because this

makes them more attractive partners for private investment (which is crucial, as these institutes increasingly have to generate their own revenue streams).

Joyce Tait spoke about the relationship between innovation and regulation. Regulatory frameworks can have a significant influence over which technologies get developed, and who develops them. She drew a parallel with the pharmaceutical industry — the R&D costs, together with the lengthy and expensive regulatory system, mean that now only multinational corporations can be real players in the market. An important issue relating to plant breeding is how one can generate new products with sufficient value to make investment worthwhile. The interaction between IP and innovation in this regard is complex and worthy of investigation.

Denis Murphy identified two core problems relating to intellectual property claims made by industry: (1) the breadth of the claims (which is increasingly acknowledged as a problem; most new claims are now subjected to greater scrutiny), and (2) attempts to patent core technologies. He highlighted that GM crops marketed by industry have to date focused on only two input traits (Bt and herbicide tolerance), and make use of quite old technology — despite there being many possible alternatives. In academia, there is a perceived need to patent, but little incentive to exploit patents (patenting is seen as an end in itself). The connectivity between public and private sectors is poor, and new, useful products are not being developed.

John O'Neill asked a number of probing questions on the basis of the morning's discussion. First, he noted that as well as the scale and speed of innovation, the *direction* of innovation is arguably an important consideration. IP regimes and regulatory frameworks can certainly influence the direction of innovation. He also questioned the common view that the role of the state is to intervene at the point of market failure, for this approach could be said to lose the notion of public goods. And finally, he asked about the possibilities and limitations of open source approaches to IP, suggesting that open source needs particular conditions to thrive (e.g. the ability to make many small, low-cost contributions).

Key issues and discussion points

Stimulating innovation in different spaces and systems

- Much of plant breeding has focused on increasing yields, often at the expense of environmental health. What characteristics are desirable or necessary for future plant varieties? It seems likely that traits such as efficiency (e.g. of nitrogen use) and optimisation of inputs–outputs will become increasingly desirable.

- Plant breeders can make a living by focusing on incremental innovations in plant varieties. However, a strategy of incremental innovation is unlikely to result in those varieties best able to help meet the challenges of climate change, population growth, etc. For plant breeders though, it seems that the benefits are not immediately commensurate with the risks attached to pursuing a different innovation strategy. This reinforces short-term approaches, not a longer-term perspective.

- There seemed to be reasonable consensus among participants that intellectual property rights stimulate commercial innovation for commercial benefits. However, the question still remains as to whether the commercial sector can be relied upon to satisfy all priorities and needs. What are the limits of intellectual property in both the private and public sectors?

- There was some suggestion that we might need a different system for 'public good' breeding and to stimulate research on orphan crops. However, it should be noted that if the current, commercially oriented system were to be weakened significantly, the role of the private sector in plant breeding would probably decrease, even for major commercial crops.

- Some participants noted that dominant models of innovation are inappropriate, and that we should be thinking about innovation systems. Innovation is a dynamic process, and requires attention to the interactions and relationships among the various actors in the system.

- There was widespread acknowledgement that the connections between agriculture, plant breeding and science have atrophied. To an extent, this is a result of academic funding and reward structures. There is a need to reinvigorate these relationships, but no clear consensus about how this might be done.

- What might be the role of public–private partnerships in plant breeding for orphan crops? Could they be seen as a productive approach in both developing and developed countries? Arguably, the capacity of the public sector alone is not sufficient to meet current needs.

- It was suggested that in practice, the intellectual property framework for plants has little influence on public sector funding. Would a much stronger or a much weaker IP system fundamentally change public investment? Perhaps the bigger question is whether governments see plant breeding research as a priority and choose to invest in it. What incentives do they need? Growing concerns regarding food and energy security are already resulting in increased public funding for plant science research.

- If environmental protection and natural resource management were actively viewed as a 'public good', would this provide further impetus for government intervention?

Regulation, access and property protection

- It is possible to think of the intellectual property framework for plants as a regulatory system of sorts. Although it is not a regulatory system designed around safety (as is the case for e.g. pesticides, pharmaceuticals), it can have the effect of narrowing the scope of research questions and reinforcing particular approaches. Some participants suggested that in this sense, the existing frameworks are stifling innovation, encouraging incremental improvements in new varieties as opposed to exploitation of the very best scientific and technological tools available.

- Access to materials (including genetic resources) and technologies is an important issue with regards to innovation, and one where the goals of public and private sector research often collide. How can this tension be managed to provide incentives for innovation without undue compromising of research activities in different sectors?

- Open access systems/repositories were described as being particularly useful in the early stages of new research endeavours, but can become problematic at the point where commercial exploitation becomes possible. Private companies can exploit publicly available resources, and then patent the applications derived from this open-source material (the classic 'freeloading' problem).

- The UK Stem Cell Bank was identified as an interesting parallel case with regards to open access for plant/crop germplasm. The Stem Cell Bank acts as a national repository for human stem cell lines, and aims to "supply well characterised cell lines under appropriate and accredited quality systems both for basic research and for the development of clinical applications."[1]

- Participatory breeding programmes (e.g. for potatoes in the Netherlands) often result in much better uptake of the new varieties. But these programmes typically revolve around relationships with individual farmers, and it is unclear whether this approach might be extended to larger groups.

- The push for university researchers to patent their research findings was identified as problematic in a few respects. However, given the current system, some participants asked whether there might be a role for patenting to make sure that particular technologies get developed. (That which is not protected is unlikely to be developed by the private sector.) Are there creative ways that universities might exploit the patent system, not strictly for profit but rather for development purposes?

- Participants agreed that the *sui generis* nature of the PVR system has the advantage of affording opportunity for change that the patent system would not.

[1] From http://www.ukstemcellbank.org.uk/overview_new.html (accessed 27 June 2008).

Appendix 1: Workshop Participants

Name	Institution
Mike Adcock	University of Durham
Andrew Barnes	Scottish Agricultural College
Bernard Le Buanec	International Seed Federation (ISF)
Emma Frow	University of Edinburgh (Genomics Forum)
Matt Hodges	University of Exeter (Egenis)
Steve Hughes	University of Exeter (Egenis)
Bram de Jonge	Wageningen University
Christine Knight	University of Edinburgh (Genomics Forum)
Niels Louwaars	Wageningen University
Denis Murphy	University of Glamorgan
John O'Neill	University of Manchester
Wayne Powell	National Institute of Agricultural Botany
Donald Smith	University of Edinburgh (Genomics Forum)
Bill Spoor	Scottish Agricultural College
Chittur Srinivasan	University of Reading
Steve Sturdy	University of Edinburgh (Genomics Forum)
Joyce Tait	University of Edinburgh (Innogen)
David Wield	University of Edinburgh (Innogen)
Mike Wray	Defra
Steve Yearley	University of Edinburgh (Genomics Forum)

Participant profiles are available upon request; please email Emma Frow (emma.frow@ed.ac.uk).

Appendix 2: Workshop Programme

Workshop on Plant Breeding and Intellectual Property

Tuesday 3 June 2008
ESRC Genomics Forum, Edinburgh

9:45 – 10:15	**Arrival and registration**
10:15 – 10:30	**Welcome and introductions**
10:30 – 11:15	The science and technology of plant breeding Wayne Powell, *NIAB*
11:15 – 11:45	**Tea / coffee**
11:45 – 12:30	Innovation in plant breeding: 'Breeding for a crust and the logjam of rights' Steve Hughes, *University of Exeter (Egenis)*
12:30 – 13:15	Development of the European IPP regime Mike Adcock, *University of Durham*
13:15 – 14:00	**Lunch**
14:00 – 14:45	Protection of plant-related innovation: concerns and current debate in the seed industry Bernard Le Buanec, *International Seed Federation*
14:45 – 15:30	Open session: Short commentaries and additional perspectives from workshop participants (5–10 minutes each)
15:30 – 16:00	**Tea / coffee**
16:00 – 17:30	Discussion and summary
17.30	**Close**
19.30	**Dinner** (drinks from 18.00)

Appendix 3: Summary of Workshop Aims

Plant breeding and intellectual property workshop

Tuesday 3 June, 2008
10am – 5.30pm

Does the current European Intellectual Property Protection regime for plants stimulate or impede investment and innovation?

Innovation in plant breeding and access to plant genetic diversity are increasingly being identified as a desirable (and some would suggest necessary) way to help meet global challenges of climate change, sustainable agriculture, food security and fuel production. Have intellectual property protection (IPP) regimes kept pace with technological, conceptual and contextual changes relating to plant breeding? The science and technology available to plant breeders have evolved considerably since the establishment of UPOV in the 1960s. Trends in public and private investment into plant breeding have also changed markedly over this time. How does IPP fit with current institutional structures and practical approaches to innovation in plant breeding in the UK?

In short, does the current European IPP regime for plants stimulate or impede investment and innovation? What changes in IPP might promote innovation in plant breeding consistent with long-term socioeconomic and environmental goals?

Workshop presentations to address:

- Trends in public and private investment in plant science research in the UK and Europe.
- Advances in the science and technology of plant breeding.
- The process of innovation in plant breeding. (Macro-view of innovation chains and relationships among actors — points of strength/weakness.)
    - Private sector view
    - Public sector view
- Development of the current European IPP regime and (other) mechanisms for protecting or sharing new plant varieties.
- Wider forces and competing interests that shape IPP regimes. (How does European IPP fit in with international approaches to the use of biological resources as outlined in e.g. the CBD or TRIPs agreements?)

Discussion to focus on scenarios for changing IPP regimes, considering the relationship with socioeconomic, environmental and innovation objectives, and current technological capabilities.