

All-Party Parliamentary Group on Science & Technology in Agriculture

Notes of a meeting held on Tuesday 26 January 2016,
Boothroyd Room, Portcullis House

IP and Innovation in Agriculture

Present:

Members

Mark Spencer MP (Chair)
Earl of Selborne

Guest Speakers

Sarah Smith, Research Fellow, Parliamentary Office of Science & Technology (POST)
Peter Button, Vice-Secretary General, International Union for the Protection of New Varieties of Plants (UPOV)
Dominic Muyldermans, Senior Legal Consultant, CropLife International

Stakeholders

Prof Jim Dunwell, University of Reading; Tim Wheeler, DfID; Mark Buckingham, Monsanto; Sez Maxted, NIAB Trust; Nicki Curtis, Intellectual Property Office (IPO); Andy Mitchell, Defra; Wendy Gray, CPA; Tori Morgan, NFU; Alex Turvey, IPO; Faith Bannier, IPO; Liz Elmhirst, D Young & Co; Jon Knight, AHDB Horticulture; Robert Howsett, Sainsburys; Elizabeth Scott, NIAB; Elspeth Nicol, Defra; Pete Border, POST; Prof Ruth Soetendorp, IP Awareness Network; Chris Peters, Sense About Science; Neil Hipps, University of Kent; Calum Murray, Innovate UK; Chris Green, Green Resources Ltd; Ian Crute, AHDB; Richard Summers, RAGT Seeds; Nigel Moore, KWS SAAT SE; Penny Maplestone, BSPB; John Bingham, retired wheat breeder; Dominic Berry, University of Edinburgh; Dr Jon Clarke, John Innes Centre; Cecilia Buffery, Kew; Duncan Barker, DfID; Daniel Pearsall, Group Co-ordinator

1. Welcome & Introduction

Mark Spencer (MS) welcomed Members, guest speakers and stakeholders to the meeting, and introduced the topic – *IP and Innovation in Agriculture* – as a critical issue for continued research and investment in the agri-tech sector. He observed that the session was particularly timely as novel breeding products and technologies brought renewed focus on the application and compatibility of different forms of IP, and the All-Party Group was fortunate to welcome leading international experts on the panel to discuss these issues. He noted that the meeting also coincided with the publication of a new POST note on this issue by the Parliamentary Office of Science & Technology, and invited the author, Sarah Smith, to summarise her work as an introduction to the topic.

2. Guest speakers

[Please note that speakers' slide presentations are available to download via the meetings section of the All-Party Group web-site at www.appg-agscience.org.uk]

Sarah Smith, Parliamentary Office of Science & Technology (POST)

Sarah Smith (SS) provided an overview of the issues covered in the recently published POST note on 'Intellectual Property in Plants', focusing on the two main systems of IP used

to protect and reward innovation in crop improvement – Plant Variety Rights (PVR) and patents.

SS explained that PVR is a specific form of IP protection used in the plant breeding industry, enabling rights holders to prevent others from propagating, reproducing or commercialising their unique new varieties, while also providing for a breeders' exemption allowing protected varieties to be used as parental material in further breeding programmes.

SS described PVR as an open access system promoting the use of protected germplasm for continued development and innovation.

SS noted that discussion is taking place over the technical criteria used to determine whether a variety is genuinely new and distinct from other known varieties, particularly in the ornamental sector.

A more significant issue in this area, however, is the move towards increased use of patents in plant breeding, not only in relation to GM crops but also in conventionally bred varieties.

SS explained that the European patent system is overseen by the European Patent Office (EPO), which is not formally an EU institution but aligned with the European Patent Convention (EPC).

Under the EPC, plant varieties are exempt from patenting, as are 'essentially biological processes for the production of plants'. The legal basis for this second exemption was clarified last year in the so-called tomato and broccoli cases, involving tomatoes with reduced water content and broccoli with increased glucosinolates for improved nutrition.

While original patent applications for the processes used to develop these crops were refused, on appeal it was determined that although the biological processes (ie conventional breeding methods) themselves could not be patented, it was possible to patent the products of those processes. SS noted that these decisions have proved controversial, with the legal clarification welcomed by some as providing an incentive for investment and innovation, but others opposed, including the European Parliament which has called on the EPO to stop awarding patents on conventionally bred crops and plants.

Other specific issues associated with the use of patents in plants concern transparency and licensing – how to determine whether a particular trait or seed is covered by a patent and how to be able to breed using that material.

SS noted that various initiatives were being developed to support greater transparency in this area such as the European Seed Association's PINTO database of patented traits, while a licensing platform had been established for vegetables allowing members to reach reasonable and fair licensing agreements when using patented material.

SS also described progress towards a new unitary patent system for EU member states, providing a centralised court for taking decisions and resolving disputes in relation to patents and their application.

SS noted that other related issues raised during her research for the POST note included whether IP could be driving market consolidation in the seed sector, preventing access to genetic material or making innovation unaffordable for smaller operators and public sector researchers.

Peter Button, International Union for the Protection of New Varieties of Plants (UPOV)

Peter Button (PB) opened his presentation by highlighting the positive contribution of scientific plant breeding in recent decades. This included dramatic improvements in the production of major food crops such as wheat – French wheat yields, for example, had increased seven-fold from 1 tonne/ha to 7 tonnes/ha since the mid-20th century.

PB cited new research into the economic, social and environmental value of plant breeding in the EU, which indicated that between 2000 and 2013, the additional agricultural GDP attributable to plant breeding amounted to €8.2 billion, and that without plant breeding the EU would have moved from being a net exporter to net importer in all major agricultural crops, including wheat and barley. The research also concluded that without plant breeding, an additional 18 million ha of arable land would be needed to match current EU production levels, equivalent to the combined arable land of the Netherlands, Belgium, Ireland, Portugal and Spain.

Turning to the importance of intellectual property rights in supporting plant breeding innovation, PB highlighted the wide range of factors plant breeders must combine when developing a successful new variety, from plant architecture and growth habit to disease and pest resistance, agronomy and end-use quality – a process typically taking 10-15 years.

PB explained that UPOV was established to encourage the development of new varieties of plants for the benefit of society. The UPOV system works by granting a specific form of IP protection – Plant Variety Rights – based on the value and unique characteristics of each new variety. PB noted that having started out 50 years ago with just a handful of European countries, UPOV is now a global system, with 74 members around the world, and a further 40 countries and organisations either in the process of establishing a PVR system or in contact with the UPOV office.

Demonstrating the positive impact of PVR protection, PB pointed to the example of Canada, which introduced a PVR system in 1991. A 10 year impact study showed that investment in plant breeding doubled from \$34m to \$68m, yields increased significantly (wheat 21%, canola 24%, peas 32%), while net exports of processed potato products also rose dramatically (from \$213m in 1992 to \$714m in 2007) because the Canadian industry could access the most globally important potato varieties.

The introduction of a PVR system in Kenya also supported an 8-fold increase in the value of cut flower exports, primarily because it allowed access to the best European varieties and opened up high quality markets for the first time to Kenyan growers.

PB added that having access to protected varieties through the UPOV system also allowed use of those varieties for breeding through the breeder's exemption – a key element of the PVR system in supporting continued innovation. For example, the development of a domestic rose breeding sector with access to the best international varieties helped convert Korea from a net royalty payer into a net royalty earner in the space of 12 years.

Looking ahead to potential barriers to IP and innovation in agriculture, PB highlighted the need to challenge negative perceptions of intellectual property rights, focusing on the demonstrable benefits for society. Similarly, the combined challenges of sustainability and climate change would not be addressed without access to modern, hi-tech agriculture, and again this would mean presenting a more enlightened view of how science-based activities such as plant breeding have helped transform agricultural productivity.

PB noted that a further issue identified in the POST note concerned access to genetic resources, whether in terms of patented traits or new international arrangements to conserve biological diversity. He emphasised that the development of these issues would require

vigilance and action by the industry, stakeholders and governments to secure outcomes which were mutually supportive and beneficial to society.

Dominic Muyldermans, CropLife International

Dominic Muyldermans (DM) highlighted the importance of new technology and innovation in agriculture to address the urgent global challenges of food security and climate change, noting that efforts to safeguard and encourage the development of new crop varieties and traits – particularly since the advent of advanced genetic solutions such as trait development and GM - would require an effective balance of both PBR and patent rights systems.

DM emphasised the time and resources required to bring crop innovations to market - US\$136m and 13 years in the case of a new GMO trait. This reflected both the research effort and the extensive regulatory processes involved. Effective IP was needed through an all-encompassing system of patents and plant variety protection since individual traits, available for use in many different varieties, could not be protected through PBR.

DM explained that in addition to traits the patent system could also provide protection for certain processes associated with trait development, as well as emerging technologies such as gene editing which offered wider applications beyond agriculture in the healthcare and industrial biotech sectors.

DM noted that discussions over the patentability of native traits and the recent tomato and broccoli cases had triggered a political debate in Europe over the balance between different IP systems in plants, including an expert group looking at the Biotech Patent Directive. But he cautioned against calls to re-open the Directive, which would endanger all biotech sectors – red, green and white - by creating uncertainty. The lack of a stable and predictable patent framework for biotechnological inventions could also lead to increased use of trade secrets, driving new knowledge underground and undermining the social contract associated with the disclosure obligation in the patenting system.

DM suggested that the debate over patentability of native traits was also linked to wider questions of how modern agriculture and the concept of 'naturalness' are perceived. While native traits are indeed obtained from natural sources, the identification and development of promising traits into material for use in commercial breeding programmes is a hi-tech, resource-intensive process, and DM argued that a native trait which complies with patentability criteria should be patentable. DM noted that between 1995 and 2013, the European Patent Office only granted 71 patents to such innovations because the threshold for patentability, for example in distinguishing between an invention and a discovery, is very high and rigorously applied.

Turning to the EBA tomato and broccoli decision of March 2015, DM noted that this ruling had clarified that products developed through essentially biological processes can themselves be patented when patentability criteria are met. This was important in providing an incentive for continued investment and research to support innovation and added value for Europe's farmers.

DM acknowledged that these developments had prompted concern among breeders over the use of varieties incorporating patented traits in breeding programmes, and this in turn had led to the introduction of a limited breeder's exemption in the single unitary patent system and in the national patent systems of Germany, France, the Netherlands and the UK.

DM also highlighted the industry-led initiatives taking place to improve transparency and licensing, such as the European Seed Association's PINTO database, and plans to extend the multilateral licensing platform for vegetables to other crops. He suggested that these

programmes were intended to give breeders the confidence to work with patented traits, again highlighting the synergy between patents and plant variety protection, and the need to strike an effective balance between both forms of IP to support continued innovation in crop improvement.

DM concluded by describing CropLife's IP52 campaign (www.IP52.org) to raise awareness of IP, using videos and infographic storyboards to highlight the positive role of intellectual property and its contribution to society.

The IP52 campaign included an economic impact study of Ogura, a non-GM hybrid oilseed rape breeding system developed by public sector researchers at INRA in France. Following upfront investment by INRA of €56 million in the development of this technique, patent protection enabled the institute to recoup its investment within 15 years as adoption of Ogura hybrids – offering 6-10% higher yields – increased to 83% of the OSR market in France. This study not only demonstrated the importance of IP protection in stimulating and rewarding successful innovation, but also highlighted the socio-economic contribution since 75% of the benefits related to Ogura accrue to farmers and consumers. DM noted that this further underlined the need to distinguish between an economic monopoly and a technological monopoly in understanding the positive contribution of IP rights.

3. Questions and discussion

The following key points arose during discussion:

Lord Selborne suggested that the central objective of the Nagoya Protocol was not to protect the interests of plant breeders, but to ensure that countries with valuable genetic resources are suitably rewarded when they are taken for financial gain. Historical examples, such as the transfer of rubber plants from Brazil to British colonies in Malaya, suggested that this had not always been the case, and governments had every right to negotiate hard with plant breeders to secure their birthright.

PB agreed that the objective of these treaties served a very positive purpose in seeking to conserve global genetic resources and diversity. The critical issue was to make sure that they work when implemented, that the resources are conserved and that the benefits flow to these countries – but that would only happen if the resources are used rather than locked up in an administrative logjam.

DM added that a further issue of concern was the degree of misunderstanding over the scope of the Nagoya Protocol and whether it could affect the use of existing varieties, which would undermine the objective to provide access and benefit sharing for natural germplasm.

Ian Crute (AHDB) considered that, on balance, patenting traits was contrary to the objectives of innovation. He cited the example of disease resistance traits in wheat and barley and the ability to characterise and isolate them, which should accelerate breeding innovation but instead patenting has impeded their use in conventional breeding programmes. The prevailing view that patents should be filed and licences negotiated was not the best way to deliver public benefits, particularly for minor crops.

DM observed that regulatory constraints also represented a major barrier to innovation and effective exploitation of these traits.

Dominic Berry (University of Edinburgh) suggested that the breeder's exemption and open access to protected material provided through the PVR system was being undermined by the encroachment of patenting. He considered that the two systems could not be synergised, and that patenting should not only be presented in terms of stimulating investment, but also

in terms of adding costs to plant breeders and plant scientists concerned about possible patent infringement, such as the resources needed to develop the PINTO database. He added that the important point in relation to the Convention on Biological Diversity is not necessarily that the material gets used, but how it is used, who by, and that its commercialisation delivers benefits to society.

DM emphasised the importance of facilitating private sector access to genetic resources as this was the business model and route to market for research, investment and delivery of crop genetic innovation.

PB indicated that control over how genetic resources are used lies with the country which owns the germplasm, and that he viewed the treaties and PVR as synergistic by making the genetic resources available on the one hand and providing an incentive to exploit them on the other. He added that UPOV does not oppose the use of patents because it is a form of IP rights which exists to benefit society.

Ruth Soetendorp (IPAN) highlighted the importance of education in presenting IP issues to the next generation of agriculturalists and scientists, for example through agricultural colleges and universities. PB agreed that raising awareness and encouraging a more positive view of IP was a major challenge for all stakeholders.

Chris Green (Green Resources) highlighted the difference between access and acceptance, expressing concern that regulations are not keeping pace with rapid developments in breeding technology. While PBR had served the plant breeding industry very well over the past 50 years, he questioned whether that would be the case for the next 50 years.

PB indicated that the breeding industry would continue to develop and bring to market entire plant varieties, as a package of traits and not as individual traits. The basic elements of PBR would therefore hold true for the future, although some fine-tuning of the UPOV Convention may be required.

Mark Buckingham (Monsanto) emphasised the high levels of investment and rigorous patentability criteria required to develop a patented trait, reflected in the relatively small number of patents awarded in relation to plant-related innovations in Europe over recent years compared with thousands of PBR protected varieties. While the opportunity did exist for an organisation not to make a patented trait available this would make no economic sense, since the value of a patented trait is derived from its use across a multitude of different varieties.

John Bingham highlighted the major challenges facing UK plant breeders in the context of a growing UK population and high grain import dependence, emphasising the importance of maintaining a strong relationship and flow of breeding material between the plant breeding industry and the public sector science base. PB noted that the UK was very fortunate in terms of the interaction between private sector breeders and the science base, and this was not always the case in other countries. This highlighted the importance of raising awareness of the societal benefits of IP and ensuring it was not perceived as opposed to the interests of the public sector.

Calum Murray (Innovate UK) asked whether there was a clear legal definition of a patentable trait, for example whether it was determined at the molecular or phenotypical level.

DM explained that it was not possible to patent a variety or simple description of a discovery – patentability required a high threshold of inventiveness, for example where the identification and isolation of a gene sequence conferring a specific trait included a new technique. Ian Crute added that most applications for patents on ‘in situ’ novel traits had

failed – successful filings mainly related to isolated gene sequences which bring about a particular characteristic when introduced into a plant not previously expressing that trait.

CM reiterated his concern that the lack of a clear legal definition of what constituted a patentable trait could affect the innovation process and the advice provided by organisations such as Innovate UK on the fastest and most effective route to market.

Nigel Moore (KWS) explained that while KWS' core activities are based on conventional breeding, the company is also investing for the future in novel breeding techniques and applications, and therefore has an interest in both the PBR and patent-based business models. He considered that the level of investment and rate of improvement required to address the challenges of population growth and climate change would not be met by PBR-based systems alone. He therefore welcomed the EPO ruling in the tomato and broccoli cases in helping to clarify the definition of patentability as regards plant-related innovation, adding that future plant breeding innovation would require synergy between PBR and patenting systems and precisely the kinds of initiatives being taken to support that process and finance the optimum level of research and innovation – eg introduction of limited breeder's exemption and development of patent database and licensing platforms.

Jonathan Clarke (JIC) suggested that one of the positive consequences of the changes taking place between PBR and patent-based systems could be to transform the traditional ownership of plant varieties and bring new sources of finance to plant breeding by supporting greater involvement from other sectors of the value chain such as primary processors, food and drink manufacturers, and retailers.

Tori Morgan (NFU) noted that in addition to the breeder's exemption under PBR, the farmer's exemption currently enabled farmers to save and plant seed on their own holding. She asked whether farm-saved seed would be permitted under a patent-based system and whether farmers would face higher seed or royalty costs.

DM explained that farm-saved seed was not permitted under the patent system simply because it would dilute and undermine the value capture process and therefore lead to higher seed prices set by the developer of the technology. This ran counter to the innovation process and would ultimately deny farmers access to the improved technologies they need to maintain their productivity and competitiveness.

Concluding the meeting, Mark Spencer MP thanked speakers and attendees for their contribution to a stimulating and informative session.