Elements of Intellectual Property Protection in Plant Breeding and Biotechnology: Interactions and Outcomes

Stephen Smith, Sergio Lence, Dermot Hayes, Julian Alston, and Eloy Corona

Stephen Smith DuPont Pioneer, 7300 NW 62nd Ave., Johnston , IA, 50131, (Stephen.Smith@Pioneer.com); Sergio Lence, Department of Economics, Iowa State University, 368E Heady Hall, Ames, IA, 50011. (shlence@iastate.edu); Dermot J. Hayes, Department of Economics, 568CHeady Hall, Ames, IA, 50011. (dhayes@iastate.edu); Julian Alston, Agriculture and Resources Economics, 2157 Social Sciences and Humanities, University of California, Davis, 95616.(julian@primal.ucdavis.edu); Eloy Corona, Bayer CropScience LP, 2 TW Alexander Drive, Research Triangle Park, NC, 27709. (eloy.corona@bayer.com).

Abbreviations: R&D, Research & Development; IPP, Intellectual Property Protection; PVP, Plant Variety Protection; IP, Intellectual Property; PBR, Plant Breeders' Rights; TRIPS, Trade-Related Aspects of Intellectual Property Rights; EU, European Union; WTO, World Trade Organisation; UPOV, L'Union internationale pour la protection des obtentions végétales; OAPI, African Intellectual Property Organization; EDV, Essentially Derived Variety; NPGS, National Plant Germplasm System; SMTA, Material Transfer Agreement; IT-PGRFA, International Treaty for Plant Genetic Resources for Food and Agriculture; TPE, target production environment.

ABSTRACT

Public and private investments in plant breeding have a proven track record of increasing agricultural productivity and thereby significantly contributing to economic well-being or social welfare. Substantial investments in Research and Development (R&D) are required before a new plant variety can be developed and released, which the private sector can only recoup through commercial sales coupled with property rights. We previously published outcomes from economic modelling, implementing different categories and hypothetical variants of Intellectual Property Protection (IPP) in the field of plant breeding and biotechnology. Our goal here is to portray these outcomes in a manner and using examples that will be more immediately familiar to the plant breeding and policy making communities. We found that Plant Variety Protection (PVP) and utility patents played important and complementary roles in promoting and adopting innovation. Voluntary licensing under patents had a major contribution to social welfare. Periods of protection much longer than the current life-span of a utility patent did not contribute maximally to the stock of social welfare. We performed a reality check comparing different types of innovation and assessment of time/risk to commercialization. We hope that this information can contribute to more effective implementation of IPP to further promote genetic gain and thus enable commercially funded plant breeders to maximally contribute to the benefit of society on a global basis.

Introduction

Public and private investments in plant breeding have a proven track record of increasing agricultural productivity and thereby significantly contributing to economic well-being (Fehr 1984; Frisvold et al., 1999; Duvick, 2005; Rubenstein et al., 2005; British Society of Plant Breeders, 2010). The application of intellectual property protection (IPP) in the field of plant breeding and biotechnology is an issue of abiding interest to many including those in academia, business, private and public sector research, policy makers, and non-governmental organizations (NGOs). For example, see Leskien and Flitner (1997), Bioversity International (1999), Cohen

(2000), Rai and Mauria (2004), UPOV (2005), Llewelyn and Adcock (2006), World Bank (2006), Wright (2006), Tripp et al. (2007), Louwaars et al. (2009), SGRP (2010), Dutfield (2011), UN HRC (2011), Blakeney (2012), ISF (2012), JIC (2012), Lieberherr and Meienberg (2014).

Means to Obtain IPP in Plant Breeding and Biotechnology

There are four major approaches that plant breeders can use to obtain IPP. These are: 1) contracts, 2) trade secrets, 3) Plant Variety Protection (PVP) or Plant Breeders' Rights (PBR), and 4) Utility Patents. The United States also provides PVP-type protection for varieties of asexually reproducing non-tuberous species through the 1930 US Plant Patent Act (35 U.S.C.§§ 161-164). Contracts include bag-tag "shrink-wrap" type protection or use in contractually "closed-loop" systems. Trade secrets can help provide protection, particularly for parent lines of hybrids. The biology of hybrids also encourages farmers to annually purchase new seed because the harvested seed is a result of one generation of inbreeding which reduces yield potential.

Under the 1995 Trade-Related Aspects of Intellectual Property Rights (TRIPS), member countries may exclude plants and animals from patentability. For example, utility patents on plant varieties *per se* are not available in the European Union (EU) although utility patents around genetically modified traits and native traits are possible in that region. Countries that exclude plants from patentability are obliged by their membership of the World Trade Organisation (WTO) to provide an effective *sui generis* IPP system; e.g., PVP. WTO members may also exclude "essentially biological processes for the production of plants" from patentability. PVP is a *sui generis* form of protection prescribed by the L'Union internationale pour la protection des obtentions végétales (UPOV). As of June 2015, there were 72 UPOV members (UPOV, 2015); two of which (the EU and the African Intellectual Property

Organization [OAPI]) are intergovernmental organizations (UPOV, 2014)(http://www.upov.int/members/en/). In addition to PVP Acts that are sanctioned as compliant with UPOV, other countries either have, or are in the process of enacting variety protection laws, some of which may or may not be UPOV-compliant (e.g., Plant Protection Variety and Farmers Rights Act of India).

The two most recent UPOV Conventions are dated 1978 and 1991, although new members can only join under the 1991 Convention. The primary differences between the two Conventions are that UPOV 1991 additionally: 1) extends to all varieties and species, 2) prevents others from producing, reproducing, or conditioning for the purpose of propagation, importing, exporting, stocking, and offering for sale, 3) introduction of the concept of an Essentially Derived Variety (EDV) where IPP ownership resides with the breeder of the initial variety, 4) optional farmers exception only for use on same farm and may be subject to license fee; private use and research allowable; 5) 5 years extension of duration of protection, and 6) double protection by both PVP and patents allowed (Dodds et al., 2007). (.http://www.iphandbook.org/handbook/ch04/p06/. Accessed Aug 13th 2015.

Patent laws may be country or regionally specific. In some countries and regions plant varieties *per se* (e.g., Europe) are not patentable, whereas in others, including Australia, Canada, and the United States, they are. Nonetheless, even if plant varieties *per se* are not allowable as patentable subject matter, methods of breeding, production, harvested material, native or genetically modified traits may remain eligible as patentable subject matter. Further variations in country or regional patent law can also include exceptions. For example, patent laws implemented in France and Germany have exceptions to allow further breeding with a variety that has a patented trait, including commercialization of a progeny variety provided that patented traits have been removed. In contrast, US patent law has no such exceptions.

Eligibility for utility patent protection requires evidence of i) utility, ii) novelty, iii) "non-obviousness" i.e., include an inventive step beyond that which could be conceived by a person having "ordinary skill in the art", and iv) enablement, (i.e., described to allow the invention to be recreated for observation and evaluation with regard to the patent *per se*). Complete written descriptions are not possible for plant varieties so enablement is established through a seed deposit maintained by an appropriate depository such as the American Type Tissue Culture Collection. It is important to understand that a deposit of biological material is "not a grant of license… to infringe the patent" and "the release of biological material from the depository to others does not grant them a license to infringe the patent" (Harney and McBride, 2007). Patentable subject matter is provided into the public domain at the expiration of the protection period as a "pact with society" in return for the grant of limited exclusivity by the patent holder (Comments, 2007). For further details on exclusions from patentability including country status see http://tinyurl.com/d5knqoo. More complete reviews of IPP methods are provided by Williams and Weber (1989), Jondle (1993), Hayes and Riley (2002), Krattiger (2004), Le Buanec (2004), CAMBIA (undated) available at http://www.patentlens.net/daisy/patentlens/1234.html, and Pardey et al. (2013). The International Seed Federation recently completed a revision of its position on IP (ISF, 2012). Helfer (2004) provides comprehensive information describing international legal regimes and policy options for intellectual property rights in plants.

Previous Economics Based Analyses of IPP Systems in Plant Breeding

Substantial investments in R&D are required before a new variety can be developed and released (Evenson, 1989; Evenson and Gollin, 1997) which the private sector can only ultimately recoup through commercialization and property rights. Kolady and Lesser (2009) and Naseem et al. (2005) found that privately funded PVP'd wheat varieties grown in Washington State and PVP'd US cotton varieties, respectively contributed to improved productivity. In the U.S., PVP may have stimulated public, but not private sector investments in wheat breeding (Alston and Venner, 2002). There was no evidence that privately funded PVP'd wheat varieties had stimulated increased genetic gain in US wheat production (Alston and Venner, 2002). A relative lack of incentives for private sector wheat breeding in the U.S. is likely associated with the lack of any requirement in the US PVP Act for PVP holders to recoup royalties for use of farm saved seed. For example, the replanting and "brown bagging" of seed harvested from PVP'd self-pollinated varieties of wheat, without royalty payment contributed to the exit of much of private industry from hard red wheat breeding in the U.S. (Grace, 2008). During 1990, both Pioneer and Cargill discontinued breeding of hard red winter wheat in the U.S. because production and sales were not profitable: Pioneer donated wheat germplasm to Kansas State University which represented the culmination of 20 years of privately funded research (Knight-Ridder, 1990). The USDA Wheat Baseline, 2008-17 updated March 12, 2008 said: "The pace of genetic improvement has been slower for wheat than for some other field crops, resulting in little growth in wheat yields. Genetic improvement for wheat has been slower because of genetic complexity and because of lower potential returns to commercial seed companies, factors that discourage investment in research." In contrast, Hayes et al. (2009) showed a positive effect of PVP for genetic gains in UK and French wheat production as a result of privately funded breeding when associated with royalty payments by farmers when harvested seed of protected varieties was used to sow the next season's crop. Likewise, Alston et al. (2012) suggested that Australia's end-point royalties system had increased private sector investment in breeding. ISF date showed higher sustained wheat yields for countries where private sector wheat breeding is a competitive business (France, Germany, U.K.) compared to countries where wheat breeding remains largely in the public domain (Argentina, Australia, Uruguay, United States). Swanson and Goeschl (2005) showed that hybridity had a similar result as effective IPP on increased productivity as a result of privately funded breeding. Kolady et al. (2012) showed that yield trends in India for maize and pearl millet had outpaced those for the development of self-pollinated varieties of rice and wheat. Lence and Hayes (2005) showed that R&D firms had reduced incentives to develop technologies for use in other countries where they can be easily adopted as a result of non-existent or ineffective IPP. They concluded that effective IPP in both countries would allow firms to conduct relevant research in each country. This conclusion has particular relevance to the field of plant breeding and agriculture where there is a very large element of genotype x environmental interaction thereby placing a premium on research and development being conducted *in situ*. Hayes et al. (2009) showed a positive association between strength of IPP and rate of genetic gain. Moschini and Yerokhin (2008) showed that when research was risky or expensive, then an IPP system with a research and commercialization exception would undermine incentives to undertake that type of research.

Use of Modelling

A modelling approach is customary where experimental approaches are impractical, very expensive, lengthy, or impossible. Modelling facilitates an understanding of complex interactions, can identify "best management" practices, and study long-term effects of undertaking various options. Models can provide predictions and improved understanding

(Thornton and Herrero, 2001; 2008). Modelling is not a substitute for research-based enquiry; rather it is an integral component of developing hypotheses for further testing. Modelling has been widely used in helping to research the physiology and genetics of complex traits in maize (Tuberosa, 2012; Shekoofa et al., 2014), and formed the basis for developing hybrids with improved native-trait based drought resistance (Cooper et al., 2014). Economists have also used modelling to investigate the attributes of various IPP systems (Lence et al., 2015). Nonetheless, a combination of IPP subject-matter and usage of a highly mathematical language may lead to a degree of opaqueness, especially to those engaged in other fields of endeavor. Consequently, practitioners in the field of plant breeding and biotechnology may prefer a more accessible description of the IPP economics studies, results, and conclusions. The objective of this paper is therefore to describe recent IPP economics research (Lence et al., 2015) in a way that can allow a greater understanding and basis for further enquiry for those interested in IPP with regard to plant breeding and biotechnology.

Research Methodology: The Conceptual Framework

The two most widely available approaches used by plant breeders to obtain IPP are PVP and utility patents and these were chosen as the main pillars of the model. Of these, PVP is the most used by plant breeders globally to protect varieties *per se*. On a practical basis, these two forms of IPP were chosen as pillars of the model primarily because of the large differences in protection and dissemination of the protected material afforded under each system (Table 1). Establishment of a model built upon the framework of two very different approaches to IPP provided a breadth of scope where outcomes of contrasting models, e.g., with different durations of protection, or with different periods under which breeder exception might apply, could also be investigated.

Describing the Model

Each of several plant breeding companies optimizes its research program based on the strength and length of IPP. Every firm can capture the benefits resulting from its own research in the period after it was undertaken. In subsequent periods, firms continue to conduct research, and the productivity of this research is determined in part by the amount of research conducted in the previous or prior periods. With utility patents, a firm may be prevented from accessing competitor research in subsequent periods until the patent protection expires, whereas under PVP alone firms have access to the commercial products resulting from other firms' research. Firms anticipate this trade-off between strength of their own IPP and accessibility to others' innovations when making their research investment decisions. We then introduced modifications to these basic models and made additional comparisons to provide a more comprehensive investigation of the components affecting IPP and the resultant development and spread of benefits (social welfare) in the form of improved agricultural production achieved *via* genetic gain.

The Costs of Acquiring Genetic Stocks

In this model, the costs of acquiring genetic stocks must be taken into consideration. The costs of acquiring events for development of GMO-traited varieties follows a similar logic although these will include not only development costs, but also regulatory costs. The possible sources of genetic stocks, native traits, or GMO traits are i) the firm's own genetic stocks, ii) genetic stocks developed by other firms if available, and iii) other more exotic and less immediately well adapted germplasm, including the development of new transgenic events sourced from other species or genera. If protection is under PVP alone then the commercialized genetic stocks of one firm are available to others for breeding during the commercial life of the variety with commercial rights available to the second breeder, unless under UPOV 1991 that second variety is essentially derived. Also, under PVP, it is the policy of the USDA to make publicly available parental lines of hybrids at the end of their PVP period. These inbreds are then available in the global public domain *via* distribution by the National Plant Germplasm System (NPGS). Such provision of access following expiration of PVP is not the mandate of UPOV, nor is it the practice of most other countries.

Under protection by utility patents, there is a period of exclusivity (20 years from filing in most countries) during which time the owner can restrict research and commercial use by others or can grant specific forms of use *via* licensing agreements. At the expiration of patent protection, the variety is available in the public domain. However, where off-patent subject matter includes genes or varieties that remain subject to regulatory requirements then those requirements will still need to be satisfied. In the United States, there is a voluntary agreement and process in place (the AgAccord) (http://www.agaccord.org/) to facilitate the continuance of regulatory requirements post-patent although significant costs will be involved to maintain regulatory approvals, especially on an international basis (Jefferson et al., 2015).

Other potential sources of genetic stocks include accessions conserved *ex situ* in genebanks or found *in situ* either under cultivation or as wild or weedy species. Many genebank accessions can be accessed from the US NPGS or from other genebanks including those of the Consultative Group on International Agricultural Research (CGIAR) such as the International Maize and Wheat Improvement Center (CIMMYT), the International Rice Research Institute (IRRI), and the International Center for research in the Semi-Arid Tropics (ICRISAT) each make materials available through a multilateral system using the standard Material Transfer

Agreement (sMTA) of the International Treaty for Plant Genetic Resources for Food and Agriculture (IT-PGRFA). Contractual terms in the present sMTA are currently under review by the Governing Body of the Treaty. Nonetheless, significant improvements remain to be made regarding accessibility of germplasm from genebanks. Bjornstad et al. (2013) reported that of seed requests sent to 121 countries, seeds were received from only 44 (36%). Additional germplasm may be available on a bilateral basis once countries have implemented biodiversity laws under the auspices of the Convention on Biological Diversity (CBD).

There are usually considerable technical challenges that must be met before exotic germplasm can be practically useful in a plant breeding program. Material may not be well characterized making choice of accessions an immediate challenge. Exotic germplasm is usually not well adapted to grow or even to set seed in a different target production environment (TPE). Consequently, years of adaptation and pre-breeding may be required before any potential for improving the already widely-used genepool can be ascertained. The costs of accessing and using genetic stocks increase as the amount, time, and risk level of research increases. These costs decrease as the supply of genetic stocks increases, the stocks become better characterized and adapted, and they become nearer in the research and development “pipeline” to commercial release. Sourcing options in order from least to most risky or expensive include, i) a firm’s own germplasm and thus freely available, ii) germplasm available from others e.g., sourcing commercially available varieties that are not protected by utility patents including via the breeder exception of PVP, following the expiration of utility patent protection, or following expiration of PVP in circumstances where parental lines are made publicly available (e.g. as practiced in the U.S. but not generally so elsewhere), iii) *via* licensing, iv) *via* a genebank, a prebreeding consortium, or v) from an *in situ* location (e.g., on farm or wild and assuming all access and benefit sharing responsibilities have been met..

The Measure of Success

The metric used for measuring success as a result of plant breeding was optimal genetic innovation which we equated with optimal social welfare. We made this connection on the basis that improvement of agricultural production through genetic gain and the improved protection of that genetic potential in the face of biotic and abiotic stresses is basic to public policies that seek to improve social welfare as a result of improved health and nutrition of consumers.

Results from Modeling

Two Key Parameters

Results were sensitive to two key parameters. The first was parameter γ, which measured the degree to which previous genetic research reduced the cost of, or levered, the ability to obtain genetic improvements in a particular period. Projects that required a high degree of prior research had a high value for γ. Intuitively, γ can also be understood as a measure of the degree of research complexity. The second key parameter was $(1 - \rho)$, the rate at which genetic improvements depreciated. Comparisons of various IPP approaches will be presented in the text. Readers who might also like to review results figuratively are directed to Lence et al. (2015).

Comparing PVP and Patents

PVP and patents were complimentary in their potential contributions to genetic gain and social welfare. Patents provided more potential for higher optimal genetic innovation than PVP due to the ability of patent holders to prevent unlicensed access for further breeding and commercial use during patent life. In contrast, PVP provided a moderate level of optimal genetic innovation coupled with faster horizontal spread of innovation among companies *via* the breeder exception. Under PVP, commercialization of new varieties is only limited under UPOV 1991, and then only when a derivative inbred line or variety which has met DUS requirements is also then determined to be essentially derived. Breeding and commercial development under the breeder exception of UPOV of PVP is an example of the horizontal diffusion of research results (Swanson and Goeschl 2005). Thus, PVP allows short- lived commercial varieties to achieve genetic gain and contributes to social welfare by ensuring that these varieties reach as many other breeders as possible even before protection on these varieties expires.

Changing the Length of Utility Patent Protection

Patent terms usually run for 20 years. Lence et al. (2005) had previously shown that, in terms of optimizing social welfare, there was an optimum patent life with regard to the contribution of plant breeding, of just longer than the 20 tear term. Extending the term of patent life much further than the 20 year protection period began to undermine overall contributions to social welfare because of a reduction of timely diffusion into the public domain. When shorter patent terms were investigated, a protection period of 10 years contributed more to social welfare than did a 5 year period of protection unless there was an extremely rapid depreciation rate for the innovation coupled with a low degree of specialization or research complexity (γ).

The Effect of Reducing the Time Needed to Create a Variety under PVP

Except for scenarios with low research complexity (γ) or high depreciation rates ($1 - \rho$), a reduction in PVP time reduced welfare and genetic gain. This was because firms would know that their competitors would be able to build upon their research program at an earlier date, and thus reduced their incentive to undertake risk during research. Reducing the time to generate a new variety accelerated diffusion of that new variety and thus the PVP system with shorter protection period led to greater genetic gain or social welfare in circumstances where varieties had a short shelf life. The base case PVP with a longer protection time led to increased genetic gain and more social welfare when specialization was important and for long-lived varieties.

All things being equal, the completion of more breeding cycles per unit time should be expected to contribute positively to genetic gain, and thus to social welfare. However, if reduced cycle times become associated predominantly or only with breeding strategies that make relatively minor genetic changes using only well-adapted germplasm then there could be risks of narrowing the widely-used and well-adapted gene pool and so reducing medium-longer-term potential to increase productivity.

The Effect of a Prolonged Period (Beyond Current PVP and Patent Terms) of Prohibition of Public Access

Potentially, when maintained as a trade secret competitors can never access the original science whereas utility patents allow for inventions to be available to the public once the patent term expires. Even when hybrids are protected solely by PVP, the preference is to breed using parental lines per se in order to develop next cycle inbreds with predictable combinations to maximize hybrid vigor. However, most countries implement PVP, with the notable exception of the U.S. in a way that allows owners of parental lines to maintain those lines as trade secrets beyond the life of PVP protection. In contrast, the U.S. implements PVP by releasing parental inbred lines into the public domain at the expiration of their PVP *via* the USDA National Plant Germplasm System (NPGS). Varieties and inbred lines protected by utility patents are also available to the public following expiration of patent protection.

There was a large set of research complexity (γ) and depreciation combinations where patents with a specific termination date contributed more to social welfare compared to trade secrets with protection lasting well beyond a regular patent term. IPP afforded by utility patents and PVP as implemented in the U.S., which provides inventions into the public domain at the expiration of their IPP term(s), added more to social welfare than if firms were instead to use a policy of prolonged trade secrets. Use of utility patents also facilitated licensing. Licensing was less feasible, if not impractical, with trade secrets as the sole form of protection.

Use of Utility Patents with Licensing

Licensing increased genetic gain and social welfare for a large set of research complexity (γ) and depreciation combinations. Licensing allowed society to more quickly access new inventions in a similar fashion to PVP, but, unlike PVP a system of patents with licensing provided greater rewards to the firm that created the technology by way of license fees and the firm's ability to restrict use by others during the patent term. Patents plus licensing maintained an incentive to conduct research of a long-term and specialized nature, while also allowing that research to be quickly disseminated. However, if licensing were to be mandatory then the benefits afforded by patent rights in stimulating innovation could be undermined

Validation

In order to better understand the size of research complexity (γ) for a range of different improvements, two seed research firms were asked to rank various genetic improvements with respect to their interpretation of this parameter. We approached the issue of research complexity in a context understandable to plant breeders by asking them to describe each type of improvement as a proportion of the time and cost involved in incorporating exotic germplasm into maize. This approach respected business confidential information and could be used as an exemplar or index because it represented a complex breeding program that employees at each company had prior experience. The transition from research complexity to a time and cost index is fairly intuitive. For example, projects that take 15 years to develop will typically have a longer expected commercial life compared with projects that take only 5 years to develop. If this were not the case then the firm would not undertake the multiyear investment.

Survey results are shown in Table 2. Results suggested that single-gene backcrossing and traditional breeding programs were activities with low research complexity (γ). Second-generation transgenes and the introduction of exotic germplasm had much greater research complexity. An IPP system that favored highly complex research was therefore more likely to provide a sufficient level of IPP to support commercial research and development programs such as those involving second generation transgenes or the incorporation of exotic germplasm.

Discussion

A modelling approach to research is widely used in numerous fields, including plant breeding and agriculture (Hammer et al., 2006). Modelling allows many permutations to be tested and can help identify important parameters and show the results of their interactions. Modelling can provide useful hypotheses which can then be further tested. One well-respected plant breeder cautioned that with modelling you get the results according to how the model was programed at the beginning. One good test of the results of modelling is to compare results with intuitive knowledge gained from practical experience. The reality check provided by two companies for different elements of research also aligned with these results.

Results from an earlier study into the outcomes of applying IPP in plant breeding (Lence et al., 2005) indicated that 1) there was an optimum life of patent protection and 2) identified major beneficiaries of research and innovation in the field of plant breeding and biotechnology. Briefly, Lence et al. (2005) found that 1) IPP was necessary to encourage private breeding companies to invest in research that would provide farmers with the best seed technology, 2) There was an optimum duration of protection in relation to the contribution of innovation in plant breeding research and product development to social welfare of just over 20 years, 3) Benefits from higher and better quality yields were captured by farmers through reduced production costs per unit harvested, 4) A multiplicity of benefits ultimately flowed to consumers contributed by a) better quality food supporting human health, b) yield gains lowering the price of harvested produce, and c) yield gains which offered the potential to take less productive or more fragile lands out of agricultural production thereby supporting biodiversity and enabling a cleaner environment.

Our results were in agreement with the discussion provided in Pardey et al. (2013) and with theoretical results derived in Moschini and Yerokhin (2008). Each of the two primary IPP systems has been shown to have advantages and disadvantages, and neither of them is better than the other under all possible circumstances. Unlike the two earlier papers, the model used here had enough structure to describe the specific parametric conditions under which one IPP system dominated the other; i.e. performed better in terms of encouraging greater genetic gain or contribution to social welfare. We were also able to consider subtle changes such as licensing and changes in the effective length of IPP and to show how these altered the outcomes in terms of genetic gain or contribution to social welfare.

The results of some comparisons were clear from the modelling results reported initially by Lence et al. (2015) and presented in a revised format here. For example, patents were more appropriate when longer term and riskier research was needed. However, much of the research conducted by plant breeders is diverse and subject to several interactions including degree of specialization, half-life of a new product, available resources, research, and business strategies. There are also implications of interactions of IPP with the stage of technology development and level of understanding of the genetic basis of important agronomic traits. For example, use of double-haploids, off-season nurseries, and molecular marker data can facilitate access to both widely used, well-adapted germplasm and to more exotic landrace germplasm especially provided the genetic control and chromosomal locations of the traits of interest are known (Tanksley and McCouch, 1997; Glaszmann et al., 2010; Lubberstedt, 2011; Kilian and Graner, 2012; Dhanapal and Govindaraj, 2015).

There are different fits for IPP according to different research strategies and different sized, or resource based companies. It is not surprising therefore, that with such dynamic complexity there is no “one-size” or “one-type” IPP that can best fit all circumstances. It is clear, however, that the ability to choose from a range of different specific IPP instruments can allow more opportunities for increased genetic gain and thus contribute more to social welfare than to foster IPP reliance upon trade secrets alone. Furthermore, choice or availability of IPP systems can influence the kind of research that is done. In addition, the ability to invoke exceptions under PVP and utility patents provides countries opportunities for flexibility in implementation. Providing breeders and biotechnologists with a wide range of choice reduces the potential dangers of imposing a relatively low ceiling on innovations developed in country. Providing incentives to develop new varieties in country is particularly important in the fields of plant breeding and agriculture because of highly significant genotype x environment effects determining agronomic performance.

For maximum benefit of society with regard to contributions that can be made by the commercial plant breeding sector an optimum balance is required to be struck between encouraging and disseminating innovation. We hope that by achieving a more complete understanding of the parameters affecting IPP, their interactions, and their overall effects on genetic gain, will help provide means to create IPP environments that can contribute further to increased social welfare achieved through research and innovation-based plant breeding and biotechnology.

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Table legends

Table 1. Main features distinguishing Plant Variety Protection (PVP) implemented according to UPOV 1991 and Utility Patents.

Table 2. Time to Product Commercialization for Different Types of Genetic Improvements

Table1. Main features distinguishing Plant Variety Protection (PVP) implemented according to UPOV 1991 and Utility Patents.

	PVP	Utility Patents
Eligibility Criteria	Distinctness, Uniformity, Stability (DUS)	Novelty, Innovative, Enabled, Useful
Protection	20 years, can vary according to crop. Others cannot copy for commercial use. Others cannot repeatedly use for direct commercial use. Harvested seed cannot be sold for resowing.	20 years No commercial use unless licensed by owner
Exceptions	Commercial variety can be used to breed and commercialize a new variety unless it is Essentially Derived. Harvested seed can be used for resowing own holding; royalties may be required.	For countries that allow utility patents on inbred lines or varieties per se there are no breeder exceptions. For trait patents, some countries allow breeding but not commercialization of the patented trait
Seed deposits	Not available for public use during life of protection. Not required by UPOV to be placed into the public domain although it is policy of USDA to make publicly available.	Made available upon issuance of patent. However, the deposit is “not a grant of license…to infringe the patent” (Harney and McBride, 2007). Available in the public domain at the expiration of protection.

Table 2. Time to Product Commercialization for Different Types of Genetic Improvements

Genetic Improvements	Index Time to Product Commervialization[8] (0-1)
• Single gene backcrossed into elite material	0.300
• Single gene backcrossed into elite recurrent parent. Example would be converting line to glyphosate resistance	0.300
• Common breeding program Elite x Elite	0.375
• Germplasm enhancement Exotic x Elite	0.650
• Develop second-generation transgenes + regulatory	0.778
• No public program. Company works through un-adapted germplasm to identify trait of interest Exotic x Exotic	1.000

[8] The index measure time to commercialization relative to time to develop the improvement.