

The ‘International Licensing Platform—Vegetables’: A prototype of a patent clearing house in the life science industry

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The challenge faced by the vegetable breeding industry

The importance of plant breeding

Plant breeding is the science of influencing the heredity of plants in order to produce desired plant types with improved characteristics (‘traits’) useful to society.¹ Breeders have the general goal to create new genetic diversity in a plant to obtain an improved phenotype. A plant breeder uses both the existing genetic variation among plant species, by means of crossing and selecting, and the methods of modern biotechnology to create new genetic variation for the development of improved plant varieties with the desired characteristics.

Over the last decades the focus of breeders has shifted from a more general, overall improvement of plants to the development and improvement of specific traits. This research has been boosted by the rapidly increasing understanding of plant genetics and the development of new methods of biotechnology which enable a predictable and reproducible re-arrangement or modification of the plant genome. Plant breeding today makes use of various and multidisciplinary techniques and methods, including genetics and mathematical statistics, combined with plant physiology, phytopathology, (bio)chemical analysis and, more recently, molecular biological concepts in plant biotechnology.²

The increasing understanding of plant genetics and the development of modern, predictable biotechnology also impact the use of intellectual property rights. While in the past protection was almost exclusively ensured by plant breeders rights (‘PBRs’), currently patents on plant-related innovations—especially new characteristics—are gaining importance. In vegetable

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This article

- In November 2014, the vegetable seed industry saw the introduction of the International Licensing Platform (ILP). The ILP’s main objective is to enable worldwide access to biological material covered by patents for the purpose of vegetable breeding, whilst safeguarding incentives to invest in patentable inventions. As a result, the ILP will boost innovation and competition in the industry.
- This contribution explains the reasons for founding the ILP and introduces its structure and inner workings, including the use of ‘baseball arbitration’ as a pragmatic mechanism for determining royalties in case bilateral negotiations fail. In addition, it explores some of the anti-trust-related challenges associated with assessing initiatives such as the ILP and discusses open questions, limitations and success factors.
- Given its innovative set-up and structure, the ILP may potentially serve as a prototype for multiparty licensing structures in other industries where intellectual property rights are prevalent and access through conventional licensing negotiation is not satisfactory. However, the suboptimal anti-trust guidance currently in place in the European Union runs the risk of chilling the willingness of private actors to introduce welfare-enhancing collaborative licensing initiatives. Accordingly, the (procedural) antitrust landscape in the relevant area arguably warrants reconsideration.

* The views expressed in the article are those of the authors alone and cannot be attributed to either the ILP, Syngenta, Stibbe or the latter’s clients.

1 General information on plant breeding and its key role in society can be found on the website of the Food and Agricultural Organization of the United Nations, see ‘Seeds and Plant Genetic Resources: A basis for life’, available at <http://www.fao.org/agriculture/crops/core-themes/theme/seeds-pgr/en/> (accessed 16 May 2016).

2 For a general description of plant breeding, see G Moore and W Tymowski, *Explanatory Guide to the International Treaty on Plant Genetic Resources for Food and Agriculture*, IUCN Environmental Policy and Law Paper No 57 (2005) 23–24, accessible at https://cmsdata.iucn.org/downloads/eplp_057_explanatory_guide_to_the_international_treaty_on_plant_genetic_resources_fo.pdf (accessed 16 May 2016).

breeding, ‘native traits’ play a dominant role;³ ‘man-made traits’⁴ are only slowly emerging in this field and none of the currently commercialized traits and vegetable plants are considered ‘genetically modified’.⁵

This increase in innovation is of critical importance for food security. According to the 1996 World Food Summit, ‘food security’ exists ‘when all people at all times have access to sufficient, safe, nutritious food to maintain a healthy and active life’.⁶ Fruits and vegetables are important components of a healthy diet. Reduced fruit and vegetable consumption is linked to poor health. An estimated 5.2 million deaths worldwide were attributable to inadequate fruit and vegetable consumption in 2013.⁷ Vegetable plant breeding forms the basis of the horticultural industry, is a crucial contributor to food security—especially in relation to nutritious food—and is an important source of vitamins in many diets. The development of improved vegetable varieties bears the responsibility for a continuous process of innovation. As societies become wealthier, a strong trend of increasing consumption of vegetables can be observed.⁸ In addition, a changing environment, climate and market lead to a strong demand for new plant varieties with new and stronger resistances against plant pests and diseases, better nutritional value and a higher yield. It is therefore apparent that plant breeding, which is employed to create new varieties that meet these demands, is important for society at large.⁹

The breeding of new, improved varieties is a risky and costly endeavour. Breeding of a new variety or the development of a new characteristic (eg insect resistance) can take 10 or more years. The related investments can be quite high, especially for the development of a new trait by the screening of hundreds to

thousands of wild species or crop relatives (‘pre-breeding’) or modern biotechnology (eg mutagenesis). Even for traits which are not considered to be genetically modified, the investment can increase beyond USD 10 million.¹⁰ Since plants are high-tech products in an easy-to-copy form and can be easily propagated by farmers or competitive breeders, such an investment can only be justified if breeders can obtain an adequate return on investment. This is ensured by society through the grant of a time-limited exclusivity by intellectual property rights.

Importantly, however, new plant varieties cannot be created out of a vacuum but are always based on existing varieties. While in theory breeders have access to many public domain genetic accession and varieties, an inability to access and use the best varieties could result in redundant breeding activities. This waste of time and resources may ultimately lead to a slowdown of innovation cycles. Modern plant varieties require a combination of both agronomic traits—such as resistance against insects or drought—and consumer traits—such as improved vitamin content or shelf-life. New varieties are not created by assembling all these traits *de novo*, but rather by adding or improving one specific characteristic in a variety which offers already a comprehensive set of traits. In consequence, breeding is crucially dependent on access to biological material (germplasm), which is the key source of genetic variation. Without access to such material, breeders would not be able to develop new varieties and breeding-induced innovation would stagnate. This requirement differentiates the plant breeding area from all other areas of technology and requires a careful balancing of intellectual property protection and access rights.

3 Plants with ‘native traits’ are usually defined as plants exclusively consisting of naturally occurring plant genetics, introduced or combined in the plant by sexual crossing. One example is the ‘Broccoli patent’ (European Patent No 1,069,819), where the trait for an increased content of certain glucosinolates is transferred from wild *Brassica oleracea* species (*Brassica villosa* or *Brassica drepanensis*) into commercial Broccoli by sexual crossing.

4 These plants comprise mutations obtained by induced, random mutagenesis by eg irradiation or directed mutagenesis through modern genome editing technologies and other new breeding technologies. See eg <http://www.nature.com/news/seeds-of-change-1.17267> (accessed 16 May 2016).

5 With the exception of sweet corn, transgenic vegetables currently play no role in the global vegetable seed market. Genetically modified eggplant with insect resistance is currently applied for regulatory approval in countries like India and the Philippines; however, due to political resistance a commercial launch is uncertain.

6 Trade Reform and Food Security, Chapter 2.2 (p. 27), FAO, Rome, 2003, available at <ftp://ftp.fao.org/docrep/fao/005/y4671e/y4671e00.pdf> (accessed 4 July 2016)

7 WHO e-Library of Evidence for Nutrition Actions (eLENA), available at http://www.who.int/elena/titles/fruit_vegetables_ncds/en/ (accessed 16 May 2016).

8 In emerging markets like China and India, vegetables consumption has grown in double-digit percentage each year for the last 3 decades. Also in developed countries like the USA, the per capita consumption of all vegetables averaged increased by 25% from 1980 to 2000. See G Lucier, ‘Vegetable Consumption Away from Home on the Rise’, USDA Food Choices & Health (1 September 2003), available at <http://www.ers.usda.gov/amber-waves/2003-september/vegetable-consumption-away-from-home-on-the-rise.aspx> (accessed 16 May 2016). The global production of vegetables has grown from 1.2 bn t in 2000 to 1.7 bn t in 2013, while in the same time frame the per capita consumption increased from 166 kg p.a. to 207 kg p.a. (own data).

9 N Louwars et al, ‘Breeding Business: The future of breeding in the light of development in patent rights and plant breeder’s rights’, Centre for Genetic Resources Report 2009-14 (30 December 2009), available at <http://ssrn.com/abstract=1720088>.

10 For GM traits, the average investment is in the range of USD 150 million with a development time of 13 years. See eg P McDougall, The Cost and Time Involved in the Discovery, Development and Authorisation of a New Plant Biotechnology Derived Trait’, A Consultancy Study for Crop Life International (September 2011), available at <https://croplife.org/wp-content/uploads/2014/04/Getting-a-Biotech-Crop-to-Market-Phillips-McDougall-Study.pdf> (accessed 16 May 2016).

IP protection for plant related innovations

Historically, PBRs were the prevailing form of IP protection for vegetable breeders.¹¹ Under the PBRs regime, the ‘breeders’ exemption’ ensures that the legally available biological material of protected varieties can be used to breed new varieties. These new varieties can, in general,¹² be commercialized without authorization from the PBR owner. As a consequence, the best properties of new varieties are available to the breeding programs of competitors, thereby stimulating innovation and competition.¹³

More recently, patents have entered the scene in the sector. Legally, the door for patent protection of plant related-inventions in the European Union was opened by the Directive 98/44/EC (‘the Biotechnology Directive’).¹⁴ The underlying cause for the increasing use of patent protection, however, lies in the ‘technification’ of plant breeding and its evolution from a predominantly empirical art to a science-based research area. The fact that these inventions can be described and reproduced by the person skilled in the art lays the ground for patentable inventions.¹⁵

Patents and PBRs differ not only in respect to the requirements for protection, but also to the resulting rights. The landscape of legislation and case law relating to the protection of plant innovation is highly complex.¹⁶ The international framework is set by the Article 27(3)(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs),¹⁷ which permits WTO members to exempt plants and essentially biological processes for their production from patentability. Member States are, however, obligated to provide protection for plant varieties either by patents or by an

effective *sui generis* system or by any combination of both. Countries have made wide use of this flexibility both with respect to the exemptions from patentability and to the interplay of patents and PBRs. In consequence, the IP protection of plants exhibits a global complexity which is likely unmatched by any other technology area.¹⁸

PBRs have a certain level of harmonization as a consequence of the legal framework provided by the International Convention for the Protection of New Varieties of Plants (‘UPOV Convention’), which created the International Union for the Protection of New Varieties of Plants (UPOV). The original Convention, adopted by a Diplomatic Conference in 1961, was subsequently revised in 1972, 1978 and 1991. National differences often result from the three different UPOV conventions and their differences with respect to protection term, scope of protectable plant species, extension to harvested goods,¹⁹ extension to products directly obtained from harvested goods²⁰ and the extension to essentially derived varieties. In addition, there are differences in the PBR examination practice: in some countries, the examination is officially conducted by the PBR offices, while in others it solely relies on data submitted by the applicant. The PBRs granted under the UPOV Convention are usually considered an effective *sui generis* system, under Article 27(3)(b) TRIPs.

With respect to patents, differences already arise on whether plants are patentable subject matter. Most members of the WTO do not allow patent claims on plants or related propagation material, excluding plant varieties, plants in general or both from protection. Even in cases where only plant varieties are excluded

11 PBRs were introduced more than 60 years ago and constitute a globally accepted standard for the protection of plant varieties. See eg the International Convention for the Protection of New Varieties of Plants (adopted 2 December 1961, entered into force 24 April 1998; revised in 1972, 1978, and 1991) 815 UNTS 89 (‘UPOV Convention’). See also <http://www.upov.org/upovlex/en/conventions/1991/content.html> (accessed 4 July 2016).

12 One exception under UPOV Convention is the development of essentially derived varieties. Here the commercialization requires the approval of the PBR owner.

13 However, it has to be noted that even under the PBR regime, access is not without limitations. Parent lines deposited with the PBR offices for the purpose of protection cannot be accessed during the term of protection. Nevertheless, the PBR system is often in general described as an ‘open-source’ IP regime.

14 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213/13 (30 July 1998) (‘Biotechnology Directive’).

15 In contrast to PBRs, patentable inventions require a ‘technical teaching to methodically utilize controllable natural forces to achieve a causal, perceivable result’: see Bundesgerichtshof (German Federal Court of Justice) BGH 27 March 1969, X ZB 15/67.

16 MD Janiset et al, *Intellectual Property Law of Plants* (OUP Oxford 2014); J Kesan (ed), *Agricultural Biotechnology and Intellectual Property: Seeds of*

Change (CABI Publishing Co, Cambridge, USA 2007); MA Kock, S Porzig and E Willnegge, ‘The Legal Protection of Plant-biotechnological Inventions and Plant Varieties in Light of the EC Biopatent Directive’ (2006) 37(2) IIC 135; F Curtis and M Nilsson, ‘Collection Systems for Royalties in Wheat an International Study’ (2012) 12(6) Bio-Science L Rev 215.

17 Agreement on Trade-Related Aspects of Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) 1869 UNTS 299 (TRIPs), Art 27 (3).

18 Committee on Development and Intellectual Property, ‘Patent-related Flexibilities in the Multilateral Legal Framework and their Legislative Implementation at the National and Regional Levels—Part III’, WIPO Doc CDIP/13/10 (27 March 2014), available at http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_13/cdip_13_10.pdf (last accessed 16 May 2016).

19 See e.g., Article 13 No. 3 COUNCIL REGULATION (EC) NO 2100/94 of 27 July 1994 on Community plant variety rights. Available under <http://www.cpvo.europa.eu/documents/lex/394R2100/EN394R2100.pdf> (accessed 4 July 2016).

20 In the Community Plant Variety Right Regulation (n. 19) this provision is only comprised as an option, which has not yet been implemented. The extension has however been implemented into the national plant variety protection laws of Germany and The Netherlands.

	AU	BR	CA	CN	EP	JP	US	
Patent Laws								
1	Are claims on plants permitted ?	Yes (incl. varieties)	No	No	No	Yes (excl. varieties)	Yes (incl. varieties)	Yes (incl. varieties)
2	Are plants indirectly patentable by claims on plant cells?	Yes	No	Yes	No	Yes	Yes	Yes
3	Are plants indirectly patentable by claims on DNA sequences?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
5	Are breeding methods patentable?	Yes	Yes (restricted)	Yes (restricted)	Yes (restricted)	No	Yes	Yes
8	Is there a farm-saved-seed exemption for patents?	No	Yes (non-commercial)	No	No	Yes	No	No
9	Is there a breeders exemption for patents?	No	Yes (non-commercial)	No	No	Yes ^a	No	No
Plant Breeders Rights								
2	Are all species protectable?	Yes	No	Yes	No	Yes	Yes	Yes
3	Is there a farm-saved-seed exemption ?	Yes	Yes	Yes	Yes	Yes	Yes	Yes
4	Is there a limitation for specific species?	No	Yes (not for sugarcane)	No	No	Yes	Yes (not for vegetative plants)	No
5	Does farm-saved-seed require payment of a compensation to the right holder?	Yes	No	Yes	No	Yes	No	No

^aIn Germany, the Netherlands, Switzerland, France, and the UPC.

from patentability, the interpretation of the exclusion can be broad, as happens in China, where all the claims that could cover a plant variety are rejected. In contrast, the European Patent Office allows patent claims as long the technical teaching of the invention is not limited to a single variety:²¹ this results in the grant of plant claims that also cover plant varieties. Canada does not allow claims on plants but on plant cells, even if such claims cover a whole plant as the cells can explicitly be found in the whole plant. A few countries, such as Australia, Japan, Korea and the USA, have no limitations, and in principle grant claims also for specific varieties; in practice, however, there are huge differences in the examination standards, which affect the number of patents granted in respect to these inventions.

Even if no claims are granted on plants, a plant could still be covered by a patent. This could be the case if the plant comprises a patented DNA-construct as a consequence of genetic modification, if the plant

consists of patented plant cells, or if it is the direct product of a patented breeding or seed-production process. The indirect protection obtainable through process claims or construct, however, is widely disputed, especially when there was a legislative intent to keep the field of plant varieties free of patents.²² Gaps in the framework of protection exist in countries like China or India, which provide PBRs only for a selected list of species, excluding all plants from patentability. The compliance of these national legislations with the TRIPs requirements is questionable.

The major differences between PBRs and patents are summarized in Table 1, taking into account the legislation in force in a number of countries.

The EU made an attempt to harmonise patent and PBR laws through the Directive 98/44/EC. While in some areas, like the farmers exception,²³ PBRs and patents have been harmonised, in other areas the rights are still substantially different. This is especially the case for

21 G 0001/98 (Transgenic plant/NOVARTIS II) of 20.12.1999, 2000 OJ EPO 111, Headnote 1.

22 This could be argued for example for Argentina, Brazil and China.

23 Biotechnology Directive, see n 14, Art 11. The farmers' exemption has been incorporated by reference from the EU PBR system into the patent

system. In consequence, farmers have the same rights to conduct farm-saved-seed irrespective whether a variety is protected by patents, PBR or both.

the breeders' exemption, which—until recently—had no direct equivalent in patent laws.²⁴ Meanwhile, a limited breeders exemption has been established under the Agreement on the Unified Patent Court (UPC) and the patent laws of Germany, France, The Netherlands and Switzerland.²⁵ It enables breeders to use patented material to breed new plant varieties, and freely commercialize the resulting new variety if it does not comprise the patented elements. However, if the new plant variety comprises the patented elements, a licence needs to be obtained before commercializing it.

Outside Europe, the scope of patents and PBRs is still fundamentally different. This is especially noticeable in the USA, where patents are frequently granted for specific plant varieties and where neither a breeding nor a research exemption exist in patent law.

In conclusion, both patents and PBRs are relevant in vegetable breeding. This often results in *de facto* double protection of plant varieties, as the same biological material may be covered both by a PBR and a patent.²⁶ This could result in an interface issue, as the exemptions of one IP regime do not limit the rights of the other IP regime.²⁷ Consequently, the PBRs breeders' exemption no longer secures the freedom-to-operate of breeders, as they now face the risk of infringing a patent when exercising their vital activity of using biological material for breeding purposes. As explained in more detail below, this reality is imperilling the societal benefits associated with plant breeding.

The challenge in a nutshell

The International Licensing Platform (ILP) was founded against the background of the challenge to

balance access and protection. This challenge is often described as an inherent conflict or unresolved interface issue between two intellectual property regimes: PBRs,²⁸ representing 'access', and patents, representing 'protection'. The related debate has intensified in view of the increased amount of plant-related patents and patent applications which are seen a threat, both for the industry and society.

The key elements of this inherent conflict are the following.

Transparency

According to seed law regulations, plant varieties have to be sold with the denomination name. This in most cases allows breeders to find out whether a variety is protected by PBRs, as the denomination name is a unique—and in principle global—identifier for plant varieties. In contrast, it is not possible to establish whether a plant variety is protected by a patent, unless the patentee has provided a non-mandatory patent warning or had to include such indication for regulatory reasons.²⁹

Scope of research and breeders exemption

While the limited breeders exemption in the UPC and the patent laws of Germany, France, The Netherlands and Switzerland³⁰ enable breeders to breed new plant varieties, a licence is needed to commercialize them if they contain patented elements. Under the PBRs, this is only required for essentially derived varieties.³¹ The compulsory licence provided by Directive 98/44 specifically for the breeding sector³² is currently only a theoretical option and has not been tested for practical

24 It is disputed whether the statutory research exemptions in patent laws would exempt the use of patent-protected plant material for breeding. Research exemptions exempted 'acts done for experimental purposes relating to the subject matter of the patented invention' (see eg Agreement on the Unified Patent Court, 2013 OJ C 175/1, Art 27(b) ('UPC Agreement')). Normally this requires generating new knowledge on the invention. Using a variety with a patented trait in a breeding program only exceptionally results in new knowledge on the patented trait. In addition, whether the genetic background of a plant covered by a patent can be freely used is unclear. While it is a part of a patented product, it is not the invention. The invention is the patented trait.

25 See UPC Agreement, above, n 24, Art 27(c); German Patent Act of 16 Dec 1980 (last revised 4 Apr. 2016), s 11 (2a); French Intellectual Property Code 9 Dec. 2004, Art L613-5-3; Dutch Patent Act of 1995 (revised 12 Dec 2013), Art 53b(2); Swiss Patent Act of 25 June 1954 (last revised 1 Jan. 2012), s 9.

26 Technically, the scope of protection between a PBR and a patent is markedly different. PBRs protect plant varieties. The full scope of PBRs is described in Article 14 of the UPOV Convention 1991. Where it concerns patents, '[i]nventions which concern plants . . . shall be patentable if the technical feasibility of the invention is not confined to a particular plant . . . variety,' see Biotechnology Directive, above, n 14, Art 4. Exempt from patentability are, amongst other things, 'essentially biological processes for the production of plants', see Convention on the Grant

of European Patents (adopted 5 October 1973, entered into force 7 October 1977) 1065 UNTS 55, Art 53(b) ('European Patent Convention').

27 *JEM Ag Supply, Inc v Pioneer Hi-Bred International, Inc*, 534 US 124, 122 S Ct 593; 151 L Ed 2d 508 (2001).

28 Additional information on the legal and substantive characteristics of PBRs in the EU can be found through the Community Plant Variety Office, at <http://www.cpvo.europa.eu/> (accessed 16 May 2016). See eg B Kiewiet, President of the Community Plant Variety Office, 'Plant Variety Protection in a Community Context' (11 September 2002), available at <http://www.cpvo.europa.eu/documents/articles/Speech11092002.pdf> (accessed 16 May 2016).

29 With respect to patent transparency, the PINTO Database of the European Seed Associations provides information on how EU plant varieties relate to patents and patent applications. See <http://pinto.euroseeds.eu/> (accessed 16 May 2016). However, a global solution so far doesn't exist. See also below, n 44.

30 See UPC Agreement, above, n 24, Art 27(c); German Patent Act, s 11(2a); French Intellectual Property Code, Art L613-5-3; Dutch Patent Act, Art 53b(2); Swiss Patent Act, s 9.

31 Council Regulation (EC) No 2100/94 of 27 July 1994 on Community plant variety rights, 1994 OJ L 227/1, Art 13(5)(a) and (6).

32 Biotechnology Directive, above, n 14, Art 12(1).

applicability.³³ This creates a dilemma for the breeder, who has to decide whether to approach the patentee early in his breeding program, with little information about the utility and value of the patent trait, or to wait and take the risk of wasting his breeding efforts if unable to obtain a licence.

Freedom-to-operate mechanisms

Even with a limited breeders’ exemption, access to patented plant material is more complex and uncertain than under the PBR regime. Under PBRs, a breeder could guarantee the freedom-to-operate for a resulting new variety by adapting a good breeding practice.³⁴ For patented plant material, it would be necessary to analyse the presence of a patented trait,³⁵ monitor the patent status and eventually negotiate a licence. Each of these activities requires legal expertise and is difficult for small and medium sized breeding companies, which form an important part of the EU breeding sector. A full breeders’ exemption under patents, which is sometimes advocated as a solution to the problem,³⁶ would create broad freedom-to-operate but would remove the incentive granted by patents. According to some commentators, this is potentially problematic under the TRIPS Agreement.³⁷

The patent landscape in the vegetable seed industry

Initially, patents for plant-related innovations were limited to genetically modified plants, certain mutants and technology or process patents. Following the Biotechnology Directive, the Enlarged Board of Appeal of the European Patent Office concluded that ‘[a] claim wherein specific plant varieties are not individually claimed is not excluded from patentability under

Article 53(b), EPC even though it may embrace plant varieties’.³⁸ The Court of Justice of the European Union (CJEU) confirmed this view in an *obiter dictum*.³⁹ Hence, patent claims can cover a plant variety although such a variety would as such not be patentable.

Over the last decade, an increasing number of patents relating to native traits were filed (Figure 1). The spectrum of applicants is quite broad and not limited to large multinational companies (Figure 2). While many of the early patents had deficits and were found to be invalid, more recent patent filings have higher quality.⁴⁰ The recent decisions of the European Patent Office’s (EPO) Enlarged Board of Appeal in the *Tomato II* and *Broccoli II* cases,⁴¹ according to which *[t]he exclusion of essentially biological processes for the production of plants in Article 53(b) EPC does not have a negative effect on the allowability of a product claim directed to plants or plant material such as a fruit*, further confirmed this reality—at least for the foreseeable future.

This has changed the situation for plant breeders, who traditionally were allowed for unimpeded breeding activities under PBRs. In light of the vital importance of access to biological material for breeding purposes, the challenge for breeders is primarily centred on patents that cover such plant material. In that context, a distinction can be made between different categories of patent claims: (i) ‘process claims’ relating to methods of plant breeding or production, (ii) ‘tool claims’ which relate, for example, to molecular markers and (iii) ‘trait claims’ or ‘plant claims’, which relate to new plant characteristics determined by one or more genetic elements and plants comprising those traits.⁴²

The plant material used by breeders is typically covered by patent claims that fall into the last category—claims

33 The compulsory licence requires a ‘significant technical progress of considerable economic interest’, which is a point of ambiguity. Switzerland follows a pragmatic approach in linking this requirement to the seed marketing authorization: see Swiss Patent Act, Art 36a-1.

34 The creation of an ‘essential derived variety’, which is the only scenario of dependency, can—in general—only occur if the breeding program includes multiple backcrossing against the protected variety or the selection of somaclonal variation. This can be easily avoided: a breeder would know by what he is doing when he is taking the risk of dependency.

35 Absent specific transparency measures, this task could become quite cumbersome with an increasing number of patented traits.

36 The Dutch breeders association Plantum advocates a ‘full’ breeders’ exemption for patents: breeding with a patented variety as well as commercializing the new variety, even if it still contains a patented trait, should be free. See <https://www.plantum.nl/Content/Files/file/Standpunten/Plantum%20Position%20on%20patent-%20and%20plant%20breeders%20rights.pdf> (last accessed 4 July 2016).

37 A full breeders’ exemption could be seen as a remuneration-free compulsory licence. While TRIPS allows parties to exempt plants from patentability under Art 27(3b) the options to enable a use without the authorization of a patent owner under an already granted patent are restricted by Article 31 TRIPS. Such authorization requires—among other—an ‘adequate remuneration’ (TRIPS, Art 31(h)).

38 G 0001/98 (Transgenic plant/NOVARTIS II) of 20 December 1999, above, n 21.

39 Case-377/98 *Kingdom of the Netherlands v European Parliament and Council of the European Union* (Suspension of Directive 98/44/EC), ECLI:EU:C:2001:523, para 46.

40 During the pendency of the *Broccoli I* and *II* decisions, discussed below, most of the patent applications relating to native traits have been stayed for up to eight years in patent examination awaiting the outcome of the precedential cases. Only recently the examination procedure has been reinitiated. While the claims on plants with native traits should now be in principle patentable, it remains to be seen how many of the pending application will eventually meet the general requirements of patentability—especially the requirements of inventive step and sufficiency of disclosure.

41 See G 0002/12 (“Tomato II”; in-official title), EPO Enlarged Board of Appeal, 25 March 2015 and G 0002/13 (“Broccoli II”; in-official title), EPO Enlarged Board of Appeal, 25 March 2015, Headnote 1.

42 See eg G 0001/98 (Transgenic plant/NOVARTIS II) of 20 December 1999, above, n 21. The European Patent Office’s Enlarged Board of Appeal found that ‘[a] claim wherein specific plant varieties are not individually claimed is not excluded from patentability under Article 53(b) EPC even though it may embrace plant varieties.’ In consequence, claims on plants can be granted, even if they comprise and cover plant varieties.

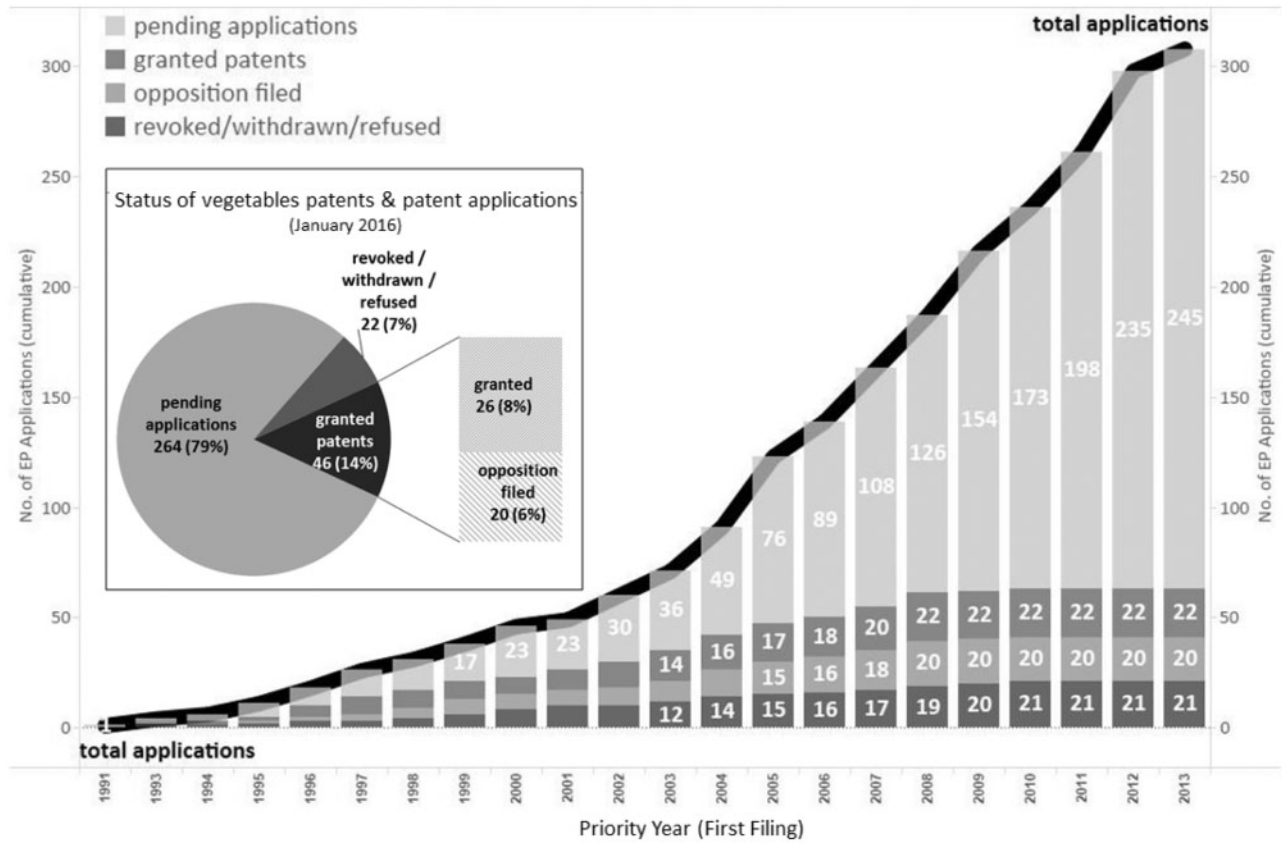


Figure 1. Patents and patent applications under the European Patent Convention (EPC) relating to vegetables.

The statistics (as at January 2016) show a substantial backlog of 245 pending applications. Of the total number of 302 valid patents and patent applications approx 50% are available through the ILP.

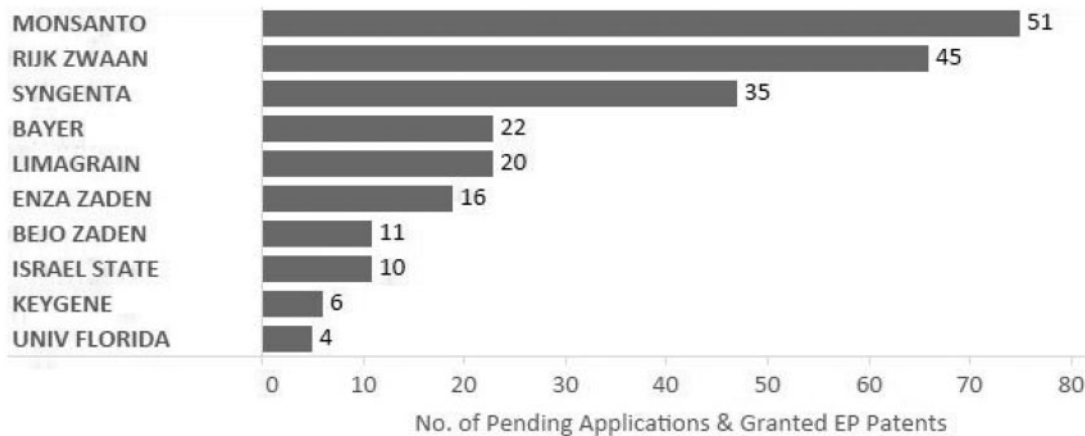


Figure 2. Ownership of patents and patent applications with EU impact relating to vegetables.

Whereas, US publications were not added, PCT applications with EP designation and national patents in EU Member States (eg France, The Netherlands) are included in the analysis. For the number of publications by assignee, EP applications with legal status 'revoked/withdrawn/refused' were omitted. Assignee names were consolidated taking into account major subsidiaries, mergers and acquisitions.

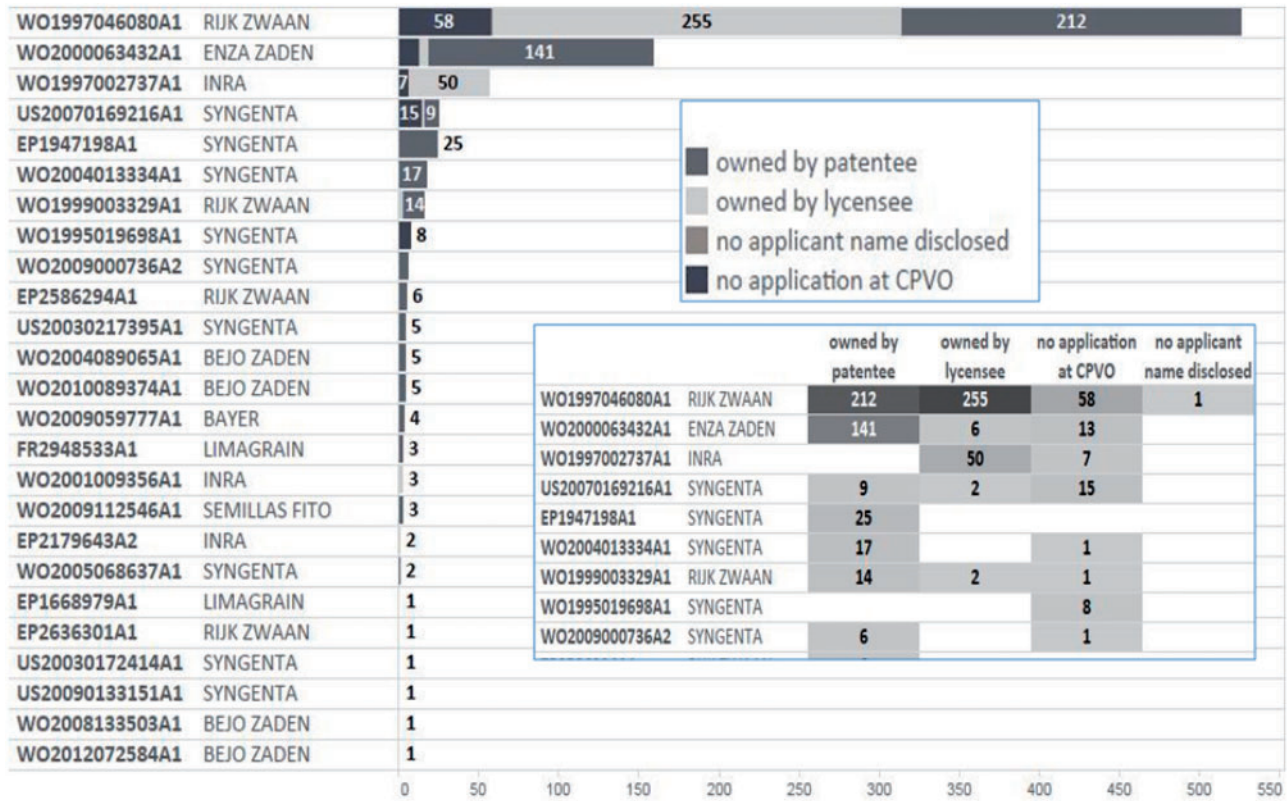


Figure 3. Number of EU plant varieties covered by EP patents and patent applications.

The statistic includes plant varieties owned by the patentee and plant varieties of licensees. In some cases the ownership status of varieties was not obtainable from the public databases. Some varieties are registered at the common catalogue but no plant variety protection has been found.

on plant traits. This type of patent would be infringed in case a breeder commercializes a variety resulting from the use the patent-protected material. By contrast, patents relating to methods or tools, while certainly having benefits for breeding, would not normally hamper conventional breeding activities, as such patents do not cover the biological material of a protected variety.

While the number of patent applications on native traits, and the related debate, has increased (Figure 1), the actual number of plant varieties covered by patents,

and the consequent impact on freedom to operate, is still small.⁴³ The PINTO database⁴⁴ of the European Seed Association shows 25 patent families relating to 889 plant varieties (Figure 3). This is a small fraction (less than 5 per cent) of the EU seeds catalogue.⁴⁵ 19 patent families relate to vegetables and only 3 patents cover more than 70 per cent of the varieties, including a higher number of third party varieties. This demonstrates that patents with a high market demand are rare.⁴⁶

43 Such impact only results if a patented trait is part of a commercial plant variety. While an unusually high percentage of native trait patents are opposed in the EPO, there is only one known patent litigation in the EU based on a native trait patent. The District Court of The Hague, in a patent dispute between Cresco and Taste of Nature, found that Taste of Nature’s patent for red radish plants was invalid since the sprouts had been made public before the patent was filed. See *Cresco Handels-BV v Taste of Nature Holding BV*, Case No C/09/4 16501 / HA ZA 12-452 The District Court of The Hague, 18 March 2015.

44 The PINTO database, above, n 29, comprises varieties which have or had EU market authorization, as long as they are linked to a non-expired, non-rejected patent or patent application. The PINTO database is public and NGO’s have already processed the data: see eg C Then and R Tippe, ‘European Patents on Plants and Animals—Is the patent industry taking

control of our food?’, ‘No Patents on Seeds’ Report (2014) 34, available at http://no-patents-on-seeds.org/sites/default/files/news/european_patents_on_plants_and_animals_2014_2.pdf (accessed 16 May 2016). Due to the fact that some companies still have not provided their data, the picture is likely only 80% complete.

45 As of 21 September 2015 the seeds catalogue currently lists 9940 varieties of maize, 3728 varieties of wheat, 2847 varieties of sunflower, 5924 varieties of tomato and 3743 varieties of lettuce. See European Commission, Plant Variety Database, available at http://ec.europa.eu/food/plant/plant_propagation_material/plant_variety_catalogues_databases/search/public/index.cfm (accessed 21 September 2015).

46 None of these patents is owned by a multinational, but by family companies and an academic institute.

Hence, the problem of patents currently seems to be in the legal uncertainty, limited patent experience, and potential costs of monitoring patents and negotiating licences. However, progress in plant breeding will lead to an increase of patents, which could further limit the free availability of, and access to, biological material for plant breeding.

This chilling effect is heightened by two major considerations. First, it is often unclear which biological material is covered by patents, as (i) the scope of the claims may not univocally identify the variety in question, and (ii) there is generally no requirement for patent marking. The associated uncertainty creates a 'patent minefield' for breeders. The deterring effect of a minefield is not necessarily closely related to the number of mines, as a small number of mines can have a substantial effect, despite the progress made in ensuring patent transparency (eg through initiatives like the PINTO database). A single patented trait unknowingly integrated may hamper an entire breeding program, as the patentee could exercise his right to exclude any commercial activity with a new plant variety covered by the patent. If left unresolved, this situation could create a fundamental threat to breeding, hindering innovation in the sector.

The second major factor that increases the chilling effect concerns the commercialization of plants with native traits, which normally happens shortly after patent filing, in contrast to the commercialization of genetically modified crops. The patent examination process is time-consuming and can exceed 10 years (see Figure 1). In addition, differences in the national patent laws may result in a complex patent claim landscape for the same trait. Long and complex procedures increase uncertainty for breeders as to the status of the biological material they want to use, or may have already commercialized, with the patent pending.

As a consequence, a breeder is faced with a dilemma. He could try to obtain an early licence, at the beginning of the breeding program: this would guarantee access, but could lead to a waste of resources if either the traits turn out to be of limited value or the patent is finally rejected. Alternatively, he could start the breeding

without a licence, under a limited breeders exemption or in a country where no patent has been filed: this would allow a breeder to test the economic potential of the trait, but would also expose him to the risk of wasting the early investment, if he fails to secure the patent holder's authorization that is necessary for the commercialization of the resulting variety.⁴⁷

Hence, the situation prior to the introduction of the ILP entailed high ambiguity and transaction costs relating to patent monitoring, opinions, oppositions and licence negotiation. Against the background of these observations, which were made not only by the plant breeding industry but also by scholars,⁴⁸ action was required to safeguard innovation through breeding.

The solution offered by the ILP

Legislation not a solution in the medium term

Numerous stakeholders have suggested various forms of legislative initiatives to address the situation.⁴⁹ However, legislative solutions all face the same crucial problem: they would be relatively slow to implement, inflexible and have a limited—national or regional—geographical scope, whereas the vegetable seed business is a worldwide business and the breeding technology is evolving rapidly.

Legislative intervention at supranational level could provide a better alternative. However, this would require changing the relevant EU legislation, and possibly also the TRIPs Agreement, which would need the unanimous consent of all its member states. In view of the increasingly differing positions on intellectual property rights globally, such process—if successful at all—would take many years. The resulting win–lose situation is unlikely to be accepted by companies which heavily invest in modern breeding technologies; further, lobbying efforts could not only delay implementation, but also absorb resources needed to meet challenges that concern all breeders, for example the implementation of the Nagoya Protocol.⁵⁰

The companies founding the ILP, responding to a call of the Dutch Parliament,⁵¹ decided not to wait for

47 In addition, as explained above, the option of obtaining a compulsory licence is untested and therefore unsure.

48 See eg Louwars et al, above, n 9, 12.

49 See above, n 25. The German Seed Association (BDP) advocate for an exception from patentability for breeding processes and plants obtained therefrom. See European Seed Association (ESA), 'On Intellectual Property Protection for Plant-related Inventions in Europe', Doc No ESA_12.0100 (February 2000), available at https://www.euroseeds.eu/system/files/publications/files/esa_12.0100_0.pdf (accessed 4 July 2016) and http://www.bdp-online.de/de/Ueber_uns/Our_positions/2015-05-20_BDP-Positionspapier_Patent-Sortenschutz.pdf (accessed 4 July 2016).

50 The Nagoya Protocol and related national biodiversity legislations creates an obstacle to access biological material that is potentially far higher than any threat from patents. See C Herrlinger and MA Kock, 'Biodiversity Laws: An Emerging Regulation on Genetic Resources or "IP on life" Through the Backdoor?' (2013) 13(4) *Bio-Science L Rev* 119.

51 See Tweede Kamer der Staten 'BDP-Position zur Ausgestaltung des Patentschutzes in der Pflanzenzüchtung' (Position of the German Breeders Association on the design of patents in plant breeding) available under-*General*, Motion filed by MP Jacobi, Parliamentary Paper No 27428 nr 166, II 2009/10, available at <https://zoek.officielebekendmakingen.nl/kst-27428-166.html> (accessed 16 May 2016) (in Dutch).

legislative intervention in the field, opting instead to move forward and address the challenge through an industry-led 'win-win' solution.

How does the ILP address the challenge?

In essence, the ILP, which falls into to the broad definition of a 'clearing house',⁵² creates a platform bringing together patentees and licensees of patents and patent applications covering biological material needed for vegetable breeding purposes.

The ILP guarantees breeders access to the patents of participating patentees, while ensuring that patentees are rewarded for their innovation. The key principle underlying the ILP may be expressed as 'free access but not access for free'. This balance is crucial for boosting innovation in the vegetable breeding industry: such innovation is dependent on access of plant material for breeding, but equally benefits from patentable inventions. Further, the achievement of this balance also allowed the ILP to involve, as its founding members, a significant portion of the global vegetable seeds industry, including both players which have substantial licensing revenue streams and players that are almost exclusively active as licensees. In order to create an industry solution with meaningful impact, key players from both categories had to be involved in the initiative.

One of the main challenges of the ILP was to translate this principle into detailed arrangements covering its structure and inner working.

Structure and inner workings of the ILP

In accordance with its goal, the ILP ensures that breeders no longer face uncertainty as to the availability of biological material covered by patents of participating patentees, as the latter pre-commit to granting access to their patented material while being assured of reasonable remuneration for doing so. As explained below, the central feature of the ILP in this respect is the system of baseball arbitration that kicks in when bilateral negotiations fail. The key characteristics of the ILP are described below.

Defined scope

The ILP provides access to two different categories of patents relevant for vegetable breeders:

- 'trait patents', which relate to new vegetable characteristics such as disease resistance, improved shelf-life, and nutritional value. With respect to trait patents, the ILP is limited to unregulated traits in vegetables.⁵³ Regulated technologies (eg genetically modified plants) are not included.
- 'variety patents', which, in certain legislations (eg the USA), protect specific plant varieties.

For trait patents, the ILP members agree to enter into good faith negotiations for bilateral licence agreements. If these negotiations fail, the ILP mechanism kicks in as a safety net, to ensure that a licence is established. The standard licence granted through the ILP permits to use legally available plant material (eg commercial seeds) for further breeding of new varieties. The standard licence does not provide access to processes, markers, or other technologies covered by the patent, nor does it oblige the patentee to provide material. However, any such rights could be granted under a bilateral licence agreement between the members.

For variety patents, the ILP members grant each other a mutual, royalty-free non-assert to use legally available material of the protected variety for the breeding and commercialization of new varieties. The non-assert has only two conditions: (i) the new variety has to be sufficiently distinct from the original variety,⁵⁴ and (ii) the party who wants to use the non-assert needs to send a notification to the patentee.⁵⁵ In this perspective, the ILP creates contractually a full breeders' exemption.

While use for research and breeding is free under the standard licence, a licensee has to pay a royalty for the commercialization of the new variety, provided the resulting product is still covered by the patent and the commercialization occurs in a country where a patent right exists. Hence, the ILP establishes 'free access but not access for free', which differs from the breeders' exemption under PBRs, which enables 'free access for free'.

52 The term 'clearing house' is derived from the banking system and refers to the mechanism where monetary assets are exchanged among members to avoid unnecessary transactional costs and only transfer the net balances. More recently the definition has been broadened to describe mechanisms which match providers and users of goods, services, and/or information. See eg AF Krattinger, 'Financing the Bioindustry and Facilitating Technology Transfer' (2004) 1 IP Strategy Today 1; E van Zimmeren et al, 'A Clearing House for Diagnostic Testing: The Solution to Ensure Access to and Use of Patented Inventions?' (2006) 84(5) Bulletin of the World Health Organization No 352 (May 2006), available

at <http://www.who.int/bulletin/volumes/84/5/352.pdf> (accessed 16 May 2016).

53 The term 'vegetables' is defined by a list of species.

54 To be sufficiently distinct, a breeder should cross twice against unrelated varieties. Recurrent backcrossing against the protected variety is excluded.

55 The notification is necessary for transparency purposes to be able to clearly differentiate a use covered by the non-assert from other uses. Obviously such notification is only necessary in countries without breeders' exemption such as the USA.

'All-in' and 'pull-in'

One challenge in establishing licensing platforms is the fact that parties are often interested in obtaining licences, but are rarely willing to make their own patents available; even when they do, they normally chose to contribute only low value patents. The ILP avoids this pitfall by establishing an 'all in' obligation: a party wanting to take a licence through the ILP has to become a member and make all its patents relating to vegetable traits and varieties available to other members.⁵⁶ While this obligation creates a conditional openness, it also results in a strong pull-in effect. In fact, the ILP already makes available more than 150 trait patent families and numerous variety patents.⁵⁷

Mandatory baseball arbitration and standard licence agreement

If bilateral negotiations between a patentee and a prospective licensee fail, the ILP provides a safety net.⁵⁸ In that scenario, the licensee would not be able to commercialize a new variety bred by using the patent-protected biological material without infringing the patent. The ILP establishes that, if the patentee and prospective licensee cannot bilaterally agree on a licence agreement within three months, the licensee can trigger the mechanism of baseball arbitration. The baseball arbitration is based on a standard licence agreement (SLA) where the only negotiable term is the royalty on net sales. No other element of the SLA is negotiable.⁵⁹

As a first step of the arbitration process, the parties submit their written proposal for a fair royalty with supporting evidence and reasoning. The submissions are exchanged and the parties are given three additional weeks to find a bilateral resolution. This step has a high likelihood of success, if the two submissions are close. If

the parties cannot resolve the issue, the case goes to the Expert Committee for a final, binding decision.

The unique feature of the baseball arbitration is that the experts can only pick the submission that they believe to be the most fair. The experts cannot propose a third royalty, for example an average of the two. Thus, if one submission is unreasonably high or unreasonably low, the other one is automatically accepted and becomes the future royalty. In addition, the losing party has to pay the costs for the arbitration proceedings.⁶⁰ The established royalty is final and binding.⁶¹ Modifications are only possible if the value of the licensed technology changes substantially.⁶²

After the Expert Committee has selected either percentage, the ILP's Secretary draws up an executive version of the ILP's SLA, incorporating the royalty. This SLA automatically becomes binding on patentee and licensee.⁶³ Within the prescribed period, only the licensee may still withdraw from the deal.

The mechanism of baseball arbitration attempts to compensate for two weaknesses in classical licence negotiation and arbitration. First, it prevents parties from adopting dilatory tactics, with unreasonable positions that prolong negotiation. Second, it eliminates the risk of 'splitting the baby',⁶⁴ which is common when arbitrators are confronted with aggressive and significantly diverging positions. Whereas other dispute resolution models may result in a compromise between the parties' positions—which may in turn invite parties to adopt more extreme positions from the get-go—baseball arbitration is governed by a different incentive structure. Knowing that the arbitrator will pick either of the two royalty rates submitted, the parties are incentivized to avoid overly aggressive submissions. Instead, they will be driven towards presenting a reasonable number to

56 Patents can only be opted out if pre-existing contractual limitations prevent a licensing through the ILP and these limitations cannot be resolved despite using reasonable efforts. After a party has become an ILP member it has to ensure that future patents relating to vegetable traits and varieties are always available to other ILP members.

57 The trait patents represent more than 50% of the relevant patent families in this field. The number of patents makes the ILP already today highly attractive. As a result, the 'pull-in effect' the ILP patent portfolio is expected to grow.

58 The 'safety net' feature is important: there are many circumstances in which two parties may prefer to enter into an alternative licensing arrangement, including cross-licensing deals, rather than opting for the standard licence agreement (explained below). The ILP does not interfere with existing incentives to enter into such alternative deals.

59 Parties can always deviate from the SLA and negotiate a bilateral agreement. However, this cannot become part of a baseball arbitration.

60 The costs are currently set at EUR 30,000.

61 There is only an opportunity for a formal review of the proceedings, ie to verify whether the experts have followed the procedure and taken into

account all evidence. There is no opportunity for an appeal on the merits of the case.

62 This can happen, eg, if there is emerging resistance for a disease resistance trait.

63 Within one month from the EC's decision, both the patentee and the licensee may request the Objection Board of the EC to review the decision. According to the Articles of Association, the Objection Board "shall solely perform a formal review of the Baseball Procedure but shall not revisit the substantive facts of the decision of the Initial Board of the Expert Committee as such." ILP - Internal Regulations of 13 Nov. 2014, Article 6.5; available under <http://www.ilp-vegetable.org/uploads/Bestanden/ILP%20Founding%20Docs/ILP%20Internal%20Regulations%202014-11-13.pdf> (accessed 4 July 2016).

64 See eg BA Tulis, 'Final-Offer "Baseball" Arbitration: Contexts, Mechanics & Applications' (2010) 20 Seton Hall J. Sports & Ent. L. 85, 88–90, available at http://scholarship.shu.edu/cgi/viewcontent.cgi?article=1002&context=sports_entertainment (last accessed 16 May 2016).

the arbitrator, in this case the Expert Committee. As noted by Lemley and Shapiro, ‘[t]he Nash equilibrium of the game should be for each party to [submit a royalty] equal to the true value of the [patent]’.⁶⁵

Game theoretic research has confirmed the intuitive position that the incentive structure required to get to reasonable submissions will only be there ‘when arbitrator error rates are low and when both parties experience little downside if they are unsuccessful on a conservative valuation and substantial downside if they are unsuccessful on an aggressive valuation’.⁶⁶ Both requirements have been implemented by the ILP.

First, safeguards are installed to minimize arbitrator error rates. These include a rigorous selection process of the Expert Committee members (see below “The Expert Committee”). The concepts of ‘little downside’ when being unsuccessful on a conservative submission and ‘substantial downside’ if unsuccessful on an aggressive submission are generally less easy to control and implement.⁶⁷ However, in the context of the ILP, the fact that the losing party has to pay the costs for the arbitration establishes a ‘substantial downside’ in case of an unreasonable submission. A further factor dissuading overly aggressive submissions may be found in that fact that ILP arbitration is a repeat game and parties will care about reputation effects vis-à-vis the Expert Commission. In addition, the royalties resulting from an unwarrantedly granted aggressive submission may be corrected in a follow-on arbitration round concerning the same patent (see below, “The most-favored-nation clause”).

In any event, the compulsory arbitration mechanism encourages the parties to reach an agreement bilaterally. Remarkably, after one year of ILP practice, the baseball arbitration mechanism has not yet been triggered. However the author’s company has entered into one major licence agreement and is involved in additional on-going negotiations. It has further granted and received a double digit number of notifications under the non-assert provision for variety patents. In addition, anecdotal evidence suggests that ILP members have started to use patented biomaterial of other ILP members in their breeding program under the limited breeders’ exemption in EU patent laws. The guarantee

of the ILP to get a licence seems to have successfully reduced the previous deterrence of patents.

The most-favoured-nation clause

The ILP encompasses a most-favoured-nation (MFN) clause which requires members to grant licences under the best terms it has granted to any other member under the SLA. The rationale for the MFN clause is (i) to lower negotiation-related transaction costs and (ii) to allow smaller members to benefit from negotiation advantages enjoyed by larger members.

Once an MFN percentage has been set, either pursuant to baseball arbitration or after bilateral negotiations resulting in the conclusion of an SLA, any prospective licensee may request the patentee to enter into an SLA incorporating the MFN percentage. If a patentee refuses such a request, the licensee can request the secretary of the ILP to draw up an SLA between the patentee and the licensee. The MFN clause only applies to running royalty rates. It does not apply to other licensing fee structures, such as lump sums or cross-licence deals. Patentees are only bound by the MFN clause in relation to royalty rates agreed upon in a SLA, whether concluded bilaterally or resulting from an Expert Committee arbitration.

The MFN clause entails that royalty rates laid down in SLAs already in existence would be automatically lowered in conformity with a more recent SLA concluded with a lower rate. However, the lower rate only applies to future sales of the licensed products and does not encompass an obligation for the patentee to make payments retroactively.

Also, a prevailing MFN-rate may be adjusted upwards or downwards by the EC on the basis of ‘convincing arguments and evidence’ as to the existence of a ‘material change to the value’ of the patented trait, which would justify a substantial correction of the MFN Percentage. In the event of a request for an upwards adjustment, the EC has to choose between the adjusted MFN percentage, suggested by the member requesting the adjustment, and the existing MFN percentage. When the requesting member asks the EC to establish a lower MFN percentage, the patentee member

65 See MA Lemley and C Shapiro, ‘Simple Approach to Setting Reasonable Royalties for Standard-Essential Patents’, Stanford Public Law Working Paper No 2243026 (2013), available at <http://ssrn.com/abstract=2243026> (accessed 16 May 2016).

66 A Habbuand and PV Buonaguro, ‘A Game Theoretic Model for Determining When Baseball Arbitration Creates the Proper Incentives

for Litigants’ (2011), available at <http://ssrn.com/abstract=1889768> (accessed 16 May 2016). The authors acknowledge that the research is still at its early stages and will require refined modelling (at *ibid*, fn 89).

67 See *ibid*, section V, for some considerations on these issues.

can also submit a percentage lower than the current MFN.

The Expert Committee

The credibility and independence of the Expert Committee is key for the success of the ILP. It not only contributes to creating trust in the solution of the licensing controversy, but also reduces the arbitrator's error rate in the baseball arbitration. Thus, the selection process for the Expert Committee members is quite extensive and ample attention has been devoted to assemble a group of experts collectively having the relevant expertise to assess the level of an appropriate royalty in the specific context of vegetable seeds industry. The Expert Committee consists of seven natural persons which have expertise in intellectual property rights, economics, the vegetable seed market, plant science and accounting.

In addition to technical expertise, a vital characteristic of an Expert Committee member is independence. An Expert Committee member should not have been, in the five year before their appointment, (i) a board member, secretary or expert or (ii) a shareholder, an employee—or another person having a special interest in or other relationship with—in a vegetable breeding company.

Equally important, the Expert Committee selection is based on a unanimous proposal of the ILP Board and is confirmed by a majority of at least 2/3 of the ILP Members.⁶⁸ This process should prevent the selection of experts potentially biased towards patentees or licensees. Finally, the rules regarding conflict of interest and remuneration further support this aim. The working methods, additional safeguards for independence and the decision-making process within the Expert Committee are laid down in Expert Committee By-Laws.

Open participation; licensing outside the ILP; no 'package' licence

Importantly, participation in the ILP is open. In other words, every interested party is allowed to join as a member and ownership of patents in the vegetable

breeding space is not required. ILP members are free to continue to license their in-scope patents to third parties, whether members or non-members of the ILP. ILP participants can freely pick and choose which in-scope patents they want to in-license. Hence, no 'bundling' of patents occurs.

Several other elements have been implemented to safeguard the pro-competitive effect of the ILP. Members are always entitled to challenge the validity of the in-scope patents and the exchange of commercially sensitive information is limited to situations where they are indispensable (e.g., as evidence under a baseball arbitration procedure) with the appropriate confidentiality obligations in place.

Ensuring EU antitrust compliance when exploring collective licensing structures

Assessing collective licensing structures⁶⁹ under the EU antitrust rules can be challenging. The mere fact that a large portion of the companies competing in a given industry comes together to determine a framework according to which future licensing relations may be structured is inherently sensitive from an antitrust perspective. Further, the IP-antitrust interface is currently a key topic on the agenda of antitrust enforcers.⁷⁰ The situation is complicated by the existence of suboptimal guidance on what these regulators consider to be acceptable forms of cooperation. Collectively, these circumstances result in a complex landscape for companies planning to launch their initiative. The sections below illustrate these points using the ILP as a case study.

The EU antitrust framework

Collective licensing structures such as the ILP are to be assessed under Article 101 of the Treaty on the Functioning of the European Union (TFEU), also known as the cartel prohibition.⁷¹ Importantly, multi-lateral initiatives aimed at facilitating IP-licensing are not covered by the European Commission's Block

68 The current Expert Committee was confirmed by all Members, which demonstrates the high standing of the experts in the field.

69 For the purposes of this contribution, collective licensing structures refer to initiatives of companies that are competing on either the technology market(s) or one or more downstream markets (or both) and that are aimed at jointly determining parameters according to which licence deals are concluded in relation to the relevant in-scope IP. Such initiatives may—to varying degrees—also cover parameters according to which the conditions of such licensing deals (including royalties) are set. They may or may not include arrangements agreed upon in the context of standard setting.

70 See eg recently EU Commissioner M Vestager, 'Intellectual Property and Competition', Speech given at the 19th IBA Competition Conference,

Florence, 11 September 2015, available at https://ec.europa.eu/competition/2014-2019/vestager/announcements/intellectual-property-and-competition_en (accessed 16 May 2016).

71 This provision prohibits all agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the prevention, restriction or distortion of competition within the internal market. It is conceivable that such structures may also be caught by the Treaty on the Functioning of the European Union (Consolidated Version), 2008 OJ C 115/47, Art 102 (abuse of a dominant position). In this contribution, we will only consider the cartel prohibition.

Exemption Regulation regarding Technology Transfer (TTBER).⁷² This is a significant aspect, as Block Exemption Regulations offer a relatively large degree of legal certainty. If the conditions laid down in the TTBER are fulfilled, the arrangement is deemed compliant with EU antitrust rules. Outside the scope of the TTBER, companies are required to conduct a more in-depth self-assessment, with a view to establishing whether the envisaged arrangement is reconcilable with the applicable rules. In this context, the recently amended Commission Guidelines regarding technology transfer agreements are a key point of reference (‘TT-Guidelines’).⁷³

The TT-Guidelines offer relatively extensive guidance for the self-assessment of technology pools, defined as ‘arrangements whereby two or more parties assemble a package of technology which is licensed not only to contributors to the pool but also to third parties’.⁷⁴ The Guidelines contain a ‘soft law safe harbour’⁷⁵ for technology pools. Accordingly, technology pools that satisfy each of the following conditions generally fall outside the scope of the cartel prohibition.⁷⁶

- (a) participation in the pool creation process is open to all interested technology rights owners;
- (b) sufficient safeguards are adopted to ensure that only essential technologies (which therefore necessarily are also complements) are pooled;
- (c) sufficient safeguards are adopted to ensure that exchange of sensitive information (such as pricing and output data) is restricted to what is necessary for the creation and operation of the pool;
- (d) the pooled technologies are licensed into the pool on a non-exclusive basis;
- (e) the pooled technologies are licensed out to all potential licensees on FRAND terms;
- (f) the parties contributing technology to the pool and the licensees are free to challenge the validity and the essentiality of the pooled technologies, and;
- (g) the parties contributing technology to the pool and the licensee remain free to develop competing products and technology.

Technology pools that fail to satisfy one or more of these conditions do not benefit from the relative legal certainty conferred by the soft law safe harbour. In those instances, the TT-Guidelines offer some additional considerations on how to factor-in certain characteristics of the pool that place the latter outside the scope of the safe harbour. For example, some guidance is offered to assess cases where the pool comprises non-essential technologies (see also below).⁷⁷

While there is still room for improvement, it is fair to say that, where it concerns technology pools, the existing framework of antitrust guidance in many instances offers valuable assistance when assessing such arrangements under EU antitrust rules.

Assessing the ILP under the EU antitrust framework

A pool or not a pool?

It is unclear whether the ILP can be considered a technology pool under EU antitrust rules. The TT-Guidelines define technology pools by referring to a *package* of technology which is licensed to participants and third parties.⁷⁸ The ILP, however, does not offer a package licence for all in-scope intellectual property rights, but only facilitates the conclusion of individual licence agreements. This raises the question whether initiatives like the ILP are at all covered by the TT-Guidelines.

At first glance, an article on the Commission’s assessment of the 3G3P case,⁷⁹ written by a Commission officer and published in a 2003 Commission *Competition Policy Newsletter*, offers some useful insights. The 3G3P structure was open to both licensors and licensees and that the in-scope patents were not bundled, ie no real pooling of patents occurred. Instead, licensees had the opportunity to pick and choose the patents and the licensing was carried out on a bilateral basis. Accordingly, there was no single licence between a given licensee and the platform. In light of

72 Commission Regulation (EU) No 316/2014 of 21 March 2014 on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements, OJ L 93/17, 28 March 2014 (aka “Technology Transfer Block Exemption Regulation”, TTBER). This was also the case under the previous TTBER. In any event, BER protection is also subject to a combined market share not exceeding certain levels (depending on the competitive relation between the parties involved). Those thresholds would be exceeded in the case of the ILP.

73 European Commission, Guidelines on the application of Article 101 of the Treaty on the Functioning of the European Union to technology transfer agreements, OJ C 89/3, 28 March 2014 (‘TT-Guidelines’).

74 Ibid, para 244.

75 The reference to soft law reflects the fact that this safe harbour is part of the TT-Guidelines rather than the TTBER. The significance of this is that the Commission would have more leeway to decide in an individual case that enforcement is warranted, even if the safe harbor conditions are met.

76 TT-Guidelines, above, n 73, para 261.

77 Ibid, para 264.

78 Ibid, para 244.

79 The 3G3P case concerned a set of agreements aimed at giving third generation (‘3G’) mobile equipment manufacturers better access to patents. See D Choumelova, ‘Competition Analysis of Patent Licensing Arrangements—The Particular Case of 3G3P’ (2003) 1 Competition Policy Newsletter 41.

these characteristics, the Commission found that ‘the legal doctrine on patent pools was not directly applicable’.⁸⁰

Inconveniently, however, the Commission’s qualifications in relation to 3G3P appear to be at odds with the TT-Guidelines. In the latter, the Commission specifically refers to the 3G3P platforms as being ‘technology pools’.⁸¹ It is unclear whether this is a slip of the pen. One might argue that since the 3G3P case predates the TT-Guidelines,⁸² the Commission has apparently decided to depart from the view, expressed in 3G3P, that the absence of a licence to a package of IP rights excludes the presence of a technology pool. However, this view is difficult to reconcile with the clear position taken in the TT-Guidelines: ‘the creation of a technology pool necessarily implies *joint selling of the pooled technologies . . .*’.⁸³ Admittedly, this language does not per se exclude a collective licensing structure that facilitate individual licensing from the definition of technology pool. Notably, however, the scope of the definition remains unclear.⁸⁴

The lack of definitional clarity constitutes a first barrier to obtaining the degree of legal certainty that is pivotally required by companies as a precondition for moving forward with implementing their initiative (which, like the ILP, may very well be welfare-enhancing). For licensing structures caught in this grey area, some limited relief may be found in a statement made by the Commission in the context of 3G3P, according to which ‘most of the rules governing patent pools under competition law could be used as guidance’⁸⁵ also for licensing structures not qualifying as pools.

Navigating the soft law safe harbour

Even assuming that the soft law safe harbour in the TT-Guidelines would also apply to initiatives not involving the licensing of IP packages, the application of this framework remains cumbersome. Particularly

problematic are two conditions required by the safe harbour: (i) ensuring that only essential technologies are included and (ii) ensuring that the pooled technologies are licensed out to all potential licensees on fair, reasonable and non-discriminatory (FRAND) terms.⁸⁶

Experience highlights the validity of the numerous observations made in academic literature with regard to the complexities of applying the notion of essentiality as a decisive criterion in the analysis of collective licensing structures.⁸⁷ Paragraph 252 of the TT-Guidelines identifies two categories of technologies that can be deemed essential. The first category comprises IP-protected technologies essential ‘to produce a particular product or carry out a particular process to which the pooled technologies relate’. The second category comprises technologies essential ‘to produce such product or carry out such a process in accordance with a standard which includes the pooled technologies’.

These two categories of essentiality seem to have been tailored on assumptions that do not appear to be workable for licensing structures like the ILP. First, the patents covered by the licensing structure should have been selected in view of their essentiality⁸⁸ in producing a ‘particular product’ or carrying out a ‘particular process’ to which the pool relates. This test is difficult to reconcile with the ILP’s objective. Indeed, the ILP aims to make available for breeding as much biological material covered by patents as possible, without any intention or requirement to do so for the production of a ‘particular product’ or for carrying out a ‘particular process’. As far as the ILP is concerned, it does not appear sensible to apply this essentiality test in an ex ante setting, where it is inherently unclear which particular varieties are going to be the outcome of the breeding activity that has been made possible by access to certain biological material. Equally, qualifying as essential every patent that would cover a variety that has resulted from breeding with patent-protected biological material would be circular and would render the

80 Ibid, 41–42.

81 TT-Guidelines, above, n 73, para 245 fn 94. The same reference was included in the 2004 version of the TT-Guidelines, para 210 fn 68. (Commission Notice, Guidelines on the application of Article 81 of the EC Treaty to technology transfer agreements (2004/C 101/02), OJ C 101/2 27 April 2004).

82 That is, both the current and previous version of the TT-Guidelines.

83 TT-Guidelines, above, n 73, para 246.

84 Indeed, there are other considerations in the TT-Guidelines that appear in to be in conflict with the notion that ‘technology pools’ also cover structures in the context of which package licensing does not take place. For example, para 253 states: ‘When the technologies in the pool are complements the technology pool reduces transaction costs and may lead to lower overall royalties because the parties are in a position to fix common royalty for the package . . .’.

85 Choumelova, above, n 79, 41–42.

86 TT-Guidelines, above, n 73, para 261.

87 See eg H. Ullrich ‘Patent Pools—Policy and Problems’ in J Drexel (ed), *Research Handbook on Intellectual Property and Competition Law* (Edward Elgar, Cheltenham, UK, 2010) 139, 152:

The fact of the matter is that the essentiality test is inherently ambiguous . . . Outside a standardization context, even the reference point for determining essentiality becomes elusive, because, by definition, whichever way parties define their technology, unless it has a monopoly (and thus is a *de facto* standard), alternative technologies will be available and the more there are, the more the essentiality criterion will lose its competitive meaning.

88 Meaning, according to the TT-Guidelines, above, n 73, para 252, there are no viable substitutes ‘both from a commercial and technical point of view’.

test meaningless. The TT-Guidelines offer no further guidance on the application of essentiality in these types of settings.

The second category of essential patents identified in the TT-Guidelines covers a different landscape from the one the ILP is active in, ie one pertaining to industry standards. In that context, essentiality is determined by reference to the technology required to produce a product in conformity with a standard. However, industry standards are not prevalent in vegetable breeding and were not amongst the drivers when establishing the ILP.

Hence, the specific notion of essential patents as defined by the TT-Guidelines, which is a condition for benefitting from the safe harbour, cannot be easily applied to licensing structures like the ILP. Again, issues of legal certainty arise.

The FRAND licensing requirement that has found its way into the soft law safe harbour raises similar questions. The only guidance offered by the TT-Guidelines in this respect is a reference to the Commission's Horizontal Guidelines,⁸⁹ which, however, discuss the FRAND issue only in reference to standard setting. Accordingly, the Commission notes that FRAND commitments are designed 'to ensure that essential IPR protected technology incorporated in a standard is accessible to the users of that standard on fair, reasonable and non-discriminatory terms and conditions'. In particular, it notes that 'FRAND commitments can prevent IPR holders from making the implementation of a standard difficult by refusing to license or by requesting unfair or unreasonable fees (in other words excessive fees) after the industry has been locked-in to the standard or by charging discriminatory royalty fees'.⁹⁰ These considerations are clearly specific to the context of standard setting.

As noted above, the ILP operates in a markedly different landscape. As a result, the more substantive suggestions contained in the Horizontal Guidelines as to

the potential determination of FRAND rates cannot easily be transposed to a scenario in which standards are not pertinent. This applies to the suggested comparison of licensing fees before and after the industry has been locked into the standard, as well as comparisons that consider royalty rates charged for the same IP in other standards.⁹¹ Generally, it is unclear if the Commission even intended to impose a FRAND licensing criterion outside the scenario of standard setting at all. If that was the intention, the TT-Guidelines fail in providing guidance on how to accomplish this, in contexts other than standard setting.

These considerations illustrate that, even assuming that the safe harbour may also be applied to multiparty licensing structures that do not license IP packages, assessing them for EU antitrust compliance remains difficult. In the next section, we explore this observation in more detail.

Observations and suggestions as to the prevailing EU antitrust framework

It is clear that the available guidance does not fit initiatives like the ILP. The TT-Guidelines were tailored having in mind licensing structures with markedly different rationales and characteristics.

The relevant paragraphs in the TT-Guidelines that aim to provide guidance on multiparty licensing structures reflect the extensive body of economic literature applying Cournot's 'complements problem' to IP.⁹² Economic theory has regarded standard essential patents and blocking patents⁹³ as complements. Moreover, the complements problem is said to often manifest itself in the context of patent thickets.⁹⁴ As a result, Cournot's classic theory of complements has entered the IP space. Under this theory, where the production of a given product entails the use of two or more patent rights owned by separate parties, each patentee in fact controls a complementary input into a production

89 Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, OJ C 11/1, 14 January, 2011, paras 287ff ('Horizontal Guidelines').

90 Ibid, para 287. The leading EU judgment on the associated issue of injunctions initiated by patentees is Case C-170/13, *Huawei Technologies Co Ltd v ZTE Corp, ZTE Deutschland GmbH*, ECLI:EU:C:2015:477.

91 Horizontal Guidelines, above, n 89, paras 289–90.

92 C Shapiro, 'Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting', in A Jaffe, J Lerner and S Stern (eds), *Innovation Policy and the Economy*, vol 1 (MIT Press Cambridge MA 2010). Shapiro builds on the anticommons notion as introduced by MA Heller and RA Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280(5364) *Science* 698.

93 The TT-Guidelines, above, n 73, para 29, note that

[A] one-way blocking position exists where a technology right cannot be exploited without infringing upon another valid technology right,

or where one party cannot be active in a commercially viable way on the relevant market without infringing the other party's valid technology right. . . . A two-way blocking position exists where neither technology right can be exploited without infringing upon the other valid technology right or where neither party can be active in a commercially viable way on the relevant market without infringing the other party's valid technology right and where the parties thus need to obtain a licence or a waiver from each other.

94 Shapiro, above, n 92, defined patent thickets as 'an overlapping set of patent rights requiring that those seeking to commercialise new technology obtain licenses from multiple partners.' There is debate on the precise definition of 'thickets'; see eg G van Overwalle, 'Of Thickets, Blocks and Gaps. Designing Tools to Resolve Obstacles in the Gene Patents Landscape', in G van Overwalle (ed), *Gene Patents and Collaborative Licensing Models. Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (CUP Cambridge 2009) 365.

process. Independent pricing of such complementary goods results in a total price for the relevant product that is higher than if all inputs were controlled by a single party.⁹⁵ Accordingly, demand for the relevant product will fall. The patent pool is one way to address the complements problem by creating a package licence for the relevant patents, the price (licensing fee) of which would be lower than in the scenario where the patentees independently determine their royalty.⁹⁶

There are ample indications that the TT-Guidelines were indeed drafted to create guidance particularly for licensing structures that clear a patent thicket or address blocking patents giving rise to a complements problem (whether or not in a standards context). For example, the TT-Guidelines state in an introductory paragraph of the section on technology pools:

Technology pools can produce pro-competitive effects, in particular by reducing transaction costs and by setting a limit on cumulative royalties to avoid double marginalisation. The creation of a pool allows for one-stop licensing of the technologies covered by the pool. This is particularly important in sectors where intellectual property rights are prevalent and licences need to be obtained from a significant number of licensors in order to operate on the market.⁹⁷

The ILP, however, was not established with a view to clearing a patent thicket by enabling parallel access to multiple licenses. In contrast, resonating academic research suggesting thickets to be prevalent in ‘complex’ rather than ‘discrete’ industries,⁹⁸ biotechnology has previously been identified as an area without significant thickets.⁹⁹ As explained above, the patent landscape in vegetable seeds may perhaps rather be qualified as a minefield, where breeders’ freedom-to-operate is

impeded since a single patented trait may hamper an entire breeding program and it is difficult to identify the biological material that is covered by patents to begin with. Accordingly, the driver behind the ILP was to unlock biological material for breeding purposes, to take away innovation impeding legal uncertainty, and to facilitate technology dissemination by reducing transactional costs and negotiation timeframes.¹⁰⁰

Consequently, the ILP’s rationale has translated into a structure that deviates from the typical multiparty licensing set-up as is envisaged by the TT-Guidelines. The key deviating feature in this respect is the absence of bundle licences. This results in a misfit with the available antitrust guidance. First, some of the key theories of harm associated with bundle licensing are not applicable in their traditional form in the absence of package licensing. This holds true for the concern of collective bundling of substitutable patents leading to price fixing,¹⁰¹ as well as to the more obvious form of technology foreclosure.¹⁰² Both are concerns that are central in the TT-Guidelines. By the same token, some of the main conditions for antitrust immunity do not apply well to the ILP, as discussed above.

The result is that these types of multiparty licensing structures face a higher degree of legal uncertainty than traditional patent pools.

Suggestions going forward

We acknowledge at the outset that antitrust regulators cannot be expected to provide clear-cut guidance covering any conceivable cooperation structure that the business world can come up with.¹⁰³ At the same time, there are number of criticalities that need to be underlined.

95 In this context, this is also referred to as ‘royalty stacking’.

96 Key publications include J Lerner and J Tirole, ‘Efficient Patent Pools’ (2004) 94 *Am Econ Rev* 691; J Farrell et al, ‘Standard Setting, Patents and Hold-up’ (2007) 74(3) *Antitrust LJ* 603; and R Gilbert, ‘Ties That Bind: Policies to Promote (Good) Patent Pools’ (2010) 77(1) *Antitrust LJ* 1.

97 TT-Guidelines, above, n 73, para 245. Similarly, the TT-Guidelines include references that reflect the relevance of this economic framework in the context of standard setting. See *ibid*, para. 245: ‘[T]here is no inherent link between technology pools and standards, but the technologies in the pool often support, in whole or in part, a de facto or de jure industry standard.’

98 ‘Complex’ industries may be described as sectors where patents have a large strategic bargaining value, while ‘discrete’ industries designate areas where patents have large stand-alone innovation value, see W Cohen, R Nelson and J Walsh, ‘Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)’, NBER Working Paper No 7552 (2000).

99 See eg Regibau and Rockett reviewing the empirical economic literature on thickets. See P Regibau and K Rockett, ‘Assessment of potential anti-competitive conduct in the field of intellectual property rights and assessment of the interplay between competition policy and IPR protection’, Study prepared for the European Commission (2011), available at http://ec.europa.eu/competition/consultations/2012_technology_transfer/study_ipr_en.pdf (accessed 16 May 2016).

100 At present, royalty stacking is not prevalent in vegetable seeds. It cannot be excluded, though, that this will change in the future given the proliferation of patents.

101 In the absence of a package licence, there is no single rate for the patents that are part of the structure. Instead, separate negotiations take place—and separate royalties may be paid—for each of the separate patents that are part of the structure. Of course, this does not inherently exclude pricing concerns but the point is that those concerns would be of a different nature from—and thus require a different assessment than—the concerns described in the current guidance.

102 At the same time, the fact that a large portion of an industry jointly determines the conditions under which licensing deals will be structured going forward, is considered inherently sensitive from an antitrust perspective. Hence, guidance is still highly relevant.

103 Likewise, this contribution does not suggest that an ‘exemption system’ should be re-introduced on the basis of which every single envisaged initiative can be submitted to the Commission with a request to issue an exemption decision. Prior to 2004, the EU had such a system in place. This system has been abolished for good reasons. See eg Council Regulation 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty, OJ L 1/1, 4 January 2003, recital 3.

First, the economic basis for focusing the available guidance on multilateral licensing structures aimed at clearing thickets seems relatively shaky. In a 2011 report commissioned by the European Commission, in the context of a review of the TTBER and TT-Guidelines, the authors observed that:

[W]hile patent thickets have achieved prominence on the agenda of both policy-makers and academic researchers, one can still legitimately wonder about the true extent of the problem. Two questions arise when assessing the importance of patent thickets. The first one is how often such thickets actually arise. The second is what the size of the inefficiency associated with patent thickets is likely to be.¹⁰⁴

Upon a review of the available economic literature, the authors concluded, on the first question, that the most sophisticated methodology currently available to detect and map thickets is still 'in its infancy'.¹⁰⁵ Regarding the second question, they found that the only rigorous empirical study available suggests that 'the welfare effects of thickets might actually be ambiguous'.¹⁰⁶ If this is the state of play regarding the economic underpinnings of the current focus of the antitrust guidance, it seems warranted to have a discussion on the scope and focus of that guidance.

Second, our experience indicates that the business world is indeed interested in exploring multilateral licensing structures that do not necessarily fit within the shapes envisioned by the current guidance. According to our knowledge, discussions similar to those which led to the ILP are emerging in the area of diagnostic markers and biotech enabling technologies. There is, therefore, a demand for more clarity on alternative structures, exacerbated by the inherent sensitivity of the IP-antitrust interface. As noted by Lerner and Tirole, '[a]t least in part, the reluctance to form pools may be due to the ambiguities surrounding the manner in which proposed pools will be evaluated'.¹⁰⁷

Third, certain key improvements to the existing guidance appear to be easily achievable. The Commission should be able to easily clarify whether it intended to exclude initiatives like the ILP from the definition of

technology pools, taking away the tension between its ex post comments on the 3G3P case and the TT-Guidelines. In addition, assuming the Commission did intend to extend the application of the TTBER to initiatives that do not entail package licensing, the guidance should make a clearer distinction between paragraphs that apply (i) to pools granting a package licence, (ii) to other licensing structures that do not grant a package licence and (iii) to both. Equally, concerns and guidance aimed specifically at standard setting contexts should be more clearly identified. Such clarifications would be particularly welcome in relation to the soft law safe harbour and the central theories of harm. Indeed, as noted above, the central antitrust concerns identified in the TT-Guidelines—ie price fixing and technology foreclosure—are less obvious in the absence of package licensing.¹⁰⁸ Accordingly, it is worth enquiring whether the concept of essentiality should have the same central role in the assessment, absent patent packaging.

Finally, the possibility to obtain case-specific guidance from the Commission could constitute effective relief for initiatives not adequately covered by the available guidance. Admittedly, in the EU, a system of guidance letters is formally in place since 2004.¹⁰⁹ While the EU institutions acknowledge that the legal certainty resulting from informal guidance 'contributes to the promotion of innovation and investment',¹¹⁰ the reality is that there has not been a single case since 2004 in which the Commission has issued such a letter. In our experience, the relatively strict conditions for guidance letters offer ample leeway for the Commission to refuse issuing one in a specific case. It is not entirely clear why the Commission has effectively turned this option into a dead letter.¹¹¹ In any event, we would argue that this is a missed opportunity that the Commission should consider seizing. This will not require changing anything else than its own internal policies as to how the tool of guidance letters is applied in practice.¹¹²

In that context, lessons can be learned from the US, where there is an effective method for increasing legal

104 P Regibeau and K Rockett, 'Assessment of potential anti competitive conduct in the field of intellectual property rights and assessment of the interplay between competition policy and IPR protection', Study prepared for the European Commission (2011), p. 14; available at http://ec.europa.eu/competition/consultations/2012_technology_transfer/study_ipr_en.pdf (accessed 4 July 2016).

105 Regibeau and Rockett, above, n 100, 38.

106 Ibid, 16.

107 J Lerner and J Tirole, 'Efficient Patent Pools' (2004) 94 *Am Econ Rev* 691.

108 As noted, we are not arguing that theories of harm related to royalties (price effects) and foreclosure are inconceivable absent package licensing. The point is that the guidance departs from a starting point where package licensing does take place, which we think may materially alter the assessment.

109 See Commission Notice on informal guidance relating to novel questions concerning Articles 81 and 82 of the EC Treaty that arise in individual cases (guidance letters), OJ C 101/78, 27 April 2004. Prior to 2004, an 'exemption system' was in place together as well as the option of 'comfort letters'. The MPEG pool, for example, was cleared under the former, whereas the 3G3P case was dealt with through the latter.

110 See Council Regulation 1/2003, above, n 103, recital 38.

111 It has been suggested in literature that the uncertain legal status of guidance letters could explain reticence in their use, see L Parret, 'Judicial Protection after Modernisation of Competition Law' (2005) 32(4) *Legal Issues of Economic Integration* 347.

112 We acknowledge that the conditions set out in the relevant notice (like the presence of a 'novel' legal question) will entail some constraints in applying this framework. However, the language of the notice leaves ample space to be effectively used in practice.

certainty for envisaged multilateral licensing structures through Business Review Letters.¹¹³ Over the last few decades, the Antitrust Division has used this instrument repeatedly, including in regards to the MPEG and DVD pools.¹¹⁴ The letters have proven to be an effective tool in increasing legal certainty.

Conclusions

Initiatives like the ILP bring about numerous challenges of a commercial, practical and legal nature. Indeed, simply identifying and formulating common grounds between a large portion of the relevant industry actors is already a very challenging task. However, the impact of these initiatives can be profound, if they receive robust industry support and adopt innovative solutions.

The ILP may be regarded as an effective answer to a pressing issue, both for the industry and for society at large. It is backed up by significant industry participation and implements numerous innovative mechanisms and safe guards to achieve a satisfactory balance between the rights of all the parties involved. Given the increasing prevalence and complexity of IP in numerous key industries, innovative licensing solutions, like the ILP, should be incentivized and allowed to develop in a clear and tailored legal framework. In the case of the ILP, this challenge was overcome by conducting legal risk management throughout the process of designing and launching the ILP, involving antitrust advisors from the initial stage of the project.

If the EU is serious about its intention to change the perception—be it right or wrong—that it is lagging

behind the USA in terms of facilitating true disruption and innovation,¹¹⁵ we suggest that there is an opportunity for improvement in the EU antitrust area. As outlined in this contribution, the Commission's existing toolkit leaves ample space for improvement.

The innovative characteristics of the ILP, including the use of baseball arbitration to set reasonable royalties in licence agreements¹¹⁶ and the compulsory use of fair and non-discriminatory licensing conditions (in addition to transparent and pragmatic procedures), make it an interesting prototype for similar challenges in other industries, even in contexts where FRAND requirements are at play. The ILP members are closely monitoring the effects of this model and would welcome experiences with baseball arbitration in other settings. Interestingly, a prominent UK judge recently suggested that baseball arbitration could be considered as a solution in FRAND disputes regarding standard essential patents.¹¹⁷

The ILP concept leaves certain questions open, such as how to deal with multiple parallel licences (licence stacking) if the sum of individual royalty payments becomes punitively expensive. While such scenario is not foreseeable for vegetables, it might be relevant for other technology areas.

We hope that the ILP will become a sustainable and successful licensing model, leading to a new standard in licensing plant-related innovations. We are aware, however, that certain developments can hamper the success. Some key patent owners are currently 'sitting on the fence', unwilling to join the ILP, but their contribution would be necessary to clear the patent minefield that affects the field. On-going initiatives to remove the

113 See US Department of Justice, 'Introduction to Antitrust Division', available at Business Reviews <http://www.justice.gov/sites/default/files/atr/legacy/2011/11/03/276833.pdf> (accessed 16 May 2016).

114 See the overview of the Antitrust Division's business reviews under <https://www.justice.gov/atr/business-review-letters-and-request-letters> (accessed 4 July 2016). One of the most recent ones concerned the Intellectual Property Exchange International Inc (IPXI), see US Department of Justice, 'Response to Intellectual Property Exchange International Inc.'s Request for Business Review Letter' (26 March 2013), available at <http://www.justice.gov/atr/response-intellectual-property-exchange-international-incs-request-business-review-letter> (accessed 16 May 2016).

115 See eg JB Stewart, 'A Fearless Culture Fuels U.S. Tech Giants', *New York Times* (18 June 2005), available at <http://www.nytimes.com/2015/06/19/business/the-american-way-of-tech-and-europes.html> (last accessed 16 May 2016).

116 An interesting overview and assessment of numerous collaborative licensing models in the genetics space can be found in van Overwalle, 'Of Thickets, Blocks and Gaps', above, n 94.

117 'Tech patent claims could go to arbitration as "practical" step, London judge says', *Mlex Report* (2 December 2015). We are aware of a number

of recent contributions discussing the employment of baseball arbitration as a mechanism to ensure FRAND royalties in a standard setting-context. Notably, Lemley and Shapiro have suggested in that context that '[s]o long as the arbitration procedure itself is unbiased, bargaining in the shadow of binding arbitration will tend to lead to reasonable rates', see Lemley and Shapiro, above, n 65. See also JL Contreras and DL Newman, 'Developing a Framework for Arbitrating Standards-Essential Patent Disputes' (2014) 23 *J Dispute Resolution*, available at <http://ssrn.com/abstract=2335732> (accessed 16 May 2016). The proposal to use baseball arbitration in the standard setting context has also been criticized: see eg P Larouche, J Padilla and R Taffet, 'Settling FRAND Disputes: Is Mandatory Arbitration a Reasonable and Non-Discriminatory Alternative?', *HOOVER IP² Working Paper Series No 13003*, Tilburg Law School Research Paper No 023/2013, available at <http://ssrn.com/abstract=2346892> (accessed 16 May 2016), and JG Sidak, 'Mandating Final-Offer Arbitration of FRAND Royalties for Standard-Essential Patents' (2014) 18 *Stanford Tech L Rev* 1, available at <https://www.criterioneconomics.com/docs/lemley-shapiro-baseball-arbitration-frand-royalties-seps.pdf> (accessed 16 May 2016).

patent system for plant-related inventions, especially in Europe,¹¹⁸ also threaten to change the scenario. Eventually, the business compromise of the ILP will only be sustainable if all participants see it as a long-term solution.¹¹⁹ We have full confidence that these

challenges can be overcome if the various stakeholders work together in a trustful way, with the common target of developing a solution which maximizes innovation in the vegetable space.

118 European Parliament, ‘Patenting of Essential Biological Processes’, available at <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+P7-TA-2012-0202+0+DOC+PDF+V0//EN>; Council of the European Union, ‘The impact of a recent decision of the European Patent office (EPO) concerning the patentability of plant traits on the plant breeders’ rights

regime’, Doc No AGRI 523 (13 October 2015), available at <http://data.consilium.europa.eu/doc/document/ST-12943-2015-INIT/en/pdf>; ‘Fruit threatened by patents; patents threatened by politician:

where will it all end?’, IPKat (15 November 2015), available at <http://ipkitten.blogspot.ch/2015/11/fruit-threatened-by-patents-patents.html> (accessed 16 May 2016).

119 The risk that Europe will abandon patents on plant-related innovations is likely one reason why certain parties do not join the ILP. They would not ‘trade’ long-term especially to US patents if the EU patent system cannot be sustained. In consequence, a continued lobbying against the EU patent system may jeopardize the ILP success.